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Original Paper

Impact of a Face-To-Face Versus Smartphone App Versus Combined Breastfeeding Intervention Targeting Fathers: Randomized Controlled Trial

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Abstract

Background: Despite the recognized health and economic benefits of exclusive breastfeeding, few Australian infants are exclusively breastfed beyond 5 months of age. Social support for breastfeeding, in particular the support of an infant's father, has been identified as a crucial element for successful breastfeeding.

Objective: The objective of this study was to determine the effectiveness of various father-focused breastfeeding interventions in terms of key infant feeding outcomes.

Methods: The study was a 4-arm, factorial, randomized controlled trial conducted in Perth, Australia. The trial arms included a control group and 3 interventions, consisting of a face-to-face father-focused antenatal breastfeeding class facilitated by a male peer facilitator; Milk Man, a breastfeeding smartphone app designed specifically for fathers; and a combination of both interventions. Expecting couples were recruited from hospital-based antenatal classes and block randomized to 1 of the 4 arms. Each partner completed surveys at recruitment and at 6 weeks and 26 weeks postpartum. Primary outcomes were duration of exclusive and any breastfeeding. Secondary outcomes included age of introduction of formula and complementary foods, maternal breastfeeding self-efficacy, and partner postpartum support.

Results: A total of 1426 couples were recruited from public (443/1426, 31.1%) and private (983/1426, 68.9%) hospitals. Of these, 76.6% (1092/1426) of fathers completed the baseline questionnaire, 58.6% (836/1426) completed the 6-week follow-up questionnaire, and 49.2% (702/1426) completed the 26-week follow-up questionnaire. The average age of fathers who completed the baseline questionnaire was 33.6 (SD 5.2) years; the majority were born in Australia (76.4%) and had attended university (61.8%). There were no significant differences between the control and any of the intervention groups in any of the infant feeding outcomes or level of breastfeeding self-efficacy and postpartum partner support reported by mothers.

Conclusions: This study did not demonstrate that any intervention was superior to another or that any intervention was inferior to the standard care delivered in routine antenatal classes. Further studies are needed to test the effectiveness of these interventions in more socioeconomically diverse populations that are likely to benefit most from additional partner supports.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12614000605695; <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12614000605695>

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KEYWORDS

breastfeeding; fathers; peer support; mHealth, smartphone app; infants; social support; feeding; smartphone

Introduction

Breastfeeding and Fathers

Breastfeeding is known to have short- and long-term health benefits for both infants [1,2] and mothers [3]. Despite the well-substantiated health [4] and economic [5,6] benefits of breastfeeding and high breastfeeding initiation rates (95%) [7], only 15% of Australian infants are exclusively breastfed beyond 5 months, and less than 6 out of every 10 still receive any breast milk at 6 months of age [7]. These statistics have remained relatively stagnant for the last 25 years or so [8,9], and new and innovative ways of increasing the duration and exclusivity of breastfeeding are needed to ensure that most Australian infants (and their mothers) receive the maximum and continued benefits of breastfeeding.

Social support for breastfeeding [10,11] and in particular support of the babies' fathers have been identified as crucial elements for successful breastfeeding. While family structure varies, research to date has focused on male partners, as does this paper. A woman's partner can act as a strong enabler or barrier to breastfeeding. There is sound empirical evidence that women who perceive their partners to be supportive of breastfeeding are more likely to initiate breastfeeding and to breastfeed for longer than women who perceive their partners to favor formula feeding or to be ambivalent as to how they feed their infant [12-16]. These findings are supported by a rapidly growing body of qualitative evidence that breastfeeding women value and benefit from the emotional and practical support of their partner [17-20].

While fathers typically describe breastfeeding as being normal and natural and want to be supportive of their breastfeeding partners, they are often poorly informed about the importance of breastfeeding and its superiority over formula feeding [21]. In addition, they can hold negative attitudes regarding breastfeeding including feeling left out, fear of not bonding with their infant, and of losing time with, and the attention of, their partner [13]. Fathers want to be involved in the breastfeeding decision-making process [20,22], and new fathers want practical advice on how they can support their partner as well as strategies for problem solving common breastfeeding difficulties that their partner may encounter [23].

However, while expecting fathers are encouraged to and frequently do attend antenatal classes with their partners, these classes are generally directed at the mothers and led by female health professionals, with men perceiving that they pay limited attention to their role and information and support needs [20]. Furthermore, work commitments may limit a father's involvement in his partner's pregnancy care and the number of

antenatal classes and appointments that he can attend [24]. Information and support, therefore, need to be targeted toward men in a way that is accessible, flexible, and appropriate [24].

The authors [25], and others [26-28], have employed father-focused breastfeeding education classes led by male peer facilitators to provide expecting fathers with practical and nonauthoritative information and advice around providing breastfeeding support for their partners. Fathers participating in classes may feel less embarrassed or intimidated in expressing their concerns and asking questions of a peer father compared with a female health professional [29]. Face-to-face programs of this kind have enhanced the knowledge and ability of expecting fathers to support their breastfeeding partner [26,29] and have resulted in increased rates of breastfeeding initiation [28,29] and modest increases in breastfeeding duration [25]. Peer support programs of this kind, however, while valued by fathers and health professionals, are labor intensive and difficult and expensive to sustain. Digital technologies, with their wide geographic and demographic reach, provide a potentially cost-effective and sustainable means of reaching large numbers of individuals directly with health information, support, and interventions [30].

Engaging With Fathers via Digital Technology

Mobile health (mHealth) interventions employing digital technologies provide a rapidly evolving means of engaging fathers and providing them with information and support to address their needs related to both breastfeeding and transitioning to fatherhood. Expecting and new parents, both mothers and fathers, have traditionally accessed the internet for information on pregnancy and early parenting [31,32], but increasingly they are accessing digital media information sources such as apps and social media platforms for this information [31,33].

The perinatal period provides a window of opportunity for connecting with fathers at a time when they are experiencing change, highly motivated, and looking for support [14]. Increasingly, men are seeking information and skills to enhance parenting and infant care (including breastfeeding), support and improve their relationship with their partner, and manage stress during this period [32]. They are accustomed to easy and immediate access to information using digital technologies and want better access to information than that offered by health professionals [33]. mHealth interventions can provide the user with readily accessible information despite geographical distance or time constraints, and the immediacy offered by digital technologies provides users with information when it is most needed [33]. Peer support can be provided through app-based online forums [34] and can assist the transition to fatherhood

by providing fathers with the opportunity to share information and experiences, provide mutual support, and know they are not alone with their concerns [34,35]. The aim of this study was to implement and evaluate the effectiveness of 2 father-focused breastfeeding interventions, a face-to-face father-focused antenatal breastfeeding class and a breastfeeding smartphone app designed specifically for fathers, individually and in combination.

Methods

The Parent Infant Feeding Initiative (PIFI) was a 4-arm, factorial, randomized controlled trial (RCT) conducted in Perth, Australia, and the study protocol has been described previously in detail [36].

Participants and Recruitment

Participants were expecting couples recruited directly by members of the research team from 261 evening and weekend antenatal classes conducted between August 2015 and December 2016 at one public tertiary, 2 public regional, and 3 private hospitals providing maternity services to the majority of the Perth metropolitan area, with approximately 50% of metropolitan deliveries occurring in the private hospitals [37]. Only 2 smaller regional public hospitals were not included as recruitment sites for logistical reasons, due to the irregular scheduling of their antenatal classes.

Inclusion criteria included ownership by the father of a smartphone (iOS or Android), internet access, residence within Perth, both partners intending to participate in the rearing of their child, and having sufficient English language skills to engage with the intervention. Couples were excluded if the mother had an existing medical condition likely to inhibit the initiation of breastfeeding or exclusive breastfeeding, was expecting a multiple birth, or if they were a same sex couple.

Interventions

The trial arms included a control group and 3 interventions consisting of (1) a face-to-face father-focused antenatal breastfeeding class (FFABC) facilitated by a male peer, (2) Milk Man, a breastfeeding smartphone app designed specifically for fathers, and (3) a combination of both interventions. Development of the individual interventions was informed by the social cognitive theory [38], which facilitated understanding of the potential interaction between overestimation of new parents' capacity to cope and underestimation of potential problems.

All participants received a congratulatory card from the project on the birth of their baby. During the course of the study, couples in all groups may have accessed professional and community-based breastfeeding support services such as a lactation consultant, local breastfeeding support groups, or the Australian Breastfeeding Association's website or 24-hour helpline. Fathers participating in the FFABC were provided with a leaflet with contact numbers of relevant support services and encouraged to use these if needed. Similarly, the Milk Man app contained links to these same services and others that participants could access directly from within the app.

Father-Focused Antenatal Breastfeeding Class Group

The primary purpose of the FFABC was to identify and discuss ways that fathers can encourage and support their partners with breastfeeding. The format and content of the FFABC was based on a "dads only" breastfeeding class trialed in the Fathers Infant Feeding Initiative (FIFI) [25]. Details of the FFABC and its process evaluation have been reported previously [39].

Briefly, the FFABC was a single class that ran for approximately 45 minutes and was conducted at the time of the hospital-based couples' antenatal class, replacing for fathers the usual breastfeeding component of that class with the father-focused class. The FFABC was led by a trained peer facilitator who was the father of at least one child aged younger than 3 years who had been breastfed for at least 3 months. The class explored issues identified in the literature [40-42] and confirmed in our earlier intervention [43] as being important to new fathers, including what it means to be a new father, the importance of breastfeeding, barriers and facilitators of breastfeeding, and anticipatory problem-solving strategies for addressing common breastfeeding problems.

Milk Man Smartphone App Group

The development of the Milk Man app, available for Android and iPhone (iOS, Apple Inc) operating systems, has been described in greater detail elsewhere [44]. Briefly, the app used gamification, social connectivity in the form of a conversation forum, and twice-weekly push notifications linking to polls and conversation starters to engage fathers with breastfeeding information contained within an information library. In addition to containing information on all of the topics introduced in the FFABC, the library contained additional breastfeeding and parenting information and links to external websites.

Combination Group

Fathers in the combination group had access to the Milk Man app from recruitment until 6 months postpartum and also attended the FFABC in place of the breastfeeding component of the hospital-based couples' antenatal class.

Following randomization, participants in the Milk Man app and combination intervention groups were provided with instructions and an ID code for downloading the app. Milk Man app use was not prescribed and fathers had access to the app from recruitment at approximately 32 weeks' gestation to 6 months postpartum, and app library content was unchanged for the duration of the study.

Control Group

Fathers in the control group received the usual care and attended the breastfeeding component of the hospital-based couples' antenatal class.

Randomization

To ensure close balance of participant numbers in each arm at any time during the trial, we used a block RCT to form the assignment list for the 4 study arms. Specifically, we used a computer-based random sequence generator to create random permuted blocks of 8 and an equal allocation ratio for each recruiting hospital, and then randomly assigned classes (of

participants) within each block into one of the 4 study arms during the course of the 18 months of recruitment. This randomization process resulted in hospitals having roughly equivalent proportions of participants in each study arm ($\chi^2_{15}=22.8, P=.09$). In view of this block randomization process, no effect of clustering was considered in our analysis.

Participants were blinded to the study arm allocation until after they had consented to participate. However, as some FFABCs were conducted on the same day as participants were recruited, it was necessary for members of the PIFI study team to be aware of the group allocation in order to organize for the peer facilitator to deliver the class. Care was taken by recruiting staff, through the use of a standardized slide presentation and recruitment script, to avoid inadvertently alerting potential participants to the study arm that their antenatal class had been allocated to, thereby influencing their decision to participate.

Collection of Data

Each partner self-completed a printed baseline questionnaire collected at the time of recruitment or returned in a return-paid envelope. Follow-up questionnaires were completed at 6 weeks and 26 weeks postpartum. Each partner was sent an email with a personalized link to an online questionnaire, developed using Qualtrics software (Qualtrics). Three reminder emails were sent, followed by a final reminder by telephone, at which time participants had the option of completing the questionnaire by telephone survey.

From 36 weeks' gestational age, fathers were sent a short message service (SMS) text asking if their baby had been born, and if so, the baby's date of birth and sex. These messages stopped once notification of the baby's birth was made, or at 42 weeks' gestational age if fathers failed to respond before this time. In addition, mothers were sent a short 3-item survey, developed using Qualtrics software, at 12 weeks and 18 weeks postpartum via SMS text, with 3 reminder SMS texts, to determine if they had stopped breastfeeding and/or introduced formula or complementary (solid and semisolid) foods. A yes response to each of these questions generated a second question that requested mothers provide the age of their child in weeks when the relevant event occurred.

Outcome Measurements

The primary outcomes were duration of exclusive and any breastfeeding. Secondary outcomes included age of introduction of formula, age of introduction of complementary foods, maternal breastfeeding self-efficacy, and partner postpartum support. Breastfeeding definitions were those used by the World Health Organization, and an infant was exclusively breastfed if they had received nothing but breastmilk (excluding oral rehydration solution or vitamins, minerals, or medicines given as drops or syrups) [45].

Infant feeding outcome measurements were derived from questions asked of both parents at 6 weeks and 26 weeks postpartum and of mothers at 12 weeks and 18 weeks postpartum via SMS text that related to current feeding method; age at which breastfeeding was stopped; and when formula, water, other beverages, or complementary foods were first

started. Where outcome data were available from both parents, data collected from the mother were used on the assumption that these would be the more accurate and reliable. However, where data were only provided by the father, these data were used. In the event that neither parent completed the 26-week questionnaire, and to allow for survival analysis [46], the last available data from the 6-week follow-up questionnaire or the 12-week and 18-week SMS text surveys were used and right censored if necessary.

The 6 weeks postpartum follow-up questionnaire completed by mothers included 2 validated and widely used self-report instruments. The 14-item short form Breastfeeding Self-Efficacy Scale (BSES-SF) [47] assesses breastfeeding confidence. Scores can range from 14 to 70, with higher scores indicating higher levels of breastfeeding self-confidence. The 25-item Postpartum Partner Support Scale (PPSS) assesses functional elements of partner support, being appraisal/emotional, informational, and instrumental support. Scores can range from 25 to 100, with higher scores indicating higher levels of postpartum partner support [48].

Statistical Analysis

Sample size was based on the proportion of women breastfeeding at 26 weeks. It was assumed that at 26 weeks, there would be at least a 10% difference in the proportion of women breastfeeding between any 2 of the groups. A sample size of 300 fathers was required in each of the 3 intervention groups and control group to be able to detect the difference at 80% power and 5% level of significance, using a log-rank survival test. Assuming a loss to follow-up of 25% in each group, 400 participants were to be recruited into each group.

Data were analyzed using the SPSS Statistics for Windows version 27 (IBM Corp). Multiple imputations of missing data were performed using fully conditional specification with iterative Markov chain Monte Carlo method. The imputations were performed for the 4 arms (ie, control, FFABC, Milk Man, and combination) separately with specified value contrarians to ensure the accuracy of the imputed results. All imputations used 10 iterations to produce 100 imputed datasets (with 1000 case and 100 draws).

Binary logistic regression was conducted to estimate the odds ratio and 95% confidence interval of exclusive and any breastfeeding at 6 weeks and 26 weeks for the intervention groups versus the control group. Survival analysis using the Cox proportional hazard model was conducted to estimate the hazard ratio and 95% confidence interval in the intervention groups versus the control group for stopping exclusive and any breastfeeding and introducing formula or complementary foods before 26 weeks. The general linear model was used to compare the level of maternal breastfeeding self-efficacy (BSES-SF) and postpartum partner support (PPSS) reported by mothers. Results are presented as the mean and 95% confidence interval of the BSES-SF and PPSS scores, along with the regression coefficient, standard error, and *P* value obtained from the regression analyses. Results for all statistical tests are presented for the original analyses, which included those participants with complete data and the pooled analyses that used the imputed datasets, and *P* < .05 was considered to be statistically significant.

Intention-to-treat analysis was conducted according to the arm of the study that fathers were randomized to at recruitment. Per-protocol analysis was conducted on all control group fathers; those fathers randomized to the FFABC who had attended the class; those randomized to the Milk Man app group who had downloaded the app; and those randomized to the combination group who had attended the FFABC and downloaded the app.

Ethics Approval and Consent to Participate

PIFI was approved by the Curtin University human research ethics committee (HR 82/2014; May 14, 2014) and the human research ethics committees responsible for the public (SCGG HREC No. 2014-111, Sept 18, 2014; SMHS HREC Reference S/15/25, Aug 27, 2015; WNHS HREC No. 2016037EW, May 4, 2016) and private (SJGHC Reference 777, April 8, 2015) hospital sites. The study was registered with the Australian New Zealand Clinical Trials Registry [ACTRN12614000605695]. Members of the research team attended each antenatal class and provided a verbal and written description of the study. Participation was voluntary, and all participants provided signed informed consent.

Results

Participants and Retention

In total, 1426 couples were recruited from public (443/1426, 31.1%) and private (983/1426, 68.9%) hospitals and randomized into the 1 of the 4 trial arms (control n=358, FFABC n=338, Milk Man n=397, and combination n=333). Of these, 76.6% (1092/1426) of fathers completed the baseline questionnaire, 86.8% (1238/1426) notified the project of the birth of their baby via SMS text survey, 58.6% (836/1426) completed the 6-week follow-up questionnaire, and 49.2% (702/1426) completed the 26-week follow-up questionnaire. Fathers recruited from private hospitals were significantly more likely to complete the baseline questionnaire than fathers recruited from public hospitals (808/983, 82.2%, vs 284/443, 64.1%; $P < .001$). Overall, 7.6% (108/1426) of recruited fathers provided no data and 43.1% (614/1426) provided complete data, with no discernible differences in level of participation in data collection surveys seen between the 4 intervention groups ([Multimedia Appendix 1](#)).

The average age of fathers who completed the baseline questionnaire was 33.6 (SD 5.2) years; the majority were born in Australia (724/1074, 67.4%) and had attended university (663/1072, 61.8%). There were no differences in the baseline characteristics between the 4 intervention groups ([Table 1](#)).

Table 1. Baseline characteristics of participating fathers by intervention group (n=1092).

Characteristic	Control (n=271)	FFABC ^a (n=263)	Milk Man (n=299)	Combination (n=259)	Total	P value
Age in years, mean (SD)	33 (4.8)	34 (4.7)	34 (5.3)	34 (5.7)	33 (5.2)	.10
Education, n (%)	— ^b	—	—	—	—	.64
High school/trade	109 (41.0)	99 (38.7)	106 (35.8)	95 (37.4)	409 (38.2)	
Some/completed university	157 (59.0)	157 (61.3)	190 (64.2)	159 (62.6)	663 (61.8)	
Place of birth, n (%)	—	—	—	—	—	.93
Australia/New Zealand	187 (70.0)	172 (67.2)	199 (67.2)	166 (65.1)	724 (67.4)	
United Kingdom/Ireland	27 (10.1)	33 (12.9)	38 (12.8)	31 (12.2)	129 (12.0)	
Africa/Middle East	14 (5.2)	12 (4.7)	20 (6.8)	19 (7.5)	65 (6.1)	
Asia	23 (8.6)	22 (8.6)	21 (7.1)	18 (7.1)	84 (7.8)	
Other	16 (6.0)	17 (6.6)	18 (6.1)	21 (8.2)	72 (6.7)	
IRSD^c deciles, n (%)	—	—	—	—	—	.82
1 and 2	8 (3.0)	7 (2.7)	7 (2.3)	6 (2.3)	28 (2.6)	
3 and 4	7 (2.6)	8 (3.0)	10 (3.3)	9 (3.5)	34 (3.1)	
5 and 6	62 (22.9)	44 (16.7)	59 (19.7)	58 (22.4)	223 (20.4)	
7 and 8	53 (19.6)	67 (25.5)	75 (25.0)	65 (25.1)	260 (23.8)	
9 and 10	141 (52.0)	137 (52.1)	149 (49.7)	121 (46.7)	548 (50.1)	
Hospital, n (%)	—	—	—	—	—	.85
Public	110 (30.7)	100 (29.6)	124 (31.2)	109 (32.7)	443 (31.1)	
Private	248 (69.3)	238 (70.4)	273 (68.8)	224 (67.3)	983 (68.9)	

^aFFABC: father-focused antenatal breastfeeding class.

^bNot applicable.

^cIRSD: Index of Relative Social Advantage and Disadvantage, where 1 = most disadvantaged and 10 = least disadvantaged.

Intention to Treat Analysis

There were no significant differences between intervention arms in the proportion of infants being exclusively breastfed at 6 weeks and 26 weeks of age or in the proportion of infants receiving any breast milk at these ages ([Multimedia Appendix 2](#)). There were no significant differences between intervention

arms in the risk of stopping exclusive breastfeeding or any breastfeeding before 26 weeks. Similarly, there were no significant differences between intervention arms in the risk of introducing formula or complementary foods before 26 weeks ([Table 2](#)). Also, there were no differences between intervention arms in the level of maternal breastfeeding confidence or postpartum partner support reported by mothers ([Table 3](#)).

Table 2. Comparison between control and intervention groups of risk of cessation of exclusive and any breastfeeding and introduction of formula and solids before 26 weeks: intention-to-treat analysis.

Intervention arm	Exclusive breastfeeding		Any breastfeeding		Introduction of formula		Introduction of complementary foods	
	HR ^a	95% CI	HR	95% CI	HR	95% CI	HR	95% CI
Original^b								
Control	1.00	— ^c	1.00	—	1.00	—	1.00	—
FFABC ^d	1.09	0.91-1.32	1.01	0.67-1.51	1.19	0.90-1.56	1.08	0.86-1.35
Milk Man app	1.04	0.87-1.25	1.08	0.73-1.58	1.07	0.81-1.39	1.06	0.85-1.33
Combination	0.97	0.80-1.18	0.90	0.60-1.35	0.89	0.67-1.19	0.91	0.72-1.15
Pooled^e								
Control	1.00	—	1.00	—	1.00	—	1.00	—
FFABC	1.11	0.86-1.42	1.06	0.57-1.99	1.18	0.64-2.21	1.09	0.80-1.48
Milk Man app	1.04	0.81-1.35	1.13	0.59-2.18	1.13	0.62-2.06	1.13	0.81-1.58
Combination	0.98	0.73-1.31	0.89	0.47-1.70	0.90	0.48-1.68	1.02	0.75-1.38

^aHR: hazard ratio.

^bOriginal analyses included those participants with complete data.

^cNot applicable.

^dFFABC: father-focused antenatal breastfeeding class.

^ePooled analyses that used the imputed datasets.

Table 3. Comparison of breastfeeding self-efficacy and postpartum partner support between control and intervention groups: intention-to-treat analysis.

Intervention arm	Mean	95% CI	β	SE	P value
BSES-SF^a					
Original^b					
Control	49.5	48.0-51.0	Ref	— ^c	—
FFABC ^d	48.7	47.1-50.3	-0.748	1.123	.51
Milk Man app	50.1	48.4-51.3	0.379	1.081	.73
Combination	49.5	48.5-51.6	0.589	1.111	.60
Pooled^e					
Control	47.4	45.0-49.7	Ref	—	—
FFABC	47.3	44.9-49.6	-0.112	1.677	.95
Milk Man app	48.3	46.1-50.5	0.919	1.731	.60
Combination	47.9	46.0-49.8	0.542	1.532	.72
PPSS^f					
Original					
Control	82.8	81.4-84.2	Ref	—	—
FFABC	82.5	81.0-83.9	-0.317	1.033	.76
Milk Man app	83.1	81.7-84.4	0.256	0.994	.80
Combination	81.2	79.8-82.7	1.595	1.026	.12
Pooled					
Control	81.7	79.2-84.2	Ref	—	—
FFABC	81.0	78.1-83.9	-0.680	2.023	.74
Milk Man app	82.8	80.2-85.4	1.146	1.765	.52
Combination	78.7	75.3-82.0	-2.991	2.161	.17

^aBSES-SF: Breastfeeding Self-Efficacy Scale–Short Form, with scores ranging from 14 to 70 with higher scores indicating higher levels of breastfeeding self-confidence.

^bOriginal analyses included those participants with complete data.

^cNot applicable.

^dFFABC: father-focused antenatal breastfeeding class.

^ePooled analyses that used the imputed datasets.

^fPPSS: Postpartum Partner Support Scale, with scores ranging from 25 to 100 with higher scores indicating higher levels of postpartum partner support.

Per Protocol Analysis

Overall, 85.1% (1214/1426) of fathers were eligible to be included in the per-protocol analysis. This included the entire control group (n=358); 87.9% (297/338) of the FFABC group, who had attended the class; 80.4% (319/397) of the Milk Man app group, who had downloaded the app; and 72.1% (240/333) of the combination group, who had attended the antenatal class and downloaded the Milk Man app. Significantly more of the participants recruited from private hospitals (871/983, 88.6%) were included in the per-protocol analysis than those recruited from the public hospitals (343/443, 77.4%; $P<.001$). Overall, there were no differences in the age, level of education, or social disadvantage of those who did or did not participate in the intervention per protocol. Within the individual intervention arms, participants recruited from public hospitals were significantly less likely to participate in any of the 3

interventions compared with those recruited from private hospitals. Younger fathers were less likely to participate in the FFABC or to download the Milk Man app, and fathers from the most disadvantaged group were less likely to participate in the FFABC ([Multimedia Appendix 3](#)).

Similar to the intention-to-treat analysis, the per-protocol analysis did not identify any significant differences between intervention arms for any of the primary or secondary outcome variables investigated ([Multimedia Appendix 4](#)).

Milk Man Engagement Analysis

An engagement index for participants in the Milk Man and combination intervention arms was calculated using app analytics data and data from the 6-week follow-up questionnaire [49]. There were no differences in the engagement index scores between participants in the Milk Man and the combination

intervention groups, and level of engagement was not associated with breastfeeding outcomes (data not presented) [49].

Discussion

Principal Findings

To our knowledge, PIFI is the largest breastfeeding intervention targeting fathers. We have previously reported on the process evaluation of the interventions and demonstrated that each intervention in terms of intent, content, and delivery was feasible, useful, and acceptable to fathers [34,39,50]. We were, however, unable to demonstrate impact of a face-to-face or mHealth intervention, either individually or in combination, on infant feeding outcomes, maternal breastfeeding self-efficacy, or level of postpartum partner support.

Comparison With Prior Work

One of the interventions was a face-to-face antenatal breastfeeding class led by a trained peer facilitator. Breastfeeding peer support programs for fathers have previously been shown to be effective in increasing breastfeeding initiation rates and prolonging breastfeeding duration among socially disadvantaged couples [27-29]. Members of the research team had previously demonstrated in FIFI that a male-facilitated antenatal class of this type, supported by printed and promotional materials at weekly intervals for the first 6 weeks postpartum, resulted in a significantly larger proportion of infants being breastfed at 6 weeks compared with the usual care [25].

Building on the feedback from participants and lessons learned in FIFI, we refined and updated the content of the FFABC, and 117 FFABCs with an average size of 4 to 6 participants were delivered by a team of 11 trained peer facilitators [39]. A short process evaluation survey was completed by 98% of class attendees, and overall satisfaction with class format, facilitation, and content was high. Participants appreciated the validation of their role and valued the opportunity to interact with other fathers. Many fathers were not aware of the importance of or potential difficulties with breastfeeding and found the discussion around parenting and specific breastfeeding support strategies valuable [39].

We did not achieve the impact of FIFI with the FFABC in this study, which may be explained by differences in the participants of the 2 studies. Participants in FIFI, which was a smaller study (n=699), were all recruited from public hospitals and only 21% were tertiary educated. In contrast, the large target sample size required for PIFI, due to the 4-arm factorial design of the RCT, necessitated the recruitment of fathers from almost all maternity services across Perth, including private hospitals, which are responsible for approximately 50% of all births in Perth [37]. A disproportionate number of participants (983/1426) was recruited from private hospitals with just under one-third of participants being recruited from public hospitals. Additionally, half of the couples resided in the most socially advantaged areas of Perth. While initiation rates are high (>90%) among Australian women regardless of socioeconomic status [7], there is a persistent gap in the duration of exclusive and any breastfeeding between the most disadvantaged and least

disadvantaged women in Australia [7,51]. Similarly, almost two-thirds of fathers and three-quarters of mothers in PIFI were tertiary educated. Maternal education has been consistently shown to be positively associated with successful breastfeeding outcomes [52,53].

There is evidence of a digital and health literacy divide, with both being directly associated with education and income [54-56]. This has important implications for digital health research projects such as PIFI, as individuals with lower health literacy may be less willing and able to participate in research that requires engagement with digital technology [54]. The characteristics of the PIFI sample indicate that we recruited a socially advantaged and highly educated sample that likely was highly digitally and health literate and as a consequence familiar with infant feeding recommendations and strongly motivated to breastfeed before entering the trial.

A key recommendation from the process evaluation of FIFI was that technology be employed in the form of internet websites and email contact to provide postnatal support for time-poor fathers [43]. FIFI was conducted between May 2008 and June 2009, and in the intervening period the technological landscape had changed, and smartphone apps increasingly were being developed and used to deliver mHealth interventions [30]. The decision was made, therefore, to develop a smartphone app for use in PIFI; the design, development, and formative evaluation of the Milk Man app has been described in detail previously [44].

The Milk Man app was downloaded by 8 of 10 participants who were randomized to either the Milk Man or combination group. As this was the first app of its kind designed especially for fathers, there is no other study to compare it with. However, an extensive process evaluation of the app was undertaken as part of the PIFI [50] using a comprehensive and customized evaluation framework, which in addition to determining the impact and efficacy of the app, also examined elements such as the robustness of the technology, the intervention principles and engagement strategies, and the interaction of the user with the technology [57]. The design and ease of use of the app rated highly, and overall, users' opinions of the app were positive, with two-thirds indicating that they would recommend the app to other fathers [50].

The app included a customized app analytics framework that tracked how and when individual fathers were using the app over time. From approximately 32 weeks' gestation to 6 weeks postpartum, there were more than 79,000 in-app user interactions, with app use being concentrated in the weeks around the birth of the baby. The conversation forum was the hub of app activity, with conversation starters prompting the reading of library articles (average of 11.5 per user) and all but one of the most accessed library articles and external organization links being associated with the conversation forum. Active engagement in the conversation forum was relatively high, with approximately one-third of fathers posting comments in the conversation forum 1126 times (average of 2.21 per user) and voting in polls 3096 times (average of 6 per user) [50]. This is higher than that reported in other studies [58,59], and it should be noted that lurkers (those who observe but don't post) may

experience benefit as well [58]. Qualitative data collected in the 6-week follow-up questionnaire from fathers randomized to either the Milk Man or combination group indicated that fathers used the online forum in a variety of ways to facilitate social support and share information and experiences with other fathers [34].

Strengths and Limitations

Strengths of PIFI are that both interventions were designed with input from the end user. Another strength is that Milk Man app use was not prescribed, instead fathers were invited to use the app of their own volition, as they would in real life. As a result, there was wide variation in use patterns, which is likely to reflect real-life app engagement [50].

There are a number of limitations to this study, the first being that recruitment took longer than anticipated and for funding reasons was stopped prior to recruiting the target sample of 1600 couples. Although almost 90% of the target sample was recruited, attrition from the study was higher than the anticipated 25%, with less than half of recruited fathers providing complete baseline and follow-up data. As a result, the study was underpowered. While for convenience, follow-up questionnaires were administered online, they contained validated instruments designed to measure a variety of psychosocial factors associated with breastfeeding and parenting [36]. Therefore, questionnaires were relatively lengthy and time consuming to complete.

In this study, response rates for the short surveys delivered via SMS text were higher than that for the online surveys, with more than 8 of 10 fathers responding to the weekly SMS text surveys sent from 36 weeks' gestation until the birth and inquiring about the arrival of their baby. Similarly, 8 of 10 and 7 of 10 mothers responded to the short infant feeding SMS text surveys administered at 12 weeks and 18 weeks, respectively. Frequent app-based breastfeeding data collected from mothers has been validated against other more labor-intensive methods such as self-administered questionnaires and health visitor reports and shown to reduce participant burden and provide reliable, more complete data [60]. Therefore, in the future in order to reduce respondent burden and attrition and gather more complete data, we recommend collecting minimal data related to feeding outcomes of interest via frequent but short surveys administered from within the app or via SMS text.

The focus on a family structure of male and female identifying partners was another limitation of this study. However, resources

were not available to adapt the individual interventions for specific sexual and gender minority groups. As such, single parents and same-sex couples were excluded from the study. Further research to adapt the intervention for specific population groups is warranted.

The major limitation of the study, however, was that participants in this study, although randomly assigned to an intervention arm, were self-selected, and the resulting sample was not representative of the general population of expecting parents. Self-selection bias has been reported for other family-based studies involving fathers, with bias tending to be in the direction of overrepresenting those of higher educational attainment and those who are more invested in their fathering role [61]. Self-selection bias of this kind affected the generalizability of our findings, and had we recruited a more socioeconomically diverse sample of fathers, we may have seen an effect of the FFABC similar to that reported previously for FIFI [25] and other peer-facilitated face-to-face interventions involving socially disadvantaged fathers [27-29]. This self-selection bias would also have contributed to our inability to detect an impact of the Milk Man app on the primary breastfeeding outcomes or secondary outcomes, including postpartum partner support.

Conclusions

This study did not demonstrate a measurable impact of either a peer-facilitated, face-to-face, father-focused breastfeeding class or a breastfeeding smartphone app developed specifically for fathers. Nevertheless, neither intervention was shown to be inferior to the standard care delivered in routine antenatal classes, and process evaluation indicates that both interventions were acceptable to, and valued by, participant fathers. Face-to-face interventions are costly and difficult to sustain, but digital technologies such as smartphone apps provide the opportunity to deliver cost effective, safe, and scalable breastfeeding interventions to geographically dispersed populations. The Milk Man app is an innovative and highly acceptable approach to engage with expecting and new fathers seeking information and support. The acceptability and effectiveness of the app and the impact of its individual app-based engagement strategies, warrant further investigation. Ideally, Milk Man should be tested under pragmatic conditions designed to reduce barriers for those Australians who are less digitally included. Better understanding of how those who are less digitally included engage with smartphone-based health information will be of wide public health interest.

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Authors' Contributions

BW designed and evaluated the Milk Man app as her PhD project under the supervision of an independent team of academic researchers with backgrounds in nutrition, breastfeeding, midwifery, and health promotion research.

Conflicts of Interest

BW is a cofounder of Reach Health Promotion Innovations (Reach HPI), which specializes in the use of technology to reach audiences for public health and health promotion purposes. Reach HPI developed the Milk Man app under contract to Curtin University, which holds the patent for the Milk Man app. BW did not participate in the outcome analysis reported in this study. The other authors have no conflicts of interest to declare.

Multimedia Appendix 1

Participation in data collection points by intervention arm.

[[DOCX File , 13 KB - *pediatrics_v4i2e24579_app1.docx*](#)]

Multimedia Appendix 2

Comparison of exclusive and any breastfeeding at 6 and 26 weeks between control and intervention groups: intention to treat analysis.

[[DOCX File , 14 KB - *pediatrics_v4i2e24579_app2.docx*](#)]

Multimedia Appendix 3

Percentage of participants completing the intervention per protocol by sociodemographic characteristics and intervention arm.

[[DOCX File , 14 KB - *pediatrics_v4i2e24579_app3.docx*](#)]

Multimedia Appendix 4

Results of per protocol analysis of primary and secondary outcomes.

[[DOCX File , 20 KB - *pediatrics_v4i2e24579_app4.docx*](#)]

Multimedia Appendix 5

CONSORT-eHEALTH checklist (V 1.6.1).

[[PDF File \(Adobe PDF File\), 368 KB - *pediatrics_v4i2e24579_app5.pdf*](#)]

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Abbreviations

BSES-SF: Breastfeeding Self-Efficacy Scale–Short Form

FFABC: father-focused antenatal breastfeeding class

FIFI: Father Infant Feeding Initiative

mHealth: mobile health

PIFI: Parent Infant Feeding Initiative

PPSS: Postpartum Partner Support Scale

RCT: randomized controlled trial

Reach HPI: Reach Health Promotion Innovations

SMS: short message service

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Short Paper

Use of the Instagram Hashtags #winemom and #momjuice Among Mothers During the COVID-19 Pandemic: Descriptive, Cross-sectional Study

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Abstract

Background: The tendency of parents to consume alcohol during the COVID-19 pandemic is likely to be moderated by pandemic-related stress combined with the ongoing demands of childcare and home-based education, which are reported to be more burdensome for females than males.

Objective: The purpose of this study was to describe alcohol-related content posted by mothers on Instagram during the COVID-19 pandemic.

Methods: Using two popular hashtags, #momjuice and #winemom, 50 Instagram posts on each were collected from the “top posts” tab. The coding categories were created inductively and were as follows: displays alcohol (drinking/holding alcohol or alcohol itself), person is making alcoholic beverages, type of alcohol featured or discussed, highlights anxiety and/or depression/mental state, highlights struggling (in general), highlights parenting challenges, encourages alcohol consumption, discourages alcohol consumption, features a person wearing clothing or shows products promoting alcohol, promotes alcohol rehabilitation, highlights caffeine to alcohol daily transition throughout the day, and highlights other drugs besides caffeine and alcohol.

Results: Overall, the 100 selected posts had a total of 5108 comments and 94,671 likes. The respective averages were 51.08 (SD 77.94) and 946.71 (SD 1731.72). A majority (>50%) of the posts reviewed encouraged alcohol consumption (n=66) and/or displayed alcohol (n=56). Of the 66 that encouraged and/or displayed alcohol, the common type of alcohol discussed or featured was wine (n=55). Only 6 posts discouraged alcohol use and only 4 provided the audience with a disclaimer. None of the videos promoted or endorsed alcohol rehabilitation in any way. Only 37 posts highlighted struggle. However, these posts garnered more than a majority of the likes (n=50,034, 52.3%). Posts that showed struggle received an average of 1359.57 (SD 2108.02) likes. Those that did not show struggle had an average of 704.24 (SD 1447.46) likes. An independent one-tailed *t* test demonstrated this difference to be statistically significant ($P=.0499$).

Conclusions: The findings of this investigation suggest that though these hashtags ostensibly exist to valorize excess alcohol consumption, they may be serving as a support system for mothers who are experiencing increased burdens and role stress during the pandemic. Given the strains placed on mothers overall and especially during the COVID-19 pandemic, efforts must be taken to increase access to and affordability of telehealth-based mental health care.

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KEYWORDS

Instagram; alcohol consumption; COVID-19; social media; communication; parenting

Introduction

Much media attention has been paid to the burdens that the COVID-19 pandemic has placed upon women in general and mothers specifically. Though previous studies have noted that representations of drinking are commonplace on Instagram, these studies tend to be focused on youth. Given that recent research suggests an alarming increase in alcohol consumption among women during the pandemic, an investigation into how this population represents alcohol use on social media is warranted. This study sought to describe and analyze posts focused on drinking among mothers on Instagram on several content dimensions (eg, promoting alcohol consumption, stress or struggle, social support), which may clarify the attitudes and motivating factors of an online subgroup of drinking mothers.

Neither the mental health nor the economic effects of the pandemic in the United States has been borne evenly. Regarding the economic fallout, alarm bells were rung regarding the potential for a COVID-19 “she-cession” given that women constituted the majority of those who either lost employment in spring of 2020 or took a leave of absence from their positions in order to care for children learning from home [1]. A recent Census Bureau report [2] describes the labor market losses women have faced over the past year as “devastating.” The authors note that as of mid-January of this year, approximately 10 million women in the United States living with school-age children were not actively in the labor market, an increase of approximately 1.4 million since January 2019 [2]. Though mothers were hit harder by the economic effects of the pandemic compared to fathers, the gap in the work status between the two groups has narrowed substantially over the past several months [2].

Nevertheless, areas of considerable concern remain. First, as the US Bureau of Labor Statistics has documented, women continue to carry far more of the burden for domestic and childcare labor than do men [3,4]. When mothers return to the labor market, they must once again balance domestic labor with paid labor [2]. This is complicated by the fact that across the country, many children continue to learn from home—whether because school districts are still operating in a remote format or because parents have chosen this mode of delivery out of an abundance of caution. This balancing act is made all the more complicated by pandemic-specific “care economy” work [5] undertaken by women wherein women are attending to the emotional well-being of family members. Second, previous studies have documented that a temporary departure from the labor force (eg, for childbirth) may have long-term negative effects on women’s earning power [2]. Given this, pandemic-related labor-force participation gaps may suppress the economic position of women for years to come.

While disparities based on race and ethnicity are not a focus of this paper, it is important to note that among women, the labor market effects of the pandemic have been uneven, with women of color facing worse economic outcomes. The economic effects

of the pandemic—as with the health impacts [6]—vary by race and ethnicity, with Asian, Black, and Hispanic women facing substantively higher rates of continued unemployment compared to White women, at 9.5%, 9.3%, 8.8%, and 5.0%, respectively, as of January 2021 [2]. Thus, the economic recovery for women of color, as well as for women of all backgrounds in harder hit industries, may take substantially longer than it will for more advantaged women [7].

In terms of mental health, Americans in general saw increases in anxiety and depression during the pandemic [8], although effects may have been worse for women than men [9]. Moreover, research suggests that increases in anxiety and worry appear to have been greater among women with children in the household than for men in such households [10-12]. Cameron et al [10] note that risk for maternal anxiety has been particularly vulnerable to financial strain.

Alcohol consumption is known to rise during crises such as pandemic illness. For instance, during the week of March 21, 2020, Nielsen [13] reported that alcohol sales were up 55%. Additional studies have found gender-based differences in alcohol use during the pandemic. Though the prevalence of drinking alcohol, including binge drinking, is generally higher among men than women [14,15], more women than men reported an increased consumption of alcohol since the pandemic began [16]. In fact, the level of pandemic-related distress has shown a positive association with the number of drinks consumed by females in both typical and heavier drinking episodes (16% and 13%, respectively) [17]. Pollard et al [18] found a greater increase in heavy drinking in particular for women compared to men. This increase may be explained by findings that women use alcohol to moderate stress and anxiety more so than do men [19].

In a 2020 survey addressing changes since the onset of the pandemic, 27% of parents reported the emergence of mental health problems and 24% a loss of childcare from March to June. Although this pattern was found evenly across racial, ethnic, income, and education groups, women consistently reported worse perceptions of their own mental health than men [20]. Additionally, since the pandemic began, both men and women reported heavier drinking during the pandemic if children were sheltering at home. This stands in stark contrast to evidence that prepandemic drinking patterns were actually less risky among parents with children at home than those adults without children [21]. This increase in alcohol consumption may be related to the intensive demands of home schooling and daily childcare responsibilities, in addition to the financial and psychological stress already exerted by COVID-19-related lockdowns [12,22-24]. Taken together, relevant studies suggest that the tendency of parents to drink alcohol during COVID-19 is likely to be moderated by pandemic related stress combined with the ongoing demands of childcare and home-based education, which are reportedly more burdensome for females than males.

Cameron et al [10] note in the context of the ongoing pandemic and social distancing directives, internet-based mental health services provide a viable option for families experiencing distress that can afford to access such services. Yet, as the authors report, the transition to remote, telehealth-based psychological interventions has been slow, and moreover, “most telehealth models do not concurrently treat mental health concerns and parenting risks, despite the evidence for the importance of addressing both” [10]. It is in this context, as well as the fact that women are more likely to seek social support online [25], that we have undertaken an examination of alcohol-related content posted by mothers on Instagram. Instagram boasts over 1 billion users per month, with the majority being female [26]. Previous studies have found that posts featuring alcohol consumption are commonplace on social media; however, these studies have tended to focus on posts created by young people, rather than adults in general or mothers specifically [27-29]. At the time of writing, we did not identify any papers in the peer-reviewed literature that examined alcohol-related content posted by mothers on Instagram during the pandemic. Addressing this gap was the purpose of this study, with the aim to better understand the elements of posts with the #winemom and #winejuice hashtags, and to be able to characterize the overall tone and elements of use of #winemom using systematic methods.

Methods

The methods for this study were similar to others on other health topics [30,31] in that the content on important and timely public health issues was assessed to determine any possible themes present in the data. This study took place in February 2021. Using two popular hashtags, #momjuice and #winemom, 50 Instagram posts on each were collected from the “top posts” tab. At the time of data collection, #momjuice had 37,800 posts and #winemom had 77,600 posts. Posts were excluded if they were in a language other than English (n=3), or if they were advertisements or giveaways (n=9). The date, number of comments, number of likes, presence of a disclaimer (ie, a statement limiting responsibility for the post), and use of an illustration were recorded. The unit of analysis considered images and corresponding captions. Using content analysis, a Microsoft Excel spreadsheet (Microsoft Corp) was created to manually analyze the presence of given themes. Our methods were best defined as follows, “a research technique for the objective, systematic and quantitative description of the manifest content of communication” [32].

The coding categories were created inductively and were as follows: displays alcohol (visible alcohol such as drinking or

holding alcohol or alcohol itself), person is making alcoholic beverages (visible ingredients or mixing materials), type of alcohol featured or discussed (if they mentioned or displayed what they were drinking), highlights anxiety and/or depression/mental state (mentions or suggests anxiety, stress, or depression whether in the context of parenting or in general), highlights struggling (mentions or suggests having difficulty overcoming obstacles), highlights parenting challenges (mentions or suggests difficulties specifically related to parenting), encourages alcohol consumption (condones alcohol as beneficial), discourages alcohol consumption (presents alcohol as an unfavorable activity), features a person wearing clothing or shows products promoting alcohol (products ranged from clothing to cups with sayings or words endorsing alcohol consumption), promotes alcohol rehabilitation (mentions or suggests that alcohol rehabilitation is beneficial), highlights caffeine to alcohol daily transition throughout the day (mentions or suggests the need for caffeine early in the day and alcohol later), and highlights other drugs besides caffeine and alcohol (mentions or suggests the use of any other drug).

Interrater reliability was established with a random sample of 10% (or 10 posts) coded by author NQ and recoded independently by author CB. NQ viewed all 100 posts and examined them for a collection of predetermined content characteristics. CB coded a random sample of 10 posts to assess them for the same content. In total, the two reviewers differed in only 4 out of 340 data points. This resulted in near-perfect agreement: an interrater reliability score of $\kappa=0.96$. The 4 discrepancies occurred in the following 3 categories: picture of a child (n=2), highlights struggle (n=1), and wearing clothing or showing products promoting alcohol (n=1). These few discrepancies were resolved through reanalysis of the posts. Data analysis was completed using Microsoft Excel (Microsoft Corp) and included running descriptive statistics and conducting independent one-tailed *t* tests ($\alpha=0.05$) on observations of note to determine statistical significance. As this study did not involve human subjects, it did not require approval from the Institutional Review Board at William Paterson University.

Results

Overall, the 100 reviewed posts had a total of 5108 comments and 94,671 likes. The respective averages were 51.08 (SD 77.94) and 946.71 (SD 1731.72).

Table 1 shows 12 different content characteristics and the total number of posts for which these characteristics were observed. Table 1 also includes the number of comments and likes received by posts featuring this content. Relative percentages are included for comparison.

Table 1. Observed content characteristics, comments, and likes of 100 alcohol-related content posted by mothers on Instagram.

Characteristic	Posts (N=100), n	Comments (N=5108), n (%)	Likes (N=94,671), n (%)
Encourages alcohol consumption	66	2762 (54.07)	40,137 (42.40)
Displays alcohol	56	2436 (47.69)	25,779 (27.23)
Highlights struggling	37	1998 (39.12)	50,034 (52.85)
Highlights parenting challenges	26	1394 (27.29)	38,546 (40.72)
Includes clothing or products promoting alcohol	19	1199 (23.47)	5641 (5.96)
Highlights anxiety, depression, or mental state	15	956 (18.72)	20,689 (21.85)
Features a picture of a child	11	419 (8.20)	5428 (5.73)
Discourages alcohol consumption	6	360 (7.05)	3796 (4.01)
Provides a disclaimer	4	700 (13.70)	971 (1.03)
Highlights caffeine to alcohol daily transition	3	120 (2.35)	1856 (1.96)
Features a person making alcoholic beverages	2	97 (1.90)	1136 (1.20)
Highlights other drugs besides caffeine and alcohol	2	395 (7.73)	11,133 (11.76)

A majority (>50%) of the posts we reviewed encouraged alcohol consumption (n=66) and/or displayed alcohol (n=56). Of the 66 that encouraged and/or displayed alcohol, the common type of alcohol discussed or featured was wine (n=55). Only 6 posts reviewed discouraged alcohol use, and only 4 provided the audience with a disclaimer. None of the posts promoted or endorsed alcohol rehabilitation in any way. Therefore, this characteristic was removed from the table.

Even though more than 50% of the posts reviewed displayed alcohol, these posts only garnered 26.95% (n=25,779) of the total likes. An independent one-tailed *t* test ($=.05$) showed this observation to be statistically significant ($P=.002$). More specifically, the *t* test showed that posts that displayed alcohol were less likely to receive a like when compared to those posts that did not display alcohol. The average number of likes for posts displaying alcohol was 460.34 (SD 1006.56) compared to 1565.73 (SD 2231.14) for posts not displaying alcohol.

Only 37% of the posts reviewed highlighted struggle. However, these posts garnered more than a majority of the likes (n=50,034, 52.3%). Posts that showed struggle received an average of 1359.57 (SD 2108.02) likes. Those that did not show struggle had an average of 704.24 (SD 1447.46) likes. An independent one-tailed *t* test ($=.05$) showed this difference to be statistically significant ($P=.0499$) as well. Therefore, the data indicate that posts highlighting struggle were more likely to receive likes than those that do not show struggle. It should be noted that the World Health Organization declared that COVID-19 had reached pandemic levels on March 11, 2020 [33]. A total of 23 posts occurred before the pandemic declaration (prior to March 11), and 77 posts occurred afterwards (on and after March 11). Of the 23 posted before the pandemic declaration, 19 (82.61%) did not have a theme of struggling and 4 (21.05%) did. Of the 77 posted during the pandemic, 44 posts (57.14%) did not highlight struggling, whereas 33 (42.86%) did. Of the 37 posts that highlighted struggle, 13 (35.14%) also displayed alcohol. None of these 13 posts displayed a person making an alcoholic beverage. However, 11 of these posts (84.61%) did encourage the consumption of alcohol.

Discussion

Our findings suggest that the sample of posts evaluated in this study, under the hashtags #momjuice and #winemom, most commonly indicated encouragement of alcohol consumption and display of alcohol, and highlighted coping struggles. The fact that content related to struggling garnered more likes than posts encouraging alcohol use suggests that #winemom and #momjuice may provide a forum for validation and support related to the burdens faced by mothers trying balance multiple forms of labor—paid and unpaid. Notably, while some of the posts in our sample were dated prior to the declaration that COVID-19 as a pandemic, those that occurred after were more likely to highlight struggling. This may be indicative of the additional “care economy” work [5] required by mothers over the past year.

While it is important to note that the “wine mom” terminology existed prior to the pandemic [34], the proliferation of “wine mom” and “mom juice” paraphernalia [35] leads to questions as to the reasons behind the movement. It is currently unknown whether the derivation of the #winemom and #momjuice movement is simply a humorous meme with limited implications, or if there is more to the message that should take into account the undue pressure placed on all parents, particularly mothers, during the COVID-19 pandemic [34-37]. In times of crisis, individuals who participate socially (eg, identify with groups, derive social support from others, feel a sense of belonging to a community) may benefit from enhanced personal resources [38,39]. Online groups such as “wine mom” may thus function as a humorous protective buffer for its members. Along with the social connection provided by the group, the humorous aspect, as well as the situational reframing, may provide a relieving counterpoint to the strong negative emotions felt by many as the pandemic unfolded, lockdowns were mandated, and women in particular faced sudden and dramatic changes in roles and perceptions of mental health [40,41].

This study is limited by the small sample size, the cross-sectional design, and the ever-evolving state of posts on this platform. Further study should focus on commentary generated on these posts as well as how these may change on a longitudinal basis. As with all cross-sectional studies, external validity is low. Further, our methodology was limited by the lack of profile data on the source of each post. Nevertheless, to our knowledge, this is the first study to examine this content in general, and specifically during a time of heightened stress and anxiety. The

findings of this investigation suggest that though these hashtags ostensibly exist to valorize excess alcohol consumption, they may be serving as a support system for mothers who are experiencing increased burdens and role stress during the pandemic. Given the strains placed on mothers overall and especially during the COVID-19 pandemic, efforts must be taken to increase access to and affordability of telehealth-based mental health care. Social media forums such as Instagram are a place to potentially highlight the availability of such services.

Conflicts of Interest

None declared.

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Original Paper

Parents' Attitudes Toward School Students' Overuse of Smartphones and Its Detrimental Health Impacts: Qualitative Study

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Abstract

Background: Parents' awareness of the risks of the overuse of smartphones (SPs) among their children and parents' attitudes toward this societal phenomenon are crucial factors to consider when investigating the causes and effects of, as well as interventions to control, this public health issue.

Objective: This study aimed to explore the awareness and attitudes of parents regarding SP overuse among their children and the detrimental impacts associated with it.

Methods: The qualitative method of semistructured face-to-face interviews was used to collect data from fathers and mothers of children aged 6-18 years from all 6 educational/governorate regions in the governmental sector in Kuwait.

Results: A total of 120 parents agreed to participate in the study; there were more female (75/120, 62.5%) than male (45/120, 37.5%) respondents. Almost all of the participants (118/120, 98.3%) were aware that the overuse of SPs could lead to their children becoming addicted to the devices; they were also aware that there could be side effects on their children's health (117/120, 97.5%). Although the participants, mostly the mothers, supervised their children's use of SPs closely (106/120, 88.3%), the majority could not control their children's length of time using SPs, as the children considered this a deprivation of their rights. Eye-related problems, headaches, and anger were the most common side effects experienced by the children.

Conclusions: Although the parents were aware of the detrimental impacts of SP overuse, the majority could not control the length of time their children spent using the devices. It was found that strong social bonds among family members play a large role in controlling the use of SPs. A number of solutions for families and the government to combat the overuse of SPs are suggested.

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KEYWORDS

smartphones; overuse impact; school students; parents' attitudes

Introduction

Background

Most of the early adopters of smart devices are from the younger generation, specifically teenagers [1]. Such devices have become

an integral part of their lives, allowing them to stay connected with their friends and parents [2,3]. Smartphones (SPs) offer numerous advantages for users other than as mobile phones for communication: they can be used for playing games, watching videos, socializing via electronic media, and experiencing the array of information available on the World Wide Web. The

widespread use of SPs has been reported worldwide, reaching 3.5 billion global users in 2020 [4], with South Korea reported to have the highest level of ownership of SPs [5]. Adolescent and elementary school students are, like adults, addicted to the use of SPs [6]. Pew Research Center reported that in 2019, 81% of Americans owned SPs [5] and nearly 95% of teens had access to SPs, and many of them had concerns about overusing them [7]. In Kuwait, according to a report on the consolidated Kuwait National Information and Communication Technology indicators, 99.5% of households owned SPs in 2019 [8].

The frequent use of SP devices for long periods of time can have an impact on users. Previous studies have shown that SP overuse is associated with physical health problems such as obesity; headaches; vision problems; and neck, shoulder, and back pain [8]. In addition, psychological problems have been identified, including anger and violence [9], loneliness and depression [10], and insomnia [11].

Furthermore, the overuse of SP devices can lead to addiction, especially among children and teenagers, who have weak self-control [12,13]. This population likes technology and uses it without awareness of the consequences. Regardless of the advantages of SP devices, the detrimental effects of their overuse are becoming apparent in society [2,14].

Context

In the extant literature, most studies have used a quantitative approach to investigate parents' perceptions of mobile technology use and its effects on their preschool children's patterns of use [15,16], parents' concerns [17], and parent-adolescent social relationships [2]. One previous study used a combined quantitative and qualitative approach to examine children's routine behaviors regarding screen time from their parents' perspectives and how the parents intervened to reduce the children's sedentary lifestyle behavior [18].

There are crucial factors that contribute to the compulsive usage of SPs, including the user's characteristics and experience. One study found that the more the user perceived enjoyment from using SPs, was satisfied with SP use, and liked using technology, the more they felt compelled to use SPs [19]. Another study found that perceived ease of use and perceived usefulness of SPs were factors that influenced behavioral intentions and thus social norms regarding the frequent use of SPs [20]. These factors are crucial aspects that cause SPs to play a prominent role in people's lives.

In regard to children's use of technology, a previous study aimed to identify strategies to control such usage [21]. In the study, 615 parents were surveyed and the results suggested that parents' awareness about the negative impacts of long periods of screen time (>1 hour per session) and parents' actions are the main requirements to regulate children's use of technology [21]. A qualitative study was conducted in India using in-depth interviews to investigate parents' opinions regarding their children's use of mobile phones and how it affects their mental health [22]. The findings suggested that the unsupervised overuse of mobile phones among children could lead to mental changes, including stress [22].

Consequently, we are of the opinion that the views and experiences of parents are an important component to understanding the phenomenon of SP overuse among children [2]. There have been few studies on the awareness of parents of the risks of their children's SP overuse and parents' attitudes toward this societal phenomenon, which are considered crucial factors when investigating and determining which interventions to use to control this public health issue. The current study addresses the knowledge gap on this topic.

Therefore, this study aimed to understand the insights of parents in regard to SP device overuse among children of school age (aged 6 to 18 years). The objectives of this research were to (1) identify children's patterns of SP use, (2) explore parents' awareness of the detrimental impacts on health due to SP overuse, (3) identify parents' attitudes toward the detrimental impacts associated with SP overuse, and (4) recommend appropriate interventions or solutions to avoid the risks to children's health.

Methods

Study Design

A qualitative design employing semistructured face-to-face interviews was used to collect data from the parents (fathers or mothers) of school students. This is considered an effective approach in exploratory research to collect attitudinal information on a large scale to obtain in-depth information about specific phenomena [23,24].

Recruitment and Data Collection

Data were collected from 120 parents of students from all 6 educational/governorate regions in the governmental sector in Kuwait: Asimah, Farwaniyah, Hawally, Jahra, Ahmadi, and Mubarak Al-Kabeer. Experts in qualitative research recommend that the optimal number of interviews should be between 12 and 60 [25]. Therefore, in this study, the data collection strategy was to interview 20 participants from each region to obtain data from different perspectives, as people from different regions can be expected to have different experiences and attitudes.

The schools were randomly selected from each educational region. The principal researcher contacted the schools' managers to schedule the interviews during the parents' meeting days. Parents were invited by the school managers to participate in this study, and those who agreed were taken to a quiet room next to the parents' meeting hall. Only parents whose children used SP devices were included in this study.

At the beginning of each interview, the title and aim of the study were introduced to the parent. The average duration of the interviews was 25 minutes. The data collection process started in September 2018 and ended in May 2019.

The interviews were conducted by the principal researcher, who has skills in interviewing and knowledge of the research themes. This aided in standardizing the method of conducting the interviews, as the conditions of the interviews did not differ from one researcher to another.

Face-to-Face Interview Guide

The interview questions were designed based on a review of the literature on related topics [2,17,18]. The interview guide aimed to achieve the objectives of the study (Textbox 1). It employed open-ended questions with probes to guide the interviews.

The interview guide was piloted with 5 parents (3 mothers and 2 fathers) to check the questions' clarity, suitability for the study

Textbox 1. The interview guide.

<p>Demographic data</p> <ul style="list-style-type: none"> Participant's age, gender, nationality, and educational level <p>Students' ownership of smartphone (SP) devices and patterns of use</p> <ul style="list-style-type: none"> The purpose of buying SP devices for your children: communication, entertainment, or education Your children's patterns of SP device use: little use (only on the weekend or less than 2 hours/day), within moderate use range (2-4 hours/day), or overuse (more than 4 hours/day). The divisions of smart technology use were adapted from the Canadian Paediatric Society statement, where moderate use was defined as 2-4 hours/day [26] <p>Level of awareness of parents of the detrimental impacts</p> <ul style="list-style-type: none"> The educational performance of your children and whether SP device use (ie, overuse) affects their performance: probes include "what is your child's average grade?" Supervision of children's SP device use: probes include close supervision, occasional supervision, or no supervision Awareness of the detrimental impacts (physical and/or mental) of overuse Physical health impacts ("have you noticed any of the following?"): seizures, nearsightedness, strabismus, dry eyes, blurry vision, transient blindness, headaches, sleep disturbance, neck/shoulder pain, lower-back pain, loss of concentration, or obesity Mental health impacts ("have you noticed any of the following?"): loneliness, anxiety, anger, depression, fear, annoyance, aggression, or lethargy <p>Parents' attitudes toward the overuse of SP devices</p> <ul style="list-style-type: none"> Reactions to the problem: start controlling the overuse, stop use (off/on), or arrange specialists to visit Overcoming this phenomenon: parental responsibility and governmental responsibility

Ethical Considerations

Approval for the study was obtained from the Research Ethics Committee at the Kuwait Ministry of Health (reference number 885/2018). Parents' consent was obtained prior to conducting the interviews, and parents were informed that they were free to withdraw from the study at any time.

Qualitative Data Analysis

The interviews were audiotaped and transcribed verbatim. The transcripts were typed into Microsoft Word documents. A thematic analysis method was used to analyze the data because this simple qualitative approach can provide explicit results that are more understandable to the public [24,27]. In addition, this method is attractive to researchers because of its high flexibility of analysis. This method includes pinpointing, examining, and recording patterns or themes [27]. Initially, codes and subcodes were developed for the entire data set based on the themes of the semistructured interview guide. Then, an iterative approach comprising constant comparison was employed, in which all of the data relating to each theme was constantly revisited after the initial coding [28]. Reviewing and refining the themes and subthemes were done by the coauthors, in addition to

objectives, and order. Accordingly, minor amendments were made, which included adjusting the order of the questions and adding a question regarding the educational performance of the children to the interview guide. The interviews were conducted in Arabic because it is the official language in Kuwait; thereafter, the transcriptions were translated into English. The translations were performed by the translation office in the Faculty of Medicine at Kuwait University.

cross-checking a random sample (n=12), to ensure consensus in the coding and the accuracy of the transcriptions. The data were entered into and analyzed using the software program MAXQDA Analytics Pro (VERBI Software GmbH), allowing the researchers to identify frequencies, compare themes, and find connections among the parents' responses.

Four themes emerged from the analysis of the parent interviews: doctor's advice, deprivation of the children's rights, addiction to SP use, and the role of the government.

Results

Demographic Data

The total number of parents invited to take part in the study was 126; 120 of them agreed to participate, which provided a response rate of 95.2%. Twenty participants were interviewed from each region. Table 1 presents the demographic data of the interviewed parents. Among the interviewees, there were more mothers (75/120, 62.5%) than fathers (45/120, 37.5%), and more parents were Kuwaiti (104/120, 86.7%) than non-Kuwaiti (16/120, 13.3%). Most of the fathers (26/45, 57.8%) were in their 40s, and most of the mothers (41/75, 54.7%) were in their 30s. The majority of parents held a bachelor's degree (fathers:

21/45, 46.6%; mothers: 49/75, 65.3%) or a diploma (fathers: 11/45, 24.4%; mothers: 17/75, 22.7%).

Table 1. Demographic data of the participants (N=120).

Characteristic	Educational region						Total, n (%)
	Ahmadi	Asimah	Farwaniyah	Jahra	Hawally	Mubarak Al-Kabeer	
Gender							
Female	14	14	10	11	11	15	75 (62.5)
Male	6	6	10	9	9	5	45 (37.5)
Age group							
20-29	1	1	0	0	0	0	2 (1.7)
30-39	12	9	9	9	3	10	52 (43.3)
40-49	5	6	11	9	12	10	53 (44.2)
50-59	2	4	0	2	5	0	13 (10.8)
Nationality							
Kuwaiti	20	19	6	19	20	20	104 (86.7)
Non-Kuwaiti	0	1	14	1	0	0	16 (13.3)
Education level							
High school	2	1	3	3	1	3	13 (10.8)
Diploma	8	4	1	2	8	4	27 (22.5)
Bachelor's degree	7	15	14	12	9	12	69 (57.5)
Postgraduate	3	0	2	3	2	1	11 (9.2)

Students' SP Ownership and Pattern of Use

The majority of the participants (113/120, 94.2%) had bought SP devices for their children, while the minority (7/120, 5.8%) had given their children their own devices to use. The main reasons for their children using SPs were for entertainment (79/120, 65.9%), including playing games and watching videos on YouTube, and/or communication purposes (31/120, 25.8%).

The participants justified buying SPs for their children as imitating others (101/120, 84.2%) and keeping up in the era of technology (18/120, 15.0%). One parent stated,

Current society forces us to keep abreast with technology and imitate others in doing so...I bought smartphones for my children because their cousins had them. [a 32-year-old Kuwaiti mother of an 11-year-old girl, Mubarak Al-Kabeer region, interview number 11]

More than half of the participants (68/120, 56.7%) declared that their children used SP devices for >4 hours/day, while 30.8% (37/120) said that their children used the devices for ≤4 hours/day. Some of the participants (15/120, 12.5%), of which 6.7% (1/15) were non-Kuwaitis, only allowed their children to use SP devices on the weekend, either with or without constraints on use:

I only allow my children to use smartphone devices at the weekend: it's like a reward for them after five days of not using them, and they use them for more than six hours during the day—playing games, watching videos via the YouTube application and

more... [a 43-year-old non-Kuwaiti father of an 8-year-old boy, Farwaniyah region, interview number 48]

One mother described her worrying about her children when they were outside the house and her decision to let her children enjoy using SPs without constraints at home because at least they were around her:

I don't mind allowing my children to have smartphone devices and use them for a long time if they are staying in the house. I worry about them when they are out and I don't know where they are or whom they are with. [a 43-year-old Kuwaiti mother of a 13-year-old girl, Mubarak Al-Kabeer region, interview number 17]

Parents' Awareness of the Detrimental Impacts of SP Overuse

The results revealed that the parents' levels of awareness of the detrimental impacts of SP overuse were not associated with the interviewee's age, gender, education level, or region. Almost all of the interviewed mothers and fathers were aware of children's potential to become addicted to SP devices (118/120, 98.3%) and that there could be side effects as a result of SP overuse (117/120, 97.5%). One of the interviewees responded,

Yes, we know that using SP devices for a long time can lead to addiction to their use and also the side effects associated with overuse, and this information has been shared through social media. [a 45-year-old Kuwaiti father of a 15-year-old boy, Hawally region, interview number 89]

When the participants were asked if the overuse of SP devices had negatively affected the educational performance of their children, 95.8% (115/120) responded with “no.” In fact, some of the parents had noticed improvements in their children’s educational performance. The majority (103/120, 85.8%) of the participants whose children were overusing SPs declared that their children had received final assessment levels of “very good” or “excellent” and sometimes showed better performance in English and general knowledge:

I have always tried to control my children’s use of smartphone devices, but I cannot do it—they still overuse them; however, their educational performance results are still the same or sometimes better. [a 39-year-old Kuwaiti mother of an 8-year-old boy, Asimah region, interview number 38]

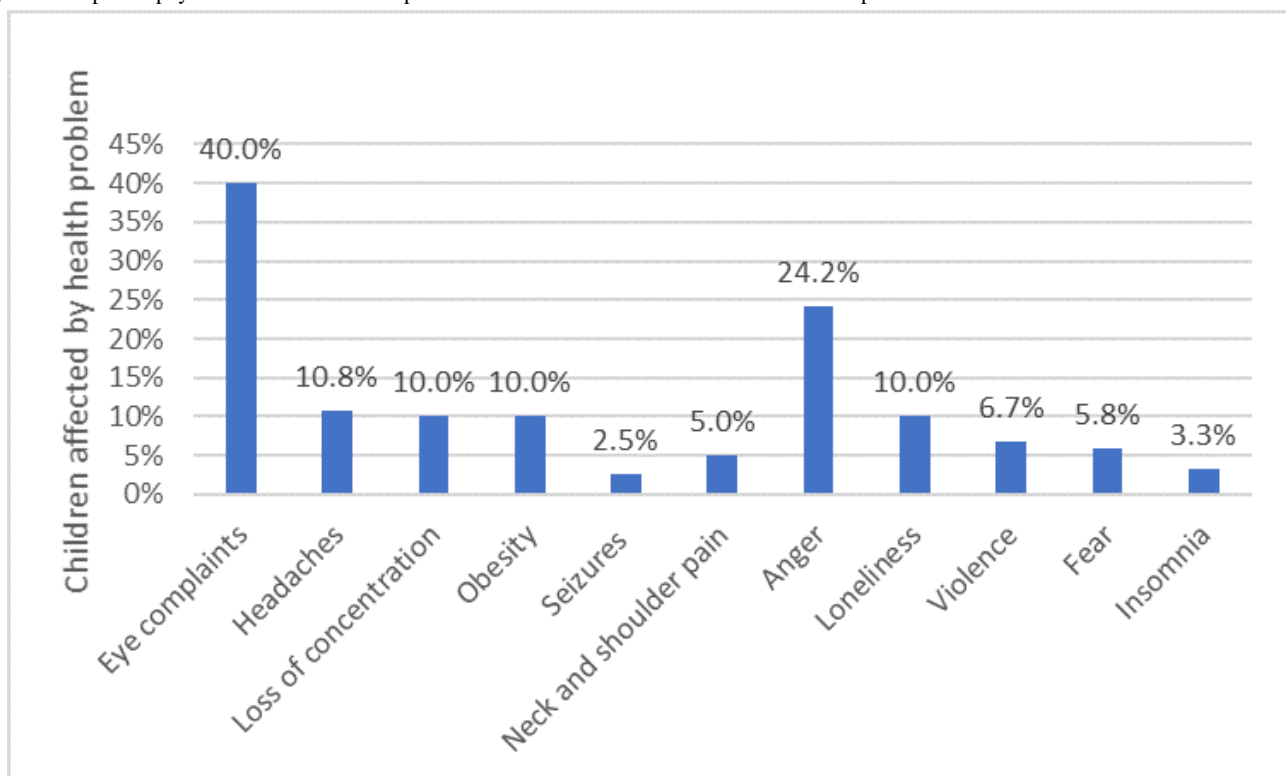
Another parent stated the following in an amazed way:

I have noticed that the English language of my son has improved, and I have realised that this is because of using SP applications and searching the internet. [a 33-year-old Kuwaiti mother of a 7-year-old boy, Jahra region, interview number 61]

Physical and Mental Health Problems

The results showed that almost one-half of the participants (56/120, 46.7%) had noticed specific health complaints among their children due to SP overuse (Figure 1), the majority of which were eye complaints (48/120, 40.0%), including eye dryness (16/120, 13.3%), blurry vision (15/120, 12.5%), and tired eyes (17/120, 14.2%). In addition, complaints related to the children’s mental state had been noticed (44/120, 36.7%) (Figure 1).

Figure 1. Reported physical and mental health problems in children due to excessive use of smartphones.



The results showed that some parents were distressed because their children often did not listen to their advice to play and socialize in “real life” and to reduce their online life with their SP. One parent expressed her dissatisfaction by noting the following:

...my daughter likes to stay alone in her room and most of the times she asks to bring the lunch and dinner meals to her room, and this is the cause of her obesity. [a 43-year-old Kuwaiti mother of a 13-year-old girl, Mubarak Al-Kabeer region, interview number 17]

Furthermore, many of the parents reported that they had observed their children becoming angry or violent during or after SP use. Some of the parents reported that their children’s use of digital media via SPs had caused them fear and insomnia:

I realised that my son became scared and sometimes faced difficulty in sleeping... [a 36-year-old Kuwaiti mother of a 9-year-old boy, Jahra region, interview number 66]

The participants’ responses revealed that the student’s age, gender, nationality, and educational region had no influence on his or her pattern of SP use and the physical and/or mental health complaints associated with it.

Attitudes of Parents Toward Their Children’s Overuse of SPs

Most of the participants (106/120, 88.3%), especially the mothers, were close to their children, supervised their SP use, and knew what their children were primarily using their devices for, such as accessing social media, communicating with friends, or playing games. When asked if they monitored their children’s

patterns of SP use, most of the fathers (40/45, 88.9%) said that their wives were closer to their children than they were; however, because the couples shared the responsibility, fathers took over the role of monitor when their wives wanted to exercise more control over their children’s SP use. When parents noticed physical and/or mental health complaints in their children as a result of SP overuse, they showed different reactions; **Figure 2** shows the different reactions of fathers and mothers. Among the non-Kuwaiti participants (16/120, 13.3%), half of them stated that SP use is necessary to keep abreast of developments in technology and that it is difficult to control SP use among children, while others believed in restricting the length of SP use. One participant’s response shows the difficulty of controlling children’s overuse of SPs:

To be honest, we tried many times to control the use of smartphone devices among our children, but we couldn’t because everybody uses them, even us...So, children feel that we deprive them of one of their rights. [a 39-year-old Kuwaiti mother of an 11-year-old girl, Mubarak Al-Kabeer region, interview number 15]

Some parents showed good control over their children’s pattern of SP use, for which they identified a strong family bond as an important factor in the effective control of SP use. As one of the mothers stated,

...we are not only close to our children but also socialising with them and providing them with exciting alternatives to make them happy away from SP use... [a 42-year-old Kuwaiti mother of an 11-year-old girl, Mubarak Al-Kabeer region, interview number 7]

The results also showed that doctors’ advice was important in encouraging parental firmness in controlling SP use among their

children. One of the participants justified his reaction of stopping his child from using SPs as being because of a doctor’s advice:

Well, I am aware of the side effects of SP overuse, as my son has had brain seizures as a result of continuous overuse, so the physician advised us to stop using SPs, despite no one in the family having this symptom of epilepsy. [a 48-year-old Kuwaiti father of an 11-year-old boy, Jahra region, interview number 72]

Another parent gave the following response:

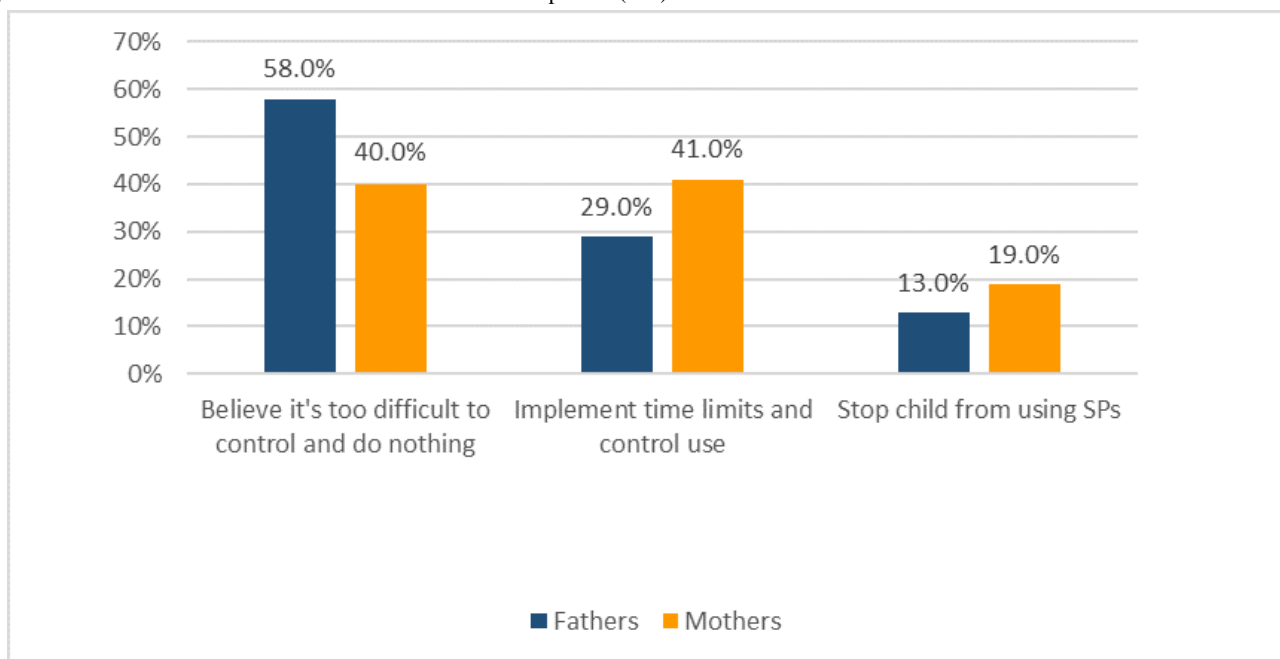
...one of my cousins was addicted to SP device use, and, as a result, he had brain seizures; this made me very strict in controlling the usage time for my children, and I succeeded, as they got used to one hour a day...so we as parents need to be firm to save our children from harm. [a 42-year-old Kuwaiti mother of an 11-year-old girl, Mubarak Al-Kabeer region, interview number 7]

Another parent had the following to say:

I know the negative effects of overusing SPs, especially among children, but, at the current time, I face difficulties in controlling their use among my adolescent children. It seems that we are waiting for something bad to happen to them to find a strong reason to stop them from using them...regrettably. [a 44-year-old Kuwaiti father of a 15-year-old boy, Hawally region, interview number 10]

The results showed that the parents could not control the SP use of their children aged 15 years old and above, as they felt that their children were old enough to take responsibility for controlling their own SP use, which is a common behavior among adolescents.

Figure 2. Parents’ reactions to their children’s overuse of smartphones (SPs).



Parents' Suggested Solutions

The parents were asked to suggest solutions to minimize the detrimental impacts of the overuse of SP devices on children (Tables 2 and 3). The most common solutions mentioned by the participants, with nationality having no influence, were implementing strict control in terms of allowing children specific times to use SP devices (fathers: 38/45, 84.4%; mothers: 67/75,

89.3%) and encouraging children to join health clubs and undertake sport activities (fathers: 23/45, 51.1%; mothers: 40/75, 53.3%). Other solutions were mentioned by a few participants: socializing as a family (fathers: 15/45, 33.3%; mothers: 27/75, 36.0%), encouraging participation in arts and science workshops (fathers: 4/45, 8.9%; mothers: 12/75, 16%), and using reward techniques (fathers: 6/45, 13.3%; mothers: 5/75, 6.7%).

Table 2. Suggested solutions from parents to minimize their children's overuse of smartphone (SP) devices (N=120).

Suggested solution	Value, n (%)
Use strict parental control to restrict SP usage time.	105 (87.5)
Socialize as a family and go out for picnics, to farms, camping, etc	42 (35.0)
Encourage children to join health clubs and undertake sport activities.	63 (52.5)
Encourage children to participate in arts and science workshops.	16 (13.3)
Increase parents' awareness of the fact that they are role models for their children.	15 (12.5)
Use reward techniques (eg, "If you study hard, you can use your SP for an hour").	11 (9.2)
Block programs/games that have bad consequences with prolonged use.	5 (4.2)

Table 3. Suggested solutions from parents for the government to minimize the overuse of smartphone (SP) devices.

Suggested solution	Value, n (%)
Hold awareness sessions for school students on a regular basis, such as presentations by health specialists using examples of students who have suffered the detrimental effects of SP overuse.	64 (53.3)
Improve the awareness of parents, including methods to reduce their children's SP overuse.	32 (26.7)
Monitor inappropriate programs for children and block them.	17 (14.2)
Use social media to provide advice and explain the detrimental impacts of SP overuse.	16 (13.3)
Arrange regular sports competitions for all ages in and outside schools for free and use famous players to increase participation rates.	18 (15.0)
Establish more sports clubs to accommodate more participants.	16 (13.3)
Reactivate science club activities.	3 (2.5)
Ensure computer classes at schools of all levels include lessons dealing specifically with the ideal use of SP devices, including recommended applications.	13 (10.8)
Establish an entertainment center in each region and arrange regular activities of all kinds throughout the year at minimal cost to attract participants of all ages.	15 (12.5)

The results showed that most of the participants (78/120, 65%) believed that it was not solely their responsibility to control the use of SP devices among their children but that the government also played a role. There were variances in the parents' responses according to the educational/governorate region, with parents—specifically fathers—from Jahra and Ahmadi making more suggestions than participants from other regions regarding how the government could establish new sports clubs to accommodate more participants and large places nearby that would be suitable for family picnics.

Some of the participants (16/120, 13.3%) were frustrated and complained that they had noticed their children overusing SP devices but could not find useful alternatives:

The government has to support us as citizens in making an entertainment centre in each region, as well as establishing new sport clubs to accommodate more participants where currently they are incapable of doing so. [a 47-year-old Kuwaiti father of a

17-year-old boy, Ahmadi region, interview number 115]

The results showed that the parents not only tried to offer advice to their children to reduce their overuse of SP devices but also gave them alternatives, as one of the respondents stated:

I have registered my children in a swimming course, and in their spare time I take them to a farm so that they can move freely without constraints. [a 48-year-old Kuwaiti father of an 11-year-old boy, Jahra region, interview number 72]

In order to overcome the detrimental consequences of SP device overuse among students of different levels (primary, secondary, and high school), the majority of the participants suggested solutions (Table 2), and more than half of them indicated that the government also had a responsibility in this (Table 3). One of the parents declared,

Actually, there is a need to develop national programmes for education, training, and entertaining that involve activities throughout the year, aiming to attract the youth to spend their time in a productive way, and it's very important to market these programmes smartly to ensure very good participation from all. [a 47-year-old Kuwaiti father of a 16-year-old boy, Jahra region, interview number 73]

Discussion

Principal Findings

The findings of this study reveal that ownership of SPs among school students in Kuwait is high due to societal peer pressure, with people seeking to imitate one another. Such devices are mainly bought for entertainment and/or communication purposes, and partly for educational purposes. The majority of the parents were aware of the detrimental impacts of SP overuse; however, they expressed that it was difficult to control the SP overuse by their children.

Children's Patterns of SP Use

Most of the parents declared that their children's use of SPs exceeded 4 hours on a daily basis, which is considered overuse by the American Academy of Pediatrics (AAP) and the Canadian Paediatric Society [26,29]. The parents admitted that they could not control their children's duration of use of SP devices. Similar results in terms of parents worrying about SP device overuse and struggling to control the use by their children were also found in a previous study [30]. Furthermore, parents' responses indicated a potential reason for their children's persistent overuse of SPs: while parents might ask their children to reduce their use, they themselves overuse such devices in front of them, making controlling the use of SPs by their children difficult. This was reported in a previous study that found that children can be influenced by parental attitudes and beliefs; for instance, when parents were positive toward media use, their children used media for a longer time, and when parents were negative toward it, their children were deterred from using it as well [31].

Awareness of the Detrimental Impacts of SP Overuse

Although almost all of the parents were aware that the overuse of SP devices could lead to addiction and other detrimental effects, including side effects related to physical and mental health problems, they also acknowledged that their children still used SPs heavily. It seems that parental awareness about the detrimental impacts was not enough to reduce SP overuse among children. Therefore, proper parental education and action are needed, wherein they can learn and use a variety of strategies to reduce the SP overuse, such as restrictions on technology use [32]. The findings revealed that almost half of the interviewed parents declared that their school-age children had suffered from numerous problems associated with SP overuse, including physical health problems: eye problems (tired, dry, and twitchy eyes), headaches, back and neck pain, difficulties in concentration, and brain seizures. These problems might be the result of staring at the screen of a small device for a long period of time and on a frequent basis, with strong light directed at the eyes. This association has been reported in previous studies in

Saudi Arabia [33], Egypt [34], Turkey [35], India [36], and Poland [37]. In regard to brain seizures, for children who have been diagnosed with photosensitive epilepsy, the Epilepsy Society in the United Kingdom recommends avoiding the overuse of SP devices and reducing the frequent exposure to flashing and contrasting lights produced by the screens, which may trigger factors in the brain that cause abnormal nerve impulses and lead to convulsions [32]. Regardless of the strength of this association, it is crucial to know the causes behind students' overuse of SP devices, which could be emotional, social, or other. Parents' attention is required to solve the problem and reduce the overuse.

Furthermore, some of the parents reported an association between their children's overuse of SPs and a sense of loneliness. More screen time, less movement, and fewer interactions with others can lead to depression and a sedentary lifestyle, which can cause obesity. This association could be because children need to play and socialize in real life, not just online, to feel connected to others [38]. Previous studies in Australia [39], Iceland [40], and China [41] have also reported that being less physically active and having more screen time are associated with depression. Interestingly, the participants in our study also believed that a sedentary lifestyle and excessive use of SP devices were associated with obesity, consistent with previous findings [18,42], and that the family environment plays an important role in this matter [18,43].

In this study, parents reported instances of their children becoming violent because of something pertaining to SP applications (such as challenging games) or angry while using social media or because they knew that their parents would stop their use at a specific time and they would be unable to continue to connect with the online world. This has also been reported in previous studies [10,12]. Some of the parents reported that their children's use of digital media via SPs had caused them some fear and insomnia, and the parents realized that the content of the media determined the level of impact. The relationship between the use of mobile devices and poor sleep has been reported in several previous studies [44-46]. Therefore, it is of paramount importance that parents monitor their children to control their overuse of SPs in order to avoid physical or mental health problems.

The findings of this study revealed that the parents did not perceive their children's overuse of SPs to be negatively impacting their educational performance, which was consistent with the findings of previous studies [47,48]. However, a study in Saudi Arabia concluded that medical students should decrease their SP use, as it was found to affect their academic achievement [33].

Attitudes of Parents Toward Their Children's Overuse of SPs

The results indicated that numerous parents were apathetic toward their children's overuse of SPs, finding it too difficult to control. Children and adolescents typically have less self-control than adults and are easily distracted [12,13]. Smart technology, with its attractions and advantages for all ages, particularly teenagers, is often enjoyable. As technological applications develop and emerge, children come to depend on

them and grow with them, resulting in a new generation with different health complaints, as this study shows. This was also consistent with a local study from Kuwait among school students, which showed similar health-related problems associated with SP overuse [45]. Most of the interviewed parents in this study stated that keeping abreast of technology is crucial but that the pattern of use must be well controlled to avoid harmful consequences. This makes good parental control of children's use of SP devices important, especially during periods of behavioral development and physical growth, when parents play a vital role in taking care of them.

In the interviews, some of the participants revealed that when family bonds were strong, resulting in better socializing, there was good and effective control of SP use. Based on the parents' responses, it appeared that not all of the parents were socializing with their children, but they showed a willingness to do so, believing it to be a good intervention to reduce the overuse of SPs. Previous studies have confirmed that good relationships between parents and children have a beneficial impact on children's patterns of SP use [2,18].

Furthermore, some parents need physicians to advise them to take a firm and rational approach to their children's SP use. One parent responded that he would probably implement a firmer approach to controlling his child's SP use if his child developed a health problem, viewing health effects as a rationale for stopping the overuse of SPs. Parents and physicians should view a child's visit to the physician's office as an important opportunity to educate the child and parent regarding the possible detrimental health impacts of SP overuse.

Thus, leaving children to use SP devices without parental control leaves them susceptible to unknown risks that could expose them to physical and/or mental health problems. Hence, parents' support via close supervision and participation with their children is of paramount importance for the safe use of SPs and healthy online participation [49]. Accordingly, the parents in this study suggested different solutions for families and the government to treat the problem of SP overuse, which should be viewed as a public health issue. In addition, the recommendations of the AAP [50] would be a very helpful resource for parents and schools in this regard. They suggest numerous ways to restrict smart technology use among children aged 0-18 years.

Strengths and Limitations

The 2 main strengths of this study were as follows: (1) the sample of interviewed parents was large and included multiple perspectives from fathers and mothers, and (2) a high proportion

of the participants were fathers (in many other studies, smaller proportions of the participants were fathers). On the other hand, this study had a number of limitations. First, it was limited to governmental sector schools, where the majority of students were Kuwaiti. Second, it only included parents, excluding their children from the study. Third, some of the questions asked the parents to recall their children's health-related symptoms as a result of SP overuse, which could be subject to recall bias. Moreover, these health-related symptoms should not be attributed to SP use alone, as confounding factors were not accounted for because of the nature of the study. Fourth, due to the lack of research on similar populations in the region, most of the results of this study can only be compared with the findings of similar studies with populations from different cultures and environments.

Conclusions

This study found that almost all of the participants, both fathers and mothers, were aware that the overuse of SPs could lead to addiction and other detrimental effects, such as physical and mental health problems. The parents were apathetic toward their children's overuse of SPs, finding it too difficult to control. However, it was found that strong social bonds among family members could play a large role in controlling the use of SPs. It can be concluded that parents who provide a healthy family environment that encourages children to both socialize and play will support the children in avoiding the overuse of smart devices.

Based on the findings of this study, the following recommendations are suggested to avoid the detrimental impacts of SP overuse. First, parents should not only supervise their children's SP use closely but also offer alternatives that help children enjoy their time away from online life. Second, although parents are generally aware of the health effects of SP overuse, they need training in cognitive and behavioral methods that can effectively improve their child's self-control regarding SP use. Third, parents of a child who is overusing SP devices should consider a physician's visit to ensure their child is free of its physical and psychological impacts and receive advice to help control their child's SP use. Fourth, physicians need to be aware of the possible detrimental health impacts that SPs can have and to recognize their crucial professional role in this context, assisting in the development of local guidelines to address this matter. Fifth, the government should react to this public health issue and implement actions to meet the public's needs for entertainment and sports facilities to provide alternatives to the use of SPs.

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Authors' Contributions

AB is the main author (guarantor), conducted the literature review, found the knowledge gap, designed the research strategy, conducted the data collection through interviews, and wrote the majority of the research manuscript. HH designed the interview

guide and wrote the discussion section. AAS performed the data analysis and software work and wrote the results section. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AAP: American Academy of Pediatrics

SP: smartphone

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Original Paper

Indigenous Mothers' Use of Web- and App-Based Information Sources to Support Healthy Parenting and Infant Health in Canada: Interpretive Description

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Abstract

Background: Web-based sources of health information are widely used by parents to support healthy parenting and aid in decision making about their infants' health. Although fraught with challenges such as misinformation, if used appropriately, web-based resources can improve access to health education and promote healthy choices. How Indigenous mothers use web-based information to support their parenting and infants' health has not yet been investigated; however, web-based modalities may be important methods for mitigating the reduced access to health care and negative health care interactions that many Indigenous people are known to experience.

Objective: This study aims to understand the experience of Indigenous mothers who use web-based information to support the health of their infants.

Methods: This interpretive description qualitative study used semistructured interviews and a discussion group to understand how Indigenous mothers living in Hamilton, Ontario and caring for an infant aged <2 years experienced meeting the health needs of their infants. The data presented reflect their experiences of using web-based sources of health information to support their infants' health. The Two-Eyed Seeing approach was applied to the study design, which ensured that both western and Indigenous worldviews were considered throughout.

Results: A total of 19 Indigenous mothers participated in this study. The resulting 4 themes included distrusting information, staying anonymous, using visual information to support decision making, and accessing a world of experiences. Although fewer Indigenous mothers used web-based sources of information compared to mothers in the general population in other studies, tailoring web-based modalities to meet the unique needs of Indigenous mothers is an important opportunity for supporting the health and wellness of both mothers and infants.

Conclusions: Web-based information sources are commonly used among parents, and ever-evolving web-based technologies make this information increasingly available and accessible. Tailoring web-based modalities to meet the unique preferences and needs of Indigenous mothers is an important method for improving their access to reliable and accurate health care information, thereby supporting healthy parenting and promoting infant health.

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KEYWORDS

Indigenous health; infant health; mothers; parenting; qualitative research; health education; health services accessibility; mobile phone

Introduction

Background

The internet is widely used for various purposes around the world, including seeking health information. It has become so important to everyday life that some argue that access is a human right, contributing to political activism and freedom of speech [1]. In 2016, the Canadian government was the first country to recognize access to the internet as an essential service [2]. Nearly all Canadians (97%) have access to wireless internet where they live [2], and most (75%) surf the web and other web-based apps via smartphones [3]. These types of technologies make accessing the internet simple and portable, resulting in our exceedingly frequent use of web-based sources of information.

Individuals, including parents, commonly use the internet and its products to seek information pertaining to their health and to support their health-related decision making. New and expecting parents, who have grown up with access to the internet, are the most frequent users of this medium for this purpose—seeking health-related information for themselves and their infants [4]. In a study examining the use of Google, new and expecting parents were found to use this search engine more than twice as often as nonparents; they most commonly searched for health-related concerns including the health of their infants, feeding issues, and infant-related products [5]. Other studies found similar findings; new and expecting parents searched the internet most frequently for health information related to breastfeeding, infant health symptoms and how to manage them, infant development, infant nutrition, and social support [4,6-13].

However, using the internet to search for health-related information is not without challenges. In studies investigating parental use of the internet to meet their health-related informational needs, parents were commonly unable to find the information they were seeking and could not discern high-quality information from low-quality information and desired reliable web-based sources to be made available by health care providers involved in their care and the care of their children [4,7,14-16].

Indigenous mothers represent a subset of parents who are known to face unique challenges in accessing health care and health information because of experiences of racism, discrimination, and social inequity resulting from racist policies that disproportionately burden Indigenous people, particularly women [17]. Their use of search engines, web-based apps, and social media to support the health of their infants is less understood but may be an important way to promote their health and wellness by improving access to health information and promoting positive parenting and healthy choices. Few studies have investigated the utility of web-based resources for Indigenous parents. In fact, no studies have examined this phenomenon in Canada. However, research in Australia—a

country that has undergone a similar period of colonization as Canada—has shown promising results, demonstrating that web-based resources can be an important way to mitigate the reduced access to health services experienced by Indigenous parents because of associated costs, wait times, and racist and discriminatory care [13,18-20]. In particular, these web-based resources are cost-effective, can reach people in rural and remote areas, are less intrusive and more confidential than traditional in-person care, and can improve communication by allowing for access in real time rather than having people wait for appointments with health care providers [18]. As is important in health initiatives with Indigenous people, health care providers and researchers can take a strengths-based approach with Indigenous mothers by acknowledging and building on existing technological skills to care for the health of their children. Furthermore, web-based apps and resources can be tailored to meet the unique needs of distinct Indigenous communities and groups, minimize language barriers, and integrate local traditional and cultural health information into accessible resources that support maternal and child health.

Objectives

The data presented here describe how Indigenous mothers living in an urban city in Ontario, Canada use the internet, web-based apps, and social media to support the health of their infants. Indigenous people in Canada are recognized by the Constitution as First Nation, Métis, and Inuit groups, and within each group, there are numerous distinct communities with diverse cultures, languages, and traditions [21]. Although originating from a study not explicitly designed to elicit a detailed account of mothers' experiences of using web-based information to meet the health needs of their infants, mothers nevertheless shared important insights into their needs related to web-based information sources. The results presented here aim to provide an initial understanding of this phenomenon, which has important implications for health care providers seeking to improve access to reliable health information and health promotional opportunities for these families.

Methods

Overview

This study used a qualitative methodology, namely, interpretive description [22], to explore the following research question: how do Indigenous mothers living in an urban city in Canada experience using health services to meet the health needs of their infants (aged ≤ 2 years)? Interpretive description is an applied approach to research that stems from nursing philosophy and seeks to create knowledge that can influence real-world changes for clinicians and patients [22]. This research also applied Two-Eyed Seeing, a framework that bridges both western and Indigenous worldviews to understand a phenomenon [23]. The first author is a non-Indigenous nurse practitioner of settler, European descent who strives to engage ethically with Indigenous people to further Indigenous research

priorities that promote community health and well-being. The second author is a First Nations nurse and PhD student who participated in this study as a research assistant. The third author is First Nations and a manager specializing in child and family advocacy at the Hamilton Indigenous Friendship Centre. In keeping with the Two-Eyed Seeing approach, this study was collaboratively designed by both authors, a Métis scholar who participated in the lead researcher's PhD committee, and members of the Hamilton Indigenous community. A full description of how the Two-Eyed Seeing approach was applied to this study can be found in another publication [24].

Participant Sample

Participant mothers were recruited from local Indigenous organizations, including the local friendship center and women's center, among others, through word of mouth and flyers posted at local health services. Mothers were included if they self-identified as Indigenous (First Nations, Métis, and Inuit), lived in Hamilton, Ontario and were caring for an infant aged <2 years. Data collection and analysis occurred simultaneously, and recruitment continued until conceptual redundancy was achieved and data were sufficiently detailed to answer the research question [25].

Data Collection

Data were collected through semistructured interviews, which lasted approximately 60-90 minutes with each participant mother and the first author at a location of convenience for the mother. All mothers were offered the presence of a research assistant, but only one mother requested this. All mothers spoke English as their first language. Interview questions were developed using *Behavioral Model and Access to Medical Care* [26] by Andersen to ensure that questions incorporated the wide breadth of factors described in the model and known to influence an individual's access to health care, including environmental factors, characteristics of the population, health-related behaviors, and the health status of the individual. Andersen model has been widely tested and validated with Indigenous and other ethnic groups [26]. Some examples of interview questions are as follows: (1) "What do you do to help your baby stay healthy; (2) "What services or sources of information do you find helpful in meeting the health needs of your baby; and (3) "Tell me more about how you use [app or website] to address your baby's health needs?" Once all interviews were completed, participating mothers were asked to come together as a group to review the initial study findings and further clarify evolving concepts. All mothers were invited, and 8 participated. Mothers verified the initial study findings and did not ask for any data to be removed. Written and verbal consent for study participation was collected when they first met each mother. Interviews were audio recorded, transcribed, and then uploaded onto NVivo 12 (QSR International) for qualitative data analysis [27]. Field notes were collected during and after each interview and during and after the discussion group. These provided context, including mothers' emotional reactions during the interviews, and added depth and meaning to the transcripts. Data were stored in a locked filing cabinet and a password-protected computer in a locked office at the university. Ethics board approval was obtained from 3 local research ethics boards, including the

Hamilton Integrated Research Ethics Board, Mohawk College Ethics Board, and the McMaster University Family Medicine Program, and the staff at the local Friendship center collaborated on and approved the study design.

Data Analysis

An iterative thematic analysis of the data was conducted by the lead researcher. Transcripts were read and reread and then coded according to the techniques described by Saldana [28], which allowed for pattern recognition and exploration of concepts, relationships, and meanings. The results presented here constitute a thematic summary of the data pertaining to mothers' use of web-based resources, including the internet, apps, and social media sources, and has been presented in a way that both provides an understanding of the phenomenon and supports researchers and clinicians applying these findings to real-world applications to meet the health information needs of Indigenous mothers and their infants.

Results

Overview

The understanding of how Indigenous mothers in Hamilton, Ontario use web-based resources to meet the health needs of their infants is informed by interviews with 19 mothers. The demographic details are presented in [Table 1](#). The mothers' number of children and education levels have been compared with local data for First Nations people [29], and the proportions of First Nations, Métis, and Inuit identities have been compared with the identities of self-identifying Indigenous people living in Hamilton [30].

Briefly, 15 mothers were identified as First Nations, 2 as Métis, and 2 were unsure of their specific Indigenous heritage, as is not uncommon for Indigenous people, due to the lasting impacts of colonization, forced assimilation, and resulting loss of identity and cultural ties. The mean age of participants was 28 years (SD 5.82 years), and nearly one-third were first-time mothers. When asked whether they used the internet or other web-based sources to answer health-related questions regarding their infants, mothers reported solely using Google as their internet search engine and Facebook as their primary social media platform. No other search engines or social media platforms were mentioned by the mothers. Within the group of 19 mothers, 10 (53%) reported using Google, 4 (21%) reported using a health-related app, 5 (26%) used Facebook, and 6 (32%) did not use the internet in any form to address their informational needs regarding their infants' health. Of the 6 (32%) mothers who used multiple internet sources, 2 (11%) used both Google and Facebook and 4 (21%) used both Google and apps, but none used all 3 types of internet sources (Google, apps, and Facebook).

When asked about the reasons for using various types of web-based resources, mothers reported using Google to search for infant norms (developmental milestones, normal temperature, normal behavior, and sleep patterns), how to care for common illnesses (especially rashes and fevers), signs and symptoms of infections, when to take the infant to see a doctor, and baby food recipes. Mothers reported using Facebook to peruse

mom-to-mom blogs, share issues with other peers, and find examples of similar experiences related to infant health. Parenting apps were used to discover infant developmental milestones, especially weekly updates on developmental changes and stages, to answer questions about normal infant health issues, guidelines for when to start feeding solids, meal planning strategies for infants, and baby food recipes.

Data analysis of mothers' experiences of using web-based resources to meet their informational needs pertaining to their infants' health resulted in 4 main themes: (1) distrusting information, (2) staying anonymous, (3) using visual information to support decision making, and (4) accessing a world of experiences. The following section describes these themes in more detail. Supporting quotations from these themes can be found in [Textbox 1](#).

Table 1. Demographic information: participant mothers.

Characteristic	Participants (n=19), n (%)	Comparison with First Nations data in Hamilton, n (%) ^a
Age (years)		
<25 years	5 (26.3)	— ^b
26-30 years	8 (42.1)	—
>31 years	6 (31.6)	—
Number of children^c		
0	0 (0)	200 (36)
1-2	12 (63.2)	200 (36)
3	2 (10.5)	83 (15)
≥4	5 (26.3)	72 (13)
Education^c		
Less than high school	9 (47.4)	316 (57)
Completed only high school	3 (15.8)	111 (20)
Some college or university	7 (36.8)	128 (23)
Indigenous identity^d		
First Nations	15 (78.9)	9695 (67.1)
Métis	2 (10.5)	3960 (27.4)
Inuit	0 (0)	165 (1.1)
Unknown (not sure if First Nations, Métis, or Inuit)	2 (10.5)	—
Regular health care provider		
Family physician	17 (89.5)	—
Pediatrician	1 (5.3)	—
None	1 (5.3)	—

^aNumber of children (% of family).

^bDemographic data are not available for Indigenous people within the city of Hamilton.

^cn=555; data obtained from Smylie et al [29].

^dn=13,820; data obtained from Statistics Canada [30].

Textbox 1. Themes and supporting participant quotes.

<p>Distrusting information</p> <ul style="list-style-type: none"> • “Well I use the internet when he’s sick...search up his symptoms and just see. I try not to do that too much because sometimes some crazy things pop up and then I get scared.” [First Nations mother of two, aged 26 years] • “I look up on the Internet and some of the stuff that comes up, it’s like, I didn’t think you were allowed to use that kind of stuff on kids! And I’m like, no, I would rather go to the doctors and get her looked at. Sometimes when you read stuff on the internet, it is not always accurate.” [First Nations mother of five, aged 27 years] • “Every time you Google something it is always going to show up cancer.” [First Nations mother of two, aged 21 years] • “Well obviously, I question them. I know I shouldn’t be on doctor Google because obviously there is conflicting information out there.” [First Nations mother of two, aged 35 years] • “If you were to type in something like an ear infection, they will give you so many different options. Some of them say the same thing and some will say other things. Like I don’t know which one is going to be better for her or I don’t know how bad it is. I don’t always trust it.” [First Nations mother of three, aged 32 years] <p>Staying anonymous</p> <ul style="list-style-type: none"> • “They do have like mom groups [on Facebook]. I don’t ask for other people’s opinions. They ask questions...like when something is wrong with their kid or something, they’ll say ‘is this normal’? and then other moms give their opinions and then I just go over it. I don’t really talk.” [First Nations mother of four, aged 21 years] • “Like mom-to-mom groups. I read. I don’t want to post in it because then all of a sudden you’re the center of the post and they never stop commenting. It will be a year later and someone is still commenting.” [First Nations mother of two, aged 21 years] <p>Using visual information to support decision making</p> <ul style="list-style-type: none"> • “Some moms will ask about their child and post a picture, and say if it is like a rash or say if they got chicken pox and they don’t know what it is. They will be like what is this? They post on there and other people will comment on what they think it is. But I thought [my son’s rash] was actually just a rash that he developed because he was sick. Then it was actually hives which when we went to the doctors she told me it was hives. An allergic reaction to something.” [First Nations mother of two, aged 21 years] • “Like they will post pictures of a rash on their kid, and be like, ‘I have a doctor’s appointment later but I am just looking for advice like if anyone else’s child has ever had this?’ What do you think it looks like? Things like that.” [First Nations mother of two, aged 26 years] <p>Accessing a world of experiences</p> <ul style="list-style-type: none"> • “I kind of just read Mom blogs. They make me feel a little bit better that there are other moms out there.” [First Nations mother of two, aged 35 years] • “Say your son has a rash, and you’re like, ‘There is this purplish-red rash, how do I get rid of it or what do I do?’ And [you get] fifteen answers from every mom who seems to be going through the exact same thing as you.” [Métis mother of one, aged 22 years] • “What kind of laundry detergent is safest for my son’s skin? There is someone else out there in the world, whose son has the same skin as your baby or goes through the same thing as your baby.” [Métis mother of one, aged 22 years] • “You are looking at ten different answers and there is one answer that appeals to you. Especially with your type of parenting style. There is someone who parents their children similar to you, right?” [Métis mother of one, aged 22 years]

“Crazy Things Pop Up”: Distrusting Information

Although most mothers used web-based sources of information to answer questions they had related to their infant’s health, development, and well-being, they also struggled to trust the information they found on the web. Mothers shared the impressions that the information was often inaccurate and did not align with other health information they had received from other, more trusted sources such as health care providers. A common complaint about using Google was that symptoms of illness were commonly associated with symptoms of cancer, which scared mothers and made them anxious. Mothers shared their struggles with navigating large amounts of information and the ways they had developed to assist them in choosing the information that they could use to make decisions. Some mothers reported reading numerous answers and choosing to believe or act on the advice that they found to be most frequent and consistent with their existing knowledge of the issue.

Another mother went with her *gut instinct* and chose the answers that she believed were best and were the easiest to apply or use. Other mothers shared that they chose to act on information that was in line with their own parenting beliefs and styles. Understanding that discerning quality and reputable web-based information was difficult, mothers had developed these tactics to choose the information that they could use or otherwise sought information from health care providers directly.

“All of a Sudden You’re the Center of the Post”: Staying Anonymous

Mothers required the ability to use web-based resources with complete anonymity. Even those who used Facebook to access parenting discussion forums chose not to engage with other mothers by replying to posts or posting their own. Instead, they chose only to read other mothers’ posts and apply relevant content to their own decision making and parenting experiences.

One mother expressed her frustration at being constantly notified of new posts to her thread if she initiated a discussion in a mom-to-mom forum. Rather than having these notifications persist, she chose not to post at all.

“What Do You Think It Looks Like?” Using Visual Information to Support Decision Making

The unique ability to share and view pictures was one of the most common reasons for mothers to use web-based resources, particularly apps and Facebook discussion forums. Although Google was used to look up pictures of specific symptoms or known illnesses, apps provided pictures of developmental stages and common newborn ailments or caregiving techniques, such as providing an infant with medicine. The use of pictures assisted mothers in interpreting health information that may have otherwise been complex and technical.

Facebook discussion forums were particularly important as they allowed mothers to post pictures of their infants' symptoms and to seek advice from thousands of other mothers worldwide. The most frequent symptom that participant mothers spoke about was their infants' rashes. These common newborn ailments were often confusing to mothers who wanted to understand the cause and source of the rashes and whether their infants' rashes warranted seeing a physician. The participants used these forums to find pictures of symptoms that were similar to those of their own infants, as they did not post their own pictures. With hundreds or thousands of mothers subscribing to each forum, mothers did not find it difficult to find pictures and descriptions similar to the issues they and their infants were experiencing. However, this type of self-diagnosis is problematic. One mother shared her experience of using such a forum to determine that her infant had a rash associated with an illness. However, when she visited her physician, she was surprised to discover that the rash had been caused by an allergic reaction. These types of self-diagnosis errors can be dangerous for infants if mothers do not seek advice from a health provider, instead choosing to assume that their understanding of web-based resources is correct.

“There Is Someone Out There Going Through the Same Thing”: Accessing a World of Experiences

Finally, web-based resources, particularly Facebook discussion forums, provided mothers with access to thousands of mothers from across the world. Participant mothers shared that they had no difficulties finding mothers with similar questions, experiences, or dilemmas. This helped to normalize their experiences, boost their parenting confidence, and lessen their stress and anxiety by reassuring them that they and their infants were like others, even if those in their immediate social network were dissimilar. Although the participant mothers did not interact with other mothers on discussion forums, these forums formed a sort of web- and app-based social network, where mothers found a place in which they felt a sense of belonging and similarity with other mothers and where they felt secure in their ability to control their information and interactions through the anonymity provided by the sites.

In summary, the use of web-based sources of information for parenting and newborn health was common among participant

mothers. These sources of information were not always reliable, and mothers struggled to determine which information to trust and act on among a sea of suggestions and advice from websites, apps, and Facebook discussion forums. The ability to anonymously peruse information was extremely important, as it facilitated mothers controlling their interactions and information-sharing with others. The use of pictures and other visual information assisted mothers in interpreting otherwise complex health information and also enabled seeking advice from other mothers. Finally, access to thousands of mothers across the world via Facebook discussion forums helped to normalize an otherwise isolating experience of parenting a newborn, linking mothers to others with similar experiences and challenges. Web-based resources are highly used sources of information for mothers and other new parents, and the data described here present some ways in which these sources may be tailored to meet the needs of Indigenous mothers while also mitigating the risks associated with unreliable information and self-diagnosis.

Discussion

Principal Findings

To the best of our knowledge, this study is the first to discuss Indigenous mothers' use of web-based resources to support the health of their infants. This understanding is important for health care providers who wish to assist Indigenous mothers in meeting their health-related informational needs. This study and the literature has demonstrated that new and expecting parents are most commonly using internet sources of information to address questions and concerns related to parenting and newborn health, yet many are challenged by the rampant availability of misinformation, their inability to discern high-quality scores from low-quality sources, and understanding complex medical information [2,5,14,31]. Certainly, this presents an opportunity for the development of innovative internet resources to meet the needs of parents while providing reliable health information in an accessible format. In today's health care environment, access to quality information that is easily understood by mothers, which results in safe and positive parenting choices, is essential to promoting healthy newborn development and facilitating the appropriate use of health care services. The results of this study suggest that a mother's ability to remain anonymous while searching and interacting with web-based information is imperative, as is a visual format and access to a wide range of parenting and newborn experiences so that mothers can easily find their place of belonging among countless possibilities. The creation of web-based modalities that meet these requirements could be a valuable asset for health care providers looking to link parents with reliable health information, especially those who are vulnerable or marginalized and at a higher risk of experiencing adverse health outcomes. In addition, web-based modalities can assist health care providers by making health education more efficient and accessible.

Despite the high prevalence of access to smartphones and internet use among Canadians, our study found that just under 70% (13/19, 68%) of mothers used the internet in some form

to answer health-related questions pertaining to their newborns. This number is significantly lower than many other studies that show that $\geq 90\%$ of parents used the internet for this purpose [4,7,12,16]. However, our sample was small and did not reflect Indigenous people across Canada or their diverse experiences. Many mothers in this study experienced lower financial means, which may have led to text-only plans on their mobile phones and limited their opportunities to use the internet. In fact, several mothers shared that they chose not to use paid apps. Other mothers shared a preference for face-to-face interactions with health care providers, choosing not to use web-based sources because of distrust of their accuracy. Despite this, the majority were using internet sources of information; thus, web-based modalities are likely an excellent way to reach these mothers with important health education related to parenting and infant health.

The distrust of web-based information found in this study is a common finding among parents using the internet for infant-related health information [6,7,9,14,15]. Not being able to locate the desired information can have significant implications on decision making. As demonstrated in a study of mothers using the internet for breastfeeding support, mothers who were unable to find the information they were seeking were more likely to choose to feed their infant formula rather than breastfeed [14]. The mothers in this study developed tactics to evaluate the information they found on the internet, most often choosing information that was repeated on various websites or by numerous mothers on discussion forums, going with their *gut instinct* or choosing information that was agreeable to them. Other studies have found that parents used similar approaches [8,32]. However, other parents did not attempt to discriminate between correct and incorrect information at all. One study found that 74% of mothers using a pregnancy app and 68% of mothers using a parenting app chose not to validate information [33]. This lack of health literacy and critical thinking can be problematic, and similar to the mothers in this study, those with lower levels of education have been found to be less critical about the information they discover on the internet [32]. Together, these findings suggest that Indigenous mothers, similar to most parents, lack the web-based health literacy skills necessary to discern between reliable and unreliable sources of information and that health care providers and educators have an important role in teaching web-based health literacy skills to parents and providing reliable sources of information to parents that can be used appropriately to answer their parenting questions [32,33].

This study found that Indigenous mothers most commonly used Google to meet their information needs on parenting and infant health issues. Fewer mothers reported using parenting apps and Facebook. This trend is similar to other studies, in which only half of internet users used parenting apps and Facebook was the most frequently used social media platform for parents [4,33,34]. In this study, the appeal of web-based sources of information for Indigenous mothers included the availability of visual information, a web- and app-based social network, and anonymity. Similarly, Skranes et al [9] found that parents appreciated the visual nature of web-based information and most commonly searched for pictures of infant rashes. This

common infant ailment presents a conundrum to parents, and accurate sources of visual information pertaining to rashes would likely be a helpful and welcome resource for them. In addition, the availability of visual information likely also supports health literacy, as parents can depend less on written information. Visual information may also be a faster and more efficient way for parents to process health-related information compared with reading.

Next, Facebook discussion forums were important to the Indigenous mothers in this study as they created a type of web- and app-based social network by instilling a sense of normalcy among thousands of other mothers with various experiences. This was particularly important for some mothers who had purposefully isolated themselves from friends and family who had negative influences in the past. Many participants had experienced negative health care encounters, racism, and discrimination within mainstream services and felt that their parenting was surveilled by child protection services. Indeed, both a lack of culturally safe health care services and Indigenous health care providers are barriers to safe and appropriate care for Indigenous families in Canada [13,17]. In the absence of culturally safe health care options, web-based discussion forums represented a safe place where they were in control of their personal information and could choose whether to anonymously view information or interact with other mothers on the forum. This phenomenon has been documented elsewhere, and other studies have found that a web- and app-based social network can provide parents with a sense of normalcy, social support, increased parenting confidence, and reduced isolation, all of which are particularly important in the postpartum period [6,8,10,35]. In a study of mothers' use of social media, Duggan et al [34] found that only 36% of mothers asked questions, whereas others chose to anonymously view content. Discussion forums appear to serve multiple purposes for Indigenous mothers, representing a web- and app-based social network, assisting mothers in finding others with similar experiences, even when rare, and promoting a safe place where mothers can choose whether to interact or view content anonymously.

Mothers did not discuss the threat of cyberbullying as a reason why they chose not to interact with mothers on discussion forums and were not directly asked about this by the interviewer. However, in their personal lives, several mothers isolated themselves from friends and family members who they felt had a negative influence on their lives. The threat of negative interactions and the potential for cyberbullying if engaging with other mothers in web-based forums, therefore, may explain their insistence on anonymity.

Although these findings require verification with a larger sample size, they have several notable implications. First, Indigenous mothers, similar to other parents, require reliable sources of parenting and infant health information. Health care providers should suggest reputable websites to parents to assist them in making informed decisions based on high-quality information [7,32,33]. Culturally safe web-based resources and those created from an Indigenous worldview in collaboration with Indigenous communities are also imperative to best meet the needs of Indigenous families. Web-based modalities represent an important opportunity to provide health education and promote

health. Second, web-based modalities such as apps should be available free of charge. Mothers and infants experiencing poverty are at high risk of experiencing adverse health outcomes; thus, their access to reliable health promotional information is paramount and should be prioritized. Charging fees to access information is prohibitive and deters mothers from using them fully, as demonstrated in this study. Third, there appears to be a missed opportunity for health care providers to monitor web-based discussion forums to ensure that accurate information is being shared and to provide reliable advice to mothers and other parents. This type of intervention would significantly improve the credibility of discussion forums, thereby amplifying the benefits of this highly used source of information.

Future Research

Given the historical, political, and social contexts that the participant mothers experience in their daily lives, these findings are likely to be relevant to other Indigenous parents who are similarly impacted by racism, discrimination, and social inequity stemming from colonization and subsequent discriminatory policies and stereotyping. Future research is needed to validate these findings with a larger and more representative group of Indigenous parents. Conversely, recognizing the vast diversity of Indigenous people in Canada, researchers seeking to create web-based information tools and technologies should collaborate with local Indigenous communities to ensure technology and content is relevant to local cultures, languages, and traditions.

How Indigenous mothers use web-based resources for their infants' health has not been previously described in Canada,

and further research is needed to better understand parents' preferences and challenges and how best to address these needs. As this study focused on mothers as the primary caregivers of infants, future work to address the information needs of fathers and other parents (two spirit, lesbian, gay, bisexual, transgender, queer, questioning, intersex, and asexual) is necessary. Finally, a more in-depth exploration of mothers' hesitancy to interact on discussion forums might reveal the dangers of cyberbullying and suggest ways to mitigate these risks and promote the benefits of social interaction for otherwise isolated mothers.

Conclusions

Parents represent one of the most frequent users of web-based information, such as Google, apps, and Facebook. This study provided initial insights into how Indigenous mothers used web-based sources of information to meet the health needs of their infants and found that web-based sources were commonly used and were helpful to mothers. Significant challenges existed for mothers who navigated vast amounts of web-based information and attempted to interpret and apply the information to their lives. Health care providers should provide parents with reputable sources of web-based information pertaining to healthy parenting and infant health to assist parents in addressing their questions and making decisions about their infants' health. Web-based modalities of health information appear to be useful opportunities to provide health education and health promotion to Indigenous mothers, and researchers and health care providers seeking to create these types of technologies should collaborate with local Indigenous communities to ensure relevancy.

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Conflicts of Interest

ALW received personal fees from Mallinckrodt Pharmaceuticals for consultation and the reimbursement of travel fees for attending a neonatal conference. RV and VM declare no conflicts of interest.

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Original Paper

Implementation of iPads to Increase Compliance With Delivery of New Parent Education in the Mother–Baby Unit: Retrospective Study

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Abstract

Background: Abusive head trauma (AHT) is a serious health problem affecting more than 3000 infants annually in the United States. The American Academy of Pediatrics and the Centers for Disease Control and Prevention (CDC) recommend that health care providers counsel new parents about the dangers of AHT. Previous studies demonstrate that parental education is effective at reducing AHT events. South Carolina law requires hospitals to offer all new parents with the opportunity to watch an educational video about AHT. This mandate is addressed in different ways at the several delivery centers within a large South Carolina health care system with a range of viewing methods utilized, from DVD players to mobile workstations to personal devices. Frequent technical barriers and workflow inefficiencies resulted in low rates of compliance with this mandate at several campuses. To improve compliance of parent viewing of this educational video, the health care system standardized video viewing protocol across all campuses by implementing the use of iPads for parental education. Existing literature suggests that patient education can be improved in the hospital setting by utilizing tablet computers, but our literature search identified a gap in research around the education of parents and caregivers during hospitalization for childbirth. We used the implementation of an iPad-based parental education delivery protocol to evaluate whether tablet computers can improve compliance with delivering new parent education in the hospital setting.

Objective: The objective of this study was to evaluate whether the standardized use of iPads to deliver education in the mother–baby unit resulted in improved rates of parents' acceptance of the opportunity to view an educational video about AHT.

Methods: We interviewed physicians and nurses to determine what previous protocols were in place to educate new parents before a standardized iPad-based protocol was implemented across 6 campuses of a large South Carolina health care system. A retrospective study was conducted by review of 5231 records from across the 6 campuses to determine the pre- and postintervention compliance rates of viewing the AHT educational video by parents in the mother–baby unit.

Results: Compliance increased overall ($P < .001$) across sites from an average of 41.93% (SD 46.24) to 99.73% (SD 0.26) ($\phi = 0.510$). As much as 4 of 6 locations saw a significant increase in compliance rates after introducing the iPad intervention ($P < .001$). The remaining 2 locations that showed no significant difference ($P > .05$) had very high rates of preintervention compliance.

Conclusions: Following the implementation of a standardized iPad-based protocol to deliver new parent education, there was a significant improvement in the percentage of new parents who viewed an educational video about AHT in the mother–baby unit. Based on these results, other health care providers should consider iPads to be a feasible and effective method for delivering hospital-based education to families in the mother–baby unit.

KEYWORDS

technology; handheld computers; workflow; education; newborn; head trauma

Introduction

Infants and Abusive Head Trauma

Abusive head trauma (AHT) in infants, commonly including “shaken baby syndrome,” is a serious and preventable cause of morbidity and mortality in the first year of life. The Centers for Disease Control and Prevention (CDC) estimates the annual incidence of AHT to be 31-35 per 100,000 infants [1]. Approximately 2000 infants are admitted for AHT to US hospitals annually, with another 1000 annual cases of AHT identified in emergency departments, but not resulting in hospital admissions [2]. These numbers likely underestimated the true incidence of AHT by failing to account for cases that do not result in hospital visits.

Parent Education Interventions

The American Academy of Pediatrics (AAP) recommends that physicians discuss the risks of AHT with all new parents starting during the birth hospitalization. The AAP specifically recommends that physicians discuss safe ways for parents to cope with the stress of inconsolable infants, provide education on the developmental timeline of crying and other stressful infant behaviors, and the specific dangers of shaking, slamming, or hitting infants [3,4]. CDC recommendations are similar, encouraging providers to ensure that an infant’s parents/caregivers have the coping skills and tools as a preventative measure for AHT for when frustrations arise [5]. Given the increase in stress and residing at home throughout the day with the COVID-19 pandemic, children are more vulnerable than previously [6]. Thus, ensuring patient education of AHT prevention is important now more than ever.

Despite this consensus on the need to provide early parental education on AHT, there is limited evidence from which to base hospital policies and procedures as to exactly what form this education should take or how it should be provided. The United States Preventive Services Task Force performed a systematic analysis concluding that there is a paucity of evidence to determine if interventions in a primary care setting can prevent child abuse and neglect [7]. Nevertheless, limited studies have shown that when health care providers consistently deliver new parent education, there is a long-lasting improvement in parental knowledge concerning AHT [8] that may translate to a reduced local incidence of AHT [9,10]. Existing studies rely on various combinations of educational booklets, DVDs, and signed contracts, with the material provided by nurses or non-health care staff. This education is delivered at varying locations and settings including home visits, in the mother-baby unit, or at prenatal classes. The variable methodology of prevailing studies therefore leaves open the question of which delivery method and media format would best serve to educate new parents on the dangers of AHT.

Technology and Patient Education

Tablet computers, such as the iPad, are an effective means of easily conveying information to patients in a hospital setting. Prior studies have shown that, when testing patient retention of knowledge, the use of tablets is as effective as verbal education by a nurse [11,12] and superior to education in paper booklets [13]. Patients in the hospital setting also report greater satisfaction [14,15] and higher confidence in their ability to understand information [16] when information is provided via tablet computers, compared with verbal or printed information.

Legislation and Care of the Newly Born

South Carolina state law requires that all hospitals provide an opportunity for each newborn baby’s parents/caregivers to view a video on the impact of shaking infants and children [17]. It is normal practice for patients in the family beginnings unit and the neonatal intensive care unit to be offered a video on AHT by nurses. The video is shown as part of the 36-hour bundle of care provided to the newborn and family, which includes a series of tests and tasks to be completed 36 hours after birth, such as metabolic, bilirubin, heart, and hearing screening as well as re-weighing of the newborn and viewing AHT and safe sleep education videos. Nurses are expected to set up the video for parents to view, but there is no direct nurse supervision required during video watching.

The law further stipulates that hospitals must ask parents/caregivers to view the video and sign a document attesting that the hospital offered the education [17]. Parents are not required to watch the video, but must sign a state-required form verifying:

I have been offered the opportunity to view the video presentations on safe sleep practices, Sudden Unexpected Infant Death (SUID), and the dangers associated with shaking infants and small children. I have also been given information about the importance of learning infant CPR. I voluntarily sign this statement acknowledging that I have received, read and understood the information and been offered the opportunity to view the videos.

If a parent refuses to watch the video, the nurses assess and document the reason for refusal including if the video was seen during pregnancy or a previous childbirth. At this time nurses also assess if there is a communication deficit such as language barriers or technical difficulties which would not allow for proper viewing of the video.

Hospitals must be compliant with the law and provide an opportunity for video viewing and document the offering of education or reason for refusal. While the video itself is a standardized presentation provided by the state, there is little flexibility in the content of information conveyed, unless a specific request is placed by the hospital system for approval of a different video. Hospitals are, however, given freedom with

regard to exactly when, where, and how the video is shown. Thereby an opportunity exists to determine if technology can assist in the delivery of the required parent education. Therefore, the purpose of this paper is to evaluate a quality improvement intervention of delivery of parent education on AHT via iPads within 6 different hospitals within a health care system.

Methods

Overview

To improve compliance, defined as parental viewing of the state-mandated video, a quality improvement effort was initiated by digitally converting the video and offering iPads for viewing to standardize information delivery at multiple birth facilities within a large health care system. The implementation was enacted in the same manner at all 6 campuses of the health care system for standardization.

Original Parent Education Delivery (Method O)

In the past, the video was only available in DVD format (Method O). Barriers to showing the video included inability of nursing staff to locate the DVD and missing or dysfunctional equipment to view the video. The alternative method was to have parents view the video using a workstation on wheels which allowed nurses to access the video in the Care Plan portion of their Epic chart. When this method did not work or was unavailable, the parents were provided a link to view the video on their personal phone, or they would have access to the video from a nurse's hospital-issued phone.

iPad Parent Education Delivery (Method N)

Nurses were informed of the new implementation method, reviewed Department of Health and Environmental Control (DHEC) requirements, and discussed administration of the video during staff meetings and "huddles" during their shift. All nursing staff had previous experience with using iPads and did not require training on using the iPads. This intervention was limited to iPads and did not include other tablets. A handout was provided at nursing stations for troubleshooting in the event there were issues with the video or the iPad. The video was also added to the discharge checklist sheet provided to parents to ensure the parents would be able to visualize that the video needed completion before discharge.

Starting in December 2018, communication boards in patient rooms began to include a check off for viewing the required baby education videos. The communication boards were

reviewed by the physicians and nurses before discharge as a second check to ensure completion and to attempt to improve compliance.

Documentation in Electronic Health Record

While the documentation of delivering education in electronic health record (EHR) by nursing staff was unchanged between Method O and Method N, an additional reminder to ensure the educational video was provided was added in the EHR summary tab. In addition to the paper attestation being scanned to the chart, an electronic flowsheet was developed, where nurses documented offering the video and when/whether video was viewed. This improved visibility of the education for physicians and nurses to easily see the workflow during hospitalization. This also allowed reports to be run from the EHR to track compliance rates over time.

Participants and Procedures

As a University of South Carolina institutional review board-approved retrospective study, data from patients of the 6 campuses were obtained through chart reviews of EHRs to determine newborn educational video compliance. Data were gathered starting in July 2018 and ending in May 2019. However, we found high rates of inconsistent or incomplete documentation during the period of review. The 6 locations yielded 6387 occasions where new parents were offered the AHT video. Events with missing information, such as location, department, date, nurse ID, or compliance were excluded from the study, leaving 5231 records for analysis (comprising 81.90% of data collected). Data for a minimum of 2 weeks prior to the intervention were used to obtain compliance rates before implementation of iPads for each campus, except for campuses 3 and 4, which did not have consistent preintervention data. Data after the intervention were collected for 9 months. The EHR system used by all campuses in the health system was Epic. Discourse with leading stakeholders and implementers of the program provided a platform to gain contextual information regarding the implementation process and barriers of the use of iPads for educational material.

Once a parent or caregiver agreed to watch the educational video, this was documented as "Yes" in the flowsheet tab of the EHR reporting system, which we operationally defined as compliance. The compliance data were extracted from 6 hospitals within the health care system by the internal data support team. Dates of Method N implementation can be found in [Table 1](#).

Table 1. Date of iPad education delivery pre- and postintervention by campus location.

Location	Preintervention data collection start date	Implementation date	Postintervention data collection start date
Campus 1	August 1, 2018	August 20, 2018	May 26, 2019
Campus 2	August 1, 2018	August 22, 2018	May 24, 2019
Campus 3	August 1, 2018	August 27, 2018	May 26, 2019
Campus 4	August 1, 2018	October 23, 2018	May 25, 2019
Campus 5	August 1, 2018	October 11, 2018	May 25, 2019
Campus 6	October 27, 2018	November 11, 2018	May 25, 2019

These dates were used as a comparison point to evaluate whether there was an improvement in compliance of parents viewing the video after the implementation of iPads (Method N) compared with Method O. An initial review of the data revealed that a large portion of the extracted data included null values that were evaluated by the data support core. Any portions of the data, for either Method O or Method N, that were incomplete were not included in analysis.

A 1-sided Fisher exact test, a statistical analysis used to assess associations between categorical variables, was performed to determine if the use of iPads to deliver the AHT video significantly increased compliance rates overall and at each of the locations. The Fisher exact test was chosen due to the expected frequency being less than 5 in some of the categories [18]. Discussions with key stakeholders allowed for the identification of barriers and facilitators to the delivery of the video education both before and after implementation.

Results

EHR data from the 6 locations were assessed to determine compliance rates for viewing the educational AHT video. Results showed that compliance increased overall ($P < .001$) across sites from an average of 41.93% (SD 46.24) to 99.73% (SD 0.26) ($\phi = .510$). Two out of 6 locations saw a significant increase in compliance rates after introducing the iPad intervention ($P < .001$), with 2 campuses showing an increase in compliance that was not statistically significant ($P > .05$). Two campuses showed close to 100% compliance (140/140 [100.00%], 387/389 [99.49%]) after the iPad intervention, but data for compliance rates prior to the intervention were limited. Two sites showed little or incomplete data for the period prior to the intervention, therefore inferential statistics were not conducted for those data (only descriptive). However, those data were included in the overall analyses. For a complete listing of EHR data collection, compliance rates, significance, and effect size, refer to Table 2.

Table 2. Fisher exact test results and compliance rates prior to and following the iPad intervention at each location.

Location	% Compliance prior to the intervention (n=632), n/N (%)	% Compliance after the intervention (n=4599), n/N (%)	Significance	Effect size (ϕ)
Campus 1	24/81 (29.63)	1406/1408 (99.86)	<.001	0.817
Campus 2	5/25 (20.00)	278/279 (99.64)	<.001	0.863
Campus 3	0/86 (0.00)	140/140 (100.00)	N/A ^{a,b}	N/A
Campus 4	2/92 (2.17)	387/389 (99.49)	N/A	N/A
Campus 5	508/508 (100.00)	1999/1999 (100.00)	>.05	0.022
Campus 6	93/94 (98.94)	389/391 (99.49)	>.05	0.027

^aN/A: not applicable.

^bAn analysis to compare these with 0 for preintervention could not be performed, because there is not enough variability.

Nurse interviews revealed that, with Method O, there was low compliance because there were not enough TVs to show the video to multiple patients at once, the DVD would go missing, DVD players were not always working in every room, or the remote would get lost or not work. Nurses also reported poor sound quality and volume issues when using the workstation on wheels prior to Method N. Once Method N was implemented with the iPads, the nurses reported minimal issues. If there were technical difficulties with Method N, the nurses had the ability to access the videos using methods previously described in Method O, although no technical difficulties were reported. Nurses and key leaders initiating the intervention reported that the portability of the iPad, along with the decreased challenges that came along with managing multiple equipment components (DVD, player, remote, batteries, TV), has made delivering the educational video easier and quicker.

Discussion

Principal Findings

This study was designed to assess the use of iPads in providing AHT prevention education. After the implementation of iPads to provide this educational material, compliance rates increased at all sites, with all nearing 100% after the intervention (Campus

1 1406/1408 [99.86%], Campus 2 278/279 [99.64%], Campus 3 140/140 [100.00%], Campus 4 387/389 [99.49%], Campus 5 1999/1999 [100.00%], and Campus 6 389/391 [99.49%]). Compliance rates of parents watching the video increased from less than 30% to 99% in campuses 1-4 after enacting the iPad intervention. Campuses 5 and 6 demonstrated very high compliance rates before the intervention, and as such, there was no significant difference in compliance rates before and after the intervention for these 2 campuses, with compliance rates remaining near 100% (1999/1999 [100.00%], 389/391 [99.49%]). This study demonstrated that compliance rates for watching the AHT education video were near 100% at all campuses after the implementation of iPads.

Unique aspects of the structure and implementation of the intervention were helpful in conducting this study. Engaging staff in process change decisions has the potential to facilitate early adoption of new patient care methods, and likely resulted in a successful implementation. Additionally, the use of iPads to show patient educational material was a smooth transition due to most staff members being familiar with the use of the device. This allowed each campus to incorporate and edit their respective workflows to suit their campuses the best. A significant hurdle for incorporating changes in hospitals or medical centers is factoring in and attempting to change

currently used and long-existing procedures. Workflow interruptions have been found to result in decreased ability of health care providers to manage workload [19]. However, providing smaller changes that are easy to implement and provide flexibility in application have been found to be effective in improving workflow [20]. This implementation of iPads appears to have streamlined the process to decrease workflow barriers, as demonstrated by the increased compliance rates at 4 of the 6 campuses.

The use of iPads to improve delivery of educational material is not a new concept. Specifically, iPads have been useful in the health care setting as a mode of delivering patient education, including education on anticoagulant medication to hospitalized patients, educational materials for patients in acute care, and improvement of inpatients' engagement in their care and patient education in the hospital [21-23]. Many of these previous studies have shown an improvement in patients' engagement in their care and education with the use of tablets such as iPads [24,25]. However, little to no research has been conducted on the use of iPads or tablets to increase acceptance of educational material. This study addresses this gap in research and shows that iPads can be used to help increase compliance with patient education delivery.

The compliance with viewing the educational video in the mother-baby unit was widely variable across the 6 sites prior to the implementation of the iPads. Following the intervention, the compliance rates at all sites were near 100%. While we cannot say with certainty that this increase in compliance at most sites was due to the implementation of the iPads, the timing of the increase in compliance rates coincides with the iPad intervention. Although the precise reason for this increase in compliance rates following the intervention remains unclear, a potential theory is that the use of iPads increased ease and efficiency for nurses in their workflow to deliver the educational material, as compared with the original method. Nurses and key leaders in initiating the intervention have reported that the portability of the iPad, along with the advantages of needing less equipment, has made delivering the educational video easier and quicker. To further support this theory, one study demonstrated that nursing staff workflow would allow for delivering a tablet to the patient bedside and retrieving it in a time that is consistent with time between rooms [26].

In our study, all campuses achieved a high compliance rate following the intervention. However, campuses 5 and 6 showed that compliance rates were high both before and after the iPad implementation, as noted previously. Interviews with nurses provide several potential explanations for these unexpected results. At campus 5, a grant had been in place for 4 years to promote further patient engagement with the video in the hospital which provided funding to send each patient home with their own educational DVD, as well as extra training for the staff on the topic of AHT and the importance of patient education. It was reported that during the period of this grant, the compliance rates increased to nearly 90%. This grant ended immediately prior to the implementation of the intervention of the iPads for this study. Thus, nurses and facilitators believed that the pre-existing project focusing on AHT education was

the reason for the already high compliance rates of patients watching the video prior to the iPad intervention in campus 5.

Similar results for campus 6 may be explained by its comparatively low delivery volumes. Notably, this campus has a slower pace for the nurses working in the mother-baby unit, according to key leaders who oversaw this intervention. Nursing staff were not pressed for time, which allowed them the ability to provide the educational video regardless of whether it was provided through the TV/DVD method or through the iPad. As such, compliance did not significantly change by incorporating the iPad intervention at this campus. This shows that this intervention may be relatively more effective and necessary in hospitals and medical centers that have a higher workflow, higher patient volume, or are generally busier.

Limitations and Future Directions

While our study showed an increase in compliance rates after the implementation of the iPads, the results should be viewed in light of the limitations. One of these limitations included missing or null data that were not incorporated in data analysis or results, limiting the overall number of records evaluated. In addition, data collection revealed that 2 of the 6 campuses, campuses 3 and 4, were not accurately recording compliance rates prior to the intervention. This resulted in 18% of the data collected not being included in statistical analysis.

An important consideration is that the periods accessed for the preintervention data were nonstandardized and differed by campus. Some campuses had an exact date of implementation, while others had a week to 2-week range for the date of implementation. While this is not believed to have affected the results significantly, it is still to be considered when looking at the results of this study.

It is important to continue to maintain high compliance of the delivery of this educational material in order to monitor the long-term impact of this intervention. To do this, it is important to monitor nursing staff at regular intervals to ensure delivery of this education via iPads, reassessing workflow to better incorporate this education, ensuring documentation consistency, and involving physicians in the process. Future studies could include assessing documented reasons for refusal, further assessment of nursing workflow by determining the time spent by nursing staff at patient bedside, and the number of interruptions experienced in nursing workflow between the 2 methods. Furthermore, retention of information could be assessed in parents/caregivers who accepted education to determine effectiveness of the education itself, while studies could monitor long-term AHT rates in the community to determine if this education potentially had an impact. Participants' demographics could also be collected and assessed in future studies to determine if variables such as education level and familiarity with iPads confounded results. Additionally, it is important to note that there is currently insufficient economic data to support the use of digital health interventions in patient education, as noted in current literature [27,28]. While this study did not examine cost-effectiveness of interventions such as this one, future studies should consider whether implementation of iPads for providing patient education could be more cost-effective over time.

Another avenue to look toward is the incorporation of the video in other languages. While the Spanish version of the educational material is currently offered along with the English version, expanding the languages offered and assessing if the appropriate language video affected rate of viewing would also be worthy of study. Perhaps most importantly, alongside long-term use of this intervention, monitoring AHT cases in the geographical areas covered by the health system would be useful to follow

to determine if the increased compliance of delivering this education has resulted in a decrease in AHT cases.

Conclusions

Based on these results, other health care systems may consider iPads or other tablet devices as a feasible and effective method for delivering hospital-based education to patients and families. This intervention has allowed the hospital system to show that they have been compliant with the law as well as meet the guidelines of patient education before discharge.

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Conflicts of Interest

None declared.

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Abbreviations

- AAP:** American Academy of Pediatrics
AHT: abusive head trauma
CDC: Centers for Disease Control and Prevention
CPR: cardiopulmonary resuscitation
DHEC: Department of Health and Environmental Control
EHR: electronic health record

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Original Paper

Parent Experiences With Electronic Medication Monitoring in Pediatric Asthma Management: Qualitative Study

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Abstract

Background: Electronic medication monitoring (EMM) is a digital tool that can be used for tracking daily medication use. Previous studies of EMM in asthma management have been conducted in adults or have examined pediatric interventions that use EMM for less than 1 year. To understand how to improve EMM-enhanced interventions, it is necessary to explore the experiences of parents of children with asthma, recruited from outpatient practices, who completed a 12-month intervention trial.

Objective: The objective of our study was to use qualitative inquiry to answer the following questions: (1) how did using an EMM-enhanced intervention change parents'/caregivers' experiences of managing their child's asthma, and (2) what do parents recommend for improving the intervention in the future?

Methods: Parents were recruited from the intervention arm of a multicomponent health intervention enhanced by Bluetooth-enabled sensors placed on inhaler medications. Semistructured interviews were conducted with 20 parents of children aged 4-12 years with asthma. Interviews were audio-recorded, transcribed, and inductively analyzed using a constant comparative approach.

Results: Interview participants reflected an even mix of publicly and privately insured children and a diverse racial-ethnic demographic. Parents discussed 6 key themes related to their experience with the EMM-enhanced intervention for the management of their child's asthma: (1) compatibility with the family's lifestyle, (2) impact on asthma management, (3) impact on the child's health, (4) emotional impact of the intervention, (5) child's engagement in asthma management with the intervention, and (6) recommendations for future intervention design. Overall, parents reported that the 12-month EMM intervention was compatible with their daily lives, positively influenced their preventive and acute asthma management, and promoted their child's engagement in their own asthma management. While parents found the intervention acceptable and generally favorable, some parents identified compatibility issues for families with multiple caregivers and frustration when the technology malfunctioned.

Conclusions: Parents generally viewed the intervention as a positive influence on the management of their child's asthma. However, our study also highlighted technology challenges related to having multiple caregivers, which will need to be addressed in future iterations for families. Attention must be paid to the needs of parents from low socioeconomic households, who may have more limited access to reliable internet or depend on other relatives for childcare. Understanding these family factors will help refine how a digital tool can be adopted into daily disease management of pediatric asthma.

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KEYWORDS

pediatric asthma; digital health; outpatient care; asthma management; pediatric; asthma; parents; caregivers; Bluetooth sensors; inhaler

Introduction

An estimated 6.2 million children in the United States currently have asthma, with 60.3% of them experiencing persistent disease severity [1]. Asthma that is persistent and poorly controlled places children at risk for frequent symptoms of respiratory distress leading to acute unscheduled health care, activity limitations, and school absenteeism [2]. Per national asthma guidelines, children with persistent asthma should be using daily preventive anti-inflammatory medications for symptom control [3,4]. Nevertheless, estimated adherence among US children with asthma to long-term control medications, such as inhaled corticosteroids (ICSs), is 40% or lower [5-9].

New technologies, such as electronic medication monitoring (EMM), allow patients and health providers to digitally track adherence to daily preventive asthma medications. EMM includes a wide range of digital devices, such as pillbox sensors that measure the opening time of medications [10] or inhaler sensors that detect the delivery of an actuation (ie, puff of medication). EMM as a digital tool, accompanied by other patient-centered supports, can also enhance provider-patient communication around chronic disease management. In asthma, studies evaluating EMM have previously focused on the experiences of EMM among adults [11]. Studies of children and adolescents with asthma have been limited to a short duration of EMM exposure (eg, 1 to 6 months) [12-14].

Enhancing pediatric asthma management with digital tools requires understanding parents' acceptance of the technology over a longer period of use and in clinical scenarios that closely reflect how patients and health providers use EMM. We present findings that explored the use of EMM by parents in a 12-month intervention trial embedded in outpatient pediatric practices. The trial studied the effects of EMM via Bluetooth-enabled inhaler sensors, accompanied by a mobile app in pediatric asthma management [15]. Sensors tracked daily inhaler medication usage, which parents and clinicians could monitor. Our qualitative study explored 2 key questions to ascertain parent experiences of participating in the intervention with EMM: (1) how did using the intervention change parents'/caregivers' experiences of managing their child's asthma, and (2) what do parents recommend for improving the intervention in the future?

Methods

Sample and Data Collection

We recruited parents from the intervention arm of the Improving Technology-Assisted Recording of Asthma Control in Children (iTRACC) trial for interviews [15]. In the original trial, caregiver and child dyads were eligible if the following criteria were met: (1) child was aged 4 to 17 years; (2) child had experienced at least one asthma exacerbation requiring oral corticosteroids in the year prior to enrollment; and (3) parent reported active

prescription of an ICS or combination ICS–long-acting beta-agonist (ICS-LABA) for at least 1 year prior to enrollment. The exclusion criteria were as follows: (1) dyad was non-English speaking; (2) child had a comorbid condition that could interfere with asthma symptom assessment (eg, cystic fibrosis); or (3) dyad was participating in another sensor-based intervention that would interfere with the use of the trial devices.

We used purposive sampling of parents of children aged 4-12 years in the intervention group because only the intervention arm dyads had the smartphone app, sensors, and EMM at their clinics [16]. We did not recruit adolescents for this qualitative study because we anticipated that they would experience a different relationship in asthma co-management with their parents than would younger children. Aligned with purposeful sampling strategies, we aimed for a balanced representation from all 5 clinic sites; public versus private insurance; and 3 general categories of adherence (low, medium, and high), measured by the sensors [16]. Adherence was categorized as low (<30%), medium (30%-70%), or high (>70%) based on the mean daily adherence of the patient to their preventive inhaler medication over a 9-month period. Since the intervention was intended to improve adherence to preventive medications, we wanted to ensure that dyads with low and medium adherence were represented. The qualitative interviews were a separate study from the original trial. Fifty-eight parents from the original trial were found to be eligible for the qualitative study, based on the aforementioned criteria, and 31 agreed to be contacted for further research at trial completion. One parent—the parent of record for the original trial—was contacted for each child. Parents were called and emailed about the qualitative study, and 20 parents were scheduled for an in-person or telephone interview, based on their preference [17]. On average, parents were interviewed 5 months following completion of the trial, and 6 parents indicated a preference for a telephone interview. The study was approved by the hospital's institutional review board (IRB 2016-698), and written informed consent was obtained from all participants. The interview study was funded by the Agency for Healthcare Research and Quality.

Intervention Description

The iTRACC trial involved a multicomponent health intervention that included (1) Bluetooth-enabled sensors placed on inhaler medications that paired with the parent's smartphone via a mobile app (Propeller Health), and (2) monitoring through a web portal and follow-up phone calls by clinic staff [15,18] (Figure 1). The EMM technology tracked the use of most ICSs, short-acting beta-agonists (SABAs), and combination ICS-LABAs that were available on the US market. Medication doses could be automatically or manually synced to a smartphone app for parents. Parents set up timed reminders for administering daily ICS medications and were notified by push notifications from the app when medications were missed. They were also provided local daily reports on environmental allergens and summaries of medication adherence upon opening the app. Alerts by email and through a web portal notified health

providers if their patients had increased SABA use (ie, >4 uses in a 24-hour period) or decreased ICS or ICS-LABA use (ie, no detected doses in 4 days). Upon receiving the alerts, clinic staff (ie, physician, nurse, or medical assistant) called parents to triage how to improve adherence or discern the cause of increased SABA use. The 12-month randomized clinical trial

was conducted from 2016 to 2018 in Chicago, Illinois, and included 5 outpatient practices that served pediatric patients (ie, 2 academic primary care clinics, 1 community primary care clinic, 1 academic pulmonary clinic, and 1 private family allergy clinic). The trial was registered at ClinicalTrials.gov (NCT02994238).

Figure 1. Inhaler sensor and mobile app (Propeller Health).



Interviews

Interviews were conducted between March and July 2019 by trained facilitators (KK, MK, AC, SS, and PL). Participants were compensated US \$100 for their time. We conducted 1-hour interviews with parents to explore their experiences with the EMM-based iTRACC intervention using a semistructured interview guide (Multimedia Appendix 1). The guide was designed to explore (1) the intervention's compatibility with the family's lifestyle, (2) perceived intervention utility, (3) the intervention's impact on the child's asthma management and health, and (4) suggestions for improving the intervention to better meet parents' needs. Interviews were audio-recorded, transcribed, and deidentified for analysis.

Data Analysis

Interview transcripts were inductively analyzed via a team-based approach to coding with constant comparison across cases [19-21]. In the first cycle of coding, 4 authors (SS, KK, PL, and MK) with expertise in qualitative research, pediatric medicine, and experience with the iTRACC trial independently conducted descriptive line-by-line coding of one transcript and discussed observations, which informed the development of a preliminary codebook [21,22]. The coders then reviewed a second transcript using the draft codebook and revised the codebook and definitions through group discussion; this same process was

conducted on a third transcript. Next, the data set (including transcripts from codebook development) was divided equally among the analysts and independently coded in Dedoose, a cross-platform app for qualitative analysis [23], using the codebook. The codebook was refined throughout the analysis process through team discussion. After finalizing the codebook and coding all transcripts, we conducted second cycle coding using thematic analysis [21,22,24,25]. In this cycle, the text for each code was extracted and reviewed in a "coding review process," during which the data for each code were reviewed and summarized, and any errors in coding were discussed by the team and corrected. Next, code summaries were reviewed by the team and codes were subsequently collapsed into overarching themes representing parent perceptions of the technology's compatibility, utility, impact on child health and asthma management, and suggestions for improvement [21,22,24].

Results

Participant Characteristics

Characteristics of interview participants (parent-child dyads) are shown in Table 1. All but one parent identified as a mother. Most parents were college-educated, and there was an even mix of publicly and privately insured children.

Table 1. Characteristics of parent-child dyads (n=20).

Characteristics	Values
Child's age (years), mean (SE)	8.7 (0.6)
Child's sex (male), n (%)	14 (70)
Child's insurance, n (%)	
Public	10 (50)
Private	10 (50)
Parent's race, n (%)	
White	8 (40)
African American or Black	7 (35)
Asian	3 (15)
Other	2 (10)
Hispanic ethnicity, n (%)	3 (15)
Parent's education, n (%)	
Graduate/advanced degree	5 (25)
College degree	9 (45)
Some college/technical degree	3 (15)
High school graduate/GED ^a	2 (10)
Some high school	1 (5)
Survey scores^b, mean (SE)	
Asthma Control Test score (range 5-25) ^c	23.0 (0.7)
Parental Asthma Management Self-Efficacy Scale score (range 1-5)	4.5 (0.1)
Pediatric Asthma Caregiver's Quality of Life Questionnaire score (range 1-7)	6.4 (0.3)
Adherence level, n (%)	
Low (<30%)	6 (30)
Medium (30%-70%)	8 (40)
High (>70%)	6 (30)

^aGED: General Education Diploma (ie, high school equivalency diploma).

^bScores are from surveys conducted at 12 months.

^cScores >19 indicate well-controlled asthma.

Parental Experiences with EMM-Enhanced Intervention

Our qualitative analysis revealed the following 6 major themes regarding parents' experiences with the EMM-enhanced intervention: (1) compatibility with the family's lifestyle, (2)

impact on asthma management, (3) impact on the child's health, (4) emotional impact of the intervention, (5) child's engagement in asthma management with the intervention, and (6) recommendations for future intervention design. Each theme is discussed below and exemplary quotes are provided in [Table 2](#).

Table 2. Caregiver experiences and recommendations for an electronic medication monitoring intervention for pediatric asthma.

Themes	Exemplar quotes
Compatibility with lifestyle	<ul style="list-style-type: none"> “The fact that we’re all attached to our phones nowadays. Your face is constantly in your phone. You can’t miss it, it’s right there. Reminding you hey, it’s time to take your medicine or hey, he missed it this many times a week or you know hey, we noticed he had to take his albuterol more often.” [participant #91^a, mother of an 8-year-old child]
Impact on asthma management	<ul style="list-style-type: none"> Prevention: “I’m so set now, I have that set schedule, ...Because at first like I said we were like did I give it to him? I don’t know and it was like we know he needed it...life got in the way and we wouldn’t remember what we had done, so [now] it’s like it’s an automatic.” [participant #47, mother of a 6-year-old child] Acute management: “I think just patterns of increases use of rescue meds...then any time that we did have to you know intervene we could sort of see what was happening in the days leading up to that intervention and sort of figure out how to avoid those in the future.” [participant #37, mother of an 8-year-old child]
Impact on the child’s health	<ul style="list-style-type: none"> No change: “Right before we started using it he had already gone a good while without any asthma symptoms. So it’s hard to say whether this made that better or...if things would have continued on the same track.” [participant #48, mother of a 7-year-old child] Better health: “I think all of that really helped us stay on top of taking his medications so if he does catch a bug it’s not a long time that he’s sick.” [participant #91, mother of an 8-year-old child]
Emotional impact	<ul style="list-style-type: none"> Confidence: “I was a conscientious parent before the app, but the app certainly...helped me feel like I was more in control and build the confidence level of being knowledgeable about what’s going on with him and how to handle stuff.” [participant #15, mother of a 6-year-old child] Security (calls): “...makes me feel better that someone else is watching him as well and saying hey, we noticed this, you need to come in or...maybe you need to take him to the pediatrician or...hospital...I’m the primary caregiver and...administers the medication and watches over that, so knowing that someone else was there doing the same made me feel better.” [participant #91, mother of an 8-year-old child] Frustration: “...towards the end it...was not recording the Flovent. Like I would give it to her and it would say you have missed this dosage...and I’m like why does it keep saying that and I’ve given it to her and I had to keep resetting it...so that was sort of frustrating.” [participant #16, mother of an 11-year-old child]
Child engagement	<ul style="list-style-type: none"> “[He] really liked it. [He] was into getting into it and...make sure it showed that he did it and he’s like let’s look at the tips and he watched the different charts that we could see...he doesn’t get a lot of screen time, so anything that was on the phone (laughs) and it was about him, he was pretty excited about.” [participant #15, mother of a 6-year-old child]
Recommendations	<ul style="list-style-type: none"> “I think [the sensor and app] would work really well for parents that don’t have a lot of structure or capability to remember [when to give medications]. ...I can’t tell you how many times I forgot or did without so people that don’t, you know, have that knowledge or that share homes, you know they go from home to home.” [participant #79, mother of a 12-year-old child]

^aQuotes are labeled with the dyad’s participant number from the original trial.

Compatibility With the Family's Lifestyle

Parents reported that using the technology was compatible with their daily schedules and daily cell phone use. Parents described the technology as “easy” because the app would show them whether their child had taken their medicine and reduced the need to ask their child repeatedly if they had taken their medicine. Parents appreciated that the technology could tell them if their child had used the rescue inhaler (ie, SABA) at school, as it can be difficult to find out from teachers and school staff if the medicine was taken. Parents reported that the app alerts were well-timed and served as a reminder to administer the medicine during hectic days. For example, some parents reported maintaining a more consistent medication schedule with the technology, as opposed to when they forgot to administer the medication or administered much later than prescribed on very hectic days.

On the other hand, parents also reported intervention barriers to compatibility, such as having multiple caregivers involved in the child’s asthma management, the involvement of grandparents unfamiliar with smartphone technology, and the intervention’s incompatibility when parents traveled out of

town. Parents in families with multiple caregivers responsible for asthma management discussed how shared caregiving responsibilities made using the technology inconvenient:

Sometimes they might go to their grandparent’s house and we have to carry the sensor. Usually we have two different inhalers, one we kept at my in-laws’ house and one over here, but if he’s using over there, he doesn’t have any sensor. [participant #118, father of an 11-year-old child]

Further, these other caregivers were often grandparents, who parents noted were often unfamiliar with smartphones, as they might not own one themselves. Lastly, parents expressed some annoyance with not being able to sync the sensors when they traveled out of town without their child.

Impact on Asthma Management

Parents reported many aspects of the intervention that shaped their preventive and acute asthma management. For daily preventive management, parents reported improvement with app reminders, using the intervention to establish a routine or schedule that mostly endured after the study ended, using the

pollen warnings to prepare for triggers, and having an increased awareness overall of their child's asthma-related needs. Parents who had already established reliable asthma management routines before the intervention reported appreciating the technology but admitted that it did not change their behaviors.

For acute management, parents felt that one of the most useful features was the ability to track SABA use during asthma exacerbations. Parents reported that reviewing their child's SABA use aided them in identifying triggers or patterns of asthma exacerbations. For example, a parent would not send their child outside to play on high trigger days because of pollen or weather changes. They also reported that the app replaced pen and paper or other previous methods in tracking SABA use. Parents described pulling up the app record for the doctor at clinic visits, enabling them to provide an accurate account to the doctor and preventing them from having to rely on their memory, which was less accurate.

Impact on the Child's Health

Parents thought that the intervention was associated with improvements in their child's health. Parents noted that they felt their child had more energy and fewer asthma attacks and that illness symptoms did not seem to last as long. Other parents, however, observed that their child had no change in their condition, reporting that the asthma was well-managed before the intervention or had improved with age. Only one parent suspected that their child's asthma might have worsened over the course of the intervention; however, the parent emphasized that the technology and intervention made them more aware of the asthma and associated triggers and felt more capable of managing the asthma as a result.

Emotional Impact

A theme that emerged in the interviews was parents' emotional experience with the technology-enhanced intervention. Parents expressed a variety of emotions with using the intervention—confidence and a feeling of security but also occasional frustration. Many parents expressed feeling confident with the aid of the technology; they were better able to know what to do for an asthma exacerbation and would better remember to administer the medication before school and thus would not worry as much about their child's asthma at school. Parents also felt more secure with a nurse monitoring their child's medication use and were reassured when nurses or clinic staff would call to talk about their child's asthma symptoms. On the other hand, parents also described frustration due to technical difficulties with syncing and tracking on the app. Also, one parent reported anxiety about being monitored: "Big brother is watching. We have to be good. We have to show them we can do this a little bit" [participant #48, mother of a 7-year-old child].

Child's Engagement in Asthma Management

An unexpected theme that emerged was how the sensor and app promoted children's engagement in self-management. Parents reported that their child became engaged with taking care of their asthma because they were interested in the technology and app; for some parents, this led to a more active role for their child in their asthma management. Parents could assign their

child a certain aspect of the asthma management responsibilities, such as pressing the sensor cap to give a dose of medication and watching its confirmation on the sensor light. Children's engagement with the technology also included monitoring themselves on the app and playing with features on the app—doing quizzes, tracking puffs, and reading summaries and tips.

Recommendations

Parents had varying opinions on how to improve the intervention, the sensor technology, and its use. Parents identified that improving the sensor technology's syncing capability was crucial; they reported that the "synchronizing issue" was difficult to resolve and were uncertain if the sensor had become "defective," was "just a tech issue," or was "disconnecting towards the end of the study...[because] it was the battery."

To aid with follow-up phone calls from alerts, parents suggested incorporating texting in lieu of phone calls from health providers. Parents also expressed a desire for more app features that would engage children in their asthma management in an effort to reduce the need for parent prompting about medications in the future.

During the trial, families on Medicaid experienced a major change in managed care organization contracts, which led to insurance not covering certain inhaler medications that children had previously been prescribed. Thus, parents also asked that the sensor devices have greater compatibility with different inhaler medications.

When sharing who they believed the sensor system would work best for, parents recommended any parent or caregiver of a child with asthma. Others recommended the sensor system for those who might be newly diagnosed with asthma to help get them into a routine early on or for those with busy schedules who need reminders.

Discussion

Principal Findings

Our qualitative study, comprised of a purposive subsample of parents from a clinical trial, found that the EMM-based intervention was compatible with parents' daily lives, positively influenced their preventive and acute asthma management, and promoted children's engagement. Thus, overall, parents in our study found the intervention acceptable and generally favorable. However, parents also emphasized key improvements for the future design and development of this multicomponent, complex health intervention utilizing EMM [26,27].

Our qualitative work highlighted children's engagement as a key component of parents' management of their child's asthma through the EMM-based intervention. The app and sensors in particular seemed to provide a mechanism for parents to intentionally engage their child in the steps of asthma management. In pediatric health, the parent-child dyadic experience of the intervention may be a crucial factor driving perceptions of acceptability and potential adoption of new digital tools. Parents realized that children develop autonomy as they

mature, but our findings also indicated that parents appreciated the early engagement of children to promote readiness for disease management in the future [28,29]. Future iterations of the mobile app program could include child-specific content through its features, such as tailoring of its tracking or quiz features to younger age groups, to encourage and sustain child engagement in asthma management. Parents further highlighted a desire for other digital features, such as videos or games, to engage their child in asthma education. While in-person asthma education is evidence-based and effective, digital delivery of asynchronous education could supplement and reinforce asthma education in the home setting for children and parents [30]. For example, digital feedback for asthma inhaler techniques is being explored as a replacement or supplement to qualitative feedback by in-person evaluation [31,32].

While the family's role in management of pediatric asthma has previously been well described, especially across urban minority families, parents described needing to change the way they coordinated asthma management with multiple caregivers when using the EMM-based intervention [33]. One prior study of inner-city families of children with asthma described that it is typical for up to four other caregivers to be involved in a child's care and this sharing of asthma responsibilities can lead to unintended nonadherence to clinical recommendations [34]. In light of previous research and the present findings, we recommend that an adequate number of sensors be provided to each family. Additional education must also then be provided on how to download and manage apps on multiple phones for the same patient. This approach will account for multiple caregiver or blended family scenarios.

Next, many families in our study described dependence on family members, especially grandparents, as a source of caregiver support. Extended family caregivers are common in pediatric asthma, as suggested in a large patient study that found that 1 in 5 patients had an alternate caregiver living outside of the household who spent at least 6 hours per week with the child [35]. Parents, however, pointed to the generational gap in familiarity with digital technology. Overall, while seniors (ie, those older than 65 years) are adopting digital technologies at a much faster rate than in previous years, there are still noticeable differences in technology use according to age, income (ie, <\$30,000 per household), and level of education (ie, high school education or lower) [36]. Supporting and educating families with extended generational caregiving of children is vital. For example, easy-to-access videos should be provided so that family members can educate each other on how to use the devices, rather than rely completely on clinical team support, and thus also reduce the burden on clinical staff [37].

Parents also expressed frustration or anxiety about how EMM interfaced with asthma management at home. The stress of caring for a child with a chronic disease is well described, and intervention design must be careful not to worsen the existing strain that families may already feel [38,39]. Issues around stress might be partly addressed by providing clearer communication about how to use the digital app and sensor and their limitations. For example, a few parents in our study expressed frustration with not being able to sync their app with the sensor when the devices were not in the same room. However, Bluetooth

technology, the connection between the sensor and app, is a wireless, short-range communication, and thus parents should not have expected long-range functionality. Educating parents and health providers about the limits of the technology (ie, what to expect) through a built-in troubleshooting mechanism in the app may be useful to curb future frustrations.

Nevertheless, the stress that parents described may be primarily related to caring for a child with a chronic disease, and it is unclear whether a technology-enhanced intervention will alleviate that. At a minimum, more thorough assessments should be conducted to ensure that layering technology into parents' asthma care management does not worsen their stress and anxiety, which in turn might worsen disease management [37]. Services for coordination and technology support are also necessary for clinical staff as they enroll families, explore their needs, and address how to use EMM appropriately for a range of family scenarios.

Parents also named specific improvements to the intervention design, including fixing syncing issues and using texts to mediate communication before phone calls. In addition to fixing the various syncing issues that parents noted, future intervention support is needed to help guide parents to handle errors they are experiencing with the devices. Parents turned to the research team for troubleshooting during the trial, but sustained implementation of the intervention will necessitate that the support roles of clinics and technology companies be clear to families or risk low adoption [37]. Parents also indicated that texting would be an acceptable intermediary step to speaking directly with the nurse or physician on the phone. Although texting should be acceptable to health providers for tracking ICS use because there is not an urgent medical need, further investigation as to the acceptability and feasibility of this approach among health providers regarding increased SABA use should be explored. In future iterations of the EMM-based intervention, texting could be considered as a first step for connecting with parents before initiating a direct conversation. An asynchronous approach for this component of the EMM-based intervention might alleviate the burden parents experience with trying to connect with the clinical team in a way that fits their busy schedules.

Given the varying experiences of and recommendations from parents, further research is needed to determine who this tool should be tailored for to support its optimal use. Factors that could be measured include technology literacy, the emotional burden of using the intervention over time, and potential changes in the home environment. Understanding and tracking these factors might aid the adaptation of EMM for clinical use while balancing patients' preferences and needs.

Limitations

Limitations to the study included a possible selection bias introduced by selecting parents who were willing to participate in the interviews. We tried to mitigate against selecting only parents with positive experiences by purposively sampling to achieve balanced representation of low, medium, and high adherence to daily therapy. However, we also wanted to include parents who had engaged in the intervention actively for 9 months, and this could have selected against parents who did

not remain engaged with the intervention up to that time. Overall, the interviewed sample reflected the original trial sample in having children with controlled asthma, which limited our study from potentially capturing dyads who still experienced poorly controlled asthma. Given the limited sample size, we were not able to identify any distinct subthemes by different characteristics, such as insurance type or adherence level. Also, the amount of time between when parents exited the original trial and when they were interviewed for our study varied, and thus those who finished the trial longer ago may not have recalled their intervention experiences as accurately. The original trial also excluded non-English-speaking parents, which limits our understanding of parent experiences with EMM of

non-English-speaking families. Further, 70% of the interview sample had a college degree or advanced degree, which reflects a highly educated interviewee participation.

Conclusions

The parents' perspective on the EMM-based intervention for asthma care was critical for understanding how a complex health intervention using technology could be improved or targeted in outpatient pediatric asthma care. While use of technology-enhanced tools is increasingly popular in health care delivery and consumer health care, our study highlighted that careful attention must be paid to the needs of parents of children with chronic diseases, such as asthma.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview guide questions.

[DOCX File, 13 KB - [pediatrics_v4i2e25811_app1.docx](#)]

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Abbreviations

EMM: electronic medication monitoring

ICS: inhaled corticosteroid

ICS-LABA: inhaled corticosteroid–long-acting beta-agonist

iTRACC: Improving Technology-Assisted Recording of Asthma Control in Children

SABA: short-acting beta-agonist

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Original Paper

Self-Care Needs and Technology Preferences Among Parents in Marginalized Communities: Participatory Design Study

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Abstract

Background: Ten million parents provide unpaid care to children living with chronic conditions, such as asthma, and a high percentage of these parents are in marginalized communities, including racial and ethnic minority and low-income families. There is an urgent need to develop technology-enabled tailored solutions to support the self-care needs of these parents.

Objective: This study aimed to use a participatory design approach to describe and compare Latino and non-Latino parents' current self-care practices, needs, and technology preferences when caring for children with asthma in marginalized communities.

Methods: The participatory design approach was used to actively engage intended users in the design process and empower them to identify needs and generate design ideas to meet those needs.

Results: Thirteen stakeholders participated in three design sessions. We described Latino and non-Latino parents' similarities in self-care practices and cultural-specific preferences. When coming up with ideas of technologies for self-care, non-Latino parents focused on improving caregiving stress through journaling, daily affirmations, and tracking feelings, while Latino parents focused more on relaxation and entertainment.

Conclusions: Considerations need to be taken beyond language differences when developing technology-enabled interventions for diverse populations. The community partnership approach strengthened the study's inclusive design.

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KEYWORDS

asthma; caregiving; self-care; parents; qualitative research; culturally appropriate technology; minority groups; marginalization

Introduction

One in four children in the United States has chronic health conditions, such as asthma and diabetes, and those who reside in marginalized communities, including racial and ethnic minority and low-income families, are disproportionately affected [1-4]. An estimated 10 million parents provide unpaid care to children living with chronic conditions, and a high percentage of these parents are part of marginalized communities. The responsibilities and demands of parents of these children are 24/7 and multifaceted (eg, monitor symptoms,

administer medications or therapies, and nighttime care). Over time, these responsibilities and demands take a toll on the physical and mental health and work of parents and family relationships, and contribute to the symptoms of fatigue, distress, disturbed sleep, and anxiety [5]. These symptoms are negatively associated with parent well-being (quality of life and family and social function), which impacts the health outcomes of children [6]. Self-care is defined as “the ability of individuals, families, and communities to promote health, prevent disease, maintain health, and cope with illness and disability with or without the support of a health care provider” [7]. Despite the

pervasiveness of these symptoms, parents often receive no training in caring for their own health. Existing interventions to improve parent symptoms of distress, fatigue, anxiety, and sleep have primarily focused on caregivers of adult populations with dementia or parents of pediatric cancer populations with moderate to high socioeconomic status [8,9]. Less is known about interventions that focus on self-care for parents residing in marginalized communities [10]. The COVID-19 pandemic has worsened the existing caregiving crisis. Effective digital health strategies can support these families virtually during the pandemic and remain useful after the pandemic [11].

In the United States, parents of children with chronic health conditions are more likely to be racial and ethnic minorities than caregivers of adults, with Latinos representing the largest minority group [12]. Nonetheless, Latinos and parents from other historically marginalized groups are underrepresented in studies of interventions that aim to support parents of children with chronic conditions [5,13]. Most published studies that explore the use of technology to enable the delivery of supportive interventions for parents of children with chronic conditions were from Europe [14-18]. To our knowledge, only one published study has been conducted in the United States, and it focused on the technology preferences of parents of children with shunted hydrocephalus, but the sample only included 1% Latinos [14]. Currently, in the United States, Latinos represent one of the largest racial/ethnic groups who care for children with chronic conditions, and their representation in parent research is lacking. Lack of representation from marginalized communities, including racial and ethnic minority and low-income families, in designing technology-enabled interventions can increase the risk of intervention-generated inequalities, including further decreased access, adoption, and updates; poor adherence; and reduced effectiveness, for people in marginalized communities [19].

Perspectives from these parents are needed to design inclusive technology-enabled interventions that support self-care among diverse populations of parents caring for children with asthma. Otherwise, design decisions can inadvertently result in intervention-generated inequalities [19]. The types of technology devices used to deliver interventions and the delivery settings (eg, workplace wellness programs and health care organizations) may be less accessible to marginalized groups [20-22]. Even within groups with equal access to technology-enabled interventions, more significant attrition and lower adherence rates were observed in groups with lower educational attainment levels [23-25]. These inequalities could be attributed to the lack of representation in the intervention design and development phases, leading to inappropriate cultural, linguistic, literacy-level, and economic-level intervention treatment components, delivery, and engagement [19].

Participatory design is a promising approach to designing inclusive parent interventions that minimize design decisions inadvertently causing intervention-generated inequalities. The premise of participatory design is to actively engage intended users in the design process and empower them to identify needs and generate design ideas to meet those needs [26]. Based on the information technology literature [27], we expect that utilizing participatory design to design technology-enabled

interventions would result in a better understanding of parents' needs and design requirements, a greater likelihood of including features that parents want, a higher level of acceptance, and an improved understanding of how the technology-enabled intervention works. As Clemensen et al described, participatory design is an iterative process that involves the following: (1) engaging intended users in identifying needs, (2) empowering intended users to generate ideas for solutions that could address these needs, (3) pilot testing and refining these solutions, and (4) assessing the effectiveness of the solutions [28]. We adopted a participatory design approach to design an inclusive technology-based intervention that promotes self-care among predominantly low-income and Latino parents of children with asthma. In this paper, we describe the first two steps in the participatory design process.

The purpose of this study was to use a participatory design approach to describe and compare Latino and non-Latino parents' current self-care practices and needs, and to identify how to leverage technology to enhance self-care practices among parents of children with asthma.

Methods

Design

This descriptive qualitative study is part of a larger study in designing and developing a technology-enabled mobile health intervention for parents of children with chronic conditions (Caring of Caregivers Online [COCO]) [29].

Sample and Sampling

We recruited stakeholders (parents and clinical experts) from an asthma coalition established with multiorganizational effort to improve the quality of life for individuals, families, and communities affected by asthma in the northwestern United States. The coalition is a community, clinical, and academic partnership to strengthen relationships among stakeholders (eg, patients, families, clinicians, researchers, and community health workers), particularly in marginalized communities underrepresented in research. There are two parent advisory groups in the coalition, one Latino and one non-Latino group. The first author is a long-term member of the coalition who presented CocoBot at multiple coalition monthly meetings to receive input on study conceptualization, grant preparation, study design, and recruitment. The research team shared the study recruitment flyer for this study with the coalition members, who distributed the flyers in the community, including child care centers, asthma clinics, and community health centers. The inclusion criteria for parents were as follows: (1) age 18 years or older; (2) ability to read and speak English or Spanish; (3) having a child (aged 3 to 12 years) with asthma; and (4) co-residing with the affected child more than 50% of the time. A parent was defined as the child's primary caregiver (biological or adopted). In addition, we invited members of the coalition who were not parents of children with asthma to participate in a clinical expert participatory design session. The inclusion criteria for clinical experts were as follows: (1) age 18 years or older; (2) ability to read and speak English; and (3) working with families of children with asthma, including health care professionals working at different settings caring for these

children and their families, local health department staff, and community health workers. Individuals who were interested in study participation contacted a study team member who screened them for eligibility. All study participants provided written informed consent. All participants who met the inclusion criteria were enrolled and completed the study.

Procedures

We conducted three in-person participatory design sessions and mailed participatory design packets for additional input. Three participatory design sessions were conducted with five Spanish-speaking parents (all Latino), four English-speaking parents (one Latino and three non-Latino), and three clinical experts in childhood asthma (one Latino and two non-Latino) in a private conference room at a public library or the coalition regular meeting space. Participatory design sessions lasted 55 to 80 minutes. We obtained audio and video recordings of the sessions and collected all artifacts generated by participants. We later invited study participants to a follow-up with written responses to elaborate on the topics discussed during the participatory design sessions. Two Latino parents, who were interested in participating but were not available to attend an in-person participatory design session, were invited to provide written responses to topics discussed during the participatory design sessions with a mailed participatory design packet. The packet contained a consent form, a demographic questionnaire, ideation materials (pens, markers, drawing paper, and post-it notes), and forms that guided study participants through the ideation process. A team member scheduled a phone session with the participants to explain the packet and questions, and instructed the participants to return the packets with completed responses via the US Postal Service. We received one packet back. The other parent said the packet could not be found after 2 months and did not want to receive another packet. The institutional review board approved all study procedures.

Data Collection

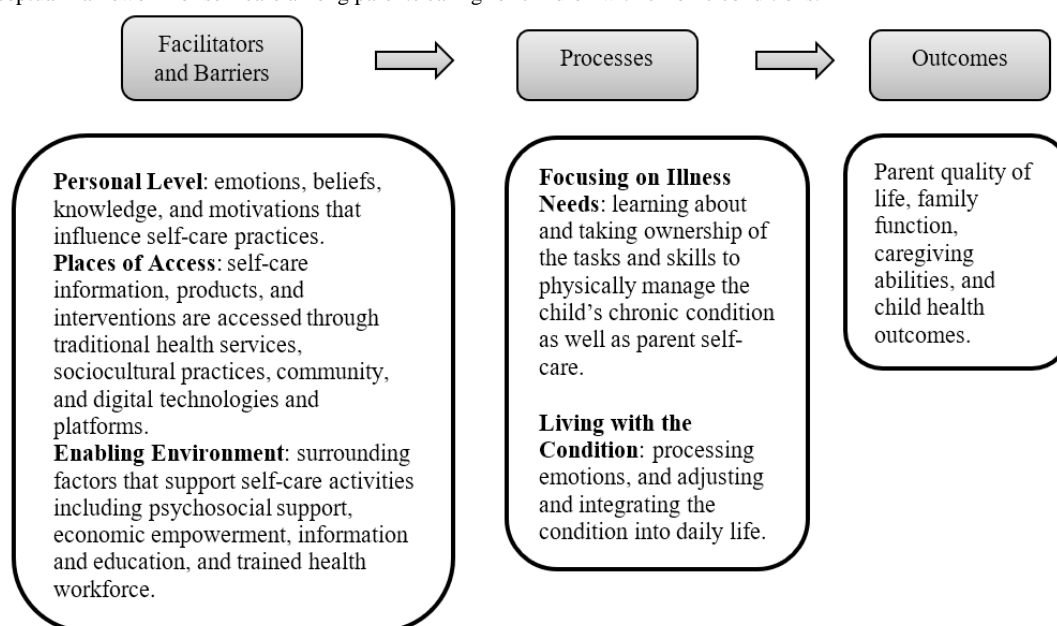
The participatory design session was designed to actively engage study participants in interactive discussions to co-design potential technology solutions to support the self-care of parents' symptoms. In the first part of the participatory design session, we asked study participants to write down parents' most common caregiving concerns and symptoms, self-care practices, and needs. We asked study participants to share their ideas with the larger group. The facilitator then used affinity diagramming to organize ideas into groupings based on common themes. In the second part of the participatory design session, we provided study participants with ideation materials (pens, markers, drawing paper, and post-it notes). We asked them to work

individually to sketch ideas for future technology solutions that could address parents' caregiving symptoms and self-care needs. We asked participants to visually share their ideas with the larger group and encouraged other study participants to ask questions and provide constructive feedback. We ended the participatory design session by asking participants to share additional technology features they could envision incorporating into parents' daily lives for self-care.

Data Analysis

To guide data analysis, we developed a conceptual framework (Figure 1) based on the Self- and Family Management Framework [30] and World Health Organization's (WHO's) Conceptual Framework for Self-Care [31]. The Self- and Family Management Framework describes facilitators and barriers to, processes involved in, and outcomes of self-management and family management of chronic conditions [30]. The facilitators and barriers to family management focus on traditional practices such as personal factors, the environment, and health care systems. WHO's Conceptual Framework for Self-Care complements the Self- and Family Management Framework by expanding the places of access and enabling the environment for self-care, including traditional routes and emerging digital health and technologies [31]. The latter is a salient field of practice to expand access to health information and communication, address health needs, and reduce health inequalities [31].

Members of the research team transcribed audio recordings verbatim, transcribed participatory design session artifacts, and transcribed participatory design packet responses in English or Spanish. Two members of the research team with qualitative research experience deductively coded the unitized data (English and Spanish) independently and used the concepts as themes according to the conceptual framework [32]. Because we focused on self-care practices and needs, we did not present the conceptual framework's outcomes in this study. Transcripts were coded in their original language. A codebook was developed with definitions and representative quotes for each domain and category. Two additional research team members performed peer debriefing on the coding in English and Spanish, according to the codebook. We used constant comparative analysis to examine each unit's fit with the coded domain and category, and the uniqueness of each unit's coding (no unit fit under two different categories) [33]. Disagreements were discussed among all four team members in a series of meetings, resulting in recoding a unit or refinement of the codebook until 100% consensus.

Figure 1. Conceptual framework for self-care among parents caring for children with chronic conditions.

Results

Demographic Characteristics

Table 1 shows the demographic characteristics of Latino and non-Latino stakeholders. We combined the parents and clinical experts into the two stakeholder groups by ethnicity to protect participant confidentiality. The majority of parents were female

(9/10, 90%), without a college degree (8/10, 80%), and employed outside the home (6/10, 60%). Most non-Latino parents earned less than US \$19,000 annual household income (*n* not reported for confidentiality). The majority (4/7, 57%) of Latino parents earned less than US \$60,000. All parents self-identified belonging to at least one of the following two marginalized communities of focus in this study: racial and ethnic minority and low-income families.

Table 1. Characteristics of non-Latino and Latino stakeholders (parents and clinical experts).

Characteristic	Non-Latino stakeholders (n=5)	Latino stakeholders (n=8)
Age (years), mean (SD)	48 (11.5)	42 (7.1)
Female, n (%)	4 (80%)	8 (100%)
Race/ethnicity, n (%)		
White	3 (60%)	0 (0%)
Black	2 (40%)	0 (0%)
Latino	0 (0%)	8 (100%)
Education, n (%)		
Less than high school	0 (0%)	1 (12.5%)
High school	1 (20%)	5 (62.5%)
Some college, no degree	2 (40%)	0 (0%)
Associate or bachelor's degree	2 (40%)	2 (25%)
Employment status		
Working now	5 (100%)	3 (37.5%)
Self-employed	0 (0%)	3 (37.5%)
Homemaker	0 (0%)	1 (12.5%)
Marital status		
Married	2 (40%)	6 (75%)
Single (eg, divorced and widow)	3 (60%)	2 (25%)

In the following sections, we present the barriers and facilitators to self-care related to personal factors, places of access, and the environment. We also present processes for self-care, including focusing on illness needs and living with the condition. In each section, we highlight the technology preferences among the two groups.

Facilitators and Barriers

Personal Level

At the personal level, non-Latino parents experienced various emotions caring for their children with asthma, including worry, stress, fear, guilt, frustration, and isolation. Parents were unaware of supportive services that were available to help them manage these emotions. An example response was as follows:

Depression? There are no easy resources... I never had one of my children's healthcare providers ever asked or checked in.

Non-Latino parents with multiple children with asthma expressed that it was challenging to fully understand each child's care needs because asthma affected each child differently (eg, children within the same family had different asthma triggers). Moreover, while non-Latino parents perceived a connection between the well-being of the parent and that of the child with asthma, they nonetheless found it difficult to justify taking the time to care for their own health (Table 2).

Similar to non-Latino parents, Latino parents expressed that being a parent of a child with asthma led to them experiencing

various emotions, including fear, worry, stress, guilt, hopelessness, and frustration. Latino parents felt these emotions when they thought about whether the precautions they were taking to reduce asthma triggers in their home would be useful, how to respond in an emergency, and how they had little to no control of the environment outside of the home (eg, school) that could trigger an asthma attack. Latino parents described prioritizing their children's needs before their own as part of the Latino culture. On discussing their self-care, Latino parents indicated that they could not focus on their self-care until the rest of their family members were taken care of. For example, one clinical expert made the following statement:

For my community, we've always taken pride in taking care of our family before we take care of ourselves.

When asked to generate ideas for how technology could address personal barriers to self-care, non-Latino parents mentioned reminders for self-care activities, including breathing and mindfulness exercises, relaxation, healthy recipes, and tracking feelings. Latino parents suggested that the information presented on digital devices be clear and concise, and minimize distractions. They also wanted the information to be accessible in English and Spanish, and designed with both parents and children as the intended audience. Finally, Latino parents described their desire to have a technology tool that presents information for both parents and children to learn about self-care in an informative, fun, and entertaining way.

Table 2. Descriptions and representative quotes from non-Latino and Latino stakeholders (parents and clinical experts).

Domain and category	Quotes from non-Latino stakeholders	Quotes from Latino stakeholders
Domain 1: Facilitators and barriers		
Personal level	<p><i>The child has asthma and it's hard to separate and it's impossible to separate when it's about caring for them or when it's caring for us, right? Or if they get better, we'll get better too, so it's kind of hard to say um... I'm going to do this just to care for myself or do this just to care for my child.</i></p> <p><i>[Parents] don't realize how the lack of sleep, mood or how that might affect their health and wellbeing I don't think [parents] recognize for themselves or they see it right or they allow themselves to have those perks.</i></p>	<p><i>Como me siento, pues me siento asustada, estresada, preocupada. Me asusta el saber, el no saber si las medidas que estoy haciendo que estoy tomando para mis hijos funcionan. Si en caso de emergencia voy a saber qué hacer y si sé que hacer, entonces, si va a funcionar para mi hogar. Translation: How I feel, well I feel scared, stressed, worried. It scares me knowing, not knowing if the measures that I am doing that I am taking for my children work. If an emergency happens, will I know what to do and if I know what to do, then if it will work for my child.</i></p>
Places of access	<p><i>Other family members who might help or not help them [parents] care for their child and the siblings.</i></p> <p><i>B aby monitor in his [child's] room where I can hear and if I hear anything that doesn't sound right I can like know, I can go back.</i></p>	<p><i>Bueno, a mi lo que me funciona cuando mi niño está enfermo y me siento frustrada y eso, es hablar con alguien, hablar con una amiga. Eso me relaja mucho. Translation: Well, what works for me when my child is sick and I feel frustrated is to talk to someone, to talk to a friend. That helps me a lot to relax.</i></p>
Enabling environment	<p><i>The doctors...don't understand that the way I'm caring for my children and the events going on at home you know you're not seeing what I'm seeing but I'm seeing it and they [doctors] will say like, you know, um [acting as the doctor not believing], just getting frustrated because you feel helpless.</i></p> <p><i>[I was] struggling to get school staff to take the illness seriously and administer the medicine responsibly and appropriately.</i></p>	<p><i>Pienso que a veces los doctores tienen muy poquito tiempo para nosotros, pero pienso que a veces pienso que ni siquiera ellos no tienen toda la información tampoco. Translation: I think that sometimes doctors have very little time for us, but I also think that sometimes, not even they have all the information.</i></p> <p><i>Que tenga un ataque de asma en la escuela y la enfermera no sepa que hacer que en un ataque de asma y mi hijo deje de respirar. Translation: [Concerns as a parent] that my child has an asthma attack at school and the nurse does not know what to do when a child is having an asthma attack and my child stops breathing."</i></p>
Domain 2: Processes		
Focusing on illness needs	<p><i>You [parent] have a child who you want to self-carry their rescue inhaler.</i></p> <p><i>You [parent] kind of lose control a little bit of what they [the child] do when they're older.</i></p>	<p><i>Que ellos tengan conocimiento de que, si tienen una condición que sepan que tienen que hacer, eso les da a ellos seguridad en sí mismos, ellos estar informados y estar en su propia condición, en su tratamiento, eso ayuda para que ellos no tengan miedo de hacer cosas, de jugar, de correr, de hacer ejercicio. Translation: They (children) need to understand that if they have a health condition, they need to know what to do. This will help them to build self-confidence. They need to be informed about and involved in their own condition and its treatment. This will help them to avoid feeling afraid of doing things, such as playing, running, and exercising.</i></p>
Living with the condition	<p><i>How am I going to go to the gym if my kid is sick at home, how am I going to eat this if it's really good if my kid can't have it, how am I going to go out on vacation if my kid I need to afford this medication, who is going to take care of them the same way I do?</i></p> <p><i>I just need to tough it out, right? Like, I don't care about myself like, I just need to pull it through to care for my child.</i></p> <p><i>Complaining to each other.</i></p> <p><i>Trying to do [everything] everyday - it's always like, is this enough?</i></p>	<p><i>Mientras ellos [hijos] están pasando por una cosa así, no puedo tener mucho con que sentirme bien. No creo que mientras que ellos estén mal, yo pueda relajarme o cosas así. Entonces lo que pasa es, por ejemplo, me ayuda el saber la reasuransa o "reassurance" de que van a estar bien... Y si puedo tener eso, entonces ya puedo tener las otras cosas [autocuidado]. Translation: If my child is going through something (asthma symptoms), there is not a lot that will help me feel better. While they are not doing well, I don't think that I could relax or anything like that. So what happens, for example, is that it helps me when I can be reassured that they are going to be okay... once I have that reassurance, then I can have these other things [related to my self-care].</i></p>

Domain and category	Quotes from non-Latino stakeholders	Quotes from Latino stakeholders
Technology preferences	<p><i>Voice would be better than writing it down.</i></p> <p><i>Seasonal reminder related to asthma.</i></p> <p><i>There are games on the phone and people can collect different like if you [parent] answer these four question you get like an award and then s ee. ..and I don't know if other people would like that, it's not for me, but I know other people do those things that they get excited about, they have evidence of what they have done.</i></p> <p><i>Reminders to take time to breathe [for the parents].</i></p> <p><i>Help you [parent] with reminders of journaling, daily affirmations and could ask you how you feel.</i></p> <p><i>They [parents] liked getting the text message weekly because that didn't feel overwhelming.</i></p>	<p><i>Una buena idea sería que haya videos de mamas con hijos con asma y saber su experiencia, entrevistas en TV o en radio, también entrevistas en persona y mostrar fotos de los lugares en casa no recomendables para niños con asma. También fotos de los productos de limpieza que usan en el hogar.</i> Translation: A good idea would be to have videos of moms with their children with asthma, to learn about their experience, on TV or on the radio. Also, interviews that show photos of places in the home that are not recommended for children with asthma. Also, photos of cleaning products that are safe to use in the home.</p> <p><i>Uso cel para oír musica para relajarme.</i> Translation: I use my cellphone to listen to music and relax.</p> <p><i>Uso mi celular para buscar informacion.</i> Translation: I use my cellphone to look for information.</p>

Places of Access

There were barriers and facilitators regarding the places that parents accessed self-care support. In their communities, non-Latino parents turned to family members and friends to care for their children with asthma and other siblings while the parents took short breaks from caregiving. Although non-Latino parents trusted their family members and friends, they still felt apprehensive about leaving their children with asthma under the care of another person. Non-Latino parents were worried about their children experiencing an asthma attack when they are away. They explained how the family members or friends caring for their children might not know what would trigger an asthma attack or how to respond if the children experienced one. One non-Latino parent made the following statement:

You [the parent] trust the person, but something can go wrong, and it could be a small thing that they don't notice, or anything could lead to a big asthma attack.

Latino parents also relied on family members and friends for self-care support, but in a different form than non-Latino parents. For Latino parents, family members and friends were a source of emotional rather than tangible support. For example, one Latino parent mentioned that speaking with a friend was an effective strategy for easing the difficult emotions associated with caring for a child with asthma (see Table 2 [quotes from Latino stakeholders]). Unlike non-Latino parents, sociocultural practices were a place of access for self-care support among Latino parents. In particular, Latino parents described the vital role of religion in their ability to cope with the challenges of having a child with asthma.

Mobile technologies were also points of access for self-care support for both groups of parents. Non-Latino parents described using apps for self-guided meditation, medication reminders, asthma management, and parenting advice. Parents used baby monitors in their children's bedrooms to hear when they struggled with asthma symptoms at night. Similarly, Latino parents described searching for information on the internet to learn about asthma and its management. Latino parents reported using apps to listen to music and watch shows and movies to help manage their stress. They also used technology to create reminders of upcoming doctor appointments, get recipes for healthy meals, share experiences with others through social

media, and track physical activity. While Latino parents recognized the advantages of mobile technologies for accessing self-care support, there was concern about how easy it was to get distracted by and addicted to technology. To that end, Latino parents desired to obtain more of the information from other sources, including asthma-related community events, health care providers, television, and radio. One Latina mother shared ideas for how information could be disseminated to parents of children with asthma using different media forms (Table 2).

Enabling Environment

There were barriers and facilitators related to the environments in which parents accessed self-care support. While non-Latino parents used mobile devices to access information on both parent and child self-care, parents felt overwhelmed by the vast amount of information they consumed on the topic. Non-Latino parents also discussed feeling anxious when searching for information online, and they encountered stories about asthma-related accidents experienced by children. While health professionals were generally helpful, non-Latino parents reported that sometimes different health professionals provided conflicting information. One parent made the following statement:

Every doctor is different so they sometimes give different recommendations and you do what they tell you and then you do another one there [as another doctor tells you another recommendation]

In addition, non-Latino parents were dissatisfied with what they perceived to be health professionals' lack of knowledge about their family and parenting style. Health professionals were unable to provide information tailored to the unique situation of their family. One parent made the following statement:

They [the doctors] are not listening, or maybe part of it is not listening, and part of it is not respecting the parent's wisdom... their wishes and wisdom about their child's asthma.

Like non-Latino parents, Latino parents used various mobile devices (mostly smartphones) to access self- and child-care information. Latino parents discussed other environments in which they accessed self-care support, including asthma-related meetings and community events. While some Latino parents were English speakers, it was still of considerable importance

that high-quality information about asthma and self-care for both parents and children be accessible in Spanish. Furthermore, Latino parents discussed accessing self-care support from health professionals. A theme among Latino parents, which was not observed among non-Latino parents, was that the former group said medical doctors did not provide sufficient education and support during clinic visits. One Latino parent described her desire for doctors to educate families on what changes they could make to have an asthma-safe home for their children. This parent explained possible reasons for the lack of education and support for families on the behalf of doctors (Table 2).

In addition to medical doctors, both non-Latino and Latino parents identified the school as a potential environment to access asthma support. However, both groups of parents generally lacked confidence in school nurses' ability to respond to their children's asthma attacks effectively. One Latino parent described her concerns about having school nurses without proper education and asthma care training (Table 2).

When providing education to parents, both groups pointed out that health professionals need to present information in small chunks over time, rather than "dumping information all at once." Breaking down information into bite-sized pieces would make it easier for parents to gradually implement changes in their home environment, rather than trying to change everything at once, as one non-Latino parent suggested. Regarding Latino parents with children with asthma, one clinical expert made the following statement:

They are so concerned about doing everything perfect that it takes all their time. It consumes their life trying to get everything perfect. Then, they're not taking care of themselves or doing anything else, you know?

Processes for Self-Care

Focusing on Illness Needs

Learning about asthma management and self-care is long term and complex. Non-Latino parents shared that they had to constantly struggle to let go of the idea that asthma is a serious condition in order to focus on management strategies one by one. There was a recognition in both groups that developing effective asthma management skills must happen slowly over time. All parents were proactive in learning how to create an asthma-safe home for their children, for example, "products [that] are triggers for our kids, so cleaners, clothes, and scents." Furthermore, parents in both groups discussed encouraging older children with asthma to take greater ownership of their asthma management. One Latino parent described why it was important to transfer asthma management responsibility from the parent to the child (Table 2). However, older children sometimes refused to use their inhaler because they perceived it as no longer needed. For this reason, non-Latino parents felt reluctant to transition self-care into a shared responsibility between parents and older children with asthma (Table 2).

Living With the Condition

Parents discussed how they coped with their children's asthma and integrated the condition into daily life. Both groups of parents felt that they could not focus on their self-care until they

knew their children were well. To provide the best care to their children, non-Latino parents believed it was necessary to process the difficult emotions associated with their children having asthma. Strategies that non-Latino parents found to help them cope with the condition included talking to family members and friends, journaling, meditating, reading affirmations, and setting self-care goals. Some non-Latino parents shared that working outside of the home provided temporary relief from these difficult emotions. Their work required them to be fully engaged instead of thinking about their children's health condition. However, non-Latino parents reported having to miss a significant amount of work because of their children's asthma symptoms.

Latino parents were reluctant to consult a mental health professional for their self-care support. One Latino clinical expert made the following statement:

We [Latinos] don't do medication, we don't do a lot of stuff that you people don't even see, you know? I don't need to go to a psychologist when I'm not crazy.

Instead, Latino parents described different ways they coped with their own difficult emotions. Strategies included listening to music, going outdoors for a walk, increasing their knowledge about asthma, and working with their children to manage asthma better. Latino parents described adjustments they have made in their homes and lifestyles to manage their children's asthma. Namely, Latino parents switched to cleaning with non-toxic products, began cooking healthier meals, and incorporated more daily physical activity for the entire family. Similar to non-Latino parents, it was not until Latino parents observed improvements in their children's asthma symptoms that they felt they could focus on their self-care (Table 2). One Latina mother, who considered herself a Catholic, described putting her trust in God. While she would continue to do what was necessary and under her control to manage her child's asthma, it helped to accept that what ultimately happens is the will of God.

Co-Designed Solutions to Address Self-Care

Study participants co-designed potential technology solutions to support both parent and child self-care needs (see Figures 2 and 3 for examples from Latino and non-Latino parents, respectively, and Table 2 for quotes). Both groups of parents described technology features that would enable their children with asthma to use technology to set reminders to take their medications. Both groups of parents also described wanting to be reminded to take deep breaths and find recipes for healthy meals. Non-Latino parents further described technology features that would enable them to share an asthma care plan with others (eg, school nurses and other parents), receive affirmations, practice journaling, track their feelings, and track information about asthma attacks (eg, when and where they happened) to identify patterns. Latino parents described technology features that would enable them to search for information about asthma and its management, set reminders for upcoming doctor appointments, listen to music, watch shows and movies, watch videos of other mothers discussing their experiences, find cleaning products that are safe to use in the home, track tasks, and track physical activity.

Figure 2. Example design artifact from a Latino parent. Technology ideas for self-care: new technology connects with other apps automatically to have more search options; use technology productively, without distractions or irrelevant information; have clear and concise information; technology should be accessible for children and adults; and technology should be fun and entertaining.

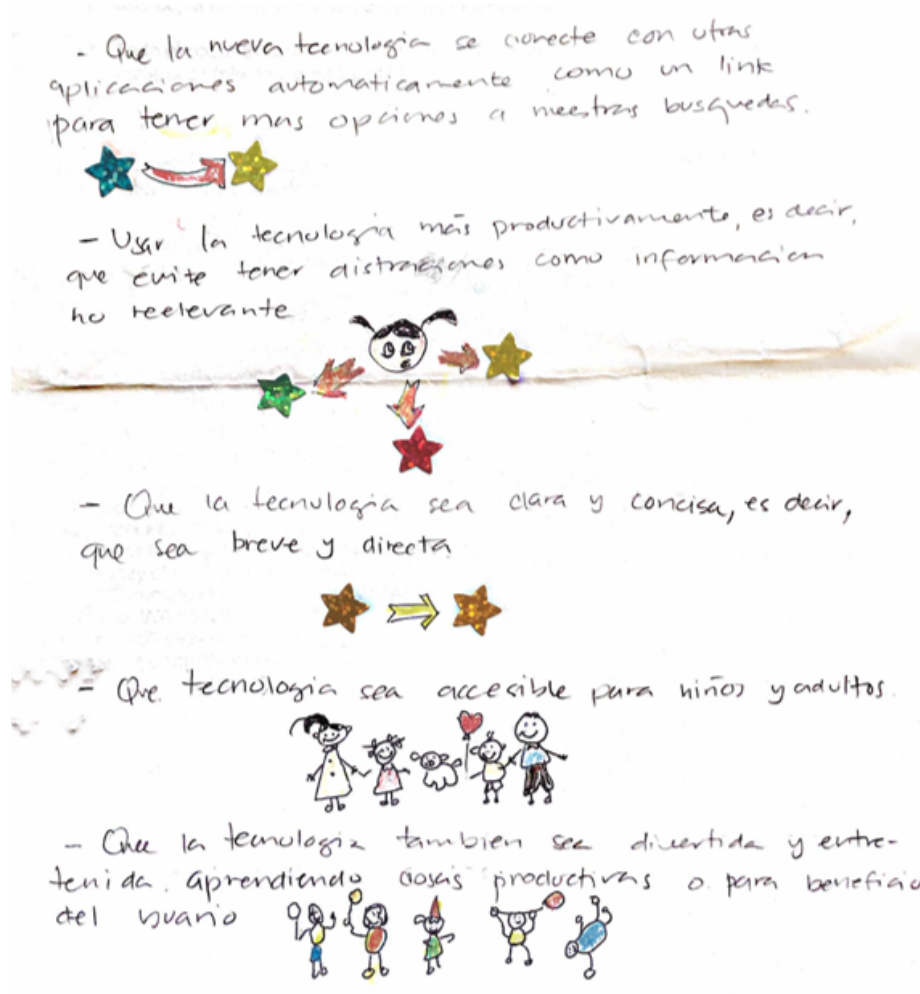
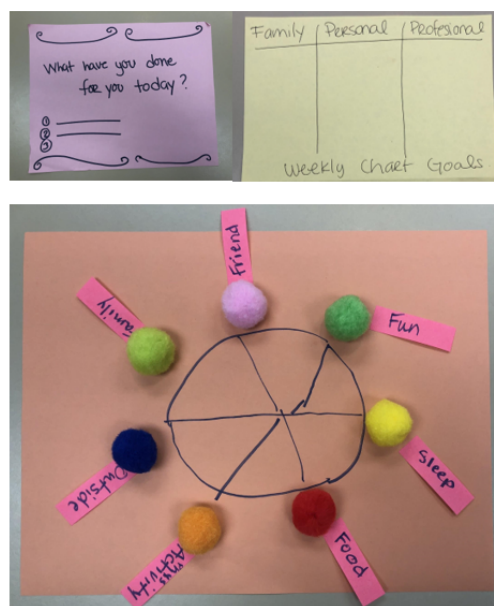


Figure 3. Example design artifacts from non-Latino parents. From left to right, top to bottom: reminder for self-care, setting weekly goals, and pie chart for self-care activities.



Discussion

Principal Findings

This study provided new knowledge about self-care needs and technology preferences among Latino and non-Latino parents in marginalized communities. Both groups of parents experienced negative emotions that would hinder their parenting abilities but could not prioritize taking care of themselves over caring for their children. The two groups differed in the places of access for self-care support, such as families, friends, and communities. Both groups of parents accessed caregiving information online and through health care providers. However, the information was perceived as overwhelming and not tailored to their specific needs. Current self-care practices using technology were similar among the two groups, including using applications for relaxation. When coming up with ideas of technologies for self-care, non-Latino parents focused on improving caregiving stress through journaling, daily affirmations, and tracking feelings, while Latino parents focused more on relaxation and entertainment.

Comparison With Prior Work

Our study found that both Latino and non-Latino parents were interested in the idea of using technology to access support for their self-care. Parents generated ideas for future technology tools that incorporated support for both the physical and mental health aspects of self-care, such as learning to make healthier meals and practicing deep breathing for relaxation. Research on the technology needs and preferences of parents caring for children with chronic health conditions is limited, particularly among historically marginalized populations. To our knowledge, we found only one published study on the topic, which focused on understanding parents' current use of technology devices and their online sources of information [14]. Notably, non-English speakers were excluded from the study, and the majority of participants were White. Nonetheless, our findings are complementary. Our study reported that parents used multiple technology devices in their everyday lives and identified the internet as a significant source of information. Further, in our research, we found that Latino parents' ideas for future technology tools included the requirement that information is not only educational but also entertaining. There is evidence to suggest that entertainment education can be an effective strategy to improve access to health-related information among Latino populations [34-36], though additional research is needed to understand the potential impact of delivering entertainment education via digital tools. Finally, our findings showed the importance of developing technology tools that clearly and concisely present information in both English and Spanish. This finding highlights the unmet need for

disseminating culturally and linguistically appropriate technology-enabled interventions among Spanish-speaking Latino populations [37].

Limitations

This research took place as part of an academic-community partnership between the University of Washington researchers and the Puget Sound Asthma Coalition and their multicultural parent advisory groups. Although partnering with a community-based organization strengthened the study's inclusive design, the results were limited as most of the participants were already members of the coalition. Thus, they were more knowledgeable about the research process and had experiences engaging in research in the past. The clinical experts also had personal experiences and connections with asthma; thus, we cannot rule out that some parents may have shared experiences as parents of children with asthma, along with their clinical experiences. One challenge in conducting this community-based bilingual research was that some participants belonged to multiple sociocultural groups (eg, Latino and preference for speaking English). We organized the participatory design sessions by preferred spoken language but analyzed the data by ethnicity. Other participants could have influenced Latino stakeholders in the English-speaking group. We did try to overcome this by asking participants to respond to questions and design prompts individually first and then share the responses with the larger group. We had a relatively small sample size as the data collection had to be stopped due to the start of the COVID-19 pandemic. The research team analyzed the data received and determined that we had sufficient data to conduct analyses. In addition, we were only able to conduct the first two steps of participatory design in this study. The research team is actively pursuing additional funding to continue this project.

Conclusions

This study is one of the first to use the first two steps of participatory design to engage stakeholders in marginalized communities to design a technology-enabled solution for family caregivers to engage in self-care. The community partnership approach strengthened the study's inclusive design. The COVID-19 pandemic has substantially increased interest in and acceptance of supportive services delivered entirely in virtual environments. In our research using participatory design to engage Latino and non-Latino parents from marginalized communities in identifying needs and generating ideas for solutions that could address these needs, we found that parents in both groups had some similarities in self-care practices but that there were also culture-specific preferences. Considerations need to be taken beyond language differences when developing technology-enabled interventions for diverse populations.

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Authors' Contributions

All authors contributed substantially to the conception and design of the work; acquisition, analysis, and interpretation of the data; and drafting and revision of the manuscript. They approved the version to be submitted for publication.

Conflicts of Interest

None declared.

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Abbreviations

WHO: World Health Organization

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Original Paper

Trends in Positive, Negative, and Neutral Themes of Popular Music From 1998 to 2018: Observational Study

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Abstract

Background: Across the United States, the incidence of adolescent depression and suicide cases has risen in the past 10 years. Despite the risk factors and causes being multifactorial, the influence of popular culture on society and adolescents in this media-driven generation cannot be mitigated. Although the impact of social media and its effect on shaping self-identity in adolescents have been observed, the impact of music and its potential for subliminal negative messages to adolescents remains unclear.

Objective: This study analyzes the lyrics and music videos of the most popular music of multiple genres to quantify the frequencies of varying music theme trends.

Methods: The frequencies of themes of 1052 total American and Latin songs were collected from the Nielsen Music and Billboard's top 100 chart performance from 1998 to 2018 for hip hop/rhythm and blues (R&B), pop, Latin, country, and rock/metal genres. Themes from songs were identified, quantified, and categorized with a rubric into negative, neutral, and positive themes by 3 different reviewers. Analysis was performed using 2-tailed *t* tests and a generalized linear model.

Results: Popular songs were reviewed for positive, negative, and neutral themes in the following 3-year intervals for ease of analysis purposes: 1998 to 2000 (n=148), 2001 to 2003 (n=150), 2004 to 2006 (n=148), 2007 to 2009 (n=156), 2010 to 2012 (n=150), 2013 to 2015 (n=150), and 2016 to 2018 (n=150). There was a significant 180% increase in the percentage of songs with negative themes between all the interval years and across all genres ($P<.001$), while there was no significant difference in the frequency of songs with positive ($P=.54$) or neutral ($P=.26$) themes by year. There were significant differences in the number of negative themes found across genres ($P<.001$), with hip hop/R&B having the highest frequency of 130 out of 208 (62.5%) of the negative themes when compared to each of the individual genres ($P<.001$).

Conclusions: This study shows there is an increase in the frequency of negative themes over the span of 20 years across all genres, with hip hop/R&B having the highest frequency among the genres. These findings point to the potential impact that music may have in popular culture and on society. Furthermore, these results can help shape discussions between caregivers and their adolescent dependents and between primary care providers and their adolescent patients.

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KEYWORDS

music; adolescent; themes; trends; primary care provider; social media; mental health; depression; anxiety; pop culture

Introduction

Overall, from 2010 to 2015, youth from the ages of 13 to 18 years in the United States were seen to have increased depressive

or anxious symptoms and suicidality [1]. An observational study that investigated the relation of 38 nationally televised stories and suicide rates showed that youth seem to be at a much greater risk for imitating suicidal behavior seen on television whether fictional or true when compared to adults [2]. Although risk

factors and causes are multifactorial, the influence of popular culture on society and adolescents in this media-driven generation cannot be mitigated. In fact, recent cross-sectional studies and meta-analyses have demonstrated a relationship between increased social media use and high-risk behavior among adolescents and the development of depressive symptoms [3,4]. Although the impact of social media and its effect on shaping self-identity in adolescents have been observed [5], the impact of music has not been studied.

Historically, music has influenced adolescents in the United States. For instance, new musical genres emerged during the countercultural movement of the 1960s that embodied the movements related to the conflicts in Vietnam, Civil Rights, and Women's Rights. Musical genres emerged as a direct outlet for youth's experimentation and need for increased liberalization through creative speech made through music. Rock and Roll music of the 1950s that originated from blues, folk, and country eventually diverged into different styles by the mid 1960s, including pop, folk, acoustic rock, and electronic music. The origins of hip hop/rhythm and blues (R&B) stem from the social injustices minorities face on a day-to-day basis that have resulted in a musical genre that uses metaphors as an outlet for African Americans and how they have come to conceptualize their environment and neighborhoods [6]. Pop music had previously embodied elements from the rock and roll of the 1950s and 1960s but eventually evolved to appeal to audiences in a way that was more "commercial, ephemeral, and accessible" [7].

Past studies have investigated how individuals employ music to induce specific emotional states in everyday situations for the purpose of emotion regulation [8]. From this perspective, the songs that receive hundreds of millions of views and the themes that their lyrics carry can potentially have unpredictable influences on adolescents. Prior research indicates that the function of musical preference as a form of identification in which adolescents can use to express their own self-concepts is indicative of the power music culture has on our youth [9]. Furthermore, recent studies are increasingly showing how music can impact interpersonal relationships, identity, agency, and emotional field in adolescent development and mental health [10].

With these factors in consideration, it is important to note that in the past two decades, hip hop and R&B music have become increasingly more prevalent and popular according to the year-end Nielsen reports, which ranked hip hop/R&B as the most-consumed genre in the years 2017 and 2018. With the rise of social media platforms such as YouTube, which amasses over 1.8 billion users a month, the medium in which music can be portrayed has diversified. Music video formats are now popular among adolescents, and studies show that music lyrics that are visually illustrated can have potentially magnified impacts [11].

The purpose of this study was to analyze the lyrics of the most popular music of multiple genres and themes, along with their respective official music videos, to capture the trends in music.

Methods

Data were collected by reviewing the sales data across the genres of hip hop/R&B, pop, rock/metal, country, and Latin music from Nielsen Music and Billboard's Top 100 chart performance within the United States. This study was submitted to the Institutional Review Board at Pennsylvania State Hershey Medical Center, which deemed the study to be exempt from ethical approval and informed consent, as our research did not include human participants.

The top 10 year-end songs from each genre from 1998 to 2018 were selected and analyzed in 3-year intervals for ease of statistical analysis. Frequency of themes in songs and music videos of hip hop/R&B (n=208), pop (n=212), Latin music (n=209), country (n=210), and rock/metal (n=211) were collected from 1998 to 2018 and categorized using a rubric [12] into negative, neutral, and positive themes.

A total of 46 themes were identified across all genres, with 11 positive, 21 neutral, and 14 negative themes. Themes were categorized based on the potential negative or positive influence certain topics could have on adolescent mental health. All other themes found to have ambiguous messages or influences were categorized as neutral. Negative influencers included topics such as drugs, weapons or violence, self-harm, suicide or death, crime, stigmatized mental health issues, abuse or domestic violence, discrimination or racism, alcohol use, gang participation, police brutality, misogyny, infidelity, and objectification. Neutral influencers included topics such as sexual innuendos, sexual freedom, fear or paranoia, seduction, need of help/support/guidance, loneliness, nostalgia, insecurity, insomnia, betrayal or hurt, vengeance, grief or loss, sex appeal or nudity, love, wealth, vanity, fame, partying or dancing, escapism, social injustice, and expression of emotions without enactment of anger or rage. Positive influencers included topics such as self-acceptance, empowerment or independence, homosexuality, faith, happiness, staying true to oneself, resilience, hope or strength, working hard, achieving dreams or dreaming, and growth or maturity.

Songs and music videos made available through YouTube were analyzed by 3 different reviewers by genre using a shared rubric. The rubric was developed as lyrics and videos were viewed until thematic saturation was reached. Discussions among the reviewers were regularly held concerning categorizations of certain themes as questions and concerns were raised throughout the data collection process.

In the analysis of the results, 2-tailed *t* tests and generalized linear models were used to find significant differences among years and among genres within each negative, positive, or neutral theme. Descriptive statistical analysis was also performed to look at the mean, median, and mode of positive, negative, and neutral themes for each category. The reliability between 2 reviewers was considered to be $\kappa=0.61$.

Results

Popular songs from genres in the following time frames between 1998 and 2018 (N=1052) were reviewed for positive, negative,

and neutral themes in 3 to year intervals for ease of statistical analysis. 1998 to 2000 (n=148), 2001 to 2003 (n=150), 2004 to 2006 (n=148), 2007 to 2009 (n=156), 2010 to 2012 (n= 150), 2013 to 2015 (n=150), and 2016 to 2018 (n=150). There was a significant 180% increase between all interval years in the percentage of songs with negative themes from 1998 to 2018 across all genres ($P<.001$; [Table 1](#)), but there was no statistical significance in that of the positive ($P=.54$) or neutral themes

($P=.26$; 1998 to 2000: 20.95% and 91.22%; 2001 to 2003: 28% and 84.67%; 2004 to 2006: 23.65% and 83.78%; 2007 to 2009: 24.36 and 84.62%; 2010 to 2012: 22% and 82%; 2013 to 2015: 26% and 83.33%; 2016 to 2018: 18.67% and 88.67%; [Table 1](#)). When the same parameters were used to analyze frequency of themes in music videos, there was no significant difference between the interval years in the frequency of negative ($P=.15$) or positive themes ($P=.24$; [Table 2](#)).

Table 1. Frequency of negative, neutral, and positive themes in lyrics based on 3-year intervals.

Period	Total themes, n	Negative themes, n (%)	Neutral themes, n (%)	Positive themes, n (%)
1998-2000	148	25 (16.89)	135 (91.22)	31 (20.95)
2001-2003	150	51 (34.00)	127 (84.67)	42 (28.00)
2004-2006	148	54 (36.49)	124 (83.78)	35 (23.65)
2007-2009	156	52 (33.33)	132 (84.62)	38 (24.36)
2010-2012	150	58 (38.67)	123 (82.00)	33 (22.00)
2013-2015	150	66 (44.00)	125 (83.33)	39 (26.00)
2016-2018	150	70 (46.67)	133 (88.67)	28 (18.67)

Table 2. Frequency of negative, neutral, and positive themes in music videos based on 3-year intervals.

Period	Total themes, n	Negative themes, n (%)	Neutral themes, n (%)	Positive themes, n (%)
1998-2000	148	8 (5.41)	42 (28.38)	1 (0.68)
2001-2003	150	17 (11.33)	45 (30.00)	6 (4.00)
2004-2006	148	22 (14.86)	45 (30.41)	2 (1.35)
2007-2009	156	24 (15.38)	24 (15.38)	1 (0.64)
2010-2012	150	19 (12.67)	18 (12.00)	2 (1.33)
2013-2015	150	21 (14.00)	19 (12.67)	2 (1.33)
2016-2018	150	18 (12.00)	32 (21.33)	4 (2.67)

There were significant differences found among the genres of hip hop/R&B, pop, country, rock/metal, and Latin music in the number of negative, positive, and neutral themes (all P values $<.001$; [Table 3](#)). An analysis of the songs that had at least one negative theme indicated that the number of negative themes differed between genres ($P<.001$; [Figure 1](#)). Specifically, when each genre was compared to all other genres, hip hop/R&B had

a significantly higher frequency of negative themes when compared to all other genres ($P<.001$; [Figure 1](#)). Pop, country, and rock/metal had a significantly higher frequency of positive themes when compared to hip hop/R&B ($P=.03$, $P=.003$, and $P=.002$, respectively; [Figure 2](#)) and Latin music ($P<.001$; [Figure 2](#)). The thematic frequency of “drugs” and “alcohol” were highest in hip hop/R&B ([Table 4](#)).

Table 3. Frequency of negative, neutral, and positive themes in lyrics based on genre.

Genre	Total themes, n	Negative themes, n (%)	Neutral themes, n (%)	Positive themes, n (%)
Hip hop/R&B ^a	208	130 (62.50)	188 (90.38)	21 (10.10)
Pop	212	51 (24.06)	180 (84.91)	44 (20.75)
Country	210	76 (36.19)	172 (81.90)	73 (34.76)
Rock/metal	211	84 (39.81)	148 (70.14)	91 (43.13)
Latin	209	35 (16.75)	209 (100.00)	17 (8.13)

^aR&B: rhythm and blues.

Figure 1. Mean number of negative themes in each genre from 1998 to 2018. Error bars reflect SE. Results show hip-hop/R&B had a significantly higher number of negative themes in lyrics when compared to other genres ($P<.001$). Additionally, Latin music significantly differed from country ($P=.03$) and rock/metal ($P<.001$). R&B: rhythm and blues.

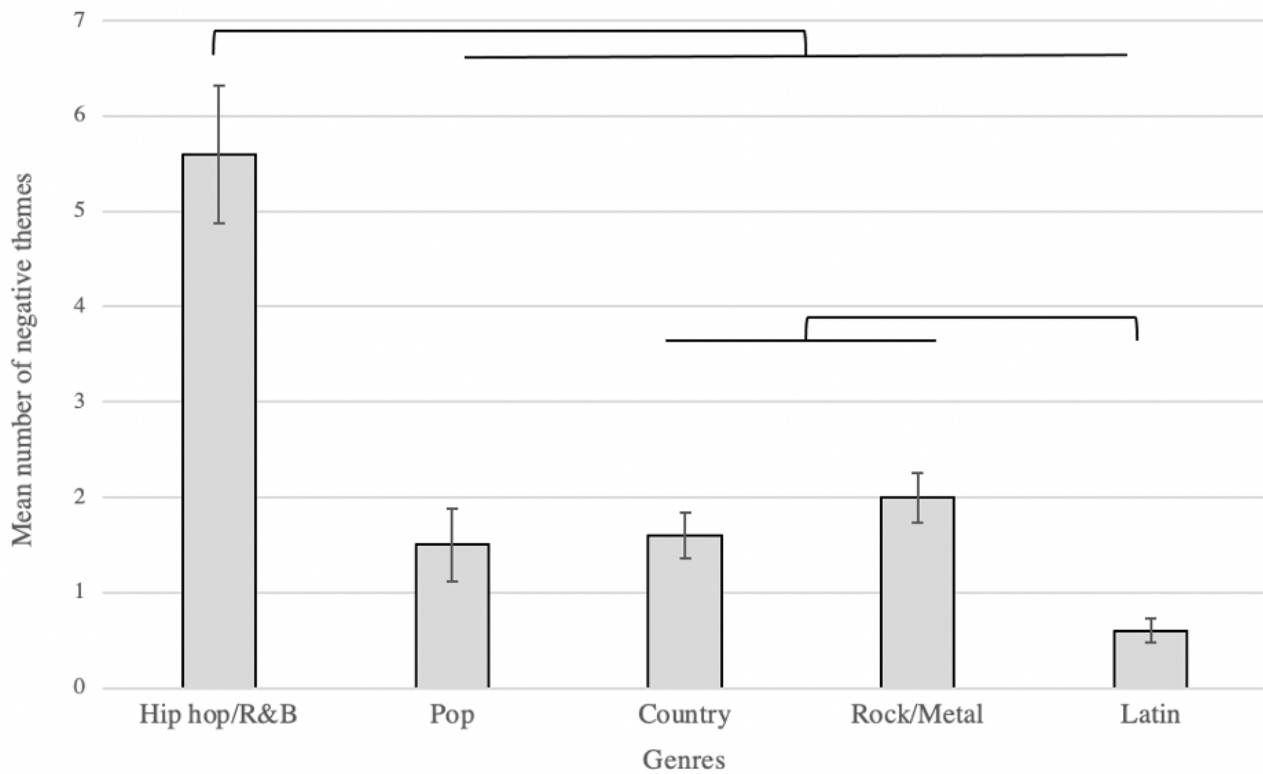


Figure 2. Mean number of positive themes in each genre from 1998 to 2018. Error bars reflect SE. Results show hip hop/R&B had a significantly lower number of positive themes in lyrics when compared to pop ($P=.03$), country ($P=.003$), and rock/metal ($P=.002$). Additionally, Latin music was also significantly different from pop, country, and rock/metal (all P values $<.001$). R&B: rhythm and blues.

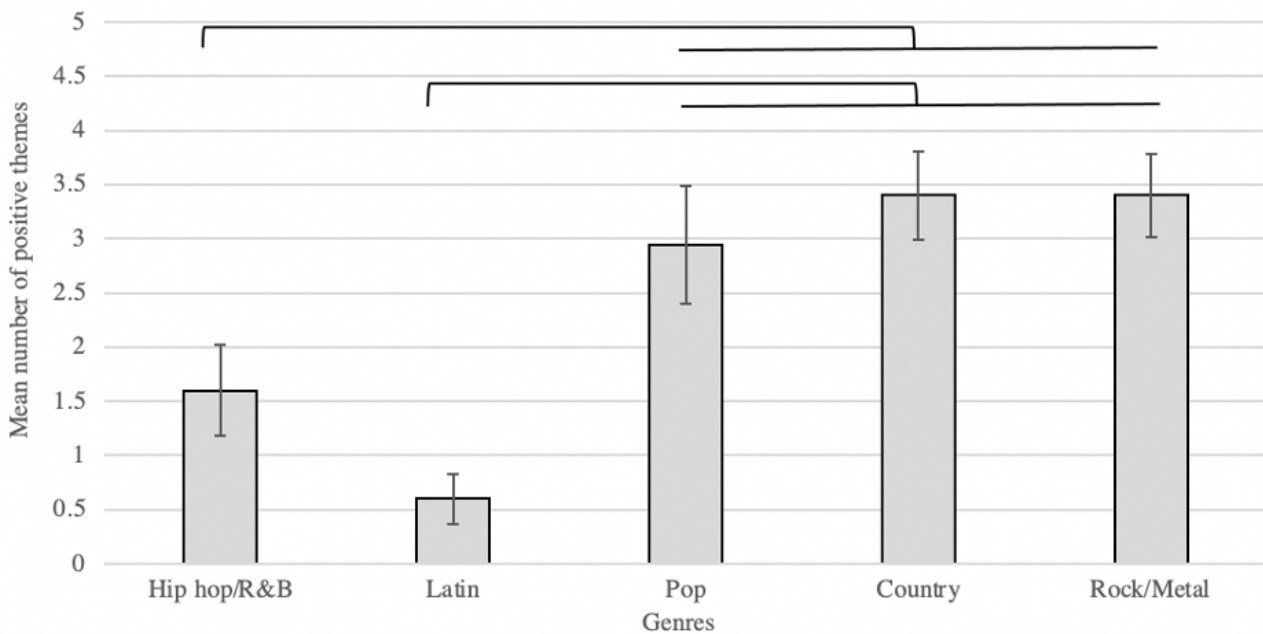


Table 4. Frequencies of themes within each genre.

Themes	Hip hop/R&B ^a , n (%) (n=208)	Pop, n (%) (n=212)	Country, n (%) (n=210)	Rock/metal, n (%) (n=210)	Latin, n (%) (n=209)
Drugs	59 (28.37)	16 (7.55)	8 (3.81)	18 (8.53)	1 (0.48)
Weapons/violence	32 (15.38)	5 (2.36)	3 (1.43)	13 (6.16)	1 (0.48)
Sex/sexual innuendos	92 (44.23)	36 (16.98)	21 (10.00)	18 (8.53)	63 (30.14)
Misogyny	12 (5.77)	0 (0.00)	1 (0.48)	2 (0.95)	0 (0.00)
Love/relationship	63 (30.29)	125 (58.96)	105 (50.00)	74 (35.07)	121 (57.89)
Wealth	88 (42.31)	18 (8.49)	1 (0.48)	6 (2.84)	2 (0.96)
Self-acceptance	1 (0.48)	5 (2.36)	3 (1.43)	2 (0.95)	1 (0.48)
Empowerment/independence	7 (3.37)	13 (6.13)	6 (2.86)	10 (4.74)	1 (0.48)
Homosexuality	0 (0.00)	2 (0.94)	0 (0.00)	0 (0.00)	0 (0.00)
Self-harm	0 (0.00)	0 (0.00)	0 (0.00)	3 (1.42)	0 (0.00)
Objectification	24 (11.54)	4 (1.89)	20 (9.52)	2 (0.95)	0 (0.00)
Alcohol	63 (30.29)	25 (11.79)	62 (29.52)	12 (5.69)	16 (7.66)
Suicide/death	7 (3.37)	0 (0.00)	0 (0.00)	36 (17.06)	0 (0.00)
Gang	15 (7.21)	0 (0.00)	1 (0.48)	1 (0.47)	0 (0.00)
Vanity	36 (17.31)	11 (5.19)	0 (0.00)	5 (2.37)	0 (0.00)
Sexual freedom	11 (5.29)	1 (0.47)	0 (0.00)	7 (3.32)	3 (1.44)
Faith	1 (0.00)	1 (0.47)	25 (11.90)	10 (4.74)	1 (0.48)
Infidelity	15 (7.21)	9 (4.25)	0 (0.00)	5 (2.37)	17 (8.13)
Fear/paranoia	5 (2.40)	2 (0.94)	0 (0.00)	6 (2.84)	0 (0.00)
Seducer	11 (5.29)	1 (0.47)	0 (0.00)	1 (0.47)	0 (0.00)
Fame	12 (5.77)	3 (1.42)	0 (0.00)	8 (3.79)	0 (0.00)
Happiness	0 (0.00)	4 (1.89)	16 (7.62)	10 (4.74)	12 (5.74)
Crime	4 (1.92)	1 (0.47)	0 (0.00)	1 (0.47)	0 (0.00)
Need of help/support/guidance	4 (1.92)	13 (6.13)	3 (1.43)	20 (9.48)	0 (0.00)
Loneliness	3 (1.44)	3 (1.42)	21 (10.00)	18 (8.53)	5 (2.39)
Partying/dancing	19 (9.13)	15 (7.08)	19 (9.05)	6 (2.84)	35 (16.75)
Nostalgia	1 (0.00)	2 (0.94)	18 (8.57)	5 (2.37)	15 (7.18)
Stigmatized mental health issues	3 (1.44)	0 (0.00)	0 (0.00)	10 (4.73)	0 (0.00)
Insecurity	4 (1.92)	4 (1.89)	0 (0.00)	6 (2.84)	0 (0.00)
Staying true to oneself	5 (2.40)	3 (1.42)	3 (1.43)	19 (9.00)	0 (0.00)
Resilience	2 (0.96)	5 (2.36)	12 (5.71)	21 (9.95)	2 (0.96)
Abuse/domestic violence	2 (0.96)	1 (0.47)	1 (0.48)	4 (1.90)	1 (0.48)
Betrayal/hurt	0 (0.00)	2 (0.94)	33 (15.71)	17 (8.06)	61 (29.19)
Hope/strength	4 (1.92)	10 (4.72)	2 (0.95)	14 (6.64)	0 (0.00)
Escapism	1 (0.48)	4 (1.89)	1 (0.48)	7 (3.32)	0 (0.00)
Vengeance	1 (0.48)	2 (0.94)	0 (0.00)	1 (0.47)	0 (0.00)
Grief/loss	2 (0.96)	5 (2.36)	21 (10.00)	11 (5.21)	24 (11.48)
Police brutality	0 (0.00)	1 (0.47)	0 (0.00)	1 (0.47)	0 (0.00)
Discrimination/racism	3 (1.44)	1 (0.47)	0 (0.00)	1 (0.47)	0 (0.00)
Working hard	4 (1.92)	1 (0.47)	8 (3.81)	6 (2.84)	0 (0.00)
Achieving dreams/dreaming	7 (3.37)	5 (2.36)	13 (6.19)	7 (3.32)	0 (0.00)

Themes	Hip hop/R&B ^a , n (%) (n=208)	Pop, n (%) (n=212)	Country, n (%) (n=210)	Rock/metal, n (%) (n=210)	Latin, n (%) (n=209)
Sex appeal/nudity	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.47)	8 (3.83)
Growth/maturing	1 (0.48)	0 (0.00)	7 (3.33)	18 (8.53)	0 (0.00)
Social injustice	0 (0.00)	0 (0.00)	0 (0.00)	5 (2.37)	0 (0.00)
Expressive emotions: anger/rage	0 (0.00)	0 (0.00)	0 (0.00)	3 (1.42)	0 (0.00)

^aR&B: rhythm and blues.

There were significant differences in the number of negative ($P<.001$) and neutral ($P<.001$) themes found among genres in music videos (Table 5), with hip hop having the highest number

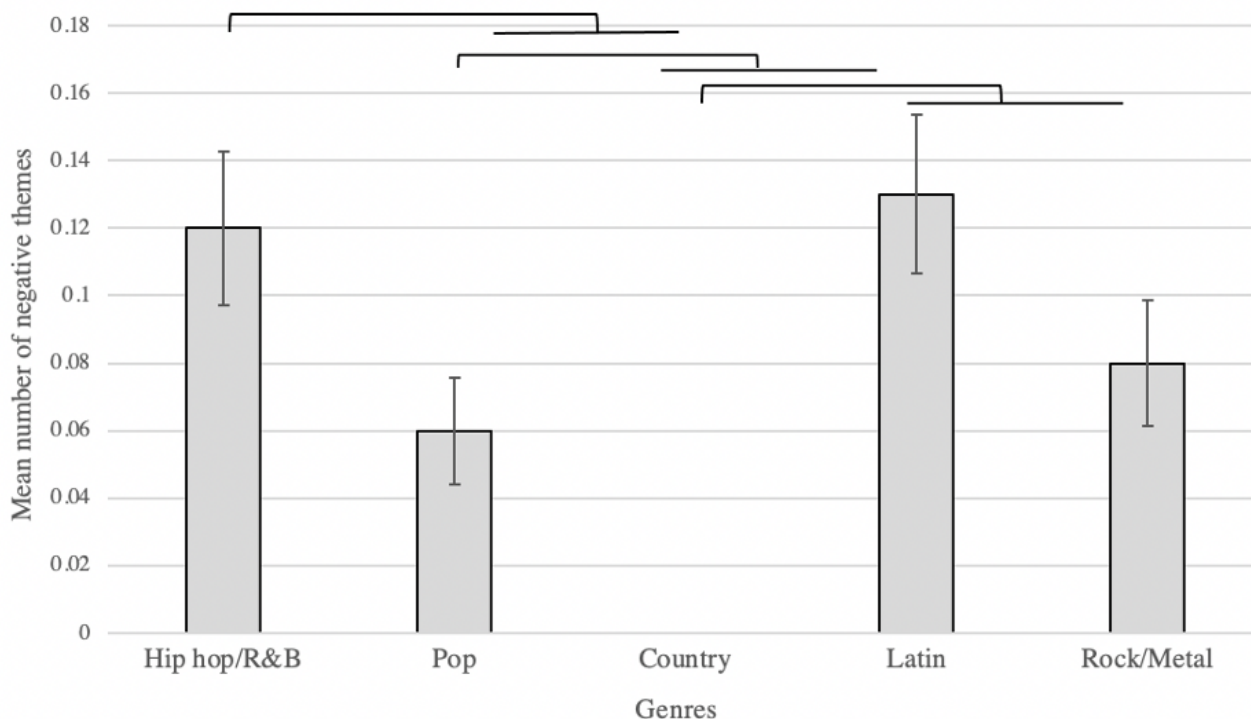
of negative themes portrayed ($P=.001$; Figure 3). There was no significant difference in the number of positive themes found among genres in music videos ($P=.10$; Table 5).

Table 5. Frequency of negative, neutral, and positive themes in music videos based on genres.

Genre	Total themes, n	Negative themes, n (%)	Neutral themes, n (%)	Positive themes, n (%)
Hip hop/R&B ^a	208	58 (27.88)	54 (25.96)	3 (1.44)
Pop	212	19 (8.96)	41 (19.34)	5 (2.36)
Country	210	0 (0.00)	0 (0.00)	0 (0.00)
Rock/Metal	211	19 (9.00)	48 (22.75)	7 (3.32)
Latin	209	32 (15.31)	81 (38.76)	3 (1.44)

^aR&B: rhythm and blues.

Figure 3. Mean number of negative themes in each genre from 1998 to 2018. Error bars reflect SE. Results show hip hop/R&B had a significantly higher number of negative themes in music videos when compared to pop ($P=.02$) or country ($P<.001$). Pop had a significantly higher number of negative themes when compared to country ($P<.001$) or Latin music ($P=.01$). Country had a significantly higher number of negative themes when compared to Latin music ($P<.001$) and rock/metal ($P<.001$). R&B: rhythm and blues.



Discussion

This study shows that there has been a significant increase in the frequency of negative themes over the span of 20 years across all genres, with hip hop/R&B having the most the most

number of negative themes among all other genres. Pop, country, and rock/metal had significantly higher frequencies of positive themes when compared individually to hip hop/R&B and Latin music. The frequency in which these negative themes are repeated in a particular song is not trivial but may contribute to

normalizing certain activities or attitudes of themes, such as the use of drugs, weapons, or alcohol.

There was also a significant difference in the number of negative themes found among genres in music videos, indicating that certain genres visually portray these negative themes more so than others. With the recent rise in popularity of music video streaming platforms, such as YouTube, themes relayed through lyrics can potentially magnify the messages delivered in a song.

Music has historically played a multifaceted role by serving as a form of creative expression to convey emotions or as a constructive outlet for individuals to explore feelings through direct engagement. It is important to note that the potential social psychological impacts of music cannot be mitigated, as music has become a pervasive part of society, especially for youths who live in a world saturated with media. In fact, with the diversity of musical genres, individuals have developed stereotypes of those who listen to particular musical genres [13]. Moreover, music has been found to influence “intergroup dynamics by shaping in-groups and out-groups” based on musical preferences [14].

Given that the average youth encounters up to 8 hours’ worth of media content [15], adolescents are potentially exposed to pop culture more, which therefore makes music a common experience of the average US teenager and is worth exploring further.

Adolescents are at a particularly impressionable age when environmental and social encounters can largely shape identity formation. Therefore, the results from this study should be noted when considering the probable ramifications of increased frequency of negative themes in both lyrical content and visual representation of music, especially those of the hip hop/R&B genre. Findings from this study can be used to guide recommendations given by parents, educators, and providers to discuss with adolescents.

There are important limitations to take into consideration. As only the top songs of each year from each genre were analyzed over the span of 20 years, making broad, generalized conclusions about a specific genre is not possible. Furthermore, there is also no causal inference that can be made concerning the findings, as this study only analyzed content and thus lacks evidence to quantify the impact on mental health. Future studies should potentially involve surveying adolescents to more accurately identify the popular music listened to by this age group, which may not be necessarily reflected in the year-end top songs.

Another limitation is the accuracy in categorization of some of the themes found within certain songs by each reviewer. Although discussions were extensively held regarding the labeling of themes and the positive, neutral, and negative categories in which we grouped them, songs frequently conveyed messages without using explicit terms through the use of analogies or wordplay that could have made the interpretation more ambiguous. Some themes such as anger or rage were categorized as neutral, which may seem controversial, but efforts were made to fully elucidate the way in which these emotions were presented in a song. If a particular song focused solely on the emotion itself, we viewed this as a neutral theme, as it is an expressive emotion that humans experience. However, when these feelings resulted in a violent act or depressive thought, themes were classified as such within the negative category. Additionally, reviewers were adults who might have interpreted certain musical lyrics and images differently from adolescents. Future studies should consider including the perspective of adolescents when categorizing musical themes. Surveys could also help to identify additional media sites that are popular among adolescents.

This study explores the trends in music in the past 20 years by quantifying the frequency at which certain themes arise. Results show that there was a significant 180% increase in the negative themes of songs of all genres ($P<.001$) but no significant difference in frequency of songs with positive ($P=.54$) or neutral ($P=.26$) themes by year. There were significant differences in the number of negative themes found across genres ($P<.001$), and hip hop/R&B had the highest frequency when compared to other genres ($P<.001$), with 130 out of 208 (62.5%) of its themes being negative. Although preliminary, these findings highlight the potential influence of music and may help to shape recommendations set by pediatricians and frame conversations held by parents with children and adolescents.

Future studies should look into increasing the number of songs analyzed per year using similar methods to increase the power of the study. Another region to explore is the influence of famous music artists on adolescents through surveys that explore the extent to which individuals have adapted their own attitudes to mirror those of their idols. Understanding how the personas of popular music artists directly affect adolescents may add an interesting dimension to future research and be used to identify those factors that have a greater correlation to mental health.

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Authors' Contributions

LK conceptualized and designed the study, collected and coordinated data collection, drafted the initial manuscript, and reviewed and revised the manuscript.

FG and DM collected the data and reviewed the manuscript.

LR conceptualized and designed the study 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

None declared.

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Abbreviations

R&B: rhythm and blues

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Original Paper

Perceptions and Acceptability of a Smartphone App Intervention (ChildSafe) in Malaysia: Qualitative Exploratory Study

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Abstract

Background: Home is a vulnerable place for accidental child injuries. Unintentional injuries are a leading cause of death, hospitalization, and disabilities. These injuries are considered preventable and if not tackled, they will continue to be a persisting problem. Smartphones have become increasingly important in our everyday life and is an important tool not only for communication but also for other purposes—they have apps that can be used for various purposes. Therefore, an app-based intervention (ChildSafe) was developed to assess and reduce child injury at home.

Objective: This study aimed to evaluate the acceptance of the ChildSafe smartphone app intervention by parents/guardians.

Methods: This study was conducted using a qualitative exploratory approach on selected participants of the ChildSafe intervention app study. A total of 27 semistructured in-depth interviews were carried out among parents or guardians who have at least one child between the age of 0 and 59 months in the area of Sungai Buloh, Selangor, between November 2017 and March 2018. Interview questions were developed from the consolidated framework for implementation research (CFIR). Interviews were recorded, transcribed verbatim, and data were thematically analyzed guided by CFIR.

Results: The study revealed users' perception on usability, feasibility, and acceptability toward the ChildSafe app. Three CFIR domains were identified: intervention characteristics, inner setting, and characteristics of individuals. A total of 5 constructs were revealed under intervention characteristics: evidence strength and quality, relative advantage, adaptability, trialability, and design quality and packaging; 2 under inner setting: implementation climate and readiness for implementation; and 4 under characteristics of individuals: knowledge and beliefs about the intervention, self-efficacy, individual stage of change, and other personal attributes. In general, participants felt the app is extremely useful and effective, easy to use, and purposeful in achieving home safety assessment via reminders. The app replaces the need for participants to search for information on home safety and dangers, as the app itself was designed as a tool to assess for this specific purpose. Even at the nascent stage and despite its limitations, the app has prompted users to consider and make changes around their own home. However, future versions of the app should be expanded to make it more attractive to users as it lacks interactive feedback and additional features.

Conclusions: Parents/guardians are accepting the use of the ChildSafe app to prevent child injury at home. However, further expansion and improvements are needed to increase the acceptability of this app by parents/guardians.

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KEYWORDS

child safety; unintentional injuries; consolidated framework for implementation research (CFIR); characteristics of individuals; Mobile App Rating Scale (MARS)

Introduction

Home is where individuals or every family member feels secured and protected. Despite providing shelter and comfort, children can still be exposed to hazards and risks, and are vulnerable to unintentional injuries. Child injuries at home are one of the most common global public health threats to their survival [1]. Unintentional injuries refer to traffic injuries, drowning, poisonings, burns, and falls and are believed to be the leading cause of death, hospitalization, and disability globally and can cause long-lasting grief to the families, society, and nation [2].

After 15 years the Millennium Development Goals (MDGs) 4 still has not achieved the two-third reduction in under 5 mortality rate (U5MR) globally [3], with 5.82 million deaths reported among children under the age of 5 worldwide; injury-specific mortality rate in the under 5 age group was 73 per 100,000 population and 3654 years of life were lost per 100,000 population in 2015 [4]. The Malaysia National Health and Morbidity Survey revealed that the prevalence of home injury among children aged under 4 years was 2.5% in 1996, whereas the rate among children aged under 7 years was 8.2% in 2011 [5].

Despite preventive measures, concerted efforts are still needed from various agencies to reduce further childhood injuries and the overall related mortality and morbidity issues [4]. The 2011 World Health Assembly urged member states to elevate child injury as a priority in the global public health policy [4]. The World Report on Child Injury Prevention highlighted the urgent need to address preventable cause of death and disability among vulnerable children worldwide; the World Health Organization, the United Nations Children's Fund, and other organizations have initiated joint effort initiatives to safeguard children's rights to healthy and safe environment free from injury and violence as emphasized by the United Nations Convention on the Rights of a Child (UNCRC) [2,6,7].

Henceforth, Sustainable Development Goals (SDGs) 2016-2030 have included targets for injury and violence prevention. The third goal is to reduce the deaths of children under 5 years of age from 9.8 million in 2000 to 5.4 million by 2017 [8].

Parenting interventions can reduce incidents of unintentional injuries in child in and around the home through the use of safety equipment and following existing safety recommendations by focusing on improving knowledge and perceptions on risks of injury, and importance of adopting safety practices [9]. Gaines and Schwebel [10] highlighted that parents and caregivers often have difficulties in identifying and recognizing hazards and perceived their own children to have less vulnerability to injuries. Importance of educating parents to find credible information and recommendations, and obtaining safety products best suited to their home were recommended.

Various intervention methods had been used with varying degrees of effectiveness, such as provision of educational

materials, health care provider counselling, safety product distribution, and hands-on experiential learning provided at safety resource centers, to prevent injuries at home. However, it accentuated the need for wide-reaching, effective, and readily available methods of interventions to reach substantial parent and caregiver audiences [11].

Academics and clinicians are keenly interested in utilizing smartphones as an option for delivery of behavioral interventions [12]. Smartphone has become an integral part of our lives as it allows us to perform certain tasks and enables getting information, entertainment, and staying connected with others. The smartphone market is growing rapidly, with estimates suggesting that there are now 3.5 billion users worldwide (45.15%), up from 2.5 billion (33.58%) in 2016 [13]. The estimated number of smartphone users in Malaysia was 15.6 million (75.9%) in 2017, 78% in 2018, and this number is expected to swell by 20.9% in 2023 [14,15]. Users have a strong attachment and dependency to their smartphones with at least one out of four users constantly checking their phones even without notification (27.1%) [15].

Smartphones are predominantly seen as a promising and cost-effective medium to deliver health-related interventions [16]. To date, there are a few app-based interventions developed for unintentional home injuries; for example, Make Safe Happen for parents of children aged 0-12 years [11,17], Caregivers for children aged 0-6 years [18], Primary Caregivers of preschoolers aged 3-6 years [19,20], and Mothers with children under 3 years of age [21]. Education and promotion can be implemented through this platform to reach a larger segment of the population. With the rapid increase of smartphone usage in Malaysia and ease of access, a smartphone app intervention could be an effective solution for child injury prevention.

The novel idea of the ChildSafe app development came around as an experimental intervention designed to educate Malaysian parents and caregivers on child injury prevention at home. The ChildSafe app consists of 4 main features and functions: the home injury hazard assessment tool, interactive home safety tutorial, reminder feature addressing hazards identified during the assessment, and "tip of the week" feature. From the home injury hazard assessment tool, parents/guardians can identify and quantify existing hazards regarding childhood injury within the home as well as monitor changes occurring as a result of the interventions. The interactive home safety tutorial provides specific information on ways by which home injury hazard risks could be altered to make the environment safer for the child. The reminder feature serves as a feedback mechanism for parents/guardians to address the hazard and correct it. Tip of the week enhances the understanding of burden of childhood injury and knowledge on addressing it. At its nascent stage, acceptability of smartphone-based technology is important to be evaluated. Thus, a study was carried out to assess parents' perception and acceptability of the app in terms of functionality, acceptability, and ease of use.

The consolidated framework for implementation research (CFIR), a conceptual framework that was established to guide systematic assessment of multilevel implementation to identify aspects that may affect implementation and effectiveness of an intervention, was used in this study. CFIR specifies 39 constructs acting as factors influencing intervention implementation and these are mapped into 5 major domains outlining potential barriers and facilitators of implementation or intervention outcomes: (1) *characteristics of an intervention*, (2) *outer setting* of the organization in which intervention is being implemented, (3) *inner setting* of the organization, (4) *characteristics of individuals* involved in the intervention, and (5) the *implementation process* [22]. With this framework in mind, this study aimed to evaluate acceptance of the ChildSafe smartphone app intervention by parents/guardians.

Methods

Study Design

This is a qualitative study assessing parental/guardian experience in using the ChildSafe smartphone app.

Setting

The study was performed in the Sungai Buloh area, Selangor, Malaysia. This suburban area was selected as it fulfilled the inclusion criteria of a growing community that is neither too rural nor overly urban based on ease of access and high penetration of smartphone use. Inclusion criteria for participants were as follows: households must have at least one child between 0 and 59 months of age, parent/guardian is available as participant, and owned an Android-based device.

Intervention

The ChildSafe app version 1.0 is a smartphone-based app designed to collect data and evaluate hazards risk reduction and prevention of child injuries at home, by focusing on feasible and measurable interventions within homes (Figure 1). The app was designed to map in-home risk of injuries among younger children (aged < 59 months), and intended to stimulate hazard reduction (Figure 2). The app is installed on the participants' smartphone during the first visit. It has 4 main functions: a home injury hazard assessment tool, a home safety tutorial, a reminder feature for addressing hazards during the assessment, and tips on child safety. It is not publicly available, but for its use within this study a specific link to download the app was created.

Figure 1. App download screen.

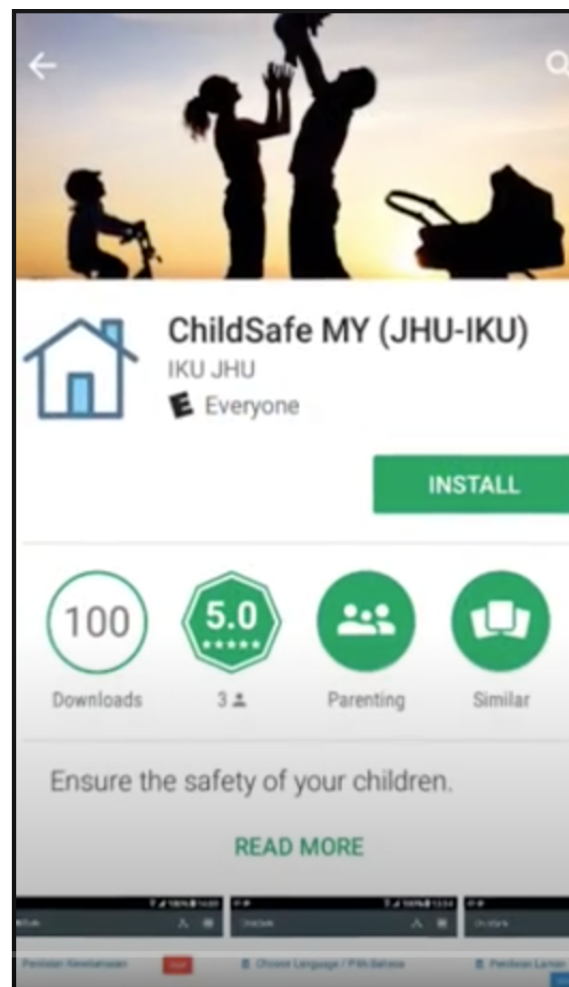
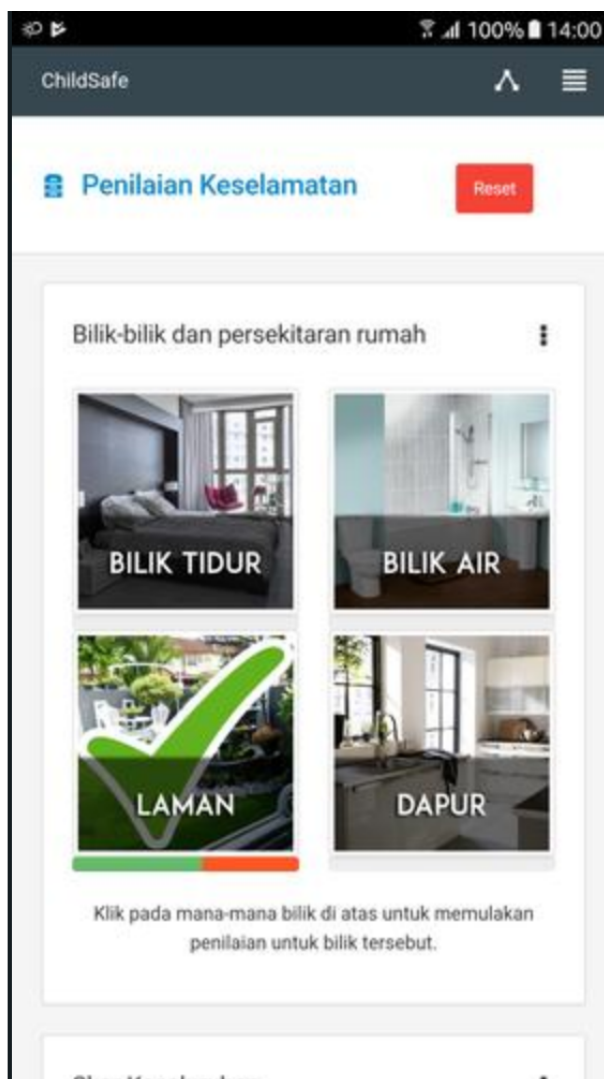


Figure 2. Safety assessment.

Study Participants

Study population included households with at least one child between the age of 0 and 59 months (Table 1). Participants were parents/guardians, able to read and converse in Malay or English, residing in the area of study during the study period, and fulfilled user app criteria of being either a complete user (completed tutorial and assessment), a partial user (completed at least tutorial but not assessment), or a nonuser (did not

complete the tutorial or assessment). Participants were drawn from the main study (prospective cohort study) population and were identified by the main study research officers. A total of 27 parents/guardians participated. The number of participants was based on data saturation whereby the interview stopped at the 27th participant when there was no more new information based on the questions asked. All participants approached agreed to be interviewed and gave consent.

Table 1. Participants characteristics (N=158).

Characteristic	Value, n (%)
Respondents' relationship to the child	
Mother	118 (74.7)
Father	36 (22.8)
Others	4 (2.5)
Gender of respondents	
Male	36 (22.8)
Female	122 (77.2)
Age group (years) respondents	
Under 30	29 (18.4)
30-39	96 (60.8)
40 and over	33 (20.9)
Educational level	
Primary education and lower	4 (2.5)
Secondary education	45 (28.5)
Tertiary education	109 (69.0)
House description	
Type of accommodation	
Flat	22 (13.9)
Terrace single	18 (11.4)
Terrace double	118 (74.7)
House ownership	
Own	120 (75.9)
Rented	38 (24.1)

Data Collection

Interviews were conducted approximately 2 months into the main study implementation (between November 2017 and March 2018). This was done on the expectation that home safety assessments were completed and possible changes were made to improve child safety at home. Interview questions were developed from the CFIR framework which was used to assess implementation process of a new intervention. The flow of questions was developed with specific prompting questions to assess user experience on the ChildSafe app. The questions were designed in both English and Malay to ease communication with participants.

Interviews were conducted face-to-face by research team members who were trained in qualitative methods and not acquainted to any participants to avoid potential response bias. Each in-depth interview was conducted at participants' home, lasted between 30 and 120 minutes, and was audio-recorded and transcribed verbatim. Confidentiality was ensured by removing participant identifiers from transcripts. Each transcript was cross-checked by the research team through audio listening and field notes.

Data Analysis

Data were analyzed using a thematic analysis, manually coded, and arranged using MS Excel by research team members who had previous experience in conducting qualitative analysis, were familiar with CFIR, and experts in their own field. The first level of analysis employed an inductive approach whereby researchers read transcribed interviews to identify preliminary themes independently. Relevant text segments were selected concerning acceptability and experience in using the app. At this stage, the researcher identified similar patterns in the data and developed first-level coding themes that could explain those patterns. Consensus on first-level themes was gained from other research members as well. The text segments were sorted using the identified themes. At the second level the research members independently identified and matched the themes together with best representative quotes for each theme and mapped them with existing domains and constructs under CFIR. Through consensus with other research members, the themes were placed under the construct that was deemed most suitable, and with identification of these constructs, the final level of identifying the respective domain that encompasses the constructs was completed (Table 2). The quotes that best represent the domains and constructs chosen to support the results are presented in Multimedia Appendix 1.

Table 2. Perception of the ChildSafe Mobile App mapped on consolidated framework for implementation research domains.

Domain, constructs, and subconstructs	Perception on change	
	Positive presence	Negative presence
Intervention characteristics		
Evidence strength and quality	✓	
Relative advantage	✓	
Adaptability	✓	
Trialability	✓	
Design quality and packaging	✓	
Inner setting		
Implementation climate		
Compatibility	✓	
Relative priority	✓	
Goals and feedback	✓	
Readiness for implementation		
Available resources	✓	✓
Access to knowledge and information	✓	
Characteristics of individuals		
Knowledge and beliefs about the intervention	✓	✓
Self-efficacy	✓	✓
Individual stage of change	✓	✓
Other personal attributes	✓	

Availability of Data and Materials

The data are not part of an online database but can be requested by writing to the Director of the Institute for Health Behavioral Research, National Institutes of Health, Ministry of Health Malaysia.

Ethics Statement

This study was granted ethical approval by the Medical Research Ethics Committee of the Ministry of Health Malaysia [KKM/NIHSEC/P19-1450(12)].

Results

Overview

A total of 27 transcripts were analyzed. From the 5 domains under CFIR, 3 were applicable: intervention characteristics, inner setting, and characteristics of individuals.

Intervention Characteristics

Of the 8 constructs in the intervention characteristics, 6 constructs which portrayed the app's acceptability were identified.

Evidence Strength and Quality

Users believed the ChildSafe app, which was created to help parents and caregivers with young children, will make their home safer as they become more aware and were able to identify the potential hazards in and around their house. Users feel the

importance of smartphones as one of the channels of information that helps disseminate safety tips on child injury prevention. Hence, they have also recommended the app to their families and friends. Additionally, users strongly recommended that the app should be promoted in governmental institutions, schools, health clinics, and nursery centers.

Relative Advantage (Observability)

With regard to the ease of availability and use of smartphones, most users approached owned one to stay connected, and thus the app was easily accessed wherever/whenever they need to check and refer about safety tips at their own pace. Users also shared that it is time saving compared with surfing information in social media and existing conventional media, and that it makes the dissemination of health information on child injury prevention easier and have wider coverage.

Apart from that, learning is made easier with the app, it engages the users to make their home safe, and it fulfills their needs on hands-on experiential learning related to the child injury issue. The app is considered a cost-effective medium to deliver the home safety information and covers a wide range of multiple topics in a single platform. Users also highlighted that the app served as their reference guide and reminder (reminder list on behavioral hazard for safety tips of the week).

Adaptability

The developers of the mobile health (mHealth) app have customized it to address the local language needs of users for

better comprehension. Users acknowledged that the bilingual option (ie, users can select either English or Malay based on their preference) made them easy to understand and follow instructions on the app.

Trialability

Because of the easy accessibility of the mobile app, most users approached were willing to download the app on child injury prevention to try it out in order to know more about its purpose and usefulness, which subsequently will contribute to making a decision on whether the app is favorable or unfavorable to adopt.

Complexity

Users perceived the app easy to operate conceptually and technically, as users who owned a smartphone would have accustomed to the functionality of the device and the app.

Design Quality and Packaging

Most users expressed their satisfaction and shared their appreciation on the feasibility and usability of the app aesthetics when navigating it (clear layout; color, size, and font used; image using real pictures; easy or clear instruction; and a wide coverage of all areas of the house concerning potential hazards at home for them to cross check at all times).

On top of that, the app does not take up too much memory space of the phone. Participants also noted that there is an interactive home safety tutorial section embedded and a constant safety reminder feature (to-do list on environmental hazard) will appear once they switch on the app whenever they have not addressed the particular hazard as recommended.

Inner Setting

Implementation Climate

Compatibility

Users perceived that because they have a smartphone and the installation process for the ChildSafe app is similar to that of other apps, it is fairly easy for them to understand and execute the task by taking safety precautions to prevent injuries to their children at home (social norms and values). Users expressed their enthusiasm to continue using the app as they found it rather convenient to learn about prevention of unintentional injuries. They strongly believed that the equipped knowledge and skills will help prevent unintentional injuries in their child as well as protect the child under their care.

Relative Priority

Users believed the app should be extended to have a wider coverage so that the community will become more aware of child safety at home and will benefit more. They also felt that this app is especially useful for parents, teachers, and caretakers.

Goals and Feedback

Users stated that the ChildSafe app will help them delve into child safety at home regardless of the level of knowledge they possess and increase their awareness on child safety at home. Users noted that the tips given via the app are very useful and that they can apply them to make improvements to their home to prevent unintentional injury. Based on the feedback from

users, the objectives of the development of the mobile app have been achieved.

Readiness for Implementation

Available Resources

Because of the necessity and availability of smartphone in our daily lives, with most having at least one, the penetration of the ChildSafe app was higher, which made it easier to disseminate information on child injury at home. Users were eager to participate in the study as they want to ensure the safety of their children at home.

Access to Knowledge and Information

Most participants commented that the ChildSafe app was easy to use, understand, and do what is instructed to do. The instructions given allow users to think about what is important and useful, which may not have been thought of previously, especially for certain target populations. Users also felt that the educational information in the app is so comprehensive and more than what is offered in textbooks. The app indirectly engaged the users to spend some time checking each place in their home thoroughly before they can proceed to the next room.

Characteristics of Individuals

Knowledge and Beliefs About the Intervention

App information developed based on study and research is believed to be more reliable, trustable, and credible. In addition, the credibility of source is recommended by recruited staff members from the Ministry of Health. The app also acts as a preventive tool, as it presents a reminder of things to be put in place in every location of the house, thereby enabling users to be more aware of it. Because parents value the importance of their child's safety, this app helped them identify the common dangers at home, based on which improvements were made.

Self-Efficacy

The app indirectly increased the confidence and influenced the parents to be more cautious and take precautions necessary to avoid injury in children. Among the measures taken are taking time to check thoroughly every corners of the house they may have missed out to ensure they are safe and buying the right toys for their children to play with and avoiding buying small toys that their children might put into their mouth.

Individual Stage of Change

The ChildSafe app has prompted the users on the receptiveness to change by making home improvement changes to avoid unforeseen unintentional injury among their children at home. With reference to the verbatim analyzed, most of the users have made changes within a short period and successfully maintained the recommended behavior changes.

Other Personal Attributes

The app served as a learning tool for the users, as they were excited to venture more given the score they have achieved, as well as created awareness among the users. Whenever users completed a task, they will be awarded a score that indirectly created interest and motivated them to go to the next stage. Users own capability and completeness in accessing the

smartphone enabled them to use the mobile-based ChildSafe app without much issue.

Discussion

Principal Findings

The CFIR conceptual framework has provided an analytic lens of evaluation to determine the key success of the ChildSafe app implementation. The intervention study results provide an overview of (1) the users' perceived characteristics of the innovation which will encourage them to use the ChildSafe app (behavioral intention), (2) the evaluation of the usability and feasibility of mHealth apps, (3) the innovation decision process that can facilitate the implementation of the app, and (4) the adoption phases that will lead to the adoption or resistance of the innovation.

Nilsen [23] has classified implementation frameworks into 5 categories: process models, determinant frameworks, classic theories, implementation theories, and evaluation frameworks. CFIR represents the determinant framework in this study to identify the confound factors that will contribute to the effectiveness of the interventions and their implementation [24], that is, evidence-based practice [25]. In line with the evidence-based practice, Damschroder et al [25] pointed out that in any intervention evaluation researchers must evaluate not only summative endpoint health outcomes but also the formative evaluation outlined in CFIR to assess the implementation effectiveness, the sustainability of the intervention, and dissemination of findings [25]. Dissemination and implementation studies particularly focus on the implementation impact to facilitate the adoption and implementation of the innovation or evidence-based intervention [26].

This ChildSafe app trial study is designed to evaluate the effectiveness of the parenting intervention in terms of the usability, feasibility, and acceptability (satisfaction on the innovation, eg, content or credibility) of parents and caregivers and their intention to reduce unintentional injuries among children at home [27].

Using CFIR and Diffusion of Innovation theory (proposed by Rogers) [28,29] as a guidance to predict adoption of mHealth apps, we assessed the users' perceived characteristics of the innovation which will lead to the use of the ChildSafe app (behavioral intention). Based on the findings of the study concerning the attributes of the *innovation characteristics* [30], our users have shown significant adoption of the mHealth app innovation. Users valued the app as a preventive and incremental (nonpreventive) innovation [31] (*relative advantage*) by making decisions to adopt, as it provides great advantages and benefits to manage their house from becoming an accident-prone site. In general, apps promoted by developers on a trial basis and those that are freely available will attract users willing to try them out (*trialability*). Furthermore, the reminder function of our app encouraged the users to check their surroundings on a frequent basis (*trialability*), as there will be a pop-up safety reminder on their smartphone screen when they turn on the app if they have not completed the checklist (self-monitoring). Most

of the users perceived the app to be easy to understand and use (*complexity*). The availability of the app in bilingual language was well received by the users as they were able to choose either Malay or English for comprehension (*adaptability*). The *compatibility* of the app is relatively high for adoption as it is convenient to install because most users were already using smartphones and thus comfortable in downloading and installing apps. The portability of the smartphone makes it handy for the users to continue enjoying the mobile learning on the move [32] at a home setting (convenience of the mHealth intervention) [33] and navigate at any time (time saving).

Concerning the evaluation of mHealth app (*design quality and packaging*) quality criteria using the Mobile App Rating Scale (MARS) as proposed by Stoyanov et al [34,35], users relayed their satisfaction with the ChildSafe app. In terms of *engagement*, the app engaged the users by sending notification or reminder once they switch it on (*interactivity*) if they have not fully completed monitoring the things in each part of the house. Parents/caregivers (*target group*) also found the visual information for each part of the house together with the checklist and language used easy to understand. Users described that instructions via the app made them easy to understand and navigate (*functionality*) while the layout, suitability, and clear visuals (*aesthetics*) improved usability. Besides, the information presented is comprehensive and from a trustworthy source recommended by the Ministry of Health (*information quality*). Furthermore, the existing users' recommendation to others on the benefit of this app and the frequency of their usage of the app (subjective quality of the app) enhanced the perceived impact of the app on the user's knowledge, attitude, and intentions to address the targeted health behavior (ie, taking preventive measures to prevent unintentional injuries at home). Similarly, the app usability evaluation as addressed by Nielsen [36,37] depends on the 5 attributes: efficiency, satisfaction, learnability, memorability, and errors.

A full adoption and sustainment of the new innovation (ChildSafe app) is highly dependent on the 5 stages of the innovation decision process (ie, knowledge, persuasion, decision, implementation, and confirmation) [28], as suggested by Rogers. The first stage starts with *knowledge* (ie, access to information and knowledge and engaging), whereby the user is exposed to innovation, followed by *persuasion*, whereby the individual becomes interested and seeks further information about the innovation (affective). Self-efficacy (ie, one's self-perception about his/her capability in using the app and his/her confidence in making his/her home a safe environment), as envisioned in Bandura's social cognitive theory, plays a central role in successful behavior change. An individual's belief is influenced by previous experiences, social persuasion, perception, and affective response to the behavior [38]. Supporting this view in the theory of reasoned action which highlights intention, attitude, and subjective norms will determine the individual's intention to perform a behavior [39].

Interpersonal communication is used to spread word of the mouth concerning the testimonies on innovation usage (eg, network and communication/goals and feedback) and social reinforcement from peers (social system). This is within the adoption process that also contributes to the facilitation of the

implementation effectiveness. The *decision* and *implementation* stages concerning the adoption of the innovation (readiness for implementation and executing) are determined by 2 predictors of attitude toward the usage, as indicated in the Technology Acceptance Model [40] on the perceived usefulness and perceived ease of use. Time of adoption also plays a crucial element in the adoption or resistance of the innovation [41]. Kaminski [42] pointed out that in Rogers' Diffusion of Innovation theory, the adoption phases are highly dependent on the 5 types of adopters, namely, *innovators* (technology enthusiast), *early adopters* (visionaries), *early majority* (pragmatist), *late majority* (conservative), and lastly the *laggards* (sceptic). Rogers' proposed phases are also comparable with the 5 stages of change in the Prochaska's Transtheoretical Model of Behavior Change [43], namely, the *precontemplation* (not thinking of changing), *contemplation* (aware and thinking about changing), *preparation* (take necessary steps to change), *action* (making changes within a short period), and *maintenance* (successfully maintain the behavior changes) [39]. The confirmation stage reflects on either the facilitation or hindrance of ChildSafe app usage (reflecting and evaluating).

These stages are also consistent with the scale criteria checklist (App Behavior Change Scale [ABACUS]) suggested by McKay [44] to assess the potential of an app in encouraging behavior change. ABACUS involves assessment of knowledge and information, goals and planning, feedback, and monitoring and actions [45]. Proctor et al [46] proposed 8 outcomes for evaluation: *acceptability* (user satisfaction with various aspects of the innovation, eg, content, complexity, and credibility), *adoption* (uptake, utilization, intention to try), *appropriateness* (compatibility, usefulness), *feasibility* (suitability for use), *fidelity* (adherence), *implementation cost* (cost-benefit), *penetration* (coverage access), and *sustainability* (maintenance) [45-47].

In particular, due to the rapid growth of technology, technology-assisted communication devices have been vastly utilized to deliver and enhance health interventions. Hence, there was some promising evidence from Omaki et al [48] that technology-assisted communication devices are indeed effective in improving knowledge, awareness, and creating favorable responsible actions pertaining to prevention of unintentional injuries. With regard to the study by Jabaley et al [49], using an iPhone (mobile device) as an in-home child safety intervention among 3 families with young children reduced home hazards to almost zero [46]. Similar studies on injury prevention apps for parents and caregivers have also been undertaken by Roberts et al [17], McKenzie et al [11], Chow et al [21], and Ning et al [18-20], and these indicated that such apps have improved parental safety knowledge, environmental modification, and successfully facilitated behavior change.

Strengths and Limitations

This study provides an underlying view on the importance of incorporating an evidence-based theoretical framework model and a health behavior change theory as a foundation when developing mHealth apps and designing mHealth interventions. CFIR itself is able to identify factors that determine the likelihood of implementing recommendations given by the app,

its impact, and its effectiveness in behavior change to prevent or reduce unintentional home injuries in children, which in turn allows for future improvements to be made to the app to ensure all aspects of the framework are addressed for the benefit of the users.

The main limitation of the study pertain to the differences in cultural aspects. As the app was originally developed for Western use, some applicability does not resonate with the Malaysian population, which caused the users to feel disconnected when giving feedback. These included fire alarms, differences in toilet bowl designs, the absence of bathtubs in the Malaysian home, which in the Western countries are important elements in the assessment. Future studies may need to include a situational analysis or feasibility study before the start of the actual study.

Recommendations

The findings warrant future research studies to explore, examine, and provide insights into the potential areas for improvement on the developmental aspects with regard to the ChildSafe app:

- The study should be extended to the community and made available in different languages such as Mandarin and Tamil to reach out to different communities.
- Further improvement on the app coverage is necessary by incorporating missing features such as first aid; information on relevant emergency contact; setting reminders to check for functionality of safety devices; feedback; discussion forum to exchange opinions or ideas related to safety at home; teleconsultation or advice by experts or pediatricians for parents, caregivers, and teachers in elementary, primary, and secondary school; and interactive learning such as videos, interactive games, animation, and quiz not only for parents but also for children to learn; as well as providing regular updates to the information on the app, so that it can serve as an information hub and learning platform for all. In addition, improvisation of the tailored home safety information necessary to prevent injury in children and information on various safety aspects outside the house should be added to the app.
- Whether the app usability and feasibility in the particular community have improved the parents' knowledge, awareness, and self-empowerment to take responsibility for their child's health and safety should be investigated by examining the incidence rate of injury (epidemiological data) or by performing a comparison study between the intervention group and the control group during the duration of the study.
- A replicate study on the pretest of the app intervention in different community settings and population to assess the usability, acceptability, and feasibility is necessary.

Conclusions

Despite being a prototype and lacking advanced features, the ChildSafe app has been perceived as a very useful tool by the participants and has induced behavioral changes in users, such as taking actions to improve their living quarters to reduce unintentional injuries for their children at home. Although some issues highlighted warrant the need to improve future versions

of the app, the study has indicated the possibilities and usefulness of app-based interventions for the Malaysian setting. The results of this study can be used as a guide to assist the relevant multidisciplinary policy makers to address the three

“Es” of interventions (education, enforcement, and engineering), as proposed in the Haddon matrix, to prevent unintentional injuries [2] on probably a larger scale should the improved app be made available publicly.

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Authors' Contributions

TY is the main author who wrote the first draft, compiled all the written sections of this manuscript, and is the corresponding author for this manuscript. KP, MA, and NJ interpreted part of the data and cowrote sections of the manuscript. MJ is the senior author of this manuscript who is also responsible for the whole analysis, interpretation, refinement, and revision of the final draft of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Example quotes organized thematically and mapped to CFIR domain and construct.

[[DOCX File , 19 KB - pediatrics_v4i2e24156_app1.docx](#)]

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Abbreviations

- ABACUS:** App Behavior Change Scale
- CFIR:** consolidated framework for implementation research
- MARS:** Mobile App Rating Scale
- MDGs:** Millennium Development Goals
- SDGs:** Sustainable Development Goals
- U5MR:** under 5 mortality rate
- UNCRC:** United Nations Convention on the Rights of a Child

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Original Paper

Wheeze Recognition Algorithm for Remote Medical Care Device in Children: Validation Study

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Abstract

Background: Since 2020, peoples' lifestyles have been largely changed due to the COVID-19 pandemic worldwide. In the medical field, although many patients prefer remote medical care, this prevents the physician from examining the patient directly; thus, it is important for patients to accurately convey their condition to the physician. Accordingly, remote medical care should be implemented and adaptable home medical devices are required. However, only a few highly accurate home medical devices are available for automatic wheeze detection as an exacerbation sign.

Objective: We developed a new handy home medical device with an automatic wheeze recognition algorithm, which is available for clinical use in noisy environments such as a pediatric consultation room or at home. Moreover, the examination time is only 30 seconds, since young children cannot endure a long examination time without crying or moving. The aim of this study was to validate the developed automatic wheeze recognition algorithm as a clinical medical device in children at different institutions.

Methods: A total of 374 children aged 4-107 months in pediatric consultation rooms of 10 institutions were enrolled in this study. All participants aged ≥ 6 years were diagnosed with bronchial asthma and patients ≤ 5 years had reported at least three episodes of wheezes. Wheezes were detected by auscultation with a stethoscope and recorded for 30 seconds using the wheeze recognition algorithm device (HWZ-1000T) developed based on wheeze characteristics following the Computerized Respiratory Sound Analysis guideline, where the dominant frequency and duration of a wheeze were >100 Hz and >100 ms, respectively. Files containing recorded lung sounds were assessed by each specialist physician and divided into two groups: 177 designated as "wheeze" files and 197 as "no-wheeze" files. Wheeze recognitions were compared between specialist physicians who recorded lung sounds and those recorded using the wheeze recognition algorithm. We calculated the sensitivity, specificity, positive

predictive value, and negative predictive value for all recorded sound files, and evaluated the influence of age and sex on the wheeze detection sensitivity.

Results: Detection of wheezes was not influenced by age and sex. In all files, wheezes were differentiated from noise using the wheeze recognition algorithm. The sensitivity, specificity, positive predictive value, and negative predictive value of the wheeze recognition algorithm were 96.6%, 98.5%, 98.3%, and 97.0%, respectively. Wheezes were automatically detected, and heartbeat sounds, voices, and crying were automatically identified as no-wheeze sounds by the wheeze recognition algorithm.

Conclusions: The wheeze recognition algorithm was verified to identify wheezing with high accuracy; therefore, it might be useful in the practical implementation of asthma management at home. Only a few home medical devices are available for automatic wheeze detection. The wheeze recognition algorithm was verified to identify wheezing with high accuracy and will be useful for wheezing management at home and in remote medical care.

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KEYWORDS

asthma; children; infant; wheezing; wheeze recognition algorithm; pediatrics; remote; medical devices; validation; home management; algorithm; detection; chronic illness

Introduction

Since 2020, people's lifestyle worldwide has been largely changed due to the COVID-19 pandemic. In the medical field, many patients are afraid to become infected with the virus in clinics and prefer remote medical care. In remote medical care, the physician cannot examine the patient directly, and therefore it is important for the patients to accurately convey their condition to the physician. Thus, remote medical care should be implemented, and adaptable home medical devices are required for this purpose.

Wheeze is the most important exacerbation sign in various respiratory diseases among all age groups [1-3]. Bronchial asthma is one of the typical diseases that requires home management, in which physicians detect wheezes by auscultation as acute exacerbation. Therefore, for the home management of asthma, caregivers should be aware of wheezing in small children at night and adolescents during play exercise. Moreover, physicians are mostly dependent on reports from family members and caregivers regarding symptoms, who may have different judgment criteria for wheezes [4-6]. Therefore, a high-accuracy objective method to detect wheezes would be beneficial for physicians and patients' families or caregivers. To the best of our knowledge, no appropriate home device has been used to detect wheezing as a mild exacerbation sign to date.

Computerized lung sound analysis, especially computerized wheeze detection, is a more objective and standardized method, which can overcome limitations of subjective auscultation [3,7]. In the medical field, technical innovation has engendered telemedicine and home-based therapy; however, the practical use of these technologies has been limited. For respiratory diseases, lung sounds represent simple physical data, which have no value by themselves and are only clinically important when evaluated with identical criteria of judgment by a physician [8-10].

For remote medical care, we developed a new handy home medical device with automatic wheeze recognition algorithms, which is available for clinical use in noisy environments such as a pediatric consultation room or at home. Moreover, the

examination time is only 30 seconds because small children cannot endure long examination times without crying or moving [11]. In this study, we aimed to validate the automatic wheeze recognition algorithm based on wheeze sound characteristics with this new small handy device for clinical use in young children, including infants, at different institutions.

Methods

Participants

Ten institutions that have pediatric respiratory and allergy specialists were registered for this study. All participants were outpatient children attending the entry clinic and hospital located in Japan (Yamagata, Kanagawa, Hiroshima, Yamaguchi, Fukuoka, and Wakayama) between September 24, 2019 and November 22, 2019. All participants were brought into the hospital for the treatment of recurrent wheezes with cough and dyspnea. Written informed consent was obtained from all participants or their legal guardians. The study protocol was approved by the ethics committee of Minami Wakayama Medical Center [approval number 2016-22(5)]. All participants aged ≥ 6 years were diagnosed with bronchial asthma, and their asthmatic severities were classified as mild asthma according to the 2017 Japanese Pediatric Guideline for the Treatment and Management of Asthma [12]. The children were treated with a leukotriene receptor antagonist and/or inhaled corticosteroid in accordance with the guidelines [12]. Participants aged ≤ 5 years had reported at least three episodes of wheezes and had been treated with a leukotriene receptor antagonist or without medicine for long-term management.

Study Procedures

A specialist physician examined all participants using a stethoscope and simultaneously recorded lung sounds during tidal breathing in the pediatric consultation room for at least 30 seconds. Recordings were obtained from the upper right anterior chest region at the second intercostal space in the midclavicular line of the chest wall. Recorded lung sounds (with or without wheezes) were then listened to by the same specialist physician who recorded lung sounds, and then confirmed and classified the sounds in accordance with previous methods [11].

A total of 177 recordings were designated as “wheeze” files and 197 were designated as “no-wheeze” files. In addition, each specialist physician who recorded lung sounds differentiated wheezes from lung sound samples, including inspiratory and expiratory lung sounds, nasal congestion, crying, and voices.

Sound Recording and Analysis

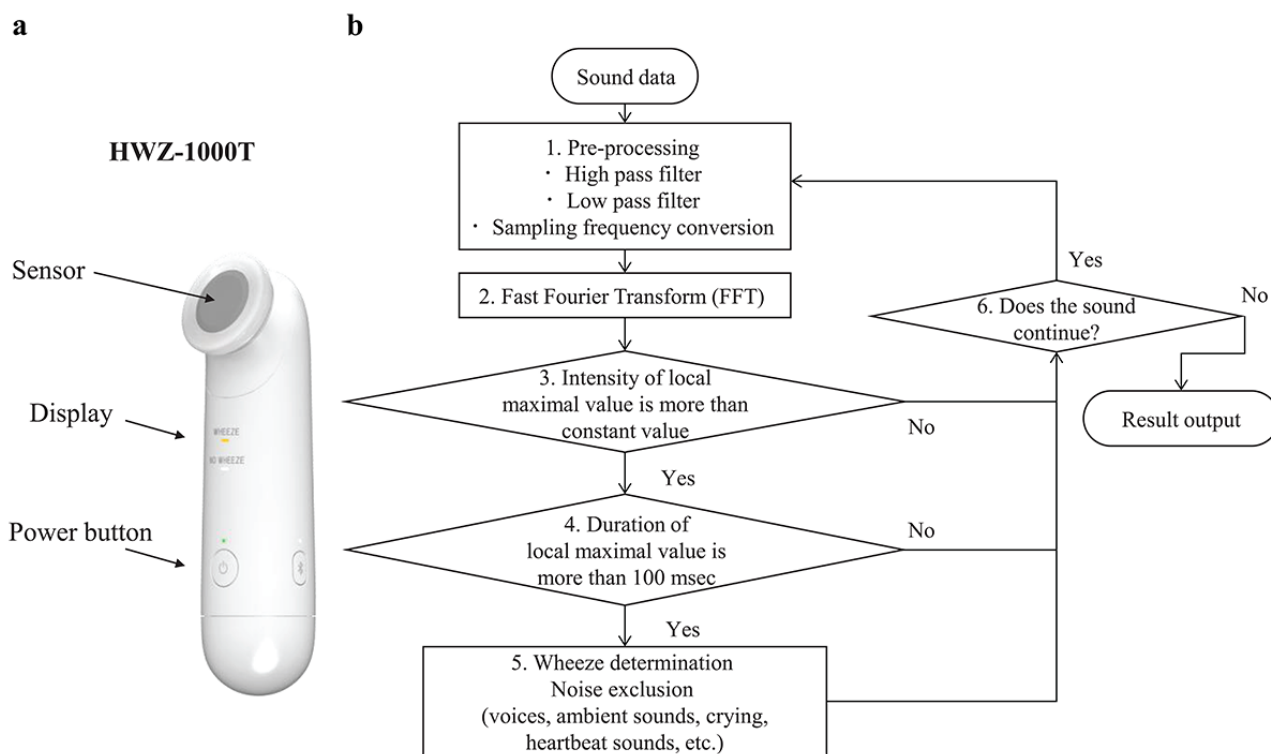
HWZ-1000T Device

Lung sounds were recorded using a small handy device with an automatic wheeze recognition algorithm (HWZ-1000T, Omron Healthcare Corporation, Kyoto, Japan) (Figure 1a).

Two microphones are installed in the sensor unit, one for recording lung sounds and the other for recording environmental

sounds. The microphone for recording lung sounds makes the judgment of wheezes through skin contact. Recorded lung sounds are processed using a wheezing recognition algorithm implemented in the internal central processing unit to automatically determine the presence or absence of wheezing, and then the results of wheezing judgment can be displayed on the device after 30 seconds. To analyze recorded wheeze sounds and compare judgment results by physicians who recorded wheezing with the automatic wheeze recognition algorithm, we attached a micro-SD memory card to the HWZ-1000 T device for confirmation of recorded lung sounds. The outline of the algorithm is described below.

Figure 1. Sound recording device and flowchart of the wheeze detection algorithm. FFT: fast Fourier transform.



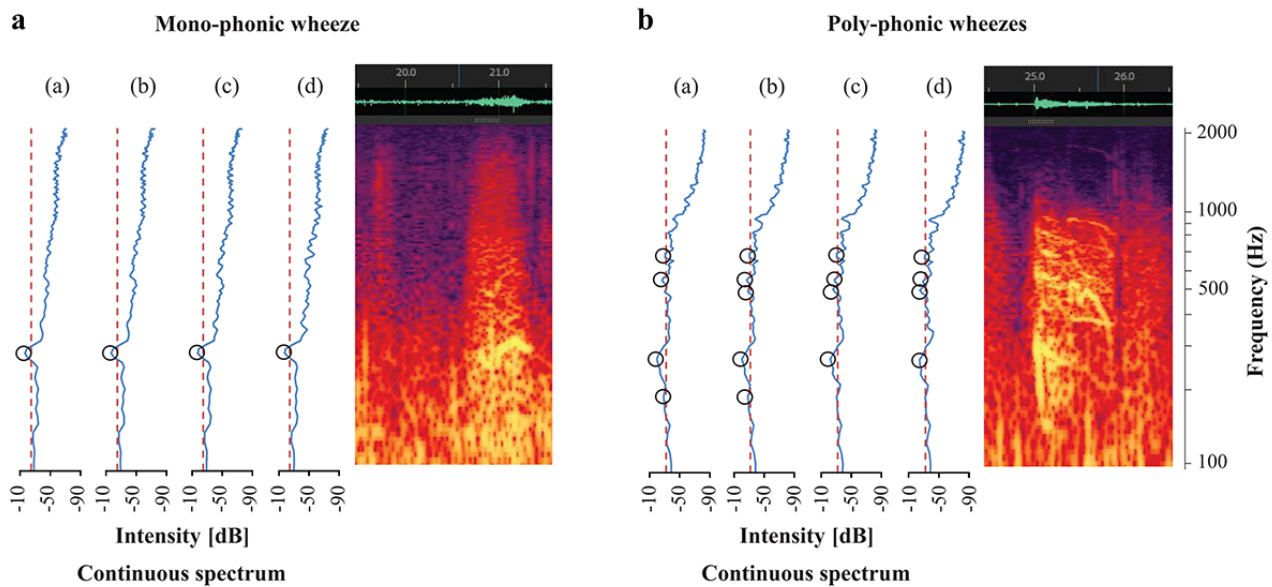
Characteristics of Wheeze by Lung Sounds Analysis

According to the Computerized Respiratory Sound Analysis guidelines, the dominant frequency and duration of a wheeze were set to >100 Hz and >100 ms, respectively [13]. Furthermore, a previous report described the frequency range of a typical wheeze to be between 100 and 5000 Hz [1]. The maximum duration of a wheeze is within the expiratory duration. A wheeze detection algorithm was developed based on this definition.

Figure 2 (right panels) shows a typical wheeze spectrogram, with time (seconds) and frequency (Hz) on the horizontal and vertical axes, respectively. The sound intensity (dB) is shown

as color and brightness. A continuous wheeze spectrum was created based on the lung sound analysis. On the left panels, horizontal axes show intensity (dB) and the vertical axis shows frequency (Hz). Wheeze sounds are shown as horizontal bars with intensity corresponding to peaks in the power spectrum display [1,13-15]. Wheeze sounds were classified into two types. On the left panel, a wheeze shows only one peak with intensity as a monophonic wheeze, and on the right panel, a wheeze shows many peaks with intensity as polyphonic wheezes. Wheezing is considered monophonic when only one pitch is heard, whereas it is considered polyphonic when multiple frequencies are simultaneously perceived. Polyphonic wheezing indicates more severe bronchial constriction than monophonic wheezing [3,16,17].

Figure 2. Monophonic and polyphonic wheezes. A: (a) Spectrum 1: Fast Fourier transform (FFT) frame, 21.000-21.372 s; (b) Spectrum 2: FFT frame, 21.018-21.390 s; (c) Spectrum 3: FFT frame, 21.036-21.408 s; (d) Spectrum 4: FFT frame, 21.054-21.426 s. B: (a) Spectrum 1: FFT frame, 25.000-25.372 s; (b) Spectrum 2: FFT frame, 25.018-25.390 s; (c) Spectrum 3: FFT frame, 25.036-25.408 s; (d) Spectrum 4: FFT frame, 25.054-25.426 s.



Wheeze Recognition Algorithm

Based on the definition of wheeze characteristics, a flowchart was created for the developed wheeze recognition algorithm from the sound collection to automatically detect wheezes to generate results. Details of the wheeze recognition algorithm were provided in our previous report [11] (Figure 1b). We describe the wheeze recognition algorithm with the following overall approach that consisted of five phases.

In step 1, sound data were preprocessed using high and low bandpass filters. Data were resampled at a sampling rate of 11.025 kHz and at a 16-bit quantization rate.

In step 2, fast Fourier transform (FFT), the most well-known acoustic analysis method, was used. FFT analyzes the intensity for each frequency of sound data. The sound data were preprocessed using a hamming window of 4096 points (372 ms), and processing was repeated every 128-point (18 ms) increase in the sound data [18-20].

Since the lung sound spectra had many local maximum points each time, in step 3, some local maximum points higher than the threshold were extracted as candidates for wheeze sounds. Black-circled points indicate the extracted local maximum points. The orange dotted line represents the threshold value used to determine the local maximum point. Threshold values were determined from overall sound pressure levels between 90 and 5000 Hz.

In step 4, whether the local maximum points selected in step 3 continued for >100 ms was determined according the definition of wheeze characteristics [13]. Continuous local maximum values selected in step 4 still included wheeze sounds and other noises, including voices, ambient sounds, crying, and heartbeat sounds.

In step 5, threshold values were determined using feature values to eliminate noises. To finally determine the presence of wheezes using both lung and ambient sounds, feature values of

wheezing candidates selected in step 4 were calculated. Finally, if at least one wheeze sound was heard in a file, it was identified as a wheeze file, whereas if no wheeze sound was heard in a file, it was identified as a no-wheeze file.

For validation, we compared the judgment of wheeze sound recognition using the algorithm to assess all files that were discriminated by each specialist physician who recorded lung sounds.

Statistical Analysis

The results fell into one of the following four categories: actual positives that were correctly predicted as positives (true positives, TP); actual positives that were wrongly predicted as negatives (false negatives, FN); actual negatives that were correctly predicted as negatives (true negatives, TN); and actual negatives that were wrongly predicted as positives (false positives, FP). We analyzed the sensitivity ($TP/TP+FN$), specificity ($TN/TN+FP$), positive predictive value ($PPV=TP/TP+FP$), and negative predictive value ($NPV=TN/TN+FN$) using the wheeze recognition algorithm results in all data files [21,22]. PPV is defined as the probability that files identified as “wheeze” files by the specialists were also identified as “wheeze” files by the algorithm. NPV is the probability that files identified as “no-wheeze” files by the specialists were also identified as “no-wheeze” files by the algorithm.

Statistical analysis was performed using R software version 3.4.1. Patient characteristics are presented as the mean and range. Wheeze sound characteristics are presented as mean (SD) and range. Noise ratios in each sound discriminated by the algorithm are presented as a percentage of all noises. The relationship between age and sensitivity of wheeze recognition was analyzed using the Jonckheere-Terpstra test [23,24]. A P value <.05 was considered statistically significant.

Results

Participant Characteristics

Table 1 shows the participant characteristics.

Table 1. Participant characteristics (N=374).

Characteristic	Value
Age (months), mean (SD)	44.3 (31.6)
Age category (months), n (%)	
4-11	54 (14.4)
12-23	70 (18.7)
24-35	52 (13.9)
36-47	38 (10.2)
48-59	48 (12.8)
60-71	19 (5.1)
72-83	18 (4.8)
84-95	45 (12.0)
96-107	30 (8.0)
Sex, n (%)	
Male	241 (64.4)
Female	133 (35.6)
Height (cm), mean (SD), range	96.2 (28.5), 56.0-133.0
Weight (kg), mean (SD), range	15.6 (6.8), 4.5-34.0

Classification of Recorded Sounds and Wheeze Characteristics

Table 2 shows the classification of recorded sounds in all lung sound samples and wheeze sound characteristics. If the wheeze

contained essentially a single frequency, it was classified as a monophonic wheeze, whereas it was classified as a polyphonic wheeze if it contained several frequencies [25].

Table 2. Classification of sounds in all recorded sound files (N=1201).

Sound classification	Value
Characteristics of wheeze sounds, mean (SD), range	
Frequency (Hz)	321 (178), 100-1600
Intensity (dB)	21.2 (7.0), 5.0-45.0
Duration (ms)	331 (220), 100-2538
Type of wheeze sounds, n (%)	
Monophonic wheeze	457 (38.1)
Polyphonic wheeze	744 (61.9)
Total	1201
Noise, n (%)	
Nasal congestion	108 (19.4)
Physician's voice	155 (27.8)
Ambient crying or voice	294 (52.8)
Total	557

Number of Local Maximum Points of Wheeze Sounds

Table 3 shows the number of local maximum points of wheeze sounds, for a total of 1201 in all recorded sounds. Among these,

457 (38.1%) wheezes were found to have one local maximum point. In addition, 352 (29.3%) wheezes had two local maximum points. Overall, <3 local maximum points accounted for >67.4% of all wheeze sounds.

Table 3. Number of local maximum points of wheeze sounds in all recorded sounds (N=1201).

Number of local maximum points	Wheeze sounds, n (%)
1	457 (38.1)
2	352 (29.3)
3	187 (15.6)
4	104 (8.7)
5	58 (4.8)
6	18 (1.5)
7	16 (1.3)
8	3 (0.2)
9	5 (0.4)
10	1 (0.1)

Accuracy of Wheeze Recognition

Table 4 displays the wheeze recognition results using the wheeze detection algorithm. The sensitivity, specificity, PPV, and NPV

for wheeze recognition in all data files were 96.6% (171/177), 98.5% (194/197), 98.3% (171/174), and 97.0% (194/200), respectively.

Table 4. Results per file obtained using the newly developed wheeze recognition algorithm for children.

Identification by the algorithm	Specialist's diagnosis by stethoscope	
	Wheeze sound	No-wheeze sound
Wheeze sound	TP ^a =171	FP ^b =3
No-wheeze sound	FN ^c =6	TN ^d =194

^aTP: true positive.

^bFP: false positive.

^cFN: false negative.

^dTN: true negative.

Influence of Age and Sex on the Sensitivity of Wheeze Detection

The sensitivity and specificity of wheeze detection are shown in Table 5. The sensitivity and specificity of wheeze detection were not influenced by age and sex.

Table 5. Influence of age and sex on the sensitivity of wheeze detection.

Group	Wheeze data			No-wheeze data		
	N	TP ^a	Sensitivity (%) (95% CI)	N	TN ^b	Specificity (%) (95% CI)
Age (months)						
0	24	23	95.8 (78.9-99.9)	30	28	93.3 (77.9-99.2)
1	45	43	95.6 (84.9-99.5)	25	25	100 (86.3-100)
2	27	26	96.3 (81.0-99.9)	25	25	100 (86.3-100)
3-8	81	79	97.5 (91.4-99.7)	117	116	99.1 (95.3-100)
Sex						
Male	110	106	96.4 (89.3-97.6)	131	130	99.2 (92.2-98.6)
Female	67	65	97.0 (90.3-99.3)	66	64	97.0 (88.6-98.3)
Total	177	171	96.6 (92.8-98.7)	197	194	98.5 (95.6-99.7)

^aTP: true positive.

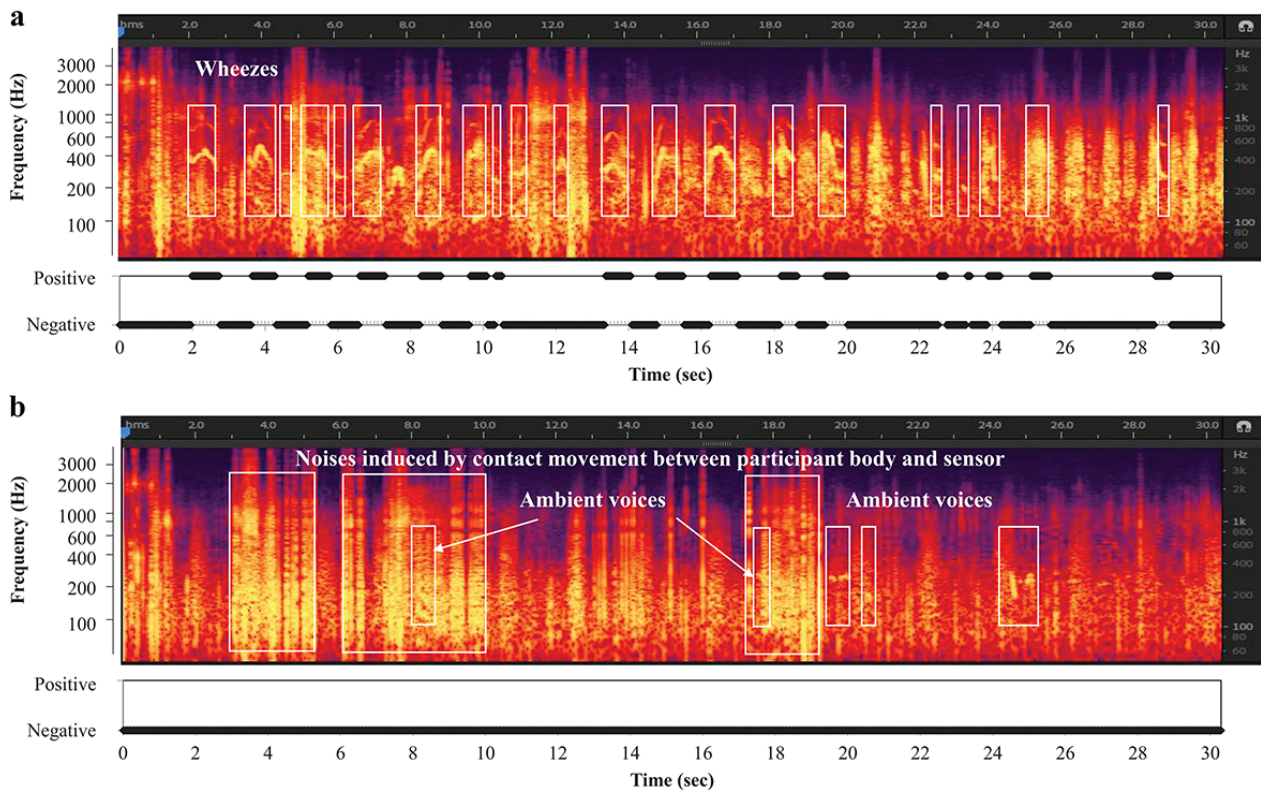
^bTN: true negative.

Automatic Differentiation of Wheezes From Other Sounds Using the Wheeze Detection Algorithm

Figure 3a shows the wheeze recognition results with wheezing before inhalation. Wheezes (white squares) were accurately detected by the automatic recognition algorithm. Figure 3b

shows the no-wheeze results after inhalation, including crying and voices (arrows). The other noises were effectively discriminated from wheeze sounds; wheezes were automatically detected, whereas heartbeat sounds, voices, and crying were automatically identified as no-wheeze sounds by the wheeze recognition algorithm.

Figure 3. Results of wheeze recognition with wheezing before and after inhalation.



Discussion

Wheezes in children, including infants, were successfully detected using the newly developed small handy device with a wheeze recognition algorithm. This algorithm could precisely discriminate wheezes from other noises in an environment with various sounds. Furthermore, based on wheeze characteristics, the automatic wheeze recognition algorithm could detect even mild wheezes in crying infants recorded for 30 seconds in a pediatric consultation room. Therefore, we have successfully developed a real-time wheeze detection system with higher robustness for clinical use.

Studies on automated wheeze detection have been performed for various clinical conditions [17,18]. These detection systems have been developed in the past three decades. In 1995, Gavriely [13] published the details of a technological approach for automated digital data acquisition and breathing sound processing. This commercial device, PulmoTrack, enabled automated and continuous wheeze monitoring. Boner et al [20] reported that monitoring wheezes during sleep was useful when treating children with asthma, and that the duration of wheezes during the recording was correlated with peak expiratory flow rate changes. Therefore, automated wheeze detection may be useful for the management of children with wheezes, especially infants. A meta-analysis found that computerized lung sound

analysis had relatively high sensitivity and specificity in a small number of studies [26,27]. Although wheeze detection systems have been successfully implemented, they have not been used clinically in children (including infants), owing to several problems that can be encountered while using automated wheeze detection systems [28-30].

One important factor is the varied wheeze intensities among children. Wheezes are continuous adventitious lung sounds that are superimposed on breath sounds. According to new definitions in the current Computerized Respiratory Sound Analysis guidelines, the dominant frequency of a wheeze is usually >100 Hz with a duration of >100 ms [25]. The most common features of detecting wheezes are the use of different wheeze peak shapes in the time-frequency plane, such as amplitude spectrum, continuity, spread, sparseness, and kurtosis. Continuous local maximum points of intensity in the spectra, which are considered as the most common features associated with wheezes during lung analysis, were analyzed. Wheeze spectra and spectrograms have many local maximum points when using FFT. Other technologies such as PulmoTrack provide respiratory rates, inspiratory/expiratory time ratios, wheeze rate during the recording duration, and wheeze duration. PulmoTrack detected >3 local maximum points. However, <3 local maximum points accounted for $>67.4\%$ of all wheeze sounds in this study and in our previous study, and our wheeze

recognition algorithm could detect >1 local maximum point. Moreover, our algorithm could also detect mild wheezes [11].

Prodhan et al [31] used PulmoTrack in a pediatric intensive care unit and reported that wheeze detection was more accurate compared with that performed by hospital staff. Nurses' judgment of wheezing has been reported to differ from that of physicians and caregivers by nearly 60% [4]. The judgment of wheezing may also differ among each physician, which could be due to the variety of wheezing sounds and many local maximum points from a few weak local maximum points. In this verification study, although 10 specialists who recoded wheezing performed independent assessments, we succeeded in obtaining highly accurate results of wheezing judgment. In other words, our developed wheeze recognition algorithm can accurately detect weak and mild wheezing, which may be judged differently by specialists. Consequently, our algorithm exhibited higher sensitivity over other wheeze detection technologies.

Another problem to be overcome is that a short examination time is required to accurately detect wheezes, and a simple procedure should be clinically used in small children. In small children, including infants, recording lung sounds without crying, moving, or being distracted by the attached adhesive pads or belt is difficult. Therefore, we selected a method that can record within a 30-second period by attaching a microphone to the chest wall by hand. In a previous study on 214 children, including 30 infants, the sensitivity of wheeze detection using our algorithm was not affected by age [12]. Moreover, this study comprising 374 children, including 54 infants, showed that the sensitivity of wheeze detection using our algorithm was not affected by age or sex. In addition, the small handy device is useful size for children and their caregivers.

A highly precise noise-canceling technology should be developed for clinical use for young children. Recording lung sounds in a noisy clinic requires more rigorous postprocessing than recording in a quiet room to compensate for the noise present in the acoustic signal. Therefore, the efficiency of classification algorithms may differ. These inconsistencies would lead to difficulties in interpreting and translating study outcomes, and they have hindered the clinical use of computerized lung sound analysis devices, especially in children [25]. To improve the accuracy of the algorithm for automatically detecting wheezing, various methods have been developed with the aim of eliminating the influence of human voices and various environmental sounds, but they have not been put into practical use [32-34].

Algorithms such as neural networks, vector quantization, Gaussian mixture model classification systems, and support vector machines have been used to analyze spectral features. A support vector machine is a supervised machine-learning algorithm used for both classification and regression [28,29]. The presence of wheezes can be identified using a decision tree with classifiers of other noises. The decision tree is a method that can classify sounds according to detailed differences in sound features. Heartbeat sounds typically last for <100 ms. Voices and other sounds produce noises of higher decibel levels on the environmental microphone than wheezes on the lung sound microphone. Crying is louder on the lung sound microphone than on the environment microphone, but shows different continuous pattern ranges compared with wheeze sounds. Therefore, no-wheeze sounds could be automatically distinguished from wheezes using the wheeze detection algorithm. We discriminated wheezes from environmental noise based on different wheeze sound characteristics. Thus, no-wheeze sounds could be automatically distinguished from other noises in a noisy pediatric consultation room.

This study has a few limitations. First, the use of the algorithm at home should have been validated. Second, in case of severe airway obstruction, it did not demonstrate any audible lung sounds (known as "silent chest"); however, patients with a severe condition show a pale face or difficulty breathing. Therefore, caregivers can easily recognize these as exacerbation signs.

Wheezing often occurs in the absence of a doctor, such as during the night, at home, or during exercise, and possibly even in the absence of a parent. Our new home medical device, equipped with a highly accurate algorithm that is not affected by environmental noise, can easily detect wheezing and may be able to properly detect asthma attacks at home in the absence of a doctor, which will further be useful for remote medical care.

We successfully developed a real-time wheeze detection system with higher robustness for clinical application using lung sound analysis in children and infants. We successfully discriminated wheezes from other noises such as heartbeats, voices, and crying using the wheeze detection algorithm in a noisy pediatric consultation room. This practical implementation may provide beneficial information for physicians and parents of children and infants. In the future, we plan to verify whether use of this device can be expanded to include older children and adults. We hope to use the novel home medical device equipped with this algorithm, which could help improve the safety of children with asthma and respiratory illnesses.

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Conflicts of Interest

NO, KA, and TS are employees of Omron Healthcare Co, Ltd. CH and KM received financial support from Omron Healthcare. The other authors have no conflicts to declare.

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Abbreviations

- FFT:** fast Fourier transform
- FN:** false negative
- FP:** false positive
- NPV:** negative predictive value
- PPV:** positive predictive value
- TN:** true negative
- TP:** true positive

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Original Paper

A Mobile App for Self-Triage for Pediatric Emergency Patients in Japan: 4 Year Descriptive Epidemiological Study

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Abstract

Background: When children suffer sudden illness or injury, many parents wonder whether they should go to the hospital immediately or call an ambulance. In 2015, we developed a mobile app that allows parents or guardians to determine the urgency of their child's condition or call an ambulance and that indicates available hospitals and clinics when their child is suddenly sick or injured by simple selection of the child's chief complaints and symptoms. However, the effectiveness of medical apps used by the general public has not been well evaluated.

Objective: The purpose of this study was to clarify the use profile of this mobile app based on data usage in the app.

Methods: This study was a descriptive epidemiological study with a 4-year study period running from January 2016 to December 2019. We included cases in which the app was used either by the children themselves or by their parents and other guardians. Cases in which the app was downloaded but never actually used were excluded from this study. Continuous variables are presented as median and IQR, and categorical variables are presented as actual number and percentages.

Results: The app was used during the study period for 59,375 children whose median age was 1 year (IQR 0-3 years). The app was used for 33,874 (57.05%) infants, 16,228 (27.33%) toddlers, 8102 (13.65%) elementary school students, and 1117 (1.88%) junior high school students, with 54 (0.09%) having an unknown status. Furthermore, 31,519 (53.08%) were male and 27,329 (46.03%) were female, with sex being unknown for 527 (0.89%) children. "Sickness" was chosen for 49,101 (78.51%) patients, and "injury, poisoning, foreign, substances and others" was chosen for 13,441 (21.49%). For "sickness," "fever" was the most commonly selected option (22,773, 36.41%), followed by "cough" (4054, 6.48%), and "nausea/vomiting" (3528, 5.64%), whereas for "injury, poisoning, foreign substances and others," "head and neck injury" was the most commonly selected option (3887, 6.22%), followed by "face and extremities injury" (1493, 2.39%) and "injury and foreign substances in eyes" (1255, 2.01%).

Conclusions: This study clarified the profile of use of a self-triage app for pediatric emergency patients in Japan.

KEYWORDS

emergency medicine; self-triage; mobile app; children; telemedicine; app; mobile health; mHealth; epidemiology

Introduction

When children suffer sudden illness or injury, many parents wonder whether they should go to the hospital immediately or call for an ambulance. When they cannot make the decision, they often call for an ambulance, which is one of the reasons why the number of ambulance calls has increased in recent years [1]. Telephone triage services have been introduced to replace various ambulance calls around the world. In the United Kingdom, the National Health Service (NHS) operates a telephone consultation service for people with sudden illness or injury [2]. In Australia, when a patient contacts the emergency dispatch center, secondary telephone triage is conducted after primary triage has taken place [3]. In Japan, telephone triage services for sudden illness and injury have been provided to people mainly in urban areas such as Tokyo and Osaka [4,5]. Osaka Prefecture is one of the largest metropolitan areas in Japan with a population of 8.8 million [6], and the number of ambulance dispatches in this area in 2016 was approximately 600,000 [7]. The Osaka Municipal Fire Department has been operating a telephone triage service (#7119) since 2012 [5]. The number of calls to the telephone triage center in Osaka has been increasing year by year, with the number totaling 284,665 in 2019 [8]. Correspondingly, the use of the telephone triage service has increased, especially during holiday seasons when few medical institutions are open, and this has caused some problems, such as difficulty in connecting to the telephone triage service due to line congestion.

In 2015, we developed a mobile app in Osaka Prefecture that allows parents or guardians to determine the urgency of their child's condition and call for an ambulance, and which indicates available hospitals and clinics when their child is suddenly sick or injured by having the parents simply select the child's chief complaints and symptoms. This application has been available in Japan for free download from the Google Play Store and Apple App Store since 2016. The information on available hospitals and clinics that can be displayed in this app is limited to Osaka Prefecture. The widespread use of this mobile app to advise parents and guardians and provide necessary support in the event of sudden illness and injury would enable us to conduct medical services more effectively and to reduce unnecessary ambulance calls and medical costs. In addition, the use of this

mobile app may provide assurance to those parents and guardians who have children or dependents with health issues. Clarifying how such a mobile app is used is important for assessing the usefulness of medical mobile apps. Therefore, the purpose of this study was to clarify the profile of the use of this mobile app based on data usage in the app.

Methods

Study Design, Population, and Setting

This was a descriptive epidemiological study whose 4-year study period ran from January 2016 to December 2019. In 2015, 17.08 million children were under 15 years old in Japan [6], of whom 1.17 million resided in Osaka Prefecture [6]. We included cases in which the app was used either by the children themselves or by their parents and other guardians in this study. The cases who downloaded the mobile app but never actually used it were excluded from our analysis.

Telephone Triage Services and Triage Protocol in Osaka Prefecture and Japan

In Japan, there are triage protocols including the Japanese Triage Acuity Scale [9], which is based on the Canadian Triage Acuity Scale, and the Emergency Assessment Protocol [10] established by the Fire and Disaster Management Agency for assessing and triaging emergency patients. Telephone triage services provided in some areas of Japan use the Emergency Assessment Protocol.

The telephone triage service in Osaka Prefecture has been described previously in detail [5,11]. The telephone triage nurses who receive phone calls from people judge the urgency of the chief complaints using software based on the Emergency Assessment Protocol. In Japan, there are 97 different protocols for judging the urgency by chief complaints [10], and the urgency is determined by selecting the signs and symptoms related to the chief complaint. In the mobile app reported here, we selected the 20 protocols from the Emergency Assessment Protocol in Osaka that were the most frequently used in the telephone triage service in Osaka Prefecture for "sickness" and "injury, poisoning, foreign substances and others" (Textbox 1) and modified some of the wording to make it easier for general users to understand.

Textbox 1. Chief complaints listed in the mobile app.

<p>Sickness</p> <ul style="list-style-type: none">• Fever• Convulsion• Cough• Nasal discharge• Asthmatic attack• Difficulty breathing• Rash• Nausea/vomiting• Diarrhea• Stomachache• Constipation• Abnormality of the stool• Ear pain• Headache• Crying• Loss of appetite• Symptoms of measles• Other <p>Injury, poisoning, foreign substances, and others</p> <ul style="list-style-type: none">• Head and neck injury• Face and extremities injury• Bleeding• Burn• Bite wound• Problem with extremities• Injury and foreign substances in eyes• Injury and foreign substances in ears• Injury and foreign substances in nose• Other problems in eyes• Other problems in nose• Other problems in mouth• Accidental ingestion of tobacco• Accidental ingestion of solid material• Accidental ingestion of liquid material• Heatstroke• Other

Mobile App for Emergency Pediatric Patients

Figure 1 shows the flow chart of the mobile app. The first step in this app is to select the age and gender of the child. Next, the user selects either “sickness” or “injury, poisoning, foreign substances and others.” When either of these is selected, the list

of chief complaints shown in Textbox 1 is displayed in the app, and the user selects the relevant chief complaint. For example, if “fever” is selected, relevant signs and symptoms with high urgency such as, “fever of 41 °C or higher,” are displayed in the app. If none of these are selected, relevant signs and symptoms with moderate urgency such as, “decreased urine volume,” are

displayed in the app. If none of them apply, the related signs and symptoms corresponding to “low urgency” are further displayed, and the urgency is determined based on the selected signs and symptoms. The app provides emergency medical services, such as the ability to call an ambulance or the telephone triage center and information on available hospitals and clinics. If there is another chief complaint, such as “convulsion,” when “fever” is selected, the app will move to the urgency assessment for the other complaint (Figures 2-7). Only hospitals and clinics in Osaka Prefecture that have agreed to register their information in the app will be displayed as available hospitals and clinics.

In addition, the GPS feature of the user’s cellphone also provides a list of hospitals and clinics in order of proximity to the location where the app is being used. During the mobile app development, we asked some mothers for their opinions about the usefulness of this mobile app, and modified the interface of the mobile app. The Android version of this app was released in January 2016, and the iOS version was released in April 2016 for free download. As for the algorithms used in this mobile app, we provided the algorithm for “fever” as one of examples (Table S1, Multimedia Appendix 1).

Figure 1. Flowchart of the mobile app.

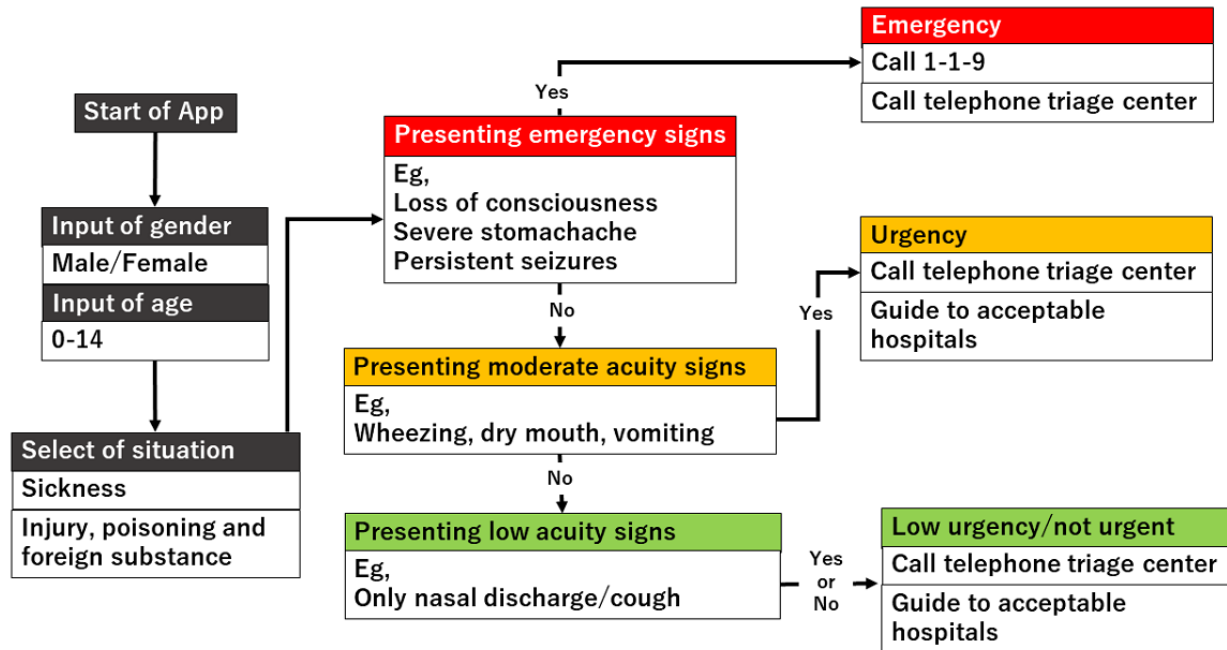


Figure 2. Screenshot of patient input about age and sex.

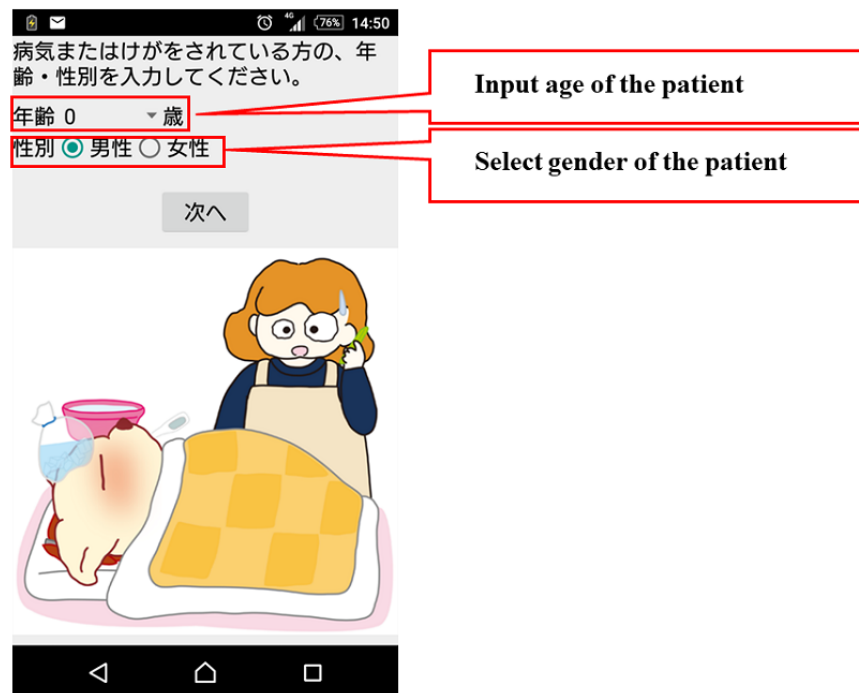


Figure 3. Screenshot of selection about “Sickness” or “Injury, poison, foreign substances and others”.

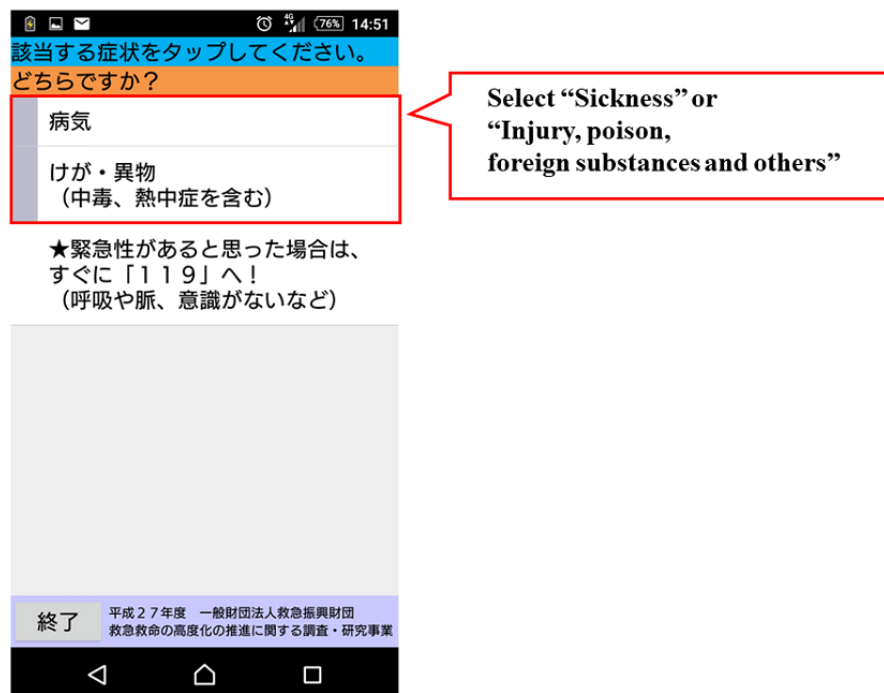


Figure 4. Screenshot of chief complaint selection.

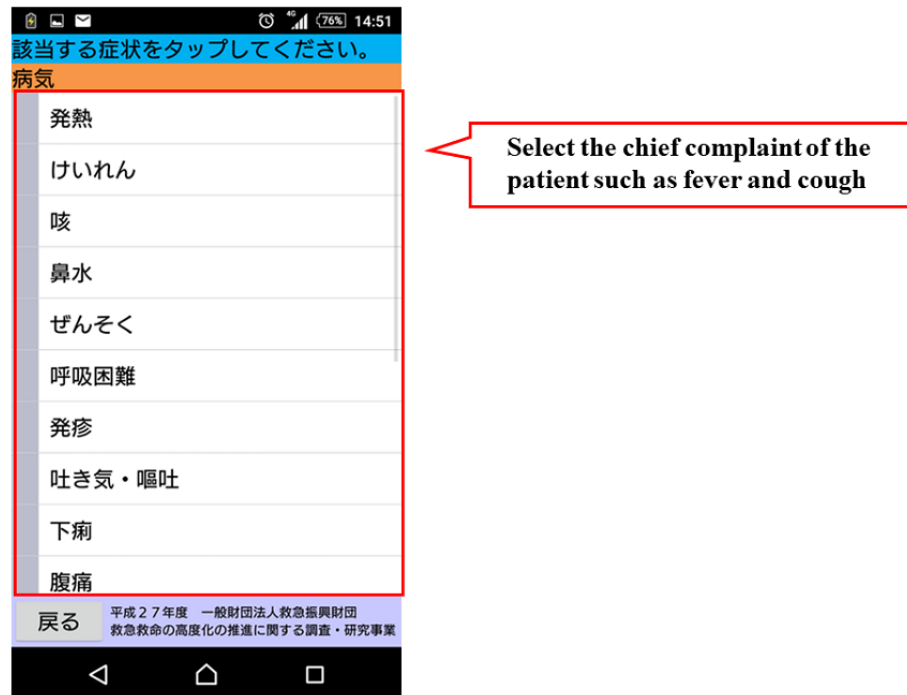


Figure 5. Screenshot about selection of signs and symptoms related to the selected chief complaint.

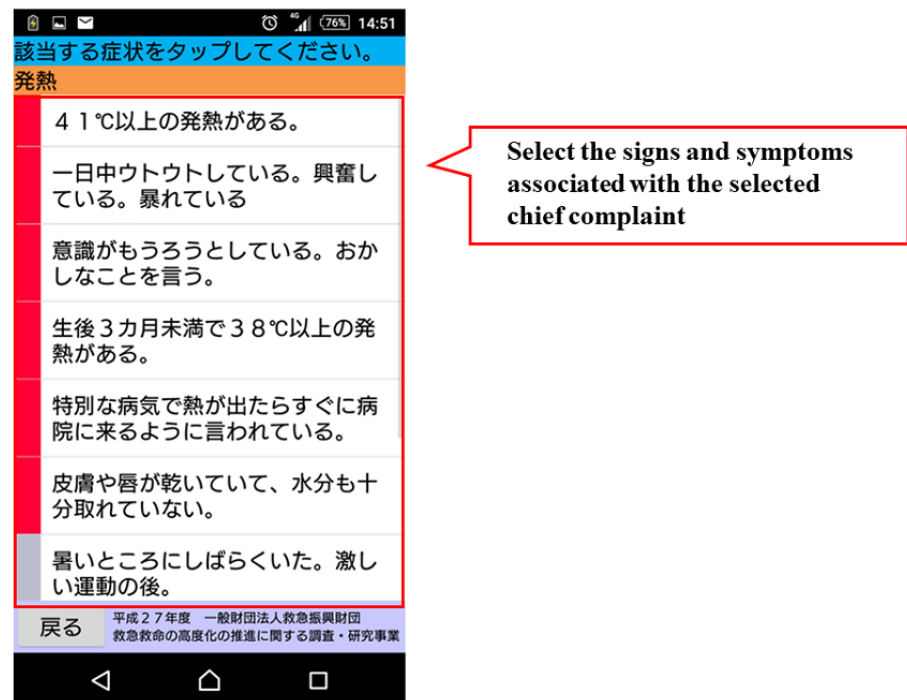


Figure 6. Screenshot of result in emergency cases.

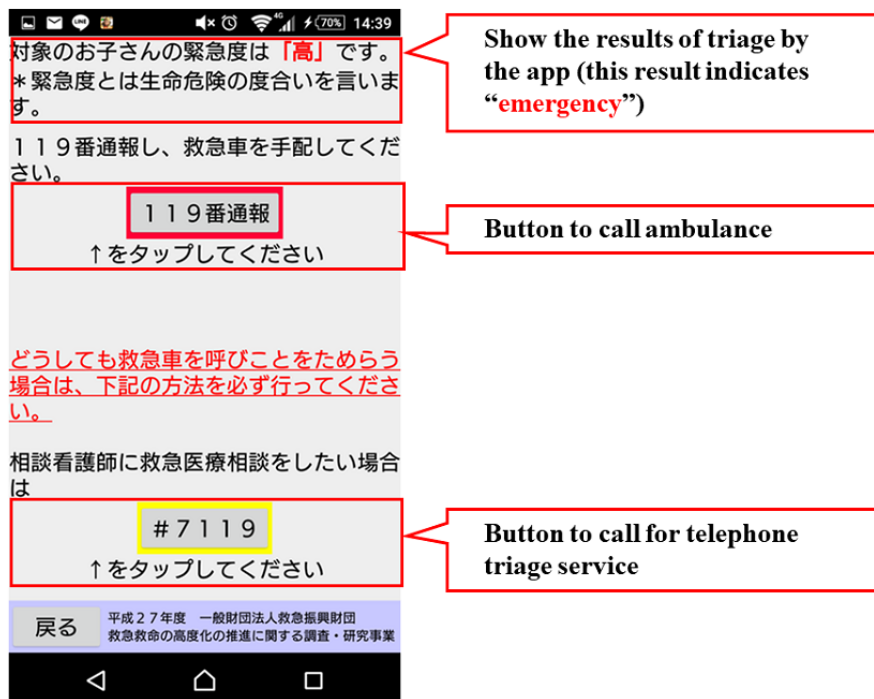
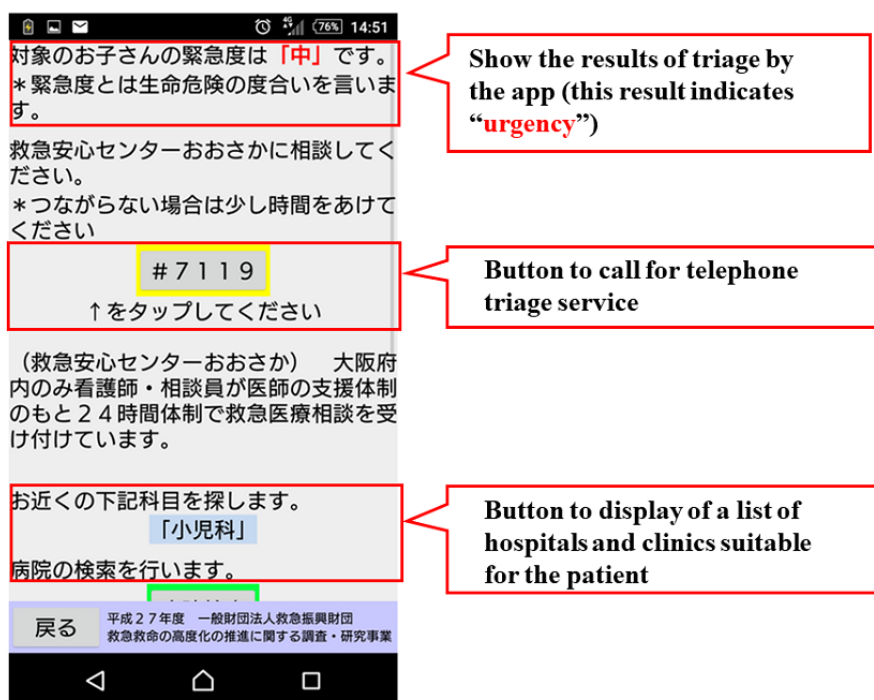


Figure 7. Screenshot of result in urgent cases.



Statistical Analysis

Continuous variables are presented as median and IQR, and categorical variables are presented as actual number and percentages. Age groups were categorized as infants (0-1 years), toddlers (2-5 years), elementary school students (6-12 years), and junior high school students (13-15 years). The time of app use was categorized as midnight to 7:59 AM, 8 AM to 3:59 PM, and 4 PM to 11:59 PM. In this study, users who used the app multiple times were counted as a single user. The data used in

this study were anonymized, but informed consent was obtained from the users at each occasion of use. This study was approved by the ethics committee of Osaka University Graduate School of Medicine (approval #20313). This manuscript was written based on the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [12].

Results

This mobile app was downloaded 24,721 times by December 2019, and we included 22,158 cases for this study, excluding about 2500 users who downloaded this mobile app but did not use it or uninstalled it before using it.

Table 1 shows the characteristics of the children for whom the app was used. The app was used from January 2016 to December 2019 for 59,375 children whose median age was 1 year (IQR 0-3 years). The app was used for 33,874 (57.05%) infants, 16,228 (27.33%) toddlers, 8102 (13.65%) elementary school students, 1117 (1.88%) junior high school students, and 54 (0.09%) children of unknown status. Moreover, 31,519 (53.08%) were male. The number of the children for whom the app was used was 10,105 (17.02%) in 2016, 13,077 (22.02%) in 2017, 17,877 (30.11%) in 2018, and 18,316 (30.85%) in 2019. Regarding the time of day of app use, the app was used between midnight and 7:59 AM by 10,289 patients (17.33%), between 8 AM and 3:59 PM by 20,487 patients (34.50%), and between

4 PM and 11:59 PM by 28,599 patients (48.16%). The app was used by 33,887 patients (57.07%) within Osaka Prefecture and by 5244 patients (8.83%) outside of Osaka Prefecture. Location information was unknown for 20,244 patients (34.10%).

Table 2 shows the clinical characteristics of the patients for whom the app was used. Among the 62,542 chief complaints selected, 49,101 (78.51%) were “sickness” and 13,441 (21.49%) were “injury, poisoning, foreign substances and others.” Among “sickness,” “fever” was the most commonly selected option (22,773, 36.41%), followed by “cough” (4054, 6.48%) and “nausea/vomiting” (3528, 5.64%). Among “injury, poisoning, foreign substances and others,” “head and neck injury” was the most commonly selected option (3887, 6.22%), followed by “face and extremities injury” (1493, 2.39%) and “injury and foreign substances in eyes” (1255, 2.01%).

Of the 4722 patients for whom some kind of emergency medical service was used, the most commonly selected option was “guide to acceptable hospitals and clinics” (3046/4722, 64.51%; **Table 3**).

Table 1. Demographic and geographic characteristics of the patients.

Characteristics	Value, n (%) (N=59,375)
Age group	
Infants (0-1 years old)	33,874 (57.05)
Toddlers (2-5 years old)	16,228 (27.33)
Elementary school students (6-12 years old)	8102 (13.65)
Junior high school students (13-15 years old)	1117 (1.88)
Unknown	54 (0.09)
Gender	
Male	31,519 (53.08)
Female	27,329 (46.03)
Unknown	527 (0.89)
Year	
2016	10,105 (17.02)
2017	13,077 (22.02)
2018	17,877 (30.11)
2019	18,316 (30.85)
Month	
January	4470 (7.53)
February	3761 (6.33)
March	3917 (6.60)
April	4713 (7.94)
May	5166 (8.70)
June	5324 (8.97)
July	5448 (9.18)
August	5053 (8.51)
September	5299 (8.92)
October	4945 (8.33)
November	4691 (7.90)
December	6588 (11.10)
Time of day	
Midnight-7:59 AM	10,289 (17.33)
8 AM-3:59 PM	20,487 (34.50)
4 PM-11:59 PM	28,599 (48.17)
Day of the week	
Sunday	10,101 (17.01)
Monday	8677 (14.61)
Tuesday	7817 (13.17)
Wednesday	8031 (13.53)
Thursday	8764 (14.76)
Friday	7477 (12.59)
Saturday	8508 (14.33)
Area	

Characteristics	Value, n (%) (N=59,375)
Inside Osaka Prefecture	33,887 (57.07)
Outside Osaka Prefecture	5244 (8.83)
Unknown	20,244 (34.10)

Table 2. Clinical characteristics.

Main presenting problem selected on the app	Value, n (%) (N=62,542)
Sickness	49,101 (78.51)
Fever	22,773 (36.41)
Convulsion	2812 (4.50)
Cough	4054 (6.48)
Nasal discharge	2576 (4.12)
Asthmatic attack	749 (1.20)
Dyspnea	1414 (2.26)
Rash	2217 (3.54)
Nausea/vomiting	3528 (5.64)
Diarrhea	2034 (3.25)
Stomachache	959 (1.53)
Coprostasis	684 (1.09)
Abnormal stool	560 (0.90)
Ear pain	793 (1.27)
Headache	598 (0.96)
Crying	1182 (1.89)
Anorexia	472 (0.75)
Measles symptoms	63 (0.10)
Symptoms of sicknesses	1633 (2.61)
Injury, poisoning, foreign substances, and others	13,441 (21.49)
Head and neck injury	3887 (6.22)
Face and extremities injury	1493 (2.39)
Bleeding	350 (0.56)
Burn	272 (0.43)
Bite wound	76 (0.12)
Problem with extremities	752 (1.20)
Injury and foreign substances in eyes	1255 (2.01)
Injury and foreign substances in ears	420 (0.67)
Injury and foreign substances in nose	358 (0.57)
Other problems in eyes	121 (0.19)
Other problems in nose	150 (0.24)
Other problems in mouth	516 (0.83)
Accidental ingestion of tobacco	622 (0.99)
Accidental ingestion of solid material	848 (1.36)
Accidental ingestion of liquid material	235 (0.38)
Heatstroke	1073 (1.72)
Other symptoms of injury, poisoning, foreign substances and others	1013 (1.62)

Table 3. Clinical characteristics.

Users' input	Value, n (%) (n=4722)
Call for ambulance	33 (0.7)
Call for telephone triage service	422 (8.9)
Call for medical consultation service of children	3 (0.1)
Guide to acceptable hospitals and clinics	3046 (64.5)
Observation	1218 (25.8)

Discussion

Principal Results

This study is the first to describe the profile of use of an emergency medical app available to the general public that guides them in the event of a child's sudden illness or injury. The app was most frequently used for infants, and it was used most frequently between 4 PM and 11:59 PM and on Sundays. In addition, about half of the uses were in Osaka Prefecture. The most common medical advice selected was "guide to acceptable hospitals and clinics." This study would be useful in the development of medical apps that can be used on mobile devices for nonmedical personnel.

We previously described the profile of patients who were transported by ambulance after telephone triage in Osaka Prefecture [5]. The most common time of day for both telephone triage and use of this app was in the evening. In Japan, some nighttime emergency clinics provide primary emergency care after many general clinics close in the evening. It is likely that when a child suddenly becomes sick or injured after clinics hours, parents use the telephone triage service or the app to decide whether they should visit a nighttime emergency clinic or emergency department immediately, call for an ambulance, or wait until the next day. This result was similar to the finding of a study of telenursing and an advice line in Australia [13]. In this study, about 57% of the users used this mobile app within Osaka Prefecture. The difference in the number of users within and outside of Osaka Prefecture might have been influenced not only by the available services, such as visiting medical institutions, but also by the public activities of the government. In Osaka Prefecture, the fire departments have not only publicized the mobile app through advertisements on trains and posters but also conducted activities to introduce the mobile app at events of basic life support for citizens. These government activities might have helped to increase awareness about this mobile app among citizens. In order to provide health services to citizens via mobile apps, it is essential for governments to repeatedly promote and educate the public.

The app assessed here not only judges urgency based on the selection of signs and symptoms but also provides medical help, such as ambulance calls and a guide to appropriate hospitals and clinics based on the results of the judgment. As a result, the number of users of this app has increased over the years, which indicates that not only the interface of this app but also the services it provides have been widely accepted by many users. There are several models that explain people's acceptance of

new technologies. Venkatesh and colleagues [14] stated that the people's acceptance of new technologies is associated with 4 factors: performance expectancy, effort expectancy, social influence, and facilitating conditions (the Unified Theory of Acceptance and Use of Technology [UTAUT]). For example, 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. The emergency room system in the United States is not common in Japan. Therefore, when people suffer from sudden illness or injury, they have to use the phone or the internet to find hospitals and clinics by themselves. This mobile app assesses the urgency level of their selected symptoms and provides information on appropriate hospitals and clinics that can treat the patient. Hence, as it is more convenient to search than the traditional search for hospitals or clinics, people's performance expectancy is applicable to this mobile app. In addition, the effort expectancy is defined as the degree of simplicity associated with the use of a system. During the development of this mobile app, we asked a few mothers for their opinions about the usefulness of this mobile app, and modified the interface of the mobile app. Thus, although this mobile app was not always developed based on behavioral theories like UTAUT, some elements from these theories may be applicable.

Comparison With Prior Work

In this study, the number of ambulance calls made via the mobile app was low. In a previous study by Morimura and colleagues [15], 12.9% of patients who used the telephone triage services connected the phone to the ambulance dispatch center. The following may explain the discrepancy between this previous study and our own. First, Morimura et al's study included not only children but also adults and older adults, whereas we included only children in this study. Therefore, children might have been taken to a medical facility by their parents or guardians instead of by ambulance even when the urgency level of their symptoms was high. Second, the parents and guardians who used this mobile app might have only wanted to know the degree of urgency or whether or not they should visit a medical facility immediately. Indeed, only 7.95% (4722/59,375) of the population who used the mobile app used medical services, such as an ambulance call or an information search on medical institutions.

Many mobile apps for medical personnel have been developed in the field of pediatric emergency medicine. For instance, another study on medical app use in Irish pediatric emergency departments reported that one-third of medical facilities and

about half of the medical personnel had medical apps installed on their personal mobile devices, with the most adopted app being the British National Formulary app developed by the NHS [16]. However, the effectiveness of medical apps used by the general public has not been well evaluated. In a review of 175 studies on medical apps that support self-management for the general public, only 30.3% of the apps were publicly available from app stores, the number of study participants was small (median number of study participants 31; IQR 11.0-29.2; maximum 11,690), and clinical outcomes were evaluated in only 36 studies (20.6%) [17]. Another study comparing the effectiveness of an app, book, and video program on child health for parents visiting the emergency department reported that the app was not widely used, and the parents did not recommend the app to others [18]. For an app to be widely accepted by the general public, the effectiveness of the service provided by the app and an easy-to-use interface for users are essential. The app assessed here not only judges urgency based on the selection of signs and symptoms but also provides medical help through services like ambulance calls and guidance to appropriate hospitals and clinics based on the results of the assessment. As a result, the number of users of this app has increased over the years, which indicates that both the interface and services of the app have been widely accepted by many users. In addition, the number of app users is larger than that in previous studies, and thus, the general validity may also be high.

The purpose of this study was to determine the profile of use for this mobile app based on data usage in the app as mentioned in the Introduction; however, we did not evaluate the effectiveness of this mobile app. The app may have effects on the prognosis of patients as well as various other aspects, such as medical costs and the number of unnecessary ambulance

calls. We are further planning to verify the efficacy of our mobile app through long-term monitoring or via a random interview survey to clarify other outcomes for users in the future, such as satisfaction of user experience.

Limitations

This study has several limitations. First, as the data entered into the app only came from users, it is possible that the data entered did not accurately reflect the patient's condition. Second, there were no data on the prognosis of any of the patients. Although the cooperation of users is essential for investigating the prognosis of the patients, there are legal problems in follow-up investigation. Moreover, this study did not ask for user demographics, and it was unclear whether a given user of the app was a parent or guardian. Third, compared to telephone triage, validation of the user's own triage using the app is problematic. We plan to examine this limitation in the future. Fourth, since the mobile app is, unfortunately, not yet sufficiently widespread in our target region, we must further make efforts to disseminate this app so that we can evaluate the effect of this app on ambulance calls and medical costs. Fifth, it was unclear to us whether users wanted to just try out the app or if they really wanted to use it. Sixth, demographics, including whether app users were adults, guardians, or the children themselves as well as other detailed information, such as average usage time and triage time, were not available in this study. Finally, we did not verify the validity of the of urgency assessment provided by this mobile app, which is something which should be determined in a future study.

Conclusions

In this study, we clarified the use profile of a self-triage app for pediatric emergency patients in Japan.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Table S1. The algorithm for "fever" in the mobile app.

[[XLSX File \(Microsoft Excel File\), 12 KB - pediatrics_v4i2e27581_app1.xlsx](#)]

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Abbreviations

NHS: National Health Service

STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

UTAUT: Unified Theory of Acceptance and Use of Technology

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Original Paper

Efficacy of a Web-Based Intervention (Smart Choices 4 Teens) for Facilitating Parent-Adolescent Communication About Relationships and Sexuality: Randomized Controlled Trial

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Abstract

Background: There is a need for interventions that promote healthy decision making among adolescents and leverage the ongoing impact of parental relationships through older adolescence and young adulthood. These interventions should maximize adolescent engagement and be easily accessible to families in terms of cost, duration, and logistics related to participation.

Objective: This study aims to test the efficacy of the healthy relationships and sexual decision-making component of a web-based intervention for older adolescents and their parents, ascertain whether the efficacy varies by gender, and assess its efficacy over time.

Methods: A randomized controlled trial was conducted for the web-based, self-paced intervention Smart Choices 4 Teens from 2014 to 2015. Families (N=411) with adolescents aged 16-17 years were randomly assigned to the intervention or control condition. Surveys assessing aspects of sexual communication were administered at baseline and at 6, 12, and 18 months. Generalized estimating equations were used to determine the impact of exposure to the relationships component of the intervention on sexual communication by parents, as reported by adolescents.

Results: Less than half (88/206, 42.7%) of the intervention group participated in the third and final intervention component, which was focused on relationships and sexual decision making. Participation in the relationships component increased the frequency of parental sexual communication and increased the number of dating rules after accounting for other significant adolescent characteristics. The impact of the intervention varied little by gender, although it did demonstrate an impact on communication reports over the follow-up survey administrations.

Conclusions: Smart Choices 4 Teens demonstrated efficacy in increasing the frequency of sexual communication between parents and adolescents in the long term.

Trial Registration: ClinicalTrials.gov NCT03521115; <https://clinicaltrials.gov/ct2/show/NCT03521115>

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KEYWORDS

adolescent; sexual behavior; parenting; intervention; randomized controlled trial; mobile phone

Introduction

Background

Adolescents frequently report that parents are their preferred source of information about romantic relationships and sexuality [1,2]. Often, this communication is more focused on daughters [3] than sons and more often initiated by mothers than fathers [4], although fathers' communication has been shown to increase after participation in interventions [5,6]. Higher amounts of parent-adolescent communication, regardless of topic or other characteristics, are strongly related to increased adolescent safer sex behavior [5,7,8]. Furthermore, the connection between parent-adolescent communication about sex and adolescent sexual behaviors is robust, firmly established [8], and durable through older adolescence and into young adulthood [9-12]. This underscores the importance of encouraging and assisting parents in communicating with their adolescents about sexual decision making.

Recent reviews of interventions designed to facilitate sexual communication between parents and adolescents [6,8,13] indicate that many interventions significantly increased parental levels of comfort and the amount of communication about sex. However, one meta-analysis found that most interventions that address parent-adolescent sexual communication focus on parents of younger adolescents (early adolescents), are often group-based with a trained facilitator, and tend to focus primarily on parents, with very few studies including adolescents [13]. Many of these programs are provided through schools [14,15], medical clinics [16], and community centers [17] and require a substantial time and logistic commitment on the part of participants. Although some programs demonstrate efficacy with their prioritized populations, there is a need to include adolescents within the intervention while extending the reach to a broader audience and more diversified populations for whom time constraints, logistics, and delivery costs present compelling barriers to intervention participation [18].

Digital and web-based delivery platforms [19], including DVDs [20], videogames [21,22], email [23], websites [24], text messages [25,26], and social media [27,28], are increasingly used to address these barriers [29]. These delivery platforms hold promise as most families have computer and internet access, including via smartphones (89%) [30].

This Study

To summarize, there is a demonstrated need for interventions that support sexual communication between parents and adolescents that (1) support the continued relationship with parents through older adolescence and into emerging adulthood; (2) engage the adolescent in full intervention participation; and

(3) address common barriers such as time limitations of participants and reduced cost via delivery in an easily accessible format for families.

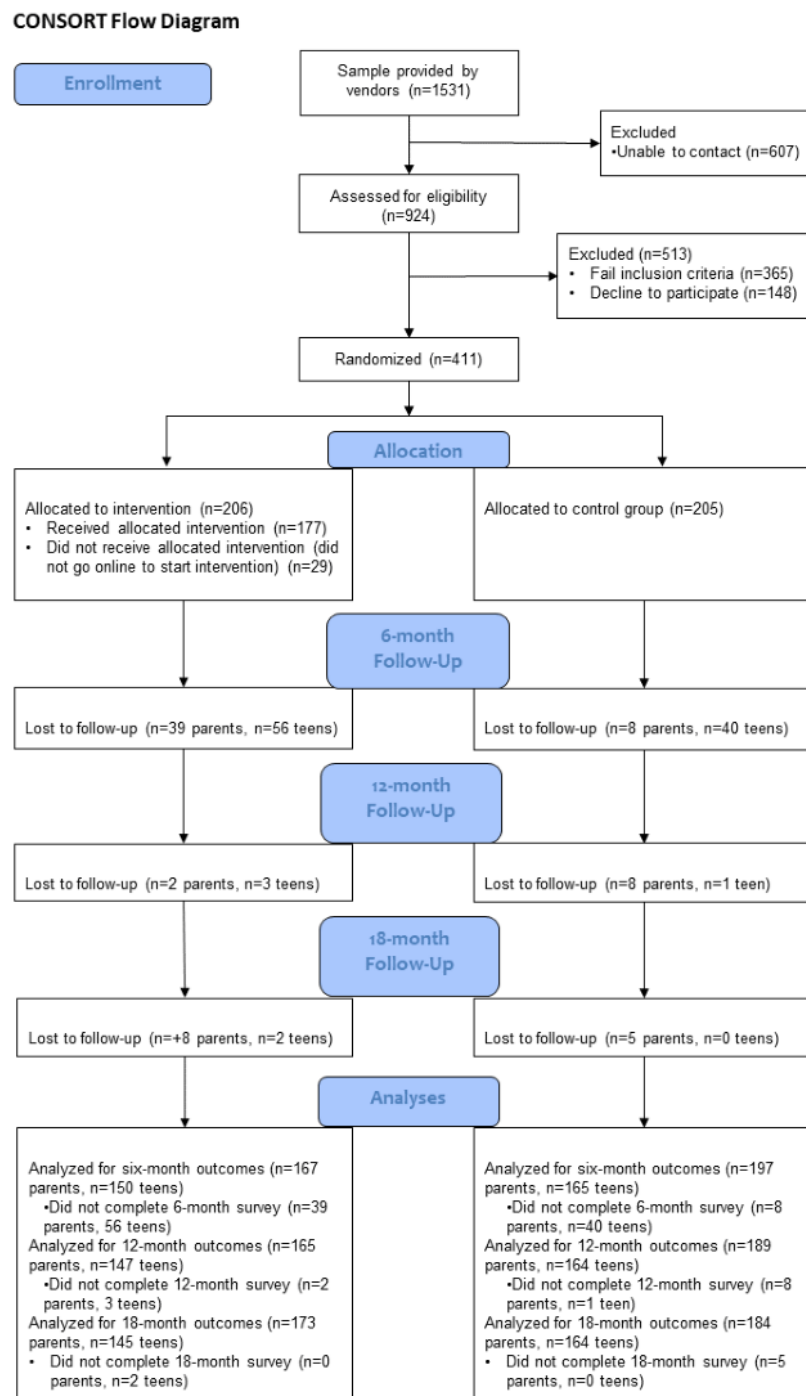
This paper aims to examine the adolescent report of sexual and relationship communication outcomes for a web-based intervention, Smart Choices 4 Teens, delivered to parents and their adolescents (aged 16-17 years at enrollment). The program focused on building communication between parents and adolescents on important issues related to adolescent alcohol use, sex, and romantic relationships. The program also provided the skills needed by adolescents to address the social scenarios that they may encounter. Smart Choices 4 Teens was self-paced, on the web only, and contained three components for both parents and adolescents—(1) introduction and parent-adolescent communication skills, (2) adolescent alcohol use, and (3) adolescent relationships and sexuality—and was tested in a randomized controlled trial with 411 parent-adolescent dyads. Results from the alcohol use component have been previously reported [31]; the adolescent relationships and sexuality component is the focus of this paper. Consistent with the theoretical frameworks of the intervention from which it was adapted (see section *Smart Choices 4 Teens Intervention*), we hypothesize that adolescents who had been exposed to the relationships component of the program, compared with those who did not, would report increased sexual communication with their parents (a main effect of intervention exposure) and the increased sexual communication with their parents would vary by gender of the adolescent (interaction effect between intervention exposure and gender).

Methods

Participants

Families with adolescents aged 16-17 years were recruited from US-focused web-based panel vendors, companies that matched and recruited participants for targeted survey studies [32], between November 2014 and November 2015 (for an in-depth description of our web-based panel methodology, see the study by Wang-Schweig et al [33]). As shown in the CONSORT (Consolidated Standards of Reporting Trials) diagram (Figure 1 and Multimedia Appendix 1), panel vendors provided contact information for 1531 adult panelists via a secure shared website. Among these, 559 were eligible (ie, parent with an adolescent aged 16-17 years; English speaking; and with a compatible tablet or computer for viewing the web-based intervention). The research team made separate contact with the adolescent to ensure eligibility, ascertain a separate email for the adolescent, and ensure confidentiality. Among the 559 eligible panelists, 411 (73.5%) families completed baseline web-based surveys and were enrolled.

Figure 1. Consolidated Standards of Reporting Trials flow diagram.



Parents provided consent for themselves and permission for their adolescents, whereas adolescents provided assent for themselves; they were then directed to the research website where they completed separate, confidential baseline surveys. Each participant received US \$30 for baseline surveys, US \$40 for 6-month follow-up surveys, and US \$50 each for 12-month and 18-month follow-up surveys via a mailed check. All study procedures were approved by the Institutional Review Board of the Pacific Institute for Research and Evaluation.

Using a 1:1 allocation ratio and a computer-generated program, parent and adolescent dyads were randomly assigned to either the intervention (n=206) or control (n=205) condition as a randomized controlled trial without a waitlist control group design. Dyads in both conditions received links to resources, including hotline numbers and websites providing information about adolescent alcohol and drug use, sexual behavior, suicide, support for gender and sexual minority adolescents, and other health issues. All families also had access to an 800 number

throughout the duration of the project for contact with the research team. Automated emails and texts were sent to invite families to complete the follow-up surveys at 6, 12, and 18 months after baseline. One week after the follow-up survey, invitations were sent and reminder emails or texts were sent to participants who had not completed the surveys, with the emails or texts repeated after another week of nonresponse. If not completed within 2 weeks, phone calls were made to the participants to encourage completion.

Smart Choices 4 Teens Intervention

The intervention was targeted to older adolescents (aged 16-17 years) not as sex education but to address decision making and skills needed in the context of increased independence and sensitivity to the needs of adolescents who may have initiated some alcohol use and sexual behavior. The intervention sought to increase parent-adolescent communication and build skills to address scenarios that adolescents encounter related to alcohol use and romantic relationships. Facilitation and clarification of adolescent choices were guided by an offline discussion of scenarios derived from real stories that require decision making by adolescents. These discussions offered opportunities for the values of the parents and adolescents to be considered. Specifically, what constituted smart decision making was determined by the families and not asserted by the intervention.

Smart Choices 4 Teens was created by adapting materials from two evidence-based prevention programs that are both booklet-based and independently completed by families: *Family Matters* [34] (designed for parents of younger adolescents) and *A Parent Handbook for Talking with College Students about Alcohol* [35] (designed for parents to prepare their adolescents for the first year as college students). *Family Matters* addresses theoretically derived risk and protective factors important to adolescent alcohol and other drug use and emphasizes parental characteristics (eg, supervision, support, communication skills, attachment, and conflict resolution skills) that can be strengthened to influence adolescents' risky behaviors. Strengthening adolescent characteristics (eg, educational achievement, communication, conflict resolution skills, and response to peer pressure) in the context of the parent-adolescent relationship subsequently creates resilience in adolescents and decreases risky behaviors. These characteristics are central to theories of socialization [36,37], social control [38,39], social development [40], and family interaction [41]. Content for the program is based on social learning and communication theories [42-45] and is delivered in booklet form to be delivered by parents to adolescents. *Parent Handbook* is designed for parents to provide practical approaches to address alcohol use among adolescents and is designed to address problems for adolescents making the transition from high school to college. On the basis of a theoretical approach that takes into account the importance of social, cognitive (eg, beliefs and social norms), emotional, and decision-making aspects of college drinking, *Parent Handbook* is effective in reducing drinking and drinking-related consequences, influences perceptions of drinking activities, and impacts perceived parental and peer approval of drinking [46]. Both programs have evidence of efficacy and effectiveness and were adapted for the following considerations: (1) age appropriateness for those aged 16-17 years; (2) parallel materials

for the adolescent; and (3) delivery of the materials to a web-based platform. The adaptation process included creating instructional objectives, content outline, activity descriptions, and scripts through a series of iterative development cycles that included review by an expert panel and input from two rounds of focus groups with parents and adolescents. Additional information on the adaptation of the interventions is available with the results for the alcohol component [31].

For each component, Smart Choices 4 Teens required that parents and adolescents complete web-based materials separately. Following completion, they chose two of four possible scenarios for discussion. These scenarios were designed to use the skills and knowledge addressed in the component activities. After the discussion was completed, the participants moved to the next component. Given the imposed chronological order of the components, families first completed the communications (parents: mean 28.13, SD 22.39 min; adolescents: mean 23.45, SD 24.04 min) and alcohol (parents: mean 18.75, SD 24.20 min; adolescents: mean 18.63, SD 25.21 min) components before moving forward with the relationships component. The average time spent on the relationships component was nearly identical between parents (mean 23.53, SD 32.37 min) and adolescents (mean 24.56, SD 35.11 min). Families typically completed the intervention over several weeks.

The goal of the relationships component was to foster communication around healthy relationships [47], increase parental monitoring [48-50], clarify expectations and values, provide skills for making healthy choices around the decisions related to relationships, and encourage reflection on decision making. This component was divided into five sections and was delivered via a video narrative, infogadget (activity with a series of tabs on a single topic, containing graphics and text), and interactive activity: (1) acknowledging how challenging parent-adolescent communication about relationships and sexuality can be (video narrative); (2) reflecting on healthy relationships (readiness for a relationship [interactive activity], prioritizing partner characteristics [interactive activity], and signs of emotional and verbal abuse [video narrative]); (3) smart decision making and sex expectancies (interactive activity), unintended health consequences such as pregnancy and sexually transmitted infections (infogadget), social media responsibility (interactive activity), and refusal skills (video examples); and (4) values and guidelines (interactive activity).

Following the completion of the web-based materials, the families were asked to engage in an offline discussion, guided by four real-life scenarios pertaining to the complexities of relational decision making, which were drawn from focus groups with adolescents for another adaptation of *Family Matters* [51]. The scenarios were presented as dilemmas facing an adolescent and created an opportunity for a dialog about the options that the hypothetical adolescent in the story had for addressing the dilemma. The four scenarios included (1) facing a situation in which adolescents were deciding whether to have sex within the context of a relationship; (2) decision making about relationships in the context of other friendships (dating a friend's sibling); (3) an adolescent who encountered a friend who had passed out from alcohol use and was possibly vulnerable to

sexual or physical assault; and (4) relationships between individuals with large age discrepancies (adolescent girls and older men). Families selected two scenarios to discuss offline and were prompted to download a tailored discussion guide for the parent-adolescent discussion. Given the normative increase in sexual exploration of older adolescents and an imperative to protect their privacy and potential safety, activities requiring communication between the dyads were designed so that self-disclosure on the part of the adolescents was not required (any sexual behaviors, sexual orientation, etc).

Measures

The following naming convention is used for reporting on the waves' descriptive and reliability statistics: baseline (T0) and follow-ups for 6 months (T1), 12 months (T2), and 18 months (T3). For all measures, baseline assessments were phrased to indicate a general (or *ever*) assessment, whereas the follow-up surveys explicitly asked for an assessment within the past 6 months or since the previous survey.

Primary Outcomes: Parent-Adolescent Communication

Overall Sex Communication Frequency

The overall frequency of sex communication was assessed with a single item adapted from the evaluation of the program Parent Handbook for Talking with College Students about Alcohol [52]—"Overall, how often have you talked to your parent about sex"—with response options ranging from (1) *never* through (5) *very often*.

Topic Specific Communication Frequency

Teens reported the frequency of ten specific parent-teen sexual communication topics [41] ('How often have you and your parent talked about your having sexual intercourse and...') with responses ranging from 'never' (1) to 'very often' (5). Topics included 'the negative impact on your social life because you would lose the respect of others', 'the importance of being committed to a healthy lifestyle and how being in a sexual relationship can impact this', 'how embarrassing it would be if I caught an STI (sexually transmitted infection)'. The mean score of these items was used for the analyses (T0: $\alpha = .92$; T1: $\alpha = .94$; T2: $\alpha = .94$; T3: $\alpha = .94$).

Topics of Conversation About Sex

Adolescents were asked to report whether their parents had talked about specific topics with them, adapted from the evaluation of *Family Matters* [53]. Items were summed for one total score and summed by topic area as detailed below.

Delaying Sex

Three items asked whether a parent had cautioned the adolescent not to have sex, not to have a serious relationship in high school, and not to have sex specifically because their religion or values forbid sex outside of marriage. A sum of the three items was taken, and reliability was adequate (T0: $\alpha = .62$; T1: $\alpha = .64$; T2: $\alpha = .68$; T3: $\alpha = .70$).

Health Risks

Two items were summed for discussions of health risks: "sex can result in pregnancy" and "sex can result in a sexually

transmitted infection." The two items were significantly correlated for all four waves (T0: $r^2 = 0.58$; $P < .001$; T1: $r^2 = 0.71$; $P < .001$; T2: $r^2 = 0.74$; $P < .001$; T3: $r^2 = 0.77$; $P < .001$).

Birth Control

A single item asked, "if you are sexually active, [your parent(s)] will provide birth control."

Sex Permissive

For adolescents, two items were summed to create a "sex permissive message" including "being sexually active is okay" and "under what circumstances, if any, it is ok to be sexually active." The two items were significantly correlated at all four waves (T0: $r^2 = 0.49$; $P < .001$; T1: $r^2 = 0.54$; $P < .001$; T2: $r^2 = 0.51$; $P < .001$; T3: $r^2 = 0.42$; $P < .001$).

Monitoring and Dating Rules

Adolescents were each asked about the expectations for behavior in romantic relationships that they had decided upon [54]. They were asked to respond no (0) or yes (1) to a list of 15 possible rules, for example, "no dates on school nights," "come home at an agreed-upon time (curfew)," "use good judgment," and "be a gentleman/lady." Responses were summed. Internal consistency was good (T0: $\alpha = .83$; T1: $\alpha = .87$; T2: $\alpha = .86$; T3: $\alpha = .89$).

Program Participation

A measure of program participation was captured in two dichotomous variables—one for those participants who only engaged with the communication and alcohol components (0 all others) and one for those who engaged with some or all of the relationships component (0 all others). Thus, participants in the control group and those in the intervention group who did not initiate the program were the referents for the analyses.

Controls

Overview

The following five baseline adolescent characteristics were included: gender, age, race or ethnicity, sexual orientation, and sexual experience. Gender was dichotomized as female (0) and male (1), and age was treated as a continuous variable. Participants were encouraged to choose all racial or ethnic backgrounds that applied to them (American Indian or Alaska Native, Asian, Black of African American, Native Hawaiian or other Pacific Islander, White, and Other) and asked separately if they identify as Latino or Hispanic. Race or ethnicity was dichotomized, with White non-Hispanic coded as 0 and any affirmative racial or ethnic minority coded as 1. The measure of sexual identity followed best practice for assessing sexual orientation [55] as a composite of several responses, as follows: how they identify (heterosexual or straight, gay or lesbian, bisexual, or other), to whom they are attracted (only females, mostly females, equally males and females, mostly males, or only males), and with whom they have had sexual contact (males only, females only, both, or neither) [56]. Using their reported gender identity, participants were considered sexual minorities if they (1) chose a nonheterosexual self-identification, (2) reported any same-sex sexual contact, or (3) reported any

attraction to the same sex. This was recoded into one final item indicating heterosexual (357/411, 74.9%; coded as 0) and sexual (79/411, 19.2%; coded as 1) minorities. Finally, adolescents' responses to the question "Have you ever had sex (vaginal, oral, or anal)?" was coded such that negative responses were 0 and affirmative responses were 1.

Selection Model

As parents and adolescents could choose how far to continue with the program, selection bias may have confounded the dosage analyses. One approach to help account for such biases is to model the selection process and then include an instrumental variable representing it as a predictor in the primary analyses [57]. In this case, we conducted a probit analysis to predict the completion of the relationships component from relevant baseline measures and calculated an inverse Mills ratio (IMR) for each respondent based on the probit model. The IMR (nonselection hazard) was calculated in Stata version 15 (StataCorp LLC) using the two-step procedure described by Heckman [57]. This ratio is a function of the predicted probability (propensity) of completing the component and represents the underlying selection process. Given the focus of the relationships component, the baseline predictors included measures of parents' and adolescents' evaluations of and levels of communication in their relationship, parent-adolescent trust, parental monitoring, sexual communication, and demographics. Overall communication, adolescents' reports of ever having sex, gender, sexual orientation, and age were included in the selection models. Parents' self-reports of gender, income, and ethnicity were also used. When the IMR is significant in a model, this indicates that the predicted probability of completing the component is associated with the outcome, that is, the same factors that predispose families to complete (or not complete) the components are related to the outcomes. In models where program exposure is significant, this indicates that even accounting for factors that predict program completion, participation in the intervention is still related to outcomes. Selection models provide several benefits, including ease of use and wide use in research (a 700% increase in use over the last decade [58,59]). Selection models also address the selection of unobservable factors, whereas alternatives such as propensity score matching require self-selection of participants to be explained completely by observable factors [59].

Analyses

Examining alternative models, such as dosage models, has been proposed for trials with limited control over program exposure

and where substantial portions of participants do not appear motivated to fully adhere to the intervention implementation protocol [60]. Participants may lack motivation to complete prevention programs because the illnesses or discomforts have not yet occurred [60,61] in comparison with treatment trials that typically aim to improve an existing problem or condition (eg, alcoholism or diabetes). High rates of nonadherence in prevention trials could introduce type II errors by underestimating the effectiveness of the intervention [60]. For these reasons, we examined outcomes for experimental participants based on the level of program exposure, testing the hypothesis that some program exposure, more so relationships component exposure, will be related to increased sexual communication.

Outcomes were assessed using generalized estimating equations in SPSS (version 25) to account for repeated measures of each outcome (inclusive of baseline report) nested within participants. In each analysis, variables included adolescent gender, age, ethnicity, sexual minority status, report of sexual experience at baseline, measurement period, the IMR, and the two dichotomous variables for exposure to the intervention (one or two components: communications and alcohol only; all three components: communications, alcohol, and relationships component), such that those with no exposure comprised the referent group. The analysis of hypothesis 1 included only tests of the main effects of the variables. The analysis of hypothesis 2 added an interaction term for gender based on exposure to the intervention.

Results

Overview

At baseline, adolescents were aged 16-17 (mean 16.4, SD 0.5) years, and slightly more than half (226/411, 55.3%) of them were girls. About one-tenth (38/411, 9.5%) of the adolescents were Hispanic or Latino. Adolescents reported the following race or ethnicities: 72.5% (298/411) White, 1.9% (8/411) Asian, 11.7% (48/411) African American, 1% (4/411) Native American, 8.3% (34/411) multiracial, 2.7% (11/411) some other race, and 1.9% (8/411) unreported. There were no significant differences in demographic characteristics between the experimental and control conditions or among the amounts of intervention dosage. [Table 1](#) presents intervention dosage and survey completion rates.

Table 1. Intervention dosage and survey completion (N=411).

Survey wave or intervention component	Intervention (n=206), n (%)	Control (n=205), n (%)
Baseline (T0) survey completion	206 (100)	205 (100)
Intervention exposure		
No exposure	29 (14.1)	— ^a
Communication or communication and alcohol	89 (43.2)	—
Communication, alcohol, and relationships	88 (42.7)	—
6-month (T1) survey completion	150 (72.8)	165 (80.5)
12-month (T2) survey completion	147 (71.4)	164 (80)
18-month (T3) survey completion	145 (70.4)	164 (80)

^aNot available; those in the control group were not permitted to participate in the intervention and thus have no exposure data.

Changes Over Four Survey Waves (Baseline Through 18-Month Follow-up)

For all adolescents regardless of randomization or program exposure, there was a significant main effect of time on most communication outcomes, with most reports by adolescents decreasing over time (data not shown). There were significant decreases over time for overall frequency of communication, average frequency of specific topics, and number of topics discussed. There were also significant decreases in conversations regarding specific topics, including delaying sex, health risks, and dating rules. In contrast, there was a significant increase in conversations reflecting sex permissiveness at 12 months and again at 18 months. Discussions related to parental provision of birth control showed no main effects across time.

Adolescent Characteristics

Gender had a significant effect on most sexual communication outcomes. Adolescent girls reported greater sexual communication with parents regarding overall frequency, average topic frequency, and number of topics and were more likely to report communicating with parents about delaying sex. They were also more likely to report a greater number of dating rules. Boys were more likely than girls to report communication indicating that parents would provide birth control. There were no differences between genders regarding communication about sex permissiveness or health risks.

Previous sexual experience at baseline had a significant main effect on reported sexual communication with parents. Adolescents who reported previous sexual experience also had greater reports of overall frequency, average frequency, and number of topics discussed with parents. Adolescents with previous sexual experiences also reported greater sex permissiveness, health risk communication, and fewer reports of birth control provision, delaying sex, and dating rules.

Adolescents' sexual minority status also had significant main effects, with those whose sexual orientation was not strictly heterosexual, reporting more sexual permissive communications with parents. They also reported a lower average frequency of communication, less discussion about delaying sex, and fewer dating rules.

A few differences were found between White and racial or ethnic minority adolescents with White adolescents reporting greater average frequency and more discussions on delaying sex.

Hypothesis 1: Main Effects of Relationships Component

Significant main effects were found for participating in the intervention after controlling for gender, racial or ethnic status, age at baseline, sexual minority status, sexual experience, the IMR, and time in the model (Tables 2-4). As hypothesized, adolescents engaged in the relationships component reported higher levels of overall frequency of sexual communication with their parents ($B=0.30$; $SE\ 0.11$; $95\% \text{ CI } 0.08-0.52$; $P=.007$) than those with no exposure and those who participated in only the communication or alcohol component. Adolescents exposed to the relationships component reported significantly higher average topic frequency ($B=0.27$; $SE\ 0.12$; $95\% \text{ CI } 0.03-0.51$; $P=.03$) and a greater number of dating rules ($B=0.72$; $SE\ 0.37$; $95\% \text{ CI } 0-1.44$; $P=.049$). There were no main effects on other communication outcomes. As noted earlier, those who were exposed to only the communications and alcohol components were considered separately from those who were exposed to the relationships component. Exposure to only the communications or alcohol components was significantly associated with lower average topic frequency ($B=-0.24$; $SE\ 0.12$; $95\% \text{ CI } -0.47 \text{ to } -0.01$; $P=.04$).

Table 2. Results from generalized estimating equations: main effects of intervention exposure on adolescent report of sexual communication: topics (T0: n=411; T1: n=325; T2: n=311; T3: n=309).

Variables	Overall frequency				Average topic frequency				Number of topics			
	B	SE	95% CI	P value	B	SE	95% CI	P value	B	SE	95% CI	P value
Intercept	2.455	3.082	-3.585 to 8.495	.43	1.825	3.126	-4.301 to 7.951	.56	4.527	5.317	-5.895 to 14.948	.39
18 months	-0.437	0.069	-0.572 to -0.302	<.001	-0.436	0.057	-0.547 to -0.324	<.001	-0.690	0.116	-0.917 to -0.462	<.001
12 months	-0.352	0.065	-0.479 to -0.225	<.001	-0.358	0.048	-0.452 to -0.264	<.001	-0.424	0.102	-0.624 to -0.224	<.001
6 months	-0.360	0.066	-0.490 to -0.231	<.001	-0.344	0.051	-0.444 to -0.243	<.001	-0.638	0.107	-0.848 to -0.427	<.001
Male gender	-0.291	0.093	-0.473 to -0.108	.002	-0.254	0.095	-0.441 to -0.067	.008	-0.507	0.161	-0.823 to -0.191	.002
Sexual minority	0.020	0.133	-0.240 to 0.280	.88	-0.268	0.129	-0.520 to -0.016	.04	-0.053	0.200	-0.445 to 0.338	.79
Sexual experience	0.402	0.107	0.192 to 0.612	<.001	0.364	0.108	0.152 to 0.576	.001	0.712	0.173	0.374 to 1.051	<.001
Age (years)	-0.087	0.096	-0.274 to 0.101	.37	0.008	0.098	-0.183 to 0.200	.93	-0.025	0.165	-0.349 to 0.299	.88
Racial or ethnic minority	-0.107	0.113	-0.329 to 0.115	.34	-0.217	0.113	-0.439 to 0.005	.06	-0.294	0.178	-0.643 to 0.055	.09
Inverse Mills ratio	1.891	2.969	-3.928 to 7.710	.52	1.081	2.909	-4.622 to 6.783	.71	0.274	4.836	-9.205 to 9.752	.96
Exposure to communications or alcohol component	-0.139	0.119	-0.372 to 0.094	.24	-0.238	0.116	-0.465 to -0.011	.04	-0.283	0.208	-0.690 to 0.124	.17
Exposure to relationships component	0.299	0.111	0.081 to 0.516	.01	0.268	0.122	0.029 to 0.507	.03	0.132	0.174	-0.210 to 0.474	.45

Table 3. Results from generalized estimating equations: main effects of intervention exposure on adolescent report of sexual communication: cautionary communication (T0: n=411; T1: n=325; T2: n=311; T3: n=309).

Variables	Delay sex				Health risks				Dating rules			
	B	SE	95% CI	P value	B	SE	95% CI	P value	B	SE	95% CI	P value
Intercept	2.657	3.208	-3.630 to 8.943	.41	2.077	1.597	-1.052 to 5.206	.19	27.295	10.318	7.072 to 47.518	.008
18 months	-0.382	0.058	-0.495 to -0.269	<.001	-0.422	0.050	-0.520 to -0.323	<.001	-1.245	0.174	-1.586 to -0.903	<.001
12 months	-0.263	0.054	-0.369 to -0.157	<.001	-0.280	0.045	-0.368 to -0.191	<.001	-0.680	0.157	-0.988 to -0.372	<.001
6 months	-0.333	0.054	-0.437 to -0.228	<.001	-0.312	0.046	-0.401 to -0.223	<.001	-0.502	0.163	-0.822 to -0.181	.002
Male gender	-0.326	0.097	-0.517 to -0.135	.001	-0.082	0.058	-0.196 to 0.032	.16	-1.282	0.318	-1.906 to -0.658	<.001
Sexual minority	-0.384	0.117	-0.613 to -0.154	.001	-0.041	0.069	-0.177 to 0.094	.55	-1.088	0.426	-1.923 to -0.252	.01
Sexual experience	-0.219	0.103	-0.420 to -0.018	.03	0.182	0.059	0.067 to 0.297	.002	-1.249	0.346	-1.928 to -0.569	<.001
Age (years)	-0.106	0.096	-0.293 to 0.082	.27	0.006	0.058	-0.108 to 0.121	.91	-0.151	0.311	-0.761 to 0.458	.63
Racial or ethnic minority	-0.276	0.110	-0.492 to -0.060	.01	-0.092	0.063	-0.216 to 0.032	.15	-0.061	0.359	-0.764 to 0.641	.86
Inverse Mills ratio	0.967	2.943	-4.802 to 6.736	.74	-0.327	1.549	-3.362 to 2.709	.83	-14.403	10.268	-34.528 to 5.722	.16
Exposure to communications or alcohol component	0	0.119	-0.234 to 0.234	.99	-0.101	0.077	-0.251 to 0.049	.19	0.066	0.368	-0.655 to 0.787	.86
Exposure to relationships component	0.075	0.114	-0.149 to 0.298	.51	0.051	0.065	-0.075 to 0.178	.43	0.720	0.365	0.004 to 1.435	.05

Table 4. Results from generalized estimating equations: main effects of intervention exposure on adolescent report of sexual communication: positive communication (T0: n=411; T1: n=325; T2: n=311; T3: n=309).

Variables	Provide birth control				Sex permissive			
	B	SE	95% CI	P value	B	SE	95% CI	P value
Intercept	11.322	6.018	-0.472 to 23.117	.06	1.193	1.889	-2.509 to 4.895	.53
18 months	-0.047	0.145	-0.331 to 0.237	.75	0.112	0.050	0.014 to 0.210	.03
12 months	0.037	0.125	-0.208 to 0.281	.77	0.105	0.046	0.015 to 0.195	.02
6 months	0.067	0.129	-0.187 to 0.320	.61	0.019	0.049	-0.076 to 0.115	.69
Male gender	0.885	0.189	0.516 to 1.255	<.001	0.071	0.059	-0.045 to 0.187	.23
Sexual minority	-0.334	0.242	-0.809 to 0.140	.17	0.272	0.086	0.103 to 0.440	.002
Sexual experience	-1.405	0.213	-1.823 to -0.988	<.001	0.441	0.075	0.294 to 0.588	<.001
Age (years)	-0.104	0.196	-0.488 to 0.280	.59	0.051	0.063	-0.072 to 0.175	.41
Racial or ethnic minority	-0.247	0.217	-0.672 to 0.179	.26	0.027	0.066	-0.102 to 0.157	.68
Inverse Mills ratio	-10.420	5.826	-21.837 to 0.998	.07	-1.924	1.898	-5.644 to 1.795	.31
Exposure to communications or alcohol component	0.414	0.232	-0.041 to 0.869	.07	-0.097	0.072	-0.239 to 0.045	.18
Exposure to relationships component	-0.153	0.222	-0.588 to 0.282	.49	-0.019	0.071	-0.159 to 0.120	.78

Hypothesis 2: Interaction Effects of the Intervention by Gender

To assess the impact of exposure to the relationships component by gender, a series of analyses was conducted with interaction terms (Tables 5-7). The findings suggest that the impact of the intervention was stronger for girls than boys for overall

frequency of sexual communication (B=-0.41; SE 0.21; 95% CI -0.81 to -0.01; $P=.046$). However, the significant main effect of the intervention did not vary by gender for average frequency of specified sexual topics (relationships component: $P=.01$; relationships component by gender: $P=.12$) or for dating rules (relationships component: $P=.01$; relationships component by gender: $P=.32$).

Table 5. Results from generalized estimating equations: interaction effects of intervention exposure on adolescent report of sexual communication by gender: topics (T0: n=411; T1: n=325; T2: n=311; T3: n=309).

Variables	Overall frequency				Average topic frequency				Number of topics			
	B	SE	95% CI	P value	B	SE	95% CI	P value	B	SE	95% CI	P value
Intercept	2.277	3.077	-3.755 to 8.309	.46	1.691	3.105	-4.396 to 7.777	.59	4.404	5.306	-5.995 to 14.803	.41
18 months	-0.437	0.069	-0.572 to -0.302	<.001	-0.436	0.057	-0.547 to -0.324	<.001	-0.689	0.116	-0.917 to -0.462	<.001
12 months	-0.352	0.065	-0.479 to -0.225	<.001	-0.358	0.048	-0.451 to -0.264	<.001	-0.424	0.102	-0.624 to -0.224	<.001
6 months	-0.360	0.066	-0.490 to -0.230	<.001	-0.344	0.051	-0.444 to -0.243	<.001	-0.637	0.107	-0.848 to -0.427	<.001
Male gender	-0.200	0.109	-0.414 to 0.014	.07	-0.175	0.108	-0.387 to 0.037	.11	-0.438	0.189	-0.808 to -0.069	.02
Sexual minority	0.033	0.133	-0.228 to 0.295	.80	-0.256	0.129	-0.509 to -0.003	.05	-0.043	0.201	-0.437 to 0.350	.83
Sexual experience	0.396	0.106	0.189 to 0.604	<.001	0.359	0.108	0.148 to 0.571	.001	0.708	0.173	0.369 to 1.047	<.001
Age	-0.085	0.095	-0.272 to 0.102	.37	0.008	0.098	-0.183 to 0.200	.93	-0.024	0.165	-0.348 to 0.299	.88
Racial or ethnic minority	-0.119	0.115	-0.344 to 0.105	.29	-0.228	0.114	-0.452 to -0.005	.05	-0.304	0.179	-0.654 to 0.046	.09
Inverse Mills ratio	2.037	2.960	-3.765 to 7.839	.49	1.201	2.887	-4.458 to 6.860	.68	0.377	4.837	-9.103 to 9.857	.94
Exposure to communications or alcohol component	-0.145	0.119	-0.378 to 0.088	.22	-0.243	0.116	-0.471 to -0.016	.04	-0.287	0.208	-0.695 to 0.121	.17
Exposure to relationships component	0.462	0.153	0.161 to 0.763	.003	0.414	0.167	0.086 to 0.742	.01	0.255	0.214	-0.164 to 0.675	.23
Exposure to relationships by gender	-0.408	0.205	-0.809 to -0.006	.05	-0.359	0.230	-0.809 to 0.091	.12	-0.306	0.342	-0.975 to 0.364	.37

Table 6. Results from generalized estimating equations: interaction effects of intervention exposure on adolescent report of sexual communication by gender: cautionary communication (T0: n=411; T1: n=325; T2: n=311; T3: n=309).

Characteristics	Delay sex				Health risks				Dating rules			
	B	SE	95% CI	P value	B	SE	95% CI	P value	B	SE	95% CI	P value
Intercept	2.630	3.205	-3.652 to 8.912	.41	1.978	1.597	-1.152 to 5.108	.22	27.001	10.275	6.864 to 47.139	.009
18 months	-0.382	0.058	-0.495 to -0.269	<.001	-0.422	0.050	-0.520 to -0.323	<.001	-1.244	0.174	-1.586 to -0.902	<.001
12 months	-0.263	0.054	-0.369 to -0.157	<.001	-0.279	0.045	-0.368 to -0.190	<.001	-0.680	0.157	-0.988 to -0.372	<.001
6 months	-0.332	0.054	-0.437 to -0.228	<.001	-0.311	0.046	-0.401 to -0.222	<.001	-0.501	0.163	-0.821 to -0.180	.002
Male gender	-0.310	0.110	-0.526 to -0.094	.005	-0.029	0.068	-0.162 to 0.103	.67	-1.117	0.360	-1.822 to -0.412	.002
Sexual minority	-0.381	0.118	-0.612 to -0.151	.001	-0.034	0.071	-0.173 to 0.105	.63	-1.063	0.425	-1.896 to -0.229	.01
Sexual experience	-0.220	0.103	-0.421 to -0.018	.03	0.178	0.059	0.063 to 0.294	.003	-1.258	0.347	-1.938 to -0.578	<.001
Age	-0.105	0.096	-0.293 to 0.082	.27	0.007	0.058	-0.107 to 0.121	.90	-0.151	0.311	-0.760 to 0.459	.63
Racial or ethnic minority	-0.278	0.109	-0.493 to -0.064	.01	-0.100	0.063	-0.223 to 0.024	.11	-0.085	0.355	-0.782 to 0.612	.81
Inverse Mills ratio	0.990	2.945	-4.782 to 6.762	.73	-0.245	1.557	-3.296 to 2.806	.88	-14.142	10.266	-34.263 to 5.979	.17
Exposure to communications or alcohol component	-0.001	0.119	-0.235 to 0.233	.99	-0.104	0.077	-0.255 to 0.047	.18	0.055	0.369	-0.668 to 0.777	.88
Exposure to relationships component	0.103	0.140	-0.171 to 0.377	.46	0.144	0.077	-0.008 to 0.296	.03	1.023	0.400	0.239 to 1.808	.01
Exposure to relationships by gender	-0.070	0.228	-0.517 to 0.377	.76	-0.230	0.130	-0.484 to 0.023	.08	-0.751	0.747	-2.216 to 0.713	.32

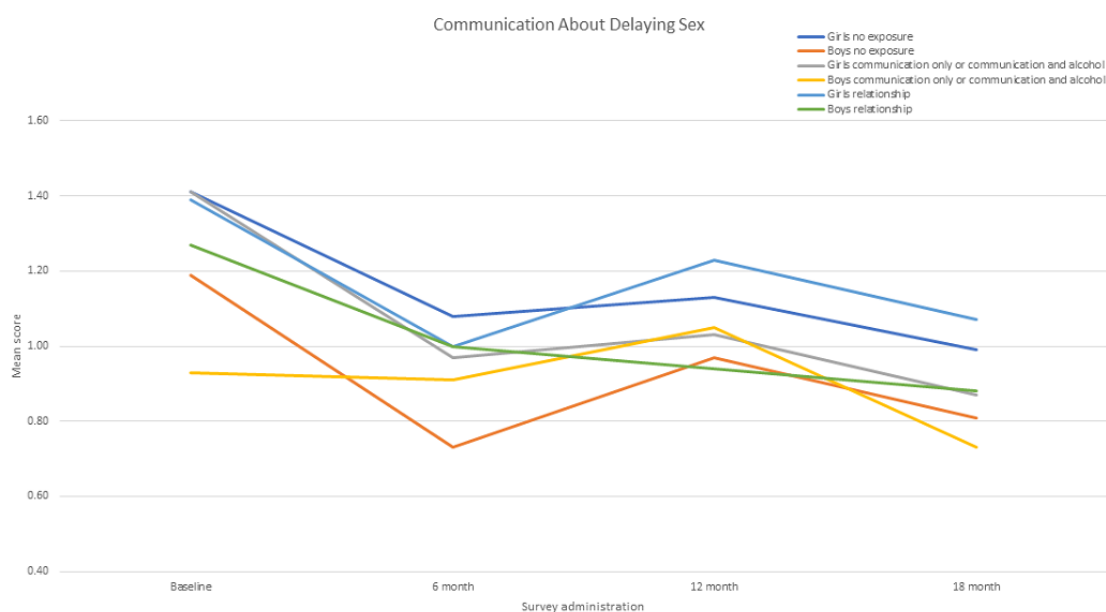
Table 7. Results from generalized estimating equations: interaction effects of intervention exposure on adolescent report of sexual communication by gender: positive communication (T0: n=411; T1: n=325; T2: n=311; T3: n=309).

Variables	Provide birth control				Sex permissive			
	B	SE	95% CI	P value	B	SE	95% CI	P value
Intercept	11.497	6.025	-0.312 to 23.307	.06	1.234	1.888	-2.468 to 4.935	.51
18 months	-0.046	0.145	-0.331 to 0.239	.75	0.112	0.050	0.014 to 0.210	.03
12 months	0.036	0.125	-0.209 to 0.282	.77	0.105	0.046	0.015 to 0.195	.02
6 months	0.067	0.130	-0.188 to 0.321	.61	0.019	0.049	-0.076 to 0.115	.69
Male gender	0.788	0.220	0.357 to 1.220	<.001	0.052	0.069	-0.083 to 0.187	.45
Sexual minority	-0.348	0.244	-0.827 to 0.131	.16	0.269	0.086	0.100 to 0.439	.002
Sexual experience	-1.399	0.214	-1.819 to -0.979	<.001	0.442	0.075	0.295 to 0.589	<.001
Age	-0.104	0.196	-0.489 to 0.280	.59	0.051	0.063	-0.072 to 0.174	.42
Racial or ethnic minority	-0.235	0.219	-0.664 to 0.194	.28	0.030	0.066	-0.099 to 0.159	.65
Inverse Mills ratio	-10.580	5.814	-21.976 to 0.816	.07	-1.960	1.897	-5.679 to 1.759	.30
Exposure to communications or alcohol component	0.419	0.231	-0.033 to 0.871	.07	-0.096	0.072	-0.238 to 0.046	.19
Exposure to relationships component	-0.308	0.288	-0.872 to 0.255	.28	-0.054	0.093	-0.237 to 0.128	.56
Exposure to relationships by gender	0.431	0.435	-0.421 to 1.283	.32	0.087	0.135	-0.178 to 0.351	.52

Post Hoc: Interaction Effects of the Intervention Over Time by Gender

Three interaction effects were added to assess the impact of the intervention over time and by gender: (1) intervention by survey administration time, (2) intervention by gender, and (3) intervention by time by gender (data not shown). There were indications of an impact of the intervention over time (regardless of gender), with higher reports of several communication outcomes. At 6 months, adolescents in the intervention group reported more communication about delaying sex (B=0.27; SE

0.14; 95% CI -0.004 to 0.54; $P=.05$) and health risk communication (B=0.22; SE 0.11; 95% CI 0.01-0.44; $P=.04$). At 12 months, they reported more communication about the provision of birth control (B=0.70; SE 0.36; 95% CI -0.01 to 1.41; $P=.05$). Only one communication outcome showed some differential impact of the intervention over time by gender: as noted in [Figure 2](#), the lighter blue line represents girls exposed to the relationships component, whose report of more communication regarding the delay of sexual behavior was significant at 12 months (B=-0.44; SE 0.22; 95% CI -0.87 to 0.01; $P=.05$).

Figure 2. Gender by exposure over time (mean scores).

Discussion

Principal Findings

The data support the efficacy of the Smart Choices 4 Teens intervention in increasing adolescent and parent communications about sexual relationships (eg, frequency) and increasing parental guidance (eg, dating rules). There was some support for our first hypothesis, in that the intervention had a main effect on frequency of communication and dating rules set for the adolescents, even after controlling for other adolescent characteristics that were also significant predictors of adolescents' reports of sexual communication with their parents, including developmental changes over time, as well as adolescent gender, sexual minority status, and sexual experience.

There was some evidence to suggest that the intervention impacts parent-adolescent communication based on the gender of the adolescent. In general, girls are more likely than boys to report more frequent parent-adolescent conversations, and there was some evidence that the intervention had a greater long-term impact on increasing conversations about delaying sex with girls. One possible explanation may be that parents either consciously or unconsciously consider adolescent girls to be more responsible for sexual decision making than boys. Another possible explanation is that mothers are engaged in more conversations with adolescents than fathers; parent-adolescent communication about sexual activity may be more *comfortable* when conducted with same-sex combinations.

However, there were more indications that the intervention had some impact on sexual communication over time, irrespective of the gender of the adolescent. When accounting for the possible interaction between the time of administration, gender of the adolescent, and exposure to the relationships component, the effect of the relationships component over time (and not by

gender) was more often the one that demonstrated an impact on the communication outcome. Throughout the literature on adolescent sexuality, although many sexual outcomes and measures of sexual communication often vary by gender, we found that this intervention had an impact on adolescents regardless of their gender. The intervention increased the number of sexual communication reports from both boys and girls, even in terms of dating rules, which also contained items that indicated the greater parental monitoring of adolescent relationships. There was no indication of an interaction effect between gender and intervention exposure on dating rules. Previous research indicates that girls (and parents of girls) tend to report greater relationship monitoring, as indicated by a higher number of dating rules. However, participating in the intervention increased the dating rules for all participants and was durable across time.

Findings from the study are limited by the overall number of families that engaged in the relationship component and the ability of the probit model to capture their most salient features [62]. The number of families completing the program also limited the ability to test differences in outcomes for adolescents who represent sexual and ethnic minorities. Replication studies that allow a more extensive examination of program effects are needed. Given that significant results were found with a reduced number of families, future replication studies that address engagement may find more robust support for the program. Forcing families to complete the two other components before accessing the relationships component contributed to the reduced completion rate for families in this component. Additional trials are needed to replicate these findings, and these efforts need to address engagement efforts that may help sustain families in completing the intervention. Future studies may also allow families to choose the order of completing the components. Engaging families in prevention programs requires overcoming

the perception of many parents that their children do not need prevention programs because they have not observed any problems in the targeted areas.

Developing a universal prevention program for families that addresses adolescent relationships requires balancing the divergent views and needs of families. By allowing adolescents and parents to separately negotiate the program, this program allowed some self-determination in covering the materials and the amount of time they spent on the various elements of the program. Providing families with four different discussion scenarios and guiding questions meant that families had some element of choice in deciding what was most relevant to their family. Future replications of this program could enhance these discussion topics to address current issues that emerge in the community (eg, emerging challenges regarding casual sexual hook-ups for adolescents to negotiate). Future replications could also embed updated factual information into existing program elements (eg, state-specific rates and types of sexually transmitted infections for adolescents). Finally, the sexual and gender diversity of the adolescents were not examined in depth to further disentangle the impact of the program on specific adolescents. Gender was measured as a binary construct, which has decreasing relevance over time, as many adolescents have chosen to identify ways that defy such rigid definitions. Future implementation and assessment of this intervention will ensure

that nonbinary gender identification choices are permitted. Although the measure of sexual diversity was inclusive, the sample size and space limitations did not permit more detailed analyses to understand nuance beyond strictly heterosexual or not.

Beyond the ability to adapt a web-based program for families, other advantages for building on an existing web-based intervention are that the costs for web-based delivery are relatively small and the reach is potentially large. Engaging families and making web-based programs accessible are important issues to be addressed in future research. Such programs can complement existing program efforts in schools and health care settings.

Conclusions

The Smart Choices 4 Teens intervention was designed to be sensitive to the transition to young adulthood and increased independent decision-making. The intervention addresses critical needs for families of older adolescents, including the perspectives of adolescents and parents, leveraging the continued influence of parents even later in adolescence, and permitting flexibility to the schedules of families. Most importantly, this intervention shows promise for long-term impact on increasing parent-adolescent sexual communication, potentially providing some skills and capacity to handle the relationship demands of older adolescents.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT (Consolidated Standards of Reporting Trials)-eHEALTH checklist (version 1.6.1).

[[PDF File \(Adobe PDF File\), 12447 KB - pediatrics_v4i2e19114_app1.pdf](#)]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials

IMR: inverse Mills ratio

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Original Paper

“It's Been Negative for Us Just All the Way Across the Board”: Focus Group Study Exploring Parent Perceptions of Child Screen Time During the COVID-19 Pandemic

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Abstract

Background: Child screen time (ST) has soared during the COVID-19 pandemic as lockdowns and restrictions have forced changes to regular family routines. It is important to investigate how families are navigating ST.

Objective: This study aimed to explore families' experiences of ST during the COVID-19 pandemic.

Methods: Virtual focus group sessions were conducted between December 2020 and February 2021 in English and Spanish. Transcripts were analyzed using reflexive thematic analysis.

Results: In total, 48 parents (predominantly Hispanic) residing in California participated in 1 of 14 focus group sessions. Children were attending school remotely at the time of the study. A total of 6 themes and 1 subtheme were identified: (1) total ST has increased; (2) children are too attached to screens; (3) ST has advantages and disadvantages but parents perceive ST as mostly negative; (4) parents and children have limited options; (5) ST restrictions (subtheme: children react negatively when ST is restricted); and (6) parents are concerned that children are not getting enough exercise.

Conclusions: This study provides a cross-sectional insight into how family life has changed with regard to ST during the COVID-19 pandemic. Parents expressed concerns about total ST, the addictive nature of it, and lack of physical activity. It is important that future studies examine the long-term effects of heavy ST and preemptively introduce ways to redirect children's ST habits as the country attempts to establish a new normal.

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KEYWORDS

children; COVID-19; experiences; family; outcomes; pandemic; parenting; parents; screen time

Introduction

The COVID-19 pandemic has transformed family life in myriad ways. The pandemic has presented an unprecedented situation where for many, work and family life have collided [1,2]. Some parents are finding themselves working from home for the first time [3], and in addition they may also be juggling distance-learning for their children [4]. Concomitant effects of the pandemic include fewer support systems available for assistance, such as in-person schooling [4,5], child care [2,6],

and even emotional support [7], thus exacerbating the complexity of the situation for parents and families. The pandemic has forced many families to create new norms and routines to reestablish an equilibrium within their homes and lives.

An area that has been affected within families is screen time (ST) [8,9]. The use of screens has increased for children as many schools nationwide shifted from conducting classes in person to conducting them remotely. Lockdowns and closures of schools, recreational centers, and organized sports have also

prevented families from engaging in regular activities. Singularly and collectively, these actions are likely to lead to an increase in the use of screens in households nationwide.

ST is associated with both positive and negative outcomes among youth [10]. Potential benefits include opportunities to engage socially with others [11], including actively engaging on social media (eg, posting content), which may provide some protection against depression [12]. ST has also been linked to children's learning [13], higher friendship quality, and a positive academic orientation [14]. Included among the negative associations are depression and anxiety [15], lower well-being [15], sleep disturbance [16], weight gain [17], and adverse dietary outcomes [18]. Observational and experimental studies have linked ST to an increased risk of obesity, and increased energy intake has received support as an explanatory mechanism [19]. Snacking during television viewing is associated with an increased risk of obesity [20], which could be exacerbated during times of stress and magnified by preferences for comfort foods. One study found that youth who watch the television for more than 5 hours a day have 5-fold higher odds of being overweight than those who watch the television for less than 2 hours a day [21]. An additional mechanism that has received support in explaining the link between ST and obesity is targeted advertising, which has intensified during the pandemic [22].

The American Academy of Pediatrics (AAP)'s guidelines for media use in school-aged children and adolescents calls for a healthy balance to be established by parents and pediatricians [23]. Parents and pediatricians are encouraged to work together to create a Family Media Use Plan that sets boundaries and is in the best interest of the child, prioritizing sleep, exercise, and breaks from media. Parents may need to reevaluate their family ST practices during a pandemic that causes changes in usual routines.

The objective of the present study is to describe families' experiences of ST during the COVID-19 pandemic. While it is expected that ST will increase, particularly owing to remote schooling, it is not clear how families are managing overall ST or what parents' perceptions are of their child's ST, and how ST is influencing family functioning during this time. Given the unprecedented situation of school closures and cyclical lockdowns, there exists a lacuna of studies on ST in families during the COVID-19 pandemic. As the nation prepares to return to a new normal, it is important to understand how ST within families will evolve as well as to anticipate any long-term attendant effects.

Methods

Sample Selection

Parents were eligible to participate in the study if they had at least 1 child between the ages of 5-18 years and access to the internet. Recruitment strategies included inviting parents to participate from a pre-pandemic contact list of families that had

indicated their interest in participating in a health study for Hispanic families (fliers were handed out at grocery stores, flea markets, local schools, and churches). Additionally, participants were recruited by word of mouth, snowballing, social media (eg, an announcement on a Parents' Group), and an email announcement through a student listserv in the Child and Family Science Department at California State University, Fresno.

Data Collection and Participants

The present study is part of a qualitative study designed to explore mealtimes, ST, and family functioning during the COVID-19 pandemic. A focus group guide was created to tap into family life during the pandemic and was developed on the basis of previous studies on family functioning and process, as well as a review of the ST literature. Focus group methodology was selected as the study design owing to the unprecedented nature of the pandemic and with the goal of offering a space for parents to engage in an open discussion on family life. In total, 48 parents participated in 1 of 14 focus group sessions (average of 3 participants per group) that were conducted between December 2020 and February 2021. Focus group sessions were conducted in English (n=6) and Spanish (n=8). All focus group sessions were conducted on Zoom and lasted 70 minutes on average. Focus groups were recorded and led by 2 trained facilitators. Participants received a US \$25 gift card for participating in the focus groups and filling out an anonymous brief demographics survey that included questions about employment, remote work, essential worker status, virtual schooling, and location.

The Department of Child and Family Science's Review Committee for the Protection of Human Subjects at California State University, Fresno, approved the study. Participants provided both written and verbal informed consent before participation.

Demographics of the Study Participants

In total, 48 parents participated in the study. All participating parents were mothers, with the exception of 1 father. Participants resided in California; most (94%) lived in the Central Valley. Our participants were predominantly Hispanic (n=39 of 48, 81%), 7 (15%) identified as White, and 2 (4%) identified as Asian. All children were engaged in distance-learning at the time of the study. The average age of the children was 11.13 (SD 5.87) years and that of the parents was 37.48 (SD 8.37) years. The median number of children per family was 2.5. More than half (n=29 of 48, 60%) of the sample reported an annual income of less than US \$50,000, and most were married or cohabitating (n=38 of 48, 79%). In total, 12 of 48 (25%) participants had a bachelor's or master's degree. A total of 18 (38%) parents were employed, half of whom (n=9 of 18, 50%) were working from home at the time of the study, and approximately half (n=25 of 48, 52%) of the sample comprised essential workers or lived with one. [Table 1](#) shows a breakdown of the participant characteristics.

Table 1. Demographic characteristics of the parents included in this study (N=48).

Characteristics	Values
Parent age (years), median (IQR)	37.5 (32.0-43.8)
Child age (years), median (IQR)	11.5 (7-15)
Children per family, median (IQR)	2.5 (2-4)
Employment status, n (%)	
Employed	18 (38)
Working remotely	9 (19)
Education, n (%)	
Less than high school	14 (29)
High school	14 (29)
Technical school	4 (8)
Professional degree	2 (4)
Bachelor's degree	5 (10)
Master's degree	7 (15)
Declined to respond	2 (4)
Annual income (US \$), n (%)	
≤19,999	13 (27)
20,000-29,999	5 (10)
30,000-39,999	6 (13)
40,000-49,999	5 (10)
50,000-59,999	3 (6)
60,000-69,999	3 (6)
70,000-79,999	2 (4)
80,000-89,999	1 (2)
90,000-99,999	1 (2)
≥100,000	8 (17)
Declined to respond	1 (2)

Data Analysis

Audio recordings were transcribed verbatim by research assistants. The 8 focus group sessions in Spanish were transcribed and translated to English by 3 proficient bilingual research assistants. Back-translations were then performed by a proficient bilingual research assistant who had no exposure to the original recording or transcript. To ensure accuracy in the translations, back-translations were compared to the original transcripts. Discrepancies were minor and resolved through consensus.

Transcripts were analyzed using reflexive thematic analysis [24] and an inductive approach within a phenomenological framework. Three researchers (AJH, EV, and RR) familiarized themselves with the transcripts and created their own codes through data immersion. Researchers shared the codes, agreed on them, and applied them independently to the transcripts. Researchers regularly discussed the codes and revised and refined them as necessary. Patterns of meaning in the data

guided the generation of preliminary themes, and the codes were then reexamined by the research team to ensure the fit of the themes. The final step involved selecting representative quotes. Data were analyzed using Dedoose (version 8.3.47, University of California, Los Angeles) [25].

Results

Results Overview

Themes did not differ between the parents who participated in the English and Spanish language group sessions. Six key themes and one subtheme were identified: (1) total ST has increased; (2) children are too attached to screens; (3) ST has advantages and disadvantages but parents perceive ST as mostly negative; (4) parents and children have limited options; (5) ST restrictions (subtheme: children react negatively when ST is restricted); and (6) parents are concerned that children are not getting enough exercise. Table 2 contains representative quotes for each theme and subtheme.

Table 2. Themes and representative quotes.

Themes	Quoted responses
Theme 1. Total ST ^a has increased	<ul style="list-style-type: none"> • “Oh, good God, I would have to say that with me, I feel like my kids are on the computer all the time.” [Participant #1, mother] • “So, I mean, they’re on it, except for dinnertime, they are on the computer.” [Participant #4, mother] • “So, screen time has exponentially increased in the pandemic.” [Participant #16, mother]
Theme 2. Children are too attached to their screens	<ul style="list-style-type: none"> • “All day long, since dawn my daughters are already watching TV, they are with the iPad in hand or with the phone and it is practically all day. If they go out to play, it is for very little, and it is because I have to be behind them, ‘leave me the phone, turn off the TV’. I go and I turn them off. If it was up to them, all day long they will be using their phone or TV.” [Participant #29, mother] • “It’s like they want to be there all the time so I literally have to remove the device, put them away where they can’t get them so they can go do something else. So, they definitely struggle with just kind of wanting to do that all the time.” [Participant #14, mother] • “Mine too, since the pandemic started. Classes on the computer, the phone, the games...the little girl who is 7 is addicted to the telephone. She has made it difficult to take it away because we don’t go outside much. Yes, even me, because I have a part-time job. Since everything is on social networks, we spend more time on the phone. My husband is the only one not so much on the phone because he has to work. When he arrives [home] he is on his phone.” [Participant #38, mother] • “I’ve noticed my kids have that addictiveness too. When they get in trouble, that’s the thing, we take away from them and it’s almost like you are taking, I hate to say it, like drugs away from a drug addict, they just get so upset and so emotional and it’s just, it’s the end of the world for them. I, I don’t like that at all, so it’s kind of like, what are we going to do, it’s because of the situation that we are in, darned if you do, darned if you don’t situation, because they need it for school and they need it for social interactions like, so I feel you almost have no choice in this situation.” [Participant #13, mother]
Theme 3. ST has advantages and disadvantages, but parents perceive ST as mostly negative	<ul style="list-style-type: none"> • “I think the good thing that we’ve noticed is that both of these kids have become extremely knowledgeable on technology. And so, for that, I would say that’s a positive. I can tell you that at four years old, I would not have been able to do the things that they do on technology. But I think that it’s good that they’re learning these skills and things as young as they are. I just want to make sure that it doesn’t continue to be their entire worlds. And they still get those opportunities to do the kids things like go outside and play, and imagine, and get creative outside of technology too.” [Participant #19, mother] • “Well, I don’t like the amount of screen time, I don’t think it’s a positive thing overall. That being said, it’s been a way for her to connect with people, with friends and that’s been good for her mental health to have that connection, and that’s why I’ve allowed her to be on her screen a lot more than I normally would, because of the connection aspect. It’s been, it’s been negative in the way of her... almost being addicted to her device, and so there has been struggle at times when I ask for the device back before bed times, and different times if I want her to focus on her homework and she’s not quite ready, however it might be, she will get, she will become challenging with me and not want to give it up so that’s created some struggle for sure during all of this time. So yeah, but it’s definitely changed and I don’t like the amount of time she’s on it, but I allow it based on the situation that we’re in.” [Participant #11, mother] • “I would definitely say for our household it’s been a negative just because I’ve noticed...more so, I mean, like they’re just fatigued easier. They’re more irritable across the board with each other. But I think it’s, almost turning into like an addiction. Like my 10-year-old has a really hard time giving up his games. Like, OK, it’s time to put it down, like, and there’s definitely more fights and definitely more angst in me. Now we have that. ‘Just let me finish this game’. ‘Let me finish this game’. You know, or like my daughter who doesn’t create problems but can retreat into her room and just sit and watch, like binge watch TV shows, you know. And so, I would say it’s been negative for us just all the way across the board.” [Participant #16, mother]
Theme 4. Parents and children have limited options	<ul style="list-style-type: none"> • “Well, I would honestly not like that much time [screen time] but then I say, well what else can they do? Sometimes I ask them to read and they just read a little and so on, or we go walk the dogs at night, but nothing else.” [Participant #31, mother] • “Like [other participant] said, I wish we can take back time, but how things are right now, we do not have a lot to replace it with. Because the sibling that is closest with him in age is 16, 7 years apart, it makes it really challenging for the both of them. She is a good sport and can be but it is really hard. Yeah, I wish it could be different but the circumstances are how they are, just like me drinking a glass every single night is not the greatest thing. That is not for me to change my actions right now because we are in the thick of it. That is kind of where I feel like my youngest is with his screen time and we try to help him and take him off of it. We watch movies together, but there is only so much you can do. There are no alternatives that can be presented to him, I do not have a lot of things to threaten him with. Options are limited.” [Participant #6, mother] • “I mean, like I said, he [dad] has really created a schedule for them. And so, he does a good job about saying, ‘nope, right now is a no technology time. Shut it off. Go play together’, or ‘this is outside time’. And so, he’s put that together. But there are some days that that doesn’t work for his work schedule and he has a meeting at that time. And so that becomes a technology time and it’s OK to kind of make those adjustments.” [Participant #19, mother]

Themes	Quoted responses
Theme 5. ST restrictions	<ul style="list-style-type: none"> “But now that I have noticed it more, that I have lost more control, and she has been more on the T.V., I have tried to set limits. I tell her, ‘No, no, no, that is enough screen time, we are going to play this’. I try to do things with her, well in my case since she is young, I make her do more manual things. I teach her things, like if I am making tortillas, I have her help me. Although she is little, I want her to interact more with me, that we are together, that she interacts more with me than the television.” [Participant #21, mother] “For me I’ve tried to set certain hours for them, they understand for a few days but then they kind of don’t care much about what I tell them. First, I used to tell her, ‘you have certain hours to use the phone, computer, television’, whatever they’re using, or I’d tell her to turn off the phone in an hour. She just did it in the first few days and then she would forget and grab it again when she wanted.” [Participant #29, mother] “In my point of view, it is more, much more difficult to restrict it. If you tried to control the personal use that they have, obviously it is very difficult because as I mentioned before, my children talk a lot among themselves and they want to do what other children do. This and especially as I mentioned before they are not interested in doing another activity and they are very clever. My oldest child tells me, ‘I do my homework, I behave well at school, I help you do my chores, why not? Why can’t I use it?’ So, it is difficult for me to explain to him that he should do something else. So, it is very difficult.” [Participant #47, mother]
Subtheme 5.1. Children react negatively when ST is restricted	<ul style="list-style-type: none"> “Yes, we have tried [screen time restrictions] but it’s super, super difficult. In truth, my family is very, very difficult. I have seven children, one 18, one 17, one 15, one 13, one 8, and a 3-year-old girl and a 6-month-old baby. It has become very, very difficult for me to set rules on this. Because the children, the two oldest, get very rebellious because they want to be playing with the other children. It’s a fight every day, they say, ‘You don’t let us play, we are not going to the park, we’re going to our friends house to play’. I can’t do anything other than to help their whims that they want to be playing on the computer. You just hear the fighting and shouting here in front of the television. ‘Oh no, they killed me’. Very angry. Oh no, it has been very difficult for me.” [Participant #42, mother] “Like, I want him to, you know, play games with friends and bond because he’s so isolated. But my problem is that he feels like he has access 24/7, and my rules, he doesn’t listen to my rules. And so, he’s going in past bedtime and I’m finding his eyes on screens or playing games and stuff. And I have tried every combination I can think of. So now they’re restricted. So now he’s more isolated. So, it’s hard. It’s very hard.” [Participant #10, mother] “It has been bad just because if we don’t allow them to, if they ask, ‘can I play on the tablet’ or ‘oh, can I play Xbox?’ and we tell them no, they are at such a young age, they can’t really comprehend or know how to calm themselves after that. When we say no, they should, they should kind of be able to calm themselves down. As in like not throw a tantrum once, once we say no. And then we try our hardest not to give in. But at times, if we’re trying to cook and...they’re just crying and just going like everywhere and not focusing on what we’re telling them to do, then we’ll just be like, ‘OK, go ahead and go on the tablet. It’s fine, but it has to be school related’. It has made their attitude a little bit, in a negative way, just because they’re craving to have that screen time when normally we would just go outside. They wouldn’t want to go outside.” [Participant #5, mother]
Theme 6. Parents are concerned that their children are not getting enough exercise	<ul style="list-style-type: none"> “And they have gained weight through the pandemic. I attribute it to all those things...the screen time, the being sedentary, the snacking and all of that stuff. And like...my son used to be you know, he would and my daughter, they would have their basketball or they would have their sports practices every day. And so, it’s like not having that motivation. Their normal activities. And they’re finally hitting this, like, pre-teen where you’re getting all these hormones. So, I’m not necessarily worrying so much about my little ones, but I’m, I am very concerned about my older ones just because that can be detrimental going into your teen years and being overweight and struggling with that and like having a whole year of not doing anything and not having all that, and then not necessarily like me being able to motivate them. I mean, they do PE, so they’ve been doing yoga for their PE classes. They have to. But I mean, like, it’s a 30-minute workout video that they do two days a week, which doesn’t really give you any benefit. So, I would say, yes, I am very concerned for my own kids.” [Participant #16, mother] “It worries me because before when they went to school they made them exercise at break time, and now they don’t do anything.” [Participant #48, mother] “They’re not doing sports, they’re not running around outside with their friends, yeah, I do have concerns.” [Participant #13, mother]

^aST: screen time.

Theme 1. Total ST has Increased

Parents described how ST changed during the pandemic. ST greatly increased, with children spending much of the day engaged with screens. Screens were used for both school and recreational purposes. The most common nonschool screen activities that children engaged in, as discussed by the parents, were watching television, playing video games (eg, on the Nintendo Switch, Xbox, and app-based games), watching YouTube videos, and spending time on social media platforms such as Facebook, Instagram, and Tik Tok. Several parents

remarked that their children played video games often with other people, usually their friends or other family members.

Parents also disclosed the amount of time their children spent on screens for purposes of school vs recreation. These values are presented here to supplement their descriptions. ST increased for families, partly because children attended school remotely; however, parents indicated that their children’s recreational use of screens represented almost half of their total daily ST. Children were on screens an average of 8.21 (SD 2.22) hours a day, with an average of 3.30 (SD 1.59) hours of that time being spent on nonschool activities. While 29% of the sample shared

that their children were spending ≤ 2 hours on their devices for recreational use during the pandemic, 36% of the sample disclosed that their child's recreational ST was ≥ 4 hours a day.

Theme 2. Children are Too Attached to Their Screens

One of the most prevalent themes was that parents felt that their children had become too attached to screens. Many parents used the word "addicted" to describe children's ST behavior during the pandemic and felt that their children would be on their devices constantly if they were allowed. Some parents described their children's behavior to consist of waking up and going to bed with screens. Parents noticed an increase in their children's desire to spend time on screens rather than engage in other activities. A few parents disclosed that their children would even race through meals or family time so that they could return to their screens. Most parents discussed an increase in resistive behaviors (eg, arguing, irritability, and refusal) when children were asked to stop using their devices. Lastly, a few mothers noted that not only the children but also the adults were "addicted" to screens during this time.

Theme 3. ST has Advantages and Disadvantages but Parents Perceive ST as Mostly Negative

Parents acknowledged both the advantages and disadvantages of ST. Parents recognized the many purposes that technology served during the pandemic, especially by providing an option for their children to continue their education from home. Advantages also included becoming more comfortable with technology, especially for younger users, and providing children, particularly adolescents, with a critical outlet for social interaction. Disadvantages included deprivation of face-to-face social interaction, less physical exercise, concerns about sleep problems, strained eyes, and limited parental oversight. Some parents expressed that it had become more difficult to monitor children's ST now that their children were spending so much time on screens.

Despite recognizing both the advantages and disadvantages of ST, most parents felt that ST had a more negative rather than positive (or neutral) influence during the pandemic. The effects they observed with regard to ST were manifold and included increased arguments at home, too much attachment to devices, less physical activity, and disobedient behavior. Many parents expressed concern that their children were simply spending too much time on screens and that it had been challenging to enforce ST rules. Some parents described this as a "constant" fight or an ongoing "battle." A few parents expressed that their children had developed "attitudes" as a result of too much ST. Only 2 parents in the sample indicated that ST was overall more positive during the pandemic.

Theme 4. Parents and Children Have Limited Options

Many parents discussed how the pandemic greatly limited what children and families could do, and that this subsequently led to an increase in ST. On the one hand, children had to use their screens for school, but they were also no longer able to spend time in their regular activities such as organized sports, attending social gatherings, and connecting with their friends in person. Children missed their friends and felt a sense of connection by being active on the internet. Sometimes this took the form of

social media, sometimes playing video games with other children on the internet, and at other times through FaceTime calls with friends or other family members. A lot of the time children felt bored, and the internet provided them with entertainment. A few parents noted that ST offered stress relief for their children and was a way for them to cope during such an uncertain time. Some parents also mentioned that they themselves were out of other options in terms of directly supervising their children while they were working; hence, ST provided their children something to do while they tended to their tasks.

Theme 5. ST Restrictions

The majority of parents expressed that they had attempted to restrict their child's ST in some capacity. This was met with varying degrees of success, but many parents reported struggling to enforce their rules. Sometimes parents resorted to taking devices away and hiding them (especially before bed) to keep their children from using them. Some discussed how they ultimately ended up relaxing the rules because they found them to be either unenforceable or that they wanted their children to feel connected to their peers through screens. The limited number of activities was also discussed as a reason for why there was an increase in leniency. A few mothers shared that their ST rules had not changed and continued to be enforced in the same way during the pandemic.

Subtheme 5.1. Children React Negatively When ST is Restricted

Parents discussed their children's reactions to ST restrictions and expressed that they tended to respond in negative ways. Parents reported that their children argued with them about pausing their use so they could do something else. For younger children, meltdowns would sometimes ensue, and with both younger and older children, parents reported that they would sometimes ignore their requests to stop using their devices. While most parents reported encountering some type of difficulty or resistance in pausing the use of screens, a few mothers expressed that their children had no problem with stopping ST.

Theme 6. Parents are Concerned That Their Children are not Getting Enough Exercise

The majority of parents were concerned about their child's physical activity and felt that they were not getting an adequate amount of physical activity during the pandemic. Some parents noted the absence of organized sports and regular school activities as contributing to the problem. Others expressed that it was challenging to get children outdoors and away from their devices. Virtual physical education (PE) was indicated by some parents, but this was mostly dismissed as inadequate in part because it was offered too infrequently, or in some cases cameras were not required to be turned on during the sessions; thus, children could easily opt out of participating. A few parents expressed that their children were not getting any exercise at all during this time.

Discussion

Principal Findings

The pandemic has upended families' regular routines, and an increase in ST has been one consequence. This study provides insight into how families have been navigating ST during the pandemic. Parents expressed concerns about total ST, the addictive nature of it, and the lack of physical activity. One pre-pandemic study found that 45% of teenagers reported that they were always connected to the internet [11]; this percentage is likely to be much higher now and to factor in younger children as well. Similar to a pre-pandemic study that reported that some parents of preschoolers described their child as being "addicted" to ST [26], the parents of children of varying ages in this study were concerned about the addictive nature of screens. Several parents described addictive behaviors that are consistent with symptoms of problematic internet usage, including preoccupation with being on the internet and withdrawal symptoms [27,28].

How children are using screens and what content they are viewing are critical for advancement of the understanding of how ST influences child development. A significant portion of ST has been spent engaged in remote-schooling during the pandemic, but parents also expressed that a considerable proportion of ST has been spent in recreational use. More than one-third of the sample indicated that their child's recreational ST accounted for ≥ 4 hours per day. Some parents also linked their child's ST to concerns regarding the lack of physical activity. Increased ST in a country where obesity is already an epidemic, with 18.5% of the youth considered to have obesity before the pandemic [29], may have a profound lasting effect on weight gain in children.

Some parents expressed that their children were engaged in a PE course that was delivered remotely by their child's school. Nonetheless, parents were not very optimistic about children gaining many benefits from the classes in part because they were offered too infrequently or because their children did not participate. A few parents also discussed the potential engagement of their children in games on their devices, which include movement; it will be helpful for future studies to assess sedentary vs nonsedentary game activities and quantify the benefits accrued from participating in screen-based physical activity games. Studies have reported that some active video games are effective in increasing physical activity [30], but more studies are needed in this area. In a recent publication, promoting physical activity via screens was recommended as a healthy way to engage in ST during the pandemic [31]. How these recommendations have been (and will continue to be) translated into practice will be important to assess. Unfortunately, most parents in our study did not report activity-based screen games as regular activities their children engaged in when using their screens, and most parents were worried about the amount of physical activity their children were getting. Additionally, 4 of 5 households have some type of device that can be used to play video games [32], and 75% of US households include a minimum of 1 person who plays video games [33], a number that is likely to increase as some

families in this study expressed that they purchased a gaming device for entertainment purposes during the pandemic, which has ramifications for continued long-term use.

Parents indicated that engaging in social media was an acceptable form of ST, especially because it provided their children an opportunity to connect with others during the pandemic. Findings on the effects of social media on development are mixed, with some studies showing an association between engagement on social media and protection against depression [12] and little to no impact on social skills [34], while another study reported that interacting on social media (specifically Facebook) is related to lower levels of well-being among young adults [35]. One report describing 3 time-use-diary studies in 3 countries found little support for the association between digital engagement and lower levels of adolescent well-being [36]. Further studies are needed to examine how children are connecting with others through screens, as well as the frequency, to determine how this relates to maintaining feelings of connectedness during lockdowns and periods in which face-to-face interactions with one's peers are greatly reduced or even nonexistent. Additionally, the AAP recommends that parents coview media with younger children, but this has become more challenging for many families as parents attempt to balance their own work (possibly from home) and family life during the pandemic. Updated guidelines and strategies by the AAP may be helpful for parents in navigating screen use in the current situation, and in potentially similar situations in the future, considering the cyclical nature of the lockdowns and unpredictability of SARS-CoV-2.

Limitations and Strengths

Our findings should be interpreted with caution. Parents in our study reported that their children were spending 8 hours a day on screens. This average is not very different from the finding of a 2010 Henry Kaiser Foundation report that revealed a daily average of 7 hours 38 minutes of media use in 8- to 18-year-olds [37]. A noticeable discrepancy is that the >7 hours in the Kaiser report represented entertainment media and was reported by youth aged ≥ 8 years, while the average in this study was reported by parents and represented a combination of education and entertainment media for children aged ≥ 5 years. This gap should be examined in more detail to determine the nature of the difference. Additionally, we did not focus on 1 specific age group, which would be helpful in gaining a more in-depth understanding of how the pandemic is affecting children by age. However, this was by design. Most parents in our study had more than 1 child (average 3), and our goal was to capture what was happening within the family unit.

The strengths of this study include a sample in which all families shared the same unique situation of children attending school remotely. In addition, parents were invited to participate in the focus group sessions 9-11 months into the pandemic, which offers a clearer insight into how families have adapted and settled into new routines around ST since the pandemic initially began. However, this study serves as a starting point, and further studies are needed to provide cross-sectional insights into how the pandemic has influenced ST in families.

A few parents shared how their own ST had increased, and that it disrupted them from being present with their children or other family members, which left them feeling guilty. Parental ST use during the pandemic was not explored in-depth in this study but is an area that warrants further attention. This may be of special interest to parents of young children because research suggests that when mothers used their devices around young children, they were less likely to talk to them [38]. However, many parents are spending unprecedented amounts of time with their children and the total amount (and quality) of conversation may be sufficient over the course of the day. The emotional connections that parents are making with their children is of particular importance with regard to child health [39], as well as the quality of parenting and ST [40], and studies should examine how parents are connecting with their children during the pandemic. Additionally, more than half of our participants were essential workers, or lived with one, more than one-third being working mothers, and studies have reported that both essential workers [7] and working mothers [41,42] have been disproportionately affected during the pandemic. Future comparative studies should target parents across different socioeconomic statuses, as well as essential workers and working mothers, to determine whether differences exist between their levels of ST. The impact of ST on long-term development needs to be examined through a new lens because

families have never been in this particular situation before. Although there are risks associated with ST, there are also benefits, and whether the positives outweigh the negatives or vice versa during a pandemic is yet to be determined.

Conclusions

ST has become even more ubiquitous in the home setting, and 2 generations of children will have spent an unprecedented amount of time on screens and social media over the past year. ST and social media are a relatively nascent force, and one that is transforming rapidly; therefore, we do not yet know the panoply of long-term effects that may be associated with its use, especially during a pandemic where there has been digital reliance to maintain a semblance of normalcy. For very young children, the pandemic has occurred during a time when healthy habits first begin to be established. Health care professionals, child psychologists, and developmental psychologists may want to focus on preventing potential negative long-term sequelae of heavy ST, which may include mental, socioemotional, and physical health challenges. The goal of this study was to describe families' experiences of using screens during this time, and to inform future studies. It is important that future studies examine the long-term effects of excessive ST, and preemptively introduce ways to redirect children's ST habits as the country attempts to establish a new normal.

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Conflicts of Interest

None declared.

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Abbreviations

AAP: American Association of Pediatrics

PE: physical education

ST: screen time

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Original Paper

Social Media Terms and Conditions and Informed Consent From Children: Ethical Analysis

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Abstract

Background: Terms and conditions define the relationship between social media companies and users. However, these legal agreements are long and written in a complex language. It remains questionable whether users understand the terms and conditions and are aware of the consequences of joining such a network. With children from a young age interacting with social media, companies are acquiring large amounts of data, resulting in longitudinal data sets that most researchers can only dream of. The use of social media by children is highly relevant to their mental and physical health for 2 reasons: their health can be adversely affected by social media and their data can be used to conduct health research.

Objective: The aim of this paper is to offer an ethical analysis of how the most common social media apps and services inform users and obtain their consent regarding privacy and other issues and to discuss how lessons from research ethics can lead to trusted partnerships between users and social media companies. Our paper focuses on children, who represent a sensitive group among users of social media platforms.

Methods: A thematic analysis of the terms and conditions of the 20 most popular social media platforms and the 2 predominant mobile phone ecosystems (Android and iOS) was conducted. The results of this analysis served as the basis for scoring these platforms.

Results: The analysis showed that most platforms comply with the age requirements issued by legislators. However, the consent process during sign-up was not taken seriously. Terms and conditions are often too long and difficult to understand, especially for younger users. The same applies to age verification, which is not realized proactively but instead relies on other users who report underaged users.

Conclusions: This study reveals that social media networks are still lacking in many respects regarding the adequate protection of children. Consent procedures are flawed because they are too complex, and in some cases, children can create social media accounts without sufficient age verification or parental oversight. Adopting measures based on key ethical principles will safeguard the health and well-being of children. This could mean standardizing the registration process in accordance with modern research ethics procedures: give users the key facts that they need in a format that can be read easily and quickly, rather than forcing them to wade through chapters of legal language that they cannot understand. Improving these processes would help safeguard the mental health of children and other social media users.

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KEYWORDS

social media; big data; ethics; children; health data; terms and conditions; trusted partnership; medical ethics; mobile phone

Introduction

Background

Social media companies have experienced tremendous growth during the last decade; however, they have largely neglected the issues of privacy and confidentiality. In addition to connecting people, social media apps (the companies) are also tremendous *data collectors*, gathering a wide range of information that spans from nonsensitive to highly sensitive data. Although many data might be nonsensitive in isolation, the combination of various types of data might subsequently allow insights into sensitive health issues [1]. In fact, many studies have used social media data to gain insights into the mental state of users [2,3]. Moreover, with children and young adults using social media apps from a young age, companies have acquired data over long time spans, which is similar to longitudinal data used in research. Keeping this in mind and knowing that predictive algorithms will become more accurate, it is of major importance to build governance and inform users about the use of their data to foster data protection. This is all the more important given the latest scandal surrounding Cambridge Analytica [4,5] and the sharing of data between Facebook and device manufacturers such as Apple and top-rated apps such as Spotify and Netflix [6]. These are prominent examples of misbehavior that illustrate the urgent need for a trusted partnership between users and social media companies.

Contractual law in the terms and conditions (also known as terms of services) and privacy policies define how privacy, confidentiality, and data sharing are handled. They are the predominant legal and contractual mechanisms that define the relationship between users and social media companies. These mechanisms are subject to various national and international regulations. The General Data Protection Regulation (GDPR) of the European Union (EU) [7] sets boundaries concerning the processing of data. In the United States, the Children's Online Privacy Protection Act (COPPA) [8] and the fair information principles issued by the Federal Trade Commission [9] are the 2 predominant regulations.

When signing up for such a service, users consent by reading or at least scrolling through the terms of service and by clicking the *agree* button. However, these terms and conditions are often long and written in a complex legal language. Thus, it remains questionable whether users—particularly children and young adults—truly understand the terms and conditions and are aware of the consequences of joining a network. Most of the platforms offer their service for free but require users to accept the preset *package* of conditions with limited privacy choices to permit access to their services.

Social media apps are ubiquitous in today's world and have changed the way we communicate, share, and interact with each other daily. They are also omnipresent in the lives of young people, and it is estimated that 1 in 3 of all internet users is under the age of 18 years [10,11]. A recent study by the UK Children's Commissioner has shown that a significant number of children access social media through their parents' accounts, whereas most adolescents (71% in the United States and 85% in Europe) have one or more social media accounts or identities

[12]. When children access social media through their parents' accounts, parents might feel that they have control over their children's media use. This is problematic for 2 reasons: first, parents will not be able to control every click, and second, as the UK Children's Commissioner points out, children might be presented with explicit adult content of which their parents remain unaware.

Letting children use parents' accounts also bypasses the age requirements imposed by social media companies. In their terms of service, social media apps and services defined the minimum age at which adolescents or children can use the app or service without obtaining parental consent. With regard to age requirements, the law plays an important role by setting boundaries for protecting children's privacy, data sharing, and profiling. In the United States, COPPA defines 13 years as the minimum age to join such communities. Before that age, explicit parental consent is needed to sign up. The EU has recently introduced the GDPR, in which Article 8 defines the necessity of parental consent for all youths aged below 16 years in situations where information society services are offered directly to them. However, the member states are free to choose and adopt their own particular regulation within the age range of 13-16 years. Some countries, such as the United Kingdom, have opted for an age of 13 years, whereas others such as Germany have set the boundary at 16 years [10]. The GDPR would thus not prohibit the use of such services before the minimum age requiring children's self-consent but would instead require parental consent to access these services and process the personal data of children, as defined in the GDPR. Most of the companies however set their minimum age requirements at the age imposed by national law, as shown in our results.

However, the efficacy of such age regulations remains to be questionable as the primary research strands in children's digital rights show that children and parents feel social pressure to join such communities [12] and thus might lie about their age when joining social media services [13]. Doing so is easy because normally, signing up relies only on the honesty of the user.

Objectives

This paper provides an ethical analysis of the most popular social media platforms and services used by children and adolescents (in the EU and the United States). It focuses on age requirements, how information about the platform is presented, how consent is obtained, how (and if) age verification is implemented, whether resources are provided to educate parents or children, and if there are community guidelines. It then discusses the emerging issues and the predominant regulations of our target countries and illustrates how experiences from research ethics could be used to develop a trusted relationship between users and companies, facilitating the *ethical* functioning of social media networks.

Methods

We conducted a thematic analysis [14] of the terms and conditions of the 20 most popular social media platforms in 2019 [15] and the 2 predominant mobile phone ecosystems, Android and iOS. Within this sample of 20 platforms, we

excluded all apps and social networks targeting only Chinese-speaking users (because of a lack of terms and conditions in English; WeChat, QQ, QZone, and Sina Weibo), discussion websites (Reddit), and those targeting only adults (LinkedIn or Viber), resulting in 10 platforms relevant to children. The terms and conditions were read in depth, emerging topics of ethical interest were identified, and categories for further in-depth analysis were created. The categories identified were the minimum age to join, how the consent process was handled, the age verification process, the presence of parental

portals (educating parents on the use of the respective platforms), and the possibility of requesting account deletion in the cases of underaged users. Note that most of the platforms are available either as web apps or as smartphone apps. The results of this in-depth analysis are summarized in [Table 1](#), and the apps are scored according to the criteria in [Table 2](#). As most of the apps are available on smartphones, we also decided to include the quasi-standard platforms such as Android and Google, as they have a gatekeeping function (in terms of age) to allow children to access those networks.

Table 1. Overview of the most popular social media apps.

Platform or app	Active users (in millions)	Provider	Predominant content	Viewable without signing in	Minimum age (years)	Age verification	Possibility to request deletion of the account	Parental consent	Parent portal or community guidelines
Social media									
Facebook	2234	Facebook Inc	Video or text or images or social messaging	Yes	13	Verification of official document when account is locked	Yes (form)	Consent by user	Yes
YouTube	1900	Google	Video creation	Yes	13 (≥14/≥16) ^a	Background check or verification of official document or credit card verification when locked	Yes	Consent by user or parents if below 13 years	Yes
WhatsApp	1500	WhatsApp Inc (Facebook Inc)	Social messaging (video or text or music)	No	13	By SMS messaging	No	Consent by user	No
Instagram	1000	Facebook Inc	Images or video	Yes	13 (16) ^a	Verification of ID when locked	Yes (form)	Consent by user	Yes
TikTok	500	Beijing Bytedance Technology	Music or images	No	13 (14) ^a	No	Yes (mail)	Yes (for certain countries)	No
Twitter	335	Twitter Inc	Text	Yes	No	Yes for sensitive posts	Yes	Consent by user	No
Skype	300	Microsoft Corporation	Social messaging	No	No	No	No	Consent by user	No
Snapchat	291	Snap Inc	Video or photo posting	No	13	By peer or birthday can be changed only a limited number of times	Yes (mail)	Consent by user	Yes
Pinterest	250	13	Images	Yes	13	By peer	Yes (form)	Consent by parents if undegraded use	Yes
LINE	203	LINE Corporation	Social messaging	No	No	No	No	No	No
Ecosystems									
iOS (Apple ID)	N/A ^b	Apple	Apps	N/A	13	Yes (Credit card or SMS)	Yes	Consent by parents if undegraded users	Yes
Android Play Store	N/A	Google	Apps	N/A	13 (≥14/≥16) ^a	Back check or verification of official document or credit card verification	Yes	Consent by parents if undegraded users	Yes

^aOn the basis of the country, the companies have adopted a different minimum age.

^bN/A: not applicable.

Table 2. Scoring the most popular social media apps.

Platform or app	Minimum age or age verification	Parental consent	Possibility to request deletion of the account	Parent portal or community guidelines	Total score
Facebook	Age restriction and implemented age verification present	Consent by user	Yes	Parent portal present	3
YouTube	Age restriction and implemented age verification present	Consent by parents	Yes	Parent portal present	4
WhatsApp	Age restriction and implemented age verification present	Consent by parents	No	No parent portal	2
Instagram	Age restriction and implemented age verification present	Consent by user	Yes	Parent portal present	3
TikTok	No age restriction or no age verification present	Consent by parents	No	No parent portal	1
Twitter	No age restriction or no age verification present	Consent by user	Yes	No parent portal	1
Skype	Age restriction and implemented age verification present	Consent by parents	No	No parent portal	2
Snapchat	Age restriction and implemented age verification present	Consent by user	Yes	Parent portal present	3
Pinterest	Age restriction and implemented age verification present	Consent by parents	Yes	Parent portal present	4
LINE	Age restriction and implemented age verification present	Consent by user	No	No parent portal	1

Results

The results of our analysis will be discussed thematically, in turn, after presenting the results of our scoring mechanism.

Scoring System

On the basis of the data in [Table 1](#), our scoring system ([Table 2](#)) awards each platform a possible score of 1 (+) or 0 (none)

across the 5 different categories used in our analysis. The criteria are presented in [Table 3](#). The category for minimum age and age verification is cumulative. One point will be awarded only if both criteria are met, because we believe this fulfills the gatekeeper function. Studies suggest that children are often happy to lie about their age and that parents even encourage their children to sign up [13,16]; thus, the efficacy of a minimum age requirement in the absence of verification remains ethically questionable.

Table 3. Constraints of the scoring system.

Topic	Criteria for point	Criteria for no point
Minimum age or age verification	Age restriction and implemented age verification present	No age restriction or no age verification present
Possibility to request deletion	Yes	No
(Parental) consent process	Consent by parents	Consent by user
Parent portal	Parent portal present	No parent portal

Age Requirements and Age Verification

[Table 1](#) shows that all companies except LINE have adopted a minimum age of 13 years for the use of their services. However, the Apple and Google (Android) ecosystems offer the possibility of using their various services at a younger age with parental consent. Google achieves this by integrating the child's account into the so-called *Family Link* [17], a platform to group and administrate family member accounts; the same applies to Apple, which has also set up an infrastructure to manage family accounts. Most service providers rely on other users reporting underage use and offer either a mailing address or a form as the only way of contact when requesting the deletion of an account created by underage children. A more sophisticated method has been adopted by Google, where a background check is

performed by verifying the age entered in any one of its services whenever the user uses another service that is part of its ecosystem. Once an account is locked, Instagram and Facebook request a copy of an official document (ID card or passport) to unlock it. Android, iOS, and YouTube adopt another way of handling this issue, where the check is performed against a valid credit card, resulting in a parent giving de facto consent. In contrast, Snapchat allows users to change their date of birth only a certain number of times [18].

Consent Process

Upon registration, the user was asked to accept the terms and conditions. In most cases, the user agrees to the terms and conditions by checking a checkbox and subsequently clicking

the *register* button or even by only clicking the *register* button (Facebook and Instagram).

Sometimes, the link to the terms and conditions is in a smaller font (see Table S2 in [Multimedia Appendix 1](#) for an overview) so that it is hardly identifiable (Snapchat). On Instagram and Facebook, it is highlighted in bold font. Although the Article 29 Working Party (an independent European advisory body on data protection and privacy created by the EU) offers some

recommendations on the consent process [19], we were not able to identify a standard presentation form or standard procedure in presenting terms and conditions. Most forms show their terms and conditions only in continuous text, whereas others have adopted a question and answer form (eg, Facebook, Instagram, and Pinterest). Pinterest is the only platform that provides a simplified version in addition to the full version of its terms ([Textbox 1](#)).

Textbox 1. Full text versus simplified terms and conditions (Pinterest).

Full text

You grant Pinterest and our users a non-exclusive, royalty-free, transferable, sublicensable, worldwide license to use, store, display, reproduce, save, modify, create derivative works, perform, and distribute your User Content on Pinterest solely for the purposes of operating, developing, providing, and using Pinterest. Nothing in these Terms restricts other legal rights Pinterest may have to User Content, for example under other licenses. We reserve the right to remove or modify User Content or change the way it's used in Pinterest, for any reason. This includes User Content that we believe violates these Terms, our Community Guidelines, or any other policies.

Simplified version

If you post your content on Pinterest, we can show it to people and others can save it. Don't post porn or spam or be a jerk to other people on Pinterest.

Parent Portals or Community Guidelines

Almost every platform (except social messaging platforms) offers a parent's portal or community guidelines. This ranges from simply linking to interesting articles (Snapchat) to providing an information center (Instagram and Facebook) to video sequences (Facebook) on problematic behavior along with short sequences showing a safe way to use the service.

Discussions

Principal Findings

On the basis of our scoring system ([Table 2](#)), most providers scored 3 out of 4 points. However, one-third of the service providers achieved poor results. This shows that the regulations that service providers comply with, either by themselves or by law, offer at least some protection for users. However, TikTok, Twitter, and LINE only scored 1 point and only 2 companies achieved the maximum score (Pinterest and YouTube).

In the following section, we will therefore discuss the categories presented in [Table 1](#) and suggest possible improvements within the framework of the 4 guiding ethical principles.

Minimum Age to Sign Up for a Service

Our analysis reveals that most apps have adopted the minimum age of 13 years for children to sign up to use their services. This complies with the US COPPA and GDPR. In contrast with the COPPA, the GDPR provides a minimum age requirement ranging from 13 to 16 years for children to register for a service. Owing to the GDPR's extraterritorial force (as mentioned in Article 3 of the GDPR), other states and companies outside the EU have to comply with EU standards when targeting users (and children) in an EU member state.

Strongly intertwined with the definition of the minimum age is the issue of age verification. As [Table 1](#) shows, the issue of age verification is currently not taken seriously by companies, and

an age requirement is largely useless in the absence of verification. Therefore, we argue that a robust age verification process needs to be adopted by service providers in the coming years. However, establishing such mechanisms needs to be implemented in a way that complies with privacy and the principles of data minimization [19]. The survey mentioned earlier [13] has shown that some children lie about their age and the ease of registering for a social media service (requiring only a few minutes) does not constitute a barrier.

Currently, some providers request verification by email or phone by sending the user a short message during the registration process (the standard procedure for setting up a WhatsApp account). The latter provides an additional security layer as cell phone companies have a minimum age for issuing a contract; when a child has a cell phone, the parents have at least agreed to the use of such a device and thus are aware that the child might sign up for such a service, even if they are potentially unaware of the services that the child subsequently signs up for. However, this might be a problem in countries where pay-as-you-go phones require no identification, either by age or by verification with an official ID card or social security card. Furthermore, implementing an age verification process by requesting verification through a text message could be seen as discriminating against children who do not possess a cell phone at all and, thus, solely have to rely on a parent to register.

Other providers delegate *age verification* to their users by setting up forms where one can report underage use. However, this method does not guarantee age verification and, in the absence of other measures, it suggests that the service provider is neither serious nor proactively interested in complying with the minimum age requirement.

Today's technologies could make it possible to approach the minimum age to check more proactively. For example, artificial intelligence could enable the use of techniques such as image classification algorithms or natural language processing to detect

underage children by analyzing their physical face properties (such as the Amazon *recognition application programming interface* [20]) or using written language with neurolinguistic programming for processing natural language. We are fully aware that the use of such technologies can lead to other ethical and legal concerns. Although these concerns are too complex to address in depth in this paper, we discuss them briefly in the following section.

Article 9 of the GDPR places biometric data in a special category: processing is prohibited unless special circumstances are met. However, notably Article 9 [7] of the GDPR permits each EU member country to introduce certain derogations with respect to restrictions on processing biometric data (*member states may maintain or introduce further conditions, including limitations*). For instance, the Netherlands has provided an opt-out option for biometric data if necessary, for authentication or security purposes, and Croatia's new data protection law exempts surveillance security systems [21]. In the United States, no federal law regulates the collection of biometric data. However, 3 states—Illinois, Washington, and Texas—have implemented regulations on biometric data [21]. On the ethical side, the introduction of such technologies to tackle the issue of age verification is also potentially problematic, as appropriate consent must be obtained from the user, who should also have a full overview where the biometric data are being used, as these types of data represent special categories that are harmful when misused. Thus, the use of such technologies should follow clear ethical guidelines. For example, such technologies should not be used to collect more information about users and data than is necessary, and they should always be used for a specific purpose. This is also because an increasing number of predictive analyses are possible [2,22] from simple social media data.

Obtaining Consent

Obtaining valid user consent (and in the case of children, parental consent) is one of the 6 lawful bases to process personal data, as listed in Article 6 of the GDPR. Generally, as consent is a tool that gives users *data subjects* control over whether personal data concerning them will be processed [19], to do so, valid consent has to meet certain criteria; it must be freely given, be specific, and be informed and include an unambiguous indication of the data subject's wishes. How consent is presented to the user, whether it is written or presented pictorially or in short video sequences, is up to the controller (company). This means that harmonization is not currently envisaged. However, the Article 29 Working Party (an advisory board of the EU on data protection issues) does lay out how data subjects (users) should provide consent. Obtaining consent by simply scrolling down and ticking a checkbox is not seen as appropriate from an ethical standpoint, although it might be sufficient from a policy perspective. Thus, the Working Party provides 2 examples of how a valid mechanism could look (outlined in [Textbox 2](#)), which is not currently met by any of the services that are subject to our investigation. As shown in our analysis, users are presented with written information on their rights and rights of companies on topics such as data protection, community rules, and minimum age. A further issue is that some of the services only provide a checkbox to tick or, in the worst case, only a button to register where the terms and conditions are not displayed during the account's creation unless the user clicks the link. This fosters a *click and forget* mentality and is far from providing a sustainable and respectful partnership between service providers and users. Often, the link to the terms and conditions is presented in smaller fonts and stands in contrast with the large textboxes filled during the registration process, as shown in the examples in Table S2 in [Multimedia Appendix 1](#).

Textbox 2. Example of how to obtain consent (examples of the Article 29 Working Party).

Appropriate way

Swiping a bar on a screen, waiving in front of a smart camera, turning a smartphone around clockwise, or in a figure-eight motion may be options to indicate agreement, as long as clear information is provided, and it is clear that the motion in question signifies agreement to a specific request (e.g., if you swipe this bar to the left, you agree to the use of information X for purpose Y. Repeat the motion to confirm). The controller must be able to demonstrate that consent was obtained this way, and data subjects must be able to withdraw consent as easily as it was given.

Inappropriate way

Scrolling down or swiping through a website will not satisfy the requirement of a clear and affirmative action. This is because the alert that continuing to scroll will constitute consent may be difficult to distinguish and/or maybe missed when a data subject is quickly scrolling through large amounts of text and such an action is not sufficiently unambiguous.

A special category for obtaining consent is imposed for children below the age of legal maturity in their respective countries. In such cases, the GDPR and COPPA require approval from the parent or guardian. This has several positive and negative aspects. On the one hand, this regulation places the burden on the parents to protect children from potential harm, which could, in turn, be built by safeguarding mechanisms of the platforms. On the other hand, overrestrictive consent processes could be a driver of inequality, as strict parents could hinder beneficial usage. A complex consent process (such as using the parents'

credit card or facial recognition) is always associated with more data being collected not only from the child but also from the parent. Thus, balancing data minimization against sufficient safeguards plays an important role in designing an ethical consent process.

Emphasizing consent is important; however, other scholars have argued that solely focusing on this aspect and implying parental consent is not enough. By making data protection impact assessment mandatory (as required by the GDPR), risks can be

already identified at an earlier stage [22]. Combining these 2 approaches for making the terms and conditions more readable and fostering data protection impact assessments would help to protect children's rights.

Educating Users and Parents

As the report of the UK Children's Commissioner [12] has shown, the safe use of social media depends on building awareness and educating children about its use and fostering digital literacy. Parents and teachers play an important role. Most of the apps we analyzed offered parents websites where the companies either provided links to useful literature (the simplest way to deal with that issue) or by providing short YouTube sequences to inform children and parents about potential harm and the security measures to take when using social media.

Given the importance of educating parents and teens [12], we suggest that future legislation should mandate the implementation of such parental portals. From an ethical point of view, it would be good to encourage companies to spend a reasonable amount of their revenue in educating parents and children about the potential harm resulting from the use of their services. A good example is provided in the Facebook Help Center, which offers short YouTube sequences and quizzes on the topics of data protection and possible harm.

Social Pressure

Social media apps have become ubiquitous among children and adolescents. It has become difficult to refuse to be part of such networks, because of both social pressure and an increasing number of institutions (such as schools) requiring such channels, resulting in social pressure to use these services for communication, regardless of whether parents regard the use of these services to be appropriate for their children. This could also be seen as a loss of autonomy concerning the freedom to decide whether and when to join. We can imagine a scenario in which children who want to participate in social media life are pressured to lie about their age on the internet by fellow schoolmates or friends because this peer group's main vehicle of social interaction is heavily mediated by online- messaging and social media, for example, children need to be on WhatsApp to be able to meet with others because all of the peer meetings are communicated that way. It is also possible that parents could incentivize their offspring to engage in online misconduct as they want their children to use online messaging services (eg, WhatsApp) out of convenience or for monitoring purposes. These phenomena can create new social inequalities. In fact, in its 2017 report, UNICEF (United Nations International

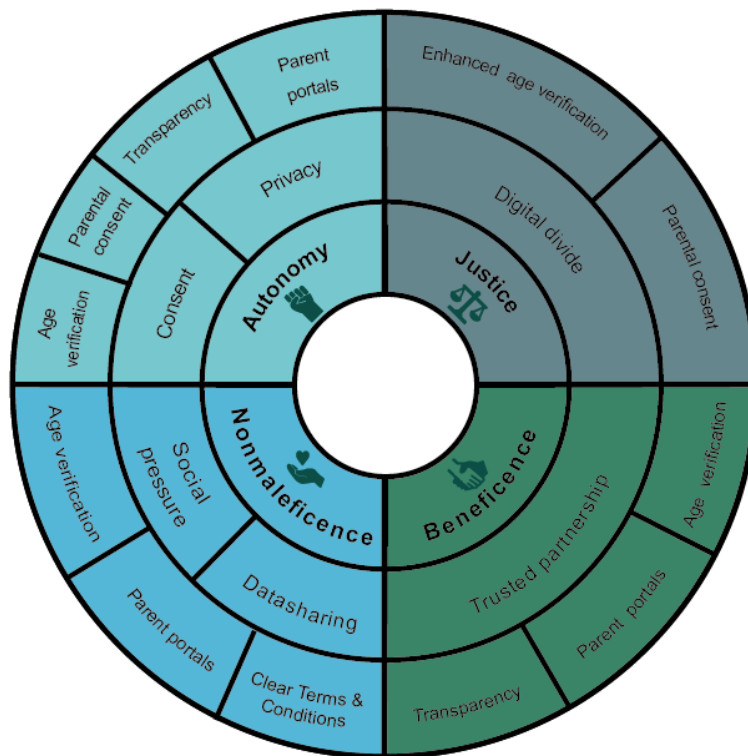
Children's Emergency Fund) warned of the formation of a significant digital divide [23], highlighting the gap between children who can connect and subsequently sign up for social media networks. This divide could be the result of either having more permissive parents who agree to the use of such services or because the child is wealthy enough to purchase a pay-as-you-go phone with data to access social media services secretly. Conversely, children who are left out of social media because their parents are more law-abiding or controlling or because their socioeconomically disadvantaged background makes personal phones unaffordable or are forced to share their parents' devices. Children in the latter group feel left out of their friends' social lives and end up being ostracized by their peers or even bullied.

With the introduction of the GDPR and the adjustment of the minimum age to 16 years in certain countries, it is expected that the topic of social pressure will defuse itself at least on an institutional level because institutions must adhere to this requirement. However, social media companies' adherence to the GDPR age requirement could, on the other hand, worsen social pressure for children as the gap between the legal age at which it is possible to join social media and children's actual social practices differs [24]. In medical care, children can give consent for themselves below the legal age of maturity; however, this exception does not apply in the case of compliance with GDPR.

Research Ethics as a Model for a Trust-Based Partnership

Similar to social media today, biomedical research used to have a bad reputation in terms of involving participants. People were included in medical studies without their consent, and their data were shared without their knowledge. To prevent such unethical practices, 4 main ethical principles have become fundamental to research ethics and biomedical ethics more widely: respect for autonomy, nonmaleficence, beneficence, and justice. In the context of social media, all of these principles are relevant; however, this is particularly true of respect for autonomy and nonmaleficence. [Figure 1](#) illustrates how social media can innovate to ensure age verification, valid consent, and other aspects to make sure that these key ethical principles are respected. Fundamentally, it is an ethical imperative to ensure that children are of suitable age and understand the risks of social media to reduce the risk of harm to their emotional well-being and mental health: evidence suggests that social media can have substantial impacts in the areas of *self-esteem and well-being, with issues related to cyberbullying and Facebook Depression* [25].

Figure 1. Mapping the four ethical biomedical principles of the use of social media to issues arising from the use of social media and links them to possible fields of actions. (Enlarged age verification: Using sophisticated mechanisms such as credit card charges could foster digital divide; Parental consent: Parents might prevent kids joining resulting in negative consequences for them).



In research ethics, the informed consent process plays a crucial role and contributes to a trusted partnership between subjects and researchers. When approached about the possibility of involvement in a clinical study (and increasingly for interviews or survey participation), potential participants are given all relevant information and time to digest and consider it before signing an informed consent form. In the past, the information provided to participants often ran to over 100 pages, thus raising the same concerns about accessibility and comprehensibility as social media terms and conditions. In recent years, however, there has been a move toward making such information much more patient- and participant-friendly, with, for example, the UK Human Research Authority supporting the use of simple information sheets in a question and answer format running to a maximum of 5-10 pages. This practice focus on communicating relevant information about risks and harms in a concise and comprehensible format could also serve as a model for building trusted relationships between social media users and companies. The problem with using terms and conditions as an information sheet is that such policies are essentially legal documents and written in dense legal language. Disentangling lengthy legal texts from the salient information required to provide informed consent is essential for social media companies. However, today's relationships are still unbalanced from the very beginning, with users required to sign up with a simple click after having to read information that is only presented in written form and complex language. This means that many users remain to be unaware of exactly what they are signing up for. Moving toward some sort of pictorial consent system would be a much more appropriate approach to informing both children and adults about the risks of social

media use. This debate is not new in the legal context; Brunschwig [26] was one of the first to show how contractual law can be exemplified with comics fostering a better understanding of otherwise complex matters. Several scholars have been working on this topic, proposing *nutrition label-like* terms and conditions [27] and grid-based terms and conditions [28]. Such pictorial forms of consent are best practices in research ethics settings, especially with sensitive study participants or those with low literacy levels. There might be some implementation issues with such solutions. Nevertheless, when we are speaking about children—a *sensitive group*—such terms and conditions are a much better means of informing users about potential harm. This is not a purely theoretical discussion and approach, as Apple recently presented *nutrition labels for their App Store* [29].

Another possible solution, and a step in the right direction, is the simplified text-based rules for several social media apps developed by the UK Children's Commissioner [30]. Research ethics also requires that data can typically only be shared and processed with the consent of the persons concerned. However, recent social media scandals [4,31] have shown that some social media companies have neglected this issue, which must also be addressed more clearly in terms and conditions. Another essential aspect of research ethics is the right to withdraw consent and the possibility of deleting data (or an account if research takes place via the internet) by the user. However, for underaged users (with respect to the minimum age required by the companies), it should also be possible for parents to delete an account without going through a complicated process. This could be done, for example, by specifying a parental contact

when registering the account. Finally, research ethics also address the potential risks in participating in a study. Most companies in our sample address possible harms of using their services in their parent portals and community guidelines.

Conclusions

Our analysis reveals that social media networks are still lacking in many respects with regard to adequate protection for children. Consent procedures are flawed because they are too complex, and in some cases, children can create social media accounts without sufficient age verification or parental oversight. Given the high risks of inappropriate content being shared and the targeting of children with specific advertisements, social media companies must improve their procedures to protect not only children but also all users. This can be achieved by standardizing the registration process in accordance with modern research ethics procedures described earlier: give users the key facts that they need in a format that can be read easily and quickly, rather than forcing them to wade through chapters of legal language that they cannot understand. Disentangling the practical

information that users need from the complex legal language would also have the benefit of facilitating standardization; regardless of the jurisdictions, the language for consent documents should be simple and straightforward. In addition, in some cases, using pictorial versions of the terms and conditions would surely leverage the efficacy of today's mostly unread versions. The vast majority of social media users have given only uninformed consent; however, the *click, consent, and forget at your peril* model must be relegated to history in favor of a more transparent and ethical system. The standardization of terms and conditions is only possible if an effective political intervention is implemented. Recent developments and discussions about monopolistic large social media companies in the US Congress are a step toward harmonization. Furthermore, the role model function of the GDPR as a quasi-standard for new data protection regulations will eventually simplify standardization. Adopting measures based on key ethical principles will safeguard children's health and well-being and those of other social media users.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Links and presentation of terms and conditions.

[DOCX File, 619 KB - [pediatrics_v4i2e22281_app1.docx](#)]

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Abbreviations

COPPA: Children's Online Privacy Protection Act

EU: European Union

GDPR: General Data Protection Regulation

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Viewpoint

Challenges and Considerations for Reducing Diabetes Distress and Fear of Hypoglycemia in Parents of Youth With Type 1 Diabetes During the COVID-19 Pandemic

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Abstract

Type 1 diabetes management can be challenging for children and their families. To address psychosocial concerns for parents of youth with type 1 diabetes, we developed two parent-focused interventions to reduce their diabetes distress and fear of hypoglycemia. Our team conducted several of these interventions during the early stages of the COVID-19 pandemic and recognized a need to make timely adjustments to our interventions. In this viewpoint article, we describe our experience conducting these manualized treatment groups during the pandemic, the range of challenges and concerns specific to COVID-19 that parents expressed, and how we adjusted our approach to better address parents' treatment needs.

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KEYWORDS

type 1 diabetes; parents; children; diabetes distress; fear of hypoglycemia; COVID-19; telehealth; diabetes; challenge; youth; young adults

Introduction

The daily self-management of type 1 diabetes (T1D) is complex and unrelenting. It involves regular glucose monitoring, healthy eating and carbohydrate assessment, insulin administration via syringe or continuous subcutaneous insulin infusion, and physical activity [1]. The goal of modern T1D self-management is to maintain near-normal glucose levels [1]. However, for many families of youth with T1D, this goal can be very hard to achieve [2,3]. There is evidence that many parents of youth with T1D experience diabetes distress and fear of hypoglycemia, which may negatively impact their functioning and quality of life [4-6]. Further, parents who report maladaptive coping strategies also report decreases in mental and physical health [7]. In our own work, we found that nearly 60% of parents of young children with T1D (<6 years) report at least a moderate level of hypoglycemia fear (FH) [8,9]. In addition, our data and

the results of published studies suggest that between 10%-74% of parents report diabetes distress (DD) [5,6,10,11]. It is because of these relatively high prevalence rates for FH and DD among parents that we developed two novel parent-focused interventions to increase adaptive coping and reduce their FH and DD.

Reducing Emotional Distress to Childhood Hypoglycemia in Parents

Reducing Emotional Distress to Childhood Hypoglycemia in Parents (REDCHiP) is a manualized and closed group video-based telehealth intervention [12]. REDCHiP includes 10 sessions (7 group sessions and 3 individual sessions) delivered over approximately 13 weeks. During REDCHiP, parents do the following: (1) review T1D education and problem-solving to increase self-efficacy for the management of hypoglycemic events, (2) learn age-appropriate behavioral

parenting strategies to manage child behaviors in the context of T1D care, and (3) learn cognitive-behavioral therapy (CBT) strategies to enhance coping with fear and stress related to hypoglycemia [12]. In our pilot work, parents receiving the REDCHiP intervention showed significant reductions in their report of FH ($P=.003$, $d=1.01$) and parenting stress ($P=.003$, $d=0.85$), and children with glycated hemoglobin (HbA_{1c}) levels >7.5% prior to REDCHiP showed a significant reduction in their HbA_{1c} levels ($P=.049$, $d=0.43$) after participating in the intervention [13]. Based on these promising results, we are now in the process of conducting a larger randomized clinical trial to test the efficacy of our REDCHiP intervention versus a relevant attention control group [14].

Cognitive Adaptations to Reduce Emotional Stress

To address parents' perceptions of DD, we developed Cognitive Adaptations to Reduce Emotional Stress (CARES) based on the theory of stress and coping [15-17]. Like REDCHiP, CARES is a manualized video-based telehealth intervention that includes weekly closed group sessions delivered over 8 or 12 weeks, depending on distress severity. In CARES, we use principles of CBT to teach parents how to identify unhelpful thoughts, feelings, and behaviors specific to T1D and how to use both mindfulness-based strategies (eg, meditation, being in the moment) and behavioral activation to manage their negative thoughts and feelings related to T1D. Our preliminary data suggest a significant reduction in parents' report of DD as a result of CARES ($d=0.71$) [18] and we are currently in the process of applying for additional grant funding to conduct a larger randomized clinical trial of this intervention.

Intervention Impacts of COVID-19

In early 2020, the United States, like many other countries, faced an unprecedented public health event with the rapid spread of COVID-19. For some families of youth with T1D, COVID-19 may be a new stressor that disrupts routine diabetes care and negatively impacts family engagement with optimal T1D self-management behaviors, including healthy eating, physical activity, and adequate insulin administration. In addition, exposure to this stressor could increase the risk of youth and/or their parents developing symptoms of anxiety and depression or exacerbate symptoms already present. Previous studies suggest that parent stress and internalizing symptoms may increase their child's risk for developing similar symptoms unless the family engages in more adaptive coping methods [19]. Further, families may also face increased fear of exposure to COVID-19, making previously typical activities of daily life (eg, shopping, work/school, recreation/physical activity) more difficult to accomplish or seemingly riskier to do. Per the Centers for Disease Control and Prevention (CDC), diabetes is a risk factor for severe illness [20], and emerging data from the T1D Exchange suggest persons with T1D who contract COVID-19 may be vulnerable to experiencing acute T1D-specific events including severe hyperglycemia and diabetes ketoacidosis (DKA) [21]. Thus, it is possible that some parents of children with T1D may be experiencing added fear

and/or distress because of COVID-19 beyond that of the general population. During the early spread of COVID-19 in the United States, our team recognized a need to make some timely adjustments to our REDCHiP and CARES interventions to help parents reduce their FH and DD in the context of COVID-19. In this viewpoint article, we describe our experience conducting these manualized treatment groups with parents of youth with T1D during the pandemic, the range of challenges and concerns specific to COVID-19 that parents brought up in groups, and how we, in turn, adjusted our approach to better address parents' experiences and treatment needs.

Participants and Author Viewpoint

All parents who participated in the treatment groups had a child with a confirmed diagnosis of T1D for at least 6 months who was following an intensive insulin regimen. We recruited families of youth between the ages of 1-6 years to the CARES intervention across sites in the Midwest region of the United States. We also recruited families of youth between the ages of 5-12 years to the REDCHiP intervention across sites in the Midwest and Southeast regions of the United States. Each treatment group contained 3-4 members. As part of the established procedures for both trials, we video recorded the telehealth sessions to allow for coding of treatment integrity. However, these recordings also enabled us to reflect on the parents' view and observe the adjustments that group leaders made in the groups they led. The challenges and adaptations discussed in this viewpoint were not objectively measured nor part of a formal qualitative study. Rather, this viewpoint article is based on experiences of 4 treatment groups (1 CARES and 3 REDCHiP) and our consensus regarding the specific concerns parents raised in the CARES and REDCHiP treatment groups during the early months of the COVID-19 pandemic in the United States and how we observed group leaders adapt the intervention content during the onset of the pandemic to better address parents' concerns.

COVID-19–Related Challenges and Concerns

The participants in our active treatment groups reported several concerns and challenges when caring for their child with T1D during the onset of the pandemic. Not surprisingly, a main concern raised by parents was the perceived risk their child with T1D may contract COVID-19, which could increase their risk of negative health outcomes. In the early months of the COVID-19 pandemic, parents reported increased stress and anxiety regarding the safety of their child (eg, one parent even remarked, “[I] see germs everywhere”). Parents commented that their child with T1D was in a high-risk group, a notion also frequently highlighted by the media. Moreover, because parents had learned of a possible association between suboptimal diabetes management and COVID-19, they felt an increased pressure to maintain tighter glycemic control for their child. Some parents also expressed significant concern that their child's T1D would be difficult to manage if either the parent or child became sick. Indeed, families specifically noted heightened anxiety about the challenges of managing out-of-range blood

glucose values when their young child with T1D was sick in the past and this seemed to exacerbate their fears about possible COVID-19 illness. One family in particular, who had previously struggled to manage diabetes when their child was sick, reported significantly changing their lifestyle during cold and flu season in other years to reduce perceived risk (eg, avoiding sport activities, libraries). Parents reported that the stress associated with their child becoming sick further intensified as they started to seek out more information about the transmission of COVID-19 (eg, airborne versus surface contact) and when trying to maintain awareness of current recommendations (ie, when/where to use a face covering) during a time when new and sometimes conflicting information was continuously available.

In addition to anxiety about COVID-19 risk, many families faced a significant challenge when stay-at-home orders took effect and schools and local businesses began to shut down, impacting their typical routines. Maintaining a consistent routine can be an important component of optimal diabetes management [1]; it can also be helpful when raising a young child [22,23]. Therefore, adjusting to a substantial change in routine was challenging for some parents who previously relied on school schedules for beneficial structure in managing their child's daily T1D regimen. Some caregivers reported increased stress due to taking on increased childcare and diabetes tasks during the day. Parents also lost access to other childcare options (ie, daycare, nannies, or extended family/other caregivers), which may have increased disease management burden as they juggled diabetes treatment tasks, online teaching, childcare, and their own work-related responsibilities. Further, many parents noted fewer opportunities for their child to engage in safe and structured physical activity and indicated that they were concerned this would negatively impact their child's glucose levels. Parents also noted their own difficulty engaging in behavioral activation strategies (ie, regular and enjoyable activities to increase mood) or healthy lifestyle behaviors as a result of stay-at-home orders and reduced access to activities they would typically choose to do. Even after stay-at-home restrictions ended for some families, parents noted a period of suboptimal glycemic control when they returned to the office after working remotely for several months. These parents expressed frustration that changing schedules negatively impacted diabetes management and indicated heightened worry and guilt about returning to the office and the potential risk of contracting or exposing their child to COVID-19.

Another major challenge of COVID-19 discussed during the treatment groups was each family's experience of social isolation. Several parents reported they felt isolated from friends and unable to use their typical resources to manage daily stress (ie, gym, church, social gatherings, self-care outside of home). Similarly, several parents reported they restricted their child's play with peers, contributing to their child's increased sense of isolation. Parents expressed new worries when they considered allowing their child to interact with other people. Moreover, they reported feeling guilty when they did not allow their child to play with a peer or visit extended family during the stay-at-home orders. Feelings of isolation were not only specific to social activities but also included managing T1D. One parent

in particular felt isolated during the stay-at-home order because her partner did not assist with T1D care and she had come to rely on her child's school nurse for help with diabetes management during the school day. Unfortunately, during the stay-at-home orders she was unable to access assistance from the school nurse. Some parents also reported that it was challenging to attend the treatment group sessions during the stay-at-home orders and that they felt overwhelmed by all their responsibilities. In fact, several families who had previously expressed interest in participating in a group declined to participate during the stay-at-home orders, citing difficulty in attending the treatment groups while simultaneously having all family members at home. Further, we had parents frequently reschedule their meeting times to accommodate changes in their daily schedules. Lastly, another untimely challenge that parents reported was COVID-19-related job loss or furloughs, which in some cases had a downstream impact on the family's financial stability and insurance status. However, even parents who did not experience job loss reported concerns about their job security or their ability to find a new job and how that could impact their family's insurance status and ability to pay for T1D management supplies.

Positive Outcomes and Family Resilience

Despite the negative impacts of COVID-19 on many families, group leaders also noted positive outcomes and family resilience during this unprecedented time. Some families did not express specific concerns for their child related to COVID-19 and adapted to changes in lifestyle and schedules smoothly. Some parents even noted an improvement in their child's blood glucose levels, which they attributed to their increased monitoring of T1D management tasks during stay-at-home orders. Families expressed gratitude for the support they received from the group members and group leaders. Even in the context of COVID-19-related challenges and concerns, many families continued to arrive to each session and remained engaged in group discussions. Several parents reported that their group participation increased as their schedules became more flexible as a result of working from home. Lastly, parents expressed appreciation for the extra family time they experienced related to stay-at-home orders.

Treatment Adjustments and Considerations

To address the unique challenges and concerns raised during the treatment groups, and to continue to reduce parent fear and distress, group leaders made small adjustments in their approach, using clinical judgment. One common adjustment was to incorporate strategies consistent with Acceptance and Commitment Therapy [24]. In the context of COVID-19, these strategies seemed particularly appropriate, especially given the uncertainty and the changes happening outside of participants' control. For example, when parents talked about their child feeling isolated from peers and unhappy, group leaders individually determined that problem-solving and information seeking might not provide parents the desired relief from negative feelings. Instead, the group leaders tried acceptance

and commitment strategies aimed at helping the parents to accept that their child could feel isolation from time to time during the stay-at-home order and to commit to moving forward in life based on their values. Similarly, specific to T1D care, when parents reported difficulty in managing their child's diabetes, the group leaders aimed to increase parents' acceptance and tolerance of temporary child blood glucose fluctuations during periods of transition, while still helping parents commit to actions aligned with an eventual return to more stable T1D management. Group leaders also employed these strategies to help parents process any feelings of guilt related to returning to the office or when discussing a family's decision to reduce their level of isolation (eg, playing with neighborhood peers, cousins). Group leaders discussed pros and cons of accepting different imperfect outcomes, such as increased feelings of isolation or increased risk of exposure, and helped families consider how they could commit to the course that best fit their perceived needs (eg, reduced risk of infection, children's social development).

In addition to adjusting some therapeutic strategies, group leaders commonly spent more time and emphasis on problem-solving than initially planned, especially when aiming to increase parents' use of behavioral activation strategies and helping them to identify available activities that were considered safe during COVID-19. For example, group leaders reported spending a lot of time on problem-solving strategies to help parents socialize and spend time with friends or extended family in a manner that felt comfortable and was within the scope of public health recommendations (eg, outdoor socially distanced walks with a friend/neighbor). The group leaders encouraged parents to embrace creative ways to achieve personal self-care (eg, spa night at home) and to integrate positive coping techniques despite the unique challenges of COVID-19 (eg, weekly video conversations with friends/family, virtual church service, outdoor and socially distant activities). Lastly, a novel behavior that many parents engaged in during groups was to seek advice from the group leader or other parents on whether their child should return to school. In these situations, the group leaders helped parents use risk-assessment strategies that were not initially part of either manualized treatment. Fortunately, problem-solving and soliciting parent examples to work through during the group sessions were already typical activities for both the REDCHiP and CARES interventions, which helped the group leaders make these adjustments more seamlessly.

Future Directions

After addressing unique COVID-19–related challenges within each treatment group, our team hypothesized that there could be an increased risk for some parents to remain inappropriately hypervigilant about their child's health after COVID-19 subsides, and that this could be an important area of ongoing concern for families. Interestingly, group leaders noted that some parents with higher levels of pre-existing anxiety reported a decrease in anxiety related to the stay-at-home orders. In many cases, these parents reported that they thought they could easily meet their child's needs without interacting with others and that having their child home would be more conducive to monitoring their child's health and T1D management nearly continuously.

Although this may seem like a short-term improvement in anxiety (and potentially T1D management), this avoidant-based coping strategy could lead to longer term risks and challenges, especially if families rely too heavily on this strategy and continue to resist leaving their home for work, school, or social/recreation activities. In the time of COVID-19, it might not have been recommended that these families expose themselves to situations that increased their anxiety (eg, going for a socially distanced walk with friends), but nonetheless, group leaders continued to challenge families to expose themselves to situations and try new activities just outside their comfort zone (but still in line with CDC and medical team recommendations) in an effort to reduce the likelihood that families might adopt a lifestyle of avoiding anxiety-producing situations.

Lastly, our a priori decision to run treatment groups via a videoconferencing platform enabled group leaders to continue with scheduled sessions as stay-at-home orders took place, without a break in either treatment group. The use of telehealth services has recently become a large focus, in both medical and mental health service delivery, and this shift in service delivery may continue well into the future now that many families have experience with a telehealth platform. Although some services will return to in-person delivery as social distancing requirements are reduced, we would encourage providers to advocate that telehealth services remain an option for families. There are several benefits to continuing to provide telehealth services after COVID-19 subsides, such as increasing access to services for families living in rural areas, with limited transportation options, or with limited time available for such services. Although the available literature specific to the transition to telehealth services during the pandemic is limited, emerging research suggests telemedicine may be an effective approach for some families. For example, Garg and colleagues [25] presented a case example of using telemedicine to provide ongoing diabetes education to a pediatric patient with new-onset T1D. Their conclusion was that a telemedicine approach could be well-suited to families who use T1D devices (ie, insulin pump, continuous glucose monitor) where it is feasible to collect data remotely. Thus, the opportunities videoconferencing and telehealth affords us may continue to improve our ability to provide effective services to youth and families and reduce disparities in health care access both now and into the future.

Conclusions

During the global COVID-19 pandemic, families of children with T1D faced new challenges, including widespread anxiety and activity restrictions to avoid COVID-19 exposure, while concurrently demonstrating marked resilience. Our research team was fortunate to work closely with families during this uncertain time through the REDCHiP and CARES group-based telehealth interventions. With some adjustments (ie, increased scheduling flexibility, greater focus on acceptance strategies, and additional time spent on problem-solving), we saw that parents continued to attend our treatment groups and to show individual success in managing negative affect related to T1D. As the COVID-19 pandemic evolves, we anticipate new concerns requiring further intervention or adjustment, such as

difficulties returning to activities previously avoided to reduce COVID-19 risk, fluctuations in blood glucose following changes in routines, and/or increased burnout as many parents continue to shoulder responsibilities for childcare, school, T1D management, and their own work with no immediate end in sight. Further, formal qualitative studies are needed to intentionally assess the concerns we present in this viewpoint as the information provided was not the result of planned data collection. Future researchers and clinicians may consider

formally assessing these concerns among patients and families to understand the extent to which these concerns impact daily functioning. We hope for the continued (and even more widespread) use of telehealth to deliver interventions to reduce anxiety and distress for families and children with T1D. Although research on the impacts of COVID-19 on families with children with T1D may be underway, it will also be important to exchange more anecdotal perspectives during this period of rapid change.

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Conflicts of Interest

None declared.

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Abbreviations

- CARES:** Cognitive Adaptations to Reduce Emotional Stress
CBT: cognitive-behavioral therapy
CDC: Centers for Disease Control and Prevention
DD: diabetes distress
DKA: diabetes ketoacidosis
FH: hypoglycemia fear
HbA_{1c}: glycated hemoglobin
REDCHiP: Reducing Emotional Distress to Childhood Hypoglycemia in Parents
T1D: type 1 diabetes

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Original Paper

Building Primary-School Children's Resilience through a Web-Based Interactive Learning Environment: Quasi-Experimental Pre-Post Study

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Abstract

Background: Resilience is a person's mental ability to deal with challenging situations adaptively and is a crucial stress management skill. Psychological resilience and finding ways to cope in crises is a highly relevant topic considering the COVID-19 pandemic, which enforced quarantine, social distancing measures, and school closures worldwide. Parents and children are currently living with increased stress due to COVID-19. We need to respond with immediate ways to strengthen children's resilience. Internet-based cognitive behavioral therapy interventions for children's stress management overcome accessibility issues such as the inability to visit mental health experts owing to COVID-19 movement restrictions. An interactive learning environment was created, based on the preventive program "Friends," to overcome accessibility issues associated with delivering cognitive behavioral therapy-based interventions in formal and informal education settings.

Objective: This study aimed to examine the effectiveness of a web-based learning environment on resilience in (1) reducing anxiety symptoms and (2) increasing emotion recognition and recognition of stress management techniques among 9-10-year-old children. We also aimed to evaluate the learning environment's usability.

Methods: A quasi-experimental pretest-posttest control group design was used. In total, 20 fourth graders in the experimental group interacted with the learning environment over 6 weekly 80-minute sessions. Further, 21 fourth graders constituted the control group. The main data sources were (1) a psychometric tool to measure children's anxiety symptoms, namely the Greek translation of the original Spence Children's Anxiety Scale, (2) 3 open-ended questions assessing emotion recognition and recognition of stress management techniques, and (3) the System Usability Scale to measure the usability of the learning environment.

Results: In both groups, there was a small but nonsignificant postintervention reduction in reported anxiety symptoms, except for obsessive-compulsive disorder symptoms in the experimental group. A paired samples *t* test revealed that students' reported symptom scores of obsessive-compulsive disorder significantly decreased from 1.06 (SD 0.68) to 0.76 (SD 0.61) ($t_{19}= 5.16$; $P=.01$). The experimental group revealed a significant increase in emotion recognition ($t_{19}=-6.99$; $P<.001$), identification of somatic symptoms of stress ($t_{19}=-7.31$; $P<.001$), and identification of stress management techniques ($t_{19}=-6.85$; $P<.001$). The learning environment received a satisfactory usability score. The raw average system usability score was 76.75 (SD 8.28), which is in the 80th percentile rank and corresponds to grade B.

Conclusions: This study shows that interactive learning environments might deliver resilience interventions in an accessible and cost-effective manner in formal education, potentially even in distance-learning conditions owing to the COVID-19 pandemic. Interactive learning environments on resilience are also valuable tools for parents who can use them with their children at home, for informal learning, using mobile devices. As such, they could be a promising first-step, low-intensity intervention that children and the youth can easily access.

KEYWORDS

COVID-19; interactive learning environment; internet-based cognitive behavioral therapy; parents; prevention intervention; primary school children; psychological resilience; teachers

Introduction

Resilience refers to a person's mental ability to adaptively deal with challenging situations and is a key skill for dealing with challenges in life [1], which typically cause stress, which, if left untreated, may escalate to anxiety. According to Ye [2], stress is the body's physical and mental response to the awareness of major changes or threats. Anxiety is one of the most common childhood mental health conditions [3,4]. A lifetime prevalence as high as 30% prior to 18 years of age has been reported in adolescents in the United States from the general population, with a median age of onset of 6 years [5,6]. Furthermore, the prevalence of subclinical anxiety has been estimated at a much larger proportion, approaching 40% in children [5].

According to Ye [2], emotional states and clinical symptoms are influenced by the COVID-19 pandemic, requiring psychological assistance and care. Anxiety is a common emotional reaction during the current pandemic [7]. Specifically, "school-aged children may be more nervous and scared, and repeatedly ask parents about the situation of the pandemic. Adolescents may have worries, irritability, and tantrums" [2]. Parents and children are living with increased stress owing to COVID-19 [8]. According to Dalton et al [9], "children are exposed to large amounts of information and high levels of stress and anxiety in the adults around them. Simultaneously, children are experiencing substantial changes to their daily routine and social infrastructure, which ordinarily foster resilience to challenging events" [9].

Stress is a problem for children and adolescents as it can have a negative emotional and social effect on children's mental health and quality of life both in school and at home. There is an overall consensus that stress should be addressed early on, through prevention interventions, before it escalates to anxiety. Prevention interventions can equip children with skills that will protect them from future mental disorders and can therefore help reduce the need for future therapeutic interventions.

The effectiveness of conventional face-to-face instructional interventions for preventing anxiety and for building mental resilience has been shown through systematic reviews that have examined the efficacy and effectiveness of school-based prevention programs for anxiety [10]. Most of these studies were based on cognitive behavioral therapy (CBT) and have shown that most of the evaluated programs were effective in reducing the symptoms of anxiety in children and adolescents. Prevention programs have been carried out in different settings, including formal education and informal education settings [11], and typically followed rigorous methodologies, including randomized controlled trials [12]. Cognitive behavioral therapy has therefore been demonstrated to be effective and is a well-established treatment for children and adolescents with anxiety disorders [3,4,13]. Meta-analyses have concluded that

approximately 60% of children following CBT treatment typically recover from the anxiety disorder that causes most interference (ie, the primary anxiety disorder) [4].

One of the most widely used and recognized CBT-based programs for preventing anxiety in children is called "Friends" [14]; it involves 10 sessions, and it was based on a program formerly called the "Coping Cat." The program was evaluated and yielded positive outcomes in Hong Kong [14], Canada [15], and other countries, and it was found to be effective in developing children's skills in managing stress. The program focuses on 3 areas: body symptoms, cognitive procedures, and management skills. Children learn relaxation and breathing techniques as ways for stress management, and they also learn how to convert negative thoughts into realistic perceptions and positive thoughts [16].

The effectiveness of the "Friends" program has been demonstrated through several studies that reported a significant reduction in stress among children who participated in the program when these were compared with control groups [17-19]. More favorable outcomes were obtained when health professionals, as opposed to educators, were involved in running the sessions [20]. There have been studies that have not shown the superiority of this program when compared to a control condition, as stress symptoms in children equally declined in both conditions [21]. Other studies have reported that the program was more beneficial for low-risk children than for high-risk children [22]. Waldron et al [23] reviewed 8 different studies that evaluated the program and reported that 5 of 8 were effective. Simultaneously, Johnstone et al [24] compared prevention intervention programs that include a large number of sessions, such as the Friends program, to short-term programs as part of their meta-analysis. They found that the former is generally more effective in teaching children how to reduce anxiety and manage stress.

There are various accessibility issues for conventional face-to-face interventions for anxiety, such as the high cost of treatment by specialized mental health experts [25], other barriers to the receipt of treatment, such as accessibility, stigma, and privacy [26] inequalities in health, emotional or practical obstacles [27], or more recently the inability to visit a mental health expert owing to movement restrictions related to the COVID-19 pandemic in various countries, including the United States [28] and China [7]. Technology can eliminate some of these obstacles. One relatively new and increasingly popular approach of increasing access to treatment is the use of web-based intervention programs [29]. For example, internet-based CBT (iCBT) for children and adolescents is a persuasive system that combines three major components to therapy: therapeutic content, technological features, and interactions between the user and the program, intended to reduce users' anxiety symptoms [30]. According to a scoping review by Ashford et al [29], the advantage of web-based

approaches is the accessibility, affordability, and anonymity of potentially evidence-based treatment. In their meta-analysis including internet-based interventions for children, the youth, and young adults with anxiety, Ye et al [31] reported that these interventions could be effective in reducing the severity of symptoms in the youth and can further be considered comparable with conventional programs that have the same goal. Several studies that were based on CBT and targeted children [32] have reported positive results with respect to the effectiveness of internet-based interventions for children aged 7-13 years [33], 9-14 years [34], and younger children aged 4-11 years [35]. For example, March et al [26] demonstrated the efficacy, feasibility, and acceptability of a web-based, publicly available self-help iCBT for children and adolescents with anxiety by assessing program adherence and satisfaction and significant changes in anxiety.

The target of studies focusing on how technology facilitates the delivery of CBT interventions in the treatment of psychological disorders is mostly adults. Fewer data exist for computer-based (standalone, self-help) and computer-assisted (in combination with face-to-face therapy or therapist-guided) programs for the youth [36]. Another problem is that relatively few web-based interventions on the world wide web have provided evidence of the intervention's efficacy, if we consider the treatment of anxiety as an example [29], and these are not necessarily appropriate for children, as the majority of them mostly target an adult population. From the large number of web-based programs available on the internet and the large number of apps that can be downloaded on mobile phones and tablets [37], only a few have been systematically tested and have published data on feasibility, acceptability, efficacy, and effectiveness [38]. For example, none of the mobile phone apps in previous studies [35,36] on eHealth interventions for anxiety management targeting young children and adolescents had published data derived from trials that examined their efficacy. Lastly, Stiles-Shields et al [39] reviewed CBT-informed behavioral intervention technologies for youth with anxiety and reported that prevention interventions receive lesser attention than therapeutic interventions, and Tozzi et al [36] confirmed this finding in their review.

Children spend a significant part of their day at school. Therefore, schools are an important setting for promoting psychological resilience in the youth [40]. The lack of easily accessible, empirically validated prevention interventions addressing school children's needs for emotional resilience have necessitated this study. This need is pressing, as the world is currently struggling to curb the influences of the COVID-19 pandemic, and as there are indications that the quarantine and social distancing policies will have long-term impacts on children's mental health [2]. According to Ye [2], innovative digital solutions and informatics tools are needed more than ever to mitigate these negative consequences on children. According to March et al [26], if effective, iCBT programs could be a promising first-step, low-intensity intervention that children and the youth can easily access. The present study attempted to examine whether a CBT-based prevention intervention that aims to build resilience in young children can

be effective when enacted in formal education through a web-based, interactive learning environment.

Methods

Research Questions

This study focused on designing and evaluating an interactive learning environment, which was enacted in formal education, to examine its potential to deliver resilience interventions in an effective and accessible manner. The research questions of the study were the following:

1. To what extent is the interactive learning environment for resilience effective in reducing 9-10-year-old children's anxiety symptoms?
2. To what extent is the interactive learning environment for resilience effective in increasing 9-10-year-old children's skills in identifying emotions and stress symptoms and in recalling stress management techniques?
3. How do 9-10-year-old children evaluate the usability of the interactive learning environment for resilience?

Interactive Learning Environment for Resilience

For the purpose of the study, an interactive learning environment to support resilience was designed and developed in accordance with the structure and recommendations of Psyllou [41], who based her work on the conventional CBT program "Friends." The protagonists in the learning environment were 6 distinct 9-year-old characters who acted as peer models for children and showed them how to manage their anxiety. The learning environment included the following: (1) narrations that children could listen to on headphones, (2) children's individual and anonymously provided written reflections on personal struggles, which were made possible through a comment feature that was only visible to the administrator (ES), to respect children's privacy, and (3) interactive quizzes, which provided instant feedback.

The web-based environment involved a series of interactive activities structured in six 80-minute sessions. In session 1, children were introduced to the 4 primary emotions (happiness, anger, sadness, and fear) and individually responded to web-based questions asking them to identify when and how specific people felt each emotion. Web-based questions also prompted them to think about times when they (or others) felt the same emotion. The final activity of session 1 required children to draw their self-portrait to show what they look like when they feel these 4 emotions.

In session 2, children were introduced to stress and anxiety, through short stories they could listen to from each of the 6 protagonists. The protagonists showed them that everyone is stressed out by different situations by sharing their own anxieties. The children were then prompted to answer web-based questions to identify an area or situation that was stressful for them with which they would like to learn how to cope.

In session 3, the protagonists explained the relationship between thoughts and emotions and demonstrated how children can change their negative thoughts to positive ones. The children could listen to brief examples derived from the protagonists'

daily life in which they experienced something that made them anxious. They then responded to web-based questions that asked them to identify a time during the previous week when they felt happy and one during which they felt anxious and describe their thoughts and emotions in each case. They were then asked to listen to a short story and respond to web-based questions to identify positive and negative thoughts that the protagonists might have had.

In session 4, children had more practice in identifying positive and negative thoughts through a web-based quiz that provided instant feedback. In the same session, they learned how they can ignore the negative thoughts and retain the positive ones through several examples of short stories narrated by the protagonists. During the last activity in session 4, the children applied what they have learned in a situation that was stressful for them by responding to web-based questions to describe this situation and by identifying a positive thought relevant to that situation.

In session 5, the protagonists taught children how to manage stressful situations and demonstrated how they could design action plans to gradually face their fears by breaking them down into manageable small pieces. Children first listened to one of the protagonists' narration of how she overcame the anxiety of reading in front of the whole class by focusing on 1 step at a time: the protagonist started out by reading a short text alone at home in front of a mirror (step 1), one of the protagonist's parents (step 2), the protagonist's whole family (step 3), one of the protagonist's friends (step 4), a group of friends (step 5), and eventually the whole class (step 6). Students responded to web-based questions to identify a stressful situation for them and to break it down to 6 smaller steps. In Session 6, the children were reminded of everything they have learned, including the acronym of the word "friends," which helps children remember the steps to follow upon feeling anxious [42]: F="feeling worried?" R="relax and feel good," I="inner thoughts (changing negative thoughts to positive ones)," E="explore action plans," N="nice work, reward yourself," D="don't forget to practice," and S="stay calm."

Several key persuasive systems' design features were used in the interactive learning environment, including "simulation with a social role," "similarity," and "social learning" [30]. For example, "simulation with a social role" was incorporated in instances where the 6 animated characters narrated their experiences while simultaneously illustrating concepts of the program. "Social learning" was incorporated when these animated characters provided suggested solutions or worked through their problems to serve as peer models for children and to demonstrate ways to solve real-life problems. "Similarity" was incorporated because the examples and activities provided in the learning environment were specific to target 9-10-year-old children and their typical everyday stressors (similarity), which included the anxiety of speaking in front of the whole class or in front of a bigger audience, and anxiety related to taking school tests.

Study Design

The study followed a quasi-experimental pretest-posttest control group design. A primary school with access to a computer

laboratory was chosen through convenience sampling to participate in the study. Children individually interacted with the web-based learning environment (1 child:1 computer), using headphones. The learning environment was enacted under the responsibility of author ES (who also designed the learning environment) in close collaboration with author GL (a licensed psychologist), who was present in all sessions. The decision to include a psychologist was based on research findings from the evaluation of the conventional program "Friends," in which more favorable outcomes were found when health professionals, as opposed to educators, were involved in conducting the sessions [20]. However, as the intervention took place primarily on the internet, the guidance provided by either the psychologist or author ES to children while interacting with the learning environment was minimal and focused on technical issues of navigation rather than psychological issues.

Based on previous studies [20,25,41], it was decided that the most appropriate age group for the intervention is 9-10 years, which corresponds to children who are in the fourth grade of primary school. There were 2 fourth grade classes in the school selected in this study. One class was randomly considered the experimental group, while the other served as the control group.

Participants

In total, 20 fourth-grade primary school students (11 boys and 9 girls) were included in the experimental group and used the web-based learning environment over six 80-minute lessons between November 2018 and March 2019. In addition, 21 fourth-grade primary school students (10 boys, 11 girls) were included in the control group and did not receive formal instruction on resilience, emotion recognition, or stress management.

Ethical Considerations

The study protocol was approved by the Center for Educational Research and Evaluation of the country in reference (proposal reference# 7.15.01.25.8.1/9), and it was evaluated by the ethics committee of the university in reference (proposal submission number 54) prior to the conductance of the study. The study adhered to the ethical standards of the American Psychological Association and General Data Protection Regulation guidelines. Our study adhered to all legal requirements of the country where it was conducted. All participants were informed in writing about the study's objective, and the students' parents signed the consent forms for their children to participate in the study voluntarily.

Data Sources and Data Analysis

Data sources were the following: (1) the Greek translation of the psychometric tool Spence Children's Anxiety Scale (SCAS) to measure children's anxiety symptoms [43-45], (2) 3 open-ended questions to assess the ability to recognize emotions and anxiety symptoms and to recall ways of managing stress, and (3) the System Usability Scale (SUS) to measure the usability of the learning environment. These 3 data sources were used to answer research questions 1, 2, and 3, respectively.

The psychometric tool SCAS [43,44] is a child self-reported tool that consists of 45 questions designed to measure symptoms

related to separation anxiety (questions 5, 8, 12, 15, 16, and 44), social phobia (questions 1, 6, 7, 9, 20, 29, and 35), obsessive-compulsive disorder (OCD; questions 14, 19, 27, 40, 41, and 42), panic agoraphobia (questions 3, 13, 21, 28, 30, 32, 34, 36, 37, and 39), generalized anxiety (questions 2, 18, 23, 25, and 33), and fears of physical injury (questions 1, 3, 4, 20, 22, and 24). The scale consists of 45 statements outlining anxiety symptoms, to which children report with the frequency by which they experience these symptoms by using a 4-point Likert scale (0="never," 1="sometimes," 2="often," and 3="always"). Six of the 45 statements are positive statements that aim to reduce the negative predisposition toward statements outlining anxiety symptoms. These 6 statements are not typically included in the data analysis. The scale was translated and weighted for the Greek population [45].

To analyze data from the psychometric tool, the Greek translation of the original SCAS for research question 1, the

response "never" received a score of 0, the response "sometimes" received a score of 1, the response "often" received a score of 2, and the response "always" received a score of 3. The total score of the symptoms was computed for each of the 6 anxiety disorders examined in this instrument so that the mean score of each disorder could be computed. Descriptive statistics (mean, SD) and inferential statistics (paired samples and independent samples *t* tests) were used for data analysis. An α level of .05 was set a priori for all statistical analyses.

For research question 2, 3 open-ended questions were used to assess the ability to recognize emotions and symptoms of anxiety and to recall ways of managing stress. These were the following: (1) "What are the four main emotions?" (2) "What symptoms do you feel on your body when you are stressed?" and (3) "What can you do to relax when you feel stressed?" The coding sheets for the evaluation of these 3 open-ended questions are provided in Tables 1, 2, and 3.

Table 1. Coding sheet for an open-ended question on basic emotion identification.

Points received	Rationale	Example student answer
0	No reference to emotions	"I don't know" [Participant #1, female]
1	Reference to 1 of 4 primary emotions	"Happiness" [Participant #10, male]
2	Reference to 2 of 4 primary emotions	"Happiness, Sadness, Joy" (joy is not one of the 4 basic emotions) [Participant #6, female]
3	Reference to 3 of 4 primary emotions	"Happiness, anger, excitement, sadness" (excitement is not one of the four basic emotions) [Participant #16, female]
4	Reference to the 4 primary emotions	"Happiness, anger, fear, sadness" [Participant #3, female]

Table 2. Coding sheet for an open-ended question on the identification of somatic symptoms when stressed.

Points received	Rationale	Example student answer
0	No reference of symptoms	"I don't have any symptoms" [Participant #1, female]
1	Reference to 1 symptom	"Trembling" [Participant #6, female]
2	Reference to 2 symptoms	"I have pain in my belly, and I tremble" [Participant #13, male]
3	Reference to ≥ 3 symptoms	"I am sweating, I have a headache, and I tremble" [Participant #3, female]

Table 3. Coding sheet for an open-ended question on the identification of stress management techniques.

Points received	Rationale	Example student answer
0	No reference to stress management techniques	"I do nothing" [Participant #1, female]
1	Reference to 1 stress management technique	"I lie down" [Participant #3, female]
2	Reference to 2 stress management techniques	"I can sleep and watch TV" [Participant #19, male]
3	Reference to ≥ 3 stress management techniques	"I close my eyes, watch TV, I use my Playstation" [Participant #13, male]

Descriptive statistics (mean, SD) and inferential statistical tests (paired samples and independent samples *t* tests) were used for data analysis for answering research question 2.

For research question 3, the learning environment's usability was measured with the SUS [46]. The SUS was selected because (1) it is a highly robust and versatile tool for usability professionals [47] and (2) it allows for the comparison of similar systems. The scale included the following ten items, with responses graded on a 5-point Likert scale ranging from "completely disagree" to "completely agree": (1) "I think that

I would like to use this learning environment frequently," (2) "I found the learning environment unnecessarily complex," (3) "I thought the learning environment was easy to use," (4) "I think that I would need help from my parents or siblings to be able to use this learning environment," (5) "I found the various functions in the learning environment were well integrated," (6) "I thought there was too much inconsistency in the learning environment," (7) "I would imagine that most children my age would learn to use this learning environment very quickly," (8) "I found the learning environment very cumbersome to use,"

(9) "I felt very confident using the learning environment," and (10) "I needed to learn a lot of things before I could get going with this learning environment."

For data analysis, the procedure for calculating usability evaluation scores proposed by Brooke et al [46] was followed. Specifically, for odd-numbered items, 1 was subtracted from the user response. For even-numbered items, the user responses were subtracted from 5. This procedure scored all values on a scale of 0 to 4 (4 being the most positive response). The converted responses for each user were summed, and the total was multiplied by 2.5. This converted the range of possible values of 0-100 instead of 0-40. An average SUS score was calculated for all participants. The SUS score was then converted into a percentile rank and a letter grade from A to F in accordance with the norms proposed by Sauro [48,49].

Results

Research Question 1

All 41 learners were pretested with regard to their level of experience of anxiety disorders. Group equivalence was first established. There were no significant differences between the 2 classes when an independent samples *t* test was performed ($t_{38}=0.083$; $P=.93$) to compare the pretest scores of students' separation anxiety for the intervention group (mean score 1.00,

SD 0.69) and the control group (mean score 0.99, SD 0.58). The same finding was obtained for all anxiety disorders, as shown in Table 4, indicating that the 2 groups were equivalent before the intervention.

After establishing group equivalence, experimental students' pre- and postintervention scores for anxiety disorders were compared. A paired samples *t* test revealed that students' reported symptom scores of OCD significantly decreased from 1.06 (SD 0.68) to 0.76 (SD 0.61) ($t_{19}= 5.16$; $P=.01$). A post hoc power analysis was performed using G*Power3 [50] where 1- β was computed as a function of α (set at .05), the population effect size parameter for a medium effect size (Cohen $d=.05$), and the sample size used in this study ($n=20$ for the experimental group). The power thus calculated was 0.695. Reported scores for the symptoms of separation anxiety, social phobia, fears of physical injury, and generalized anxiety decreased slightly but nonsignificantly from before to after the intervention (Table 4). Panic agoraphobia symptoms were, however, slightly but nonsignificantly increased.

Furthermore, we compared the scores for students' anxiety disorders before and after the intervention for the control group. In total, the scores for 4 of 6 disorders (separation anxiety, OCD, panic agoraphobia, and fears of physical injury) were slightly but nonsignificantly reduced from before to after the intervention (Table 4).

Table 4. Anxiety disorders before and after the intervention for the experimental and control groups.

Anxiety disorders	Experimental group (n=20)		Control group (n=21)		Comparison of pretest scores	
	Preintervention, mean (SD)	Postintervention, mean (SD)	Preintervention, mean (SD)	Postintervention, mean (SD)	<i>t</i> value	<i>P</i> value
Separation anxiety	1.00 (0.69)	0.79 (0.62)	0.99 (0.58)	0.93 (0.58)	0.083 ^a	.93
Social phobia	0.97 (0.57)	0.75 (0.47)	0.87 (0.54)	0.99 (0.67)	0.550 ^b	.58
Obsessive-compulsive disorder	1.06 (0.68)	0.76 ^c (0.61)	0.97 (0.60)	0.83 (0.59)	0.213 ^d	.83
Panic agoraphobia	0.39 (0.48)	0.45 (0.51)	0.49 (0.41)	0.45 (0.48)	-0.721 ^e	.62
Generalized anxiety	0.78 (0.39)	0.77 (0.58)	0.90 (0.61)	0.87 (0.57)	0.203 ^a	.84
Fears of physical injury	0.83 (0.66)	0.60 (0.57)	0.79 (0.59)	0.82 (0.52)	-0.760 ^a	.45

^adf=38.

^bdf=37.

^c $P=.01$.

^ddf=36.

^edf=39.

Research Question 2

All 41 learners were pretested with regard to their level of knowledge of the 4 basic emotions, their ability to identify somatic stress symptoms, and their ability to identify ways to manage their stress. As shown in Table 5, students in the control group initially outperformed those in the experimental group in the pretest score. We observed a significant difference between the 2 classes when an independent samples *t* test was performed ($t_{39}=0.005$; $P=.005$) to compare the students' total

pretest score for the experimental (mean 3.35, SD 1.79) and control (mean 5.05, SD 1.83) groups.

However, in general, the performance score of the students in the control group was lower in the posttest (mean 4.71, SD 1.52) rather than the pretest (mean 5.05, SD 1.83) conditions. For the 3 areas that were examined, the performance of the students in the control group remained the same after the intervention, as was the case for the identification of the 4 basic emotions (mean 2.86, SD 1.35) or it was lower, as was the case for the

identification of somatic symptoms of stress and stress management techniques.

On the contrary, the performance of the students in the experimental group increased from 3.35 (SD 1.79) of 10 in the pretest condition to 7.65 (SD 0.88) in the posttest condition. This increase was significant ($t_{19}=-10.46$; $P<.001$) and a large effect was observed (Cohen $d=1.88$; 95% CI 1.136-2.625) [51].

As shown in Table 5, a significant increase was also observed for students in the experimental group with regard to the identification of basic emotions after the intervention, where a large effect was observed (Cohen $d=1.22$; 95% CI 0.546-1.897) [51]. Significant, large effects were also observed for the identification of somatic symptoms of stress (Cohen $d=1.56$; 95% CI 0.853-2.269) and the identification of stress management techniques (Cohen $d=1.248$; 95% CI 0.57-2.925).

Table 5. Identification of basic emotions, somatic stress symptoms, and stress management techniques before and after the intervention for the experimental and control groups.

Anxiety disorders	Experimental group (n=20)			Control group (n=21)	
	Preintervention, mean (SD)	Postintervention, mean (SD)	<i>t</i> value ^a	Preintervention, mean (SD)	Postintervention, mean (SD)
Identification of the 4 basic emotions	1.55 (1.05)	3.35 ^b (0.05)	-6.99	2.86 (1.35)	2.86 (1.01)
Identification of somatic symptoms of stress	0.70 (0.66)	2.15 ^b (0.13)	-7.31	1.05 (0.74)	1.00 (0.77)
Identification of stress management technique	1.05 (0.69)	2.15 ^b (0.67)	-6.85	1.14 (0.73)	0.86 (0.73)
Total score	3.35 (1.79)	7.65 ^b (0.88)	-10.46	5.05 (1.83)	4.71 (1.52)

^aPaired samples *t* test; *df*=19.

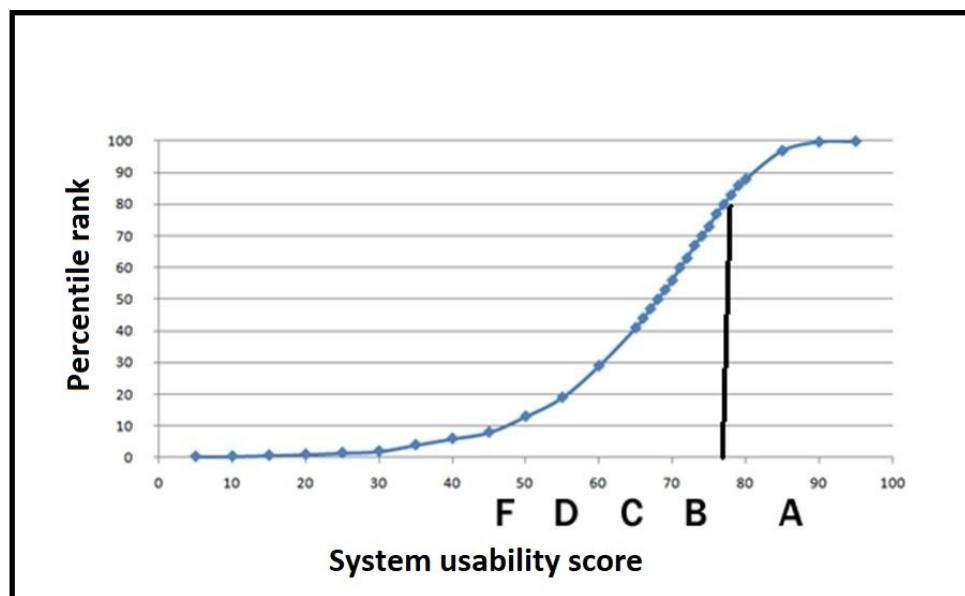
^b $P<.001$.

Research Question 3

The average SUS scores reported for the 20 children in the experimental group were calculated to answer research question 3. The learning environment received a satisfactory usability score. The raw average SUS score was 76.75 (SD 8.28), which was in the 80th percentile rank and corresponded to grade B.

Figure 1 shows how the percentile ranks are associated with SUS scores and letter grades [48,49]. This process is similar to “grading on a curve” based on the distribution of all scores. For example, a raw SUS score of 74 converts to a percentile rank of 70. A SUS score of 74 has higher perceived usability than 70% of all products tested [48,49].

Figure 1. The raw average system usability score of the interactive learning environment on resilience, based on a sample of 20 participants. A, B, C, D, and F are the corresponding letter grades.



Discussion

This study aimed to examine the effectiveness of a technology-supported learning environment on resilience in reducing anxiety symptoms among 9-10-year-old children and in increasing children’s recognition of emotions and stress

management techniques through a quasi-experimental pretest-posttest control group design. The study initially showed that anxiety symptoms of participating students generally manifested at a low level in both the experimental and control groups, as prior to the intervention, all anxiety disorders that were examined, specifically separation anxiety, social phobia,

OCD, panic agoraphobia, generalized anxiety, and fear of physical injury received low scores that did not exceed 1 on a scale ranging from 0 (“never”) to 3 (“always”). This finding suggests that students, on average, “sometimes” experience symptoms associated with the aforementioned disorders. Despite low levels of reported anxiety symptoms before the intervention, there was a significant reduction in symptoms associated with OCD after the intervention in the experimental group, which indicates that the learning environment on resilience effectively reduced reported symptoms associated with OCD, especially since the students in the control group did not display a significant reduction in their scores. A comparison of pretest and posttest scores for the experimental group revealed a slight but nonsignificant reduction in the frequency of reported symptoms associated with disorders, such as separation anxiety, social phobia, generalized anxiety, and a fear of physical injury.

Regarding research question 2, the interactive learning environment on resilience was shown to be effective in increasing children’s ability to recognize basic emotions, identify somatic stress symptoms, and recall stress management techniques they can use in real-life settings to alleviate stress. This was evident from a significant increase in their scores for open-ended questions after the intervention both overall and for each specific area examined, as opposed to the control group, whose performance scores did not increase.

Psychological resilience and finding ways to cope during a crisis is a highly relevant topic owing to the recent COVID-19 pandemic, which enforced quarantine and social distancing measures and school closures worldwide. During the pandemic, the youth have faced challenges associated with the loss of face-to-face social interaction [52]. According to Ye [2], psychological crises often cause children to have feelings of abandonment, despair, incapacity, and exhaustion and even raise the risk of suicide. Children with mental illnesses are especially vulnerable during the quarantine and social distancing period. Even though the world has been struggling to curb the influences of the pandemic, quarantine and social distancing policies will have long-term impacts on children [2]. Therefore, according to Ye [2], innovative digital solutions and informatics tools are needed more than ever to mitigate the negative consequences on children. March et al [26] reported that web-based self-help CBT might offer a feasible and acceptable first step for delivering mental health care services to children and adolescents with anxiety. Accordingly, the interactive learning environment on resilience that was described and evaluated in our study is an example of a digital solution toward this direction. As revealed by research question 1, the learning environment was found to be effective in reducing anxiety symptoms of OCD, at least based on children’s self-reports; moreover, the learning environment effectively supported children in identifying stress symptoms and in recalling stress management techniques through a web-based intervention with minimal guidance from a teacher or mental health expert.

Pusey et al [1] recently reported that interactive technologies can deliver effective resilience interventions in an accessible, cost-effective, and flexible manner. Their review included several types of interactive technologies used in resilience interventions, such as serious video games, virtual reality

simulations, social robots, and commercial off-the-shelf video games. Their review did not, however, include web-based interactive learning environments. Our study shows that interactive learning environments seem to have the potential to deliver resilience interventions in formal education settings in an accessible and user-friendly manner as well, as revealed by our usability findings. Children in this study were assisted by an adult to a very small extent as they mostly navigated through the learning environment using headphones at their own pace and individually responded to web-based questions. The proposed resilience intervention can potentially be accessible beyond the classroom’s confined environment for providing support to children anywhere and anytime, with a smaller need for support by adults. This would allow for children’s individual, independent use of the intervention at their own pace at school or at home. The web-based learning environment on resilience can be a useful and empirically validated digital resource for parents to use with their children at home or for teachers to use in classes conducted on the internet to focus on their mental health, which can be delivered either synchronously or asynchronously.

Limitations

The sample of the study was small and random assignment in the 2 conditions was not possible. Convenience sampling was used rather than random sampling, which would have been preferred to increase the generalizability of our findings.

The psychometric instrument that we used was lengthy and included difficult terms. Its completion proved to be challenging for students. Moreover, even though it is a standardized instrument, it relies on the accuracy of young children’s self-reporting of symptoms. It would have been better if the data on students’ reported anxiety symptoms were triangulated with the use of additional qualitative data collection methods, such as parental interviews or teacher interviews. The role of parents and teachers in the program was potentially important, as it is possible that they might have already performed other effective interventions to manage children’s mental health. This contextual information was not collected at the time and is therefore not available to support our understanding of the characteristics of the selected participants.

Overall, the study was based on self-reported quantitative data. The addition of qualitative data in the form of a large number of student interviews would strengthen the study. Only 4 interviews were conducted with students of the experimental group, whose assessments are not included in this study. Longitudinally measuring students’ anxiety symptoms would also significantly add to the study, as it is possible that such interventions may have long-term effects rather than short-term effects, as previous studies have shown [14,23,53].

Future Directions

Ignoring the immediate and long-term psychological effects of the COVID-19 pandemic would be unconscionable, especially for children and the youth, who account for 42% of our world’s population [9]. With respect to short-term future goals, we therefore urgently need to utilize effective strategies to strengthen teachers and families to respond to the global

situation of the pandemic, as suggested by Cluver et al [8]. We need to respond with immediate ways to strengthen children's resilience, as "COVID-19 is not the first virus to threaten humanity, and it will not be the last" [8]. iCBT for child and adolescent anxiety has demonstrated efficacy in randomized controlled trials, but it has not yet been examined when disseminated as a public health intervention [26]. Effective iCBT programs could be a promising first-step, low-intensity intervention that can be easily accessed by the youth [26]. As a short-term research goal, the proposed intervention can be disseminated to a large sample of students who are currently taking classes through distance-learning while being isolated at home owing to COVID-19 movement restrictions imposed by several countries.

The interactive learning environment on resilience was used with children of the general population who experienced minimal stress at the time of the intervention (2018-2019), and it was shown to reduce 9-10-year-old children's anxiety symptoms slightly. It might prove to be more valuable when used by high-risk rather than low-risk children. This could be

a direction for future studies. As it is currently unknown whether implications from this study can be applied to different age groups, using the learning environment on resilience with children who are younger or older than the children that were recruited in this study could be another direction for future studies.

Engagement with interactive technology and whether users engage with target behaviors outside of the interactive technology in reference is difficult to measure and remains an unresolved challenge [1,35,54,55]. With respect to long-term future goals, studies should aim to follow-up with participants through longitudinal studies and embed evaluation systems that will enable assessing intervention fidelity and adherence to suggested stress management techniques in real-life settings. In this study, children only accessed the interactive learning environment at school. In future studies, especially if the intervention is made accessible among students on their mobile devices outside of school, there might be a way to measure "acceptability, dropout rates, and frequency of use," as measures that would imply engagement, according to Pusey et al [1].

Conflicts of Interest

None declared.

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Abbreviations

iCBT: internet-based cognitive behavioral therapy

OCD: obsessive-compulsive disorder

SCAS: Spence Children's Anxiety Scale

SUS: System Usability Scale

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Original Paper

A Data-Free Digital Platform to Reach Families With Young Children During the COVID-19 Pandemic: Online Survey Study

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Abstract

Background: The COVID-19 pandemic and containment measures have severely affected families around the world. It is frequently assumed that digital technologies can supplement and perhaps even replace services for families. This is challenging in conditions of high device and data costs as well as poor internet provision and access, raising concerns about widening inequalities in availability of support and consequent effects on child and family outcomes. Very few studies have examined these issues, including in low- and middle-income countries.

Objective: The study objectives were two-fold. The first objective was to gather data on the impact of the COVID-19 pandemic on families of young children using an online survey. The second objective was to assess the feasibility of using a data-free online platform to conduct regular surveys and, potentially, to provide support for parents and families of young children in South Africa.

Methods: We used a data-free mobile messenger platform to conduct a short digital survey of the impact of the COVID-19 pandemic on caring for young children in South Africa. We report on the methodological processes and preliminary findings of the online survey.

Results: More than 44,000 individuals accessed the survey link and 16,217 consented to the short survey within 96 hours of its launch. Respondents were predominantly from lower classes and lower-middle classes, representing the majority of the population, with urban residential locations roughly proportionate to national patterns and some underrepresentation of rural households. Mothers comprised 70.2% (11,178/15,912) of respondents and fathers comprised 29.8% (4734/15,912), representing 18,672 children 5 years of age and younger. Response rates per survey item ranged from 74.8% (11,907/15,912) at the start of the survey to 50.3% (8007/15,912) at completion. A total of 82.0% (12,729/15,912) of parents experienced at least one challenge during the pandemic, and 32.4% (2737/8441) did not receive help when needed from listed sources. Aggregate and individual findings in the form of bar graphs were made available to participants to view and download once they had completed the survey. Participants were also able to download contact details for support and referral services at no data cost.

Conclusions: Data-free survey methodology breaks new ground and demonstrates potential not previously considered. Reach is greater than achieved through phone surveys and some social media platforms, men are not usually included in parent surveys, costs are lower than phone surveys, and the technology allows for immediate feedback to respondents. These factors suggest that zero-rated, or no-cost, services could provide a feasible, sustainable, and equitable basis for ongoing interactions with families of young children.

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KEYWORDS

families; parenting; children; COVID-19; digital; survey; data-free

Introduction

The COVID-19 pandemic has affected families everywhere, both directly through illness and death, and indirectly through the effects of containment measures on economic activities and routines of daily life. Lockdowns, with varying degrees of restriction, have been imposed in many countries, and by the end of March 2020, more than 20% of the world's population was estimated to be under lockdown [1]. Many countries are, or will soon be, under second or third lockdowns. Although SARS-CoV-2 has had less serious effects on the morbidity and mortality of young children compared to older age groups, preschool children have been severely affected by indirect effects [2].

In South Africa, as in many other countries, early childhood development centers, public nurseries, kindergartens, and preschools have been closed since late March 2020 under one of the strictest lockdowns in the world. Private facilities began to reopen in late July 2020, but by August 2020, only 13% of children under the age of 6 years were attending their usual facility [3]. Movement restrictions and bans on visiting between households meant that families were not able to draw on the assistance of relatives and friends for relief childcare. As a consequence, families have had the sole responsibility for providing nurturing care for young children 24 hours a day, ensuring children's good health and nutrition, safety and security, and early learning opportunities as well as providing love and affection [4].

Among exacerbating concerns about childcare, some 3 million South Africans are estimated to have lost their jobs as a result of the effects of the COVID-19 pandemic on the economy, with women most affected [5]. Inestimable numbers of informal workers, mostly women, also lost their ability to generate income. As only 34% of South African children live with both parents [6], mothers, grandmothers, and aunts carry a heavy burden for both childcare and financial support for young children. Providing educational input for older siblings under school closures is an added responsibility for many families, given that most households have more than one child [7]. Confinement in small, crowded living spaces, together with fear of infection, are adding to mental health stresses in South Africa as in other countries, with potentially further adverse effects on children [8], particularly younger children [9].

Both short- and long-term adverse physical, psychological, and social effects of the pandemic conditions on children are predicted, with supporting evidence emerging. These include interrupted, delayed, and missed preventive health care visits for pregnant women and children, separation of parents and neonates at birth, closure of day care facilities, household poverty and food shortages, parental and child mental health stresses, and increased risk of parental substance abuse and interpersonal violence, including child abuse [10]. Ongoing longitudinal studies confirm that parental mental health has deteriorated, that children are more irritable and sleep less [11], that younger children are more likely than older children to manifest symptoms such as clinginess and fear that family

members might become infected [12], and that women and working parents are finding it hardest to cope [13].

There is considerable optimism about the potential application and expansion of digital technologies to fill gaps in knowledge and supplement health and social care during the pandemic [14]. These include public communication using mobile phones and the internet, surveys, digital surveillance and contact tracing, electronic clinical monitoring, telehealth, and counseling services [15]. Along these lines is a proliferation of digitally delivered parental guidance, advice, activities, and learning materials produced by governments, civil society groups, and multinational organizations to help maintain healthy adult-child interactions to support young children's development [16,17]. Digital technologies and methods are also being used to investigate the effects of pandemic conditions on families and young children. These include surveys delivered by phone and video, Facebook, Instagram, and Twitter [18-20].

While important efforts are being made to understand the effects of the COVID-19 pandemic on parents and young children using digital technologies, a number of challenges have to be addressed. Among these are that few studies have specifically looked at effects on preschool children; survey samples tend to be small, undefined, and/or selective, and questionnaires tend to be long, taking 40 minutes to an hour to complete [19,21]. Further, one-off surveys close to the start of initial lockdowns likely underestimated the long-term effects on children through continued job losses in families, increased household poverty, chronic parental mental health problems, and repeat lockdowns. What would be most helpful are repeat, tailored surveys to monitor compounding impacts on families, how family coping strategies evolve, and the interventions that give greatest relief at different stages of the pandemic's impact.

In low- and middle-income countries, the most immediate challenge is to establish communication channels to reach the greatest number of affected families in order to convey accurate information on how families can protect themselves and their children, solicit the changing needs of families, and respond effectively to their needs. In this respect, it has been recognized that even in high-income countries, few of the most marginalized groups are reached by digital technologies, and that it is essential to develop tools to address gaps in internet access to avoid a COVID-19-related increase in inequality due to the "digital divide" [15,22]. According to UNICEF (United Nations Children's Emergency Fund) [23], distance learning has failed to make up for school attendance, with about one-third of children in the countries surveyed not reached at all. Even in countries where distance learning exists, only two-thirds of children are reached by television and one-quarter by online delivery.

It is estimated that internet usage worldwide varies from approximately 87% in Europe to approximately 34% in Africa, with the lowest access (23%) among African women [24]. The most common reasons for lack of internet use are the high cost of devices and data, and poor provision and access to data services. Like many other countries, South Africa is highly unequal. Internet penetration is estimated at around 62%, with most people having access through their mobile phones. About

double the number of users live in urban as compared to rural areas [25]. Only about 10% of South Africans have a stable internet source in their homes [26]. WhatsApp—a data-driven platform—is the most frequently used social media app, followed by Facebook (87%), Instagram (61%), and Twitter (44%) [25]. WhatsApp has evolved into one of the primary methods of communication between individuals and between communities, governments, and nongovernmental organizations (NGOs).

Some online surveys have been conducted to ascertain understanding, practices, and impacts of the COVID-19 pandemic among South Africans, although none specifically have focused on parents of young children or on young children themselves [27-29]. In order to survey large numbers of parents of preschool children to ascertain their most pressing needs during COVID-19 lockdown conditions and how families were coping, we trialed the use of a data-free, zero-cost social media platform. If successful, the platform and similar other channels could be used to establish ongoing communication with parents of young children in order to communicate prevention measures, survey COVID-19 impacts, and provide appropriately targeted interventions.

Methods

Study Design

We designed a short questionnaire consisting of between 18 and 30 questions, depending on response options, with one item displayed on-screen at a time and a progress indicator. Skip patterns and branching logic were used to streamline questions and improve participant experience by reducing the number of irrelevant questions requiring a response. The small number of questions also eliminated the need for their randomization. Participants were required to provide a response for each question to move forward in the survey and nonresponse options in the form of *other* were included, but participants could move backward to edit prior responses. The questionnaire was translated into the most common languages used in South Africa: Afrikaans, English, Sesotho, isiZulu, and Sepedi. The questionnaire and translated versions were programmed into REDCap (Research Electronic Data Capture), a secure web platform designed to support survey distribution and data capture for research [30,31]. A list of national referral and support services for families was uploaded in Adobe Acrobat format and made available to download at the conclusion of each completed survey.

A set of screening questions excluded participants younger than 18 years of age, those not caring for a child under 5 years of age, and those not living in South Africa. All participants were required to consent to the survey, as mandated by the Human Research Ethics Committee of the University of the Witwatersrand (H20/06/38). The informed consent process included disclosures of the nature and purpose of the survey, risks and benefits of participation, uses to which the data would be put, guarantees of anonymity, and investigator contact details as well as those of the responsible ethics committee. Demographic details were kept to a minimum to make the survey as short as possible and encourage participation.

Questions covered challenges of caring for young children, sources and types of help received, as well as unmet needs. The questionnaire was piloted among staff and colleagues speaking each of the languages. The English version of the questionnaire is attached as [Multimedia Appendix 1](#). Coding of multilingual responses was held constant to allow for integrated analysis and immediate graphic presentation of results.

We used the Moya Messenger platform, hosted by biNu (now called Datafree), as our population source for convenience sampling [32]. biNu's technology offers two services: the first is to reverse-bill online content through partnerships with all major cellular networks in South Africa, and the second is the data-free Moya Messenger platform. Their Moya Messenger app is a growing platform of users who are able to send messages to other users without incurring data costs. The app offers unlimited texting, group chat, end-to-end security with automatic encryption, and contact discovery, similar to WhatsApp and Viber, but without the use of the individual's data. The platform is monetized through a Moya Discover service where external parties pay to have their websites, surveys, and content featured. Surveys are pinned to the platform and open to all users subscribed to Moya. Users of the Moya platform are made aware of the terms and conditions associated with using the app, including exposure to advertising.

The data-free services are used in two ways. The first is to have all survey content reverse-billed. This generates a data-free link that can be shared through any medium so that participants can access and complete the survey without paying for data. The second is to share survey links with the sample of Moya subscribers who have access to the interface where the survey is pinned and are able to complete the survey without incurring any data costs. A grant awarded to the University of the Witwatersrand was billed for data used by participants at the rate of 20 South African cents (US \$0.015) per megabyte, averaging R6 (US \$0.44) per survey response. By February 2020, the Moya platform had in excess of 2.3 million active daily users [33] of all genders, age categories, and income groups. The user profile is 53% female and 90% so-called non-White, with 80% of the sample falling into a Living Standards Measure of between 3 and 7 deciles based on urbanization and asset ownership [34], and 92% earning less than R15,000 per month (US \$1000). That is, users fall into lower-class and lower-middle-class groups.

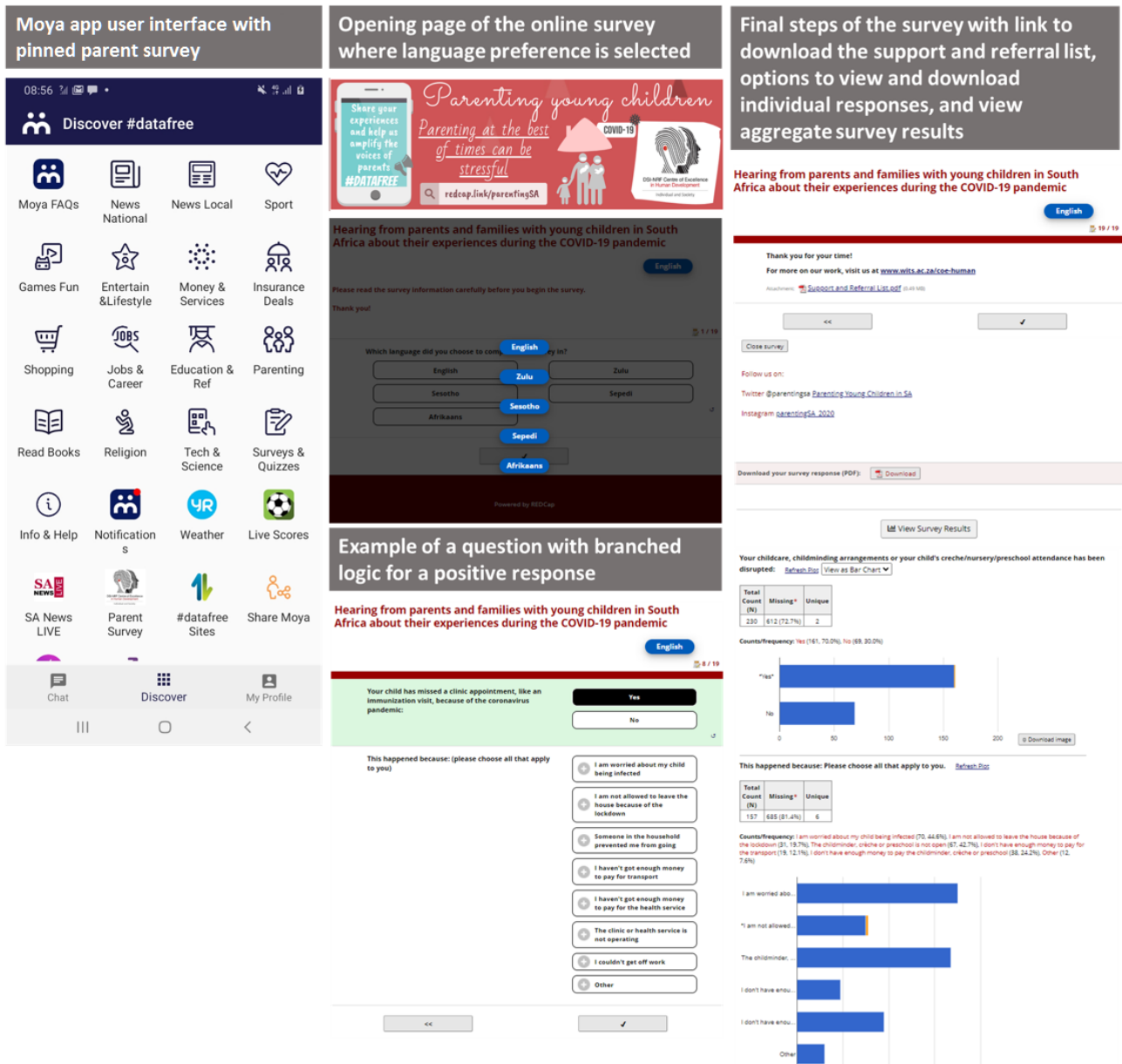
Distribution of the Survey

REDCap generated a URL link to the survey that could be distributed from the web platform or from other sources. biNu reconfigured the URL and all its content to be reverse-billed to a secure account held by the research team. All responses linked to the URL were transmitted directly to the REDCap server and collated in a secure database. For distribution on the Moya Messaging platform, biNu placed a pinned notice of the survey on the platform's interface where users are able to view news, updates, and survey alerts. Since the survey link was available to any user of the platform, it was considered an open survey. The link was the initial contact with potential participants who were able to see the pinned notice on their user interface and could open it to complete it ([Figure 1](#)). Once the survey link

was opened from the Moya interface, users were asked to choose their language preference and were directed to the information section of the survey, which detailed the purpose of the survey, eligibility, and consent and that there would be no incentive for participation. Each time the link was opened, a record of that response was created in REDCap as a single observation. The survey was not restricted to a single response per device. The survey was pinned to an app—Moya Messenger—and was only accessible from a device with the app installed. The absence of an incentive was also thought to discourage multiple entries from the same individual. Cookies were not collected, but

REDCap did collect Internet Protocol addresses along with a master log file of all survey activity, which could be analyzed retrospectively to identify duplicate responses; however, this data are not accessible to normal end users and strict processes to ensure anonymity must be adhered to before REDCap grants access to this data. During the piloting phase, the survey took between 4 and 8 minutes to complete, with an average of 5 minutes. Accurate survey lengths could not be calculated during the data collection phase because participants were allowed to leave the survey and return at a later time to complete it.

Figure 1. Screenshots of the online survey, including language selection, questions, and individual and aggregate findings, as pinned on the Moya app.



Analysis

Responses to the survey were collected and stored in REDCap in real time, allowing continuous online analysis of data. Once the responses reached time and budget allocations for the study, the survey was terminated on both the REDCap and Moya platforms. Data cleaning and quality control were undertaken on the REDCap platform using built-in data validation features.

The data were exported into SPSS, version 26.0 (IBM Corp), for further data cleaning and analysis. Cases with missing data were not excluded from the analysis and no statistical corrections were performed to adjust for any nonrepresentativeness.

Results

The progression of participation in the survey was tracked by calculating attrition at each stage of the screening questions. The survey link was opened by 44,292 users within 96 hours of it appearing on the data-free platform; 21,993 participants were of eligible age, 17,325 participants were caring for a child under the age of 5 years, and 16,217 participants consented to

participate in the survey, at a recruitment rate of 36.6%. A total of 1.9% of respondents (305/16,217) were caregivers of groups of children in day care centers. These responses were excluded from the analysis, and 15,912 eligible consenting participants comprised the analytical sample.

Response rates and missing values are shown in [Table 1](#). More than half of the participants (8007/15,912, 50.3%) responded to all questions.

Table 1. Response rates to survey questions and missing values.

Variable	Participants who responded (N=15,912), n (%)	Participants who did not respond (N=15,912), n (%)
Missed clinic visits	11,907 (74.8)	4005 (25.2)
Disruption in ECD ^a services	10,646 (66.9)	5266 (33.1)
Breastfeeding challenges for children 0 to 6 months of age	1545 (73.8)	548 (26.2) ^b
Child-feeding challenges	9954 (62.6)	5958 (37.4)
Difficult to be affectionate	9310 (58.5)	6602 (41.5)
Violence toward child	9001 (6.6)	6911 (43.4)
Child behavior challenges	8668 (54.6)	7244 (45.5)
Receiving community help	8439 (53.0)	7473 (46.9)
Receiving government help	8246 (51.8)	7666 (48.2)
Receiving nongovernmental organization help	8007 (50.3)	7905 (49.7)

^aECD: early childhood development.

^bCalculated from a total of 2093 children aged 0 to 6 months of age.

By residence, respondents were roughly representative of the South African urban population residing in cities, suburbs, and townships, with lower representation from rural respondents who have less access to mobile phones and the internet ([Table 2](#) [35,36]). By 2016, 99% of South Africans in urban areas had

a smartphone, compared to 83% in rural areas [37]; however, only 45% of rural households were able to access the internet using their mobile devices, compared to 64% of urban households [38].

Table 2. Representativeness of the sample by area of residence.

Area of residence	Participants (n=15,204), n (%)	National average, %
City or suburb	4959 (32.6)	27
Township ^a	6578 (43.3)	40 [35]
Rural settlement, village, farm, or tribal area	3068 (20.2)	33 [36]
Other	599 (3.9)	N/A ^b

^aTownships were created as segregated dormitory suburbs in urban areas to house African workers under Apartheid.

^bN/A: not applicable; an *other* category was added to this survey but is not included in the national census. A nonspecific response option is generally recommended, especially if respondents are required to give a response before moving on to the next question.

Although the majority of South Africans are African-language speakers, 83.0% of respondents (13,207/15,912) completed the survey in English, the main language of instruction in South African schools, following the teaching of mother tongues in Grades 1 to 3. A substantial proportion of participants were fathers (4734/15,912, 29.8%).

[Table 3](#) shows the age and gender of children to whom respondents referred in the survey. Children were roughly evenly

divided between those aged 0 to 3 years and those aged older than 3 to 5 years, as well as between boys and girls. A total of 18,672 children were included in the analysis, but questions were not answered in reference to a single index child. About half of the parents (6799/13,228, 51.4%) reported 1 child under 5 years of age in the home, and 40.9% (5125/12,522) reported 2 to 3 children under 5 years of age in the home.

Table 3. Characteristics of children to whom respondents referred in the survey.

Characteristic	Children, n (%)	Cumulative %
Age (n=18,238)		
0 to 6 months	2093 (11.5)	11.5
>6 months to <1 year	2252 (12.4)	23.8
1 to 3 years	4954 (27.2)	50.9
>3 years to 5 years	8939 (49.0)	100
Gender (n=18,672)		
Female	9361 (50.1)	50.1
Male	9311 (49.9)	100

Responses to the survey questions (Table 4) showed that families were severely affected by the government's attempts to contain the COVID-19 pandemic. The detailed results of the effects of COVID-19 on families are under preparation. One-third of children (3920/11,907, 32.9%) were reported to have missed an immunization visit, mainly because parents feared that their child would become infected; 68.7% (7313/10,646) of children's day care and crèche arrangements were discontinued or disrupted, also mainly because of fear of infection. This response was fairly constant from parents with children 0 to 6 months of age to 3 to 5 years of age, indicating that closure of services and facilities also affected parents with very young infants. One-third of mothers (367/1049, 35.0%) and fathers (117/403, 29.0%) reported that breastfeeding a child under 6 months of age was difficult, citing fear of infecting their baby. Half of all parents (4964/9954, 49.9%) were finding it difficult to feed their young child, mainly because the family did not have enough money to buy appropriate food. A total of 41.2% of parents (3832/9310)—proportionately more fathers (1150/2419, 47.5%) than mothers (2372/6135, 38.7%)—were finding it difficult to be affectionate toward their child, due to an even division between parental stress and depression, household tension, and child irritability and crying. Close to one-third of parents (1662/5760, 28.9%), slightly more mothers, were finding it difficult to deal with their young child's behavior. Responses as to how parents were coping ranged from trying to comfort a distressed and crying child (960/2391, 40.2%), punishing a child for being naughty (745/2391, 31.2%), feeling hopeless and not knowing what to do (764/2391, 31.9%), and asking other household members for help to distract and comfort a child

(239/2391, 10.0%). A total of 13.8% of fathers (320/2314) and 11.0% of mothers (657/5961) reported that someone in the household had been angry and violent toward their child. Most often, violence was reported to be perpetrated by another adult in the household (720/1123, 64.1%), but 17.7% (60/339) of fathers and 12.4% (85/687) of mothers reported that they had been angry and violent toward their child. The most frequent reasons given for getting angry and violent with a young child was when an adult lost their temper (469/1070, 43.8%), when the child broke or took something they were not supposed to touch (350/1070, 32.7%), and to prevent the child from being hurt or injured by, for example, fire, poison, or an open water source (173/1070, 16.2%).

Two-thirds of parents said they needed help, the majority of whom were in urgent need of money, vouchers, or food parcels. Clothes; blankets; personal protective equipment (PPE), such as masks and soap; and medicine were also high on their list of needs. When asked what help they had received from different sources, more parents reported getting assistance from governmental organizations (2581/8246, 31.3%) than from neighbors and community groups (2028/8439, 24.0%) or from NGOs (1106/8007, 13.8%). Among those who did receive help, the most common form was reported to be money or vouchers from governmental organizations (1175/3349, 35.1%). Help received from NGOs was most frequently reported to be food parcels (612/1619, 38.8%). Neighbors and community groups were reported to give a wide range of help, most commonly food, financial loans, PPE, information, relief childcare, and emotional support for mental distress.

Table 4. Responses regarding challenges and support by parent type.

Survey item	Mothers, n (%)	Fathers, n (%)	Total, n (%) ^a
I have missed a clinic appointment, like an immunization visit, because of the coronavirus pandemic			
Total	7468 (100)	3422 (100)	11,907 (100)
Yes	2446 (32.8)	1165 (34.0)	3920 (32.9)
No	5022 (67.2)	2257 (66.0)	7987 (67.1)
My childcare, childminding arrangements, or my child's crèche, nursery, or preschool attendance has been disrupted			
Total	6845 (100)	2911 (100)	10,646 (100)
Yes	4641 (67.8)	2027 (69.6)	7313 (68.7)
No	2204 (32.2)	884 (30.4)	3333 (31.3)
Breastfeeding my baby is difficult during this time			
Total	1049 (100)	403 (100)	1545 (100)
Yes	367 (35.0)	117 (29.0)	510 (33.0)
No	682 (65.0)	286 (71.0)	1035 (67.0)
I am struggling to properly feed my young child			
Total	6489 (100)	2636 (100)	9954 (100)
Yes	3185 (49.1)	1407 (53.4)	4964 (49.9)
No	3304 (50.9)	1229 (46.6)	4990 (50.1)
It is difficult to be affectionate with my child during this time			
Total	6135 (100)	2419 (100)	9310 (100)
Yes	2372 (38.7)	1150 (47.5)	3832 (41.2)
No	3763 (61.3)	1269 (52.5)	5478 (58.8)
Someone in my household has been angry and violent toward my child			
Total	5961 (100)	2314 (100)	9001 (100)
Yes	657 (11.0)	320 (13.8)	1070 (11.9)
No	5304 (89.0)	1994 (86.2)	7931 (88.1)
The angry and violent person was:			
Total	687 (100)	339 (100)	1123 (100)
You	85 (12.4)	60 (17.7)	157 (14.0)
Another adult	454 (66.1)	205 (60.5)	720 (64.1)
Another child	148 (21.5)	74 (21.8)	246 (21.9)
I find my child more difficult to deal with			
Total	5760 (100)	2209 (100)	8668 (100)
Yes	1662 (28.9)	532 (24.1)	2391 (27.6)
No	4098 (71.1)	1677 (75.9)	6277 (72.4)
I have received help from my neighbors, community, or faith groups			
Total	5625 (100)	2137 (100)	8439 (100)
Yes	1332 (23.7)	532 (24.9)	2028 (24.0)
No	2759 (49.0)	1032 (48.3)	4085 (48.4)
I don't need help	1534 (27.3)	573 (26.8)	2326 (27.6)
I have received help from the government			
Total	5500 (100)	2082 (100)	8246 (100)
Yes	1849 (33.6)	536 (25.7)	2581 (31.3)
No	3137 (57.0)	1359 (65.3)	4867 (59.0)

Survey item	Mothers, n (%)	Fathers, n (%)	Total, n (%) ^a
I don't need help	514 (9.4)	187 (8.9)	798 (9.7)
I have received help from nongovernmental organizations			
Total	5341 (100)	2021 (100)	8007 (100)
Yes	687 (12.9)	319 (15.8)	1106 (13.8)
No	4135 (77.4)	1508 (74.6)	6097 (76.2)
I don't need help	519 (9.7)	194 (9.6)	804 (10.0)
What kind of help do you need most to look after yourself and your child?			
Total	13,788 (100)	5534 (100)	19,232 (100)
Food parcels	2893 (21.6)	1035 (18.7)	3928 (20.4)
Clothes and blankets	1588 (11.5)	548 (9.9)	2136 (11.1)
Medicine	1180 (8.6)	527 (9.5)	1707 (8.9)
Information	504 (3.7)	288 (5.2)	792 (4.1)
Masks, soap, sanitizer, and gloves to protect us from the coronavirus	1533 (11.1)	616 (11.1)	2149 (11.2)
Clean water	540 (3.9)	290 (5.2)	830 (4.3)
Money or vouchers	3016 (21.9)	1258 (22.7)	4274 (22.2)
Childcare	595 (4.3)	244 (4.4)	839 (4.4)
Help in the home	327 (2.4)	131 (2.4)	458 (2.4)
Transport to the clinic or to the shop	314 (2.3)	158 (2.9)	472 (2.4)
Protection from someone in the house who is violent	162 (1.2)	91 (1.6)	253 (1.3)
Support for mental distress, such as counseling	628 (4.5)	216 (3.9)	844 (4.4)
I don't need any help	418 (3.0)	132 (2.4)	550 (2.9)

^aTotal values exceed the sum of values for mothers and fathers since they include responses that have not specified parent type.

Discussion

Principal Findings

We assessed the feasibility of an online survey delivered through a data-free platform to investigate the variability of challenges facing families of young children. We restricted the survey to individuals living in South Africa and to adults caring for children 5 years of age and younger at home. In this paper, we report on the strengths and weaknesses of the use of an online survey in general, and of a data-free platform in particular, to monitor COVID-19 effects on families over time. This is an important question, given the likely long-term aftereffects of the pandemic on daily life [28] and the generally high cost of devices and data and, consequently, low rate of internet access in sub-Saharan African. South Africa will remain under varied levels of lockdown throughout 2021, which includes an overnight curfew, mandatory mask wearing, social distancing, and restrictions on gatherings. The government has issued directions of "conditions of return" for day care centers and preschools, including screening, masks for children over 2 years of age, clearly indicated spacing between children, and smaller staff to child ratios [39]. Financial losses and a likely very slow economic recovery mean that the shocks of the pandemic will be felt for the greater part of early and middle childhood for this cohort of children. Families who continue to get poorer may be forced to leave their homes to live with relatives; remove

children from preschool and school because they cannot afford fees, transport, and supplies; and send one or more children to live with family in other parts of the country, as has occurred during other crises endured on the subcontinent. This study was able to rapidly and cost-effectively gather data from a large sample on a relatively broad range of challenges affecting families with young children with no cost to participants. One-off surveys administered in the early stages of lockdown must be repeated over time to track cumulative effects on children over the next 4 to 5 years. The University of Oregon's RAPID-EC (Rapid Assessment of Pandemic Impact on Development–Early Childhood) study [40] and the University of Oxford's Co-SPACE (COVID-19 Supporting Parents, Adolescents, and Children in Epidemics) study [41] are two examples of ongoing, large-scale, repeat online surveys including parents and young children.

We were not able to locate any published COVID-19 surveys that focused on young children and that were delivered on a data-free online platform, a gap that this paper attempts to fill. Many surveys used phone or email interviews [42] or social media platforms, such as Facebook, Twitter, and LinkedIn [18,43], to deliver survey links. These methods are subject to a number of selective factors. They all presume existing paid internet use and, in the case of phone interviews, a pool of what are often frequently changing mobile telephone numbers [44].

In contrast, online data-free surveys cast a wide net and arguably reach those most affected by the pandemic, as demonstrated through the findings of our study. This reach is dependent on the availability of telecommunication entities with the capacity to partner with multiple major networks in a given country to offer reverse-billing services. The additional user pool that the Moya Messenger platform presented—users who were familiar with the survey alert system—contributed to the high response rate. Efforts to share the survey links on Twitter and other social media sites garnered drastically fewer responses without a strong and sustained communication strategy and networks with access to large groups. Eligibility criteria led to a large drop-off of respondents, suggesting that users of zero-rated (ie, no-cost) services “cruise” around looking for topics of interest to them and, most likely, those that offer incentives. The effects of incentives on response rates and data quality have long been debated, particularly in the context of online surveys where control of multiple responses is much more complicated. The offset costs of online surveys, compared to traditional data collection methods, may encourage the use of incentives for respondents, particularly with some evidence that incentives increase response rates without reducing data quality [45].

In contrast to telephone interviews, data-free online surveys are very cheap. We received 15,912 surveys at a cost of R110,000 (US \$7333), including setup costs, or R6.9 (US \$0.46) per survey. By our calculation, using current rates for interviewers, training, and telephone supervision costs, as well as second or third attempts, approximately 20% of the time, to get an answer from calling telephone numbers [44], a single 20-minute phone interview in South Africa would cost around R80 (US \$5.33). Repeat surveys using online data-free surveys are, therefore, feasible and affordable. A sample such as the one available on the Moya user platform offers a ready group of potential respondents who are familiar with surveys. While there are disadvantages to the use of a single, albeit large, convenience sample such as this, there are also advantages. The closed nature of the sample allows for easier penetration for repeat surveys, the sample is well-defined based on user demographics analyzed by the host entity, and, specifically for Moya, the data-free service attracts those in groups who are most in need. Such a platform is valuable where the purpose is to rapidly and efficiently reach a large sample that can be generalized to a larger proportion of the population and to collect data that can be quickly acted on to guide policy and practice, particularly in emergencies. Online surveys outside of such a platform and in the public sphere are equally useful, if not more so in terms of generalizability, but require substantially more time and effort to recruit potentially representative participants through social media platforms, television, radio and newspaper adverts, and databases of individuals. Accessing large databases of individuals raises ethical questions when beneficiaries and customers have not agreed to be solicited for participation in

surveys, regardless of personal or societal benefits. Legal frameworks, including South Africa’s Protection of Personal Information law (Act 4 of 2013), are perhaps further along than ethical bodies governing digital research.

The use of online surveys offers a larger degree of anonymity compared to other data collection methods and may be more effective at eliminating social desirability bias for sensitive issues and at encouraging participation from those who would otherwise be reluctant. The wide reach of data-free online platforms is illustrated by the comparatively large number of fathers (30% of all respondents) who completed a survey about young children. It is notoriously challenging to engage male caregivers in parenting issues [46], and men are less likely to be targeted by phone surveys about family issues. Men’s perspectives on family challenges are important, as they are frequently the financial providers and decision makers.

We were able to provide immediate feedback on response trends on the data-free platform for those respondents who were interested to look at them. This was made possible because the questionnaire was designed in REDCap [47] and survey responses were directed seamlessly back into the secure REDCap server, which provided individual and aggregate analyses of available data. In addition, a list of referral services for families needing immediate help was available for download at nil data costs once the survey was completed (Figure 2). We were also able to program the survey in additional languages, another feature of REDCap. In the South African context, where the poorest and hardest-to-reach groups are often those not fully literate in English, the additional, minor cost of translation warranted the effort for the 17% of the sample who chose to answer the survey in an African home language.

Digital and other technologies are advancing quickly to fill gaps created in information collection and service provision occasioned by the COVID-19 pandemic [48]. However, the danger of growing inequities due to differential access to the internet is acknowledged, an issue that is particularly pertinent in low- and middle-income countries. Data-free platforms supported by governments, external funders, and the private sector have the potential to expand internet access and can be used to monitor the effects of the pandemic, adapt supports, and create and expand two-way communications between families with young children and service providers. Data-free content that increases access to learning and knowledge has seen some growth during the pandemic, with universities and other institutions either subsidizing data costs or offering zero-rated websites. In the public domain, UNICEF’s Internet of Good Things [49] hosts mobile-packaged content designed to make content on many issues, from maternal health and positive parenting to sexual and reproductive health, available for free, even on low-end devices.

Figure 2. Support and referral services in English and isiZulu.

HEARING FROM PARENTS AND FAMILIES OF YOUNG CHILDREN IN SOUTH AFRICA – WHAT HELP DO YOU NEED THE MOST DURING THE COVID-19 PANDEMIC?



REFERRAL LIST

If you need any additional support you may contact the following organizations and services:

National COVID-19 24-hour hotline telephone number	0800 029 999
National COVID-19 WhatsApp number	0600 12 3456
Sign-up for MomConnect	*134*550#
Child Welfare South Africa	087 822 1516, national@childwelfare.org.za
Childline	0800 055 555 0800 123 321
Depression and mental health	0800121314 SMS 31393
Home Affairs, birth registration and identity documents	0800 601 190
SASSA	0800 601 011

If you have any queries or concerns about the study, please contact the researchers:

Prof. Linda Richter: linda.richter@wits.ac.za 011 717 2382/082 [REDACTED]
Ms. Sara Naicker: sara.naicker@wits.ac.za 011 717 2382/072 [REDACTED]

UKUZWA KUBAZALI NEMINDENI YABANTWANA ABANCANE ENINGIZIMU AFRIKA - YILUPHI USIZO OLUDINGA KAKHULU NGESIKHATHI SOKUQHUBEKA KWE-COVID-19?



UHLU LOKUDLULISELWA

Uma udinga usizo olwengeziwe ungaxhumana nalezinhlangano nezinsizakalo ezilandelayo:

National COVID-19 24-hour hotline telephone number	0800 029 999
National COVID-19 WhatsApp number	0600 12 3456
Sign-up for MomConnect	*134*550#
Child Welfare South Africa	087 822 1516, national@childwelfare.org.za
Childline	0800 055 555 0800 123 321
Depression and mental health	0800121314 SMS 31393
Home Affairs, birth registration and identity documents	0800 601 190
SASSA	0800 601 011

Uma unemibuzo noma ukukhathazeka mayelana nalolu cwaningo, sicela uxhumane nabaphenyi:

Prof. Linda Richter: linda.richter@wits.ac.za 011 717 2382/082 [REDACTED]
Ms. Sara Naicker: sara.naicker@wits.ac.za 011 717 2382/072 [REDACTED]

Challenges and Limitations

As anticipated, families from rural areas were underrepresented compared to national population distributions. Rural households in South Africa and other countries have less access to smartphones, and even when these devices are present, access to the internet due to high data costs and available signal is lower than in urban areas. Data-free technology goes a long way to reaching rural families, but additional measures, such as WhatsApp and push message services, may be needed to close the gap further. Zero-rated services are not new. Concerns that they are not *net neutral* and that service providers can exercise control over content [50] need to be addressed to increase global internet access at a time when the COVID-19 pandemic has made it most needed.

We refrained from asking for detailed personal information (age, education, employment, race, etc) for fear of deterring respondents from completing the survey in the face of a long run-in of questions perceived to be less salient to the topic to which respondents were attracted [51]; that is, the challenges of caring for young children during the COVID-19 pandemic. Nonetheless, such information would be useful for more fine-grained analysis of the data. Further, our survey was designed as a single cross-sectional enquiry. Repeat surveys are critical in the context of the anticipated long-run consequences of the COVID-19 pandemic on families, and we did not test the willingness of respondents to be identified or to be anonymously resurveyed at a later time. Although we made the real-time results of the survey available on the platform, together with a list of referrals, we did not, at this time, monitor how many

respondents accessed the results or downloaded the referral sources.

Many of the features of the online data-free survey described here are specific to the technology used by the researchers. Capabilities for programming multilingual surveys and revealing individual and aggregate findings instantaneously, among others, are not standard across the growing number of online survey platforms. In addition, the use of any individual feature is rarely without disadvantages on the flip side. For example, the option to prevent a single device from submitting multiple responses may prevent an individual from submitting multiple survey responses, but does not allow more than one eligible household member to complete the survey when relevant. Forced response options, which conventionally were thought to improve completeness of data, result in an individual dropping out of the survey altogether rather than missing individual items along the survey path. Researchers need to carefully consider the packages, platforms, and survey options against their research aims and objectives to ensure that the benefits of online surveys are fully realized and that disadvantages are minimized.

Conclusions

Although digital technologies show tremendous promise to bridge gaps created by the suspension of face-to-face surveys and services, we have yet to come to grips with the very stark inequalities of internet access, both between and within countries. In this study, we demonstrate the feasibility and value of using a zero-rated service provider to conduct a survey of COVID-19 pandemic impacts on families of young children in a lower-middle-income country. The response rate was higher

than comparable surveys, the survey was affordable, and it drew in a wide audience, demonstrated by the large number of fathers who participated. Further developments in digital services to respond to COVID-19 pandemic impacts, whether through

surveys or online services such as counseling and education, need to consider using data-free platforms to ensure that the most vulnerable families are reached and can participate, and new sources of funding need to be opened up to do so.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

English version of the South African parent survey.

[PDF File (Adobe PDF File), 394 KB - [pediatrics_v4i2e26571_app1.pdf](#)]

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Abbreviations

- Co-SPACE:** COVID-19 Supporting Parents, Adolescents, and Children in Epidemics
NGO: nongovernmental organization
PPE: personal protective equipment
RAPID-EC: Rapid Assessment of Pandemic Impact on Development–Early Childhood
REDCap: Research Electronic Data Capture
UNICEF: United Nations Children’s Emergency Fund

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Original Paper

A Virtual Reality Resident Training Curriculum on Behavioral Health Anticipatory Guidance: Development and Usability Study

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Abstract

Background: Behavioral health disorders have steadily increased and been exacerbated by the COVID-19 pandemic. Though behavioral health disorders can be successfully mitigated with early implementation of evidence-based parent management strategies, education for pediatric residents on behavioral health anticipatory guidance has been limited to date, with training challenges compounded by the physical distancing requirements of the COVID-19 pandemic. Virtual reality (VR) simulations provide an opportunity to train residents on this complex competency by allowing deliberate practice of necessary skills while adhering to current social distancing guidelines.

Objective: This study explored the usability of a VR-based behavioral health anticipatory guidance curriculum for pediatric residents.

Methods: This mixed methods study included 14 postgraduate third-year pediatric residents who completed the behavioral health anticipatory guidance VR curriculum. Residents completed the MEC Spatial Presence Questionnaire to assess immersion in the virtual environment. Semistructured interviews were used to elucidate residents' perspectives on the curriculum's content and format. The interviews were analyzed using conventional content analysis.

Results: Quantitatively, residents reported a high degree of immersion, spatial presence, and cognitive involvement. Most residents (11/14, 79%) agreed or strongly agreed that it seemed as though they took part in the action of the simulation. Qualitatively, two themes emerged from the data: (1) the curriculum expands behavioral health anticipatory guidance and motivational interviewing knowledge and skills and (2) VR technology is uniquely positioned to develop competence. These themes revealed that the curriculum expanded their current level of knowledge and skill, addressed training gaps, and was applicable to all residents. Additionally, residents experienced VR as immersive, feasible, realistic to the clinic setting, and a safe space to practice and learn new skills.

Conclusions: Pilot data indicates that VR may be an effective tool to teach pediatric residents behavioral health anticipatory guidance, meeting a current gap in medical education training. This VR curriculum is particularly relevant in the context of the COVID-19 pandemic given the increased behavioral health concerns of families.

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KEYWORDS

resident education; virtual reality; behavioral health promotion; COVID-19

Introduction

Background

The behavioral health trajectory of children and youth in the United States is troubling [1,2], with 15% of children currently diagnosed with a behavioral health disorder that affects their mental and physical health during childhood and into adulthood [3,4]. The emergence of behavioral health concerns begins early in life, as do behavioral health promotion opportunities [5,6]. The development of behavioral health disorders may be mitigated with the implementation of evidence-based parenting strategies that address typical childhood behaviors. Although the COVID-19 pandemic has limited traditional sources of caregiver support, such as social networks, pediatric primary care remains a safe and trusted setting to address behavior concerns and decrease parental stress using evidence-based behavioral health anticipatory guidance [7]. Behavioral health anticipatory guidance refers to recommendations that a clinician shares with a caregiver to support optimal child development and health, such as introducing and modeling the concept of praise to reinforce behaviors. Behavioral health anticipatory guidance can serve as a powerful tool to mitigate negative outcomes when coupled with motivational interviewing skills, which enhance motivation for action [1,2]. Despite its potential for significant impact on childhood health, curricula that effectively train providers on administering behavioral health anticipatory guidance have been limited to date, providing an opportunity to use novel technology to address this educational gap.

Prior to the COVID-19 pandemic, behavioral concerns constituted more than 30% of pediatric primary care encounters [6,8,9]. The COVID-19 pandemic has exacerbated child behavioral health disorders due to increased family stress, isolation, and financial hardship [10]. Similarly, disruption of routines is expected to increase the prevalence and severity of behavioral concerns [7,11,12]. This context coupled with increased caregiver stress may result in caregivers not responding to behaviors in the most effective manner. These factors suggest that, now more than ever, behavioral concerns will present in the primary care setting. Thus, ample opportunities exist to engage in behavioral health promotion and prevention efforts.

Bright Futures is the American Academy of Pediatrics' set of evidence-based anticipatory guidelines for pediatric primary care in health promotion in the context of family-centered care [13]. However, current pediatric residency training infrastructure regarding the development and evaluation of behavioral health anticipatory guidance skills remains insufficient to prepare pediatric residents to effectively and efficiently identify, promote, and manage common pediatric behavioral health concerns [14-16]. This training gap impedes resident competence in applying social-behavioral science to patient care while attending to contextual factors, counseling families, and effectively communicating with diverse patient populations [17-19], as recommended by the American Academy of Pediatrics and the Accreditation Council of Graduate Medical Education. The American Academy of Pediatrics encourages

facilitating enhanced communication skills, promoting social-emotional development in training, and incorporating mental health specialists in teaching clinics to ensure learners engage in mental health care [18]. In fact, the American Board of Pediatrics emphasizes the importance of pediatric providers in preventing and managing behavioral health by inclusion in several entrustable professional activities (EPA; EPA-6 [medical home] and EPA-9 [mental/behavioral health problems]) [20]. Ideally, residents would demonstrate competence prior to graduation and board certification.

Despite these recommendations and research supporting the primary care provider's role in behavioral health promotion, limited guidance exists regarding the development of behavioral health anticipatory guidance skills [8,9]. Effective evaluation of curricula aimed at developing these competencies is crucial to effective skill acquisition. Direct observation is a common strategy to assess residents' skills and provide feedback; however, it can be challenging to predict when behavioral concerns might naturally arise during the course of a clinical encounter. Moreover, limitations on supervising clinicians' time and productivity makes direct observation less feasible in real-world settings. In addition, the COVID-19 pandemic has further limited opportunities for direct observation due to social distancing guidelines and decreased patient encounters for routine preventative care [7]. Inadequate preparation in delivering behavioral health anticipatory guidance holds unique implications for medical trainees, as research indicates that deficient training negatively impacts future care provision [17,21].

Technology may offer opportunities to address current barriers to residents' education on administration of behavioral health anticipatory guidance while adhering to public health measures during the COVID-19 pandemic. Virtual reality (VR), a computer-generated environment where users interact with graphical characters called avatars, has demonstrated success with clinician training on communication skills including delivering bad news, addressing vaccine hesitancy, and working within interprofessional teams [22-24]. Within VR, a facilitator designs different scenarios based on specific training needs to promote deliberate practice, a goal-oriented method for skill development. Deliberate practice, characterized by engaging in the task, receiving immediate feedback, then repeating the task while incorporating this feedback [25], has demonstrated effectiveness in pediatric education but has not been evaluated in behavioral health training [26,27].

Implementation and evaluation of resident training on behavioral health anticipatory guidance using VR is novel; thus, usability testing, defined as factors affecting participants' experience in using the device for its intended purpose, is an important first step to understand its strengths and weaknesses and determine if the curriculum is achieving its aims [28-32]. Thus, we conducted a mixed methods study assessing the usability of our VR curriculum, Promoting Resilience and Emotional health through Virtual Education iN Training (PREVENT), which provides a virtual environment for deliberate practice of providing behavioral health anticipatory guidance, among a cohort of postgraduate third-year pediatric residents. Exploring residents' perspectives on PREVENT is critical to assessing its

potential to support skill acquisition and address the educational gap related to training on this important topic in childhood health.

Study Goals

This mixed methods, single-site study explores the usability and utility of PREVENT—a novel behavioral health training curriculum that uses VR simulations—to address current educational gaps related to behavioral health anticipatory guidance skills. We hypothesized that residents would find the VR training curriculum useful, immersive, and applicable to clinical practice.

Methods

Study Setting and Participants

The study was conducted in an institution with one of the largest pediatric residency training programs in the country, which trains approximately 204 residents per year. The urban pediatric primary care clinic at which the usability testing occurred is the continuity clinic site for approximately 84 residents and serves as the medical home for 19,000 patients, with approximately 33,000 visits annually. The patients are predominantly African American (75%) and publicly insured (90%). Approximately 40% of graduating residents pursue a career in general pediatrics.

Pediatric postgraduate third-year residents were eligible to participate. Recruitment was limited to senior residents due to their familiarity with common behavioral health concerns in primary care and willingness to provide their perspective on PREVENT's ability to meet behavioral health training gaps. Participants were informed that this was an educational study that was not tied to their evaluation process in the resident training program. The study was deemed exempt by the Cincinnati Children's Hospital Medical Center's institutional review board. Consent was obtained from each participant prior to participation.

Resident Training Curriculum

PREVENT used VR simulations as the primary educational strategy to enhance learners' competence in behavioral health anticipatory guidance and foundational motivational interviewing skills. Motivational interviewing skills were included in the curriculum as successful administration of behavioral health anticipatory guidance requires use of motivational interviewing to build rapport and enhance motivation for action. Preparation to participate in the VR simulations included the review of four 15-minute didactic presentations, which provided content on development, behavioral management, and motivational interviewing principles. For the VR simulations, participants counseled

caregiver avatars regarding typical behavior concerns for a 3-year-old child. All scenarios featured a caregiver with concerns about tantrums causing stress and an expressed desire for behavior management strategies. Each scenario was associated with learning objectives related to specific behavioral health anticipatory guidance and motivational interviewing skills ([Multimedia Appendix 1](#)). A collaborative team of pediatricians, psychologists, experts in health professional education, and technologists developed the scenarios in an iterative fashion that employed a specific algorithm for each scenario to promote standardization of the experience between learners.

The virtual visits occurred in an environment that replicated an actual examination room. The caregiver and child avatars were designed to reflect common caregiver and patient demographics and characteristics at our primary care center, including physical appearance (ie, race, gender), spoken language, and nonverbal cues. Avatars assumed a range of body positions to indicate different emotions, and audio was recorded and synchronized with the avatars' facial expressions and mouth movements. Across the three scenarios, the resident participant counseled the avatar family on behavioral concerns and the avatar caregiver responded in real time in a realistic manner driven by a single facilitator (FJR). As the COVID-19 pandemic meant that residents could not participate in person via a VR headset, all sessions were completed on Zoom, a cloud-based videoconferencing service that allows screen sharing and secure recording. Participants accessed Zoom via an internet-capable device (eg, laptop, tablet, mobile phone) and were able to view the virtual environment and interact with the avatars ([Figure 1](#)). Following each scenario, the resident received feedback from the facilitator (FJR) about their demonstration of learning objectives. If residents did not meet the learning objectives for the case, they repeated the case to deliberately practice specific skills by incorporating the facilitator's feedback [25]. The scenarios were scaffolded to increase in difficulty and complexity, building on the participant's baseline skills over time. Details of the scenarios and corresponding learning objectives are described in [Multimedia Appendix 1](#). The three scenarios and corresponding feedback were completed in approximately 30 minutes.

Participation in virtual patient simulators via a computer screen is consistent with the approach of many prior VR curricula targeting communication skills [23]. Our team previously demonstrated the impact of immersive 3D VR training on residents' communication skills related to addressing influenza vaccine hesitancy; however, the benefits of 3D versus 2D virtual environments for medical communication training in this population require further investigation [22].

Figure 1. PREVENT included real-time interaction with an avatar family via the Zoom teleconferencing platform. Avatars were able to assume a number of different body positions including the ability for the child avatar to throw a tantrum during the clinical encounter. PREVENT: Promoting Resilience and Emotional health through Virtual Education iN Training.



Data Collection

Following the completion of the PREVENT curriculum, participants completed the MEC Spatial Presence Questionnaire to assess presence and immersion in the virtual environment [33]. This instrument uses a 5-point Likert scale ranging from strongly disagree (1) to strongly agree (5). The instrument has prior validity evidence and has previously been used to assess immersion in virtual medical curricula [34].

A semistructured interview guide was used to assess residents' perceptions of the usability of PREVENT (Multimedia Appendix 2). Interview guide questions were adapted from usability testing literature [35-37]. The interview primarily queried participants about three topics: (1) residents' preparation for, learning from, and recommended changes to the curriculum, (2) usability of Zoom (eg, ease of participation and use of technology), and (3) ability to be immersed in VR and any associated side effects of the technology. At the end of each interview, the researcher confirmed all relevant information had been included to ensure the quality and accuracy of the data. All interviews were recorded, transcribed, verified for accuracy, and entered into the qualitative analysis software ATLAS.ti (ATLAS.ti Scientific Software Development GmbH) [38].

Statistical Analysis

Quantitative

We used descriptive and summary statistics for participant demographics and scores on the MEC Spatial Presence Questionnaire.

Qualitative

The principal investigator (RH), a psychology postdoctoral fellow (TR), and a research assistant (AM) analyzed the interview data using an inductive approach via conventional qualitative content analysis as outlined by Hsieh et al [39]. This methodological approach mirrors traditional thematic analysis as it focuses on identification of repeated patterns of meaning across a data set and differs from summative content analysis, which focuses primarily on counts and quantification of data [40].

All three individuals have had advanced training related to behavioral health and have prior experience conducting qualitative research. The researchers independently reviewed 20% of the interviews to obtain an overall framework of residents' experiences with PREVENT. The researchers subsequently coded the key concepts in this subset of transcripts that aligned with the interview questions [39]. Once the data were independently coded from the subset, the researchers discussed preliminary findings, as the use of multiple analysts to contribute to the development of codes enhances the findings' credibility [41]. Codes were added or revised to reflect emerging patterns in the data. After the development of consensus around these initial codes, the researchers independently coded the remaining transcripts. Coding led to the formation of categories and subsequently principal themes. Differences between researchers were resolved by discussing the underlying meanings of categories, revisiting the data, and reflecting on underlying elements to reach consensus. Saturation was reached when no new codes emerged. Coding checks (ie, ongoing comparisons of independent coding, discussions to rectify differences) with two independent coders resulted in eventual consistency of

greater than 90%, indicating further review was not necessary [41].

To promote credibility, the researchers reflected on potential sources of bias. These included the researchers' mental health training and emphasis on promoting behavioral health—which may have influenced the clarifying questions asked during the interviews and interpretation of participant responses—and the researchers' role in developing and implementing PREVENT. The principal investigator completed an independent audit of 20% of transcripts to verify the credibility of the coding. Using two independent coders and credibility checks with participants were strategies employed to address and minimize potential bias and positionality while optimizing accurate representation

of participants' perceptions [41]. One resident participant reviewed the categories following data analysis to assess alignment with their personal experience of having completed the PREVENT curriculum (ie, member checking).

Results

Overview

A total of 36 categorical pediatric postgraduate third-year residents were eligible to participate and 14 (39%) enrolled in the study to complete PREVENT and provide data regarding its usability. Participants had a mean age of 29.4 years (Table 1). Of the 14 participants, 11 were female (79%), 11 were Caucasian (79%), and 10 were non-Hispanic (92%).

Table 1. Participant demographic data (N=14).

Characteristic	Participants
Age (years), mean (SD)	29.4 (2.6)
Sex, n (%)	
Male	3 (21)
Female	11 (79)
Race, n (%)	
Caucasian	11 (79)
Asian	1 (7)
Other	1 (7)
Prefer not to answer	1 (7)
Ethnicity, n (%)	
Hispanic	1 (7)
Non-Hispanic	13 (93)

Quantitative

On the MEC Spatial Presence Questionnaire, 100% of residents (14/14) agreed or strongly agreed that they could devote their whole attention to the VR experience. There were 11 residents (79%) who agreed or strongly agreed that the VR experience captured their senses and that it seemed as though they actually took part in the action of the presentation. A total of 8 residents (57%) reported that it felt like they were actually in the environment of the presentation. There were 12 residents (86%) who agreed or strongly agreed that the VR presentation activated their thinking. In addition, 7 participants (50%) disagreed or

strongly disagreed that they felt they could do things with the objects in the virtual presentation (Multimedia Appendix 3).

Qualitative

In this study, two themes emerged from the data: (1) the PREVENT curriculum expands behavioral health anticipatory guidance and motivational interviewing knowledge and skills and (2) VR technology is uniquely positioned to develop competence. These themes encompassed residents' perspectives on the purpose of PREVENT, the curriculum's structure, and the use of the VR modality for instruction. Table 2 provides an overview of themes, categories, and codes, as well as supporting participant quotes.

Table 2. Qualitative results from resident interviews.

Theme, category, and code	Supporting participant quotes
Theme 1. PREVENT^a expands behavioral health anticipatory guidance and motivational interviewing knowledge and skills	
Category 1. Building on previous experiences and didactic knowledge	
Beyond medical school curriculum	<ul style="list-style-type: none"> • “The general MI [motivational interviewing] concepts - we learned that in med school. But trying to incorporate in family interactions, that’s next level that I really liked. That was new for me.” • “So all of the things that I feel really knowledgeable about with medication management and things are not always the most common things that parents are worried about or concerned about. So having a little bit extra after medical school to help give real advice could be helpful.”
Preparedness for activity	<ul style="list-style-type: none"> • “Pre-clinic [didactic] teaching definitely gets the baseline and I have it fresh in my mind. So, for the spanking example, I remember that lecture pre-clinic, and then I had a parent who spanked, so I could immediately use what was just learned.”
Category 2. PREVENT addressed training gaps	
Helpful and practical	<ul style="list-style-type: none"> • “I was pleasantly surprised with what we were able to do. By the second visit, there seems to be about four to five sort of set responses... At the same time, I know that visits can go different ways, and so by the last visit when the kid was acting up, I was very pleasantly surprised by that, because I’m like, okay, let me reset here and figure out what I want to do next. And I think that’s a very recurring theme in clinic, where you’re like, okay, that was a curveball. For example, when you threw the corporal punishment on me, I wasn’t expecting to talk about this. Let me go back and bring out what I like to do in these cases.”
Length of experience	<ul style="list-style-type: none"> • “It was very engaging and active participation on my part. I was able to address multiple skills in the time. So, I thought it was just right.”
Depth of content and skills	<ul style="list-style-type: none"> • “I liked when you were coaching us, like what to talk about and just kind of reviewing briefly different methods of trying to like redirect, trying to ignore, things like that. It was giving a refresher as well as giving examples. It was like nice and short and sweet, not too long, but high yield.”
Scaffolding and repetition	<ul style="list-style-type: none"> • “It was super helpful. Going from visit to visit made this scenario [say] can you add this into the mix? It’s a little challenging to integrate things, and it’s also an immediate technique to improve yourself. Because hopefully someone is coming in and asking open ended questions, asking permission [then] let’s work on redirection. Let’s work on these other techniques. Integrating that as you’re going forward can only be helpful, because oftentimes it’s easy [for the preceptor] to say ‘next time, try not to do this, this, and this.’ Then you just don’t practice it.”
Category 3. Unique benefits of PREVENT	
Safe	<ul style="list-style-type: none"> • “I think it creates this safe space where, even if I know you’re listening, I’m just focused on ‘this is the roleplay I’m doing. I don’t know this cartoon person. They’re not judging me.’” • “I liked that it was not real patients. Sometimes I think experimenting on real people feels wrong or just a little bit icky feeling, so it was nice to be able to practice and make mistakes when the stakes were lower.”
Recommend and applicability	<ul style="list-style-type: none"> • “I recommend [PREVENT] because this was a positive experience. It was a minimal time commitment, it doesn’t have the social pressure of real people, and I was able to gain new skills in a short amount of time.” • “It’s good practice and you get feedback that could change your practice. If you were going into private practice, you’d probably be having a lot more of these conversations than I’ve had as a resident. And I would not feel prepared to be having those conversations.”
Applicability to all pediatric residents	<ul style="list-style-type: none"> • “Even if they’re not going to be primary care physicians, they should all have these skills and they can utilize them in all the different [pediatric] specialties.”
Theme 2. Virtual reality technology is uniquely positioned to develop competence	
Category 4. Technology was feasible	
Ease of use	<ul style="list-style-type: none"> • “I love how you’ve transitioned over for our VR. It gives us a lot of flexibility in what we’re able to do and especially because you have us [the residents] really engaged in the curriculum/software, you know.” • “I actually haven’t used Zoom before this, and so I just like downloaded it, and it was super easy.”

Theme, category, and code	Supporting participant quotes
Facilitation of activity	<ul style="list-style-type: none"> “I like to see a diagram of things, so I thought that visualizing [resident feedback] in a slide was really nice.”
Transportability	<ul style="list-style-type: none"> “It [was transportable] specifically for me on maternity leave, but more for the whole coronavirus, this works well. It could be good things for people to use to continue [to learn].” “Really easy, and it took away barriers. [For people] wanting to do it, it was more flexible. I’m on my ER rotation now, so I have time in between shifts, so it was an easy enough way to participate.”
Side effects	<ul style="list-style-type: none"> “No, no side effects. It all worked out great.”
Zoom compared to virtual reality	<ul style="list-style-type: none"> “Yeah, and [VR] was neat, because you could control looking around the room, and maybe especially in this scenario, where the kid is like having those behaviors... But I still felt it was effective on Zoom.”

Category 5. Realism of virtual reality similar to clinic and aided learning

Immersive environment	<ul style="list-style-type: none"> “It’s immersive enough that you’re like, ‘all right, I’m taking this seriously.’ I’m in this visit. This is a real set of responses that I might get and let me see how I might address that. That’s why I seriously appreciate this curriculum.” “I actually really liked that it mimicked PPC [clinic], because it just felt more comfortable, even the office looking the same... It just made it feel less like intimidating than going into some random like standardized room so I liked that it mimicked what we do every week at PPC [clinic].”
Interactive and engaging	<ul style="list-style-type: none"> “The interactive nature of it [is helpful], so it’s not just reading off a script. They’re actually giving you different responses depending on what you ask. So, a little bit more flexible than just a set script.”
Nonverbals/body language	<ul style="list-style-type: none"> “I think I didn’t pick up on like a huge amount from the parent. I think there was some that just showed that she was kind of interacting with me, but I didn’t get a huge sense of like ‘Oh, she’s leaning in now, so she’s more engaged like, oh, she’s pulling away, so she’s less.’ But the tantrum that the child had in clinic was well done.”

^aPREVENT: Promoting Resilience and Emotional health through Virtual Education iN Training.

Theme 1: PREVENT Expands Behavioral Health Anticipatory Guidance and Motivational Interviewing Knowledge and Skills

Overview

Participants articulated how the curriculum built upon their previous experiences in medical school and residency to develop competence in managing common behavioral presenting concerns. This theme captured how the unique structure of PREVENT, with the inclusion of both behavioral health anticipatory guidance and motivational interviewing skills in a singular curriculum, the use of deliberate practice, and safe and accessible VR technology, was crucial to PREVENT’s usability. Residents also indicated awareness of their prior limited skills in behavioral health anticipatory guidance and motivational interviewing, which made them doubt their competence to support families’ behavioral health concerns prior to participation in PREVENT. Theme 1 encompassed three categories.

Category 1: Building on Previous Experiences and Didactic Knowledge

Participants described how PREVENT expanded their motivational interviewing and behavioral health anticipatory guidance knowledge and skills beyond previous educational activities. Specifically, they described limited medical school training, while noting these are the topics that “we have the

least experience in coming out of medical school, but it’s [behavioral concerns] a super frequent problem with patients in the primary care setting.” In addition, participants indicated that the didactic teaching on motivational interviewing and behavioral health anticipatory guidance provided sufficient foundational knowledge to prepare them to participate meaningfully in the VR scenarios.

Category 2: PREVENT Addressed Training Gaps

Participants shared the unique benefits of VR as an educational strategy. Anchored in the recognition that the motivational interviewing and behavioral health anticipatory guidance skills used in VR are directly translatable to actual clinical experience, participants described how PREVENT met learning goals and scaffolded skill development. One participant shared “I think it was a great practice strategy for refreshing me on what I already know but then getting more of those [motivational interviewing and behavioral health anticipatory guidance] skills.” Specifically, participants noted that the length of the experience, depth of content and skills, and structured repetition over increasingly challenging scenarios provided opportunities for deliberate practice that enhanced their motivational interviewing and behavioral health anticipatory guidance competences.

Category 3: Unique Benefits of PREVENT

Participants indicated that the training met their educational needs and VR provided an opportunity to learn in a safe space:

"I liked that it was not real patients...sometimes I think experimenting on real people feels wrong or just a little bit icky feeling, so it was nice to be able to practice and make mistakes when the stakes were lower." In addition, participants highly recommended the training for other residents, describing PREVENT's applicability to all pediatric residents. "I wish I had this during intern year ... I [am] actually trying to put this into practice and I could have gotten further [with my skill development] ... I could have learned throughout my residency by really advancing my motivational skills."

Theme 2: VR Technology is Uniquely Positioned to Develop Competencies

Overview

This theme captured how PREVENT's VR technology increased engagement through immersion and created an ideal learning environment that was easy to access and use, uniquely facilitating residents' development of skills and competencies. Theme 2 encompassed categories 4 and 5.

Category 4: Technology Was Feasible

Participants outlined the benefits of VR. Specifically, they noted that VR is easy to use, comfortable to engage in across various settings (eg, at home, in a clinic room), and the behind-the-scenes facilitation was minimally apparent. All participants denied VR side effects. Finally, they reported that the VR experience via Zoom was sufficiently immersive and engaging. Those with previous VR experience perceived this VR training via Zoom as equally effective to VR training using a 3D-mounted headset.

Category 5: Realism of VR Similar to Clinic and Aided in Learning

Participants commented on the unique aspects of VR as an educational modality. Specifically, participants described how the immersive environment of PREVENT made interactions feel realistic. They indicated that this experience was augmented by the interactive nature of the avatars, such as avatar responses to participants' language. Finally, some participants indicated that the nonverbal communication of the avatars felt realistic, while others reported that the nonverbal communication was subtle and that they desired more pronounced body language.

Discussion

Principal Results

Results from this usability study demonstrated PREVENT's applicability to common presenting concerns and ease of use among pediatric residents. Quantitatively, resident participants in PREVENT reported a high level of immersion, spatial presence, and cognitive involvement. Qualitative data indicated that residents perceived PREVENT as effective in expanding their behavioral health anticipatory guidance and motivational interviewing knowledge and skills by providing the appropriate breadth and depth of content and effectively employing deliberate practice to promote skill development. Residents indicated that the curriculum was applicable to real-world practice and balanced the depth of skill development with a feasible length of training. The use of Zoom, which arose

because of COVID-19 restrictions, was well received and reported as sufficiently immersive for the specific learning objectives of PREVENT.

Participants underscored PREVENT's applicability to all levels of pediatric residents, regardless of training year or pediatric subspecialty, and reported that PREVENT expanded their competence to meet the behavioral health needs of families with young children. This is particularly crucial with recent increased family stress and the higher prevalence of behavioral health concerns secondary to COVID-19 [7]. This curriculum could be applicable and generalizable to other programs. The VR modality provided portability and transferability that circumvented the barriers associated with traditional face-to-face training in the context of physical distancing due to the pandemic. Due to its convenience and acceptability, VR programs may continue to be applicable to resident training after physical distancing restrictions are lifted. This study provided preliminary support for the effectiveness of transitioning VR from a 3D platform (VR headset) to a 2D platform (Zoom) for communication training given the reported sufficiency of attention allocation and spatial presence among participants.

Tantrums are a common presenting concern, but few opportunities exist to scaffold skills needed to coach a caregiver through managing a tantrum. Through PREVENT's novel use of VR, we provided residents with an immersive and realistic educational opportunity to develop motivational interviewing and behavioral health anticipatory guidance skills, which are important and commonly used skills, but ones with limited prior opportunities to practice. The VR environment also enables the integration of motivational interviewing and behavioral health anticipatory guidance skills, which are required concurrently in actual clinical practice. The structure of increasingly complex scenarios with feedback between scenarios, a key element of deliberate practice, allowed for scaffolding of learning. Although deliberate practice may require more infrastructure and resources than other educational modalities attempting to promote behavior change (eg, webinars) [42,43], this approach (deliberate practice) appears to be a critical component of PREVENT's perceived effectiveness.

The safe learning environment of PREVENT was an unanticipated study finding. Residents described their sense of incompetence and imposter syndrome prior to PREVENT. They described the expectation to use motivational interviewing and behavioral health anticipatory guidance skills, which are challenging skills to implement, as anxiety-provoking when limited opportunities for skill development exist. PREVENT offers a strategy to decrease resident stress through scaffolded experiences and a framework to use for collecting history and implementing interventions. The VR environment can help shape resident skills that resemble real-life encounters in a safe environment without patients, thus decreasing anxiety during practice and potentially decreasing stress when experienced in an actual clinical setting.

Limitations and Strengths

This article has several limitations. First, as a single-site study, our results may lack transferability to other settings with

different types of learners and resources. However, since we reached saturation with our qualitative results, we believe these may be transferable. Second, we only investigated the use of VR on behavioral health anticipatory guidance so our results may not be generalizable to other behavioral or mental health conditions. Third, as a pilot study, we investigated the usability of VR as an educational tool for behavioral health anticipatory guidance and motivational interviewing training but did not collect data on residents' actual performance with patients. Finally, a social desirability bias may have been present during qualitative interviews, despite attempts to minimize this bias by emphasizing that honest responses would promote residents' ability to help cocreate curriculum adaptations. Additional research is needed to study PREVENT's effectiveness and impact on resident competence.

Due to these limitations, our next steps include performing a randomized controlled trial of our intervention to provide efficacy data. Longitudinal data and patient-reported outcomes will generate crucial learnings about the short- and long-term impact on skill development and behavioral health promotion. Future multisite trials will provide data about the generalizability and transferability of the curriculum to other training sites. The development of artificial intelligence is an important future step as it will eliminate the need for a human facilitator in the VR environment, allowing scalability and potentially decreasing cost. Finally, future research could explore testing PREVENT with scenarios focused on other behavioral health presenting concerns (eg, picky eating, sleep).

Despite these limitations, our study has several strengths. First, we used semistructured interviews, which allowed us to obtain both a breadth and depth of information about the content of the curriculum and the process of delivering PREVENT. We believe the interview guide explored important aspects of both the curriculum and the VR experience itself. Second, we were able to establish both credibility and trustworthiness in robust ways while reducing bias. Third, we selected an appropriate expert population for usability testing. Finally, we believe our

study is particularly pertinent to the COVID-19 pandemic, given that our methods were executed virtually.

Comparison With Prior Work

The curriculum meets training gaps identified by the pediatric residency training leadership, aligning with calls for action from American Academy of Pediatrics and American Board of Pediatrics for common factors approaches to emerging behavioral health concerns [15,17,18,20]. PREVENT builds competence in teaching parental behavioral health management skills that have been exclusively taught through parenting programs [44] and are vital to meeting family needs in the context of primary care. PREVENT also aligns with the calls for increased prevention and positive parenting in primary care through the development and implementation of training initiatives [5].

Finally, the use of VR in medical education to increase health care providers' communication skills and subsequently change practice behaviors and impact health outcomes has been documented in vaccine uptake, although it has not been applied to behavioral health anticipatory guidance until now [22]. A recent systematic review of virtual patient simulators reported that effective curricula emphasized scaffolding and human feedback, positive features of PREVENT identified by our participants [23]. This work also underscores the importance of usability testing of VR applications prior to real-world deployment to establish quality and safety measures of the approach [31]. Our mixed methods design to usability testing may provide a practical roadmap for others.

Conclusions

PREVENT provides promising usability data that VR may be an effective tool to train pediatric residents on behavioral health anticipatory guidance and motivational interviewing skills. The curriculum aligns with calls to action in the medical education training community. Finally, the curriculum's focus is of increased importance in the context of COVID-19, as traditional face-to-face training opportunities are limited, while family behavioral health needs are increased.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Virtual reality scenarios were scaffolded with increasing complexity and difficulty over time to allow demonstration of advanced skills.

[DOC File, 66 KB - [pediatrics_v4i2e29518_app1.doc](#)]

Multimedia Appendix 2

Usability postcurriculum questions.

[DOC File, 67 KB - [pediatrics_v4i2e29518_app2.doc](#)]

Multimedia Appendix 3

The MEC-Spatial Presence Questionnaire, an instrument for assessing immersion in a virtual environment, utilizes a 5-point Likert scale from strongly disagree (1) to strongly agree (5). Individual item and subscale scores for resident participants in PREVENT indicated a high level of attention allocation, spatial presence, and cognitive involvement.

[DOC File , 99 KB - [pediatrics_v4i2e29518_app3.doc](#)]

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Abbreviations

EPA: entrustable professional activities

PREVENT: Promoting Resilience and Emotional health through Virtual Education iN Training

VR: virtual reality

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Original Paper

Leveraging Digital Technology in Conducting Longitudinal Research on Mental Health in Pregnancy: Longitudinal Panel Survey Study

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Abstract

Background: Collecting longitudinal data during and shortly after pregnancy is difficult, as pregnant women often avoid studies with repeated surveys. In contrast, pregnant women interact with certain websites at multiple stages throughout pregnancy and the postpartum period. This digital connection presents the opportunity to use a website as a way to recruit and enroll pregnant women into a panel study and collect valuable longitudinal data for research. These data can then be used to learn new scientific insights and improve health care.

Objective: The objective of this paper is to describe the approaches applied and lessons learned from designing and conducting an online panel for health care research, specifically perinatal mood disorders. Our panel design and approach aimed to recruit a large sample (N=1200) of pregnant women representative of the US population and to minimize attrition over time.

Methods: We designed an online panel to enroll participants from the pregnancy and parenting website BabyCenter. We enrolled women into the panel from weeks 4 to 10 of pregnancy (Panel 1) or from weeks 28 to 33 of pregnancy (Panel 2) and administered repeated psychometric assessments from enrollment through 3 months postpartum. We employed a combination of adaptive digital strategies to recruit, communicate with, and build trust with participants to minimize attrition over time. We were transparent at baseline about expectations, used monetary and information-based incentives, and sent personalized reminders to reduce attrition. The approach was participant-centric and leveraged many aspects of flexibility that digital methods afford.

Results: We recruited 1179 pregnant women—our target was 1200—during a 26-day period between August 25 and September 19, 2016. Our strategy to recruit participants using adaptive sampling tactics resulted in a large panel that was similar to the US population of pregnant women. Attrition was on par with existing longitudinal observational studies in pregnant populations, and 79.2% (934/1179) of our panel completed another survey after enrollment. There were 736 out of 1179 (62.4%) women who completed at least one assessment in both the prenatal and postnatal periods, and 709 out of 1179 (60.1%) women who completed the final assessment. To validate the data, we compared participation rates and factors of perinatal mood disorders ascertained from this study with prior research, suggesting reliability of our approach.

Conclusions: A suitably designed online panel created in partnership with a digital media source that reaches the target audience is a means to leverage a conveniently sized and viable sample for scientific research. Our key lessons learned are as follows: sampling tactics may need to be adjusted to enroll a representative sample, attrition can be reduced by adapting to participants' needs, and study engagement can be boosted by personalizing interactions with the flexibility afforded by digital technologies.

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KEYWORDS

digital; longitudinal; pregnancy; postpartum; perinatal; panel; study design; mental health

Introduction

Mental health and mood disorders, such as depression and anxiety, can cause negative outcomes for women [1] and can lead to health and developmental problems for their offspring [2]. A better understanding of perinatal mental health is needed to help families lead healthier lives. To observe the totality of perinatal depression, it is important to include women early in pregnancy and obtain repeated assessments starting at this early stage and into the postnatal period. The challenges to accomplish this include lack of access to pregnant women before they have been assessed in clinical settings, where many pregnancy studies recruit participants, and difficulty maintaining cooperation throughout pregnancy and into the postpartum period.

An additional roadblock when researching perinatal depression is the reluctance of pregnant women to participate in scientific or medical studies, as pregnant women exhibit lower cooperation rates than the general population of women [3]. Concern for the fetus and pregnancy and lack of connection with the research goals contribute to this reduced cooperation [4]. In addition, enrolling a representative pregnant population may be difficult, as research has shown that African American pregnant women are less willing to take surveys associated with medical research; this can challenge researchers to construct and maintain representative samples [3]. It has been shown that building trust is pivotal when conducting research among pregnant women and necessary to increase participation [5].

There have been successful longitudinal cohort studies conducted in Europe and Asia. The Maternal Anxiety in Relation to Infant Development (MARI) Study recruited 483 pregnant women at weeks 10 to 12 from community clinics in Dresden, Germany [6]. The Growing Up in Singapore Towards healthy Outcomes (GUSTO) Study recruited 1247 women during their first clinical visit of pregnancy (ie, <14 weeks) and followed them through birth and to 36 months postpartum [7]. Our study aimed to conduct longitudinal research with a panel that was representative of US women giving birth, starting from week 4 of pregnancy.

BabyCenter was a suitable platform to recruit a large population of pregnant women into a panel that was similar to the profile of pregnant women in the United States. It is a digital resource for pregnancy and parenting information that reaches 3 in 4 pregnant women in the United States [8]. Pregnant women begin

accessing the BabyCenter website early in pregnancy, often before their first prenatal visit; over three-quarters of BabyCenter pregnancy website registrations occur during the first trimester, with weeks 4, 5, and 6 of pregnancy seeing the largest percentage of registrations, according to BabyCenter's internal tracking data.

We designed and conducted a comprehensive longitudinal study of perinatal mental health among a large panel of women reflective of all US women giving birth. We administered frequent assessments using electronic patient-reported outcome assessments beginning early in pregnancy and through the postnatal period. The goal was to minimize participant attrition and generate a well-characterized data set to further the knowledge of perinatal mood disorders. The aim of this paper is to demonstrate methods used to recruit pregnant participants into an online panel to ensure we obtained a large representative sample and describe how we reduced attrition. We also describe lessons learned that could improve future online panel recruitment and retention for difficult-to-survey populations.

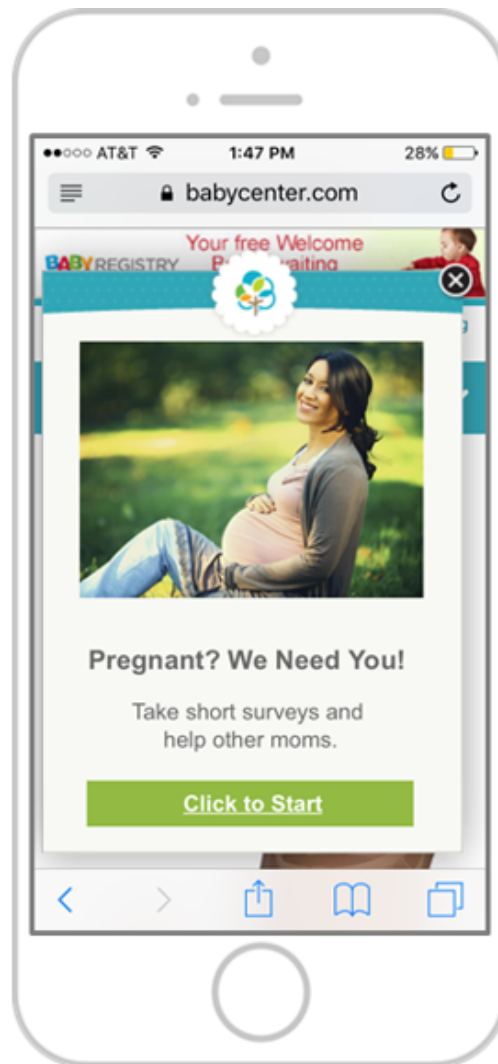
Methods

Recruitment and Enrollment

We conducted a longitudinal study with a population-based sample of pregnant women, aged 18 years and older, in the United States, from early in pregnancy to 12 weeks postpartum. The sampling frame for this work was the BabyCenter website. Additional inclusion criteria for the study were as follows: weeks 4 to 10 of pregnancy (Panel 1) or weeks 28 to 33 of pregnancy (Panel 2) and not currently participating in other research studies.

From August 25 to September 19, 2016, BabyCenter website visitors were selected at random and shown a floating invitation during their website experience (see [Figure 1](#)). Invitations used friendly language, a description of incentives for participation, and an altruistic approach, as this has been shown to be a key motivator for pregnant women to participate in research [3]. The recruitment goal was to enroll 1200 participants in a 6-week period. The goal of 1200 participants was determined with consideration to power calculations, anticipated time frames for recruitment, and an effort to sample a similar or larger panel size than had been demonstrated in previous longitudinal studies of pregnancy and mental health.

Figure 1. Survey floater invitation on a mobile device. The advert shows a smiling pregnant lady with the text “Pregnant? We Need You! Take short surveys and help other moms.”



Participants enrolled in the study on their own, without support of study researchers, within the digital survey environment upon completion of a screening and enrollment baseline assessment. They were provided detailed information about the study’s timing, protocol, and incentives. Participants’ consent was obtained via digital agreement within this same baseline assessment. We had New England Institutional Review Board approval to complete this work.

Recruitment strategies were designed to balance the sample to closely match the demographic profile of US women giving birth as reported by government agencies [9]. To this end, adjusting specific digital sampling parameters either increased or decreased the proportion of participants in certain demographic groups.

Study Content

The baseline assessment included screening questions, health history, demographic profiling, pregnancy health assessment, and information about recent life events. The final assessment, administered at 12 weeks postpartum, measured the birth experience. The study contained a battery of standardized

psychometric assessments relevant to the topic of perinatal mood disorder that repeated at set intervals throughout the course of the study, measuring anxiety, stress, and obsessive-compulsive tendencies (see [Table 1](#)). The study employed the Edinburgh Postnatal Depression Scale (EPDS), the accepted standard measure of mood in the perinatal period, as the primary indicator of major depressive disorder [10]. We excluded the suicidality item in the EPDS scale due to the study’s lack of provision for intervention for women who may have self-identified to be at risk.

There were two iterations of short-form assessments, labeled *Mini A* and *Mini B*, and one iteration of a long-form assessment, labeled *Full*. Each of the three total assessment types contained varied sets of psychometric scales alternating in the study protocol to maximize the types of information collected, provide measurements at regular intervals of 1 to 4 weeks, and reduce monotony and response burden (see [Figure 2](#) and [Multimedia Appendix 1](#)).

Panel 1 had the opportunity to complete a total of 15 assessments including the one at baseline, while Panel 2 could complete a total of 8 assessments including the one at baseline.

Table 1. Collected data, assessment instruments, and time points of measurements.

Collected data or assessment instrument	Baseline ^a	Mini A ^b (short form)	Mini B ^c (short form)	Full ^d (long form)	Final ^e
Health history	✓ ^f				
Demographic profile	✓				
9-item Edinburgh Postnatal Depression Scale	✓		✓	✓	✓
4-item Perceived Stress Scale	✓		✓	✓	✓
6-item State-Trait Anxiety Inventory	✓		✓	✓	✓
4-item PROMIS ^g Emotional Support	✓		✓	✓	✓
7-item Generalized Anxiety Disorder	✓			✓	✓
18-item Obsessive-Compulsive Inventory-Revised				✓	✓
4-item PROMIS Pain Interference		✓			
4-item PROMIS Sleep Disturbance		✓			
8-item PROMIS Sleep-Related Impairment		✓			
4-item PROMIS Anxiety		✓			
2-item Patient Health Questionnaire		✓			
14-item Perinatal Post-Traumatic Stress Disorder Questionnaire-Modified					✓
Birth data					✓

^aData were collected at pregnancy weeks 4-10 and 29-33.

^bThe Mini A (short-form) instrument contained five psychometric questions and, on average, took 5 minutes to complete. Data were collected at pregnancy weeks 6, 7, 9-11, 15, 25, 32, and 34 and postpartum week 1.

^cThe Mini B (short-form) instrument contained four psychometric questions and, on average, took 5 minutes to complete. Data were collected at pregnancy weeks 9, 11, 12, 18, and 28 and postpartum +2 days and week 8.

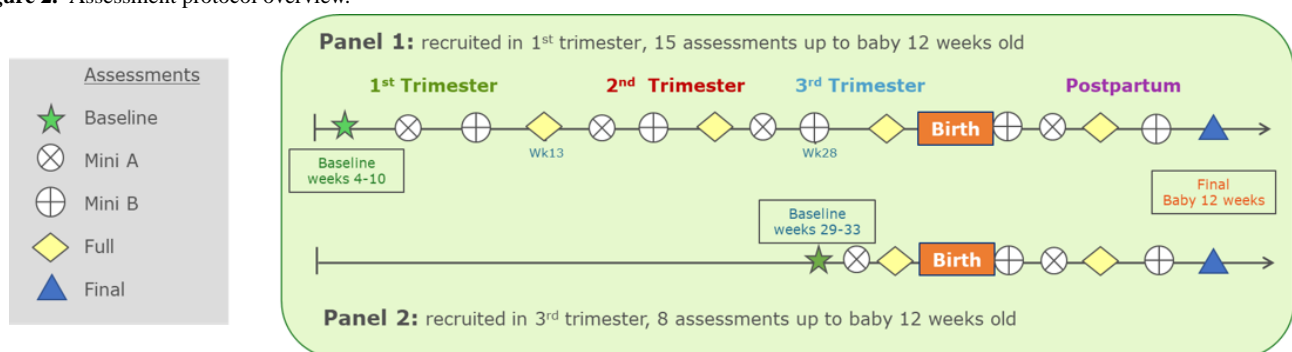
^dThe full (long-form) survey contained six psychometric questions and, on average, took 7 minutes to complete. Data were collected at pregnancy weeks 12, 13, 21, 32, and 35 and postpartum week 4.

^eData were collected at postpartum week 12.

^fCheck marks indicate that the indicated data were collected or the indicated version of the assessment instrument was conducted at this time point.

^gPROMIS: Patient-Reported Outcomes Measurement Information System.

Figure 2. Assessment protocol overview.



Assessments were meant to create a panel experience that was enjoyable and stress free. At the beginning of every assessment, respondents were asked two or three pregnancy or parenting lifestyle questions unrelated to the psychometric assessments. These included questions about pregnancy, diet, the baby’s sex, and preparation for the baby’s arrival. The inclusion of these lifestyle questions was intended to foster participant engagement and counterbalance the serious nature of the psychometric assessments (see [Multimedia Appendix 2](#)).

Assessments were optimized for mobile devices for easy viewing and completion of questions. All assessments were administered through the Qualtrics platform, and respondent data were stored in the secure environment of Qualtrics Target Audience, which is currently known as Qualtrics Core XM [11].

Assessment Invitations

Participants received invitations to complete assessment surveys by email. The assessment interval was an established protocol, but the actual date a participant was invited to complete a survey

was customized for each participant based on the date of enrollment and the pregnancy week at baseline. We created an application programming interface (API) within Qualtrics that enabled unique protocol dates for each participant. The API distributed automated email invitations, reminders, and incentives. The API deployed reminders as needed, with up to three reminders delivered over the duration of each survey window, which was typically 7 days. This volume and timing of communication was intended to maximize response but not overburden participants with emails.

A challenge when studying a pregnant population into the postnatal period is that the birth date of the baby is an unknown time variable that cannot be pre-established. To address this, as pregnancy progressed into the late third trimester, we invited women to complete a birth survey to confirm the arrival of the baby. Participants received birth survey invitation emails through week 42 of pregnancy. Completing the birth survey initiated a new protocol within the API, with the baby's birth date now serving as the baseline date for initiating the postnatal surveys.

Incentives

Declining participation in epidemiologic studies has necessitated the use of monetary incentives; this is an accepted method to increase cooperation [12]. This study's duration—9 to 11 months for most participants—required an incentive strategy to head off attrition. Participants in Panel 1 had the opportunity to earn a total of US \$180 in e-gift cards over the course of the study, and participants in Panel 2 had the opportunity to earn a total of US \$125 in e-gift cards over the course of the study. When an incentive was attained, it was fulfilled automatically by the API via email, making it easy for participants to track and redeem their rewards.

We included a second incentive to help maintain participation through the study's end: a sweepstakes to encourage participants to complete the maximum assessments. Separate US \$1000 sweepstakes were offered for Panel 1 and Panel 2 participants. A respondent in Panel 1 who completed all 15 assessments would increase their odds of winning by earning 15 entries. A respondent in Panel 2 who completed all 8 assessments would increase their odds of winning by earning 8 entries. The sweepstakes were conducted as a random drawing after the final assessment for each panel concluded. No empirical tests were conducted to measure the impact of incentivization.

Engagement Strategies

As the study progressed, we implemented incremental ways to encourage participation. Texting on mobile devices is the most prevalent means of communication for Americans under 50 years of age [13]. To leverage this behavior, we introduced the

option to have text reminders sent to mobile devices as an additional prompt to complete an assessment.

To help participants connect with the study and foster a sense of community, selected pregnancy and lifestyle top-line results were shared periodically with participants in assessment invitations. Results shared included the number of pregnant women actively participating in the study and facts about common pregnancy concerns and behaviors. At the study's end, selected findings were also shared in an article hosted on the BabyCenter website, as participants had told us via feedback survey that they were interested to see what we had learned [14].

We closely monitored participation behaviors to identify chronic nonresponders, defined as participants that did not respond to two or more consecutive assessments. At four strategic intervals over the course of the study, before the more in-depth, longer *full* assessments were scheduled to deploy, dedicated emails were sent specifically to nonresponders in addition to the standard invitation protocol, asking them to return to active participation and reminding them of the potential to earn new entries into the sweepstakes.

Results

Recruitment

In 26 nonconsecutive calendar days, 476,863 invitation impressions were served, garnering 5843 clicks (1.2% click rate). This rate was typical for the floater intercept recruitment methodology used by BabyCenter as per their internal data. Industry benchmarks for random intercept survey invitations are not readily available, but as proxy, the click rate on a typical website display ad unit in the health category was 0.31% [15]. A 2016 study with a niche user population utilizing Twitter as a recruitment source noted click rates between 0.43% and 0.50% on its targeted study recruitment ads [16].

We manipulated recruitment tactics to achieve a more representative profile of pregnant women. Those recruited on the weekend were more likely to be employed than those recruited during the week. Those recruited with targeting on desktop devices were more likely to be in older age groups, compared to those recruited via mobile devices. We tested the impact of inclusion and exclusion of the monetary incentive during intercept recruitment on the proportions of household income and determined that not mentioning the incentive increased participation among higher-income groups, but skewed the recruitment toward older women with a higher level of education attainment (see Table 2). The sampling approach was fine-tuned based on these learnings to yield the initial baseline sample.

Table 2. Results of selected recruitment tactics.

Participant characteristics ^a	Total participants				Participants where no incentive was offered			
	Recruited on a weekday, n (%)	<i>P</i> value	Recruited on a weekend, n (%)	<i>P</i> value	Recruited on a weekday, n (%)	<i>P</i> value	Recruited on a weekend, n (%)	<i>P</i> value
Age (years)								
Total	371 (100)		389 (100)		135 (100)		43 (100)	
18-24	98 (26.5)	.06	82 (21.1)	.19	33 (24.4)	.72	5 (11.6)	.06
25-34	208 (56.9)	.36	237 (60.9)	.11	68 (50.4)	.06	30 (69.8)	.11
≥35	65 (17.5)	.39	70 (18.0)	.56	34 (25.2)	.04	8 (18.6)	.96
Household income (US \$)								
Total	338 (100)		353 (100)		124 (100)		40 (100)	
<25,000	101 (29.9)	.11	91 (25.8)	.54	30 (24.2)	.46	8 (20.0)	.31
25,000-49,999	89 (26.3)	.67	102 (28.9)	.33	31 (25.0)	.56	10 (25.0)	.76
50,000-99,999	103 (30.5)	.52	98 (27.8)	.43	33 (26.6)	.49	16 (40.0)	.13
≥100,000	45 (13.3)	.03	62 (17.6)	.58	30 (24.2)	.02	6 (15.0)	.76
Employment status								
Total	371 (100)		385 (100)		134 (100)		43 (100)	
Full time	142 (38.3)	<.001	200 (51.9)	.01	71 (53.0)	.11	22 (51.2)	.54
Not employed full time	229 (61.7)	<.001	185 (48.1)	.01	63 (47.0)	.11	21 (48.8)	.54
Educational level								
Total	368 (100)		388 (100)		132 (100)		45 (100)	
High school or less	80 (21.7)	.81	81 (20.9)	.78	33 (25.0)	.27	5 (11.1)	.09
Some college	130 (35.3)	.35	128 (33.0)	.76	34 (25.8)	.04	21 (46.7)	.06
4-year degree or higher	158 (42.9)	.28	179 (46.1)	.60	65 (49.2)	.30	19 (42.2)	.69

^aExcludes participants that preferred not to disclose their demographics.

Of the 5028 respondents who started the baseline assessment, 1557 completed it and met the inclusion criteria. The most common reasons for disqualification were pregnancy week out of target range, not pregnant, participating in other research, and out of target age range (see [Table 3](#)).

A total of 1179 participants met the eligibility requirements, completed the baseline screening survey, and opted to participate. While the panel recruited more quickly than we planned, the panel size was slightly shy of our target, as a few responses showed duplicate email addresses and were removed. This is a risk when using a digital recruitment method and

offering gift card incentives. To mitigate this, we instituted email validation, which excluded baseline submissions from previously submitted email addresses, and monitored responses coming from the same IP addresses.

Two panels were recruited. Panel 1, with 858 women, was recruited early in the first trimester at weeks 4 to 10 of pregnancy. The 321 women in Panel 2, were recruited early in the third trimester at weeks 28 to 33 of pregnancy. Panel 2 was included in the event of undue attrition to insure a sufficient sample size in the critical postnatal period for future statistical modeling in health care research.

Table 3. Sample disposition.

Sample characteristics	Value, n (%)
Total site intercept impressions (n=476,863)	476,863 (100)
Clicks on site intercept survey, out of total impressions (n=476,863)	5843 (1.2)
Baseline assessment survey starts, out of total clicks (n=5843)	5028 (86.1)
Disqualified participants, out of number of starts (n=5028)	
Total disqualified ^a	3471 (69.0)
Pregnancy week not within targets	2186 (43.5)
Did not complete the screening section	557 (11.1)
Not pregnant	317 (6.3)
Participating in other research	190 (3.8)
Age outside range (ie, <18 years of age)	151 (3.0)
Outside the United States	75 (1.5)
Male	55 (1.1)
Qualified participants, out of number of starts (n=5028)	1557 (31.0)
Agreed to participate, out of qualified respondents (n=1557)	1535 (98.6)
Completed baseline survey ^b , out of respondents who agreed to participate (n=1535)	1179 (76.8)

^aRespondents could have more than one disqualifier.

^bDuplicate entries from the same email address were removed.

Participation and Retention

Of the 1179 participants initially enrolled at baseline, 79.2% (934/1179) completed at least one additional assessment, 65.6% (773/1179) informed us about the birth of their child, 63.7%

(751/1179) completed one or more assessments in the postpartum period, and 60.1% (709/1179) completed the final assessment in the study. There were 245 out of 1179 women enrolled in the study that did not return to take any additional assessments after baseline (20.8%) (see [Table 4](#)).

Table 4. Study attrition and retention into the postpartum period.

Attrition and retention groups	Value (N=1179), n (%)
Total participants enrolled at baseline	1179 (100)
Participant attrition	
Total who dropped out	429 (36.4)
Dropped out after baseline	245 (20.8)
Dropped out after postpartum period	184 (15.6)
Postpartum retention of participants	
Total retained	750 (63.6)
Completed pregnancy and postpartum assessments	736 (62.4)
Completed postpartum assessment only	14 (1.2)

A total of 45.1% (532/1179) of women completed all potential full surveys: 351 out of 532 (66.0%) in Panel 1 and 181 out of 532 (34.0%) in Panel 2. By the end of the study, 2.2% of participants (26/1179) actively opted out of the study, some noting pregnancy loss and others providing no reason.

Participation rates for each assessment varied and were impacted by the type of assessment, the incentives offered, and the position in the protocol. Short assessments and long assessments showed similar cooperation rates—64.6% (4669/7222) and 65.0% (3088/4754), respectively—but attributing cooperation

to survey length alone cannot be established, as we put more effort into garnering responses to longer surveys.

After closing recruitment for the fifth assessment after baseline (ie, time point [T] 6 [T6]) with a 51.6% (431/835) participation rate (see [Table 5](#)), we began aggressively implementing re-engagement strategies starting with the next full survey at T7. Strategies included revising email invitation copy, sending dedicated correspondence to nonresponders, and implementing text reminders.

Completion rate trends point to engagement strategies boosting the total number of assessment surveys completed. Following T6, which had a cooperation rate of 51.6% (431/835), cooperation began to increase, with cooperation rates of 58.5% (490/837) at T7, 59.9% (692/1156) at T8, 59.8% (499/835) at T9, and 64.2% (742/1156) at T10. Among the 370 participants that opted in for text reminders, response rates improved by as much as 40% over the group that did not opt in. Communications sent to nonresponders during pregnancy encouraged 229 nonengaged participants to re-engage with the study and complete future assessments. A portion of these

nonresponders may have returned on their own without re-engagement efforts; however, that proportion is unknown.

The attrition of participants after giving birth was expected, as this pivotal event shifts priorities. We were pleased to retain 80.4% (751/934) of the active sample after this life-changing point in time. In fact, the T12 assessment was administered 0 to 5 days after giving birth and achieved a 93.4% (465/498) participation rate. This reaffirmed our confidence in the approach and ability to continue measurement of the pregnancy sample into the postnatal period.

Table 5. Participation rate by assessment instrument and time point.

Time point (T)	Assessment instrument	Invitations, n (%) ^a	Completed assessments out of number of invitations, n (%)
Pregnancy (n=858)			
T1 (Panel 1: weeks 4-10; Panel 2: weeks 29-33) (n=1179)	Baseline assessment	476,863 ^b	1179 ^b
T2 (Panel 1: weeks 6-11)	Mini A ^c	853 (99.4)	538 (63.1)
T3 (Panel 1: weeks 9-11)	Mini B ^d	853 (99.4)	469 (55.0)
T4 (Panel 1: weeks 12 and 13)	Full ^e	840 (97.9)	482 (57.4)
T5 (Panel 1: week 15)	Mini A	835 (97.3)	448 (53.7)
T6 (Panel 1: week 18)	Mini B	835 (97.3)	431 (51.6)
T7 (Panel 1: week 21)	Full	837 (97.6)	490 (58.5)
T8 (Panel 1: week 25; Panel 2: week 32) (n=1179)	Mini A	1156 (98.0)	692 (59.9)
T9 (Panel 1: week 28)	Mini B	835 (99.4)	499 (59.8)
T10 (Panel 1: week 32; Panel 2: week 35) (n=1179)	Full	1156 (98.0)	742 (64.2)
T11 (weeks 38-42) (n=1179)	Birth survey	1156 (98.0)	773 (66.9)
Postpartum (n=773)^f			
T12 (+2 days)	Mini B	498 (64.4)	465 (93.4)
T13 (week 1)	Mini A	594 (76.8)	539 (90.7)
T14 (week 4)	Full	768 (99.3)	665 (86.6)
T15 (week 8)	Mini B	763 (98.7)	588 (77.1)
T16 (week 12) (n=1179)	Final assessment ^g	1153 (97.8)	709 (61.5)

^aThe number of invitations for each assessment varied due to women opting out and opting back in as the study progressed.

^bRecruitment at baseline was performed via random intercept, versus email invitations as with subsequent assessments; 476,863 represents the number of site impressions for the intercept and 1179 represents total participants enrolled at baseline.

^cThe Mini A (short-form) instrument contained five psychometric questions.

^dThe Mini B (short-form) instrument contained four psychometric questions.

^eThe Full (long-form) survey contained six psychometric questions.

^fIn the postpartum period, the length of time that had elapsed from giving birth to responding to the birth survey determined which assessment a respondent was next eligible to complete, which also impacted the number of invitations sent. The invitations sent during the postpartum period were only sent to those women who had confirmed the birth of her child via the birth survey.

^gAll respondents, regardless of birth survey response, were invited to take the final assessment.

Two population-based maternity studies with similar assessment timing allowed for a remedial comparison of participation statistics: the MARI Study, a longitudinal study conducted among pregnant women recruited from community clinics in Dresden, Germany, and the GUSTO Study, which was conducted among families in Singapore recruited during their first clinical visit of pregnancy and then followed through birth

and 36 months postpartum [6,7]. In the late-second trimester and early-third trimester assessments, in which the EPDS or similar instruments were administered, the BabyCenter study had a participation rate (529/858, 61.7%) that was within the range of the MARI Study (57.6%) and the GUSTO Study (77.5%). For assessments conducted at approximately 3 to 4 months postpartum, all three studies showed remarkably similar

participation rates, ranging from 57.7% (719/1247) for the GUSTO Study to 59.3% (509/858) for the BabyCenter study (see [Table 6](#)).

Table 6. Comparison of participation rates in longitudinal perinatal depression studies.

Participant details at each time point	BabyCenter longitudinal study of perinatal mood disorders (United States) (n=858) ^a	MARI ^b Study (Germany) [6] (n=483)	GUSTO ^c Study (Singapore) (n=1247) [7]
Qualified at baseline			
Pregnancy weeks	4-10	10-12	<14
Participants, n (%)	858 (100)	483 (100)	1247 (100)
Pregnancy assessment			
Pregnancy weeks	32	35-37	26
Participants, n (%)	529 (61.7)	278 (57.6)	967 (77.5)
Postpartum assessment			
Postpartum months	3 months	4 months	3 months
Participants, n (%)	509 (59.3)	283 (58.6)	719 (57.7)

^aOnly Panel 1 participants were included.

^bMARI: Maternal Anxiety in Relation to Infant Development.

^cGUSTO: Growing Up in Singapore Towards healthy Outcomes.

Population Profile

At baseline, the profile of participants was similar to the population of women and births in the United States for age, marital status, presence of children, employment, and ethnicity [9,17]. The study sample had a higher concentration of women who had achieved a college or higher education degree, consistent with an online population [18]. Participants in the study demonstrated lower median household income than the US median [19]. This is potentially a result of the monetary incentives offered.

Attrition that occurred over the course of the study period is not inconsequential for demographic characteristics, with potential impact on mood-related characteristics as well. Participants retained through completion of the final assessment demonstrated a sample profile that differed from the baseline

profile. The sample at final assessment showed higher median age, higher household income, higher incidence of marriage, and higher education attainment. This subset also demonstrated a different ethnic makeup, with a higher proportion reporting ethnicity as White, and fewer identifying as African American, Black, or Hispanic (see [Table 7](#)). Attrition characteristics are similar to those from other perinatal studies, such as the EDEN study (Etude sur les déterminants pré et post natals précoces du Développement psychomoteur et de la santé de l'ENfant), the mother-child EDEN cohort study based in France [20].

Participants completing the final assessment showed similar characteristics for number of babies, type of birth, and birth week.

[Table 8](#) shows the birthing profile of participants determined during the final assessment.

Table 7. Participant profile ascertained at baseline and at the final assessment versus US births.

Participant characteristics	Baseline respondents: 4-10 weeks pregnant (N=1179), n (%)	Final respondents: 12 weeks postpartum (n=709), n (%)	US births (n=3,945,875), n (%)
Have two or more children, including current pregnancy	697 (59.1)	419 (59.1)	2,445,998 (62.0) [9]
Marital status: married	699 (59.3)	815 (68.1)	2,376,079 (60.2) [9]
Employment status: employed	759 (64.4)	748 (62.5)	2,493,453/3,939,144 (63.3) [17]
Education: 4-year college degree or higher	561 (47.6)	652 (54.5)	1,262,680 (32.0) [9]
Single race			
White	656 (55.6)	701 (58.6)	2,056,332 (52.1) [9]
Black or African American	178 (15.1)	142 (11.9)	558,622 (14.2) [9]
Asian or Pacific Islander	53 (4.5)	68 (5.7)	254,471 (6.4) [9]
Ethnicity: Hispanic (any)	225 (19.1)	186 (15.5)	918,447 (23.3) [9]
Age of mother in years			
15-24 ^a	254 (21.5)	123 (17.3)	1,013,787 (25.7) [9]
25-29	344 (29.2)	211 (29.8)	1,149,122 (29.1) [9]
30-34	359 (30.4)	223 (31.5)	1,111,042 (28.2) [9]
35-39	183 (15.5)	130 (18.3)	547,488 (13.9) [9]
40-44	40 (3.4)	22 (3.1)	113,140 (2.9) [9]
Annual household income (US \$) (US births n= 3,969,962)			
<25,000	199 (23.2)	131 (18.5)	640,062 (16.1) [19]
25,000-49,999	211 (24.6)	171 (24.1)	828,406 (20.9) [19]
50,000-74,999	123 (14.3)	117 (16.5)	705,117 (17.8) [19]
75,000-99,999	98 (11.4)	93 (13.1)	559,027 (14.1) [19]
≥100,000	154 (17.9)	142 (20.1)	1,237,350 (31.2) [19]
Prefer not to answer	73 (8.5)	55 (7.8)	N/A ^b

^aThe National Center for Health Statistics (NCHS) reports births by the following age ranges of the mother: *Under 15*, *15-19*, and *20-24 years*; the BabyCenter study reports births by the mother's age starting at 18 years.

^bN/A: not applicable. The survey instruments in this study permitted respondents to opt out of providing personal information by selecting *Prefer not to answer*. NCHS reports characteristics for the entire population.

Table 8. Birthing profile ascertained in final assessment.

Participants' birthing details	Final respondents: 12 weeks postpartum (n=709), n (%)	US births [9] (n=3,945,875), n (%)
Birth location		
Hospital	667 (94.1)	3,883,255 (98.4)
Birthing center	30 (4.2)	19,767 (0.5)
At home	7 (1.0)	38,830 (1.0)
Number of babies		
Single	694 (97.9)	3,810,149 (96.6)
Twins or multiples	15 (2.1)	135,726 (3.4)
Type of birth		
Vaginal	496 (70.0)	2,684,803 (68.0)
Caesarean section	213 (30.0)	1,258,581 (31.9)
Birth term		
Full (≥ 39 weeks)	467 (65.9)	2,551,797 (64.7)
Early (37 or 38 weeks)	172 (24.3)	1,005,014 (25.5)
Preterm (≤ 36 weeks)	70 (9.8)	388,669 (9.9)

Data Set Validation

We investigated the factor structure of the psychometric scales and compared these to previously published results. The EPDS measurement of Panel 1 at baseline, despite exclusion of the suicidality item, was similar in structure to published results

from the Postpartum Depression: Action Towards Causes and Treatment (PACT) Consortium, with three analogous factors of mood disorder: depressed mood, anxiety, and anhedonia (see Table 9) [21]. The Obsessive-Compulsive Inventory was noted to be remarkably similar in structure to the published version (see Multimedia Appendix 3) [22].

Table 9. Factor structure of the Edinburgh Postnatal Depression Scale (EPDS) and comparison with the Postpartum Depression: Action Towards Causes and Treatment (PACT) study.

EPDS item (item No.)	PACT: relative contributions of EPDS items to dimensions and factors [21], factor score			BabyCenter EPDS factor analysis at baseline: Panel 1 (n=858), factor score		
	Depressed mood	Anxiety	Anhedonia	Depressed mood	Anxiety	Anhedonia
Suicidal thoughts (10)	97	-17	-2	N/A ^a	N/A ^a	N/A ^a
Unhappy: crying (9)	79	19	4	80	1	5
Unhappy: difficulty sleeping (7)	76	15	4	66	7	6
Felt scared or panicky (5)	51	41	0	6	71	4
Felt sad or miserable (8)	51	44	-2	74	7	11
Anxious or worried (4)	3	74	1	-5	75	12
Things on top of me, difficulty coping (6)	11	68	-7	41	26	17
Looked forward with enjoyment (2)	-2	2	83	9	-3	81
Been able to laugh (1)	-7	8	81	6	3	78
Blamed myself unnecessarily (3)	13	-17	57	18	56	-14

^aThis item and dimension was not included in EPDS instrument in the BabyCenter Study.

Participant Feedback

After completing the final assessment, we offered participants the opportunity to provide feedback about their overall experience via a survey. Overall, 61.0% of participants active in the postpartum period (459/752) provided feedback.

Of those who responded to this feedback survey, 98.3% (451/459) were *satisfied* or *very satisfied* with their experience

participating in the study, 86.7% (398/459) felt the incentives were *very fair*, 91.5% (420/459) said the number of questions in each survey was *the right amount*, and 89.5% (411/459) said the number of emails received in relation to the study was *the right amount*. We note that nonresponse bias in this assessment may not be inconsequential, as nonresponders to the feedback survey were less engaged with the study; overall, they completed 18% fewer assessments than responders in the postpartum period.

Discussion

Overview

In this paper, we showed that it is possible to recruit a large and representative sample of pregnant women into an online panel via the BabyCenter website. We implemented a range of methods to keep participants active and reduce attrition. Our panel provided high-quality data that can now be used to learn new insights into mental health during and shortly after pregnancy.

Lessons Learned

In this study we demonstrated that leveraging digital methods to measure a niche population over a length of time to collect a longitudinal data set is both viable and logical, as digital methods afford the following:

1. Ability to reach a specific population with a digital media partner.
2. Capability to recruit a large convenience sample into an online panel in a short period of time.
3. Capacity to readily adjust recruitment strategies to help construct a more representative panel profile.
4. Tools to automate and optimize otherwise tedious processes when collecting repeated measures (ie, API).
5. Flexibility to easily introduce additional retention elements as needed.
6. Means to execute longitudinal data collection for the validation of existing knowledge and the advancement of scientific study.

We were able to recruit a large and representative sample of pregnant women into an online panel during a 26-day period. The key recruitment lessons learned were as follows:

1. Partner with a website that is known to interact with the required population.
2. Adapt the demographic sampling parameters to get a representative population.
3. Use friendly language in the advert's invitation copy that focuses on altruism.
4. Employ email or IP and time stamp validation to reduce duplicate and invalid participants.
5. Offer an initial incentive at enrollment that is fair but not overly generous to encourage legitimate enrollment.

The study duration was as long as 9 to 11 months from early pregnancy. Our online panel captured a baseline survey and one follow-up survey for approximately 80% of respondents and had similar attrition to previous longitudinal panel studies. The methods we used to reduce attrition were as follows:

1. Being transparent by providing details and expectations of the survey at enrollment so participants would know the required commitment.
2. Reducing monotony by alternating survey questions and varying survey lengths.
3. Adding friendly questions at the beginning of the survey about the participants' experience to increase engagement.
4. Making the surveys easy to complete by optimizing them based on device (ie, desktop vs mobile devices).

5. Providing participants with interaction options (ie, text and email), but being careful not to unnecessarily overburden.
6. Sending personalized emails to chronic nonresponders and reminders of incentive status.
7. Using a combination of monetary and nonmonetary incentives, such as sharing study findings.

Limitations

During the recruitment period, although the study invitations served on BabyCenter were randomized, there is no way to determine the characteristics of site visitors that chose not to click on the invitation. This is due to the anonymity of intercepting in a digital environment and online data privacy issues. To address this limitation, extra care was taken to monitor the composition and characteristics of the panel at all stages.

When using a digital-only methodology without the human-to-human contact that is often part of a clinical study approach with pregnant women, attrition is likely to be problematic. Of the participants who did not complete an additional assessment after baseline, attrition occurred disproportionately within Panel 1. Recruitment of Panel 1 participants occurred very early in pregnancy, at 4 to 10 weeks, when rates of pregnancy loss and false positives can be as high as 20%. Although we did receive participant-initiated requests to opt out, it is likely that a portion of women who experienced pregnancy loss or false positives did not notify us and did not return to complete another assessment. We had no alternative means to contact these women.

It is also realistic to assume that the incentive for completing the baseline assessment, a US \$25 e-gift card, was sufficient reward for some women who chose not to continue in the study. We hypothesize that a smaller reward at enrollment may have extended the period needed to recruit the target number of participants but resulted in higher cooperation rates.

As stated, the study design did not include direct contact between participants and researchers, unless an inquiry was initiated by the participant. This was intentional but created another limitation. We chose not to include the suicidality item in the EPDS scale, confining the measurement and analysis to only 9 of the 10 standard items. Without the appropriate means to support women that may have expressed an inclination toward self-harm, we chose to exclude it. We provided links to suicide prevention and mental health resources in the study materials. We do not believe the omission of suicidality measurement has hampered achievement of the overall study objective but does create an unknowable gap in the data set.

Digital surveys may offer the advantage of increased accuracy with the convenience and anonymity they afford. Results from one perinatal depression study demonstrated that responses submitted by mail showed higher EPDS scores compared to responses collected by phone [23]. Another investigation found that women preferred to complete the EPDS assessment in the more comfortable environment of their own home versus in a clinical setting, in which interacting with a researcher impacted how women responded [24]. Testing this hypothesis was not within the scope of our study.

There are challenges to contextualizing results with other studies. To our knowledge, longitudinal studies from pregnancy to the postpartum period conducted exclusively online have not been published. Comparing a perinatal sample to population studies of different nonmaternal targets is problematic due to the nature of the birth of a child, a pivotal component of attrition. It is difficult to compare the participation rates of this study to prior perinatal depression research due to the inclusion in our study of women early in pregnancy at 4 to 10 weeks of gestation, and the fact that many other studies were conducted with patients recruited later in their pregnancies in clinical settings. That said, two other population-based longitudinal studies of

perinatal depression with similar assessment time frames showed comparable retention rates at about 3 to 4 months postpartum.

Conclusions

Recruiting participants into an online panel from a trusted digital media source and administering a well-designed study exclusively in an online environment can successfully be utilized for scientific research. We approached this study with a focus on maximizing engagement, reducing attrition, and building trust with participants, which resulted, to the best of our knowledge at the time, in the collection of the largest, most comprehensive longitudinal data set to date measuring perinatal mood disorders from early pregnancy.

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Conflicts of Interest

JR and KW are employees of Janssen Research & Development and are shareholders of Johnson & Johnson. Janssen, a division of Johnson & Johnson, funded this study. BM, ML, and LL were employees of BabyCenter at the time of the study; BabyCenter was a division of Johnson & Johnson and received financial compensation for the research conducted. They are shareholders of Johnson & Johnson. MW was an employee of Janssen Research & Development and is a shareholder of Johnson & Johnson.

Multimedia Appendix 1

Assessment instruments.

[[DOCX File, 47 KB - pediatrics_v4i2e16280_app1.docx](#)]

Multimedia Appendix 2

General interest and health questions.

[[DOCX File, 26 KB - pediatrics_v4i2e16280_app2.docx](#)]

Multimedia Appendix 3

Obsessive-Compulsive Inventory factor structure.

[[DOCX File, 1708 KB - pediatrics_v4i2e16280_app3.docx](#)]

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Abbreviations

API: application programming interface

EDEN: Etude sur les déterminants pré et post natals précoces du Développement psychomoteur et de la santé de l'ENfant

EPDS: Edinburgh Postnatal Depression Scale

GUSTO: Growing Up in Singapore Towards healthy Outcomes

MARI: Maternal Anxiety in Relation to Infant Development

PACT: Postpartum Depression: Action Towards Causes and Treatment

T: time point

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Original Paper

Participatory Design of an Activities-Based Collective Mentoring Program in After-School Care Settings: Connect, Promote, and Protect Program

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Abstract

Background: Out of school hours care (OSHC) services provide a unique opportunity to deliver early intervention programs to enhance primary school-aged children's social, emotional, physical, and cognitive well-being; however, such programs are currently lacking.

Objective: This study aims to address the lack of well-being programs for children accessing OSHC services in the research literature by using participatory design (PD) to collaboratively develop and test an OSHC well-being program—the connect, promote, and protect program (CP3).

Methods: The study employed methods of PD, user (acceptance) testing, and iterative knowledge translation to develop a novel well-being program framework—CP3—with key stakeholders (eg, children, OSHC staff, volunteers, families, clinicians, educators, and researchers). Thematic techniques were used to interpret and translate the qualitative information obtained during the research and design cycles.

Results: The co-design process generated the CP3 model, which comprises a group-based mentoring approach to facilitate enhanced activities in OSHC settings. Activities are underpinned by 4 key principles of program delivery: build well-being and resilience, broaden horizons, inspire and engage, and connect communities.

Conclusions: To our knowledge, the CP3 program is the first co-designed well-being program developed specifically for OSHC services. This co-design process is key to ensuring local community needs—particularly those of young people accessing OSHC—are met and that these individuals are meaningfully and actively involved in all stages of the research and design process, from conception to implementation, evaluation, and continuous improvement.

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KEYWORDS

participatory design; children; after school care; health; well-being; program development; community consultation

Introduction

Background

In the most recent report by the Australian Early Development Census (AEDC), 22% of primary school-aged children were

found to be vulnerable to experiencing a developmental delay in one or more areas of functioning [1]. This included delays in social competence, emotional maturity, language and cognitive skills, communication and general knowledge, and/or physical health and well-being [1]. The rates of developmental

vulnerability are reflected in other Organization for Economic Co-operation and Development (OECD) countries and have sparked international discussions on how governments, educators, individuals, and communities can work together to minimize the risk of developmental vulnerability and maximize the likelihood that all children have the best chance of a positive early start [2]. A key focus area that has arisen is the importance of using existing educational structures to optimize the environments in which children learn and grow [2]. This includes broadening the scope of educational curriculums to include programs that target children's health and well-being and, importantly, delivering programs not only in formal school hours but also in before and after school care [3].

Out of school hours care (OSHC) services offer a safe and supervised environment for primary school-aged children before and after school. These centers provide vital services for many families by enabling parents and caregivers to achieve a balance between childcare, social responsibilities, and work [4]. In Australia, OSHCs are supported by the My Time, Our Place Framework [5], which seeks to assist services in responding to children's needs, interests, and choices. The framework forms part of the Australian government's National Quality Framework [6], which focuses on ensuring that children receive a high standard of education and care while attending OSHC. In addition, OSHC offers a unique opportunity to implement extracurricular programs designed to enhance children's health and well-being in a multidimensional way, including socially, emotionally, physically, and cognitively [7]. However, despite their potential, OSHCs often function as supervised childcare facilities, resulting in a missed opportunity to implement prevention and early intervention programs [8]. As such, there has been increased attention from researchers, educators, the government, and the broader community into how specific well-being-focused programs delivered during out of school hours could be better used to support children's learning and growth.

Globally, there is currently a dearth of literature on how health and well-being programs for primary school-aged children can be developed, implemented, and evaluated in OSHC settings. Although numerous programs have been developed to target adolescent groups [9], far less research has been conducted examining health and well-being programs to support children in the primary school years (aged 5-11 years), aptly named the *in-betweeners*, as they fall in between the toddler and postpubertal groups [10]. Programs developed for these *in-betweeners* have been overwhelmingly skewed toward physical health and nutrition [11,12], and although interventions targeting healthy eating and physical activity are undoubtedly beneficial, they fail to consider children's health more holistically. Moreover, many existing programs have tended to be highly specific and nongeneralizable, providing limited scope beyond the implementation of the program itself [13,14]. Such programs at this age are critical, as experiences from early to middle childhood, including a child's environment and relationships, shape their brain development and lay the foundations for their future social, emotional, cognitive, and physical well-being [15-17]. Disruptions in this developmental

process can have long-term impacts, affecting the way children learn and interact with others [18].

In OSHC services, the provision of high-quality programming, characterized by positive staff-child relationships, a variety of enrichment activities, and children's choice and input into program activities, has been positively associated with children's engagement and motivation [19-21] as well as their cognitive and social outcomes [22]. The presence of appropriately trained staff and out-of-school coordinators to assist with professional development and networking are other factors related to OSHC quality [23]. Given that OSHC services differ in geographic location, expertise of staff, and the characteristics and number of children who attend, programs that are suitable for one OSHC service may not be feasible or appropriate for another. As such, providing a model that allows OSHC programs to be individually tailored to meet the needs and preferences of children and their families, the skill set of staff, and broader ethos and goals of the community is critical.

At present, there are no clear models in the literature detailing how well-being-focused programs, including appropriate mentorship and program development, can be developed and delivered in OSHC settings. As such, there is an urgent need to develop an evidence-based framework to guide staff, educators, community members, and other key stakeholders who are responsible for the delivery of well-being-focused programs to children in primary school years. To develop a program framework that best meets the needs of the community and service, the involvement of key stakeholders (eg, children, parents and caregivers, staff, volunteers, educators, clinicians, and community members) in the co-design and evaluation of the intervention is critical [7].

One way to develop this model is through the use of participatory design (PD) research methods, also known as co-design, in which stakeholders are placed at the center of the design process [24,25]. Often used in designing digital technologies, PD is part of a paradigm shift toward collaborative bottom-up engagement, whereby stakeholders jointly explore and create solutions to program design and service delivery. The PD process involves a series of iterative design cycles in which all stakeholders contribute their knowledge to produce a program model [25,26]. The ideas generated within each cycle are discussed, evaluated, and built upon during the subsequent design phases. Importantly, all stakeholders participate in each development cycle [24], as they share equal responsibility with the research team for outcomes [27]. This iterative research design cycle of development, feasibility, evaluation, and implementation follows the Medical Research Council guidelines for developing complex interventions [28].

Objectives

The primary aim of this study is to use a multidisciplinary collaboration between members of an OSHC community (eg, staff, volunteers, parents, and caregivers), local community members (eg, youth workers from local organizations, clinicians, and educators), and researchers to co-design a well-being program model for delivery in OSHC settings. The program has been termed the connect, promote, and protect program (CP3).

Methods

Ethics

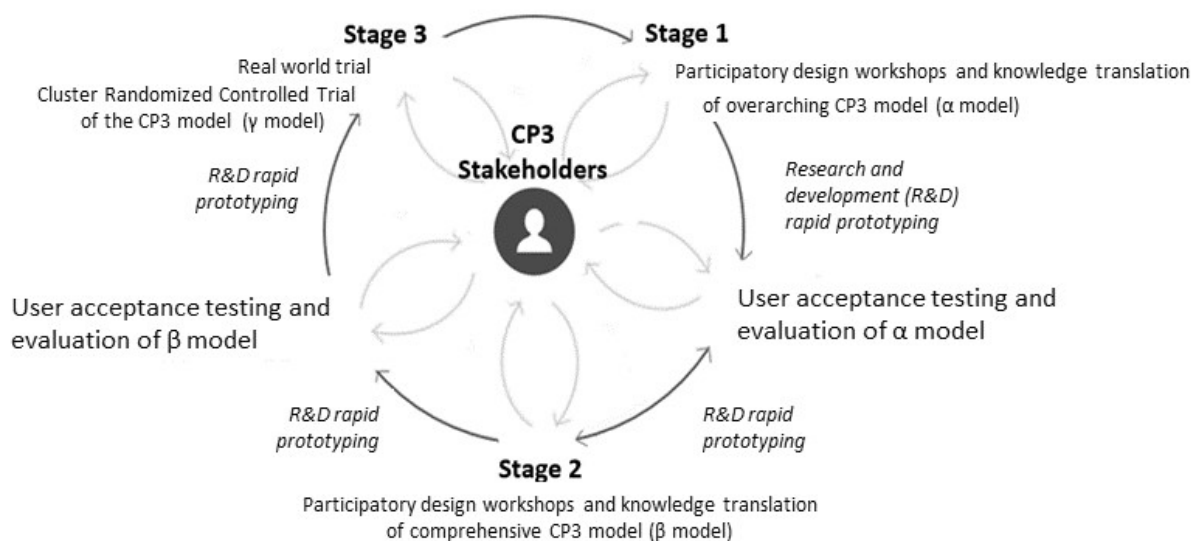
This research was approved by the University of Sydney's Human Research Ethics Committee (protocol numbers: 2017/509 AND 2018/832).

Study Design

This study employed a prospective observational design, including PD and user (acceptance) testing methodologies. The

research and development cycle was conducted in a series of stages based on previously established processes in the academic literature [25,29]. The co-design and build of CP3 included several iterative stages that were built upon each other (Figure 1). This research reports on stage 1, which involved PD workshops and knowledge translation, whereby knowledge and ideas generated during workshops were translated to produce an overarching CP3 program model (α model). Stages 2 and 3 and in train will be reported elsewhere in the future.

Figure 1. Connect, promote, and protect program research and development cycle. CP3: connect, promote, and protect program; R&D: research and development.



Participants

Adult participants were recruited from a community sample in Illawarra, New South Wales region, between July 2017 and September 2018. Electronic and paper-based advertising materials were used to notify potential participants of the study. Passive snowballing through the networks of identified participants was also used to increase the participant pool [30]. Participants comprised 3 main stakeholder groups: (1) parents, guardians, or primary carers of primary school children; (2) volunteers or employees of the nongovernment organization establishing the OSHC; and (3) stakeholders such as local community members, supportive others (such as grandparents, aunts, or uncles), academics, educators, and school personnel from Illawarra (where the program was to be established). The inclusion criteria were as follows: (1) identification as part of one of the main stakeholder groups; (2) ability to participate in English; and (3) provision of written informed consent to participate in the research. Participants did not receive any compensation or reward for participating in the workshops; however, all workshops were catered.

PD Workshops

A total of four 3-hour PD workshops were held at the OSHC, where the program was initially piloted. The PD workshops were facilitated by a psychologist (AM) and co-facilitated by a second researcher. Co-facilitators had experience in either the

OSHC sector or youth mental health (LOP, SP, RA, and NA). A scribe was present in each PD workshop to take detailed notes. Within each PD workshop, adult stakeholder backgrounds were intentionally mixed, meaning that parents and guardians, volunteers or employees, and other community stakeholders all participated together. This mixed participant approach enriches the workshop discussion by drawing on a range of participant experiences, ultimately enhancing the overall program design solution [31].

In line with other academic literature, the workshop agenda includes 3 phases: discovery, evaluation, and prototyping [25,31,32]. In the discovery phase, stakeholders were involved in the design process by identifying local needs and issues and defining research objectives, strategies, and goals. These discussions help to identify key issues and shape creative concepts and ideas for program development and implementation. In the evaluation phase, stakeholders worked together to evaluate program ideas (whether they are ideas from external sources such as other programs or those generated in previous workshops) to understand how they might be improved and refined to fit the local program needs. In the prototyping phase, stakeholders collaborated to develop and refine content and work through implementation strategies to determine the optimal program design.

Workshop sessions applied an iterative knowledge translation process so that preliminary ideas generated within earlier

workshops were further developed (and fed back on) by participants in later workshops.

Data Analysis

Qualitative data sources (artifacts) from PD workshops included detailed notes from the scribe and notes written by participants on handouts, worksheets, and surveys. All data were uploaded to the NVivo (QSR international, version 11) software. Qualitative data were interpreted using previously established thematic techniques [33] by 2 researchers (AM and NA). All qualitative data sources from the workshops and feedback surveys were reviewed by noting the relevant points. Key concepts were subsequently analyzed across all participants to develop an initial coding framework. Notes were then coded in NVivo [34] using this framework by 2 researchers per transcript. The coding followed an iterative process of reading, coding, and discussing the pattern and content of the coded data. Similarities and differences in opinion were discussed until a consensus was reached. An initial report was written for the knowledge translation team, who then established the CP3 model for user acceptance testing and evaluation. The knowledge translation process involves researchers working with stakeholders to synthesize, exchange, and apply knowledge to enhance systems and improve outcomes [35].

Compliance With Ethical Standards

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (including the name of committee+reference number) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent

All individuals completed an informed consent form before participating in the study. All data, including images and figures in this publication, are presented in nonidentifiable formats.

Results

Sample Characteristics

In total, 28 participants took part in the initial 3 workshops during August and September 2017, and a further 6 adult participants took part in 2018. The demographic characteristics of participants are presented in [Table 1](#) (see [Multimedia Appendix 1](#) for a full breakdown of participant characteristics for individual workshops).

Table 1. Basic participant demographics.

Demographic item	Values
Population, N	34
Detailed participant type^a, n (%)	
Parent, guardian, or primary carer of a primary school-aged child	8 (24)
Community volunteers	4 (12)
Supportive other of a primary school-aged child	1 (3)
Potential future mentor of CP3 ^b	8 (24)
Researcher or academic	1 (3)
Teacher or educator	10 (29)
Local community member	19 (56)
Other child-focused community organization	9 (26)
Age range (years), n (%)	
16-24	3 (9)
25-34	2 (6)
35-44	6 (18)
45-54	6 (18)
55-64	6 (18)
≥65	4 (12)
Did not answer	7 (21)
Gender, n (%)	
Male	11 (32)
Female	23 (68)
Language spoken at home^a, n (%)	
English	27 (79)
Other	4 (12)
Did not answer	6 (18)

^aMultiple response options provided.

^bCP3: connect, promote, and protect program.

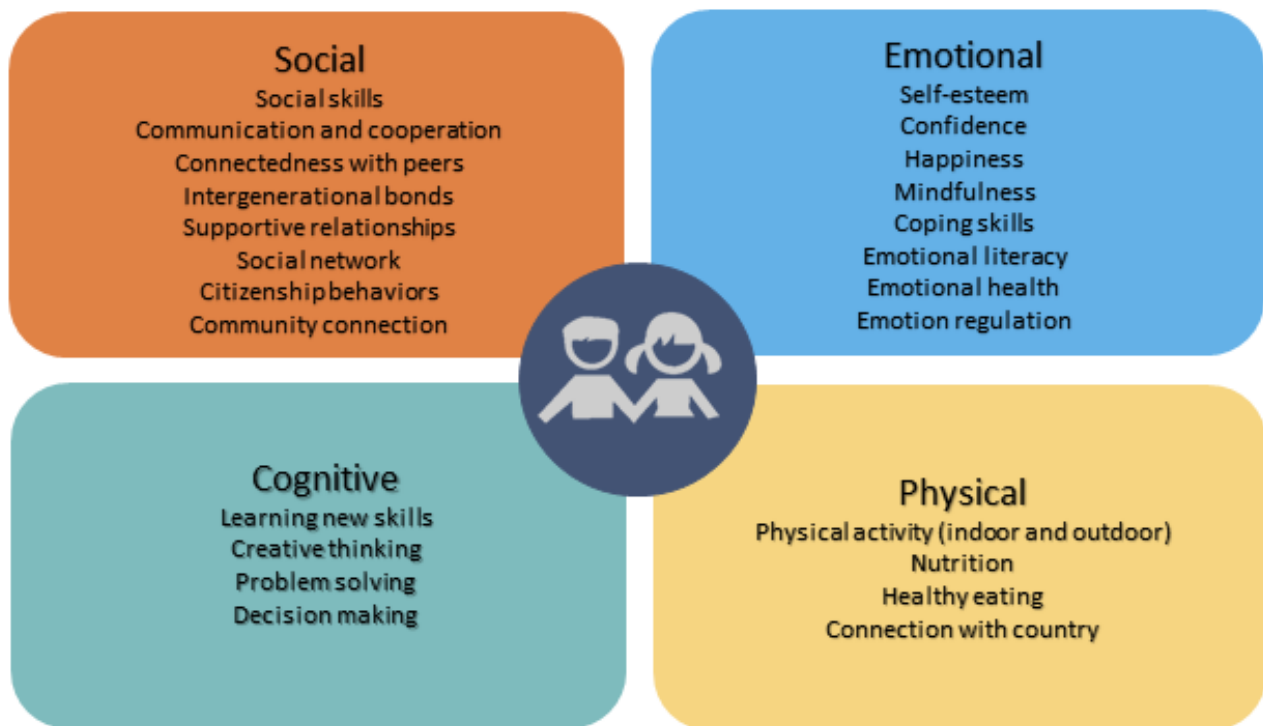
CP3 Principles

Discovery of CP3 Principles

In the discovery phase, which focused on creating CP3 principles, stakeholders chiefly identified the program goals. A total of 4 key themes were generated, which related to (1) enhancing well-being (*build well-being and resilience*), (2) creating opportunities for development and growth (*broaden horizons*), (3) meaningfully engaging children (*inspire and engage*), and (4) promoting social and community connectedness (*connect communities*).

Workshop participants emphasized that CP3 should aim to enhance children's well-being in a multidimensional and holistic way. The multiple ideas generated relating to improving well-being were categorized into 4 key domains: social,

emotional, physical, and cognitive well-being (Figure 2). Enhancing the child's social well-being was the most frequently referenced domain, followed by emotional well-being, cognitive well-being, and physical well-being. Social well-being items included building communication and social skills, enhancing citizenship behaviors, promoting positive and supportive relationships, and feeling connected to the local community. The focus of emotional well-being is related to building self-esteem, confidence, happiness, emotional health, resilience, and coping skills. Cognitive well-being items are chiefly related to problem solving and decision making. Physical well-being items predominately focused on healthy eating, undertaking physical activity (indoor and outdoor), connecting with the environment, and understanding the benefits of healthy lifestyles.

Figure 2. Children's wellbeing domains.

The theme relating to broadening the child's opportunities and skills by providing a diverse range of experiences that children might not generally have access to in their day-to-day lives was highlighted in all workshops. Participants emphasized that the activities on offer in CP3 should be enriching in that they help primary school-aged children broaden their horizons, develop new skills, and contribute to their personal and social development.

The theme related to meaningfully engaging children had a number of different areas of focus. Consistent themes raised in the workshops related to the best approach to facilitating CP3 chiefly centered around flexibility and choice for children; "...giving the children some freedom to choose what activities they enjoy" (OSHC manager, workshop 2) was viewed as important as it was reported to be "...nearly impossible to expect all children to engage in a controlled activity after a long day at school, especially if they are not interested in it" (OSHC manager, workshop 2). This flexibility included the children helping to provide input and co-design into what the activities program would look like: "It would be great if the activities could be tailored to the child as much as possible and be child-led. Child input and choice is important as is flexibility in programming" (community member, workshop 3).

Although the importance of social connection was also raised as part of the well-being component, participants in all workshops emphasized that enhancing social connectedness would be an important focus for CP3 as a distinct principle—not only for children accessing CP3 but also for families connected to CP3, staff and volunteers delivering CP3, and the wider community. It was hypothesized that if the program could build social connectedness, it would also create more awareness, tolerance, and understanding in the local communities through contact with others. The program would need to establish firm pathways to community resources (including people, organizations, and web-based resources) for children, their families, and the staff and volunteers delivering CP3. These community resources could range, for example, from skill development to mental health resources and services (such as counseling).

Prototyping the CP3 Principles

The prototyping phase led to the full formation of 4 key CP3 principles and the definitions (presented in [Textbox 1](#)), which are underpinned by the existing *My Time Our Place Framework* [5] and the *National Quality Standards* [6].

Textbox 1. Connect, promote, and protect program principles.

Build well-being and resilience

- Provide activities that seek to promote and enhance children’s social, emotional, cognitive, and physical well-being

Broaden horizons

- Broaden opportunities and skills by providing a diverse range of experiences that children might not generally have access to in their day-to-day lives

Inspire and engage

- Focus on creating a spark in children as the activity is interesting, motivating, and fosters a growth mindset. Encourage meaningful involvement by promoting children’s leadership, decision making, and choice

Connect communities

- Promote connectedness, communication, and belonging as children—and their families—forge strong links with local resources and their community

CP3 Core Program Features

Discovery

In the discovery phase relating to program design, stakeholders chiefly identified 2 key features of CP3: (1) group-based (collective) mentoring and (2) the provision of enhanced activities.

Evaluation

In the iterative evaluation phase, the provision of a mentoring component forming part of CP3 was viewed as highly acceptable across all workshops. A number of participants also highlighted that the key differentiation between CP3 and regular OSHC programming would be this mentoring component, which would require considerable focus to establish and sustain in the future:

The real point of difference of the program is the mentoring component, [we] need to capitalize on this and ensure that the program doesn’t just turn into another OSHC. [Community worker, workshop 3]

The value of mentoring was also highlighted throughout the workshops:

Including the mentoring component in the program might have positive impacts for the wider community, as it plants the seed for growth and can broaden perspectives. [Community member, workshop 2]

The mentoring component was not only seen as beneficial to the children accessing the OSHC but also viewed as giving the mentors themselves skills, confidence, social connection, and “a feeling of ‘giving back’” (mentoring benefits artifact, workshop 3).

Concerns were raised about child protection, and an emphasis was placed on the need to ensure that the program uses “...the right people in the right capacity” (mentoring mind map artifact, workshop 3). It was the prevailing view that such issues could be addressed through rigorous mentor recruitment, training, supervision, policies, and procedures.

In all workshops, the suggestions generated by participants highlighted that the OSHC activities on offer in CP3 should be enriched and enhanced, especially when compared with regular

OSHC services. The term created for this component by participants in early workshops was *enhanced activities* as they are “...more than just extracurricular activities” (parent and community worker, workshop 1), which was subsequently accepted and adopted in the later workshops. Enhanced activities were viewed as the vehicle for carrying out the CP3 principle of *broaden horizons*—as the activities would be enriched, allow children to develop new skills, and contribute to their personal and social development. Some participants viewed this program component as particularly beneficial for more vulnerable children who might access CP3:

Enhanced activities would be wonderful. Especially as they can be completely out of reach for some young people. [Parent and community worker, workshop 1]

Enhanced activities were viewed as needing to be stimulating to ensure that the children were engaged and motivated to take part. This was directly related to the CP3 principle of *inspire and engage* and went hand-in-hand with the mentoring component: “The mentoring and activities should create a spark for the child” (school teacher, workshop 3).

The overarching, iterative feedback generated during the workshops was chiefly positive:

This type of program could have huge benefits for wider community change as it sets out to make positive community connections—this can be powerful on a large scale and be a catalyst for huge community change. [Community worker, workshop 3]

Prototyping

When prototyping the mentoring component design, participants developed a plan for group-based (collective) mentoring, otherwise defined as collective mentoring. The collective mentoring of children in group settings was viewed as more beneficial in an OSHC environment, compared with one-on-one mentoring, as it addressed concerns relating to program acceptability, matching children with mentors, mentor recruitment, and turnover, and this could easily run alongside general OSHC activities.

To enhance mentoring options for the children accessing OSHC and ensure CP3 was not a “...blanket one size fits all program...” (school teacher, workshop 3), a 3-level approach to mentoring was generated during workshop discussions. This included skill-based mentoring, CP3 mentoring, and peer-to-peer mentoring. Skill-based mentoring meant that mentors with special skills would facilitate activities in their area of expertise. It was highlighted that these “...mentors should be passionate about what they are teaching...” (school teacher, workshop 3) to motivate, inspire, and engage children in CP3. The second type of mentor identified was a CP3 mentor, trained in CP3 principles, and could provide support to the enhanced group-based activities as well as the OSHC’s day-to-day running. Peer-to-peer mentoring was also proposed as an additional avenue for CP3 to engage primary school children attending OSHC to take on a leadership role, which reflected the *inspire and engage* CP3 principle.

Specialized CP3 training, designed for both staff and volunteer mentors, was seen as crucial to the delivery of CP3. Prototyped areas of training included vision and mission of CP3; mentoring processes and relationships; building emotional literacy; child development; working with special needs; managing challenging

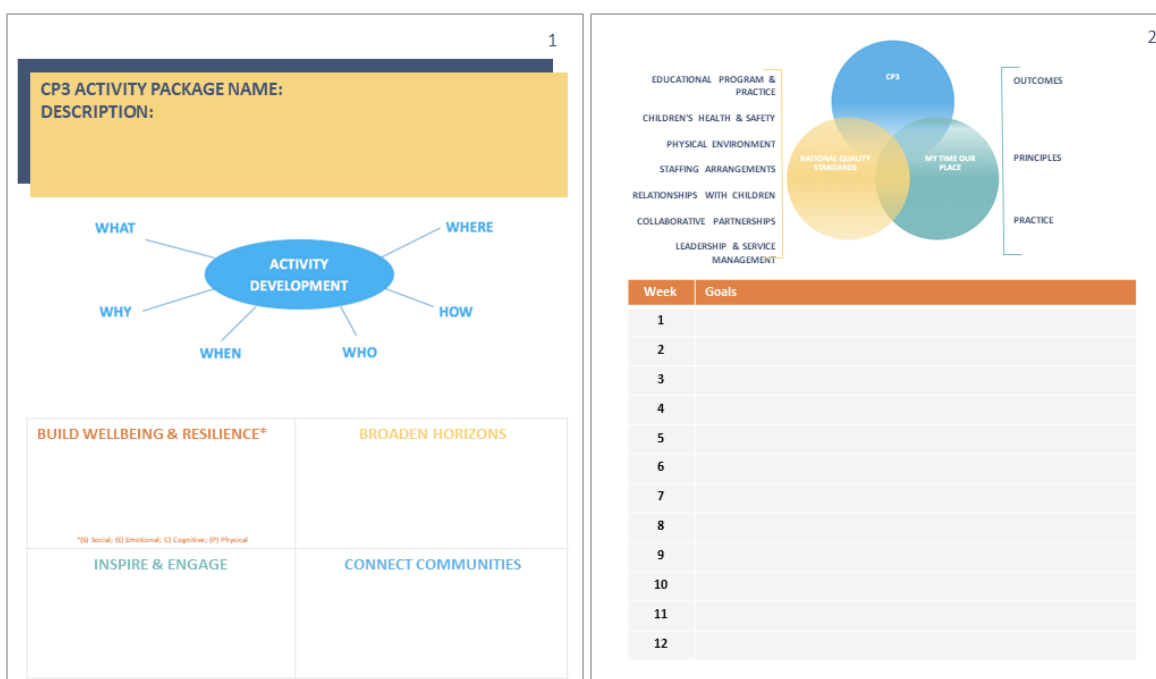
behaviors and situations; referral pathways and support; and risk management and safety.

When prototyping the enhanced activity component, participants highlighted that during the implementation of CP3, the program would need to avoid activities being delivered in a “piecemeal manner...” (teacher, workshop 1), that is, there needed to be a coherent structure to the program, where activities link together to form a greater purpose of working toward the CP3 principles:

The building blocks system or foundation as part of the program—where it’s not just one lesson and then move on will be important. It needs a framework that everyone is privy to. [Educator, workshop 1]

On the basis of this feedback, a CP3 activity development guide was prototyped. This is a tool for selecting and designing enhanced activities. It ensures that the staff and children think purposefully about programming so that it provides every opportunity to enhance the experience in terms of the CP3 principles, the *My Time Our Place Framework* and the *National Quality Standards*. The tool also supports reflective practice and sharing of ideas. An example summary page from the CP3 activity development guide is provided in Figure 3.

Figure 3. Example page from the connect, promote, and protect program activity development guide after prototyping and knowledge translation.



Additional Program Features

Discovery

A total of 2 additional features of CP3 were identified, which included the provision of one-on-one well-being support for children with greater needs and involving families meaningfully.

Evaluation and Prototyping

The idea generated by participants that CP3 could provide additional one-on-one psychological support for children with additional biopsychosocial needs, such as “...if there was a grief issue or if there was a diagnosis that required further support...” (teacher, workshop 1), received positive feedback when iteratively evaluated. Participants emphasized that if additional support was offered, it would need to be carried out by a

registered psychologist or other qualified health professionals. The provision of such additional support was seen as particularly beneficial for the prevention and early intervention of social, emotional, physical, or cognitive difficulties.

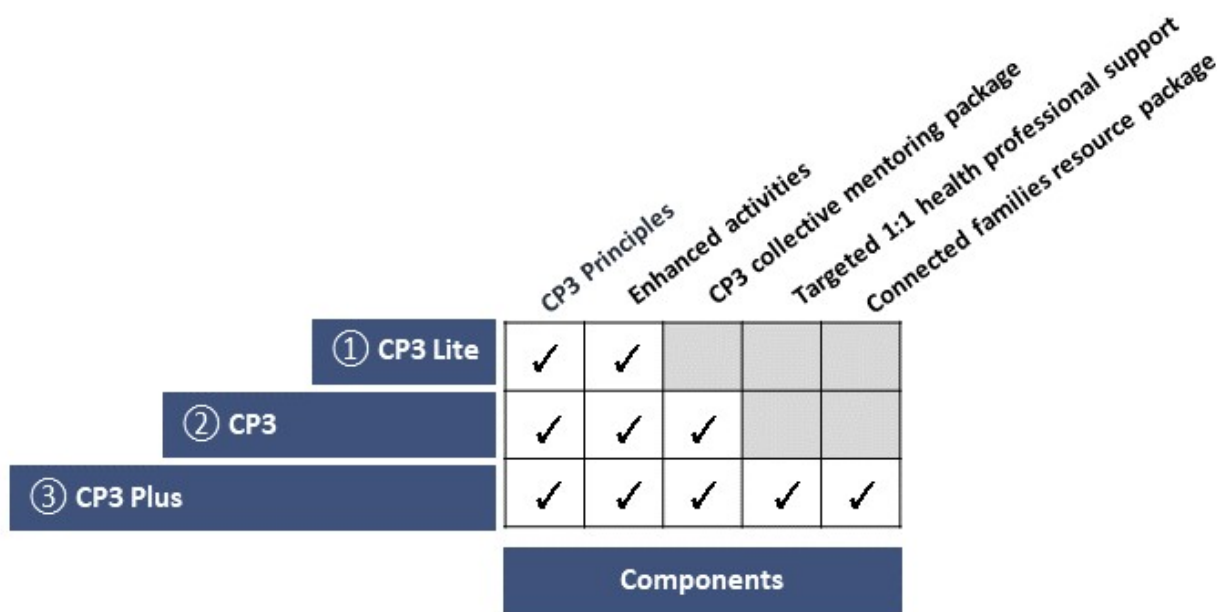
Participants also recommended that “...there needs to be a whole family approach...” (workshop 3, community member) for CP3 implementation. Ideas generated included CP3 “...build[ing] the capacity of parents...” (parent and community worker, workshop 1), which included developing a resource kit for parents, providing support pathways and “...link[ing] parents with counseling services...” (community worker, workshop 2), “...resources to support their children effectively...” (teacher, workshop 3), such as “...active parenting programs...” (teacher, workshop 3), “...positive parenting programs or circles of security...” (parent, workshop 2). Providing clear communication channels such as a “...feedback cycle between the child, families and school...” (CP3 mindmap artifact, workshop 3), finding out “...positives about their children through feedback from the program...” (parent program outcomes artifact, workshop 2),

telling parents “... about the focus of the learnings... for example, we are going to talk about character and strength this week...” (community member, workshop 3), and creating a CP3 newsletter or social media page (eg, Facebook) was recommended. Third, building a sense of community for parents, such as providing a “...chance to meet and interact with others of similar interests, problems etc...” (parent program outcomes artifact, workshop 2) and having an “...open day...” (community worker, workshop 3).

Knowledge Translation

A stepped approach to implementation was raised as a possibility in the workshops for the development and evaluation of CP3. In the knowledge translation phase, this idea was refined into 3 components: CP3 Lite, CP3, and CP3 Plus (outlined in Figure 4). These components can be implemented in a stepwise manner and are now being iteratively developed, delivered, and evaluated through a formative evaluation implementation process.

Figure 4. Components of connect, promote, and protect program stages. CP3: connect, promote, and protect program.



CP3 Lite is the minimal viable product of CP3 (α-build). This component is the first implementation step and provides enhanced activities underpinned by the CP3 principles (*build well-being and resilience, broaden horizons, inspire and engage, and connect communities*) using the CP3 activity development

guide. CP3 Lite is facilitated by OSHC educators and qualified community experts. Example excerpts from the CP3 activity planning process, which led to the establishment of the CP3 activity development guide for training and trialing, are presented in Figure 5.

Figure 5. Example excerpts from connect, promote, and protect program enhanced activity planning.

FARM TO FORK

WHAT? Growing vegetables

WHY? - Knowledge healthy eating → portion control. - To wear cooking
- Responsibility / caring for garden.
- Sense of achievement.

WHEN? - Link to afternoon tea → planning to grow on veges for afternoon tea.

WHO? - OSHC staff
- volunteer → gardener, chef

WHERE? Community garden - onsite activity.

Additional notes:
- Physical health / mental health
- planning / functional roles
- team work / working with others
- likes/dislikes
- Inspire Engage: supported by passionate volunteer. children's choice - what to grow where.
- Develop an OSHC cookbook - input into menu. - After food to 'Eat Cole' - Nutritionist / Dietician - letter / feedback from site.

② Farm to fork

Where community gardening and cooking meet as children learn to nourish their bodies and minds in fun and engaging ways. Here, children learn gardening skills whilst growing their own vegetables in the local community garden. These foods are then used in the kitchen where the focus is on cooking skills, healthy eating and nutrition to promote positive relationships with food. Children develop the menu and can share it with their peers at OSHC during afternoon tea. Children also create their own recipe books so they can take home their newly learnt skills to cook both local and international cuisine.

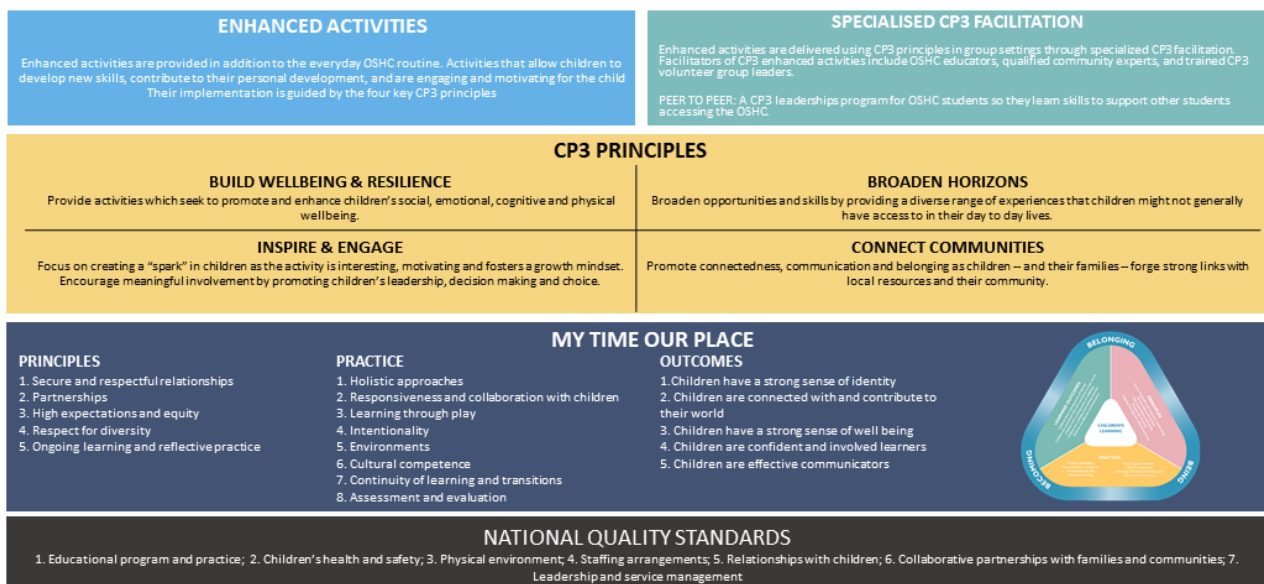
<p>BUILD WELL-BEING AND RESILIENCE?*</p> <p>Developing skills such as; sequencing, planning and numeracy (C), communication and cultural competence (S), the relationship between outdoors, good nutrition and mental health (E), nutrition, fine motor skills, and outdoor exercise (P).</p>	<p>BROADEN HORIZONS?</p> <p>Access to a community garden and kitchen. Learning about gardening, cooking and culture.</p>
<p>INSPIRE AND ENGAGE?</p> <p>Child-led gardening and recipe planning. Facilitated by members of the CP3 team who are skilled and passionate gardeners and are inspired cooks.</p>	<p>CONNECT COMMUNITIES?</p> <p>Learning from people who are from various cultures. Child (and family) involvement in and use of a community garden within and outside of OSHC time. Connecting with local resources and groups such as farmers markets.</p>

*Well-being domain key: C=cognitive well-being; S=social well-being; E=emotional well-being; P=physical well-being.

The next component is the implementation of CP3 (Figure 6), which is underpinned by the existing *My Time Our Place Framework* [5] and the *National Quality Standards* [6] that are used in OSHC services. This includes the facilitation of enhanced activities and a fully developed collective mentoring component. This component includes the development of a training package for CP3 volunteers to aid staff in facilitating

CP3 and may also use peer-to-peer support. The final component, CP3 Plus, is implemented as the final step and provides enhanced activities, collective mentoring and the additional family resource package, and one-on-one support. Ultimately, service evaluation outcomes determine the need, utilization, and effectiveness of these components.

Figure 6. Connect, promote, and protect program model underpinned by the existing My Time Our Place Framework and the National Quality Standards. CP3: connect, promote, and protect program.



Discussion

Principal Findings

In this study, we used PD (or co-design) research methods to develop a novel health and well-being program for primary school-aged children (aged 5-12 years) to be delivered in OSHC: CP3. To our knowledge, CP3 is the first health and well-being program model designed specifically for OSHC

settings that allows tailored interventions to be developed depending on the unique needs and preferences of the end users, including children (in later stages), their parents and guardians, staff, volunteers, and the broader community. CP3 adopts a holistic, community-focused approach, encouraging active participation of community members, peer-to-peer and adult-led mentoring, and interventions that not only focus on physical development but also foster social, emotional, and cognitive well-being. In this way, CP3 addresses the goals and objectives

of the AEDC [36] and OECD [2] for early childhood education and care, which focus on building supportive environments and developing strength-based programs to build children's competencies during primary school years.

CP3 addresses a major gap in the literature and in the delivery of universal health and well-being programs in educational settings. Unlike existing OSHC programs, which tend to be prescriptive, narrowly focused, and nongeneralizable, CP3 offers a framework for flexible program development and delivery while ensuring that a high standard of program development will be maintained. The 4 CP3 principles co-designed during PD workshops (ie, *build well-being and resilience, broaden horizons, inspire and engage, and connect communities*) ensure that the goals of CP3 interventions can be clearly delineated. This is critical, as one of the pitfalls in the implementation of new well-being programs is that they often fail to adhere to the core components of best practice and frequently do not use a program model [37,38]. Moreover, as highlighted in the Medical Research Council guidelines for developing complex interventions, the first step to developing novel interventions is the identification or development of a theoretical model, which this study has achieved [28]. In addition, CP3 provides more specific guidance on essential program features, namely collective mentoring and enhanced activities. The involvement of mentors is a key point of difference between CP3 and existing OSHC programs and promotes the CP3 principle of *connect communities*. Currently, the available evidence in the literature indicates that for a program to be effective, it is necessary to follow best practices in recruiting, training, and providing ongoing support and supervision to mentors [37,39]. The views were generated by participants in the PD workshops, particularly because of the importance of child protection when delivering the program. Such support for mentors may also assist them in building and sustaining their relationship with the OSHC over an extended period, as high staff turnover can negatively impact engagement [40].

CP3 has been designed to ensure universal access to a health- and well-being-focused program for all children, meaning equal opportunities and adequate fit regardless of socioeconomic background, geographic location, community resources, goals and expertise of service providers, and preferences and needs of the community. Therefore, one of the major advantages of CP3 is its appropriateness and ability to adapt to disadvantaged and vulnerable groups, such as children from low socioeconomic backgrounds, geographically isolated communities, Aboriginal and/or Torres Strait Islander people, and people from culturally and linguistically diverse groups. By placing communities at the center of the design and development process, CP3 ensures that interventions will be culturally sensitive and relevant, will respect local knowledge and meaning, and will empower communities to take action by taking matters into their own hands. This community-based approach transitions power back to local communities and is central to allowing communities and, subsequently, their young people to thrive.

Despite the goal of universal access and participation, research has shown that the simple introduction of a universal program does not in itself guarantee equal access or equal participation [41]. Therefore, one of the mandates of the CP3 coordinator

role is to assist families and communities with greater socioeconomic challenges to actively participate in both the design of the program and using OSHC services. This is important as research and evaluations of OSHC programs have found greater positive effects on outcomes for at-risk populations compared with more heterogeneous samples [42,43]. The success of the universal program approach to design and delivery will be further evaluated during the full program evaluation, which will take into account both service-specific and external factors such as the Australian government changes to parent activity testing and childcare subsidies introduced in 2018 [44].

Strengths and Limitations of the Research

A current limitation is that this study reports on the development of the CP3 program only. Future research is required to ensure a robust evidence base. Stage 2 of the project is currently being conducted (July 2020 to June 2021), which involves iterative user (acceptance) testing via a naturalistic formative service evaluation of the implementation CP3 combined with further PD workshops. This stage will test and refine the ideas generated in stage 1 in partnership with a wider group of stakeholders associated with the OSHC (ie, also include the children attending the OSHC) to inform a more comprehensive CP3 model (β model). In the future, stage 3, a real-world cluster randomized controlled trial will be carried out on the CP3 model (β model).

In designing the CP3 α model, an iterative PD approach was employed that placed key stakeholders at the center of the design and development process. This process of co-design and development will continue to be used, as CP3 is implemented and evaluated in stages 2 and 3. These co-design research methodologies are also embedded in the program design itself in the continuous process of re-evaluation and re-responding to community needs as children and their communities grow and change over time. For instance, the CP3 principles of community collaboration (*connect communities*) and meaningfully engaging children in the decision-making process (*inspire and engage*) emphasize the importance of engaging end users at all stages of the intervention development process. Children themselves form part of the co-design process; however, this research is still underway, as it forms part of the evaluation and thus will be reported elsewhere. This co-design and collaborative management means that the OSHC can be delivered according to the communities' strengths while ensuring that the level of program consistency is maintained. Despite these benefits, the use of PD methods is also challenging. For example, in this research, PD workshops could only take place in English because of budget limitations, that is, this research did not have funds to provide translators and to translate all study materials (such as consent forms and participant information statements). This may limit the generalizability of the research, although people who spoke English as a second language participated. Interestingly, the percentage of individuals who only speak English at home (7/34, 79%) accurately reflected the demographics of the Illawarra region (80.6%) [45]. Furthermore, the PD process takes considerable time and commitment from OSHC staff, researchers, and the wider community. Academics designing a well-being program to be delivered and evaluated without input from a wider group of stakeholders would

certainly be less time intensive; however, this would take away from the deep understanding and ability to respond to local community needs, which arguably leads to a better program.

Research suggests that health programs can take up to 17 years to move 14% of original research into actual service delivery [46]. However, here the use of an ongoing formative evaluation process allows for the program design to be agile and actively respond to local needs as they arise over time. For example, when new opportunities arise (such as when mentors or staff with particular skills are recruited), additional enhanced activities can be designed using the CP3 activity development guide, which is guided by CP3 principles, the *My Time Our Place Framework* [5] and the *National Quality Standards* [6]. Using this approach, the CP3 model can grow and be improved in real time. This iterative design cycle of development, feasibility, evaluation, and implementation follows recommendations by the Medical Research Council's newer guidelines for developing complex interventions [28].

Formative and Future Evaluation of CP3

CP3 is currently undergoing a formative evaluation, and plans are being made for future full-scale evaluation. These evaluation stages of research are crucial, as research suggests that many new mentoring programs are pursued without any supporting evidence from reliable or valid process or outcome evaluations [37,38]. Furthermore, research into what collective (group based) mentoring with enhanced activities has not, to our knowledge, been investigated either within or outside of OSHC settings. Therefore, future evaluation of outcomes will influence the proliferation of this type of program. Finally, one-on-one mentoring interventions that use evidence-based practices and provide the child with long-term, high-quality relationships (as a stand-alone one-on-one mentoring intervention or in combination with structured activities) can yield small but positive improvements in a range of psychosocial, health behavior, and academic outcomes [37,38,47]. However, lower quality one-on-one mentoring interventions can negatively impact children. Thus, ensuring that CP3 applies high-quality programming and has an evidence base is vital.

Additional PD with children at multiple OSHC sites will occur from 2019 to 2021 as part of the formative evaluation of CP3 and thus are yet to be reported. Further plans are also being made to measure the effectiveness of the CP3 model in a large-scale randomized controlled cluster trial. The major challenge is ensuring that engagement continues to be high when research extends to new sites. There is a possibility that successful PD engagement is because of the nuances of the pilot OSHC community. For example, the first pilot OSHC site for CP3 was a brand new service; thus, a focus on culture change to move away from a traditional OSHC model toward the CP3 is not required, whereas other already-established OSHC *early adopter* sites may require a different focus. Specifically, the need for effective staff by in and change management may be required when CP3 is introduced into already-operational OSHC sites. Ultimately, the competence and capacity of local facilitators will be crucial for successful implementation. This will be evaluated as CP3 is rolled out further in already-established OSHC sites.

Conclusions

To our knowledge, CP3 is the first co-designed health and well-being program to be delivered to primary school-aged children in an OSHC setting. The co-design process is key to ensuring that local community needs are met and that they are meaningfully and actively involved in all stages of the research and design process, from conception to implementation, evaluation, and continuous improvement. By providing a framework that encourages tailored interventions to be developed depending on the unique needs and preferences of the end users (eg, children and their families, staff, volunteers, and the broader community), CP3 takes an important step forward toward achieving universal access to a holistic health and well-being program for all children. The CP3 model is currently under evaluation, and the results will be used to determine the overall success and inform ongoing development and implementation.

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Conflicts of Interest

IH was an inaugural commissioner on Australia's National Mental Health Commission (2012-18). He is the Co-Director, Health and Policy at the Brain and Mind Centre (BMC) University of Sydney. The BMC operates early intervention youth services at Camperdown under contract to headspace. He has previously led community-based and pharmaceutical industry-supported (Wyeth, Eli Lilly, Servier, Pfizer, and AstraZeneca) projects focused on the identification and better management of anxiety and depression. He was a member of the Medical Advisory Panel for Medibank Private until October 2017, a Board Member of Psychosis Australia Trust, and a member of the Veterans Mental Health Clinical Reference group. He is the chief scientific advisor to and an equity shareholder in Innowell. Innowell was formed by the University of Sydney and PwC to deliver the Aus \$30 million (US \$23 million) Australian government-funded "Project Synergy." Project synergy is a 3-year program for the transformation of mental health services through the use of innovative technologies. All other authors declare that they have no conflict of interest.

Multimedia Appendix 1

Basic participant demographics.

[\[DOCX File , 14 KB - pediatrics_v4i2e22822_app1.docx \]](#)**References**

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Abbreviations

- AEDC:** Australian Early Development Census
 - BMC:** Brain and Mind Centre
 - CP3:** connect, promote, and protect program
 - OECD:** Organization for Economic Co-operation and Development
 - OSHC:** out of school hours care
 - PD:** participatory design
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