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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.

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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 FFBAC 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 (χ^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, FFBAC, 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)	
IRSAD[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)	

[a]FFABC: father-focused antenatal breastfeeding class.

[b]Not applicable.

[c]IRSAD: 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

[a]HR: hazard ratio.

[b]Original analyses included those participants with complete data.

[c]Not applicable.

[d]FFABC: father-focused antenatal breastfeeding class.

[e]Pooled 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

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

[b]Original analyses included those participants with complete data.

[c]Not applicable.

[d]FFABC: father-focused antenatal breastfeeding class.

[e]Pooled analyses that used the imputed datasets.

[f]PPSS: 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 interventions 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 =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 (=.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 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.

Textbox 1. The interview guide.

Demographic data

- Participant's age, gender, nationality, and educational level

Students' ownership of smartphone (SP) devices and patterns of use

- 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]

Level of awareness of parents of the detrimental impacts

- 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

Parents' attitudes toward the overuse of SP devices

- 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 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]

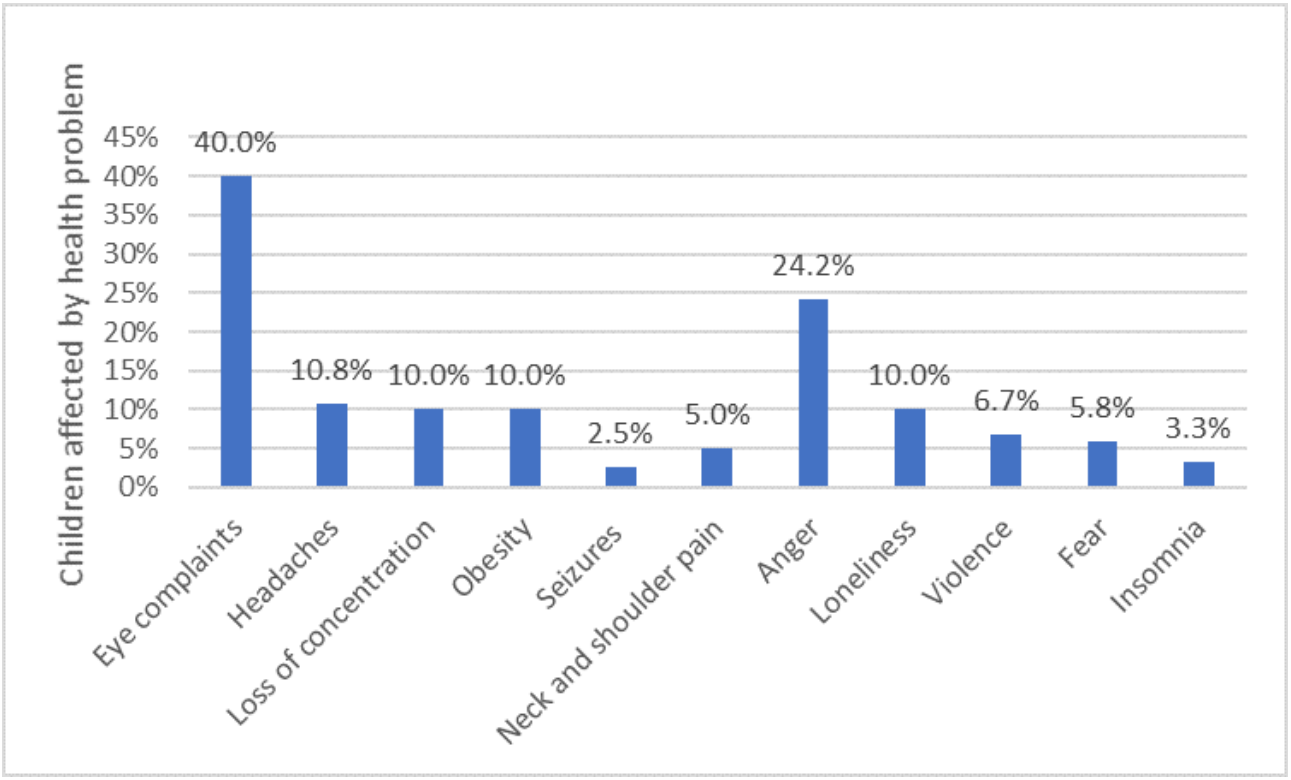
Another parent stated the following in an amazed way:

> *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:

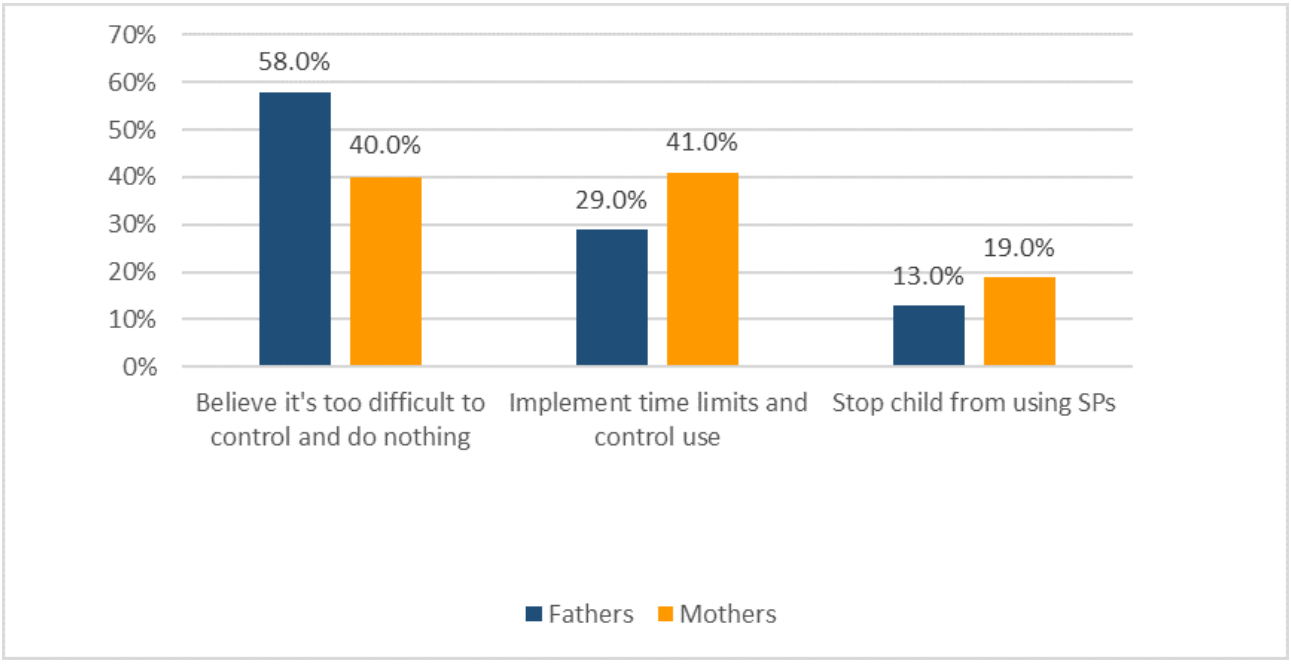
> *...one of my cousins was addicted to SP device use, and, as a result, he had brain seizures; this made me very strict in controlling the usage time for my children, and I succeeded, as they got used to one hour a day...so we as parents need to be firm to save our children from harm.* [a 42-year-old 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

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)

[a]GED: General Education Diploma (ie, high school equivalency diploma).

[b]Scores are from surveys conducted at 12 months.

[c]Scores >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	• "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	• 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	• 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	• 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	• "[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	• "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]

[a]Quotes 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

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 underaged 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 underaged 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 underaged users	Yes

[a]On the basis of the country, the companies have adopted a different minimum age.

[b]N/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

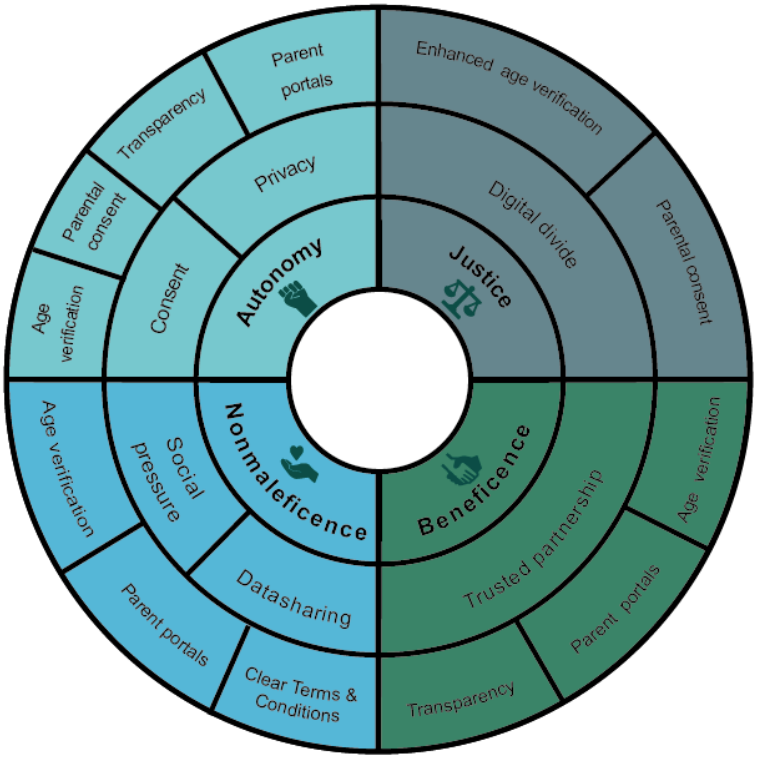
Social media apps have become ubiquitous among children and adolescents. It has become difficult to refuse to be part of such networks, because of both social pressure and an increasing number of institutions (such as schools) requiring such channels, resulting in social pressure to use these services 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' adhesion 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

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.

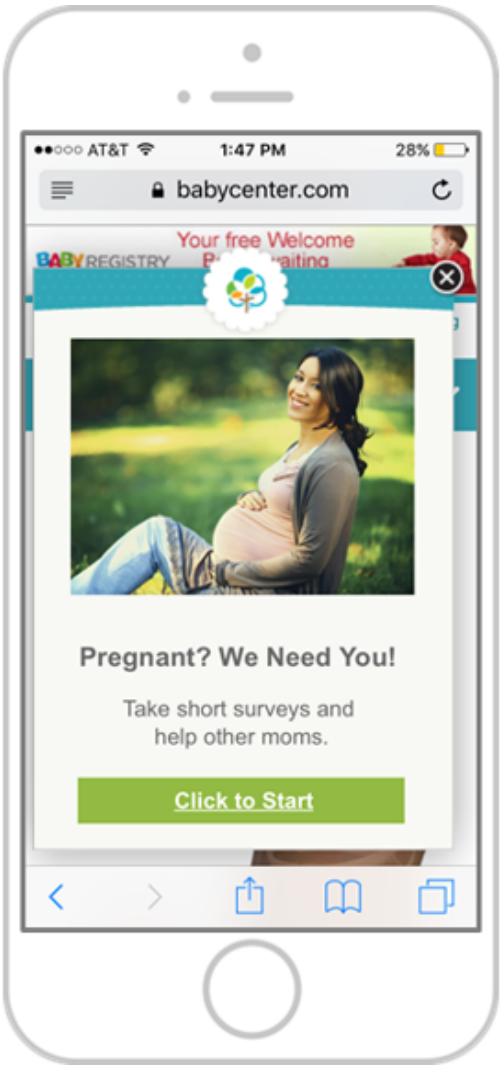
Methods

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					✓
Birthing data					✓

[a]Data were collected at pregnancy weeks 4-10 and 29-33.

[b]The 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.

[c]The 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.

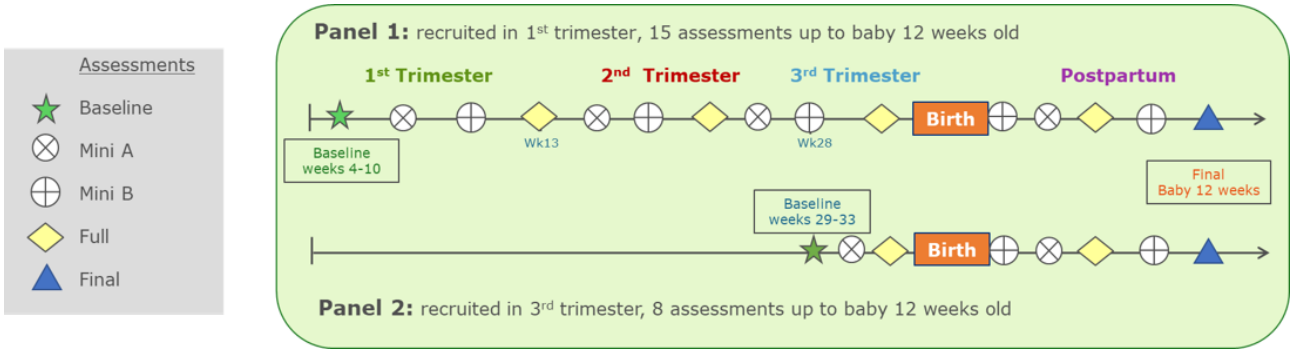
[d]The full (long-form) survey contained six psychometric questions and, on average, took 7 minutes to complete. Data were collected at pregnancy weeks 12, 13, 21, 32, and 35 and postpartum week 4.

[e]Data were collected at postpartum week 12.

[f]Check marks indicate that the indicated data were collected or the indicated version of the assessment instrument was conducted at this time point.

[g]PROMIS: 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 (%)	*P* value	Recruited on a weekend, n (%)	*P* value	Recruited on a weekday, n (%)	*P* value	Recruited on a weekend, n (%)	*P* 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

[a]Excludes 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)

[a]Respondents could have more than one disqualifier.

[b]Duplicate 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)

[a]The number of invitations for each assessment varied due to women opting out and opting back in as the study progressed.

[b]Recruitment 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.

[c]The Mini A (short-form) instrument contained five psychometric questions.

[d]The Mini B (short-form) instrument contained four psychometric questions.

[e]The Full (long-form) survey contained six psychometric questions.

[f]In 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.

[g]All 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)

[a]Only Panel 1 participants were included.

[b]MARI: Maternal Anxiety in Relation to Infant Development.

[c]GUSTO: 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]

[a]The 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.

[b]N/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

[a]This 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 disproportionally 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

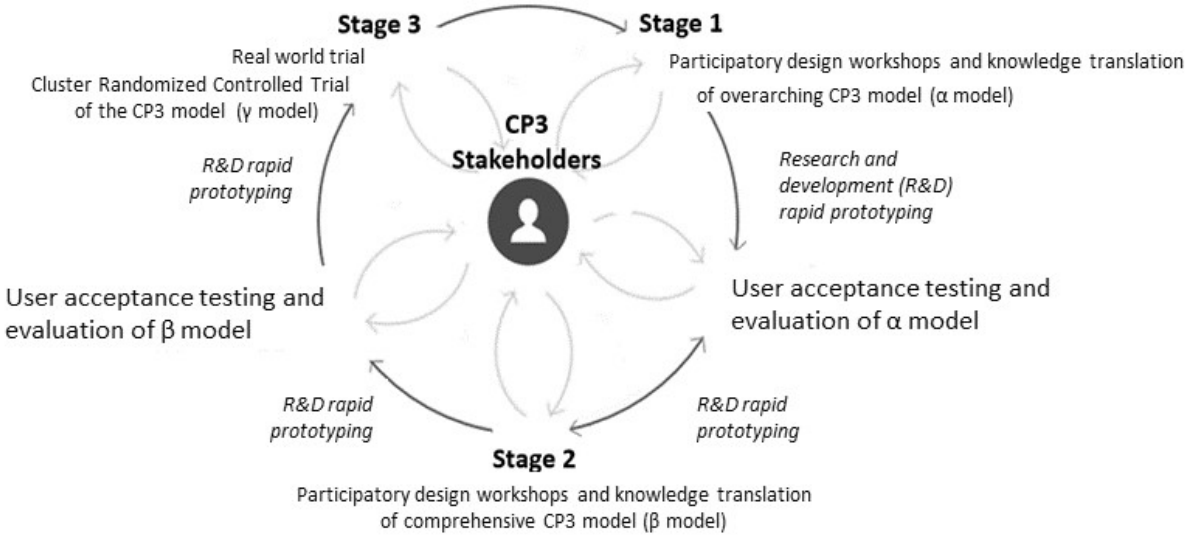
Ethics

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, aunties, 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)

[a]Multiple response options provided.

[b]CP3: connect, promote, and protect program.

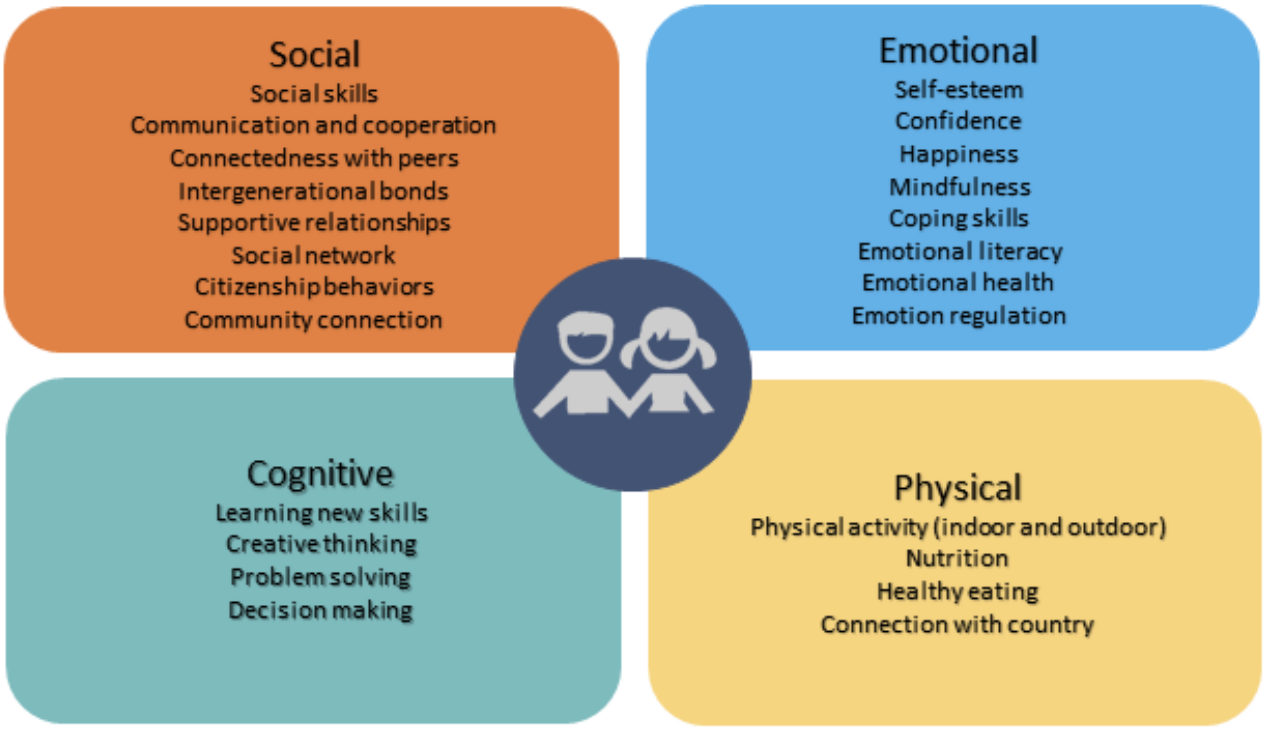
CP3 Principles

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

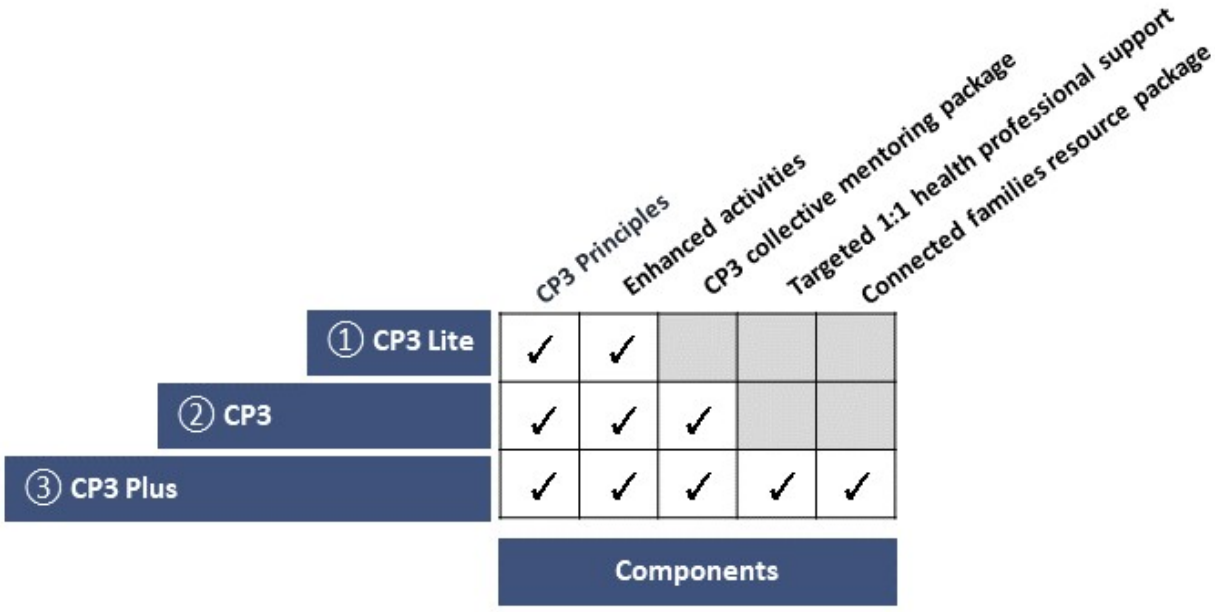
registered psychologist or other qualified health professionals. The provision of such additional support was seen as particularly beneficial for the prevention and early intervention of social, emotional, physical, or cognitive difficulties.

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

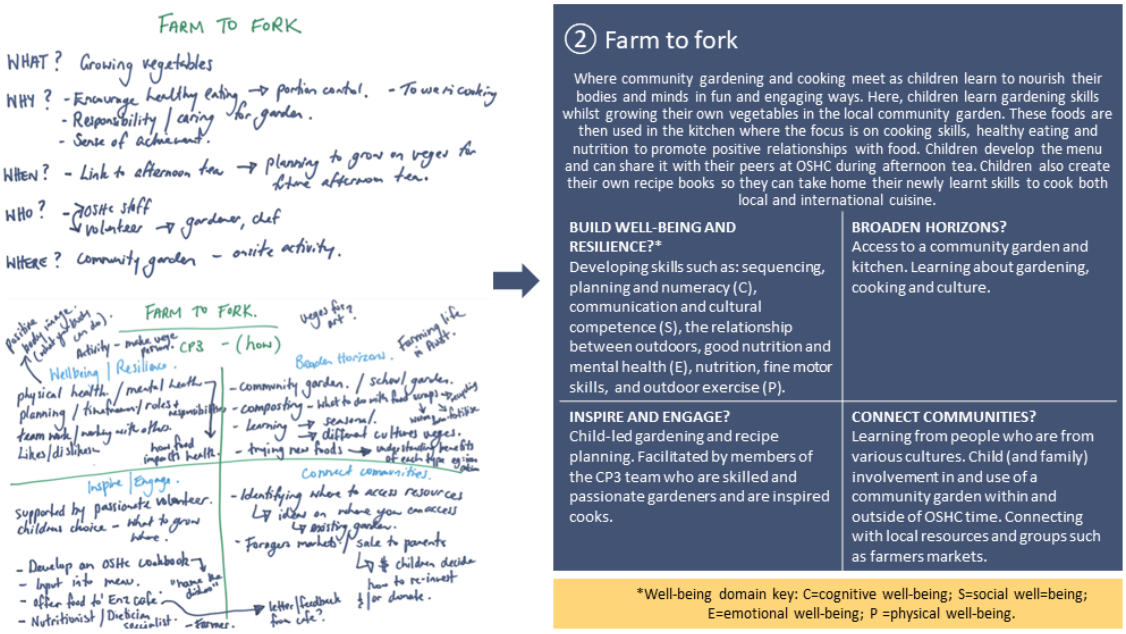
A stepped approach to implementation was raised as a possibility in the workshops for the development and evaluation of CP3. In the knowledge translation phase, this idea was refined into 3 components: CP3 Lite, CP3, and CP3 Plus (outlined in Figure 4). These components can be implemented in a stepwise 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.



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 Lily, 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]

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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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