JMIR Pediatrics and Parenting

Impact Factor (2023): 2.1
Volume 6 (2023) ISSN 2561-6722 Editor in Chief: Sherif Badawy, MS, MD, MBA

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Exploring Parental Experiences With School-Aged Children Receiving Web-Based Learning: Cross-Sectional Study

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Abstract

Background: Web-based learning has transformed education. Its ability to overcome physical barriers and deliver knowledge at the click of a button has made web-based learning popular and ensured that it will continue to be used in the future. The involvement of parents in web-based learning is fundamental to the success of the educational process, but limited attention has been paid to the impact of web-based learning on parents.

Objective: This study examined parental experiences with school-aged children receiving web-based learning in Jeddah, Saudi Arabia.

Methods: We sent cross-sectional, anonymous web-based questionnaires to school-aged children's parents. A total of 184 parents completed the survey.

Results: Parents' negative experiences of web-based learning (mean 4.13, SD 0.62) exceeded their positive experiences (mean 3.52, SD 0.65). The most negative experience reported by parents was their child's boredom due to prolonged sitting in front of a device (mean 4.56, SD 0.69). The most positive experience was their child's technological skill enhancement (mean 3.98, SD 88). Their child's lack of social interaction and friendship building promoted stress among parents (r=−0.190; P=.01). At the same time, their child's technological skill enhancement reduced stress among parents (r=0.261; P=.001). The most reported (63/184, 34.2%) obstacle to web-based learning was having multiple learners in the same household.

Conclusion: Web-based learning is a fundamental learning method and will continue to be used in the future because of its ability to overcome many barriers to education. Parental involvement in the continuity and success of the web-based learning process is crucial. However, the findings of this study illustrated that parents' experiences of web-based learning were more negative than positive. Parents who reported negative experiences reported an increase in stress and faced more obstacles due to web-based learning. Thus, more attention and intervention are needed to promote positive web-based learning experiences among parents.

(JMIR Pediatr Parent 2023;6:e50892) doi:10.2196/50892

KEYWORDS

education; obstacles; online learning; stress reduction; obstacle; parent; parents; parental; parenting; e-learning; child; children; school; schools; student; students; experiences; experience; interaction; health outcome; health outcomes; family; dynamic; dynamics; parental experiences

Introduction

In December 2019, a new strain of the coronavirus emerged [1], and many countries enforced anticontagion policies to slow the virus's spread [2]. Over 107 countries around the world closed their schools, causing 862 million children and young adults to remain home during the pandemic [3].

The Ministry of Education in the Kingdom of Saudi Arabia (KSA) suspended traditional face-to-face classes and implemented web-based learning to enforce social distancing policies; ensure the safety of teachers, students, and the community; and maintain the continuity of learning [4]. Web-based learning in the KSA included live sessions with student or recorded classes. It relied heavily on the provision of internet access to all students and teachers [5]. Additionally, the Ministry of Education used TV to broadcast lessons to students who lacked internet access. Over 127 teachers broadcast lessons to 19 TV channels [6]. The digitalization of education in the KSA during COVID-19 was essential to maintain students' academic achievements. It included the development of over 19 applications to serve the public, including the education sector. Collaboration between the government and telecommunication companies was initiated [6].

The shift in the educational process forced parents and children to transform their way of life, creating many advantages and disadvantages [7]. Web-based learning was introduced across the world, including in India [5], Pakistan [8], Indonesia [9], New Zealand [10], and Jordan [11]. It placed parents in an unusual situation, requiring increased parental involvement in children's education, compensation of children's social and interactional needs, and rearrangement of priorities to ensure the continuity of academic achievements [5,8].

Because of the gravity of COVID-19 and its devastating consequences, many parents agreed to the KSA's school closure and web-based learning policy. However, the parents faced multiple obstacles to web-based learning, such as an inability to manage several responsibilities, an inability to motivate children to carry out web-based learning, and feelings of uncertainty about web-based learning's effectiveness [12].

Parents in Indonesia reported the inability of their children to focus on their classes. The children felt bored, and parents were not able to motivate them [13]. Further, parents could not enforce web-based learning because children did not take it seriously, and they had limited understanding of the educational material [13].

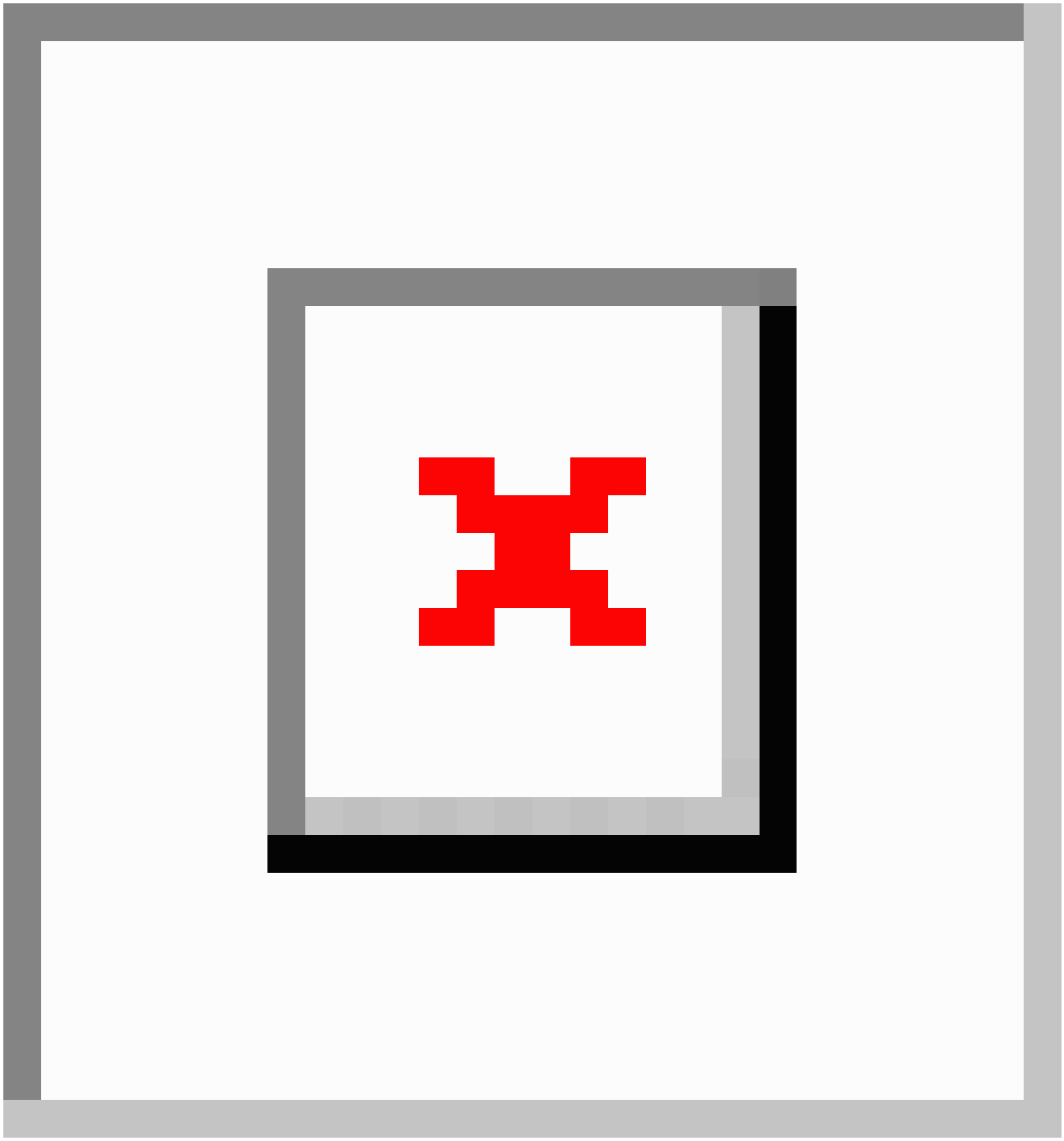
Multiple factors affect parental involvement and web-based learning management, including the lack of communication between parents and teachers, lack of time to manage teaching and homework, and technological difficulties [14]. Parents also lack teaching skills and have little knowledge of educational materials [14].

Parents can use adaptation strategies for web-based learning. Coping strategies can include the establishment of a daily routine, an increase in physical activities, and positive reappraisal [15]. In studies of mindfulness and cognitive therapy, stress reduction is defined as the individual's ability to accept any unpleasant situation and promote a relationship between themselves and stressful ideas through emotional regulation [16].

As time passed and pandemic restrictions were lifted, the global perception toward educational systems changed. Many schools and universities started to view web-based learning as a new and important approach to overcome physical distance as a barrier to education.

Literature on the impact of web-based learning on parents and their children is still lacking in Saudi Arabia. Parental experiences of the shift in their children's educational processes from traditional classes to web-based learning need further investigation. This study aimed to explore parents' self-identified positive and negative experiences of web-based learning as a teaching method for their school-aged children. Figure 1, adapted from Garbe et al [12], shows the positive and negative experiences parents face during web-based learning [12]. We examined these experiences and their impact on stress reduction after 1 year of web-based learning and reported the obstacles they found. The results of this study will guide future research on the impact of web-based learning on parents and will help stakeholders formulate policies and procedures to enhance web-based learning and overcome identified obstacles.

Figure 1. Parental experiences of web-based learning.



Methods

Design

A quantitative cross-sectional study design was used to explore parents' positive and negative experiences of web-based learning and parents' stress after 1 year of web-based learning. The relationship between the learning obstacles that parents reported and parents' negative web-based learning experiences was also examined.

Instrument

Data were collected through a web-based survey. The survey and informed consent form were sent electronically to participants after obtaining institutional review board (IRB) approval from King Abdullah International Medical Research Center. The survey consisted of questions about parents' demographics (10 questions), their school-aged children (13 questions), their overall positive and negative web-based learning experiences (13 items for negative experiences and 11 items for positive experiences), their stress reduction regarding web-based learning (3 questions), and the obstacles to web-based learning that they observed (3 questions).

Every item in the survey was graded on a 5-point Likert scale with 5 responses: strongly disagree (score of 1 point), disagree (2 points), neutral (3 points), agree (4 points), and strongly agree (5 points). Higher scores were associated with increased perception of a variable. The survey was adapted from Garbe et al [12] and then modified and translated to Arabic. Bajamal

et al [17] used the Arabic version to examine parents' positive or negative experiences of web-based learning. Internal consistency via Cronbach α was reported at .890 and .892, with a confirmed correlation coefficient ranging from 0.52 to 0.73 and from 0.43 to 0.76. Additionally, exploratory factor analysis demonstrated a single factor with a total percentage variance of 52.89 for positive experiences and 56.83 for negative experiences [17].

Sample, Setting, and Data Collection

Participants were recruited using nonprobability snowball sampling. The study targeted parents with school-aged children who were enrolled in web-based classes during the COVID-19 pandemic in Jeddah, Saudi Arabia.

Those who met all of the following criteria were eligible to participate in the study: (1) mother or father of school-aged children taking web-based courses, (2) resident of Jeddah city, (3) ability to speak and read Arabic, and (4) ≥18 years of age. Participants filled out the informed consent form prior to answering the survey. The exclusion criteria were not being a parent, inability to speak and read Arabic, and younger than 18 years of age. Potential participants were recruited via snowball sampling on WhatsApp and Facebook. After the potential participants filled out the survey, the researchers identified those who met the inclusion criteria and enrolled them in the study. If participants agreed to participate in the survey after reading the informed consent form, they were directed to the survey page directly. For this descriptive study, the α significant level was set at .05 with a power of 0.8. The sample size was estimated using G*Power software (Heinrich-Heine-Universität Düsseldorf). This study was the first to examine Saudi parents' experiences with web-based learning and the effect of obstacles to web-based learning on these experiences during the COVID-19 pandemic. No effect size was used when conducting the power analysis. In cases such as this study, where an effect size has not been reported in the literature, the estimation of effect size is based on the researcher's logic and judgment [18]. Therefore, a medium effect size of 0.05, power of 0.80, and α significance level of .05 were used to guide the statistical analysis. The targeted sample size was set at 180 parents, with the percentage of missing data presumed to be 10%. The total targeted sample size was as follows: N = 180 + 18 = 198.

Data Analysis

SPSS computer software (SPSS for Mac, version 28.0; IBM Corp) was used to analyze the data. Different types of analysis were proposed for this study. Descriptive statistics were calculated for all variables of interest, including means, SDs, frequencies, and percentages. In regard to inferential statistics, Pearson correlation coefficients were used to examine the relationships among continuous variables. Spearman correlation was used to examine the relationship among the survey items. Statistical significance was based on the standard α level of .05.

Ethical Considerations

This study received ethics approval from the IRB of the King Abdullah International Medical Research Center (NRJ21J/111/04).

Electronic informed consent followed the same template of the informed consent form filed to the IRB committee. Electronic signature occurred via checking a box next to the following statement: "By checking this box, I hereby sign this informed consent electronically." Researchers' contact information was available in case questions were raised regarding the study. Potential participants were notified about the voluntary nature of participation in the study and its descriptive purpose. The fact that participation in the study involves minimum risks was also added to the consent form.

To ensure confidentiality, electronic data are stored in a computer protected by 2 passwords. Researchers used the collected data for the purpose of the study only, and data access was granted to study personnel only. Participants' data were anonymous. No compensation or incentive was delivered to the participants.

Results

Participant Characteristics

As Table 1 shows, a total of 184 participants completed the survey. Of these participants, 139 (75.5%) were mothers. Most (n=98, 53.3%) of the participants were in the age group of 30-40 years. More than half (n=110, 59.8%) of the participants had an undergraduate degree.

Table . The sample's demographic characteristics (N=184). There were missing data (n=83, 45.1%) for working hours, work shifts, and occupation related to education.

Demographic variable		Participant, n (%)
Person completing the survey		
	Mother	139 (75.5)
	Father	40 (21.8)
	Nonparent	5 (2.7)
Age group (y)		
	<30	7 (3.8)
	30-40	98 (53.3)
	40-50	64 (34.8)
	>50	15 (8.2)
Educational level		
	Primary school	5 (2.7)
	Intermediate school	2 (1.1)
	High school	23 (12.5)
	Undergraduate degree	110 (59.8)
	Postgraduate degree	44 (23.9)
Family income (SR $; SR $1=US 0.26$)		
	<3000	8 (4.3)
	3000-5000	10 (5.4)
	5000-8000	25 (13.6)
	8000-12,000	33 (18)
	>12,000	108 (58.7)
Residency status		
	Family house	48 (26.1)
	Separate apartment	136 (73.9)
Person following web-based learning		
	Mother only	121 (65.8)
	Father only	4 (2.2)
	Mother and father together	53 (28.8)
	Another family member	6 (3.3)
Parent occupation status		
	Working	101 (54.9)
	Not working	83 (45.1)
Working hours (n=101)		
	Full-time	86 (85.1)
	Part-time	15 (14.9)
Work shift (n=101)		
	Day	91 (90.1)
	Night	10 (9.9)
Occupation related to education (n=101)		
	Yes	49 (48.5)
	No	52 (51.5)

Demographic variable		Participant, n (%)
Parents deal with technology		
	Yes	164 (89.1)
	Somewhat	20 (10.9)
Internet connection during school closure		
	Yes	180 (97.8)
	No	4 (2.2)
Number of children		
	1	15 (8.2)
	2	48 (26.1)
	3	51 (27.7)
	>3	70 (38)
Number of school-aged children		
	1	35 (19)
	2	64 (34.8)
	3	53 (28.8)
	>3	15 (8.2)
	All[a]	17 (9.2)

[a]All children in the household, regardless of the total number of children, are school-aged and underwent web-based learning.

Further, more than half (n=136, 73.9%) of the participants lived in a separate home or apartment. Most (n=121, 65.8%) of the participants who followed up with their children for web-based learning were mothers.

Moreover, most (n=101, 54.9%) of the participants who followed up with their children for web-based learning were currently working. Most (91/101, 90.1%) of them were working during the day. More than half (52/101, 51.5%) of the participants' jobs were not related to the education field.

During school closure, almost all participants (180/184, 97.8%) had an internet connection. Almost all participants (n=164, 89.1%) knew how to use web-based learning technology.

As Table 2 shows, most (77/184, 41.8%) of the children who needed follow-ups by their parents during web-based learning were enrolled in elementary school, followed by children from elementary or intermediate school (n=33, 17.9%) and children from elementary, intermediate, or high school (n=24, 13.0%). Most (n=158, 85.9%) of these children shifted to web-based classes during COVID-19; only 26 (14.1%) participants reported that their children went to hybrid classes. During web-based learning, all children needed support from their parents. Most children (n=56, 30.4%) needed a total of 60-120 minutes of support, and the smallest proportion of children (n=34, 18.5%) needed 120-180 minutes of support.

Table . Academic profile of the children (N=184).

Demographic variable		Children, n (%)
Education level		
	Kindergarten	6 (3.3)
	Elementary school	77 (41.8)
	Intermediate school	12 (6.5)
	High school	5 (2.7)
	Elementary or intermediate school	33 (17.9)
	Elementary or high school	16 (8.7)
	Intermediate or high school	4 (2.2)
	Elementary, intermediate, or high school	24 (13)
	University level	7 (3.8)
Fully dependent during web-based classes		
	Yes	158 (85.9)
	Hybrid	26 (14.1)
Support time from parents (min)		
	<60	44 (23.9)
	60-120	56 (30.4)
	120-180	34 (18.5)
	>180	50 (27.2)

As Table 3 shows, during school closure, participants spent more time with their children doing activities such as school activities (117/184, 63.6%), web-based activities (n=67, 36.4%), watching TV (n=66, 35.9%), and nonschool activities (n=45, 24.5%).

Table . Activities parents did with their children (N=184).

Activities	Participant, n (%)
School activities	117 (63.6)
Web-based activities	67 (36.4)
TV	66 (35.9)
Nonschool activities	45 (24.5)
Reading	33 (17.9)
Outdoor activities	29 (15.8)
Other activities	27 (14.7)
Indoor games	26 (14.1)

Table 4 shows which courses parents felt should be given priority. Table 5 shows parents' feelings and experiences of school closure (mean 3.88, SD 1.13) and toward school support during school closure (mean 3.39, SD 1.03).

Table . Subjects that parents felt should be prioritized during school closure (N=184).

Subjects	Participant, n (%)
Reading	142 (77.2)
Mathematics	135 (73.4)
Writing	120 (65.2)
Sciences	85 (46.2)
Others	86 (46.8)

Table . Descriptive statistics for parents' feelings.

Parents' feelings	Score, mean (SD)
Parents' feelings about school closure	3.88 (1.13)
Parents' feelings about school support	3.39 (1.03)

Table 6 shows the most reported obstacles parents observed with regard to web-based learning. The highest reported obstacle was having multiple web-based learners in the same household at the same time (63/184, 34.2%). This was followed by time constraints (n=58, 31.5%) and having an uncooperative child (n=47, 25.5%).

Table . Reported obstacles (N=184).

Obstacles	Participant, n (%)
Time constraints	58 (31.5)
Financial concerns	16 (8.7)
Noncooperative child	47 (25.5)
Many web-based learners in the same household	63 (34.2)

Descriptive Statistics of Negative and Positive Experiences

The below data illustrate the overall positive and negative experiences of parents. The mean of negative experiences of web-based learning exceeded that of positive experiences, indicating that parents required more interventions to better equip them to manage web-based learning.

As shown in Table 7, the total score of the negative experiences of parents regarding web-based learning was mean 4.13 (SD 0.62). The highest mean score was reported for feeling bored after sitting for a long time in front of a PC or laptop at 4.59 (SD 0.69). This was followed by a lack of social spirit and the loss of the ability to build new friendships at 4.49 (SD 0.75). The lowest mean score was reported for indigestion due to stress at 3.43 (SD 1.05), indicating that parents' negative experiences of web-based learning did not include physiological symptoms.

Table . Descriptive statistics for negative experiences of web-based learning (N=184).

Negative experiences	Score, mean (SD)
Weak direct interaction between teacher and student	4.24 (0.87)
Loss of educational motivation and low spirit of competition	4.25 (0.90)
Lack of social spirit and loss of ability to build new friendships	4.49 (0.75)
Boredom from sitting for a long time in front of the PC or laptop	4.59 (0.69)
Child's forgetfulness, inability to focus, or slowness in the development of speech or language	4.21 (0.91)
Teacher's inability to assess student performance and achievement	3.91 (1.01)
Weak vision due to sitting in front of the PC or laptop	4.19 (0.92)
Muscle pain due to sitting in front of the PC or laptop	4.16 (0.92)
Weight gain due to the lack of movement	4.05 (1.03)
Lethargy or headache	4.04 (0.95)
Spinal curvature	3.97 (1.00)
Indigestion due to stress	3.43 (1.05)
Total negative experience	4.13 (0.62)

Next, as Table 8 shows, the total score for the positive experiences of parents regarding web-based learning (mean 3.52, SD 0.65) was lower than that for negative experiences (mean 4.13, SD 0.62). Out of all the positive experiences of

web-based learning, the enhancement of the child's technological skills had the highest reported mean score at 3.98 (SD 0.88). The lowest reported mean score was 3.05 (SD 0.95) for available time for hobbies.

Table . Descriptive statistics for positive experiences of web-based learning (N=184).

Positive experiences	Score, mean (SD)
Development of the child's research or learning skills	3.59 (0.92)
Availability of many educational resources	3.50 (0.88)
Feeling comfortable staying at home	3.54 (1.04)
Enhancement of the child's technological skills	3.98 (0.88)
Improvement of the child's independence	3.60 (1.07)
Availability of time for hobbies	3.05 (0.95)
Strengthening of the social relationship among family members	3.38 (0.97)
Strengthening of the child's ability to use many educational resources	3.63 (0.91)
Identifying the child's learning strengths or weaknesses	3.50 (0.98)
Strengthening the relationship with the child on a personal and educational level	3.46 (0.95)
Acting as a teacher for children as needed	3.50 (0.88)
Total positive experiences	3.52 (0.65)

Association Between Negative or Positive Experiences, Stress Reduction, and Obstacles to Web-Based Learning

Table 9 shows the Pearson product-moment correlations among the study variables. Weak correlation was found between the variables of stress reduction after 1 year of web-based learning and the experiences of parents. However, stress reduction after 1 year of web-based learning was positively correlated with parents' positive experiences (r=0.237; P<.01) more often than with parents' negative experiences. Further, obstacles reported by parents positively correlated with their negative experiences (r=0.209; P=<.01). The results showed that parents' experiences of web-based learning affected their stress reduction and the obstacles they reported.

Table . Pearson product-moment correlations among positive experiences, negative experiences, stress reduction, and obstacles toward web-based learning (N=184).

Variables	Stress reduction after 1 year	Negative experience	Positive experience	Obstacles
Stress reduction after 1 year				
r	1	–0.121	0.237	0.017
P value	—[a]	.10	.001	.82
Negative experience				
r	–0.121	1	–0.378	0.209
P value	.10	—	<.001	.004
Positive experience				
r	0.237	–0.378	1	–0.101
P value	.001	<.001	—	.17
Obstacles				
r	0.017	0.209	–0.101	1
P value	.82	.004	.17	—

[a]Not applicable.

Association Between Negative Experiences and Stress Reduction

Table 10 shows the Spearman correlations between negative experiences and stress reduction after 1 year of web-based learning. The results showed poor correlation between stress reduction and negative experiences.

Table . Spearman correlations between negative experiences and stress reduction 1 year after web-based learning (N=184).

Variable	Stress reduction after 1 year, *r*	*P* value
Stress reduction after 1 year	1.00	N/A[a]
Weak direct interaction between teacher and student	−0.114	.12
Loss of educational motivation and low spirit of competition	−0.043	.56
Lack of social spirit and loss of ability to build new friendships	−0.190	.01
Boredom from sitting for a long time in front of the PC or laptop	−0.129	.08
Child's forgetfulness, inability to focus, or slowness in the development of speech or language	−0.050	.50
Teacher's inability to assess student performance and achievement	−0.018	.81
Weak vision due to sitting in front of the PC or laptop	−0.080	.28
Muscle pain due to sitting in front of the PC or laptop	−0.035	.64
Weight gain due to the lack of movement	0.007	.93
Lethargy or headache	−0.056	.45
Spinal curvature	−0.191	.009
Indigestion due to stress	−0.170	.02
Negative experience score	−0.161	.03

[a]N/A: not applicable.

According to Table 10, stress reduction after 1 year of web-based learning was negatively correlated with spinal curvature (r=−0.191; P=.009) and the lack of social spirit and loss of ability to build new friendships (r=−0.190; P=.01), followed by indigestion due to stress (r=−0.170; P=.02) and the total negative experience score (r=−0.161; P=.03).

Association Between Positive Experiences and Stress Reduction

Table 11 shows the Spearman correlations among the positive experience items. Stress reduction after 1 year of web-based learning was positively correlated with the enhancement of the child's technological skills (r=0.261; P<.001), followed by strengthening of the child's ability to use many educational resources (r=0.219; P=.003), improvement of the child's independence (r=0.172; P=.02), strengthening of the social relationship between family members (r=0.171; P=.02), development of the child's research or learning skills (r=0.157; P=.03), and the total positive experience score (r=0.194; P=.008).

Table . Spearman correlations between positive experiences and stress reduction 1 year after web-based learning (N=184).

Variable	Stress reduction after 1 year, *r*	*P* value
Stress reduction after 1 year	1.00	N/A[a]
Development of the child's research or learning skills	0.157	.03
Availability of many educational resources	0.131	.08
Feeling comfortable staying at home	0.141	.06
Enhancement of the child's technological skills	0.261	<.001
Improvement of the child's independence	0.172	.02
Availability of time for hobbies	0.064	.39
Strengthening of the social relationship among family members	0.171	.02
Strengthening of the child's ability to use many educational resources	0.219	.003
Identifying the child's learning strengths or weaknesses	−0.003	.96
Strengthening the relationship with the child on a personal and educational level	0.129	.08
Acting as teacher for children as needed	0.115	.12
Positive experience score	0.194	.008

[a]N/A: not applicable.

Discussion

Principal Findings

This study was the first to examine parents' reported experiences of their children's web-based learning in the city of Jeddah, Saudi Arabia. Parents' reported obstacles to web-based learning and stress reduction after 1 year of web-based learning were also explored. Our results indicated that parents' negative experiences exceeded their positive ones. Additionally, parents who had positive experiences reported less stress after 1 year of web-based learning. Parents with negative experiences reported more obstacles to web-based learning compared to parents with positive experiences.

Web-based learning increased parents' responsibilities and their crucial role in web-based learning, causing them to face many challenges and difficulties. Findings from 2 international studies conducted in China and Indonesia examined parental experiences of web-based learning during the COVID-19 pandemic. Their findings agreed with this study's findings [19,20].

Out of all the negative experiences reported by parents, children's boredom from sitting in front of electronic devices scored the highest. Children's prolonged use of electronic devices to attend classes and do their homework led to a sense of boredom and decreased motivation. This sense of boredom can pose a great challenge to parents who aim to increase their child's interest and maintain their curiosity about the learning process. In 2 previous studies in Indonesia, parents used the same term, "boredom," to describe their child's feelings during web-based learning. Child boredom is associated with web-based learning and with the quarantine during the COVID-19 lockdown [21,22].

Parents recognized that the global pandemic led to the transformation of education and that with every hardship their child encountered, they had a positive experience or gained a skill. Skills such as independence in the learning process and the use of multiple educational resources remained crucial after the pandemic ended because web-based learning did not stop. Parents' positive attitudes and perception toward web-based learning has been proven in studies conducted in India and Indonesia [23,24]. In both countries, parents reported enhanced parental engagement in their children's education and noted the ability of web-based learning to allow education to persist despite social distancing.

Out of all the positive experiences, the enhancement of children's technological skills was the most reported by parents. Before COVID-19, the education system in some high-income countries gradually incorporated electronic devices to overcome barriers to education, such as distance and high absenteeism [25,26]. However, when the pandemic began, a rapid transformation occurred, and children had to digitalize their education. The literature argues that children's technological skills are crucial not only for education but also for their future careers [26]. Multiple studies examined the role technology plays in advancing education. Digital transformation is inevitable in the modern world. Therefore, equipping children with the necessary technological skills is important, and countries that lack resources for web-based learning will face challenges [27,28].

Parents who had more positive experiences reported stress reduction after 1 year of web-based learning. The findings of

this study confirmed that parents who adapted to web-based learning, used adaptive strategies, and viewed web-based learning as a positive event tended to experience less stress. Adaptive strategies such as planning, support, and proper communication with schools are important to facilitate the learning process, reduce stress, and enhance psychological health [29,30].

Participants with negative experiences reported greater obstacles in the education process, specifically having multiple learners within the same household. For web-based learning to be successful, proper collaboration between parents and schools and parental supervision during school days are needed. Parental engagement and supervision were reported by 81.7% of parents [24]. Parent involvement in the learning process requires parents to be attentive to children's educational needs, to ensure an environment conductive to learning, and to play the role of the teacher. All these factors can be stressful and difficult for parents with multiple children undergoing web-based learning at the same time within the same household [31]. Obstacles to web-based learning can be culturally specific as well. An Arab household can contain multiple children with ages proximate to each other, which might not be a challenge for parents from a different culture. Parents with multiple children need to give their full attention and engagement to each child, which can be challenging for the parent and for the child [32].

Limitations

Study data were collected from parents residing in the city of Jeddah, Saudi Arabia. Therefore, the findings might not be generalizable to parents in different cities and regions within the KSA. Another limitation is the gender of the parents. The number of mothers who participated was 3 times more than that of fathers. Therefore, the results of the study are less applicable to fathers.

The use of self-reporting limited the findings because self-reports can induce social desirability bias. This can be overcome through the use of more vigorous and objective measures. However, because of financial and time constraints, only self-reports were used. Another limitation was the study's cross-sectional design. Cross-sectional study designs create ambiguity about the direction of the causal relationship between parental experiences and stress reduction. For example, did parents with positive experiences of web-based learning have lower stress, or was it the other way around?

Conclusion and Recommendations

The findings of this research highlight the experiences parents underwent when their children studied via web-based learning during the COVID-19 pandemic. Parents' experiences were more negative than positive, and parents with negative experiences reported more obstacles than parents with positive experiences. Regarding stress reduction after a year of web-based learning, parents with positive experiences were able to reduce their stress and adapt to their child's web-based learning. Given the results of the study and the possible continuation of web-based learning even after the end of the pandemic, it is important that future research investigate the ramifications of web-based learning for children's educational level, parents' ability to manage children's educational needs, and the support needed to be delivered to parents and children.

Conflicts of Interest

None declared.

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Abbreviations

IRB: institutional review board
KSA: Kingdom of Saudi Arabia

Edited by S Badawy; submitted 18.07.23; peer-reviewed by A Zuair, M Wang; revised version received 09.11.23; accepted 10.11.23; published 19.12.23.

Please cite as:
Al Anazi S, Bajamal E, Hantira N, Esheaba O
Exploring Parental Experiences With School-Aged Children Receiving Web-Based Learning: Cross-Sectional Study
JMIR Pediatr Parent 2023;6:e50892
URL: https://pediatrics.jmir.org/2023/1/e50892
doi:10.2196/50892

Original Paper

How People Use Web-Based Parenting Information to Support Others in Their Social Circle: Qualitative Descriptive Study

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Abstract

Background: Almost two-thirds of the North American population have searched for health information on the web, and the majority report searching on behalf of someone else in their social circle, a phenomenon referred to as *proxy seeking*. Little is known about how proxy seekers use web-based health information and the outcomes they experience.

Objective: The main aim of this study was to explore why proxy seekers used a parenting website on behalf of parents in their social circle and the outcomes they reported.

Methods: A qualitative descriptive study was conducted in the context of a partnership with a web-based parenting resource to explore the contexts and motivations for proxy web-based health information seeking, use of information, and subsequent outcomes. A total of 14 participants who self-identified as family members, friends of parents of young children, or professionals who worked with young children were interviewed, and a thematic analysis was conducted.

Results: The following 4 reasons for proxy seeking were uncovered: for reassurance, out of personal curiosity, as part of a professional role, or following an explicit request from the parents. Information was used to provide informational support for parents or material support for a child. Positive outcomes of using the information and some of the resulting interpersonal tensions were described.

Conclusions: This study provides an in-depth look at proxy seeking behavior and outcomes among users of a web-based parenting resource.

(JMIR Pediatr Parent 2023;6:e40043) doi:10.2196/40043

KEYWORDS

consumer health information; information seeking behavior; child development; child health; information outcomes; health information; digital health; parenting; web-based information

Introduction

Online Health Information

In 2020, over two-thirds of Canadians (69%) reported searching for health information on the web [1]. This is in line with results from the Health Information National Trends Survey in the United States between 2008 and 2017, in which two-thirds of respondents reported turning to the internet first for health information [2]. *Online health information* (OHI) is the term generally used to refer to information on all aspects of health (including mental, physical, and social) created for and directed toward the general public [3]. OHI is available in many formats, such as text and video, and is available at government health sites and from professional organizations, health journals, and blogs among other sources. Moreover, individuals are exposed

to OHI "posts" shared by their network through social media platforms such as Facebook [4].

Outcomes of OHI Seeking

Previous work has explored the different outcomes of OHI seeking from the individual self-seeker's perspective, and these outcomes are described at 4 levels: situational relevance, cognitive impact, use, and subsequent health outcomes of information [5]. People can use OHI in many ways, most commonly to discuss with health care providers, engage in their own health care, modify or comply with a management plan, or support relatives or friends with health conditions [5]. Using OHI is generally associated with positive perceived outcomes such as increased empowerment of consumers and their families and improved health outcomes [6-9]. There may be negative outcomes (referred to as *tensions* in previous work), such as increased anxiety or worsening of the patient-physician relationship; however, there are strategies, such as providing trustworthy resources, to reduce these tensions [10].

Several contextual factors are associated with OHI outcomes. These include age, education, income, eHealth literacy, and sources of social support [5]. Source of social support is an important factor because one of the main reasons people search for and use OHI is to support their relatives or friends with health conditions [11]. Moreover, findings from a study exploring internet use trends between 2008 and 2013 showed a significant increase in the involvement of family and friends to obtain health information [12]. Individuals are sometimes more likely to turn to their social circle to make sense of the information they find, rather than discuss it with a health professional [13,14].

Social Support

Social support is one of the positive products of "social relationships," which may have short- and long-term effects on health, for better and for worse, depending on their quality and quantity [15]. A model by Uchino [16] describes 2 broad dimensions of support: structure and function. Structural aspects of support are the extent or composition of one's social network (size, contact, type, density, and strength) and the interconnections among them. Functions are organized along 2 levels—perceived support and actual support—and have 3 aspects that are highly related to each other—informational, emotional, and tangible aspects. Most relevant to this study is informational support, which includes the provision of advice or guidance, and it may provide direction and carry an emotional message when received from a close source. Informational support can be construed as supportive, unsupportive, or mixed depending on context [17-19]. Emotional support is the offering of warmth and nurturance, including encouragement, empathy, trust, affection, and other positive facets, that can reduce stress or other negative emotions [16,20]. Tangible support involves the provision of material (practical) aid [16,20].

Informational social support can occur in 2 ways: an individual can request informational support from the social support provider (by discussing health information with them and asking for their help) or it can be unsolicited (the provider searches on behalf of the individuals and shares it with them). In the first case, for example, an individual's selection of the source of information depends on the individual's needs and expectations, so they may consult their friends and families when they need "more tailored emotional support in obtaining complex and serious health information" [21,22]. In the second case, a social support provider is aware of the individual's information need (eg, recently diagnosed health condition) and searches for information on their behalf to share with them, supporting their health care management. Although informational support has been explored in the past, few studies have focused on its outcomes in an OHI context, and none have looked at it from the perspective of both the provider and the receiver.

Proxy OHI Seeking

Proxy information seekers can be defined as "those who seek information in a nonprofessional or informal capacity on behalf (or because) of others without necessarily being asked to do so" [14]. Proxy seekers may also be "experts," such as health librarians or health care professionals with specialized knowledge or skills to use the information with the individual with whom they share a personal relationship [23]. Although this phenomenon of proxy information-seeking behavior has been explored in the literature, especially in relation to health information, few studies have explored the context of proxy OHI seeking being linked to the use of OHI and subsequent health outcomes.

This constitutes a critical knowledge gap. People may be able to overcome low eHealth literacy by discussing the information they find with others [10]. Proxy seekers in a person's social circle may help them overcome information-seeking barriers and illness challenges (eg, they are too physically weak or mentally incapacitated to search themselves) [14]. By better understanding how proxy seekers use information with people in their social circles, information providers can better adapt the information to meet their needs, and public health interventions can target patients' friends and family with information for dissemination and use [24]. Thus, the objective of this qualitative study is to explore the motivations, contexts, and outcomes of proxy seeking behavior from the perspective of proxy seekers.

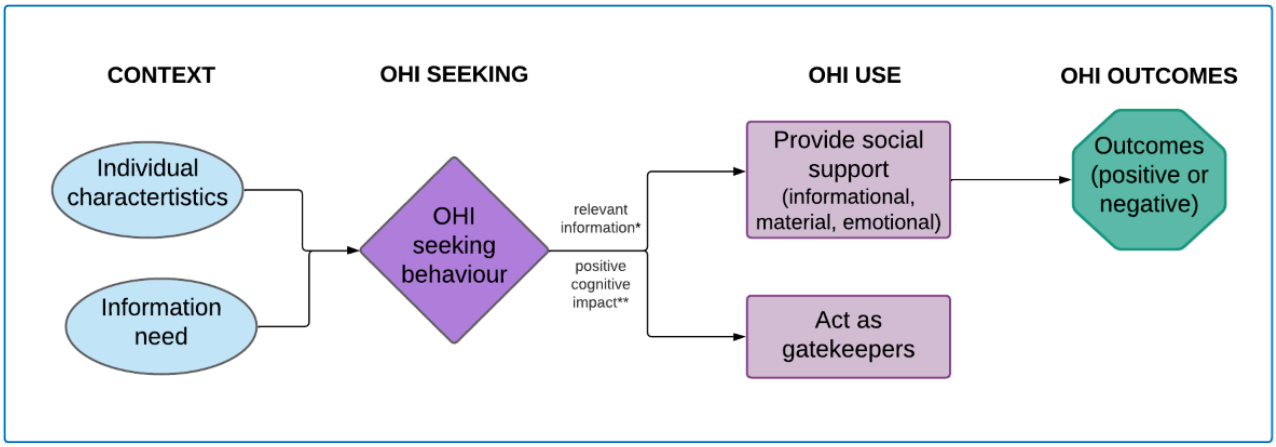
Methods

Theoretical Model

The model guiding this work was developed by following a mixed studies literature review on proxy OHI-seeking behavior and was published elsewhere [25]. The findings from the thematic analysis of 28 included studies were used to revise the existing conceptual framework [5]. Our Outcomes of Proxy OHI Seeking model is presented in (Figure 1). Individual characteristics such as age and gender influence proxy OHI seeking, for example, most studies report that proxy seekers are more likely to be women and aged between 31 and 64 years [13,26]. The OHI-seeking process is triggered by another individual's information need, which may be explicit (stated to the proxy seeker) or implicit (eg, observed by the proxy seeker). The proxy seeker will then actively search for or passively monitor OHI to fulfill this information need. When they find a situationally relevant information object that has a positive

cognitive impact, they will use it to provide informational, tangible, or emotional support for someone else. A common example of use would be the sharing of information between caregiver and patient either directly by sending them a link or printout or indirectly by discussing the information found. The proxy seeker could also act as information gatekeepers for the individual to reduce the burden of information overload or prevent conflict. OHI use will lead to separate outcomes experienced by the individual and the proxy seeker. These outcomes are generally positive; for example, information can help people make a health behavior change like quitting smoking or allow them to feel more confident and able to discuss the information with their health care providers and request different management options. There are also negative outcomes such as increased anxiety for both the proxy seeker and the individual, for example, with conflicting information or with conflicting preferences for information in general [25].

Figure 1. Outcomes of proxy online health information (OHI) seeking framework. *If no relevant information is found then there is no OHI use, as well as no outcomes **If there is a negative cognitive impact then there is no OHI use as well as no outcomes.



Resource: Naître et Grandir

The Naître et Grandir (N&G) website provides free, expert-based, web-based parenting information content in French that caters to people with lower health literacy levels (Grade 8 reading levels) with additional audio and video content [9]. Web-based parenting information, which encompasses all mental, physical, and social aspects of children's health, is a large subset of web-based health information on the internet [27]. In addition to directly accessing the website, N&G readers can sign up to receive a weekly newsletter containing parenting tips and links to N&G webpages tailored to their child's age and evolution.

N&G is funded by the "Lucie and André Chagnon" Foundation, a Quebec-based philanthropic organization that seeks to create conditions and environments that are favorable to the educational success of children. Since 2014, the research team of 3 coauthors (PP, RG, and RES) has worked in partnership to implement the Information Assessment Method (IAM) questionnaire to evaluate this parenting information. When N&G readers land on a web page corresponding to a specific topic (directly or from the newsletter link), a lateral tab appears, inviting them to complete the survey. The first question asks the respondents to identify with one role for the purpose of this specific web page they are rating: parent, grandparent, family member, friend or neighbor, or professional who works with children aged 0 to 8. N&G editors have been able to improve their informational content using the comments provided by the readers through the IAM questionnaire [28]. Further details on the IAM and quantitative analysis of responses from parents and entourage members have been published elsewhere [9]. The translated version of the current questionnaire is available elsewhere [29].

Study Design

A qualitative descriptive study was conducted using semistructured remote interviews with IAM respondents who identified as entourage members. This type of study is used to provide an accurate account of the events or experiences of participants attributed to those events [30].

Ethics Approval

Institutional Review Board approval from McGill University was obtained before the start of the study (Institutional Review Board study number: A12-B73-18A). Methods and results were reported using the COREQ (Consolidated Criteria for Reporting Qualitative Research) [31]. This study was the second component of a mixed methods convergent study, and the details of the quantitative study have been published elsewhere [29].

Study Participants

A purposive sampling strategy was used to select potential participants from a data set of IAM questionnaires received between April 13, 2019, and March 30, 2021. IAM responses that were completed by an entourage member who agreed to be contacted for an interview were exported into a separate Excel (Microsoft Corporation) file. After excluding those with no valid email addresses, the final list included 71 potential participants (25 grandparents, 17 family members, 15 friends or neighbors, and 14 professionals caring for children). An invitation email was sent to these potential participants, 4 per week, in the order they had completed the questionnaire, from the oldest to most recent.

Data Collection

An interview guide was developed using an iterative process based on the Outcomes of Proxy OHI Seeking model. The guide

was pilot-tested with 2 graduate students, and the researcher's notes and interviewee's feedback were used to revise it and produce the final version. A total of 14 individual semistructured interviews were conducted in French over the phone or videoconference (Zoom [Zoom Video Communications Inc]), depending on each participant's preference. When participants responded to the invitation email, they were sent the consent form and were asked to respond with their written consent and any questions that they had.

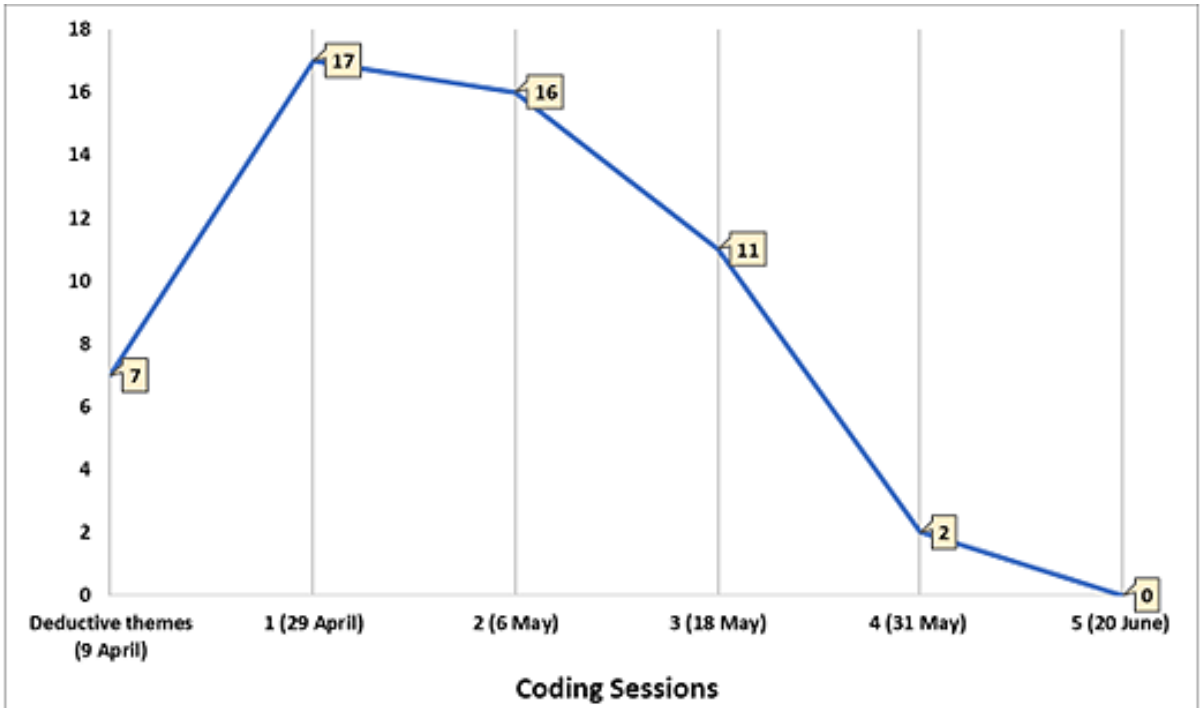
After being introduced to the purpose of the study, the participants were asked general questions regarding web-based consumer health information and the context and resources of their information-seeking behavior. They were asked about their role as entourage members and about the members of their social circle with whom they were frequently in contact. They were reminded of the N&G web page they had rated using the IAM questionnaire and were asked to describe how and why they had landed on that page. Finally, they were asked how they used the information on the page and what outcomes they perceived as a result. The interviews were recorded, and the recordings were transcribed by a professional transcriber, translated into English by 2 of the authors, and analyzed using web-based translation software (deepl [32]).

Data Analysis

Transcripts were imported into NVivo (Release 1.5; QSR International), and a deductive-inductive analytical approach was adopted for coding [33,34]. A coding manual was created and discussed with another coauthor (VP). The codes were progressively clustered into themes and subthemes. Coding was conducted by the first author by participant and by coding meaningful extracts into the major themes first; then, the extracts in each theme were coded into subthemes. Themes and subthemes were discussed with the coauthors throughout the coding process, and their feedback was incorporated into the coding manual.

The interview transcripts were analyzed over 5 coding sessions, as shown in Figure 2. During the fourth coding session (after 12 interviews had been conducted and analyzed), only 2 new themes emerged. Two more interviews were conducted and analyzed, and no new themes emerged. Therefore, saturation had been reached, and data collection stopped.

Figure 2. Qualitative data analysis: saturation of themes reached after 4 coding sessions.



Results

Description of Participants

In total, 14 participants were interviewed, comprising 5 (36%) grandmothers, 4 (29%) family members, 4 (29%) professionals, and 1 (7%) friend. Most of them were female (12/14, 86%) and had a bachelor's degree or higher (8/14, 57%). Respondents completed an average of 4 IAM questionnaires over the 2 years of study period (range 1-14). Full details of the participants are presented in Table 1.

Table 1. Participant characteristics.

Pseudonym	Age group (years)	Income[a] (CAD $)	Education	Profession	Entourage type	Average internet use (hours/day)
Alisson	26-44	>60,000	Bachelor's	Teacher	Family	2
Sarah	26-44	<60,000	High-school diploma	Retailer	Family	5-6
Mark	26-44	<60,000	College	Practical technician	Family	3
David	>45	<20,000	High-school diploma	Unemployed	Friend	2-3
Mary	>45	>60,000	College	Admin in adult education center	Grandmother	3
Nadia	>45	>60,000	Master's	Research coordinator on aging	Grandmother	3
Sophie	>45	N/A[b]	Bachelor's	Spanish interpreter	Grandmother	5
Nathalie	>45	>60,000	Master's	Retired	Grandmother	2-3
Joelle	>45	>60,000	Master's	Retired school principal	Grandmother or professional	3
Florence	26-44	>60,000	High-school diploma	Kinder garden child educator	Mother or professional	1-2
Norma	26-44	>60,000	Bachelor's	Nurse	Professional	4
Alice	26-44	>60,000	Master's	Psychoeducator (0-7 years old)	Professional	3-4
Emilia	26-44	<60,000	Certificate	Kindergarten educator	Professional or friend	>8 (work + personal)
Mathilde	<25	<60,000	CEGEP[c]	Student	Sister	1

[a]The Institute for Research and Socioeconomic Information has identified CAD $60,000 (CAD $1=US $0.70) as the sustainable income index for a family of 4, indicating the income a household should have to not only meet its basic needs but also get out of poverty, while the index for a single person is approximately CAD $27,000 [35].

[b]N/A: not applicable.

[c]CEGEP: CollèGe D'Enseignement GéNéRal Et Professionnel. It is the equivalent of Grade 13 in Quebec, Canada.

Contexts and Motivations of Proxy OHI-Seeking Behavior

Two main themes were discussed in relation to the context of proxy information-seeking behavior: individual characteristics of the entourage members and the information needs that triggered the seeking of web-based parenting information. The entourage members were reminded of the N&G web page they had landed on before completing the IAM questionnaire and were prompted to recall the reason they were on that topic. The specific N&G web pages and the reasons are reported in Table 2.

All the participants described who they considered as their social circle, and in addition to family members and friends, some professionals included their colleagues and clients (parents of children in their care) in their social circle. All entourage members were in close contact with the people for whom they were seeking information by proxy. This contact may be in person, but many also described remote contact because of either geographic location or restrictions imposed by the pandemic:

> *Let's say they don't live that far away, but with the COVID context, what I was doing, I was Face Timing with them on the weekends, because, among other things, their mother was extremely strict about visitation and all that. But let's just say in a context, if I look at past years, we would see each other almost every week, we would go for a little walk, but that hasn't been the case since March 2020.* [Nathalie, a grandmother]

Proxy information seeking was triggered by different motivations falling under 4 broad themes: for reassurance, out of personal curiosity, for work as a caregiver, and following an explicit request from someone else. Excerpts corresponding to each theme are presented in Table 3. Several entourage members described wearing multiple hats, as professionals who worked with children and as family members or friends with children in their personal circle.

Table 2. Latest Naître et Grandir (N&G) web page rated by the participants.

Participant	Last N&G page rated	Context
Alisson (family)	Development: Around 5 years old	"It was really from the beginning of [my nephew's] life, when he was very small, because he came into the world prematurely and he had some pretty close follow-ups in the first months of his life."
Sarah (family)	Learning to walk	(Could not recall the specific N&G page so referenced another page). Nephew: "Well, when he first started teething, I was wondering if it was normal, say, for him to have a lot of fever, rashes, things like that, what to do to help with the toothache."
Mark (family)	Verbal dyspraxia	"Yes, it was about my son's behavioural problems...It was one of the few times that it was pretty clear that I was overwhelmed by the situation. The calls to the family didn't inform me well enough, in my opinion, about the situation, which was still pretty sharp and pretty specific, so I went looking for very specific information on a specialized and credible site that I knew and came straight to it."
David (friend)	Tantrums: Understanding them to better intervene	Friend's child: "This is not the first time I've seen a child have a meltdown. It was because she was coming up to three years old and I was wondering what the age range really is in that."
Mary (grandmother)	The benefits of music	"My interest in the education of this grandson."
Nadia (grandmother)	The benefits of reading with your child	"Granddaughter of a child who is one and a half years old...She comes to spend, usually, one day a week on weekends at my house."
Sophie (grandmother)	2 to 2.5 years: intellectual development	Grandchild: "How to understand her, but also how to interact well so that I can give her all the...so that her development is as good as possible."
Nathalie (grandmother)	The child who doesn't like kisses	"With the [grand]children I live with now, they have two completely different personalities. Bella, the little one, she is extremely affectionate. She always wants to be stuck to us. Matteo is the complete opposite. He's a very independent child, who has to be approached gently, and me, anyway, I don't want to impose my kisses and all that."
Joelle (grandmother and professional)	Grief in children	"It was my daughter-in-law who passed away...So, I shared that information first with my son and his girlfriend. I sent them the link...The child lives with them full time now. I sent him the link to Naitre et Grandir to encourage him to go see it..."
Florence (mother or professional)	The child who doesn't talk yet	"I have my own private home daycare...As far as my son or my friends' children are concerned, because we talk about it a lot, or the kids I currently have in my daycare, because we are confronted with little viruses, little bacteria, and big worries from parents as well, Naître et grandir is a great, great source."
Norma (professional)	The basics of breastfeeding	"I'm a nurse. I work in early childhood. I've always worked in the childcare setting."
Alice (professional)	Sleep: effects on development and behavior	"I am a psychoeducator for young children aged 0-7. My clientele is mostly children with autism spectrum disorders and their families as well. Yes, it was for one of my families that I'm following up with."
Emilia (professional or friend)	Yogurt: Which one to choose? & Food rewards	"It's because basically in a course where I'm going to be doing observations, there's also the health element, and I talk to students sometimes about nutrition and being able to offer a variety without necessarily threatening to take the dessert away."
Mathilde (sister)	Lessons and homework: accompanying your child	"Sometimes, also, on health, it's more my little brother. But for kids in general, it's mostly for my babysitting."

Table 3. Themes related to motivations for proxy information seeking (N=14).

Theme	Excerpt	Frequency, n (%)
For reassurance	"I was clearly overwhelmed by the situation. It was one of the few times that it was pretty clear that I was overwhelmed by the situation. The calls to the family didn't inform me well enough, in my opinion, about the situation, which was still pretty sharp and pretty specific, so I went looking for very specific information." [Mark, a family member]	4 (29)
Out of personal curiosity	"It's more of a special interest, because now I'm a grandmother and the context is that I don't have a spouse anymore, so my priority now is my children and my grandchildren." [Nathalie, a grandmother]	3 (21)
For work as a caregiver	"It was to go and get ideas for games to incorporate into my program, because I was going to explain something...Learning, active play, we explain that a little bit, and here I had to give examples of games" [Alisson, a family member who is also a teacher]	4 (29)
Following an explicit request	"Actually, it was to reassure a pregnant friend about COVID vaccine" [Norma, a professional]	1 (7)

OHI-Seeking Behavior

Participants described their strategies for searching for OHI and how they assessed the credibility of the information they found. Many participants would typically start searching for OHI by entering ≥1 keyword into a search engine (eg, "Googling the word 'vaccine'") and clicking on the first few links or selecting links to resources they recognized. In contrast, 2 participants mentioned that they started from websites they had bookmarked, including N&G, rather than Google.

Participants had different ways of thinking about the credibility of a website, and for the most part, they preferred websites from institutions they recognized:

> *Mostly I look for it to be recognized, for it to be something I've heard of or seen before, if it's a medical clinic I know, Mayo Clinic in the United States.* [Alice, a professional]

Some participants would check the credentials of the authors, and the validity of the references. Websites that had "too many ads" or "several spelling mistakes" were considered less credible. Several described using a critical attitude when assessing websites:

> *There's a bit of intuition, there's a bit of experience. I have a little trouble believing anything too. There's a lot of quackery on the Internet, and I'm wary of sites that aren't officially licensed.* [Mary, a grandmother]

After checking a few sites or trying different keywords, the seeker would decide that they had found something relevant after triangulating from different resources:

> *After three references that talk about the same thing, that give about the same result.* [Alice, a professional]

Some participants described the cognitive impact of the information, which gave them personal satisfaction to know more, allowed them to learn something new, or confirmed something they already knew:

> *It's because of what I've already studied and what I know, and then I'm mostly looking for either validation of the information I already have or to see if it's already out there in the mainstream at this point, if there is another way to explain it more easily.* [Alice, a professional or aunt]

Using Relevant Web-Based Parenting Information

Participants described how they used the information they found on the N&G web page that they recently rated in symbolic and instrumental manners. Themes related to information use are listed in Table 4. With regard to *symbolic use*, most used the information to provide informational support to someone in their social circle. They sometimes shared the link to a relevant web page directly with the child's parent:

> *A lot of times I'll send her [the child's mother] a little message on Facebook in a private message, I'll send her the link outright.* [Sophie, a grandmother]

The 29% (4/14) of professionals described situations in which they would share the links to N&G web pages with the parents of children in their care after the parent had mentioned specific concerns on the topic:

> *I have a child who went to get vaccinated, and the mom was worried because he had had a reaction to his vaccines before and now, he was on the next vaccine. So, to reassure her, I sent the link two days ago to the mother which came from Naître et grandir.* [Florence, a professional]

Other times, participants discussed the content of the web page without sharing the link itself:

> *I share my perspective (with my son), but my perspective is kind of informed by that information from N&G .* [Nadia, a grandmother]

The entourage member would sometimes also discuss the information they found with people other than the individual for whom they were searching to help them make sense of it:

> *I am lucky enough to work with professionals in speech therapy, special education, and psychology, so at work it's fun to have a credible second opinion, to confirm or to refute.* [Mark, a family member]

In contrast, in some situations, they did not share the information at all, often to avoid tension or conflict with the individual.

For example:

> *I'll take on the role of the specialist with respect to my sister, so sometimes that leads to discussions that are less pleasant.* [Emilia, a professional]

Overall, 14% (2/14) of grandmothers discussed not sharing the information because they did not want to appear too intrusive or too judgmental about their children's parenting, as one of them said the following:

> *Giving out information that is not sought after is, in my opinion, a waste of time* [Nathalie, a grandmother]

Another way the participants used the information was to provide material support (ie, *instrumental use*). This was specifically true for family members who were occasionally entrusted with the care of a child. Mathilde described using the information she found to help her brother with his homework while she was babysitting him in the evenings. A total of 36% (4/11) of grandmothers described learning new ways to interact with their grandchildren while they were spending time with them:

> *I'm going to make him do a recipe. We're not going to do math, we're not going to do written problems, we're going to do a muffin recipe.* [Alisson]

Finally, one grandmother described providing emotional support to her bereaved son after she read relevant information on N&G:

> *It was more with my son that I talked about it, but really, him, it wasn't so much about where I found the information as it was about discussing the grief.* [Joelle, a grandmother and professional]

Table 4. Themes related to proxy information use (N=14).

Theme	Excerpt	Frequency, n (%)
Did not share with someone	"I don't want to give them the impression that I'm watching how they are. I find that everyone gives so much advice when you're a parent. Everyone has their idea of what's best and what not to do and all that, so I try to gauge that, not put too much on it. It's more that I keep it in mind for if they ever bring it up or something like that." [Nadia, grandmother]	7 (50)
Doing something	"It helped me to be able to guide my brother in his learning at school, to know how to help him more, what I should do." [Mathilde]	5 (36)
Shared with someone else	"I shared that information first with my son and his girlfriend. I sent them the link. There are things that I photocopied and showed to my son." [Joelle]	10 (71)
To discuss with HCPs[a]	"I am lucky enough to work with professionals in speech therapy, special education, and psychology, so at work it's fun to have a credible second opinion, to confirm or specially to refute." [Mark]	3 (21)
To discuss with others	"I usually print the page out or email it to the parents to read. It depends. Sometimes they read more when it's paper because I email it and it gets lost with all the other emails. But I give, and afterwards, at my meeting after: 'What did you understand? Did you get a chance to read it? Do we read it together?' and so on." [Alice]	5 (36)
To make decisions	"I'm going to go back and read it again to confirm, actually, that the approach that I want to implement is really in line with the information that I've had, because I wouldn't want to go on and just like stay within my capabilities and it's like just motivated me, but not really being applied."[Mark]	1 (7)
To provide emotional support	"It was more with my son that I talked about it, but really, him, it wasn't so much about where I found the information as it was about discussing the grief." [Joelle]	1 (7)

[a]HCP: health care professional.

Outcomes of Using Web-Based Parenting Information

Themes related to the outcomes of information use are presented in Table 5. The reported outcomes of using N&G information were generally positive. The most common outcome was improvement in the relationship with others. In the case of Sophie, reading the information on her granddaughter's intellectual development allowed her to better understand her behavior. This allowed her to change her interactions with her granddaughter, which led to them being more comfortable with each other. Another grandmother, Nadia, explained how the information allowed her to be more reassuring and supportive of her son and daughter-in-law. After sharing information a few times and feeling validated, one grandmother described feeling more comfortable discussing what she had read with her son again in the future, and a professional described how sharing information with the parents of a child in her care led to better discussions.

Another commonly reported outcome was reassurance. Sarah, a family member, described feeling reassured after finding answers to her questions about miscarriages on the web. She discussed the information she had found with her partner, and they both felt reassured as a result. Norma, a professional, was approached by her pregnant friend who was concerned about the COVID-19 vaccine. After Norma shared the N&G web page on the safety of the vaccine during pregnancy, her friend was reassured and proceeded to keep her vaccination appointment.

Some participants also felt more confident in making decisions with others and being more involved in the care of the child as one grandmother described:

> *Yes, it gives me more confidence that I'm doing it the right way and that it's okay to do it, let's say. I guess it gives me more confidence in how I'm intervening with her* [Nadia, a grandmother]

One professional reported that the parents in her care were the ones who felt more confident in their interventions with their child following a discussion of the information she had shared:

> *Yeah, it's not perfect, they don't all change their behavior, because it's still a loop, but they quietly start to realize, and then the kids' behavior starts to decrease, and then the parents become more confident in their interventions.* [Alice, a professional]

A total of 2 (14%) of the 14 participants described negative outcomes or tensions as a result of sharing information. Alisson who shared information with her sister describes one such outcome:

> *I have to be careful, because she didn't take it very well. She, she thought I was doubting her...she wasn't too keen on me telling her about it after all.* [Alisson]

Emilia, who is a proxy seeker both as a professional and as an aunt, described how her sister would sometimes be resistant to the advice and information she shared:

> *At one point she told me he wasn't that bad, but sometimes when she feels exhausted about it, she tells me about it like it's a mountain, and other times, once I bring the information, it seems like she doesn't want to.* [Emilia, a professional]

Emilia concluded that she had better experience of sharing information in a professional context than in a personal one.

Table 5. Themes related to outcomes of proxy information use (N=14).

Theme	Excerpt	Frequency, n (%)
Improved relationships	"Yes. In the relationship, it's clearer when we talk. They already know what we're talking about, how, and they know." [Alice]	4 (29)
Less worried	"Not necessarily, but it reassured me. Going to see that information really reassured me. I was kind of full of questions and stuff and I was not sure about everything, so I was like, 'Okay. At the same time, I do not necessarily want to call a doctor and ask him a little bit...probably bother him for nothing.' When I saw that, I was like, 'Okay, that's good. Okay, that explains some things.' It put some answers to my questions, and I was better with myself after reading that and I felt much better." [Sarah]	3 (21)
More confident in decision-making	"Yes, it gives me more confidence that I'm doing it the right way and that it's okay to do it, let's say. I guess it gives me more confidence in how I'm intervening with her." [Nadia]	3 (21)
Tension	"I have to be careful because she didn't take it very well. She, she thought I was doubting her...I was curious, and at the same time I told her about it, but she wasn't too keen on me telling her about it after all. 'You don't mind your own business, old girl.'" [Alisson]	2 (14)

Discussion

Principal Findings

This study explored the motivations, context, and outcomes of proxy seeking behavior from the perspective of 14 entourage members of parents of young children, seeking information on a web-based parenting resource. Most respondents played one or more roles as family members, friends, or professionals who worked with younger children. They were proxy seeking for reassurance, out of personal curiosity, as part of their professional role, or following an explicit request from their parents. They used the information to provide informational support (either by sharing the web page or discussing its content) or to provide material support for a child in their care. In some cases, they did not share the information to avoid causing tension with the parents in question. Furthermore, they generally reported positive outcomes of using the information: feeling less worried, finding an improvement in their relationship with the parent or child, and feeling more confident in future interactions. Some interpersonal tensions were described as a result of sharing the information, specifically when it was unsolicited and when it was shared in the context of a personal relationship.

This study highlights the role of social support in web-based health information–seeking outcomes. Social support has consistently been linked to better health [16,36,37]. Several explanations have been proposed to explain why this occurs; for example, social support can act to reduce the impact of stress, which subsequently improves mental health [15]. Another potential explanation is that the provision of informational support encourages the receivers to manage their health, as demonstrated in a study that explored the relationship between maintaining an improved cardiovascular health status and social support networks [38]. If we use pregnant women as another example, those who were more satisfied with perceived and received social support initiated prenatal care earlier than those who were less satisfied [39]. Pregnant women who received more informational support from people in their social network delivered newborn infants with higher APGAR (Appearance, Pulse, Grimace, Activity, and Respiration) scores (a measure of health 5 minutes after birth) and higher birth weight [39,40]. Although informational support has been explored in the past, few studies have focused on its outcomes in the OHI context.

Negative outcomes were reported by 2 participants after proxy OHI use, specifically related to interpersonal tension. In general, negative outcomes are rarely reported: a literature review found limited reports of patient anxiety or decisions to refuse cancer treatment [41]. There were 2 studies that reported that the proxy seekers themselves experienced more anxiety sometimes owing to information overload [42,43]. The proxy seeker and the individual did not always have the same approach to OHI; situations in which the individual did not want to "know" or ignored the information led to tension and conflict [44,45]. Moreover, a mixed methods study in the context of patients with diabetes reported that the greater the proxy OHI seeking, the lesser the family members were perceived to be supportive, owing to attempted influence and interference by proxy seekers [46].

To our knowledge, this is the first qualitative study to focus on the entourage of young children's parents in the context of web-based parenting information. A recent review of the literature conducted by the authors on proxy OHI-seeking behavior included 10 qualitative studies: 6 explored the perspectives of both proxy seekers and self-seekers; 3 explored the perspective of proxy seekers only; and 1 explored the perspective of self-seekers who relied on others to make sense of the information. Most studies (7/10, 70%) focused exclusively on caregivers of patients diagnosed with a chronic or acute illness; 2 focused on the care of older adult family members; and only 1 explored the health information–seeking behavior in the general population. The latter explored how Singaporeans came to make sense of web-based health information seeking and described how people's roles within family relationships necessitated proxy seeking [47]. Similar to our study, that study reported positive outcomes of proxy OHI seeking and use, such as feeling less worried.

In this study, most participants were grandparents, who also represented 12% (6309/51,325) of N&G-IAM survey respondents in the previous quantitative study [29]. One contribution of this study is the perspective of older OHI consumers as the proxy seekers rather than the recipients of support. In 2018, almost 71% of Canadians aged ≥65 years used the internet, and in 2020, almost 50% searched for health

information on the web (Statistics Canada [48]) [1]. The grandparents in our study were frequent internet users who used the information they found on the web to provide informational and material support to their children and grandchildren and reported benefits such as improved relationships and increased confidence in their abilities. A recent study that explored web-based health information seeking in older adults reported that self-seeking and proxy seeking were active coping strategies to reduce health risks and improve health promotion in health care [49]. A large number of N&G readers are professionals who work with young children outside the health care field, as reflected in our study population that included 5 educators. Although they are considered important influences in the lives of young children, few studies have explored the OHI-seeking behavior of these professionals, as reported in a recent systematic review [50].

Another strength of our work is the partnership with N&G. One major limitation of empirical studies on OHI is the inability to assess the quality of the OHI used by the participants. N&G is an expert-based OHI source for people with low health literacy levels, with additional audio and video content [9]. By decreasing the health literacy gap, people are better able to process and use information [51]. This provides a context in which the phenomenon of proxy OHI seeking can be explored without major concerns about the quality of the information. N&G is neither a traditional scientific and medical resource nor a blog. In previous research, comments from the readers of websites and blogs have been analyzed, but few researchers have conducted interviews with users of parenting websites to explore their motivations and outcomes in-depth [52].

Our study allowed us to explore different concepts within the Outcomes of Proxy OHI Seeking model in the context of entourage members of parents of young children [25]. The context, OHI-seeking behavior, OHI use, and outcomes described in this study provide tangible examples to illustrate the different outcomes. Therefore, this work provides empirical support for the Outcomes of Proxy OHI Seeking model. In addition, we can now improve the IAM questionnaire to allow for response items catered to entourage members, as the IAM was originally developed and validated with parents.

There are 4 main limitations to our study. Although we attempted to recruit more men, most participants were women (12/14, 86%), and this corresponds to the gender of the respondents to the IAM questionnaire (on average, 90% of respondents were women). Although this lack of heterogeneity may be considered a limitation, studies have consistently reported that most OHI proxy seekers are women, as reflected in our sample [13,53-55]. In a recent analysis of IAM responses by N&G users with low socioeconomic status, our team reported that fathers were more likely to report the benefits of N&G information than mothers [56]. This highlights the need to target men OHI seekers with inclusive information and to explore their use of OHI in future studies. The second limitation is that we only explored the viewpoint of proxy seekers and did not interview the parents for whom they were searching. These interviews may have provided a fuller picture of this phenomenon but were beyond the scope of this study. The third limitation is that the author who conducted the qualitative data analysis (in English) was not the author who conducted the interviews (in French). To mitigate this, the authors held frequent meetings throughout the study: before and after each interview and during the qualitative data analysis. The final limitation is that the contextual factors related to proxy OHI-seeking outcomes were not assessed within the scope of this study. Future work can explore the relationship between proxy seekers' characteristics and the outcomes they report.

Conclusions

This study supported our Outcomes of Proxy OHI Seeking model. We plan to use this study to improve the IAM questionnaire implemented by information providers in Canada. From a practical standpoint, this is an important topic for information specialists, primary health care practitioners, and public health officials. By better understanding how an individual's entourage uses information and experiences subsequent outcomes, information providers can better adapt their information to meet their needs, while health care practitioners can target the patients' entourage with web-based health information resources. Public health interventions aimed at supporting parents can do so by improving their social networks (eg, by facilitating longitudinal relationships with proxies such as other parents or extended family members). Other professionals involved in the support of parents and their children (eg, day care educators and teachers) can be specifically targeted with reliable OHI to promote positive outcomes.

Acknowledgments

This study was sponsored by the Canadian Institutes of Health Research through a doctoral research award (# 201710GSD-402379-251380) granted to the first author and by Naître et Grandir (Foundation *Lucie & André Chagnon*). This study is part of the first author's doctoral project, and the coauthors are her colleague, supervisor, and members of her thesis committee.

Authors' Contributions

All authors contributed to the study design and review of this manuscript. PP, RG, and VP contributed to the data collection. The first author and VP conducted the qualitative data analysis. All authors contributed to the interpretation of the results (*Discussion* section). The authors gratefully acknowledge the help of Quan Nha Hong for the revision of this manuscript and Geneviève Doray (Naître et Grandir Editor-in-Chief) for her ongoing support.

Conflicts of Interest

PP and RG are consultants for Naître et Grandir.

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Abbreviations

APGAR: Appearance, Pulse, Grimace, Activity, and Respiration
COREQ: Consolidated Criteria for Reporting Qualitative Research
IAM: Information Assessment Method
N&G: Naître et Grandir
OHI: online health information

Edited by S Badawy; submitted 26.08.22; peer-reviewed by C McKinley, D Jones, J Busch-Casler; comments to author 25.11.22; revised version received 31.01.23; accepted 07.03.23; published 28.04.23.

Please cite as:
El Sherif R, Pluye P, Paquet V, Ibekwe F, Grad R
How People Use Web-Based Parenting Information to Support Others in Their Social Circle: Qualitative Descriptive Study
JMIR Pediatr Parent 2023;6:e40043
URL: https://pediatrics.jmir.org/2023/1/e40043
doi:10.2196/40043
PMID:37115603

Original Paper

Evaluation of an mHealth Intervention (Growin' Up Healthy Jarjums) Designed With and for Aboriginal and Torres Strait Islander Mothers: Engagement and Acceptability Study

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Abstract

Background: Aboriginal and Torres Strait Islander women have access to and interest in mobile health (mHealth), although few culturally relevant, evidence-based mHealth programs are available. We codeveloped an mHealth program in New South Wales with Aboriginal and Torres Strait Islander women, focusing on women's and children's health and well-being.

Objective: This study aims to assess the engagement with and acceptability of the Growin' Up Healthy Jarjums program among mothers caring for Aboriginal and Torres Strait Islander children aged <5 years and assess the acceptability of the program among professionals.

Methods: Women were given access to Growin' Up Healthy Jarjums—a web-based application, a Facebook (Meta Platforms, Inc) page, and SMS text messages—for 4 weeks. Short videos of health professionals presenting health information were tested within the application and on the Facebook page. Engagement with the application was examined through the number of log-ins, page views, and links used on the application. Engagement with the Facebook page was examined through likes, follows, comments, and the reach of posts. Engagement with the SMS text messages was examined through the number of mothers who opted out, and engagement with the videos was examined through the number of plays and videos watched and duration of the video watched. The acceptability of the program was examined through posttest interviews with mothers and focus groups with professionals.

Results: A total of 47 participants joined the study (n=41, 87%, mothers and n=6, 13%, health professionals). Interviews were completed by 78% (32/41) of the women and 100% (6/6) health professionals. Of the 41 mothers, 31 (76%) women accessed the application, 13 (42%) scrolled the main page only, and 18 (58%) clicked on other pages. There were 48 plays and 6 completions of the 12 videos. The Facebook page received 49 page likes and 51 followers. The post with the most reach was a supportive and affirming cultural post. No participants opted out of the SMS text messages. Almost all mothers (30/32, 94%) reported that Growin' Up Healthy Jarjums was useful, and all mothers reported that the program was culturally appropriate and easy to use. Of the 32 mothers, 6 (19%) mothers reported technical problems with accessing the application. Moreover, 44% (14/32) of mothers suggested improvements to the application. All the women reported that they would recommend the program to other families.

Conclusions: This study demonstrated that the Growin' Up Healthy Jarjums program was perceived useful and culturally appropriate. SMS text messages had the highest engagement, followed by the Facebook page and then the application. This study identified areas for technical and engagement-related improvements to the application. A trial is needed to assess the effectiveness of the Growin' Up Healthy Jarjums program at improving health outcomes.

(JMIR Pediatr Parent 2023;6:e43673) doi:10.2196/43673

KEYWORDS

mobile health; mHealth; co-design; Aboriginal and Torres Strait Islander; mother; baby; young children; mobile phone

Introduction

Background

Aboriginal and Torres Strait Islander people are the oldest surviving culture in the world [1]. The health of Aboriginal and Torres Strait Islander people changed significantly upon colonization and has continued to be disrupted by subsequent policies [2]. Improving the health and lives of Aboriginal and Torres Strait Islander people is a national priority. Mothers and babies receiving the best possible care and support for a good start to life is 1 of the 12 health priorities of the National Aboriginal and Torres Strait Islander Health Plan 2013-2023 [3]. Providing access to culturally responsive health information and services is an important strategy for achieving this goal [3].

Improving health literacy provides a foundation for individuals and communities to take action to improve their own health [4]. There is limited evidence on effective health literacy programs for Aboriginal and Torres Strait Islander people [5]. A systematic review examining interventions for improving health literacy among Aboriginal and Torres Strait Islander people included 5 studies with the following interventions: exercise classes, nutrition and cooking workshops, discussions and role plays, presentations, other learning activities, incentives, and reduction in the cost of fresh and frozen produce and low-sugar beverages and education at the point of sale [5]. All the included studies demonstrated statistically significant improvements in at least 1 health literacy–related outcome measure, although it should be noted that study quality was compromised because of small sample sizes and poor attendance [5]. More rigorous trials are needed on health literacy programs designed and implemented by Aboriginal and Torres Strait Islander people for Aboriginal and Torres Strait Islander people.

An array of mobile technologies is available to find, share, and generate health information [6]. The major benefit of mobile health (mHealth) is its ability to reach a large number of consumers, including those who cannot attend health services. Aboriginal and Torres Strait Islander women have a high interest in using mHealth [7] but have different preferences for delivery as well as content. Evidence to date shows that Aboriginal and Torres Strait Islander people are frequent users of Facebook (Meta Platforms, Inc) [8-11] and SMS text messaging [12-14] and report high acceptability of, but low engagement with [15], apps, as is often the case universally [16]. Content that centers on culture and frames positive health messages has greater acceptability [9,10,17]. Furthermore, certain delivery mechanisms may be particularly engaging to mothers. A report on Australian women's use of digital health found that women caring for infants and young children were more likely than other women to use social media and web-based forums to share and create health information [8], whereas other studies have found SMS text messaging to have high acceptability among mothers [10,11].

Available mHealth programs for Aboriginal and Torres Strait Islander mothers or their children are limited but growing, including an app, a website, and SMS text messaging on infant feeding [18]; SMS text messaging, videos, and multimedia messaging service for otitis media in children [13]; SMS text messaging, a phone call, Facebook, or an email for postpartum blood glucose screening [12]; a prototype app for social and emotional well-being during pregnancy [19]; and a mindfulness app for women and children of all ages [20]. In the gray literature, the authors are aware of the Deadly Tots app and interactive website on child development [21] and Facebook pages such as Stay Strong and Healthy page for health during pregnancy [21] and Yarn and Heal—Our way for Aboriginal women of all ages to connect and yarn [22]. It is important that we seek to advance mHealth solutions developed by and for Aboriginal and Torres Strait Islander women to promote digital inclusion and access to health information, particularly as it is known that cultural minorities are less likely to use mainstream web-based health technologies [6].

In 2019, we co-designed a multimodality mHealth program for Aboriginal and Torres Strait Islander women's and children's health [23]. The aim of the program was to improve health literacy and health behaviors as well as increase access to health services. Formative research with 31 women and 11 health professionals took place in 3 communities in New South Wales (NSW) and included focus groups with storyboards, card sorting, and design activities [23]. On the basis of the findings from the formative research, we developed a web-based prototype application, an SMS text message library, and a Facebook page, collectively called the Growin' Up Healthy Jarjums (an Yugambeh word used on the East Coast of Australia meaning children) program.

Following a formative research phase, subsequent steps to develop and evaluate mHealth interventions include conducting a pilot study, a randomized control trial, and an evaluation of the implementation impact [24]. The purpose of the pilot study stage is to determine acceptability, improve and refine the intervention, and test the content and regimen early in the research process [24]. Refining the intervention is often an iterative process in each research phase and beyond [24]. Continual improvements to mHealth interventions are important, given the constant upgrades to technology and that long-term engagement with mHealth can be difficult to achieve [25]. We used a pilot study design to evaluate the acceptability of and

engagement with the Growin' Up Healthy Jarjums prototype program.

Objectives

The aims of this study were (1) to assess the engagement with the Growin' Up Healthy Jarjums program among mothers (or other women) caring for Aboriginal and Torres Strait Islander children aged ≤5 years; (2) to assess the acceptability of the Growin' Up Healthy Jarjums program among mothers (or other women) caring for Aboriginal and Torres Strait Islander children aged ≤5 years; and (3) to assess the acceptability of the Growin' Up Healthy Jarjums program among health professionals and early educators.

Methods

Project Design

A 4-week pilot study of the Growin' Up Healthy Jarjums mHealth program was undertaken with Aboriginal and Torres Strait Islander women caring for children aged <5 years. Health professionals and early educators from the participating services provided feedback on the intervention in focus groups. Details on the development of the Growin' Up Healthy Jarjums mHealth program can be found elsewhere [23]. The Aboriginal Health and Medical Research Council (AH&MRC) Ethical Guidelines: Key Principles (2020) version 2.0 were used to guide the implementation of this pilot study [26].

Research Team

This research was governed by an Aboriginal advisory board in partnership with Aboriginal organizations (listed in the *Acknowledgments* section) and coled by a Kuku Yalanji and Lama investigator (KH), as well as 2 non-Indigenous investigators (BB and JM). In total, 3 team members were Aboriginal women from (or connected to) the communities where the research took place: a Gumbaynggirr woman (NS), Gomeroi woman in the Kamilaroi Nation (BL), and Worimi woman working in the Awabakal community (BH). The cultural identities of the remaining team members are Macedonian-Australian (BB), German-Australian (JM), Pakeha or European-New Zealand (RD), and European-Australian (SJP). The team has various professional backgrounds: 4 women with Aboriginal lived experience (KH, NS, BL, and BH), a behavioral scientist (BB), a pediatrician and academic (JM), a nurse and public health researcher (KH), an mHealth and public health researcher (RD), an early educator (BH), an Aboriginal health practitioner (NS and BL), and an occupational therapist and PhD candidate (SJP). All team members contributed to the conception of this study. Aboriginal researchers from the participating communities (NS, BH, and BL) led the implementation of the project to support cultural safety.

Participant Sampling

Women aged ≥16 years who were either mothers or primary carers of Aboriginal or Torres Strait Islander children aged birth to 5 years or were pregnant (≥30 weeks' gestation), owned or regularly used a smartphone, and had accessed a participating service (an Aboriginal health service or NSW health service) were eligible to participate. Health professionals from the participating health services and early educators from the participating preschools of all cultural identities who worked with women or children were eligible.

Procedures

This study was conducted remotely from August 2020 to March 2021 using telephone, SMS text messages, and videoconferencing owing to COVID-19 restrictions. Participants were recruited from 3 regional locations in NSW, Australia. A total of 5 Aboriginal organizations (2 Aboriginal health services, 2 Aboriginal preschools, and 1 Aboriginal family and parenting corporation) and 3 NSW health sites participated. In total, 2 Aboriginal researchers (NS and BH) completed most of the recruitment, consent procedures, interviews, and communication with the participants and services in line with the AH&MRC Ethical Guidelines to ensure culturally safe, best practice research procedures *(2.2.3, 2.3.3, 2.5.2, and 3.3.1)* [26].

Women who participated in the co-design phase [23] were contacted via phone and invited to participate in the pilot study. Convenience snowball sampling was also used [27]. The Aboriginal researchers (BH, NS, and BL) used their personal networks to recruit additional participants. The participants were also asked whether they would like to recommend a friend or family member to the study. The participating health services also reached out to potential participants. Potential participants were screened for eligibility when contacted by the researcher via phone. The researcher explained the study and obtained informed consent. The participants were sent an SMS text message with a link to a baseline survey on REDCap (Research Electronic Data Capture; Vanderbilt University) before starting the pilot study. During the 4-week study period, the participants were given access to the intervention (Textbox 1). The participants were sent a link via an SMS text message to access the application, and where possible, the research team contacted the participants to check whether they were able to access the application, explain the use of the application, check whether they were receiving SMS text messages, and explain how to like the Facebook page. The participants were asked to access the application as often as they felt compelled to, that is, there was no required amount of time that women needed to spend on the application or other parts of the program. Following the Facebook page was optional. After 4 weeks, the participants were contacted via telephone for an interview. Semistructured interviews with a mixture of open- and closed-ended questions [28] were conducted by Aboriginal researchers (NS and BH) and a non-Indigenous PhD student (SJP). The interviews were 6 to 25 minutes in length. They were recorded and transcribed, and interview notes were taken as a backup to recordings [28]. The participants were reimbursed with a shopping voucher worth Aus $20 (US $30) at baseline, a shopping voucher worth Aus $10 (US $15) per week for the 4-week pilot study Aus $40 (US $60) in total to cover data use, and a shopping voucher worth Aus $20 (US $30) for participating in the follow-up interview. The interviews were completed between August and September 2020.

Textbox 1. Components of the prototype intervention.

Application

- The application is a central place for users to access all content. The application is primarily for the user who wants in-depth information and has the necessary digital device, internet connection, and literacy skills to access it. The application has four menu screens as follows: (1) home screen, (2) women's health, (3) children's health, and (4) contacts. The Facebook (Meta Platforms, Inc) page content feed was embedded into the home screen. The women's health menu page includes six buttons, one for each of the women's health modules as follows: (1) smoke-free families, (2) safe drinking, (3) feeling good, (4) women's business, (5) eating, and (6) exercising. The Jarjum's Health modules include (1) breathing well; (2) sleeping; (3) milestones; (4) feeding and eating; (5) vaccinations and medicines; and (6) ears, eyes, and teeth. Each topic includes (1) key messages incorporating the perceived threat of illness and benefits of changing health behavior; (2) tips to address the barriers to change through reassurance and credible advice; (3) cues to action, for example, "Each time jarjum sees a nurse or GP ask them to have a quick look in bub's ears to check if there is any infection"; and (4) links to further information, including information regarding skills and activities such as exercises and healthy recipes to support self-efficacy. The information is presented using small chunks of written information and videos using the same layout in each module.

Videos

- A total of 12 videos were developed (1 per topic). The length of the videos ranged from 1 minute and 42 seconds to 5 minutes. The videos included health professionals from the participating sites or contacts of the research team presenting key messages on each health topic. The presenters were given short scripts and encouraged to use their own expertise and experience. The videos were displayed in the application under each topic as well as added to the Facebook feed at least once. The users were able to watch the videos within the application; however, on Facebook, the users were taken to an external Vimeo (Vimeo, Inc) platform to view.

Facebook page

- The purpose of the Facebook page was to create community and connection, allow 2-way communication, and use a platform that is highly popular among users. Daily content was added to the Facebook page, including (1) links to reliable health websites, (2) activities for families, (3) weekly competitions, (4) key messages on the health topics listed earlier (written and video), (5) events in the community, and (6) supportive affirmative posts. The page was administrated by 2 Aboriginal team members (NS and BH), who shared posts relevant to their community and region.

SMS text messaging

- The SMS text messaging component allowed the users access to health information regardless of their mobile phone type, Wi-Fi access, or digital literacy. The SMS text messaging portion of the program was 1 way (unidirectional). The SMS text messages included two core topics: (1) breathing well and (2) smoke-free families, and the participants chose 3 additional topics (from the topics covered in the application). The women received 1 message per day for 5 days per week for 4 weeks (20 SMS text messages in total).

The professionals who participated in the co-design phase were contacted via phone and invited to participate in the pilot study. Where these professionals were no longer working at the service, other professionals known to the Aboriginal researchers were contacted to participate. A total of 2 focus groups were conducted in February and March 2021. Focus groups [28] were conducted rather than individual interviews as per the professionals' preference. Consent was initially obtained over the phone and then again in person, videoconference, or email before starting the focus group. A brief survey was conducted at the start of the focus group. The professionals accessed the program during the focus group only (not during the 4-week pilot study). We were interested in the professional's feedback on the content only, not in how they might engage with the program over 4 weeks, as they were not the target end users. It was important, however, to obtain feedback from professionals who routinely provide health information to mothers, as they may be instrumental to the implementation of the program, if the program is effective. One focus group was conducted in person (as COVID-19 restrictions had been lifted) and another over videoconference. The focus groups were 13 and 21 minutes in length. The professionals were not reimbursed.

Measures

Demographics and Cultural Characteristics

The survey completed by mothers was a 16-item survey including demographic, cultural, and socioeconomic items. The items were selected from a previous study [29], with all items having been tested with Aboriginal and Torres Strait Islander mothers previously. The survey completed by professionals comprised 5 items related to demographic and professional practice characteristics.

Engagement

Objective measures are common for measuring the engagement of applications [30]. The user activity metrics collected included the number of log-ins, number of page views, length of page view, and number of links used on the application. We used user activity metrics in combination with interview data to identify user typologies. Data collected for the videos included the number of plays in total and per video, number of videos watched in full (completions), duration watched (in seconds; mean seconds and percentage), and number of unique videos. Data collected for the Facebook page included the number of posts by administrators, number of page likes, number of comments, number of followers, and the reach of posts and videos. Data were collected on topics that the women chose to receive SMS text messages on and the number of women who

opted out of receiving SMS text messages. User engagement was evaluated only for the women participants (end users), not for the professionals.

Acceptability

An interview schedule was adapted from a previous study on the acceptability of a culturally tailored SMS text messaging program for mothers [31]. The interview schedule included the following topics: usefulness of the program, cultural appropriateness of the program, ease of understanding, appropriateness of the program, relevance of the program, perceived impacts, and suggestions for improvements. A shortened and adapted version of the interview schedule was used with professionals, which included items on usefulness and cultural appropriateness.

Data Analysis

The interview data were analyzed and summarized using descriptive quantitative analyses including means, SDs, and proportions [32]. Qualitative comments were analyzed using a simple thematic analysis with predetermined codes based on the research areas, for example, cultural appropriateness [28]. One of the researchers (SJP) cleaned and coded the responses for each predetermined code. Then, 3 researchers (SJP, BH, and NS) reflected on and discussed the participant quotes to form a summary statement for each code and select representative quotes.

Ethics Approval

Human research ethics approval was received from the AH&MRC (1485/19) and University of Newcastle (H-2019-00760).

Results

Overview

A total of 47 participants were recruited for the study: 41 (87%) women and 6 (13%) health professionals. The average age of the women was 31 (SD 7.35) years. The women were from 15 different communities; Kamilaroi (12/41, 29%) and Gumbaynggirr (10/41, 24%) were the most common. Almost half of the women (20/41, 49%) in this study had participated in the co-design phase of the project. The demographic characteristics of the participants are presented in Tables 1 and 2.

Table 1. Demographic and cultural characteristics of women (n=41).

Characteristics	Values
Age (years), mean (SD; range)	31.54 (7.35; 17-50)
Participation in the co-design phase, n (%)	
Yes	20 (49)
No	19 (46)
Not sure	2 (5)
Indigenous status, n (%)	
Aboriginal	34 (83)
Torres Strait Islander	0 (0)
Both	0 (0)
Nonidentified	6 (15)
Unknown	1 (2)
Identified with an Indigenous community, n (%)	
Yes	25 (61)
No	5 (12)
Unknown	11 (27)
Maintain cultural connections at home (yes), n (%)	28 (68)
Ways of connecting to culture, n (%)	
Music or dance	22 (82)
Storytelling	21 (78)
Art	20 (74)
Indigenous television	18 (67)
Food	12 (44)
Indigenous internet sites	12 (44)
Indigenous newspapers	7 (26)
Traditional medicine	5 (19)
Indigenous radio	4 (15)
Other	3 (11)
Family members from the Stolen Generations[a], n (%)	
Yes	14 (34)
No	13 (32)
Unknown	14 (34)
Education of the mother, n (%)	
Did not finish high school	7 (17)
High school	13 (32)
Certificate	11 (27)
Bachelor’s degree	4 (10)
Diploma	3 (7)
Postgraduate degree	2 (5)
Not applicable	1 (2)
Number of people living in household, mean (SD; range)	4.17 (1.72; 1-8)
Number of children (aged <18 years) living in household, mean (SD; range)	2.44 (1.48; 1-6)
Smoking status of the mother, n (%)	

Characteristics	Values
Nonsmoker	31 (76)
Yes, daily	10 (24)
Yes, at least once a week	0 (0)
Yes, less often than once a week	0 (0)
Number of cigarettes smoked per day (on smoking days), mean (SD; range)	10 (4.32; 2-15)
Smoking status of the partner (yes; n=25), n (%)	9 (36)
Number of smokers in household, n (%)	
0	24 (59)
1	14 (34)
>2	3 (7)
Child exposure to indoor tobacco smoke (yes), n (%)	0 (0)
Child exposure to outdoor tobacco smoke (yes), n (%)	7 (17)
Child exposure to tobacco smoke in the car (yes), n (%)	0 (0)

[a]The Stolen Generations refers to a period in Australia's history where Aboriginal children were removed from their families through government policies. This happened from the mid-1800s to the 1970s [33].

Table 2. Demographics of professionals (n=6).

Characteristic	Values
Service type, n (%)	
Aboriginal medical service	3 (50)
Aboriginal preschool	3 (50)
Sex (female), n (%)	6 (100)
Indigenous status, n (%)	
Aboriginal	2 (33)
Torres Strait Islander	0 (0)
Nonidentified	4 (67)
Role at health service, n (%)	
Registered nurse	2 (33)
Midwife	1 (17)
Codirector or early educators	3 (50)
Number of years at service, mean (SD; range)	10.5 (8.8; 1-25)

User Engagement (n=41 Women)

App

Of the 41 women, 31 (76%) participants accessed the application. Among these 31 participants, there were 154 log-ins, with an average of 5 log-ins per person. Of these 31 women, 13 (42%) users scrolled the main page only, and the remaining 18 (58%) users moved past the main page by clicking on other pages. A total of 23% (7/31) of the users clicked on 10 website links.

A total of four user typologies were identified: (1) could not use the app, (2) obligated to use the app, (3) reviewers, and (4) researchers. The "couldn't use the app" group included those who could not log into or download the application. The "obligated to use the app" group included those who used the app to provide feedback in a research context and probably would not use the application in a real-world setting. The "reviewer" group included those who logged in once or twice out of curiosity to see what the application included but did not consistently use the application. The "researcher" group included those who used the application more regularly; they were users who likely wanted more information than available in the SMS text messages or on the Facebook page. By analyzing the user activity metrics, we estimated that 20% (8/41) of the women were "researchers," indicating that they may have long-term engagement with the application in the real world.

Videos

There were 48 plays of the 12 videos (Table 3). The number of plays ranged from 0 for "Milestones" and "Exercise" videos to 11 plays for "Sleeping" video. The number of unique viewers

ranged from 1 to 5 per video. The highest number of unique viewers was for the "Feeling Good" video. Among the 48 plays, there were only 6 (13%) video completions. The mean viewing time was 38 seconds. The ability to obtain feedback on the video content may have been limited by the fact that the videos were not watched by most women. One reason for this was that to watch the videos on the Facebook page, the user needed to leave the Facebook page and watch them on an external host (Vimeo [Vimeo, Inc]). Another reason may have been that the videos were not clearly displayed in the application. Finally, the duration of the videos may have been too long.

Table 3. Engagement with the application videos.

Video	Plays (n=48), n (%)	Completions (n=6), n (%)	Viewing time (seconds)[a], mean	Unique viewers, n[b]
Sleeping	11 (23)	1 (17)	22	3
Ear health	9 (19)	1 (17)	77	3
Eating well	7 (15)	1 (17)	6	3
Breastfeeding	5 (10)	1 (17)	115	4
Feeling good	5 (10)	0 (0)	63	5
Women's business	4 (8)	1 (17)	72	1
Smoke free	4 (8)	0 (0)	11	1
Safe drinking	1 (2)	0 (0)	0	1
Vaccinations	1 (2)	0 (0)	0	1
Breathing well	1 (2)	1 (17)	89	1
Milestones	0 (0)	0 (0)	0	0
Exercise	0 (0)	0 (0)	0	0

[a]Total mean viewing time was 38 (SD 42.2) seconds.

[b]The average number of unique viewers was 2 (SD 1.62).

Facebook Page

Facebook administrators (Aboriginal researchers BH and NS) posted 101 posts over the 4-week pilot study. The page received 49 page likes and 51 followers, indicating reach beyond the study participants. The post with the highest reach was a supportive and affirming cultural post, which reached 308 people and had 17 reactions, comments, or shares. The second most popular post was a competition post, which reached 58 people and had 23 reactions, comments, or shares. The videos posted on Facebook (n=12) had an average of 20 people reach but only 1 to 2 reactions, comments or shares or clicks to watch externally.

SMS Text Messages

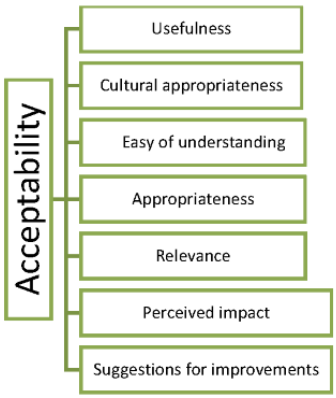
No participants opted out of the SMS text messages. The participants selected 3 topics to receive SMS text messages on. In the order of popularity, the topics chosen were ears, eyes, and teeth (23/41, 56%); sleeping (19/41, 46%); exercising (17/41, 41%); feeding and eating (13/41, 32%); eating (12/41, 30%); women's business (12/41, 30%); milestones (10/41, 24%); feeling good (10/41, 24%); vaccinations and medicines (6/41, 14%); and safe drinking (0/41, 0%).

Acceptability

Overview

Of the 41 women, 32 (78%) were interviewed at the end of the pilot study. All the 6 professionals were interviewed. There were 7 themes identified in the analysis related to the acceptability (Figure 1).

Figure 1. Themes.



Usefulness

Almost all women (30/32, 94%) reported that the Growin' Up Healthy Jarjums program was useful. On a scale of 1 (a little useful) to 5 (extremely useful), the mean rating of usefulness was 3.9. Furthermore, 84% (27/32) of the women reported that the program was relevant to them.

All women (30/32, 94%) reported that they would recommend the program to other families; the reasons included the following: helpful to first-time mothers, younger mothers, and mothers without family and other supports; ease of having all information in 1 spot; connection with other mothers; provides a sense of community; visually appealing and representative of Aboriginal and Torres Strait Islander people; and an accessible place for women feeling too ashamed or isolated to go the hospital or physician to access reliable health information:

> *I reckon just the feeling of still being connected, and being supported. I think it's a nice way, especially for mums with little, little kids, I reckon sometimes you feel pretty isolated, especially if you're not working and stuff. I think it's a nice way to still feel like someone's looking out for you or thinking of you.* [Participant 6]

> *I think it's a good tool for our community, especially the young ones that we've got who may not have anywhere else to go to find that information or who are too ashamed to ask. I think having it in a way that they can find it themselves in an easy format is a good thing.* [Participant 27]

All professionals (6/6, 100%) reported that the Growin' Up Healthy Jarjums program was useful. On a scale of 1 (a little useful) to 5 (extremely useful), the mean rating of usefulness was 3.3. All the professionals reported that they would recommend the program.

The professionals reported that the program would be useful to families for different reasons. Some of the cited reasons are as follows: the program is relatable to mothers because of co-design methods; using Facebook will result in family and friends seeing the health information; "Storytime" would be good for families that have less access to books; Facebook page was welcoming, easy to access, and visually attractive; the app was easy to navigate and would be easy for mothers to look through while "on the go"; overall, the program has a good balance of content, including health information, affirmations, and what is on in community; the Facebook page may be a good place for women to get ideas from each other and chat about recommendations from the posts; the Facebook page would be a good place for women to connect and not feel isolated; and the content is largely positive, which is important:

> *I like, on the Facebook page, it gives you a sense of not being so isolated. The Facebook page is a really nice place for Aboriginal mums or families to not feel isolated if they're being recommended all this stuff and things to do outside of their lives, and then there's the affirmations. It's probably a really nice place for them to be especially if they're suffering any mental health or with any isolation in their own lives.* [Participant 6]

Cultural Appropriateness

All the women (32/32, 100%) reported that the program was culturally appropriate. They reported that the colors, graphics, and language used were culturally representative. Of the 32 women, 1 (3%) woman recommended using different languages depending on what community the program is intended for. Another woman who had no exposure to her culture said that it was a helpful way to learn about her culture:

> *I'm Aboriginal, but I only just learnt of my Aboriginality, so I wasn't actually brought up that way [according to her culture]. So it was helpful for me to learn new terminologies and stuff like that.* [Participant 3]

All the professionals reported that the program was culturally appropriate. A total of 33% (2/6) of the professionals commented on the cultural appropriateness of the language in a positive light. Overall, 17% (1/6) questioned whether the language would be difficult for some women to understand. She emphasized the need to ensure that representatives from each community that the program would be used in be involved in developing the content as well as to administer the Facebook page to ensure that the program continues to be relevant to women from different communities:

> *You've got different lingos, different meanings, different sayings that's going to grab attention [in different communities]. When I look through these text messages there are some words in here that I would think some of our women wouldn't really understand. You actually need the women to do it, they're very different to the workers. They're the ones that are going to give you the right language.* [Participant 1]

> *It's all culturally appropriate...the language is really nice. It's really easy to read and interpret. It doesn't have any of those big, yukky words that can be quite clinical.* [Professional 5]

Easy to Understand

All the women (32/32, 100%) reported that the content was easy to understand. They talked about the program being jargon free but not too simplified:

> *It was spoken to you normally, not like all the medical jargon, do you know what I mean? It was understandable and relatable. I think if it's too technical sometimes, it gets overwhelming.* [Participant 20]

> *It wasn't dumbed-down. Like some things that we give to Aboriginal families that we get, some of them are so simplified that makes people think that we're stupid, but this wasn't. It was easy to understand, but it didn't make me feel stupid, didn't make me feel bad.* [Participant 27]

Appropriate

Most women (28/32, 88%) reported that the activities and information were appropriate. However, of the 32 women, 1 (3%) woman suggested that the language in the SMS text messages could have been more professional rather than colloquial:

> *We followed what was on those messages each day. We made it a project with our kids because we thought we would see how it would go. My son likes looking at the pictures of it when they've had the Facebook competitions because it was all kids that he knew.* [Participant 27]

Relevance

Most women (27/32, 84%) reported that the program was relevant to them and their family. They said that it was good having other mothers to relate to and access to reliable health information to talk to family about:

> *Just sort of seeing other women with kids and stuff and sort of just having someone to relate to, somebody that's a little bit more similar to me. So you don't feel so alone in what you're kind of going through. Things that you might think are silly or you're a bit shamed to ask anyone. At least the messages address it and then you can see other women on the Facebook page.* [Participant 4]

> *I learnt some good stuff. I think the thing I like most about the program for us personally, it allowed me to have conversations with my partner about smoking. With the program I was able to say 'hey I got a text about smoking,' 'do you know this' it meant that it wasn't just me making points. I sort of used the app as the conversation starter.* [Participant 18]

The women who did not find the content relevant to them (2/32, 6%) said that they already knew the information or felt that the information was targeted toward women caring for younger children. Of the 32 women, 2 (6%) women also made comments about some SMS text messages not always being relevant to their family:

> *Some of them [SMS] might not be relevant to me personally, but I think as a community they are. The messaging was consistent, and I think that's really important.* [Participant 6]

> *My little boy is older now, he's two. So I felt like a lot of the messages and stuff like that, was more around the newborn stuff. But in saying that, if I had a newborn still, then it would have been more relevant.* [Participant 10]

Perceived Impact

Of the 31 women who commented on the overall positive impact of the program, 22 (71%) women reported that the program had an overall positive impact on themselves and their family. Table 4 presents a summary of the perceived impacts. The most common perceived impact was feeling more supported (21/29, 72%), followed by improvements in knowledge or understanding of child health (13/26, 50%), eating habits (11/29, 38%), and exercise (11/29, 38%). Many women commented on the supportive and affirming aspects that the program provided, including the validation of how hard parenting can be; information that certain health problems, such as ear infections, are common in children (validating that it was not their fault); the feeling that a service cared about their child's health; and the feeling that someone cared about them, which arose because of the reception of regular messages:

> *The favourite text of mine was the reminder that we all have rough days...And that it was okay, I thought you know what, yeah, I am going to take a breath right now, and it is all okay.* [Participant 10]

> *It was good to know that there was a service out there that did care I guess or had an interest in my son's health.* [Participant 14]

Other positive impacts that the women discussed included getting their child's ear health checked by a general practitioner, more play with children, spending time together as a family, taking children for hearing and vision tests, more exercise, taking care of themselves, talking to friends and family about quitting or reducing smoking, cooking with children, limiting alcohol, getting their child immunized, improved knowledge of contraception, and improved family eating:

> *Usually I'm the type where I walk to the park and then watch her play. When I read the messages, I'm like, I should actually try with her more, and be more active with her at the park.* [Participant 24]

> *I was drinking far too much, it was just a stress handling thing, because we did have a lot of problems, and it was difficult the first couple years. And so, getting that information, that really helped me to kind of kick that habit and to look at my own lifestyle and stuff.* [Participant 9]

Other women experienced stressful life situations at the time and had competing priorities, limiting the potential impacts of the program.

Table 4. Perceived impact (n=32).

	Participants who responded, n (%)	Participants whose response was yes, n (%)
Overall positive impact	31 (97)	22 (71)
Improvements to your smoking habits (if a smoker)	30 (94)	5 (17)
Family or friend smoking habits (if a smoker)	30 (94)	2 (7)
Child's exposure to second-hand smoke	29 (91)	8 (28)
Positive impact on family eating habits	29 (91)	11 (38)
Positive impact on physical activity	29 (91)	11 (38)
Improvements to knowledge of women's health	28 (88)	8 (29)
Improvements to knowledge of child health	26 (81)	13 (50)
Feeling more supported	29 (91)	21 (72)

Suggestions for Improvements

The most common suggestion for improving the program was to make changes to the application to overcome technical challenges. Of 32 women, at least 6 (19%) experienced technical problems. Difficulty in downloading and saving the web-based application, rather than accessing an Android or iOS (Apple Inc) app, was the main difficulty. Almost half of the women (14/32, 44%) suggested improvements to the application, including making the web-based application an Android or iOS app so that it "looks" like an app, removing the step of saving to the application to home screen, implementing single log in, making navigation simpler, making the application accessible on all phone types, localizing the application to specific communities, and making the application more interactive:

> *I had to log back in and it would take me to the web page. It kept wanting me to resave it to my home screen, but it was already saved to my home screen. I wasn't too sure what was going on there.* [Participant 30]

The next most common suggestion is related to the SMS text messages. A total of 59% (19/32) of the women reported that there was just the right number of SMS text messages, but 38% (12/32) of the women reported that the SMS text messages were too frequent. The women indicated the preferred timing of SMS text messages to be earlier in the day and a preference to have SMS text messages from the same sender phone number for ease of reviewing.

Other suggestions to improve the program overall included suggestion to ensure better tailoring to the child's age as well as suggestions for alternate topics (eg, parenting, toilet training, separation, toddler development, mental development for boys, available services, preschool readiness, allergies, and resources and services specific to Aboriginal people), suggestion to provide less content about smoking, suggestion to provide more links to further information (eg, local mothers' groups), and suggestion to provide to make the program more interactive:

> *If it is targeting under five, some of the information could be more around toilet training, difficulties with separation, entry to preschool, advice on services and stuff, like Koori stuff around.* [Participant 9]

In total, 6% (2/32) of the women talked about web-based groups: 1 woman suggested a Facebook group (rather than a Facebook page) and another suggested a chat group within the application (to discuss specific topics). Moreover, 6% (2/32) of other women talked about the importance of the continuation of the program and the longevity of Aboriginal and Torres Strait Islander health programs in general, as Aboriginal health programs often have short funding cycles and the community is left with a gap:

> *I would have benefited more with the Facebook group if it was an actual group created, because normally you get notifications and stuff when you're in the group and it tells you who's posted what. I probably would have had more interaction with that if that was a constant notification coming up.* [Participant 13]

> *Keep it going. We find sometimes that programs are really good and then they stop. When the funding runs out or it doesn't get approved or whatever it stops and then that's a gap.* [Participant 27]

The professionals suggested several ways to improve the program, including continued involvement of women in the development of the program to ensure that the language and content remain relevant and appropriate, including for families living in regional and remote areas. Another professional suggested that the content should be current and tailored to the age of the child. Another suggested a "search" feature in the application so that families could easily search for the health issue or topic that they are interested in (otherwise, mothers will likely Google health information, which can make it difficult to determine reliable sources). Another suggested more specific steps about how to manage certain illnesses and to include more common childhood illnesses. Another suggested that the application needs to be more interactive, for example, tailored specifically to the child's age, with notifications for activities for that age group or milestones. One other professional suggested forums or private group chats so that discussions are not public, whereas another suggested providing grandparents and other family members access to the program.

Discussion

Principal Findings

Overall, the Growin' Up Healthy Jarjums program was found to have high acceptability. The results indicate that women found the program to be useful, culturally appropriate, and easy to use, and most women reported positive impacts. None of the participants withdrew from the SMS text message portion of the program, which indicated the high acceptability of and engagement with this component. Engagement with the Facebook page was found to be higher than that with the application. Individual users preferred different modes (SMS text message, Facebook page, or application), indicating that a multimodal intervention increases reach. Importantly, this pilot study showed several ways to improve the program, including technical changes to the app.

Similar to other studies with Aboriginal and Torres Strait Islander people, the SMS text message component of this program appeared to have high acceptability and engagement [12-14]. This pilot study provided an additional opportunity to focus on mothers and examine the desired frequency of SMS text messages. The frequency of SMS text messages sent in mHealth trials is often 1 SMS text message per day, although it can vary from multiple SMS text messages per day to weekly SMS text messages [34]. In our study, women were sent 1 SMS text message per day for 5 days of the week over 4 weeks. Most women (19/32, 59%) reported that the frequency was just right, 38% (12/32) of the women reported that the SMS text messages were sent too often, and 3% (1/32) of the women reported that the SMS text messages sent were not enough. This finding is similar to that of another study that reported that 1 SMS text message per day was preferred by the majority (42%), whereas the remaining 58% preferred either more or less frequency [24]. Giving a choice of frequency of either 1 SMS text message per day or 3 SMS text messages per week may be more appealing to users.

The women reported that they liked having a choice of topics for SMS text messages, as this increased relevance. Some women commented on the core (requisite) topics, indicating (1) breathing well and (2) smoke-free families as being irrelevant to them and their families. SMS text messages on smoking cessation and child lung health were requisite based on the original focus of the intervention to promote child lung health, including smoking cessation. The focus on child lung health was based on the call for more culturally appropriate information on childhood coughs [35]. In addition, there is strong evidence that SMS text messages are effective for quitting smoking [36]; thus, we decided to keep the focus on child lung health, including smoking cessation, for the SMS text message portion of the pilot. Furthermore, many of the SMS text messages were targeting the first 2 years of life, as that was the age range in which we expected to recruit most children; however, many of the children were older, which meant that some of the information was not relevant, although most women commented that they could see how beneficial the information would have been when their children were young. Encouragingly, the number of women who reported the SMS text messages to be irrelevant was low (3/30, 10%), similar to another study on SMS text messages for new mothers (6/22, 21%) [31]; however, giving users the choice of all topics may be a more acceptable and useful approach allowing for better tailoring to end users' health information needs and interests.

Many participants experienced technical challenges in accessing the app, with nearly one-fourth (10/41, 24%) having been unable to access it. The prototype application used in the pilot study was a web-based application. A web-based application is accessed through an internet browser, such as Google Chrome (Google LLC) or Firefox (Mozilla Foundation), and is essentially a website designed to look like an Android or iOS app. Android or iOS apps are downloaded from an app store and saved on the phone [37]. The benefits of web-based applications are that they are fast to build, they are cost-effective, and their content can be changed easily [37]. The benefits of Android or iOS apps are that they are faster than web-based applications; they can work without internet connection; and end users are generally more familiar with them, including with downloading and saving them [37]. Using a web-based application for this trial resulted in many women having difficulty logging in and saving the application on their home screen. The women also commented that it did not "look" like an application and that it was slow. Other application trials with Aboriginal and Torres Strait Islander people have largely used Android or iOS apps [15,38-41]. Of these studies, 1 was unable to collect use data for 34% (21/61) of the participants reporting flat batteries, connectivity issues, and other problems [41]. A second study reported technical difficulties for participants with using the "challenge" function and signing in and out, although it was noted that technical challenges did not significantly impact the use for many participants [15]. In a third study, an app was used by clients with a practitioner present, and technical difficulties were reported with an Android emulator to enable compatibility with Windows [40]. The fourth study used the same app as the previous study [40] with a different population; thus, it was also used by clients with a practitioner present, but no technical difficulties were reported [39]. Although many studies evaluating mHealth apps have reported technical challenges, it seems that using a web-based application may have resulted in more users experiencing technical challenges and a more substantial challenge of not being able to log in or save the application. With a large proportion of women having had difficulty accessing the application, most of the feedback on the application was centered on the technical challenges, and there was limited feedback on the content. However, it was useful to discover during this early phase that a web-based application is not feasible. An Android or iOS app will need to be considered before further evaluation with a small group of end users to provide detailed feedback on content and navigation.

In addition to considering the technical barriers to accessing applications, careful consideration must be given to long-term engagement [16]. In a longitudinal study examining the reasons for continued use of mHealth apps, two connected factors were described: (1) users' assessment of the mHealth app (related to the technology and content) and (2) users' persistence of health goals (ie, those who have higher persistence toward reaching

their goals appear to have longer engagement with health apps) [16]. The authors concluded that long-term engagement with health apps occurs when there is high user assessment and high persistence toward health goals [16]. With improvements to the technical aspects of the Growin' Up Healthy Jarjums application, we expect to see improvements in initial access and a small increase in long-term engagement, although it is evident that an application is not going to be engaging to all users. Health applications are suggested to be most engaging for users who are younger, are more educated, and have higher levels of eHealth literacy skills [42]. It is also suggested that the use of health applications can improve when support from a clinician or another medical professional is provided [43]. The findings from this pilot would also suggest that those experiencing distressing life situations may find it difficult to engage with a health application, similar to the findings that suggest mental health applications may be more suitable for those with less severe illness [43]. As health applications are likely to continue to improve as technology continually does, engagement with health applications will also improve. However, at this point in time, it seems apparent that mHealth tools should be provided in a range of delivery modes to increase reach, digital inclusivity, and equity.

One such delivery mode is social media. It has been established that Aboriginal and Torres Strait Islander people are avid users of social media, Facebook in particular [8-11], which is a key reason why a Facebook page was part of the Growin' Up Healthy Jarjums program. The qualitative findings from our pilot suggest that the Facebook page had high acceptability. The women commonly reported that they valued the connection and seeing what other families were doing. It can be difficult to track engagement with Facebook using objective data because of privacy measures and the complexity of identifying whether users accessed the page as "observers," rather than more active users, which can be done only by examining page likes, comments, shares, etc [10]. A qualitative study examining social media and health information sharing among Aboriginal and Torres Strait Islander people shed more light on how social media are used for health promotion by identifying six typologies: (1) observer, (2) post sharer, (3) positive supporter, (4) educator, (5) expert, and (6) influencer [10]. Although we do not have the data to compare all typologies with the previous study, our results indicate that mothers were more likely to be "observers," with many women reporting the value of connection and seeing what other families were doing but not often commenting, liking, or sharing posts during the study. Posts that were shared or commented on were more likely to have been posts uploaded by Aboriginal organizations, posts affirming Aboriginal culture, or posts about competitions where a prize could be won. The previous study used a methodology different from the one used in this study, wherein they had participants monitor their social media accounts for health-related content and conducted weekly interviews to explore perspectives and actions on posts. Interestingly, the authors found that users moved between typologies depending on the health topic and how information was provided [10]. In future research on the Growin' Up Healthy Jarjums Facebook page, it may be useful to use a similar methodology with a subset of participants to better understand what and how health information is shared among mothers with young children, as well as how this correlates with changes in health literacy offline; given the high acceptability of and engagement with Facebook among this group of end users, Facebook has great potential to improve health literacy.

Limitations

A limitation of this study was the need to conduct all recruitment and instruction of the program remotely using SMS text messages, links, and phone calls owing to COVID-19 restrictions. In the initial protocol, we proposed recruiting women, setting up the app, and providing instructions on how to use the application in person to reduce technical problems. Unfortunately, this was not possible, and women experienced a high number of technical problems. With a large proportion of women having had difficulty accessing the application, most of the feedback on the application was centered on the technical challenges, and there was limited feedback on the content; however, it was useful to discover during this early phase that a web-based application is not feasible. An initial in-person setup would be considered important for further use of the program.

Another limitation of this study is that generalization to other communities is limited. Aboriginal and Torres Strait Islander communities are made up of many diverse cultural and language groups [1]. Each community has a unique history, cultural practices, and health needs. The Growin' Up Healthy Jarjums program would need to be adapted, including by making changes to language, images, and health advice, to ensure cultural safety and relevance to women from other communities.

Conclusions

This study demonstrates that the Growin' Up Healthy Jarjums program was perceived as useful and culturally appropriate by users and health professionals. The SMS text messages had the highest engagement, followed by the Facebook page and then the application. This study identified suggestions for improving the application. A trial is needed to assess the effectiveness of the Growin' Up Healthy Jarjums program at improving health outcomes.

Acknowledgments

The authors would like to acknowledge and pay their respects to the Aboriginal and Torres Strait Islander women who shared their views and knowledge in the study. They would also like to acknowledge the Aboriginal Community Controlled Health Services that participated—Armajun Aboriginal Medical Service (AMS), Galambila AMS, Awabakal AMS, Kulai Aboriginal preschool, and Muloobinba Aboriginal Corporation—and the New South Wales health sites that participated—Aboriginal Maternal and Infant Health Services located in Inverell, Coffs Harbour, and Newcastle. Furthermore, the authors would like to acknowledge

the incredible graphic designs completed by Krystal Randall of Culture, Art and Digital Design. Finally, the authors thank the researchers from the National Institute for Health and Innovation, Auckland University, for sharing their expertise on mobile health.

Conflicts of Interest

None declared.

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Abbreviations

AH&MRC: Aboriginal Health and Medical Research Council
mHealth: mobile health
NSW: New South Wales
REDCap: Research Electronic Data Capture

Edited by S Badawy; submitted 19.10.22; peer-reviewed by V Kerrigan, M Cozad; comments to author 20.01.23; revised version received 17.03.23; accepted 30.03.23; published 26.05.23.

Please cite as:
Perkes SJ, Huntriss B, Skinner N, Leece B, Dobson R, Mattes J, Hall K, Bonevski B
Evaluation of an mHealth Intervention (Growin' Up Healthy Jarjums) Designed With and for Aboriginal and Torres Strait Islander Mothers: Engagement and Acceptability Study
JMIR Pediatr Parent 2023;6:e43673
URL: https://pediatrics.jmir.org/2023/1/e43673
doi:10.2196/43673
PMID:37234043

Original Paper

Features, Design, and Adherence to Evidence-Based Behavioral Parenting Principles in Commercial mHealth Parenting Apps: Systematic Review

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Abstract

Background: There is a need to disseminate evidence-based parenting interventions for adolescent externalizing concerns. Although family-based treatments have demonstrated efficacy for such concerns, they have limitations and challenges when disseminated in the community. Behavioral-based parenting techniques form an integral part of well-established, family-based interventions for adolescent behavioral problems and are ideal for dissemination through coupling with smartphone technology. Despite the vast number of "parent" apps currently available in commercial markets, there is a dearth of reviews focused on evaluating mobile health apps through the lens of behavioral parenting training (BPT).

Objective: This study aimed to conduct a systematic review of commercial mobile health apps for parents to increase effective parenting skills that include behavioral components.

Methods: A search of the Google Play and Apple App Stores identified 57 apps that were included in the review and coded for availability, popularity, and infrastructure. In total, 89% (51/57) of them were sufficiently functional to be assessed for app design quality (engagement, functionality, esthetics, and information), and 53% (30/57) proceeded to the final evaluation of level of adherence to BPT principles.

Results: In total, 57 apps met the initial inclusion criteria. Accessibility was high across these apps given that 44% (25/57) were available on both the Google Play and Apple App Stores and 68% (39/57) were free of charge. However, privacy concerns were addressed inconsistently among the apps. App design quality was average across the included apps, and apps with positive user star ratings or a high number of downloads received higher ratings on app design quality. In contrast, the identified apps largely fell short in providing BPT components adequately and with high interactivity, with low levels of adherence to BPT (mean 20.74%, SD 11%) across all commercial apps evaluated. Commercially popular apps did not show higher levels of adherence to BPT. Overall, a moderate relationship between app design quality and adherence to BPT was found. App features that have been found to increase user engagement, such as gamification and individualization, were only observed in a small minority of apps. Overall, there was a lack of focus on teenage development.

Conclusions: Future app developers hoping to increase the dissemination of BPT should aim for free and accessible apps that balance high-quality design features (eg, simple esthetics, interactivity, and individualization) with content consistent with BPT principles. They should also consider key issues that are inconsistently addressed in current apps, including privacy and teenage development. Future app developments will likely benefit from multisector (industry and academic) collaboration throughout the design process and involving end users (ie, parents) during different stages of app development.

(JMIR Pediatr Parent 2023;6:e43626) doi:10.2196/43626

KEYWORDS

mobile phone; parent; behavioral parent training; parent management training; mobile apps; mobile health; mHealth; child; adolescent

Introduction

Background

The need for effective parenting interventions for parents of adolescents with behavioral problems in community service settings is an important public health issue in the United States [1,2]. National surveys indicate a high prevalence of behavioral or conduct problems in children and adolescents, whereas only half have received any treatment [3]. Despite this high demand, there is a substantial lack of evidence-based parenting support programs specific to parents or as part of services for adolescents in the community [1]. Although family-based therapies are more commonly found in community mental health clinics and are efficacious in increasing the use of effective parenting strategies [4,5], barriers such as cost and provider expertise limit implementation and dissemination [1]. However, behavioral-based parenting techniques [6-8] are an integral part of these interventions [9,10] and can be effectively delivered through smartphone technology [11].

Mobile health (mHealth) has emerged as a promising option for using smartphone technology to increase the reach of behavioral-based parenting programs such as behavioral parenting training (BPT) for parents of adolescents with behavioral problems [12]. The commercial industry of mHealth has certainly proliferated, and there is parent demand. The number of health and wellness app downloads has reached an estimated 3.35 billion worldwide [13], and previous research suggests that parents turn to resources on the internet or smartphone apps to receive help with parenting to manage child behaviors [14,15]. Moreover, parents of teenagers with behavioral problems such as substance misuse have expressed interest in receiving support delivered through mHealth [16]. Although there has been a proliferation of commercial mHealth apps, research has not kept pace with evaluating parenting apps through the BPT framework [14,17,18], which limits our understanding of the usefulness of commercially available parenting apps for the management of child or adolescent behavioral problems.

The goal of this review was to identify commercial mHealth apps that include components of behavioral parenting techniques and evaluate the identified apps on app features, app design, and adherence to the theoretical framework behind BPT techniques and interventions. The intent of this review was to inform the selection of mHealth apps by providers and the development of new apps designed for parents of adolescents with behavioral problems [17].

Although there are several systematic reviews evaluating commercial mHealth apps related to physical activity (eg, exercise) and medical health conditions (eg, diabetes) [19], there are fewer reviews of commercial mHealth apps for mental health interventions other than for adult depression and substance misuse [20,21]. Regarding commercially available parent-targeted mHealth apps, the vast majority of previous reviews have focused on evaluating apps that provide information or interventions for medical or health concerns such as pregnancy; prenatal, postnatal, and infant care [18,22-28]; nutrition, physical activity, weight management, and medication adherence [29-31]; or parent education and health literacy about particular topics [14,32]. In comparison, few reviews of commercial apps have focused on evaluating the content and quality of parenting apps devoted to providing skills to parents through a BPT lens [17] (Magnuson, PsyD, unpublished data, May 2023).

We found 2 systematic reviews of parent-targeted commercial mHealth apps that focused on parenting children who have behavioral or mental health concerns [33,34]. Păsărelu et al [34] reviewed mobile apps addressing parenting skills for the management of child attention-deficit/hyperactivity disorder and noted the presence or absence of evidence-based elements. However, the review did not comprehensively evaluate the recommended treatments covered in the apps. Trahan et al [33] focused on parenting apps designed for low-income fathers in the United States but included a special focus on evaluating the apps through the lens of paternal self-efficacy and evidence-based factors that contribute to low-income father engagement. Evaluation of the extent to which apps adhere to specific evidence-based intervention strategies or theoretical principles is needed in a review of commercial mHealth apps for parenting practices.

Objectives

Given the empirical basis of BPT for child behavioral problems, the potential advantages of leveraging mHealth apps to deliver BPT, and the dearth of reviews focused on evaluating mHealth apps for their BPT or BPT-informed components, the major objective of this study was to conduct a systematic review of commercial mHealth apps for parents to increase effective parenting skills that include behavioral components. More specifically, we aimed to answer four main research questions regarding the identified apps: (1) What are the general characteristics of parent-targeted apps with BPT components or BPT-informed components that are available in the most frequently used commercial app stores (ie, Apple App Store and Google Play Store)? (2) What is the app quality (using the Mobile App Rating Scale [MARS] framework [35]) of parent-targeted apps with BPT components or BPT-informed components? (3) Are commercial apps with BPT components or BPT-informed components adherent to the theoretical framework of behavioral parenting interventions? and (4) What is the association among app characteristics (eg, platform and popularity), design quality, and adherence to the theoretical framework of BPT?

The results are discussed within the context of optimizing the digital translation of BPT into mHealth apps for parents. This review provides a picture of what is on the menu for the general public and could inform future development of mHealth apps

that aim to provide behavioral parenting interventions for parents of children with behavioral problems.

Methods

Search Strategy

A systematic review framework was used to search, screen, and assess commercial apps in English. An initial search of the US Google Play and Apple or iOS App Stores was completed by the first author (KL) in December 2021. A second, independent, parallel search of both stores was also conducted by the third author (LD) to ensure reproducibility and confirm the comprehensiveness of the initial app search. The searches focused on the US Google Play and Apple App Stores as they are the 2 leading mobile phone app markets [36,37]. Search terms were selected based on type of intervention (ie, parenting), target audience (ie, parents), and topic of concern (ie, child externalizing or behavioral concerns), consistent with the goals of this review. Colloquial paraphrases were added based on descriptions in app stores and terms used in previous reviews. Specific search terms included "parent," "parenting," "parenting tips," "parenting advice," "parenting teens," "child behavior," and "child discipline."

The preliminary determination of inclusion and exclusion was conducted based on descriptions and images published by app developers on the US Google Play and Apple App Stores, a process consistent with previous commercial app reviews [38]. Apps with questionable eligibility were downloaded for further analysis, and those that did not meet the eligibility criteria were not included in this review.

Apps that met the inclusion criteria were downloaded and installed on an iPhone XS or Samsung Galaxy S10 Plus (SM-G975U) device depending on the accessibility of each app in either system. Apps were then assessed based on four broad domains: (1) accessibility and popularity, (2) infrastructure, (3) app quality, and (4) adherence to behavioral parenting principles or strategies. Apps that were unusable or rated as having low interactivity under app quality (see the *Data Extraction* section) were excluded from further evaluation of BPT adherence.

Inclusion and Exclusion Criteria

This study included commercially available apps whose primary function is to offer parenting skills or "tips" to address child or adolescent behaviors that are key targets for behavioral parenting techniques such as co-operation; compliance; or establishing expectations, rules, and limits (eg, completing chores).

This study excluded apps that (1) were not offered in English; (2) were intended for use by professionals or individuals other than parents or caregivers; (3) required access codes from a health professional or a research or medical program to be used; (4) targeted areas of parenting or parent education unrelated to managing child behaviors (eg, pregnancy or infant care, information on developmental milestones, and other medical or nutritional needs of children); (5) were aimed at infant or prechildhood care and milestone trackers; (6) were listed for "age 0 to 3" (apps listed for "age 0 to 5" were further evaluated for whether they contained BPT components); (7) were intended for coparenting because of this review's focus on improving parenting in parent-child contexts; (8) functioned as communication platforms between parents and care professionals (eg, health care professionals, pediatricians, and childcare or daycare options) or schools; (9) focused on early learning, homeschooling, or games for cognitive development; (10) were designed for specialized developmental or neurodevelopmental conditions (eg, autism spectrum disorder, developmental delays, learning disorders, and special education or needs) as these concerns often require additional interventions and approaches [34,39] distinct from parenting techniques that may be part of the intervention [40]; (11) functioned as catalogs, electronic libraries, or electronic books or magazines for parenting; (12) functioned as forums or internet-based communities; or (13) functioned exclusively as technical aids to facilitate implementation of specific parenting activities (eg, token or reward trackers, house chore checklists, digital safety monitors, or geographic locators) without providing interventions or teaching underlying BPT principles such as reinforcement, house rules, and monitoring and supervision. In contrast, apps that included embedded technical aids (eg, token trackers) but also provided some verbal guides on practicing related parenting skills were included in this review.

Data Extraction

Retrieved apps were categorized and evaluated based on the criteria used to evaluate commercial apps across previous reviews [36,37], including accessibility and popularity, infrastructure, app quality, and level of adherence to BPT strategies and their underlying principles [41,42].

Accessibility and Popularity

Accessibility was coded based on whether the app could be found on one or both app stores and on cost. Given that the actual number of views or downloads of an app is rarely accurately reported on either the Google Play or Apple App Store [36], several indicators of popularity were coded as approximations. These indicators included any available information provided about the number of downloads, number of users that rated the app, and average user star ratings (based on a 5-star system). However, it should be noted that, typically, only apps with a substantial pool of user ratings will display their specific number of reviews and average star ratings.

Infrastructure

To evaluate app infrastructure, the evaluators coded whether the app had a privacy statement and, if so, where one could access it (ie, on the app store, on a separate website, or within the app). In addition, the evaluators explored whether there was a website associated with each app as an indicator of the app's supporting infrastructure.

App Quality

The MARS was used to evaluate app quality. The MARS is a 23-item scale designed to provide objective and reliable multidimensional measures of the quality of health-related apps [35]. It was developed by a multidisciplinary team of psychologists, scientists, and technology development experts. It encompasses several subscales, including engagement (eg, interactivity), functionality (eg, ease of use), esthetics (eg, graphics), and information quality and effectiveness (eg,

accuracy of app description on the app store) and has emerged as a promising measure of user experience and quality of health apps [35]. The rating of each MARS item is based on a 5-point Likert scale (1=inadequate, 2=poor, 3=acceptable, 4=good, and 5=excellent). Previous research has shown that the MARS has strong internal consistency (Cronbach α=.92) and interrater reliability (intraclass correlation coefficient [ICC]=0.85) [35]. For this study, the internal consistency of the primary evaluator (KL) was acceptable (Cronbach α=.79). To calculate reliability, a second independent rater (LD) randomly chose 20% of the included apps (10 apps) to rate app quality, and the interrater reliability between the 2 evaluators was moderate (ICC=0.52) [43].

Adherence to Behavioral Parenting Strategies and Principles

Adherence to the strategies and principles of behavioral parenting interventions was evaluated by examining app content against 91 BPT strategies that are part of the most widely used protocols. The strategies were distilled from current protocols following a sequence of steps by the first (KL) and second (KM) authors, who are doctoral clinical psychology students with training in cognitive and behavioral theories and child interventions related to BPT. A codebook that listed the behavioral parenting strategies was developed to guide our codes. For this study, the core clinical strategies for BPT were summarized as a list of individual statements comprising the codebook by the first author (KL).

Specifically, first, the first (KL) and second (KM) authors and a team of trained undergraduate students searched the scholarly literature, treatment manuals, and nonacademic web-based sources promoting effective parenting strategies in managing child or adolescent behaviors. The first and second authors reviewed the comprehensive compilation and generated a list of parenting strategies grouped by domain. This process of search and consolidation was supervised by the senior author (SRP)—a licensed psychologist specializing in treating child and adolescent externalizing behavior. In addition, the first author independently consulted several evidence-based treatment manuals grounded in BPT and social learning theory as well as manuscripts on behavioral parenting mechanisms of change [44,45] to add to or revise the list of strategies and domains for the final list of BPT strategies. The manuals that were reviewed included the Oregon model of parent management [8,46-48], the behavior modification approach to parenting by Kazdin [6], Helping the Noncompliant Child [9], Parent-Child Interaction Therapy [41], Functional Family Therapy [42,44], and Multisystemic Family Therapy [10].

Second, a codebook that listed the behavioral parenting strategies was developed to guide data extraction while reviewing the commercial apps. For this study, the core clinical strategies for BPT were summarized as a list of individual statements by the first author (KL). A total of 91 unique core statements or BPT strategies were identified and grouped into twelve domains: (1) psychoeducation (2 statements), (2) setting behavioral targets and goals (6 statements), (3) tracking (9 statements), (4) supervision (5 statements), (5) positive reinforcement (15 statements), (6) positive verbal support or praise (6 statements), (7) consequences (15 statements), (8) setting limits or clear rules (11 statements), (9) making effective requests (9 statements), (10) communication and family relationship (7 statements), (11) parent mental health and self-care (3 statements), and (12) maintenance and additional resources (3 statements). See Multimedia Appendix 1 for the complete list of 91 core statements grouped by domain.

Third, consistent with previous reviews evaluating adherence to evidence-based principles [36,45], the first author (KL) rated apps against each of the 91 core statements on a scale from 0 to 2 to evaluate adherence, where 0=there was no information about the statement, 1=there was some information related to the core statement (eg, information was incomplete or implicit), and 2=the app provided explicit and comprehensive verbal instruction that paraphrased the statement. After each core statement was rated, the mean adherence score of each domain was obtained by averaging the ratings of all statements within this domain. Finally, an overall adherence level was obtained by dividing the sum of the domain scores by the maximum possible total score of 24 (ie, 2 points for each of the 12 domains) and converting it to a percentage. A percentage was calculated instead of the mean score to reflect a more diverse range of possible adherence levels. Table 1 displays an illustration of the scoring system using the psychoeducation and setting behavioral targets and goals domains as examples. The remaining 10 domains were scored following the same procedure.

Only apps scoring ≥3 on the MARS interactivity evaluation were coded for adherence to behavioral parenting strategies and principles. The apps that were not evaluated for adherence were those with potentially limited impact on changing user behaviors. Previous research indicates that interactivity (defined in the MARS as whether the app "allows user input, provides feedback, contains prompts such as reminders, sharing options, notifications, etc" [35]) is a key consideration for effectively translating traditional face-to-face behavioral health interventions to digital platforms [49-51]. Interactivity considerably affects the user's attitude toward the digital intervention, intentions for behavior change, and the manner and extent to which intervention content is psychologically processed by the user [52-54]. Low interactivity likely substantially limits the effectiveness of behavior change interventions delivered digitally [54-56]. Consistent with this literature, those apps that scored either 1 or 2 on the item "interactivity" (indicating below-average or below-sufficient interactivity) based on the MARS evaluation were excluded from the evaluation of adherence because of the potentially limited effect in changing user behaviors.

In this study, the internal consistency of BPT adherence for the primary evaluator (KL) was acceptable (Cronbach α=.75). To calculate reliability, a second independent rater (LD) randomly chose 20% of the final apps (7 apps) to rate adherence to BPT principles. The interrater reliability between the 2 evaluators was moderate (ICC=0.63) [43].

Table 1. Scoring system for each app using 2 domains as an illustration.

Domain and statement	Rating for each statement			Domain mean adherence (range 0-2)	Overall adherence (range 0%-100%)
	0	1	2		
Psychoeducation					
Normative child development for child's age	None	Some	Clear	Average rating of all items in psychoeducation domain	Sum of all domain means divided by the total score of 24 (ie, 2 points × 12 domains), converted to a percentage
Problem or risk behaviors for child's age	None	Some	Clear	Average rating of all items in psychoeducation domain	Sum of all domain means divided by the total score of 24 (ie, 2 points × 12 domains), converted to a percentage
Setting behavioral targets and goals					
Goals are achievable, realistic, developmentally appropriate, measurable, specific, and time limited	None	Some	Clear	Average rating of all items in the setting behavioral targets and goals domain	Sum of all domain means divided by the total score of 24 (ie, 2 points × 12 domains), converted to a percentage
Selection of behaviors to target	None	Some	Clear	Average rating of all items in the setting behavioral targets and goals domain	Sum of all domain means divided by the total score of 24 (ie, 2 points × 12 domains), converted to a percentage
Defining problem behavior as well as replacement behavior	None	Some	Clear	Average rating of all items in the setting behavioral targets and goals domain	Sum of all domain means divided by the total score of 24 (ie, 2 points × 12 domains), converted to a percentage
Pinpointing	None	Some	Clear	Average rating of all items in the setting behavioral targets and goals domain	Sum of all domain means divided by the total score of 24 (ie, 2 points × 12 domains), converted to a percentage
Guidance on establishing behavior contract	None	Some	Clear	Average rating of all items in the setting behavioral targets and goals domain	Sum of all domain means divided by the total score of 24 (ie, 2 points × 12 domains), converted to a percentage
Guidance on establishing token economy	None	Some	Clear	Average rating of all items in the setting behavioral targets and goals domain	Sum of all domain means divided by the total score of 24 (ie, 2 points × 12 domains), converted to a percentage

Statistical Analysis

Data were collected by manually coding the extracted data, and all statistical analyses were performed using SPSS (version 28; IBM Corp [57]). The relevant characteristics of accessibility (eg, cost and platform), popularity, and infrastructure were determined in advance. Summary statistics, including means, SDs, and percentages, were used to describe app characteristics of interest. Descriptive statistics were used to describe the quality of the apps based on the MARS subscales and adherence to BPT strategies and principles across the 12 domains. Independent-sample 2-tailed *t* tests and 1-way ANOVAs were performed on MARS scores and BPT adherence scores between apps with different characteristics (eg, platform and popularity). The relationships between the MARS ratings and BPT adherence scores were computed using Pearson *r* correlations.

Results

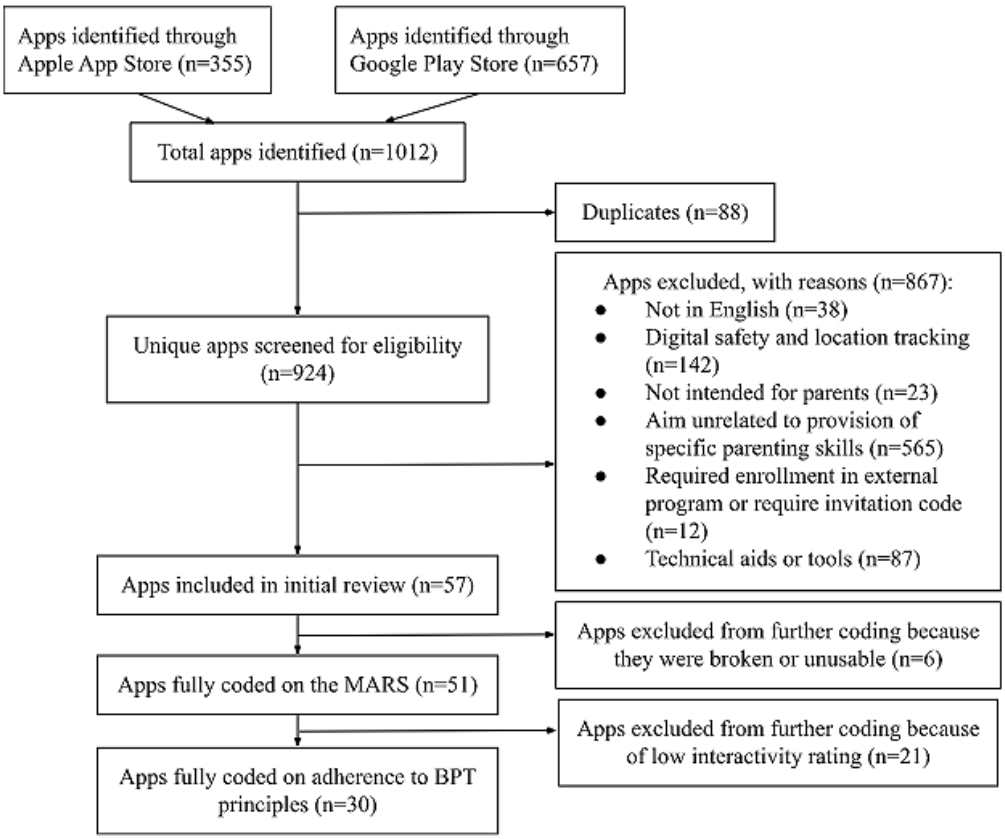
Search of mHealth Apps

The search of the commercial marketplace identified a total of 1012 apps (657/1012, 64.92% from the Google Play Store and n=355, 35.08% from the Apple App Store). After duplicates (88/1012, 8.7%) were removed, the search yielded 924 unique apps related to "parenting." After exclusion, 57 apps met the final criteria for inclusion in the review (Multimedia Appendix 2). Notably, a substantial number of apps (87/924, 9%) were excluded because they only served as digital aids or tools that assisted the implementation of specific behavioral parenting techniques (eg, token tracker and house chore checklist) but did not provide information on how to practice the skills.

After excluding 11% (6/57) of the apps, which were unusable owing to technological glitches within the app, a total of 51 apps had complete MARS ratings. An additional 21 of the 57 (37%) apps were excluded due to receiving low interactivity rating on MARS. These excluded apps primarily presented

parenting skills in a text-based way that could be similarly achieved by reading a book or through a web-based catalog search (eg, presenting chapters of books and listing web-based articles related to parenting). After exclusion of low-interactivity apps, 30 apps were analyzed for adherence to behavioral parenting principles (Figure 1).

Figure 1. Flow diagram illustrating the exclusion of apps at various stages of the study. BPT: behavioral parenting training; MARS: Mobile App Rating Scale.



App Characteristics

Accessibility

Of the 57 apps included in the review, 24 (42%) were only available on the Google Play Store, 8 (14%) were only available on the Apple App Store, and 25 (44%) had versions on both platforms. Consistent with previous research [36,37], there appeared to be more apps in general through the Google Play Store compared with the Apple App Store. Of the 57 apps included, 49 (86%) were free to download. Of the 8 paid apps, 1 (12%) cost US $0.99, a total of 5 (62%) cost US $2.99, a total of 1 (12%) cost US $3.99, and 1 (12%) cost US $9.99 to download (mean US $3.74, SD US $2.49). Of the 49 apps that were free to download, 10 (20%) involved in-app purchases or subscriptions. In-app costs depended on whether the user selected a monthly or yearly subscription, ranging from US $0.99 to US $14.99 for the initial period of subscription (eg, 1 month).

Popularity

For each app, the Google Play Store reported a range of the number of downloads to date, whereas the Apple App Store did not. On the basis of the 49 apps listed on the Google Play Store, the median number of downloads was between 1000 and 5000. A total of 10% (5/49) of these apps were installed <100 times. Across both the Google Play and Apple App Stores, average star ratings were only reported for apps with user downloads or sufficient user star ratings. Among the 41% (20/49) of apps that reported user ratings on the Google Play Store, the mean number of ratings was 610.55 (SD 2138.76; range 2-9892), and the mean star rating across the apps was 4.05 (SD 0.72; range 2.7-5) out of 5. In the Apple App Store, 48% (16/33) of apps reported user ratings. The mean number of ratings was 114.81 (SD 226.63; range 1-734), and the mean rating was 4.52 (SD 0.74; range 2-5) out of 5.

A total of 40% (23/57) of unique apps were considered highly rated by users based on an average user rating of >3 on either the Google Play or Apple App Store (Multimedia Appendix 2). The use of 3 as the cutoff was consistent with previous reviews of commercial apps [21].

Most user star ratings and numbers of downloads centered on the same 4 apps (The Happy Child, Weldon, Parent Lab, and Thumsters), all of which had versions on both platforms. On the basis of the available information on the Google Play Store, 75% (3/4) of these apps had >10,000 downloads, whereas Thumsters had between 1000 and 5000 downloads.

Infrastructure

Of the 57 apps included in this review, 18 (32%) did not have their own associated website. In terms of the location of the privacy policy, 2% (1/57) of the apps had their privacy policy located exclusively within the app. A total of 32% (18/57) of

the apps did not have any privacy policy (including 1/57, 2% of apps whose website was unreachable), 58% (33/57) provided privacy policies that were accessible within the web-based app store, and the remaining 9% (5/57) provided privacy policies on websites external to the app store.

App Design Quality

Overall Quality

A total of 89% (51/57) of the apps were evaluated for app quality using the MARS as 11% (6/57) were unable to function correctly and, thus, could not be evaluated further (Figure 1). See Multimedia Appendix 3 for the MARS ratings of each app. The overall objective quality of all 51 apps was rated as average (mean 3.86, SD 0.51). Regarding the subscales, the apps received the highest rating on functionality (mean 4.50, SD 0.40), followed by esthetics (mean 3.80, SD 0.78), information (mean 3.63, SD 0.64), and engagement (mean 3.49, SD 0.72).

App Quality Between Platforms

A 1-way ANOVA was conducted to examine whether the MARS score was related to being on one or both platforms (Table 2). Significant differences were found in the overall MARS score as well as in the engagement, esthetics, and information subscales at $P<.01$. The results consistently showed that apps available on both platforms received significantly higher overall score, higher engagement, and higher esthetics at $P<.001$ and higher information at $P=.004$, compared to apps exclusive to the Google Play Store. However, there was no statistically significant difference between apps exclusive to the Apple App Store and apps found on both platforms or apps exclusive to the Google Play Store. Notably, there was no significant difference found between platforms in the functionality subscale ($P=.49$), which suggests that apps had similar levels of functioning, performance, and usability across platforms.

Table 2. Mobile App Rating Scale (MARS) scores by platform (n=51).

MARS	Apple App Store (n=6), mean (SD)	Google Play Store (n=22), mean (SD)	Both (n=23), mean (SD)	*F* test (*df*)	*P* value (2-tailed)
Overall	3.91 (0.31)	3.54[a] (0.47)	4.14[a] (0.41)	11.27 (2,48)[b]	<.001
Engagement	3.57 (0.48)	3.05[a] (0.67)	3.89[a] (0.57)	10.91 (2,48)[b]	<.001
Functionality	4.67 (0.13)	4.5 (0.39)	4.45 (0.45)	0.73 (2,48)	.49
Esthetics	3.72 (0.61)	3.29[a] (0.71)	4.30[a] (0.53)	14.88 (2,48)[b]	<.001
Information	3.70 (0.52)	3.31[a] (0.57)	3.92[a] (0.61)	6.133 (2,48)[b]	.004

[a]Means differ from each other at $P<.001$ (Tukey honestly significant difference [HSD] test).

[b]$P<.01$.

App Quality Based on User Star Ratings

Independent-sample 2-tailed *t* tests were used to determine whether there was a difference in MARS scores between apps with user star ratings of >3 and apps with low or no user ratings (Table 3). There were significant differences in overall MARS, engagement, esthetics, and information scores. Compared with apps with low or no user ratings, apps with higher user ratings received significantly higher overall MARS ($P=.008$), engagement ($P=.01$), esthetics ($P=.01$), and information ($P=.03$) scores. There was no significant difference in the functionality subscale between the 2 groups ($P=.67$).

Table 3. Mobile App Rating Scale (MARS) scores of highly rated apps compared with others (n=51).

MARS	High rating (n=23), mean (SD)	Low or no rating (n=28), mean (SD)	*t* test (*df*)	*P* value (2-tailed)
Overall	4.06 (0.46)	3.69 (0.49)	2.75 (49)	.008
Engagement	3.76 (0.65)	3.26 (0.70)	2.58 (49)	.01
Functionality	4.52 (0.35)	4.47 (0.44)	0.43 (49)	.67
Esthetics	4.10 (0.73)	3.55 (0.74)	2.67 (49)	.01
Information	3.85 (0.50)	3.46 (0.71)	2.21 (49)	.03

App Quality of the 4 Most Downloaded Apps—The Happy Child, Weldon, Parent Lab, and Thumsters

Independent-sample 2-tailed *t* tests were used to determine whether there was a difference in MARS scores between the 4 most downloaded apps and the remaining apps (Table 4). Statistically significant differences were found across all comparisons (ie, overall, $P=.002$; engagement, $P=.007$; functionality, $P=.05$; esthetics, $P=.01$; and information, $P=.04$), with the 4 most downloaded apps consistently receiving higher average MARS scores than the remaining apps. The largest differences were observed in the overall MARS score and the engagement and esthetics subscales.

Table 4. Mobile App Rating Scale (MARS) scores of the most downloaded apps compared with others (n=51).

MARS	Most downloaded (n=4), mean (SD)	Others (n=47), mean (SD)	*t* test (*df*)	*P* value (2-tailed)
Overall	4.57 (0.19)	3.79 (0.48)	3.2 (49)1	.002
Engagement	4.4 (0.26)	3.41 (0.69)	2.84 (49)	.007
Functionality	4.88 (0.14)	4.46 (0.40)	2.05 (49)	.046
Esthetics	4.75 (0.33)	3.71 (0.75)	2.7 (49)	.01
Information	4.27 (0.39)	3.58 (0.63)	2.11 (49)	.04

Adherence to Behavioral Parenting Principles

Overall and Domain-Specific Adherence

Across all 30 apps (after removing apps with low interactivity), overall adherence to BPT principles was quite low (mean 20.74%, SD 11%). This is consistent with previous reviews of commercial apps that examined adherence between mental health apps and treatment principles (eg, mHealth apps for depression and cognitive behavioral therapy principles) [36,37]. The median level of adherence to BPT principles was 19.30% (range 5.56%-44.69%). See Multimedia Appendix 4 for the BPT adherence ratings for each app.

The relationship and communication domains had the highest average adherence and were addressed by most of the apps (27/30, 90%). In contrast, supervision had the lowest mean level of adherence and was addressed by only 13% (4/30) of the apps. In addition, none of these 13% (4/30) of apps that addressed supervision received an adherence rating of >1. Table 5 shows the number of apps that addressed each domain and the mean levels of adherence in each domain. Notably, 13% (4/30) of the apps (Parenting Plus, The Happy Child, Parenting Advice How to, and Parenting Solutions) only had information on communication or relationships or parental mental health but did not at all address tracking, supervision, positive reinforcement, consequences, clear rules, or effective requests.

Table 5. Domain-specific adherence (n=30).

Domains	Apps, n (%)	Level of adherence, mean (SD)
Relationship and communication	27 (90)	1.06 (0.49)
Praise	24 (80)	0.51 (0.42)
Parent mental health	23 (77)	1 (0.70)
Consequences	22 (73)	0.37 (0.30)
Psychoeducation	19 (63)	0.98 (0.73)
Behavioral targets or goals	19 (63)	0.41 (0.38)
Positive reinforcement	19 (63)	0.26 (0.27)
Clear rules	19 (63)	0.35 (0.35)
Maintenance or resources	19 (63)	0.42 (0.36)
Making requests	18 (60)	0.36 (0.30)
Tracking	10 (33)	0.16 (0.33)
Supervision	4 (13)	0.05 (0.15)

Overall Adherence Between Platforms

Across platforms, apps exclusive to the Apple App Store averaged 14.86% (SD 7%) on adherence level, apps exclusive to the Google Play Store averaged 22.76% (SD 7%), and those available on both stores averaged 21.37% (SD 12%).

Overall Adherence Based on App Popularity

Independent-sample 2-tailed *t* tests were used to determine whether there was a difference between apps with a user star rating of >3 and apps with low or no user ratings. There was no significant difference between the 57% (17/30) of highly rated apps evaluated for adherence (mean 20.32%, SD 12%) and the remaining 43% (13/30) of apps (mean 21.36%, SD 8%) in the level of adherence (t_{29}=−0.25; P=.80).

Independent-sample 2-tailed *t* tests were used to determine whether there was a difference between the 4 most downloaded apps and the remaining apps. There was no significant difference between the most downloaded apps (mean 25.95%, SD 18%) and the remaining 90% (27/30) of the apps (mean 19.93%, SD 10%) in the level of adherence (t_{29}=1.04; P=.31).

App Quality and Adherence

The Pearson correlation was calculated between the MARS overall score and overall adherence level. There was a significant positive correlation between the MARS score and adherence level (r_{28}=0.4; P=.03), suggesting that, as the adherence score increased, the MARS rating also increased.

Other Notable Apps and Features

Gamification

A notable app feature emerging from this review was gamification. A particularly notable example is an app named "Parent Hero," which involves engaging cartoon or graphic stories of everyday scenarios. The app user is tasked with choosing responses at multiple points in a story, and their choices determine the plot that follows. At the start of each scenario, the app introduces the parenting skill to be practiced. For example, in the scenario "when a child doesn't want to do something," the user is first guided through cartoons that set the scene ("it's almost time to take your child to kindergarten, but she still doesn't have her shoes tied, so you said, 'Katie, it's time to go'"). Then, the user reaches a decisional point where they need to select a response from a list of possible options ("Boy, laces can really be difficult!"; "Come on, you're a big girl. You know how to tie your shoes yourself"; and "We're going to be late! Give me your foot!"). After selection of a response, the plot that follows the response is presented (eg, a quarrel gradually ensues following a selection of "We're going to be late! Give me your foot!"). At the end of the story, informational pages are presented that discuss the reasons for the success or ineffectiveness of the selected response. The app contains a total of 17 unique scenarios categorized under 4 types of parenting skills—handling emotions (eg, "when a child wants something he cannot have"), engaging co-operation (eg, "when a child won't clean up"), resolving conflicts (eg, "when children fight"), and praise and appreciation (eg, "when a child performs"). Thus, the parent can play with different responses in each story and learn responses that may be more effective in an entertaining way through the engaging stories. This app received consistently high MARS ratings across all subscales and overall scores (range 4-5; Multimedia Appendix 3). This indicates that the app is engaging while relatively well designed and functional.

Another approach to gamification is illustrated by the app "Parenting Challenge Quiz: 100+ Puzzles for Parents," in which parents can take quizzes on a range of topics, from psychoeducation on child development to parenting skills. An example question from this app is "Rewards are something...: A. that are bought and given; B. need not be purchased; C. something that has high value." Following selection of an answer, feedback is provided on whether the answer is correct or incorrect along with an expandable link to read further explanations. On the MARS, this app received acceptable overall and subscale ratings (from 3.4 on information to 4.75 on functionality; Multimedia Appendix 3). This app's quiz-based nature helped its engagement compared with other text-based apps while maintaining high functionality (eg, performance and simplicity of navigation). However, its engagement may be improved, such as by incorporating images or videos within its quizzes or adding gamification features such as setting "accomplishments" or "goals" with answering quizzes.

Individualization

Although most apps (50/57, 88%) focused on general parenting skills with limited differentiation between child problem areas, some (7/57, 12%) targeted specific user populations and needs (Multimedia Appendix 2). Specifically, 9% (5/57) of the apps aimed to provide parenting tips for fathers (one of which had a counterpart for mothers, which included slightly different content). In addition, 4% (2/57) of the apps targeted a specific geographic location. For instance, "SMC Parenting for Dads" is an app that targets fathers in San Mateo County in California. Owing to its specificity, this app was able to include information about local resources, ideas for activities with children (eg, local playgrounds, hiking trails, and events), and even employment opportunities for fathers. However, compared with other apps, apps with these specifications did not appear to yield better MARS scores because of "acceptable" ratings on other MARS items, nor did they receive higher adherence ratings (Multimedia Appendices 3 and 4).

Parenting strategies differ across development. To guide future research, we also evaluated the extent to which the target age was considered as part of the app descriptions. Of the 57 apps, only 19 (33%) explicitly indicated an age range that the app was intended for either in the app store descriptions or screenshots, with 16 (28%) apps covering age ranges of ≤14 years and 8 (14%) covering an age range of ≥13 years (Multimedia Appendix 2). Furthermore, 67% (38/57) of apps that did not explicitly indicate an age range typically used language (eg, "kids" and "early development") or examples (eg, tantrums) that suggested a focus on childhood concerns. The app quality and BPT adherence of age-specific apps did not appear to be significantly distinct from those of general apps, and the level of age-appropriate content was inconsistently (if not insufficiently) addressed across these apps. For example, the app "Raising Healthy Kids Age 6-17" provided content on developmental milestones, human papillomavirus vaccines, bullying, alcohol and drug use (vaping and kratom), sex, and resources for suicide. Although these topics are relevant for parents of teenagers, the content was broad and informational rather than specific and skill-based.

Discussion

Overview

This systematic review represents one of the first efforts to identify commercial parenting apps that include components of behavioral parenting techniques and to evaluate these apps on design quality (engagement, functionality, esthetics, and information) and adherence to strategies that are consistent with BPT interventions. The results of this review can be used to inform the development of behavioral parenting mHealth apps for parents of teenagers with behavioral problems given research that shows interest [16,17,58].

App Characteristics

This review of commercial apps on 2 of the most widely used platforms (ie, Google Play Store and Apple App Store) revealed that parent-targeted mHealth apps with behavioral parenting components comprise a small percentage of available apps for "parents." However, these apps were accessible. Most apps (49/57, 86%) were free to download, and only approximately one-fifth (10/49, 20%) of the free apps included in-app purchases.

The results also showed that 44% (25/57) of the apps were accessible on both app stores, 42% (24/57) were only accessible on the Google Play Store, and 14% (8/57) were exclusive to the Apple App Store. In addition, there were more downloads and user star ratings for the Google Play Store, suggesting higher engagement with apps on this platform. These results could be due to the larger number of people in the United States who own devices compatible with Google Play [59]. Nonetheless, these findings suggest that future app developers may prioritize releasing apps on the Google Play Store but should aim to release them on both platforms to maximize dissemination.

Consistent with previous literature on challenges and concerns regarding mHealth privacy [60,61], this study found that commercial apps dedicated an inconsistent and limited amount of attention to privacy. The locations of privacy policies varied across parenting apps, and some apps (17/57, 30%) did not include any information. Although it has been covered to a lesser degree in previous reviews of commercial apps, recent research suggests that privacy is an issue of particular concern for parents of adolescents with behavioral problems, and their teenage children have specific ideas about how privacy notices are to be displayed and made transparent (Ryan-Pettes, PhD, unpublished data, May 2023). Taken together, the results suggest that providers of parents should be aware of privacy concerns before recommending apps, and developers should be accountable for improving the accessibility (eg, privacy agreement in an easy-to-access location within the app) and transparency (eg, type of information shared and with whom the information may be shared) of privacy information [62-64].

App Design Quality

Consistent with user star ratings between the Google Play and Apple App Stores, the MARS functionality ratings were similar across platforms. The MARS ratings also showed that apps accessible on both platforms had generally higher app design quality ratings compared with apps accessible only on the Google Play Store. These findings suggest that access to functional apps that are easy to use and simple to navigate appears to be approximately the same regardless of the app store used.

The finding that app quality was higher among apps on both the Apple App and Google Play Stores compared with those exclusive to the Google Play Store is consistent with previous mHealth literature [36,37]. An explanation is that apps meeting the release standards for both platforms also had more resources during development and design. Apps designed exclusively for the Google Play Store may require fewer resources given that the Apple App Store has stricter app release guidelines [65]. Despite apparently similar user star ratings for apps between these 2 platforms, the MARS scores suggest that apps released on both platforms have a higher design quality, which is related to user experience and engagement with the app [35]. Future developers of behavioral parenting intervention apps for parents should consider leveraging resources to meet the release criteria for both platforms or focusing on buttressing design quality by enhancing esthetics and engagement (eg, interactivity) before an exclusive release on the Google Play Store.

Importantly, the findings indicate that there is much room for improvement in the design quality of parenting apps. Average ratings of overall app quality as well as esthetics, information, and engagement were all within an “acceptable” range (rating of 3 on the MARS), whereas functionality appeared to be “good” on average (rating of 4 on the MARS). “Acceptable” quality ratings represent meeting the most basic criteria for design rather than an optimal or highly attractive design. Importantly, a substantial number of apps (21/51, 41%) evidenced minimal or simplistic designs (ie, a rating of 2 or below on interactivity on MARS), such as by using simple text-based presentation of information rather than high-quality designs that are adaptive and responsive. Given the importance of interactivity [66], future parent-targeted mHealth apps should focus on balancing high functionality with straightforward designs without sacrificing the features most relevant for engagement and behavior change [67]. For example, a future parent-targeted app may use minimalist yet professional and visually appealing color palates and straightforward navigation planes to preserve functionality. It may include user-friendly engaging features such as daily challenges that prompt parents to engage in specific effective parenting techniques (eg, praise their teenage child for a job well done and pause and take a deep breath before reacting to an upsetting child behavior).

Furthermore, the findings indicate that evaluation of app quality is important for an app’s commercial success. Consistent with the literature on user uptake and engagement, this study found that the most popular apps (higher user ratings and top downloads) received higher app quality scores on all domains of the MARS (ie, overall rating and all subscale ratings). In other words, the MARS ratings largely overlapped with user preference and popularity. Future development of parent-targeted mHealth apps for parenting may consider using established app quality rating scales such as the MARS to guide development.

Adherence to Behavioral Parenting and Other Notable Features

In terms of adherence to different BPT domains, parental supervision (10/57, 18% of the apps) and tracking (4/57, 7% of the apps) were the 2 domains least addressed by the apps. These findings are unfortunate given the importance of these parenting skills for parents of adolescents with behavioral problems. However, encouragingly, the domain most addressed by the apps—family relationship and communication—also had the highest adherence scores.

An interpretation of these findings is that there may be more widespread interest in and higher demand for the relationship domain of parenting in mHealth apps. However, current apps do not cover communication strategies for issues that are common among parents of adolescents with behavioral problems (eg, delinquency, peer deviance, and substance use) [68]. Therefore, with this interpretation, the findings would suggest that parents of children with behavioral problems may still find current apps insufficient to meet all their needs and concerns. Indeed, previous research has shown that parents of children with substance use problems who are interested in using mHealth apps to support their parenting want additional

parenting strategies related to monitoring, the implementation of consequences, and the initiation of positive activities with their teenage children in addition to communication skills [16]. Taken together, formative research with parents of children with behavioral problems is needed to help determine which additional BPT strategies should be included in a parent-targeted app for this population. As most developers do not use user-centered designs during commercial app development and instead evaluate the finished product, the limited existing formative research on commercial apps will likely not fill this gap [69,70].

A second interpretation of these findings is that there is a heavy focus on family relationships and communication as most apps (33/57, 58%) were designed for parents of young children or preadolescents. Research shows that building strong parent-child relationships is a central focus in childhood, and this shifts to monitoring and supervision during the teenage years [47]. With this interpretation, the results highlight an urgent need for research and development of apps for parents of teenagers or older children with behavioral problems. Focusing on this target population may help address gaps in access to evidence-based parenting support that is in high demand [3].

Importantly, across all parenting domains, the mean level of adherence to BPT principles and strategies was low among the included apps (mean 20.74%, SD 11% adherence to the strategies listed in our codebook). This finding suggests that most of the current commercial parenting apps do not sufficiently teach or approximate behavioral parenting techniques. Combined with results on low interactiveness, our findings suggest that commercial apps that are currently available to consumers generally underutilized the affordances of app technology to promote user engagement with the behavioral parenting components. First, a considerable number of apps (n=87) were excluded from this review as they served merely as aids or tools for enforcing parenting skills (eg, checklist of daily chores and a tracker for tokens) but did not provide didactic information on how to practice the underlying skills (eg, establishing house rules, reviewing house rules with the child, and consistently enforcing agreed-upon contingencies). Among the apps included in this study (all of which provide some informational instructions on parenting skills), many (21/51, 41%) present information in an unengaging and poorly adaptive and responsive way (eg, simple aggregation of texts taken from book chapters). Previous research suggests that interactivity with knowledge (consistent with the principles of social learning) is key such that parents can behaviorally practice and refine the skills [10]. Thus, current apps in the commercial market generally represent a suboptimal way to deliver BPT interventions or components digitally.

To improve adherence and enhance the effective delivery of behavioral parenting strategies, mHealth apps should integrate both didactic instructions and adaptive and responsive features consistent with social learning principles such that the underlying BPT skills can be learned and shaped into practice. As an illustration, the behavioral principle of consistency when implementing house rules (eg, a curfew of 9 PM) can be supported by app features such as daily push notifications at 8:50 PM to check the house for the teenager, and if the parent indicates “rule broken” on the app, it will be followed by automatic prompts for the parent to inform the teenager of this rule-breaking behavior and enforce the predetermined consequences right then (eg, decreased allowance). Insights from notable app features such as individualization and gamification can also be incorporated. For instance, parents may choose to personalize the time and frequency of prompts and receive individualized recommendations or examples of house rules based on the child’s age and the target problem behavior. The app can also include a progress tracker of the parent’s improvement over time and gamify the experience to boost engagement.

Despite low adherence, the apps included in this review showed a large number of downloads and average user ratings, suggesting good user satisfaction. Consistent with previous reviews [34], these findings suggest that parents’ willingness to try an app and their ratings of the app are not related to the degree to which the app includes intervention components that are scientifically grounded or implements parenting skills in a way that is related to increasing effective parenting. This study found that only 12% (6/51) of the apps received a rating of 5 on the “accuracy of app description” item on the MARS information subscale, suggesting that app descriptions on commercial app stores often do not provide a comprehensive view of the identity and expertise of app developers. Taken together, the results of this study add support for those calling for more regulation of health promotion mHealth apps in the commercial market, such as by mandating a description of the type of developer (eg, for profit) and expertise of the development team. The results also extend this call and recommend that app descriptions specify the extent to which the app features and content converge with the scientific basis.

This study found a medium positive correlation between overall app quality and overall level of BPT adherence. Although this result appears promising, it should be interpreted with caution. A reason is that the MARS inherently includes some measures of empirical support [35]. Specifically, the information subscale includes items such as “quality of information” (to what extent the overall app content is scientifically accurate and relevant), “credibility” (based on who the app developers are), and “evidence base” (whether there is empirical literature investigating this specific app; this item is scored as “n/a” and not counted toward the total score if no empirical literature was found). These 3 items may have some overlap with the app’s level of adherence to evidence-based parenting strategies, suggesting that the correlation found between app design quality (ie, MARS) and BPT adherence level may be overestimated in this study. However, these results are encouraging as they suggest the possibility of designing evidence-based behavioral parenting apps without sacrificing the features most relevant for engagement and behavior change. Examples include using simple (yet appealing) esthetics, easy-to-digest presentation, and personalization [67].

Limitations

First, this review only included apps available in English in the US app stores and only looked at the 2 most popular commercial platforms. This excludes apps developed in other countries and

languages from the scope of this review. There may also be English-language apps that are not currently found on either store that were not included in this review. However, surveying these 2 most dominant commercial platforms is consistent with previous research practices and adequately encompasses the dominant options for mHealth currently [37,38]. This study also excluded apps that were rated as <3 on the interactivity item in the MARS when adherence to behavioral parenting strategies and principles was assessed. It is possible that some of the excluded apps included more strategies and had higher adherence than the apps that were reviewed. However, our review of those with an interactivity of ≥3 showed that the commercial app industry is in the infancy stage of using effective app design and smartphone features to leverage the underlying BPT principles. Thus, it is highly unlikely that the excluded apps performed better. In addition, as discussed previously, they likely had poor user engagement because of low interactivity, limiting effectiveness for behavior change [53,66].

Second, given the lack of transparency in commercial app stores regarding information such as the specific number of downloads, it was difficult to obtain further empirical data on patterns or correlations related to the popularity of apps. Similarly, the number of reviews for an app may affect whether information on average user ratings was presented in the app store. In addition, user ratings may be highly variable and inconsistent, potentially raising questions about reliability [33,71]. Although this appears to be a common obstacle in reviews of commercial mHealth apps [36,37], it should be considered when interpreting the findings of this study.

Third, this study showed moderate levels of interrater reliability, particularly with regard to ratings of adherence to behavioral parenting techniques. Although the first author (KL) was the primary coder in this review, the BPT codebook was developed based on previous concerted efforts in the laboratory that involved a team of undergraduate students, 2 advanced doctoral students, and a clinical psychology faculty. The moderate level of reliability may be due to the differences in training and expertise between the 2 raters (KL and LD). Although the second rater (LD) was trained for 4 weeks before independently rating the apps, this rater was an undergraduate student in the laboratory who did not otherwise have coursework or experience in behavior theories or BPT.

Finally, this study aimed to inform the future design of mHealth apps for parents of adolescents. However, most of the apps identified (49/57, 86%) were either ambiguous regarding age range or focused on childhood (ages of <14 years). Although the review generated important insights for delivering behavioral parenting techniques via mHealth, the age range may be a key limitation when using currently available commercial apps to inform future apps for parents with adolescents.

Conclusions

This study reviewed existing commercial apps for parenting skills and provided recommendations for future research. The 51 functional parenting apps identified across the Google Play and Apple App Stores largely fell short of providing BPT components in an adaptable, responsive, and engaging way, suggesting that current commercial apps still inadequately address BPT strategies in a way that is consistent with the underlying principles needed to increase the use of effective parenting strategies in the target population. This study found a moderate relationship between app quality and BPT adherence level and revealed that popular parenting apps appeared to have better app quality but not necessarily a higher level of adherence to evidence-based BPT strategies and principles. Findings from this review suggest that future app developers should consider novel, adaptive, responsive, and engaging ways to adapt traditional in-person behavioral parenting techniques to the mHealth format, such as gamification, individualization, and tailored content that is easy to digest and relatable to parents. Future researchers hoping to increase the dissemination of BPT-informed mHealth apps for parents should aim for free-to-download apps that are accessible on both platforms and balance high-quality design features (eg, simple esthetics, interactivity, and individualization) with content consistent with BPT principles. This may be accomplished through multisector (industry and academic) collaboration throughout the design process and involving end users (ie, parents) during different stages of app development.

Acknowledgments

The outcomes reported in this publication were supported by the Frances Fowler Wallace Memorial Award and in part by funds from the Vice Provost for Research at Baylor University.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Behavioral parenting core domains and examples.
[DOCX File , 29 KB - pediatrics_v6i1e43626_app1.docx]

Multimedia Appendix 2
Accessibility, popularity, and infrastructure parameters for each app.
[DOCX File , 27 KB - pediatrics_v6i1e43626_app2.docx]

Multimedia Appendix 3
Mobile App Rating Scale scores for each app.
[DOCX File , 23 KB - pediatrics_v6i1e43626_app3.docx]

Multimedia Appendix 4
Behavioral parenting adherence ratings for each app.
[DOCX File , 25 KB - pediatrics_v6i1e43626_app4.docx]

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Abbreviations

BPT: behavioral parenting training
ICC: intraclass correlation coefficient
MARS: Mobile App Rating Scale
mHealth: mobile health

Edited by S Badawy; submitted 26.10.22; peer-reviewed by D Bounds, A Serlachius, A Hogue; comments to author 16.11.22; revised version received 25.01.23; accepted 27.03.23; published 01.06.23.

Please cite as:
Li K, Magnuson KI, Beuley G, Davis L, Ryan-Pettes SR
Features, Design, and Adherence to Evidence-Based Behavioral Parenting Principles in Commercial mHealth Parenting Apps: Systematic Review
JMIR Pediatr Parent 2023;6:e43626
URL: https://pediatrics.jmir.org/2023/1/e43626
doi:10.2196/43626
PMID:37261886

Original Paper

Commercially Available Mobile Apps With Family Behavioral Goal Setting and Tracking for Parents: Review and Quality Evaluation

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Abstract

Background: Goal setting and tracking are well established behavior change techniques. Little is known about the extent to which commercially available mobile apps are designed to guide parents in using these strategies, their evidence base, and their quality.

Objective: This study aims to review commercially available apps that target parents in relation to setting and tracking behavioral goals for their children. The objectives were to classify the apps' general characteristics, features, evidence base, and target behaviors and assess app quality overall and separately for apps that target health-related behaviors (HRBs) and apps without a health-related behavior (WHRB).

Methods: Apps were identified using keyword searches in the Apple App Store and Google Play in the United States. Apps were included if their primary purpose was to assist with setting goals, tracking goals, tracking behaviors, or giving feedback pertaining to goals for children by parents. App characteristics and common features were documented and summarized. Two reviewers assessed app quality using the Mobile App Rating Scale (MARS). Descriptive statistics summarized the MARS total score, 4 quality subscales, and 6 app-specific items that reflect the perceived impact of the app on goal setting and tracking, overall and with subgroup analysis for HRB and WHRB apps.

Results: Of the 21 apps identified, 16 (76%) met the review criteria. Overall, 9 apps defined and targeted the following HRBs: nutrition and mealtime (6/16, 38%), physical activity and screen time (5/16, 31%), sleep (7/16, 44%), and personal hygiene (6/16, 38%). Three apps targeted specific age groups (2 apps were for children aged 6-13 years and 1 app was for children aged ≥4 years). None of the apps provided tailored assessments or guidance for goal setting. None of the apps indicated that they were intended for the involvement of a health professional or had been tested for efficacy. The MARS total score indicated moderate app quality overall (mean 3.42, SD 0.49) and ranged from 2.5 to 4.2 out of 5 points. The Habitz app ranked highest on the MARS total score among HRB apps (score=4.2), whereas Thumsters ranked highest (score=3.9) among the WHRB apps. Subgroup analysis revealed a pattern of higher quality ratings in the HRB group than the WHRB group, including the mean MARS total score (mean 3.67, SD 0.34 vs mean 3.09, SD 0.46; *P*=.02); the engagement and information subscales; and the app-specific items about perceived impact on knowledge, attitudes, and behavior change.

Conclusions: Several high-quality commercially available apps target parents to facilitate goal setting and tracking for child behavior change related to both health and nonhealth behaviors. However, the apps lack evidence of efficacy. Future research

should address this gap, particularly targeting parents of young children, and consider individually tailored guided goal setting and involvement of health professionals.

(JMIR Pediatr Parent 2023;6:e41779) doi:10.2196/41779

KEYWORDS

goal setting; goal tracking; nutrition; health behavior; nutrition; parents; children; mobile apps

Introduction

Background

Several taxonomies and reviews of health behavior change techniques (BCTs) indicate that goal setting is a foundational aspect of initiating and maintaining health behavior change [1-3]. Goal setting and tracking form the basis for conceptualizing, operationalizing, and documenting change and are intrinsic aspects of human behavior [4]. At the most basic level, the process of goal setting for individuals who have a desire to make behavioral changes includes the need to identify a goal, identify behaviors that need to be modified, generate specific strategies that will be used to implement the goal, a time frame for implementation of a plan, and a metric for how success will be defined [5,6]. Basic research in goal setting often integrates a framework from organizational behavioral theory for operationalizing key characteristics of the goal [5]. In health behavior research and practice, goal setting is often designed around development of SMART goals (specific, measurable, achievable, relevant, time-bound). Use of these common sense characteristics is commonly found in goal-setting interventions. However, regardless of the use of the SMART goals process, setting goals in general may optimize adherence to a process and the probability of goal achievement [7].

Behavior change research is not always able to provide specific guidance on the translation of theory into real-world activities to achieve health behavior change. For example, although goal-setting and tracking interventions may be informed by the social cognitive theory through the assessment of self-efficacy and facilitators and barriers related to success [8], the interaction of the individual with feedback, the use of peers in goal attainment, and engaging individuals in the change process may be implemented in many ways. Conceptually, self-efficacy may be the most studied construct related to goal attainment and has been related to the nature of the goals selected, the strength of commitment, and outcomes expectancies [8]. Other conceptual factors and processes that have been shown to correlate with goal implementation and achievement include individual abilities, use of feedback, goal commitment, relevant resources, level of stressors, and rewards for progress toward goal attainment [9]. However, these are factors that are characteristics of individuals and not part of the intervention itself. As such, any review of intervention or mobile app characteristics surrounding goal setting and achievement cannot predict or determine who will be successful in using the app regardless of the features.

After setting a goal, it is important to monitor progress to identify whether an individual is on track with regard to the nature of change, quantity of change, or timeline of the goal progress. Monitoring, or tracking, may also be used to document barriers to change or progress. The importance of this aspect of using goals in behavior change can be observed in the many health behavior tracking tools and apps available commercially. The importance of tracking behaviors is not only to raise awareness to the goal behavior on a regular basis through the act of tracking but also in the use of aggregated feedback over time. Patterns in goal achievement may be useful for identifying problems and refocusing attention or resetting a goal if it is not appropriate [10].

Goal setting and tracking are appealing for use by parents in relation to their children's behavior because they provide a concrete process upon which to map and operationalize change, create opportunity for integrating adaptive assessment and personalized action plans, and may be used in a time-limited or cyclical manner. For example, tracking may be used to focus parental attention toward a goal on a daily or habitual basis. Nutrition and physical activity interventions that incorporate goal setting as a behavioral strategy have been generally evaluated as effective [8,11], including the incorporation of goal setting in childhood obesity prevention intervention studies focused on families, children, and adolescents [1,12,13]. Given the role of parents in creating the home food environment and making shopping choices, particularly for young children, the need for holistic family-based approaches to improve pediatric diet, weight, screen time, and physical activity has long been recognized [14,15].

Several recent studies have reviewed mobile health (mHealth) apps related to nutrition, physical activity, and weight management in children and adolescents. A 2015 review by Burrows et al [16] of 27 mobile apps for adolescents aged ≥13 years focused on weight management found that goal setting was the most common BCT, used in more than half of the apps (56%). A 2017 review by Schoeppe et al [17] assessed 25 mobile apps for child and adolescent users aged 2 to 18 years that focused on diet, physical activity, or sedentary behavior and found that one-third of the apps included goal setting as one of the BCTs. Finally, a 2022 review by Brown et al [18] of 259 nutrition-themed apps intended for children aged ≤12 years found that 18% of the apps included goal setting and planning as BCTs. In the review by Brown et al [18], approximately two-thirds of the child-focused apps were considered food games, and 17 of the apps were classified as "habit trackers," which they defined as apps that enabled the children to log their food and drink intake. These reviews demonstrate interest in apps that support goal setting and tracking for child behavior, but they only included apps targeting children and adolescents as the app users, not apps that target parents as the primary users. In addition, although some of the reviewed apps included goal-setting features, this was not the focus of the reviews. Parents may wish to set goals to improve health-related

behaviors (HRBs) and promote prosocial behaviors in their children, such as chores and homework.

Thousands of mHealth apps promote nutrition, physical activity, weight management, sleep, and other wellness behaviors for adults, but few are designed for parents to influence their children's behaviors [19,20]. Little is known about the extent to which mobile apps that are designed to guide parents in using goal setting and tracking as BCTs for their children are commercially available or the intended context for apps to be used. For example, apps could be designed for parents to them at their home. Alternatively, apps could be used in coordination with health professionals in various contexts (eg, medical care, nutrition education, behavioral therapy, or personal coaching), such as sharing their app data with the health professional or using an app as part of a larger intervention [21]. Furthermore, little is known about the evidence base and quality of such existing apps [22,23].

Objectives

Given the established evidence for goal setting and tracking as BCTs and the limited examination of mHealth apps in this domain in the context of families, we sought to address this gap. This study aims to review commercially available apps related to setting and tracking goals that target parents and children, both overall and specifically for apps that focus on HRBs. The specific objectives were to (1) classify the general characteristics, features, evidence base, and target behaviors of the apps and (2) assess the quality of the identified apps using an existing validated tool, overall and separately for the apps that target HRBs versus apps that do not include any HRBs. This review is a first step toward making recommendations for the use of mobile apps for goal setting and tracking with parents to influence child health behaviors.

Methods

Search Criteria and App Identification

The Apple App Store (iOS operating system) and Google Play (Android operating system) in the United States were searched once weekly between June and August 2021, using the following keywords to identify a pool of apps related to goal tracking for parents of children: *child goals*, *kids health goals*, *toddler parenting app*, *child nutrition goal tracking*, and *kids' nutrition goals*. Relevant apps were also identified using a snowball approach through similar apps recommended by the app stores during searches.

Inclusion criteria included those apps with the primary purpose of assisting parents with goals related to their children's behaviors, including setting goals, tracking goals, tracking goal progress or behaviors (good or bad), or giving feedback pertaining to goals. Only apps that were available for download in the United States were included. Exclusion criteria included apps that functioned primarily as scheduling or daily planners, list making, time management, allowance tracking, or finance management.

Classification of Apps

App characteristics, features, and target behaviors were tracked and documented in an Excel (Microsoft Corp) sheet throughout the review process based on review of the app store description and app content. Certain app characteristics remained constant (eg, app name, developer, and Android or iOS availability), whereas others could change over time (ratings, downloads, reviews), so these were all documented on the same date (April 19, 2022). Features that were only available through paid upgrades were noted in the classification table. These paid upgrade features were reviewed based on descriptions and screenshots within the app and in the app store overview, and we did not directly test them.

All the app features were tabulated and described for each app. Then categories of features were created via the identification of commonly occurring themes. No app features were omitted from the assessment, and overlapping features were noted in the table. For each app, we documented the specific behaviors associated with possible goals that could be set and tracked. On the basis of the target behaviors, we assigned the apps to 1 of the 2 categories: apps with HRBs and the remaining apps without HRBs (WHRBs).

To characterize the evidence base, we reviewed the descriptions of the apps in the Apple App Store and Google Play, within the app, and on the developers' websites, when applicable. In addition, we searched for the app names and developer names in PubMed, PsycINFO, and Google Scholar databases to locate any published research on the apps.

Quality Evaluation

Use of the Mobile App Rating Scale

App quality was assessed using the Mobile App Rating Scale (MARS), a tool used to measure the quality of mobile apps. The MARS is a validated scale that is considered both objective and reliable [24]. The MARS has been used in similar app reviews and systematic app reviews pertaining to a variety of topics such as nutrition and physical activity for families and children [17,18,20,25,26]. The MARS quality subscale is composed of 19 items grouped into four domains: (1) engagement (5 items), (2) functionality (4 items), (3) aesthetics (3 items), and (4) information (7 items). Items are measured on a 5-point Likert scale, with 5 representing the highest quality. A score for each domain subscale is computed as the mean of the items in that domain. The total MARS quality score is computed as an average across the 4 domains and has demonstrated high internal consistency (Cronbach α=.90) [24]. The MARS instrument also includes a set of 6 app-specific items that can be used to assess the perceived impact of the app on users for the target behavior in terms of awareness, knowledge, attitudes, intention to change, help seeking, and the likelihood of actual change in the target health behavior (behavior change).

Each app was assessed independently by 2 reviewers using the MARS tool. The first author reviewed all the apps as the primary reviewer, and 4 additional authors served as the second reviewer on 4 apps each. All reviewers hold advanced degrees in their respective fields of nutrition, public health, psychology,

sociology, or health informatics. All reviewers were trained using the web-based MARS training video and group discussion of the scoring instructions [27]. Reviewers were encouraged to refer back to the video, if necessary, to confirm their understanding of the most accurate and appropriate evaluation of each MARS domain. Differences greater than one point between the 2 reviewers were resolved by discussion and, if needed, a final decision by a third reviewer was applied when needed. Following the process of previous reviews using MARS [17], differences of one point in the assessments were resolved by taking the average of the 2 items.

Data Analysis

For the first objective, the general characteristics (ratings, installs, target age, etc), features (user options, available settings, visual displays, etc), evidence base, and health-related target behaviors for each app were tabulated and described. For the second objective, internal consistency of the total MARS quality scale and its subscales was calculated using Cronbach α. Descriptive statistics were used to summarize the mean and SD for the total MARS quality scale, 4 MARS quality subscales, and the 6 MARS app-specific items for each app individually, overall for all the apps combined, and separately for HRB apps and WHRB apps. As part of the subgroup analysis, we also tested for differences between the HRB apps and WHRB apps using a Kruskal-Wallis test, with a significance level of .05.

Results

App Identification

A total of 21 apps were downloaded during the keyword search and initial review of app descriptions in the app stores. Next, the downloaded apps were screened for the inclusion and exclusion criteria. Of these, 9% (2/21) of the apps did not meet the inclusion criteria for goal tracking (ie, KidBehave and Wello). Some apps used the word *habits*, not in line with the technical definition of habit from psychology but rather using the lay meaning that is equivalent to behaviors and goals [28], so these apps were retained. Furthermore, 9% (2/21) of the apps were excluded because they were allowance trackers (ie, Homey and Chores & Allowance Bot), and 1 app was excluded because it was not available for use in the United States (ie, Goalstar Rewards Notification). The remaining apps (n=16) were included in the review.

Classification of Apps

General app characteristics and features of the 16 apps are presented in Tables 1 and 2. All apps were available on the Apple App Store (iOS) and 9 apps were available on Google Play (Android). The apps defined goals, tasks, and behaviors in different ways. For example, in 11 apps (ie, Habitz, FamJam, Points, Happy Kids Timer, Reward Chart, Go Hero, Smiles & Frowns, iReward, S'moresUp, Our Home, and Child Reward), goals were operationalized as trackable, desirable (or undesirable) behaviors, where points, stars, or some type of positive or negative feedback were associated with the behaviors. In such cases, the points, stars, or other tracking item could later be redeemed for a reward determined by the app or the user. Many of these apps often contained a predefined selection of goals, tasks, or behaviors (often under different categories) and the option for the user to add their own goals, tasks, or behaviors.

A total of 9 apps contained predefined goals that allowed users to track the following HRBs: nutrition and mealtime (n=6, 66%), physical activity and screen time (n=5, 55%), sleep (n=7, 77%), and personal hygiene (n=6, 66%; Table 1). Specific trackable behaviors that appear in each health-related category are listed in Table 3. Examples of trackable non–health-related behaviors include child routines, chores or home care, homework or school performance, attitudes or moods, and treatment of others. Moreover, 5 of the apps included in the WHRB category (ie, Thumsters, Stellar, punti, Points Wallet, and Chore Pad) did not include any predefined behaviors for goals and required the user to manually define their own behavior goals.

Table 1. Characteristics of commercially available family goal setting and tracking mobile apps for parents that target health-related behaviors (as of April 19, 2022).

	Apps targeting health-related behaviors (n=9)								
	iRewardChart	Points	OurHome	Happy Kids Timer	S'moresUp	Go Hero	FamJam	Smiles & Frowns	Habitz
App characteristics									
Apple App Store (iOS)									
Average rating (out of 5)	3.6	4.1	4.3	4.3	4.3	__[a]	4.6	4.2	4.4
Number of ratings	227	34	1500	750	697	—	29	43	642
Google Play (Android)									
Average rating (out of 5)	2.5	4.1	3.2	4.3	3.8	—	3.9	—	—
Number of ratings	669	217	>4000+	>19,000	783	—	90	—	—
Number of downloads	>10,000	>10,000	>500,000	>1,000,000	>100,000	>1,000	>10,000	—	—
Target child age range specified	—	—	—	—	4-6 years, 7-10 years, >11 years	—	—	—	6-13 years
Tested in research studies or trials	No	No	No	No	No	No	No	No	No
Features									
Allows multiple children on family profile	P[b]	✓[c]	✓	—	✓	✓	✓	✓	✓
Child user account available on same device	—	—	✓	—	✓	✓	✓	—	✓
Family network option with children on separate devices	—	✓	—	—	✓	✓	—	✓	✓
Option to choose cartoon icons for child	—	—	✓	—	✓	—	✓	—	✓
Option to choose photo for child	✓	✓	—	—	✓	✓	✓	✓	—
Provides individually tailored guidance on recommended goals	—	—	—	—	—	—	—	—	—
Can set up multiple goals	✓, P[d]	✓	✓	✓	✓	✓	✓	✓	✓
Allows parents to set rewards	✓	✓	✓	P	✓	✓	✓	✓	✓
Can change reward values	—	✓	✓	—	✓	✓	✓	✓	—
Visual chart for tracking over time	✓	✓	✓	✓	✓	✓	✓	✓	✓
Additional features via paid upgrade (not reviewed)	—	—	—	P[e]	—	—	—	—	—
Health-related target behaviors									
Nutrition and mealtime	✓	—	✓	✓	✓	—	—	✓	✓

	Apps targeting health-related behaviors (n=9)								
	iRewardChart	Points	OurHome	Happy Kids Timer	S'moresUp	Go Hero	FamJam	Smiles & Frowns	Habitz
Physical activity and screen time	✓	—	✓	—	✓	—	✓	—	✓
Sleep	✓	✓	✓	✓	✓	✓	—	—	✓
Personal hygiene	✓	—	—	✓	✓	—	✓	✓	✓

[a]Data not available in app store or the feature not included in the app.

[b]P: the feature available via paid upgrade (not directly tested in the review).

[c]✓: the feature included in the app and tested.

[d]Paid upgrade for >4 goals.

[e]Additional paid upgrades: custom order and time length of goals, email, or print reward certificate.

Table 2. Characteristics of commercially available family goal setting and tracking mobile apps for parents that target other behaviors (as of April 19, 2022).

	Apps targeting other behaviors (n=7)						
	Child Reward	Stellar	Chore Pad	Punti	Reward Charts	Points Wallet	Thumsters
App characteristics							
Apple App Store (iOS)							
Average rating (out of 5)	1.3	4.6	2.8	4.7	4.5	4.5	4.8
Number of ratings	4	276	24	6	13	53	717
Google Play (Android)							
Average rating (out of 5)	3.3	—[a]	—	—	—	—	4.2
Number of ratings	405	—	—	—	—	—	203
Number of downloads	>50,000	—	—	—	—	—	>10,000
Target child age range specified	—	—	—	6-13 years	—	—	—
Tested in research studies or trials	No	No	No	No	No	No	No
Features							
Allows multiple children on family profile	✓[b]	✓	P[c]	✓	✓	✓	✓
Child user account available on same device	—	—	—	—	—	—	—
Family network option with children on separate devices	—	—	—	P	—	—	—
Option to choose cartoon icons for child	✓	—	—	—	—	—	—
Option to choose photo for child	✓	✓	✓	—	✓	✓	✓
Provides individually tailored guidance on recommended goals	—	—	—	—	—	—	—
Can set up multiple goals	✓	P	✓, P[d]	✓, P[e]	✓	—	✓
Allows parents to set rewards	✓	—	—	—	✓	✓	—
Can change reward values	✓	—	✓	—	—	✓	✓
Visual chart for tracking over time	✓	—	—	✓	✓	—	✓
Additional features via paid upgrade (not reviewed)	—	—	—	P[f]	—	—	—

[a]Data not available in app store or the feature not included in the app.

[b]✓: the feature included in the app and tested.

[c]P: the feature available via paid upgrade (not directly tested in the review).

[d]Paid upgrade for >4 goals.

[e]Paid upgrade for >5 goals.

[f]Daily reminders to track goals.

Table 3. Apps containing features that allow users to track health-related goals.

Name of app	Description of features
Apps that track nutrition, food, or mealtime-related behaviors (n=6)	
Habitz	Eat healthier foods (12 types of food choice goals may be selected); cut out unhealthy foods (5 types of food choice goals may be selected)
Happy Kids Timer	Can select the activities linked to the goal of completing a morning or nighttime routine: eat your breakfast, pack your lunch
iRewardChart	No junk food, sit through the meal, eat fruit
OurHome	Kitchen, meals, shopping
S'moresUp	Cook simple foods, set and clear table, no device at mealtime, cook simple meal with supervision, drink water and stay hydrated, eat breakfast, help make and pack lunch, learn to read labels on food, make breakfast, make your own snacks, help make dinner, learn to read labels on food
Smiles & Frowns	Using good table manners, refusing to eat properly (negative), behaving poorly at the table (negative)
Apps that track physical activity and screen time behaviors (n=5)	
FamJam	Exercise
Habitz	Physical activity, 2 hours screen time
iRewardChart	Exercise
OurHome	Exercise
S'moresUp	Device limitations (homework first, during family time, at school, etc), play outside for 45 min, practice sports for 45 min
Apps that track sleep, sleep routine, or bedtime behaviors (n=7)	
Go Hero	Evening ritual
Habitz	On time bedtime last night, Woke up on time
Happy Kids Timer	Can select and complete a series of activities linked to the goal of completing a nighttime routine and going to sleep (eg, toilet, pajamas, read a book, lights off, go to sleep)
iRewardChart	On time to bed
OurHome	Bedroom, bedtime routine
Points	Bedtime on time
S'moresUp	No screen within an hour of bedtime, sleep at least 10 hours per day, wake up on time, get ready for bed
Apps that track personal hygiene–related behaviors (n=6)	
FamJam	Brush teeth, washing hands
Habitz	Brush your teeth
Happy Kids Timer	Can select the activities linked to the goal of completing a morning or nighttime routine: brush your teeth and wash your hands, take a shower or bath
iRewardChart	Brush teeth, take bath
Smiles & Frowns	Brushing teeth, washing up or bathing, not washing or brushing teeth (negative)
S'moresUp	Deodorant, brush teeth, take a shower or bath, wash hands

Among the 9 HRB apps in the Apple App Store, OurHome had the highest number of user ratings (>1500 ratings), followed by Happy Kids Timer (750 ratings), S'moresUp (697 ratings), and Habitz (642 ratings; Table 1). The highest average user ratings were obtained for FamJam (4.6 rating) and Habitz (4.4 rating). The Apple App Store does not report the number of downloads. Among the 7 HRB apps on Google Play, Happy Kids Timer had the highest number of user ratings (>19,000 ratings), highest average rating (4.3 rating), and highest number of downloads (>1 million). OurHome had the second highest number of user ratings (>4000 ratings) and downloads (>500,000 downloads), but Points had the second highest average user rating (4.1 rating).

Among the 7 WHRB apps in the Apple App Store, the apps with the highest user ratings were Thumsters (717 ratings) and Stellar (276 ratings; Table 2). Thumsters also had the highest average user rating (4.8 rating), followed by punti (4.7 rating) and Stellar (4.6 rating). Among the 2 WHRB apps on Google Play, Child Reward had the largest number of downloads (>50,000 downloads) and user ratings (405 ratings), whereas Thumsters had the highest average user rating (4.2 rating).

Overall, 3 apps explicitly stated that the apps were designed for children of specific age ranges. One HRB app (Habitz) and one WHRB app (Punti) were targeted for children aged 6 to 13 years. Another HRB app (S'moresUp) offered a feature to select the age range of children to tailor some of the visuals and features for 3 separate age groups (4-6 years, 7-10 years, and >11 years).

Furthermore, 5 apps offered optional features through paid upgrades, which were described in the apps and app stores. Of these 5 apps, 4 (80%) apps (iRewardChart, Stellar, Chore Pad, and punti) included the paid option to remove limits on 2 existing features—the number of child profiles and the number of goals. The paid upgrade options in the fifth app, Happy Kids Timer, allowed the parents to specify rewards, to customize the order and time length of goals, and to email or print reward certificates. In addition, punti offered paid upgrade options to sync multiple devices on a family network and to provide daily reminders about tracking goals.

In a review of the app store descriptions, information within the app, and developer websites, research was only mentioned on the websites for 2 apps, Habitz and S'moresUp, which stated that research was consulted to inform the development of these apps. The Habitz website described that the development team included experts in nutrition, psychology, and pediatric behavior, and it also mentioned that the team had conducted internal testing of the app, but no details were provided. Searches of scientific databases did not reveal any publications indicating that the apps had been tested in published clinical trials or other studies.

Quality Evaluation

The MARS quality rating tool demonstrated high internal consistency and reliability for rating the goal-setting and tracking apps, with a Cronbach α of .92 for the total score, and high scores for the 4 subscales: engagement (α=.80), functionality (α=.85), aesthetics (α=.88), and information (α=.82).

The MARS app quality ratings for each reviewed app and overall for the 16 apps are reported in Table S1 in Multimedia Appendix 1. Overall, the apps had a mean total score of 3.4 (SD 0.5). Among the HRB apps, Habitz had the highest score of 4.2, followed by Smiles & Frowns (score 4.1) and FamJam and Go Hero tied for third (score 3.8). In addition, Habitz had the highest subscale scores for engagement, aesthetics, and information, whereas Smiles & Frowns had the highest score for the functionality subscale. For the top-ranked WHRB apps, Thumsters ranked first (score 3.9), followed by Reward Chart (score 3.2), Points Wallet (score 3.2) and punti (score 3.2) tied for the second. Thumsters had the highest subscale scores for engagement, functionality, and aesthetics, and it tied with Reward Chart and Points Wallet for the highest score on the information subscale score.

With regard to the lowest ranked HRB apps, iRewardsChart and Points ranked lowest in total score and ranked low in most of the subscales, except for functionality. Comparably, among the WHRB apps, Child Reward and Stellar ranked the lowest overall, with Child Reward receiving a score of 1.9 in the area of information and Stellar receiving a score of 1.9 for the engagement subscale. With regard to the 6 goal-setting scores, we observed that Child Reward and Stellar had the lowest scores, with Stellar receiving the lowest scores of all ranked categories, with a consistent 1.5 score in 5 out of the 6 goal-setting categories.

Table S1 in Multimedia Appendix 1 lists the scores for the 6 app-specific items that reflected reviewers' perceived impact of the apps on aspects of goal setting and goal tracking. Among the HRB apps, 4 apps (Habitz, Smiles & Frowns, FamJam, and Go Hero) received ≥4.0 in at least 4 of the 6 items. Smiles & Frowns had the most items scored at 4.5, followed by Habitz and Go Hero. At the same time, Habitz was ranked first in the important category of behavior change, and 4 other apps tied for the second highest score in behavior change (score 4.0).

Among the WHRB apps, Thumsters received the highest ratings on the app-specific items, with a score of 4.5 on 4 of the items. Reward Chart had the next highest ratings, with a score of ≥3.5 on 4 items. Thumsters scored the highest on the behavior change item (score 4.0), followed by Chore Pad (score 3.5).

Figure S1 in Multimedia Appendix 1 illustrates the ranking of the total score for each app, with the HRB apps in black and the WHRB apps in gray. Notably, 8 of the top 9 ranked apps were HRB apps. The exception was Thumsters, which ranked third overall and received the highest total score among the WHRB apps.

This pattern was consistent in the mean comparison tests of the MARS quality scores for the HRB apps and the WHRB apps, as presented in Table 4. We observed a significantly higher total score for the HRB apps (mean 3.67, SD 0.34) compared with the WHRB apps (mean 3.09, SD 0.46; *P*=.02). Among the subscales, the engagement subscale was higher for the HRB apps (mean 3.60, SD 0.30) compared with the WHRB apps (mean 2.86, SD 0.60; *P*=.01), and the information subscale was higher for the HRB apps (mean 3.03, SD 0.44) compared with the WHRB apps (mean 2.86, SD 0.3; *P*=.01). The functionality and aesthetics subscales did not differ significantly between the 2 groups.

Among the app-specific items on reviewers' perceived impact of the apps on goal setting and goal tracking, we observed that three of the six items were significantly higher for HRB apps versus WHRB apps: (1) knowledge (HRB apps: mean 3.83, SD 0.43; WHRB apps: mean 3.00, SD 0.91; *P*=.02), (2) attitudes (HRB apps: mean 3.83, SD 0.35; WHRB apps: mean 2.86, SD 0.9; *P*=.01), and (3) behavior change (HRB apps: mean 3.78, SD 0.44; WHRB apps: mean 3.07, SD 0.53; *P*=.02). The 2 groups of apps did not differ significantly in the perceived impact of the apps on awareness, intention to change, or help seeking.

Table 4. Comparison of Mobile App Rating Scale scores for apps targeting health-related behaviors versus other apps.

	Apps targeting health-related behaviors (n=9), mean (SD)	Apps targeting other behaviors (n=7), mean (SD)	*P* value
App quality			
Total score	3.67 (0.34)	3.09 (0.46)	.02
Subscales			
Engagement	3.60 (0.3)	2.86 (0.6)	.01
Functionality	4.04 (0.61)	3.70 (0.61)	.18
Esthetics	4.02 (0.69)	3.33 (0.54)	.08
Information	3.03 (0.44)	2.48 (0.3)	.01
App-specific items (perceived impact on goal setting or tracking)			
Awareness	3.83 (0.66)	3.21 (0.95)	.13
Knowledge	3.83 (0.43)	3.00 (0.91)	.02
Attitudes	3.83 (0.35)	2.86 (0.90)	.01
Intention to change	3.83 (0.35)	2.93 (1.02)	.07
Help seeking	3.28 (0.44)	2.93 (0.73)	.37
Behavior change	3.78 (0.44)	3.07 (0.53)	.02

Discussion

Principal Findings

In summary, more than half of the 16 goal-setting and tracking apps in this review targeted HRBs, which included behaviors related to nutrition and mealtime, physical activity and screentime, sleep, and personal hygiene. Only 3 apps were tailored for specific ages of children, including 2 apps for middle childhood to early adolescence, and 1 app for 3 age groups spanning from 4 years through adolescence. No evidence was found indicating that any of the apps had been tested in clinical trials, experimental studies, or other studies. Most of the apps offer features for personalizing the user experience of tracking multiple children, and some of the apps offer the option for both parents and children to directly use the apps together as a family. However, none of the apps provided individually tailored assessments or guidance to recommend specific goals for each child, and none suggested using the app in coordination with their children's health care provider.

The app quality assessment indicated an overall moderate app quality and substantial variation in quality ratings, with only a handful of apps consistently scoring high across subscales and app-specific items. Among the HRB apps, Habitz had the highest MARS quality rating and the third-highest user rating in the Apple App Store, and among the WHRB apps, Thumsters ranked the highest on both. Aside from these 2 apps, the rank order of apps in our MARS quality ratings and in the average user ratings from the app stores were fairly inconsistent. Ranking the apps and descriptive subgroup analysis revealed a pattern of higher quality ratings in the HRB group than the WHRB group, including the MARS total score, the engagement and information subscales, and the app-specific items about perceived impact on knowledge, attitudes, and behavior change.

Comparison With Prior Work

To our knowledge, this is the first review of commercially available mobile apps that specifically target parents and include goal-setting features. Three recent reviews of commercially available mobile apps targeting HRBs are relevant for comparison with our study because the authors reported that a substantial proportion of the reviewed apps included goal-setting BCTs, ranging from 18.1% (47/259, including 17 "habit trackers") [18] to 32% (8/25) [17] to 56% (15/27) [16]. The key difference is that these reviews focused on apps that targeted children and adolescents as the primary users rather than parents. Although 7 of the 9 HRB apps in our review provided the option for children to directly use the apps in addition to the parents, none of the apps included in those reviews overlapped with the apps reviewed in our study. Possible reasons for the lack of overlap are that the authors reviewed apps that were available on the app stores in their respective countries and in different years—ours in the United States in 2021 versus the others in Australia in 2013 [16] and in 2016 [17] and Canada in 2018 to 2019 [18].

Two of these reviews assessed app quality using the MARS tool [17,18]. Schoeppe et al [17] reported a mean MARS total score of 3.6 out of 5 possible points for the 25 nutrition and physical activity–focused apps (range 2.4-4.4), indicating moderate quality, but the subgroup of 8 apps with goal-related BCTs had a higher mean of 4.0 and less variation (range 3.6-4.4). Brown et al [18] indicated that the mean MARS total score for the 259 nutrition-related apps was also 3.6 (range 2.2-4.7), or moderate quality, and indicated a similar mean of 3.5 with less variation (range 3.2-4.2) for the subgroup of 17 apps in the "habit tracker" subgroup. In comparison, in this review, all apps included goal setting or tracking, with a mean MARS total score of 3.4 (range 2.5-4.2), and the subgroup of HRB apps, most of which included nutrition or physical activity, had a slightly higher mean of 3.7 (range 3.2-4.2). Thus, the

quality scores for the HRB subgroup in our study fell in between the relevant subgroups in the reviews by Brown et al [18] and Schoeppe et al [17].

The highest scoring MARS subscale was functionality for the review by Schoeppe et al [17] (4.10 overall; 4.3 goal subgroup), Brown et al [18] (4.0 overall; 4.0 habit tracker subgroup), and our review (3.9 overall; 4.0 HRB subgroup). However, the reviews differed in the lowest-scoring MARS subscale. Engagement was lowest for the review by Brown et al [18] (2.9 overall; 3.3 habit tracker subgroup), whereas information was lowest for the review by Schoeppe et al [17] (2.8 overall; 3.2 goal subgroup) and our study (2.8 overall; 3.0 HRB subgroup). These findings across reviews suggest that commercial apps for parents and children that focus on HRBs or use goal setting as a BCT tend to perform well on the functionality domain of MARS, which includes performance, ease of use, navigation, and gestural design, but they may be weaker on the information and engagement domains.

In the third review, Burrows et al [16] noted that none of the 27 apps related to child weight management that were commercially available in 2013 were tested through research studies, which was also found in our review. They also noted that most of the app developers did not report on the involvement of content area experts, which was the same for all but one of the apps in our review. Furthermore, most of the apps in the review by Burrows et al [16] contained content that they deemed was not consistent with relevant best practices, that is, national dietary guidelines. Although the review by Burrows et al [16] did not include a quantitative quality assessment using a tool, such as MARS, the findings are consistent with our finding related to the information domain of MARS. The items comprising this domain include clear and achievable goals, correct and comprehensive information, credibility of the app source or developer, and the scientific evidence base of the app [24]. In our review, credibility and evidence base were consistently the lowest-scoring items, which reduced information domain scores. This finding of a low information domain score driven by low ratings on the credibility and evidence base items is also consistent with reviews of commercially available apps for adults that focus on nutrition, physical activity, and other health promotion behaviors [20,29].

Although the HRB apps with goal-setting features reviewed here were not tested through research, the specific HRBs that the apps targeted through predefined goal options were largely consistent with the current scientific literature and best practices related to child and adolescent health. For example, 3 of the 6 apps that target nutrition and mealtime behaviors had predefined goal options on child consumption of specific healthy and unhealthy food options, such as increasing intake of vegetables, fruit, or water, and decreasing intake of junk food (eg, fast food and sugar-sweetened beverages). Promoting goals targeting these behaviors has the potential to positively influence child dietary patterns based on the existing scientific evidence related to these broad behaviors [23,30-35]. Similarly, 4 apps offered predefined goal options for increasing physical activity (eg, general exercise, outdoor play, and practicing sports) and 2 apps included goal options for limiting screen time, reducing total screen time, and contingent access to electronic devices. Both increased physical activity and decreased screen time have been consistently linked to health and other benefits for children [36-40]. Moreover, 7 of the apps included sleep and bedtime routine behaviors for goals. Both sleep duration and sleep quality have been associated with a number of health-related outcomes in children, such as physical development, cognitive development, emotional and behavioral problems, and excessive weight gain [41-44]. Furthermore, 6 of the apps included predefined goals related to personal hygiene in children, such as brushing teeth, washing hands, and bathing, which support current oral health guidelines [45,46], effective public health hand hygiene strategies [47-49], and other benefits for young children related to sleep and emotional connection with caregivers [50]. Therefore, although the parent-targeted apps we reviewed have not been individually tested for efficacy, our findings suggest that some of the apps focus on HRBs that have a general scientific evidence base and could potentially be leveraged for health promotion and chronic disease prevention.

Interestingly, our review identified a smaller number of commercially available parent-targeted apps than the number of child-targeted apps identified in previous reviews, even after restricting to apps that include goal-related features [18]. The large number of mobile apps targeting young children as the primary users is inconsistent with the vast scientific literature that has established the crucial role of parental influence and environmental changes in shaping children's behavior before adolescence [14,15,51]. This notion is supported by the concept of parental health-related empowerment by Gago et al [15], which they define as "the process by which parents realize control over their life situation and take action to promote a healthier lifestyle." Their work demonstrated that increasing parental empowerment can improve weight-related parenting practices, which in turn can influence children's behaviors and promote prevention of obesity and chronic diseases.

Limitations

Although this is one of the only objective reviews of parent-targeted goal-setting apps for child-focused behavior change, we acknowledge its limitations. Although a strength of the evaluation process was the use of a validated instrument that has been successfully used in many previous studies and provides valuable insights, the evaluation did not include using the apps with the target population of parents. It is possible that parents would have rated the quality domains differently, thus limiting the inferences we can make regarding the utility and engagement features. Although the inclusion of actual use-case testing was not feasible and outside of the scope of the review, this can be pursued in future research.

Second, because of the dynamic nature of the app stores that do not indicate the number of apps meeting search criteria, it is possible that eligible apps could have been missed. We mitigated this challenge by using multiple search terms and by using a snowball approach of reviewing similar apps recommended by the app store when viewing each app that appeared in the searches. Finally, we did not directly test features that were only available through paid upgrades to maintain consistency across the apps and because paid versions are likely not accessible for

all parents. It is possible that some of the MARS ratings, particularly the app-specific items, may have scored higher when including the paid upgrades.

Implications for Research and Practice

The overall average app quality was rated as moderate in this review of commercially available apps that target parents to facilitate goal setting and tracking for child behavior change. Of note, several of the apps were rated as high quality, particularly among the apps that target HRBs, and several were rated as having strong potential to generate changes in knowledge, attitudes, and behaviors. However, even the apps with high-quality ratings lack documented evidence of efficacy. Although the field of mHealth continues to grow along with technological advances, potential mHealth adaptations of existing behavioral intervention strategies may or may not offer improvement over traditional delivery formats; for example, Is goal setting more effective for parents when they are prompted during a conversation with their child's physician or when they are prompted by a mobile app while they are at home [52]? Furthermore, the context in which parents interact with mobile apps related to goal setting and tracking will likely influence the effectiveness on behavior initiation and maintenance. For example, a parent could set a goal to initiate a new food purchasing behavior during a visit with a nutritionist at a public assistance program, then use a mobile app provided by the nutritionist when they go home to track goal progress, receive ongoing reinforcement, and share their progress with the nutritionist [53-55].

The provision of evidence supporting the impact of the apps is relevant for parents, clinicians, and other health professionals and could positively influence parent uptake if an app was supported scientifically. An evidence-based rating system could guide health professionals in identifying the most effective apps to recommend to parents of children in clinical settings and public health programs [56]. This is critical given that behavior change can be a challenging process and may require repeated attempts to be successful. Although the apps reviewed here may be efficacious, health professionals and parents currently have no basis for recommending or selecting an app for their families. In addition, apps that have not been proven effective could waste parents' time and energy on strategies that are not likely to improve the target behavior. This represents a missed opportunity to engage parents in evidence-based strategies, and in some cases, it could potentially pose an ethical dilemma if health care professionals recommend ineffective apps to parents. Future app development and research should focus on this opportunity.

More research is needed to assess whether using a mobile app for parents to set and track goals for child HRBs is effective using existing apps or newly developed apps. Furthermore, future research should examine which specific goals or combination of goals within each behavior domain are most important, how they interact with each other, and the mechanisms that lead to changes in health outcomes [57]. For example, while it has been established that certain aspects of children's eating routines such as family member presence, frequency of family meals, frequency of fast food consumption, positive mealtime atmosphere, parental modeling, and longer meal duration are associated with diet quality and health outcomes [58-61], it is difficult to establish the mechanisms that lead to weight-related outcomes of these routines and practices. Furthermore, the dietary and weight-related goals of motivated parents trying to establish positive mealtime routines and climates can be easily thwarted by factors such as strong child food preferences, preservation of the child's self-esteem, desire for conflict avoidance, and inflexible time and finances [62].

Although parents were the primary users of the apps in this review, most of the HRB apps also offered options for the children to engage with the app, either as another user on the parent's phone or on the child's own device, linked together as a family. These features offer the opportunity to include the whole family in change, which could potentially enhance the impact of the apps as family-based interventions. A small but growing body of research is beginning to explore the delivery of family-based interventions through mobile apps, which show promise, but much more research needs to be done [63-65]. This could also provide an opportunity for parents to connect with the children's health care provider to share the family's goal progress data for remote monitoring and feedback. An important dimension to explore is developmentally appropriate levels of involvement for children of different ages, potentially with more involvement as children age. A notable gap identified in this review was the lack of goal-setting apps for parents of young children, with only one targeting parents of children aged 4 to 6 years and none targeting parents of children aged <4 years. During the infant, toddler, and preschool years, parents obviously exert a great influence on their children and have great potential to initiate healthy behaviors even at those young ages.

Finally, another gap identified in this review was that none of the apps provided validated assessments to guide goal selection or other individually tailored guidance to help recommend goals for children based on their unique needs. Previous research has demonstrated the feasibility and effectiveness of guided goal setting in in-person intervention settings [66-68], and more research is needed to extend and evaluate this strategy using mHealth and mobile technology in general.

Conclusions

This review identified several high-quality commercially available apps that target parents with a focus on goal setting and tracking for child behavior change, both for HRBs and for non–health-related behaviors. However, these apps lack documentation of research-tested effectiveness. Future research should address this gap in the literature. In particular, more research is needed to assess the effectiveness of leveraging mobile apps to facilitate individually tailored guided goal setting for parents of young children. In addition, future research should explore options for integrating parent-focused apps as a complement to and reinforcement of health professionals' interactions with parents around goal setting and tracking.

Acknowledgments

This research was supported by the US Department of Agriculture (grant 2017-68001-34846) and the National Institutes of Health National Center for Advancing Translational Sciences (grant UL1TR001998). The content is solely the responsibility of the authors and does not necessarily represent the official views of the US Department of Agriculture or the National Institutes of Health.

Authors' Contributions

SJW, PCH, SAM, and AF were involved in study conception and design; SJW, PCH, SAM, AF, and MB collected the data; SJW, PCH, SAM, AF, MB, TK, LS, and SLG performed analysis and interpretation of results; SJW, PCH, SAM, AF, MB, TK, LS, and SLG prepared the draft of the manuscript; and PCH was involved in funding acquisition. All authors have reviewed the results and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplemental Table 1. Mobile App Rating Scale scores for each reviewed app and overall (N=16). Supplemental Figure 1. MARS total quality score for reviewed apps.
[DOCX File , 35 KB - pediatrics_v6i1e41779_app1.docx]

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Abbreviations

BCT: behavior change technique
HRB: health-related behavior
MARS: Mobile App Rating Scale
mHealth: mobile health
SMART: specific, measurable, achievable, relevant, time-bound
WHRB: without health-related behavior

Edited by S Badawy; submitted 01.03.23; peer-reviewed by K Nuss, B Chaudhry, D Albright; comments to author 04.05.23; revised version received 31.07.23; accepted 29.08.23; published 13.10.23.

Please cite as:
Weber SJ, Mulvaney SA, Faiola A, Brown M, Koyama T, Sun L, Goggans SL, Hull PC
Commercially Available Mobile Apps With Family Behavioral Goal Setting and Tracking for Parents: Review and Quality Evaluation
JMIR Pediatr Parent 2023;6:e41779
URL: https://pediatrics.jmir.org/2023/1/e41779
doi:10.2196/41779
PMID:37831486

Original Paper

Understanding the Tensions of "Good Motherhood" Through Women's Digital Technology Use: Descriptive Qualitative Study

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Abstract

Background: Research suggests that expectant and new mothers consult and value information gathered from digital technologies, such as pregnancy-specific mobile apps and social media platforms, to support their transition to parenting. Notably, this transitional context can be rich with profound physiological, psychological, and emotional fluctuation for women as they cope with the demands of new parenting and navigate the cultural expectations of "good motherhood." Given the ways in which digital technologies can both support and hinder women's perceptions of their parenting abilities, understanding expectant and new mothers' experiences using digital technologies and the tensions that may arise from such use during the transition to parenting period warrants nuanced exploration.

Objective: This study aims to understand mothers' use of digital technologies during the transition to parenting period.

Methods: A descriptive qualitative study was conducted in a predominantly urban region of Southwestern Ontario, Canada. Purposive and snowball sampling strategies were implemented to recruit participants who had become a parent within the previous 24 months. Researchers conducted focus groups using a semistructured interview guide with 26 women. The interviews were audio recorded, transcribed, and thematically analyzed.

Results: Participants' experiences of using digital technologies in the transition to parenting period were captured within the overarching theme "balancing the tensions of digital technology use in the transition to parenting" and 4 subthemes: self-comparison on social media, second-guessing parenting practices, communities of support, and trusting intuition over technology. Although digital technologies purportedly offered "in-the-moment" access to community support and health information, this came at a cost to mothers, as they described feelings of guilt, shame, and self-doubt that provoked them to question and hold in contention whether they were a good mother and using technology in a morally upright manner.

Conclusions: These findings raise critical questions concerning the promotion and commercialization of digital technologies and the ways in which they can further push the boundaries of hegemonic parenting practices, provoke feelings of inadequacy, and compromise well-being among expectant and new mothers.

(JMIR Pediatr Parent 2023;6:e48934) doi:10.2196/48934

KEYWORDS

motherhood; parenting; digital health; apps; social media; mother; parent; technology use; use; computer use; interview; interviews; perspective; perspectives; mothers; mobile phone

Introduction

Background

Expectant parents, predominantly mothers, regularly use internet-based resources such as websites, internet-based forums, and blogs for informational needs, access to services, and social support during the transition to parenting [1-4]. The transition to parenting period consists of 4 stages—pre-conception, pregnancy, labor, and postpartum—which uniquely mark the time in a person's life when they become a parent for the first time or add another child to their family [1,4]. These stages will inevitably vary from person to person depending on their unique family dynamic and health circumstances [1,3,4]. Nonetheless, advances in digital technologies (eg, computers, web cameras, wearable technologies, smartphones, and internet-based applications), along with the introduction of social media in the mid-2000s, have expanded the technological landscape in which expectant and new parents gather information and connect with others to support their parenting practices throughout these nascent stages of parenthood [5]. During the transition to parenting, recent studies suggest that new and expectant mothers consult and value information gathered from digital technologies such as pregnancy-specific mobile apps and social media platforms such as YouTube to search for signs of normality and risks of illness and to find a maternal community [1,5]. Social media and pregnancy apps have been found to promote women's well-being by reducing feelings of isolation and improving their own and their new or developing infants' health outcomes by providing immediate access to medical information and how-to videos on infant care [1,6,7].

The proliferation of digital technologies, particularly within the health and medical sector, offers expecting parents endless opportunities and novel ways to use their personal digital devices to monitor, photograph, index, catalog, video record, and compare their maternal bodies to others in real time [8]. Within the transition to parenting period, comparing and evaluating one's pregnant body and the developing fetus or newborn against those of other pregnant and fetal bodies has become a normalized parenting practice and way to "do pregnancy" [9]. In fact, pregnancy-related apps are the most-used health apps [10] and the number of pregnancy app downloads that offer expectant parents an avenue to self-monitor their bodies and that of their growing fetus continues to increase yearly across major app platforms [9]. For example, as of May 2023, Pregnancy +, the most popular pregnancy tracking app available on the Apple App Store and Google Play, has an estimated 50 million users worldwide [11]. Within the highly competitive commercialized app world, pregnancy apps are marketed specifically to cisgender women to document and benchmark their prenatal and early parenting practices as a taken-for-granted aspect of parental care and marker of being a "good mother" [9].

The widespread datafication and dataveillance [12] aligned with the ideals of good motherhood within North American culture encourages mothers' development of self-knowledge and peace of mind through daily digital technology use; these practices simultaneously reinforce sociotechnical structures and systems that allow corporate entities such as app developers and technology conglomerates to track and mine data for enhanced business intelligence and performance [9]. Within this context, *datafication* refers to personal behaviors such as bodily movements, thoughts, and emotions that are monitored and quantified through digital interfaces to produce data that can be analyzed and explored to deepen our understanding of human behavior [12]. *Dataveillance*, on the other hand, is a concept that refers to the broader internet-based environment wherein datafication occurs and the ways in which users' personal behaviors are constantly being watched and guided by the technical infrastructure they are interacting with [12].

On Guilt in the Transition to Parenting

The transition to parenting is a period rich with profound physiological, psychological, and emotional fluctuations for individuals as they cope with the demands of new parenthood and navigate cultural expectations of successful parenting. Specifically, women are charged with the responsibility to take it upon themselves to enter the ranks of performing good motherhood [3,13]. As some research notes, North America's cultural ideology of good motherhood asks women to give their all—physically, emotionally, psychologically, and intellectually—at all times, which consequently presents women with a model of nearly unachievable expectations [14]. Within the transition to parenting period, good motherhood in North America is associated with women showing unrelenting consideration, care, and love for their expectant or new infants by willingly engaging in vigilant self-care and information-seeking practices to ensure a healthy pregnancy, delivery, and optimal infant development during the early postpartum years [15].

With such demanding sociocultural expectations placed on new mothers, it is foreseeable that mothers regularly report feeling guilty when they do not or cannot exude the narrowly defined social standards of good motherhood, which positions White, heterosexual, cisgender, and middle-class mothers as normative [14,16,17]. In fact, maternal guilt is so pervasive in North American culture that it is considered an expected, almost inherent aspect of mothering norms by some scholars [14,18]. In psychological terms, a person experiences guilt—a negative evaluation of their own behavior or attitude—when they become conscious that they have wronged someone else; guilt involves criticizing one's *actions specifically* [19].

In this way, North America's cultural expectations of good motherhood are inextricably linked to women's "moral selves," as they are expected to navigate a social system with purported "right" and "wrong" ways to mother [14,18,19]. For example, the "right" way to mother may involve having an unmedicated birth; breastfeeding; and feeling *only* joy, happiness, and gratitude for the privilege of becoming a mother during the postpartum period. Therefore, the "wrong" way to mother might consist of drug-involved labor (eg, the use of a narcotic for pain relief); formula feeding; and expressing feeling sad, angry, or otherwise disappointed following a new baby's arrival [13]. The idealized good mother is thereby "involved," always present and attentive to the needs of their infants or children, a constant model, guide, and teacher [20]. Through this lens, North

American mothers are set up to experience constant maternal guilt in a cultural landscape that positions any shortcoming of meeting "right ways" to mother as a personal, moral failing.

In relation to digital technologies, experiences of guilt are amplified through the perpetual supply of curated content by other mothers [17]. Despite the potential benefits that pregnancy-specific apps and social media platforms offer mothers as tools for health information seeking and finding social support, the use of these technologies has been found to perpetuate feelings of guilt, shame, inadequacy, and self-doubt that are bound up within cultural expectations of good motherhood [17-19]. For example, research that focused on mothers' use of digital technologies during the perinatal period found that they reported feelings of anxiety in relation to the developmental milestones of infants described in the apps [13]. Although these indicators of developmental milestones are meant to act as resources for parents, the very existence of such guidelines perpetuates normative standards by which parents inevitably compare their infants against a bell curve [13].

Consequently, social media can be seen to extend spaces of comparison among mothers with negative repercussions. For example, research has found that mothers who spent considerable time on social media after giving birth to connect with a broader maternal community and share information about their new infant expressed feelings such as failure, enhanced anxiety, and doubt in relation to their own parenting abilities [13]. Such feelings of insecurity were amplified among mothers exposed to the posts of other mothers, who by comparison appeared to effortlessly return to their prebaby body or better manage their overlapping roles as mothers, partners, and workers [13].

Objectives

In this paper, we present key findings from a larger qualitative descriptive study [21], where we explored expectant and new parents' use of digital technologies within the transition to parenting period [1]. This study generated many rich findings and provided novel insights into a relatively understudied area of inquiry as it focused on new parents' experiences using digital technologies across preconception to postpartum periods to support their early parenting practices [1]. This paper focuses on the findings that identify how new and expectant mothers negotiated tensions of resultant guilt with perceived gains through their use of digital technologies within the transition to parenting period. By using a sociotechnical perspective [22] to interpret the mothers' experiences, we show how new and expectant mothers' digital technology use is a complex process that encompasses a wide range of nuances and cannot be simply categorized as entirely "good" or "bad."

Methods

Theoretical Perspective

The current ubiquity of digital technologies makes it difficult to differentiate between one's internet-based and offline self [15,22] and, by extension, internet-based and offline forms of parenting. Through a sociotechnical lens [22], digital technologies extend and redefine users' thoughts, emotions, movements, curiosities, interests, and physical bodies into sites of information represented as a digital code. Humans' navigation of their social world and place within it—their practices of selfhood are then understood as information sites [22].

Although digital technologies have been found to bring moments of relief and companionship to expectant and new mothers [1,4], research that explores the nuances of new and expectant parents' experiences with guilt alongside perceived gains as they relate to digital technology use throughout the transition to parenting remains scarce. When it comes to understanding mothers' experiences particularly with digital technologies, scholars note the importance of considering the layered contexts where the domestic and social demands of women's lives overlap in their roles as mothers, partners, friends, consumers, citizens, and employees [20,23].

Recruitment and Participants

This study was conducted from 2018 to 2019 in a predominantly urban region of Southwestern Ontario, Canada. Researchers used a purposive sampling strategy along with a snowball sampling technique [24] to recruit adults who had become parents within the past 2 years. Participants were recruited through flyers posted in community spaces with high volumes of new parents, such as day care centers, family health clinics, public health clinics, and children's play centers. Digital recruitment flyers were also distributed on internet-based buy-and-sell platforms such as Kijiji and social media sites such as Facebook and Twitter. To be eligible to participate in the study, participants had to (1) identify as a new or expectant parent who transitioned to parenting within the last 2 years, (2) identify as aged between 16 and 35 years, and (3) speak fluent English. The age bracket was set to an upper limit of 35 years as the health care needs and risks of women who are of advanced maternal age tend to be different, and they tend to have generationally different levels of education, financial stability, life experience, and emotional maturity. All eligible parents provided written informed consent and were given a US $15 honorarium for their participation before data collection began.

Ethical Considerations

Ethics approval to conduct this research was granted by the nonmedical research ethics board of Western University (2020-114165-36905). All participants were provided with a letter of information and gave their consent to participate in the focus groups and follow-up interviews. Each participant was assigned a study ID number to protect their anonymity.

Data Collection and Analysis

Focus groups was chosen as the method of data collection as it honors the coconstruction of knowledge between group members and has been used to engage in meaningful dialogue with new parents [21]. In-person focus groups and follow-up interviews were conducted by members of the interdisciplinary research team. Researchers met participants in pre-agreed locations, including a children's center, public libraries, and a shelter. Before beginning each focus group, the researchers administered a demographic questionnaire to the parents to capture descriptive characteristics. The main area of inquiry that guided the focus group discussions was parents' use of and experiences with

digital technologies—including pregnancy apps, infant care apps, social media, internet-based support groups, and internet-based health information resources—during their transition to parenting. Participants were asked to reflect on their experiences during the 4 phases of the transition to the parenting period, and probing questions were asked to elicit a deeper discussion of their experiences and interactions with digital technologies. Participants contributed insights based on hearing the responses from others and were prompted by focus group facilitators. All focus groups were audio recorded and transcribed verbatim. Facilitators took field notes throughout the focus groups to capture additional data, specifically nonverbal communication, which could not be documented through digital audio recordings.

Data analysis followed an iterative thematic approach [21,25]. Iterative thematic analysis within the context of qualitative research is a systematic approach to data analysis that is used to identify, analyze, and report patterns or themes within a data set of textual, audio, or visual information [21,25]. This dynamic approach involves multiple rounds of data examination and theme refinement to gain a deeper understanding of the underlying meanings and patterns present within the data set and is particularly useful when examining complex, multifaceted issues [21]. In following this process, each member of the research team individually analyzed the focus group transcripts and field notes to generate an initial coding matrix. Thematic coding was tracked using a tabular matrix with supporting quotes from the transcripts as a semantic guide. Members of the research team iteratively compared their initial codes and emerging insights to coconstruct thematic findings through in-person meetings. Recruitment and data analysis occurred simultaneously and ended once data saturation was achieved when no new themes were generated within focus group discussions or among research team members through iterative analytic discussions [21].

Triangulation and reflexivity were used as mechanisms to ensure rigor and trustworthiness across thematic findings [21,26]. The goal of triangulation within the context of qualitative research is to strengthen the credibility of findings by cross-referencing information from multiple sources or perspectives (ie, researchers) to confirm and strengthen the interpretation of themes or patterns identified in the data. Triangulation is a process that reduces the potential for bias and enhances the reliability of interpretation across multiple data sources [26]. Members of the research team further practiced reflexivity to enhance the rigor and validity of the findings. Reflexivity is a vital component of rigorous qualitative research as it promotes researchers' self-awareness and active engagement within the research process through acknowledgment and examination of their own beliefs, biases, and assumptions that they bring to their work and how these factors shape their data analysis and interpretative processes. When examining the respective positionalities and lived experience of the researchers within the context of this research, it is important to note that all members of the research team who participated in the data analysis process came from academic backgrounds, including nursing, doula studies, public health, and health professional education, and that most also identified as parents. The research team members' children ranged in age from 7 to 30 years at the time of data collection. Owing to their diverse experiences within the transition to parenting period at the time of their child or children's birth, research team members offered different perspectives regarding their personal engagement with digital technologies to support their parenting to bring to the data analysis process. As such, each team member relied on interrelational reflexive practice to guide their dialogues with each other and challenge their own tacit assumptions about using digital technologies within the transition to parenting as codes and eventual themes were identified.

Results

Overview

In total, 26 individuals who identified as heterosexual women participated in the study across 10 in-person focus groups (2-4 mothers/focus group). Overall, the age of the participants ranged from 17 to 35 years: 31% (8/26) of the participants were aged ≤20 years, 15% (4/26) of the participants were aged between 21 and 29 years, and 38% (10/26) of the participants were aged between 30 and 35 years. Most participants (18/26, 69%) identified as White, and 12% (3/26) of the participants identified as racialized. In terms of marital status, half of the participants (13/26, 50%) identified as married; 27% (7/26) of the participants identified as single and never married; and 4% (1/26) of the participants identified as separated from their partner. Regarding employment status, one-third of the participants (9/26, 35%) identified as unemployed, 27% (7/26) of the participants identified as a full-time employee, and 12% (3/26) of the participants identified as a part-time employee. Educational background differed among participants at the time the study was conducted; of the 26 participants, 7 (27%) were in the process of completing their secondary school diploma, 1 (4%) held a high-school diploma, 1 (4%) held a community college certificate, 10 (38%) held a university undergraduate degree, and 2 (8%) held a university undergraduate degree as well as a graduate degree. Finally, the socioeconomic status across the participants varied as well; 15% (4/26) of the participants reported a yearly household income of <CAD $20,000 (<US $14,814); 12% (3/26) of the participants reported a yearly household income between CAD $20,000 (US $14,814) and CAD $50,000 (US $37,037); 15% (4/26) of the participants reported a yearly household income between CAD $50,000 (US $37,037) and CAD $99,999 (US $74,073); and 19% (5/26) of the participants reported a yearly household income of >CAD $100,000 (>US $74,074). It is notable that recruitment strategies were inclusive of all genders who become pregnant and a parent; however, all those who expressed interest in the study and enrolled as participants were assigned female at birth.

Overall, participants' experiences of using digital technologies within the transition to parenting period were analyzed and captured within the overarching theme "balancing the tensions of digital technology use in the transition to parenting" and four subthemes: (1) self-comparison on social media, (2) second guessing parenting practices, (3) communities of support, and (4) trusting intuition over technology.

Balancing the Tensions of Digital Technology Use in the Transition to Parenting

Participants expressed concerns that their prior digital technology habits were encroaching upon their newfound parenting moments and responsibilities. Navigating smartphone and social media use during infant feeding, sleeping, and bonding time constantly put participants in a conflicted space between feelings of relief and normalcy with respect to their prebaby behaviors and guilt for using it once their baby arrived. For example, they described how they became hyperaware of how frequently they used their smartphone around their new baby:

> *I'm on it all the time. But not when he—I don't like to do it when he's around. So, if he's busy I'll do it, but I don't like to be on it while he's playing. Like I want to be interactive with him, but I'm still on it as much as I was before.* [T1]

Participants also recognized how frequently they were on their phone and expressed feelings of guilt, recognizing that not all the time they spent on their device was in service of good motherhood (ie, looking up information or educational sources):

> *I do feel a little bit, like, I'm on my phone too much, like, I feel like it's always in my hand or, like, I'm always on it. And, like, not reading, like, you know, it's not like I'm reading something super informational or educational, right.* [T6]

There were also times when participants used their smartphone to augment pragmatic and essential parenting responsibilities such as breastfeeding, which caused them to question their technology use habits. The following quote demonstrates how a participant balanced their necessity to stay awake to breastfeed using a smartphone as an aid:

> *...smartphone scrolling was almost just a way...to stay awake while nursing her.... I sometimes will use it just to like play candy crush or just to kind of stay awake or even if I'm Googling something that she's doing like it's probably not the best, but [my smartphone is] always near me.* [T7]

Participants' technology use was mirrored back to them by their infants. One participant felt guilty about using her phone as an entertainment source for her toddler after noticing that they picked up on how to use its touchscreen interface and "swipe" notifications out of the way:

> *If my child is watching a show on my phone and a text message pops there, she's only 19 months, she can swipe it out of the way. Swipes it out so that it's off the screen. But I'm like is this my doing that I allow this. And then I feel guilty, but then I'm so exhausted.* [T12]

These participants undoubtedly questioned the presence of their smartphone and their use of them in front of their infants as they reflected on feelings of guilt and perceived shortcomings in their transition to parenting.

Self-Comparison on Social Media

Participants described how social media could be both a beneficial tool for social support and a drawback at the same time because of the opportunities it opens for self-comparison:

> *I think especially in that fragile postpartum period, we're so vulnerable and we're so out there, like not feeling good really about where we are.... And, you know, when you feel lonely with your infants, like, I feel like.... You turn...to more social media because it...makes you feel, like, connected in a way but then it makes you more disconnected from where you are...it's a twisted sort of world.* [T12]

In terms of self-comparison, the postpartum body was a particular point of comparison for participants, irrespective of their knowledge that social media photos are staged and curated. For example, they described how social media contributed to feelings of body shame:

> *I think sometimes [social media] is bad for people too like because you are comparing a lot...Like I think it's good, but it can be bad too because you compare.... I felt like big and ugly...because you're comparing. You see these like photos, picture perfect pictures that are like set up and the perfect angle and stuff.* [T12]

Furthermore, participants acknowledged how digital technologies and social media created opportunities to compare themselves to other mothers by reflecting on whether they were meeting cultural expectations of good motherhood:

> *I have a seven-month-old at home and a three-year old and trying to do all this stuff and just like watching...other people do this and thinking, okay, well maybe I should do that or maybe, you know, I'm not doing enough or I'm not living up to like those expectations. So, I was putting on like unsolicited expectations on myself that weren't even coming from me, what I wanted and I started kind of like [spiraling].* [T12]

Participants described balancing the tension between their use of digital technologies as tools to gather parenting information while also recognizing how such technologies can entrap them into making developmental comparison with respect to their infant and other infants:

> *I feel like I rely on [digital technologies] a lot when it's like for questions, but I agree with what you [another participant] said about sometimes you're [likely to] compare to other people if you're on social media and you see stuff that their kid is doing, maybe not even milestones, but like anything, right. You're like, oh wow, that's a– should my kid be doing that or should, I don't know.* [T11]

Second-Guessing Parenting Practices

Although participants remarked how convenient these technologies were in terms of providing them with instantaneous access to health and parenting information, the work of discerning information to inform their parenting practices and

infant development was burdensome to participants. Within the transition to parenting period, participants remarked how digital technologies, "definitely guides you...but worries you at the same time and you kind of question everything you're doing" (T2).

With respect to pregnancy, the participants identified the tension between experiencing relief and self-doubt in their personal application of digital technologies. For instance, a participant used their own home Doppler ultrasound device to listen to their fetus's heartbeat. Google and YouTube were used as tools to augment the use of the Doppler to search and discern different in utero sounds when they were not sure if what they were hearing was the fetal heartbeat:

> *...at first, I was like there's different sounds too right. Like there's the placenta and then there's the baby's heartbeat. So, for me, it was like okay, like YouTubing the sound of like the placenta blood flow versus like a baby's heartbeat. Like so, I mean I feel like [the doppler] did put me at ease for the most part, maybe when I was having difficulty finding it, then it was like more stressful. And I know like my husband had to like hide it from me from time to time because I was using it too much and then I was like googling like will it like, is it like sound wave safe. Like should I like not be using it. So, I don't know.* [T11]

Google was also frequently turned to within the postpartum stage as participants tried to make sense of their babies' development and determine what was considered normal against the influx of updates and posts of friends' babies. Participants expressed how digital technologies generated feelings of self-doubt via comparison with others' posts and their own baby's developmental progress:

> *I find it's hard.... I'm constantly like comparing him to my other friends who have babies around like one of our good friends, [their] baby and him are two days apart and it's like, yeah, like he's like really good at holding his head up and but he's like still kinda wobbling. So, I'm like, is this normal and just googling when do they, when can they do this or when should they be doing this...* [T11]

Communities of Support

Participants described how smartphones and social media platforms, such as Facebook, provided crucial opportunities to connect with other mothers to receive support in the form of parenting advice, product information, and tips, and to relieve moments of intense isolation. From Facebook "mommy groups" to texts with friends, informational and social support were notable gains associated with participants' digital technology use. For example, participants remarked on how comforting it was to "chat" with other parents in Facebook groups and read about their postpartum experiences:

> *So, there were some [Facebook] groups I joined just to hear other peoples' stories and things and then others—one I just joined recently and it just talks about anything from like a newborn to toddler.... Just to see other peoples' experiences and what worked for them, what didn't work.... And oftentimes, I still kind of make a decision for myself, but it's nice to know that, okay, someone went through this or someone else had these questions or did this.* [T2]

Internet-based parenting groups also provided opportunities for the participants to experience social connectedness. For example, participants remarked on how comforting it was to be able to scroll their timelines and stay up to date with others' lives through their posts even when they were unable to join in such activities. For instance, one participant who was spending most of her time at home and experiencing postpartum depression and feelings of isolation: "looking on Facebook and stuff kinda helped me to just to like, to see what everyone else was doing and it kind of make me feel like I'm still like...connected" (T3). Beyond social media, digital technologies, such as smartphones, also played a crucial role in facilitating a sense of social connectedness and support through SMS text messaging. For example, participants remarked how using their smartphone to connect with others through text made them feel like they were never alone: "it's so easy to like send a text to someone at three in the morning being like, this is happening or [ask] is this happening to you?" (T11).

Trusting Intuition Over Technology

Finally, it is important to note that although participants reported the incessant use of digital technologies, they also questioned, challenged, and resisted the pervasive power of digital technologies in the transition to parenting. Participants demonstrated resistance in choosing to trust their own intuition. Rather than using digital technologies that amplified anxieties (instead of soothing them), participants noted specific occasions on which they resisted emerging parental surveillance trends. As one participant noted, they resisted the need to reply on digital technology to alleviate the fears of "unknowing" in parenting:

> *I'm not gonna put a monitor in there [infant's room] looking at my kid all the time because I'm just gonna be looking at my kid all the time and freaking out and thinking they have something.... I literally just, I need to trust that they're okay.* [T10]

Participants were particularly aware of their capacity to obsess over information (in this case, a real-time video stream of their infant sleeping) and adopted ways they could challenge their own knowledge: "I need to trust that I did a good job. That I tucked them in [that] Some stuff didn't fly across the room and cover their face" (T10).

Discussion

Principal Findings

Participants expressed conflicting feelings toward digital technologies and social media use. On the one hand, they expressed feelings of appreciation and relief, noting these technologies offered "in-the-moment" access to various sources of information and pragmatic support. In line with previous research on pregnancy and digital technology use [2,3,5,27], our findings shed light on the sense of community, timely access to information, reassurance, and validation that digital

technologies can provide new parents. However, on the other hand, participants expressed feelings of guilt for using such means as some felt they were not living up to the cultural expectation of good motherhood, which aligns with findings from studies emerging out of psychology [18,19].

The discourse of good motherhood permeated participants' responses as they described their experiences when encountering "perfect" images of motherhood posted on social media. Although such instances were acknowledged by the participants in this study as performative, the bombardment of these idealized images appeared to impact their self-perception and led to moments of self-critique accompanied by espoused feelings of guilt or anxiety. In addition, participants reported similar experiences of self-critique when consulting commercialized pregnancy and infant care apps as they compared their bodies or infant's progress against the norms and developmental milestones encoded within a particular app. The implications of these findings such as adverse health outcomes, for example, poor mental health, support recent research that notes the tension between the unrealistic demands of hegemonic motherhood within North America and the inadequate—often harmful—support systems and tools, inclusive of digital technologies such as apps, which actively detract from women's well-being while strengthening the very patriarchal structures that define these impossible parenting standards in the first place [27,28].

Within the transition to parenting period, expectant and new parents are promised peace of mind, flexibility, efficiency, and connectivity through marketing tactics focused on assurances of a "normal" and "healthy" pregnancy and postpartum experience [5,9]. These strategies are supported by (as they are of benefit to) neoliberal systems where responsibility for health care and specifically maternal and fetal health becomes "self-responsibilitized," that is, when the responsibility of care falls on the shoulders of individuals [5,9,23]. The pregnant body and the developing fetus become sites of quantifiable information that are entangled and inseparable from the social media platform or app's information system in which they are being explored and monitored. Under the guise of intimate surveillance, practices of selfhood and care become redefined as practices of information management and data production [9,22].

Although mothers' use of various social media platforms and apps, such as Facebook, can be seen as a means for them to care for their fetus or new infant by gathering information, advice, and resources, they also perform a form of digital labor by virtue of their user activity across the platform itself [29,30]. In sociotechnical terms [30], the information collected on users' behaviors, habits, and preferences as they traverse digital spaces—be it social media platforms, apps, or search engines—indirectly produces information capital for app developers and domain hosts to take advantage of, which is why most digital tools and apps are free or offered at a relatively low cost [29]. This unwaged labor mothers are performing across digital technologies, apps, and social media platforms through their day-to-day actions and health work as parents can become exploited by developers for profit [29,31]. For example, mothers' comments, likes, posts, and shares on Facebook and within the parenting support groups it hosts can be commoditized and sold to third parties for marketing purposes.

Not only are social media platforms and app developers profiting from the sale of users' (mothers') information but also the companies that purchase this information may further profit through targeted advertisements and sales of products to the very users (mothers) who accessed such support groups for health information in the first place [29,31]. For health care providers and organizations, this creates opportunities to consider and explore the impact of emerging internet-based health care settings and to question the accountability of predominant stakeholders (health care providers–clinicians, public health organizations, governments, and multinational companies such as Google, Facebook, and Amazon) within the digitally informed health care ecosystem and to question who is driving our health care agenda [29-31].

For mothers in this study, the idealized good mother was illustrated and reinforced through their ubiquitous use of digital technologies to achieve ideal motherhood; yet the promises of good mothering subsumed in the ubiquitous use of digital technologies also contributed to their feelings of guilt and self-doubt, potentially compromising their well-being. Social media platforms and apps can be misleading. Mothers using these digital technologies are at once chasing an unattainable ideal of good motherhood yet perpetuate their use of these apps for surveillance of self and fetus lest they be considered a "bad mother." From a sociotechnical perspective, we must ask ourselves who benefits from the entanglement of mothers' and their unborn or newborns' bodies being digitized into information outside of the transition to parenting period [15,22]. The experiences reported by mothers in this study raise critical questions as to how mothers best use digital technologies to support their transition to parenting in ways that are health enhancing and personally constructive.

Limitations

Data were collected before the COVID-19 pandemic. As we continue to move beyond the COVID-19 pandemic on a global front, it is important to consider the pandemic's influence on patterns of digital technology use during pregnancy and parenting given the widespread and necessary reliance on digital technologies to access health information and services. We recognize that our study population was demographically limited in terms of gender identity, racial identity, and age among other equity-deserving groups. All mothers in this study spoke English as their first language and were predominantly White. Future research should seek out the experiences of lesbian, gay, bisexual, transgender, queer, intersex, asexual, allies, and other parents as well as disabled parents within this context as they are underserved and have unacknowledged demographics in many pregnancy-related and parenting-related apps. It would be important to explore whether these parents find community and information in particular places designed with their needs and experiences in mind. We want to acknowledge that parents in different geographic or cultural contexts may experience the importance of the role of these digital technologies in different ways that intersect with the health care and social supports they

are receiving or not receiving from other sources dependent on their location.

Conclusions

Mothers in this study turned to digital technologies for immediate access to health information to support their parenting practices as well as an outlet to connect with other mothers who were in similar stages of the transition to parenting. Performative images of "perfect" motherhood across social media and normative milestones embedded within pregnancy and parenting apps caused the mothers to constantly self-critique. Although digital technologies satisfied these mothers' informational and social needs, they simultaneously encouraged feelings of guilt and self-doubt that urged them to appropriate whether they were a good mother. By understanding how mothers use technology within the context of pediatric care and the inherent complexity that is bound up within this use, health care providers may work toward providing guidance on reliable health information sources to ensure that parents receive credible information to inform their parenting practices, engaging with internet-based parenting communities to share evidence-based advice and address concerns, and developing mental health and wellness resources that are attuned to the complex nature of technology engagement during this intensive and vulnerable time, all of which can contribute toward improving pediatric outcomes.

Acknowledgments

This study was supported by the Fanshawe College Research Fund (#2019-08-FRF award).

Conflicts of Interest

None declared.

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Edited by S Badawy; submitted 17.05.23; peer-reviewed by B Eshrati, K Ayers; comments to author 10.09.23; revised version received 19.09.23; accepted 20.09.23; published 25.10.23.

Please cite as:
Facca D, Hall J, Hiebert B, Donelle L
Understanding the Tensions of "Good Motherhood" Through Women's Digital Technology Use: Descriptive Qualitative Study
JMIR Pediatr Parent 2023;6:e48934
URL: https://pediatrics.jmir.org/2023/1/e48934
doi:10.2196/48934
PMID:37878372

Detection and Characterization of Web-Based Pediatric COVID-19 Vaccine Discussions and Racial and Ethnic Minority Topics: Retrospective Analysis of Twitter Data

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Abstract

Background: Despite pediatric populations representing a smaller proportion of COVID-19 cases and having a less severe prognosis, those belonging to racial and ethnic minority groups are at an increased risk of developing more severe COVID-19–related outcomes. Vaccine coverage is crucial to pandemic mitigation efforts, yet since the start of the COVID-19 pandemic, vaccine hesitancy has increased and routine pediatric immunizations have decreased. Limited research exists on how vaccine hesitancy may contribute to low pediatric COVID-19 vaccine uptake among racial and ethnic minority populations.

Objective: This study aimed to characterize COVID-19 vaccine–related discussion and sentiment among Twitter users, particularly among racial and ethnic minority users.

Methods: We used the Twitter application programming interface to collect tweets and replies. Tweets were selected by filtering for keywords associated with COVID-19 vaccines and pediatric-related terms. From this corpus of tweets, we used the Biterm Topic Model to output topics and examined the top 200 retweeted tweets that were coded for pediatric COVID-19 vaccine relevance. Relevant tweets were analyzed using an inductive coding approach to characterize pediatric COVID-19 vaccine–related themes. Replies to relevant tweets were collected and coded. User metadata were assessed for self-reporting of race or ethnic group affiliation and verified account status.

Results: A total of 863,007 tweets were collected from October 2020 to October 2021. After outputting Biterm Topic Model topics and reviewing the 200 most retweeted tweets, 208,666 tweets and 3905 replies were identified as being pediatric COVID-19 vaccine related. The majority (150,262/208,666, 72.01%) of tweets expressed vaccine-related concerns. Among tweets discussing vaccine confidence, user replies expressing agreement were significantly outweighed by those expressing disagreement (1016/3106, 32.71% vs 2090/3106, 67.29%; $P<.001$). The main themes identified in the Twitter interactions were conversations regarding vaccine-related concerns including adverse side effects, concerns that the vaccine is experimental or needs more testing and should not be tested on pediatric populations, the perception that the vaccine is unnecessary given the perceived low risk of pediatric infection, and conversations associated with vaccine-related confidence (ie, the vaccine is protective). Among signal tweets and replies, we identified 418 users who self-identified as a racial minority individual and 40 who self-identified as an ethnic minority individual. Among the subcodes identified in this study, the vaccine being protective was the most discussed topic by racial and ethnic minority groups (305/444, 68.7%).

Conclusions: Vaccine-related concerns can have negative consequences on vaccine uptake and participation in vaccine-related clinical trials. This can impact the uptake and development of safe and effective vaccines, especially among racial and ethnic minority populations.

(JMIR Pediatr Parent 2023;6:e48004) doi:10.2196/48004

KEYWORDS

COVID-19 vaccine; vaccine hesitancy; pediatric vaccine; pediatric COVID-19 vaccine; vaccine beliefs; vaccine-related concerns; vaccine-related confidence; vaccine barriers; vaccine facilitators; racial and ethnic minority

Introduction

COVID-19 has caused significant morbidity and mortality globally, leading to over 6 million hospitalizations and claiming more than 1 million lives in the United States alone as of September 2023 [1,2]. Specific risk factors for clinical severity such as older age, underlying medical conditions, and racial and ethnic minority status have been previously identified [3]. Although all age groups can be infected by COVID-19, children represent a smaller proportion of all cases reported and generally present with milder symptomology and improved clinical outcomes when compared to adults [4,5]. Despite the overall lower risk, the American Academy of Pediatrics reported that there have been over 15.6 million COVID-19 cases in children reported in the United States as of May 2023, and since the start of the pandemic, incidence among pediatric populations plateaued at an average of approximately 24,000 cases per week and have more recently declined [6,7].

Furthermore, similar risk factors for severe COVID-19 infections identified in adults, such as racial and ethnic minority status, also place pediatric populations at increased risk, whereas other serious conditions, such as multisystem inflammatory syndrome in children, represent a unique health risk in this group [4,8]. Additionally, COVID-19 pediatric hospitalization rates, although lower than those of adults, mimic rates of prevaccine hospitalizations of now vaccine-preventable diseases [9]. However, pediatric COVID-19 hospitalization rates are not uniformly distributed, with multiple studies identifying higher rates and intensive care unit admissions among Hispanic or Latino and non-Hispanic or non-Latino Black children [10,11].

Crucially, parental uncertainty toward the pediatric COVID-19 vaccines has and continues to be a key concern and is a driving factor in the success or failure of vaccination programs and achieving high immunization rates. Globally, vaccine hesitancy rates vary by characteristics and predictors, with parents and youth in some countries expressing low vaccine hesitancy and high vaccine confidence, whereas others express negative vaccine sentiment and outright refusal [12-14]. Reflecting these conflicting attitudes and opinions, as measured in June 2022, more than 18 million children in the United States had yet to receive their first dose of a COVID-19 vaccine [15]. Furthermore, differential rates of vaccination in pediatric populations mimic those of adults, with racial and ethnic minority populations historically having lower COVID-19 vaccine uptake [16,17].

Prior to the COVID-19 pandemic, barriers to increased adolescent immunization rates included parental acceptance of vaccines, vaccine knowledge, and attitudes toward vaccination [18]. Prepandemic conditions included parents outright refusing and others choosing to delay or spread out routine vaccinations [19]. Since the start of the pandemic, vaccine hesitancy, especially concerning pediatric vaccinations, has increased, and overall pediatric vaccination rates have declined [20,21]. Similar to vaccine uptake, vaccine hesitancy is not uniformly distributed, with greater hesitancy existing among African American and Hispanic populations [15,22,23]. Although pediatric mortality has declined by 96% to 100% in the United States due to recommended routine vaccinations, recent vaccine hesitancy has contributed to outbreaks of previously vaccine-preventable diseases such as measles and influenza, emphasizing the importance of countering misinformation and overall hesitancy sentiment [22].

Recent pediatric COVID-19 vaccine research has largely focused on the efficacy and safety of the vaccine, with few papers examining individuals' or communities' opinions on vaccine administration [24-26]. Furthermore, the limited but growing research on racial and ethnic minority COVID-19 vaccine hesitancy has focused primarily on adult populations, although some studies have reported varying parental intent to vaccinate children [14,27]. However, no study to our knowledge has focused on pediatric COVID-19 barriers and facilitators among racial and ethnic minority groups and the extent of web-based engagement generated by information sharing and measured the impact of certain concerns and beliefs within these populations. Hence, additional research is needed to better characterize knowledge, attitudes, and behaviors associated with pediatric COVID-19 vaccines among disproportionately impacted groups, namely racial and ethnic minority populations.

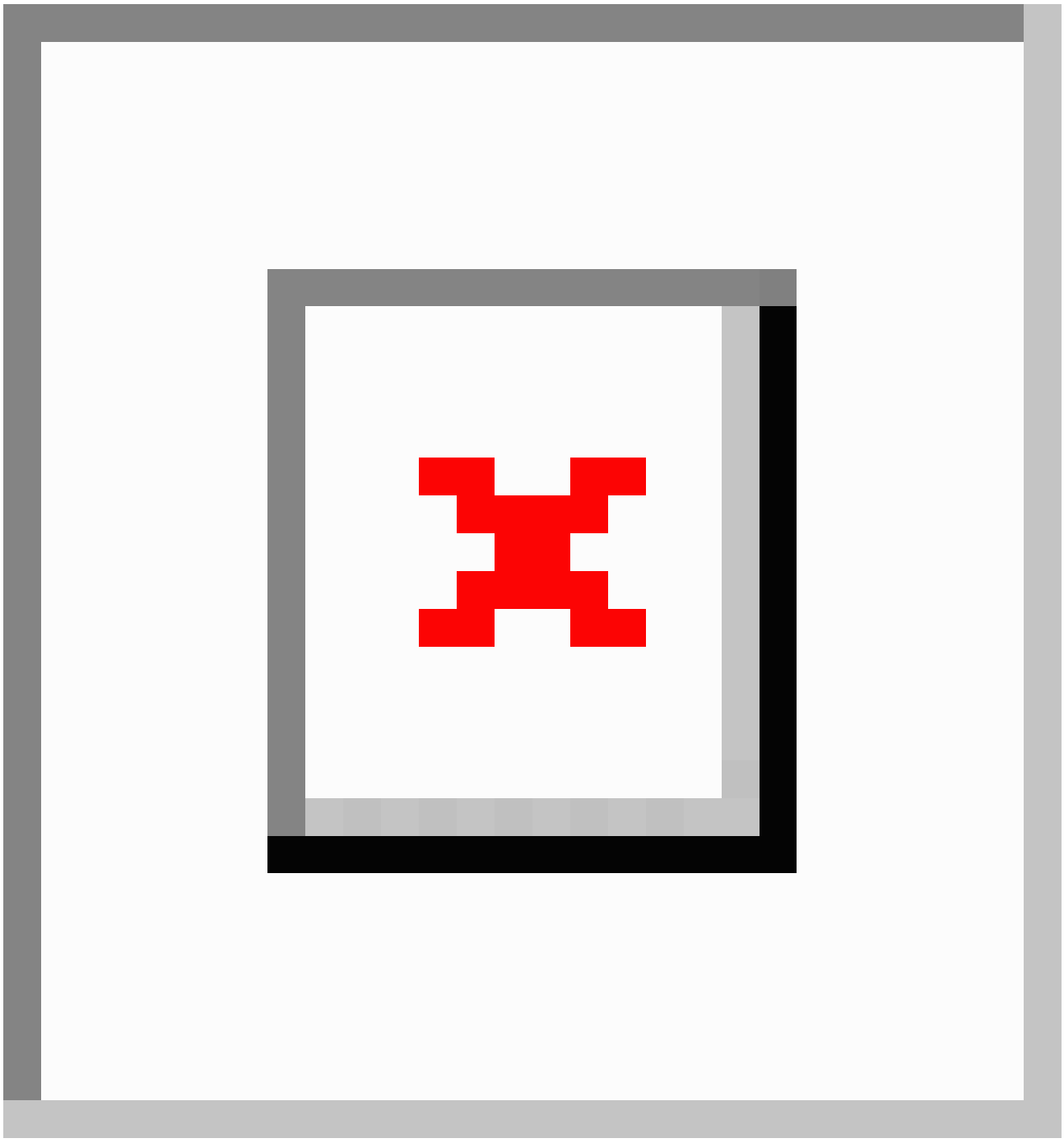
The first step to tailored outreach efforts is to increase understanding of the barriers and concerns held by disproportionately affected and historically underrepresented groups and determine whether these beliefs are representative within a particular community. Social media's emergence as a popular channel for information seeking and sharing and health behavior discussion has resulted in several studies characterizing COVID-19 and vaccine confidence and hesitancy [28,29]. Hence, the aim of this study was to add to this body of literature using approaches in natural language processing and content analysis to identify and characterize pediatric vaccine discussion topics, sentiment, and user interactions, including among users self-reporting racial and ethnic minority affiliation on Twitter (now rebranded as "X"), a common microblogging social media platform used by 1 in 5 US adults [30].

Methods

Overview

This study was conducted in three distinct phases: (1) data collection of COVID-19 vaccine– and pediatric-related tweets using keyword querying and filtering; (2) using unsupervised machine learning with topic modeling to identify topics and themes relevant to vaccine confidence, hesitancy, and minority user topics specific to COVID-19 pediatric vaccination; and (3) conducting in-depth qualitative analysis of tweets and comments using an inductive coding approach. Additionally, user profile metadata from all publicly available tweets were collected to assess if users self-reported racial or ethnic minority affiliation and whether they had verified Twitter accounts. A visual summary of the study methodology is provided in Figure 1.

Figure 1. Methodology summary and flowchart. The general methodology of the study is broken down into (1) data collection using the Twitter API; (2) COVID-19 and pediatric keyword filtering; (3) Biterm Topic Model and tweet selection; (4) qualitative analysis; and (5) metadata analysis. API: application programming interface.



Ethical Considerations

As this study only analyzed secondary, publicly available data and does not report any individually identifiable information on users, it was deemed exempt by WCG IRB.

Data Collection

We first manually searched for tweets with COVID-19 vaccine–related keywords on Twitter, the social media platform selected for this study. After assessing the returned results, we generated a list of keywords and hashtags that are commonly used in COVID-19 vaccine Twitter discussions, such as “Moderna,” “COVID19 vaccine,” and “Pfizer” (see Table 1 for the full list of study keywords). Data collection was conducted from October 24, 2020, to October 1, 2021, using the Twitter public application programming interface (API) to prospectively collect tweets that contained study keywords. Two sets of streaming data were collected; 1 set contained only original tweets (non-retweeted posts), and the other set contained only retweets. With the same manual search process, we generated keywords for general pediatric topics, which are “pediatric” and “paediatric,” and filtered our general COVID-19 data sets for tweets that contained these 2 keywords to generate a separate filtered non-retweeted and retweeted data set. From both non-retweeted and retweeted data sets, we collected all associated comments generated by users replying to these tweets

with the full-archive Twitter API using the "Conversation_id" attribute to better sample both original tweets and their interactions (ie, comments) with these keywords.

Table . The keywords related to "COVID-19 vaccine" and "pediatric COVID-19 vaccine" that were selected in this study.

Topic	Related keywords
COVID-19 vaccine	Sputnik V, Gam-COVID-Vac, Moderna vaccine, mRNA-1273, AXD1222, COVID19 vaccine, ChAdOx1, Pfizer, BioNTech, Johnson vaccine, AstraZeneca, J&J's vaccine, JNJ-78436735, Ad26.COV2.S, AZD1222, Oxford vaccine, and Comirnaty
Pediatric COVID-19 vaccine	Pediatric and paediatric

Unsupervised Machine Learning

Due to the large volume of data for the non-retweeted pediatric data set, we used natural language processing and unsupervised machine learning to extract topics of interest and the corresponding tweets relevant to our study objectives. We used the Biterm Topic Model (BTM), an unsupervised machine learning approach that cluster texts into different topics and outputs the word terms that are the most correlated to each topic. We chose the BTM as it is efficient in analyzing short texts (such as tweets that are limited to 280 characters) and due to its use in prior health and COVID-19 topic exploration studies, particularly when existing training data for supervised machine learning approaches are not available [31-33]. Because the non-retweeted pediatric data set volume was double the size of usual BTM training sets used in prior studies, we split the non-retweeted pediatric data set into 2 even data sets for BTM topic modeling output. For each BTM process, we used the parameter k=20, which generated 20 topics for each set of BTM modeling phases. For each topic, we outputted the top relevant terms for each topic and ranked all tweets within that topic and then outputted the 10 most retweeted tweets (based on retweet counts) that were the most correlated within the outputted topic for purposes of further human review and annotation.

Content and Statistical Analysis

This study's manual content analysis of tweets focused on characterizing specific COVID-19 pediatric vaccine–related discussion and sentiment, specifically among racial and ethnic minority groups. Following the use of BTM, the top 10 retweeted tweets from each topic cluster were outputted and coded using a binary coding scheme to identify tweets relevant to the topic of pediatric COVID-19 vaccines (ie, "signal"). Tweets were deemed as signal tweets if they (1) appeared to be user generated (ie, not posted by organizations or news or media outlets) and (2) discussed a topic relevant to the pediatric COVID-19 vaccine, including its indication, safety, efficacy, approval or authorization, beliefs, and associated barriers and facilitators. Topic clusters that had retweeted tweets that did not meet the study objective were excluded from further analysis (ie, "noise"). Tweets related solely to news or media coverage about the vaccine, advertisements, and tweets not related to the pediatric COVID-19 vaccine (eg, tweets associated with pediatric vaccines for other diseases) were considered noise. All tweets were first reviewed by the first (TM), second (CW), and third (NL) authors independently, and a general inductive approach was then used to develop a coding framework for tweets to assess thematic content.

Following the initial binary coding scheme and review of all tweets, all detected themes were inductively classified into 2 parent codes: vaccine-related confidence and vaccine-related concerns. Subcodes were inductively added to the codebook under the 2 parent codes. These attributes were selected by the first 3 authors, with high interrater reliability (Cohen κ=0.95). Discrepancies were resolved through discussion among the first through third authors. Following the qualitative content analysis of the top retweeted tweets, all comments to signal tweets were retrieved, and the first 3 authors followed a binary coding scheme for the relevance of the comment to the original tweet. Comments were also manually annotated for agreement, disagreement, or neutral sentiment toward the original tweet. All comments were coded independently and achieved high intercoder reliability (Cohen κ=0.95).

A 2-by-2 table for user replies was constructed. The exposure condition was a parent tweet (ie, by parent tweet, we mean a tweet that was selected for this study and generated additional user interactions through comments) expressing confidence in the pediatric vaccine, with the counterfactual being a parent tweet expressing concern; the outcome condition was a user reply expressing either agreement or disagreement with the parent tweet. A χ^2 test was performed to determine if the proportion agreeing with confidence-expressing tweets was significantly different than the proportion disagreeing with confidence-expressing tweets. Statistical analysis was performed in RStudio (version 3.6.1; Posit). A P value of <.05 was considered statistically significant.

User Metadata Analysis

We wanted to further characterize specific topics, discussions, and sentiments associated with pediatric COVID-19 vaccines that were specific to racial and ethnic minority populations. We examined publicly available metadata of users associated with signal tweets and signal comments for self-identifiable minority status as well as Twitter verified user account status. In this study, we included 4 major racial groups (American Indian and Alaska Native, Asian, Black or African American, and Native Hawaiian or Other Pacific Islander) and 1 ethnic group (Hispanic or Latino). The classification used only publicly available profile data from the users' profile on Twitter to assess whether there was sufficient information to identify at least 1 of the abovementioned minority groups. If a user included no self-identification information within their public profile bio, no racial or ethnic minority status was assumed. These data were collected for purposes of aggregation, and no results contained in this study include individually identifiable

information or make any representation to the accuracy of a claimed minority or ethnic classification of a user.

Results

Collected Data

We collected a total of 863,007 tweets from Twitter over the approximately 1-year study period, which were filtered for COVID-19– and pediatric-related keywords. After applying the BTM, we reviewed the top 200 most retweeted tweets (representing 233,612 tweets and retweets) from each topic cluster output, from which 163 (81.5%) of the 200 most retweeted tweets were identified as signal tweets based on our binary coding approach. These signal tweets corresponded to a total of 208,666 tweets and retweets (208,666/863,007, 24.18% of the entire corpus) and specifically included user-generated topics related to the pediatric COVID-19 vaccine. From this set of tweets, a total of 15,524 user replies via comments were collected. Within these user replies, 6224 replies were posted in response to tweets from verified racial or ethnic minority users that were then selected for further racial and ethnic minority content–specific analysis. Of the 6224 comment replies selected for analysis, 3905 (62.74%) were relevant to the parent tweet's COVID-19 vaccine topic and were further analyzed for agreement, disagreement, or neutral sentiment.

Content and Statistical Analysis

Based on our qualitative analysis and inductive coding approach of tweets and retweets, we derived 8 topics within 2 major parent domains (refer to Table 2 for identified topic themes and anonymized and paraphrased examples from tweets). The detected topics were first classified into 2 major domains: vaccine-related concerns (150,262/208,666, 72.01%) and vaccine-related confidence (58,404/208,666, 27.99%). Of the 3905 comment replies to the parent tweets that were identified as signal retweets using our binary coding approach, 3385 (86.68%) were in response to vaccine-related confidence tweets and 520 (13.32%) were in response to vaccine-related concern tweets. Of 3385 vaccine-related confidence reply comments, we found that 1016 (30.01%) users agreed, 2090 (61.74%) disagreed, and 279 (8.24%) had neutral sentiment toward conversations regarding the vaccine being safe and protective. In response to vaccine-related concerns, 278 (53.5%) out of 520 users agreed, 219 (42.1%) disagreed, and 23 (4.4%) had neutral sentiment toward conversations regarding the vaccine having adverse side effects, it being too experimental, and other vaccine concern topics.

Table . Code list and identified topic themes (including deidentified and paraphrased examples). Specific company names have been deidentified and replaced with generic labels (eg, “Company A”).

Topic and code number	Code name	Example	Tweets and retweets (n=208,666), n (%)
A. Vaccine-related concerns			
A-1	Adverse side effects	• Boston Children’s Hosp series of 15 post Pfizer C19 vax myocarditis cases revealed 80% had “late gadolinium enhancement,” a prognostic marker assoc with increased risk (~4.6 fold) for adverse cardiac events long term.	37,571 (18.01%)
A-2	Requires more testing (experimental, unethical, and questioning approval)	• Healthy children do not need this vaccine and it’s been advised not to give them the jab. This won’t keep a single school open or save children’s lives. This is immoral, unethical and, what’s worse, you KNOW it.	40,279 (19.3%)
A-3	Control tactic	• The Johnson regime is intent on ruining the country and destroying freedom. They have announced vaccine passports and experimental injections for children and now a #Lockdown. • It is time for regime change.	12,122 (5.81%)
A-4	Questioning authority	• Why is Biden telling children to get the vaccine. He is not a medical doctor. This girl should be allowed to sue Biden for practicing medicine without a license.	8420 (4.04%)
A-5	Vaccine is unnecessary (high risk to individual benefit)	• J&J announced plans to test the shot on newborns, despite the risks and evidence that COVID poses nearly no risk to healthy children.	36,859 (17.66%)
A-6	Company history	• In 1996, one of Pfizer’s drugs was still in clinical stage of development when it was tested on about 200 children without consent. Pfizer claimed it was “safe,” but 181 kids were injured and 11 died.	15,011 (7.19%)

Topic and code number	Code name	Example	Tweets and retweets (n=208,666), n (%)
B. Vaccine-related confidence			
B-1	Vaccine is protective	• What amazing news to wake up to! Pfizer vaccine provided 100% protection in 12-15 y olds. The sample is small, but gives me so much hope for schools opening soon.	35,975 (17.24%)
B-2	Vaccine is safe	• JUST IN - Pfizer has started late-stage clinical trials of their #COVID19 vaccine in young children ages 5 to 11	22,429 (10.75%)

Within the vaccine-related concern parent topic (parent code A), we identified tweets that shared concerns (A-1) regarding possible adverse side effects of the pediatric COVID-19 vaccine; (A-2) that the vaccine required more testing; (A-3) that the vaccine was being used as a control tactic; (A-4) questioning authority figures associated with vaccination or government (eg, the perception that current President Joe Biden is wrongly encouraging vaccination and a statement expressing the idea that certain government authorities lack the requisite expertise to demand health initiatives); (A-5) that the vaccine was unnecessary; and (A-6) about the history or purported activities of pharmaceutical companies (eg, previous mismanagement and greed claims against pharmaceuticals). Within the vaccine-related confidence parent topic (parent code B), we identified tweets that shared that the pediatric COVID-19 vaccine is (B-1) protective and (B-2) safe (see Table 2). Among these topics, tweets expressing concerns regarding the vaccine requiring more testing and that it was still experimental or should not be approved had the highest volume (A-2; 40,279/208,666, 19.3%), followed by discussion surrounding the possible adverse side effects associated with the pediatric COVID-19 vaccine (A-1; 37,571/208,666, 18.01%).

Among those who responded to tweets via comments expressing confidence in pediatric vaccines, 30.01% (1016/3385) agreed, 8.24% (279/3385) were neutral, and 61.74% (2090/3385) disagreed. Among those who responded to tweets expressing concern about pediatric vaccines, 53.5% (278/520) agreed, 4.4% (23/520) were neutral, and 42.1% (219/520) disagreed. Agreement with tweets was determined by (1) explicit agreement statements (eg, “I agree,” “true,” “definitely,” etc); (2) supportive statements that reiterate or add to the original parent tweet (eg, “this is great information”); (3) personal, supportive anecdotes (eg, “this has happened to me”); or (4) contextual information on a case-by-case basis such as the use of supportive emojis within a reply (eg, thumbs up). Disagreement with tweets was determined by (1) explicit disagreement statements (eg, “I disagree,” “this is not true,” etc); (2) counterarguments or sharing counterfactual news or informational links; (3) criticizing the tweet or the author of the tweet (eg, “how could you post this fake information,” etc); or (4) contextual information on a case-by-case basis such as the use of opposing emojis within a reply (eg, thumbs down). Neutrality was determined by (1) requesting additional information or (2) the lack of strong agreement or disagreement language.

Excluding neutral-sentiment responses, the proportion of user replies expressing agreement with provaccine (ie, confidence) tweets was significantly lower than those expressing disagreement with provaccine tweets (1016/3106, 32.71% vs 2090/3106, 67.29%; χ^2_1=98.6, P<.001). As tweets in this sample were either provaccine or antivaccine (ie, concern), statistical testing also indicated that the proportion expressing agreement with antivaccine tweets was significantly higher than those expressing disagreement with antivaccine tweets (278/497, 55.9% vs 219/497, 44.1%; χ^2_1=98.6, P<.001).

User Metadata Analysis

In total, this study identified 418 users who self-identified as a racial minority individual and 40 users who self-identified as an ethnic minority individual among signal parent tweets and reply comments. From the top 200 retweeted tweets included for analysis in this study, 14 were identified as being posted by a verified racial or ethnic minority Twitter user, who generated 2.8% (24,140/863,007) of the tweets or retweets of the entire corpus. Specifically, from the sample of identified verified racial or ethnic minority Twitter users, 3905 replies to these tweets were identified as a signal tweet, of which 444 (11.37%) were identified as being posted by a user who also self-identified with a racial or ethnic minority group, whereas 673 (17.23%) were from White users and 2788 (71.4%) were unable to be identified. We identified that of the 3905 users who replied to verified Twitter accounts, 9 (0.23%) self-identified as American Indian or Alaskan Native, 310 (7.94%) as Asian, 84 (2.15%) as Black or African American, 39 (1%) as Hispanic or Latino, and 2 (0.05%) as Native Hawaiian or Other Pacific Islander. Within the parent topic of vaccine-related confidence, 331 racial minority individuals and 37 ethnic minority individuals posted reply tweets; within the parent topic of vaccine-related concern,

74 racial minority individuals and 2 ethnic minority individuals posted reply tweets.

Among the 8 subcodes identified in this study, the vaccine being protective (B-1) was the most discussed topic by racial and ethnic minority groups (305/444, 68.7%). Additionally, 287 reply comments were posted by users who self-identified as a racial minority individual and 18 were by those who self-identified as an ethnic minority individual. Overall, 6 American Indian or Alaskan Native, 243 Asian, 37 Black or African American, 18 Hispanic or Latino, and 1 Native Hawaiian or Pacific Islander users replied to tweets that discussed the vaccine as being protective. Importantly, a larger proportion of reply comments disagreed with provaccine parent tweets, with Asian populations specifically representing most of the identified users with disagreement sentiment (170/261, 65.1%; refer to Tables 3 and 4 for a complete breakdown of racial and ethnic minority sentiment for topics related to vaccine-related concerns and confidence). Among self-identified Black or African American populations in this study, the vaccine being safe (B-2) and the adverse effects of the vaccine (A-1) were tied for the topics receiving the second most engagement among these groups, with 23 reply comments in each of these topics. Finally, the vaccine being unnecessary for pediatric populations (A-5) was the topic with the second most engagement among Asian populations. Furthermore, contradicting the initial finding of disagreement with vaccine-related confidence was the disagreement of vaccine-related concerns among 61% (30/49) of comment replies posted by Asian users.

Table . Vaccine-related concern sentiment by racial and ethnic minority status.

Race or ethnicity	Agree, n (%)	Disagree, n (%)	Neutral, n (%)
American Indian or Alaska Native (n=1)	0 (0)	1 (100)	0 (0)
Asian (n=49)	17 (35)	30 (61)	2 (4)
Black or African American (n=24)	11 (46)	12 (50)	1 (4)
Hispanic or Latino (n=2)	1 (50)	1 (50)	0 (0)
Native Hawaiian or Other Pacific Islander (n=0)	0 (0)	0 (0)	0 (0)

Table . Vaccine-related confidence sentiment by racial and ethnic minority status.

Race or ethnicity	Agree, n (%)	Disagree, n (%)	Neutral, n (%)
American Indian or Alaska Native (n=8)	3 (37.5)	5 (62.5)	0 (0)
Asian (n=261)	75 (28.7)	170 (65.1)	16 (6.1)
Black or African American (n=60)	26 (43.3)	26 (43.3)	8 (13.3)
Hispanic or Latino (n=37)	15 (40.5)	20 (54.1)	2 (5.4)
Native Hawaiian or Other Pacific Islander (n=2)	0 (0)	1 (50)	1 (50)

Discussion

Principal Findings

This study found 208,666 signal tweets related to pediatric COVID-19 vaccine topics and 3905 signal comments in response to relevant parent tweets. The tweets included 2 parent categories of vaccine-related concern and vaccine-related confidence topics and 8 corresponding subcodes. In relation to conversations (tweets) and interactions (comment replies) from racial or ethnic minority users on Twitter, we found 458 tweets and replies posted by users who self-identified as a member of 1 of 4 racial minority groups or 1 ethnic minority group.

For all tweets reviewed, we found that close to three-quarters (150,262/208,666, 72.01%) of all discussions reviewed expressed vaccine-related concerns, with the subtopic of the pediatric COVID-19 vaccine requiring more testing (A-2) driving most of the conversations on Twitter (40,279/150,262, 26.81%). We also found that most user replies reviewed were in response to vaccine-related confidence tweets (ie, that the vaccine was safe and protective; 3385/3905, 86.68%), although the majority (2090/3385, 61.74%) of these replies disagreed with this sentiment of supporting vaccination. Additionally, the proportion expressing agreement with provaccine tweets was significantly lower than those expressing disagreement with provaccine tweets (1016/3106, 32.71% vs 2090/3106, 67.29%; $P<.001$). These findings may indicate that when provaccine sentiment is shared on Twitter, a larger proportion of interactions ensuing may conversely generate antivaccine sentiment from users in the form of comment replies, which is a concerning finding particularly as over 800 users in this study self-identified as belonging to a racial or ethnic minority group and may have been exposed to predominantly negative vaccine sentiment content.

Among users self-reporting their race or ethnic status in response to a verified minority user Twitter account, Asian, Black or African American, and Hispanic or Latino groups were the top 3 reported affiliations, with other racial groups (American Indian

or Alaskan Native and Native Hawaiian or Other Pacific Islander) having a lower number of users relative to their smaller proportion of the US population. Most racial or ethnic minority users' comment replies were in response to vaccine confidence, specifically, the vaccine being protective, with generally more of these minority users disagreeing with the vaccine-related confidence sentiment but conversely also more users disagreeing in replies to the vaccine-related concern sentiment. This may indicate that different and specific minority groups on Twitter are having separate conversations and interactions regarding vaccine confidence or hesitancy, with some pushing back against vaccine-related concerns (such as Asian users) and some disagreeing with vaccine confidence statements (again with Asian users, although stratification for different Asian ethic subgroups may yield more specific results). In contrast, Black or African American users were more evenly split on their sentiment toward vaccine-related confidence or concern in their replies to tweets.

Specific Twitter verified user accounts reporting racial or ethnic minority affiliation may have also influenced these conversation topic groupings, which included users who are political figures, epidemiologists, and prominent journalists who have high follower accounts (range 56,453-22,474,858). This high number of Twitter followers in turn generated a higher volume of interactions via user replies. Topics in the tweets of these verified users varied, including mistrust regarding federal regulatory agencies, general COVID-19 vaccine announcements, and tweets related to vaccine or COVID-19 fear-mongering language.

Overall, clinical trial results supporting vaccine authorization, as with other aspects of the COVID-19 pandemic, was met with mixed sentiments [34,35]. Public opinion about the need for a pediatric vaccine varied, with individuals, primarily those who are parents, questioning whether COVID-19 posed enough risk to children to necessitate the testing and development of a pediatric vaccine [36]. The results of our study reinforce these observations, similarly finding that public opinion on Twitter toward vaccine confidence- and concern-related tweets and interactions is mixed, including when specifically examining racial and ethnic minority user sentiment.

Limitations

This study has certain limitations. First, the primary aim of the study was to characterize pediatric COVID-19 vaccine discussion and attitudes among general users as well as racial and ethnic minority users on Twitter. By using a single social media platform, our scope is limited based on the demographic of Twitter users and may not be representative of general attitudes among various racial and ethnic minority groups. Additionally, we only collected data from Twitter and limited our study keywords to the English language. This likely biased study results to native English speakers, excluding minority individuals for whom English is a second language or those who do not speak English, thus further limiting generalizability. Additionally, our keywords related to COVID-19 vaccine topics were chosen based on our own manual searches on the platform but may not have been inclusive of all conversations related to the study aims. Finally, we identified users' race and ethnicity status based solely on users' publicly available metadata, and we did not cross-validate the veracity of users' race and ethnicity status with any other sources or follow-up. Future studies should explore combining multiple data layers from different sources to better validate users' race and ethnicity status as well as to better assess if users' reported attitudes, perceptions, and behavior are associated with validated vaccine confidence, hesitancy, or uptake using other data sources.

Conclusions

Although the results from this study are primarily exploratory, they nevertheless provide important and diverse insights on current beliefs, attitudes, opinions, and possible behavior queues toward intent, willingness, and hesitancy to vaccinate children to protect them from COVID-19. Hence, our study results have the potential to inform the design of future health education, vaccination campaigns, and other health promotion efforts that can be targeted toward specific minority users on the web while also identifying relevant themes and topics that can influence vaccine confidence and hesitancy sentiment. Incorporating social listening with traditional public health surveillance approaches is critical to ensuring equitable vaccine uptake, including in the context of new vaccine candidates and COVID-19 boosters among both parents and their children. Future studies may look to further stratify racial and ethnic subgroups to better understand how intraracial attitudes and behaviors may vary to more effectively target pediatric vaccine campaigns.

Acknowledgments

This manuscript has been seen by all authors, who have approved its content.

Authors' Contributions

T McMann, QX, and T Mackey contributed to conceptualization. T McMann, ZL, and T Mackey contributed to methodology. ZL and REC contributed to software. T McMann, CW, NL, ZL, QX, and REC contributed to validation. T McMann, CW, NL, QX, and REC contributed to formal analysis. T McMann, QX, and T Mackey contributed to investigation. T Mackey contributed to resources. ZL contributed to data curation. T McMann, QX, REC, and T Mackey contributed to writing. T Mackey contributed to supervision. T McMann and QX contributed to project administration. T Mackey contributed to funding acquisition.

Conflicts of Interest

QX, T McMann, CW, ZL, and T Mackey are employees of the minority-owned small business S-3 Research LLC. S-3 Research is a company previously and currently funded by the National Institutes of Health—National Institute on Drug Abuse through the Small Business Innovation and Research program and has contracts with other government agencies to provide public health and data science services. T Mackey is also the Editor-in-Chief of JMIR Infodemiology.

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Abbreviations

API: application programming interface
BTM: Biterm Topic Model

Edited by S Badawy; submitted 07.04.23; peer-reviewed by B Eshrati; revised version received 20.09.23; accepted 21.09.23; published 30.11.23.

Please cite as:
McMann T, Wenzel C, Le N, Li Z, Xu Q, Cuomo RE, Mackey T
Detection and Characterization of Web-Based Pediatric COVID-19 Vaccine Discussions and Racial and Ethnic Minority Topics: Retrospective Analysis of Twitter Data
JMIR Pediatr Parent 2023;6:e48004
URL: https://pediatrics.jmir.org/2023/1/e48004
doi:10.2196/48004

Original Paper

Using Human-Centered Design and Cocreation to Create the Live 5-2-1-0 Mobile App to Promote Healthy Behaviors in Children: App Design and Development

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Abstract

Background: The prevalence of obesity among Canadian children is rising, partly because of increasingly obesogenic environments that limit opportunities for physical activity and healthy nutrition. Live 5-2-1-0 is a community-based multisectoral childhood obesity prevention initiative that engages stakeholders to promote and support the message of consuming ≥5 servings of vegetables and fruits, having <2 hours of recreational screen time, participating in ≥1 hour of active play, and consuming 0 sugary drinks every day. A Live 5-2-1-0 Toolkit for health care providers (HCPs) was previously developed and piloted in 2 pediatric clinics at British Columbia Children's Hospital.

Objective: This study aimed to co-create, in partnership with children, parents, and HCPs, a Live 5-2-1-0 mobile app that supports healthy behavior change and could be used as part of the Live 5-2-1-0 Toolkit for HCPs.

Methods: Three focus groups (FGs) were conducted using human-centered design and participatory approaches. In FG 1, children (separately) and parents and HCPs (together) participated in sessions on app conceptualization and design. Researchers and app developers analyzed and interpreted qualitative data from FG 1 in an ideation session, and key themes were subsequently presented separately to parents, children, and HCPs in FG-2 (co-creation) sessions to identify desired app features. Parents and children tested a prototype in FG 3, provided feedback on usability and content, and completed questionnaires. Thematic analysis and descriptive statistics were used for the qualitative and quantitative data, respectively.

Results: In total, 14 children (mean age 10.2, SD 1.3 years; 5/14, 36% male; 5/14, 36% White), 12 parents (9/12, 75% aged 40-49 years; 2/12, 17% male; 7/12, 58% White), and 18 HCPs participated; most parents and children (20/26, 77%) participated in ≥2 FGs. Parents wanted an app that empowered children to adopt healthy behaviors using internal motivation and accountability, whereas children described challenge-oriented goals and family-based activities as motivating. Parents and children identified gamification, goal setting, daily steps, family-based rewards, and daily notifications as desired features; HCPs wanted baseline behavior assessments and to track users' behavior change progress. Following prototype testing, parents and children reported ease in completing tasks, with a median score of 7 (IQR 6-7) on a 7-point Likert scale (1=very difficult; 7=very easy). Children liked most suggested rewards (28/37, 76%) and found 79% (76/96) of suggested daily challenges (healthy behavior activities that users complete to achieve their goal) realistic to achieve. Participant suggestions included strategies to maintain users' interest and content that further motivates healthy behavior change.

Conclusions: Co-creating a mobile health app with children, parents, and HCPs was feasible. Stakeholders desired an app that facilitated shared decision-making with children as active agents in behavior change. Future research will involve clinical implementation and assessment of the usability and effectiveness of the Live 5-2-1-0 app.

(JMIR Pediatr Parent 2023;6:e44792) doi:10.2196/44792

KEYWORDS

childhood obesity; mobile health; health behaviors; prevention; mobile health app; mHealth app; human-centered design; cocreation; participatory approach; mobile phone

Introduction

Background

In Canada, the number of children with obesity has more than doubled over the past 40 years [1], with the prevalence in children aged 2 to 17 years increasing from 6% between 1978 to 1979 to 12% in 2015 [2]. In parallel, the rates of lifelong chronic disease caused by childhood obesity have also increased; for example, a recent Canadian surveillance study reported a 68% increase in the minimum incidence of childhood-onset type 2 diabetes over a 10-year period [3]. Obesity in childhood tends to persist into adulthood, along with its associated physical and psychosocial consequences [4]. An estimated 60% of children today are expected to be obese by the age of 35 years [5].

Childhood represents a desirable time for chronic disease prevention interventions focused on regular monitoring of height and weight and healthy behavior counseling [6]. In particular, the ages of 8 to 12 years serve as a critical period for the development of lifelong habits and behavior adoption as this is when children experience substantial physical and developmental changes, including the initiation of puberty, increased autonomy in decision-making, and identity formation [7]. To date, these interventions are mostly conducted in person, requiring children and parents to travel to a specified location to attend regularly scheduled sessions, resulting in low participation rates and high attrition, thus leading to minimal changes in key health outcomes such as BMI and healthy diet changes [8]. The use of digital technologies such as smartphones and tablets may address these challenges owing to their wide accessibility that transcends geographic location or socioeconomic status. According to the 2020 Canadian Internet Use Survey, the rate of smartphone ownership has been increasing among various socioeconomic groups, from 80.3% in 2018 to 84.4% in 2020 [9]. In fact, since the onset of the COVID-19 pandemic in 2019, to overcome social distancing and prevent disease transmission, many weight management and obesity prevention interventions have shifted from in-person to telephone-based or internet-based services, such as via telehealth, videoconferencing, and mobile health apps [10,11]. Although these telephone-based or internet-based health services fueled by the pandemic have reduced barriers to care, the evidence regarding their effectiveness in addressing childhood obesity is mixed [10].

Mobile health use has experienced exponential growth over the years. The penetration rate (percentage of active users over the total number of potential users in the target market) of the Canadian mobile health market was 46.5% in 2021 and is expected to reach >53.7% by 2026 [12]. Various interventions have demonstrated the potential role of mobile health apps in supporting children in adopting and sustaining healthy behavior changes [13,14]. However, their effectiveness and reliability remain unclear as many mobile health apps are not evidence-based (informed in their design by behavior change theory, clinical guidelines, or clinical trials), do not involve end users (ie, clinicians or patients) in the development process [15], and suffer from low use and user retention [16]. Our previously published systematic literature review found that apps for health behavior promotion interventions have the potential to increase healthy behavior adoption among children, but their effectiveness in improving anthropometric measures remains unclear [17].

The use of participatory research methods, which involves direct collaboration between researchers and end users in a process of cocreation [18], has the potential to address these challenges. However, participatory research is not without its drawbacks. Potential challenges include skepticism and the lack of interest from stakeholders, time constraints of participants, conflicts between the expectations of funders and those participating in cocreation (ie, researchers and end users), and the incapability of participatory researchers to relinquish control for authentic cocreation to occur [19].

The Live 5-2-1-0 initiative works with community partners to create healthy environments for children via its message of consuming at least 5 servings of vegetables and fruits, engaging in <2 hours of recreational screen time, participating in at least 1 hour of active play, and drinking 0 sugary drinks per day [20]. A component of the Live 5-2-1-0 initiative is the Live 5-2-1-0 health care provider (HCP) Toolkit, which provides clinicians with the knowledge, skills, and resources to integrate the promotion of healthy behavior into their clinical practice. A pilot study in 2 pediatric subspecialty clinics at British Columbia Children's Hospital (BCCH; Vancouver, British Columbia [BC], Canada) demonstrated that the use of the HCP Toolkit resulted in increased frequency of lifestyle assessments and counseling performed by HCPs [21]. A mobile healthy living app based on the Live 5-2-1-0 principles may complement the Live 5-2-1-0 HCP Toolkit by engaging patients and families in healthy living between patient visits and allowing HCPs to monitor progress in behavior change.

Objectives

In this paper, we described our approach to co-designing, with children, parents, and HCPs, the Live 5-2-1-0 mobile app (hereinafter referred to as *the app*) using participatory research methods. The goal of the app was to support HCPs in delivering healthy behavior counseling in a clinical setting and motivate healthy behavior change in children in their daily lives.

Methods

Ethics Approval

This study was approved by the University of BC and Children's and Women's Health Centre of BC Research Ethics Board (H18-00700; SA; August 16, 2018).

Study Design

This study was conducted and reported using the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines [22]. Using a mixed methods embedded research design, 3 sets of focus groups (FGs) were conducted between October 2018 and January 2019 to obtain the perspectives of children, parents, and HCPs. Each FG was approximately 2 hours long and was held in person at BCCH (our study was performed before the onset of the COVID-19 pandemic) by facilitators from an external technology consulting firm (Striven) or our app developer partner (Tactica). FG guides (Multimedia Appendix 1) consisted of open-ended questions that reflected the Fogg Behavior Model, which posits that motivation, ability, and triggers must all be present to influence an individual to perform a target behavior [23]; in the case of health interventions, this is to influence a patient to adopt healthy behavior change. Human-centered design (HCD) is a participatory method that engages stakeholders throughout the development process to generate solutions that reflect the needs of end users [24]. It consists of three phases: (1) inspiration (immersing the researcher in the lives of participants to understand their needs), (2) ideation (knowledge from inspiration is used to brainstorm ideas and create a prototype), and (3) implementation (the solution is brought to life and evaluated).

The child and parent participants received a CAD $50 (US $37.35) gift card for their time and to offset the costs of participating; HCPs received a CAD $5 (US $3.73) Starbucks gift card.

Participants

Children aged 8 to 12 years and their parents were recruited via posters at BCCH, advertisements in a patient newsletter (Sunny Hill Connect), and announcements posted on BCCH and Live 5-2-1-0 social media channels (Facebook and Twitter). Recruitment material included the names of the principal investigators, eligibility criteria for participants, and a brief description of the goal of the research team to develop an app that supports healthy living habits. Interested participants contacted a research assistant via phone or email to receive additional study information and provide informed consent in writing. The eligibility criteria were (1) ability to read, speak, and understand English and (2) willingness to attend at least one FG session. A maximum of 1 child and 1 parent per family could participate. Participants with severe intellectual difficulties were excluded. BMI or other weight-related characteristics of children and parent participants were not part of the inclusion criteria as the aim of the study was to develop an app that could serve as a tool in primary prevention of childhood obesity and would apply to all children regardless of BMI. HCPs within the University of BC Department of Pediatrics at BCCH were invited to participate via an email containing study information and contact information for the research assistant. Given that the Live 5-2-1-0 initiative is multisectoral and cross-disciplinary, the representation of physicians and medical trainees, nursing staff, and allied health professionals was sought to capture a wide range of clinician perspectives in the app's design.

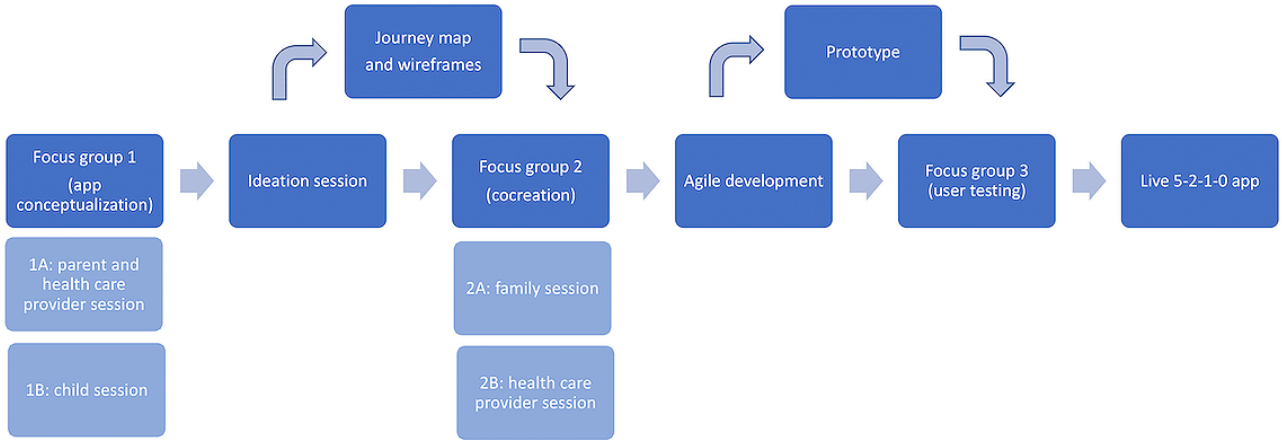
Quantitative Data Collection

Children and parents completed a sociodemographic questionnaire that included age, gender, and ethnic background of both the child and parent, as well as parents' marital status, educational level, and annual household income. Parents completed an adapted version of the Healthy Habits Questionnaire (Multimedia Appendix 2), a tool that has previously been shown to be useful and feasible in the primary care setting, to assess the Live 5-2-1-0 behaviors, sleep habits, and eating behaviors of their children [25]. Study data were collected and managed using REDCap (Research Electronic Data Capture; Vanderbilt University), a secure web-based software platform designed to support data capture for research studies, hosted at the BCCH Research Institute [26,27]. Participants in the user-testing FG were asked to complete specific surveys on the usability and content of the prototype.

Qualitative Data Collection

A schematic outlining the sequence of research activities can be found in Figure 1.

Figure 1. Schematic of research activities for Live 5-2-1-0 app development.



FG 1 (App Conceptualization)

The first FG (FG 1) aimed to inform the app's conceptualization and consisted of separate child and adult (parents and HCPs) sessions. In total, 8 parents and 3 HCPs (2 dieticians and 1 physician) participated in the adult session, and 9 children participated in the child session. In the adult session (FG 1A), participants discussed the challenges in ensuring the adoption of healthy habits by their children, followed by an app feature prioritization activity. The children's session (FG 1B) began with a discussion on their digital device and app use, followed by a drawing activity on how mobile devices played a role in their typical day. Facilitators then led a discussion where children reflected on what being healthy meant for them and their motivators for adopting healthy behaviors.

Ideation Session

In total, 8 members of the research team, 1 health technology consultant, and 3 members of the app development team participated in an ideation session to generate insights from the qualitative data obtained from FG 1 and identify design opportunities. Participants were guided through three HCD inspiration rounds for themes uncovered in FG 1: (1) family habit tracking and accountability; (2) behavior change techniques; and (3) family, child, and HCP collaboration. Each round began with "How Might We" questions, an HCD technique where challenges are framed as questions to prompt innovative solutions [24], followed by a brief brainstorming session and rating activity of proposed ideas.

FG 2 (Cocreation)

Key themes that emerged from FG 1 and the ideation session were presented in the second set of FGs (FG 2). Separate sessions were held for families and HCPs 1 week after the ideation session. In total, 7 parents and 6 children participated in the family cocreation session (FG 2A), of whom 71% (5/7) of the parents and 67% (4/6) of the children had previously participated in FG 1. Parents and children were presented with wireframes (design layouts of requested features) and asked to rank features and daily challenge completion reward ideas by applying stickers that represented different ratings on printed wireframes. The HCP session (FG 2B) was attended by 15 HCPs from BCCH and facilitated by the health technology consultant. It aimed to gather feedback on questions that would help HCPs understand the baseline health behaviors of their patients, the design of the HCP dashboard wireframe, and the structure of the in-app daily challenges.

Agile Development

Agile development refers to the process of developing software that addresses stakeholders' desires through short iterative cycles [28]. We used a subset of agile development known as "Scrum" that is characterized by high productivity and responsiveness to changing requests [28]. This process began by creating user stories, or short phrases that represented a desired functionality, and categorizing them under app features using Trello (Atlassian Corporation Plc), a Kanban-style web-based project management tool centered on list making. Next, the research team prioritized user stories based on available resources and complexity to provide guidance to the app developers on what features to develop next. A key feature of the Scrum framework is the use of development cycles known as sprints [28]. A total of 3 sprints were performed. For each sprint, the app developers were given 1 week to develop app features based on the research team's prioritization. A demonstration of new or revised features developed during the week was sent to the research team approximately 48 hours before a 30-minute weekly sprint meeting, where the research team provided feedback. Shorter sprints that lasted 3 to 4 days were performed near the end of app development to address technical issues that arose during the previous iterations. The output of the agile development phase was an app prototype.

FG 3 (User Testing)

FG 3 was cofacilitated by the app development and research teams. A total of 11 parents and 14 children participated in FG 3. In total, 82% (9/11) of the parents and 77% (10/13) of the children had participated in at least one of the previous FGs. Each parent and child pair, or child only when a parent was not present, was given an iPad preloaded with the app prototype and asked to provide feedback on the prototype's usability and content by completing and rating the difficulty of 5 tasks on a scale of 1 (very difficult) to 7 (very easy). FG facilitators minimized the guidance they provided on how to use the app to allow participants to independently explore the prototype. Next, participants were asked to brainstorm reward ideas as part of the app's gamification feature and rate a list of predefined rewards generated by the research team. The FG ended with a brainstorming session of daily challenges and the categorization of these challenges into different levels of difficulty.

Data Analysis

Descriptive statistics (means and SDs for continuous variables, counts and percentages for categorical variables, and medians and IQRs for ordinal variables) were generated to describe the sociodemographic characteristics of the participants, ease in completing tasks using the prototype, and ratings of rewards and daily challenges. Quantitative data were analyzed using SPSS (version 25.0; IBM Corp).

FG sessions were audio recorded and transcribed verbatim by KWY and reviewed by SK to ensure transcription accuracy. Transcripts were not returned to participants for comments or corrections given that our sessions were group sessions and not individual interviews. KWY and SP independently conducted a thematic analysis of all transcripts using NVivo (QSR International). Following the immersion-crystallization framework [29], qualitative data generated from the FGs were organized into coding categories that were continuously revised throughout the transcript reviewing process, followed by a discussion between the 2 authors to review the preliminary coding categories and reduce the data further using thematic coding and content analysis. Any discrepancies were discussed between the 2 authors until a consensus was reached.

Results

Demographics

Most children (n=14; mean age 10.2, SD 1.3 years; 5/14, 36% male; 5/14, 36% White participants) and parents (n=12; 9/12,

75% aged 40-49 years; 2/12, 17% male; 7/12, 58% White) participated in at least 1 of 3 FGs. The Live 5-2-1-0 behaviors of the FG child participants are summarized in Table 1. Most of the parent participants (9/12, 75%) were aged between 40 and 49 years, and 92% (11/12) were married. Most parents (8/12, 67%) had at least a bachelor's degree, with the remainder having a trade certificate, diploma, or university certificate. Moreover, 70% (7/10) had an annual household income of >CAD $80,000 (US $59,756.30). HCPs (n=18) participated in at least 1 of 3 FGs and included physicians (5/18, 28%), nurses (3/18, 17%), nurse practitioners (2/18, 11%), dieticians (5/18, 28%), pharmacists (2/18, 11%), and physiotherapists (1/18, 6%).

Table 1. Live 5-2-1-0 behaviors of focus group child participants (n=14).

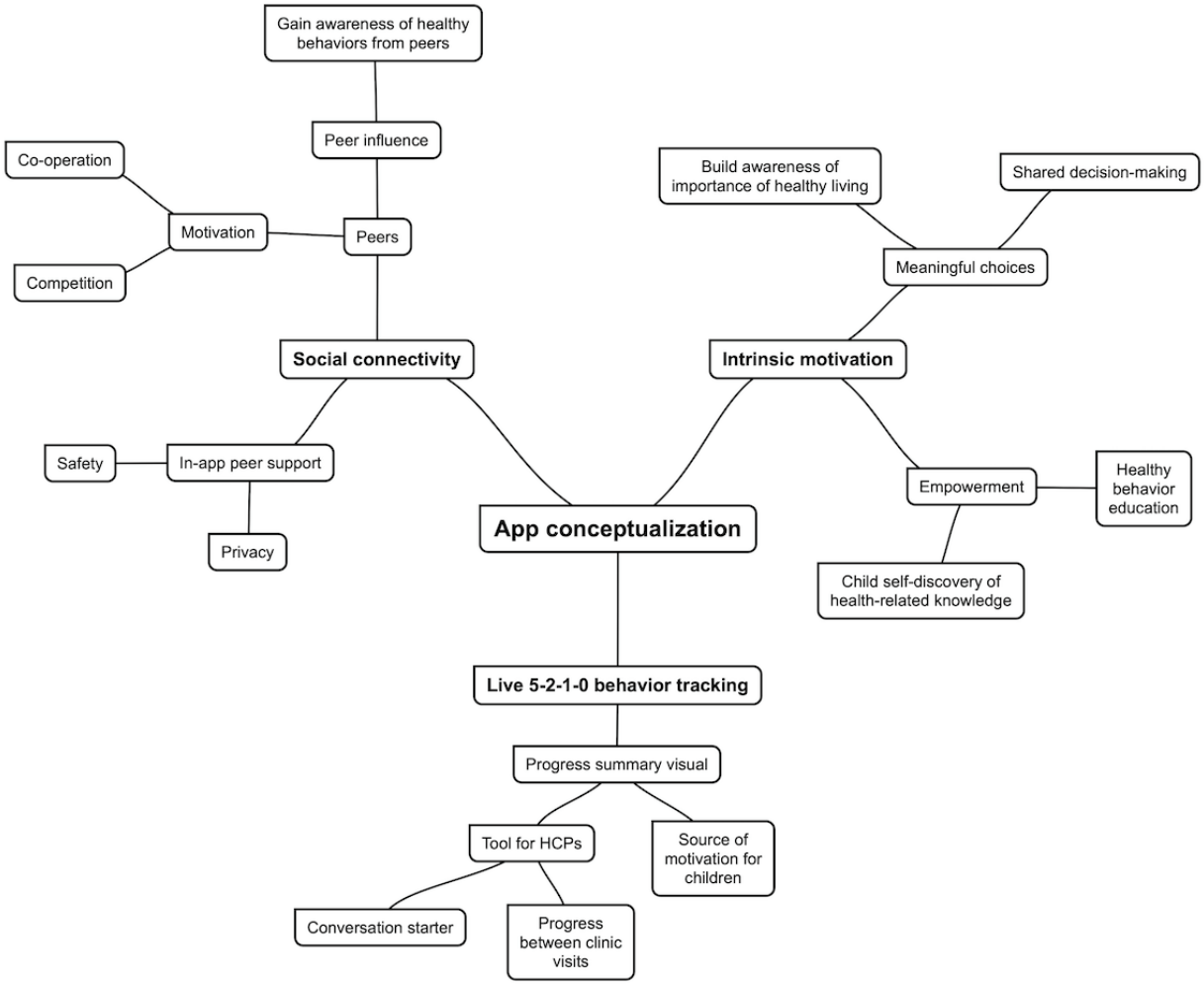
Live 5-2-1-0 behaviors	Values, median (IQR)
Servings of fruits and vegetables per day[a]	3.5 (2-6)
Hours of screen time per day (excluding time for schoolwork)	1 (1-2)
Days per week physically active for at least 1 hour (n=13)	5 (3-6)
Cups of sugary drinks per day	0.5 (0-1)

[a]1 serving=half a cup.

FG 1—App Conceptualization

Coding categories and themes that emerged from FG 1 are illustrated in Figure 2.

Figure 2. Concept map outlining themes that emerged from focus group 1 (app conceptualization). HCP: health care provider.



Empowerment and Intrinsic Rewards Lead to Development of Healthy Behaviors

Parents described their children's tendency to gravitate toward choices that were meaningful to them and that the empowerment of the child would lead to the establishment of long-term habits. Children's self-discovery of health knowledge was thought to result in better adherence rather than a top-down approach in which parents instructed their children on what to do:

> *When kids feel empowered that they are making the decision...instead of being directive as parents, we would be non-directive and...coach them.* [Parent]

Both parents and HCPs agreed that an app that facilitates shared decision-making between children and parents would empower children to become actively involved in making healthy behavior changes. The importance of personal awareness was reflected in the child session, during which guilt was often discussed in association with knowledge of the optimal amount of screen time. Children expressed that guilt from excessive amounts of screen time discouraged them from playing with their electronic devices even when they had not exceeded their daily screen time limit. Education and awareness of the consequences of their actions played a role in their decision-making related to healthy behaviors:

> *I saw [a] fact on my agenda. It said if you play [on your device] four hours a day, it's good to get out sometimes, so limit your time [to] two hours.* [Child]

Social Connectivity as a Key Motivator for Children and Families

According to HCPs, and confirmed by children, children are more willing to engage with an app if it requires them to complete tasks cooperatively with or competing against their peers. Parents commented that children tended to gain awareness of healthy behaviors from their peers, which was far more effective than parental directives or encouragement. HCPs commented that, once children take ownership of their own health, they tend to develop a sense of responsibility for their family, and it may encourage them to adopt healthy behavior changes together. The sense of accountability and responsibility can also transform into a source of motivation:

> *Making it as a family activity that's like "you need the physical activity but your parents also need it," so going together and then doing some physical activity...making them (children) responsible for [their] parents' health.* [HCP]

Parents believed that a blog or group chat for sharing healthy behavior tips would encourage children to mutually support each other as they make healthy behavior changes. However, both parents and HCPs agreed that any communication tool should be regulated by a moderator to ensure the accuracy and appropriateness of the information presented. Children identified connectivity with peers (ie, using digital messaging applications and social media platforms to communicate with their peers about play and engage in competition) and customizability (progressing through increasing levels of difficulty and selecting different modes of play) as key features they desired for the Live-5-2-1-0 app.

Behavior Tracking Changes Child Behavior and Supports HCPs

Parents and HCPs were supportive of the idea of the app tracking children's daily Live 5-2-1-0 behaviors as the data collected could be summarized in a visual interface for the user to view their progress, which in turn could be a source of motivation. It could also be used by HCPs during clinical encounters to become aware of their patients' progress since their last visit:

> *A graph when they come to see us...a snapshot picture...my physical activity is going up...going down. It...motivates them, they're on the right track.* [HCP]

HCPs also explained how the availability of tracking data would serve as a conversation starter and enable them to further investigate the facilitators and barriers faced by the child. This would allow HCPs to build stronger relationships with children, who identified HCPs as individuals of authority and would be more likely to comply with their recommendations to improve their health behaviors.

Ideation Session

Visual Summary as a Tool for Collaborative Decision-making

A key discussion point during the ideation session was to identify ways for the app to facilitate collaborative decision-making, goal setting, and Live 5-2-1-0 behavior tracking among children, parents, and HCPs. A summary visual of the user's progress was proposed to motivate users and guide HCPs in behavioral counseling. However, it was noted that the user may view the visual summary as discouraging if it reflects minimal progress. To address this, the idea of allowing for progressive changes in goal setting was proposed. For goal setting and progress data to be meaningful and comprehensible, it was agreed that the visual interface and user experience design had to be tailored to each stakeholder (child, parent, and HCP) while ensuring that the metrics were identical between different stakeholders.

Need for Adaptive and Customizable Goals

Adaptive goals that were customizable based on the user's preference and reflected progress in the behavior change journey were identified as essential. A suggestion was to include a baseline health assessment that would allow children, parents, and HCPs to set goals collaboratively based on current behavior and readiness to change via the app. Even though users may not choose to act on these behaviors immediately, it is still valuable for them to become aware of what behaviors can be improved upon. However, users should be able to choose which behavior to focus on regardless of the recommendations that arise from the baseline assessment. Finally, the choice to select "small steps" (daily challenges) toward achieving the Live 5-2-1-0 goals was proposed, addressing children's desire for an app that allows for progression and choice of difficulty level.

Design Elements for Gamification

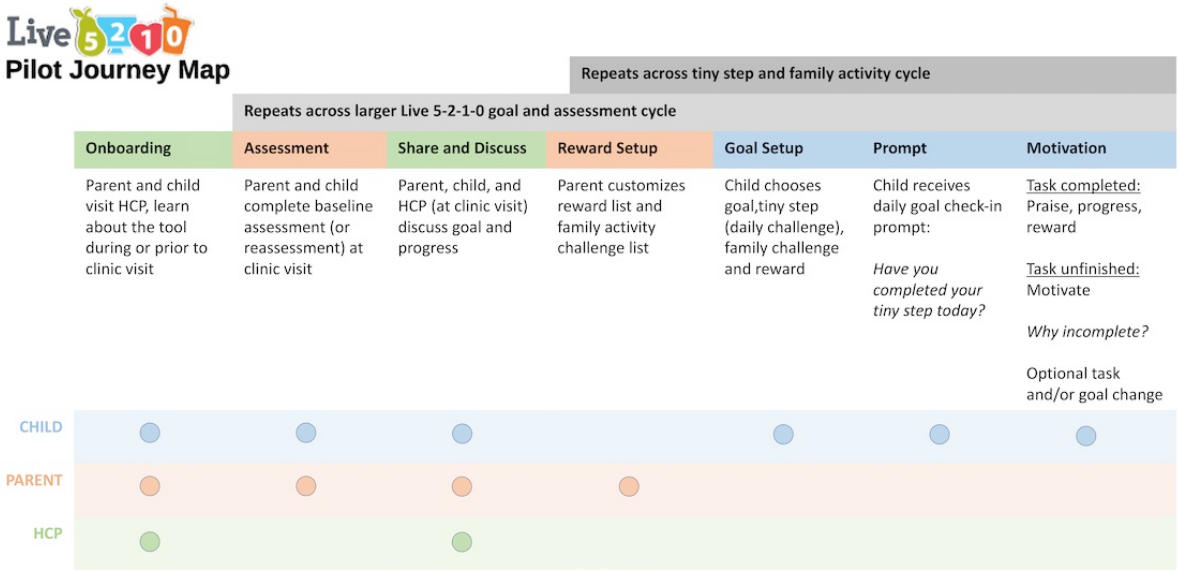
Children suggested a progress bar for visualizing their healthy behavior change journey and progression through increasing levels of difficulty for their small steps to be completed toward achieving a health behavior goal. To do this, the decision was

that users initially had to complete easier small steps before being allowed to attempt more difficult small steps toward their goal. In addition, given parents' belief that intrinsic rewards are more likely to lead to sustained healthy behavior change, the inclusion of a mix of intrinsic and extrinsic rewards within the app was discussed. Intrinsic rewards may include creating an avatar of the user and their home and earning badges that recognize progress. Ideas proposed for external rewards included those that further encourage healthy behaviors; could easily be provided by parents; and promote family engagement, such as going to the local swimming pool, visiting a new playground, or going to a local park. To address parents' desire for customizable external rewards, the option to manually enter a reward of their choice was suggested.

Pilot Journey Map and Screen Wireframes

Information gathered in the app conceptualization FGs and the ideation session was used to create a pilot journey map (Figure 3) to reflect a user's experience with accompanying wireframes demonstrating initial designs of various screens (Multimedia Appendix 3). It is this journey map that was presented to the child, parent, and HCP participants in the cocreation FGs (FGs 2A and 2B).

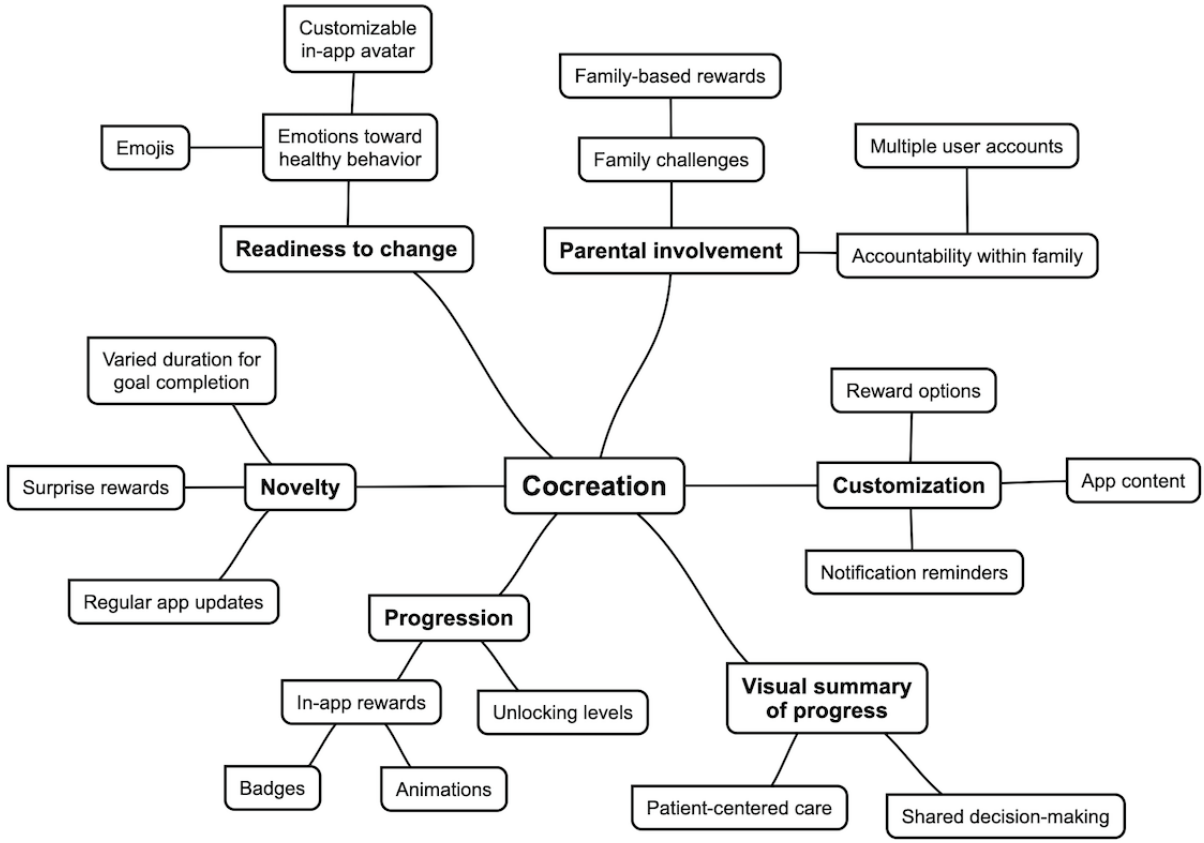
Figure 3. Journey map presented to participants in focus group 2A (cocreation—family session). HCP: health care provider.



FG 2A—Cocreation (Parents and Children)

Coding categories and themes that emerged from FG 2 are illustrated in Figure 4.

Figure 4. Concept map outlining themes that emerged from focus group 2 (cocreation).



Parental Involvement via Family Challenges

Completing challenges as a family on a weekly basis appealed to children and parents, with children indicating parental involvement as a key motivator for app use. Participants were enthusiastic about the idea of keeping participating family members accountable by having everyone set their own goals via individual user accounts but being able to achieve the family challenge only if everyone completed their respective individual goals:

> *Let's say you all have the app...one of you would do five fruits, one does two hours of TV, one does one hour activity, and another does no sugary drinks...if one doesn't do it...they all do not get a reward...all eyes are on each other.* [Child]

Parents suggested that family challenges could be designated as rewards for children upon goal completion, such as a family bicycle ride or going on a camping trip.

Novelty and Progression Promote User Retention

Parents and children both pointed to the importance of novelty in promoting user retention and were supportive of a notification system that would remind users to record their daily challenge progress in the app. Suggestions for triggers included varied durations for goal completion and surprise rewards rather than user-selected rewards. Finally, an app that is regularly updated with new content and features was a suggested strategy to decrease attrition rates. Parents suggested the option for users to begin with an easier level to identify which of the 4 healthy behaviors to address before launching the rest of the app. Children added that rewards should be unlocked progressively such that users who achieve more difficult challenges would be awarded greater rewards.

Customization and In-App Rewards Enhance User Experience

Participants stated that the ability to personalize app content and customize settings within app features would enhance their experience. Parents stressed the importance of commitment to follow through with rewards and stressed that the option for parents to input their own reward ideas was essential:

> *Maybe going to a local lake...if there's a movie your family really wants to see...you can customize to what's happening to your life at that time.* [Parent]

The ability to customize the time and frequency of notification reminders for completing daily challenges was identified as a desired feature. Participants believed that reminders that could be customized to be sent at an ideal time and frequency would increase the chance that users would complete daily challenges and log their progress in the app. Discussion regarding rewards included in-app features that could themselves serve as rewards. Suggestions included badges and celebratory animations that are shown in the app when users accomplish a goal:

> *It (the badge) could have a picture of what you did and then it could have like rainbows and sparks coming out of it.* [Child]

FG 2B—Cocreation (HCPs)

Supporting Patient-Centered Care and Shared Decision-making

HCPs were enthusiastic about the app's potential to support patient-centered care and shared decision-making with families. HCPs shared that, although collecting metrics and following the medical model of care are important, patient communication about their health priorities is also crucial to ensure patient- and family-centered care where HCPs are meeting the patient where they are at:

> *I've got my checklist of stuff that I want to get from my patient...the flipside of it is to help patients communicate what they want [us] to help them with, so that we can actually address their goals, not so much our goals.* [Physician]

HCPs believed that a visual summary of the user's progress would allow them to easily pinpoint areas of opportunity and concern to address during clinical encounters. An app feature that provides users with the opportunity to input reasons for not completing a daily challenge was deemed to be useful for HCPs to identify barriers to successful goal completion. Given that users may not have the opportunity to visit an HCP frequently, participants agreed that the app should have educational content that parents can review with their children for extra support. The inclusion of a flagging system that would directly alert HCPs if users faced challenges with completing their goals was suggested.

Readiness to Change Promotes Healthy Behavior Adoption

HCPs stressed the importance for the app to be able to capture the child's readiness to make changes in addition to their healthy behavior status. Specifically, HCPs called for capturing the child's emotional feelings toward each healthy behavior and believed that children would be more likely to make changes if they felt positive toward the behavior and were motivated internally. Suggestions for facilitating this included allowing users to indicate how they feel (using child-friendly graphics such as emojis) related to the progress of their chosen goal and choose their own avatars with the option to customize their facial expressions to reflect their feelings on their goal progress.

FG 3—User Testing

On the basis of the feedback collected in the FGs and after rounds of iterative development, a prototype of the Live 5-2-1-0 app was created, which included seven main features: (1) a Healthy Habits Questionnaire to support a baseline assessment at the time of onboarding, (2) goal setting, (3) tiny steps (daily challenges), (4) rewards, (5) gamification, (6) daily notifications, and (7) a progress dashboard. During the FG, parent-child dyads were asked to complete five assigned tasks using the prototype, which included (1) completing the baseline assessment; (2) selecting a behavior to work on, a reward, and a tiny step; (3) responding to a daily notification for their current tiny step and reporting progress; (4) completing a further tiny step and receiving a reward for completing their goal; and (5) reviewing goal progress and changing their behavior goal. Families reported ease in completing the 5 assigned tasks, with a median score of 7 (IQR 6-7; range 2-7) on a 7-point Likert scale, where a score of 1 represented "very difficult" and 7 represented "very easy" (Table 2).

Table 2. Median scores for prototype testing during focus group 3 (user testing) on a 7-point rating scale (1=very difficult; 7=very easy).

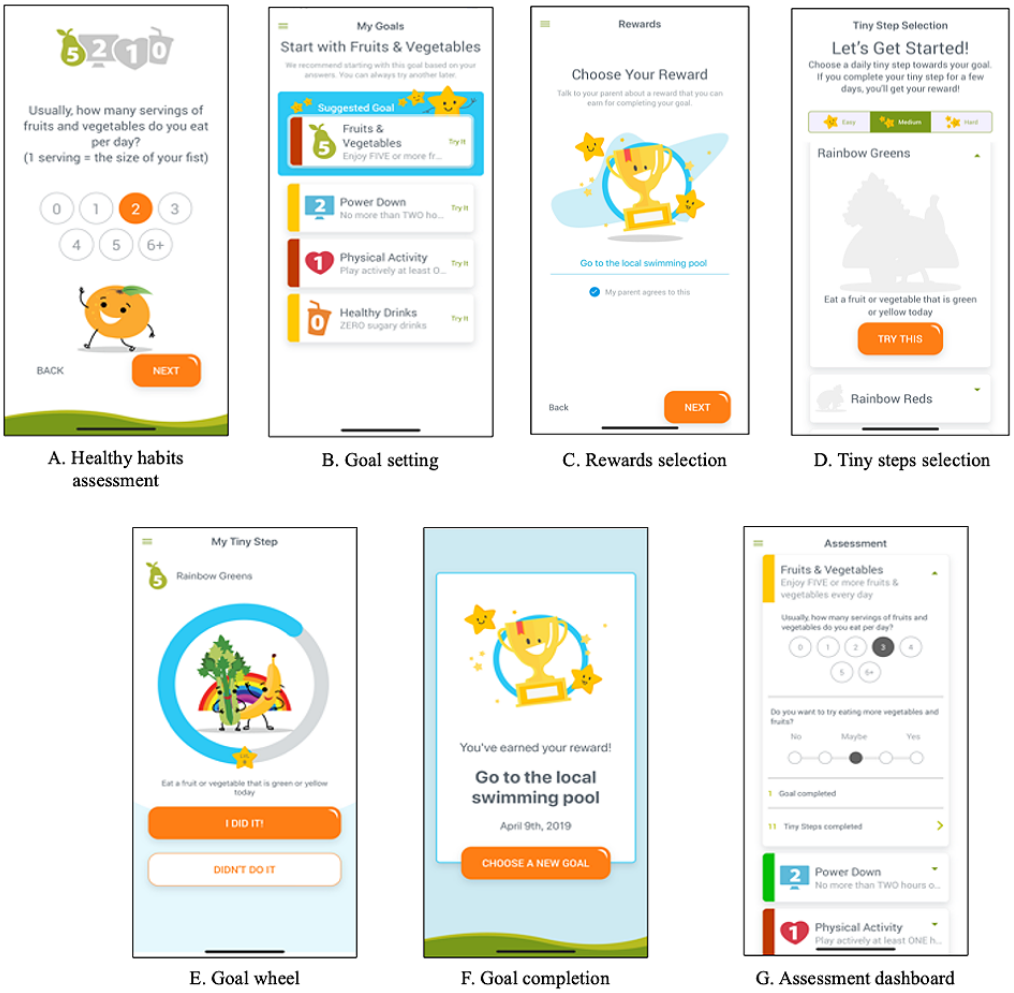
Task	Values, median (IQR)
Complete baseline assessment	7 (6-7)
Select a behavior to work on, a reward, and a tiny step	6 (6-7)
Respond to a daily notification for your current tiny step	6 (5-7)
Complete a tiny step and receive a reward for completing your goal	7 (6-7)
Review goal progress and change your behavior goal	6 (6-7)

Following prototype testing, families shared that they were pleased with the graphics and found the app easy to use overall. Most identified the rewards screen as their favorite but also found it the most challenging to navigate because of difficulty in scrolling through a long list of reward options. Parents also suggested a feature in which custom rewards entered by the user could be saved for future selection. Children desired more animation and sound effects as a reward for completing daily challenges and goals. A total of 64% (7/11) of the regular reward ideas and 81% (21/26) of the family challenge rewards proposed by the research team were "liked" by >50% (8/13, 62%) of the children who completed the scoring task.

Final Product of the App Development Process

After 8 months of app development, the Live 5-2-1-0 app was launched on both the Apple App Store and Google Play Store. The main app features, including the Healthy Habits Questionnaire, goal setting, reward selection, tiny step selection, goal wheel, goal completion, and assessment dashboard, are shown in Figure 5.

Figure 5. Screenshots of various app features. (A) Upon launching the app, users initially complete a Healthy Habits Questionnaire consisting of 8 questions about the user's current practices for the Live 5-2-1-0 behaviors and readiness to make changes for each. (B) On the basis of the user's response to the Healthy Habits Questionnaire, the app labels each behavior goal with either a green, yellow, or red tab representing meeting, almost meeting, and not meeting each behavior goal, respectively. The app also highlights a suggested goal for the user. (C) Users select a reward from a drop-down menu or input their own reward. (D) Users select a daily challenge (tiny step) related to their chosen behavior goal. Challenges are categorized into 3 levels of difficulty (easy, medium, and hard). (E) Visualization of the user's progress toward achieving a goal. Completion of a tiny step earns users points that are used to fill the goal wheel. (F) Users are notified that they have earned their reward after the goal wheel is filled. (G) A visual summary of the user's assessment response and goal completion progress.



A. Healthy habits assessment | B. Goal setting | C. Rewards selection | D. Tiny steps selection

E. Goal wheel | F. Goal completion | G. Assessment dashboard

Discussion

Principal Findings

Overview

Guided by cocreation and participatory design research principles, we developed a mobile app with features and content that are meaningful and relevant to the behaviors and lifestyles of children. Although other health behavior promotion apps for children have also used iterative design processes [30] and user-centered design approaches [31] and involved end users in the app development process [30], our app is unique as families (end users), researchers, and app developers were actively engaged as collaborators throughout the entire app development process.

Several key themes emerged from the qualitative data gathered across the 3 sets of FGs. Children, parents, and HCPs desired an app that facilitated shared decision-making and empowerment of children to become active agents in behavior change. Desired app features that emerged included gamification, goal setting, daily challenges, family-based challenges, and an interface that illustrates behavior change progress. Previous studies describing the development of healthy behavior apps for children have also reported similar features, such as gamification [30] and graphical visualization of behavior change progress [31], as being desired by stakeholders. After testing a prototype that was created based on the ideas proposed by stakeholders, families reported that the app prototype was easy to use, and children "liked" the rewards and daily challenges included.

Shared Decision-making Supports Healthy Behavior Changes in Children

A dominant theme that emerged from our research was the need for the app to support shared decision-making when making healthy behavior changes. By combining HCPs' medical expertise with the children's goals and preferences, shared decision-making facilitates patient-centered care [32] and

increases the children's chances of achieving their desired health outcomes [33]. In a controlled intervention for children with a family history of cardiovascular disease that was based on shared decision-making principles, intervention participants showed a significant reduction in fat (P<.001) and salt (P=.01) intake, as well as a significant increase in exercise, compared with controls [34]. Seventh-graders who took part in a school-based intervention comprising health coaching and health promotion sessions stated that taking part in shared decision-making with researchers in the context of choosing topics for the health promotion sessions encouraged them to take responsibility and be more motivated to engage in the sessions [35]. In our app, the *assessment* dashboard is intended to facilitate shared decision-making among children, parents, and HCPs by providing a visual summary of the child's progress in making healthy behavior changes and serving as a conversation starter during healthy behavior counseling.

Family and HCP Connectivity Encourages the Adoption of Healthy Behaviors

Parents and children identified family connectedness as a key motivator, and children were enthusiastic about the idea of making healthy behavior changes through family challenges. However, results from studies that investigated the effectiveness of childhood obesity prevention and treatment interventions with parental involvement have been mixed [36]. A family-based obesity prevention and treatment intervention reported positive intervention effects on children's weight loss when both children and parents were educated in healthy behavior changes together [36]. However, a 3-month multidisciplinary program aimed at managing childhood obesity reported that parental involvement in weekly sessions did not result in significant reduction in weight among children who were overweight [37]. More research in this area is needed. Children identified peer connectivity (ie, peer-to-peer digital texting within the app) as a desirable feature but recognized potential challenges, such as the need for a moderator. A review of peer support–based mobile apps pointed to ethical and privacy considerations as substantial limitations (eg, bullying, spam, and limiting disclosure of personal information) and suggested that closed access to apps and monitoring of peer interactions are needed to address any misuse by users [38].

Child-HCP connectivity, where the assessment dashboard allows users to keep track of their progress and facilitates better communication with their HCPs at clinical visits, was also identified as important and achievable. In an intervention that addressed childhood overweight via the 5-2-1-0 goals and included the use of paper-based goal trackers for children to record their behaviors, youth and parents reported increased self-perceived quality of care and counseling from their HCP, whereas HCPs felt better supported in providing medical evaluations and counseling on healthy behaviors [39]. Connections between HCPs and patients outside of clinic visits have been shown to be effective in chronic disease management (eg, in an app aimed at supporting asthma self-management among adolescents and the inclusion of a pharmacist chat function increased medication adherence [40]). Our stakeholder engagement revealed that connection with HCPs via the app outside of clinic visits is a potential strategy to enhance the adoption of healthy behaviors. Future app development should explore how HCPs can be engaged in children's progress in adopting healthy behaviors *between* clinical visits.

Intrinsic Goals as Motivators for Progressive Behavior Change

Adults and HCPs explained that children would be more likely to adopt healthy behavior changes if the app meaningfully educated them about healthy behaviors. This contradicts evidence from the existing literature claiming that solely providing health knowledge is unlikely to lead to behavior change [41]. Interestingly, children participating in our FGs reported feeling guilty about their behaviors when they were knowledgeable of recommendations (ie, <2 hours of recreational screen time). However, previous literature has pointed to the role of education in developing self-efficacy [42]. Increased self-efficacy is often linked to decreased stress levels, which can encourage children to become active agents in making healthy behavior changes. Whether an individual will initiate and sustain behavior change depends on their expectations of the outcomes and their perceived ability to do so [43]. This concept is reflected in the Fogg Behavior Model, which posits that individuals are more likely to perceive themselves as having a high *ability* to achieve a task that is simple [23]. When the app educates children about healthy behaviors, the knowledge gained may decrease the cognitive effort required to achieve healthy behavior changes.

To allow children to act as active agents of their own behavior change, the app was designed such that users could select goals and rewards based on their perceived *ability*. The flexibility that the app provides through progressive levels of difficulty in tiny steps makes the behavior change journey more accessible to all users regardless of their current healthy behavior practices and motivation level. By providing an opportunity for children to master easier challenges first before advancing to more difficult ones, the app has the potential to provoke a feeling of satisfaction, which can become a source of motivation. In a study examining exercise goal setting and its relationship with cognitive, affective, and behavioral outcomes, setting intrinsic goals was found to be positively associated with self-reported exercise behavior and psychological well-being and negatively associated with exercise anxiety [44]. A systematic review that aimed to assess the effectiveness of family-based interventions on obesity-related behavior change in children reported intrinsic motivation as a key facilitator in encouraging behavior change in children regardless of the behavior change strategies and techniques used [45].

Clinical and Research Implications

A unique element of our study was the inclusion of stakeholders (children, parents, and HCPs) as research partners throughout the entire app development process. Researchers were able to seek input directly from stakeholders, analyze the ideas through a methodological lens, and relay the information to app developers such that the abstract ideas of stakeholders could be transformed into app design requirements that were then integrated into tangible features in the app.

This reflects the strengths of participatory research, including the focus on the everyday lives of stakeholders and the ability to address pressing issues via action and research [46]. App development that does not incorporate cocreation and participatory approaches often leaves researchers disappointed when app features that they believed would be appealing are not well received by users. For example, in a pilot study investigating the effectiveness of a mobile app on weight loss, a peer support buddy chat and in-app bulletin board were expected to encourage user engagement. However, these features were undesirable to users because of the discomfort they experienced in exchanging sensitive information such as body weight [47]. Had end users participated in the development process, their perspectives regarding peer support could have been captured earlier in the design process and resources could have been put toward app features that aligned with their needs and values.

Strengths and Limitations

The Live 5-2-1-0 app is one of the few mobile health apps aimed at promoting healthy behavior changes among children that used HCD and engaged stakeholders as collaborators throughout its development. The engagement of HCPs was particularly important to provide insight into how the app could best be incorporated into their clinical workflow to enhance patient care. Our approach, which included FGs and agile app development methodologies, can potentially be applied by others interested in developing a mobile app to support health interventions.

Despite these strengths, our development process also had several limitations, among them the inability to include all features discussed during the FGs owing to limited resources, such as 2-way communication between users and HCPs and remote monitoring of progress by HCPs. To create an app that closely resembled the overall vision of the participants, the research team, with guidance from the app development team, prioritized features that emerged from the FGs before the agile development phase. Although the app's current version supports neither parental profiles nor multiple accounts, the app encourages parents to participate by including reward options and daily challenges that involve performing an activity with the family. Involving stakeholders in the feature prioritization activity and sprints during agile development would allow for their direct input on decisions regarding feature prioritization and resource allocation. Most participants in FG 3 (user testing; 19/24, 79%) also participated in at least 1 of the 2 previous FGs, which may have led to bias as the features tested were those that participants had suggested previously.

Selection bias from voluntary response sampling could have led to an overrepresentation of participants who were interested in mobile health and highly motivated to respond positively to the app, as well as those with higher socioeconomic status who had the ability to travel and the time to attend the FGs. To address this, we provided reimbursement for transportation and parking to families as well as scheduling FGs in the evenings to minimize conflict with work schedules. Finally, given that our study was conducted before the COVID-19 pandemic and the increasing use of telephone-based and internet-based care and digital health services since then, the perspectives we gathered may not truly reflect current stakeholder needs and desires.

A potential limitation of the app's feasibility is its low compliance with health behavior tracking. However, previous studies that have investigated the feasibility of mobile health apps for children that were based on self-monitoring have shown promise. For example, a study investigating the feasibility of a handheld computer program with self-monitoring of fruit and vegetable intake and reminder systems to track behaviors among children reported high completion rates for fruit and vegetable goal reminders [48]. With family involvement (eg, family challenges and daily challenges that involve parental support) being an integral part of our app, there is the potential for children to track their health behaviors together with their parents, especially those who do not have their own mobile device, which may promote increased adherence.

In a broader context, the success of childhood obesity prevention initiatives can also be influenced by socioecological factors surrounding those populations that an initiative aims to have an impact on [49,50]. The app on its own cannot address social determinants of health that may pose barriers to behavior change, such as economic inability to purchase healthy foods; however, the app is a component of the larger system-level Live 5-2-1-0 initiative that engages multiple sectors across communities to work at local policy and environmental levels to address systemic barriers.

Future Directions

We had initiated a pilot feasibility study in the General Pediatrics Clinic at BCCH intending to collect data to improve the app further, but it was later halted because of the COVID-19 pandemic. Despite this, we still gathered data from our partners at Shapedown BC, a weight management program at BCCH, and based on these data, a second iteration of the app was created. This new iteration includes some of the outstanding features not included in the app's initial version, including the ability to build 1 weekly goal, input customized goals outside of the 5-2-1-0 habits (eg, mindfulness and sleep), and set the frequency of reminders. Using this new app iteration, another 1-group pretest-posttest quasi-experimental pilot feasibility study will be conducted in Shapedown BC to assess the app's effectiveness. The results will inform the feasibility of using the app as a tool in behavioral weight management programs and primary care clinics and provide a basis for designing full-scale studies in the future. Concurrently, the app will also remain available to other HCPs at BCCH as an element of the Live 5-2-1-0 HCP Toolkit, with ad hoc feedback also helping inform future iterations.

Conclusions

We described the design and development process of the Live 5-2-1-0 app aimed at promoting healthy behavior change among children. This study demonstrated the feasibility of cocreating a mobile health app prototype with children, parents, and HCPs through participatory action research. Although further work is needed to investigate the effectiveness of the app in promoting health behavior change, our findings may serve as a reference

for those who are interested in developing mobile apps that address behavior change in collaboration with stakeholders.

Acknowledgments

This study was part of KWY's master's thesis [51], is part of the Live 5-2-1-0 eHealth App project, and was funded by a Personalized Health Catalyst Grant from the Canadian Institutes of Health Research (PCG-155551; principal investigator: SA). MG holds a Michael Smith Health Research British Columbia scholar award. The authors wish to thank Shelley Keidar for her supporting role as a research coordinator for this study.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Focus group guiding questions.
[DOCX File , 22 KB - pediatrics_v6i1e44792_app1.docx]

Multimedia Appendix 2
Healthy Habits Questionnaire.
[DOCX File , 436 KB - pediatrics_v6i1e44792_app2.docx]

Multimedia Appendix 3
Focus group 2 (cocreation) materials.
[DOCX File , 310 KB - pediatrics_v6i1e44792_app3.docx]

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Abbreviations

BC: British Columbia
BCCH: British Columbia Children’s Hospital
COREQ: Consolidated Criteria for Reporting Qualitative Research
FG: focus group
HCD: human-centered design
HCP: health care provider
REDCap: Research Electronic Data Capture

Edited by S Badawy; submitted 03.12.22; peer-reviewed by S Mulvaney, A Lee; comments to author 25.01.23; revised version received 12.03.23; accepted 24.03.23; published 17.05.23.

Please cite as:
Yau KW, Tang TS, Görges M, Pinkney S, Amed S
Using Human-Centered Design and Cocreation to Create the Live 5-2-1-0 Mobile App to Promote Healthy Behaviors in Children: App Design and Development
JMIR Pediatr Parent 2023;6:e44792
URL: https://pediatrics.jmir.org/2023/1/e44792
doi:10.2196/44792
PMID:37195754

Original Paper

Health Information From Web Search Engines and Virtual Assistants About Pre-Exposure Prophylaxis for HIV Prevention in Adolescents and Young Adults: Content Analysis

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Abstract

Background: Adolescents and young adults are disproportionately affected by HIV, suggesting that HIV prevention methods such as pre-exposure prophylaxis (PrEP) should focus on this group as a priority. As digital natives, youth likely turn to internet resources regarding health topics they may not feel comfortable discussing with their medical providers. To optimize informed decision-making by adolescents and young adults most impacted by HIV, the information from internet searches should be educational, accurate, and readable.

Objective: The aims of this study were to compare the accuracy of web-based PrEP information found using web search engines and virtual assistants, and to assess the readability of the resulting information.

Methods: Adolescent HIV prevention clinical experts developed a list of 23 prevention-related questions that were posed to search engines (Ask.com, Bing, Google, and Yahoo) and virtual assistants (Amazon Alexa, Microsoft Cortana, Google Assistant, and Apple Siri). The first three results from search engines and virtual assistant web references, as well as virtual assistant verbal responses, were recorded and coded using a six-tier scale to assess the quality of information produced. The results were also entered in a web-based tool determining readability using the Flesch-Kincaid Grade Level scale.

Results: Google web search engine and Google Assistant more frequently produced PrEP information of higher quality than the other search engines and virtual assistants with scores ranging from 3.4 to 3.7 and 2.8 to 3.3, respectively. Additionally, the resulting information generally was presented in language at a seventh and 10th grade reading level according to the Flesch-Kincaid Grade Level scale.

Conclusions: Adolescents and young adults are large consumers of technology and may experience discomfort discussing their sexual health with providers. It is important that efforts are made to ensure the information they receive about HIV prevention methods, and PrEP in particular, is comprehensive, comprehensible, and widely available.

(JMIR Pediatr Parent 2023;6:e41806) doi:10.2196/41806

KEYWORDS

pre-exposure prophylaxis; PrEP; prophylaxis; internet use; search engine; adolescent; youth; pediatric; adolescence; young adult; readability; human immunodeficiency virus; HIV; virtual assistant; health information; information quality; accuracy; credibility; patient education; comprehension; comprehensible; web-based; online information; sexual health; reading level

Introduction

The HIV epidemic is a major health concern, with the Centers for Disease Control and Prevention (CDC) reporting 37,698 new HIV diagnoses in the United States in 2018 [1,2]. While individuals aged 25-44 years had the highest incidence of HIV, youth aged 13-24 years comprised more than half of all new diagnoses [1].

Pre-exposure prophylaxis (PrEP) is an effective daily prevention method and should be considered for use by HIV-negative populations at higher risk of HIV [3]. When taken as prescribed, PrEP can offer almost complete protection against HIV; however, previous studies have shown that PrEP uptake is lower in higher risk populations [4,5]. Barriers to PrEP uptake include limited awareness and limited access as a result of PrEP marketing and additional socioeconomic challenges, respectively [5].

Moreover, adolescents and young adults are major consumers of technology and often rely on the internet for health information [1,6-8]. Since adolescents and young adults may be consulting the internet instead of health care providers for HIV prevention information, it is critical that health information on the web is accurate and readable. To the authors' knowledge, there is limited research assessing the quality of PrEP information available on the web. Therefore, the objectives of this study are to determine if accurate and readable PrEP information can be found using web search engines and virtual assistants. Additionally, this study aimed to assess how PrEP information found via both methods compared among and between search engines and virtual assistants.

Methods

Ethical Considerations

The institutional review board at Children's Hospital of Philadelphia determined that approval was not necessary for this study as it did not contain human subjects.

Developing a Framework for Evaluating PrEP Internet Content

Common PrEP information themes were determined for future searches within the United States using English only: PrEP basics, PrEP access, and PrEP use (Textbox 1). A total of 50 questions were compiled through an iterative process with an expert panel of adolescent medicine researchers and physicians who work with adolescents and young adults at high risk of contracting HIV as well as youth living with HIV. Items were narrowed down to 23 questions designed to address concerns adolescents and young adults may have about general use, privacy, and confidentiality (Table 1).

Textbox 1. PrEP categories.

Pre-exposure prophylaxis (PrEP) basics

- The questions in this category aim to find general information about PrEP for HIV prevention to introduce and educate potential users about this intervention method.

PrEP access

- The questions in this category aim to find information about ways users can access PrEP in addition to information about privacy concerns.

PrEP use

- The questions in this category aim to find information regarding the proper use of PrEP so that potential users can receive the maximum benefits.

Table 1. PrEP internet search questions.

Question	Category
What is PrEP[a]?	Basics
What kinds of PrEP are available?	Basics
What is Truvada?	Basics
What is Descovy?	Basics
What is the difference between Truvada and Descovy?	Basics
Does PrEP protect against other sexually transmitted infections/sexually transmitted diseases?[b]	Basics
Should I take PrEP?	Basics
What are the side effects of taking PrEP?	Basics, use
Will PrEP make me feel sick?	Basics
How does PrEP work?	Basics, use
What is the difference between PEP[c] and PrEP?	Basics
How effective is PrEP?	Basics, use
Where can I find PrEP?	Access
How can I get PrEP?	Access
Do I need insurance to get PrEP?	Access
Do I need my parents' permission to get PrEP?	Access
Will my parents know that I'm using PrEP if I'm on their insurance?	Access
How much does PrEP cost?	Access
How do I take PrEP?	Use
When can I stop taking PrEP?	Use
How long does it take for PrEP to start working?	Use
What happens if I miss a dose of PrEP?	Use, basics
How do I refill my PrEP prescription?	Use, access

[a]PrEP: pre-exposure prophylaxis.

[b]This question was asked using both "sexually transmitted infections" and "sexually transmitted diseases" due to the recent change in terminology.

[c]PEP: postexposure prophylaxis.

Data Collection: Web Search Engines and Virtual Assistants

Questions were entered into search engines—Ask.com, Bing, Google, and Yahoo—using a private Mozilla Firefox browser and verbally posed to virtual assistants—Amazon Alexa, Microsoft Cortana, Google Assistant, and Apple Siri—using new user accounts apart from Apple Siri where a pre-existing account with cleared browsing history was used. Questions were asked to search engines and virtual assistants on separate days in March 2021 with a maximum of 10 times for virtual assistants to generate a response. Excluding advertised content, information from the first three web search engine results and virtual assistant nonverbal results were transcribed as listed on the website and recorded in corresponding Excel (Microsoft Corporation) sheets for future analysis. Verbal responses from each virtual assistant were recorded, transcribed, and saved in Excel.

Data Analyses: Scale Development, Rating System for Information Accuracy, and Readability Assessment

A six-tier scale was created and reviewed by an adolescent medicine physician and a researcher to code example content (Table 2). The examples were used as content validation to ensure that results were coded using the same criteria. Results received two scores from two different coders who assigned final scores after reaching a consensus. Final scores were then used to calculate an average quality score for each web-based resource in each category. The data collected were also entered into a web-based literacy measurement tool [9] to assess readability using the Flesch-Kincaid Grade Level Scale [10].

Table 2. PrEP Information Quality Rating Scale.

Rating number	Meaning	Example content (question: what is PrEP[a]?)
0	The resulting answer did not include any information about PrEP.	"HIV (human immunodeficiency virus) is a virus that attacks the body's immune system. There is currently no effective cure. Once people get HIV, they have it for life" [11]
1	The resulting answer included information about PrEP that was completely inaccurate.	"PrEP is a medication taken only right before sex in order to prevent HIV. While taking PrEP, individuals do not need to use condoms" [12]
2	The resulting information about PrEP was partially correct but contained some errors/misleading information. The source providing information was unreliable.	"PrEP is a pill taken before sex, so it is pre-exposure. Prophylaxis means to prevent infection. So you can use PrEP to greatly reduce the risk of becoming HIV positive" [13]
3	The resulting information was accurate but lacked many important details.	"Pre-exposure Prophylaxis, also known as PrEP, is when people take medicine to lower their risk of getting HIV" [14]
4	The resulting information was detailed, accurate, and from a reliable source. However, the information included was outdated.	"PrEP is an experimental approach to HIV prevention and consists of antiretroviral drugs to be taken before potential HIV exposure in order to reduce the risk of HIV infection and continued during periods of risk" [15]
5	The resulting information was detailed, accurate, and from a reliable source. Additionally, the result included the latest information available.	"Pre-exposure prophylaxis (or PrEP) is a way for people who do not have HIV but who are at very high risk of getting HIV to prevent HIV infection by taking a pill every day. The pill (brand name Truvada) contains two medicines (tenofovir and emtricitabine) that are used in combination with other medicines to treat HIV. When someone is exposed to HIV through sex or injection drug use, these medicines can work to keep the virus from establishing a permanent infection. When taken daily, PrEP is highly effective for preventing HIV. Studies have shown that PrEP reduces the risk of getting HIV from sex by about 99% when taken daily. Among people who inject drugs, PrEP reduces the risk of getting HIV by at least 74% when taken daily. PrEP is much less effective if it is not taken consistently. As PrEP only protects against HIV, condoms are important for the protection against other STDs. Condoms are also an important prevention strategy if PrEP is not taken consistently." [16]

[a]PrEP: pre-exposure prophylaxis.

Results

Web-Based PrEP Information Quality

From all search engines and virtual assistants, 422 results were compiled and assigned a score from the PrEP Information Quality Scale (Table 2). The results show that Google search engine and Google Assistant more frequently provided higher quality information than resources from other companies, and that search engines provided higher quality information than virtual assistants (Table 3). Google search engine provided more comprehensive results directing potential users to websites with information on the ideal candidates, proper use, and access. However, Ask.com often provided the lowest quality information directing users to websites containing no information about PrEP. Bing and Yahoo provided information quality between Google and Ask.com.

Table 3. Search engines' and virtual assistants' average PrEP information quality scores[a].

Resource	PrEP[b] basics	PrEP access	PrEP use
Search engines			
Ask.com	1.8	0.8	0.5
Bing	3.7	2.7	3.1
Google	3.4	3.7	3.5
Yahoo	3.4	2.8	2.9
Virtual assistants			
Amazon Alexa	1.1	0.9	1.4
Apple Siri	2.4	1.8	3.3
Google Assistant	3.2	3.3	2.8
Microsoft Cortana	2.3	2.5	2.0

[a]PrEP information score meanings: 0=irrelevant, 1=inaccurate, 2=partially correct/misleading, 3=accurate but missing important details, 4=accurate but outdated, 5=accurate and current.

[b]PrEP: pre-exposure prophylaxis.

The following responses were given to the question "How much does PrEP cost?"

> *...A month's supply of Truvada is nearly $2,000 without insurance. Most private health insurance companies, Medicare, and Medicaid will cover the cost...* [WebMD via Google]
>
> *Launching a startup...* [Ask.com]

Within virtual assistants, Google Assistant typically provided more informative results when compared to the other virtual assistants selecting relevant text from websites to respond to posed questions. Amazon Alexa generally provided the lowest quality information with irrelevant responses including "Sorry, I don't know that one." Microsoft Cortana and Apple Siri provided information quality between Google Assistant and Amazon Alexa.

The following responses were given to the question "What is the difference between Truvada and Descovy?"

> *There are now two medications approved by the U.S Food and Drug Administration (FDA): Truvada and Descovy...which medication might be right for you, take a look at the similarities and differences between the two medications below...* [SFAF.org via Google Assistant]
>
> *Pharmaceutical product. Star Trek Discovery...* [Amazon Alexa]

Web-Based PrEP Information Readability

The readability assessment using the Flesch-Kincaid Grade Level scale revealed that information from web search engines produced by questions in all three categories requires a literacy level that aligns with that of an eighth grade, ninth grade, or 10th grade student, while virtual assistant results require literacy levels ranging from a second grade to eighth grade student in the United States (Table 4). The required literacy level of information produced by search engines and virtual assistants appears to correlate with the quality of information produced by each, as the search engines more frequently provided information of higher quality than the virtual assistants.

Table 4. Search engines' and virtual assistants' average PrEP information readability scores[a].

Resource	PrEP[b] basics	PrEP access	PrEP use
Search engines			
Ask.com	8.3	9.2	8.3
Bing	10.2	8.1	9.1
Google	9.3	9.6	8.6
Yahoo	9.7	8.1	9.2
Virtual assistants			
Amazon Alexa	7.0	2.7	5.4
Apple Siri	8.4	4.8	7.1
Google Assistant	7.4	8.3	6.9
Microsoft Cortana	7.0	6.4	7.7

[a]PrEP information readability score formula: grade level = 0.37 (words/sentence) + 5.84 (syllables/word) – 15.59.

[b]PrEP: pre-exposure prophylaxis.

Discussion

Principal Results

Google search engine and Google Assistant produced higher quality PrEP information more frequently than the other web-based resources used. Authors found resulting answers to PrEP questions that conflicted with each other within a single search engine/virtual assistant, which may lead to incorrect use of PrEP and ultimately reduced effectiveness. Additionally, the resulting information generally was presented in language between a seventh and 10th grade reading level, therefore, often exceeding the average reading level of adolescents and young adults in the United States [17].

Comparison With Prior Work

To the authors' knowledge, there are no other studies that have specifically evaluated the quality of PrEP information for HIV prevention produced by virtual assistants or the readability of health information found on the web. However, a New Zealand study titled "In Bed with Siri and Google Assistant: A Comparison of Sexual Health Advice" used Google search engine, Google Assistant, and Apple Siri to assess the quality of sexual health advice received from each source. The results of this study are consistent with researchers' findings that Google search engine had the best responses, followed by Google Assistant then Apple Siri, when asked questions about sex and sexual health [18].

Limitations

The study limitations include the variability of results produced by search engine and virtual assistant algorithms. To account for the possibility of different top results for the same questions, searches were performed on a single day for all search engines and on a separate day within the same week for all virtual assistants. Future studies may consider conducting a time-based analysis where searches are completed at set time intervals over 1 year or more to compare top results for the same questions over time. Another limitation is the condensed list of questions. Future studies should include youth perspectives on what questions adolescents and young adults would ask in addition to provider opinions. Additionally, the study was conducted in English, which may exclude individuals whose primary language is not English. Furthermore, at the time of this study, injectable PrEP had not yet been approved and are not included in the search results.

Conclusions

Adolescents and young adults may turn to technology due to discomfort discussing their sexual health with providers, yet we found that there is much room for improvement in the quality and readability of educational information on PrEP through web-based resources.

Acknowledgments

This research was directly supported by grants from the National Institute of Mental Health P30MH097488 (principal investigator: Dwight Evans) and K23MH119976-01A1 (principal investigator: SW) and the Leadership Education in Adolescent and Young Adult Health program.

Conflicts of Interest

None declared.

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Abbreviations

CDC: Centers for Disease Control and Prevention
PrEP: pre-exposure prophylaxis

Edited by S Badawy; submitted 09.09.22; peer-reviewed by U Belkind; comments to author 04.03.23; revised version received 31.03.23; accepted 01.04.23; published 18.07.23.

Please cite as:
Darien K, Lee S, Knowles K, Wood S, Langer MD, Lazar N, Dowshen N
Health Information From Web Search Engines and Virtual Assistants About Pre-Exposure Prophylaxis for HIV Prevention in Adolescents and Young Adults: Content Analysis
JMIR Pediatr Parent 2023;6:e41806
URL: https://pediatrics.jmir.org/2023/1/e41806
doi:10.2196/41806
PMID:37463044

Original Paper

Health Care Professionals' Experiences and Views of eHealth in Pediatric Care: Qualitative Interview Study Applying a Theoretical Framework for Implementation

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Abstract

Background: The development and evaluation of eHealth interventions in clinical care should be accompanied by a thorough assessment of their implementation. The NASSS (Non-adoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies) framework was designed to facilitate the implementation and scale-up of health technology programs, providing an option for analyzing the progression of these initiatives as they are implemented in real-time. Considering health care provider perspectives within the framework for implementation offers valuable insights into the early identification of barriers and facilitators in the implementation of potentially effective eHealth innovations. Nevertheless, there is a dearth of studies on eHealth interventions that encompass longer time frames and delve into the complexities of scaling up and sustaining such interventions within real-world health care environments.

Objective: This study aims to investigate the perspectives and insights of health care professionals (HCPs) regarding the implementation of an eHealth intervention in pediatric health care while applying the NASSS framework to theorize and evaluate the conditions influencing the implementation of eHealth solutions.

Methods: Semistructured interviews were performed with health care providers, including both staff and management personnel, within a university pediatric hospital (N=10). The data collection process occurred concurrently with a clinical trial focused on developing and assessing an eHealth app for self-management in pediatric care following hospital discharge. Using an abductive approach, the interviews were initially analyzed qualitatively and subsequently mapped onto the 7 domains of the NASSS framework to identify factors influencing implementation, encompassing facilitators, barriers, and varying levels of complexity.

Results: In the realm of pediatric care, the family was identified as the primary unit of care, and patient heterogeneity was a prominent feature. The implementation of eHealth tools, while deemed usable and flexible, was also seen as a delicate balance between safety and adaptability, highlighting challenges related to health care integration. Child participation and secrecy, especially for adolescents, contributed to the complexity of using eHealth. HCPs had high eHealth literacy, and thus challenges concerning adoption were related to work adaptations and the risk of "app overload." The readiness for implementation was experienced as induced through the research study and the pandemic situation. However, to move from research to implementation in clinical practice, organizational challenges identified a need to update the concept of care and ensure activity measurements. In a wider context, HCPs raised concerns related to regulatory requirements for documentation, public procurement, and data safety. Implementation became more complex due to a lack of overview in a large organization.

Conclusions: Important perspectives for implementation were considerations of regulatory requirements, as well as the need for a shared vision of eHealth and the establishment of eHealth-related work as part of regular health care. Key contextual factors

that support reach and impact are communication channels between different levels at the hospital and a need for paths and procedures compatible with legal, technological, and security concerns. Further research should focus on how eHealth interventions are perceived by children, adolescents, their parents, and other stakeholders.

Trial Registration: ClinicalTrials.gov NCT04150120; https://clinicaltrials.gov/ct2/show/NCT04150120

(JMIR Pediatr Parent 2023;6:e47663) doi:10.2196/47663

KEYWORDS

communication; digital; experiences; eHealth; health care professionals; implementation; NASSS; pediatric care

Introduction

Technological development and increased access to the internet and mobile technology have led to a flurry of eHealth interventions to support families and children in pediatric care [1-3]. The general purpose of eHealth, defined as the use of information and communication technologies for health [4], is to facilitate high-quality and equal care and health for populations through, for example, increased access to care and improved health information exchange. Many countries have adopted national eHealth policies or strategies aiming to enhance person-centered care [5].

To ensure that the goals of eHealth are met, interventions that are developed and scientifically evaluated need to be studied from the perspective of a real-world context. Recent studies have raised the importance of attending to the complexity of the context of these interventions to support a move from innovation to implementation [6,7].

The NASSS (Non-adoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies) framework is a validated tool developed to support the implementation and scale-up of health technology programs, offering a structure for studying the unfolding of such initiatives in 7 domains (Textbox 1) [8].

Textbox 1. The 7 domains in the NASSS (Non-adoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies) framework.

1. The condition or illness
2. The technology
3. The value proposition
4. The adopter system
5. The organization
6. The wider context
7. Embedding and adaptation over time

The NASSS framework has been used in numerous studies, incorporating qualitative data such as interviews and focus group discussions. These studies have used a combination of inductive and deductive approaches to inform their analyses [9-12]. Thus, the framework can serve as a guiding tool for development and decision-making. It can assist in avoiding common high-probability issues and, in certain situations, prompt discussions about discontinuing high-risk projects rather than continuing to invest resources.

The insights provided by health care professionals (HCPs) in various roles within the health care system are crucial for the advancement and integration of innovative care delivery methods. The NASSS framework has proven valuable in structuring and contrasting HCPs' encounters with eHealth, thus revealing potential intricacies and obstacles in the adoption and dissemination of such technologies. Examining the broader landscape beyond individual projects can offer valuable perspectives for strategic planning and implementation, with a particular focus on understanding how contextual factors can introduce complexities that either facilitate or impede the adoption and expansion of innovative solutions [13].

Interventions incorporating eHealth technologies are inherently multifaceted, entailing complexities associated with technology development, support, maintenance, and financing. Much of the existing research on eHealth interventions has concentrated on individual technologies and the challenges and enablers tied to their implementation [8]. A systematic review of the literature highlighted substantial gaps and obstacles concerning the implementation of eHealth and called for a more comprehensive analysis of the experiences of various stakeholders [14]. Relatively few studies have delved into longer time frames that encompass the scaling up and long-term sustainability processes within the intricate landscape of real-world health care environments [8].

The objective of this study was to investigate the experiences and perspectives of HCPs regarding the implementation of an eHealth intervention in pediatric health care, using the NASSS framework as a theoretical lens to conceptualize and assess the factors influencing eHealth implementation

Methods

Design

We used a qualitative research design with a descriptive abductive approach rooted in naturalistic inquiry [15]. Qualitative data gathered through focus groups and individual interviews with HCPs were initially analyzed using an inductive approach. Subsequently, these findings were applied deductively within the NASSS framework to elucidate the factors influencing the implementation of eHealth [8]. This study was conducted in parallel with a controlled experimental clinical trial [16], registered under ClinicalTrials.gov identifier NCT04150120. The trial design adhered to the Medical Research Council's framework for complex intervention trials [6,17].

Study Setting

The study was conducted from January to June 2021 in 4 pediatric departments located at a university hospital in southern Sweden. These departments provide care for children with severe illnesses at the local, regional, and national levels. The primary focus of the research revolved around an eHealth intervention developed as part of the eChildHealth research (eCH) program. The eCH program aimed to facilitate self-management for pediatric patients following their discharge from the hospital. It encompassed 4 specialties: pediatric surgery, neonatology, oncology, and cardiology [16]. The eCH program involved the development and evaluation of an app that was installed on tablets provided to families upon hospital discharge. Additionally, it included a web-based interface designed for HCPs to facilitate bilateral communication. The software offered a range of functionalities, such as daily reporting, video calls, and text messaging, among others.

Participants

The study included a total of 10 participants, who were HCPs divided into 2 subsamples: (1) staff members from various professions directly engaged in the further development [16] and evaluation [18] of the eCH intervention; and (2) management personnel within the relevant pediatric departments. In the autumn of 2020, invitation letters for participation in focus group interviews were distributed via email to all staff members who had previously been involved in the development and evaluation phases of the eCH intervention. Those who did not initially respond received a follow-up email between 4 and 8 weeks later. In total, 15 pediatric nurses and physicians were invited to participate; 10 of them responded affirmatively to the initial invitation, and 5 were available for participation. In a subsequent step, all managers at different hierarchical levels within the pediatric departments (n=25) were contacted by email and invited to join a focus group interview. A reminder email was sent to those who did not respond, resulting in the participation of 5 managers.

Data Collection

Because of the COVID-19 pandemic, data collection was planned and performed for digital interaction via Zoom (Zoom Video Communications), allowing for increased flexibility regarding scheduling and the number of participants. In total, the data collection involved 2 focus group interviews and 1 individual interview with 5 HCPs, as well as 5 individual interviews with managers. During the interviews, 2 out of 3 researchers responsible for data collection (CC, RH, and RML) were present, with each taking turns as the interviewer and notetaker. Structured interview guides were used, with separate versions for staff and managers. These guides included questions about participants' general experiences with eHealth and their specific involvement in an ongoing clinical trial [16]. The interviews with staff began with an oral introduction explaining the study's purpose, while the interviews with management included a brief presentation, supported by an MS PowerPoint slide show (Microsoft Corporation), introducing the concept of eHealth and the ongoing clinical trial [16]. The primary areas explored during the interviews were as follows: (1) What were the experiences and primary concerns of staff and management regarding the feasibility of implementing eHealth in routine care? (2) In which areas did their accounts of their involvement indicate a sense of knowledge and efficacy, and in which areas were they more uncertain or less prepared? Although the interviews initially focused on a specific clinical trial [16,18], they were conducted within a broader context of eHealth. The interviews had varying durations, ranging from 42 to 59 minutes.

Analysis

Audio-recorded and transcribed interviews were analyzed in 3 separate analytical steps: 2 data driven and 1 theory driven. First, an inductive analysis of data was performed. Three of the authors (CC, RML, and RH) read the text of each interview and divided it into meaningful units, which were condensed and coded by CC and RML, following the initial steps of qualitative content analysis [19]. Second, codes were applied deductively using the NASSS framework [8] as a theoretical lens of analysis by identifying and organizing codes into the 7 domains of the NASSS by the 3 authors. All codes were considered and the NASSS framework was used as a guide to identify relevant codes. Codes not fitting into any of the domains of the NASSS, comprising background information about the participants and reflections related to the term eHealth or the scope of the clinical trial, were deemed impertinent to the analysis and therefore excluded. Third, codes within each domain were grouped based on content, and then summarized and presented with representative quotes. Parallel to this step, the level of complexity within each domain was considered based on the codes grouped into each separate domain. Finally, the result was discussed and agreed upon by all authors. Data were managed using the software Open Code (Umeå University) [20].

Ethical Considerations

The study was approved by the Swedish Ethical Review Authority (approval number 2019-0341). All participants were given written information about the study in advance and additional oral information with the possibility of asking questions at the time of the interview. Voluntary participation was stressed, and informed consent was obtained. All participants were well acquainted with the research and its underlying principles. The authors possess extensive expertise in qualitative methods, implementation research, and nursing. Additionally, they were actively engaged in the research project

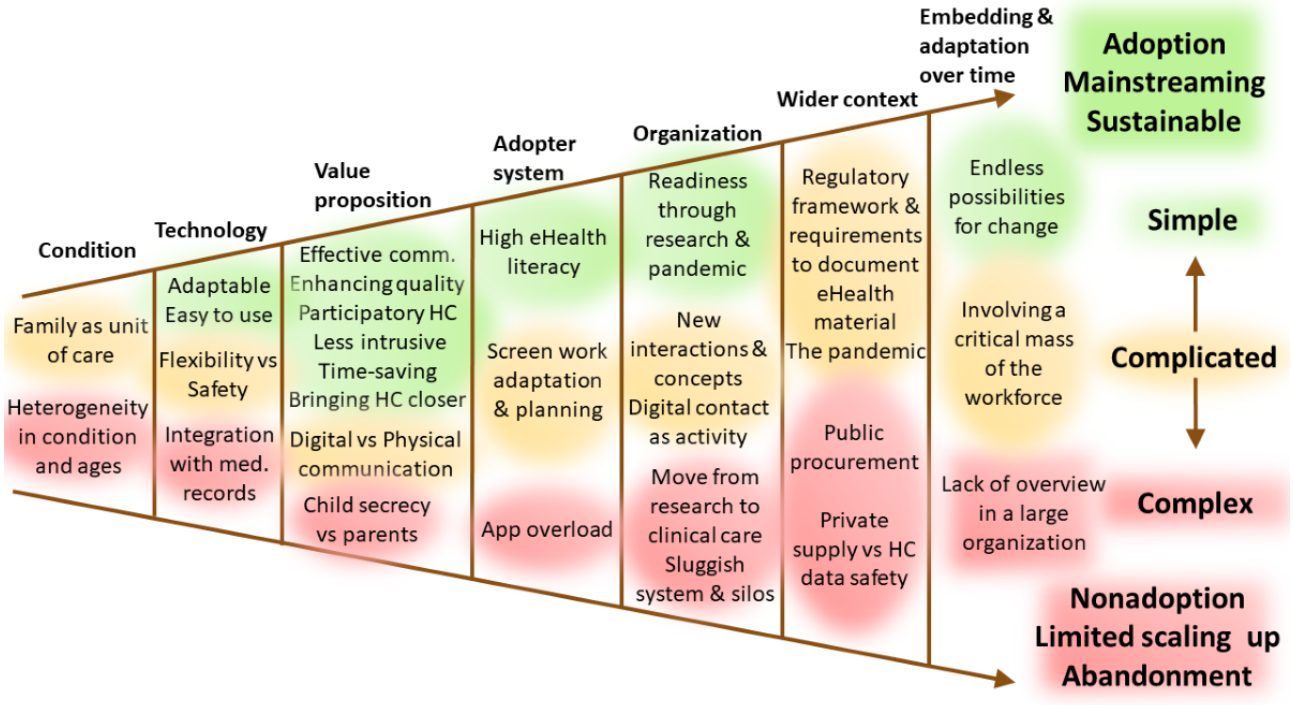
that designed and assessed eCH, although none of the authors were directly involved in the application of eCH.

Results

Overview

The presentation of HCPs' perspectives on eHealth, structured based on the NASSS framework, encompassed both eHealth in a broader sense and various specific eHealth interventions, including eCH. Feedback related to eCH predominantly emanated from staff representing various professions directly engaged in the research, while managers shared more generalized experiences. Figure 1 visually depicts the continuum of simplicity (green), through complexity (yellow), to high complexity (red) in terms of implementation within each domain.

Figure 1. Health care professionals' experiences and views on the eChildHealth intervention applied to NASSS conditions for implementation. comm: communication; HC: health care; med: medical; NASSS: Non-adoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies.



Domain 1: The Condition or Illness

In their discussions about eHealth in general and specifically the eCH, HCPs highlighted a significant diversity of circumstances, encompassing care for neonates through to adolescents, with an emphasis on the family as the central unit of care. The presence of long-term and recurrent hospital admissions, in conjunction with outpatient care, added layers of complexity to the implementation of eHealth across the hospital setting. The HCPs recognized that children grappling with chronic conditions, such as cystic fibrosis, diabetes, cardiac diseases, anorectal malformation, or cancer, faced considerable challenges in their daily lives due to their illnesses. Consequently, there was a perceived necessity for eHealth initiatives that could facilitate communication and provide support to these children and their families in a home-based context.

> *What is so exciting about this project [eCH]...is that it's specifically oriented towards children. We do not have any systems directed at children. We have to tweak many systems a little to make them fit children's needs. This is developed for children.* [Interview 3 staff]

Furthermore, the HCPs noted that the diversity in family structures, language proficiency, health literacy, and socioeconomic status added to the intricacy of implementing eHealth interventions. They emphasized the importance of recognizing and addressing these variations when designing and delivering pediatric care.

Domain 2: The Technology

The HCPs described eCH as accessible and ready to use with functions that could be activated or deactivated according to one's needs. By contrast, one HCP described that too many functions could lead to confusion and the possibility of missing data.

> *When the system offers a great number of functions and the patient only uses some of them, then you might start to wonder. It´s a problem with 'missing data' really. Does the patient not feel any pain or is this [the technology] something the patient doesn't need?* [Interview 3 staff]

The HCPs found that technical skills among staff were most effectively developed through hands-on experience and with support from reliable supplier companies. They highlighted the importance of eCH being developed and adjusted through collaborative research involving HCPs, researchers, and the

supplier company, rather than being presented as a finalized product. While the collaboration with supplier companies was deemed valuable and appreciated, it was also described as complex due to a lack of a common language and challenges in understanding each other's perspectives.

While apps that could be easily downloaded to patients' own private devices were seen as convenient, health care–provided encrypted devices such as those in the eCH approach were viewed as offering easily accessible communication without security concerns. The HCPs stressed the importance of user-friendly interventions to prevent the use of the family's private technology, such as FaceTime (Apple Inc./AT&T Inc.) on smartphones for video meetings or texting. Furthermore, a larger-sized tablet, such as the one used in eCH, was preferred for video calls over a smartphone. However, using a tablet for photography or having to carry an additional device was seen as less convenient for the patients.

The HCPs highlighted the necessity for ongoing technological development to seamlessly integrate eHealth tools such as eCH with existing electronic systems, particularly medical records. This integration would help reduce the burden of duplicated work or data transfer while ensuring compliance with data protection and patient data laws [21].

> *One feels that one might be less careful with security aspects if I am to start transferring photographs to my computer and then print them and then scan them to somewhere.* [Interview 2 staff]

The HCPs believed that many of the challenges related to intersystem information and data transfer would be resolved with the implementation of a new regional system (ie, the Scania [a region in Sweden] digital health care system or SDV). This system would offer unified patient records and facilitate the connection of mobile devices, medical equipment, and imaging to support home care.

Domain 3: The Value Proposition

The HCPs highlighted that eCH provided various communication channels that could be tailored to individual preferences. This approach was seen as empowering families and allowing them to feel more engaged and in control of their care. eCH facilitated 2-way, asynchronous communication, enabling families and staff to interact without the risk of inconveniencing each other during potentially busy periods, as telephone calls might do. eCH was viewed as an efficient and convenient means of communication.

The HCPs also emphasized the importance of eHealth communication, with eCH being one example, in terms of promoting equitable and inclusive health care. They pointed out that while telephone calls might exclude or bypass children, text or video chats allowed for more direct communication with the child and a better understanding of their situation. Chat messages were seen as a way to facilitate small talk and build rapport. Additionally, follow-up care for children with chronic or long-term illnesses could be conducted through quick text messages, reducing the need for frequent hospital visits. The HCPs believed that this approach enabled children to communicate with health care providers confidentially, on their own terms, and without parental involvement, potentially giving them more responsibility and a sense of ownership over their care.

> *We were a bit surprised/overwhelmed by the positive response we got from the children. It was like: This is my app. I want my own. You cannot write in my app. I'm the one who is writing there [not you].* [Interview 4 staff]

The HCPs also discussed how eHealth could empower children to become more involved in their prehospital care. For instance, they mentioned the possibility of children filling out electronic questionnaires at home or participating in virtual tours of health care facilities and procedures to help them feel more prepared for their hospital visits. This approach was seen as leading to better care outcomes, with children feeling more confident and less anxious. Over the long term, the HCPs believed that eHealth could be used to gradually provide children with chronic illnesses with more information and responsibility, better preparing them for the eventual transition to adult care.

The HCPs also highlighted how eHealth streamlined their work by offering a comprehensive view of patients and their care needs. They particularly valued electronic reports, which provided data on patients' weight, health status, and pain through eHealth. Additionally, the use of eHealth for communication was seen as a way to bridge the gap between research units and health care facilities across Sweden. HCPs at national health care centers could participate in digital 3-party meetings with families and other HCPs at local hospitals, fostering collaboration and knowledge-sharing.

> *When there was a patient who was going to meet the doctor at the local hospital we participated via the tablet. And I hope to be able to do that more in the future...They were going to support us with some of the child's care. So, we came along, and we could exchange experiences and we could support a bit. So that was nice. To be able to feel as one [unit] all over the country.* [Interview 2 staff]

The HCPs emphasized that eHealth should not be viewed as a panacea for health care challenges but rather as a supplementary tool that offers flexible and effective communication. They discussed the complexity of maintaining patient privacy and the confidentiality of children in particular. Providing digital care for young children and infants was seen as less complex, but when dealing with adolescents, the same interventions could both challenge and strengthen the care relationship. Safeguarding the child's privacy was a concern, especially during video conversations through a tablet or computer at home, where the child might not want to share everything with their parents, and they should have the right to withhold information. The HCPs also expressed concerns about the reduced ability to identify cases of unhealthy domestic environments in digital interactions, as the nuances of verbal and nonverbal communication were lost.

Domain 4: The Adopter System

The HCPs noted that children and parents are generally proficient in adopting and using digital technologies, sometimes

even more so than health care staff. However, they emphasized the need to align the expectations of families regarding eHealth with individual circumstances. For example, reporting data through eCH required patients and family members to take on tasks typically performed by HCPs. The HCPs stressed the importance of eHealth aligning with valid and reasonable expectations from the child and their family while minimizing the effort required from families. They emphasized that family needs should determine the extent of eHealth use, with careful consideration of when and what to offer digitally versus in person. Establishing a relationship digitally was seen as challenging, and the HCPs recommended that the nursing relationship be initially established in person and then continued digitally when beneficial.

The HCPs discussed the necessity of adapting their work practices to incorporate eHealth into their regular schedules. This adaptation involved more frequent contact with each patient and an increase in working hours dedicated to digital communication. HCPs also mentioned that they had established scheduled daily time slots for eHealth communication to minimize interruptions and gain better control over their workday. They emphasized the need to strike a balance between additional tasks related to both physical and digital care to ensure manageable workloads and maintain the quality of care. Managing conversations with multiple families concurrently required a strategy for shifting attention and a logistical system that did not lead to stress.

> *It implies a different way [to work] that we might not have found to hundred percent yet,.... Because one would typically often start the morning by checking the eCH. And at that time, it is not a problem. But then one wants to check at least two more times, to be able to respond somewhat regularly and keep up the dialogue. I think I have had as many as nine tablets operating in parallel. And then, this were like, some days, as if I would have nine extra physically present which was a bit...It takes some juggling.* [Interview 2 staff]

The HCPs explained that various eHealth devices served distinct purposes, either sequentially or concurrently. For instance, eCH was used for 2-way communication, while 1177 [22], a national health care hub in Sweden providing advice, information, and health services via phone and web, was primarily used for administrative functions such as appointment cancellations, transferring certificates for parental allowances, and prescribing medications. The HCPs emphasized the importance of being mindful of the potential for an overload of apps and the need to evaluate whether a new eHealth initiative was necessary or if existing digital communication systems could fulfill the same function.

> *It is a balancing act...and then the teenaged patient would have said something like I cannot take any more apps. I do not want another app. I´m tired of apps! That's also a view to take with you. Is there a limit? What apps should be prioritized and what should not be prioritized app-wise so to speak, and in digital form?* [Interview staff 4]

Domain 5: The Organization

In general, the HCPs expressed optimism regarding the organization's preparedness and ability to transition toward enhanced digital care. They noted that the COVID-19 pandemic had accelerated this readiness. They also had confidence in the future funding of eHealth initiatives. Furthermore, being part of a research program supported the initial stages of implementation by providing additional time or necessary human resources. The HCPs identified high user value and a clearly defined purpose as the primary facilitators for implementing eHealth within the organization, particularly when extra effort or patience was needed.

The HCPs highlighted various factors influencing the organization's readiness to implement eHealth. These factors included individual attitudes, preconceived notions, and the age of the HCPs involved in the implementation. They emphasized that the shift toward increased eHealth usage required time and effort, as sticking to familiar routines might seem more comfortable and less costly in the short term. They mentioned that they often settled for using only a few features, such as utilizing the chat function in eCH, even though video conversations were recognized as valuable and readily available. The HCPs believed that a positive collective experience with eHealth, such as their involvement in the research project (eCH), encouraged readiness and reduced resistance to future innovations.

The HCPs also pointed out the absence of a unified strategy and alignment within the hospital concerning eHealth. They noted that various parts of the organization were at different stages of readiness for change. A fragmented organizational structure with separate management for nursing and medical staff was identified as an obstacle to establishing partnerships, leading to a slow-moving system that operated in isolation. Therefore, they emphasized the need to enhance coordination and collaboration to fully leverage existing eHealth initiatives and prevent redundant efforts.

They highlighted the necessity for a revised care model to facilitate the implementation of eHealth. They discussed the need to broaden the definition of health to encompass meaningful communication between parties, considering it as a service provided from 1 party to another in various ways and forms. They emphasized the necessity of redefining and renegotiating communication norms to integrate eHealth initiatives as a seamless component of regular professional health care services. They mentioned that if eHealth was perceived as an ancillary activity, it might be at risk of being deprioritized in comparison to physical tasks or regarded as an additional responsibility for nurses without a clear purpose. The health care providers described an ongoing challenge in achieving a point where digital meetings could be formally recorded as regular visits and recognized as a documented activity. They emphasized the importance of management not expecting to save time by implementing eHealth but rather to enhance the quality of care. They emphasized the importance of organizational-level reflection regarding how changes, such as reducing physical visits, would impact the necessity for other

modifications in care delivery and how this might influence the need for facility adaptations.

> *There can be six people in that room at the same time as one is active with communicating on the tablet.* [Interview 3 staff]

They were concerned that if eHealth were implemented without careful planning, it could result in increased workloads and heightened expectations from families for greater access to care, for which the organization was unprepared.

Research projects with stringent inclusion criteria focused on a minority of patients, such as children with specific diagnoses or ages, and those that only included certain aspects of care through eHealth, were seen as more challenging to integrate into routine care. The HCPs shared experiences of how implementation became easier when someone was willing to take the lead in the everyday clinical implementation, which others could then follow. Having enthusiastic individuals in place was described as a key factor for successful implementation and for providing technical support. By contrast, unclear responsibility or purpose of care could make the implementation of research in clinical care more complex. According to HCPs, a perceived lack of support functions for IT systems could make implementation difficult and reduce the capacity for change. Thus, the need for time to discuss challenges and errors was emphasized as important for facilitating implementation.

Domain 6: The Wider Context

The HCPs mentioned the strict regulatory requirements for health care documentation, emphasizing the need for careful consideration of how to handle information produced through the usage of new eHealth interventions. A significant part of the material produced through eCH, such as text chat messages, was unsuitable or not intended for patient records. However, they emphasized the importance of actively considering the regulatory framework when deciding how to handle produced material, such as text, photographs, and reported health care data. When the pandemic started in Sweden, eCH was described as extremely useful in departments where the project was already well integrated into care (pediatric surgery and neonatology). However, other departments were at earlier stages in the process, with ongoing development or just beginning patient inclusion (oncology and cardiology). For these departments, the pandemic became a hurdle, limiting time for project meetings and leading to changed prioritizations within the organizations, ultimately putting the research on hold.

Public procurement of eHealth services originating from a research project was described as a time-consuming and challenging process, involving significant effort in terms of preparation and communication. The HCPs expressed frustration with an unclear and slow procurement process, even though there was a high sense of urgency to ensure the continued delivery of eHealth services such as eCH, which had become vital for the organization. They were concerned about the risk of service interruption during the transition from research to clinical practice.

> *There are rules regarding public procurement. And then there is technology, and you have to turn to the IT-department. And then you get all sweaty.* [Interview 1 management]

The ambition of Sweden to become a leader in eHealth was considered in light of the evolving nature of digital communication as the norm, especially among the younger population. However, this had to be balanced with the strict requirements for safety and confidentiality in health care. The HCPs highlighted the challenges related to data safety, particularly in collaborations with suppliers, where there were uncertainties about what was allowed and feasible. For instance, certain age restrictions on digital IDs for children were seen as a complicating factor in the use of eHealth.

Domain 7: Embedding and Adaptation Over Time

The HCPs explained that eHealth was in a constant state of development, offering numerous possibilities for changing and enhancing health care. They observed that different systems evolved into more complex and versatile tools, each having its unique challenges, errors, and strengths. Some eHealth systems seemed to seamlessly integrate into daily routines, while others disappeared discreetly. In some cases, the HCPs mentioned that they adopted these systems without a deep understanding of why or how it was done, although they emphasized the importance of management support and dedicated time as critical factors in this process.

> *It takes managers who believe in it and are willing to devote time and provide opportunity. To have the energy to think long-term. That's very important because there are always running-in problems and inexperience. And it is easy to give up in the beginning no matter what it is. But if there is an understanding to set aside time to learn. Then it will become an established way of working.* [Interview 5 management]

They highlighted the importance of involving a critical mass of staff in the implementation of an eHealth intervention to reduce the risk of unforeseen errors. Additionally, they stressed that considerations regarding eHealth should be integrated into the early planning stages of future care to allow for necessary reflections, which could be crucial for successful adaptation.

The HCPs identified a lack of organizational oversight regarding available eHealth services and limited efforts to share experiences and build upon them as significant barriers to long-term adoption.

Discussion

Principal Findings

We used the NASSS framework [8] to analyze conditions for the implementation of an eHealth intervention, eCH, in pediatric care. The starting point of our study was a local, bottom-up development project initiated by HCPs in collaboration with researchers. Our findings indicated a mix of simple, complicated, and complex conditions for the implementation of eHealth, which was generally perceived to have a high value within the context of pediatric hospital care. Barriers to implementation

tended to be on a rather detailed level, regarding what is safe and allowed, given the heavy regulatory requirements in health care. In addition, results indicated the need to establish a shared vision for eHealth-related work to become part of regular health care. This points toward the need for bottom-up eHealth initiatives to connect to a wider group of stakeholders within their institutional setting. These results also point toward a need for organizational eHealth strategies compatible with legal, technological, and security concerns. First, we discuss circumstances that contribute to relatively simple conditions favorable to adoption and scaling up according to the NASSS framework. Second, circumstances contributing to increased complexity are discussed.

Facilitation of Adoption and Scaling Up

Aspects such as ease of use, adaptability, small scalability, and specificity with a high perceived value regarding both the services and the patients contributed to the classification of eCH as simple with significant potential for adoption and scaling up. eHealth interventions such as eCH have a great potential to complement other forms of communication through increased flexibility, access to care, and a perceived sense of security for families caring for children at home. These notions are also recognized from previous research based on interviews with parents evaluating their use of eCH [16,18]. Hence, the perceived value of eHealth appears to be relatively coherent for patients and HCPs.

Front-line staff encountered the need for changes in routines and work organization early on, requiring support from management to address these challenges. A key factor in dealing with these processes is the active contribution of enthusiasts and project leaders who can identify obstacles and bring stakeholders together to facilitate the process. The extent to which organizational units have had the opportunity to participate in the development of digital tools dedicated to well-defined groups of patients and tailored to the demands of both patients and HCPs, such as eCH [16], appears crucial for continuation and adoption.

The pandemic appeared to have sped up the innovation and change in the services at hospital departments where eHealth was already up and running. Nevertheless, the implementation of eHealth during a pandemic presented a substantial challenge for departments that were not fully prepared before the outbreak, resulting in the need to temporarily halt project-related work. Previous research on the adoption of eHealth services across Europe during the coronavirus pandemic highlights various factors that could diminish the public value of eHealth [23]. Therefore, proceeding cautiously in the face of rapidly changing circumstances may be crucial to prevent compromising quality and the impact on public health.

Potential Barriers to Adoption and Scaling Up

HCPs expressed a preference for digital interventions that streamlined their workflow and could be seamlessly integrated with other systems such as medical records. However, they noted that this integration was a complex challenge that required careful navigation. The complex and sometimes conflicting demands of complying with health care regulations concerning documentation, patient safety, and information security, combined with aging systems not aligned with ongoing development projects, can undermine the realization of eHealth initiatives. While many of the strengths and positive experiences of new digital tools and eHealth were related to participation in development and implementation, there was less confidence in the hospital and region's capability to provide a context for learning and adaptation over time. Indeed, there are very few examples of familiarity with strategies, guidelines, or interfaces between ongoing bottom-up activities (such as eCH) and the general architecture of eHealth at the hospital and in the region [24]. This observation is in line with previous research that showed that HCPs can be motivated to pursue development despite a lack of alignment in this regard [13].

The handling of patient-generated health care data collected in everyday environments from patients would require new standards as well as technical and organizational support to ensure that the data are well-managed and tailored toward clinical objectives to ensure success [25]. The relatively loose coupling and provisional supplier model in the research project provided flexibility and was advantageous for the project, but it introduced uncertainties in the long run. Challenges related to procurement and delays in large IT projects within the regional health care organization appeared to create an atmosphere of uncertainty and, in some cases, cynicism among health care providers. Effective public procurement of eHealth requires specialized skills regarding, for example, interoperability and life-cycle costing [26].

The HCPs described the pediatric health care population as heterogenous in age and maturity with a capacity for autonomy that changes over time, implying a need for the continuous adaptation of routines. Sociotechnical aspects related to potential changes in routines, work division, and workload were often postponed to a later phase of implementation. Over time, this somewhat fragmented approach may elevate the complexity of implementation and place excessive demands on both patients and health care providers. Besides, eCH may be based on strict inclusion criteria and may exclude patients in terms of sociocultural factors. To ensure equity and participation, the implementation of eHealth should address cultural hurdles [27]; for example, in the case of eCH, this can be achieved by incorporating adaptations such as interpreter services.

It is vital that the integration of eHealth includes considerations related to secure communication and privacy in traffic and data transmission [28]. It can be argued that this difference constitutes a sort of "app-gap" leading to increased risk for improvisation, cutting corners through using private technology rather than complying with the digital tools provided by the hospital. Such app-gaps may also contribute to frustration, negative attitudes, and diminishing legitimacy for IT governance and information security.

Our findings support previous research in that the organizational capability for adoption and scaling up is dependent on sophisticated collaboration and alignment between professions, clinics, and divisions within the hospital, which contributes to complexity and vulnerability [8,29]. This needs to proceed from a shared view and definition of health care that incorporates

eHealth-related work as health care provision. Organizations that depend on resources provided by research and development projects to engage in new eHealth technologies risk adding extra workload to staff. In this perspective, it is important to be able to identify the true value of eHealth beyond economic terms [30].

Strengths and Limitations

This study incorporates both staff and managers' experiences and views of eHealth. Although the sample size was small, it comprised staff with deep familiarity and insight into both eCH and their respective specialties as well as different management levels in pediatric care. Experiences shared related to both the specific project and eHealth in general. This was deemed important and a strength of the project because development, evaluation, and implementation take place in an organizational context in which different eHealth interventions and innovations are ongoing, coexisting, and coevolving over time. The study was performed during the COVID-19 pandemic, which increased the study period and likely reduced the number of participants. Furthermore, the study was conducted in 1 of 21 regions in a small, high-income country with a nationally regulated and regionally provided health care system. While the country, in general, has a high level of digitalization, health care continues to struggle with the standardization and integration of eHealth. These perspectives may be considered in relation to the transferability of the results. The results fit well into the domains of the NASSS framework for implementation and contribute to a holistic and contextual perspective, which may support the translation of eHealth research into policy and practice [31].

Conclusions

The study enhances our comprehension of how eHealth initiatives can harmonize with the organizational environment within their specific context, thereby enhancing the potential for adoption and scalability. It further adds to the body of research indicating that the NASSS framework has the potential to be of great use in the planning and coordination of eHealth development in health care settings [32,33]. While studies on implementation are mainly concerned with difficulties in reaching out, changing, and institutionalizing new behaviors, this study indicates the need for a much broader approach. Thus, there is a need to establish networks and communication channels between staff, managers, IT professionals, legal departments, researchers, and supplier companies [25]. This study should be complemented with research into how specific eHealth interventions are perceived by the market, regional information and communications department, procurement, and information security professionals at the hospital and in the region. The possible business case or value for suppliers or investors in eHealth was not addressed by participants in this study, although it had a significant impact on implementation according to NASSS [8]. Deepened knowledge about HCPs' understanding of, and collaboration with, a wider eHealth innovation system could thus further support sustainable implementation.

Conflicts of Interest

None declared.

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Abbreviations

eCH: eChildHealth
HCP: health care professional
NASSS: Non-adoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies

Edited by S Badawy; submitted 28.03.23; peer-reviewed by M Loades, MA Islam; comments to author 02.06.23; revised version received 16.06.23; accepted 17.06.23; published 18.10.23.

Please cite as:
Castor C, Lindkvist RM, Hallström IK, Holmberg R
Health Care Professionals' Experiences and Views of eHealth in Pediatric Care: Qualitative Interview Study Applying a Theoretical Framework for Implementation
JMIR Pediatr Parent 2023;6:e47663
URL: https://pediatrics.jmir.org/2023/1/e47663
doi:10.2196/47663
PMID:37851500

Original Paper

Effects of a Smartphone App on Fruit and Vegetable Consumption Among Saudi Adolescents: Randomized Controlled Trial

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Abstract

Background: Dietary patterns and nutritional status during adolescence have a direct effect on future health outcomes.

Objective: This study aimed to promote fruit and vegetable intake among adolescents using a smartphone app called MyPlate.

Methods: This randomized intervention study was conducted in an urban area of Jeddah, Saudi Arabia. We included 104 adolescents aged 13 to 18 years, who were randomized into intervention (n=55) or control (n=49) arms. We examined the effects of MyPlate on fruit and vegetable intake over 6 weeks in the intervention group. Pre- and postintervention questionnaires were used in the intervention and control groups.

Results: The control group showed a significant increase in fruit consumption scores between baseline (1.15, SD 0.68) and postintervention (1.64, SD 0.98; *P*=.01), but no significant difference in vegetable consumption scores was observed before (1.44, SD 0.97) and after intervention (1.55, SD 0.90; *P*=.54). However, there was no significant difference between scores at baseline and after 6 weeks of using the smartphone app for fruit (1.48, SD 0.99 and 1.70, SD 1.11, respectively; *P*=.31) or vegetables (1.50, SD 0.97 and 1.43, SD 1.03, respectively; *P*=.30) in the intervention group. Our findings showed no significant impact of using a smartphone app on fruit and vegetable consumption.

Conclusions: These findings suggest that a smartphone app did not significantly improve fruit and vegetable intake among adolescents.

Trial Registration: ClinicalTrials.gov NCT05692765; https://clinicaltrials.gov/ct2/show/NCT05692765

(JMIR Pediatr Parent 2023;6:e43160) doi:10.2196/43160

KEYWORDS

smartphone app; fruit and vegetable consumption; Saudi Arabia; adolescents; nutrition; health outcome; digital health intervention; digital health app; pediatrics; youth

Introduction

Adolescence is a critical period in the growth and development of an individual. Thus, dietary habits during this timeframe are important in shaping future health outcomes [1]. A large proportion of adolescents worldwide do not receive optimal nutrition [2]. Typically, adolescent diets are characterized by low fruit and vegetable (FV) intake and a high intake of energy-dense, nutrient-poor foods, including sugar-sweetened drinks and fast foods [3]. As a result, anemia and micronutrient deficiencies are common among adolescents, which have a significant effect on their quality of life [4]. The incidence of overweight and obesity among adolescents continues to increase worldwide and is associated with an increased risk for

noncommunicable diseases, including hypertension, atherosclerosis, nonalcoholic fatty liver disease, and metabolic syndrome [5].

A diet rich in FVs is associated with numerous health benefits. FVs are a good source of vitamins A and C, minerals, electrolytes, phytochemicals, antioxidants, and dietary fiber [6]. The World Health Organization recommends FV intake amounting to ≥400 grams per day to maintain optimal health; reduce the risk of noncommunicable diseases, including heart disease, cancer, type II diabetes mellitus, and obesity; and prevent micronutrient deficiencies [6]. However, FV consumption among adolescents does not meet these recommendations. For instance, the UK National Diet and Nutrition Survey found that consumption of fruits during adolescence declined compared with early childhood, even though vegetable consumption showed no change [7]. In Saudi Arabia, most adolescents report that they consume low amounts of FVs daily [8,9]. Education and knowledge about food and nutrition are among the factors that influence food choices [6]. School-based nutrition education intervention targeting increased consumption of FVs has been shown to be an effective solution for low intake of FVs among children and adolescents. A 2-year nutrition intervention study showed a significant increase in FV consumption among children and their parents [10]. Using technology is one strategy to increase consumption of FVs among adolescents [11].

Recently, smartphone apps have been used to promote health and wellness among individuals in various communities. As a result, several nutritional interventions have been attempted to determine the usefulness of these apps in promoting healthy dietary habits. One of the advantages of these apps is that they can serve as cost-effective and flexible platforms for implementing behavioral changes in nutrition [12]. Additionally, mobile phone use is common across all education and income levels, and smartphone apps can serve as an appropriate platform to deliver healthy diet interventions, such as FV-related information, to adolescents and young adults [12]. Moreover, FV intake in adults and adolescents has been promoted by smartphone apps and web-based interventions [13,14]. The MyPlate software was developed by the US Department of Agriculture as a simple and powerful educational tool to aid individuals of different age groups in the appropriate distribution of food groups and creation of balanced meals according to the American Dietary Guidelines [15,16]. Brown et al [17] reported a significant increase in fruit consumption among an intervention group in comparison with a control group; the study used frequent text messages to provide nutrition-related knowledge and encouraged healthy behaviors among study participants. Likewise, Schroeter et al [18] demonstrated a significant increase in the intake of whole grains and FVs in an intervention group compared with a control group; the intervention group participated in MyPlate nutrition education meetings for 4 weeks, which positively affected their health behaviors.

In this study, we aimed to examine the effects of the MyPlate smartphone app on FV intake over 6 weeks in adolescents from Jeddah, Saudi Arabia.

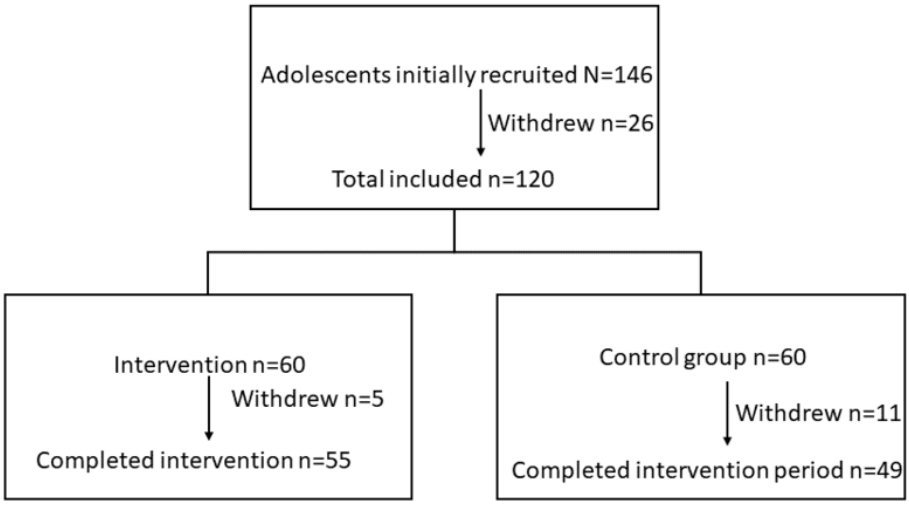
Methods

Participants and Recruitment

This randomized intervention study was conducted between February and March 2021 among adolescents from Jeddah, Saudi Arabia. Since schools were closed because of the COVID-19 pandemic, adolescents were recruited through invitations sent via email and WhatsApp to their parents using snowballing recruitment. The invitation to the study was first sent to members and bachelor of science students at the Food and Nutrition Department of King Abdulaziz University to help the research team with recruitment. Then, the research team contacted the parents and adolescents, who voluntarily agreed to participate in the study. The study procedures were explained to the parents or guardians of all prospective participants. There were no imposed circulation restrictions or curfews in Jeddah during the study period. Participants were included if they were in good health (based on the self-reported absence of diseases, such as diabetes mellitus, that may influence food intake), aged 13 to 18 years, attending school, and had access to a smartphone, either their own or their parents'. The exclusion criteria were poor health or an age not within the age range of this study. In total, 146 adolescents were initially recruited, of whom 26 withdrew from the study because they did not complete the baseline questionnaire or voluntarily decided to withdraw. The remaining 120 adolescents were randomly divided into intervention and control groups. Microsoft Excel (version 22, Microsoft Corp) with the *RAND* function was used to randomize the sample. After generating a random number, the participants were divided into control and intervention groups. As 16 adolescents decided not to complete the study or did not fill in the final questionnaire, 104 adolescents (24 adolescent boys and 80 adolescent girls) completed the intervention phase of the study (Figure 1).

The sample size was determined based on the ability to detect an expected mean difference of 0.7 servings, a value that was chosen based on a previous parallel intervention study [18,19], with 80% power and a 5% significance level. The calculated required sample size was 33 adolescents in each group [20]. Thus, anticipating a nearly 50% drop-out rate, we recruited 60 participants for each group.

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) diagram for the trial.



Ethics Approval

The study procedures were approved by the Unit of Biomedical Ethics Research Committee at King Abdulaziz University (101-21). All adolescents participated voluntarily and provided verbal consent for participation in the study; their parents or guardians provided written informed consent. This trial was registered on ClinicalTrials.gov (NCT05692765).

Study Design

This was a randomized intervention study conducted with 104 adolescents: 49 in the control group and 55 in the intervention group. Adolescents in the intervention group were divided into 11 smaller groups, each containing 5 participants, to explain the app. One of the researchers conducted video conference calls with each of these small intervention groups. The researcher provided a brief presentation about the health benefits and appropriate serving sizes of FVs and explained how to use the smartphone app. An instructional brochure was provided in Arabic to all adolescents in the intervention group. The research team was available to assist participants at any time during the study period. The participants were required to choose 3 of 7 goals for fruits and 3 of 7 goals for vegetables. The fruit goals were as follows: (1) have fruit with dinner; (2) add fruit to your salad; (3) snack on fruit; (4) have fruit for a sweet treat; (5) have fruit with lunch; (6) add frozen, canned, or dried fruit to your meal; and (7) start your day with fruit. The vegetable goals were as follows: (1) have vegetables with dinner; (2) have a dark green vegetable; (3) start your day with vegetables; (4) have a red or orange vegetable; (5) have vegetables with lunch; (6) snack on vegetables; and (7) make a salad or side dish using beans, peas, or lentils. After choosing 6 goals (3 for fruit and 3 for vegetables), the participants were required to mark the goal that they chose daily and were requested to adhere to their chosen goals until the end of the study. They were encouraged to turn on notifications for the app to receive reminder messages. The research team also sent weekly WhatsApp text message reminders (in Arabic) to the adolescents. The intervention period was 6 weeks. Adolescents in the control group were not exposed to the smartphone app and did not receive any advice to promote their FV consumption, which may have affected their FV consumption. Instead, they were only asked to complete the pre- and postintervention questionnaires.

This study used the free nutritional MyPlate smartphone app, which is readily available on both iOS and Android platforms, to promote FV intake among adolescents. The app uses a multicomponent communications plan that was developed by the US Department of Agriculture Food and Nutrition Service in 2011. The app aids in translating the American Dietary Guidelines to the public and can be used as a nutritional education resource for children and adults. The app icon is an easy, effective, visual platform that helps promote healthy food choices that include all food groups and create a balanced plate at mealtimes. The app allows one to set daily healthy eating goals for each food group and track individual progress [15,16]. Additionally, the Saudi dietary guidelines (including Healthy Saudi Plate) have been developed based on evidence from several dietary guidelines, including the American dietary guidelines [21]. Since no Arabic-language apps are available in smartphone stores with similar features, we used the MyPlate app in the current study.

Data Collection

All measures were collected via an online questionnaire on Google Forms. The questionnaire consisted of two parts. The first part included sociodemographic data, including information regarding age, sex, school type (private or public), weight and height of the adolescent and their parents, the parents' education level (high school or lower, bachelor's degree, or postgraduate degree), the parents' employment status (employed or unemployed), number of children in the family, and family income. This part of the questionnaire was completed by the participant with the assistance of one of their parents. The research team provided instructions to participants on the appropriate way to measure height and weight using a weight scale and measuring tape. BMI was calculated as the weight in kilograms divided by the height in meters squared (kg/m^2). BMI was evaluated using the Saudi growth chart (BMI for age). A BMI between the 15th and 85th percentiles was considered normal; BMI between the 85th and 95th percentiles was considered overweight, and BMI above the 95th percentile indicated obesity [22].

FV Consumption Questionnaires

A validated food-frequency questionnaire (FFQ) was used to compare FV consumption in adolescents at baseline and after the intervention period in both groups. The FFQ was one that has previously been used with some adaptations to make it suitable for Saudi adolescents [13,18]. The response for each FV item was recorded as 1 of 7 frequency options (never, 1-3 times per month, 1 or 2 times per week, 3-4 times per week, 5-6 times per week, once per day, or 2 or more times per day). In total, 22 FFQ items were directly related to vegetable intake, whereas 18 FFQ items were directly related to fruit intake (Multimedia Appendix 1 shows the FVs listed in the FFQ). The response for each FV item had 7 frequency options; thus, it was scored based on a 7-level scale. The highest score was 7 for 2 or more per day, and the lowest score was zero (ie, never). The FV scores were calculated separately, and the sum of the scores for all fruit items for each participant was divided by the total number of fruit items in the FFQ (18); a similar process was used for vegetable scores.

Data Analysis

Descriptive and inferential statistics were calculated using SPSS for Windows (version 27.0; IBM Corp). Frequency analysis was conducted to evaluate the baseline sociodemographic characteristics of the sample. The differences in age and BMI for adolescents and parents at baseline between the two study groups were compared using a 2-tailed *t* test. Changes in FV scores between baseline and after the intervention period in the control and intervention groups were analyzed using univariate regression. The smartphone app's effectiveness was examined by comparing FV scores between the intervention and control groups at 6 weeks through univariate regression. Univariate linear models were adjusted for age, sex, parental education, family income, adolescent and parental BMI, and baseline values in the analysis to test the effects of the smartphone app. The data are reported as means (SD). A *P* value <.05 was considered statistically significant.

Results

Demographic Characteristics of the Study Sample

In total, 104 adolescents completed the study, of whom 23.1% were boys (24/104). The mean age of the adolescents was 15.1 (SD 1.6) years, and 75% (78/104) attended public school. The mean body weight was 56.9 (SD 15.8) kg. Most of the adolescents were in the normal body weight range, whereas 10.6% (13/104) were overweight, and 4.8% (6/104) were obese (Table 1). The majority of parents held a bachelor's degree as their highest level of education. Most fathers were employed, whereas most mothers were unemployed. Most families had a middle to high income level, defined as a household income of 10,000 to 20,000 SR (US $2666 to $5333). The proportion of boys was lower in the intervention group. No other significant baseline differences were evident for either group. Fathers in the control group had a significantly higher BMI (28.30, SD 9.09 kg/m^2) compared with fathers in the intervention group (26.54, SD 3.76 kg/m^2; *P*=.02). Among mothers, the highest proportion were unemployed and held a bachelor's degree, although no significant differences in maternal demographic factors or BMI were observed between the control and intervention groups.

The main fruit goals chosen by the adolescents were starting the day with fruit or having fruit as a snack (29/55, 52%), having canned fruit or fruit as a sweet (25/55, 45%), and having fruit salad or fruit at dinner (16/55, 29%), whereas the least preferred goal was having fruit at lunch (8/55, 14%). Among the vegetable goals, the most frequently chosen goals were having vegetables at lunch (56%, 31/55), having bean salad (52%, 29/55), having dark green vegetables (47%, 26/55), having vegetables as a snack (36%, 20/55), starting the day with vegetables (34%,19/55), and having red or orange vegetables (32%,18/55), whereas the least chosen goal was having vegetables at dinner (30%,17/55).

Table 1. Baseline characteristics of the study participants in the control and intervention groups. Differences between the control and intervention groups were analyzed using the chi-square test.

	Control group (n=49)	Intervention group (n=55)	*P* value
Age (years), mean (SD)	15.57 (2)	14.74 (1)	.11
Sex, n (%)			<.001
Adolescent boys	20 (41)	4 (7)	
Adolescent girls	29 (59)	51 (93)	
Type of school, n (%)			.77
Government	36 (73)	42 (76)	
Private	13 (27)	13 (24)	
BMI (kg/m^2), n (%)			.84
Normal	40 (82)	45 (83)	
Overweight	7 (14)	6 (11)	
Obese	2 (4)	4 (6)	
Paternal education, n (%)			.31
High school or lower	18 (36)	17 (32)	
Bachelor	27 (55)	28 (51)	
Postgraduate	4 (8)	10 (19)	
Paternal occupation, n (%)			.08
Unemployed	1 (2)	3 (6)	
Employed	42 (86)	37 (67)	
Retired	6 (12)	15 (28)	
Paternal BMI (kg/m^2), mean (SD)	28.30 (9)	26.54 (4)	.02
Maternal occupation, n (%)			.46
Unemployed	28 (57)	35 (65)	
Employed	18 (37)	19 (34)	
Retired	2 (4)	1 (2)	
Student	1 (2)	0	
Maternal education, n (%)			.37
High school or lower	16 (33)	18 (33)	
Bachelor	22 (45)	31 (56)	
Postgraduate	11 (22)	6 (11)	
Maternal BMI (kg/m^2), mean (SD)	26.55 (6)	26.41 (4)	.90
Number of siblings, mean (SD)	4.93 (2)	4.61 (2)	.50
Family monthly income (SR[a]), n (%)			.20
Less than 5000	4 (8)	5 (9)	
5000 to <10,000	4 (8)	13 (24)	
10,000 to <20,000	21 (43)	22 (41)	
>20,000	20 (41)	15 (28)	

[a]A conversion rate of 3.75 SR=US $1 applied.

Effects of Using the Smartphone App on FV Scores

The baseline fruit consumption score in the intervention group (1.48, SD 0.99) was slightly higher than that in the control group (1.15, SD 0.68; Table 2). In the intervention group, no significant differences were observed between the scores obtained before and after the intervention for the consumption of either fruit (1.48, SD 0.99 and 1.70, SD 1.11, respectively;

P=.31) or vegetables (1.50, SD 0.97 and 1.43, SD 1.03, respectively; *P*=.30). The control group showed a significant increase in fruit consumption scores between before (1.15, SD 0.68) and after the intervention (1.64, SD 0.98; *P*=.01), although it did not show a significant difference in vegetable consumption score (*P*=.54). However, no significant difference was observed between the intervention and control groups in fruit or vegetable consumption after the intervention.

The intake of individual fruit items increased in both groups (Multimedia Appendix 2). In the control group, there was a significant increase in the consumption of fruit juice (*P*<.001), fruit salad (*P*=.003), kiwi (*P*=.003), and pineapple (*P*=.01), whereas in the intervention group, there was a significant increase in the consumption of fruit juice (*P*=.02), grapefruit (*P*=.03), and guava (*P*=.02). No significant changes were observed in vegetable intake in the control group. However, there was a significant decrease in the consumption of potatoes (*P*=.003), lettuce (*P*=.007), and Jew's mallow (*P*=.01) and an increase in the consumption of sweet potatoes (*P*=.02) in the intervention group. Moreover, a significant difference was found between the intervention and control groups after the intervention period (6 weeks) in some items, including grapefruit (*P*=.007), potatoes (*P*=.02), sweet potatoes (*P*=.04), carrots (*P*=.007), and cucumber (*P*=.007). Grapefruit and sweet potato intakes were higher in the intervention group after 6 weeks, whereas potato, carrot, and cucumber intakes were higher in the control group after 6 weeks.

Table 2. Fruit and vegetable scores in the control (n=49) and intervention (n=55) groups at baseline and after 6 weeks. The adjusted model was assessed using regression analysis. The estimates were adjusted for age, sex, the adolescents' BMI, the parents' education and BMI, and family income.

	Preintervention	Postintervention	Adjusted *P* value within group
Fruit score, mean (SD)			
Control	1.15 (0.68)	1.64 (0.98)	.01
Intervention	1.48 (0.99)	1.70 (1.11)	.31
Adjusted *P* value between groups	.11	.52[a]	N/A[b]
Vegetable score, mean (SD)			
Control	1.44 (0.97)	1.55 (0.90)	.54
Intervention	1.50 (0.97)	1.43 (1.03)	.30
Adjusted *P* value between groups	.35	.35[a]	N/A

[a]These estimates were also adjusted for preintervention values; these *P* values reflect the different effects of using the smartphone app between the control and intervention groups.

[b]N/A: not applicable.

Discussion

Principal Findings

The use of mobile phone–based approaches to encourage healthier lifestyles is becoming more common. To our knowledge, this is the first study conducted in Saudi Arabia to investigate the effects of using a smartphone app on FV intake among adolescents. Although the fruit consumption score was higher in the intervention group at baseline, this group showed no significant increase in fruit intake after 6 weeks of using the app, whereas the control group showed significantly higher fruit consumption. Both control and intervention groups showed no significant changes in vegetable consumption scores before or after the intervention. The control and intervention groups showed a significant increase in consumption of some fruit items, such as fruit juice, compared with the preintervention period. The intake of some vegetable items (ie, potatoes, lettuce, and Jew's mallow) decreased in the intervention group after 6 weeks of using the app, whereas no significant changes in vegetable consumption were observed in the control group. Moreover, we found a significant difference in the consumption of some FV items between the control and intervention groups after 6 weeks of the intervention.

Consistent with our findings, several previous studies have demonstrated low FV consumption among school-aged children from different regions in Saudi Arabia. According to a previous cross-sectional study, only 12.8% and 22.8% of adolescents (n=2908, age 14-19 years) reported daily consumption of fruits and vegetables, respectively [23]. Similarly, two studies, one conducted among 1335 boys and the other among 512 girls, confirmed low FV intake (less than one portion per day) among teens in Saudi Arabia [9,24]. Additionally, data from 725 Saudi children (age 7-12 years) showed that 69% and 71.4%, respectively, did not consume FV daily [25]. These results highlight the importance of identifying approaches to promote FV consumption among young children and adolescents in Saudi Arabia. Furthermore, the prevalence of overweight and obesity reported in this study was relatively higher than that among Dutch adolescent boys (12.8% and 1.8%, respectively) and girls (14.8% and 2.2%, respectively) [26]. However, our study's prevalence of overweight and obesity was similar to that reported among French adolescents (17.5% and 5.2%, respectively) [27]. Conversely, countries such as Greece have shown higher rates of overweight and obesity among children and adolescents, exceeding 35% [28].

In contrast to our findings, previous studies have confirmed the positive effects of technological interventions, including web-based platforms and smartphone apps, in promoting FV consumption. In one study, an innovative web-based platform (Team Nutriathlon) was used to promote FV intake among

adolescents aged 13 to 14 years from the Quebec City region in Canada for 6 weeks. Team Nutriathlon is a 6-week school-based nutrition intervention. The website provided a 6-week calendar on which adolescents were asked to record their consumption of FVs from Monday to Friday. Team Nutriathlon increased FV consumption in the intervention group (n=193) by 3.4 servings, in comparison to an increase of 0.39 servings (n=89) in the control group [13]. Another study evaluated 154 university students (age 18-26 years) to assess the efficacy of web-based nutritional interventions and web interventions with daily text-messaging reminders to increase FV intake. The use of web interventions with daily text-messaging reminders for 4 weeks significantly increased vegetable intake, but not fruit intake [29]. A meta-analysis of the pooled results of 2 computer-based game interventions also showed increased FV consumption [30]. Even without the use of technology, interventions focused on promoting FV intake among children and adolescents showed a significant increase [31,32].

Indeed, it is crucial to note the role of parents in shaping eating behaviors and food preferences from an early stage. Parents are responsible for the availability of healthy food and encouraging children and adolescents to consume and accept different flavors, especially fruits and vegetables, as these foods are not very tasty [33]. Previous research indicates that children who are encouraged by their parents to consume and try fruits and vegetables in their early years have higher acceptance of these food items in their adolescence and adulthood [34]. Moreover, parental involvement in nutrition intervention targeting FV consumption among adolescents significantly improved adolescents' intake of FV [35]. Furthermore, parents may provide positive role modeling to their children in the intake of healthy food. Previous studies showed that college students who dine away from their families and home are highly obese, as they consume foods high in fat and calories and low amounts of fruits and vegetables compared with their counterparts who eat with their families [36]. Thus, our study's low consumption of FV among adolescents might be directly or indirectly related to their parents.

Several prior studies were conducted in schools with the involvement of teachers and peers, which had a positive effect on the adoption of healthy habits and increased FV consumption [37,38]. However, in the current study, the absence of support from teachers and peers due to the closure of schools as a result of the COVD-19 pandemic could be one of the reasons for the lack of a significant increase in FV consumption. The observed increase in fruit consumption in the control group in the current study could be explained by the Hawthorne effect [39], since the adolescents in this group were informed that there was a questionnaire to complete after the intervention period, which may have encouraged them to increase their consumption, especially after completing the baseline questionnaire (prior to the intervention). Moreover, in our study, we observed an increase in fruit juice intake in both the control and intervention groups. According to the National Health and Nutrition Examination Survey, fruit juice is the main contributor to fruit intake among US adolescents [40,41]. Nevertheless, during the study period, food shops were not closed, nor were there any restrictions placed on circulation that could have had an impact on family FV purchasing power. Moreover, given that the study was conducted between February and March (late winter and early spring), there were no seasonal differences affecting the availability of FV on the market.

Limitations

Our study has several limitations, including a limited duration, which should be extended in future research. Second, measuring FV consumption using a self-administered questionnaire may have led to some limitations, although previous studies conducted among individuals in the same age group have employed the same questionnaire, and previous studies showed that a self-administered FFQ is an easy and useful tool for assessing dietary intake among adolescents [42,43]. Third, self-reported weight and height data are considered a limitation of this research; however, the research team instructed all participants on the appropriate methods for measuring weight and height, and a previous study confirmed that self-reporting weight and height is a valid method [44]. Fourth, the lack of involvement of parents in this intervention was also a limitation. However, our study has important strengths. The app is free, straightforward, and easily understood by adolescents, and a brochure explaining the use of the app in Arabic was provided to all adolescents in the intervention group. Moreover, our sample size had sufficient statistical power, and to our knowledge, this was the first study in Saudi Arabia that examined the effects of using a smartphone app to enhance FV intake among adolescents.

Conclusions

The low FV intake among adolescents in Saudi Arabia highlights the importance of implementing an approach to promote FV intake in this population. However, the use of a smartphone app in the current study did not increase FV consumption among adolescents in the intervention group after 6 weeks. Future nutritional educational studies aiming to enhance the dietary patterns of adolescents should involve parents, as they have an important role in their children's dietary patterns. Moreover, increased involvement by peers and teachers in schools can promote FV intake among adolescents with beneficial effects.

Acknowledgments

We thank the adolescents for their time and participation in the study.

Authors' Contributions

IMS conceptualized the research topic, designed the study, recruited participants, collected data, and produced the initial manuscript draft. RSA, MFB, DAH, and JKS recruited participants, conducted the interviews, collected data, conducted the analyses, and

assisted in writing the initial manuscript draft. NM Aljefree and NM Almoraie conceptualized the research topic, revised the data analysis, and revised the manuscript. All authors critically reviewed and approved the submitted manuscript.

Conflicts of Interest

None declared.

Editorial Notice

This randomized study was only retrospectively registered due to lack of awareness of registration requirements. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1
Supplementary Table 1. Fruit and vegetables listed in the food frequency questionnaire.
[DOCX File , 30 KB - pediatrics_v6i1e43160_app1.docx]

Multimedia Appendix 2
Supplementary Table 2. Comparison of fruit and vegetable item scores for the control (n=49) and intervention (n=55) groups at baseline and after 6 weeks.
[DOCX File , 42 KB - pediatrics_v6i1e43160_app2.docx]

Multimedia Appendix 3
CONSORT-eHEALTH checklist (V 1.6.2).
[PDF File (Adobe PDF File), 93 KB - pediatrics_v6i1e43160_app3.pdf]

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Abbreviations

FFQ: food frequency questionnaire
FV: fruit and vegetable

Edited by S Badawy, G Eysenbach; submitted 01.10.22; peer-reviewed by E Johnson; comments to author 24.10.22; revised version received 21.11.22; accepted 25.12.22; published 09.02.23.

Please cite as:
Shatwan IM, Alhefani RS, Bukhari MF, Hanbazazah DA, Srour JK, Surendran S, Aljefree NM, Almoraie NM
Effects of a Smartphone App on Fruit and Vegetable Consumption Among Saudi Adolescents: Randomized Controlled Trial
JMIR Pediatr Parent 2023;6:e43160
URL: https://pediatrics.jmir.org/2023/1/e43160
doi:10.2196/43160
PMID:36757770

Original Paper

Evaluating the Effectiveness of Interventions to Improve the Follow-up Rate for Children With Visual Disabilities in an Eye Hospital in Nepal: Nonrandomized Study

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Abstract

Background: Monitoring ocular morbidity among pediatric patients requires regular follow-up visits. We found that the follow-up rate was poor among children in our setting. Therefore, we intended to assess the effectiveness of 2 interventions—(1) counseling and (2) SMS text messaging and phone calls—to improve the follow-up rates.

Objective: This study aimed to evaluate the effectiveness of 2 interventions, counseling and SMS and phone calls group, as well as a routine standard care for improving the follow-up rate of pediatric patients.

Methods: A Nonrandomized, quasiexperimental design was used. Children (aged 0-16 years) with ocular conditions requiring at least 3 follow-up visits during the study period were included. A total of 264 participants were equally allocated to the 3 intervention groups of (1) counseling, (2) SMS and phone calls, and (3) routine standard care group. A 20-minute counseling session by a trained counselor with the provision of disease-specific leaflets were given to those in the counseling group. For the second intervention group, parents of children received an SMS text 3 days before and a phone call 1 day before their scheduled follow-up visits. Participants allocated for the routine standard care group were provided with the existing services with no additional counseling and reminders. Participants attending 3 follow-ups within 2 days of the scheduled visit date were considered compliant. The difference in and among the proportion of participants completing all 3 follow-up visits in each group was assessed.

Results: The demographic characteristics of the participants were similar across the study groups. Only 3% (8/264) of participants completed all 3 follow-up visits, but overall compliance with the follow-up, as defined by the investigators, was found to be only 0.76% (2/264). There was no statistically significant difference in the proportion of follow-up between the intervention groups. However, the proportion of participants attending the first and second follow-ups, as well as the overall total number of follow-ups, was more in the SMS and phone-call group followed by the counseling group.

Conclusions: We did not find any evidence on the effectiveness of our interventions to improve the follow-up rate. The primary reason could be that this study was conducted during the COVID-19 pandemic. It could also be possible that the intensity of the interventions may have influenced the outcomes. A rigorously designed study during the absence of any lockdown restrictions is warranted to evaluate intervention effectiveness. The study also provides useful insights and highlights the importance of designing and systematically developing interventions for improving the follow-up rate and ensuring a continuum of care to children with visual disabilities in Nepal and similar contexts.

Trial Registration: ClinicalTrials.gov NCT04837534; https://clinicaltrials.gov/ct2/show/NCT04837534

International Registered Report Identifier (IRRID): RR2-10.2196/31578

(JMIR Pediatr Parent 2023;6:e43814) doi:10.2196/43814

KEYWORDS

counseling; follow-up; intervention study; Nepal; ophthalmology; pediatrics; public health

Introduction

Background

Childhood visual impairment and blindness remain an important public health issue. An estimated 1.4 million children globally are blind [1]. The Nepal Pediatric Ocular Disease study in 2014 estimated a childhood blindness and severe visual impairment (visual acuity<6/60) prevalence of 70/100,000 [2]. Another study in the Narayani Zone of Nepal in 2017 estimated the prevalence of childhood blindness and severe visual impairment as 30/100,000 and moderate visual impairment as 25/100,000 [3]. Increasing the global knowledge base and planning for effective childhood eye care services is a top priority to enable children with visual impairment to realize their full visual potential [4]. Follow-up of pediatric patients is important for their regular ocular morbidity monitoring, especially for amblyopia management [4,5].

The pediatric eye care teams at Bharatpur Eye Hospital (BEH) observed that there was poor adherence to follow-up visits of children with visual impairment. An exploratory analysis of data during the first week (January 1, 2019, to January 7, 2019) revealed that follow-up compliance was very low among children aged 0 to 16 years in the pediatric department. Among the children advised for follow-up, only 22% were found to have come for at least one follow-up visit. A problem analysis showed that a lack of awareness in children and their parents regarding the importance of follow-up and patients forgetting the dates of the follow-up visit (usually when there is a long gap for follow-up) may be the major contributing factors to poor adherence to follow-up.

A study from India revealed distance and cost as major barriers, as was the inability of the eye care center to communicate the importance of follow-up [6]. Another study conducted in Nepal found poor follow-up rates for patients following pediatric cataract surgery, which, however, improved after the implementation of a high-quality pediatric counseling service, a follow-up program, a tracking system, and phone reminders [7]. Many studies have compared different methods of reminder options such as telephone calls, email, and SMS text messages to improve compliance with follow-up [8-12]. A study done to improve the neonatal follow-up showed that the monthly first-visit show rate increased from 60% to 76% during the intervention period, and 75% of families who received parent education presented for their initial visit, compared to 51% of families who did not receive parent education [13]. Although several interventions were experimented in previous studies, it is still not clear which kinds and components of the interventions were influencing treatment effectiveness. It is also documented that the interventions and the definition of follow-up differed in terms of intensity, duration, and time, respectively. Therefore, in order to improve the follow-up of children with visual impairment in BEH and Nepal in general, we intended to assess the effectiveness of different kinds of interventions to improve follow-up in these client groups.

Primary Objective

The aim of this paper is to assess the effectiveness of 2 different interventions, namely counseling and SMS and phone calls, against routine standard care to improve follow-up of children with visual impairment in BEH Nepal.

Methods

Study Design

This is a nonrandomized, quasiexperimental study.

Setting

This study was conducted at the Hiralal Santudevi Pradhan Institute of Ophthalmic Sciences. BEH is a centrally located tertiary eye hospital in the Chitwan district of Nepal.

Participants

The participants of this study were selected considering the following criteria:

- Children with a visual impairment, aged 0-16 years
- Enrolled in the pediatric department of BEH
- Diagnosed with ocular conditions requiring at least 3 follow-up visits
- Supported by parents or guardians having a mobile phone who can use the mobile phone and read SMS texts

Intervention

Counseling Group

The parent or guardian and the child received a 20-minute counseling session from a trained counselor (SK) as per a structured counseling protocol at every follow-up visit where the disease-specific leaflet was used as a counseling tool, a copy of which was also handed over to them. The counseling protocol for common ocular conditions had been designed by the research team. Children, along with their parents or guardians, received counseling irrespective of participant age, parental education, ocular conditions, and other factors. If more than one guardian or both parents accompanied the child, both were included in the counseling session. The counselor delivered verbal counseling for all participants in all follow-up visits irrespective of the ocular conditions and other factors.

SMS Text Message and Phone Call Group

The parents of children received an SMS text 3 days before and a phone call 1 day before their scheduled follow-up visits. Text messages were sent until it was confirmed that the message had been received. In the case of message delivery failure, it was sent 3 more times to ensure successful delivery. A phone call

was deemed to be completed once it was received by the respondent; calls were repeated at least 3 times if the phone was not answered in the first or second instance. If the call was not answered even after 3 attempts, the participant was excluded from the study.

Routine Standard Care Group or Control Group

In this group, the children underwent visual acuity testing and refraction by an optometrist. The pediatric ophthalmologist performed a detailed ocular examination and advised necessary investigations to diagnose and formulate a treatment plan. Basic counseling was done by the consultant regarding the ocular condition, treatment, and need for follow-up. No additional counseling or reminders were offered to these patients.

Compliance to Follow-up

The participants' first visit to the hospital and the 3 scheduled follow-up visits needed to be completed for them to be considered compliant with the follow-up. Only those participants who completed the first follow-up were considered for the second follow-up, and only those who came for the second follow-up were considered for the third follow-up. This definition was adopted from a protocol used in an earlier study in Nepal [7].

The patients were considered compliant to follow-up only if they came within the window period of (+/–) 2 days close to their scheduled visit. The rescheduling of the next follow-up date was calculated from the attended date as per the follow-up schedule for each ocular condition. The purpose of observing compliance to follow-up was to determine the impact of counseling and reminders through SMS texts and phone calls on the increment of the proportion of children completing their 3 follow-up visits based on the developed proforma and to find out if the differences in the proportion in the follow-up rate between the 3 different groups were statistically significant.

Data Analysis

Data were processed and analyzed using Excel (Microsoft Corp) and STATA version 14.2. (Stata Corp) The results were presented in terms of frequency counts with percentages for categorical variables. The significant association or difference between different intervention groups was measured by chi-square with degree of freedom for qualitative variables. A *P* value of less than .05 was considered significant.

Ethical Considerations

Ethics approval was obtained from the Ethical Review Board (ERB) of the Nepal Health Research Council (ERB protocol registration #761/2020 P and ClinicalTrials.gov No: NCT04837534). Written consent was taken from the children in an assent form (if aged 9 years or older) and from their parents or guardians in a consent form before enrolling them in the study. All the information collected was secured and stored safely by the chief investigators. The data were completely anonymized for the purpose of privacy and confidentiality. The participants were not compensated for participating in the study.

Results

Demographic Characteristics

A total of 264 participants were enrolled in this study. The participants were divided randomly (alternate sequence) and were equally allocated into 3 study groups. Routine standard care group, SMS text message and phone call group, and the counseling group. Demographic characteristics of the participants, such as gender, age groups, ethnicity, parental educational status, parents or guardian accompanying the child, and occupation of parents were equally distributed among the study groups, and the difference was not statistically significant. About 62% (n=164) of the participants were male, and 38% (100) were female. Factors such as the total distance from the hospital, the time taken, and the cost incurred for the travel by participants to reach the hospital in the 3 study groups were also not statistically significant. The baseline characteristics of the participants in each group were not very different. Table 1 provides the details of the participants' demographic characteristics.

Table 1. Sociodemographic profile of the participants based on different study groups (N=264).

Characteristics	Routine standard care, n (%)	Counseling, n (%)	SMS and phone call, n (%)	Total, n (%)	Chi-square (*df*)	*P* value
Gender					0.2254 (2)	.89
Male	56 (63.64)	53 (60.23)	55 (62.50)	164 (62.12)		
Female	32 (36.36)	35 (39.77)	33 (37.50)	100 (37.88)		
Age group					4.36 (2)	.11
≤8 years	58 (65.91)	69 (78.41)	68 (72.27)	195 (73.86)		
>8 years	30 (34.09)	19 (21.59)	20 (22.73)	69 (26.14)		
Parents or guardian					1.9003 (4)	.75
Mother	58 (21.96)	58 (21.96)	67 (25.37)	183 (69.31)		
Father	17 (6.43)	19 (7.19)	14 (5.30)	50 (18.93)		
Others	13 (4.92)	10 (3.78)	7 (2.65)	30 (11.36)		
Ethnicity					0.7858 (2)	.68
Aryan	54 (61.36)	54 (61.36)	49 (55.68)	157 (59.47)		
Mongol and others	34 (38.64)	34 (38.64)	39 (44.34)	107 (40.53)		
Educational status of parent or guardian					8.87 (6)	.18
Illiterate	10 (11.36)	6 (6.82)	10 (11.36)	26 (9.85)		
Primary	5 (5.68)	11 (12.50)	7 (7.95)	23 (8.71)		
Secondary and higher secondary	62 (70.45)	54 (61.36)	49 (55.68)	165 (62.50)		
Bachelor and above	11 (12.50)	17 (19.32)	22 (25)	50 (18.94)		
Occupation					0.9126 (2)	.63
Non–income-generating occupation	53 (6023)	59 (67.05)	55 (62.50)	167 (63.26)		
Income-generating occupation	35 (39.77)	29 (32.95)	33 (37.50)	97 (36.74)		
Distance (km)					2.39 (4)	.66
0-50	76 (86.36)	76 (86.36)	71 (80.68)	223 (84.47)		
51-100	6 (6.82)	6 (6.82)	6 (6.82)	18 (6.82)		
>100	6 (6.82)	6 (6.82)	11 (12.86)	23 (8.71)		
Time taken (min)					5.2414 (4)	.26
0-30	59 (67.05)	60 (68.18)	56 (63.64)	175 (66.29)		
31-60	17 (19.32)	19 (21.59)	13 (14.77)	49 (18.56)		
>60	12 (13.64)	9 (10.23)	19 (21.59)	40 (15.15)		
Cost of 2-way travel (NR[a])					4.002 (4)	.41
0-100	40 (45.45)	49 (55.68)	43 (48.86)	132 (50.00)		
101-500	40 (45.45)	30 (34.09)	32 (36.36)	102 (38.64)		
>500	8 (9.09)	9 (10.23)	13 (14.77)	30 (11.36)		

[a]NR: Nepalese Rupee (US $1=NR 132).

Impact of the Intervention on Follow-up

This study did not find any statistically significant difference between the study groups during the follow-ups (first follow-up chi-square: χ^2_2=3.19, *P*=.20; second follow-up chi-square: χ^2_2=0.92, *P*=.62; and third follow-up chi-square: χ^2_2=0.25, *P*=.86). However, the proportion of participants attending the first and second follow-ups as well as the overall total number of follow-ups was more in the SMS and phone call group followed by the counseling group. In the routine standard care group, only 3 participants attended all 3 follow-up visits, and out of them, only 1 participant attended all the follow-ups on schedule. Similarly, 3 participants in the counseling group and 2 participants in the SMS and phone call attended all 3 follow-ups, respectively. Among them, none of the participants attended the follow-up on schedule in the counseling group, and only 1 participant was on schedule in the SMS and phone

call group. The overall compliance with the follow-up as defined by the investigators was found to be 0.76% (2/264). Table 2 provides more details related to the participants' follow-up. Except for the first follow-up, it was also observed that most participants who attended the second and third follow-ups attended it after the schedule.

The cost for 2-way travel between the groups was also not statistically significant (Table 3). A comprehensive cost-effectiveness analysis of the interventions is being carried out, and its results will be published as a separate paper.

Comparing the compliance to the follow-up with some specific demographic characteristics showed no statistically significant difference (Table 4). About 50%-55% of parents or guardians who had secondary or higher secondary education attended the first, second, and third follow-ups. Male children were brought to the follow-ups more in all 3 groups compared to female children. Among the participants who attended all 3 follow-ups, all were accompanied by their mothers. About 65% (127/195) of the participants who attended the follow-ups belonged to the non–income-generating group.

Table 2. Impact of the interventions on follow-up.

Variables	Routine standard care (n=88), n (%)	Counselling (n=88), n (%)	SMS and phone call (n=88), n (%)	Total (N=264)	Chi-square (*df*)	*P* value
F/u[a] category						
Advised for f/u	88 (100)	88 (100)	88 (100)	N/A[b]	N/A	
First f/u attended	24 (28.92)	25 (28.41)	34 (38.64)	83 (31.44)	3.19 (2)	.20
Second f/u attended	9 (10.23)	10 (11.36)	13 (14.77)	32 (12.12)	0.92 (2)	.62
Third f/u attended	3 (3.41)	3 (3.41)	2 (2.27)	8 (100)	0.25 (2)	.86
Total f/u visits	36 (29.27)	38 (30.89)	49 (39.84)	123 (100)	2.83 (2)	.24
Actual attended date at first f/u (n=83)					5.57 (4)	.23
Prior to schedule	6 (25.00)	5 (20.00)	3 (8.82)	14 (16.87)		
On schedule	10 (41.67)	9 (36.00)	21 (61.76)	40 (48.19)		
After schedule	8 (33.33)	11 (44.00)	10 (29.41)	29 (34.94)		
Actual attended date at second f/u (n=32)					3.25 (4)	.51
Prior to schedule	2 (22.22)	0	2 (15.38)	4 (12.50)		
On schedule	1 (11.11)	3 (30.00)	4 (30.77)	8 (25.00)		
After schedule	6 (66.67)	7 (70.00)	7 (53.85)	20 (62.50)		
Actual attended date at third f/u (n=8)					4.00 (4)	.40
Prior to schedule	0	1 (33.33)	1 (50.00)	2 (25.00)		
On schedule	1 (33.33)	0	1 (50.00)	2 (25.00)		
After schedule	2 (66.67)	2 (67.67)	0	4 (50.00)		

[a]F/u: follow-up.

[b]N/A: not applicable.

Table 3. Travel cost with follow-up attendance (N=264).

Variables	Presenting, n (%)	First f/u[a], n (%)	Chi-square (*df*)	*P* value	Second f/u, n (%)	Chi-square (*df*)	*P* value	Third f/u, n (%)	Chi-square (*df*)	*P* value
Cost category (NP[b])			4.84 (2)	.09		5.73 (2)	.06		5.15 (2)	.08
Up to 100	132 (50.00)	36 (43.37)			13 (40.63)			1 (12.50)		
101-500	102 (38.64)	40 (48.19)			18 (56.25)			6 (75.00)		
>500	30 (11.36)	7 (8.43)			1 (3.13)			1 (3.03)		

[a]F/u: follow-up.

[b]NP: Nepalese Rupees; cost of 2-way travel per person (US $1=NR 132).

Table 4. Comparison of compliance to follow-up rate with sociodemographic profile.

Characteristics	First f/u[a] attended (n=83), n (%)	*P* value	Second f/u attended (n=32), n (%)	*P* value	Third f/u attended (n=8), n (%)	*P* value
Gender		.34		.26		.45
Male	55 (66.27)		17 (53.13)		6 (75)	
Female	28 (33.73)		15 (46.88)		2 (25)	
Age group		.16		.79		.94
≤8 years	66 (79.52)		23 (71.88)		6 (75)	
>8 years	17 (20.48)		9 (28.13)		2 (25)	
Parents or guardian		.14		.90		.16
Mother or both parents	62 (79.49)		23 (79.31)		8 (100)	
Father	16 (20.51)		6 (20.69)		0	
Others	5 (1.89)		3 (1.13)		0	
Ethnicity		.15		.69		.58
Aryan	44 (53.01)		18 (56.25)		4 (50)	
Mongol and others	39 (46.99)		14 (43.75)		4 (50)	
Educational status of parent or guardian		.31		.21		.90
Illiterate	10 (12.05)		3 (9.38)		1 (12.50)	
Primary	9 (10.85)		1 (3.13)		1 (12.50)	
Secondary and higher secondary	45 (54.22)		18 (56.25)		4 (50)	
Bachelor and above	19 (22.89)		10 (31.25)		2 (25)	
Occupation		.68		.21		.48
Non–income-generating group	51 (61.45)		17 (53.13)		6 (75)	
Income-generating group	32 (38.55		15 (46.88)		2 (25)	

[a]F/u: follow-up.

Discussion

Principal Findings

This study aimed to assess the effect of counseling as one intervention and SMS and phone call together as another intervention compared to the routine standard care (control group) to increase the follow-up rate of children with visual impairment in 1 tertiary care hospital in Nepal, and it did not find any statistically significant difference between the study groups on the follow-up rate. The baseline data on follow-up in the pediatric department from January 2019 was 22%, which we assumed would be improved to 50% with our intervention; however, compliance to follow-up, as defined in our study, was very low (ie, 0.76%). Nevertheless, compared to the standard as well as counseling group, the proportion of participants in the first, second, and third follow-up combined was more in the SMS and phone call group. This was only applicable if the strict definition for compliance to follow-up was not applied.

There may be several reasons for poor compliance to follow-up in this study. One of the possible reasons could be the COVID-19 pandemic and the lockdown restriction imposed during the time when participant recruitment took place. Fear of potential risks of COVID-19 infection as well as the serious health and socioeconomic consequences of breaching the pandemic restrictions might have influenced compliance to follow-up.

The other potential reason could be the intensity and the timing of the intervention. The content of the counseling intervention and the duration of 20 minutes might not have been effective enough to produce a sizeable effect on the outcomes of this study. This is very similar to the number of calls, the content of the conversation, and the acceptability of the text messages by the participants. Given that the intervention was developed based on previous experience rather than systematic development as recommended by the Medical Research Council guidelines, the factors that could influence treatment effectiveness may have been missed out. Lastly, the affordability of the participants for 3 continued follow-ups as recommended by the investigator team may also have been a factor to consider. This is of immense interest to the investigators, and a comprehensive study is in progress to understand the effect of costs on compliance with follow-up.

Different studies have shown varied results regarding the effect of these kinds of interventions on people with visual impairments. Follow-up rates have been found to improve with these types of interventions in some studies, while other studies show no significant improvement [7-21]. For example, a similar study conducted in Nepal to improve follow-up among pediatric

patients with cataract found that the rate of follow-up for first, second, and third follow-up visits increased from 87% to 96%, 60% to 81%, and 37% to 57% without and with the intervention, respectively [7]. However, there was a full-time pediatric counselor, a tracking system, and a cell phone reminder used as intervention packages, which are different from the interventions used in this study.

This study has several implications. Firstly, there is a need to systematically develop interventions to address the growing needs of people with visual impairments, particularly in the community. Given the economic situation of most participants in a country such as Nepal, continuum of care through sustainable interventions must be explored further. Given the complexity of the intervention, it is also essential to have a dedicated team trained exclusively to focus on follow-up and community-based care rather than using the task transfer or multitasking approach to address the needs of persons with visual disabilities. This study also highlights the need for an inclusive program during the pandemic that must be organized by the government for people with visual impairment in a country such as Nepal, considering the risks and consequences of the pandemic on this vulnerable group.

Limitations

Similar to other studies on this topic, there are certain limitations. The study was quasiexperimental in design, and a controlled clinical trial would be a rigorous design to evaluate the effects accurately. Recruitment during the pandemic, especially for an outcome related to follow-up, may not seem feasible. However, this study has provided the opportunity to understand the disadvantages of recruitment for a study related to follow-up during lockdown travel restrictions. This knowledge will help the investigators conduct a feasibility study before embarking on a sufficiently powered, large clinical trial. Lastly, a very strict definition of compliance to follow-up could have also been a reason for poor compliance.

Visual impairment is an important public health problem in Nepal. Given the geographical and attitudinal barriers to accessing specific evidence-based eye care services, it is important to sensitize people experiencing disability due to visual impairments about the importance of the continuum of care. Similarly, it is also very important to build the capacity of institution-based teams to develop pathways, protocols, and effective interventions to address the unmet needs of people with visual impairments in Nepal through inclusive and affordable strategies.

Acknowledgments

We gratefully acknowledge the Seva Foundation and the Indian Institute of Public Health–Hyderabad for their valuable guidance and support of this work, as well as the management and staff of Bharatpur Eye Hospital (BEH) for their contributions to various aspects of this study.

Data Availability

The data collected have been presented in the manuscript. Any request for additional data will be reviewed by the advisory committee and will be shared upon request.

Authors' Contributions

MS, GB, SKR, SKK, AGG, BP, RG, DSC, and RB conceptualized and designed the study. DA, RK, and SK were responsible for the consent form and information leaflets. SK provided counseling to the study participants. DA and RK conducted the data collection and data entry. MS, GB, BP, SKK, VA, and HBP did the data analysis. MS, GB, and SKK drafted the manuscript. All authors read and approved the final manuscript.

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Conflicts of Interest

None declared.

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Abbreviations

BEH: Bharatpur Eye Hospital

Edited by S Badawy; submitted 25.10.22; peer-reviewed by P Venkatesan, Y Jeem; comments to author 09.01.23; revised version received 23.01.23; accepted 31.01.23; published 23.02.23.

Please cite as:
Shrestha M, Bhandari G, Kamalakannan S, Murthy GVS, Rathi SK, Gudlavalleti AG, Agiwal V, Pant H, Pandey B, Ghimire R, Ale D, Kayastha S, Karki R, Chaudhary DS, Byanju R, Operational Research Capacity Building Study Group
Evaluating the Effectiveness of Interventions to Improve the Follow-up Rate for Children With Visual Disabilities in an Eye Hospital in Nepal: Nonrandomized Study
JMIR Pediatr Parent 2023;6:e43814
URL: https://pediatrics.jmir.org/2023/1/e43814
doi:10.2196/43814
PMID:36821366

Demographic and Support Interest Differences Among Nonbirthing Parents Using a Digital Health Platform With Parenthood-Related Anxiety: Cross-Sectional Study

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Abstract

Background: The transition to parenthood is a period of major stressors and increased risk of anxiety for all parents. Though rates of perinatal anxiety are similar among women (4%-25%) and men (3%-25%), perinatal anxiety research on nonbirthing partners remains limited.

Objective: We aimed to examine whether demographic characteristics or digital perinatal support preferences differed among nonbirthing partners with compared to without self-reported high parenthood-related anxiety.

Methods: In this large cross-sectional study of nonbirthing partners using a digital perinatal health platform during their partner's pregnancy, users reported their parenthood-related anxiety through a 5-item Likert scale in response to the prompt "On a scale of 1=None to 5=Extremely, how anxious are you feeling about parenthood?" High parenthood-related anxiety was defined as reporting being very or extremely anxious about parenthood. During the onboarding survey, in response to the question "Which areas are you most interested in receiving support in?" users selected as many support interests as they desired from a list of options. Chi-square and Fisher exact tests were used to compare demographic characteristics and support interests of nonbirthing partners with low versus high parenthood anxiety. Logistic regression models estimated the odds ratios (ORs), with 95% CIs, of high parenthood-related anxiety with each user characteristic or digital support interest.

Results: Among 2756 nonbirthing partners enrolled in the digital platform during their partner's pregnancy, 2483 (90.1%) were men, 1668 (71.9%) were first-time parents, 1159 (42.1%) were non-Hispanic White, and 1652 (50.9%) endorsed an annual household income of >US $100,000. Overall, 2505 (91.9%) reported some amount of parenthood-related anxiety, and 437 (15.9%) had high parenthood-related anxiety. High parenthood-related anxiety was more common among non-White nonbirthing partners: compared to those who identified as non-Hispanic White, those who identified as Asian, Black, or Hispanic had 2.39 (95% CI 1.85-3.08), 2.01 (95% CI 1.20-3.23), and 1.68 (95% CI 1.15-2.41) times the odds of high parenthood-related anxiety, respectively. Lower household income was associated with increased odds of reporting high parenthood anxiety, with the greatest effect among those with annual incomes of <US $50,000 compared to >US $100,000 (OR 2.13, 95% CI 1.32-3.34). In general, nonbirthing partners were interested in receiving digital support during their partner's pregnancy, but those with high parenthood-related anxiety were more likely to desire digital support for all support interests compared to those without high parenthood anxiety. Those with high parenthood-related anxiety had more than 2 times higher odds of requesting digital education about their emotional health compared to those without high parenthood-related anxiety (OR 2.06, 95% CI 1.67-2.55).

Conclusions: These findings demonstrate the need for perinatal anxiety-related support for all nonbirthing partners and identify nonbirthing partners' demographic characteristics that increase the odds of endorsing high parenthood-related anxiety. Additionally, these findings suggest that most nonbirthing partners using a digital health platform with high parenthood-related anxiety desire to receive perinatal mental health support.

(JMIR Pediatr Parent 2023;6:e46152) doi:10.2196/46152

KEYWORDS

nonbirthing parent; paternal mental health; perinatal anxiety; parenting anxiety; digital health; anxiety; perinatal; mental health support; digital platform; pregnancy; parents; spouse; partners; support; support groups; online support

Introduction

The transition to parenthood is a period of major stressors and increased risk of mental health issues, regardless of whether or not the parent gives birth [1-4]. Indeed, when stratified by gender (which frequently corresponds to birthing and nonbirthing roles), rates of perinatal anxiety are similar among women (4%-25%) [1,2] and men (3%-25%) [3,4]. Despite the similar burden of perinatal anxiety between parents and the known interplay between maternal and paternal perinatal mood disorders [5-7], perinatal anxiety research on nonbirthing partners remains limited, and little is known about the desire of nonbirthing partners to receive mental health support during the perinatal period [8]. Thus, we aimed to examine whether demographic characteristics or desired mental health supports differed among nonbirthing partners with compared to without high parenthood-related anxiety.

Methods

Eligibility Criteria/Recruitment

This study examined a cohort of users enrolled in the partner pathway in Maven, a digital health platform for pregnant people and their partners, from March 16, 2021, through October 20, 2022. Access to Maven is a sponsored benefit through an employer or health plan of the user or their partner. Users consented to the use of their deidentified data for scientific research upon creating an account on the digital platform. As previously described [9], users self-reported demographic information, desired support interests, and parenthood-related anxiety on a health survey at onboarding. For race and ethnicity, users selected a single option from a list of choices. In response to the question "Which areas are you most interested in receiving support in?" users selected as many support interests as they desired from the following list: "choosing a healthcare provider/team," "labor and delivery options," "preparing to be a working parent," "infant care," "learning about childcare options," "my own emotional health," "understanding my partner's physical experience during pregnancy," and "understanding my partner's emotional experience during pregnancy." Users reported their parenthood-related anxiety on a 5-item Likert scale in response to the prompt "On a scale of 1=None to 5=Extremely, how anxious are you feeling about parenthood?" To be included, users had to be enrolled in Maven's partner track and have completed the Maven Clinic's onboarding survey while their partner was pregnant. Thus, data for these analyses included platform utilization and user-reported data from the onboarding questionnaire.

Statistical Analysis

Due to small sample sizes, participants who reported their race/ethnicity as American Indian or Alaskan Native, Native Hawaiian or other Pacific Islander, or multiple races were categorized in the "other" category. Income was assessed categorically. High parenthood-related anxiety was defined as responding to the question on parenthood-related anxiety with a 4 ("very") or 5 ("extremely"). Some parenthood-related anxiety was defined as responding to the question on parenthood-related anxiety with any response other than a 1 ("none") on the Likert scale. Descriptive analyses assessed user demographics and support interests stratified by presence of high parenthood-related anxiety. In bivariate analyses, the chi-square or Fisher exact tests were used to assess categorical variables. Logistic regression models estimated the odds ratio (ORs) and 95% CI of reporting high parenthood anxiety with each user characteristic or educational support preference. All analyses were conducted in R (version 3.6.3; R Foundation for Statistical Computing).

Ethical Considerations

The study was designated as exempt by the WCG Institutional Review Board, an independent ethical review board.

Results

Of the 4188 users enrolled in Maven's partner pathway during the study period, 3705 (88.5%) completed the onboarding survey. Of these, 2756 (74.4%) completed their survey while their partner was pregnant and were included for analysis. Overall, most (n=2483, 90.1%) nonbirthing partners self-identified as male, 2034 (73.8%) identified as first-time parents, and 2505 (91.9%) nonbirthing partners endorsed feeling at least some parenthood-related anxiety.

In this study population, 437 (15.9%) of nonbirthing partners were categorized as having high parenthood-related anxiety. Some demographic characteristics increased the odds of endorsing high parenthood-related anxiety (Table 1). Specifically, compared to non-Hispanic White nonbirthing partners, the odds of participants reporting high parenthood-related anxiety were more than 2-fold higher among Asian (OR 2.39, 95% CI 1.85-3.08) or Black (OR 2.01, 95% CI 1.20-3.23) nonbirthing partners and more than 60% higher among Hispanic nonbirthing partners (OR 1.68, 95% CI 1.15-2.41). Similarly, compared to non–first-time parents, first-time nonbirthing partners had twice the odds of reporting high parenthood-related anxiety (OR 2.01, 95% CI 1.55-2.65), and those with annual incomes of <US $50,000 or between US $50,000 and US $100,000 had more than 2-fold or 48% increased odds, respectively, of endorsing high parenthood-related anxiety compared to those with annual incomes of ≥US $100,000 (<US $50,000: OR 2.13, 95% CI 1.32-3.34; US $50,000-US $100,000: OR 1.48, 95% CI 1.07-2.01). The odds of endorsing high parenthood-related anxiety were similar between male and female nonbirthing parents (OR 1.20, 95% CI 0.69-1.98).

Table . Nonbirthing partner characteristics and support interests by parenthood-related anxiety level.

Nonbirthing partner characteristics		Overall (n=2756), n (%)	Low parenthood-related anxiety (n=2319, 84.1%), n (%)	High parenthood-related anxiety (n=437, 15.9%), n (%)	Odds ratio (95% CI)	*P* value
Race/ethnicity						
	Non-Hispanic White	1159 (42.1)	1033 (44.5)	126 (28.8)	Reference	N/A[a]
	Asian	714 (25.9)	553 (23.8)	161 (36.8)	2.39 (1.85-3.08)	<.001
	Hispanic	265 (9.6)	220 (9.5)	45 (10.3)	1.68 (1.15-2.41)	.006
	Black	117 (4.2)	94 (4.1)	23 (5.3)	2.01 (1.20-3.23)	.006
	Other	501 (18.2)	419 (18.1)	82 (18.8)	1.60 (1.19-2.16)	.002
First child						
	No	722 (26.2)	651 (28.1)	71 (16.2)	Reference	N/A
	Yes	2034 (73.8)	1668 (71.9)	366 (83.8)	2.01 (1.55-2.65)	<.001
Biological sex						.84
	Female	98 (3.6)	80 (3.4)	18 (4.1)	1.20 (0.69-1.98)	.50
	Male	2483 (90.1)	2091 (90.2)	392 (89.7)	Reference	N/A
	Missing	175 (6.3)	148 (6.4)	27 (6.2)	N/A	N/A
Household income (US $)						.002
	Less than $50,000	103 (3.7)	76 (3.3)	27 (6.2)	2.13 (1.32-3.34)	.001
	$50,000-$100,000	299 (10.8)	240 (10.3)	59 (13.5)	1.48 (1.07-2.01)	.02
	More than $100,000	1652 (59.9)	1416 (61.1)	236 (54)	Reference	N/A
	Did not disclose	702 (25.5)	587 (25.3)	115 (26.3)	N/A	N/A
Support interests						
	Leaning about child care options	1403 (50.9)	1159 (50)	244 (55.8)	1.28 (1.04-1.59)	.02
	Choosing a health care provider/team	789 (28.6)	632 (27.3)	157 (35.9)	1.51 (1.21-1.88)	<.001
	My own emotional health	1032 (37.4)	806 (34.8)	226 (51.7)	2.06 (1.67-2.55)	<.001
	Infant care	2016 (73.1)	1674 (72.2)	342 (78.3)	1.47 (1.13-1.92)	.005
	Labor and delivery options	1200 (43.5)	969 (41.8)	231 (52.9)	1.60 (1.29-1.97)	<.001
	Understanding my partner's emotional experience during pregnancy	1981 (71.9)	1635 (70.5)	346 (79.2)	1.72 (1.32-2.26)	<.001
	Understanding my partner's physical experience during pregnancy	1825 (66.2)	1495 (64.5)	330 (75.5)	1.82 (1.42-2.34)	<.001
	Preparing to be a working parent	1779 (64.6)	1469 (63.3)	310 (70.9)	1.47 (1.16-1.86)	.001

[a]N/A: not applicable.

In general, nonbirthing partners were interested in receiving digital support during their partner's pregnancy: the most requested support interests overall were infant care and understanding their partner's emotional experience during pregnancy (Table 1). However, those with high parenthood anxiety were more likely to desire digital support from all support interests compared to those without high parenthood anxiety. In particular, the odds of nonbirthing partners desiring

to learn more about their own emotional health or their partner's physical or emotional experience during pregnancy were markedly higher compared to those without high parenthood-related anxiety (own emotional health: OR 2.06, 95% CI 1.67-2.55; partner's physical experience in pregnancy: OR 1.82, 95% CI 1.42-2.34; partner's emotional experience in pregnancy: OR 1.72, 95% CI 1.32-2.26).

Discussion

Principal Results

In this large sample, nearly all nonbirthing partners reported feeling at least some parenthood-related anxiety, and a substantial proportion of nonbirthing partners desired education about their own or their partner's emotional health during the perinatal period. These findings demonstrate the need for perinatal mental health support for all parents, not just those who give birth, and suggest that digital health platforms may serve as logical entry points for nonbirthing partners to receive perinatal mental health support, as has been proposed [10]. Furthermore, demographic factors such as identifying as non-White or having an annual income of less than US $50,000 were associated with increased odds of high parenthood-related anxiety. This suggests that some nonbirthing partners may face a disproportionate burden of parenthood-related anxiety, and perinatal support interventions targeting these subpopulations may improve equity for nonbirthing partners.

Comparisons With Prior Work

The rate of high parenthood-related anxiety in our study is consistent with levels of paternal anxiety in the literature (3%-25%) [3,4]. Furthermore, the high prevalence of any self-reported anxiety in our study population supports prior findings suggesting that the most common mental health diagnosis for nonbirthing partners in the perinatal period is adjustment disorder with anxiety symptoms [11].

Clinical and Research Implications

In the United States, most current perinatal care delivery models do not provide much perinatal education and mental health support to nonbirthing partners [12]. Furthermore, nonbirthing partners are known to have lower rates of engagement with health care than birthing partners [12,13]. In this study, nonbirthing partners who were participating in a digital perinatal health platform not only actively selected the perinatal educational support topics about which they wanted to learn but voluntarily endorsed the presence and extent of their parenthood-related anxiety. These findings suggest that digitally screening nonbirthing partners during their partner's pregnancy for their perinatal mental health and pregnancy-related health education needs could fill an important gap in nonbirthing partners' perinatal experience. Mental health support and educational content could be delivered digitally or via in-person education provided from prenatal care providers when nonbirthing partners present to prenatal care visits, as has been proposed [10,14]. However, prior to widespread transformation of prenatal care delivery models, more research is needed to determine the optimal way to screen nonbirthing partners for mental health needs or perinatal educational preferences and to provide requested education and support based on the results of this screening.

Limitations

Despite the large study population, our study has limitations. Parenthood-related anxiety was self-reported, rather than identified via a validated anxiety measure. There is also a risk of selection bias since all participants in this study were already actively engaged in a digital health platform. Additionally, the cross-sectional design of this study limits causal interpretation of our results. Furthermore, because outcomes were not adjusted for confounders, some bias may remain in our unadjusted analyses. Lastly, though our study population was large, generalizability of our findings may be reduced as many participants reported annual incomes of >US $100,000 and people of some races/ethnicities were overly represented in the sample.

Conclusions

Among nonbirthing partners who used a digital health platform, most had some parenthood-related anxiety, and the odds of endorsing high parenthood-related anxiety were increased among non-White birthing partners, as well as those with annual incomes of less than US $100,000 and, in particular, less than US $50,000. Furthermore, though nonbirthing partners desired education on their own or their partner's emotional health during the perinatal period, the odds of desiring perinatal mental health support were higher among nonbirthing partners who endorsed high parenthood-related anxiety. These findings demonstrate not only the need for perinatal anxiety-related support for all nonbirthing partners, but that most nonbirthing partners with high parenthood-related anxiety using a digital perinatal platform desire to receive digital perinatal mental health support.

Acknowledgments

AKL and ESM are supported by the National Institute of Child Health and Human Development (K23HD103961-01A1 and R01HD105499, respectively).

Conflicts of Interest

AKL is a paid member of medical advisory boards at Shield Therapeutics and Pharmacosmos Therapeutics. In addition, AKL has an ongoing research grant from Pharmacosmos Therapeutics that is paid directly to his institution to support an ongoing R-01 clinical trial funded by the National Institute of Child Health and Human Development. LR-M, HRJ, and NH are employed by Maven Clinic. NH and HRJ also own equity in Maven Clinic.

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Abbreviations

OR: odds ratio

Edited by S Badawy; submitted 31.01.23; peer-reviewed by A Premkumar, JVD Heuvel, R McAdams; revised version received 11.10.23; accepted 16.10.23; published 20.11.23.

Please cite as:
Lewkowitz AK, Rubin-Miller L, Jahnke HR, Clark MA, Zlotnick C, Miller ES, Henrich N
Demographic and Support Interest Differences Among Nonbirthing Parents Using a Digital Health Platform With Parenthood-Related Anxiety: Cross-Sectional Study
JMIR Pediatr Parent 2023;6:e46152
URL: https://pediatrics.jmir.org/2023/1/e46152
doi:10.2196/46152

Original Paper

Improving Knowledge About Pregnancy for Deaf South African Women of Reproductive Age Through a Text Messaging–Based Information Campaign: Mixed Methods Study

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Abstract

Background: Signing Deaf South Africans have limited access to health information and, consequently, limited knowledge about health. Maternal and neonatal mortality rates are high. Cell phone use is high, making it a potentially effective way of communicating about maternal and child health.

Objective: The primary aim of this study was to assess whether an SMS text messaging–based health information campaign could improve knowledge about pregnancy, antenatal care, and healthy living during pregnancy for signing Deaf South African women of reproductive age. The secondary aim was to evaluate the acceptability of such an intervention.

Methods: This study was designed as a pretest-posttest study. A baseline questionnaire assessed participants' knowledge about pregnancy, antenatal care, and healthy living during pregnancy before an SMS text messaging–based information campaign was conducted. After the campaign, an exit questionnaire was administered containing the same questions as the baseline questionnaire with additional questions on general acceptability and communication preferences. The results were compared between baseline and exit using the McNemar and Wilcoxon signed rank tests. A focus group aimed to obtain further information on the impact and acceptability of SMS text messages. The focus group was analyzed inductively.

Results: The study showed a statistically significant improvement in overall health knowledge among participants. Despite this, some participants found the medical terminology challenging to understand. Several ways of improving SMS text messaging campaigns for the Deaf were identified, including using Multimedia Messaging Services with a person signing messages and linking information campaigns to a communication service that would enable Deaf people to pose questions. The focus group also suggested that SMS text messages might play a role in motivating healthy behaviors during pregnancy.

Conclusions: The SMS text messaging campaign effectively improved Deaf women's knowledge about pregnancy, antenatal care, and healthy living during pregnancy and has the potential to affect health behavior. This contrasts with a similar study on hearing pregnant women. This suggests that SMS text messages may be particularly effective in improving Deaf people's health knowledge. However, attention should be paid to Deaf participants' specific needs and communication preferences to optimize impact. The potential of using SMS text messaging campaigns to affect behavior should be studied.

Trial Registration: Pan-African Clinical Trials Registry (PACTR) PACTR201512001352180; https://tinyurl.com/3rxvsrbe

(JMIR Pediatr Parent 2023;6:e40561) doi:10.2196/40561

KEYWORDS

SMS text messages; cell phones; mobile health; mHealth; health information; health literacy; healthy behavior; maternal health; antenatal care; Deaf; South Africa

Introduction

Background

This study aimed to assess whether an SMS text messaging–based health information campaign can improve knowledge about pregnancy, antenatal care, and healthy living during pregnancy for signing Deaf South African women of reproductive age. In addition, this study aimed to assess the acceptability of such an intervention. We use Deaf (capitalized) to refer to permanently, sensorily disabled people with congenital or early onset deafness whose first language is sign language (in this context, South African Sign Language [SASL]).

Both maternal and child health are considerable challenges in South Africa, as in many low-and middle-income countries. Since 1994, South Africa has provided free antenatal care for all pregnant women [1]. Maternal deaths have decreased since 2011 but remain high. South Africa's aim to reduce maternal deaths to 38 per 100,000 births as part of the Millennium Development Goals did not materialize. The latest figure on maternal deaths from 2014 showed 141 deaths per 100,000 births [2].

South Africa also has high rates of perinatal deaths (both stillbirths and early neonatal deaths), with 11 deaths per 1000 live births [3]. The rate increased between 1997 and 2009, after which there was a slight decrease. Since 2010, it has fluctuated relatively highly with no consistent patterns [3]. The leading cause of death has been determined to be maternal factors and pregnancy complications, labor, and delivery, accounting for 21% of deaths [3]. Estimates suggest that 32% and 54% of all maternal and neonatal deaths, respectively, are preventable [4]. Proper health care is critical for preventing these deaths [4].

Regular antenatal care is important for the health of both mother and child as it can identify pregnancy complications [5]. For instance, there is a known association between few antenatal care visits and subsequent preterm birth [5]. According to a report from 2011, a total of 23.4% of assessable maternal deaths among South African women are associated with insufficient antenatal care [2]. Many South African pregnant women access antenatal care late, have low attendance, and experience barriers to receiving quality care [6-9]. This results in challenges in addressing complications during pregnancy. Known reasons for barriers to using antenatal care include the affordability, availability, and acceptability of health care [7-10]. Studies suggest that low use of antenatal care is linked to how pregnant women understand and perceive the benefits of antenatal care to mother and child health [9,10]. In addition, South Africa is reported to have the highest worldwide incidence of fetal alcohol syndrome (FAS) and partial fetal alcohol spectrum disorder [11] because of high levels of alcohol consumption during pregnancy.

Deaf women face challenges in accessing quality health care, and as a result, health outcomes are often worse than for hearing women. There is some evidence suggesting that this is also the case for antenatal care. A study from the United States showed that women with hearing loss have more preterm deliveries and more frequently give birth to babies with low birth weight [12]. Similarly, a study with women with hearing and visual impairments in the United Kingdom demonstrated that disabled women were more likely to have preterm babies [13]. Another US study found no difference in pregnancy outcomes between hearing and Deaf women [14]. A study conducted in Cape Town, South Africa, showed that most Deaf women (96%) accessed antenatal care, though only approximately half initiated care in the first trimester as recommended by the World Health Organization (WHO) [15]. This pattern is consistent with South African hearing women's antenatal care patterns [9,16-20]. However, 18% of the women taking part in the study with Deaf South African women only accessed antenatal care in the third trimester, citing, among other things, a lack of awareness of the need for antenatal care as a reason for their late booking [15]. Furthermore, the study found that 31% of Deaf women had experienced a miscarriage, compared with 16% of hearing women. We did not find any information on neonatal deaths or FAS prevalence in Deaf South Africans, the target population for this study. However, there is no reason to believe that it should be lower than that of the general population.

Mobile health (mHealth) is the application of mobile technology to address health care issues. The WHO defines telemedicine as healing from a distance using information and communications technology to overcome geographical boundaries and increase health outcomes. mHealth is a subset of telemedicine [16]. In 2011, the WHO defined mHealth as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices" [17].

In recent years, mHealth has become widespread in high-income and low- and middle-income countries [21-30]. A particular form of mHealth is SMS text messaging.

mHealth has been used to address several health issues. These include distributing health information, affecting behavior change, promoting healthy living, promoting adherence, and reminding patients of appointments [21-30]. However, there is limited evidence on the effectiveness of mHealth and a paucity of knowledge of what it is effective for. In a systematic review, Vodopivec-Jamsek et al [29] concluded that there was limited evidence that health promotion via mobile phone messages effectively supported preventative health care and improved healthy behavior. In contrast, the authors of another systematic review concluded that mobile phones were a promising tool for disease control interventions in low- and middle-income countries [30]. The 2016 review paper by Zhao et al [31], which concerns health apps rather than just SMS text messages, suggests that information conveyed via mobile technology can

affect health behavior. Notably, the study only comprised papers from high-income countries and may not necessarily apply to low- and middle-income countries. Nevertheless, the study by Zhao et al [31] is important in noting some of the features that made some health apps effective: they were less time-consuming and perceived to have a user-friendly design.

mHealth has also been used in studies related to maternal and child health [5,32-35]. A systematic review including 15 articles on mHealth initiatives for maternal, newborn, and child health in low- and middle-income countries found that many studies were of poor quality [34]. Of the 15 articles in the review, only 1 study demonstrated improvement in morbidity and mortality [34]. Similar results were found in a systematic review [32]. However, although this review did not observe improvements in maternal and neonatal health outcomes, it noted that some studies improved antenatal and postnatal care attendance. There was also an increase in the number of women who gave birth at a health facility or with a skilled birth attendant. The review also assessed how mHealth interventions affected health knowledge, but the findings on this were inconclusive. Finally, the study stressed some contextual features of campaigns linked to their success. These included using lay terms, communicating in local languages, and considering how to communicate with illiterate populations. The article stressed the latter's importance as mHealth studies risk increasing health inequities because access to mHealth interventions may be biased toward people of higher socioeconomic status and those residing in urban areas. Another systematic review [33] concluded, contrary to the other papers [32,34], that mHealth for prenatal and newborn health services demonstrated positive outcomes. However, in most cases, the interventions consisted of providing people in rural areas with mobile phones and data to enable them to contact health services. Only 1 study in this review focused on the use of mHealth for health promotion. A review article from 2019 concluded that maternal health was one of the areas in which mHealth was most frequently and successfully used [35].

An important paper to mention is that by Lund et al [5], which reports on a cluster randomized controlled trial in Zanzibar focusing on an SMS text messaging campaign with the primary outcome measure being the number of women who attended 4 antenatal visits as recommended by the WHO. The study found that more women in the intervention arm attended the recommended antenatal visits. Most participants also stated that the educational SMS text messages were helpful during their pregnancies. Furthermore, the authors concluded that the study showed that mobile phones could improve the quality of care by creating awareness about services on the demand side. Similarly, Maslowsky et al [36] found positive evidence for using a mobile phone–based education program in Ecuador. The study noted improvements in breastfeeding, contraceptive use, and infant health but not in postpartum maternal health. A study with second-language English speakers in Cape Town (2012-2013) evaluated an SMS text messaging–based health information campaign on pregnancy and antenatal care [27]. The results showed no statistically significant improvements in health knowledge at exit. However, participants reported that their behavior changed because of the SMS text messaging campaign.

Between 500,000 and 1.5 million South Africans are estimated to be Deaf and use SASL [37]. Communication is a serious barrier to Deaf people's access to health care and health information with poorer health status [38-43]. Communication problems between Deaf people and health care providers result in delays in diagnosis, missed appointments, repeat visits, misdiagnoses, and misunderstandings [38-42].

Furthermore, Deaf people are often excluded from health research and have limited access to health education programs. Consequently, according to American and Australian studies, their health literacy is poorer than that of the general population [43-45]. Illustrative of this is an American study, which concluded that the Deaf individuals were almost 7 times more likely to have inadequate knowledge about health than hearing participants [45].

There is a paucity of research on health literacy among the Deaf population in low- and middle-income countries. We did not find any studies focusing on health literacy in low- and middle-income countries, including South Africa. However, Deaf South Africans generally have low educational levels, with the average reading level for those attending schools for the Deaf population being lower than the fourth grade [46]. This indicates that their health literacy levels would be equally low.

Health information in South Africa is provided in several ways, including television programs; written material such as pamphlets and posters, which are often displayed at public health clinics; and talks at public health clinics. None of these are easily accessible to Deaf people. The text-heavy written information is inaccessible because of their low literacy and the language level used [46]. Television programs are inaccessible because of the Deaf individuals' disability, as are talks at the clinics as they are conducted without sign language interpreters. Health communication in sign language has its own challenges. Sign language is a unique language of so-called limited diffusion [47]. This means that it has a limited vocabulary in areas such as health. In other words, certain health concepts may not have an equivalent sign.

Cell phones can be considered an alternative way of communicating health information with signing Deaf people. Most South Africans (75%) have access to a cell phone [48]. Figures are not known for the Deaf population, but we know from our long-term association with Deaf South Africans that SMS text messages have become an important method of communication. For instance, we have previously used SMS text messages to advertise an interpreter service in health care for Deaf people [39].

Limited studies have focused on evaluating SMS text messaging campaigns for the Deaf population. The authors of this paper were involved in a similar study focusing on hypertension knowledge [49], which demonstrated a statistically significant improvement in health knowledge after the SMS text messaging intervention and, thus, indicated that SMS text messages can improve signing Deaf people's health knowledge. Apart from this study, we did not find any study that evaluated SMS text messaging campaigns with Deaf people. Other health information campaigns focusing on the Deaf population that were identified used videos to convey information on various

forms of cancer [50-53]. These studies were conducted in the United States and concluded that videos successfully improved short-term health knowledge.

Research Justification

This study is based on our knowledge that Deaf people have limited health literacy, but we know from our day-to-day experiences with the Deaf population that they are familiar with using SMS text messages for health care. On the basis of this, we hypothesized that providing Deaf women of reproductive age with easily understandable information about pregnancy, antenatal care, and healthy living during pregnancy via SMS text messages could improve their knowledge. We assumed, drawing on the Health Belief Model [53] and the Theory of Planned Behavior [54], that adequate knowledge is a prerequisite to health-seeking behavior. Furthermore, General Comment 14 on the Covenant on Economic, Social, and Cultural Rights [55], an expert interpretation of the right to health, considers informational access an important component of the right to health. South Africa ratified the covenant in 2015. In line with a human rights framework and behavior theories, we viewed informational access as both a human right and a prerequisite for improving access.

Methods

We aimed to explore whether an SMS text messaging–based health information campaign for Deaf women of reproductive age could improve their knowledge of pregnancy, antenatal care, and healthy living during pregnancy (Multimedia Appendix 1). The secondary aim was to assess the acceptability of an SMS text messaging campaign among the target population.

Study Population

The study population was adult Deaf women of reproductive age (18-45 years) whose first language was SASL. Deaf South Africans are a hard-to-reach population. There is no database of this population, and they are geographically dispersed. They also do not use the same health services, meaning that sampling is challenging. Consequently, we used convenience sampling, relying on our contacts with Deaf people and Deaf organizations. Although a larger sample size would have been preferable, preliminary work suggested that we would not be able to include >50 participants in the study.

Study Design

The study was a mixed methods study consisting of a quantitative component in the form of questionnaires before and after the SMS text messaging intervention. The quantitative part was conducted between June 2013 and November 2013. Although a controlled trial would have resulted in more robust evidence, we believed that such a study design was unreliable as Deaf people in Cape Town form a very close community. This increased the risk of participants sharing information, rendering a controlled trial study design invalid. The second research component was qualitative, a focus group, which explored the results of the quantitative data. The focus group was conducted in May 2014.

The SMS text messaging campaign drew on a campaign with hearing pregnant women, where topics for the campaign had been identified in collaboration with a midwife obstetric unit in a resource-poor setting. A health promotion specialist and an obstetrician also commented on the SMS text messaging campaign. The campaign was amended to address women who were not necessarily pregnant during the campaign and to take Deaf people's limited literacy and health knowledge into account by simplifying the language. Deaf research assistants vetted the baseline and exit questionnaires (Multimedia Appendices 2 and 3). The campaign was also piloted with Deaf research assistants. The campaign contained 66 SMS text messages distributed over 22 weeks.

Recruitment and Consent

Recruiting was challenging as the group was geographically dispersed and not registered in a database. We relied on our association with Deaf people and their organizations, primarily the Deaf Community of Cape Town (DCCT), to invite potential participants to information meetings. These meetings were conducted in SASL via an interpreter. In addition, we showed a DVD that explained the research and the consent process in SASL. Potential participants were invited to enroll in the research project on a separate occasion, where Deaf research assistants and translators proficient in SASL answered questions and ensured that participants were informed and consented voluntarily.

Written project information sheets, consent forms, the SMS text messages, and the baseline and exit questionnaires were translated from English into Afrikaans and isiXhosa, the 2 languages used in addition to English in Cape Town. Back translations, in which the Afrikaans and isiXhosa translations were translated into English, ensured consistent information and meaning across the 3 languages.

Data Collection

After obtaining consent, research assistants administered the baseline questionnaire in SASL. The baseline questionnaire contained 9 questions measuring participants' knowledge about pregnancy, antenatal care, and healthy living during pregnancy. In total, 4 questions had simple binary answers, such as "Is it important for a pregnant woman to attend pregnancy clinic?" A total of 5 questions had multiple answers, such as "How can a pregnant woman stay healthy during pregnancy?" These questions were presented as multiple-choice questions. In addition to the questions on health knowledge, the exit questionnaire contained questions about communication preferences, acceptability of the SMS text messages, and the experience of receiving the SMS text messages.

A focus group with participants who had received most of the SMS text messages took place 6 months after the exit questionnaire and after analyzing the quantitative data. On the basis of the quantitative results, an interview guide was developed to explore the impact, acceptability, and experience of the SMS text messages. The main author conducted the focus group with the assistance of sign language interpreters and Deaf research assistants. The focus group (the interpreter's voice-over) was recorded and transcribed.

For the focus group, we invited only participants who had received >80% of our SMS text messages. The research team monitored the delivery of SMS text messages and was aware that not all the SMS text messages were delivered. First, some participants opted out of the campaign or lost their phones. Second, some SMS text messages were not delivered as the phone numbers changed or the phones were left uncharged or switched off for some time. In addition, we found out that it is quite common to share phones among friends and family or change numbers frequently. The loss of cell phones, frequent number changes, uncharged or switched-off phones, and the sharing of phones present confounding factors. As we only became aware of these factors after the quantitative data had been collected, we were not able to control for them.

Data Analysis

To determine whether there was a change in knowledge, each question and an individual's total score were analyzed. Each question generated either categorical or continuous data. To determine if the intervention resulted in significant knowledge change, the categorical data were coded into binary outcomes, with "1" signifying correct answers and "0" signifying incorrect answers. The proportion of correct answers was then compared between baseline and exit using the McNemar test for continuous data, and the score for each question was tallied. Correct answers were worth "1," and incorrect answers were worth "−1." "Don't know" was worth "0." Owing to the relatively small sample size, a Wilcoxon signed rank test was used for all continuous data. The overall score was calculated by tallying the scores of each question at both baseline and exit. The main author analyzed the qualitative data using inductive thematic analysis and discussed it with the other authors.

Ethics Approval and Informed Consent

This study adhered to the Declaration of Helsinki and was approved by the University of Cape Town Health Science Faculty Human Research Ethics Committee (044/2011). Participants provided written informed consent.

Results

Quantitative Results

The study recruited 50 participants at baseline, of whom 8 (16%) were lost to follow-up, leaving 42 (84%) to complete the exit questionnaire. Furthermore, 19% (8/42) of the participants were excluded before the analysis of the survey data as they stated that they did not receive or were uncertain about receiving the SMS text messages. Therefore, the exit survey involved 34 participants.

The mean age of the participants was 34.88 (SD 18) years. Their marital status varied, with 26% (9/34) being married, 18% (6/34) living with a partner, 24% (8/34) living with family, and the rest being single or living with others (11/34, 32%). Most (31/34, 91%) had not finished their high school education. A total of 65% (22/34) were employed but earning a relatively low salary. Most (32/34, 94%) stated that they had been pregnant at least once.

A summary of the demographic profile of the participants is provided in Table 1.

The survey results showed a statistically significant improvement in overall knowledge between baseline and exit (P=.002). Tables 2 and 3 show the knowledge improvements for questions with 1 correct answer and multiple correct answers, respectively.

When analyzed individually, 33% (3/9) of the continuous questions showed a statistically significant increase. These were (1) How can a pregnant woman stay healthy during pregnancy? (2) How do drugs and alcohol affect the baby growing in the womb? (3) Should a pregnant woman seek medical help outside her appointments at a pregnancy clinic?

Table 4 shows the improvements for the questions that showed a statistically significant improvement as well as the overall results when all questions were tallied.

The exit questionnaire also explored the acceptability of the SMS text messaging campaign and aimed to assess its usefulness. On a question to determine its usefulness, 94% (32/34) said that the campaign was useful. In line with the survey results, most participants (31/34, 91%) indicated that the SMS text messages had improved their knowledge. A total of 82% (28/34) were unsure, whereas 3% (1/34) of the participants said that it did not improve their knowledge. In total, 65% (22/34) reported that they found the SMS text messages easy to understand, whereas 8% (3/34) did not. Approximately 27% (9/34) were uncertain of how accessible the information was.

One question assessed what participants liked about the SMS text messages. The main quality was that they provided information (31/34, 92%), whereas 76% (26/34) indicated that they considered them trustworthy. A similar number stated that the SMS text messages made them feel cared for. However, 14% (5/34) indicated that the information was irrelevant.

Notably, 59% (20/34) of the participants indicated that they preferred health communication from Deaf organizations, mainly the DCCT. This was followed by information from friends, family, and colleagues, which 19% (6/34) preferred. Written material was preferred by 14% (5/34) of the participants. Interestingly, only 14% (5/34 of respondents indicated that they preferred SMS text messages. Similarly, friends, family, and colleagues were the most common source of information (15/34, 43%). Written material was used by 35% (12/34) of participants, and SMS text messages were used by 32% (11/34). For an overview of communication preferences and acceptability, see Table 5.

Table 1. Demographics for participants in the exit survey (N=34).

	Values
Age (years), mean (SD)	35 (18)
Marital status, n (%)	
Divorced	0 (0)
Married	9 (26)
Single, living alone	5 (15)
Single, living with family	8 (24)
Single, living with a partner	6 (18)
Single, living with nonfamily	5 (15)
Widow	1 (3)
Educational level, n (%)	
Below grade 7	15 (44)
Between grade 7 and grade 12	16 (47)
Passed high school	2 (6)
Post–high school education	1 (3)
Employment status, n (%)	
Employed	22 (65)
Pensioner	1 (3)
Unemployed	7 (21)
Not looking for employment	1 (3)
Never worked	3 (9)
Monthly income, n (%)	
None	7 (21)
Pension or social grant	8 (24)
<ZAR 4000 (US $222.59)	14 (41)
Between ZAR 4000 and ZAR 10,000 (US $222.59-$556.48)	2 (6)
>ZAR 10,000 (US $556.48)	0 (0)
No answer	3 (9)
Preferred language for reading and writing, n (%)	
English	26 (76)
Afrikaans	5 (15)
isiXhosa	3 (9)
Gravidity, n (%)	
0 pregnancies	2 (6)
1 pregnancy	8 (24)
2 pregnancies	11 (32)
3 pregnancies	9 (26)
4 pregnancies	2 (6)
5 pregnancies	2 (6)

Table 2. Knowledge scores for questions with binary answers presented as the number of people with adequate knowledge at baseline and exit (N=34).

Question	Baseline, n (%)	Exit, n (%)	*P* value
Is it important for pregnant women to attend pregnancy clinics?	30 (88)	33 (97)	.25
Should a pregnant woman ask for the results of her pap smear (a test that checks for cancer of the mouth of the womb)?	21 (62)	23 (68)	.80
Why do the nurses test the urine and blood pressure when pregnant women attend a clinic for pregnancy?	13 (38)	14 (41)	>.99
Why should a pregnant woman take folic acid tablets (which she gets at the clinic) during pregnancy?	5 (15)	12 (35)	.12

Table 3. Knowledge scores for questions with multiple correct answers (N=34).

Question (number of correct answers/number of options) and number of correct answers selected	Baseline, n (%)	Exit, n (%)	*P* value
Why do the nurses test the blood of pregnant women? (3/7)			.96
0	19 (56)	22 (65)	
1	13 (38)	6 (18)	
2	2 (6)	6 (18)	
3	0 (0)	0 (0)	
How can a pregnant woman stay healthy during pregnancy? (4/9)			.03
0	8 (24)	5 (15)	
1	6 (18)	3 (9)	
2	9 (26)	3 (9)	
3	6 (18)	11 (32)	
4	5 (15)	12 (35)	
How do drugs and alcohol affect the baby growing in the womb? (2/3)			.048
0	22 (65)	10 (29)	
1	9 (26)	24 (71)	
2	3 (9)	0 (0)	
Should a pregnant woman seek medical help outside her appointments at the pregnancy clinic? (2/4)			.001
0	22 (65)	8 (24)	
1	10 (29)	15 (44)	
2	2 (6)	11 (32)	
What are the signs of labor? (3/6)			.16
0	16 (47)	14 (41)	
1	12 (35)	9 (26)	
2	5 (15)	7 (21)	
3	1 (3)	4 (12)	

Table 4. Knowledge scores for questions with a statistically significant improvement.

Question	*P* value
How can a woman stay healthy during pregnancy?	.03
How do drugs and alcohol affect the baby growing in the womb?	.048
Should a pregnant woman seek medical help outside her appointments at a pregnancy clinic?	.001
Overall score	.002

Table 5. Acceptability of SMS text messages (N=34).

Question	Participants, n (%)
Read all or most of the SMS text messages	34 (100)
Felt that the SMS text messages improved their pregnancy knowledge	28 (82)
Thought that the SMS text messages were easy to understand	31 (91)
Found the SMS text messages useful	31 (91)
Found the SMS text messages trustworthy	28 (82)
Felt that somebody cared about them	25 (74)
Found the SMS text messages entertaining	20 (59)
Found the information in the SMS text messages not helpful	3 (9)
Found the SMS text messages to be irritating	1 (3)
Did not like the SMS text messages	1 (3)
Felt that the SMS text messages were the best way of giving information to Deaf people	5 (15)

Qualitative Results

A total of 11 women took part in the focus group. This is equivalent to 30% (11/34) of participants in the exit survey. In total, 36% (4/11) of those participating in the focus group indicated that they had been pregnant during the SMS text messaging campaign. The demographic data of the focus group participants were largely similar to those of the participants in the survey.

The focus group confirmed that Deaf people have a health knowledge gap that SMS text messaging campaigns can potentially address. Participants explained that they faced challenges in accessing health information. Consequently, the focus group was used to seek more information and clarity on issues raised during the SMS text messaging campaign.

The focus group also confirmed the survey results by indicating that the SMS text messaging campaign gave participants important new information and raised their awareness. A participant summarized it as follows:

> *I found all the messages interesting, and I learnt things I never knew.* [Participant 1]

Another participant compared the SMS text messages with other information sources such as pamphlets handed out at the clinics:

> *At the clinic, they always have people who come and teach health information, but we never have an interpreter for us. They give us pamphlets with complex language...So, it is very hard for us to understand. So, it was easy for us to learn with the UCT's (University of Cape Town) SMSs.* [Participant 2]

In general, participants argued that their understanding was facilitated by the SMS text messages using simple language and being brief, as illustrated by the following quote:

> *For me, it's easy to understand UCT's SMSs because they have simplified the terminology. (It is easier) than having to read a pamphlet from the clinic that is made for hearing people and that is made for academic people. That terminology I really don't understand as much as I understand the SMSs.* [Participant 3]

However, some participants argued that they found the SMS text messages challenging to understand, mirroring the survey, where 27% were uncertain of how accessible the information was. Medical terminology was particularly challenging. Words such as *abdominal* and *fetal alcohol syndrome* were noted as being particularly difficult. A participant explained that there was no sign for the word *abdominal*. Referring to an SMS text message about the possible harmful effects of alcohol in increasing the risk of FAS, another woman explained the following:

> *So, that word, I don't understand. (The baby) might be born with what? So I think I still need to clarify and learn more about that because I understood from the SMSs that when a woman is pregnant, she must not drink because "this" (foetal alcohol syndrome) could happen to the baby. But I don't know what could happen to the baby.* [Participant 4]

Another participant had a different experience with the SMS text message referring to FAS. She explained that she had seen posters at the clinic saying that pregnant women should not drink but had not understood the reason. According to her, it was different with the information in the SMS text messages:

> *During pregnancy, we go to the hospital, and you will see posters around with a picture of a pregnant woman and then a bottle of alcohol saying, "you must not drink alcohol," but you won't know how serious it is. How can it affect the baby? Then you'll find yourself continuing drinking while you are pregnant, but with UCT's SMSs it was more clear. We understand that we must not take alcohol because it can affect the baby.* [Participant 5]

Participants who found the SMS text messages difficult to understand talked about their poor educational background resulting in their difficulties with written information. Several participants suggested that the SMS text messages could be made more accessible by using simpler language. Others argued that the SMS text messages could use "sign language structure,"

a form of informal writing that uses the unique structure of sign language, which has its own word order and grammar:

> *So, if you can just make it like easier for us Deaf people, you can put it in sign language structure. That will actually be helpful for us.* [Participant 6]

However, there was disagreement on this point, with some participants arguing that the SMS text messages should be in plain English but at the same time introduce medical terminology, which should be explained. They reasoned that it was important to retain medical terminology in the SMS text messages as this could improve their knowledge of it. Knowing medical terms, they argued, would make it easier for them in a health care setting, as illustrated in the following quote:

> *The SMSs that we received, they helped us a lot because before UCT sent the SMSs, we didn't know anything. Even when we go to the doctor, we don't know; we don't notice when something is about to happen. But then, when we received the SMSs, we could see that this had happened to me before, but I didn't know. I couldn't go to the clinic because I didn't know what was happening. The SMSs helped us a lot to understand and to see what we missed on...so the SMSs were really helpful.* [Participant 7]

The use of pictures in the SMS text messages was also advocated for by participants, who explained that Deaf people are more familiar with visual communication, which can help them understand written language:

> *If UCT's SMSs could be accompanied by pictures. It's easy when they speak about feet or about the nose; then there will be a picture of the nose.* [Participant 8]

Another theme raised in the focus group was that the SMS text messages were insufficiently detailed, and participants requested more information. This is not surprising when considering that the SMS text messages were limited to 160 characters. Participants suggested that the SMS text messaging campaign be combined with a communication service where they could write back and ask to have a word explained further or obtain more information.

An important suggestion for improvement was using signed video messages (Multimedia Messaging Services [MMSs]). Participants suggested that this was a better mode of communication for Deaf people than written SMS text messages:

> *I did not like the fact that it was written. I would have preferred videos of a sign language interpreter. We should have been able to obtain it (the information) via sign language.* [Participant 9]

A theme that also indicated Deaf people's preference for visual communication was a preference for the health dramas organized by the DCCT. Participants said that they preferred these dramas as they found them both informative and entertaining. Furthermore, many participants argued that using different communication modes would strengthen the campaign's effectiveness:

> *I would say DCCT is good, but it's more good [sic] when you mix DCCT with the SMSs that you receive from UCT because you will see them having a drama at DCCT and then it will match what you will receive from the SMSs. So, it's like a learning curve that is big. So together, they make a lot of sense.* [Participant 10]

Notably, the quotes highlight that the combination of different communication modes can be useful as it bridges the gap between a form of communication familiar to Deaf people—signs and visual communication—with the medical world dominated by words and medical terminology. There was consensus among focus group participants that effectiveness would likely improve by using different methods to convey the same health information. This was related not only to the dramas and SMS text messages but also to the pamphlets they received at the clinics.

Similarly, the repetition of information, built into the SMS text messaging campaign, improved effectiveness. Most participants felt that repetition was beneficial for retaining the knowledge conveyed:

> *It is good because it is like you receive a reminder. Maybe you will get an SMS first, and then with time, because you receive a different SMS...and then when that SMS comes again, it's like a constant reminder that you must not do this. So that's why it is good.* [Participant 11]

Similarly, many participants said that they kept the SMS text messages on their phones for easy retrieval, and some wrote down the SMS text messages in a notebook. This enabled them to use the messages to gain further information or seek clarity on the meanings that they did not understand. Being able to reread information also seemed to be beneficial, as the following quote indicates:

> *Some of them were a bit hard for me to understand, but now because they are on my phone, I can always go back and refer. So now the words I didn't understand a bit, now I can understand because it being there, I can always refer back.* [Participant 12]

Our primary aim was to improve knowledge among participants, and our study population comprised women of reproductive age. However, 36% (4/11) of the focus group participants had been pregnant during the SMS text messaging campaign. All women who had been pregnant (4/4, 100%) commented that the campaign had affected their health-seeking behavior. This suggests that SMS text messages may also be an effective way of influencing healthy behavior. In particular, their eating habits were altered. A woman said that nurses had complained about her "behaviour" during her first 2 pregnancies but explained that she changed after receiving the SMS text messages:

> *So UCT helped me to understand that during my pregnancy, I need to eat healthy food. I need to cut the drinks aside, fats aside. So, it helped me a lot, and I was able to have a normal pregnancy until I delivered.* [Participant 13]

In a similar way, the following woman explained how the SMS text messaging campaign assisted her in having a healthy pregnancy:

> *Ok, on my first pregnancy, I was going to the hospital alone, and then I didn't understand what to eat, and then all the time, nurses and midwives would shout at me, "why is your blood pressure so high?," "Why are you not taking care of yourself?" And then I fell pregnant again. And still, I didn't understand because UCT was not there, and there were no sign language interpreters. But then, when I went for the third time, luckily, I had the SMSs, and I had interpreters with me. And then I understood what is important to eat and all that. So, I'm grateful to UCT because I managed to change my lifestyle.* [Participant 14]

None of the women commented that the campaign influenced their clinic attendance. Furthermore, it is important to note that a healthy pregnancy and delivery for the aforementioned woman were also linked to the availability of a sign language interpreter during clinic appointments and delivery.

Discussion

Principal Findings

The results showed that participants' knowledge improved at exit, suggesting that SMS text messages can improve Deaf women's knowledge about pregnancy, antenatal care, and healthy living. A similar SMS text messaging–based health promotion campaign with hearing pregnant women attending an obstetric unit in a similar resource-poor setting showed no statistically significant improvement in knowledge after the SMS text messaging campaign [27]. Notwithstanding the fact that the women in the hearing study were pregnant, whereas the participants in the Deaf study were women of reproductive age, the difference between the 2 studies could suggest that SMS text messaging campaigns are particularly effective for Deaf populations. A possible explanation for the difference could be that Deaf participants' baseline knowledge was lower than that of participants in the hearing campaign. Therefore, the potential for impact was greater. Accessing health information is challenging for Deaf people, and methods that address these challenges, such as SMS text messages, may be particularly well suited for this group. This argument is supported by a similar study on hypertension among Deaf South Africans, which also showed an overall statistical improvement between baseline and exit [48]. In contrast, a linked study with hearing patients with hypertension did not show statistically significant improvements. Thus, although 2 SMS text messaging campaigns among hearing women in the same geographical locality did not result in improvements, 2 campaigns among Deaf populations did. We have not identified any other SMS text messaging studies with the Deaf population.

In addition to noting the overall statistically significant improvement, it is worth noting that knowledge improved for all 9 questions, although the gains were statistically significant for only 3. The first individual question that showed a statistically significant improvement was about healthy living during pregnancy, focusing on healthy eating, exercise, smoking, and alcohol consumption. The second individual question that showed statistically significant knowledge improvement related to how drugs and alcohol affect the unborn baby. This is particularly important to take cognizance of given that the Western Cape province, where this study took place, has the world's highest rate of FAS [11]. The woman who argued that new knowledge let her "to put the drinks aside" exemplifies how knowledge about the effects of alcohol was linked to self-reported behavior change.

Finally, a question assessing knowledge of when pregnant women should seek medical assistance outside clinic appointments registered a statistically significant improvement. The information conveyed in the SMS text messages and assessed in the questionnaire focused on symptoms such as bleeding, persistent frontal headache, sudden swelling, and lack of fetal movements. Given South Africa's many avoidable maternal deaths [4], it is important to explore ways of addressing these issues, including for Deaf women.

It is also important to note the research that found that 18% of Deaf pregnant women only seek antenatal care in the third trimester [15], partly because they lack knowledge of the importance of antenatal care. Furthermore, they have twice as many miscarriages as hearing South African women, which could be linked to not seeking antenatal care in emergencies. The literature has suggested that SMS text messages successfully got hearing women to attend 4 antenatal visits as recommended by the WHO [5,32], showing that SMS text messages can affect attendance patterns. Other studies have found that low antenatal attendance is linked to how women perceive benefits to mothers and children [2,10]. The fact that women in this study indicated that they understood the importance of accessing emergency care is a testimony to the impact that SMS text messaging campaigns could have on antenatal care attendance patterns. This should be studied further.

Despite the main finding of this study, it is important to note that 27% of participants were unsure of how accessible the information in the SMS text messages was. This is not surprising considering their low health and general literacy and the fact that sign language often lacks health terms [47]. Medical terminology was complicated for some participants, as illustrated by the quote on FAS. This affected the overall success of the campaign. This points to the importance of taking cognizance of Deaf people's needs and preferences for visual communication, such as pictures and posters, when designing health information campaigns. In particular, the proposal to use signed MMSs to disseminate health information at regular intervals seems promising.

An important advantage of signed MMSs is that medical terms can be better explained and more detailed information can be conveyed. However, signed MMSs may also have disadvantages compared with written SMS text messages. Some participants argued that it was essential for them that the written SMS text messages introduced them to written medical terminology, which they found helpful in clinical settings where they often rely on written notes to communicate with their health care provider. Although sign language interpreters can improve patient-provider communication [38], the reality for most Deaf

South African patients is that medical encounters occur without a sign language interpreter, resulting in difficulties in provider-patient communication [39]. In light of this, it is easy to understand why participants in the focus group stressed the importance of improving their understanding of written medical terminology.

Here, it is important to consider that sign language is a language of limited diffusion. It is worth considering initiatives such as the Australian Medical Signbank [47], which addresses this by developing signs related to health and medicine. Similar initiatives for SASL could strengthen health communication between providers and Deaf patients and be useful in signed MMS-based campaigns. However, in the absence of medical signs and sign language interpreters in medical consultations, Deaf South Africans' reliance on written notes for communicating with their health care providers means that knowing written medical terminology is an advantage. Whether signed MMSs and written SMS text messages are preferable should not be treated as an either-or question. Signed MMSs may be superior in imparting health information, whereas SMS text messages can introduce the Deaf individuals to written medical terminology essential in patient-provider communication. A possible solution could be to combine signed and written messages. Interestingly, a South African health app for the Deaf population is being developed and is considering combining text and signs [56]. However, data price should be considered when using MMSs as data costs are a barrier for Deaf South Africans [56].

Our project has shown that SMS text messaging campaigns are a valuable method to communicate health information to the Deaf population that currently seems underused. Other methods used with this target group include internet training workshops, peer education programs, and videos. The latter has successfully raised cancer awareness [50-53]. Compared with written SMS text messages, videos communicate in sign language and, thus, have similar advantages to MMSs. However, it is important to consider the context in which these video screenings took place. Although video screenings may work in the United States, where the studies were conducted, video screenings with Deaf South Africans could be challenged by limited geographical reach.

Furthermore, video screenings are one-off events, and retaining the information may be difficult. The studies on videos assessed knowledge 2 months after the screenings, and it is impossible to determine long-term knowledge retention, as it was in our study. Interestingly, participants in our studies mentioned that they kept the SMS text messages on their phones or wrote down the content in a notebook to be able to retrieve the information. They also noted that they appreciated that information was repeated as it aided their understanding. In some of the video studies, the video was uploaded to the internet, making it accessible for more than one viewing. However, it may present a barrier in the South African context, where most Deaf people have limited internet access, limited computer literacy skills, or cannot afford to access the internet [56]. In this context, MMSs may be a preferable option.

The secondary aim of this study was to assess the acceptability of the SMS text messaging campaign. The focus group suggested that SMS text messages were an effective and acceptable way of addressing participants' health knowledge gap. Participants appreciated the informative value of the SMS text messages, their briefness, and the accessible language. This is in line with the study by Zhao et al [31], which argued that design issues are important for successful mHealth campaigns. The features included not being time-consuming and being user-friendly and easily accessible. However, it is also important to acknowledge that 27% of our participants were unsure of how accessible the information was. This points to pilot campaigns' importance in assessing and addressing language and design issues.

A total of 12% (4/34) of the participants, who were pregnant during the study, reported behavior change. No clinical data were available to confirm this, and it is difficult to know whether the changes were real or reflected social desirability. However, self-reported behavior change should be seen at least as a desire or intent to change behavior. Furthermore, participants linked their new knowledge to behavior change, indicating that SMS text messages could be the first step in health-seeking behavior. Theoretically, this aligns with the Health Belief Model and the Theory of Staged Behavior [53,54,57].

Moreover, these tentative findings are similar to those of a study conducted by the same authors, which evaluated an SMS text messaging campaign on hypertension for the Deaf individuals [49]. This study showed self-reported behavior change among participants with hypertension. Although the results of both studies should be interpreted with caution because of the small sample sizes, they point to behavior change as an important area for future studies.

Areas for Further Research

Campaigns that combine different communication methods such as dramas, posters, pamphlets, and signed MMSs or written SMS text messages should be explored as encountering information in different ways seemed to aid understanding and knowledge retention. Signed MMSs, either on their own or in combination with written SMS text messages, seem to be a promising avenue for further research. In addition, combining information campaigns with an interactive communication service that enables Deaf participants to raise questions that can provide more detailed information should be considered. Such campaigns could benefit from the development of new signs for health and medical terms.

This study suggests that SMS text messaging campaigns may affect behavior change, but more rigorous studies are needed to investigate this area. In the field of antenatal care, several potential research areas were identified, including health care attendance in emergencies. Campaigns with Deaf women could assess the impact of SMS text messaging and mixed information campaigns on health-seeking behavior. A particular area is using mHealth to create awareness of the harmful effects of alcohol, which could potentially affect FAS incidents.

Longitudinal studies with a larger sample size and, if possible, randomized controlled designs would be useful to determine the potential of SMS text messaging campaigns among Deaf populations, improving knowledge and health behavior.

Evidence of their potential effects on behavior would be strengthened by including clinical measures.

Strengths and Limitations

The main strength of this study is that it demonstrates that SMS text messages can improve health knowledge about pregnancy, antenatal care, and healthy living during pregnancy for Deaf South African women of reproductive age. Along with a similar paper on hypertension knowledge among Deaf South Africans, it strengthens the argument that SMS text messages can address Deaf people's health knowledge gap. We have not been able to identify other studies that show this. Hence, this study contributes to understanding ways of improving Deaf people's health knowledge. This study also contributes to understanding how information campaigns for the Deaf population can be improved by paying attention to design aspects.

Loss to follow-up presents a limitation. The relatively small sample size may also limit the generalizability of our findings. Possible selection bias should be noted. Possibly, those who decided to participate had a particular interest in the topic. Similarly, it is conceivable that loss to follow-up resulted from participants finding the SMS text messages challenging to understand or uninteresting. It should also be noted that the study was conducted in a metropolitan area, which may affect the generalizability of our findings. A further limitation is that there may be volunteer bias among those attending the focus group. The possibility exists that only those who appreciated the SMS text messaging campaign decided to accept the invitation to attend the focus group. Behavior change was self-reported, was not supported by clinical data, and could reflect social desirability. The exit questionnaire for this SMS text messaging campaign was completed 3 weeks after the campaign ended, making it difficult to assess how much knowledge would be retained in the long term. Confounding factors such as loss of phones, uncharged phones, and sharing of phones should be controlled for in future studies.

Conclusions

Deaf people have limited access to health information. This study documents that SMS text messages were an effective and acceptable way of imparting information about pregnancy, antenatal care, and healthy living to Deaf women of reproductive age. SMS text messages for Deaf people need to pay attention to language and medical terminology. SMS text messaging campaigns for the Deaf population can be improved by paying close attention to Deaf people's communication preferences, for instance, using pictures or signed MMSs. Ideally, SMS text messaging campaigns for the Deaf population should be combined with an interactive form of communication that would enable Deaf participants to seek further information and ask questions. Furthermore, campaigns should explore the combination of different communication forms using signs and written language. Future research should examine whether SMS text messages can motivate behavior change.

Acknowledgments

The National Research Foundation, South Africa, and the University of Cape Town funded this study. The funding agencies played no role in the study design or in collecting, analyzing, and interpreting the data. Neither did they play a role in writing this paper. Their financial support is acknowledged with appreciation. The authors thank the Deaf people of Cape Town for participating in the project. They also thank their Deaf research assistants, sign language interpreters, and colleagues. The authors thank Kristen Daskilewicz, who analyzed the quantitative data. They also thank the South African National Research Foundation and the University of Cape Town for their funding.

All authors declared that they had insufficient funding to support open access publication of this manuscript. JMIR Publications provided APF support for the publication of this article.

Data Availability

The data set used during this study is available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
SMS text messaging campaign.
[DOCX File , 20 KB - pediatrics_v6i1e40561_app1.docx]

Multimedia Appendix 2
Baseline questionnaire.
[DOCX File , 21 KB - pediatrics_v6i1e40561_app2.docx]

Multimedia Appendix 3
Exit questionnaire.
[DOCX File , 23 KB - pediatrics_v6i1e40561_app3.docx]

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Abbreviations

DCCT: Deaf Community of Cape Town
FAS: fetal alcohol syndrome
mHealth: mobile health
MMS: Multimedia Messaging Service
SASL: South African Sign Language
WHO: World Health Organization

Edited by S Badawy; submitted 27.06.22; peer-reviewed by C Kruse, Y Xiang; comments to author 24.10.22; revised version received 15.12.22; accepted 25.12.22; published 22.05.23.

Please cite as:
Haricharan HJ, Hacking D, Lau YK, Heap M
Improving Knowledge About Pregnancy for Deaf South African Women of Reproductive Age Through a Text Messaging–Based Information Campaign: Mixed Methods Study
JMIR Pediatr Parent 2023;6:e40561
URL: https://pediatrics.jmir.org/2023/1/e40561
doi:10.2196/40561
PMID:37213174

Original Paper

Comparing the Effectiveness of a Web-Based Application With a Digital Live Seminar to Improve Safe Communication for Pregnant Women: 3-Group Partially Randomized Controlled Trial

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Abstract

Background: Medical internet interventions such as asynchronous apps and synchronous digital live seminars can be effective behavior change interventions. The research question of this study was whether digital interventions based on the Health Action Process Approach can improve pregnant women's safe communication and patient safety in obstetric care.

Objective: This study aims to compare a digital live seminar with a web-based application intervention and a passive control group and to identify which social cognitive variables determine safe communication behavior and patient safety.

Methods: In total, 657 pregnant women were recruited, and hereof, 367 expectant mothers from 2 German university hospitals participated in the pre-post study (live seminar: n=142; web-based app: n=81; passive control group: n=144). All interventions targeted intention, planning, self-efficacy, and communication of personal preferences. The 2.5-hour midwife-assisted live seminar included exercises on empathy and clear communication. The fully automated web-based application consisted of 9 consecutive training lessons with the same content as that of the live seminar.

Results: Controlled for sociodemographic characteristics, repeated measures analyses of covariance revealed that pregnant women significantly improved their self-reported communication behavior in all groups. The improvement was more pronounced after the digital live seminar than after the web-based application (P<.001; η_p^2=0.043). Perceived patient safety improved more for pregnant women participating in the live seminar than for those participating in the web-based application group (P=.03 η_p^2=0.015). A regression analysis revealed that social cognitive variables predicted safe communication behavior.

Conclusions: Overall, the web-based application intervention appeared to be less effective than the digital live training in terms of communication behavior. Application interventions addressing communication behaviors might require more face-to-face elements. Improving intention, coping planning, and coping self-efficacy appeared to be key drivers in developing safe communication behavior in pregnant women. Future research should include social learning aspects and focus on the practical application of medical internet interventions when aiming to improve pregnant women's communication and patient safety in obstetrics.

Trial Registration: ClinicalTrials.gov NCT03855735; https://clinicaltrials.gov/ct2/show/NCT03855735

(JMIR Pediatr Parent 2023;6:e44701) doi:10.2196/44701

KEYWORDS

Health Action Process Approach; HAPA; intention; safe communication behavior; patient safety; obstetric patients; digital intervention; web-based app

Introduction

Background

Medical internet interventions, such as asynchronous applications and synchronous digital live seminars, can be effective behavior change interventions [1]. In health care, several digital approaches have been used to improve patient safety [2-4]. Especially during the COVID-19 pandemic, digital interventions gained significance in reducing the risk of infection through personal contact [5]. Owing to lower costs, a potentially broader reach, and reduced logistic hurdles, research has focused on asynchronous training apps. Nevertheless, implementing an intervention can only be successful if the circumstances and stakeholder interests are considered [6].

One of the fields in which digital interventions could be especially useful is antenatal education and care [7]. Respectful maternity care, including safe and respectful communication, is an important aspect of obstetric practice and research [8]. Health care workers (HCWs) are encouraged to offer evidence-based care while also focusing on the personal needs and preferences of pregnant women and their families [8,9]. For a positive labor and birth experience, safe communication between the HCW and pregnant women and their families in a trusting, respectful, and empathetic environment is necessary [10]. In such an environment, pregnant women can openly share their feelings and needs [11-13].

Safe communication can be described as a multilateral process that involves sharing emotions, cognitions, and actions on a verbal and nonverbal level [14]. Although previous literature has mainly focused on communication competencies among HCWs, the literature is lacking in understanding safe communication behavior from the perspective of pregnant women and their families [15,16]. Previous research [9] showed that more than one-third of pregnant women reported that they felt unsure to ask questions or raise concerns while giving birth [17]. The reasons were perceived time constraints of HCWs, perceived power differences, and the worry of being perceived as a burden [17,18]. Despite these barriers, pregnant women's communication competencies are rarely considered during antenatal digital interventions. As a result, the literature on digital safe communication trainings for pregnant women is currently scarce and lacks evidence.

This is particularly important because poor and ineffective communication in health care settings is a contributing and leading factor for adverse events that are a threat to patient safety, according to the report of the Joint Commission [19]. Patient safety is the absence of harmful events that could have been prevented under the given circumstances; for example, by safe communication [20]. Both preventable and nonpreventable adverse events may lead to detrimental outcomes for patients [21-23]. In obstetric care, not only the mother but also the unborn child might be affected by adverse treatment processes, such as inadequate patient-provider communication, which have the potential to result in preventable adverse events [24,25].

It is evident that effective communication is a prerequisite for safe care in obstetrics. Communication behavior can thus be seen as a crucial preventive health behavior [15]. There is extensive literature on health behavior change, indicating that multiple psychological and social factors have to be addressed. A variety of theories and models have been developed and applied to explain and predict behavior change [26]. However, many theories and models struggle to predict not only intention but also the translation of a behavioral intention ("I will always voice my concerns") into behavior. There can be situational barriers, for example, pain and exhaustion during birth, as well as a lack of volitional factors such as coping planning [27]. A model that focuses on bridging this so-called intention-behavior gap to achieve behavior change is the Health Action Process Approach (HAPA) that examines social cognitive determinants of behavior [28].

The HAPA model assumes 2 distinct phases: first, in the motivational phase, an intention to act (in this case, to safely communicate with the HCW) is developed based on the individual's outcome expectancies and risk perceptions. In the second phase, the volitional phase, this intention is brought into action through planning. During all the stages of behavior change, situational barriers and facilitators intercorrelate with this process [28]. Self-efficacy beliefs are crucial for planning, adopting, and maintaining a new behavior [29].

To actually improve safe communication behavior instead of the intention to communicate safely and thus reduce potential preventable adverse events, digital interventions must be tailored to the social cognitive barriers and facilitators for pregnant women. Previous literature has demonstrated that interventions based on motivational and volitional theories, such as the HAPA, are effective in improving health-related behaviors such as safe communication [16,30,31]. The HAPA model has rarely been applied to predict and improve safe communication behaviors in health care [16,31]. Most interventions are solely offered to the HCW.

Current Research

Taken together, pregnant women's safe communication behavior in the context of obstetrics requires further examination, especially regarding digital antenatal communication interventions during the COVID-19 pandemic. Therefore, this study will evaluate 2 digital interventions that are hypothesized to improve perceived communication behavior and perceived patient safety within the sample of pregnant women and investigate behavior change determinants. The aim of this study was to compare the effectiveness of a web-based application intervention with a digital live seminar and a passive control group (CG).

Thus, the hypotheses are as follows:

- Hypothesis 1: pregnant women who use the web-based application before giving birth will show greater improvement in the primary outcome of safe communication behavior and the secondary outcome of perceived patient safety than women from a passive CG. Their improvement was comparable with an intervention group that received a web intervention (web live seminar).
- Hypothesis 2: the HAPA model can explain the safe communication behavior of pregnant women after

web-based application interventions; coping planning, coping self-efficacy, and intention are associated with safe communication behavior after digital interventions.
- Hypothesis 3: perceived patient safety is associated with safe communication behavior after web-based application use.

Methods

TeamBaby Project

Data collection took place within the TeamBaby Project, which aimed to investigate and improve the psychological mechanisms underlying safe communication behavior in obstetrics, specifically before and during birth. The TeamBaby Project is funded by the German Innovation Fund (project number 01VSF18023) of the Gemeinsamer Bundesausschuss (G-BA) and registered with ClinicalTrials.gov (ClinicalTrials.gov identifier: NCT03855735).

Recruitment and Procedures

Participants

All participants were pregnant women intending to give birth at 1 of 2 project-affiliated university hospitals providing the highest level of care in affiliated neonatal intensive care units. Within the 2 university hospitals, expecting mothers were approached by a project-affiliated study nurse and a research associate. Recruitment was facilitated by distributing flyers, posters, and registration forms at key locations (antenatal clinics, waiting rooms, wards, corridors, and lifts) as well as through social media posts. In addition, gynecologists in private practice, midwives, counseling centers, and pharmacies were approached with additional material to distribute to their clients. Participants registered via email by filling in a registration form. During the registration process, participants were provided with an informed consent form offering a detailed description, including the outcomes of the study. Furthermore, as part of the informed consent, participants were informed of whether they were randomly allocated to the intervention or passive CG. In addition, participants were informed that no harm or unintended effects were expected as part of their participation. To ensure the privacy and confidentiality of the obtained data, each pregnant woman was asked to generate a unique pseudonymization code and subsequently received a baseline questionnaire (provided that informed consent was given) afterward. Further inclusion criteria were sufficient knowledge of German and age of maturity (>18 years). Expectant mothers created their own participant codes, using the following scheme: (1) the first 2 letters of the father's surname, (2) the first 2 letters of the mother's surname, and (3) the birthday of the expectant mother. In accordance with the data security approval obtained, the process of pseudonymizing the data allowed for no conclusions regarding personal data.

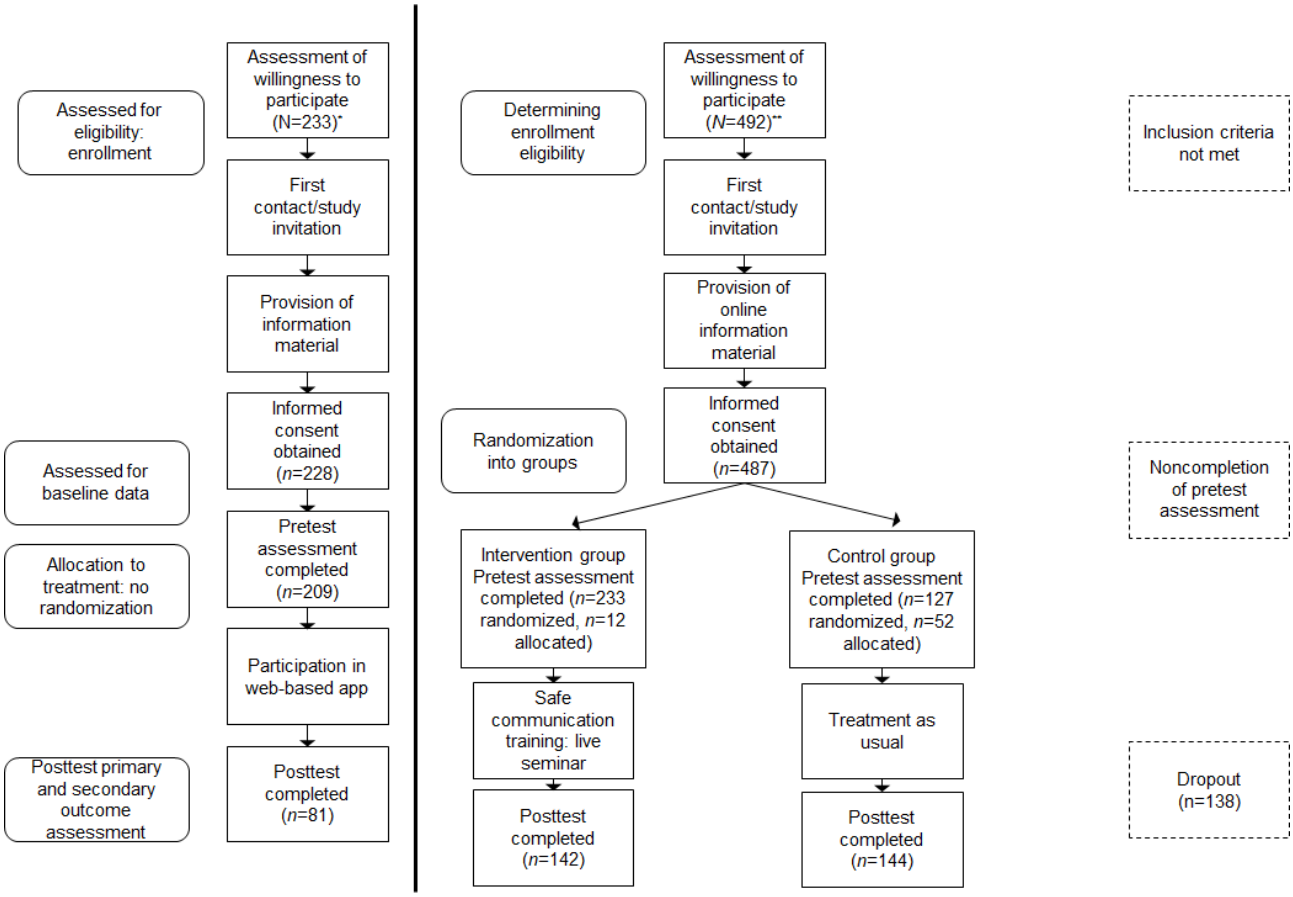
Between June 2020 and August 2021, participants were randomized to either an intervention group that received a digital live seminar training (live seminar group [IG1]) or a passive CG. Women in the passive CG were fully informed about the study, including the possible intervention, before the randomization. They did not receive any additional intervention or educational material. The randomization for the live seminar was prepared and performed by project-affiliated team members (study nurses and research assistants) at the 2 hospitals. For this purpose, closed envelopes were prepared in a ratio of 3:2 for 77.6% (222/367) of pregnant women.

Although a complete randomization was planned, 52 (36.1%) of 144 women had to be allocated to the CG owing to their expected due date. To ensure that the live seminar worked in a group setting, 12 (8.3%) of 144 women who provided postpartum survey data for the intervention group were not randomized but were assigned when the live intervention started between August 2021 and June 2022, and a third group of expectant mothers were recruited for the web-based application intervention (web-based application group [IG2]). Participants were informed of the study in writing and asked to provide informed consent before participation. As with the digital live trainings, participants were asked to create a unique pseudonymization code to ensure that all privacy and confidentiality regulations were met as part of the data collection and evaluation.

Different recruitment periods were planned from the beginning to avoid overlapping recruitment efforts at the 2 hospitals. Nevertheless, the recruitment of pregnant women for the digital live seminar took place during COVID-19 pandemic restrictions, including access restrictions for both support persons and the study personnel. Participants answered the survey questions twice (before and after birth), with the abovementioned interventions conducted before giving birth. The participants did not receive any form of compensation for their participation in the study.

A detailed description of the recruitment process and dropout from the interventions is shown in Figure 1.

Figure 1. Flowchart of study participation. *Study flow for the web-based application intervention group. **Previous live seminar intervention and the passive control group.



Interventions

For the digital live seminar, content for communication training was developed by 2 organizations that consulted on patient safety and communication in collaboration with the research team. The content was delivered through a 2.5-hour web session facilitated by 2 communication trainers, including a *physician* and midwife. Details of the training provided to the pregnant women and their partners have been described elsewhere [32]. The HAPA and Behaviour Change Taxonomy were used to guide intervention development [33]. To prepare for the live seminar, pregnant women completed a self-reflection questionnaire regarding their birth preferences. The live seminar consisted of an introduction round to uncover individual needs and potential communication approaches. Subsequently, an exercise on perspective taking (“empathy maps”) was included to invite participants to take the point of view of the HCW. Then, the pregnant women practiced communication competencies while considering typical situations in obstetrics. “Speaking up” to voice own concerns and “closed-loop communication” to facilitate mutual understanding were introduced. Finally, participants were invited to develop a behavioral plan regarding the communication of their individual needs.

The training used in the web sessions was adapted for the fully automated web-based application intervention. The web-based application was also based on the HAPA and behavior change techniques (BCTs) [33], aiming to (1) raise awareness of the importance of communication behavior, (2) create an intention to apply communication strategies, and (3) raise belief in one’s ability to use and implement strategies. In line with the live seminar targeting pregnant women’s safe communication behavior, the psychological interventions implemented in the web-based application focused on BCTs that could be linked to the HAPA. These included goal setting (outcome; BCT 1.3), commitment (BCT 1.9), monitoring of emotional consequences (BCT 5.4), instruction on how to perform the behavior (BCT 4.1), discrepancy between current behavior and goal (BCT 1.6), information about health consequences (BCT 5.1), and feedback and monitoring (BCT 2).

Content and adaptations for the German web-based application were developed with physicians from 2 university hospitals (n=4), psychologists (n=4), and the German Alliance for Patient Safety. The content from the web training was further iterated by project researchers (psychologists), obstetricians at clinics, and web application developers. The development process included a beta version of the web-based application tested by an affiliated health insurance company. The web-based application was accessible through all web browsers. It consisted of 10 consecutive lessons, from basic communication competencies to action plans. The details of the modules in the web-based application are provided in Tables S1 and S2 in Multimedia Appendix 1.

Measures

Overview

The primary outcome of the study was pregnant women's communication behavior, and the secondary outcome was perceived patient safety. As behavioral determinants, action planning and coping planning were assessed using self-reported questionnaires. Items stemmed from previously validated scales [34-36], which were revised by the project team (obstetricians and health psychologists). The questions were administered in German.

Communication Behavior

Communication behavior was assessed via 7 items from a self-constructed scale based on the communication competencies by Rider and Keefer [35], "During pregnancy, I have communicated my needs clearly." The answer categories ranged from 1 (does not apply at all) to 6 (applies fully and completely), with a Cronbach α of .63 at the first time point (T1) and .81 at the second time point (T2).

Perceived Patient Safety

Perceived patient safety was measured as perceived patient safety risks with 9 items that were adapted to the pregnant women's perspective from a self-constructed and previously validated scale [37], "Before, during and after birth, I observed at least once that not enough healthcare workers were present." The answer categories ranged from 1 (does not apply at all) to 6 (applies fully and completely) at baseline and 1 to 4 in the questionnaire after birth, with a Cronbach α of .82 at T1 and .85 at T2. Baseline values were recorded using the formula "Y = (B − A)*(x − a)/(b−a) + A," with the old minimum (a), new minimum (A), old maximum (b), and new maximum (B) [38]. Higher levels indicate more perceived risks and thus a lower perceived safety.

Coping Planning

Coping planning was measured with a single item based on previously validated items in other behavioral domains [34]: "I was able to practically apply my plans for communicating during birth, even when encountering difficulties." The answer categories ranged from 1 (*much lower compared with other patients*) to 5 (*much higher compared with other patients*).

Coping Self-Efficacy

Coping self-efficacy was assessed via a self-constructed single item on the basis of previously validated items in other behavioral domains [34]: "I was sure I could communicate well even when I was tired or exhausted." The answer categories ranged from 1 (does not apply at all) to 6 (applies fully and completely).

Intention

Intention was assessed via 2 self-constructed items on the basis of previously validated items in other behavioral domains [34], "I intend to always pay attention that I communicate safely with the doctors and midwives." The answer categories ranged from 1 (does not apply at all) to 6 (applies fully and completely), with a Spearman ρ of 0.71 at T1.

Sociodemographic Data

Age, marital status, highest level of education, and nationality were assessed in categorical data. Age (1: "younger than 20 years of age"; 2: "20-29 years"; 3:"30-39 years"; 4: "40-49 years"), education (1: "middle school degree or lower"; 2: "high school diploma"; 3: "vocational training"; 4: "university degree"), and marital status (1: "single"; 2: "in a relationship"; 3: "married"; 4: "divorced/separated") were measured in 4 categories. Nationality (1: "German" or 2: "Other") was measured dichotomously.

Statistical Analysis

All analyses were conducted using SPSS software (version 29.0; IBM Corp). The authors were not blinded to the analysis. Regarding hypothesis 1, 2 repeated measures analyses of covariance were used to examine and compare changes in safe communication behavior and patient safety across the 3 groups (IG1, IG2, and CG) in a pre-post design. For the repeated measures analyses of covariance, age, nationality, relationship status, and education were recoded into binary variables, so they could be added as covariates. For age, 2 binary variables were used to compare younger patients with patients in the age range of 30 to 39 years and older patients with patients in the age range of 30 to 39 years. Nationality was recoded to compare German participants with pregnant women of a different nationality. Relationship status was recoded to compare pregnant women currently in a relationship with those currently single for different reasons (including separated or divorced). The educational level was recoded as "university degree" versus "other." Finally, the group factor was added as 2 binary variables to compare IG2 with IG1 and the CG. To test the drivers of safe communication behavior (hypothesis 2) and the association of patient safety with communication behavior (hypothesis 3), regression paths based on the HAPA model were analyzed for all 3 groups (IG1, IG2, and CG). Table S3 in Multimedia Appendix 1 shows the partial intercorrelations between variables. In the partial correlations of the studied variables, age, marital status, education level, and nationality were included as control variables. Missing values occurred in ≤5% of all cases. Thus, missing data were handled via listwise deletion.

Ethics Approval

The Declaration of Helsinki was adequately addressed, and this study was approved by the Ethics Committee for Human Research of the University Hospital Ulm (number 114/19) and the Ethics Committee for Medical Research of the University Hospital Frankfurt (number 19-292). Approval for this study was obtained without any exemption.

Results

Participants

In total, 367 (IG1: n=142; CG: n=144; IG2: n=81) expectant women participated in the 2 survey waves, while providing matchable codes, and were thus included for data analysis. Figure 1 depicts the details of the participation process and dropouts, including all expectant mothers who had originally intended to participate in the study (IG1: n=225; CG: n=199;

IG2: n=233). Dropout between the 2 survey waves (IG1: n=83; CG: n=55; IG2: n=152) occurred in the following cases: delivery at another clinic, no completion of the second survey wave, preterm delivery before the web intervention or web-based application, and delivery-related health complications. As highlighted in Figure 1, there were cases in which participants could not be randomized and were thus allocated to either the control or intervention group because of upcoming delivery dates.

Table 1 provides an overview of the sociodemographic data. Most participants were aged between 30 and 39 years, predominantly well educated (a university degree), married or in a stable partnership, and of German nationality.

Table 1. Sociodemographic characteristics and intervention group affiliations of expectant mothers.

Items	IG1[a] (n=142), n (%)	CG[b] (n=144), n (%)	IG2[c] (n=81), n (%)	Missing values[d], n		
				IG[e]	CG	App
Age group (years)						
>20	N/A[f]	N/A	N/A	N/A	N/A	N/A
20-29	14 (9.9)	19 (13.2)	9 (11.1)	0	4	5
30-39	119 (83.8)	107 (74.3)	57 (70.4)	N/A	N/A	N/A
40-49	9 (6.3)	14 (9.7)	10 (12.3)	N/A	N/A	N/A
Marital status				0	4	5
Single	2 (1.4)	3 (2.1)	3 (3.7)			
In a committed relationship	34 (23.9)	27 (18.8)	13 (16)			
Married or registered partnership	106 (74.6)	109 (75.7)	60 (74.1)			
Divorced or separated	N/A	1 (0.7)	N/A			
Highest educational level				0	4	5
No school-leaving qualification	1 (0.7)	N/A	N/A			
Secondary or elementary school leaving	N/A	N/A	1 (1.2)			
Secondary school diploma	2 (1.4)	3 (2.1)	2 (2.5)			
A levels	7 (4.9)	6 (4.2)	4 (4.9)			
Completed vocational training	19 (13.4)	27 (18.8)	11 (13.6)			
University degree[g]	27 (19)	26 (18.1)	17 (21)			
University degree	86 (60.6)	78 (54.2)	41 (50.6)			
Nationality				0	4	5
German	122 (85.9)	122 (84.7)	72 (88.9)			
Other	20 (14.1)	18 (12.5)	4 (4.9)			

[a]IG1: live seminar group.

[b]CG: control group.

[c]IG2: web-based application group.

[d]Missing values for each group.

[e]IG: intervention group.

[f]N/A: not applicable.

[g]Special German university degree (Hochschule).

Descriptive Statistics

Descriptive statistics on age, relationship, and education level, as well as the nationality of expectant mothers included in the study, are shown in Table 1. All descriptive descriptions of expectant mothers are subdivided with regard to the form of intervention and missing values, whereby the respective frequency and percentage are provided in Table 1.

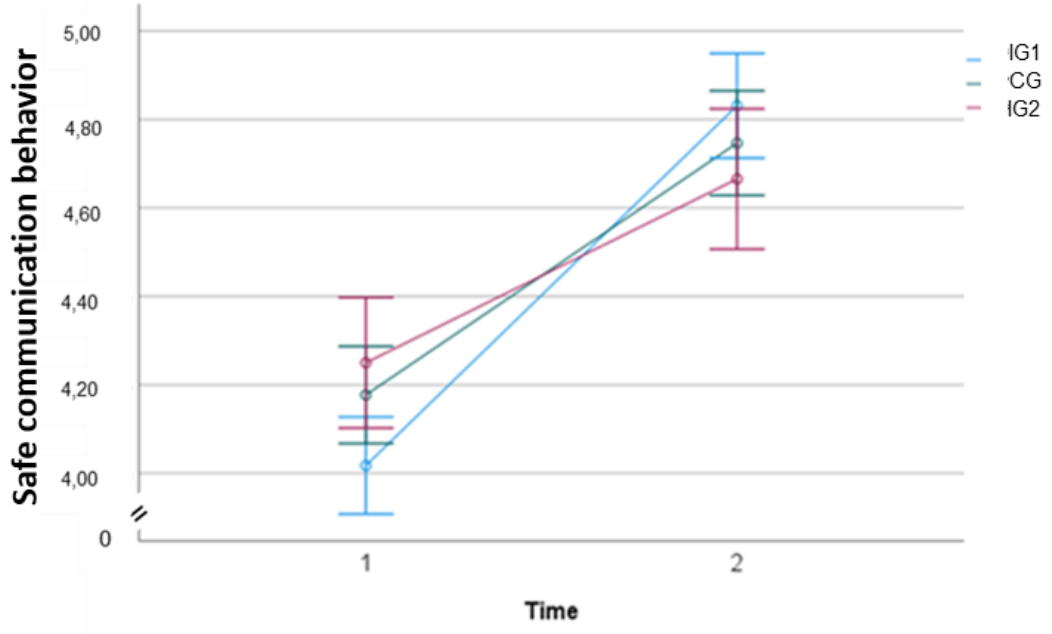
In addition to Table 1, groups of participants were compared using chi-square tests for categorical sociodemographic data. The results indicated no differences between the groups in age (χ^2_4=4.2; *P*=.38, education level (χ^2_{12}=8.3; *P*=.76), marital status (χ^2_6=4.5; *P*=.61), or nationality (χ^2_4=5.5; *P*=.24). More detailed results are presented in Table S4 in Multimedia Appendix 1. Finally, participants who dropped out were compared with participants who provided T2 data in their respective study group using chi-square tests for categorical sociodemographic characteristics to test differences in the mentioned study groups and their sociodemographic characteristics (Table 1). Pregnant women who discontinued the web-based application differed

from those who completed it and provided T2 data regarding their sociodemographic characteristics in terms of age with χ^2_3=49.7; *P*≤.001 and nationality with χ^2_1=5.9; *P*=.02. No significant differences were found in marital status (χ^2_2=2.3; *P*=.32) and education level (χ^2_5=3.2; *P*=.66). The same picture emerged for IG1 for age (χ^2_3=2.9; *P*=.39), nationality (χ^2_1=0.2; *P*=.67), marital status (χ^2_2=1.4; *P*=.49), and education level (χ^2_6=5.4; *P*=.50). Finally, no significant differences were found in the CG for age (χ^2_2=3.5; *P*=.17), nationality (χ^2_2=2.2; *P*=.34), marital status (χ^2_3=1.5; *P*=.68), and education level (χ^2_5=7.9; *P*=.16). The results of all the mentioned groups are depicted in Table S5 in Multimedia Appendix 1.

Communication Behavior

Regarding hypothesis 1, the main effect of time on communication behavior scores was not statistically significant ($F_{1,336}$=3.322; *P*=.07; η_p^2=0.010). This suggests that across groups, the mean level of communication behavior scores did not exhibit a significant trend over the measurement points (Figure 2).

Figure 2. Estimated marginal means of safe communication behavior over 2 time points. CG: control group; IG1: live seminar group; IG2: web-based application group.



There was a significant time × group interaction effect, meaning that the change in communication behavior across time differed between IG1 and IG2 ($F_{1,336}$=15.046; *P*<.001; η_p^2=0.043). Between the CG and IG2, no significant time × group interaction effect emerged ($F_{1,336}$=2.732; *P*=.10; η_p^2=0.008).

Perceived Patient Safety

The main effect of time on perceived patient safety scores was not statistically significant ($F_{1,304}$=0.013; *P*=.91). This suggests that, across groups, the mean level of patient safety scores did not exhibit a significant trend across the measurement occasions (Figure 3).

There was a significant time × group interaction effect, meaning that the change in perceived patient safety across time did significantly differ between IG1 and IG2 ($F_{1,304}$=4.709; *P*=.03; η_p^2=0.015). There was no significant time × group interaction effect between CG and IG2 ($F_{1,304}$=0.108; *P*=.74; η_p^2≤0.001).

To investigate hypothesis 2 and assess whether social cognitive HAPA variables were associated with safe communication behavior after web-based application use, a multiple regression analysis was performed (Figure 4; Table 2).

Figure 3. Estimated marginal means over 2 time points of perceived patient safety. CG: control group; IG1: live seminar group; IG2: web-based application group.

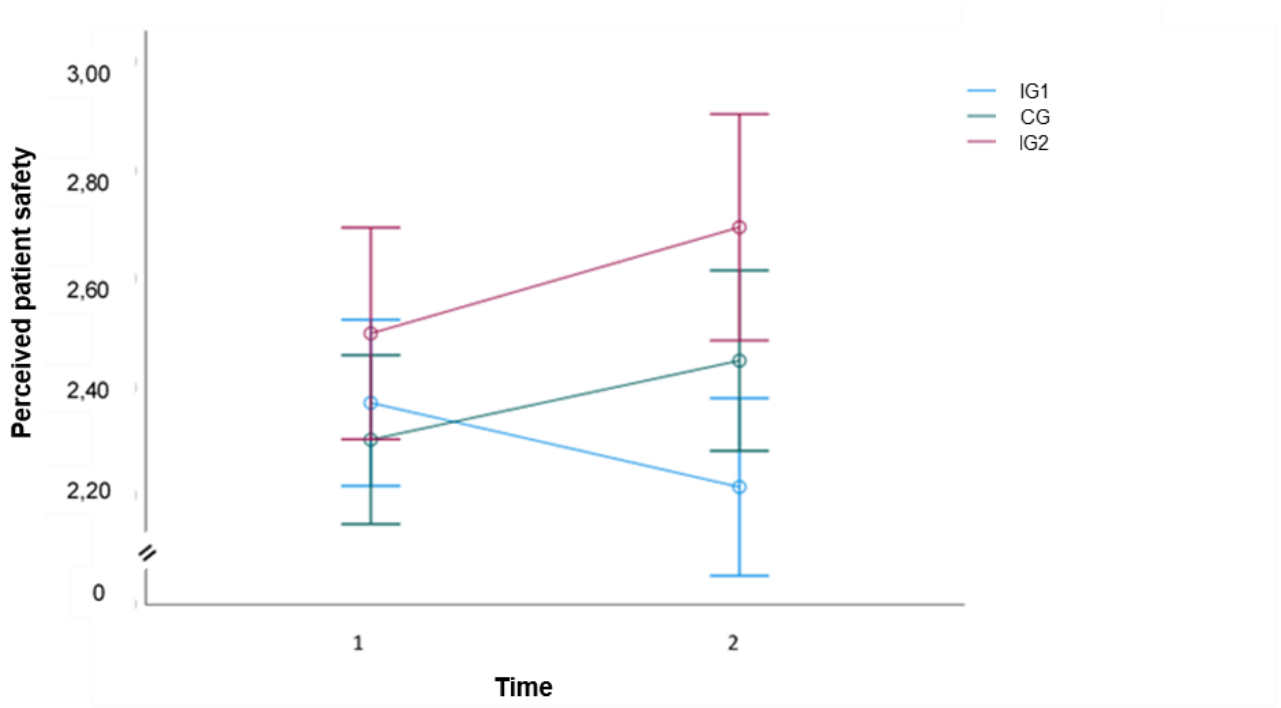


Figure 4. Regression model of social cognitive Health Action Process Approach variables and safe communication behavior across all groups. CG: control group; IG1: live seminar group; IG2: web-based application group. *β is significant at the *P*=.05 level. ***β is significant at the *P*=.001 level.

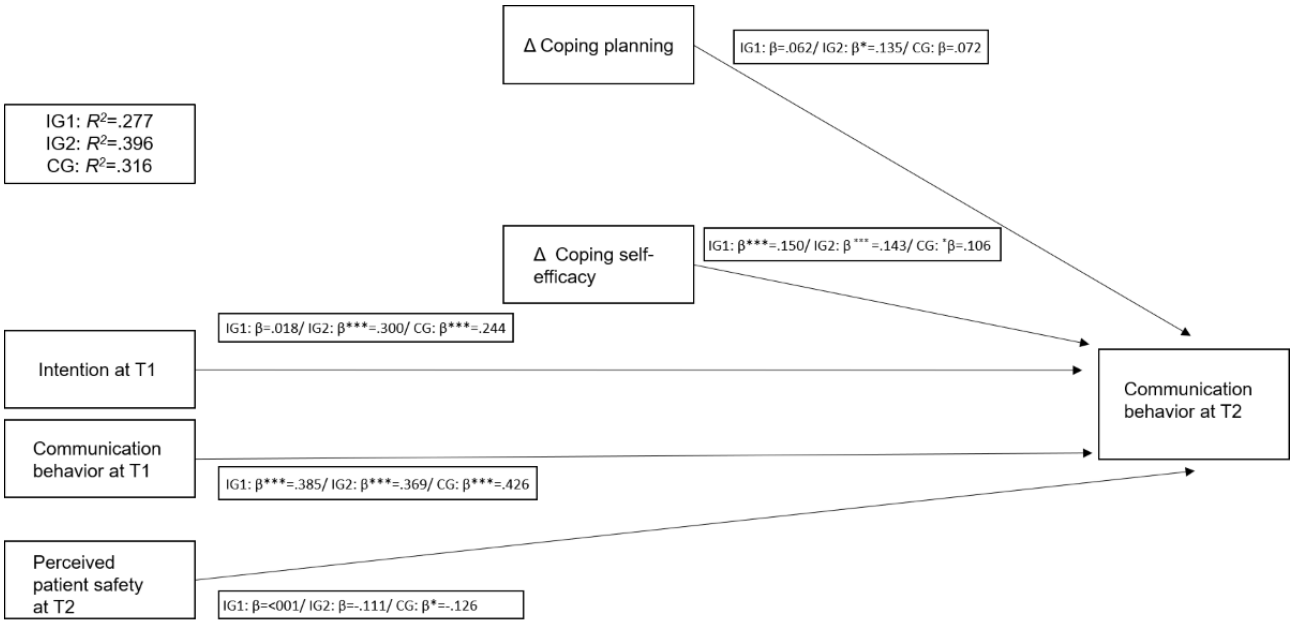


Table 2. Results from the social cognitive regression model in the Health Action Process Approach framework across all 3 groups.

	B[a] (95% CI; SE)	β[b]	*P* value	Tolerance	VIF[c]
Parameters (web-based application group)[d]					
Intention T1[e]	0.300 (0.124 to 0.476; 0.088)	.351	.001[f]	0.794	1.260
Δ Coping self-efficacy	0.143 (0.015 to 0.272; 0.064)	.259	.03[g]	0.627	1.594
Δ Coping planning	0.135 (0.015 to 0.262; 0.064)	.270	.04[g]	0.522	1.915
Communication at T1	0.369 (0.007 to 0.598; 0.115)	.350	.002[h]	0.714	1.401
Perceived patient safety	−0.111 (0.140 to 0.025; 0.068)	−.153	.11	0.965	1.036
Parameters (live seminar group)[i]					
Intention at T1	0.018 (0.070 to 0.440; 0.088)	.018	.84	0.924	1.082
Δ Coping self-efficacy	0.150 (0.004 to 0.207; 0.044)	.290	.001[f]	0.672	1.488
Δ Coping planning	0.062 (−0.013 to 0.157; 0.038)	.142	.16	0.687	1.457
Communication at T1	0.385 (0.236 to 0.715; 0.088)	.369	.001[f]	0.916	1.092
Perceived patient safety	<0.001 (−0.250 to −0.002; 0.063)	<.001	>.99	0.881	1.135
Parameters (control group)[j]					
Intention at T1	0.255 (0.070 to 0.440; 0.093)	.221	.007[h]	0.924	1.082
Δ Coping self-efficacy	0.106 (0.004 to 0.207; 0.051)	.196	.04[g]	0.672	1.488
Δ Coping planning	0.072 (−0.013 to 0.157; 0.043)	.157	.10	0.687	1.457
Communication at T1	0.426 (0.236 to 0.615; 0.096)	.362	.001[f]	0.916	1.092
Perceived patient safety	−0.126 (−0.250 to 0.002; 0.063)	−.166	.047[g]	0.881	1.135

[a]Unstandardized coefficient.
[b]Standardized coefficient.
[c]VIF: variance inflation factor.
[d]n=77.
[e]T1: first time point.
[f]B is significant at the *P*=.001 level.
[g]B is significant at the *P*=.05 level.
[h]B is significant at the *P*=.01 level.
[i]n=125.
[j]n=119.

As summarized in Table 2, safe communication behavior after web-based application use was significantly predicted by the reported intention to communicate safely at baseline. Safe communication behavior at baseline significantly predicted safe communication behavior after participation in the web-based application. Safe communication behavior was also significantly determined by a change in coping planning and a change in coping self-efficacy between time points.

Nevertheless, safe communication behavior after participating in IG1 was not significantly predicted by the reported intention to communicate safely at baseline (Table 2). Safe communication behavior at baseline significantly predicted safe communication behavior after participating in the live seminar. Behavior was also significantly determined by a change in coping self-efficacy but not in coping planning between time points.

Expectant mothers' safe communication behavior in the CG was significantly predicted by their reported intention to communicate safely at baseline. Safe communication behavior at baseline significantly predicted safe communication behavior after giving birth. Finally, safe communication behavior was significantly determined by a change in coping self-efficacy but not by a change in coping planning between time points. All results across the abovementioned groups are presented in Table 2.

Regarding hypothesis 3, it could not be empirically supported that patient safety also played a role in communication behavior after using the web-based application; no significant association with perceived patient safety at the end of the observation period emerged with safe communication behavior. Similar results were observed for IG1. In the CG, an association emerged between perceived patient safety after birth and safe communication behavior. Notably, on a bivariate level, there

were significant correlations between perceived patient safety and communication at T2 only in the CG (Table S1 in Multimedia Appendix 1).

Discussion

Principal Findings

This study aimed to compare and identify the effectiveness of different digital intervention modes for pregnant women regarding the primary outcome of safe communication behavior and the secondary outcome of perceived patient safety in obstetric care. It was hypothesized that participation in a digital web-based application would prove to be equally effective as a live seminar and more effective than a passive CG. However, this could not be empirically supported: compared with the intervention group, the pregnant women who used the web-based training application improved their safe communication behavior significantly less and not more than a passive CG that did not receive any intervention.

There are very few studies [39-41] on the effectiveness of (digital) interventions in the context of pregnant women's safe communication behavior in obstetrics. Thus, hypotheses could only be drawn based on other literature concerning the HAPA framework [42-44]. Thus, it is even more important to gain evidence in this area of research, especially regarding behavior change interventions [42,45,46]. It seems that theoretical foundations regarding BCTs in communication research are lacking and that tangible BCTs are missing or insufficient, as the literature demonstrates [47].

There are several theoretical explanations for the lower effectiveness of the web-based application intervention. Expectant mothers using the web-based application might have started with a different general understanding of their own ability to communicate safely and also of what safe communication behavior entails. As Figure 2 shows, their baseline score is, on average, higher than that of the other 2 groups. In addition, the web-based application was a more rigid knowledge-based approach to teaching safe communication behavior as compared with the web seminar with its practical and interactive elements. However, the interactive element, even if only "on-screen," might be crucial so that participants understand their own limits regarding safe communication and how to translate theoretical knowledge concerning communication behavior into action to bridge the intention-behavior gap. This is consistent with the finding of the dropout analyses that pregnant women with a different nationality than German were more likely to not complete the web-based application, probably because it was too text based. In contrast, there were no differences in the sociodemographic characteristics of women who completed the study and those who dropped out in IG1 and CG. The web-based application encompasses a knowledge-based learning experience [48] but no practical rehearsal in a natural environment, thus hindering potential learning and transfer effects. Although knowledge-based interventions can be effective in enhancing health literacy [49], health behavior change might only be possible if interventions are enriched with elements that target behavioral planning and enhancing self-efficacy [50].

In this context, professional and personal support can be perceived as trustworthy and knowledgeable [48,51]. In our digital live seminar, the trainers were experts in the field, thus providing guidance beyond the scope of the web-based application intervention. Furthermore, BCTs were not as effective in their implementation in the application intervention as found previously [32]. The implementation of BCTs in the application may not have worked as well as in the training, as BCT in the web-based application focused on the motivational phase of HAPA. However, more proximal factors, such as volitional factors, have been found to have a more direct and thus larger effect on behavior [52]. Compared with the live seminar, the web-based application offered fewer opportunities for individual action planning. Future research should evaluate which BCT is best for implementing volitional factors in digital interventions.

In previous literature, legitimacy has been identified as a crucial factor [51]. Digital and especially asynchronous tools are limited with regard to such effects, and notably, such elements were absent in the currently applied web-based applications. Digital interventions based on BCTs are already widely used for health maintenance, including the prevention and management of health problems [53]. Nevertheless, they might need to be revised under these considerations to provide the opportunity for contact with a trainer [48].

Contact with a trainer could also positively impact the user experience of pregnant women and their partners [54]. User barriers include the perception of irrelevant or unsuitable content, lack of time, and not having the option to save the digital tool on a mobile phone [54]. Consistent with the literature [55], there are 2 key characteristics of successful digital interventions on which the web-based application is improvable: inclusion of the target group in the development of the web-based intervention and the application of clear guiding principles. Guiding principles should be identified that answer key context-specific behavioral issues in the respective research field [55], such as a lack of respectful maternity care and patient involvement. Applied to the context at hand, context-specific stakeholders, including expectant mothers, their support persons, and HCW should be trained, and their communication strategies should be aligned. It should be noted that such elements have been included in developing the current version of the web-based application (eg, through tasks on perspective taking), although potentially more iterations could have been needed to adapt the web-based application even further to context-specific behavioral needs and preferences. Improving the web-based application on these points could lead to higher overall effectiveness, more closely resembling the effectiveness of a face-to-face intervention.

Consequently, it is necessary to identify effective mechanisms of (digital) interventions in addition to simply demonstrating their overall effectiveness [56]. We investigated the potential mechanisms in hypothesis 2 to understand what drives individual differences among participants regarding their improvements in safe communication behavior over time. For pregnant women who participated in the web-based application, coping planning and self-efficacy determined safe communication behavior. Various intervention studies have shown that both self-efficacy

and coping planning can be trained in interventions targeting knowledge and self-regulation [42,57-59]. This indicates that a theoretical understanding and appraisal of safe communication behavior are important determinants of improvement among participants using the web-based application.

Notably, a different picture emerged in the live seminar and in the CG, where coping self-efficacy was the main determinant of pregnant women's safe communication behavior. Thus, the web-based application stands out in the sense that multiple HAPA constructs predicted safe communication behavior at T2. Not only does the belief that one can communicate safely in difficult situations (coping self-efficacy) seem to play a role but also does the transfer of knowledge regarding concrete plans for these situations (coping planning). This further illustrates the need to incorporate elements regarding the social aspect of learning as well as further chances to translate theoretical knowledge into practice within a natural setting [60]. Ultimately, personalized or interactive elements seem to be an essential aspect in a variety of (digital) intervention studies [61]. One possibility would be to enrich the web-based application with a face-to-face format or a chatbot [62] to increase effectiveness and maintain practical advantages of digital training compared with a more extensive stand-alone, face-to-face intervention.

Another topic of concern was to investigate whether and how participation in the web-based application related to perceived patient safety. We expected that recipients of the web-based application would improve more than a passive CG and to a similar degree as recipients of a live seminar intervention. This was not empirically supported. In addition, an association between perceived patient safety and safe communication behavior emerged only in the CG. It is possible that participants in the CG had worse birth experiences and thus perceived higher patient safety risks. As safe communication behavior is central to good birth experiences, their perceptions of birth might have acted as a confounding factor in both perceived risks and communication. IG2 and IG1 focused on safe communication behavior, which is, although important, only one aspect of perceived patient safety and might be overshadowed by more obvious medical aspects and behavioral variables in this specific context, such as the birth experience. In this case, the web-based application in its current form was not able to improve perceived patient safety.

Limitations and Recommendations for Future Research

This study was the first approach to design and apply a digital training tool in the form of a web-based application to improve expectant mothers' safe communication. This study has several limitations. First, the lack of available previously published evidence negatively affected the ability to design and tailor such a web-based application to expectant mothers' needs and the accuracy of the hypothesized effectiveness. Future research in this area will benefit from the insights generated in this study. Consecutive research designs should permit more rigorous testing and a thorough development phase for the design and content according to the needs of participants before using a medical internet intervention. Similarly, optimizing the intervention effect and user experience could be achieved by incorporating face-to-face elements or the possibility of social exchange into the digital intervention design [48].

From a methodological perspective, the group of web-based application users was smaller than the other 2 groups. Absolute sample size and potential distortions (eg, due to dropout issues and social desirability) might explain the difference between hypothesized and empirically observed group differences [63,64]. The use of the web-based application by expectant mothers took place without further observation or consultation with the research staff, which is why interference effects (eg, frequent interruption of an exercise, multitasking, or an environment) could not be controlled. The assessments were self-reported measures and thus potentially biased by subjective beliefs and social desirability. In addition, we used only subjective reports and single-item scales for reasons of feasibility, but they might have had low reliability. Therefore, future research might benefit from developing and further validating multi-item scales to assess safe communication behavior or using observation assessments for a more objective assessment. This could offer additional insights regarding potential subjectivity within self-reported measures.

In this study, mostly well-educated women participated, which probably had an effect on the results, and thus limited generalizability. The web-based application should also be tested and verified with other sociodemographic groups with lower levels of education and migration backgrounds [40,65]. Consequently, future studies should aim for a more diverse participant pool [40,66]. Collaboration with cultural associations or municipal services could aid in this strategy and the sustainability of the intervention [55].

In addition, it should be mentioned that the data collection in the live seminar between June 2020 and August 2021, the COVID-19 pandemic was associated with restrictions at the hospitals. For example, expectant fathers were partially not allowed to be present during the birth, and interpersonal contacts were limited to a minimum to prevent the spread of the pandemic. All these points may have had an impact on the communication within the hospitals, for example, due to higher vigilance of patients in the current situation or a lack of resources.

Another limitation concerns the randomized group assignment, in which only a partly randomized allocation could be achieved. In addition, there was a comparably high dropout rate in IG2 that was potentially selective, which is typical for asynchronous web-based interventions [65,67,68]. It is possible that mothers with high self-efficacy and communication competency dropped out because they felt that they could not learn anything new. On the other hand, women with communication difficulties might have dropped out because they felt overwhelmed. Thus, the dropout might have caused an overestimation or underestimation of the effects [69]. In future studies, adequate measures should be taken to avoid dropouts. To summarize, both of the abovementioned limitations impaired the comparability of the 3 study groups. This should be considered when interpreting results and designing future studies.

Conclusions

The evaluated digital interventions had different effects on communication behavior and patient safety. The intervention that was developed and delivered as a web-based training application appeared to be not sufficient in changing communication behavior in pregnant women and perceived patient safety risks when compared with a passive CG. Hence, it seems reasonable to combine the web-based application with other face-to-face interventions to achieve better effectiveness. Changes and adaptations to the existing web-based applications should be examined more closely in the future. In addition, more precise analyses of communication behavior and the interrelation of social cognitive determinants are warranted. Future research should control for more potential confounding variables, such as socioeducational status and prior knowledge of pregnancy and profession. Qualitative methods can be applied to gain more precise insights into the existing web-based applications to adjust. Future web application developers and researchers should also consider the mode of delivery and create a “native app” to make the intervention more accessible.

Acknowledgments

The authors thank Katharina Schiffer, Kim Sousa, and Maya Ahlden for proofreading the manuscript with regard to referencing style and language. They are thankful and appreciative of the help by Dr Marina Schmiedhofer, Prof Dr Frank Louwen, Prof Dr Frank Reister, Johanna Dietl, Freya Häußler, and Sandra Riedmüller in the data collection.

This study is funded by the German Innovation Fund (project number 01VSF18023) of the Federal Joint Committee (Gemeinsamer Bundesausschuss [G-BA]) as part of a third-party project funding.

Data Availability

The data that support the findings of this study are available on request from the corresponding author, SL. The data were not allowed to be made publicly available because of privacy and data security reasons of the research participants.

Authors' Contributions

LK, CD, FMK, and SL were involved in data collection and monitoring as well as in the conceptual aspects of this study. LK analyzed and described the data statistically and wrote all parts of the manuscript. CD advised on the methodology and structure. SL, CD, and FMK provided advice on the rationale and structure of this paper. All coauthors approved this version of the manuscript and contributed to its preparation.

Conflicts of Interest

The web-based application is owned by Constructor University Bremen gGmbH, represented by SL. LK (the first author) was the main project manager in all aspects of the web-based application.

Multimedia Appendix 1
Comparison of the effectiveness of a web-based application with a digital live seminar to improve safe communication for pregnant women: 3-group partially randomized controlled trial.
[DOCX File , 38 KB - pediatrics_v6i1e44701_app1.docx]

Multimedia Appendix 2
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 351 KB - pediatrics_v6i1e44701_app2.pdf]

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Abbreviations

BCT: behavior change technique
CG: control group
G-BA: Gemeinsamer Bundesausschuss
HAPA: Health Action Process Approach
HCW: health care worker
IG1: live seminar group
IG2: web-based application group
T1: first time point
T2: second time point

Edited by S Badawy; submitted 29.11.22; peer-reviewed by V Perez Jover, M Rahimi; comments to author 05.05.23; revised version received 22.05.23; accepted 05.06.23; published 24.07.23.

Please cite as:
Kötting L, Derksen C, Keller FM, Lippke S
Comparing the Effectiveness of a Web-Based Application With a Digital Live Seminar to Improve Safe Communication for Pregnant Women: 3-Group Partially Randomized Controlled Trial
JMIR Pediatr Parent 2023;6:e44701
URL: https://pediatrics.jmir.org/2023/1/e44701
doi:10.2196/44701
PMID:37486755

Original Paper

Parental Information Needs and Intervention Preferences for Preventing Multiple Lifestyle Risk Behaviors Among Adolescents: Cross-sectional Survey Among Parents

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Abstract

Background: Parents play an influential role in the health behaviors of their children, such as physical activity, dietary intake, sleep, screen time, and substance use. However, further research is needed to inform the development of more effective and engaging parent-based interventions targeting adolescent risk behaviors.

Objective: This study aimed to assess parents' knowledge about adolescent risk behaviors, barriers and facilitators to engaging in healthy behaviors, and preferences for a parent-based prevention intervention.

Methods: An anonymous web-based survey was conducted from June 2022 to August 2022. Eligible participants were parents of children aged 11 to 18 years and were residing in Australia at the time of this study. The survey assessed the parents' perceived and actual knowledge about Australian health guidelines for youth, parent and adolescent engagement in health behaviors, parenting style and attitudes, barriers and facilitators to engaging in healthy behaviors, and delivery and component preferences for a parent-based preventive intervention. Descriptive statistics and logistic regressions were conducted to analyze the data.

Results: A total of 179 eligible participants completed the survey. The mean age of the parents was 42.22 (SD 7.03) years, and 63.1% (101/160) were female. Parent-reported sleep duration was high for both parents (mean 8.31, SD 1.00 hours) and adolescents (mean 9.18, SD 0.94 hours). However, the proportion of parents who reported that their child met the national recommendations for physical activity (5/149, 3.4%), vegetable intake (7/126, 5.6%), and weekend recreational screen time (7/130, 5.4%) was very low. Overall, parents' perceived knowledge of health guidelines was moderate, ranging from 50.6% (80/158) for screen time to 72.8% (115/158) for sleep guidelines (for children aged 5-13 years). Actual knowledge was lowest for vegetable intake and physical activity, with only 44.2% (46/104) and 42% (31/74) of parents reporting correct guidelines for these behaviors, respectively. The key issues of concern reported by parents were excessive use of technology, mental health, e-cigarette use, and negative peer relationships. The top-rated delivery method for a parent-based intervention was via a website (53/129, 41.1%). The highest rated intervention component was opportunities for goal-setting (89/126, 70.7% rated very or extremely important), and other important program features were ease of use (89/122, 72.9%), paced learning (79/126, 62.7%), and appropriate program length (74/126, 58.8%).

Conclusions: The findings suggest that such interventions should be brief and web based and should aim to increase parental knowledge of health guidelines; provide opportunities for skill-building, such as goal-setting; and include effective behavior change techniques, such as motivational interviewing and social support. This study will inform the development of future parent-based preventive interventions to prevent multiple lifestyle risk behaviors among adolescents.

(JMIR Pediatr Parent 2023;6:e42272) doi:10.2196/42272

KEYWORDS

parents; adolescents; prevention; risk behaviors; intervention; mobile phone

Introduction

Background

Lifestyle risk behaviors, such as physical inactivity, poor sleep, sedentary behaviors (ie, sitting time and recreational screen time), poor diet, alcohol use, and tobacco smoking (the "Big 6"), are highly prevalent among adolescents worldwide. For example, an estimated 81% of adolescents globally report insufficient physical activity [1] and a recent meta-analysis of global adolescent dietary patterns found that 42.8% drank carbonated soft drinks at least once per day and 46.1% consumed fast food at least once per week [2]. The Big 6 are associated with a range of short- and long-term negative health outcomes, including obesity [3], mental illness [4,5], and chronic disease [6,7], which places considerable economic burden on already strained health care systems [8].

It is well established that adolescence is a critical period of behavior development, with lifestyle habits formed during this period typically persisting over time [9,10]. Thus, adolescence represents a valuable opportunity for the delivery of preventive interventions. In addition to being highly prevalent, lifestyle risk behaviors also tend to cooccur [11], with >80% of adolescents worldwide engaging in ≥2 risk behaviors concurrently and more than one-third engaging in ≥3 behaviors [12]. Engaging in multiple risk behaviors compounds the overall risk for chronic disease [13,14] and is associated with poor mental health outcomes [15]. Multiple health behavior change interventions seek to address this harmful trend, based on the notion that improving one behavior can increase self-efficacy to improve others without additional effort [16]. Although school-based multiple health behavior change interventions that are delivered via eHealth technology have proven effective in improving adolescent risk behaviors, such as physical inactivity and screen time, the effects are modest and short-lived [15]. Identifying intervention strategies that can augment the effects of school-based interventions are needed. Given the considerable influence of parents on adolescent health behaviors, involving parents in the preventive efforts represents an important opportunity to improve adolescent outcomes.

Parent-based interventions (ie, programs delivered through parents) provide the opportunity to continue intervention efforts within the home environment, the primary location of adolescent development [17]. Indeed, several modifiable parenting factors are associated with adolescent risk behaviors. For example, parental modeling is associated with increased diet quality [18], sleep quality [19], and physical activity [18] and decreased tobacco use [20], whereas rule-setting is associated with longer, better quality sleep [19] and decreased screen time [18,21]. Different parenting styles have also been linked to adolescent behaviors. For example, controlling parenting is associated with increased excessive screen time [21], and permissive parent behavior has been shown to increase sugar-sweetened beverage intake [22].

Despite this, surprisingly few interventions to prevent adolescent risk behaviors are parent based and family centered [23], and such interventions are typically characterized by high attrition [24] and low engagement [25], leading to decreased intervention success [26]. A recent meta-analysis of 36 randomized controlled trials [27] found that parent-based interventions for multiple lifestyle risk factors were associated with small improvements in adolescent physical activity and reduced screen time and junk food intake. However, parent-based interventions were not effective for alcohol and tobacco use, and no studies have addressed adolescent sleep. Further research is required to develop more effective parent-based interventions for preventing multiple adolescent risk behaviors. A critical part of this is working with parents to better understand their information needs, attitudes toward parenting and adolescent risk behaviors, and preferences for healthy lifestyle interventions.

Objective

To inform the development of a new, parent-based intervention targeting the Big 6 lifestyle risk behaviors (physical inactivity, poor diet, recreational screen time, poor sleep, smoking, and alcohol use) among adolescents, this study aimed to assess parents' knowledge about Australian health guidelines for the Big 6 for youth; explore attitudes and parenting practices in relation to the Big 6; and identify barriers, facilitators, and preferences for a parent-based preventive intervention.

Methods

Participants and Procedure

An anonymous cross-sectional survey was administered on the web through the Qualtrics (Qualtrics International Inc) survey platform from June 2022 to August 2022. Parents of children aged 11 to 18 years, who were residing in Australia at the time of this study, having access to a device connected to the internet to complete the survey were eligible. Participants were recruited through paid and unpaid advertising on social media (eg, Facebook and Twitter), as well as emails to professional and personal networks. Paid advertising was also conducted via state-based parents and carers associations, and hard copy flyers were distributed to households across Greater Sydney (Multimedia Appendix 1). These advertisements contained hyperlinks and QR codes to access the survey. All participants were required to provide informed consent before participation. Participants had the option upon completing the survey to enter a prize draw to win 1 of 5 gift vouchers valued at Aus $100 (US $68) each.

Ethics Approval

This study was approved by the Human Research Ethics Committee of the University of Sydney (ethics approval: 2022/359).

Measures

Demographic data included postcode, number and age of children, household income, education, employment, main language spoken at home, and marital status. Participants were also asked to self-report their age, sex, height, and weight (used to calculate BMI).

Parents' Self-reported Health Behaviors

Physical Activity

To reflect the Australian physical activity guidelines for adults [28], the following two items were used to assess parents' moderate to vigorous physical activity (MVPA): "About how many days per week do you do moderate intensity physical activity for at least 30 minutes?" and "About how many days per week do you do vigorous intensity physical activity for at least 20 minutes?" The response options ranged from 0 to 7 days per week.

Sedentary Time and Screen Time

Parents were asked the following two items: "In a typical day, how many hours do you spend sitting?" and "In a typical day, how many hours do you spend on your mobile phone, iPad, computer or another device for recreational (non-work) purposes?" (hours/day). The validity and reliability of single-item measures of daily sedentary time have been shown to be equivalent to those of other longer questionnaires [29].

Fruit and Vegetable Consumption

Average daily serves of fruits and vegetables were assessed using validated items [30,31].

Sleep Duration

Parents reported the time they usually went to bed at night and woke up each morning. Sleep duration (in hours) was calculated as the difference between wake time and bedtime [32]. Self-reported estimates of bedtime, wake time, and sleep duration have been shown to be reliable and valid [32].

Substance Use

Using items modified from the National Drug Strategy Household Survey [33], parents were asked to report how frequently they had consumed a standard drink of alcohol in the past 6 months (ranging from daily or almost daily to never); their smoking status (current smoker, former smoker, tried a couple of times, and never smoked); and their e-cigarette use (ever used and frequency of use). Self-reported substance use has been shown to be valid and reliable, particularly when participants are assured of confidentiality as they were in this study [34-36].

Parent-Reported Adolescent Health Behaviors

Parents were asked to select 1 adolescent (aged 11-18 years) child and answer the following questions in relation to that child.

Adolescent MVPA

A validated instrument [37] was used to assess adolescent MVPA. Parents were asked to report the number of days (0-7 days) their children were physically active for a total of at least 60 minutes per day over a typical week.

Recreational Screen Time

A modified version of the Adolescent Sedentary Activity Questionnaire [38] was used to assess recreational screen time (hours or minutes per typical school day and weekday). Sitting time was not assessed because of the lack of Australian guidelines for this risk behavior.

Fruit and Vegetable Consumption

Parents were asked to indicate how many serves of fruits and vegetables their adolescent children consume per day [30,31].

Sleep Duration

Parents were asked to estimate their children's usual bedtime and wake time. Usual sleep duration per night (in hours) was calculated as the difference between wake time and bedtime. Similar items have been used in previous studies [32]; however, in this study, we did not differentiate between school days and weekend days.

Substance Use

A total of 3 items modified from the National Drug Strategy Household Survey [33] were used to assess adolescent use of alcohol, tobacco, and e-cigarettes (yes, no, sometimes, and unsure).

Knowledge About Adolescent Health Guidelines

A total of 7 items were used to assess parents' perceived and actual knowledge about national health guidelines for adolescents in relation to physical activity, sleep duration (for children aged 5-13 years and 14-17 years), screen time, fruit and vegetable consumption, and alcohol use. National health guidelines provide a meaningful way to assess current health behaviors and are commonly used in adolescent health research, particularly in an intervention context [39-42]. Parents were first asked whether they knew the relevant guideline (yes, no, or unsure). For example, "Do you know the recommended amount of physical activity Australian teenagers should be getting?" Participants who responded "yes" were then asked to specify the recommended number of minutes or hours or serves for the relevant guideline.

Parenting Styles and Attitudes Toward Health Behaviors

The following two items, adapted from a study of parental support of child physical activity [43], were used to assess supportive parental attitudes: "I believe it is important that my child develops healthy lifestyle behaviours (physical activity, healthy diet, and healthy sleep)" and "Supporting my child's participation (through driving, participating, or paying for their activities, etc.) in physical activity is important to me."

A total of 3 items were adapted from Theory of Planned Behavior questionnaires, which evaluate perceived norms, perceived behavioral controls, and intentions [44], including "I consistently uphold expectations for healthy behaviour and openly communicate these expectations with my child in a positive and supportive manner."

One item, "I am able to do the things that will improve my child's behaviour" was taken from the Brief Parent Self-Efficacy Scale [45], a validated measure to assess parent beliefs of

self-efficacy and capability. Responses were coded from 1 (strongly disagree) to 5 (strongly agree).

Parental Control and Rule-Setting

A total of 6 items adapted from the Parenting Strategies for Eating and Activity Scale [46] were used to assess parental control and rule-setting in relation to each of the Big 6, including "I monitor and set rules for my adolescent child in relation to how much screen time they can have per day." Responses were coded as 0 (never and rarely) or 1 (sometimes, often, and always).

Perceived Importance of Health Behaviors

An open-ended question was used to ask parents what they perceived to be the biggest issues and concerns for young people today. Participants were also asked to rank which of the Big 6 items they would most like to support their adolescent child to improve, change, or resist (1=most important to 6=least important). Parents were also asked a similar question regarding their own behaviors.

Barriers and Facilitators

Parents were asked about the barriers and facilitators they faced and those that their child faced in engaging in healthy behaviors. For example, "What are the main things that stop YOU from engaging in healthy behaviours" and "What would you consider to be the biggest factor or factors that allow YOUR ADOLESCENT CHILD to engage in health behaviours?" Items were adapted from a systematic review of barriers to and facilitators for the uptake and maintenance of healthy behaviors [47].

Intervention Preferences

Parents who indicated that they would be interested in accessing a healthy lifestyle program about adolescent health were asked about their intervention preferences (eg, frequency, format, length, content, and components). A combination of open-ended questions, such as "Is there anything that would encourage you to participate in a parent-based healthy lifestyles program"; multiple choice questions, such as "How much time would you be willing to spend per week completing the program"; and Likert scales, including one for "How important is an easy-to-use parenting program to you," were used. Items were adapted from a previous study of parents to inform the development of an eHealth alcohol prevention program [48].

Statistical Analysis

Descriptive statistics were conducted using SPSS (version 26; IBM Corp) to describe the demographic data (frequency, percentage, mean, SD, and range). Scores on validated measures were calculated using established scoring procedures, and the mean responses and percentages were reported. Bivariate correlations were conducted to examine the associations between parents' engagement in the 6 risk behaviors and parent-reported youth engagement in the risk behaviors. Chi-square tests were conducted to explore differences in parental rule-setting by adolescent age (children aged 11-14 years vs those aged 15-18 years) for each risk behavior. Binary logistic regression was conducted to examine the associations between parental knowledge of national guidelines for each risk behavior and their child's adherence to the guidelines. Separate logistic regression models were conducted to examine whether parental rule-setting about the Big 6 was associated with adolescent engagement in each risk behavior (ie, meeting guidelines, yes or no). Owing to the small sample size and multiple tests conducted, a conservative *P* value was used ($P<.01$). Thematic analysis was used to examine the open-ended responses. Using an inductive approach [49], 1 author (EH) coded the responses, examined the data for frequent or significant responses, and grouped them according to key themes. A second author (KEC) confirmed the coding and grouping, with any discrepancies resolved via discussion.

Results

Sample Characteristics

A total of 353 participants completed the survey. Of them, 49.3% (174/353) were excluded per eligibility criteria (19 individuals had no children; 93 parents did not have children aged between 11 and 18 years; 4 parents were aged <24 years; and 58 individuals were not living in Australia), resulting in 50.7% (179/353) eligible participants. The mean age of the parents was 42.22 (SD 7.03) years, and 63.1% (101/160) were female. The mean age of the selected index child was 14.62 (SD 1.81; range 11-18) years. Table 1 presents the characteristics of the entire sample.

Table 1. Sample characteristics (N=179).[a]

	Values, n (%)
Parent sex (n=160)	
Female	101 (63.1)
Male	57 (35.6)
Prefer not to answer	2 (1.2)
Household income, Aus $[b] (n=161)	
<18,200	3 (1.9)
18,201-45,000	19 (11.8)
45,001-120,000	52 (32.3)
120,001-180,000	48 (29.8)
>180,001	33 (20.5)
Prefer not to say	6 (3.7)
Education (n=161)	
Postgraduate degree	49 (30.4)
Graduate diploma or graduate certificate	20 (12.4)
Bachelor's degree	57 (35.4)
Advanced diploma or diploma	17 (10.6)
Certificate I, II, III, or IV	12 (7.4)
High school	6 (3.7)
Employment (n=160)	
Employed full-time	115 (71.9)
Employed part-time or casual	31 (19.3)
Unemployed	2 (1.2)
Retired	1 (0.6)
Home duties	8 (5)
Other	3 (1.9)
Main language spoken (n=179)	
English	146 (96.7)
Other	5 (2.8)
Postcode (n=121)	
Living in NSW[c]	71 (58.7)
Marital status (n=160)	
Married	125 (78.1)
Divorced	12 (7.5)
De facto	12 (7.5)
Other	11 (6.9)
Age of adolescent (index child), years (n=132)	
11	5 (3.8)
12	12 (9.1)
13	23 (17.4)
14	22 (16.7)
15	26 (19.7)

	Values, n (%)
16	21 (16)
17	16 (12.1)
18	7 (5.3)

[a]Discrepancies in participant N values are due to missing data.

[b]Aus $1=US $0.68 (at time of prize draw).

[c]NSW: New South Wales.

Parent and Adolescent Health

Most parents rated their own health as "good" (67/157, 42.7%); however, 46.4% (83/179) reported having been diagnosed with a chronic condition, most commonly arthritis (24/179, 13.4%) and high blood pressure (21/179, 11.7%). On average, parents were overweight (BMI: mean 25.75, SD 9.12). Table 2 reports the parent-reported engagement in each Big 6 risk behavior for parents and adolescents. The parents reported consuming an average of 1.6 serves of fruit per day, but only 2.4 serves of vegetables, well below the national recommendation of 5 daily serves (Multimedia Appendix 1 lists the Australian guidelines for each behavior). However, on average, sleep duration was adequate among the sample, with parents sleeping for an average of 8.3 (SD 1.38) hours per night (range 5-12.5 hours). Although only 19.7% (31/157) were current tobacco smokers, nearly one-quarter of the parents (37/156, 23.7%) reported having used e-cigarettes, of whom 51% (19/37) reported vaping at least weekly.

Table 2. Parent and adolescent engagement in Big 6 risk behaviors.

	Parent's health behaviors	Adolescent health behaviors
Fruit intake (serves/day), mean (SD)	1.66 (0.98)	1.84 (1.09)
Vegetable intake (serves/day), mean (SD)	2.37 (1.33)	2.14 (1.18)
Physical activity (days per week), mean (SD)		
30 minutes moderate	4.13 (1.84)	N/A[a]
20 minutes vigorous	3.07 (1.92)	N/A
60 minutes MVPA[b]	N/A	3.93 (1.6)
Sleep duration (hours/day), mean (SD)	8.31 (1.00)	9.18 (0.94)
Sitting time (hours/day), mean (SD)	7.15 (3.33)	N/A
Recreational screen time (hours/day), mean (SD)	2.77 (1.51)	N/A
Weekday	N/A	2.42 (1.55)
Weekend	N/A	4.48 (2.47)
Alcohol use, n (%)		
Ever used[c]		
Yes	N/A	9 (5.8)
No	N/A	99 (63.5)
Sip or 2	N/A	40 (25.6)
Unsure	N/A	8 (5.1)
Frequency[d]		
Daily or almost daily	21 (13)	N/A
Weekly	40 (24.7)	1 (11.1)
2-3 times monthly	27 (16.7)	7 (77.8)
Once a month	21 (13)	1 (11.1)
Less than a month	32 (19.8)	N/A
Never	21 (13)	N/A
Tobacco use[e], n (%)		
Never smoked	67 (42.7)	N/A
Tried smoking	26 (16.6)	N/A
Former smoker	33 (21)	N/A
Current smoker	31 (19.7)	N/A
Ever used[f]		
Yes	N/A	12 (7.8)
No	N/A	125 (81.7)
Unsure	N/A	16 (10.5)
Frequency[g]		
<Monthly	N/A	6 (50)
Once a month	N/A	1 (8.3)
2-3 times a month	N/A	1 (8.3)
Weekly	N/A	3 (25)
Daily or almost daily	N/A	1 (8.3)
e-Cigarette use, n (%)		

	Parent's health behaviors	Adolescent health behaviors
Ever used[h]	37 (23.7)	N/A
Yes	N/A	24 (15)
No	N/A	117 (73.1)
Unsure	N/A	19 (11.9)
Frequency[i]		
<Monthly	9 (24.3)	4 (17.4)
Once a month	4 (10.8)	3 (13)
2-3 times monthly	5 (13.5)	11 (47.8)
Weekly	9 (24.3)	1 (4.3)
Daily or almost daily	10 (27)	4 (17.4)

[a]N/A: not applicable.

[b]MVPA: moderate to vigorous physical activity.

[c]Adolescents: n=156.

[d]Parents: n=162; adolescents: n=9.

[e]Parents: n=157.

[f]Adolescents: n=153.

[g]Adolescents: n=12.

[h]Parents: n=156; adolescents: n=160.

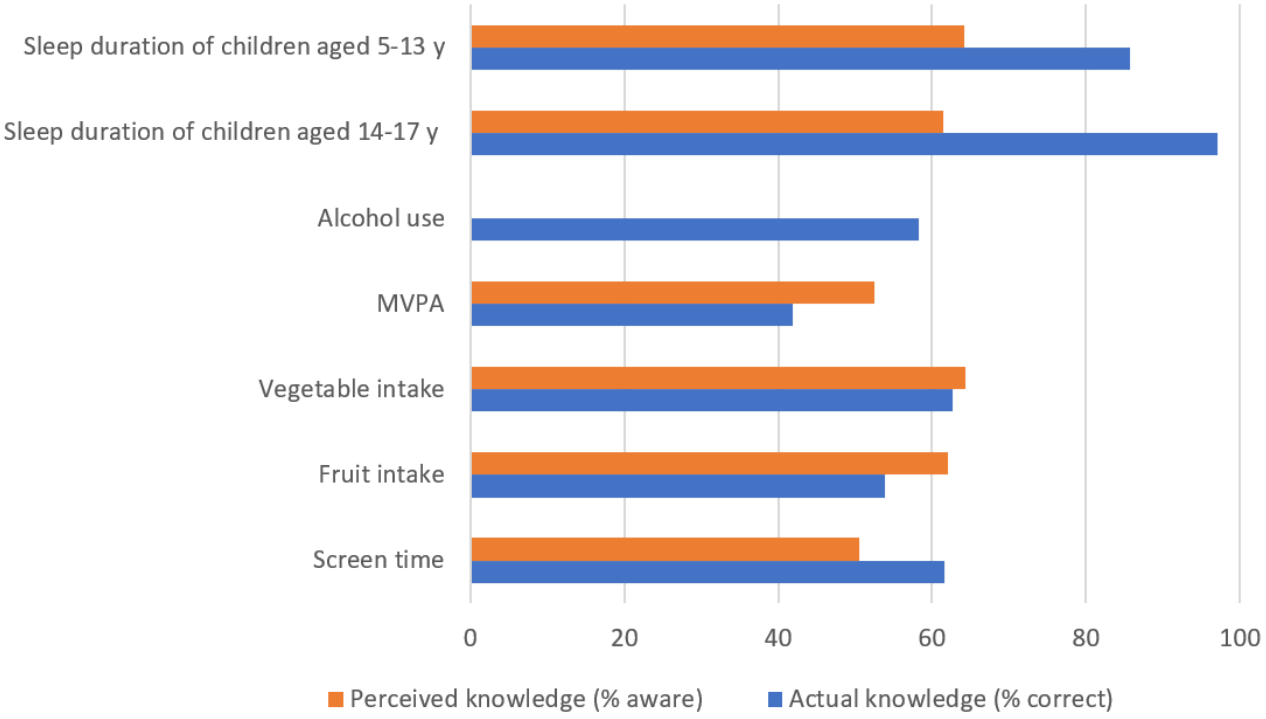
[i]Parents: n=37; adolescents: n=23.

Approximately half of the parents (71/131, 54.2%) reported that their child consumed the recommended minimum of 2 serves of fruit per day; however, only 5.6% (7/126) indicated that their child ate the recommended 5 serves of vegetables. Similarly, only 3.4% (5/149) of parents reported that their adolescent child achieved the recommended guideline of 60 minutes of MVPA per day. In contrast, adolescent sleep duration was perceived to be high, with parents reporting a mean of 9.18 (SD 1.58) hours per night and the vast majority perceiving their child to meet recommended sleep guidelines (33/37, 89% for children aged <14 years; 68/81, 84% for children aged >14 years). A total of 39.2% (51/130) of parents indicated that their adolescent child met the national guidelines of <2 hours of daily screen time on school days; however, only 5.4% (7/130) of parents reported that their child met the guidelines on weekend days. In terms of substance use, 5.8% (9/156) of parents reported that their child had ever used alcohol; 7.8% (12/153) of parents reported that their children had smoked tobacco, and 15% (24/160) of the parents reported that their children had ever used e-cigarettes. Parent vegetable intake was moderately and positively correlated with parent-reported adolescent vegetable intake (r=0.618; P<.001), however, the correlations for all other risk behaviors were weak (Multimedia Appendix 1).

Knowledge About Adolescent Health Guidelines

Figure 1 depicts parents' perceived (% aware) and actual knowledge (% correct) of national health guidelines for each risk behavior. Overall, perceived knowledge was moderate, ranging from 50.6% (80/158) for screen time to 72.8% (115/158) for sleep guidelines (for children aged 5-13 years).

Figure 1. Parent knowledge of national youth guidelines for the Big 6 (perceived knowledge not assessed for alcohol use). MVPA: moderate to vigorous physical activity.



Parents tended to overestimate their knowledge regarding fruit and vegetable intake and MVPA. For example, although nearly two-thirds of the parents (111/157, 70.7%) thought that they knew how many serves of fruit their child should be consuming, only half of them (56/104, 53.8%) reported the correct guideline. Of the parents who answered incorrectly, most overestimated the recommended daily serves (45/104, 43.2%, thought the guideline was ≥3 serves). Actual knowledge was lowest for vegetable intake and MVPA, with only 44.2% (46/104) and 42% (31/74) of parents reporting the correct guidelines for these behaviors, respectively. Just over half of the sample (92/158, 58.2%) knew that it is recommended that adolescents must not consume alcohol, and 60% (45/73) of the parents correctly identified that the recommended daily limit for screen time was 2 hours.

In contrast, actual knowledge of sleep guidelines was very high. A total of 85.6% (90/105) of the parents correctly reported that 9 to 11 hours per night is the recommended guideline for younger children. Similarly, although 70.1% (110/157) of parents reported an awareness of the guidelines for children aged 14 to 17 years, nearly all the parents (100/103, 97.1%) correctly identified the recommended 8 to 10 hours per day. Results from the logistic regression analyses indicated that except for screen time on school days, parental knowledge of national health guidelines was not significantly associated with adolescents' adherence to the guidelines (Multimedia Appendix 1).

Parenting Styles, Attitudes, and Rule-Setting

Most parents reported supportive and positive attitudes toward parenting and their child's health. Many parents (120/149, 80.6%) agreed that supporting their children's participation in healthy behaviors was important to them, and most of them (126/147, 85.7%) reported that they enjoy helping their children engage in physical activity, for example, by driving their child to a sports practice or watching their child participate in activities. In terms of role-modeling, most parents (123/149, 82.5%) agreed that they model healthy lifestyle behaviors for their adolescent children, and nearly all (137/150, 91.3%) reported that they upheld expectations for their child and positively communicated them. Finally, most participants reported a strong sense of parenting self-efficacy, with 71.2% (104/146) agreeing that they could do the things that would improve their child's behavior.

Parental control and rule-setting were moderate to high across the 6 risk behaviors. Nearly three-quarters of the parents (104/145, 71.7%) reported that they monitored and set rules about their child's bedtime and wake time. Approximately half of the parents indicated that they monitored what their child could and could not eat or drink (83/148, 56.1%), how much time they could spend on screens per day (81/146, 55.4%), and how much physical activity they engaged in (75/147, 51%). In terms of rules about substance use, 67.9% (99/146) and 67.3% (99/147) of the participants reported monitoring and setting rules about alcohol use and tobacco use, respectively. Nearly all parents (57/62, 92%) reported setting rules about alcohol use for younger adolescents (aged 11-14 years), compared with three-quarters of parents (47/63, 75%) of older adolescents (15-18 years; P=.01). Similarly, parental rule-setting regarding tobacco use was higher for younger adolescents (55/62, 86%) compared with older adolescents (45/63, 71%); however, this difference was not statistically significant (P=.02). Except for rules about dietary intake, the proportion of parents setting rules for physical activity, screen time, and sleep was higher for

younger than older adolescents; however, these differences were not significant (Multimedia Appendix 1). Results from the logistic regression analyses indicated that across all the Big 6, parental rule-setting was not significantly associated with adolescents' engagement in the risk behaviors (Multimedia Appendix 1).

Perceived Importance of Health Behaviors

When asked about the biggest issue facing young people today, parents commonly reported concerns about adolescents' use of technology, including addiction to smartphone devices and social media. Other concerns included mental health, substance use, and negative peer relationships. The key themes extracted from the open-ended responses of 62 participants are presented in Table 3. A total of 36% (54/150) of parents ranked diet as the behavior they would most like to support their adolescent child to change or improve, whereas 17.3% (26/150) of parents ranked screen time as the most important, and 15.3% (123/150) of parents selected sleep. Similarly, when thinking about their own behaviors, 41.5% (61/147) of parents ranked diet as the most important behavior to change, followed by physical activity (26/147, 17.7%), and sleep (19/147, 12.9%).

Table 3. Summary of key themes in relation to parents' biggest concern for adolescents today.

Theme	Example
Technology	
Excessive screen time	"Addicted to electronic devices" (Female parent of a child aged 17 years)
Social media	"The content (not quantity) that they are exposed to online" (Female parent of a child aged 12 years)
Video games	"Staying up late playing games" (Female parent of a child aged 16 years)
Mental health	
Mental health	"Vaping" (Female parent of a child aged 13 years)
Stress	"Stress from school" (Female parent of a child aged 17 years)
Substance use	"Social isolation and mental health" (Female parent of a child aged 12 years)
Peer relationships	
Peer pressure	"Social pressures to conform" (Female parent of a child aged 16 years)
Peer acceptance	"Being accepted by their peers" (Female parent of a child aged 14 years)
Physical health	
Insufficiently active	"Low activity levels" (Male parent of a child aged 15 years)

Barriers and Facilitators to Engaging in Health Behaviors

Table 4 presents the top 3 barriers, motivators, and enablers related to parents' own health behaviors and their adolescent children's behaviors. The most common barrier for both parents and adolescents was lack of motivation, endorsed by 42.5% (76/179) and 50.8% (91/179) of the parents, respectively. In terms of motivating factors, the most endorsed option for parents was setting a good example for their children (108/179, 60.3%) and enjoying a healthy lifestyle for adolescents (87/179, 48.6%). The top 3 factors that enabled a healthy lifestyle were the same for parents and their adolescent children, namely, integration of healthy behaviors into their lifestyle and routine, access to healthy options, and social support and encouragement (Table 4).

Table 4. Barriers, motivators, and enablers associated with healthy behaviors (N=179).

	Parents, n (%)	Adolescents, n (%)
Barriers		
Lack of motivation	76 (42.4)	91 (50.8)
Limited facilities or resources	43 (24)	N/A[a]
Financial constraints	41 (23)	N/A
Lack of access to healthy options in the home	N/A	39 (21.8)
Lack of time	N/A	34 (19)
Enablers		
Integration of healthy behaviors into lifestyle	111 (62)	93 (52)
Access to healthy options	82 (45.8)	81 (45.2)
Social support and encouragement	59 (33)	95 (53.1)
Motivators		
Setting a good example	108 (60.3)	N/A
Desire to be healthy	103 (57.5)	69 (38.5)
Mental health benefits	100 (55.9)	71 (49.7)
Enjoyment of a healthy lifestyle	N/A	87 (48.6)

[a]N/A: not applicable.

Intervention Preferences

A minority of participants (21/156, 13.5%) indicated that they were not interested in accessing a parent-based healthy lifestyles intervention to improve adolescent health owing to following reasons: they already had adequate knowledge, had already implemented health-promoting strategies at home, and reported a lack of time. Of the nearly three-quarters of parents (115/156, 73.7%) who indicated that they would be interested, 41.1% (53/129) of the parents said their preferred delivery method was through a website. The second most preferred delivery method was face-to-face sessions (29/129, 22.5%), followed by mobile apps (25/129, 19.4%). Most parents (80/134, 67.1%) indicated that they would be willing to spend 10 to 40 minutes per week on a parent-based program, with approximately one-quarter of the parents (32/134, 23.9%) reporting that they would spend 30 to 40 minutes. Regarding intervention components and content, most parents (89/126, 70.7%) rated opportunities for goal-setting as "very" or "extremely" important for developing a parent-based adolescent health intervention, followed by parent-child joint sessions (88/125, 70.4%) and case studies (81/123, 65.9%). Other important program features identified by the parents were ease of use (89/122, 72.9%), appropriate program length (74/126, 58.8%), and paced learning (79/126, 62.7%).

Discussion

Principal Findings

This study aimed to explore parents' knowledge about the Australian guidelines for the Big 6 risk factors (physical inactivity, poor diet, recreational screen time, poor sleep, smoking, and alcohol use); attitudes and parenting practices in relation to the Big 6; barriers and facilitators; and preferences for a parent-based preventive intervention. Although most parents perceived themselves and their adolescent children to be achieving adequate sleep, engagement in the other lifestyle risk behaviors was high. Parents reported low vegetable consumption by themselves and their adolescent child, which aligns with the latest national prevalence data on youth [50]. Although closer to the recommended serves, the average fruit consumption was still below the national guideline for both parents and adolescents. Perhaps unsurprisingly, when asked which of the Big 6 behaviors they would most like to change, parents reported dietary habits as the most common response for both themselves and adolescents. In terms of adolescents, the most concerning behaviors were the low proportion of youth meeting the national recommendations for MVPA and screen time on weekends. This is consistent with the high rates of these risk behaviors observed in other large samples of adolescents in Australia [9] and worldwide [1,51] and highlights the urgent need for preventive measures to improve these behaviors among youth.

Overall, parental self-efficacy was high, and most parents reported a supportive parenting style and positive attitudes toward their child's health behaviors. However, parental knowledge of the national youth guidelines for the Big 6 was moderate. Except for sleep, there were clear knowledge gaps regarding the guidelines for fruit and vegetable intake, MVPA, alcohol use, and screen time, as well as mismatches between perceived and actual knowledge of the guidelines. Concerningly, a large proportion of parents (66/158, 41.8%) were unaware that abstaining from alcohol was the safest option for adolescents, as stipulated in the national guidelines, highlighting a clear priority for further parental education. Parental control and rule-setting were moderate to high across the 6 risk behaviors, with parents more likely to set rules about alcohol and tobacco use for younger adolescents (aged 11-14 years)

than for older adolescents (aged 15-18 years); however, these were not statistically significant differences. This aligns with research suggesting that parental rule-setting should be appropriate to an adolescent's developmental stage to effectively protect against risk behaviors [52]. Although higher parental behavioral control, or rule-setting, may be suitable for younger adolescents, there is an increased need for autonomy and independent decision-making regarding health behaviors alongside rules as adolescents grow [52,53]. However, given the strong evidence for rule-setting as a protective factor against adolescent alcohol and tobacco use and related harms [54,55], parents should set rules in line with the Australian National Guidelines for alcohol and tobacco use, supporting abstinence for those aged <18 years. Although parental rule-setting was not significantly associated with adolescents' engagement in any of the Big 6 risk behaviors, prior research has found rule-setting to be important for adolescent behaviors, particularly in relation to alcohol use [54,55], sleep [19], and screen time [56]. This suggests that rule-setting should be considered when designing new parent-based interventions to improve adolescent health, and further research exploring associations between the Big 6 risk behaviors and parental control and rule-setting among larger samples of parents and youth may be warranted.

Comparison With Prior Work

There is some evidence to suggest that adolescent knowledge of guidelines is associated with better adherence to guidelines [57]; however, the relationships between parental knowledge of guidelines and adolescent health behaviors have not been well studied. Prior research has found that the related concept of parental health literacy, that is, competency in accessing, understanding, appraising, and applying health-related information [58], is associated with adolescent health behaviors, particularly in relation to healthy dietary intake [59]. For example, in a German study of >4000 parents, children (>11 years) of parents with better health literacy reported eating more vegetables and salad and consuming fewer sweetened beverages [59]. In another study of parent-adolescent dyads in the United States, the odds of obesity among youth decreased with higher levels of parental health literacy [60]. Although we did not find evidence of an association between parental knowledge of national health guidelines and adolescents' adherence to guidelines in this study, our analyses were limited by our small sample size, low cell counts for some variables, and parent-reported, rather than adolescent-reported, risk behaviors. Nonetheless, in the context of prior work, the findings suggest that health promotion campaigns and preventive interventions are needed to improve parents' health literacy and knowledge about national guidelines for the Big 6 risk behaviors, particularly in relation to diet, MVPA, alcohol use, and screen time. However, increasing knowledge alone is unlikely to be sufficient to promote behavior change among adolescents [61], and including opportunities for skill-building for parents and adolescents is also critical.

Implications for Prevention

This study has several important implications for parent-based interventions to prevent multiple lifestyle risk behaviors among adolescents. First, the most highly rated intervention component by parents was goal-setting, a commonly used and effective behavior change technique (BCT) in interventions targeting the Big 6 risk factors [62]. This suggests that future interventions should include opportunities for parents to set and track goals to improve their families' health. In addition, our finding that the most common barrier to engaging in healthy behaviors was a lack of motivation suggests that future parent-based interventions should include motivational interviewing or other effective BCTs such as "feedback on behaviour," which has been shown to increase engagement and provide motivation [63]. Other common barriers reported by parents were limited facilities or resources and financial constraints, indicating that interventions should seek to educate and empower parents about adopting healthy behaviors, such as eating healthily on a budget and doing physical activity beyond organized sports and paid activities, which are within budget and practical limitations. Similar research has found that practical constraints such as cost and access to resources play an important role in parents' engagement in adolescent healthy lifestyle programs [64]. In terms of enabling factors, the top 3 factors were integration of healthy behaviors into lifestyle, access to healthy options, and social support and encouragement. Indeed, social support is increasingly recognized as an important BCT for health interventions targeting multiple behaviors [65,66] and was identified as the most effective BCT in a recent systematic review of parent-based interventions [27]. Therefore, future prevention efforts for parents should aim to support families in embedding new skills into their lifestyle and routines and provide opportunities for social support, both emotional and practical.

The findings from this study also support the use of eHealth approaches, particularly web-based interventions. eHealth programs can be completed remotely and flexibly and reduce financial, travel, and work-related costs, making them a viable option for many parents [67]. This includes families from disadvantaged backgrounds who typically have higher rates of chronic disease risk factors [68] and poorer health outcomes [69,70]. In addition, other findings suggest that future parent-based interventions targeting the Big 6 should be brief (10-40 minutes per week), easy to use, and offer paced learning. Finally, qualitative data indicated that parents were primarily concerned about adolescents' use of technology, including the excessive use of smartphones, social media, and gaming, as well as mental health, substance use, and negative peer relationships. This coincides with recent data indicating the growing prevalence of screen time [9], vaping [33], and poor mental health [71] among Australian adolescents, particularly in the aftermath of the COVID-19 pandemic [72,73]. Previous research has similarly advocated the inclusion of parents within adolescent interventions, particularly those targeting mental health [64,74], as a means of maximizing outcomes. Taken together, this suggests that parents are likely to be receptive to a brief eHealth program designed to address contemporary issues, such as vaping and mental health, alongside programs that target chronic disease risk factors and those that aim to circumvent the practical (eg, transport [74], cost [64,74], scheduling [74]) and social (eg, stigma [74] and fear of judgment about parenting) barriers that have traditionally hindered engagement.

Limitations

This study has several limitations that should be considered. First, although 353 parents responded to the survey, nearly half of them (n=174, 49.3%) were deemed ineligible, resulting in a small sample of 179 parents. In addition, although we recruited participants nationwide via social media, most participants in the sample were well educated, employed, and English speaking, which limits the generalizability of our results. Given the well-known health inequalities among parents and adolescents from low socioeconomic backgrounds and culturally and linguistically diverse populations, further work among more diverse populations is needed. In contrast, nearly 40% of our sample were male participants, which is a strength, as fathers typically find it difficult to engage in this type of prevention-related research [48]. In addition, this study was cross-sectional in nature, and further longitudinal research is needed. Another limitation is that parents were asked to self-report their engagement in risk behaviors, increasing the probability of bias and random error. Self-reporting is subject to several biases, including social desirability and recall bias, which may have led to the overestimation of healthy behaviors across the sample [75]. Furthermore, data on adolescent's engagement in the risk behaviors were parent reported, which limits their reliability and validity, especially in relation to substance use and sleep. Indeed, research shows that parents typically overestimate their adolescents' sleep duration, highlighting the importance of using adolescent-derived estimates of sleep patterns in this age group [32]. Although it was not feasible to recruit parent-child dyads in this study, future research should seek to do so to supplement parent-reported data. This would provide a more comprehensive picture of health behaviors and related factors within the family unit and enable more robust explorations of whether parenting factors, such as role-modeling, rule-setting, and knowledge of guidelines, are associated with improved adolescent risk behaviors. The inclusion of peers, who become particularly influential among the older adolescents, may also be of benefit in such research.

Conclusions

This cross-sectional survey of Australian parents revealed important findings regarding information needs and intervention preferences for preventing multiple lifestyle risk behaviors among adolescents. The results suggest that to promote healthy behaviors among adolescents, future parent-based interventions should be delivered via eHealth methods, and they must aim to increase parental knowledge of health guidelines; provide opportunities for skill-building, such as goal-setting; and include effective BCTs such as motivational interviewing and social support.

Acknowledgments

This review was funded by the Prevention and Early Intervention in Mental Illness and Substance Use National Health and Medical Research Council (NHMRC) Centre of Research Excellence; the Paul Ramsay Foundation; and an NHMRC Early Career Fellowship to KEC (APP1120641), NHMRC Career Development Fellowship to NCN (APP1166377), and NHMRC Investigator Grant to MT (APP1195284).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Additional analyses, recruitment flyer, and national health guidelines for adolescents.
[DOCX File , 819 KB - pediatrics_v6i1e42272_app1.docx]

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Abbreviations

BCT: behavior change technique
MVPA: moderate to vigorous physical activity

Edited by S Badawy; submitted 06.10.22; peer-reviewed by S Khor, T Baranowski; comments to author 25.12.22; revised version received 15.02.23; accepted 16.02.23; published 04.04.23.

Please cite as:
Champion KE, Hunter E, Gardner LA, Thornton LK, Chapman C, McCann K, Spring B, Slade T, Teesson M, Newton NC
Parental Information Needs and Intervention Preferences for Preventing Multiple Lifestyle Risk Behaviors Among Adolescents: Cross-sectional Survey Among Parents
JMIR Pediatr Parent 2023;6:e42272
URL: https://pediatrics.jmir.org/2023/1/e42272
doi:10.2196/42272
PMID:37014696

Parental Attitudes on Social Media Monitoring for Youth: Cross-Sectional Survey Study

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Abstract

Background: Online environments dominate the daily lives of American youth and pose evolving challenges to their health and well-being. Recent national poll data indicate that social media overuse, internet safety, and online bullying are among parents' top child health concerns, particularly during the COVID-19 pandemic. While parents are uniquely positioned to help youth navigate social media, their attitudes on monitoring media use may be impacted by a myriad of personal and family factors.

Objective: This study aimed to examine factors associated with parental attitudes about monitoring social media use among youth.

Methods: Data were analyzed from the Voices of Child Health in Chicago Parent Panel Survey, administered to parents over the web and by telephone. Parents with at least 1 child aged ≥11 years responded to questions about bullying and social media monitoring from May to July 2020. The primary outcome was their response to the following question: "Do you think parents should monitor their children's use of social media platforms such as Facebook, Twitter, and Instagram?" Bivariate analyses and multivariable logistic regression were used to examine parental agreement with frequent social media monitoring and concerns about bullying, adjusted for sociodemographic characteristics. Analyses were weighted to represent the parent population of Chicago.

Results: Among 1613 survey respondents, the analyzed sample included 808 parents with at least 1 child aged ≥11 years. Overall, 62.9% (n=566) of parents agreed with frequent parental monitoring of their children's social media use. Compared with parents aged ≤35 years, parents who were >35 years old were significantly less likely to agree with frequent social media monitoring (adjusted odds ratio [aOR] 0.45, 95% CI 0.25-0.81). Parents expressing a high level of concern regarding the effects of bullying were more likely to agree with frequent monitoring of youth social media (aOR 2.15, 95% CI 1.24-3.73).

Conclusions: Parents' personal characteristics and concerns about bullying may influence their attitudes toward monitoring social media use among youth. Given the potential impact of these attitudes on parental monitoring behaviors and the subsequent health impact on youth, pediatricians should consider these factors when counseling about bullying and social media. Child health professionals can support families in developing a safe media use plan that fits family circumstances.

(JMIR Pediatr Parent 2023;6:e46365) doi:10.2196/46365

KEYWORDS

social media; bullying; cyberbullying; parenting; pediatrics; well-being; wellbeing; online; monitoring; youth; internet safety; parent; survey; internet; online; mental health; cross-sectional survey

Introduction

Online environments dominate the lives of American youth and pose evolving challenges to their health and well-being. The overwhelming majority of adolescents have smartphone access and almost half report being online "almost constantly" [1]. Social media represents an important proportion of youth's internet use, providing novel and rapidly shifting platforms for communication and content-sharing [2,3]. While social media may positively impact youth by facilitating social connection [4] and providing resources for seeking support [5], there are numerous potential health risks associated with online platforms,

including sleep disruption [6], problematic internet use [7], and cyberbullying [8-10]. Cyberbullying, defined as the use of electronic communication technologies to bully others [11,12], is widespread among youth, with 59% of US teens reporting that they have experienced online victimization [13].

The impact of online media is also felt by parents. In a recent national poll [14], parents rated overuse of social media, cyberbullying, and internet safety among their top child health concerns. Parents are uniquely positioned to help youth navigate online environments. The extant literature demonstrates that parental monitoring and involvement in media use can mitigate associated risky health behaviors and reduce cyberbullying [15-17]. However, much remains unknown about factors that impact parental monitoring behaviors. For pediatricians and child advocates, who may support families in navigating online media use, it is important to take these factors into consideration.

Drawing on the theory of planned behavior, which maintains attitudes as core determinants of human social behavior [18], we posit that an improved understanding of parental attitudes around social media and cyberbullying may be key to impacting their approach to monitoring youth's online activities. Using parent survey data, this study sought to characterize parental attitudes on social media monitoring for youth. We hypothesized that parental agreement with frequent social media monitoring is related to parents' personal characteristics and their concerns about bullying.

Methods

Ethical Considerations

The institutional review board at Ann & Robert H Lurie Children's Hospital of Chicago determined this study to be exempt (IRB 2019-3063) and that all methods were in accordance with ethical standards. The institutional review board at NORC (National Opinion Research Center) also approved all study activities.

Study Design

Participants were first recruited from the probability-based Voices of Child Health in Chicago (VOCHIC) panel and NORC's AmeriSpeak panel with a 66.2% response rate (1035 responses from 1564 eligible invitees). To ensure a sufficient sample size, the probability sample was augmented by calibration-weighted, non–probability-based responses through opt-in, web-based panels (n=578). The survey was administered by NORC via the web and telephone from May to July 2020 (n=1613) (see additional details in Multimedia Appendix 1 [19-21]). Eligibility criteria included age ≥18 years, being the parent of at least 1 household child, and Chicago residence [19-21]. The present study focused on a subgroup of parents with at least 1 child aged ≥11 years (n=808) to capture parents of children most likely to be active users of social media. Respondents were compensated US $10 for survey completion.

Measures

All measures included in this analysis were part of a broader survey of social emotional learning among children and adolescents, obtained during the VOCHIC summer 2020 administration.

Dependent Variables

The primary outcome measure was the response to the question, "Do you think parents should monitor their children's use of social media platforms such as Facebook, Twitter, and Instagram?" Based on sample response distribution, and to facilitate analyses with a focus on frequent social media monitoring as best aligned with existing recommendations for parental monitoring [22], response options of "yes, frequently," "yes, some of the time," and "no" were collapsed to create a dichotomous variable of "yes, frequently" and "some of the time or no."

Independent Variables

We explored demographic variables and parents' concerns about bullying as potential predictors. Household income was combined into 3 groups based on the US federal poverty level (FPL; <100% FPL, 100%-399% FPL, ≥400% FPL) [23]. Parent education (high school education or below, some college, college degree or higher) and parent age (18-35 years, ≥36 years with midpoint based on subsample distribution) were also assessed. Parents' self-reported race and ethnicity were combined into 4 groups (Black, White, Latinx, and Asian/Other race). Race and ethnicity were included in the analyses to investigate previously reported differences in parental concerns regarding cyberbullying and internet safety [12], as well as differences in youth internet use [1], among minoritized racial and ethnic groups. We examined the age of the oldest child in the household using a dichotomized variable (11-13 or 14-17 years old). The cutoff at 13-14 years was selected to differentiate younger adolescents and preadolescents from their high school–aged counterparts, who may demonstrate different social media use patterns. Parent gender was assessed as male, female, or nonbinary. Due to the small subsample size of nonbinary parents (n=3), this group was omitted from gender analyses. Child school type was coded as "public," "private/charter," or "other."

We assessed parents' level of concern about bullying with the item, "How concerned are you about the following?" followed by 4 bullying concerns compiled as a composite variable, as outlined in Textbox 1.

Textbox 1. Survey items and composite variable related to parental concerns about bullying.

Parental concerns

1. Long-term effects of bullying, such as effects that last into adulthood
2. Short-term effects of bullying, such as kids feeling left out
3. Physical harm or injury due to bullying
4. Mental health or psychological effects of bullying

Response options

1. Not at all concerned
2. Not very concerned
3. Somewhat concerned
4. Very concerned
5. Extremely concerned

Composite variable

1. Low bullying concern
   - 0: “very” or “extremely” concerned responses
2. Medium bullying concern
   - 1-3: “very” or “extremely” concerned responses
3. High bullying concern
   - 4: “very” or “extremely” concerned responses

Statistical Analysis

Bivariate analyses compared survey responses across sociodemographic characteristics and bullying concern categories. χ^2 tests determined the association between predictors and parental agreement with frequent social media monitoring. A multivariable logistic regression model included statistically significant (P<.05) predictors from bivariate analyses. All statistical analyses were population weighted (see Multimedia Appendix 1), used a significance level of P<.05, and were performed using SAS software (version 9.4; SAS Institute).

Results

Of the 808 parent respondents with at least 1 child aged ≥11 years, 566 (62.9%) agreed that parents should frequently monitor their children’s social media. Only 30 (5.2%) parents responded “no” to the primary outcome question, with the remainder responding “yes, some of the time” (n=212, 31.9%). For all other analyses, responses to the primary outcome were dichotomized as described in the *Methods* section. Bivariate analyses demonstrated significant differences (Ps<.05) in response to frequent social media monitoring across parent race/ethnicity, parent and oldest child age, parental education, child school type, and bullying concern level, but not household income or parent gender (Table 1).

Table . Sociodemographic characteristics of the survey sample, by parental agreement with frequent social media monitoring for youth.

		Responses[a]		*P* value[b]
		"Yes, frequently," n (%)[c]	"Some of the time" or "no," n (%)	
Survey sample		566 (62.9)	242 (37.1)	—[d]
Parent race/ethnicity (n=808)				<.001
	White, non-Hispanic/Latinx	208 (63.3)	79 (36.7)	
	Black, non-Hispanic/Latinx	147 (77.2)	45 (22.8)	
	Hispanic/Latinx	188 (61.5)	92 (38.5)	
	Asian/Other[e], non-Hispanic/Latinx	23 (32.5)	26 (67.5)	
Parent age (n=808)				.009
	≤35 years	137 (74.1)	53 (25.9)	
	>35 years	429 (60.1)	189 (39.9)	
Household income (n=790)				.77
	<100% FPL[f]	99 (59.2)	38 (40.8)	
	100%-399% FPL	227 (63.5)	103 (36.5)	
	≥400% FPL	227 (63.5)	96 (36.5)	
Parental education (n=802)				.03
	High school or less	122 (58.4)	71 (41.6)	
	Some college or technical school	149 (74.2)	46 (25.8)	
	College degree or higher	291 (62.2)	123 (37.8)	
Parent gender (n=803)				.08
	Male	170 (58.0)	91 (42.0)	
	Female	394 (67.1)	148 (32.9)	
Oldest child age (n=808)				.01
	11-13 years	251 (71.8)	62 (28.2)	
	14-17 years	315 (58.4)	180 (41.6)	
Child school type (n=762)[g]				.04
	Private/charter	188 (71.5)	65 (28.5)	
	Public	353 (60.6)	156 (39.4)	
Bullying concern level (n=797)				.005
	Low	123 (53.5)	74 (46.5)	
	Medium	189 (61.0)	85 (39.0)	
	High	247 (72.8)	79 (27.2)	

[a]Responses to the survey item "Do you think parents should monitor their children's use of social media platforms such as Facebook, Twitter, and Instagram?"

[b]A significance level of $P<.05$ was used as the threshold for variable inclusion in the multivariable analysis.

[c]Survey-weighted frequencies are displayed as percentages in rows; number (n) of participants are displayed as unweighted counts.

[d]Not applicable.

[e]The Asian/Other race group included non-Hispanic/Latinx groups self-identifying as Chinese, Filipino, Japanese, Korean, Vietnamese, Asian Indian, Samoan, Guamanian or Chamorro, Native Hawaiian, Other Pacific Islander, American Indian or Alaska Native, and "Some other race."

[f]FPL: federal poverty level.

[g]Child school type was coded as "public" if all children aged 11-17 years attended public school, "private/charter" if all children aged 11-17 years attended private or charter school, and "other" if children attended another type of school or if children in the household attended different types of schools. The "other" group was omitted from analyses due to heterogeneity and small sample size.

In multivariable logistic regression, parents over age 35 had significantly lower odds of agreeing with frequent social media monitoring for youth (adjusted odds ratio [aOR] 0.45, 95% CI 0.25-0.81), compared with younger parents (Table 2).

Table . Adjusted odds ratio (aOR) of parental agreement with frequent social media monitoring for youth, by sociodemographic characteristics and bullying concerns.[a]

	aOR	95% CI	*P* value
Parent race/ethnicity (ref[b]: White, non-Hispanic/Latinx)			
Black, non-Hispanic/Latinx	1.85	0.92-3.73	.08
Hispanic/Latinx	0.97	0.51-1.83	.92
Asian/Other, non-Hispanic/Latinx	0.34	0.14-0.82	.02
Parent age (ref: ≤35 years)			
>35 years	0.45	0.25-0.81	.007
Parental education (ref: high school or less)			
Some college or technical school	1.88	1.03-3.43	.04
College degree or higher	1.11	0.61-2.00	.74
Parent gender (ref: male)			
Female	1.12	0.68-1.84	.65
Oldest child age (ref: 14-17 years)			
11-13 years	1.57	0.94-2.62	.08
Child school type (ref: all children in public)			
All children in private/charter	1.47	0.86-2.49	.16
Bullying concern level (ref: low)			
Medium	1.72	0.98-3.02	.06
High	2.15	1.24-3.73	.007

[a]Multivariable regression model adjusted for all variables listed in the table.

[b]Ref: reference.

Respondents who identified as Asian/Other race also had lower odds of agreement with frequent social media monitoring (aOR 0.34, 95% CI 0.14-0.82) than White parents. Parents had higher odds of agreement with frequent monitoring if they had some college or technical school education (aOR 1.88, 95% CI 1.03-3.43), compared with high school or less. Having a high level of concern about bullying was associated with 2.15 times increased odds of agreement with frequent social media monitoring among parents (95% CI 1.24-3.73), compared with a low level of bullying concern. In adjusted analyses, parent gender, child age, and child school type were no longer associated with agreement with social media monitoring.

Discussion

Principal Findings

In a representative sample of parents in a large, socioeconomically diverse, urban population, we found that most parents agreed with frequent monitoring of social media use among youth. Parents were more likely to have positive attitudes about frequent social media monitoring if they were younger and more concerned about the negative effects of bullying. As attitudes are a key determinant of behavior, these findings add important context to the literature surrounding the monitoring of media use in youth, amid mounting parental concerns regarding online environments and child health [14].

In addition to personal attitudes, recent studies have suggested that elements such as knowledge, perceived control, and risk assessment may be key to understanding parents' involvement in youth social media and cyberbullying prevention [24,25]. Indeed, our results indicated that younger parents, who might have more personal familiarity with social media than older parents, were more likely to agree with frequent monitoring of youth. In discussing the monitoring of youth media use, it is important for pediatricians to consider how parents' own experiences and familiarity with various platforms may impact their attitudes and, therefore, behavior.

Our findings also highlight that concerns about the risks of bullying may be an important driver of parents' attitudes on social media monitoring. For pediatricians who routinely provide guidance around bullying, these conversations may afford an ideal opportunity to also explore families' media use practices and address concerns about online environments. Child health

professionals are well positioned to provide education and make recommendations, including on the development of a family media plan and active supervision of youths' online activities [11].

Limitations

It is important to acknowledge this study's limitations. While results are weighted to represent households in Chicago, they may not generalize to other populations. However, Chicago is a diverse city with similar demographics to the United States more broadly, so we expect that results likely generalize to other large US cities [26]. Importantly, respondents were voluntary members of a panel and may respond differently than parents in the general population. Responses to the primary outcome variable were collapsed from 3 into 2 options based on subsample sizes and alignment with recommendations for parental monitoring practices, and may not fully capture nuanced differences among participants' attitudes. Similarly, some demographic data, such as parent age, were measured categorically, limiting analysis options. The subsample of participants identifying as Asian/Other race/ethnicity was small and heterogeneous, limiting the interpretability of results for this group. Finally, the effect of nonresponse bias should be considered given the study's survey-based design.

Conclusions

Amid mounting parental concerns regarding online media, this large study of a diverse group of urban parents indicates that attitudes regarding monitoring of youth social media use vary. Personal characteristics such as parent age and concern for the health impact of bullying were associated with parents' agreement with frequent social media monitoring for youth. These factors may provide helpful context for pediatricians as they support families in navigating safe media use. Improved understanding of parents' attitudes about social media will continue to be an essential focus as future research examines targets for intervention to promote healthy social media use among youth.

Acknowledgments

The Voices of Child Health in Chicago survey is supported by an anonymous family foundation dedicated to supporting research that advances community health in low-resource neighborhoods and the Patrick M Magoon Institute for Healthy Communities at Ann & Robert H Lurie Children's Hospital of Chicago. The content is solely the responsibility of the authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplemental information on methods.
[DOCX File, 15 KB - pediatrics_v6i1e46365_app1.docx]

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Abbreviations

aOR: adjusted odds ratio
FPL: federal poverty level
NORC: National Opinion Research Center
VOCHIC: Voices of Child Health in Chicago

Edited by S Badawy; submitted 22.03.23; peer-reviewed by C Pehora, K Roystonn, L VonHoltz; revised version received 13.09.23; accepted 27.09.23; published 16.11.23.

Please cite as:
Cohen A, Bendelow A, Smith T, Cicchetti C, Davis MM, Heffernan M
Parental Attitudes on Social Media Monitoring for Youth: Cross-Sectional Survey Study
JMIR Pediatr Parent 2023;6:e46365
URL: https://pediatrics.jmir.org/2023/1/e46365
doi:10.2196/46365

Problematic Social Media Use and Lifestyle Behaviors in Adolescents: Cross-Sectional Questionnaire Study

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Abstract

Background: The use of social media by adolescents has increased considerably in the past decade. With this increase in social media use in our daily lives, there has been a rapidly expanding awareness of the potential unhealthy lifestyle-related health effects arising from excessive, maladaptive, or addictive social media use.

Objective: This study aims to assess the association between adolescents' social media use and health-related behaviors.

Methods: We used a cross-sectional research approach and analyzed data from 96,919 adolescents at high schools throughout the Netherlands. A structured 43-item questionnaire was used to gather data on sociodemographics, dietary and lifestyle factors, and the degree of social media use based on the Compulsive Internet Use Scale. Logistic regression analyses were performed to assess the association between problematic social media use (PSMU) and lifestyle behaviors while adjusting for sociodemographic factors.

Results: Of the 96,919 included adolescents, 7.4% (n=7022) were identified as at risk for PSMU. Furthermore, logistic regression results showed that adolescents who are at risk for PSMU were more likely to report alcohol consumption and smoking while simultaneously having significantly lower levels of health-promoting behavior such as healthy eating habits (eating fruits, vegetables, and breakfast regularly) and physical activity.

Conclusions: This study confirms that adolescents at risk of PSMU were more likely to exhibit an unhealthy lifestyle. Being at risk for PSMU was a determinant of soft drug use, alcohol consumption, smoking, poor eating habits, and lower physical activity independent of the additional adjusted covariates including demographic variables and remaining lifestyle variables. Future research is needed to confirm this observation in an experimental setting.

(JMIR Pediatr Parent 2023;6:e46966) doi:10.2196/46966

KEYWORDS

problematic social media use; lifestyle factors; adolescents; lifestyle behaviors; social media; addictive social media use; high school; users; risk factor; sociodemographic factors; addiction; internet; internet use; social media use

Introduction

Nowadays, social media is an important part of the daily life of adolescents. In today's society, social media has been widely adopted, and adolescents have the highest rates of social media use of any age group [1]. As the time spent by adolescents online has almost doubled in the past decade, the widespread interest in how this might be affecting them led to the development of scientific evidence mapping potential associations between social media use and health outcomes [2,3].

Adolescence is a developmental stage in which parental influence decreases and the opinions of peers become more important in determining behavior [4,5]. Therefore, adolescence has been proposed to be an important time for the development of lasting health behaviors [6]. Following the behavior learning theory, individuals learn from one another via observation, imitation, and modeling [7]. Previous scientific evidence has shown that exposure to online behavior is a significant source of influence on adolescents' health attitudes, intentions, and behaviors in which adolescents are motivated to fit into group identities and adopt the normative behaviors of their peers [4,8,9].

Social media provides clear benefits, of which social interaction is the most important [10]. The interactive nature can provide opportunities to engage with peers on issues and access support networks [4]. Other reasons for social media use are the gathering of information and entertainment purposes such as watching movies and listening to music [1,11,12]. Despite these benefits, the negative impacts of social media use have become increasingly apparent, in particular, excessive, maladaptive, or addictive use of social media, which is a condition also known by terms such as problematic social media use (PSMU) [13]. In general, PSMU can be defined as "Use of social media that creates physiological, social, school, and/or work difficulties in a person's life" [14]. There are notable unhealthy lifestyle behaviors associated with PSMU among adolescents, such as

physical inactivity, substance use, and poor dieting habits, and related to each other by confounding. Likewise, social media use is positively associated with sedentary behavior [11,15]. For adults, there is strong evidence linking sedentary behavior to a higher risk of overweight and obesity, cardiovascular disease, metabolic dysregulation, insufficient sleep, osteoporosis, and a reduction of psychosocial functioning [15,16]. Additionally, these negative health consequences are more likely to develop in adults who spent greater amounts of time sedentary in their youth [15,17]. These consequences highlight the importance of restricting sedentary time among young people and adolescents [15].

International concern for the well-being and health of adolescents has been growing after reports of increases in unhealthy lifestyle behaviors [18]. The literature showed both positive and negative associations between health behavior and social media whereby the overall conclusion states that the time spent on social media replaces time spent otherwise on health-related behaviors, such as physical activity or sleeping [1,3,5,11,12]. These findings are consistent with the displacement hypothesis, which declares that interactions through online relationships would displace the time allocated for offline activities, resulting in a disruption to one's supposedly more valuable offline relationships [6,19]. However, most of the research on this topic has been conducted in Asian countries, and therefore, European results are of great interest as an addition to the current literature [14]. Furthermore, most studies did not account for other lifestyle factors that can confound the observed associations. Therefore, this study aimed to explore the health impacts related to a lifestyle of social media use among adolescents living in the Netherlands.

Methods

Data Source

The data used for the study were collected from the Public Health Monitor Youth 2015, which is a nationally representative observational cross-sectional survey of eighth and 10th grade adolescents in the Netherlands [20]. The Public Health Monitor Youth collected data through anonymous digital questionnaires in 596 high schools throughout the Netherlands. To obtain a nationally representative sample of schools and pupils, the survey used a random sampling design in a total of 25 municipal health care service regions. The size of samples varied per region. Schools were invited by letter to participate. Both parental consent and adolescents' consent were obtained in advance of the questionnaire. Participation in this study was voluntary. Adolescents completed the questionnaire anonymously via the internet during class.

Participants

A total of 596 schools were asked to participate. The school response rate to the survey was 63.1% (n=376), and nonresponse was mostly due to an overload of other surveys and fundamental objections. We derived the study sample from Public Health Monitor Youth surveys conducted in 2015 [20]. The data consisted of a pooled sample of 96,919 adolescents between the ages of 12 and 19 years who answered the questions on social media use and health behaviors.

Ethical Considerations

Data collection procedures were approved (W19_148 # 19.183) by the ethical committee of The National Institute for Public Health and the Environment. Further details on the study design and methods are described elsewhere [20]. Following Dutch law (Wet medisch wetenschappelijk onderzoek met mensen), ethical review and approval were not required for the Public Health Monitor Youth as participants were not subjected to any intervention or treatment. Additionally, parents and children were informed by letters that by filling out the questionnaire, they consented to the anonymous use of data for research.

Questionnaire

A questionnaire with 43 multiple-choice questions was used to elicit information regarding each adolescent's social media use and lifestyle behavior (Multimedia Appendix 1). The questionnaire was divided into five parts. In the first part, adolescents were requested to respond to general and demographic questions (eg, sex, age, type of education, and origin). The second part covered the perceived physical, social, and mental health of the adolescents. The third part provided questions about their lifestyle behaviors. Questions on lifestyle behaviors included substance use (eg, "What types of substances have you ever used?"), alcohol consumption (eg, alcohol use per 4 wk and in a lifetime), smoking (eg, "Have you ever smoked?" and "How often do you smoke"), eating habits (breakfast habits and the number of days eating fruits or vegetables), and physical activity (number of days per week of physical activity for at least 1 h). In the fourth part, the adolescents were asked about their school life experiences (eg, functioning at school or bullying). The last part addressed questions related to adolescents' social media use, gaming resilience, and sexuality. Questions related to social media referred to the use of messaging via smartphone, tablet, or PC (eg, WhatsApp or Snapchat); social network sites (eg, Facebook or Twitter); and forum sites. The frequency of social media use ("How often are you active on social media?") was measured by a Likert-like scale with 6 response possibilities: never, <1 day per week, 1 day per week, 2-3 days per week, 4-5 days per week, or (almost) every day.

Problematic Social Media Use

To measure the consequences of PSMU, the abbreviated version of the Compulsive Internet Use Scale from the Dutch research institute IVO was used [21]. The outcome variable, at risk for PSMU, was based on the following 7 items of the Compulsive Internet Use Scale: "How often do you find it difficult to quit social media?" "How often say others that you should spend less time on social media?" "How often would you rather use social media than spend time with others in real life?" "How often do you feel restless, stressed or annoyed when you can't use social media?" "How often do you neglect your homework to use social media?" "How often are you using social media because you feel bad?" and "How often do you lack sleep through social media?" A Likert-like scale was used with 5 possible responses: never (0), seldom (1), sometimes (2), often (3), and very often (4). The mean values of the sum of the Likert scale responses were calculated, and a mean score of 0 to 2 was labeled as no or low risk of PSMU, and a total of 2 to 4 was

labeled as at risk of PSMU. These cutoffs were based on the approach of Van Rooij et al [22] who found groups demarcating potential addiction and high-risk use for high engagement based on latent class analysis in the general population.

Covariate Assessment

Covariates of interest were derived from the existing literature. All covariates were measured by the original questionnaire. The following covariates were considered important because of their relationship with PSMU: sex (male/female); age (continuous); family composition (two parents, stepfamily, co-parenting, single-parent household, or living with others or on its own); educational level (prevocational secondary education, senior general secondary education, or preuniversity education); soft drugs (never, ever, or recently used marijuana or hash); hard drugs (never, ever used, or recently using ecstasy, cocaine, psychedelic mushrooms, amphetamine, lysergic acid diethylamide, gamma hydroxybutyrate, heroin, or laughing gas); alcohol consumption (never, ever, or recently used alcohol); smoking (never smoked, ever smoked, or daily smoker); physical activity (weekly physical activity at a club or gym: yes/no); and eating breakfast (5 or more times a week: yes/no), fruits (5 or more times a week: yes/no), or vegetables (5 or more times a week: yes/no). For soft drugs, hard drugs, and alcohol, the "recently used" category indicates that someone used drugs or alcohol in the last 4 weeks.

Statistical Analysis

The *P* value for trend was calculated by using a linear regression model. Results of the multiple logistic regression models to analyze the association between PSMU and individual lifestyle factors were presented in an unadjusted model (model 1); a model adjusted for sex, age, and educational level (model 2); and a model between the risk of PSMU and lifestyle behaviors, corrected for sex, age, educational level, family composition, mutual adjustment for substance use (soft and hard drugs), alcohol consumption, smoking, physical activity, and eating habits (fruit, vegetable, and breakfast intake; model 3). The associations were reported as odds ratios (ORs) with 95% CIs. *P* values <.05 were considered to be statistically significant. Missing values were imputed by using the Markov chain Monte Carlo method. After the imputation procedure, the effect estimates were pooled. The pooled estimates were used to perform the analyses in this study. All analyses were performed by using the statistical software SPSS version 26 (IBM Corp).

Results

Study Population Characteristics

Table 1 presents the characteristics of the study sample over two groups based on the risk for PSMU. The study sample consisted of adolescents who answered questions on social media use and health behaviors (N=96,919) in which 89,710 (92.6%) of the adolescents were not at risk or were at low risk for PSMU, while 7209 (7.4%) were at risk for PSMU. The at-risk PSMU group consisted of a higher number of female adolescents 4749 (65.9%). Both groups had approximately equal mean ages (14.29, SD 1.25 years vs 14.48, SD 1.22 years), ranging from 12 to 19 years. Preuniversity education was more common among low-risk users (n=19,151, 21.4%) than in the at-risk PSMU group (n=856, 11.9%), and the majority of both groups attended prevocational school or senior general secondary education. Lifestyle behaviors such as substance use, alcohol consumption, and smoking were more commonly observed among the at-risk PSMU group. No-risk or low-risk users skipped breakfast, fruit, and vegetable intake less often compared to the at-risk PSMU group.

Table . Baseline characteristics of included adolescents (N=96,919).

			No or low-risk problematic social media use	At-risk problematic social media use	*P* value
Total, n (%)			89,710 (92.6)	7209 (7.4)	N/A[a]
Sex (female), n (%)			43,292 (48.3)	4749 (65.9)	<.001
Age (years), mean (SD)			14.29 (1.25)	14.48 (1.22)	<.001
Family composition, n (%)					<.001
	Two parents		68,537 (76.4)	4877 (67.7)	
	Stepfamily		5801 (6.5)	647 (9.0)	
	Co-parents		5838 (6.5)	518 (7.2)	
	Single parent		8573 (9.6)	956 (13.3)	
	With others or on its own		961 (1.0)	211 (2.9)	
Educational level, n (%)					<.001
	Prevocational secondary education		45,760 (51)	4622 (64.1)	
	Senior general secondary education		24,799 (27.6)	1731 (24.0)	
	Preuniversity education		19,151 (21.4)	856 (11.9)	
Substance use, n (%)					
	Soft drugs				<.001
		Never used	81,190 (90.5)	5601 (77.7)	
		Recently used	4248 (4.7)	917 (12.7)	
		Ever used	4272 (4.8)	693 (9.6)	
	Hard drugs				<.001
		Never used	88,193 (98.3)	6819 (94.6)	
		Recently used	546 (0.6)	149 (2.1)	
		Ever used	972 (1.1)	241 (3.3)	
Alcohol use, n (%)					<.001
	Never used		59,433 (66.3)	3096 (42.9)	
	Recently used		23,510 (26.2)	3398 (47.1)	
	Ever used		6767 (7.5)	715 (10.0)	
Smoking, n (%)					<.001
	Never smoked		77,081 (85.9)	4778 (66.3)	
	Ever smoked		8749 (9.8)	1563 (21.7)	
	Daily smoker		3881 (4.3)	868 (12.0)	
Physical activity, n (%)					<.001
	Weekly, yes		69,794 (78.1)	4968 (68.9)	
Eating habits, n (%)					
	Breakfast ≥5 d/wk, yes		76,194 (84.9)	4625 (64.2)	<.001
	Fruit ≥5 d/wk, yes		45,160 (50.3)	2661 (36.9)	<.001
	Vegetables ≥5 d/wk, yes		72,187 (80.5)	4937 (68.5)	<.001

[a]N/A: not applicable.

PSMU and Lifestyle Behaviors

The association between being at risk for PSMU and various lifestyle variables is shown in Table 2. Model 1 demonstrates that, without any adjustments, being at risk for PSMU was positively associated with soft drugs (recently used: OR 3.12, 95% CI 2.90-2.35; ever used: OR 3.12, 95% CI 2.90-2.35) and hard drugs (recently used: OR 3.53, 95% CI 2.88-4.33; ever used: OR 3.20, 95% CI 2.67-3.84), alcohol consumption (recently used: OR 2.77, 95% CI 2.71-2.83; ever used: OR 2.03,

95% CI 1.96-2.10), and smoking (recently used: OR 2.88, 95% CI 2.71-3.07; ever used: OR 3.61, 95% CI 3.50-3.73), and negatively associated with physical activity (OR 0.63, 95% CI 0.62-0.65) and fruit (OR 0.58, 95% CI 0.57-0.59), vegetable (OR 0.53, 95% CI 0.52-0.54), and breakfast intake (OR 0.32, 95% CI 0.31-0.33). After adjusting for sex, age, and educational level (model 2), the model showed similar significant results. Furthermore, model 3 revealed that after adjusting for sex, age, educational level, household composition, and the remaining lifestyle behaviors, only the association with hard drugs became nonsignificant (recently used: OR 1.12, 95% CI 0.90-1.39; ever used: OR 1.09, 95% CI 0.87-1.37) when compared to the other models.

Table . Logistic regression results showing the association between the risk of problematic social media use and lifestyle behaviors among the adolescents.

Outcome variable		Model 1[a], OR[b] (95% CI)	Model 2[c], OR (95% CI)	Model 3[d], OR (95% CI)
Soft drugs				
	Never used	1.00 (reference)	1.00 (reference)	1.00 (reference)
	Recently used	3.12 (2.90-3.37)[e]	3.32 (3.06-3.60)[e]	1.43 (1.29-1.59)[e]
	Ever used	2.35 (2.16-2.56)[e]	2.32 (2.12-2.54)[e]	1.19 (1.07-1.32)[e]
Hard drugs				
	Never used	1.00 (reference)	1.00 (reference)	1.00 (reference)
	Recently used	3.53 (2.88-4.33)[e]	3.30 (2.66-4.09)[e]	1.12 (0.90-1.39)
	Ever used	3.20 (2.67-3.84)[e]	2.72 (2.24-3.29)[e]	1.09 (0.87-1.37)
Alcohol use				
	Never used	1.00 (reference)	1.00 (reference)	1.00 (reference)
	Recently used	2.77 (2.71-2.83)[e]	3.11 (3.03-3.18)[e]	2.26 (2.10-2.43)[e]
	Ever used	2.03 (1.96-2.10)[e]	2.20 (2.12-2.28)[e]	1.80 (1.64-1.98)[e]
Smoking				
	Never used	1.00 (reference)	1.00 (reference)	1.00 (reference)
	Ever used	2.88 (2.71-3.07)[e]	2.73 (2.66-2.80)[e]	1.51 (1.47-1.56)[e]
	Daily use	3.61 (3.50-3.73)[e]	3.37 (2.25-3.49)[e]	1.32 (1.26-1.38)[e]
Weekly physical activity				
	No	1.00 (reference)	1.00 (reference)	1.00 (reference)
	Yes	0.63 (0.62-0.65)[e]	0.74 (0.72-0.75)[e]	0.84 (0.82-0.86)[e]
Fruit intake				
	<5 d/wk	1.00 (reference)	1.00 (reference)	1.00 (reference)
	≥5 d/wk	0.58 (0.57-0.59)[e]	0.59 (0.58-0.60)[e]	0.73 (0.72-0.75)[e]
Vegetable intake				
	<5 d/wk	1.00 (reference)	1.00 (reference)	1.00 (reference)
	≥5 d/wk	0.53 (0.52-0.54)[e]	0.55 (0.54-0.56)[e]	0.67 (0.65-0.69)[e]
Eating breakfast				
	<5 d/wk	1.00 (reference)	1.00 (reference)	1.00 (reference)
	≥5 d/wk	0.32 (0.31-0.33)[e]	0.38 (0.37-0.39)[e]	0.52 (0.50-0.53)[e]

[a]Model 1: unadjusted.

[b]OR: odds ratio.

[c]Model 2: adjusted for sex, age, and educational level.

[d]Model 3: adjusted for sex; age; educational level; household composition; soft drugs; hard drugs; alcohol; smoking; physical activity; and fruit, vegetable, and breakfast intake.

[e]$P<.001$

Discussion

This study showed that adolescents who are at risk of PSMU were more likely to exhibit an unhealthy lifestyle. Being at risk for PSMU was positively associated with substance use, alcohol consumption, and smoking, and negatively associated with physical activity and eating breakfast, vegetables, and fruits regularly, independent of the additional adjusted covariates including demographic variables and remaining lifestyle variables.

In this survey, the prevalence of PSMU was 7.4%, which is mostly in line with previously conducted studies [23-25]. The international variations of PSMU prevalence rates are reported on in a recent study by Cheng et al [26]. In Europe and the United States, prevalence rates ranged from 7.9% to 25.2% among adolescents, and prevalence rates in the Middle East and Africa ranged from 17.3% to 23.6% [23]. Moreover, the highest variation in prevalence among adolescents was observed in Asian studies, with a reported prevalence between 8.1% and 50.9% [23]. Nevertheless, the direct comparison of these studies is complicated due to the different diagnostic criteria and methodologies used (eg, the lack of a consensual definition of PSMU) [23,27]. This study found an independent association of social media with alcohol consumption and less physical activity, which is comparable with the previous Dutch study by Busch et al [28]. They investigated the relationship between screen time (including excessive internet, TV, and video gaming) and several health-related behaviors (eg, soft drugs, alcohol use, smoking, unsafe sex, skipping school, bullying, poor nutritional behavior, and physical activity) in adolescents. The results demonstrated that screen time was independently associated with alcohol consumption, bullying, and less physical activity. However, this study did not account for the mutual relation between health behaviors and only adjusted the analyses for demographic characteristics.

Screen-based sedentary behaviors have been recognized as a significant contributor to negative health indicators in various aspects of adolescents [16,29]. Physical consequences consisted of being overweight and having risk factors for cardiovascular diseases (eg, obesity, hypertension, and high-density lipoprotein dysfunction) due to a lack of physical activity and passive food consumption [16,30,31]. Adolescent screen time and skipping breakfast regularly are associated with a higher calorie intake [32]. Eating in front of a screen and not having a regular breakfast routine can lead to excessive snacking and poor food choices [33]. This results in a higher calorie intake, which can contribute to weight gain and other health problems. Furthermore, sleep quality is affected by exposure to bright and blue lights emitted by digital devices that may suppress melatonin production and cause circadian disruption [16,34]. Another mechanism that affects sleep is chronic sympathetic arousal. Psychophysiological arousal may increase due to playing video games, which leads to sympathetic dysregulation [16,34]. As a result, pre-bedtime relaxation may be impeded, which leads to delayed and shortened sleep [16,35]. At the same time, chronic sympathetic arousal is also associated with metabolic dysregulation, including lower levels of cortisol and insulin resistance [16]. Lastly, a study by French et al [36] observed that outdoor activity stimulates the release of dopamine from the retina. This release of dopamine suppresses the development of myopia. Hence, adolescents who spend more time inside are more likely to become myopic.

Neurophysiological issues can accompany PSMU. One of these issues is a low level of support, resulting in decreased social coping, for example, less social support and attachment with family and peers [16,37,38]. This decrease in social coping comes at the expense of face-to-face contact, which in turn is strongly associated with positive well-being and life satisfaction [16,38]. All of these components together increase the risk for depression, isolation, and loneliness, and may further maintain addictive behavior [16,37]. Likewise, neuroanatomical changes may occur, including decreased impulse control and dysfunctional decision-making and emotional processing, and can involve craving behavior and maintain addictive behavior [16]. Furthermore, it is known from recent studies that several health-related behaviors have a clustered profile. These behaviors influence each other instead of acting independently on one's health [39]. This clustered profile is accompanied by a synergetic effect, which means that certain behaviors increase the likelihood of being involved in other risk behaviors [40]. Consequently, due to this covariance, the risk of disease is higher with clustered behaviors compared to nonclustered behaviors. This increase can be explained by the "Gateway" hypothesis that, on top of the health risks that come with certain risk behaviors, someone's mindset and decision-making abilities are affected by partaking in other risk-taking behaviors [39,41,42]. Empirical support for this theory has been found. For example, alcohol users are more likely to take part in smoking than nonalcohol drinkers [39,41]. Another explanatory hypothesis for the co-occurrence of risk behaviors during adolescence is the "Problem Behavior Theory," which suggests that partaking in "problem behavior" in early adolescence is enacted as a means of demonstrating maturity and independence and repudiating conventionality [42]. This theory has been empirically supported by a few studies that analyzed both common risk and protective factors for risk behaviors [42,43].

This study was strengthened by the fact that this study was conducted with nearly 100,000 adolescents in the Netherlands, using one of the largest surveys ever conducted in terms of the number of samples of epidemiological research into PSMU among adolescents [44]. Besides the large sample size, the participating schools were randomly selected nationwide. This random selection supports the assumption that this sample is representative of the entire Dutch population. Analyses were also strengthened by not only adjusting for potential confounding factors (sex, age, and socioeconomic status) but also mutually adjusting for other lifestyle factors as unhealthy behaviors cluster together [45]. A limitation of this study was that the data was collected as a cross-sectional study. For this reason, it is not possible to determine whether significant associations between PSMU and the presumed outcomes such as an unhealthy lifestyle are causal or whether adolescents with an unhealthy lifestyle are more likely to engage in PSMU; additional longitudinal data assessments with multiple measures of social media addiction are needed. Additionally, social desirability may have influenced the results, as the data was

collected using a self-reported questionnaire. However, since the questionnaire was anonymous and not linked to adolescents' health records, bias due to social desirability was more likely to be diminished. Another shortcoming is the missing data about mental health. The psychiatric profile of the adolescents was not assessed in this study and could be an important factor according to recent research [46]. Therefore, it is possible that mental health problems such as depression have gone unnoticed and may have biased the outcome results, assuming that adolescents with mental issues are less likely to make healthy lifestyle choices. Furthermore, the questionnaire has not been validated. Therefore, differential misclassification could influence the results. Lastly, it can be asserted that, over the past 8 years, social media has undergone transformations that make contextual alignment between 2015 and 2023 somewhat challenging. Nevertheless, we intentionally opted to use pre–COVID-19 pandemic data due to its reduced bias. Subsequent research endeavors should aim to replicate our findings using the same methodology to validate our outcomes.

Concerns about PSMU have increased since the prevalence increased due to the COVID-19 pandemic [47-49]. Given its impact on health, it is important to develop interventions to reduce PSMU. Both pharmacotherapeutic and psychological interventions have been studied to reduce PSMU [50]. Pharmacotherapeutic interventions have mainly paid attention to dopamine regulators and selective serotonin reuptake inhibitors since these medications have proven effective for other psychological conditions such as attention-deficit/hyperactivity disorder, substance use disorder, and obsessive-compulsive disorder [51,52]. A recent meta-analysis by Kim and Noh [53] showed that cognitive behavioral therapy, family-based interventions, and counseling programs can reduce the severity of PSMU [53]. However, evidence on which intervention is most effective in reducing the severity of PSMU and its subsequent impact on health and health behavior is limited. Given the nearly universal accessibility of social media, public health authorities have the opportunity to disseminate messages to adolescents in an innovative way using social media to promote healthy decision-making and thereby a healthy lifestyle. Nowadays, there is considerable interest in digital interventions for behavior change that seem cost-effective [54]. Despite the wide use of some health apps or devices, only a few health apps contain evidence-based behavioral change strategies or theoretical frameworks, or are based on clinical guidelines, and most of them ignore the totality of health behaviors including PSMU [55,56]. Therefore, the validation of the effectiveness of these digital interventions requires future research to address both the challenge of PSMU as well as other health behaviors.

Social media use is currently one of the most popular activities in today's world, which has further increased after the COVID-19 pandemic, with adolescents being more likely to develop PSMU. While social media use is not inherently negative, offering several benefits such as social connection and interaction, excessive and uncontrolled social media use can be accompanied by negative health-related behaviors. This study confirmed that adolescents who are at risk of PSMU were more likely to exhibit an unhealthy lifestyle. Being at risk for PSMU was an independent risk factor for substance use, alcohol consumption, smoking, poor eating habits, and physical activity independent of the additional adjusted covariates including demographic variables and remaining lifestyle variables. To develop effective social media interventions, public health must prioritize studying the clustering of multiple health-related behaviors.

Acknowledgments

We would like to acknowledge the Municipal Health Service–Medical Emergency Services Organization in the Region for providing the data used in this research.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Basisvragenlijst Gezondheidsmonitor Jeugd 2015.
[DOCX File, 59 KB - pediatrics_v6i1e46966_app1.docx]

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Abbreviations

OR: odds ratio
PSMU: problematic social media use

Edited by S Badawy; submitted 03.03.23; peer-reviewed by D Lambert, N Esfandiari; revised version received 27.10.23; accepted 01.11.23; published 28.12.23.

Please cite as:
Ardesch FH, van der Vegt DD, Kiefte-de Jong JC
Problematic Social Media Use and Lifestyle Behaviors in Adolescents: Cross-Sectional Questionnaire Study
JMIR Pediatr Parent 2023;6:e46966
URL: https://pediatrics.jmir.org/2023/1/e46966
doi:10.2196/46966

Parents' Use of Social Media for Health Information Before and After a Consultation With Health Care Professionals: Australian Cross-Sectional Study

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Abstract

Background: Social media is a crucial source of health information for many parents due to its integration into modern life, raising critical concerns for public health. Parents use various social media platforms to find health information for their children, with most information created and shared by parents with no medical or health training. The extent to which parents seek health information from social media before and after a consultation and their motivations for doing so remain underresearched.

Objective: This study aimed to investigate Australian parents' use of social media for health information for their children, aged between 6 months and 5 years, before and after consulting with health care professionals.

Methods: A representative cross-sectional survey of 1000 Australian parents with children aged 6 months to 5 years was conducted between November and December 2021. Data were cleaned and analyzed using IBM SPSS software. The primary outcomes were (1) parental motivation and prevalence of social media use for health information and (2) parental motivation for using social media before and after a consultation with their child's health care professional.

Results: Of the 1000 parents surveyed, 82.2% (n=822) reported using social media for health information for their child. Parents were more likely to consult social media before and after a health consultation if they were aged 30-39 or ≥50 years and born in Australia. Parents with higher levels of education were less likely to consult social media. Parents were motivated to seek health information before a consultation for a variety of reasons, including exchanging opinions and experiences (639/767, 83.3%), having information that is available 24/7 (622/767, 81.1%), receiving emotional support (599/767, 78.1%), having previous positive experiences (597/767, 77.8%), and having friends and family that use social media for health information (577/767, 75.2%). Parents sought information after a consultation to connect with parents with similar experiences (546/794, 68.8%), seek a second opinion (505/794, 63.6%), fact-check information provided by their health care professional (483/794, 60.8%), and look for other treatment options (353/794, 44.5%).

Conclusion: Using social media for child health information is part of the modern parenting experience. It can be challenging to discern the quality of health information on social media, leaving parents open to incorrect information and misinformation. Although access to immediate social support is a welcomed feature of social media, receiving incorrect health information can have unwanted consequences for the child, family, health provider, and wider community. The upskilling of parental health literacy to navigate the unique health literacy challenges that social media brings, alongside the creation and delivery of accessible, evidence-based information in varying formats, is urgently required. The provision of this information is the responsibility of every level of the health system, not just the treating health care professional.

(JMIR Pediatr Parent 2023;6:e48012) doi:10.2196/48012

KEYWORDS

social media; information seeking behavior; parenting; child; infant; health literacy; patient education; digital platform; information; health information; public health

Introduction

Social media platforms such as Facebook, Instagram, Twitter, Pinterest, and YouTube are key resources for parents seeking health information for their children [1-4]. The convenience and opportunity to meet like-minded parents has made social media central to modern parenting. In contrast to traditional health information accessed via books, internet web pages, or health care professionals, social media gives access to immediate health information from like-minded people, which is more likely to be ideologically aligned than evidence based. This democratization of health information risks downstream impacts including abstinence from formal health care [4], delay in seeking necessary health care [5], and the choice of

non–evidence-based treatments [6], all of which impact health outcomes for children.

More broadly, the use of social media by parents has implications for health care professionals and public health. Although traditionally, health care professionals were one of the limited sources for health information that parents could find, health information can now be sourced almost instantaneously. This has direct impacts on how health care professionals provide care to their pediatric patients, with parents being able to actively seek out alternative information that may contradict or challenge the evidence-based information and treatment options that are being offered to them and their child during consultations [7,8]. Poor quality information from non–evidence-based sources has impacts on the community more broadly, with misinformation spread in the community setting by way of stories based on lived experience or rumor being exchanged between parents. Research has shown that misinformation can impact parents' health decisions [9], for example, decisions about infectious disease and childhood immunization. Finally, when delayed evidence-based health care is eventually sought by parents, it is the health system that needs to provide it. This may result in more intense and resource-heavy care for the child [10].

Parents need to have a more diverse and honed set of health literacy skills when using social media for health information than previously required. This is due to the available health information being authored, compiled, or shared by parents that have little to no health expertise, making it almost certain to have a subjective bias to some degree. However, it is also because of this very fact that parents are seeking health information on social media—to gain insights from the lived experience of other parents further ahead on the same health journey that they have found themselves on. The skills needed to navigate social media health information sources include being able to discern quality evidence-based information from that of opinion [1] and politically or emotionally driven information [6]; tracing information to its source to determine context and relevance [11]; having the numeracy skills to be able to discern relative and absolute risk [9]; as well as being able to manage the sheer amount of information that is available [12], all of which is vying for the parent's attention. In addition, parents need to have sophisticated social skills to be able to access some forms of health information, especially that of lived experience from other parents, where potentially complex interpersonal and group dynamics [13] can complicate access.

A variety of intrinsic and extrinsic factors have been found to motivate parents' use of social media for health information. Intrinsic motivations include an increased sense of empowerment [6,14], self-efficacy, and self-determination and feeling more educated about the condition of concern [15,16]. Extrinsic motivators include being able to socialize [17] with like-minded people [18] to exchange support and advice [14,17,19], being offered reassurance and validation for health decisions [20], normalizing the challenges experienced [21], and having a sense of safety and privacy [18].

Three studies to date have provided evidence that parents use social media for health information before and after a diagnosis because they are medically underserved [14], want to use alternative health care [6], lack information that aligns with their health goals for their child [18], or lack appropriate information from health care professionals [18]. These studies focus on niche groups (those who are vaccine hesitant, infants with severe combined immunodeficiency, and mothers who exclusively express and bottle-feed) [4,14,18]. Social media's utility has been demonstrated within these niche groups. However, considering social media's ubiquity and fast pace of adoption and integration into people's lives on a population level, we sought to understand how prevalent parents' use of social media for health information before and after a health consultation is, alongside the reasons that parents use social media for health information. This representative study investigated the use of social media for health information among Australian parents, before and after consulting with health care professionals.

Methods

Study Design

A national quantitative cross-sectional survey was conducted between November and December 2021 among Australian parents of children aged 6 months to 5 years. For this study, "parent" was defined as anyone that was a biological parent, adoptive parent, or court-appointed guardian or caregiver of a child aged between 6 months and 5 years.

Variables

A 47-item survey developed from previously validated tools combined multiple-choice questions with optional open-text fields and Likert scales [22,23]. The first section explored parents' use of social media, the information sought, and motivations for using social media for child health information. The next section asked parents about their motivations for using social media before consulting with a health care professional. The final section asked parents their motivations for using social media for health information after consulting with a health care professional. Demographic data were collected.

A web-based research company (Quality Online Research [QOR]) was engaged to recruit parents from their web-based panel of preregistered participants and to administer the survey. Parents were recruited by way of a single-use email link, preventing multiple responses from a single participant. Eligibility criteria included being an Australian citizen or permanent resident who is caring for a child aged 6 months to 5 years. The company identified the participants by the demographic information that the participants provided when they joined the panel in preparation for survey opportunities. For our study, this was guided by our inclusion criteria. Exclusion criteria were limited command of the English language and not having an active social media account.

Due to the large and unknown population of parents of children aged 6 months to 5 years, a sample size of 1000 was chosen to give a CI of 3.1. Stratification parameters of the Australian 2016 census [24] ensured that the sample was representative of Australian states and territories and gender demographics. Parents were offered a small incentive (about Aus $2.80 [US

$1.80]) to participate. The survey was refined with 2 rounds of corrections during the prepilot phase to ensure skip steps and question formatting were done correctly. The survey was pilot-tested among 122 parents, with responses checked by researchers for quality before being formally launched in the field. Fieldwork took 16 days (November to December 2021) to gather a total of 1000 eligible completed surveys (including the pilot test) from parents. The survey was kept at arm's length from the researchers and was administered by QOR, with the data being cleaned and anonymized by QOR before being transferred to the researchers for analysis. The cleaned data were checked for quality control by researchers before commencing statistical analysis.

Ethical Considerations

Participants were presented with a participant information sheet (PIS) as the first screen after opening the email link from QOR. This PIS informed participants about the project, why they have been invited (inclusion criteria), what their participation will involve, and the risks and inconvenience they can expect. They were also made aware that their participation was entirely voluntary and that there would be no penalty for their withdrawal at any point during the survey. Participants indicated their consent by commencing the survey after reading the PIS. As the data were being collected by a third-party research company, the researchers were not, at any point, exposed to any identifying information. Participants were given direct contact information for both the Ethics Secretariat and the lead investigator, if they required further information or follow-up. There was a consent form that outlined the main points highlighted in the PIS, which participants were able to click out of if they wished to discontinue or click forward to continue with the survey. Discontinuing their participation in the survey (returning an incomplete survey) was counted as a withdrawal, with the data being excluded from the final analysis. Ethics approval was obtained from the Human Research Ethics Committee at the University of Technology Sydney (UTS HREC ETH21-6598). This report is guided by the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement [25] for cross-sectional studies with supplementary guidance from the Consensus-Based Checklist for Reporting of Survey Studies [26].

Analysis

Data were imported to IBM SPSS Statistics for Mac (version 28; IBM Corp) [27] for analysis. Descriptive statistics were calculated for sociodemographic data and parental use of social media. X^2 tests of association were conducted to determine which aspects of parent motivation were statistically significant. Logistic regression was used to determine the significant predictors of social media use for health information before or after a consultation with a health care professional. Covariates with $P<.25$ were entered into the model, as well as Socio-Economic Indexes for Areas (The Index of Relative Socio-economic Advantage and Disadvantage) [28] codes corresponding to postcodes. Statistical significance was set at $P<.05$ to produce the most parsimonious model. There were some missing data (26/1026, 2.5%), possibly either due to participant error when entering their postcode or circumventing the requirement to answer before proceeding to the next question.

Results

Of the 1563 parents who opened the survey link in QOR's email invitation, 1026 (65.6%) completed the survey. In all, 26 surveys were deemed ineligible for analysis upon further data cleaning, leaving 1000 surveys for analysis, indicating a 64% (1000/1563) completion rate. Of the 1000 Australian parents surveyed, 57.5% (n=575) identified as female, 41.3% (n=413) identified as male, 0.8% (n=8) identified as nonbinary, and 0.4% (n=4) preferred not to say. Only 9.4% (n=94) of parents were not born in Australia (Table 1). Australian-born participants were found to be statistically more likely to use social media for their children's health than non–Australian-born participants ($P=.009$). Variations by gender ($P=.59$); marriage status ($P=.64$); location by state ($P=.71$); language spoken at home ($P=.69$); and metro, rural, or remote location ($P=.50$) were not statistically significant. Covariates with $P<.25$ were imported into a logistic regression for further analysis.

Table . Participant characteristics.

Characteristics		Total (n=1000), n (%)	Use social media (n=822), n (%)[a]	Do not use social media (n=178), n (%)[a]	*P* value
Gender					.59
	Male	413 (41.3)	340 (82.3)	73 (17.7)	
	Female	575 (57.5)	471 (81.9)	104 (18.1)	
	Nonbinary	8 (0.8)	8 (100)	0 (0)	
	Prefer not to say	4 (0.4)	3 (75)	1 (25)	
Age group (years)					.12
	18-29	308 (30.8)	255 (82.8)	53 (17.2)	
	30-39	412 (41.2)	343 (83.3)	69 (16.7)	
	40-49	235 (23.5)	193 (82.1)	42 (17.9)	
	≥50	45 (4.5)	31 (68.9)	14 (31.1)	
Location (by state or territory)					.71
	New South Wales	322 (32.2)	268 (83.2)	54 (16.8)	
	Australian Capital Territory	13 (1.3)	10 (76.9)	3 (23.1)	
	Queensland	205 (20.5)	174 (84.9)	31 (15.1)	
	Victoria	269 (26.9)	214 (79.6)	55 (20.4)	
	South Australia	75 (7.5)	59 (78.7)	16 (21.3)	
	Tasmania	29 (2.9)	25 (86.2)	4 (13.8)	
	Northern Territory	4 (0.4)	4 (100)	0 (0)	
	Western Australia	83 (8.3)	68 (81.9)	15 (18.1)	
Education					.05
	High school	273 (27.3)	219 (80.2)	54 (19.8)	
	Trade qualification[b]	193 (19.3)	150 (77.7)	43 (22.3)	
	University qualification	534 (53.4)	453 (84.8)	81 (15.2)	
Marital status					.64
	Never married	207 (20.7)	169 (81.6)	38 (18.4)	
	Married or de facto marriage	754 (75.4)	623 (82.6)	131 (17.4)	
	Separated, divorced, or widowed	39 (3.9)	30 (76.9)	9 (23.1)	
Country of birth					.009
	Australia	906 (90.6)	754 (83.2)	152 (16.8)	
	Outside of Australia	94 (9.4)	68 (72.3)	26 (27.7)	
Language spoken at home					.69
	English	955 (95.5)	786 (82.3)	169 (17.7)	
	Other	45 (4.5)	36 (80)	9 (20)	
SEIFA[c] (n=974 valid responses)					.18
	Q1 (highest)	213 (21.3)	179 (84)	34 (16)	
	Q2	218 (21.8)	178 (81.7)	40 (18.3)	
	Q3	217 (21.7)	168 (77.4)	49 (22.6)	
	Q4 (lowest)	326 (32.6)	275 (84.4)	51 (15.6)	

Characteristics	Total (n=1000), n (%)	Use social media (n=822), n (%)[a]	Do not use social media (n=178), n (%)[a]	*P* value
First child	769 (76.9)	623 (81)	146 (19)	.07
Metro	601 (60.1)	498 (82.9)	103 (17.1)	.50

[a]Percentages reflect the proportion of each subgroup (ie, the denominator is the n value in the Total column).

[b]Apprenticeship or other training to become a tradesperson.

[c]SEIFA: Socio-Economic Indexes for Areas (The Index of Relative Socio-economic Advantage and Disadvantage) [28].

A majority (822/1000, 82.2%) of parents used social media for information about their child's general health and well-being. Parents were asked about their general motivations for using social media for health information (Table 2), before and after consulting a health care professional. Health care consultations were not defined beyond "visited the health care professional of your choice" to include any clinic or hospital visit. Parents' use of social media for health information before a consultation was motivated by the ability to exchange opinions and experiences with other parents (639/767, 83.3%; *P*=.002), the information being available 24/7 (622/767, 81.1%; *P*<.001), receiving emotional support from other parents (599/767, 78.1%; *P*=.002), positive previous experiences using social media for health information (597/767, 77.8%; *P*<.001), having friends and family use social media for health information (577/767, 75.2%; *P*<.001), and the information being up to date (518/767, 67.5%; *P*<.001). Parents' motivations for using social media after a consultation were similar, with the addition of anonymity while seeking health information (543/749, 72.5%; *P*=.009).

Table . Australian parents' sentiments about using social media for health information.

Sentiment		Total (n=822), n (%)[a]	Use social media before an HCP[b] visit, n (%)[a]		*P* value	Use social media after an HCP visit, n (%)[a]		*P* value
			Yes (n=767)	No (n=55)		Yes (n=749)	No (n=73)	
The information is available 24/7					<.001			.008
	Agree	652 (79.3)	622 (81.1)	30 (54.5)		598 (79.8)	54 (74)	
	Neutral	113 (13.7)	96 (12.5)	17 (30.9)		98 (13.1)	15 (20.5)	
	Disagree	57 (6.9)	49 (6.4)	8 (14.5)		53 (7.1)	4 (5.5)	
The information is up to date					<.001			<.001
	Agree	540 (65.7)	518 (67.5)	22 (40)		512 (68.4)	28 (38.4)	
	Neutral	213 (25.9)	189 (24.6)	24 (43.6)		174 (23.2)	39 (53.4)	
	Disagree	69 (8.4)	60 (7.8)	9 (16.4)		63 (8.4)	6 (8.2)	
I can retain my anonymity (people don't know who I am)					.10			.009
	Agree	583 (70.9)	551 (71.8)	32 (58.2)		543 (72.5)	40 (54.8)	
	Neutral	168 (20.4)	150 (19.6)	18 (32.7)		142 (19)	26 (35.6)	
	Disagree	71 (8.6)	66 (8.6)	5 (9.1)		64 (8.5)	7 (9.6)	
I have had good experiences with it					<.001			<.001
	Agree	624 (75.9)	597 (77.8)	27 (49.1)		583 (77.8)	41 (56.2)	
	Neutral	168 (20.4)	142 (18.5)	26 (47.3)		136 (18.2)	32 (43.8)	
	Disagree	30 (3.6)	28 (3.7)	2 (3.6)		30 (4)	0 (0)	
My friends and family use them as well					<.001			<.001
	Agree	603 (73.4)	577 (75.2)	26 (47.3)		565 (75.4)	38 (52.1)	
	Neutral	160 (19.5)	136 (17.7)	24 (43.6)		135 (18)	25 (34.2)	
	Disagree	59 (7.2)	54 (7)	5 (9.1)		49 (6.5)	10 (13.7)	
It's a place where I can exchange opinions and experiences with other parents					.002			<.001
	Agree	678 (82.5)	639 (83.3)	39 (70.9)		624 (83.3)	54 (74)	
	Neutral	119 (14.5)	106 (13.8)	13 (23.6)		105 (14)	14 (19.2)	
	Disagree	25 (3)	22 (2.9)	3 (5.5)		20 (2.7)	5 (6.8)	
To receive emotional support from other parents					.002			.007
	Agree	633 (77)	599 (78.1)	34 (61.8)		584 (78)	49 (67.1)	
	Neutral	142 (17.3)	122 (15.9)	20 (36.4)		122 (16.3)	20 (27.4)	
	Disagree	47 (5.7)	46 (6)	1 (1.8)		43 (5.7)	4 (5.5)	

[a]Some percentages may not sum to 100% due to rounding.

[b]HCP: health care professional.

When asked which statements were true of their use of social media for health information, parents' responses varied (Table 3). A total of 60% (503/838) of parents sought general information about a condition of concern for their child on social media. Parents used social media to determine if medical attention was required (363/838, 43.3%) and seek information about alternative treatments such as natural remedies (350/838, 41.8%) and other medical treatments (293/838, 35%) for the condition of concern. When seeking general health information, parents were the least likely to use social media for information about self-management strategies (292/838, 34.8%).

Table . Parental motivations for using social media for children's health information.

Motivations for using social media	Yes[a], n (%)
Children's health information in general (n=838)	
To seek general information about the health problem or illness	503 (60)
To determine if medical attention was required	363 (43.3)
To seek information about alternative treatments for the health problem or illness	350 (41.8)
To seek information about possible medical treatments for the health problem or illness	293 (35)
To seek information about self-management strategies	292 (34.8)
Health information *before* a health care professional visit (n=823)	
To seek general information about the health problem or illness	510 (62)
To determine if medical attention was required	425 (51.6)
To seek information about alternative treatments for the health problem or illness	351 (42.6)
To seek information about possible medical treatments for the health problem or illness	326 (39.6)
To seek information about medications	325 (39.5)
Health information *after* a health care professional visit (n=794)	
To find examples of lived experience	546 (68.8)
I wanted a second opinion	505 (63.6)
To check the information I received at the doctor's office	483 (60.8)
To seek further information about the health problem or illness	453 (57.1)
To determine if further medical attention was required	373 (47)
I did not receive enough information at the doctor's office or clinic	364 (45.8)
The information from the doctor's office was unclear	357 (45)
To seek information about alternative treatments for the health problem or illness	353 (44.5)
To seek information about possible medical treatments for the health problem or illness	314 (39.5)
To seek information about medications	291 (36.6)

[a]Parents were asked to check all that applied.

When parents were asked about seeking information on social media before a consultation, most (510/823, 62%) looked for information about the health condition. About half (425/823, 51.6%) sought to determine if medical attention was required. Alternative treatments (351/823, 42.6%) were sought also, with 39.5% (326/823) of parents seeking information about (other) possible medical treatments.

When parents were asked about their motivations for using social media for health information after visiting a health care professional, 68.8% (546/794) stated they did so because they wanted to find examples of lived experience. Parents also wanted a second opinion (505/794, 63.6%), to check the information provided during the consultation (483/794, 60.8%), or to seek further information about the health condition (453/794, 57.1%). Just under half of all parents who used social media after a consultation did so to determine if further medical attention was required (373/794, 47%), having felt that they did not receive enough information from their health care professional (364/794, 45.8%), or that the information they were given was unclear (357/794, 45%). Other reasons included wanting to seek alternative treatments (353/794, 44.5%), information about possible medical treatments for the condition

(314/794, 39.5%), or information about medications (291/794, 36.6%).

The results of the logistic regression conducted (Table 4) show that Australian-born parents were more likely to use social media for health information for their children both before (odds ratio [OR] 2.545, 95% CI 1.521-4.259) and after a health consultation (OR 2.045, 95% CI 1.228-3.407) than those born outside of Australia. Parents aged 30-39 years were the most likely to use social media before (OR 3.212, 95% CI 1.475-6.996) and after a consultation (OR 3.799, 95% CI 1.821-7.926) when compared to the reference group of parents aged 18-29 years. Parents aged ≥50 years were also more likely to use social media before (OR 2.324, 95% CI 1.066-5.068) and after a consultation (OR 3.428, 95% CI 1.625-7.233) than parents aged 18-29 years.

Education was a significant predictor for social media use among parents before and after a consultation. Parents with university (OR 0.513, 95% CI 0.332-0.794) or trade qualifications (OR 0.535, 95% CI 0.352-0.814) were less likely to consult social media before a consultation than parents with high school qualifications. Parents with a university (OR 0.515, 95% CI 0.319-0.719) or trade qualification (OR 0.631, 95% CI 0.395-0.882) were also less likely to use social media for health information after a health consultation.

Table . Predictors for parental use of social media before and after a consultation with a health care professional.

Predictor		Use social media before consultation		Use social media after consultation	
		OR[a] (95% CI)	*P* value	OR (95% CI)	*P* value
SEIFA [b] , [c]					
	Q1 (highest)	Reference		Reference	
	Q2	1.666 (1.027-2.700)	.04	1.270 (0.796-2.027)	.32
	Q3	0.795 (0.519-1.335)	.45	0.685 (0.429-1.093)	.11
	Q4 (lowest)	1.252 (0.776-2.086)	.34	0.885 (0.551-1.423)	.62
Age group (years)					
	18-29	Reference		Reference	
	30-39	3.212 (1.475-6.996)	.003	3.799 (1.821-7.926)	<.001
	40-49	1.918 (0.917-4.010)	.08	1.818 (0.912-3.626)	.09
	≥50	2.324 (1.066-5.068)	.03	3.428 (1.625-7.233)	<.001
Country of birth					
	Outside of Australia	Reference		Reference	
	Australia	2.545 (1.521-4.259)	<.001	2.045 (1.228-3.407)	.006
Education					
	High school	Reference		Reference	
	Trade qualification	0.535 (0.352-0.814)	.003	0.631 (0.395-0.882)	.01
	University qualification	0.513 (0.332-0.794)	.003	0.515 (0.319-0.719)	<.001

[a]OR: odds ratio.

[b]SEIFA: Socio-Economic Indexes for Areas (The Index of Relative Socio-economic Advantage and Disadvantage) [28].

[c]974 responses included.

Discussion

Principal Findings

The Australian parents most likely to use social media for health information before and after a consultation were aged 30-39 years (Generation Y or millennials) and born in Australia. Reasons for this could include that because Generation Y or millennials, as digital natives, have their parenting experience colored by their everyday use of social media, digital health information and traditional health information are seamlessly intertwined [29]. Parents with university education were found to be the least likely to use social media for health information before or after a health consultation, which is consistent with other studies [2]. This may reflect literacy or health literacy confidence. Parents who have higher levels of education may be more confident to seek health information, resulting in being able to ask pertinent questions and better understand the health information received during a health consultation. This allows the parent to leave the health consultation feeling satisfied with the information they have received [30].

Previous studies have sought to understand why parents use social media for general health information. Reasons have

included social media's information immediacy [20]; timely access despite geographical [21] or logistical [15] barriers; detailed, customized, and relevant information [20]; and perceived trustworthiness [31]. Parents view social media as being unbiased [20], aligning with their personal perspectives [21] and values [32], and providing insights to lived experience not available elsewhere [19,21].

Although parents' use of social media before a health consultation is often to seek information about a health issue or to determine if treatment is needed, some of the reasons why parents may use social media for health information after a consultation raise questions about communication and health literacy. Almost half of all Australian adults read at a low level [33] and 60% have low levels of health literacy [34], with both of these factors potentially creating barriers to parents' understanding of traditional health information. Social media health information is multimodal, combining personal stories, conversational text, videos, infographics [35], subtitles, and other design features that make it more inclusive for those with varying literacy levels [36]. The interactive and conversational nature of social media makes information more accessible, making it a preferable source for some parents [32]. Our nationally representative study shows that this is not only the experience of parents who are part of specific niche groups, as shown in the extant literature [14,16,18,19], but is true of the wider parenting experience.

Health information goes beyond the evidence-based information provided by health care professionals in consultations [2]. Parents seek emotional support [2] on social media and insights into how the health journey will impact their child, themselves, and their wider orbit. This information (which is often practical [32]) from other parents with lived experience is highly valued and sought after, allowing parents to feel more empowered and socially supported [37], thus increasing self-efficacy [16,38]. The democratized sharing of stories of lived experience is a unique feature of social media, which is also a strong motivator for parents who use social media for health information. Stories of lived experience allow parents to see what might lie ahead for their health journey, providing reassurance while also allowing them to allay uncertainties. It also allows parents to get health information beyond the clinical data, with practical tips and help to navigate the health system. Although these are only a few examples of information sought by parents based on lived experience, the power of stories for health communication has been long established. A scoping review by Dudley et al [39] found that narratives are appealing to audiences, stimulate emotions, make it easier to understand health and science information, improve the memory of information, and capture attention through suspense. Stories also "enable people to make sense of themselves, others, relationships, responsibilities, life changing circumstances, uncertainties, their social world, and possible futures" [40], all of which are heightened at emotionally vulnerable times such as when a child is unwell. Stories also make the parent more open to the messaging held within a story, whether that be evidence based or not, which is where social media starts to reveal its complexity as a health information source. Although stories on social media make health information easier for parents to understand, the use of social media for health information brings with it health literacy challenges unique to social media. For example, when using social media to seek health information, parents need to be able to distinguish evidence-based health information from low-quality information, a lot of which is delivered by stories, within conversations, or as part of a social information exchange. This requires a parent to be able to navigate the dynamic social context they are currently in; use high-level health literacy skills; and if required, research context and the original source of information, all simultaneously in real time. Rarely, if at all, has this combination of skills been required previously of parents when seeking health information, let alone at the level of sophistication that is often required by social media. As a result, the lack of the unique health literacy skills as required by social media often results in parents being ill-equipped to navigate the health information available on social media.

For health care professionals, it may be of value to consider how to integrate better provision of accessible evidence-based health information to parents [41] into their practice. By accepting the use of social media for health information as the "new normal," clinicians can also facilitate frank conversations with parents [42] about reliable web-based information sources and offer high-quality information in more accessible forms, such as referring patients to videos formatted for viewing on mobile phones and social media content known to be evidence based or facilitating live question and answer sessions on Instagram or TikTok.

Finally, the impacts of using social media for health information will inevitably seep into other aspects of the health system, including public health. This can perhaps be seen most clearly with preventable childhood infectious diseases. With parents independently accessing non–evidence-based, emotively laden, and politically motivated health information [41], primary prevention gains may be lost (whether it be lowered rates of disease or the elimination of disease) with an increase in outbreaks of diseases, as seen overseas [43] such as the Disneyland measles outbreak in 2014 [8]. This led to public health units needing to invest in health promotion resources to highlight the importance of vaccination and fund programs to boost vaccination coverage to sustain herd immunity.

The scarcity of accessible evidence-based health information that meets parents' information needs leaves parents vulnerable to finding low-quality health information when they turn to social media. Inclusive, accessible, and evidence-based health information urgently needs to be more readily available at all levels, from public health units down to in-consultation resources for health care professionals to guide conversations, as well as postconsultation resources for parents to take home. This will allow parents to consider evidence-based information in their own time, improve patient education, and reduce the reliance on non–evidence-based health information found on social media [44].

Limitations

Inherent with any cross-sectional study design, responder bias is a confounding factor. Although measures were taken to limit the impact of responder bias, including having very broad inclusion criteria not related to the survey questions, as well as

the stratification of data to the Australian Bureau of Statistics 2016 census data, the fact that the participants were from the research company's preselected panel is a limitation.

Second, this survey required proficiency in English. Although the participants were stratified to be representative of the broader Australian population, not providing the survey in multiple languages limits representativeness in a multicultural society.

Third, the inclusion criteria stipulated that only parents with a social media account were to be included in this study. To access this survey, parents had to be able to access an internet connection; as such, we did not ask about their access to the internet as infrastructure was outside the scope of this study. This, however, did limit the study to only include those that have access to both the internet and social media.

Lastly, although cross-sectional studies cannot demonstrate causation, this study establishes a baseline for further research in this emerging area, which has substantial implications for clinical practice.

Conclusion

With many Australian adults having low levels of health literacy, and almost half of all parents who used social media after a consultation reporting that the information from their health care professional was unclear, how evidence-based health information is delivered needs to be reconsidered to meet parents at their health literacy level. This could include resources that take a similar form to those found on social media that parents are already engaging with, such as those that are simplified, graphic, or video based. Public health units and, more broadly, the health system can support clinicians with their education of parents by providing inclusive health promotion communications and resources that are reliable and evidence based and meet parents at their health literacy level. Parents of patients could then be directed to quality resources, leading to health decisions that are informed and supported by evidence-based health information.

Acknowledgments

The authors would like to acknowledge the Gadigal people of the Eora Nation upon whose ancestral lands our university now stands. We would also like to pay respect to the Elders both past and present, acknowledging them as the traditional custodians of knowledge for these lands. We would also like to thank Professor Andrew Hayen for his guidance and assistance with the statistics for this manuscript. This study was able to be conducted with the following financial support: financial support from the University of Technology Sydney and National Health and Medical Research Council funding.

Data Availability

The data sets generated and/or analyzed during this study are not publicly available, as there are further reports to be published by the authors. The data will be available from the corresponding author after all reports from the data set have been completed and published.

Conflicts of Interest

None declared.

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Abbreviations

OR: odds ratio
PIS: participant information sheet
QOR: Quality Online Research
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

Edited by S Badawy; submitted 08.04.23; peer-reviewed by J Taylor, J Galvez; revised version received 25.07.23; accepted 18.08.23; published 20.10.23.

Please cite as:
Frey E, Bonfiglioli C, Frawley J
Parents’ Use of Social Media for Health Information Before and After a Consultation With Health Care Professionals: Australian Cross-Sectional Study
JMIR Pediatr Parent 2023;6:e48012
URL: https://pediatrics.jmir.org/2023/1/e48012
doi:10.2196/48012

Original Paper

Web-Based Conversations Regarding Fathers Before and During the COVID-19 Pandemic: Qualitative Content Analysis

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Abstract

Background: Studies of new and expecting parents largely focus on the mother, leaving a gap in knowledge about fathers.

Objective: This study aimed to understand web-based conversations regarding new and expecting fathers on social media and to explore whether the COVID-19 pandemic has changed the web-based conversation.

Methods: A social media analysis was conducted. Brandwatch (Cision) captured social posts related to new and expecting fathers between February 1, 2019, and February 12, 2021. Overall, 2 periods were studied: 1 year before and 1 year during the pandemic. SAS Text Miner analyzed the data and produced 47% (9/19) of the topics in the first period and 53% (10/19) of the topics in the second period. The 19 topics were organized into 6 broad themes.

Results: Overall, 26% (5/19) of the topics obtained during each period were the same, showing consistency in conversation. In total, 6 broad themes were created: fatherhood thoughts, fatherhood celebrations, advice seeking, fatherhood announcements, external parties targeting fathers, and miscellaneous.

Conclusions: Fathers use social media to make announcements, celebrate fatherhood, seek advice, and interact with other fathers. Others used social media to advertise baby products and promote baby-related resources for fathers. Overall, the arrival of the COVID-19 pandemic appeared to have little impact on the excitement and resiliency of new fathers as they transition to parenthood. Altogether, these findings provide insight and guidance on the ways in which public health professionals can rapidly gather information about special populations—such as new and expecting fathers via the web—to monitor their beliefs, attitudes, emotional reactions, and unique lived experiences in context (ie, throughout a global pandemic).

(JMIR Pediatr Parent 2023;6:e40371) doi:10.2196/40371

KEYWORDS

social media; expecting fathers; new fathers; Twitter; Reddit; content analysis; topic model; topic analysis; parent; father

Introduction

When studying expecting parents, studies have predominantly focused on the mother, leaving a large gap in knowledge about expecting fathers. However, studies have shown that men want to be involved in their partner's pregnancy, but they struggle with knowing how to be involved [1]. Others criticize that the prenatal health care system is not set up to support the father's involvement [2]. Thus, more studies are needed to understand how to effectively reach out to and connect with new and expecting fathers. A medium to reach this audience is social media. Social media is an effective tool to communicate with

an audience, and by studying web-based conversations, researchers can understand what individuals care about and want to share with the world. Social media is a useful tool to understand people's experiences, and in a health context, the insights obtained from social media analyses can be used to guide public health messages and efforts [3-5].

Studies analyzing fathers and their use of social media and web-based platforms have explored how different types of fathers use different sites including Black fathers using Facebook [6], Swedish first-time fathers writing blogs [7], and fathers using Reddit for peer support [8]. This study took a broad approach by capturing publicly available social media posts (Twitter and Reddit) that are related to being or becoming a new or expecting father, thus capturing posts that originate not only from fathers but also from other close ties. By casting a broad net, we contribute to a more heterogeneous understanding of the web-based content surrounding new and expecting fathers and enrich the research on expecting fathers. This study is also unique in that it compares 2 periods to see if there has been a change in web-based conversation owing to the advent of the COVID-19 pandemic. The social media posts that were collected for the analysis were shared by either a new or expecting father or an account discussing content related to being a new or expecting father. The findings provide insight into the web-based behavior of new and expecting fathers, along with the accounts interacting with this group. Therefore, the following research question (RQ) was proposed:

> *RQ1*: What topics emerge from the web-based conversations surrounding new and expecting fathers?

Social media data were collected over a 2-year period—between February 1, 2019, and February 12, 2021. In the middle of this period, the COVID-19 pandemic was declared as a global health emergency, affecting all aspects of life, including parenting. During the pandemic, parents faced unique challenges, including childcare and education [9]. Owing to the many changes, challenges, and heightened stress that parents faced and continue to face during the pandemic [10], we decided to split the data and compare the periods of 1 year before the pandemic and the first year of the pandemic. Thus, our second RQ was the following:

> *RQ2*: Do the web-based conversations from before the pandemic differ from those during the pandemic?

The findings from the study can guide public health communication strategies regarding how to reach new and expecting fathers via the web. By understanding what fathers and other relevant accounts post on the web, communication professionals—either public health or marketing and advertising professionals—will be able to better connect and communicate with fathers.

Methods

Data Acquisition

The data set for this study was obtained using Brandwatch, a social media listening software that is designed to collect publicly shared posts, comments, and web-based conversations [11]. Twitter and Reddit data were included as sources for data collection using Brandwatch. Although Twitter and Facebook have gained more attention in the literature, Reddit attracts >330 million active users and serves as a source for sufficient data collection [12]. Next, using Brandwatch's query editor, the authors wrote queries by combining simple terms to form a Boolean expression [13] based on social media mentions and language relating to experiences of new fatherhood (eg, "becoming a father"). The variations were selected based on common English adverbs and adjectives that could be associated with a person using first-person reference to becoming a father. Filters were applied to collect English-language posts that excluded profanities, pornographic content, promotions, and giveaways. Then, using a manual process of trial and error, the language in the returned posts was reviewed for accuracy and to mitigate noise in the data set. Irrelevant conversations were identified and then removed using negation operators (eg, NOT "I miss him greatly" NOT "Almighty" NOT "begotten" NOT "cops") until the results appeared to be consistent in quality and relevance. The query operators and examples used in the study are shown in Table 1, and the entire Boolean code is provided in Multimedia Appendix 1.

The full data set returned 122,663 English-language conversations that occurred between February 1, 2019, and February 12, 2021. Then, the data set was cleaned using *R*, removing all duplicate posts (ie, retweets) and retaining variables of interest, before being divided into 2 separate data sets of conversations that occurred either *before* or *after* the pandemic was announced as a global health emergency by the World Health Organization on January 31, 2020 [14]. After removing duplicates, the corpus included 44,335 relevant posts. Next, after removing *organizational* posts (eg, posts from an organization), the final clean data set included 42,298 observations, with 18,303 (43.27%) occurring before and 23,995 (56.73%) occurring after the announced pandemic. The final data set included a sample of 37.12% (8907/23,995) Reddit observations and 62.88% (15,088/23,995) Twitter observations collected after the pandemic had been announced, a 31% increase in mention volume from the first data set collected before the pandemic, which contained 25.96% (4752/18,303) Reddit observations and 74.04% (13,551/18,303) Twitter observations. The 18,303 posts that occurred before the pandemic comprised 14,622 unique users, with an average of 1.246 (SD 2.161) posts per individual. The second data set resulted in a similar ratio, with 18,710 unique users making up 23,995 posts, with an average of 1.276 (SD 2.519) posts per individual.

As was provided by the web-based location metadata of the users in this sample, before the pandemic, of the 19,272 posts, approximately 11,988 (62.2%) posts originated in North America, 3439 (17.84%) originated in Europe, 1780 (9.24%) originated in Africa, 1422 (7.38%) originated in Asia, 514 (2.67%) originated in Australia and Oceania, and 129 (0.67%) originated in South America. Regarding the during-pandemic users, the sample containing 23,995 posts was summarized in the same ordinal fashion, with similar geographical distribution of approximately 13,582 (56.6%) posts originating in North America, 5003 (20.85%) originating in Europe, 2843 (11.85%)

originating in Africa, 1965 (8.19%) originating in Asia, 336 (1.4%) originating in Australia and Oceania, and 265 (1.1%) originating in South America. The geolocation information has also been summarized and provided in Table 2.

Table 1. Query operators[a].

Description	Operator	Example	Result
Basic	The *QUOTES* operator	"becoming a father**"**	Finds mentions of the exact phrase, "becoming a father"
Basic	The *OR* operator	#newdad *OR* #expectantfather	Finds mentions of #newdad or mentions of #expectantfather
Complex	The *NEAR/n* operator	("I am" OR "I will") *NEAR/10* ("be a father" OR "becoming a dad")	Finds mentions of "I am" within 10 words of "becoming a dad" or "be a father" and mentions of "I will" within 10 words of "becoming a dad" or "be a father"
Complex	The wildcard operator	"expect* dad"	Finds mentions with the root word, *expect*; eg, expecting dad and expectant dad

[a]The full query is provided in Multimedia Appendix 1.

Table 2. Summary of user posts according to location.

Source location	Posts before the pandemic (n=18,303), n (%)	Posts during the pandemic (n=23,995), n (%)
North America	11,385 (62.2)	13,583 (56.61)
Europe	3266 (17.84)	5003 (20.85)
Africa	1691 (9.24)	2843 (11.85)
Asia	1350 (7.38)	1965 (8.19)
Australia and Oceania	488 (2.67)	336 (1.4)
South America	122 (0.67)	265 (1.1)

Text Analysis

During the next step in the text analytic process, the 2 samples were analyzed using SAS Text Miner (version 15.1; SAS Institute) [15] through natural language processing and machine learning techniques to identify otherwise hidden themes in the conversations. SAS Text Miner provides the ability to parse and extract information from text, filter and store the information, and assemble tweets into related topics for introspection and to obtain insights from the unstructured data [16]. First, the text topic node was used to combine terms into topic groups. Then, a text filter node was used to exclude words that appeared in <4 messages, as a conservative measure to reduce noise. The parsing process handled by the software involves sorting all the words into separate terms and assigning a numerical identifier to them. Words that are not essential ("of," "and," and "but") are removed. After the software completes this process, the filter feature allows the researcher to review the output and remove unrecognizable characters and strings of letters. A single reviewer followed a systematic process to maintain objectivity. The same process has been used in multiple studies examining RQs related to public reactions, health, and other issues across social media.

SAS Text Miner sorted the posts into topics, and the authors agreed on a 9-topic solution for period 1 (before the pandemic) and a 10-topic solution for period 2 (during the pandemic). To interpret and make sense of each topic, a random sample of approximately 30 posts per topic was manually assessed. An author performed the initial assessment, and then, the interpretations were discussed among all authors until consensus was reached. Next, the final 19 topics were manually sorted into 6 broad themes based on similar characteristics and patterns of the posts within each topic and the overall subject matter of the topic.

Finally, a sentiment analysis of the posts was performed. Analysis of emotion words in textual data was performed using the R package, *Syuzhet*, and the *get_nrc_sentiment* function. The packages implement the National Research Council Emotion Lexicon by Saif Mohammad, which comprises 8 basic words of emotion expressions for anger, fear, anticipation, trust, surprise, sadness, joy, and disgust [17].

Ethical Considerations

Ethics approval was not needed for this study, as public social media posts are considered as part of the public domain. Analysis of these public posts is not considered to be human participants research.

Results

Overview

The data revealed that 47% (9/19) of the topics appeared between February 1, 2019, and January 30, 2020 (before the pandemic), and 53% (10/19) of the topics appeared between January 31, 2020, and February 12, 2021 (during the pandemic). The number of mentions, the topics, a brief description, and an example social media mention are shown in Table 3 for the *prepandemic* period and in Table 4 for the *during-pandemic* period. Additional topic analysis results are also presented visually using the R package, *wordcloud2*, in Multimedia Appendices 2 and 3.

The first 5 topics across both periods were the same (father readiness, interpersonal troubles, Father's Day, best dad proclamations, and pregnancy announcements). The remaining topics were unique across the 2 periods. The 19 topics were divided into 6 broad themes: fatherhood thoughts, fatherhood celebrations, advice seeking, fatherhood announcements, external parties targeting fathers, and miscellaneous. The themes and their corresponding topics are described in the following sections.

Differences between the 2 groups were further examined using sentiment analysis. The analysis measured anger, fear, anticipation, trust, surprise, sadness, joy, and disgust. The results are shown in Multimedia Appendix 4.

Table 3. Prepandemic topics, descriptions, and examples.

ID	Topic	Description	Example	Number of posts (n=15,408), n (%)
Pre1	Fatherhood readiness	Users share whether they are ready to be a father	"People ask me if I'm ready to be a father, and I say I'm as ready as I will be."	2475 (16.06)
Pre2	Interpersonal troubles	Users share interpersonal troubles between them and their expectant partner or parent of their child, hoping for advice	"I have been dating [removed for privacy] for around 2 years. Marriage and kids was always discussed, but I never felt like it was the right time for either...6 months ago she announced she was pregnant."[a]	2329 (15.12)
Pre3	Father's day	Users celebrate Father's Day on the web	"I am proud to be a father today, and every day. Happy #FathersDay!"	2232 (14.49)
Pre4	Best dad proclamations	Users claim that they will be the best father	"And I promise for my child I will be the best father a kid could ask for."	1235 (8.02)
Pre5	Pregnancy announcements	Users share their pregnancy news on the web	"I'm gonna be a dad!!!"	1654 (10.73)
Pre6	New father celebration	Users celebrate becoming a father	"I'm gonna be a father. This is not a drill. I'm gonna be a father."	1261 (8.18)
Pre7	Expecting parent content	Content originating from or targeting expecting parents	"Pregnancy Definitions: Here are 122 of the top pregnancy terms pregnant parents need to know!"	1543 (10.01)
Pre8	Becoming a father again	Fathers announce that they are going to be a father again	"I'm going to be a father in a few months. Am I ready? YES!"	664 (4.31)
Pre9	Newborn-related articles	Links to external articles about various topics about newborns	"About newborn sleep [link removed for privacy]."	2015 (13.08)

[a]For brevity, this example includes only the first 3 sentences of the post.

Table 4. During-pandemic topics, descriptions, and examples.

ID	Topic	Description	Example	Number of posts (n=18,745), n (%)
Dur1	Fatherhood readiness	Users state whether they are ready to be a father	"I am ready to be a husband but not ready to be a father."	2253 (12.02)
Dur2	Interpersonal troubles	Users share interpersonal troubles between them and their expectant partner or parent of their child or issues regarding pregnancy, hoping for advice	"Firstly, I know professional help is needed, I just want to get some feedback here, please. 38 y/o male. Wife {34 y/o} and I have been married for about 7 years...We never really discussed having kids vs. not having kids until after we were married, but the understanding was kind of always that we would...or at least I thought that's what it was."[a]	2903 (15.49)
Dur3	Father's day	Users celebrate a happy Father's Day	"I am blessed to be a father. Happy Father's Day to all the father figures out there."	2846 (15.18)
Dur4	Best dad proclamations	Users state that they will be the best father	"I will be the best dad I can be."	1612 (8.59)
Dur5	Pregnancy announcements	Users share that they are going to be a father	"Hey everybody! I'm gonna be a dad!"	1934 (10.32)
Dur6	Pregnancy congratulations	Users congratulate other users for their pregnancy announcements	"Awwwwwww congratulations."	953 (5.08)
Dur7	New dad life	Posts from new fathers experiencing life with their new baby	"Is it the weekend yet? Oh wait, I have kids!"	2794 (14.91)
Dur8	Account replies	An account called Family Core is replying to users' posts	"If YOU are EXPECTING...We are here to HELP Join The Family Core today."	436 (2.33)
Dur9	Comedic replies	Comedic replies to other users' posts	"I am available to be your new dad, if you would like."	2493 (13.29)
Dur10	Financial help requests	Replies to other posts, asking for financial help for a small-scale business loan	"Good day! Please I need your help financially, any amount so I can start up a small scale business for myself and be able to help my family. I'm going to be a father in few months and I don't have a job. Please I really need help financially please."	521 (2.78)

[a]For brevity, this example includes only the first 3 sentences of the post.

Fatherhood Thoughts

This theme consisted of the largest number of topics. Fathers used social media as a place to share their thoughts on fatherhood and fatherhood-related topics. Pre1 and Dur1 focused on fatherhood readiness. Pre1 consisted of social media mentions (often replies to other people's posts) that state "I am ready to be a father" or "I am not ready to be a father." Dur1 included users sharing their readiness (or lack thereof) for being a father. The posts were about users who are exclaiming that they are ready to be a father. Pre4 and Dur4 focused on fathers proclaiming that they will be the "best dad." Pre4 included users exclaiming that they will be the best father they can be for their child. Some users did not have children yet, but said that when they do have kids, they will strive to be the best father they can be. In Dur4, the posts showed users stating that they will be "the best dad" or "the best dad in the world." Some posts tagged another user, so that the tagged user will see the post, thus making it more conversational and interactive. Dur7 included posts from new fathers experiencing life with their new baby and sharing these experiences on the web.

Fatherhood Celebrations

Many fathers and other users used social media to celebrate different aspects of fatherhood, including celebrating Father's Day and becoming a father. Pre3 and Dur3 focused on celebrating Father's Day on the web. Both topics captured straightforward posts of users celebrating Father's Day. Families were thanking the fathers and father figures in their lives, and fathers were thanking their families for wishing them a happy Father's Day. Fathers also posted about being lucky to be a father to their children. Pre6 included users celebrating becoming a father. Users shared their excitement on finding out that they are going to be a father. Some users also shared their excitement about public figures and celebrities becoming fathers. Dur6 showed users congratulating other users for their pregnancy announcements, using the word "congratulations."

Advice Seeking

Some fathers wanted to use the web space to seek advice about pregnancy and parent-related situations. Pre2 and Dur2 focused on interpersonal troubles of users who are expecting or have children. These topics were unique in that the social media mentions originate from Reddit, which allows for long posts. Pre2 and Dur2 included social media mentions from Reddit of

users sharing personal stories about a situation in their life regarding being pregnant, having a pregnant partner, or having children. Users made these posts seeking advice for their situation. Advice seekers wrote about a conflict that had been occurring between the 2 expecting parents. Some of the posts from Pre2 included posts about a man whose fiancée had a miscarriage, a woman with 4 children whose partner left after her last pregnancy, and a man whose partner is pregnant but the 2 of them have been struggling to stay together. Some of the posts from Dur2 included posts about a woman who is pregnant and will be a single mother and a man who is in a long-term relationship and does not want children, whereas his partner does.

Fatherhood Announcements

Overall, 16% (3/19) of the topics consisted of fathers using social media to share father-related news. Pre5 and Dur5 captured pregnancy announcements on the web. Both topics included straightforward posts of users exclaiming "I'm gonna be a dad!" Pre8 captured posts with fathers announcing that they are going to be a father again. The posts were either from users announcing that they will be a father again or focused on announcements of a celebrity being a father again.

External Parties Targeting Fathers

In this theme, the topics consisted of social media mentions that included content related to pregnancy and newborns. Pre7 captured content originating from or targeting expecting parents. Some social media posts included content that originated from companies that are selling newborn-related products, such as milestone blankets and pregnancy books. Some posts included *parent cheat sheets*, which included links to external articles that provide baby-related and parenting advice. Other posts showed users announcing that they are expecting a baby and that they are a "mom to be" or a "dad to be." Pre9 included links to external articles about various topics regarding newborns. The articles included information about newborn sleep, preventing colic, baby's stress, reading with newborns, and newborn brain development. Dur8 included replies from an account called Family Core. Family Core was replying to other users' posts and promoting their account by stating that "they can help if you are expecting."

Miscellaneous

Overall, 11% (2/19) of the topics (Dur9 and Dur10) that were captured included social media mentions that do not directly fit with the other fatherhood-related topics. This theme only consisted of topics that were present during the pandemic. Dur9 captured comedic replies to other users' posts. The replies included the word "dad" (eg, "I am your new dad."). This was typically a comedic reply in response to a post in which another user would have benefited from having the replier as "their dad." Dur10 captured replies from an account that is replying to other users' posts (often the posts of Senators or Congress people), asking for financial help through a small business loan. This user was asking for financial help because they are going to be a father in a few months.

Discussion

Principal Findings

This study examined web-based conversation originating from or related to new and expecting fathers. The study examined social media mentions over a 2-year period—1 year before the COVID-19 pandemic and 1 year during the pandemic. During the 2 periods, much of the conversation was similar, as approximately half of the topics (10/19, 53%) overlapped with each other. Overall, the findings show that new and expecting fathers used social media to share good news, celebrate fatherhood, seek advice, and interact with other fathers. Other relevant accounts used social media to advertise baby products to fathers and promote baby-related articles to fathers.

The similarity in half of the topics (10/19, 53%) showed the consistency in the web-based conversations of new and expecting fathers. This 53% (10/19) of the topics (father readiness, interpersonal troubles, Father's Day, best dad proclamations, and pregnancy announcements) related to content originating from a new or expecting father, as opposed to content being targeted to fathers from companies or websites. This 53% (10/19) of overlapping topics showed what fathers are sharing on the web both before and during the pandemic and that they tend to maintain similar interests.

The topic covering *interpersonal troubles* provided the deepest insight into struggles that expecting fathers face, especially regarding their pregnant partner. These posts were obtained from Reddit. Compared with Twitter, Reddit is perceived by users as a more private space on the web, and the subreddit where the posts came from focused on advice seeking. Users shared their personal stories, with the hope that other users may reply and provide advice and guidance. Studies show that sharing information on the web can be therapeutic and cathartic, especially during a crisis [18]. Ammari and Schoenebeck [19] interviewed fathers to understand their relationship with social media and found that men have concerns regarding privacy and judgment when it comes to posting about their children on the web. Reddit may act as a safe space for fathers to remain anonymous and share their struggles without fear of judgment. The difference in use between Twitter and Reddit can be explained through the theory of uses and gratifications [20], which is used to understand why people use certain types of media by examining the needs people have when using a media type and the gratifications people get from using the media. New and expecting fathers seem to use Twitter to share announcements and celebrate fatherhood, whereas Reddit can be used when fathers are seeking advice for a problem—particularly when they may prefer anonymity. Future studies should consider other media channels that fathers rely on and what needs those channels satisfy.

Strong emotions related to the transition to fatherhood—such as trust, joy, and anticipation—were often expressed by new and expecting fathers in both prepandemic and during-pandemic phases of the analysis. Interestingly, compared with posts in the period before the pandemic, posts during the pandemic had decreased levels of joy and increased levels of fear and sadness, which can represent the difficult nature of this period.

Fatherhood comes with challenges, and the pandemic produced unique stressors for parents, which would certainly result in experiencing negative emotions. Emotional analysis provides insight into potential attitudes and cognitions of fathers, as emotions affect attitudes and behavior. Moreover, in both study periods, fathers used the web to share advice, seek social support, and connect with others dealing with similar situations and interpersonal troubles. The need for social support is important for new and expecting fathers [2]. It would be worthwhile for future studies to examine the utility of leveraging these emotional appeals in health communication efforts regarding childbirth, child rearing, and parenthood, along with incorporating the importance of social support. In addition, future studies should examine whether there are substantial differences in emotions expressed on the web according to the platform (ie, Twitter vs Reddit vs Facebook).

Overall, the findings outlined in this paper tend to diverge from previous scholarship examining fatherhood-related conversations that occur within social media environments. For instance, by using a latent topic modeling approach to data stemming from the Daddit subreddit, Ammari et al [19] uncovered 3 topics from the data including (1) conversations related to experiences in the neonatal intensive care unit, (2) Halloween and Halloween costumes, and (3) legal challenges experienced by users. However, none of these topics explicitly materialized in our analysis. Sepahpour-Fard et al [21] also applied topic modeling techniques to characterize the parenting conversations on parenting subreddits—including the Daddit subreddit—and out of the 12 latent topics that were reported in the paper, only 1 topic re-emerged in this study. Specifically, there is an interesting similarity in sentiment between the *thank you and appreciation* theme determined by Sepahpour-Fard et al [21] and the *pregnancy congratulations* theme that we found in our analysis. The overlap in these findings point to and underscore the positive emotions that are experienced in the transition to fatherhood, despite considerable societal change. This finding is further bolstered by the results from our sentiment analysis, which determined that trust and joy were the top 2 emotions expressed in web-based conversations surrounding fatherhood, throughout the transition from a prepandemic society to a postpandemic society. It is important to note that unlike our analysis, which used data from both Reddit and Twitter platforms, the studies by Ammari et al [19] and Sepahpour-Fard et al [21] solely analyzed Reddit data, which may partially explain why the study findings diverged so drastically. Furthermore, relative to previous studies, themes of interpersonal troubles are highly represented in our analysis, which may serve as a digital signature indicative of increased pandemic-related stressors experienced by new fathers and their growing families.

Other scholars have used social media analyses to examine changes in emotion and sentiment as societies across the globe grappled with and responded to the COVID-19 pandemic. For instance, using data retrieved from Twitter, several textual and sentiment analyses have been conducted to explore health care providers' emotional reactions during the global disaster, with studies finding that, in general, levels of positive emotions (eg, joy) have decreased over time, whereas levels of negative emotions (eg, sadness and disgust) have increased [22,23]. However, specific to the emotional experiences of expecting and new fathers, a few qualitative studies have reported that fathers experienced high levels of stress related to both the transition to parenthood and the transition to a postpandemic society [2,24]. The findings of this study are consistent with these results overall. Specifically, the themes of *interpersonal troubles* and *financial help requests* that emerged are well aligned with previous studies, suggesting that stress was an affective state experienced widely by new and expecting fathers during the COVID-19 pandemic.

The results of this study also include a *miscellaneous* theme. Social media analyses are typically exploratory in nature; therefore, the researchers cannot predict what type of conversations will be uncovered. Although most captured posts will be directly related to the topic of interest, there is still potential to obtain *random* posts that are unrelated to the main topic. In this study, the miscellaneous theme included topics that were not directly related to new and expecting fathers. For example, Dur9 captured humorous responses; however, they were not necessarily related to fatherhood. This topic occurred only in the *during-pandemic* period, which could show an increase in humorous responses on the web. This use of humor in web spaces may be evidence of coping with the pandemic, as the world becomes more stressful to navigate and increasingly digital. It is well known that humor can function as a means of emotional regulation and act as a coping strategy for negative and stressful life situations [25-28]. More studies should be conducted to determine the effectiveness of humor as a potential health communication message appeal for efforts targeting expecting fathers.

Implications

The findings from the study provide insight and guidance on strategies for both communication and public health professionals to better connect with new and expecting fathers on the web. Social listening analyses, such as the one conducted in this study, can be used to better understand the changing dynamics, behaviors, and needs of certain populations during rapidly changing events—such as pandemics and natural disasters—which can inform public health efforts in almost real time. For instance, the results of this analysis imply that fathers may use social media to cope with pandemic-related stress and seek advice related to fatherhood; therefore, public health officials should consider using the web to conduct campaigns and for interventions containing information related to parenting and stress management. In addition, these results suggest that online support groups and peer support interventions may be appealing to and safe for new and expecting fathers who are seeking enhanced social support as the world continues to battle the deadly COVID-19 pandemic.

Another useful finding for public health practitioners is understanding how external accounts are communicating with new and expecting fathers to promote baby-related information. Social media analyses are useful to see not only what a specific group is saying but also who is speaking to that group. For example, the *external parties targeting fathers* theme shows that social media accounts are targeting new and expecting fathers to promote a variety of baby products and articles with

baby-related information. Further study of these posts and their levels of engagement can be useful for improving public health efforts that use social media to reach new and expecting fathers. Moreover, in almost real time, public health officials can use these types of social listening analyses to obtain a rapid assessment of the material and information needs that people who are pregnant, and their partners, may require during other health-related situations that call for immediate response such as abortion restriction, outbreaks of Zika virus, or natural disasters.

Limitations and Future Studies

This study examined posts from both Reddit and Twitter; however, analyzing these 2 platforms together can present issues. These platforms provide different purposes and outlets for users, and the users and audience may have different characteristics. Although we searched for the same keywords in both platforms, users may divulge different information depending on the platform they are using. Relatedly, it is important to note that a portion of the social media posts that were captured cannot be definitively identified as coming from a new or expecting father.

There are also limitations to the data. First, the social media posts were limited to English-speaking users, resulting in the inability for generalizing the findings. Future studies should consider examining posts in other languages, such as Chinese and Spanish, as they are the second and third most commonly used languages, respectively, on the internet after English [29]. Future studies may also include alternative social networks, such as Weibo, to understand other samples. Second, the data set could not include every post related to new and expecting fathers, which ultimately limits the number of posts collected. Therefore, the results cannot reflect the entire population of interest. However, this study is exploratory in nature, and it is among the first to analyze Twitter posts for this specific audience. Future studies can apply this study's insights toward quantitative research that is generalizable. The findings of this study can work toward future research that explores social media use among new and expecting fathers.

Another route of future studies includes a focus on emotions and sentiment analysis within social media analyses. Social media posts can correlate with the emotional well-being of an audience, and taking a deep dive into the sentiment of social media posts related to new and expecting fathers can provide a snapshot of this population's well-being.

Conclusions

With the onset of the COVID-19 pandemic, new and expectant parents faced unprecedented challenges amid a global pandemic. In addition, the current stream of literature that examines this group tends to give priority to the mothers, suggesting that fathers are overlooked or simply feel unprepared. Thus, this study sought to enrich research by focusing on new and expecting fathers, namely, by examining social media discourse related to this group both before and after the COVID-19 global pandemic was announced. Overall, the arrival of the COVID-19 pandemic appeared to have little impact on the excitement and resilience of new fathers as they transition to parenthood, in spite of considerable stress. These results speak to the immense resilience displayed by expecting fathers during the pandemic and imply that a major source of this resilience may stem from positive emotions that accompany becoming a parent. When communicating with new and expecting fathers, campaigns and interventions may consider appealing to the positive emotions and resilience that are commonly displayed during the transition to parenthood, as a means to promote prosocial coping behaviors among this unique population.

Altogether, these findings provide insight and guidance on the ways in which public health professionals can rapidly gather information about special populations—such as new and expecting fathers on the web—to monitor their beliefs, attitudes, emotional reactions, and unique lived experiences in context (ie, throughout a global pandemic). Insights gathered from studies such as these are enormously helpful for health communicators, as they think through the most efficient and effective ways to tailor messages for various audiences that, when taken together, comprise a specific population. Ultimately, we argue that public health officials engaged in health promotion should consider complementing traditional surveillance activities with social listening analyses, given the immense amount of heterogeneity that exists within communities and populations.

Acknowledgments

This project was partially funded through the Texas Safe Babies project (HHS000820100001) from the Texas Department of Family and Protective Services. The findings and conclusions reported in this paper are those of the authors and do not represent the official position of the Texas Department of Family and Protective Services.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Boolean code used to collect social media posts.
[DOCX File , 12 KB - pediatrics_v6i1e40371_app1.docx]

Multimedia Appendix 2

Word cloud of topics from before the pandemic.
[PNG File , 818 KB - pediatrics_v6i1e40371_app2.png]

Multimedia Appendix 3
Word cloud of topics from during the pandemic.
[PNG File , 833 KB - pediatrics_v6i1e40371_app3.png]

Multimedia Appendix 4
Emotion in fatherhood posts according to volume.
[PNG File , 60 KB - pediatrics_v6i1e40371_app4.png]

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Abbreviations

RQ: research question

Edited by S Badawy; submitted 17.06.22; peer-reviewed by T Ammari, A Elyashar; comments to author 30.07.22; revised version received 22.10.22; accepted 25.12.22; published 15.02.23.

Please cite as:
Bouchacourt L, Henson-Garci´a M, Sussman KL, Mandell D, Wilcox G, Mackert M
Web-Based Conversations Regarding Fathers Before and During the COVID-19 Pandemic: Qualitative Content Analysis
JMIR Pediatr Parent 2023;6:e40371
URL: https://pediatrics.jmir.org/2023/1/e40371
doi:10.2196/40371
PMID:36790850

Original Paper

Using Digital Communication Technology to Improve Neonatal Care: Two-Part Explorative Needs Assessment

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Abstract

Background: The birth of a premature infant and subsequent hospitalization are stressful events for parents. Therefore, accurate and easy-to-understand communication between parents and health care professionals is crucial during this period. Mobile health (mHealth) technologies have the potential to improve communication with parents at any time and place and possibly reduce their stress.

Objective: We aimed to conduct a 2-part explorative needs assessment in which the interaction between the pediatrician and parents was examined along with their digital communication technology needs and interest in an mHealth app with the aim of improving interpersonal communication and information exchange.

Methods: Overall, 19 consultations between parents of preterm infants and pediatricians were observed to determine which themes are discussed the most and the number of questions asked. Afterward, the parents and the pediatrician were interviewed to evaluate the process of communication and gauge their ideas about a neonatal communication mHealth app.

Results: The observations revealed the following most prevalent themes: breastfeeding, criteria for discharge, medication, and parents' personal life. Interview data showed that the parents were satisfied with the communication with their pediatrician. Furthermore, both parents and pediatricians expected that a neonatal mHealth app could further improve the communication process and the hospital stay. Parents valued app features such as asking questions, growth graphs, a diary function, hospital-specific information, and medical rounds reports.

Conclusions: Both parents of hospitalized preterm infants and pediatricians expect that the hypothetical mHealth app has the potential to cater to the most prevalent themes and improve communication and information exchange. Recommendations for developing such an app and its possible features are also discussed. On the basis of these promising results, it is suggested to further develop and study the effects of the mHealth app together with all stakeholders.

(JMIR Pediatr Parent 2023;6:e38435) doi:10.2196/38435

KEYWORDS

mobile health; mHealth; physician-patient communication; questions asking; needs assessment; explorative; mobile phone

Introduction

Background

The birth of a preterm infant has an incredible impact on the family. Parents suddenly have to adjust to unfamiliar surroundings, cope with the infant's uncertain survival and outcome, adjust to the hospital setting, learn new medical vocabulary, and eventually care for a vulnerable infant at home [1,2]. These factors are a source of stress, uncertainty, and fear [3]. For parents, adequate communication and information is one of the most important needs for coping with these factors and successfully navigating through the emotional hospital stay [1,4-6].

Most preterm infants are hospitalized for weeks to months in neonatal wards. During this period, parents typically receive daily medical updates from nurses and pediatric residents. In

addition, patients have a weekly update consultation with their principal pediatrician. The principal pediatrician has responsibility over medical decisions during hospital stay and maintains long-term contact with the parents and patient. Although the information exchange between parents and pediatricians has improved considerably over the last few years [7,8], recent research has also revealed that the information exchange is not yet in its most optimal form. Parents still yearn for more information and do not always feel comfortable asking questions [9]. To gain a sense of control, parents often seek information from external sources, such as educational materials, the internet, and mobile health (mHealth) apps [4,8-11].

It has been suggested that mHealth technologies have the potential to further improve communication and interpersonal relationships in neonatal units [12-14]. The use of mHealth apps is gaining popularity owing to their ubiquitous availability and accessible use. In addition, practically all young parents now own a smartphone and have considerable skills in using the device [14-16].

The number of mHealth apps developed to improve communication and medical conditions is increasing, demonstrating the demand for such apps in society. A literature review by Richardson et al [12] found 18 different neonatal mHealth apps in both the Apple App and Google Play store. In general, these apps provide information on premature births, advice or tips, and monitoring of infants' data. However, only 1 of these 18 mHealth apps (MyPreemie) was supported by scientific research [17]. There is hardly any scientific knowledge regarding the development and evaluation of neonatal mHealth apps [18,19].

To successfully build mHealth apps and have a fair possibility of successfully implementing a potential mHealth solution, it is important to involve all stakeholders during the development process [20]. Involving mHealth users from the beginning of the process, from conceptualization of the ideas to development to evaluations, enhances app adoption [19,20]. Unfortunately, potential users have rarely been involved.

Furthermore, efforts to develop technological interventions for neonatal care and guiding interpersonal communication in the neonatal ward are hampered by a distinct lack of scientific data on how parent-provider interactions organically unfold [18]. Little is known about the actual course, the contents, the themes parents find important to discuss, and the effectiveness of the interaction and information exchange between parents and medical caregivers during hospitalization [18]. Therefore, it is important to also understand communication in the neonatal ward when developing an mHealth solution [18].

Study Aims

In this study, a 2-part exploratory needs assessment was conducted. The first part of this study (research question [RQ] 1, 2, and 3) consisted of observing, examining, and evaluating the weekly update consultation held between the principal pediatrician and the parents. The themes that were discussed and questions from parents and pediatricians were explored. This information provided a solid base for the second part of this study (RQ 3, 4, and 5). In part 2, we begin by outlining and examining interest in the idea of an mHealth app. We propose an mHealth app that can be used by parents to store themes, concerns, and questions for discussion with the pediatrician for the subsequent consultation, given that patients or parents of patients frequently forget questions they would like to ask during a consultation owing to emotional overload [4,9]. In addition, professionals are often confronted with questions that they cannot immediately answer during the consultation. Using the same app, the pediatrician could read these themes, concerns, and questions beforehand and prepare for the consultation. We speculate that using such an app could increase patient and professional satisfaction and improve communication and information exchange [21]. To investigate our aims, we propose the following RQs:

- RQ1: Which themes are discussed between the parents and pediatrician during the weekly consultation and who initiates these themes?
- RQ2: How many questions do parents and pediatricians ask during consultations?
- RQ3: How do the parents evaluate the consultation?
- RQ4: What are the parents' opinions regarding an mHealth app?
- RQ5: Which features would the parents value in a neonatal mHealth app?
- RQ6: What are the pediatricians' opinions regarding an mHealth app?

Methods

Sample

In total, 20 consultations of parents with the pediatrician were observed. Each parent-couple (PC) was observed once, and 7 individual pediatricians were enrolled. One observation was excluded from the eventual data set owing to a missing survey, resulting in a final data set of 19 consultations. Research has shown that qualitative interview studies with at least 13 samples are robust [22]. In addition, we noted that data saturation was reached after 13 consultations. Therefore, this sample size was sufficient. The consultations lasted between 10 and 45 minutes. In total, 10 consultations were first-time consultations for the parents and 9 were second or third consultations. Mothers (mean age 32.1, SD 4.9 years) were always present (n=19) and fathers (mean age 32.7, SD 4.6 years) were present in 15 consultations.

The 19 mothers had a total of 22 preterm infants (3 twins). The postnatal age of the preterm infants ranged from 5 to 59 (mean 17.7, SD 15) days. For 11 parents, their premature newborn was their first child; for 6 parents, the newborn was their second child; and for 2 parents the newborn was their fourth child. In 3 cases, the parents had premature twins. All infants were admitted to a level II neonatal intensive care unit (NICU) during the study. Level II NICUs provide special high or medium care for moderately ill infants [23]. Twelve of the 22 infants had previously been admitted to a level III and IV NICU where they had been critically ill at that time. Ten infants had been admitted to the level II NICU only. Table 1 presents the characteristics of the sample.

Table 1. Demographic and obstetric characteristics of the sample.

Characteristics	Values
Parent details (n=35)	
Nationality , n (%)	
Dutch	33 (94.2)
Moroccan	1 (2.9)
Turkish	1 (2.9)
Education level , n (%)	
High school	9 (25.7)
Intermediate vocational education	14 (40)
Higher vocational education	12 (34.3)
University	0 (0)
Birth details (n=22)	
Gestational age (weeks), n (%)	
27-28	4 (18.2)
29-30	3 (9.1)
31-32	7 (31.8)
33-34	6 (27.3)
35	2 (9.1)
NICU[a] admission (age in days)	
Level III or IV NICU transfers	
Value, n (%)	12 (54.5)
Value, mean (SD)	23.8 (18.3)
Level II NICU	
Value, n (%)	10 (45.5)
Value, mean (SD)	11 (6)

[a]NICU: neonatal intensive care unit.

Materials and Procedure

This study was conducted from March to July 2019. In total, 17 consultations were conducted at the Elisabeth TweeSteden Hospital, Tilburg, the Netherlands. Two consultations were conducted at the Jeroen Bosch Hospital, Den Bosch, the Netherlands. These 2 level II NICUs were 20 km apart, worked closely together, and followed the same medical and conversational policy. Parents and pediatricians received oral and written information regarding the study. All participants who were approached were willing to participate in the study and provided written informed consent. The observations were audio recorded with participants' permission for any subsequent analysis.

The weekly update consultations were planned (date and time) by the parents and principal pediatrician. The consultations between the parents and the pediatrician were conducted in a single-family room. In these private rooms, parents could stay over and sleep next to their infant's bed. The researcher observed the consultation while simultaneously typing along a basic synopsis of the conversation, noting the questions asked by either the parents or the pediatricians, and the themes that were discussed. A theme checklist was created during the observations: once a theme was brought up, it was written down. If this theme appeared again in another consultation, it was marked in the checklist. The person (mother, father, or pediatrician) who raised a question or theme was also marked for each theme.

After the consultation, parents were asked to complete a questionnaire assessing basic demographic characteristics and their smartphone use. The researcher would leave to give the parents some time to complete the questionnaire. After approximately 15 minutes, the researcher returned to the single-family room to interview the parents. The interviews were audio recorded, and the researcher simultaneously typed the answers. The length of the interviews ranged from 10 to 40 minutes, depending on how elaborate the parents' answers were. None of the parents declared feeling hindered by the researcher during the consultation. The pediatricians were interviewed either between the consultation and the parents' interview or after the interview with the parents, depending on whether the pediatrician was busy.

Analysis

Observations

Immediately after the observation, the audio recording and basic synopsis of the consultation were checked alongside the theme checklist for possible missed themes. The questions that were written down in the synopsis were highlighted and classified as asked by the mother, father, or pediatrician. All observational data (demographics, questionnaire information, themes, and questions asked) were interpreted using Microsoft Excel.

Interviews

The qualitative interview data were analyzed according to Halcomb and Davidson [24]. First, a basic interview overview was created by writing along a basic synopsis throughout the interview, while the interviews were also being audio recorded. Then, immediately after the interview, the researcher reflected on the data collected in the interview. Third, the interview overviews were evaluated together with the audio recordings to create an accurate interview summary. Relevant information was transcribed precisely into the interview summary accordingly. After completing this process, all the final interview summaries were printed. Using a color-coding system, relevant interview answers of the parents were highlighted and categorized. Conclusions were accordingly drawn from these files.

Ethical Considerations

On the basis of the nature of the study being an explorative with noninvasive questionnaires the Scientific Board Elisabeth Tweesteden Ziekenhuis declared that the study did not require ethics approval. The study followed all good clinical practice guidelines.

Results

Part 1: The Consultation

Themes and Questions

In the 19 consultations that were observed, 32 different themes arose (see Table 2 for an overview and explanation of the content). The most frequent topics included feeding and breastfeeding (n=17), introductions of oneself (n=14), parents' personal life (n=14), criteria for discharge (n=13), and follow-up after discharge (n=13). Except for feeding or breastfeeding and parents' personal life, most themes were brought up by the pediatrician. The themes most frequently initiated by the parents, included the road to labor (n=7), infant feeding problems (n=7), infant vomiting (n=7), and growth in terms of height (n=7).

With regard to the number of questions asked during the consultations by the parents and pediatricians (RQ2), questions asked by the pediatrician ranged from 0 to 11 care-related questions per consultation, with a mean of 3.7 (SD 2.9) questions per consultation. In sum, the pediatricians had 71 questions for the parents. Mothers (n=19) asked 80 questions (0-15 questions per consultation, with a mean of 4.2, SD 4.3). Fathers (n=15) asked 37 questions with a mean of 2.5 (SD 1.9) questions per consultation. Pediatricians explicitly invited parents to ask their questions by asking if they had "any further questions?" in all but 1 (PC03) consultation.

Additional demographic information (Table 1) of the parents was analyzed to determine whether the number of questions from either parents or pediatricians was influenced by aspects such as parents' age, educational level, how many children they had in total, the health of their infant, the gestational age of their infant, the amount of time spent in the hospital, or the duration of the consultation. However, no noticeable trends were discovered concerning any of these aspects.

The interview data showed that all (PCs; n=19) thought that they had sufficient opportunities to ask questions and were satisfied with the pediatrician's answers. Six PCs mentioned that they had sometimes forgotten to ask certain questions during the consultation. However, in their explanations, they attributed the reason for this happening to personal reasons (eg, PC 21: "Dad is often not present so he comes up with questions later"). Six PCs stated that if they had forgotten to ask something during the consultation, they would just go and ask the nurses:

> *Mother: Sometimes we are like 'we should've asked that' but then we just ask those questions to the nurses, in many cases they know the answers.* [PC13]
>
> *Father: The nursing staff is our go-to resource. The nursing staff often has the answers to the questions we typically ask the pediatrician. Sometimes they have to consult with the pediatrician but we get answers soon after their consultation.* [PC13]

Table 2. Content of the themes and the total number of times a theme was brought up by the pediatrician or the parents for all 19 consultations.

Theme	Content	Values (n=19), n (%)	Introduced by pediatrician[a], n (%)	Introduced by parents[a], n (%)
Feeding and breastfeeding	Progression of breastfeeding, milk expression, positive effects	17 (90)	9 (53)	8 (47)
Introduction	Pediatrician introduces oneself; their tasks; the department; daily program	14 (74)	14 (100)	0 (0)
Personal	Personal information about the parents and their lives like work status and psychosocial situation	14 (74)	7 (50)	7 (50)
Criteria	Criteria for discharge	13 (68)	11 (85)	2 (15)
Postdischarge follow-up	Explanation how postnatal follow-up will be scheduled	13 (68)	9 (69)	4 (31)
Respiratory support and caffeine	Supplemental oxygen and pressure, and how these are decreased; medication like caffeine	12 (63)	10 (83)	2 (17)
Not care related	Small talk	11 (59)	4 (36)	7 (64)
Monitor or alarms	Why and for how long the infant will be connected to the monitor; alarms that went because of low oxygen saturation or low heart rate	10 (53)	6 (60)	4 (40)
Department	Opinion and experiences of parents regarding the department; the employees; the nurses; the care; other parents	10 (53)	4 (40)	6 (60)
Talking about the future	The preterm's future; how will they grow up, which problems may they face, school	8 (42)	6 (75)	2 (25)
Weight	The weight or growth of the preterm infant.	8 (42)	5 (62)	3 (38)
Tube feeding	Whether the preterm is or will be given tube feeding; how much; how long	8 (42)	5 (62)	3 (38)
Temperature of the child	Can the preterm keep themselves warm; external source for heating; incubator; phototherapy for icterus	8 (42)	6 (75)	2 (25)
Ultrasound or MRI[b] of the brain	Ultrasound or MRI of the brain; and results of them	8 (42)	6 (75)	2 (25)
Vaccinations	Parent's consent for vaccinations and scheduling	8 (42)	6 (75)	2 (25)
Birth	The process, experience, and possible complications of labor	7 (37)	1 (14)	6 (86)
Vomiting	If and why the preterm is vomiting (explanations)	7 (37)	1 (14)	6 (86)
Height and growth	The length, weight, and growth charts	7 (37)	1 (14)	6 (86)
Laboratory values	blood draw; blood transfusions	7 (37)	7 (100)	0 (0)
How to care at home	After discharge; what should be paid attention to; differences and similarities from raising a term baby and extra concerns	7 (37)	2 (29)	5 (71)
Recap	A recap is given of everything that has happened at the NICU[c] so far	6 (32)	6 (100)	0 (0)
Emotional	The emotional state of the parents regarding the situation; their preterm; the hospital	6 (32)	5 (83)	1 (17)
Bowel movements	Bowel movements of the preterm; use of enemas	6 (32)	3 (50)	3 (50)
Vitamins	The needed vitamins; iron supplementation	6 (32)	4 (67)	2 (33)
Child specific	Issues specific for the preterm	6 (32)	4 (67)	2 (33)
Data or counting	How the birth date and age of the preterm should be corrected for regarding growth, and scheduling of vaccinations	5 (26)	3 (60)	2 (40)

Theme	Content	Values (n=19), n (%)	Introduced by pediatrician[a], n (%)	Introduced by parents[a], n (%)
Infections	Recent infections; chance of infections; antibiotics	5 (26)	5 (100)	0 (0)
Eyes (retinopathy)	Explaining why the eyes are checked; ophthalmologist appointments	4 (21)	1 (25)	3 (75)
NICU level III experience	How parents experienced their stay at the level III NICU; what happened there before transfer	4 (21)	1 (25)	3 (75)
After the NICU	Aftercare by the NICU department; what, when, and how	3 (16)	1 (33)	2 (67)
(Possible) operations	Possible operations of the heart, lungs, brain, body are discussed and explained	2 (11)	1 (50)	1 (50)
Lungs	Explaining pulmonary edema; lung capacity	2 (11)	1 (50)	1 (50)

[a]Total (n)=252. Introduced by pediatrician=155; introduced by parents=97.

[b]MRI: magnetic resonance imaging.

[c]NICU: neonatal intensive care unit.

Consultation Evaluation

How parents value the weekly consultation with their principal pediatrician was also studied given that the parents see many different medical professionals daily (RQ3). Overall, the data showed that most PCs needed consultation with their principal pediatricians (n=15). There were 3 overarching reasons parents valued those consultations: finally getting a clear overview of everything (n=6), nice to be kept up to date (n=6), and finally having an interaction with the principal pediatrician (n=3). An example of the latter category is presented in the following quote:

> *Yes, we had a great need actually. We actually had some of our questions answered during rounds, but that moment is fairly short. That was also explained to us. For certain questions, they make sure we get moments like this [the weekly meeting with the main pediatrician]. This was a great moment. We had many questions about what will happen when we leave. These came forth from changes that have been happening. Those things all come together now and we just want to know what will happen next week.* [PC14]

Four PCs had a lesser need for weekly consultations. These parents stated that the consultation did not provide extra information because they had already received information from nurses or other professionals during their daily rounds. However, 1 PC (as noted in the aforementioned quote) did have a need for the weekly meeting with the pediatrician despite having received information during daily rounds. Thus, valuing the consultation seems to depend on the parents' perspectives and experiences.

Almost all parents were pleased with how the different professionals of the neonatal unit communicated. Repeatedly, parents gave short answers if they were satisfied with the level of communication (eg, PC06: "Yes, very satisfied with the communication"). The parents unanimously declared to have felt included and stated that no decisions were made without consulting the parents first. PCs that were slightly less positive (n=4) shared the same overarching reason for their opinion: the medical staff members' team is large, and there are many different professionals who have their own way of communicating and caring. This opinion is best summarized in the following statements:

> *In general, the communication is very good. Yes, I know that for sure. However, you do notice that everyone has his own method of caring for our baby. And ehm...that is a disadvantage because it is a large team. You get acquainted with someone who is taking care of us, you just get to know someone and their ways and then the next person arrives. You keep switching between how people do everything.* [PC10]

> *I do however notice that when another nurse takes over something, that I can just pick up where I left off with everything that I was saying. I don't have the idea that I have to fill in certain blanks.* [PC20]

Part 2: Parents' and Pediatricians' Interest in an mHealth App

Parents' Need for an mHealth App

Next, we examined whether the parents would appreciate a communication and question-asking mHealth app that could be used during the hospitalization period (RQ 4, 5, and 6). This hypothetical app could give parents the opportunity to disclose questions, themes, and concerns to the pediatrician days before the consultation.

In total, 17 of the 19 PCs' valued the idea of this type of app, 10 of whom indicated that they would definitely use it; 8 of these couples mentioned that they believe it is practical to be able to write down their questions as soon as they think of one:

> *Sometimes you think of questions when you are not in the room [and do not have anything with you to take notes] and you of course, always have your phone with you [...]. Just easier when you have an app, especially now that we live in a mobile era.* [PC19]

> *Yes, I think it has value [the app]. You can, the moment you think of a question, write it down. That might bring you peace.* [PC05]

Seven couples liked the idea of the app but did not believe they would use it themselves. In explaining their point of view, 2 PCs (PC09 and PC14) mentioned that they could, however, understand the benefits of the app for medical professionals:

> *Well, not that much [need for such an app for us] actually. I can imagine there are people who would have a need for such an app but I don't think we would use it that often [...] I do think it is a good initiative. There is a low threshold to present certain problems to the doctor and the doctor can then focus on the needs of the parents and prepare themselves better [...]. And, as a doctor you get to say "I have to come back to that later" less often, in terms of efficiency it is very useful. Yes, I am positive about an app, not necessarily for us, but I do believe that parents can benefit from this. Especially new parents.* [C14]

Overall, 14 of the 19 PCs stated that using such an app could probably change the way they ask questions. Parents provided various reasons for this. For example, most (n=10) PCs mentioned that they would probably ask more questions because they were less likely to forget them. Four parents stated that given the potential features of the mHealth app, they would probably have more questions because they had access to more information:

> *If there would be, for instance, a questions suggestions list, then I would probably ask more questions. Or certain information about preterm infants in general, which I haven't personally thought about yet, then I would think like "hey I would want to know something about that.*" [PC11]

Four PCs stated that they would probably ask fewer questions if the app contained basic medical information about preterm infants. One PC (C10) mentioned that they would probably ask more in-depth questions during the consultation because their questions have already been made clear to the caregiver beforehand. This could make consultations elapse more efficiently and satisfactorily.

The motivations of the 2 PCs (PC06 and PC12) who did not need the app were similar. They preferred real-life contact over all else and were not, in their words, the "app kind of people."

An overview of parents' ideas for the mHealth app is presented in Table 3 (RQ4). The most mentioned feature by the parents was a graph feature, which included their infants' growth. Most parents valued this function because of entertaining grounds (eg, C14: "something like a weight tracker is fun"), whereas others valued this feature because of their need to keep track of their infant's progress (eg, PC05: "keeping track of their progress would be nice [by using trackers], I keep track of everything myself now but in an app would be nice, clear").

Parents who valued a diary or achievements feature had similar reasons for why they would like such a feature: either because of entertaining properties or because they wanted to keep track of their infants' progress. One of the PCs proposed the option of having a list to mark off specific milestones (eg, weight >2000 g) in a playful way as part of the diary function. They believed that this would help keep the parents motivated in working toward discharge from the hospital.

Table 3. Features, the content of features, and frequency of interviews the feature was mentioned in.

Features	Content	Frequency of interviews in which the feature was mentioned (n=19), n (%)
Graphs	Graphs including their infants' growth or weight and what is normal for infants to grow or weigh (comparisons)	8 (42)
Diary or achievements	Diary in which parents could write their own experiences and condition of their infant	6 (32)
Information	Practical basic information, glossary of terms, what to expect with a preterm infant	6 (32)
Medical rounds reports	Report of what is discussed during medical rounds provided by all medical caregivers, including the current values	5 (26)
Baby cam	Camera feature that shows their infant in their bed at the hospital	5 (26)
Agenda	Schedule including planning or appointments	4 (21)
Frequently asked questions	Frequently asked questions with answers	3 (16)
Question suggestions	Suggestions on what the parents could ask their caregivers	2 (11)
Pictures	Saving and sending pictures	2 (11)
Information medical exams	Explanation of different medical exams	1 (5)
Results medical exams	Results of the exams (eg, blood testing, MRI[a])	1 (5)
Parental presence	Giving parents the option to state when they are at the hospital and when they are gone	1 (5)

[a]MRI: magnetic resonance imaging.

The medical rounds report feature is the final feature worth mentioning. During medical rounds in the morning, general care-related information about the infant is discussed, as well as information such as what happened during the night [9]. Several parents indicated that they saw medical caregivers typing along the discussed information during medical rounds and would also like to have that information:

> *During rounds you see the doctor typing little reports, you remember it [the information discussed] as a parent but it is still nice to check it later on. Sometimes I forget the easy things like their weight. Just some broad outlines I would definitely like to have. Also, maybe if later on something happens that you are able to see that back.* [PC20]

The main reason some PCs wanted these reports was that they simply wanted to be able to reread the information.

Pediatricians' Need for an mHealth App

The pediatricians (n=7) were also asked how they would feel about using the hypothetical mHealth app (RQ6). All pediatricians were positive about the idea of a communication app. Four of 7 pediatricians believed the app could personally help them in being better prepared for the consultation because of the potential app's function to read parents' concerns and questions beforehand. Three of the 7 pediatricians thought that the app may be particularly helpful for the more anxious parents by having them store questions and concerns at any moment at any place, thereby relieving some stress:

> *Yes [I would value such an app] because you can see what the parents are occupied with beforehand so you can already prepare yourself for the questions they are having instead of having to get back to it during medical rounds.* [D06]

> *It would be nice if I was able to check the old-fashioned lists parents normally bring to the consult. Imagine that they would ask something I wouldn't know the answer to, for instance "when is the appointment with the eye doctor?", then I could look this up beforehand and would be able to have a more efficient interaction. For that matter, there are also questions that you of course expect [...] however, unexpected questions do happen and having that [such an app] would be nice to have.* [D03]

Discussion

Principal Findings

The interaction between the pediatrician and parents, as well as their digital communication technology needs, were evaluated in a 2-part exploratory needs assessment, with the goal of improving interpersonal communication and information exchange. The results from the first part of the study showed that pediatricians introduced most themes, of which feeding and breastfeeding, personal introductions, the consultation office, medication (caffeine), and parents' personal lives were the most frequent ones.

Themes initiated by the medical caregivers such as introducing themselves or asking the parents about their personal lives are not medical themes but topics that reflect a caring environment in the neonatal department [23]. The pediatricians seem to be engaged in ensuring that parents understand the hospital situation and all staff members. This is also demonstrated by the pediatricians' concern for the parents' questions and satisfaction with the communication. However, there was 1 aspect that received some criticism from multiple parents, namely, the constantly shifting nursing staff. This is not a novel result and is difficult to change [5]. However, most of the parents stated that although the nursing staff is always changing, all the nurses are up to date on how the parents and the infant are doing, and transitioning between nurses is relatively easy.

Regarding question asking, observational results showed that mothers asked more questions than fathers, and the majority of the PCs stated that they did not forget to ask certain questions during the consultation. This answer could potentially be explained by having the interview conducted shortly after the consultation. Given that the parents were still processing the information from their appointment with the pediatrician [10], it could be that parents did not realize that they had forgotten to ask a question. Fortunately, the interview results show that parents experience a hospital environment in which they are able to ask questions to various medical caregivers 24/7. Several parents explained that if they forgot to ask something or came up with a question randomly, they just asked the nurses. Finally, although parents are going through difficult and stressful times while they are in the hospital [6], they were all quite optimistic during the interview and talked highly of the neonatal unit and its staff.

Then, the second part of our study used the mHealth app. Nearly all parents seemed to value the idea of the mHealth app and recognize the possible benefits it would have for them. Providing information has been the main purpose of most existing neonatal mHealth apps, and this study has shown that the same remains an important feature of an mHealth intervention [12]. In essence, almost all features frequently mentioned by the parents are linked to retrieving information. Some parents expressed this by simply desiring a standard information feature, some by wanting the reports from the medical rounds, whereas others valued the most frequently asked questions, and so on. This resembles what is depicted in the literature regarding the needs of parents of preterm infants: parents have extensive information needs and crave to satisfy these needs by seeking information from various sources [11,12,15].

Previous studies have repeatedly shown that patients and physicians value different aspects of supporting interventions, and this study supports that notion [20]. For example, during the observations, the parents often initiated the theme "increase in length," whereas the pediatricians were not concerned about the length because, from a medical standpoint, weight gain is much more important than increase in length. The length was also the most frequently mentioned app feature that parents would find valuable. This illustrates that there seems to be a discrepancy between what parents want to know and what is important for professionals [20]. Furthermore, it supports the

idea that it is important to include all the different stakeholders in developing an mHealth app [19].

According to parents, the actual use of the hypothetical app will depend on a variety of personal factors, such as their general opinion of electronic interventions or how difficult or easy the hospital stay is. These are personal experiences and points of view that are likely to be expressed in connection with other possible electronic interventions and are not necessarily related to a particular mHealth app's content.

In summary, even though parents are positive about the consultations, most parents still value using an mHealth app because they have a strong need for information and a desire to feel deeply involved in the entire process [6]. The proposed mHealth app mostly received good feedback from both parents and pediatricians.

Theoretical and Societal Implications

This study has several theoretical and practical implications. First, to our knowledge, this study is one of the few studies to observe how consultations organically unfold at a level II neonatal unit [18]. The findings from the observations have provided a comprehensive list of themes that are discussed during consultations in addition to who initiates these themes, allowing for insights into the topics that both pediatricians and parents deem crucial to discuss. This could help medical caregivers guide their consultations. In addition, by supplementing observational data with interview data, a comprehensive understanding of the current interactions and how parents felt about the consultations was obtained.

Furthermore, this study is one of the few to our knowledge to use scientific research to gather insights for the creation of a neonatal mHealth app and to examine parental perceptions before app development, which will hopefully boost the possibility of creating an appropriate intervention [22]. Although the major purpose of the mHealth app was to give parents the option of asking their caregivers questions ahead of time, our interview data revealed that parents wanted several other functionalities. In addition, for other neonatal mHealth developers, we recommend that at least the following features are present in such an app: (1) graphs about the child's growth with the option of comparing and checking milestones, (2) information including frequently asked questions that resemble the information a hospital provides because parents value hospital-specific information instead of general preterm information, and (3) a summary of the daily medical rounds.

Furthermore, based on our findings, we were able to make some concrete recommendations that mHealth app developers, in general, may consider when designing an mHealth app. Of course, different mHealth apps require various recommendations. However, the recommendations in Textbox 1 are what we advise for comparable apps.

Textbox 1. Recommendations for mHealth developers.

- Future users should be involved early in the app's development process.
- The app should have an attractive nonmedical look and feel.
- The app should be a useful tool, it should not replace aspects such as general information provision, sharing specific medical data, or planning.
- The app should not be intrusive for medical caregivers. It should not disturb daily work nor add to the workload of the caregivers.

Limitations and Suggestions for Future Research

Our findings must also be viewed in light of these limitations. First, these premature infants were not critically ill, which rendered positive and hopeful consultations that could have positively influenced their parents. Nevertheless, there is not necessarily a reason to believe that pediatricians will behave differently in consultations when the infant is in a more critical health condition. To be able to evaluate the impact of the preterm infant's health on the caregiver-parent dialogue, future research on this topic should therefore include a more diverse patient population.

The next limitation is that the sample was taken from 2 Dutch hospitals. It could therefore be argued that our results lack generalization because every country has its own culture and also its way of communicating. Our data reflect Dutch neonatal structures and ways of communication. Future research should examine and compare the communication at more neonatal units internationally to obtain a clearer picture of the current communication structures.

Finally, although parents were satisfied with the consultation, we did not examine whether the physicians' information was fully understood by the parents. Research has shown that parents tend to have difficulty understanding what is being said [4,25]. As correct parental understanding is also highly important for navigating the emotional hospital period and time thereafter [4], we propose future research on this topic.

Conclusions

On the basis of the results from both the observations and interviews, it is possible to conclude that, according to parents, communication at the neonatal unit is effective, informative, and satisfying. The second part of the study showed great interest in the potential mHealth app by both the parents and the pediatricians and yielded interesting insights for the development of mHealth apps.

This explorative study is a foundation for things to come. This study has paved the way for the next step in creating the communicative mHealth intervention in which there will still be plenty to be discovered regarding the app and its potential. We believe that an mHealth intervention has potential benefits for both parents and medical professionals. Hence, continuing research and development of mHealth apps is encouraged.

Acknowledgments

The authors would like to thank P Jira, MD, PhD, a pediatrician at the Jeroen Bosch Hospital.

Conflicts of Interest

None declared.

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Abbreviations

mHealth: mobile health
NICU: neonatal intensive care unit
PC: parent-couple
RQ: research question

Edited by S Badawy; submitted 10.06.22; peer-reviewed by B Nievas Soriano, W Langewitz; comments to author 30.07.22; revised version received 23.09.22; accepted 17.10.22; published 07.02.23.

Please cite as:
Tenfelde K, Antheunis M, Krahmer E, Bunt JE
Using Digital Communication Technology to Improve Neonatal Care: Two-Part Explorative Needs Assessment
JMIR Pediatr Parent 2023;6:e38435
URL: https://pediatrics.jmir.org/2023/1/e38435
doi:10.2196/38435
PMID:36749606

Original Paper

Designing a Collaborative Patient-Centered Digital Health Platform for Pediatric Diabetes Care in British Columbia: Formative Needs Assessment by Caregivers of Children and Youths Living With Type 1 Diabetes and Health Care Providers

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Abstract

Background: Digital health apps are becoming increasingly available for people living with diabetes, yet data silos continue to exist. This requires health care providers (HCPs) and patients to use multiple digital platforms to access health data.

Objective: In this study, we gathered the perspectives of caregivers of children and youths living with type 1 diabetes (T1D) and pediatric diabetes HCPs in the user-centered design of TrustSphere, a secure, single-point-of-access, integrative digital health platform.

Methods: We distributed web-based surveys to caregivers of children and youths living with T1D and pediatric diabetes HCPs in British Columbia, Canada. Surveys were designed using ordinal scales and had free-text questions. Survey items assessed key challenges, perceptions about digital trust and security, and potential desirable features for a digital diabetes platform.

Results: Similar challenges were identified between caregivers of children and youths living with T1D (n=99) and HCPs (n=49), including access to mental health support, integration of diabetes technology and device data, and the ability to collaborate on care plans with their diabetes team. Caregivers and HCPs identified potential features that directly addressed their challenges, such as more accessible diabetes data and diabetes care plans. Caregivers had more trust in sharing their child's data digitally than HCPs. Most caregivers and HCPs stated that an integrative platform for T1D would support collaborative patient care.

Conclusions: Caregiver and HCP perspectives gathered in this study will inform the early prototype of an integrative digital health platform. This prototype will be presented and iterated upon through a series of usability testing sessions with caregivers and HCPs to ensure the platform meets end users' needs.

(JMIR Pediatr Parent 2023;6:e46432) doi:10.2196/46432

KEYWORDS

application design; challenge; child; design; development; diabetes; diabetic; digital health; digital solution; engagement; feature; needs assessment; patient engagement; patient need; pediatric; perception; privacy; secure; security; trust; Type 1 diabetes; Type 1; usage; user centered; user need; youth

Introduction

The COVID-19 pandemic has shown the promise of digital health to transform health care delivery and improve patient experience and clinical care outcomes through virtual care visits, mobile health, telemedicine, and remote patient monitoring [1]. An estimated 300,000 digital health apps are available, and more than 200 new apps are added daily [2]. Specifically, many stand-alone diabetes digital apps do not integrate regulated medical devices, such as insulin pumps or continuous glucose monitors (CGMs) [3,4]. However, the uptake of digital health apps has lagged as they are not user-friendly and difficult to navigate [5]. There are also concerns around digital health literacy, data privacy and security, and barriers to accessing technology for populations in varying socioeconomic and geographic backgrounds [1].

Most diabetes digital apps are designed for self-management, targeting patients living with type 2 diabetes [4,6]. In a systematic review that evaluated 656 diabetes health apps for iOS and Android in patients 50 years and older, it was found that 54% of the apps were limited to providing 1 function, which was a documentation feature [3]. This entailed manual recording of blood glucose values, monitoring of food, physical activity, and medication frequency, often linked with a reminder function [3]. However, only 18% of the diabetes apps allowed analysis of the recorded data and graphical results display [3]. A total of 96% of these apps were designed specifically for patients, but only 3.7% addressed the needs of both patients and health care providers (HCPs) [3].

User-centered design of digital health apps is an approach that incorporates stakeholder input at any point during the development process, from as early as when the idea is first conceived, as part of usability testing of initial prototypes that undergo iterative development, to the eventual pilot implementation of a minimal viable product [7,8]. User-centered design is considered necessary to ensure feasibility, usability, and eventual uptake of digital health solutions by end users, such as HCPs and patients [7]. User engagement in evaluating diabetes digital apps is low, and most apps have involved patients only after the apps have been created [6]. Some apps have studied the needs and key features desired by patients with diabetes in the design of digital health platforms [9-11]. Adults living with diabetes prioritize access to their diabetes data and communication with the health care team as key functions in diabetes apps [9,11]. A diabetes app that motivates adolescents with type 1 diabetes (T1D) to self-manage their diabetes by recording their glucometer data identified social interaction in a group, customization, and tangible rewards as motivating factors to use the app [10]. However, the perceptions of HCPs in the design of these apps were not evaluated [9,10].

Children with T1D have the most significant uptake of diabetes technology from CGM use to automated insulin delivery systems [12], which store a vast amount of patient-generated health data. Data from these devices are uploaded onto various proprietary digital platforms, and HCPs, patients, and their families must access these platforms using multiple usernames and passwords [13]. Tidepool, a cloud-based open-source digital platform that can integrate data from any diabetes device, was created to break down the siloed data [13]. Digital apps that provide education on diabetes self-management or in response to blood glucose data are limited but desired by patients [14]. Apps that allow people living with diabetes to interact with their health care team are limited and are mostly designed for adults living with type 2 diabetes [15,16].

To our knowledge, a digital platform that enables diabetes data integration from various devices while also providing easy access to diabetes care plans, educational resources, and a seamless digital connection to a diabetes health care team does not yet exist. As diabetes devices become increasingly interoperable, there is an unprecedented opportunity for automated streaming and integration of patient-generated health data into 1 trusted digital space viewable by both patients and their caregivers and HCPs, where they can also access information that will support the optimization and personalization of care experiences and diabetes self-management such as insulin dose adjustment.

Our transdisciplinary research team partnered with industry partners to assemble the TrustSphere consortium. This consortium aims to cocreate a digital health platform to support a collaborative and continuous care experience for patients, their caregivers, and their HCPs. TrustSphere provides a secure, single digital access point to view diabetes data and care plans. This study describes TrustSphere's user-centered design approach at the conceptual phase of developing our digital health platform. The objective of this study was to gather perspectives of caregivers of children and youths living with T1D and pediatric diabetes HCPs on their current challenges, barriers, and facilitators of digital technology trust and usage for clinical care, and desired features early in the conceptual stage of designing this single-point-of-access secure integrative digital health platform.

Methods

Description of TrustSphere

At this early, formative stage of our project, the TrustSphere platform existed as a high-level concept and was described to caregivers of children and youths living with T1D as follows:

> *A secure online platform that will be customized for child and youth patients and their families, and will integrate a patient's health information such as diagnoses, medications and treatments, appointments, lab test results, wearable data (eg, FitBit), etc. This platform would use secure and trusted digital identification and follow the highest health care industry and public standards of privacy protection. The platform would help make it easier for children and families to access their health information and care plans and to communicate directly with health care providers. It would also allow users to share their health information and care plans, if desired, with others involved in their child's care, as well as donate their data confidentially for research.*

TrustSphere was described to HCPs as follows:

> *… a patient-centered integrated digital platform customized for patients and families of children and youth with T1D, and for the health care providers who serve them. This integrated patient platform will use secure and trusted digital identification and will be in compliance with the highest health care industry and public standards of privacy protection. It will provide a single-point-of-access dashboard for care providers and patients that will integrate patient data from a range of sources including clinical data from EMRs and labs, glucose sensors and insulin pumps, and wearables (eg, FitBit), and will enable the creation of personalized patient care plans. This integrated platform will allow for direct communication between patients/families and members of their care team, and the ability for patients to share their medical data and diabetes care plans, if desired, with other individuals within their circle of care (ie, primary care, nursing support services, etc).*

Ethics Approval

This study was approved by the University of British Columbia Children's and Women's Research Ethics Boards (H20-03105).

Data Collection

For caregivers of children and youths living with T1D in British Columbia (BC), a 35-item web-based survey was developed (Multimedia Appendix 1), which gathered perceptions of digital trust and security, challenges related to caring for their child with T1D, perspectives toward the proposed digital platform, importance of various potential features, and likelihood of future platform use based on the description above.

A 25-item web-based survey was developed for pediatric diabetes HCPs using REDCap (REDCap Consortium) (Multimedia Appendix 2) [17]. Survey items assessed critical current challenges in HCPs' practice when providing care to children and youths with T1D, essential features in digital tools that support patient care, levels of concern around digital security and data privacy, and the likelihood of use of the digital platform based on the description above.

The surveys had a list of potential features that were compiled through a review of features in existing T1D platforms and apps and consultation with clinical stakeholders on the study team. Free text "other" answer categories were also offered to ensure respondents could describe features that may not be listed if needed.

Participants

Using the BC Children's Hospital (BCCH) Diabetes Clinic database, email invitations with study information and a survey link were distributed to caregivers of patients living with T1D who were younger than 18 years, who were accessing pediatric diabetes care at BCCH (n=760). A total of 99 caregivers of children and youths living with T1D in BC completed the survey with a response rate of 13%.

The HCP survey was distributed to pediatric diabetes HCPs (pediatricians, pediatric endocrinologists, diabetes educators, and dietitians) across the Canadian province of BC using the Annual BC Pediatric Diabetes Day email listserv (maintained by the University of British Columbia's Continuing Professional Development administrative staff). This conference is attended by pediatric diabetes clinicians, such as physicians, diabetes nurse educators, dietitians, and pharmacists (n=232). The email contained information about the study and a link to the survey. A total of 49 HCPs completed the survey with a response rate of 21%.

Analysis

Descriptive statistics were used to analyze quantitative survey data results. Qualitative data obtained through open-ended survey questions underwent conventional content analysis by a single coder trained in qualitative analysis to generate preliminary coding categories; 2 researchers then reviewed results independently, after which both researchers worked together to deliberate and finalize the coding guide, resolve inconsistencies, and identify themes.

Results

Participant Demographics and Technology Use

Table 1 shows the demographics of total caregiver respondents of children and youths living with T1D (n=99), though important to note that not all caregivers completed each section. The breakdown of HCP respondents (n=49), the Health Authority in which they practice within the province of BC, and the number of children and youths younger than 18 years with T1D followed by their practice are shown in Table 2.

Caregivers reported that 66% (65/99) of their children used CGM, and 54% (53/99) used an insulin pump. A total of 27% (27/99) reported that their children used health and well-being monitoring apps on their smartphones, while 34% (33/99) of caregivers used similar apps. Many caregivers (76/99, 77%) also stated that if their child was older than 7 years, they shared the decision-making responsibility when managing their diabetes.

Table 1. Participant characteristics of caregivers of children and youths who are <18 years old with type 1 diabetes (total caregiver respondents, N=99).

Characteristic	Participants
Gender (n=94), n (%)	
Female	71 (76)
Male	23 (24)
Area of residence (n=94), n (%)	
Urban	42 (44)
Suburban	40 (43)
Rural	12 (13)
Household income (CAD $[a]; n=85), n (%)	
Less than 45,000	6 (7)
45,000 to less than 75,000	9 (11)
75,000 to less than 100,000	7 (8)
100,000 to 150,000	33 (39)
150,000 to 300,000	21 (24)
Greater than 300,000	9 (11)
Education (n=91), n (%)	
High school graduation or less	5 (6)
Graduated from trade school	3 (3)
Some college or university degree	24 (26)
College or university undergraduate degree	33 (36)
College or university graduate degree	26 (29)

[a]CAD $1=US $0.76.

Table 2. Participant characteristics of health care providers (HCPs).

	Participants (n=49), n (%)
HCPs	
Diabetes nurse educators	18 (37)
Nursing support services[a]	12 (25)
Pediatricians	9 (18)
Dieticians	6 (12)
Pediatric endocrinologists	4 (8)
HCP health authority of practice	
Vancouver Island Health Authority	11 (22)
Provincial Health Services Authority	8 (16)
Northern Health Authority	8 (16)
Fraser Health Authority	8 (16)
Interior Health Authority	8 (16)
Vancouver Coastal Health Authority	6 (12)
Children and youths <18 years old with T1D[b] in their practice	
Less than 25	20 (42)
25-49	7 (14)
50-99	6 (12)
100-149	5 (10)
150-200	3 (6)
More than 200	8 (16)

[a]These health care providers support care of children living with type 1 diabetes in schools.

[b]T1D: type 1 diabetes.

Reported Challenges

Caregivers of Children and Youths Living With T1D

Caregivers identified access to diabetes management technologies, diabetes support in schools, and mental health as the top challenges in caring for a child with T1D (Table 3). Qualitatively, they also identified barriers such as insufficient knowledge about diabetes technologies, access to financial coverage for diabetes technologies, and diabetes self-management skills (eg, insulin dose adjustments). Caregivers also reported that keeping track of all their child's health information (55/99, 56%) and sharing this information among different HCPs (40/99, 40%) was challenging, with 65% (64/99) of caregivers using a combination of paper and digital sources.

Table 3. Challenges reported by caregivers of children and youths living with type 1 diabetes. ("What are the biggest challenges that you currently face related to caring for your child with T1D? Select your top 3.")

Challenge	Participants (n=84), n (%)
Access to diabetes management technologies (ie. insulin pumps and glucose sensors)	45 (54)
Support for your child's diabetes care in school	45 (54)
Access to mental health support (social worker or psychologist)	41 (49)
Accessing your child's medical information (ie, glucose sensor data, pump data, and lab test results)	33 (39)
Connecting with your diabetes team between visits	32 (38)
Access to a pediatric diabetes doctor	17 (20)
Access to a registered dietician with experience in pediatric diabetes	9 (11)
Access to a diabetes nurse educator	5 (6)
Other	25 (30)

Diabetes HCPs

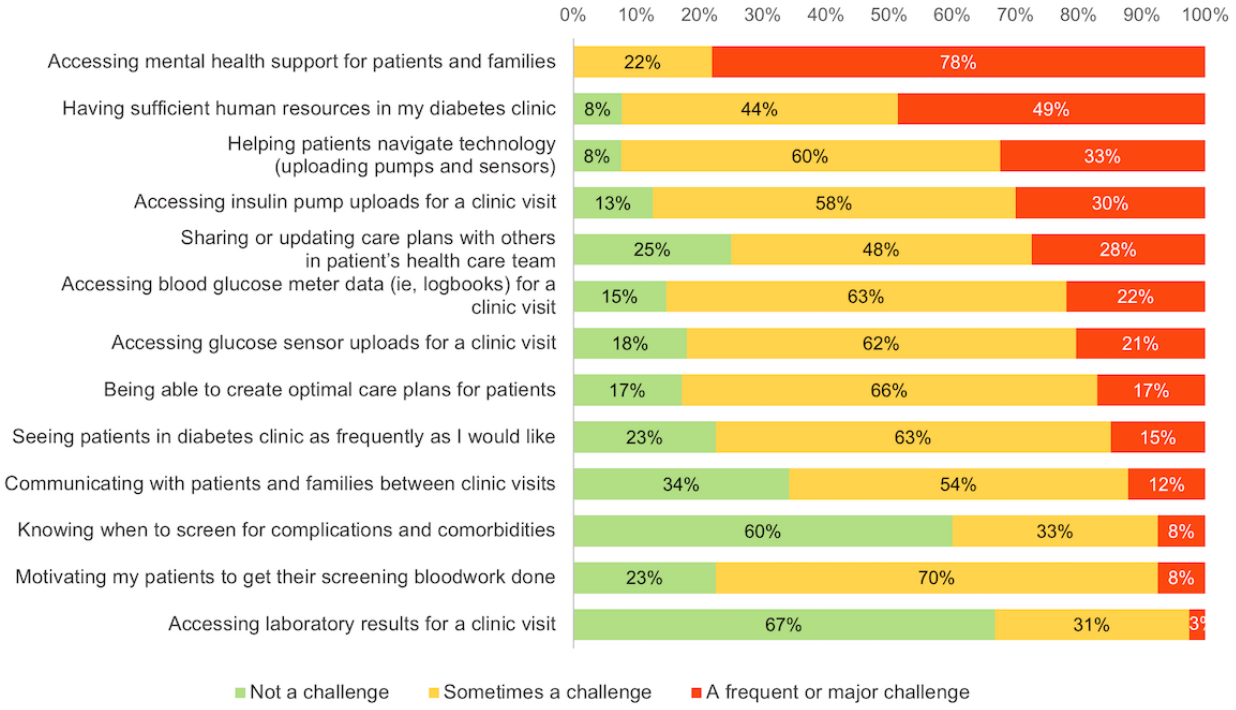
Table 4 outlines HCPs' perspectives on the key challenges faced by patients and their families living with T1D, with the most common being related to access to mental health support (ie, a social worker or psychologist), diabetes management technologies (ie, insulin pumps and CGM), and their child's clinical information. Qualitative data identified other challenges, including patients' inability to implement HCPs' recommendations into their day-to-day lives, financial barriers, and the different approaches to diabetes management at home versus at school.

HCPs reported similar challenges in their clinical care of children living with T1D. Insufficient mental health services (42/42, 100%), patients' inability to use technology to prepare for a clinic visit (ie, uploading pump, and glucometer and CGM data; 37/41, 90%) leading to unavailability of insulin pump (35/41, 85%) and glucose data (35/42, 83%) during a clinical encounter, were identified as "frequent and major" or "sometimes" a challenge (Figure 1). Other challenges that were reported by HCPs qualitatively included a lack of web-based patient support resources (eg, guidance on filling out disability tax credit forms and paperwork for insurance companies), staying up to date on the latest diabetes technologies, having enough time to provide diabetes education during clinic visits, empowering patients to self-manage their diabetes between clinic visits, and lack of peer support programs.

Table 4. From the perspective of health care providers: current key challenges faced by patients with type 1 diabetes and their families. ("What are the current key challenges that your T1D patients and their families report facing? Select top 3.")

Challenge	Participants (n=49), n (%)
Access to a pediatric diabetes doctor	6 (12)
Access to a diabetes nurse educator	5 (10)
Access to a registered dietitian with experience in pediatric diabetes	6 (12)
Access to mental health support (social worker or psychologist)	41 (84)
Access to diabetes management technologies (ie, insulin pumps and glucose sensors)	26 (53)
Support for their child's diabetes care in school	17 (35)
Accessing their child's clinical information (ie, glucose sensor data, pump data, and lab investigations)	19 (39)
Connecting with their diabetes team between visits	17 (35)
Other	5 (10)

Figure 1. Current degree of challenges faced by health care provider in their practice. ("When providing care to children and youths <18 years of age with T1D in your clinic, to what degree do you find each of the following to be a current challenge in your practice? *Select one answer per row*.").

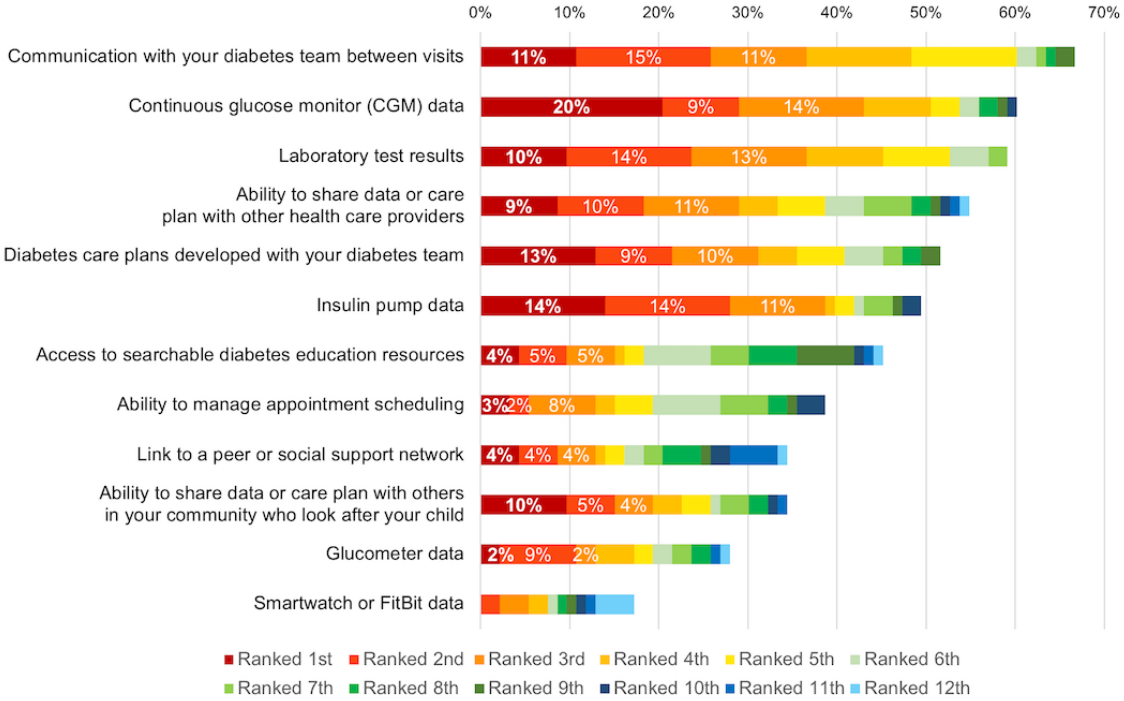


Preferences for Features of a Digital Health Platform for T1D

Caregivers of Children and Youths Living With T1D

Caregivers were asked to rank the most useful features that could be offered by this platform. From the comprehensive list of potential features, 43% (40/93) ranked accessing CGM data in the top 3 priorities (20% [19/93] ranked highest, 9% [8/93] ranked second, and 14% [13/93] ranked third). This was followed by insulin pump data (39% [36/93] ranked in the top 3), communication with the diabetes team between visits (37% [34/93] ranked in the top 3), and laboratory test results (37% [34/93] ranked in the top 3) as useful features. Other features frequently ranked as highly useful included accessing diabetes care plans developed with the diabetes team and the ability to share diabetes care plans with other HCPs (Figure 2).

Figure 2. Priority ranking of information that caregivers of children and youths living with type 1 diabetes want to include in this digital platform (n=93). ("If this platform was customized for children and youths with type 1 diabetes and their parents/caregivers, what integrated data or features would be most useful for you? *Rank in priority*.").



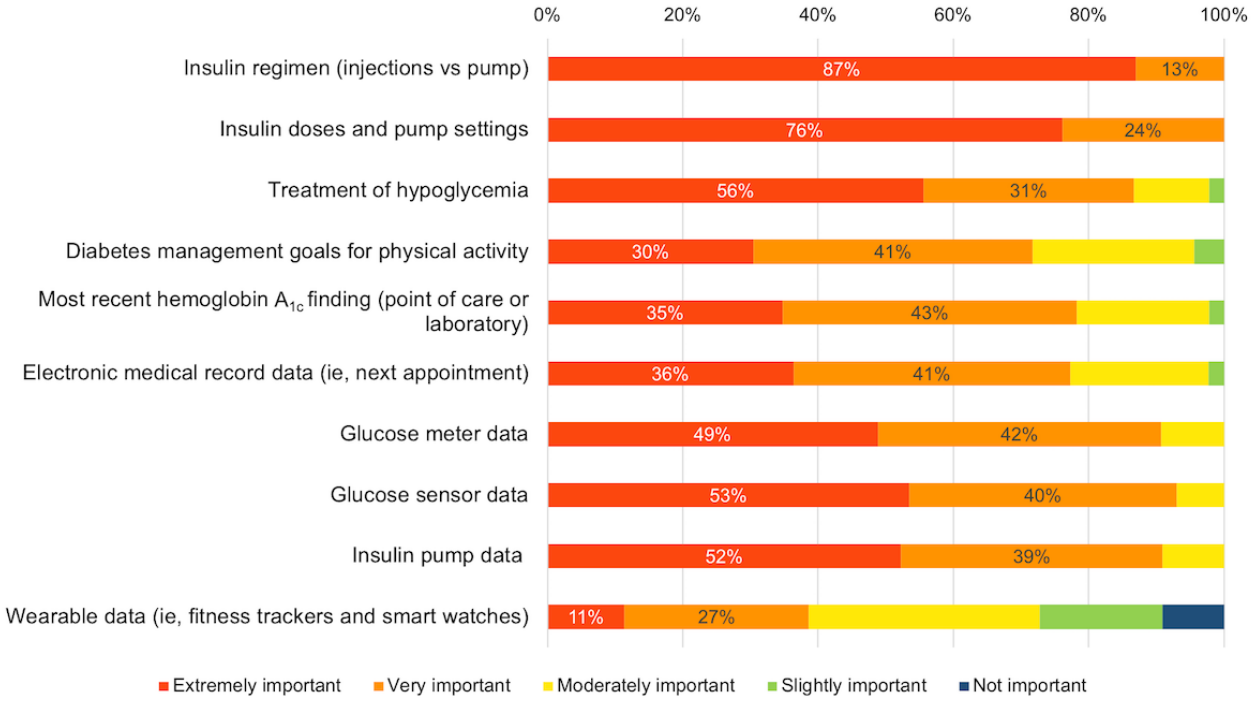
Diabetes HCPs

HCPs reported that in a digital single-point-of-access platform, it would be extremely important to include information about patient demographics (43/46, 94%), other medical diagnoses (41/46, 90%), non–diabetes-related medications (33/46, 72%), duration of diabetes (31/46, 68%), and age at diabetes diagnosis (29/46, 63%). HCPs also outlined the importance of including information on a patient's insulin regimen, insulin doses, and glucometer and CGM data (Figure 3).

Further, HCPs stated it would be extremely important to include information on the results of diabetes complications screening laboratory tests (38/43, 88%), automated notifications for HCPs to complete complications screening based on Diabetes Canada Clinical Practice guidelines (33/44, 75%) [18], and patient anthropometric measurements such as blood pressure, height, and weight (31/43, 72%). Another essential feature for HCPs was integrating this digital platform with electronic medical records (EMRs).

When asked about securely communicating with patients and families through the platform, HCPs stated it would be very important to have a direct messaging feature (30/45, 67%), a platform email address (38/45, 84%), a link for videoconferencing (38/45, 84%), as well as the capability to manage clinic appointments (26/45, 58%).

Figure 3. Importance of information that health care providers want to include in this digital platform. ("How important is it to include/integrate the following features/data in an integrated patient platform for T1D? *Select one answer per row*.").



Perceptions About the Digital Platform and Likelihood of Use

Caregivers of Children and Youths Living With T1D

Caregivers reported that they would be likely to use the platform (65/98, 66%) and stated that the platform would be helpful for their child (83/98, 85%), themselves (97/99, 98%), as well as their HCPs (99/99, 100%) and researchers (99/99, 100%). Caregivers were very willing to share their child's data with their diabetes health care team (97/97, 100%) and other HCPs (96/97, 99%). Still, they would be willing to only share some of their data with members outside the diabetes team, such as other family members (52/97, 54%), school health nurses (66/97, 68%), teachers (65/97, 67%) and after-school program staff (57/97, 59%).

Diabetes HCPs

HCPs stated that the integrated patient platform would be very helpful (38/44, 86%) and greatly simplify their care for children and youths living with T1D (21/45, 47%). A total of 75% (34/45) of HCPs were likely to use this platform. However, some (10/45, 22%) were undecided due to concerns such as integration with their current EMR, the need for additional documentation and duplication in charting, and that patient participation and engagement were necessary. HCPs also raised concerns related to inequitable access based on socioeconomic status and education, as well as challenges for non–English-speaking families or those who experience barriers in accessing technology or the internet.

Discussion

Overview

In this study, we found that caregivers of children and youths living with T1D and pediatric diabetes HCPs reported similar challenges in managing T1D as well as desirable features for a digital platform to address these challenges, such as access to data from diabetes devices, laboratory results, mental health support, and resources and tools to support diabetes self-management (including school support). For caregivers, the ability to communicate more easily and frequently with their diabetes care team, particularly between clinic visits, and share their diabetes care plans with others in their circle of care were also emphasized as critical features. Most HCPs and caregivers stated they were likely to use the described platform and that an integrative platform would be helpful for collaborative patient care. The results of our study confirm that a digital platform for collaborative use by both caregivers and HCPs (with some user-specific features) has the potential to address key pain points and ultimately improve the care experience.

Most diabetes health apps only seem to be designed for patients [3] and integrating preferences in the design of the diabetes digital apps from both patients and HCPs is limited [3,9-11,14,19]. To successfully implement digital solutions in health care, it is essential to involve end users in the design and development as early as possible. Our study is novel in addressing the needs of caregivers of children and youths living with T1D and pediatric HCPs, which includes physicians, dieticians, and diabetes nurses, at the conceptual stage in the user-centered design of the *TrustSphere Consortium's* digital platform, which will increase its likelihood of meeting end users' needs. Unique to our study, we found that caregivers would also want to share their child's diabetes care plan not

just with HCPs, but also with others caring for their children. Further, HCPs stated that they would also like to see diabetes complications screening laboratory tests as a feature on this digital platform, which has not been reported before.

Adult patients also desire mental health apps geared toward social support and well-being to be a part of diabetes digital apps [9,19]. In this study, insufficient access to mental health support was identified as one of the key challenges by caregivers and patients cared for by HCPs. Caregivers stated it'd be helpful to have links to peer group and social support networks as a feature on the digital platform (data not shown); however, this was not identified as one of the top 3 key features desired. While addressing unmet mental health needs is clearly a priority in this population, this remains a challenging service to provide safely and effectively through a mobile app. Attempting to meet this widespread need through a virtual provision of support would be outside the scope of the platform being designed as part of this study; however, the data on the current unmet need for mental health support will inform future strategic planning around partner services, resources, information, and peer support apps and links that may be integrated into the platform in future iterations.

Patients' demographic characteristics play a role in the uptake of diabetes digital health apps. A recent systematic review revealed that younger, female adult patients, those with a higher level of education and higher monthly incomes are more likely to adopt digital health apps [14,19]. Similarly in our study, 76% (71/94) of the caregivers were female, 65% (59/91) had a college or university degree, and 74% (63/85) had an annual income bracket greater than CAD $100,000 (US $ 76,645.50; Table 1).

Apps that offer multiple features, including documentation, reminders, educational resources, consolidation of diabetes data from different diabetes devices, and nutritional support are more likely to foster long term patient engagement and use [14]. Our study results have uncovered key features as noted in Figures 2 and 3 that will guide the design of the integration of various diabetes data devices within our digital platform. Further, our team has adopted an existing digital health platform, Careteam Technologies, a *TrustSphere Consortium* industry partner, that will support health care coordination and collaboration among patients, their families, and HCPs. This will be done through a dashboard that will contain diabetes care plans (eg, recommendations of insulin doses), real-time data from connected devices, educational resources, and assigned tasks (eg, completion of blood work) to enhance personalization of pediatric diabetes care. Future developments of our app can look into integration with Learn Diabetes [20], a web-based educational platform developed at BCCH for children living with T1D. It has been shown that the successful implementation of innovative medical technologies depends on acceptance by all health care team members; therefore, it is essential to identify and address barriers to adopting a new digital platform in the clinical workflow as early as possible [21]. A study investigating barriers to uptake digital health technology in cardiovascular care identified poor internet connection and difficult-to-use technology as reported by patients and increased workload and perceived app usefulness as reported by HCPs [22]. Facilitators to improve the uptake of digital health technology included improved communication with clinicians, personalized components among patients and improved efficiency and organizational support among HCPs [22]. HCPs in our study identified key barriers that have been considered in the design and development of TrustSphere's digital platform. For example, the platform must be synergistic with, not duplicative of, EMRs. Further, the onboarding process and workflow must support engagement from all HCPs, as well as caregivers, for the platform to succeed.

Strengths and Limitations

Our study involved pediatric HCPs and caregivers of children and youths living with T1D as early as possible in the design and development of a digital integrative platform to optimize its potential to address key pain points, ensure ongoing usability, acceptance and adoption by HCPs and patients, and ultimately improve patient experience and outcomes.

User-centered design and digital app use are prone to selection bias since participants are often Caucasian, female, more educated, tech-savvy, and identify English as their primary language [19,23]. In addition, currently many diabetes management apps are unavailable in languages other than English [4]. This study is limited because caregivers of children and youths living with T1D were only recruited from a tertiary-level pediatric diabetes clinic at BCCH, which provides care to about 40%-50% of children and families living with diabetes in the province of BC. Also, the participants were mostly female and had a higher education and household annual income. We did not collect participant data on race or ethnicity, hence, making it difficult to generalize our findings to more diverse populations. A total of 25% of American adults with household incomes less than CAD $30,000 (US $22,791.85) do not own a smartphone. Of those who do, 27% are smartphone-only internet users, indicating they rely solely on their phone's cellular data services [24]. The surveys were sent electronically to HCPs and caregivers in this study, so only those with access to a smartphone or the internet could easily participate. It is important to consider critical issues of equity and access so that new technology closes, rather than widens, the current divide in diabetes technology use across socioeconomic and educational levels [25].

The surveys in this study were distributed at 1 point in time to both caregivers and HCPs, to gather their perspectives on the current challenges and key features desired for this digital platform. As part of the user-centered design approach, following the quantitative data gathered through these needs assessment surveys, focus groups and web-based bulletin boards were conducted to collect qualitative data. This will inform the first stage of cocreating a digital platform for children living with T1D. The resulting prototype will be iteratively presented to caregivers of children and youths living with T1D and pediatric diabetes HCPs across BC in multiple rounds of usability testing (data forthcoming) with the integration of feedback and findings into a minimal viable product that will subsequently be tested in a clinical pilot study.

Future strategies to minimize the divide in the uptake of digital technology include automating and standardizing the collection of race, ethnicity, and primary language data, and obtaining

input from ethnic minorities and those with limited English proficiency or poor digital literacy early in the usability testing process. Also, improving literacy can involve distributing educational materials in languages other than English, so patients and their families can better understand and interpret the information provided by digital apps [26]. It is challenging to develop policies that allow for equitable access to all forms of technology, such as smartphones or improving cellular data coverage or home internet access in rural areas; however, this can be argued if it relates to digital health technology. The UK National Health Service has extended the coverage of real-time CGM to all children living with T1D, including those from lower socioeconomic groups or ethnic minorities [27]. Similarly, BC PharmaCare, which covers medical devices and prescriptions, has expanded the approval of Dexcom G6 real-time CGM to all patients on intensive insulin therapy who are older than 2 years [28]. Policies such as these will be critical in minimizing and eliminating the digital divide and the associated disparities in health outcomes, and potentially expand the use and usefulness of an integrative T1D digital platform such as the one described here to more diverse populations.

Conclusions

This study demonstrates the importance of implementing user-centered design as early as possible in developing new digital solutions to ensure optimal use, acceptance, and adoption by HCPs and patients alike. It is novel in identifying the needs of both caregivers of children and youths living with T1D and pediatric HCPs to inform the design of an integrative T1D platform. This study will also inform future digital innovation in the T1D space with an ongoing opportunity to use participatory, user-centered design to achieve higher-quality integrated digital health apps.

Authors' Contributions

FSA led the manuscript preparation. SP designed data collection methods, performed data analysis, and assisted with manuscript preparation. TvR conceived of the platform concept. MG contributed to the data collection methods and assisted in manuscript preparation. SA conceived of the platform concept, designed the study and data collection methods, and assisted with manuscript preparation. Research reported in this publication was supported by the Canadian Digital Technology Supercluster [29], the University of British Columbia’s Office of the Vice-President, Research and Innovation, and Mitacs.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey Items used for Caregivers of Children & Youths Living with T1D.
[DOCX File , 16 KB - pediatrics_v6i1e46432_app1.docx]

Multimedia Appendix 2
Survey Items used for Pediatric Diabetes Healthcare Professionals.
[DOCX File , 24 KB - pediatrics_v6i1e46432_app2.docx]

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Abbreviations

BC: British Columbia
BCCH: BC Children's Hospital
CGM: continuous glucose monitor
EMR: electronic medical record
HCP: health care provider
T1D: type 1 diabetes

Edited by S Badawy; submitted 16.02.23; peer-reviewed by AHY Lee, F Wang; comments to author 13.04.23; revised version received 18.05.23; accepted 12.06.23; published 13.07.23.

Please cite as:
Abdulhussein FS, Pinkney S, Görges M, van Rooij T, Amed S
Designing a Collaborative Patient-Centered Digital Health Platform for Pediatric Diabetes Care in British Columbia: Formative Needs Assessment by Caregivers of Children and Youths Living With Type 1 Diabetes and Health Care Providers
JMIR Pediatr Parent 2023;6:e46432
URL: https://pediatrics.jmir.org/2023/1/e46432
doi:10.2196/46432
PMID:37440296

Review

Physical Activity Surveillance in Children and Adolescents Using Smartphone Technology: Systematic Review

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Abstract

Background: Self-reported physical activity (PA) questionnaires have traditionally been used for PA surveillance in children and adolescents, especially in free-living conditions. Objective measures are more accurate at measuring PA, but high cost often creates a barrier for their use in low- and middle-income settings. The advent of smartphone technology has greatly influenced mobile health and has offered new opportunities in health research, including PA surveillance.

Objective: This review aimed to systematically explore the use of smartphone technology for PA surveillance in children and adolescents, specifically focusing on the use of smartphone apps.

Methods: A literature search was conducted using 5 databases (PubMed, Scopus, CINAHL, MEDLINE, and Web of Science) and Google Scholar to identify articles relevant to the topic that were published from 2008 to 2023. Articles were included if they included children and adolescents within the age range of 5 to 18 years; used smartphone technology as PA surveillance; had PA behavioral outcomes such as energy expenditure, step count, and PA levels; were written in English; and were published between 2008 and 2023.

Results: We identified and analyzed 8 studies (5 cross-sectional studies and 3 cohort studies). All participants were aged 12-18 years, and all studies were conducted in high-income countries only. Participants were recruited from schools, primary care facilities, and voluntarily. Five studies used mobile apps specifically and purposely developed for the study, whereas 3 studies used mobile apps downloadable from the Apple App Store and Android Play Store. PA surveillance using these apps was conducted from 24 hours to 4 weeks.

Conclusions: Evidence of PA surveillance using smartphone technology in children and adolescents was insufficient, which demonstrated the knowledge gap. Additional research is needed to further study the feasibility and validity of smartphone apps for PA surveillance among children and adolescents, especially in low- and middle-income countries.

(JMIR Pediatr Parent 2023;6:e42461) doi:10.2196/42461

KEYWORDS

physical activity; surveillance; children; adolescents; smartphone technology; smartphone apps; smartphone; technology; application; database; mobile phone

Introduction

Background

Research suggests that the period of childhood and adolescence are critical in a person's development and growth [1]. Engagement in adequate physical activity (PA) results in various health benefits for children, such as lowering the risk of childhood obesity and improving cognitive functioning [2]. Evidence has shown that children who meet PA recommendations have a healthier cardiovascular profile and are likely to become active adults as part of the behavioral

carryover effects [3]. According to the World Health Organization, children and adolescents (aged 5-17 years) are recommended to do on average at least 60 minutes of moderate to vigorous PA (MVPA) per day to achieve the associated health benefits [4]. However, the latest World Health Organization report in 2019 found that approximately 80% of school-going adolescents (85% of girls and 78% of boys) aged between 11 and 17 years did not meet this recommendation [5].

Engagement in regular MVPA is associated with numerous health benefits [6,7], including positive cognitive development in children and adolescents [8,9]. Research has also shown that greater benefit may come from vigorous activity intensities, in which aerobic-based activities have the greatest health benefit in school-aged children and youth [6]. Given this, it is of paramount importance that PA in children is accurately measured and assessed to identify current PA levels, monitor compliance with PA recommendations, and assess the effectiveness of intervention programs designed to promote PA in children and adolescents [10,11]. Traditionally, PA in this age group is measured using self-report methods such as questionnaires, diaries, and activity logs as well as objective measurements such as heart rate monitoring, direct observation, doubly labeled water, pedometers, and accelerometers [10,11].

However, in recent years, there has been an increasing demand in the use of digital communication technologies in daily life [12-14]. The modernization of health services, delivery, and systems has encouraged the development of digital health, which is now considered a cornerstone in participatory or personalized health [15]. The advent of smartphones and wearable devices has greatly influenced mobile health (mHealth), offering new opportunities in health research, including PA research. These technologies offer real-time and continuous biological, behavioral, and environmental data that enable researchers to understand the etiology of health and disease as well as provide new approaches for the measurement of PA in children and adolescents [16-18]. With the evolution of technology, smartphone apps and wearable activity trackers are currently among the range of mHealth technologies used to measure PA in children and adolescents.

To date, several existing reviews have addressed the use of mHealth in PA research in adult and adolescent populations [19-26]. There are 3 reviews involving adolescents and postsecondary students to date: a study by Lee et al [21], which discussed the efficacy and efficiency of mHealth apps in PA promotion with adolescents; a study by Böhm et al [26], which focused on evaluating the effects of mHealth to increase PA outcomes among children and adolescents; and a study by Ly [23], which aimed to examine the relationships between mobile phones and PA behaviors in postsecondary or university students, with a focus on text messaging interventions. Mönninghoff et al [19] and Laranjo et al [25] aimed to understand the effects of mHealth apps such as smartphone apps and activity trackers interventions to increase PA in adults. Meanwhile, other reviews addressed the use of mHealth technology, specifically smartphone apps, to promote PA and reduce weight in adults [20] and understand the trajectory of smartphone-based interventions for PA promotion in adults and adolescents for the past 10 years [24]. Although informative and useful for addressing the promotion of PA using mHealth technologies, these reviews did not explore the use of smartphone apps for the surveillance of PA in children and adolescents.

Studies have also shown that objective measurements such as smartphone technologies have the potential to improve PA measurement [27] and potentially reduce the costs of PA surveillance when compared with traditional methods [28,29]. Face-to-face measurements are standard practice; however, in certain conditions, these methods may not be ideal. For example, the COVID-19 pandemic has affected the whole world and changed the way research has been conducted. Smartphone technology offers a different approach for PA measurements, where it allows individual users to install, configure, and run the apps of their choice [30]. These smartphone apps with built-in sensors that can monitor the duration, frequency, and intensity of PA are ideal alternatives for PA measurements and surveillance research [31]. Given this, it would be beneficial to assess whether the advancements in smartphone apps are usable and practical for PA surveillance in children and adolescents.

Objectives

This systematic review aimed to explore the use of smartphone technology for PA surveillance among children and adolescents. This review focuses on smartphone apps for PA surveillance and whether they are built into smartphones, downloadable from app stores, or study-specific developed apps.

Methods

This systematic review was conducted following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement [32]. The quality of each study included in this review was assessed using the Strengthening of the Reporting of Observational Studies in Epidemiology (STROBE) checklist.

Identifying the Research Question

On the basis of the current research gap, three research questions were identified to guide this systematic review:

1. How has smartphone technology been used in the PA surveillance of children and adolescents?
2. How accurate are smartphone technology surveillance methods when compared with objective measures of PA?
3. What are potential research gaps within the existing literature requiring further research?

Identifying Relevant Studies

A systematic literature search was performed on all articles published between January 7, 2008, and December 22, 2022. This date restriction was applied because the Apple App Store was introduced in July 2008 by Apple Inc and Google Play Store was launched into the market in 2012, after the rebranding of the Android Market [33]. Five databases were accessed (PubMed, Scopus, CINAHL, MEDLINE, and Web of Science) to find peer-reviewed publications, and Google Scholar was used to find gray literature and additional studies related to the topic. These databases were selected after consultation with a university librarian, who also provided advice on developing

the search terms (Multimedia Appendix 1). The search terms used were "smartphone*" OR "smartphone app*" OR "mobile phone" OR "mobile app*" OR "smartphone technolog*" OR "mobile technolog*" AND "physical activity" OR "physical activity level" OR "step count*" OR "energy expenditure*" OR exercise AND child* OR adoles* AND measurement* OR assessment* OR surveillance. All the search terms were derived after consultation with the university librarian and discussion among authors. The search terms were applied to both abstracts and full texts during the searching process.

Study Selection

To be included in this systematic review, all articles must (1) include children and adolescents within the age range of 5 to 18 years; (2) use smartphone technology as PA surveillance; (3) have specific PA behavioral outcomes including energy expenditure, steps count, and PA levels; (4) be written in English; and (5) be published between 2008 and 2023. The exclusion criteria were as follows: (1) participants out of age range; (2) not written in English; and (3) producing behavioral outcomes other than energy expenditure, steps, and PA levels (eg, sedentary behavior and sleep behavior).

Data Extraction

All studies identified from the search were imported into the Endnote 20 referencing software. Endnote library was used for its invaluable reputation in managing records and keeping track of articles [34]. All records imported into Endnote included the following: title, authors, publication year, journal name, publisher, abstract, keywords, and the date on which it was searched. At this stage, all duplicates were removed using the software. All remaining records were then reviewed for applicability to scope based on the title and abstract and by referring to both the inclusion and exclusion criteria. Then, a full text of each remaining article was obtained and read to examine if it fully met the inclusion criteria and was therefore deemed fit for the data extraction process. In agreement with all authors, data extracted from the studies included study design, country, population, sample size, study duration, app name, app purpose, primary outcome, benefits of using the app, and limitations of using the app.

Critical Appraisal of Evidence

In this systematic review, each study was assessed using the STROBE checklist for observational studies, which include cohort, case-control, and cross-sectional studies. This checklist was introduced to help produce a clear presentation of what was planned and performed in these types of studies. It consists of a checklist of 22 items, including the title, abstract, introduction, methods, results, and discussion section of the assessed study. In reference to Jain and Yuan's review [35], the 22-items in the STROBE checklist were broken down into 47 distinct indicators for each marked study. A grading system was used based on the percentage of STROBE checklist criteria reported by each study: <55% was categorized as −, 55% to 65% was categorized as +, and ≥65% was categorized as ++. NINN reviewed the quality of all studies, with MEGA and JM reviewing 50% each. All authors met to discuss any discrepancies, and agreement was reached regarding the critical appraisal of each study.

Results

Study Selection

The selection process of all articles is shown in Figure S1 in Multimedia Appendix 2, documented in a Preferred Reporting Item for Systematic Reviews and Meta-Analyses study flow diagram. The database search yielded 584 unique and potentially relevant articles, including 15 articles from searching on Google Scholar, resulting in a total of 599 articles. After removing duplicates, 540 articles remained for title and abstract screening using the inclusion and exclusion criteria. At this stage, 482 articles were excluded for not meeting the inclusion criteria (268/482, 55.6%), not using smartphone technology for PA measurements (89/482, 18.5%), and not having relevant outcomes (125/482, 25.9%). This resulted in 10.7% (58/540) of articles that remained for full-text screening. Eight articles were included in this systematic review after the full-text screening (Multimedia Appendix 2). Initially, titles and abstracts were screened by the first author (NINN), with the other 2 authors (MEGA and JM) independently reviewing 50% each. Cohen κ was completed between NINN, MEGA, and JM, which showed an 89.3% agreement level (Cohen κ=0.89). The final selection of studies was performed after checking against the inclusion and exclusion criteria. This process involved thorough discussion among the authors until an agreement was reached.

Study Characteristics

The included studies had a large sample size (6-492 participants), with a total sample of 881 children and adolescents, aged 9 to 18 years, as shown in Table 1. Of these, 5 studies involved healthy children and adolescents and the other 3 focused more on those who were overweight, obese, or had been diagnosed with type 1 diabetes mellitus. The studies were conducted in Germany (N=3) [36-38], Spain (N=1) [39], Australia (N=1) [40], the United States (N=1) [41], Sweden (N=1) [42], and Singapore (N=1) [43]. Most studies used a cross-sectional design (N=5) [40-43] or cohort design (N=3) [36-38]. The most common recruitment sites were primary care facilities [36-38] and schools [39-42], followed by 1 study involving volunteered children and adolescents [43]. As for the duration of the studies, there was a large range in the period of PA measurement, from 24 hours to 4 weeks.

Table 1. Characteristics of the studies (N=8).

Study	Country	Population	Sample size, n	Study duration	Quality of study[a]
Cross-sectional					
Viciana et al [39], 2022	Spain	Children and adolescents (aged 12-18 years)	56	5 days	++
Dahlgren et al [42], 2021	Sweden	Children and adolescents (age: mean 12.1, SD 1.5 years)	121	7 days	++
Seah and Koh [43], 2020	Singapore	Adolescent girls (aged 15 years)	36	4 weeks	++
Hartwig et al [40], 2019	Australia	Eighth-grade students (age: mean 13.5, SD 0.5 years)	492	35-50 minutes	++
Dunton et al [41], 2014	United States	High school students (aged 15-18 years)	6	24 hours	+
Cohort					
Schiel et al [36], 2012	Germany	Overweight and obese adolescents (age: mean 13.5, SD 2.8 years)	124	1-4 days	++
Schiel et al [37], 2011	Germany	Children and adolescents with type 1 diabetes mellitus (age: mean 14.5, SD 2.2 years)	16	1-3 days	++
Schiel et al [38], 2010	Germany	Overweight and obese adolescents (mean age 14.3 years)	30	1-4 days	++

[a]Percentage of Strengthening of the Reporting of Observational Studies in Epidemiology checklist criteria reported: +: 55%-65% and ++: >65%.

Quality of Included Studies

In this systematic review, 5 studies were cross-sectional studies and 3 were cohort studies. All 8 studies were retrospective and critically appraised using the STROBE checklist. The percentage of indicators met by each study is shown in Figure S1 in Multimedia Appendix 3), and the overall quality is presented in Table 1. The STROBE checklist used in the critical appraisal process revealed that most of the included studies were of good quality. Items that were well reported across all studies included the following: title and abstract, background or rationale, quantitative variables, key results, limitations, and interpretation. However, there was less consistency across the studies in reporting aspects related to bias (3/8, 38%), study size (2/8, 25%), sensitivity analyses (2/8, 25%), reasons for nonparticipation at each stage (1/8, 13%), use of a flow diagram (1/8, 12%), number of participants with missing data (3/8, 38%), boundaries when continuous variables are categorized (1/8, 13%), other analyses done (eg, subgroups and sensitivity) (3/8, 38%), and generalizability (3/8, 38%).

Smartphone Technology for PA Measurements

As stated previously, studies that were included used the app in smartphones or mobile phones as a surveillance tool for PA in children and adolescents. They either used a built-in and downloadable smartphone app from the Android Play Store and Apple App Store or used a study-specific developed smartphone app. In addition to using smartphone technology, several studies have added self-report questionnaires for PA recall [36,38,41,43] and accelerometers or pedometers [40,41,43], which in turn allowed comparisons between the methods.

Table 1 shows that the shortest period of PA measurement was 24 hours, which was conducted as a cross-sectional study [41]. Meanwhile, all 3 studies by Schiel et al [36-38] took 1-4 days for PA measurement in overweight and obese adolescents. The cross-sectional study by Viciana et al [39] was conducted for 1-5 days in adolescents aged 12-18 years. Another cross-sectional study conducted by Dahlgren et al [42] took approximately 7 days to measure PA in children and adolescents. Seah and Koh [43] measured the PA of high school adolescent girls for 4 weeks. The other 2 studies, instead of stating the overall time, focused more on the time spent for each measurement session. There were 3 groups involved in the study by Hartwig et al [40]: training sample, validation sample, and convergent validity. Each group had different periods of measurement: 68.7 (SD 22.2) minutes for the training sample, 67.6 (SD 21.6) minutes for the validation sample, and 47.0 (SD 0.7) minutes for the convergent validity group.

Study-Specific Developed Apps

Five studies used a self-developed smartphone app designed specifically for the study [36-38,40,41], as shown in Table 2. Schiel et al [36-38] in all 3 studies used a self-developed technology comprising a mobile motion sensor (MoSeBo), which is a PA sensor, integrated into a mobile phone with a digital camera (DiaTrace), both developed by Fraunhofer Institut für Graphische Datenverarbeitung, Rostock, Germany. This app could analyze the type, intensity, and duration of PA. Each of the studies involved different participants but still focused on overweight and obese adolescents. Meanwhile, Dunton et al [41] used the Mobile Teen app, a self-developed smartphone technology that combines both objective and self-reported PA assessment through sensor-informed context-sensitive ecological momentary assessment and sensor-assisted end-of-day recall. Another study that used a specifically developed app was from Hartwig et al [40], in which the SmartLAB move+ app was used to measure feedback on the PA level achieved during physical education lessons.

Table 2. Summary of findings (study-specific developed apps).

Study	App name	App purpose	Primary outcome	Pros and cons
Hartwig et al [40], 2019	Custom-designed mobile app, wirelessly connected to a pedometer (SmartLAB move+)	Measure feedback on PA[a] levels achieved during PE[b] lessons	PA levels	• Pros: feedback available immediately and increased PA during PE lesson Cons: translation of step counts to percent MVPA[c]. Available only for the particular study and not readily available for download from app stores
Dunton et al [41], 2014	Mobile Teen (installed on LG Nexus 4 smartphone)	The Mobile Teen app has 2 major components: sensor-informed CS-EMA[d] and end-of-day sensor-assisted recall	EMA[e] question sequence designed to measure major activity types, smartphone placement on the body, reasons for smartphone nonwear, and other psychological and contextual factors related to behavior	• Pros: records phone location and useful in providing bouts of a specific type of behavior • Cons: compatible with Android phones only and EMA prompts >1 in an hour. Available only for the particular study and can only be used in Android phones
Schiel et al [36], 2012	MoSeBo and DiaTrace system (motion sensor board with a digital camera)	Analyze type, intensity, and duration of PA	Type, intensity, and duration of PA	• Pros: accurate measurement of PA (time, intensity, and duration) compared with a self-report questionnaire • Cons: available only for the particular study and not readily available for download from app stores
Schiel et al [37], 2011	MoSeBo and Diatrace system (motion sensor board with a digital camera)	Analyze type, intensity, and duration of PA	Type, intensity, and duration of PA	• Pros: visualization of PA and real-time display • Cons: available only for the particular study and not readily available for download from app stores
Schiel et al [38], 2010	MoSeBo and Diatrace system (motion sensor board with a digital camera)	Analyze type, intensity, and duration of PA	Type, intensity, and duration of PA	• Pros: more accurate measurement compared with questionnaire and improves both intrinsic and extrinsic motivation • Cons: unable to measure water-based activities. Available only for the particular study and not readily available for download from app stores

[a]PA: physical activity.

[b]PE: physical education.

[c]MVPA: moderate to vigorous physical activity.

[d]CS-EMA: context-sensitive ecological momentary assessment.

[e]EMA: ecological momentary assessment.

Readily Downloadable Apps

Three studies used readily downloadable apps from Apple App Store and Android Play Store. In the study by Viciana et al [39], 4 apps were used including Pedometer and Pacer Step Counter, which can be downloaded from the app store, whereas Google Fit and Apple Health were 2 built-in apps in the Android and iOs systems. Meanwhile, the SCRIIN app was used in the study by Dahlgren et al [42] to measure PA in children and adolescents, alongside the SCRIIN activity tracker. In the study by Seah and Koh [43], several apps were used, including MapMyFitness, Health (Apple), Samsung Health, Pacer Step Counter, Pedometer, and Weight Loss Coach. All these apps were used to track PA behaviors and step counts.

The Primary Outcome of Each App

All smartphone and mobile phone apps from the studies included in this review had the same primary outcome, that is, measuring PA. As shown in Tables 2 and 3, although all apps are used to measure PA, each app has a different focus and function. The apps that were built purposely for the study have specific functions to answer questions specific to the study. In the study by Hartwig et al [40], the primary outcome of the SmartLAB move+ app was the PA level. The MoSeBo and Diatrace system in the studies by Schiel et al [36-38] also produced results on PA intensity, in addition to PA type and duration. In contrast to other studies, the study by Dunton et al [41] used a sensor-informed context-sensitive ecological momentary assessment–measured type of PA only, but this app also produced results regarding smartphone placement on the body, reasons for smartphone nonwear, and other psychological and contextual factors related to behavior.

Table 3. Summary of findings (readily downloadable apps).

Study	App name	App purpose	Primary outcome	Pros and cons
Dahlgren et al [42], 2021	SCRIIN activity tracker	Measure PA[a]	Active minutes and steps count	• Pros: SCRIIN activity tracker can be purchased; SCRIIN app can be downloaded via Apple App Store and Google Play Store • Cons: missing and incompleteness of data from SCRIIN app owing to children's and adolescents' need to have access to a smartphone
Viciana et al [39], 2022	Pedometer, Pacer Step Counter, Google Fit, Apple Health	Measure PA aspects and step count	Step counts and PA in free-living conditions	• Pros: all apps are built-in and can be downloaded from App Store. Some of the apps have been used in previous studies • Cons: apps are all not empirically validated
Seah and Koh [43], 2020	MapMyFitness (for PA), Apple Health, Samsung Health, Pacer Step Counter, Pedometer, Weight Loss Coach (for step count)	Track PA aspects and step count	Duration, distance, pace, speed, elevation, calories burned, and route traveled	• Pros: quick feedback and easy for self-monitoring • Cons: apps are all not empirically validated

[a]PA: physical activity.

Most existing and downloadable apps have specific functions that produce specific PA outputs such as energy expenditure, step counts, and PA level. The SCRIIN app used in the study by Dahlgren et al [42] can produce results on active minutes and step count. In the study by Seah and Koh [43], several apps were used to measure PA (MapMyFitness) and step count (Health, Samsung Health, Pacer Step Counter, Pedometer, and Weight Loss Coach) differently, but the outcomes from all the apps were PA duration, distance, pace, speed, elevation, calories burned, and route traveled. Apps used in the study by Seah and Koh [43] were similar to those used in the study by Viciana et al [39], in which Pedometer and Pacer Step Counter were used to measure step counts and Google Fit and Apple Health were used to track both energy expenditure and step counts.

Pros and Cons of Each App

When considering the usefulness of different methods to measure PA in children and adolescents, it is important to highlight the common pros and cons reported across the included studies. The first advantage of smartphone apps is the additional features available when measuring PA. For example, the SmartLAB move+ app [40] and all apps used in the studies by Seah and Koh [43] and Viciana et al [39] provided immediate feedback to participants during PA measurement. This allowed research participants to have personal health monitoring, in which they could easily access their PA data at any time. In comparison with research-grade accelerometers, raw data produced by accelerometers will have to be translated before being transformed into PA summaries (eg, calories and step counts) [44]. Furthermore, the Mobile Teen app offers a feature that records mobile phone location, which is useful for determining where PA took place [41].

A second advantage is the accessibility of the apps used in studies, where using the apps is a low-cost option and the apps are easily downloadable from Apple App Store and Google Play Store. For example, the SCRIIN app that was used in the study by Dahlgren et al [42] and all apps used in the study by Seah and Koh [43] are readily available and can be downloaded via Apple App Store and Android Play Store. In addition, these 2 studies revealed that users are more interested in fun, easy-to-use, and functional apps that offer visual appeal, as highlighted in a previous study by Schoeppe et al [45]. Considering that the target participants are children and adolescents, fun and user-friendly apps will assist in the PA monitoring of this specific age group [46].

The third advantage is the usability of all apps, which means that the apps used are easily downloadable into users' smartphones, easy to use, and enable young users such as children and adolescents to self-monitor their PA measurements. However, it is worth mentioning that the advantages of all apps discussed are heavily dependent on the studies included in this review. In terms of usability of the apps among research participants, the study by Seah and Koh [43] revealed that participants preferred to have more control over the PA data while using the apps, including setting their own goals and social connectivity. A similar response was reported in the study by Viciana et al [39], in which the usability of the apps allowed participants to monitor and control the apps on their own and enabled them to view previous activities. For researchers, data generated through apps that can be easily obtained instantly was noted as a strength [47].

In all the studies by Schiel et al [36-38], the MoSeBo and Diatrace system demonstrated a better visualization of PA and real-time display, and the system has been shown to provide more accurate measurements (time, intensity, and duration) than the self-report questionnaire. Meanwhile, the Mobile Teen app is useful in providing bouts of PA performed by the participants [41], a feature similar to accelerometers, providing greater detail regarding the times spent in different PA intensities. Furthermore, the SCRIIN app used in the study by Dahlgren et al [42] showed a high correlation (r=0.72; P<.001) between the SCRIIN activity tracker and app with the ActiGraph accelerometer in the validation they conducted. This showed that the app is a valid measure for PA monitoring in children and adolescents, when compared with accelerometry.

Nevertheless, all apps also have disadvantages, especially in the accessibility of apps, validity, and practicality in measuring PA. Regarding the apps' accessibility, some apps were specifically developed for the studies and were not downloadable via Apple App Store and Google Play Store [36-38,40,41]. In addition, some apps have not been properly validated for measuring PA in children and adolescents. In the studies by Seah and Koh [43] and Viciana et al [39], although all the apps used were free and convenient for measuring PA in participants, they were not empirically validated. It was also mentioned in Seah and Koh's study [43] that caution should be taken when reading and interpreting the results.

In addition, the SmartLAB move+ app used in the study by Hartwig et al [40] requires researchers to translate step counts to percent MVPA using an equation that is unlikely to be generalizable to populations other than those tested in this study. This factor affects the usability of this app to researchers, where researchers will have to do the *extra work* rather than obtaining the readily available PA data directly from the app. Meanwhile, the MoSeBo and Diatrace system used in all the studies by Schiel et al [36-38] is unable to measure water-based activities. In terms of the practicality of the apps, a con of the Mobile Teen app is its compatibility with Android phones only, which will limit its use [41].

Finally, it was mentioned that real-time feedback is a strength of these apps but could also create a potential Hawthorne effect (leading to unexpected changes in behavior) because participants know their behavior is being measured [48]. In this case, being able to see PA levels may cause a person to be more active because they know that PA is being assessed [49]. This leads to a recommendation to assess the validity of these apps against known criterion measures of PA, for instance, smartphone apps versus research-grade accelerometry.

Discussion

Smartphone Technology in PA Surveillance

This systematic review identified and examined 8 articles on the use of smartphone technology in PA surveillance of children and adolescents globally. This review specifically focuses on smartphone or mobile phone apps that can be used for PA surveillance among children and adolescents. The low number of studies included in this review indicates limited research on using smartphone apps for PA surveillance in children and adolescents. Nonetheless, there are existing studies on adults who have used smartphone apps for PA surveillance [50-54]. As smartphones are considered a *must-have* item nowadays and are often carried throughout the day, this allows them to be a method to measure and monitor PA in real time [55]. Currently, new apps are being developed that allow users to track and monitor their PA using their smartphones, increasing the possibility of obtaining richer objective PA profiles, which will complement the traditional or subjective methods of PA measurement [56]. Some included studies used specifically designed apps for measuring PA among children and adolescents, which may be because of the limited number of commercially available smartphone apps for PA surveillance at the time.

As mentioned earlier, smartphone and mobile phone apps were first introduced between 2008 and 2012. However, as subjective assessments are more widely used [49,57,58], the number of studies using apps for PA surveillance in children and adolescents remains limited [41,56,59]. As seen from the results of this review, most of the current studies (after 2019) used readily downloadable smartphone apps to measure PA in children and adolescents. The advancement of smartphone technology over the years has influenced the development of PA monitoring apps in smartphones, thus allowing researchers to use these apps in their validation studies of PA measurement in children and adolescents [56,60,61].

Another important finding is that all studies in this review were conducted in high-income countries, including Australia, the United States, Greece, Sweden, and Singapore [62]. This highlights the progressive development of the mobile phone and smartphone industry in high-income countries, which allows the use of smartphone technology for PA surveillance among children and adolescents [63]. The recent evolution of smartphones has resulted in the emergence of numerous apps with novel ways to promote healthier lifestyles, including measuring and monitoring PA [52]. However, this point also crucially shows the lack of PA research using smartphone technology in low- and middle-income countries (LMICs).

In 2017, a group of researchers from Stanford University conducted a study using smartphone data to track PA among adults globally, specifically using the free Azumio Argus smartphone app [64]. This study revealed that from the 46 countries involved with at least 1000 users, 90% of the users were from 32 high-income countries and only 10% of the users were from 14 middle-income countries [64]. However, there were none from low-income countries. This showed that people in high-income countries are more exposed to smartphone apps that can be used to track their PA. Another important finding from this study is that countries with high PA inequality (ie, the gap between highly active people and less active people) also have high obesity rates. The PA levels used to determine PA inequality were calculated from the PA data collected using the smartphone app [64].

In their systematic review, Bort-Roig et al [56] also revealed that all studies that used smartphone technology to track PA in adults were conducted in highly economically advantaged countries, where most of the studies were conducted in the United States, Germany, and Finland. Measurements of PA in this review included smartphone apps with built-in accelerometers and pedometers, and some studies used wearable activity trackers to pair with the apps. This finding strengthens the point that PA research using smartphone technology to track PA in children and adolescents is widely conducted in high-income countries; however, it is still lacking in LMICs, particularly.

Smartphone Technology Versus Other PA Objective Measures

As stated in a review by Tudor-Locke and Myers [65], there are various methods of PA measurement that are often categorized into subjective and objective measures. For children and adolescents, objective measures of PA include direct

observation, direct and indirect calorimetry, doubly labeled water, heart rate monitoring, and the use of motion sensors such as pedometers and accelerometers. Pedometers and research-grade accelerometers have been widely used to measure step counts and PA in children and adolescents [16,66-68]. Some researchers have used pedometers for PA surveillance in children and adolescents, as they are low cost, more feasible, and have been shown to be reliable and valid in school children and adolescents [69-71].

However, pedometers may underestimate vigorous-intensity activities, which in contrast can be more accurately measured by accelerometers [72,73]. Objectivity and low subject reactivity are pros of accelerometers, characteristics that overcome some of the challenges with subjective measures [73]. Moreover, accelerometers have been shown to provide valid measures of PA in school children [73]. Nevertheless, it is important to note that research-grade accelerometers are expensive and may not be affordable for everyone.

In this particular review, smartphone apps used to measure PA and step counts have the same principle of objective measurement as pedometers and research-grade accelerometers; however, they are downloadable onto smartphones. This important feature allows users to have a personal health monitoring device, which provides better compliance data and continuous evaluation of free-living activities [55]. It is also important to note that smartphones have multiple built-in sensors and capabilities that include large memory storage, fast processors, and microelectromechanical systems, facilitating a better opportunity for PA measurement [55].

In addition, for research that uses smartphone apps and technology, potential participants will already own this *research device* and are more likely to carry it wherever they go and keep it charged, which will be a different situation to devices handed out in research studies [55]. The advantages of smartphone apps and technology include their availability (free or low cost, provided the research participant owns a smartphone), accessibility (downloadable), quick feedback, low cost, and ease of monitoring, which influenced the 3 studies included in this review to use them for PA measurement of children and adolescents [40-43].

Potential Research Gap

This systematic review has highlighted 2 important points for future studies. First, it was demonstrated throughout this review that smartphone apps and technology are a potential alternative for the objective measurement of PA among children and adolescents. As mentioned in the *Discussion* section, objective measures would benefit younger people and allow a more feasible assessment that can include numerous dimensions and domains of PA. Second, this review identified conflicting evidence on the validity and reliability of smartphone apps in measuring PA in children and adolescents. This shows a lack of evidence owing to the dearth of individual primary studies that assess the psychometric properties of smartphone apps.

Apart from having more validation studies involving smartphone apps and technology in PA surveillance in this age group, it is equally important to include subjective measures. This is because the use of combined measures may offer a better comparison between the 2 and provide a better understanding of the characteristics of PA in children. On the basis of a review by Troiano et al [74], it was revealed that accelerometer-based devices (where smartphone apps may fall in this category) are more accurate in measuring self-reported PA variables such as frequency and duration in comparison with using a series of questions in questionnaires. However, it is unfitting to conclude that PA measures using accelerometer-based devices are better than using questionnaires. Each approach has complementary strengths, but it is important to note that behavioral reports and device-based measures are not interchangeable [74].

Apart from these points, no studies have assessed the usability of smartphone apps for PA surveillance among children and adolescents in LMICs. All studies included in this review were conducted in high-income countries, raising the question of whether socioeconomic status influences the use of smartphone apps and technology in PA measurement. Understanding the use of smartphones among children and adolescents in LMICs could further highlight the potential of using smartphone apps as PA surveillance tools in this setting.

Despite its numerous advantages, it is undeniable that smartphone apps and technology also has some limitations. One of the notable limitations of smartphone apps and technology is the proprietary algorithms used in the apps, commonly known as nonfree or closed-source algorithms, which restrict users' freedom to obtain data collected through the apps [75]. This type of algorithm may require researchers to have proper permission or licensing from app developers and manufacturers to obtain collected data [75,76].

Strengths and Limitations

A systematic approach was used to identify articles on PA surveillance using smartphone technology for children and adolescents. It was conducted using several databases that were relevant to the research topic, which further strengthened this review. Another advantage of this review was the use of independent screening conducted by 3 researchers. However, the searching process only included articles written in English, which may limit the potential of exploring established studies on PA surveillance in children and adolescents that were not published in English. This factor may also have affected the lack of studies from LMICs included in this review owing to the use of languages other than English. In addition, the focused research questions resulted in a small number of articles being included in this review. Another important limitation to note is the fact that smartphone apps are continuously evolving and being created, meaning findings from this review, although useful, might not apply to the most recent apps.

Conclusions

The overall results from this review demonstrate conflicting and insufficient evidence regarding the validity and reliability of smartphone technology PA surveillance in children and adolescents. This review also suggests that additional research is needed to further assess the usability and usefulness of smartphone technology for PA surveillance in children and adolescents. This is especially important for LMICs.

Acknowledgments

The authors would like to thank Majlis Amanah Rakyat Malaysia for providing a PhD scholarship for conducting this study.

Authors' Contributions

MEGA and NINN conceived and designed the study. NINN, MEGA, and JM conducted the study, including articles' screening, extraction, charting, and analysis. NINN drafted the manuscript, with help from MEGA and JM. MEGA and JM reviewed the manuscript and provided critical feedback. All authors reviewed, read, and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Detailed search strategy applied to all databases.
[DOCX File , 21 KB - pediatrics_v6i1e42461_app1.docx]

Multimedia Appendix 2
Summary of the selection of the articles presented in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.
[DOCX File , 81 KB - pediatrics_v6i1e42461_app2.docx]

Multimedia Appendix 3
Critical appraisal of the included studies.
[DOCX File , 216 KB - pediatrics_v6i1e42461_app3.docx]

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Abbreviations

LMIC: low- and middle-income country
mHealth: mobile health
MVPA: moderate to vigorous physical activity
PA: physical activity
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

STROBE: Strengthening of the Reporting of Observational Studies in Epidemiology

Edited by S Badawy; submitted 05.09.22; peer-reviewed by F Fraysse, W Barletta, A A Cecchetti, J Granhagen Jungner, Y Jeem, W Perveen; comments to author 25.12.22; revised version received 30.01.23; accepted 23.02.23; published 29.03.23.

Please cite as:
Nasruddin NIN, Murphy J, Armstrong MEG
Physical Activity Surveillance in Children and Adolescents Using Smartphone Technology: Systematic Review
JMIR Pediatr Parent 2023;6:e42461
URL: https://pediatrics.jmir.org/2023/1/e42461
doi:10.2196/42461
PMID:36989033

Original Paper

The Usefulness of Web-Based Communication Data for Social Network Health Interventions: Agent-Based Modeling Study

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Abstract

Background: Social network interventions are an effective approach to promote physical activity. These interventions are traditionally designed using self-reported peer nomination network data to represent social connections. However, there is unexplored potential in communication data exchanged through web-based messaging apps or social platforms, given the availability of these data, the developments in artificial intelligence to analyze these data, and the shift of personal communication to the web sphere. The implications of using web-based versus offline social networks on the effectiveness of social network interventions remain largely unexplored.

Objective: This study aims to investigate the differences in the impact of social network interventions on physical activity levels (PALs) between networks derived from web-based communication and peer nomination data.

Methods: We used the data on sociometric questionnaires, messages from a web-based communication app, and PAL (number of steps per day) of 408 participants in 21 school classes. We applied social network analysis to identify influential peers and agent-based modeling to simulate the diffusion of PAL and explore the impact of social network interventions on PAL among adolescents in school classes. Influential peers (n=63) were selected based on centrality measures (ie, in-degree, closeness, and betweenness) to spread the intervention. They received health education, which increased their PAL by 17%. In sensitivity analyses, we tested the impact of a 5%, 10%, and 20% increase in PAL among influential peers.

Results: There was a 24%-27% overlap in selected influential peers between the 2 network representations. In general, the simulations showed that interventions could increase PAL by 5.0%-5.8% within 2 months. However, the predicted median impact on PAL was slightly higher in networks based on web-based communication data than peer nomination data for in-degree (5.7%, IQR 5.5%-6.1% vs 5.5%, IQR 5.2%-5.8%; P=.002), betweenness (5.6%, IQR 5.4%-5.9% vs 5.0%, IQR 4.7%-5.3%; P<.001), and closeness centrality (5.8%, IQR 5.6%-6.1% vs 5.3%, IQR 5.0%-5.6%; P<.001). A large variation in impact was observed between school classes (range 1.5%-17.5%). Lowering the effectiveness of health education from 17% to 5% would reduce the overall impact of the social network intervention by 3-fold in both networks.

Conclusions: Our findings showed that network interventions based on web-based communication data could increase PAL. Web-based communication data may therefore be a valuable addition to peer nomination data for future social network intervention design. Artificial intelligence methods, including agent-based modeling, can help to design these network interventions and provide insights into the role of network characteristics in their effectiveness.

(JMIR Pediatr Parent 2023;6:e44849) doi:10.2196/44849

KEYWORDS

agent-based modeling; peer nomination network data; physical activity; social network analysis; social network interventions; web-based communication network data

Introduction

Social networks can influence health behaviors significantly, as people and their health behaviors are known to be connected [1-3]. Youth are particularly susceptible to influences from role models in their social networks (eg, family and peers), who can encourage or discourage health behaviors. For example, studies have shown that peers and peer groups shape consumption behavior and physical activity among youth [4-7]. Developments in social network theory have provided opportunities to exploit social networks as a tool to promote positive behaviors, such as physical activity [8]. Network interventions are rooted in the diffusion of innovation theory [9], which presumes that ideas and behaviors spread through a social network. A common approach in designing social network interventions is to identify influential peers (ie, role models) based on network properties, such as centrality measures [8]. The selected individuals can then be educated and trained to promote healthy behaviors among their peers [9].

The selection of influential peers is traditionally based on social network representations derived from self-reported peer nomination data [10]. Participants are asked to name and rank peers based on questions such as "who are your close friends?" [4]. Although such networks can provide a relatively realistic representation of real-life relationships, they have some known limitations. First, self-reporting of peers could result in underreporting of relationships with undesired peers (social desirability bias) or overestimating relationships with whom they interacted recently (recall bias) [11,12]. Second, survey questions may be interpreted differently and therefore result in an incomplete or nonrepresentative network. Third, nonresponse is a serious concern, as questions to derive a nominated network can be considered tedious [13]. Nonresponse can result in gaps in the network that may affect the understanding of the network, and, as a result, the intervention design (eg, misinterpreting centrality measures). Finally, as nominated networks only focus on the most important relationships, weak ties may be overlooked. Weak ties can play an important role in diffusing information or behaviors in a network [14,15].

Communication data from web-based social platforms or other forms of web-based media communication could provide a useful addition for measuring social relationships [16-18]. Connections and interactions on web-based social platforms can be used to create a representation of web-based social networks. A connection on web-based social platforms is only meaningful when interactions between peers have taken place [18]. The number of interactions between peers can more accurately measure the quality of a relationship and opportunities to exchange information and can therefore be a good proxy for assigning the strength of ties (ie, weighted ties) in a social network. Artificial intelligence (AI) methods, such as natural language processing (NLP) techniques, could be used to filter meaningful conversations and calculate weights. Web-based social networks have also become an attractive target for promoting healthy behaviors [19,20]. Web-based relationships can provide supportive interactions to encourage healthy behaviors and can increase an individual's physical activity through social comparison [19,21,22].

Studies have shown that web-based and offline social networks capture (to a large extent) different connections between adolescents [23,24]. This may suggest that web-based and peer nominated social networks measure different types of relationships, which would likely affect the design of social network interventions (ie, selection of influential peers). As a result, the effectiveness of these interventions in promoting healthy behaviors may be different as well. There is little knowledge about the consequences of social network interventions design and effectiveness when based on web-based communication data as compared to peer nomination data.

Therefore, this study aims to investigate the differences in impact of social network interventions between networks derived from web-based communication and peer nomination data. We examined the effectiveness of social network interventions to promote physical activity, where interventions are designed based on web-based communication data, and compared it to peer nomination data. We apply social network analysis (SNA) to a longitudinal data set collected among school classes in the Netherlands [25]. This data set contains information about participants' physical activity levels (PALs), the socioeconomic status of their family, peer-nominated social contacts, and web-based text messages exchanged between classmates. To assess the effectiveness of social network interventions, we apply agent-based modeling, a powerful tool combined with AI to address complex problems, as an alternative to real-world trials. An agent-based model (ABM) can conduct experiments in simulated environments to assess the causal effect of interventions on health behaviors [26]. ABMs are increasingly being used to compare the impact of various social network intervention strategies (ie, selection of influential peers) [27-30], and to investigate the potential (long-term) impact of network interventions on health behaviors, such as physical activity behavior [31,32]. In this study, we present an ABM to simulate the diffusion of physical activity among youth in social networks and use it to compare the effect of social network interventions on PALs in networks derived from web-based communication and peer nomination data.

Methods

Participants

We used the data from the MyMovez research project investigating youth's social networks and health behaviors [25]. The participants were children and adolescents, between 8 and 15 years of age, from 21 Dutch primary and secondary schools. They received a smartphone with a research app to fill out questionnaires, including sociometric questionnaires about the relationships with and impressions of other classmates. The app also included a web-based social platform for communication between peers. Furthermore, participants received a wrist-worn accelerometer to measure PALs.

The data were collected during a 3-year period in 7 data waves: February 2016 (W1), April 2016 (W2), June 2016 (W3), February 2017 (W4), February 2018 (W5), April 2018 (W6), and June 2018 (W7). Each data wave lasted for 7 days. The web-based social platform was introduced in W4 of the project, but this wave had a high attrition rate and participants leaving

schools. In W5, new classrooms were added, and the web-based social platform was used by 617 out of 736 (84%) participants. Therefore, we used W5 to infer social networks from both web-based communication and peer nomination data and to measure PAL and family affluence scores. W1 was only used to assign the initial PAL of the participants in the model.

We included participants who both filled out the sociometric questionnaires and used the web-based social platform in W5 (614 participants in 44 classes). Only participants from classes with more than 60% participation and at least 15 participants were included to ensure a representative sample within each class [33]. In total, our sample included 408 adolescents in 21 school classes (19 primary and 2 secondary). The mean age was 10.6 (SD 1.0) years, and 220 (54%) participants were female (Multimedia Appendix 1).

Measures

Social Networks

Web-Based Communication Data

Web-based social networks in school classes were created using communication data from the web-based social platform in the research app in W5. Participants could post messages on the message board of the classroom or send private messages to classmates on the web-based social platform. To create a network of personal relationships, we only used private (one-to-one) messages between participants within a class (c). Every message m sent by a participant i_c (ego) to a classmate who received the message j_c (alter) was considered a connection, resulting in a directed network. The weight of a connection between 2 peers was based on the total number of messages agent i_c (ego) receives from peer j_c (alter) and on the maximum number of peer-to-peer messages in a class max (m_c). The total weight of a connection in the communication network between an agent i_c (ego) and j_c (alter) in class c is given by:

Peer Nomination Data

Social networks in school classes were created based on peer nomination data derived from sociometric questions. In W5, 4 general sociometric questions were asked, including (1) who they hang out or have contact with [5]; (2) who they go to for advice; (3) who they consider as leaders; and (4) who they want to be like [34]. Participants received these 4 questions $N(q)$ through the research smartphone at a random time during the day. For each question (q), participants were required to nominate at least one peer, with no maximum on the nominated peers, and self-nominations were not possible. We only considered nominations from within a class (c). Question 1 was used to generate a directed network with edges from the participant i_c (ego) to a nominated peer j_c (alter), because it mostly resembles web-based exchanged messages between peers. The weight of a connection, which reflects the amount of influence that an ego has on an alter, was based on all 4 nomination questions. The weight of a connection in the nominated network between agents i_c (ego) and j_c (alter) is derived as follows:

PAL Measure

PALs were measured using the accelerometer (Fitbit Flex), which participants wore for 7 consecutive days in each wave. We excluded days 1 and 7 because the data on these days were not full days of measurement by default. Also, days with less than 24 hours of data collection and days with less than 1000 steps were excluded because these were incomplete data (eg, nonwear time). The PAL was calculated as the mean of steps per day for at least three days of valid data in a wave. For participants with less than 3 days of valid data, the number of steps per day was imputed using single multilevel (predictive mean matching) imputation. Missing data were imputed based on other physical activity data of the same participant, day of the week, measurement period, sex, and age [35]. The number of steps per day of an individual was divided by 10,000. The mean PAL was 0.92 (minimum 0.12 and maximum 1.87) in W5 (Multimedia Appendix 1).

Family Affluence Scale

The Family Affluence Scale (FAS) is a self-reported measure of the socioeconomic status of participants' families [36,37]. This measure was included in our ABM to account for the impact of socioeconomic circumstances on PALs. Participants were asked the following four questions: (1) does your family own a car, van, or truck? (2) Do you have your own bedroom for yourself? (3) During the past 12 months, how many times did you go on a holiday with your family? (4) how many computers does your family own? The scores of all possible answers were summed, with higher scores representing a better socioeconomic position (range 0-12). The mean score was 9.1 (minimum 2 and maximum 12; Multimedia Appendix 1).

Procedure

SNA Procedure

SNA was performed on both social networks to investigate network structures and select influential peers based on centrality measures. SNA was conducted using the package *NetworkX* 2.8 in Python 3 (Python Software Foundation).

Both social networks were compared based on number of connections, average connection weight, network density, and a similarity score. Network density indicates the level of cohesion in a network and is measured as the ratio between the number of connections in a network and the number of all possible connections. To measure the similarity between social networks derived from web-based communication and peer nomination data, we used the Jaccard similarity index. It divides the number of connections in a class shared between both social networks by the total number of connections (shared and unshared). The Jaccard similarity index will be 0 if none of the affiliating node pairs co-occurs in both social networks and 1 if both networks are identical in connections.

Selection of Influential Peers

Social network interventions engage influential peers to disseminate behavior change. Influential peers are typically selected based on centrality measures (ie, network position), because it is assumed that being central in a network makes an individual more influential [8]. There are various ways to measure centrality. In this study, social network interventions were based on 3 common centrality measures for selecting influential individuals: in-degree, betweenness, and closeness centrality [38].

In-degree centrality refers to the number of connections directed toward an individual. This measure is related to the number of peer nominations or web-based messages an individual receives. Individuals with higher in-degree centrality can be seen as important holders of information and are perceived as the most popular in school settings [38].

Betweenness centrality is a measure of centrality based on how often an individual is part of the shortest paths between all nodes in a network. It is often used to find individuals that link different subgroups together, so-called “bridge” individuals. This means that an individual with high betweenness centrality controls the flow of information between other peers in the network. If the betweenness central agents are not selected as influential peers, entire subgroups might be restrained from the intervention [38].

Closeness centrality provides a measure of how close an individual is to all other peers in a network. Individuals with the highest closeness centrality values have, on average, the shortest path to all other peers in a network. This means that the intervention will reach the entire network in the lowest number of steps.

In this study, the top 15% (63/408) of individuals with the highest centrality score were selected as influential peers in each class. The number of influential peers selected per class ranged between 2 and 4 (depending on the class size) in both network representations. In case multiple individuals had a similar centrality score, these individuals were ranked on highest PAL. If there was still a tie, the influential peer was randomly selected.

Agent-Based Modeling

Model Description

An ABM was developed to describe the diffusion dynamics of physical activity through a social network. Our model was built upon previously published ABMs by van Woudenberg et al [30] and de Mello Araujo et al [39], which were based on the model framework by Beheshti et al [29] and Giabbanelli et al [40]. The model was programmed in Python. Model source code and scripts are available on GitHub [41].

In the model, each agent is characterized by a PAL and socioeconomic environment score (ie, the FAS score). An agent’s PAL may change over time as a result of two key factors: (1) the influence through the social network and (2) influence of socioeconomic environment. At each time step (ie, day), an agent determines whether to change his or her PAL. To change PAL, the impact of social influence and the socioeconomic environment should exceed a threshold (T_{PAL}), which is the minimum amount of influence an agent needs to receive to change behavior. If the condition is true, the agent increases or decreases his or her PAL by a factor I_{PAL} (Multimedia Appendix 2 for full description).

Model Calibration

A grid search was used to calibrate two model parameters (T_{PAL} and I_{PAL}). The model was calibrated using the modeled social network based on web-based communication and peer nomination data separately. Both models were run until predictions had reached a steady state. Initial PALs of each agent were randomly sampled from the distribution of PALs by sex in W1 (Multimedia Appendix 3). The simulated PALs in the steady state were compared to the empirical data per class in year 1 (W2-W3), year 2 (W4), and year 3 (W5-W7). The goodness-of-fit was measured by the sum of squared errors. The objective function was to minimize the sum of squared errors. We selected 100 best-fitting model parameter combinations for both social network representations separately. In this study, all simulations were run using these parameter combinations (ie, 100 runs) to account for uncertainty in the parameter estimates. Multimedia Appendix 2 provides a full description of the calibration procedure.

Simulation of Social Network Interventions

The calibrated model was used to simulate the impact of hypothetical social network interventions on PAL in social networks based on web-based communication and peer nomination data separately. The social network intervention featured health education among the top 15% (63/408) most influential peers, which would motivate them to increase their PAL (eg, through intensive personal counseling). In the model, we assumed that the health education intervention would increase the PAL of influential peers by 17%. This artificial increase was based on previous modeling studies [29,30]. In addition, we assessed the impact of an increase of 5%, 10%, and 20%. We tested three strategies to select influential peers for the social network intervention: (1) in-degree, (2) betweenness, and (3) closeness centrality measure (see Selection of Influential Peers section).

We simulated the social network intervention strategies for an additional 200 days from the calibrated model outcomes. Each social network intervention strategy was simulated 100 times (ie, for each calibrated parameter combination). For each run, we calculated the average PAL over all agents in the model. We presented the median from the 100 simulation runs. The variation in impact between runs (ie, uncertainty interval) was presented in a box plot. The primary outcome measure is the relative impact of each network intervention on the mean PAL per class per day. The relative impact represents the difference in PAL at the start (day 0) and the end (day 200) and was expressed as a percentage of change.

Ethical Considerations

Informed consent was obtained from 1 of the parents of the participants in the MyMovez project. Study procedures were approved by the Ethics Committee of the Radboud University (ECSW2014–100614-222).

Results

SNA Procedure

Table 1 and Multimedia Appendix 3 present the overall characteristics of web-based communication and peer nomination network data per school class. In the web-based communication network data, a total of 25,739 messages were exchanged among all participants. The number of messages exchanged ranged from 143 to 5301 between classes. Multimedia Appendix 4 provides information about the distribution of the exchanged messages. The number of connections per individual varied significantly among classes (mean 8, SD 6). In the peer nomination network data, there were a total of 3063 peer nominations among the 21 classes (mean 146, SD 59). There were on average 8 (SD 5; in and outgoing) connections per individual, with a variation among the classes ranging from 4 to 12 connections per individual on average.

Table 1. Characteristics of web-based communication and peer nomination data.

Characteristic	Value
Participants, n	408
Web-based communication data	
Web-based messages, n	25,739[a]
Number of connections per participant, mean (SD)	8 (6)
Average connection weight, mean (SD)	0.10 (0.12)
Network density, mean (SD)	0.38 (0.18)[b]
Peer nomination data	
Peer nominations, n	3063[c]
Number of connections per participant, mean (SD)	8 (5)
Average connection weight, mean (SD)	0.43 (0.14)
Network density, mean (SD)	0.40 (0.09)[b]
Network similarity, mean (SD)	0.69 (0.09)

[a]The mean number of web-based messages per school class is 1225 (SD 1309).

[b]No significant difference between web-based and peer nominated social networks (P=.47; Mann-Whitney U test).

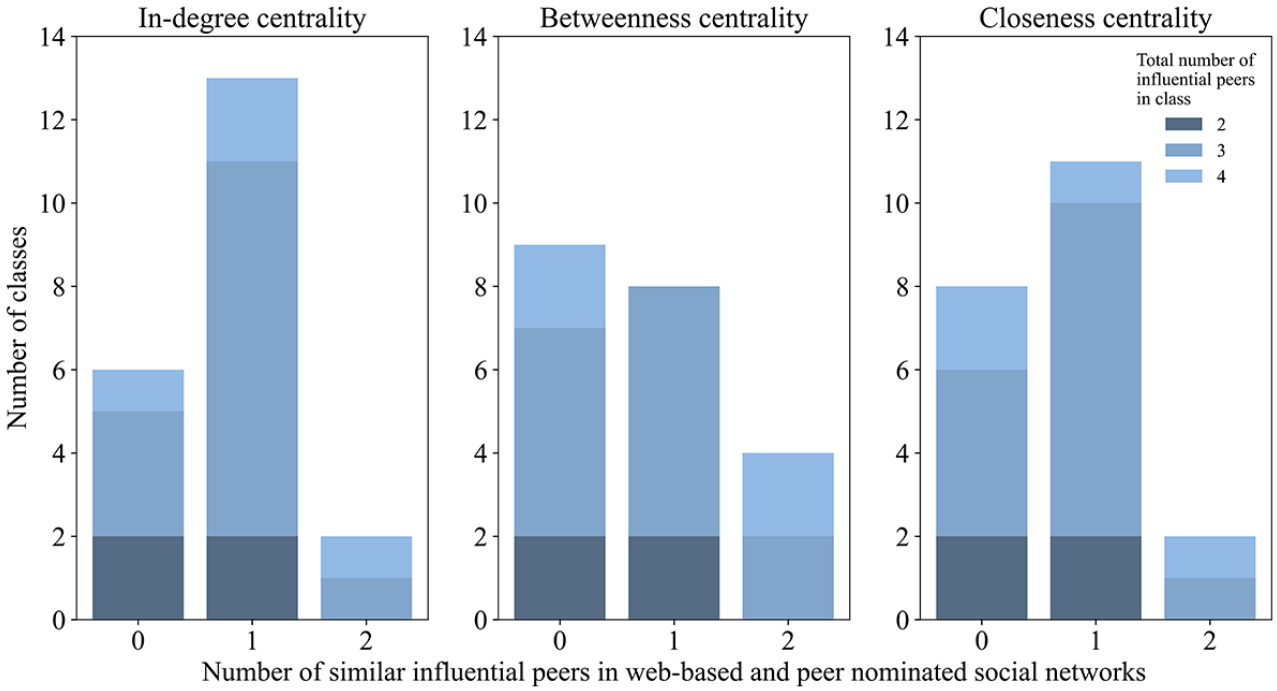
[c]The mean number of peer nominations per school class is 146 (SD 59).

The overall average network density was similar in web-based social networks (0.38) and peer nominated social networks (0.40). The average connection weight was 0.10 (SD 0.12) in web-based social networks compared to 0.43 (SD 0.14) in peer nominated social networks. The overall similarity between networks based on web-based communication compared to peer nomination data was 0.69 (ie, 5253/7700 connections appeared in both networks). Overall, networks based on peer nomination data had significantly higher closeness (0.56 vs 0.54) centrality than networks based on web-based communication data (Multimedia Appendix 5). The overall in-degree (0.40 vs 0.39) and betweenness (0.03 vs 0.04) centrality was similar in both network representations. Participant-level SNA is available in Multimedia Appendix 6, providing comparative insights from an ego-level perspective.

Selection of Influential Peers

The majority of the selected influential peers were different in networks based on web-based communication and peer nomination data. On average, 17/63 (27%; in-degree), 16/63 (25%; betweenness), and 15/63 (24%; closeness) of the selected influential peers were the same in both networks. In more than 6 classes, the selected influential peers were completely different (Figure 1). In web-based social networks, in-degree and closeness centrality had an 86% (54/63), in-degree and betweenness had 63% (40/63), and betweenness and closeness had 67% (42/63; Multimedia Appendix 7) overlap in influential peers. In peer nominated social networks, this was 81% (51/63; in-degree vs closeness), 44% (28/63; in-degree vs betweenness), and 43% (27/63; betweenness vs closeness).

Figure 1. Frequency distribution of the number of similar influential peers in web-based and peer nominated social networks per class.



Agent-Based Modeling

Figure 2 shows the predicted PAL from the model (100 simulation runs and its mean) using web-based and peer nominated social networks with the observed data from all waves. The mean predictions of PAL (blue line) were within the CIs of the empirical data for all data points, indicating a good fit. The 100 simulation runs (light gray lines) indicate the variation due to parameter uncertainty, which were in the same order for both network types.

Figure 3 illustrates the predicted effect of network intervention strategies on the mean change in PAL among all participants in both social networks. All 3 strategies for network interventions increased the average PAL in both data network types. The median impact on PAL was higher in networks based on web-based communication than peer nomination data for in-degree (5.7%, IQR 5.5%-6.1% vs 5.5%, IQR 5.2%-5.8%; P=.002; Mann-Whitney U test), betweenness (5.6%, IQR 5.4%-5.9% vs 5.0%, IQR 4.7%-5.3%; P<.001), and closeness centrality (5.8%, IQR 5.6%-6.1% vs 5.3%, IQR 5.0%-5.6%; P<.001). In social networks based on web-based communication data, the increase in PALs corresponds with an average increase of 581, 569, and 594 steps per day when influential peers were selected based on in-degree, betweenness, and closeness centrality, respectively. In peer nominated social networks, the increase in PALs corresponds with an average increase of 561, 512, and 537 steps per day for in-degree, betweenness, and closeness centrality, respectively. The increase in PALs varied by selection strategy, with closeness showing the largest impact, followed by in-degree and betweenness using web-based social networks (Figures 3A and 3C). For peer nominated social networks, in-degree centrality showed the largest impact, followed by closeness and betweenness (Figures 3B and 3D). Multimedia Appendix 8 provides more information about the variation in impact between school classes.

Figure 2. Results of calibrating the model to the observed physical activity level.

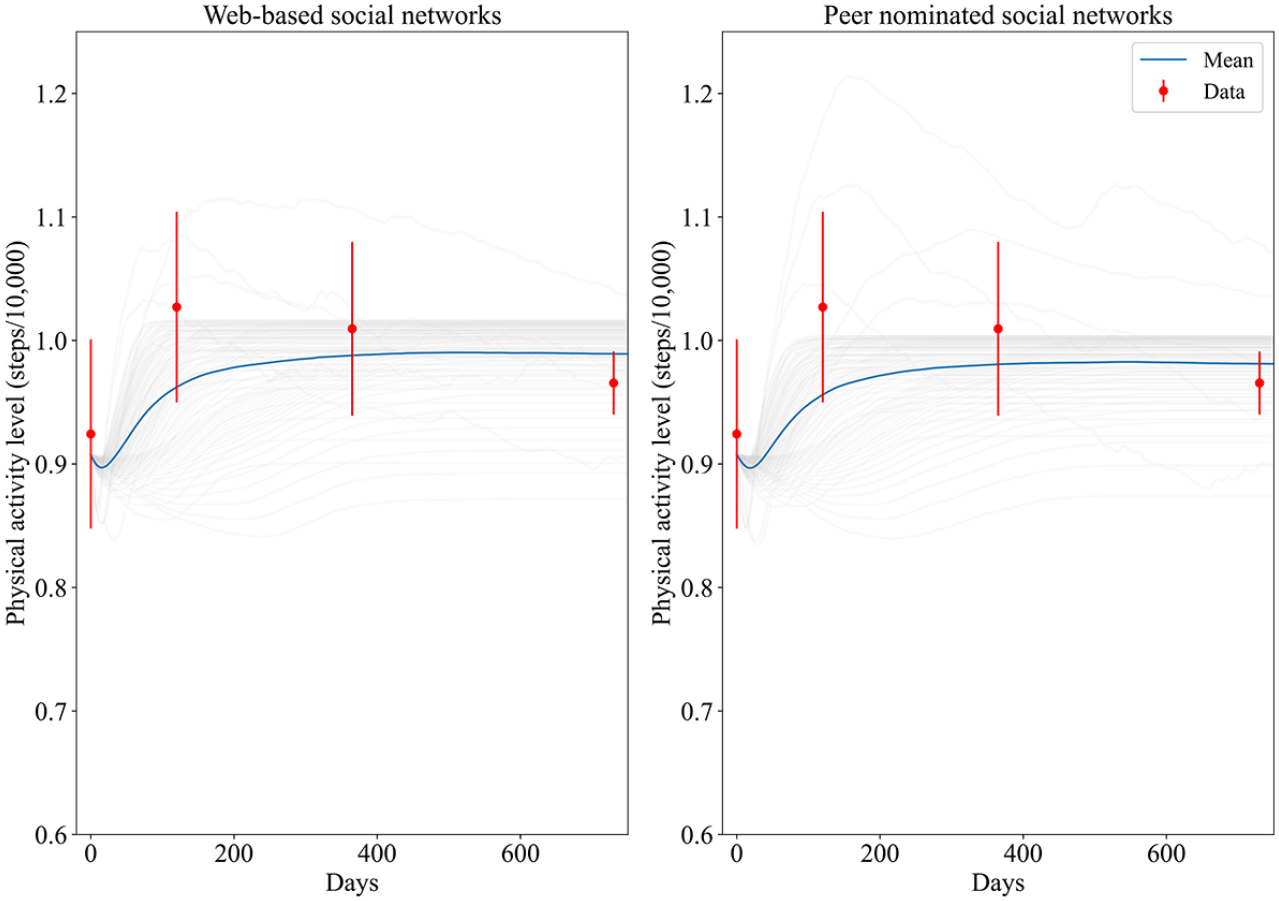
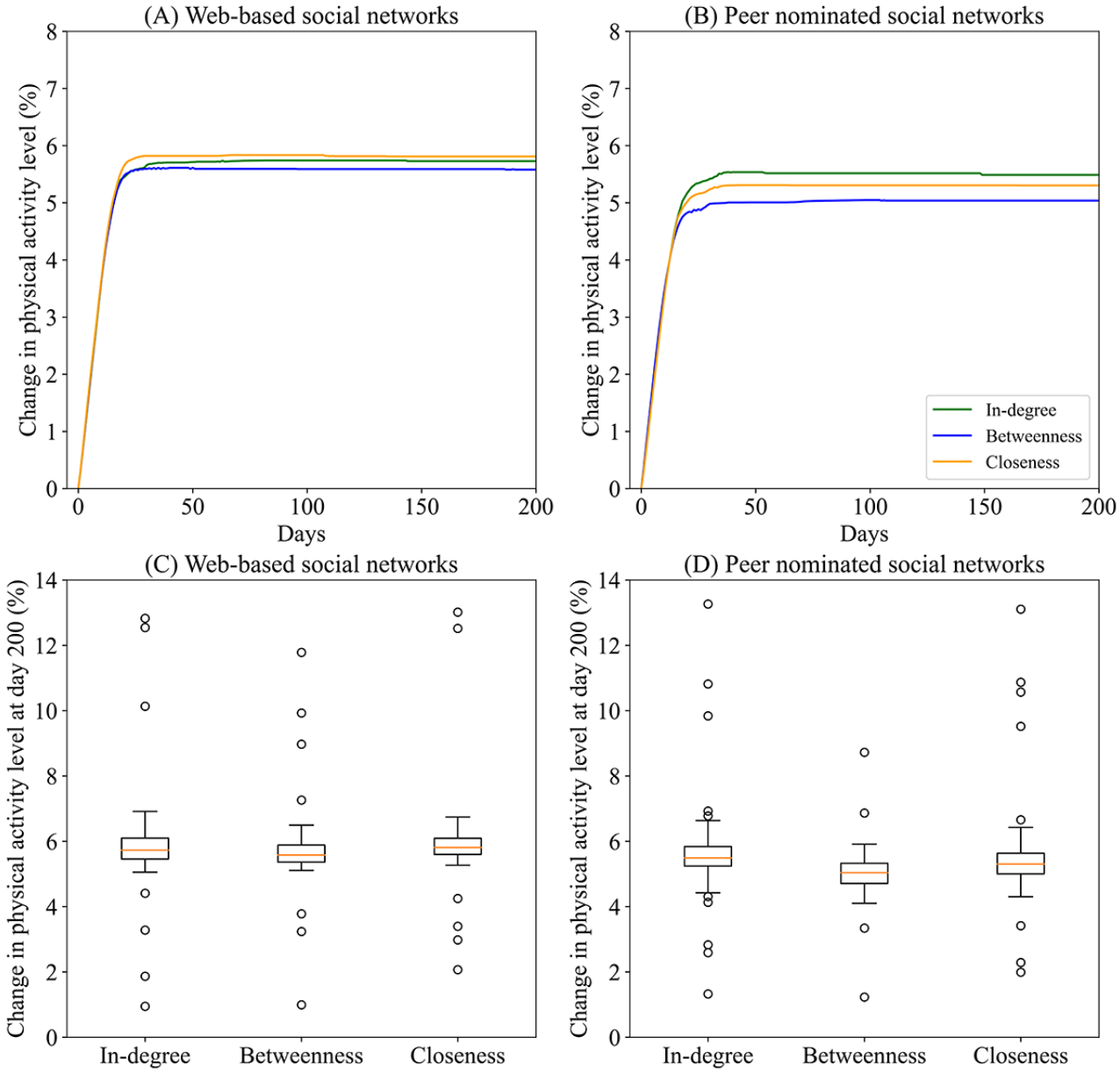
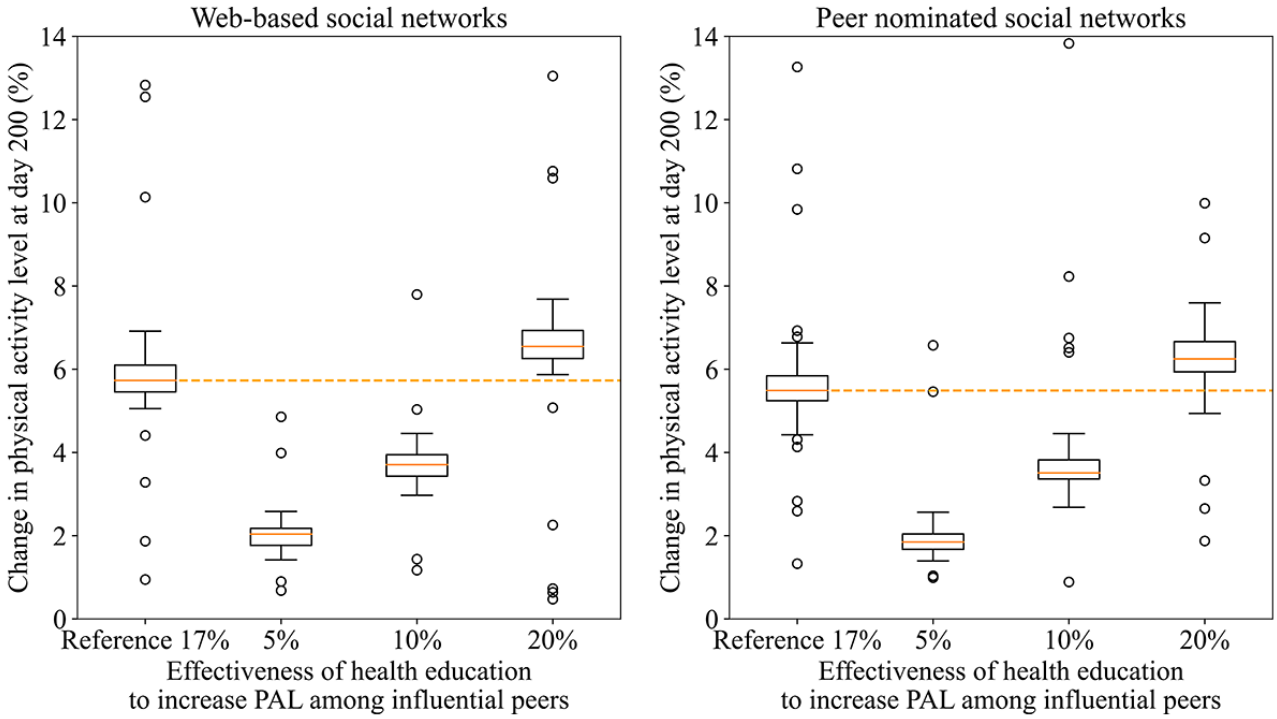


Figure 3. Modeled effect of social network interventions on the average physical activity level over a period of 200 days.



Varying the effectiveness of health education to increase PAL among influential peers (selected based on centrality measures) changed the overall impact of the social network intervention (Figure 4 and Multimedia Appendix 9). Assuming an effectiveness of 5% or 10% would yield an average population-level impact that is approximately 67% or 34% lower, respectively, than the reference (17%). Increasing the effectiveness to 20% would increase the PAL by 12%-16% compared to the reference.

Figure 4. The impact of social network interventions on physical activity levels with varying effectiveness of health education to influential peers. PAL: physical activity level.



Discussion

Overview

This study investigated the differences in impact between using web-based communication data and peer nomination data for designing social network interventions. In both network representations, interventions could increase PALs substantially (5%-5.8%) within 2 months. Generally, the predicted impact of the interventions was slightly higher in networks based on web-based communication than peer nomination data. The selection strategy for influential peers only slightly affected the impact of the social network interventions in both types of networks. However, varying the increase in PAL among influential peers (ie, the effectiveness of health education) significantly changed the impact, with lower effectiveness resulting in a lower impact.

The differences in impact using web-based communication and peer nomination network data could be explained by the differences in the constructed network. Social networks derived from web-based communication and peer nomination data showed 69% similarity, suggesting that almost one-third of the connections are different. Also, web-based social networks had significantly lower connection weights but similar density compared to the peer nominated networks. Nevertheless, the impact was slightly higher in web-based social networks. This is primarily due to substantial differences in the selection of influential peers between the 2 data representations (approximately 25% overlap). Influential peers that were selected in web-based social networks had a significantly higher number of connections than in peer nominated social networks. In 2 school classes, influential peers in web-based social networks were connected to all classmates and in 8 classes connected to more than 80% (range 19/23-20/20) of all classmates, while in peer nominated social networks, the latter occurred in only 1 school class. This suggests that being fully or very connected may compensate for the lack of strength of connection in the effectiveness of social network interventions.

As selection strategies for influential peers are usually based on network positions, choosing web-based or offline data for representing social networks is crucial. It is known that web-based and offline connections differ substantially, as peers on the internet are not necessarily the same as the closest peers offline [23,24]. This study also found substantial differences in connections in both networks, although we attempted to align both networks by selecting the nomination question ("who they hang out or have contact with") that mostly resembles web-based exchanged messages between peers. This suggests that the frequency of web-based communication does not necessarily equal the number of peers one physically hangs out with. This should be considered when selecting web-based versus offline connections to design network interventions aimed at increasing physical activity.

Our findings showed that the choice of a particular selection strategy for influential peers (ie, in-degree, betweenness, or closeness) only slightly affected the impact on PAL in both networks. The differences were at most 0.2% in web-based social networks or 0.5% in peer nominated social networks. The relatively small variation in impact was the result of the large overlap in selected influential peers between selection strategies (ie, in-degree, betweenness, and closeness) in both networks. A plausible explanation for this large overlap could be the small social network sizes (on average, 8 connections per class in both networks). This may suggest that for relatively small network sizes, any selection strategy (ie, in-degree, betweenness, or closeness) could be used to achieve a similar positive impact.

The impact of social network interventions was very sensitive to the assumed effectiveness of health education (ie, increase in PAL among influential peers). Assuming lower effectiveness would reduce the overall impact of the social network intervention by 3-fold in both networks. This underlines the importance of developing effective methods to train and educate influential peers for social network interventions to be impactful.

In this study, networks based on web-based communication data had significantly lower weights than peer nomination data. This is inherent to the method of calculating weights and the limitations of the data sets. In peer nomination networks, the weight was based on 4 nomination questions, resulting in a weight of either 0, 0.25, 0.5, 0.75, or 1. In web-based social networks, the number of messages exchanged between individuals was used as a weight, resulting in more granular weights (approximating a continuous scale from 0 to 1). This resulted in a larger variation in the weight of the connection (right-skewed distribution). A continuous scale might provide a more realistic reflection of the importance of connection. However, although weights in peer nomination data were restricted, these weights might better reflect influential potential as the peer nomination questions were influence-oriented.

This is the first agent-based modeling study to directly compare the effect of social network interventions on PAL using web-based communication versus peer nomination data. A strength of this work is that our ABM was based on an existing model of social network diffusion of PAL that has been previously (and independently) tested [29,30,39]. Also, we calibrated the model using actual data. These data were unique as they included information on participants' peer-nominated friendships, web-based interactions, and PALs, allowing a direct comparison between the implications of using web-based communication versus peer nomination data. Moreover, this study used a published framework for agent-based modeling studies (in the field of public health) to assess the quality of the model [42]. Our ABM complies with the principles related to data, parameters, sensitivity analysis, validation, and documentation. All parameter values used were reported, including those derived from data and distributions based on data. Calibration values for the model were also provided, ensuring transparency and accuracy in representing the underlying dynamics of the system. Sensitivity analyses were applied to the effectiveness of health education (ie, increase of PAL among influential peers) and network density. Model validation is conducted by comparing the simulation run outcomes with reference data sets, that is, the empirical data. Finally, we have fully documented the experiment for reproducibility through open data access, open-source code, and code documentation.

Nevertheless, the presented ABM could be further refined by including, for example, individual personality traits (eg, age effects), seasonality, and other relevant environmental factors (eg, neighborhood characteristics). Moreover, the temporality of the networks should be included in the design since social connections change over time, while the current model assumes static social networks. This could provide better-informed suggestions for designing interventions.

The data in this study were derived from a web-based social platform of a research app that participants could freely use, but they were not instructed or forced to use the app's web-based platform. Therefore, while our web-based communication data may not reflect all web-based communication, it is likely that participants may also have been communicating through other social media apps with classmates during the study. As a result, connection weights might be underestimated since they were derived based on the number of limited web-based interactions. Future studies could ask the target audience to donate their social media data [43].

Another limitation is that we considered every text message exchanged between participants in the web-based communication data to be equally meaningful. However, it is conceivable that in youth's web-based communication, this is not always the case. For example, it is very unlikely that exchanging greetings (eg, "hi") or ending a conversation (eg, "bye") can be used to persuade or influence someone to change his or her behavior. Similarly, more messages sent within 1 conversation cannot be directly interpreted as a more persuasive conversation. Therefore, future work should look more closely at the content of web-based interactions. For example, one straightforward improvement would be weighting the messages based on a word count instead of a message count. Another option would be to weigh connections based on how meaningful the interactions are. NLP techniques could be used to filter meaningful conversations related to a certain topic or behavior. For example, NLP techniques can analyze text messages and assign weights to network edges based on the level of interaction expressed. Lower weights could be assigned to surface-level interactions, such as simple greetings, while higher weights can represent more complex interactions, such as detailed discussions where peers react to each other's ideas.

Clearly, web-based communication data are complex by nature and therefore allow numerous ways for more sophisticated network modeling. The data offer many opportunities for future work on representing real-life social networks and designing network interventions. On the contrary, peer nomination data describe a snapshot of close relationships, which can be considered a limitation in terms of representing real-life social dynamics. One potentially promising approach is to combine data coming from web-based communication and peer nomination sources to design more realistic multimodal network representations.

Another way to enrich the proposed network representations is by using sampling techniques to correct the social network data or applying mixed approaches. For example, snowball sampling procedures, a type of respondent-driven sampling (RDS), can be applied to sample hidden (or hard-to-reach) populations [44]. One can consider influencers as a type of hidden population within a network. RDS exploits the social network structure to reach the target population through the participants' own peers [45]. However, instead of a static peer nomination network, with snowball sampling, the network grows as participants refer other peers. Moreover, mixed methods can also be applied. For instance, a web-based social network strategy combined with RDS peer referral has been shown to recruit a more representative sample for recruitment of a very specific group

of young transwomen compared to using only RDS [46]. We imagine that in the case of the identification of influential peers, a similar mixed methods strategy combining web-based social media sources with well-established sampling techniques can lead to some promising outcomes.

Conclusions

Altogether, the findings of this study indicate that network interventions designed based on web-based communication network data can be promising. This analysis showed that there are noticeable structural differences between the web-based communication and peer nomination network data, which affect the selection of influential peers and the outcomes of the network interventions. Generally, interventions could increase PAL substantially within 2 months in both network representations. Web-based communication data may therefore be a valuable addition and alterative to peer nomination data for future social network intervention design to overcome the disadvantages of peer-nomination-only procedures. With advances in technology, people are shifting much of their real-life communication to web-based social media. This offers an unprecedented opportunity for new ways of interpreting social connections and peer influence. AI methods, including agent-based modeling, can help to better understand these social phenomena and serve as a useful tool for designing network health interventions.

Acknowledgments

This publication is part of the project “SocialMovez: effective and responsible health campaigns for adolescents using online social networks” (project VI.C.181.045) of the research program Vici, which is partly financed by the Dutch Research Council.

Data Availability

The data used in this study are stored at the Data Archiving and Networked Services [47]. Model source code and scripts are available on GitHub [41].

Conflicts of Interest

None declared.

Multimedia Appendix 1
Demographic characteristics of the participants in wave 5 by school class.
[PDF File (Adobe PDF File), 85 KB - pediatrics_v6i1e44849_app1.pdf]

Multimedia Appendix 2
Model description and calibration.
[PDF File (Adobe PDF File), 704 KB - pediatrics_v6i1e44849_app2.pdf]

Multimedia Appendix 3
Characteristics of web-based communication and peer nomination data by school class.
[PDF File (Adobe PDF File), 164 KB - pediatrics_v6i1e44849_app3.pdf]

Multimedia Appendix 4
Frequency distribution of messages in web-based communication data.
[PDF File (Adobe PDF File), 116 KB - pediatrics_v6i1e44849_app4.pdf]

Multimedia Appendix 5
Centrality measures of generated social networks using web-based communication and peer nomination data by school class.
[PDF File (Adobe PDF File), 127 KB - pediatrics_v6i1e44849_app5.pdf]

Multimedia Appendix 6
Distribution of participants with same connections in web-based and peer nominated social networks.
[PDF File (Adobe PDF File), 246 KB - pediatrics_v6i1e44849_app6.pdf]

Multimedia Appendix 7
Number of similar influential peers between in-degree, betweenness and closeness.
[PDF File (Adobe PDF File), 206 KB - pediatrics_v6i1e44849_app7.pdf]

Multimedia Appendix 8

Variation of the impact of social network interventions on physical activity levels between school classes.
[PDF File (Adobe PDF File), 194 KB - pediatrics_v6i1e44849_app8.pdf]

Multimedia Appendix 9
The impact of social network interventions on physical activity levels with varying effectiveness of health education to influential peers.
[PDF File (Adobe PDF File), 255 KB - pediatrics_v6i1e44849_app9.pdf]

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Abbreviations

ABM: agent-based model
AI: artificial intelligence
FAS: Family Affluence Scale
NLP: natural language processing
PAL: physical activity level
RDS: respondent-driven sampling
SNA: social network analysis

Edited by S Badawy; submitted 06.12.22; peer-reviewed by P Giabbanelli, R Xu, Y Zhou; comments to author 05.04.23; revised version received 01.07.23; accepted 04.10.23; published 22.11.23.

Please cite as:
Blok DJ, Simoski B, van Woudenberg TJ, Buijzen M
The Usefulness of Web-Based Communication Data for Social Network Health Interventions: Agent-Based Modeling Study
JMIR Pediatr Parent 2023;6:e44849
URL: https://pediatrics.jmir.org/2023/1/e44849
doi:10.2196/44849
PMID:37991813

Original Paper

Using Digital Measurement–Based Care for the Treatment of Anxiety and Depression in Children and Adolescents: Observational Retrospective Analysis of Bend Health Data

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Abstract

Background: A growing body of evidence supports the efficacy of measurement-based care (MBC) for children and adolescents experiencing mental health concerns, particularly anxiety and depression. In recent years, MBC has increasingly transitioned to web-based spaces in the form of digital mental health interventions (DMHIs), which render high-quality mental health care more accessible nationwide. Although extant research is promising, the emergence of MBC DMHIs means that much is unknown regarding their effectiveness as a treatment for anxiety and depression, particularly among children and adolescents.

Objective: This study uses preliminary data from children and adolescents participating in an MBC DMHI administered by Bend Health Inc, a mental health care provider that uses a collaborative care model to assess changes in anxiety and depressive symptoms during participation in the MBC DMHI.

Methods: Caregivers of children and adolescents participating in Bend Health Inc for anxiety or depressive symptoms reported measures of their children's symptoms every 30 days throughout the duration of participation in Bend Health Inc. Data from 114 children (age 6-12 years) and adolescents (age 13-17 years) were used for the analyses (anxiety symptom group: n=98, depressive symptom group: n=61).

Results: Among children and adolescents participating in care with Bend Health Inc, 73% (72/98) exhibited improvements in anxiety symptoms and 73% (44/61) exhibited improvement in depressive symptoms, as indicated by either a decrease in symptom severity or screening out of completing the complete assessment. Among those with complete assessment data, group-level anxiety symptom T-scores exhibited a moderate decrease of 4.69 points (P=.002) from the first to the last assessment. However, members' depressive symptom T-scores remained largely stable throughout their involvement.

Conclusions: As increasing numbers of young people and families seek DMHIs over traditional mental health treatments due to their accessibility and affordability, this study offers promising early evidence that youth anxiety symptoms decrease during involvement in an MBC DMHI such as Bend Health Inc. However, further analyses with enhanced longitudinal symptom measures are necessary to determine whether depressive symptoms show similar improvements among those involved in Bend Health Inc.

(JMIR Pediatr Parent 2023;6:e46154) doi:10.2196/46154

KEYWORDS

digital mental health intervention; anxiety; depression; child; adolescent; collaborative care; mental health; caregiver; pediatric; youth; demographic; health outcome; retrospective; treatment; e-mental health; symptoms

Introduction

In 2021, 5.6 million children and adolescents aged 3-17 years were diagnosed with anxiety and 2.4 million were diagnosed with depression. Although rates of anxiety and depression have increased steadily since 2016, 1 in 5 young people still do not receive adequate mental health care services [1]. As such, the demand for high quality and accessible mental health care for youth is more pressing than ever. In recent years, this demand has been addressed in part by the increased availability of mental health care via digital and telehealth platforms [2,3]. Several studies and meta-analyses have shown that digital mental health interventions (DMHIs) are as efficacious as in-person psychotherapy for the treatment of anxiety and depression [4-7], particularly among young people. Children and adolescents are accessing the internet at increasing rates and at increasingly younger ages [8]. Indeed, there is promising evidence that young people may glean more therapeutic benefits from DMHIs than their older counterparts due to their familiarity and comfort with web-based spaces as digital natives [9,10]. For example, in a systematic overview of 18 meta-analyses, Lehtimaki et al [4] found that computerized cognitive behavioral therapy interventions significantly improved mental and behavioral health problems in youth compared to those in nontreatment controls, with the most pronounced therapeutic effects among patients exhibiting anxiety and depressive symptoms.

Despite the promising evidence offered by burgeoning literature, the efficacy of DMHIs is still limited in several ways. These limitations largely fall within 2 categories: (1) lack of ability to meet clients' and patients' needs and (2) limited high quality evidence demonstrating the effectiveness of DMHIs. First, many DMHIs are administered using a standardized approach (eg, a single user interface or a treatment plan that does not adapt based on user responses), thus showing restricted ability to tailor their services to patients' individual needs and circumstances [5,11]. This lack of adaptability restricts many DMHIs in their ability to address acute crises and issues of comorbidity [11]. Moreover, DMHIs are limited by their lack of human interaction. Hollis et al [12] and Grist et al [13] found that the involvement of a therapist or caregiver in the patient's treatment plan significantly increases the therapeutic effects. Similarly, DMHIs that include supervision, such as those delivered in the context of a hospital, school, or therapy group, are far more likely to achieve clinically significant results [14]. The majority of DMHIs do not include human interaction, and thus, low patient engagement, high rates of dropout, and negligible improvements in symptoms remain the pressing issues [15,16]. Second, the evidence for DMHI's effectiveness remains unclear and inconclusive largely due to the widespread lack of evidence-based practice utilized by DMHIs [13,17,18]. Although a number of DMHIs have been shown to effectively reduce youth anxiety and depression [4], methodological limitations such as sample size and quality of measures undermine the robustness of these findings [19]. This dearth of research also means that many questions remain regarding the basic factors associated with treatment effectiveness, such as the length of treatment and demographic and socioeconomic status [17]. This lack of methodological rigor paired with the issues of personalization and supervision mentioned above highlights the need for DMHIs to be both personalized and measurement based. These issues may be ameliorated by administering DMHIs within the context of collaborative care.

In recent years, collaborative care models have emerged as an effective framework for mental health care, particularly for the treatment of anxiety and depression [20-22]. The simplest collaborative care models are defined by a clear partnership between primary care providers (PCPs) and care teams, which comprise external behavioral health professionals (eg, case managers, therapists, coaches, psychiatrists) in order to facilitate comprehensive mental health treatment for an individual [23]. The additional support of the care team allows the PCP to delegate tasks to other team members while still tracking patient progress and optimizing treatment in real time. This optimization occurs via measurement-based care (MBC), which is another core component of the collaborative care model. MBC involves the frequent evaluation of patient symptoms and mental health status to allow for the continual tracking of patient progress. Additionally, MBC facilitates the prompt identification of treatment issues so that the DMHI can be adapted to address the patient's existing needs.

Among adults, MBC consistently confers greater treatment effects than the traditional non-MBC across multiple types of diagnoses [24-26]. Although studies of MBC among children and adolescents remain scarce, they too offer promising results. In a 2017 meta-analysis of 12 studies [27], youth who were engaged in measurement-based mental health care tended to show greater improvements in symptoms than those treated using more traditional methods. Despite its clear utility as an effective tool for mental health treatment, both collaborative care models and MBC have been infrequently used within DMHIs. As such, little is known regarding the effectiveness of DMHIs in treating anxiety and depression among young people, particularly within the context of collaborative care and MBC.

The purpose of our study was to utilize member (eg, children, adolescents) data from a novel digital mental health company (Bend Health Inc) that administers MBC via collaborative care to determine the effects of an MBC DMHI on anxiety and depressive symptoms in children and adolescents. We hypothesized that both anxiety and depressive symptoms would decrease significantly over time of involvement with Bend Health Inc.

Methods

Study Design and Participants

Children (age 6-12 years) and adolescents (age 13-17 years) receiving treatment from Bend Health Inc, an MBC DMHI, between May 2022 and December 2022 were eligible for inclusion in this study. Scores on the Patient-Reported Outcomes Measurement Information System (PROMIS) validated anxiety and depression measures were used to determine whether a member should be included in the retrospective analysis. Specifically, members with baseline PROMIS scores indicating at least mildly severe symptoms of anxiety were included in the "elevated anxiety symptom severity" group, and members with

baseline PROMIS scores indicating at least mildly severe symptoms of depression were included in the "elevated depressive symptom severity" group. Scoring and cutoff scores were determined by previously validated PROMIS scoring norms [28,29]. Many members included in our analyses exhibited additional comorbidities, including attention-deficit/hyperactivity disorder, mania, and posttraumatic stress disorder. The rates of comorbidities are reported in Multimedia Appendix 1.

Ethical Considerations

All Bend Health, Inc. members above the age of 12 (adolescent members and participating caregivers) complete informed consent prior to enrolling in services. Caregivers consent on behalf of their children ages 12 and under. The informed consent process includes essential information about Bend Health, Inc.'s telemedicine services and privacy policies. Given the current study was a retrospective analysis, it was classified as exempt from consent requirements under human subjects review and approved by BRANY IRB (Study ID 23-12-034-1374, 16 January 2023). Study data were de-identified and stored on a HIPAA–compliant online drive using industry standard encryption. Participants received no additional compensation for participation.

Treatment

Bend Health Inc is an MBC DMHI for children and adolescents (age 2-17 years) based on a measurement-based collaborative care model. Most current Bend Health Inc members enroll through a pediatric PCP referral. PCPs remain closely involved in members' care throughout their time at Bend Health Inc, helping to determine and execute the member's care and receiving updates on the member's progress up to 2 times per month (once after a monthly psychiatric provider session, if applicable, and once at the end of each month). Outside of PCP referrals, there are several other pathways to enrollment at Bend Health Inc: enrolling in employer benefits, enrolling in insurance benefits, and paying a monthly fee (direct to consumer).

Bend Health Inc uses a team-based treatment approach, leveraging regular involvement from PCPs, mental health professionals, and caregivers to holistically treat mental and behavioral health problems among youth members. After a member is enrolled and assessed, a behavioral care coordinator coordinates with their PCP as well as other relevant care team members (eg, psychiatrist, therapist, coach) to determine the member's care program (eg, the plan of care developed based on a member's presenting symptoms and age). The behavioral care coordinator then oversees the execution of the member's care program under the direction of the PCP. Each member's care program includes synchronous video-based (virtual) care sessions between the member and a coach or therapist, asynchronous instant messaging with their coach or therapist, and access to informational resources via the web-based platform. In general, care programs last between 4 and 6 months, as determined by the member's care team. However, members can transition to a new care program if their ongoing symptoms indicate that they would be more benefitted by another program; as such, a member may begin with a depression-oriented care program and transition to an attention-deficit/hyperactivity disorder–oriented care program depending on their symptom presentation.

Care programs are adapted to be developmentally appropriate for those receiving care from Bend Health Inc, with modifications in the care program based on member age. For example, programs for children (members aged 12 years or younger) require an adult caregiver to be present in synchronous sessions, during which the caregiver actively engages with and assists their child throughout the program. Programs for adolescents (members aged 13-17 years) do not require caregivers to attend sessions with their child. However, adolescent programs still include aspects that involve and support the caregiver during and between sessions, and caregivers are still required to be readily accessible throughout sessions (eg, in the same general area). Program components such as scripts and tasks are also adapted to match cognitive and emotional abilities across a range of ages, such that a child-oriented program includes simpler language and tasks (eg, drawing vs writing) and an adolescent-oriented program includes more complex language and tasks.

All members may participate in up to 5 sessions per month with any of the following health care providers (depending on treatment plan and insurance coverage): behavioral care coordinator, coach, therapist, or psychiatrist. Coaching sessions are 30 minutes in duration, and members may attend a total of up to 2-3 coaching or therapy sessions per month as part of their 5 sessions allowed per month. Caregivers of Bend Health Inc members have access to web-based one-on-one asynchronous messaging with the behavioral care coordinator, coach, therapist, or psychiatrist. Every 30 days, caregivers are asked to complete web-based assessments of mental health outcomes, including symptoms of depression and anxiety. Due to variations in caregivers' responsivity and availability to complete assessments, the rates of interassessment duration vary.

Bend Health Inc coaching sessions are intended to provide the members and their families with appropriate evidence-based behavior change tools, help members with self-reflection, strengthen self-efficacy and autonomy, and, when appropriate, serve as a gateway to additional mental health support via sessions with a licensed therapist. Therapy sessions are intended to provide diagnostic clarity to inform a clinical framework, uncover potential sources of unwanted and targeted behaviors, and address trauma or other complicated clinical psychopathology. Coaching and therapy sessions are based upon cognitive behavioral therapy, behavioral activation, parent management training, mindfulness-based cognitive therapy, motivational interviewing, and mindfulness-based stress reduction. All Bend Health Inc coaches and therapists are trained in these modalities.

Study Measures

Upon enrollment, caregivers are asked to complete screening questions for depression, anxiety, and other mental and behavioral health symptoms. Anxiety and depression screener questions were drawn from the Diagnostic and Statistical Manual of Mental Disorders, fifth edition, text revision Cross-Cutting Symptom Measure for children aged 6-17 years [30]. These screeners are intended to flag members with

depressive or anxiety symptoms while minimizing the workload for caregivers of members less likely to have these symptoms. For anxiety symptoms, the screening question items are as follows: [my child has] (1) said they felt nervous, anxious, or scared, (2) not been able to stop worrying, and (3) said they could not do things they wanted to or should have done because it made them feel nervous. For depressive symptoms, the screening question items are as follows: [my child has] (1) had less fun doing things than they used to and (2) seemed sad or depressed for several hours. If the response to any of the screening questions is "almost never" or more (eg, a raw value of 2 or greater), caregivers are required to complete the entire depression or anxiety PROMIS measure. The depression and anxiety PROMIS measures were developed for caregivers of children aged 6-17 years [28,29]. The PROMIS depression measure has 11 questions, and the anxiety measure has 10 questions. After being prompted with, "during the past 2 weeks, how much (or how often) has your child," caregivers select the best-fit response to each item using a 5-item Likert scale (ranging from "not at all" to "nearly every day"). Assessment scores are reported to the caregiver and care team members on a web-based member portal and used to guide the patient's care plan. To increase the accuracy of symptom reports, caregivers are explicitly instructed to complete screening questions and assessments with their child alongside them ("Be sure you have your child or teen with you. You'll be answering a series of questions that will be used to create your personalized care plan."). Additionally, at enrollment, caregivers were asked to report their child or adolescent's demographic information, including age, sex at birth (male or female), and race/ethnicity (American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or other Pacific Islander, White, or Other).

Statistical Analysis

The total raw scores for the depression and anxiety PROMIS assessments were calculated by adding the individual scores of all items. Raw scores were converted to standardized T-scores based on established criteria [28,29]. For both questionnaires, T-scores less than 55 indicated a nonclinically significant level of depression or anxiety (no to slight symptom severity), T-scores between 55 and 59.9 indicated mild symptom severity, T-scores between 60 and 69.9 indicated moderate symptom severity, and T-scores exceeding 70 indicated severe symptoms. In all descriptions of the symptom severity classifications, scores of those who were screened out of completing the full assessment(s) (due to no longer reporting anxiety or depressive symptoms per screener questions) were classified as screened out. Because of this limitation, 2-tailed *t* tests were used to determine whether those who screened out at later assessments showed lower symptom severity at baseline.

Each member's δ (change) score was calculated as the final T-score (last assessment) – baseline T-score (first assessment) to quantify the change in the T-score from baseline to the end of treatment. Negative change scores indicated an improvement (decrease) in symptom severity. One-tailed Wilcoxon signed-rank tests were conducted on complete assessment data to determine whether change scores for depression and anxiety were significantly less than 0. For other descriptive statistics of change in symptom severity, members were considered to show improvement if they either (1) exhibited a decrease in anxiety or depressive scores or (2) were screened out of completing an entire assessment based on reports of low symptom severity in the screener questions.

Changes in depression and anxiety T-scores over time were further assessed by linear mixed-effects models with a fixed effect of time of assessment (eg, days from baseline) and a random effect of member (identification number) on the intercept. The number of days from baseline was used as the time variable because there was variability in the interassessment duration (eg, some members' second assessments took place 25 days after baseline while others' assessments took place 40 days after baseline). The average number of treatment sessions per month (calculated as time between the first and last assessments divided by the number of sessions with a coach, therapist, or psychiatrist) was added to this basic model as an additional predictor, and the alternative model was compared to the basic model by a likelihood ratio test. If the likelihood ratio test indicated that the predictor improved model fit (eg, $P<.05$), it was retained in the final model. Finally, analysis of variance was performed on the model effects to determine whether each effect was significant. The primary linear mixed-effects models for depressive and anxiety symptoms were first performed on only complete assessment data for all members. Then, follow-up linear mixed-effects models were conducted on those with complete data for the first 3 assessments (eg, completed assessments at baseline, assessment 2, assessment 3). These follow-up sensitivity analyses were performed to test the robustness of findings to dropout effects and are reported in Multimedia Appendix 1.

For all analyses, group trends were reported with standard descriptive statistics, including percent of sample (%), mean (SD), and median (IQR). Due to low response rates in the anxiety measure for assessments 5-7 for the elevated anxiety group, descriptive statistics for anxiety T-scores are not reported past assessment 4. Similarly, due to the low response rates in the depression measure for assessments 4-5 for the elevated depressive symptom group, descriptive statistics for depression T-scores are not reported past assessment 3.

Results

Baseline Characteristics of the Participants

A total of 114 members (age 6-17 years) met the inclusion criteria for elevated symptoms of anxiety or depression, with 85.9% (98/114) included in the anxiety analyses and 53.5% (61/114) included in the depression analyses. Approximately 42.1% (48/114) of all the members in this study met the inclusion criteria for both analyses. Due to variations in the rates of completion of screeners versus assessments as well as the total duration of participation with the DMHI, the rates of PROMIS measure completion decreased over assessments for both symptom groups. All included members completed the first assessment (baseline), and few members completed the subsequent assessments (see Table 1).

The members in the group with elevated anxiety symptoms were 11.9 (SD 3.3) years old, with adolescents comprising approximately half of the group (51/98, 52%). Approximately two-thirds of the anxiety group were females (66/98, 67%). Most members in the anxiety group identified as White (57/98, 58%) or other (31/98, 32%). The members in the group with elevated depressive symptoms were 13.2 (SD 2.7) years old, with a larger proportion of adolescents than children (45/61, 74%). The depression group consisted of predominantly females (43/61, 71%). Most members in the depression group identified their race/ethnicity as White (33/61, 54%) or other (22/61, 36%). Table 2 shows the comprehensive demographic information of the anxiety and depressive symptom groups at baseline.

Table 1. Rates of Patient-Reported Outcomes Measurement Information System measure completion for depression and anxiety groups.

Assessment number	Elevated depressive symptom group (n=61), n (%)		Elevated anxiety symptom group (n=98), n (%)	
	Complete assessment	Screener or complete assessment	Complete assessment	Screener or complete assessment
1 (baseline)	61 (100)	61 (100)	98 (100)	98 (100)
2	12 (20)	25 (41)	34 (35)	44 (45)
3	3 (5)	13 (21)	21 (21)	22 (22)
4	1 (2)	5 (8)	7 (7)	9 (9)
5	1 (2)	3 (5)	2 (2)	3 (3)
6	0 (0)	2 (3)	0 (0)	1 (1)

Table 2. Demographic information of the members in the depression and anxiety groups at baseline.

Demographics	Elevated depressive symptom group (n=61)	Elevated anxiety symptom group (n=98)
Age (years), mean (SD)	13.2 (2.7)	11.9 (3.3)
Child (6-12 years), n (%)	16 (26)	47 (48)
Adolescent (13+ years), n (%)	45 (74)	51 (52)
Sex, n (%)		
Female	43 (71)	66 (67)
Male	18 (30)	31 (32)
Race/ethnicity, n (%)		
White	33 (54)	57 (58)
Other	22 (36)	31 (32)
Asian	5 (8)	8 (8)
Hispanic/Latino	0 (0)	1 (1)
Black/African American	1 (2)	1 (1)
American Indian or Alaska Native	0 (0)	0 (0)

Elevated Anxiety Symptom Severity Group

While receiving care from Bend Health Inc, members in the elevated anxiety symptom group attended 0-19 (median 0 [IQR 2]) sessions with a coach, therapist, or psychiatrist. Those in the elevated anxiety symptom group who completed at least 2 assessments (eg, screeners or complete measures; n=45) attended a median of 2 (IQR 3) sessions with a coach, therapist, or psychiatrist and an average of 1.50 (SD 0.73; range 0-3.6) sessions per month. Members completed their first and last assessments between 0 and 221 days apart (median 0 [IQR 1.5] sessions). The duration between the assessments ranged from 8 to 90 days, with the central tendency approximately equal to a month (median 34 [IQR 15] days).

Members with elevated anxiety symptoms had a mean PROMIS anxiety T-score of 64.97 (SD 6.71) at baseline, which is classified as moderate anxiety symptom severity. For members who completed at least 2 screeners or complete assessments, 73% (72/98) had improvements in anxiety symptom severity from baseline to their last assessment, as indicated by either a decrease in symptom severity scores or screening out of completing the entire assessment. Indeed, rates of moderate to severe anxiety symptom severity decreased across assessments, and rates of screening out of the complete assessment increased across assessments (Figure 1 and Table 3). Specifically, 23% (10/44) of the members with elevated anxiety symptoms at baseline screened out of the complete second anxiety PROMIS assessment, and 5% (1/22) screened out of completing the third anxiety PROMIS assessment. PROMIS anxiety T-scores at baseline for participants who screened out of the second PROMIS assessment (mean 61.78 [SD 7.14]) were slightly lower than those of participants who took the complete assessment (mean 65.89 [SD 5.82]), with the *t* test trending toward statistical significance (t_{44}=1.88; P=.07). For those with

at least one complete follow-up assessment (n=38), anxiety symptoms decreased from the first (mean 65.97 [SD 6.27]) to the last assessment (mean 61.28 [SD 9.92]; t_{37}=–3.12; P=.002).

In the linear mixed-effects model of those with complete PROMIS anxiety assessment data (eg, excluding those at each assessment who had completed the screener only), the addition of number of sessions per month (with a coach, therapist, or psychiatrist) as a predictor did not improve model fit (χ^2_1=1.6; P=.20). Thus, the final model included the main time variable (days from baseline) as a fixed effect and member as a random effect on the intercept (Figure 2, Table 4). The model explained 10.4% of the total variance, and the main effect of days from the baseline was statistically significant ($F_{1,64}$=14.25; P<.001; Figure 2). Specifically, the model estimated a decrease in anxiety T-score of 0.06 points per day (1.8 points per month). When the linear mixed-effects analysis was repeated on assessments 1 through 3 for those with at least 3 complete assessments (n=17), the results did not differ substantively from the primary model results (Multimedia Appendix 1).

Figure 1. Distribution of anxiety symptom severity categories across assessments (including those who screened out of the assessment, indicated in purple).

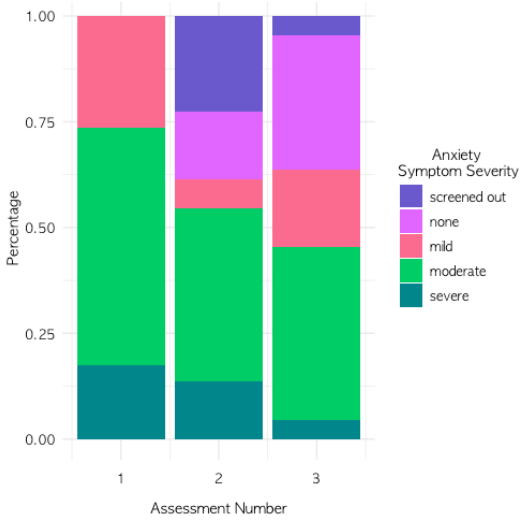

Table 3. Rates of Patient-Reported Outcomes Measurement Information System anxiety symptom severity categories across assessments.

Anxiety symptom severity	Assessment 1 (n=98), n (%)	Assessment 2 (n=44), n (%)	Assessment 3 (n=22), n (%)
Screened out (no complete assessment)	0 (0)	10 (23)	1 (5)
None	0 (0)	7 (16)	7 (32)
Mild	26 (27)	3 (7)	4 (18)
Moderate	55 (56)	18 (41)	9 (41)
Severe	17 (17)	6 (14)	1 (5)

Figure 2. Linear mixed-effects model results demonstrating the main effect of days from first assessment on anxiety T-scores.

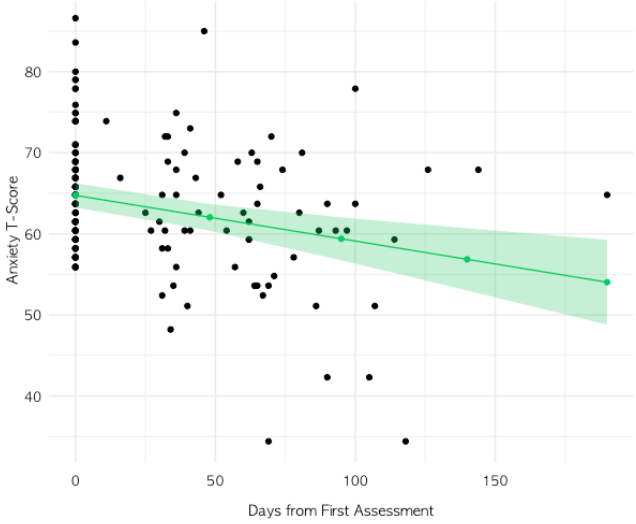

Table 4. Results of the linear mixed-effects model for the anxiety symptom group.[a]

Predictors	Anxiety T-score estimates	*P* value
(Intercept) (95% CI)	64.74 (63.24 to 66.25)	<.001[b]
Days from baseline, estimate (95% CI)	–0.06 (–0.09 to –0.03)	<.001[b]
Random effects		
σ^2	37.64	N/A[c]
τ_{00}[d]	22.49	N/A

[a]Total sample size at baseline=98; 163 observations; marginal R^2=0.104.

[b]Statistically significant effects (P<.05).

[c]N/A: not applicable.

[d]Random intercept variance (also known as between-individual variance).

Elevated Depressive Symptom Severity Group

While receiving care from Bend Health Inc, members in the elevated depressive symptom group attended 0-10 (median 0 [IQR 2]) sessions with a coach, therapist, or psychiatrist. Those in the elevated depression symptom group who completed at least 2 screeners or full assessments (n=26) attended a median of 3 (IQR 2.75) sessions with a coach, therapist, or psychiatrist with an average of 1.45 (SD 0.68; range 0-2.6) sessions per month. Members completed their first and last screeners or complete assessments between 0 and 168 days apart (median 0 [IQR 62] days). The duration between screeners only or complete assessments ranged between 20 and 90 days, with the central tendency approximately equal to a month (median 32 [IQR 17] days).

Members with elevated depressive symptoms had a mean PROMIS depression T-score of 68.20 (SD 7.48) at baseline, which is classified as moderate depressive symptom severity. For members who completed at least 2 screeners or complete assessments, 73% (44/61) had improvements in depressive symptom severity from baseline to their last assessment, as indicated by either a decrease in symptom severity scores or screening out of completing the complete assessment. Indeed, the rates of more severe depressive symptoms decreased across assessments and the rates of screening out of the complete assessment increased across assessments (see Figure 3 and Table 5). Specifically, 52% (13/25) of the members with elevated depressive symptoms at baseline screened out of the complete second depression PROMIS assessment, and 77% (10/13) screened out of completing the third depression PROMIS assessment. Although PROMIS depression T-scores were slightly lower for those who screened out of the second PROMIS assessment (mean 66.08 [SD 4.42]) versus those who took the complete assessment (mean 68.00 [SD 8.27]), this difference was not significant (t_{24}=0.97; P=.34). For those with at least one complete follow-up assessment (n=13), depressive symptoms remained stable at moderately severe from the first (mean 68.20 [SD 8.33]) to the last assessment (mean 68.02 [SD 9.35]; t_{12}=–0.08; P=.47).

Figure 3. Distribution of depressive symptom severity categories across assessments (including those who screened out of the assessment, indicated in purple).

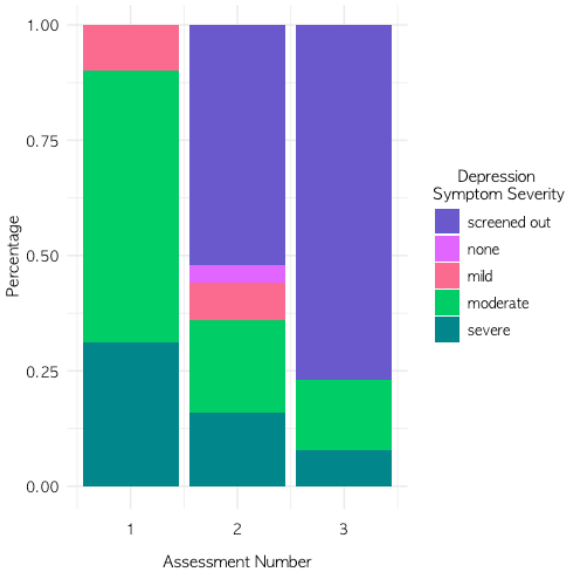

Table 5. Rates of Patient-Reported Outcomes Measurement Information System depressive symptom severity categories across assessments.

Depressive symptom severity	Assessment 1 (n=61), n (%)	Assessment 2 (n=25), n (%)	Assessment 3 (n=13), n (%)
Screened out (no complete assessment)	0 (0)	13 (52)	10 (77)
None	0 (0)	1 (4)	0 (0)
Mild	6 (10)	2 (8)	0 (0)
Moderate	36 (59)	5 (20)	2 (15)
Severe	19 (31)	4 (16)	1 (8)

In the linear mixed-effects model of complete PROMIS depression assessment data (excluding those at each assessment who had completed the screener only), the addition of the number of sessions per month (with a coach, therapist, or psychiatrist) as a predictor did not improve model fit (χ^2_1=2.6; P=.11). Thus, the final model included the main time variable (days from baseline) as a fixed effect and member as a random effect on the intercept (Figure 4, Table 6). The model explained none of the total variance (0%), and the main effect of days from the baseline was not significant ($F_{1,16}$=1.02, P>.99; Figure 2). When the linear mixed-effects analysis was repeated on assessments 1 through 3 for those with at least 3 complete assessments, the results did not differ substantively from the primary model results (Multimedia Appendix 1).

Figure 4. Linear mixed-effects model results demonstrating the main effect of days from first assessment on depression T-scores.

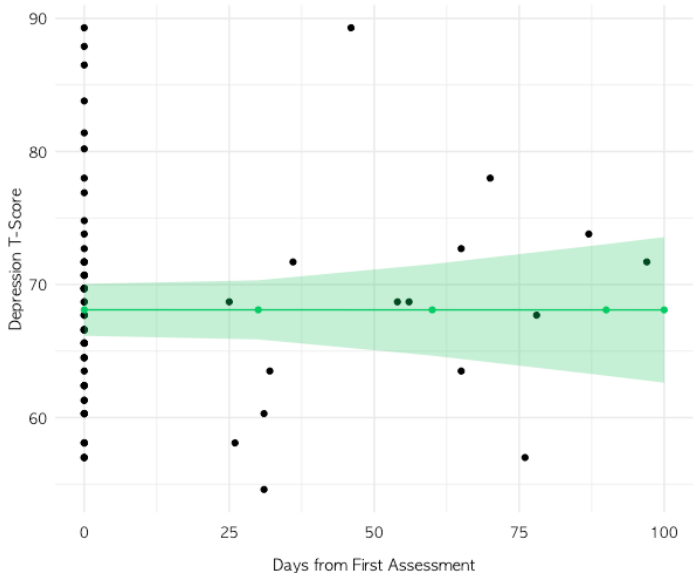

Table 6. Results of the linear mixed-effects model for the depressive symptom group.[a]

Predictors	Depression T-score estimates	*P* value
(Intercept) (95% CI)	68.10 (66.15 to 70.06)	<.001[b]
Days from baseline, estimate (95% CI)	0.00 (–0.06 to 0.06)	.99
Random effects		
σ^2	32.59	N/A[c]
τ_{00}[d]	26.92	N/A

[a]Total sample size at baseline=61; 78 observations; marginal R^2=0.000.

[b]Statistically significant effects (P<.05).

[c]N/A: not applicable.

[d]Random intercept variance (also known as between-individual variance).

Discussion

Principal Results

The purpose of this study was to utilize member data from Bend Health Inc to determine the effects of an MBC DMHI on depressive and anxiety symptoms among children and adolescents. To our knowledge, this is the first study evaluating the effects of a DMHI that uses a measurement-based collaborative care model to reduce symptoms of depression and anxiety in children and adolescents over time. We found that

youth receiving care from Bend Health Inc exhibited improvements in both anxiety and depressive symptoms over time. Notably, depressive symptoms remained largely stable over time when assessing only those who did not screen out (eg, those with higher depressive symptoms at later assessments). As such, more comprehensive measures are necessary to fully elucidate the effects of Bend Health Inc on those with more severe depressive symptoms. Given that depressive symptoms and episodes often increase in early adolescence [31-33], it is notable that depression severity remained stable even among Bend Health Inc members with persistent symptoms.

Depressive and anxiety symptom frequency and severity decreased between baseline and subsequent assessments in child and adolescent members who were receiving care with Bend Health Inc. However, the method in which members' symptoms were assessed introduced significant nuances into our study design and interpretation of results. Members exhibited improvements at subsequent assessments via one of the 2 pathways: by showing decreases in symptom scores or by screening out of symptom measures entirely. When considering the full cohort together, including those who completed the full measures and those who screened out, we observed, across both anxiety and depressive symptom groups, (1) decreased frequency of moderate and severe symptoms and (2) increased frequency of those whose symptoms were low enough to screen out of the full measures. Specifically, 73% (72/98) of the anxiety symptom cohort and 73% (44/61) of the depressive symptom cohort either showed a decrease in symptom severity or screened out between their first and final assessments. However, when confining our analyses to those with only completed assessments, only anxiety symptoms showed significant decreases over time. Given that completion of the full symptom assessments was dependent upon elevated severity of symptoms (as proxied by the screener questions), analyzing only those with completed assessments may have naturally highlighted those with the most persistent and severe symptoms. Moreover, the depressive symptom group was particularly limited by low power to detect changes over time, as over half of those who exhibited elevated depressive symptoms at baseline screened out by the second assessment. More comprehensive symptom measures are necessary to untangle the nuances of our findings.

Despite these limitations, our results are still promising. As an increasing number of young people and families seek DMHIs over traditional mental health treatments due to their accessibility and affordability, this study offers preliminary evidence that MBC DMHIs such as Bend Health Inc have the potential to mitigate anxiety and depressive symptoms in those younger than 18 years. Previous meta-analyses of DMHIs have found that interventions involving supervision, such as asynchronous video calls or follow-ups by telephone or instant messaging, are associated with greater improvements in depressive and anxiety symptoms when compared to unsupervised self-guided interventions [14,18]. Therefore, future research of MBC DMHIs ought to compare various care methodologies such as those involving both supervised and unsupervised care.

We found that the length of involvement in Bend Health Inc care was the foremost predictor of anxiety symptom severity over time, such that members' anxiety symptoms decreased as their duration of participation increased. Several studies have investigated the complex associations between DMHI length and symptom improvement among youth, with some suggesting that longer involvement in therapy (eg, number of months or hours involved in intervention) is associated with larger reductions in symptoms [34,35]. Conversely, some studies have found that the positive effects of various care programs on symptom severity are the greatest among interventions of 1-2 months in duration [36] or are not related to treatment duration at all [12]. Our study supports the former finding that length of treatment is indeed closely linked to changes in symptom severity among Bend Health Inc members. Because the length of involvement in our sample was relatively brief, with the average duration of treatment equaling just longer than a month for those with anxiety or depressive symptoms, further studies on Bend Health Inc patients who have engaged in treatment for longer periods of time (eg, 4-6 months) are necessary to determine the full scope of the association between duration of time in treatment and symptom improvement.

Limitations and Future Directions

Our study is limited by several factors. Primarily, our findings are limited by a lack of specificity in symptom measurement. To reduce member and caregiver burden, those who did not report significant anxiety or depression symptoms using preliminary screener questions were not given the opportunity to complete the full anxiety and depression questionnaires. As such, we did not have complete assessment data for most members who exhibited low anxiety and depressive symptoms after their first assessment. This lack of data among those arguably exhibiting the largest improvements likely skewed our longitudinal analyses to primarily reflect those with more persistent and severe symptoms. However, it should be noted that depressive symptoms often exhibit marked increases in early adolescence [31-33]. Conversely, Bend Health Inc members who continued to report elevated depressive symptoms exhibited stability in their symptoms over time. When compared to commonly observed increases among untreated adolescents, this stability offers promising evidence that Bend Health Inc programs are beneficial even for youth with persistent depressive symptoms. Moreover, our study is limited by its use of caregiver-reported assessments of child and adolescent symptoms. Although there is a precedent for using observer (eg, caregiver, clinician) ratings to track symptom progression in MBC [37-39], evidence also suggests that caregiver reports may not capture potential internalizing problems as effectively as youth self-report [40]. Follow-up studies that include both adolescent-reported and caregiver-reported metrics are necessary to determine whether our results are robust to reporters.

Many studies evaluating DMHI effectiveness have compared patients receiving treatment to nonactive controls (eg, those participating in no intervention). Subsequent studies of Bend Health Inc could be improved by the inclusion of various levels of treatment in order to test whether care with Bend Health Inc confers greater effects than alternatives (eg, no treatment, traditional face-to-face treatment, nonmeasurement-based

DMHIs). Furthermore, the duration of care in our study was relatively moderate and highly variable, with average participation lasting approximately a month but ranging from 0 to 168 days. Although our follow-up analyses of members with 3 or more assessments suggest that decreases in symptoms are robust to dropout effects, the rigor of future studies can be improved by increasing the number of participants with longer involvement and more assessment points.

Importantly, our study did not have adequate power to investigate differences in symptom change across demographic groups such as age, gender, race, and ethnicity. A number of studies have demonstrated that the risk for anxiety and depression increases in adolescence [41]. Moreover, females often report higher rates of anxiety and depression than males, despite depression and suicide being one of the leading causes of death among men [42-44]. Mental health disparities between racial and ethnic groups have also been reported, although findings are inconsistent about which group is the most at risk [43,45]. Further studies are necessary to determine whether those involved in an MBC DMHI like Bend Health Inc exhibit similar demographic differences. Information generated by these future studies will be crucial to informing care programs at Bend Health Inc and other DMHIs.

The principal finding of this study indicates that children and adolescents involved in Bend Health Inc show a significant reduction of anxiety and depressive symptoms over time. As such, our study offers preliminary evidence suggesting that MBC DMHIs such as Bend Health Inc may aid in reducing anxiety and depressive symptoms in youth. Future studies bolstered by improved measurement of symptoms and a larger and more diverse cohort of youth are paramount in order to establish the effectiveness of Bend Health Inc as an evidence-based provider of DMHIs in the United States.

Authors' Contributions

LGH and DLS contributed to conceptualization, methodology, formal analysis, writing the original draft, manuscript reviewing and editing, and visualization of this study. JH contributed to conceptualization, writing the original draft, manuscript reviewing and editing, and supervision of this study. MR and KR reviewed and edited the paper and acquired funds. AP and RG reviewed and edited the paper. JW curated the data and reviewed and edited the paper.

Conflicts of Interest

All authors are employed by Bend Health Inc, which delivered the treatment used in this retrospective study. However, authors' employment status and salary are not dependent upon the results of their research.

Multimedia Appendix 1
Supplementary data.
[DOCX File , 98 KB - pediatrics_v6i1e46154_app1.docx]

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Abbreviations

DMHI: digital mental health intervention
MBC: measurement-based care
PCP: primary care provider
PROMIS: Patient-Reported Outcomes Measurement Information System

Edited by S Badawy; submitted 31.01.23; peer-reviewed by A Radovic, S Lüttke; comments to author 23.02.23; revised version received 08.03.23; accepted 30.03.23; published 20.04.23.

Please cite as:
Huffman LG, Lawrence-Sidebottom D, Huberty J, Roots M, Roots K, Parikh A, Guerra R, Weiser J
Using Digital Measurement–Based Care for the Treatment of Anxiety and Depression in Children and Adolescents: Observational Retrospective Analysis of Bend Health Data
JMIR Pediatr Parent 2023;6:e46154
URL: https://pediatrics.jmir.org/2023/1/e46154
doi:10.2196/46154
PMID:37079366

Original Paper

Implementing a Digital Depression Prevention Program in Australian Secondary Schools: Cross-Sectional Qualitative Study

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Abstract

Background: Depression is common during adolescence and is associated with adverse educational, employment, and health outcomes in later life. Digital programs are increasingly being implemented in schools to improve and protect adolescent mental health. Although digital depression prevention programs can be effective, there is limited knowledge about how contextual factors influence real-world delivery at scale in schools.

Objective: The purpose of this study was to examine the contextual factors that influence the implementation of the Future Proofing Program (FPP) from the perspectives of school staff. The FPP is a 2-arm hybrid type 1 effectiveness-implementation trial evaluating whether depression can be prevented at scale in schools, using an evidence-based smartphone app delivered universally to year 8 students (13-14 years of age).

Methods: Qualitative interviews were conducted with 23 staff from 20 schools in New South Wales, Australia, who assisted with the implementation of the FPP. The interviews were guided by our theory-driven logic model. Reflexive thematic analysis, using both deductive and inductive coding, was used to analyze responses.

Results: Staff perceived the FPP as a novel ("innovative approach") and appropriate way to address an unmet need within schools ("right place at the right time"). Active leadership and counselor involvement were critical for planning and engaging; teamwork, communication, and staff capacity were critical for execution ("ways of working within schools"). Low student engagement and staffing availability were identified as barriers for future adoption and implementation by schools ("reflecting on past experiences").

Conclusions: Four superordinate themes pertaining to the program, implementation processes, and implementation barriers were identified from qualitative responses by school staff. On the basis of our findings, we proposed a select set of recommendations for future implementation of digital prevention programs delivered at scale in schools. These recommendations were designed to facilitate an organizational change and help staff to implement digital mental health programs within their schools.

International Registered Report Identifier (IRRID): RR2-10.1136/bmjopen-2020-042133

(JMIR Pediatr Parent 2023;6:e42349) doi:10.2196/42349

KEYWORDS

implementation; youth; digital; depression; secondary school; qualitative; consolidated framework for implementation research; teacher; educator; perspective; mental health; student; child; adolescent; adolescence; school; social work

Introduction

Background

Meta-analytic findings estimate the pooled lifetime prevalence for major depressive disorders in adolescence to be 19% [1]. This lifetime prevalence estimate is concerning because adolescent depression is associated with serious social, educational, and health impairments across development [2,3]. The onset of depression is typically around mid- to late adolescence [4], yet many young people remain undiagnosed and untreated [5,6]. Of the young people who do receive evidence-based treatments for depression, relapse rates remain high and approximately 50% do not respond [7,8]. One reason for limited effectiveness is that treatment alone is not sufficient [9]. Prevention is also important, with estimates showing that psychological programs can reduce the incidence of depressive disorders in adolescents by up to 29% (compared with care-as-usual or control groups) [10]. Evidence-based depression prevention programs delivered at scale are crucial to address the depression burden and reduce the pressure on the mental health system. Scalability can be achieved by delivering evidence-based prevention programs in schools using digital approaches.

Schools are a critical touch point for the early identification of mental ill-health and the delivery of prevention programs for adolescents. Mental health support can be provided universally to all students in schools, which facilitates normalization of common emotional and behavioral experiences and overcomes barriers to help-seeking [11,12]. Among young people who do receive mental health care services, more than half first receive mental health care through their school [13]. School teachers and counselors perceive that supporting the mental health of their students is part of their role, and they are motivated to provide evidence-based programs during school time [14,15]. Given that depression in adolescence is associated with poorer academic performance [2,16] and school absence [17], prevention also aligns with the more traditional goals of educators and school administrators. Overall, partnering in the delivery of prevention programs is a natural fit for schools.

School-based depression prevention programs are effective. Meta-analyses have found that school-based prevention programs have a small preventive effect on depressive symptoms [18,19]. This preventive effect held regardless of whether the programs were delivered universally to all young people or were delivered to a targeted subsample with symptoms or risk factors [18]. An updated meta-analysis replicated these results and showed that 8 (7%) of the evaluated programs were digital (eg, delivered via a web platform through computers or laptops, or via smartphone apps) [20]. Digital programs were either supported by school staff (eg, classroom teachers) or by external facilitators in the classroom (eg, research assistants or trained psychologists). There was preliminary evidence that digital programs might be just as efficacious as face-to-face programs [20], which aligns with the pattern of results outside of the school setting [21]. These results demonstrate that staff-supported universal digital depression prevention programs may be an effective and feasible option for schools.

There are many practical benefits for delivering depression prevention programs digitally in schools. Digital delivery, including that via smartphones, is typically perceived by young people as an appropriate and accessible way to access mental health information and support [22,23]. Young people can progress through content at their own pace or potentially select modules that address their primary needs [24]. Teachers and counselors similarly perceive that using technology in schools to deliver mental health programs to students is appropriate and can integrate with existing ways of working [25]. Further, digital delivery is typically more cost-effective than face-to-face therapies [21] because it requires fewer resources to implement. Given that therapeutic content in digital programs is already developed, there is little (or indeed no) need for trained mental health facilitators. Despite the potential for maximizing reach, there is limited understanding about how to optimally deliver digital prevention programs at scale in schools.

Schools are complex environments for delivering digital mental health programs, and many factors will affect their implementation by staff and uptake by students. There has been a paucity of research to date that has evaluated the barriers and facilitators to implementing school-based digital mental health programs for students. One cross-sectional survey study from our research group addressed this gap by focusing on school staff perspectives. We evaluated staff perceptions about barriers and facilitators that would affect their implementation of a hypothetical digital depression prevention program in Australian schools [25]. Barriers included a lack of time and resources (ie, staff and rooms), concern about privacy issues in digital delivery, and a lack of clarity around staff roles and responsibilities [25]. Facilitators included upskilling staff through training; embedding the program into the curriculum; and other program factors including universal delivery, screening of students' mental health, and clear referral pathways [25]. The extent to which these factors are important for real-world, scaled delivery of digital depression prevention programs in schools remains unclear.

In the context of clinical effectiveness trials, implementation evaluations aim to identify the contextual factors that influence how programs are put into practice "in the wild" (ie, hybrid type 1 designs) [26]. Such information is pivotal to understanding why programs work in some contexts and not in others because it can pinpoint sources of variation across different sites and individuals [27]. Implementation research in schools has primarily focused on evaluating the implementation of multicomponent physical activity interventions [28-32], mental health and well-being programs [33], or suicide prevention programs [34] delivered in person. Converging results show that there is variation in implementation processes

across different schools, including the level of staff and institutional support, delineation of staff roles, and recruitment of other school-level resources [31,34]. Contextual factors, including cultural norms, location (eg, rurality), school-level buy-in, and program complexity, can also influence implementation [31,34]. The implication of these findings is that adaptation of implementation strategies by supporting staff may be essential for feasible delivery of school-based programs [31]. Different individual and contextual factors likely influence how school staff implement digital depression prevention programs.

The Current Implementation Evaluation

The current implementation evaluation provides a qualitative analysis of the contextual factors that influence implementation of the Future Proofing Program (FPP) from the perspectives of school staff. The FPP is a 2-arm hybrid type 1 effectiveness-implementation trial evaluating whether depression can be prevented using an evidence-based smartphone app (SPARX [Smart, Positive, Active, Realistic, X-factor thoughts]) [35] delivered universally to year 8 students (13-14 years of age; see the trial protocol) [36]. Hybrid type 1 trials test the effects of an intervention on relevant outcomes while observing and gathering information about implementation [26]. Recruitment for the FPP trial occurred between August 2019 and March 2022. A total of 6388 students from 144 Australian schools in urban, regional, and rural areas enrolled and will participate in the trial until 2026. A total of 67 schools were allocated to the intervention condition, comprising 3266 students. The primary outcome of the FPP trial is the change in symptom severity of depression. Secondary outcomes include anxiety, psychological distress, and insomnia. Student-level outcomes are assessed at 6 weeks, 12 months, 24 months, 36 months, 48 months, and 5 years. Only the methods relevant to the current implementation evaluation will be described hereafter.

Aim

The aim of this paper is to evaluate staff perceptions about (1) their involvement in supporting the FPP in their schools and (2) the extent to which contextual factors (eg, school organizational characteristics and staff characteristics) influenced their ability to implement the FPP. Findings will help to develop a practical guide outlining how to best deliver digital mental health programs to young people in schools.

Methods

Study Design

The evaluation was only conducted on the intervention arm of the study and is guided by the Consolidated Framework for Implementation Research (CFIR) [37]. The CFIR was used to identify barriers and facilitators to intervention implementation and effectiveness. The research team also developed a logic model that combines these frameworks to identify contextual factors hypothesized to impact the implementation processes and outcomes. For more details, see Figure S1 in Multimedia Appendix 1 and the implementation evaluation protocol [38].

The Intervention

Students in the intervention arm of the trial received an evidence-based cognitive-behavioral therapy program for depression called SPARX [35,39]. The trial used a prevention version of the program (SPARX-R) that was delivered via a smartphone app. Skills learnt through SPARX-R include emotion identification, emotion regulation, behavioral activation (being active), recognizing and challenging unhelpful thoughts, and practical problem-solving. SPARX-R consists of seven 20-minute modules that are completed sequentially. The program is fully automated, and the therapeutic components are standardized. Students had access to SPARX-R for 6 weeks.

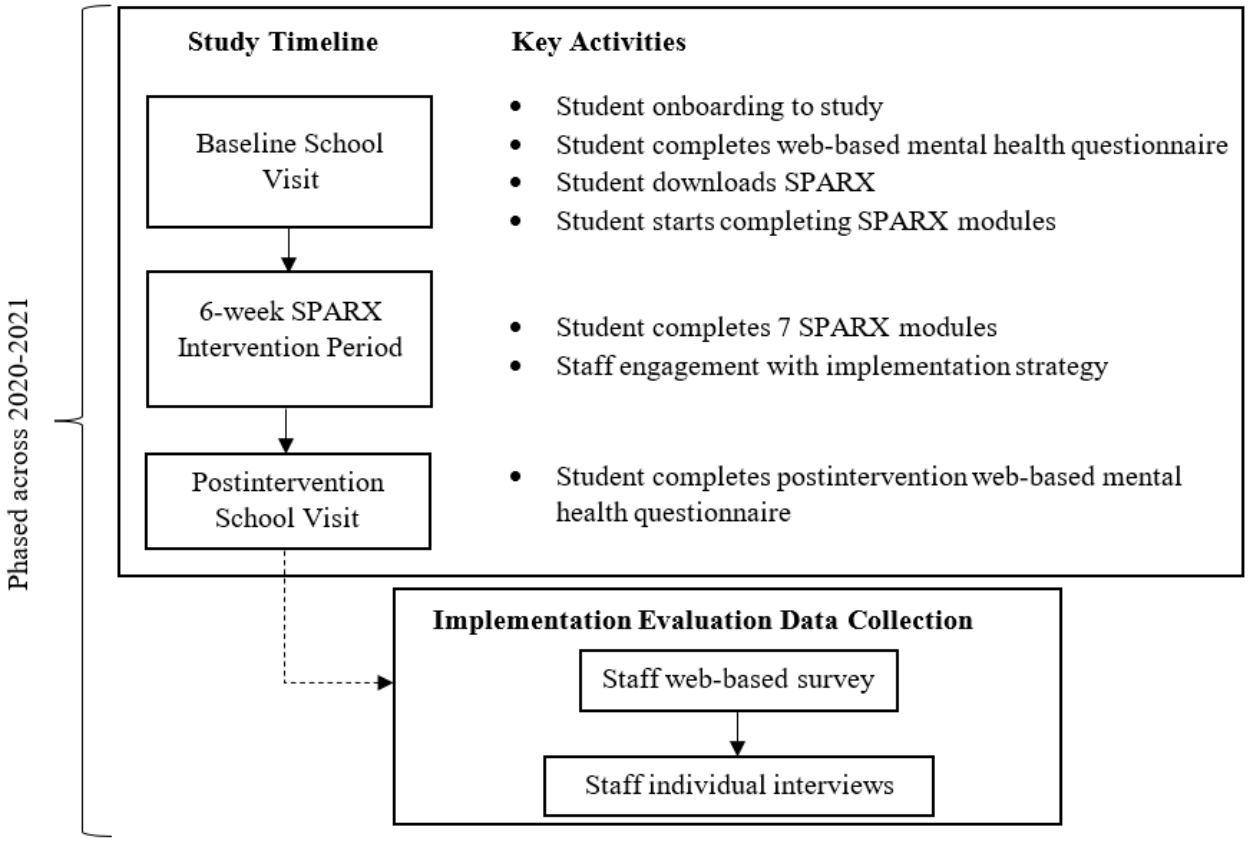
The Implementation Strategy

An implementation strategy targeting school staff was developed to assist during the 6-week active intervention phase. The strategy involved (1) establishment of study implementation teams in schools (typically incorporating a classroom teacher and school counselor), (2) allocation of a minimum of four 20-minute school class sessions for SPARX-R completion, (3) provision of information about SPARX-R to schools by the research team, (4) weekly reminders by the school implementation team for students to use SPARX-R, (5) dissemination of information about the trial and mental health tips to schools by the research team, and (6) weekly liaison between the school implementation team and the research team to troubleshoot problems. The strategy, and alignment with recommended implementation strategies adapted for school contexts [40,41], is outlined in Table S1 in Multimedia Appendix 1. These outcomes were tracked by the research team although not formally recorded by schools because of feasibility constraints.

School Visits

Participating schools allocated to the intervention arm of the trial completed a baseline school visit, 6-week intervention period, and a postintervention school visit (see Figure 1 for a simplified timeline). The baseline visit served to orient enrolled students and supporting staff to the trial and encourage buy-in by providing information about what they were being asked to do and why. This visit also involved a web-based self-report mental health questionnaire for students. In the remaining time, students were encouraged to complete the first SPARX-R app module. Students were then given 6 weeks to complete SPARX-R. One to two modules were intended to be completed each week; however, students had autonomy to complete the modules in their own way (eg, all at once). As part of the implementation strategy, schools were encouraged to schedule sessions during school hours for students to complete the modules; this was not always feasible, meaning that some students only completed modules in their own time. Schools then hosted a postintervention visit whereby students completed a follow-up web-based mental health questionnaire.

Figure 1. Study time line and flow of implementation evaluation data collection from school staff in the intervention arm of the trial. SPARX: Smart, Positive, Active, Realistic, X-factor thoughts.



Data Collection and Sampling

This paper focuses on qualitative short-answer and interview data provided by school staff. These data were collected in 2 cohorts occurring between October-December 2020 and April-May 2021 from intervention schools only after the postintervention school visit (see Figure 1 for timings). Data from quantitative self-report surveys (eg, demographic and employment characteristics such as age, gender, and role) and the publicly available Myschool database are used to characterize the staff sample. Myschool contains data on every school in Australia; of relevance to this study were location, sector, Index of Community Socioeconomic Advantage, number of teaching staff, and number of enrolled students.

On the basis of the CFIR and FPP logic model, we developed a semistructured individual interview guide for school staff. The guide assessed the influence of contextual factors on implementation, including individual characteristics and school leadership, as well as implementation outcomes, including appropriateness and acceptability of the intervention (see "School Staff Interview Guides" in Multimedia Appendix 1). The interviews lasted between 20 and 60 minutes and were audio recorded. The recording failed for 3 interviews; in these instances, the interviewer took written notes during and after the interviews.

Procedure

All school staff in the school implementation teams were invited via email to complete web-based surveys. After the provision of informed consent, web-based surveys were completed via Qualtrics [42]. Staff who completed the surveys were then invited to take part in optional interviews via phone or Zoom. As such, data were collected sequentially. Sequential methods enabled the research team to flexibly schedule interviews based on respondent availability, facilitating integration into their existing workflow and minimizing burden.

Ethics Approval

Ethics approval was provided by the University of New South Wales Human Research Ethics Committee (HC180836) and New South Wales Government State Education Research Applications Process (2019201). For the implementation evaluation, staff from participating schools were asked to provide active informed consent to participate. Collected data were deidentified. For compensation of their time, staff received Aus $20 for completing the interview and Aus $10 for completing the survey.

Data Preparation and Analysis

Descriptive summary statistics were calculated for quantitative data in SPSS (version 25; IBM Corp). Qualitative data were transcribed by 5 project personnel verbatim into Word (Microsoft Corp). Transcription was checked for accuracy by a second researcher who conducted all interviews. Four team members independently coded subsets of the data in pairs; all data were double coded. A benefit of having multiple coders is the capacity to deepen reflexive engagement with the data [43]. Coding discrepancies were discussed as part of the final thematic analysis.

Qualitative data were analyzed with NVivo 12 [44] using a modified form of Clarke and Braun's [45,46] 6-stage reflexive thematic analysis guidelines. Reflexive thematic analysis enables the identification, interpretation, and reporting of meaningful patterns within data [47] and is advantageous due to its flexibility and rigor [48,49]. The coding team independently immersed themselves in the transcripts during the familiarization phase (phase 1), and then generated codes and themes using an inductive and deductive approach (phases 2 and 3). The team debated which codes and subcodes from the CFIR best represented the discourse from staff and what constituted appropriate and useful definitions for these codes. Coding pairs then independently coded their assigned transcripts (11-12 each), routinely meeting to discuss codes and meanings. The team reviewed the codes (phase 4) by examining examples and discussing whether the codes provided sufficient, adequate, and accurate representations of staff discourse. Phase 5 involved defining and naming themes. The first author integrated and creatively rationalized the codes, forming a narrative of themes and subthemes that was presented to the coding team and larger academic advisory group for review. Phase 6 involved producing the report.

Rigor in Thematic Analysis

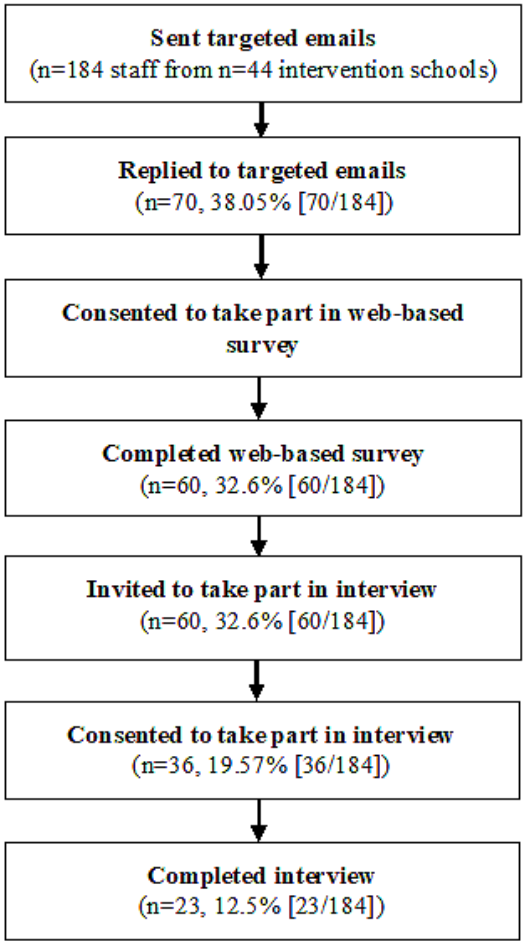
Rigor in thematic analysis was addressed by attending to established trustworthiness criteria [50,51]. Credibility was addressed by prolonged engagement with the subject matter, acknowledgment of the school context, and researcher triangulation. Transferability was addressed by providing thick descriptions (ie, situating experiences within a context) and documenting research steps. Dependability was addressed by describing and documenting each stage of the coding and theme development process. Reflexivity was addressed by engaging in regular team discussions, recursive engagement with the data, and acknowledgment of the teams' role in knowledge production and interpretation.

Results

Recruitment and Completion Rates

A total of 184 staff from 44 intervention schools were sent targeted emails inviting them to take part in the implementation evaluation. Of the 184 staff, 70 (38%) replied to the expression of interest. Of the 70 who expressed interest, 68 (97%) consented to take part in the web-based survey, and of the 68 who provided consent, 60 (88%) completed the survey. Completion was defined as finishing ≥80% of the survey questions. These staff were employed at 36 different schools, representing a total coverage rate of 82% (36/44). Some schools had multiple respondents. Of the 60 staff who completed the web-based surveys, 36 (60%) consented to take part in follow-up interviews, and of the 36 who consented, 23 (64%) completed the interview. These staff were employed at 20 different schools, representing a total coverage rate of 45% (20/44; Figure 2).

Figure 2. Absolute recruitment, consent, and completion rates for staff surveys and interviews.



Staff Characteristics

Of the staff who completed the interviews, 39% (9/23) of them identified as a key leader who helped to drive and deliver the FPP in their school and 61% (14/23) identified as assisting with the delivery of the FPP in their school. The sample was primarily female (16/22, 73%) with a mean age of 40.9 (SD 11.82, range 24-60) years. The primary employment role of respondents was related to psychology or counseling (ie, psychologist, counselor, guidance or well-being officer; 14/22, 64%), and most respondents were employed full time (16/22, 73%). Approximately 60% (14/23) of the interviewed staff were from schools from the 2020 cohort, whereas approximately 40% (9/23) were from the 2021 cohort. Cohorts were conceptually similar in terms of key individual (ie, gender, age, number of years worked, and current role) and school characteristics (ie, sector, location, Index of Community Socioeconomic Advantage; $P>.07$). The schools that provided data for the implementation evaluation were representative of the schools taking part in the broader randomized controlled trial. See Table 1 for additional sample details.

Table 1. Characteristics of the staff sample that completed the interview (N=23).[a]

Sample characteristics	Statistics
Age (years), mean (SD)	40.09 (11.82)
Gender, n (%)	
Female	16 (73)
Male	6 (27)
Aboriginal or Torres Strait Islander, n (%)	
Yes	1 (5)
No	21 (96)
Born in Australia, n (%)	
Yes	19 (86)
No	3 (14)
Highest level of education, n (%)	
Undergraduate degree	10 (46)
Postgraduate degree	12 (55)
Role in future proofing, n (%)	
Key leader who helped to drive and deliver the FPP[b]	9 (39)
Assisted with delivery	14 (61)
Employment role, n (%)	
Teacher or year adviser, head teacher	7 (31.8)
Psychologist, counselor, well-being officer, or guidance counselor	14 (64)
Principal or deputy	1 (5)
If counselor, only counselor in school, n (%)	
Yes	2 (18)
No	9 (82)
Total number of schools worked in, mean (SD)	8.36 (10)
Number of schools currently working in, mean (SD)	2.23 (3)
Number of years worked at current school, mean (SD)	6.64 (7)
Number of years worked in current role, mean (SD)	3.80 (3)
Employment status, n (%)	
Full-time	16 (73)
Part-time	6 (27)

[a]Cumulative percent reported. Characteristics from one respondent are missing due to user error.

[b]FPP: Future Proofing Program.

Qualitative Themes

Four superordinate themes captured important factors about barriers and facilitators to implementing a digital mental health program in schools: (1) right place at the right time, (2) innovative approach, (3) ways of working within schools, and (4) reflecting on past experiences to improve future implementation. See Table S2 in Multimedia Appendix 1 for mapping of themes onto CFIR domains and example quotes.

Right Place at the Right Time

Overview

This theme reflects that schools were perceived by staff as critical touch points that can identify and respond to the needs of students at a time when they need it most. Staff confirmed that supporting the mental health of students was part of their role and described that schools were an appropriate place to deliver digital mental health programs. The main benefit of using schools was increased access and reach to all students. However, a consistent message from staff was the need to balance implementation of new programs with feasibility. Some staff reported that mental health was not an actionable priority in schools because of a lack of time or resources. Others noted that individual capacity, which fluctuates across the school year, can limit availability to support non–curriculum-based programs. Overall, staff reported that many programs are constantly being implemented in schools and are vying for space in an already congested curriculum. Two subthemes expand on the complexities of digital mental health programs in schools, which are discussed below.

A Blessing and a Curse

Staff reported that the COVID-19 pandemic emphasized the need for targeted mental health support for young people but that it also complicated program implementation for some schools. Delivery of the FPP was often delayed because of social distancing restrictions, school closures, and staff time constraints. In total, 56 schools withdrew their participation after March 2020 when the COVID-19 pandemic arrived in Australia. To accommodate government guidelines and school preferences, the school visits were redeveloped to allow remote and face-to-face sessions. Remote delivery of school visits worked well when staff were organized and proactively engaged students; face-to-face visits worked well in larger classrooms with students who had varying levels of support needs. Flexibility was a relative advantage of the FPP.

Addressing a Gap in the Community

Staff from rural or regional areas reported that the availability of youth mental health services in the community was low and that the FPP addressed an unmet need. Staff consistently described that the FPP provided an age-appropriate screening service (for suicide risk) and an evidence-based psychological program that would otherwise not be available. However, there were tensions about how screening would affect counselors' capacity to support students and fulfill duty of care. Counselors worried that screening would identify at-risk students yet leave them with insufficient support options beyond the school.

Innovative Approach

Overview

Staff consistently intimated that the current reactive and piecemeal approach to student mental health in schools was not sufficient for a meaningful change. The FPP offered a new way of proactively identifying and addressing mental health needs in students, with no other programs like it offered in schools. Two subthemes exploring innovative features of the FPP were identified.

Screening

There was consensus that a universal preventative program with a screening component was appropriate for the needs of students and was compatible with the school context. Attitudes toward screening were generally positive, and clear advantages were noted for both staff and students. Counselors perceived that the confidential screening and risk alert system directly enhanced their ability to support students. The system enabled the identification of suicidal students who would have otherwise flown under the radar, enabling timely follow-up in a safe and secure setting.

Technology

Staff reported many benefits of using technology. The gamified app was perceived by staff as being more engaging for students than other school-based face-to-face programs. Leveraging students' own devices was described as a positive because it was personalized, facilitated disclosure, and potentially motivated students to participate. Perceived appropriateness varied. Staff voiced strong opinions that a gamified app and standardized web-based survey might not be a good fit for all students. Staff identified that young people who have higher mental health risk, attention or behavioral difficulties, and low literacy levels might be less able to engage than their peers. Language and cultural diversity were also identified as challenges. Further, there were tensions about increased reliance on technology for educational purposes in schools in general. Staff commented on how technology changed teaching methods as well as the nature of student-student and teacher-student interactions. Some staff expressed concern about increasing screen time in schools and misalignment with existing school "no-phone" policies. Others reported that, with leadership support, using phones for a specific and time-limited purpose was acceptable.

Ways of Working Within Schools

Overview

Staff described what worked well and what did not work well in their schools, providing insights into how digital programs could be integrated into existing systems. Three subthemes were identified that explored issues relating to planning, engaging, and executing.

School Buy-in and Staff Ownership

The school executive was consistently described as being the primary decision maker in whether a school took part in the trial; yet they provided little practical support to FPP implementation. Staff reflected that greater input from leadership would have facilitated greater school-wide buy-in and

ownership. Examples of input included formal recognition for staff involvement or allocation of time for planning and preparation. In addition to executive support, trust and reputation in the FPP provider was critical for buy-in among staff.

Bringing All the Right Players Onboard

There was staff consensus that involving the right people—those with the capacity, expertise, and interest or motivation to support student mental health—at the right time was essential for effective implementation. Internal (eg, values, interest, and altruism) and external motivations (eg, mandated role) to be involved in the trial were both prevalent, but the former was linked to higher engagement, commitment, and support in the long term. Individual capacity influenced who was best placed to be involved. Staff availability and competing demands often determined the amount of time they could dedicate to plan, engage, and execute the FPP. This was particularly the case for staff who described having to do extra work to engage parents and students. A consistent message from counselors was that, given their expertise and knowledge about other programs available in schools, they should have been critical decision makers for FPP adoption and central in planning and engagement. In practice, because of significant capacity issues in some schools, counselors were often not involved to this degree and had limited knowledge about the FPP and SPARX-R.

Communication and Support

The level of communication and practical support between staff varied across schools. Some staff reported a high level of quality communication and in-school support (eg, from the executive, head teachers, administrators, and counselors), describing a clear allocation of responsibilities and sharing of tasks. In these cases, communication and planning were generally organic and incorporated into routine meetings. Some staff reported having sole responsibility for supporting the FPP with minimal in-school support. Lack of communication and support was challenging in the context of already high workloads and pressing demands. For example, in some schools, counselors were not aware that a school visit had been planned until it began and they had to cancel standing appointments with students. Staff provided hypotheses for communication breakdowns including broader issues within school workplace culture and high staff turnover with a lack of handover.

School Visits and SPARX-R Sessions

School visits were generally described as being executed effectively. The level of support and quality of resources (eg, Wi-Fi and devices) provided by the research team were described as appropriate. Some staff described themselves as having an active and hands-on role in the school visits (eg, encouraging students to complete the survey and app modules, and managing behavior). The main difficulty for staff organizing the sessions was ensuring that the right students were in the room. Despite being encouraged in the trial protocol, few staff indicated that they scheduled separate school sessions dedicated to SPARX-R completion. The major barrier was extra resources needed for organization, planning, and execution (eg, time out of own schedule or curriculum).

Screening and Risk Alert System

Identifying high-risk students through screening increased demand on counselors when plans had not been established to manage caseloads. Counselors from some schools reported difficulty with following up students within a short time frame when more were identified than expected, no other counselors were available, or scheduling of FPP sessions did not align with their availability. In such cases, follow-up was described as reactive and often required counselors to cancel existing appointments to keep up with demand.

Reflecting on Past Experiences to Improve Future Implementation

Future Adoption

Reasons for future adoption focused on the benefits of the risk and referral process. Key benefits were related to the relative advantage of the FPP over other available programs for young people (eg, tech-based approach, tracking of mental health over time, facilitation of referrals, and normalization of the counseling service) and the tension for a change within schools to address mental health differently (eg, reactively vs proactively). However, there were barriers to future adoption. These barriers were related to individual capacity (eg, high workloads and limited availability), process factors (eg, poor communication or planning among staff members and disruptions to normal lessons), and innovation characteristics (eg, out of date gamification and graphics; note that SPARX was originally developed in 2012). The general sentiment among staff was that high student engagement is necessary to make the personal effort worthwhile. Maximum student sign on to the FPP (reach), and level of completion of the SPARX-R app (uptake) across the whole year was described as essential for school adoption. Many staff reported that student reach and SPARX-R engagement were lower than expected. The primary barriers for reach that staff identified were parent consent into the FPP and accessibility of technology and infrastructure in certain communities (eg, lower socioeconomic and rural or regional areas). Multiple hypotheses were raised for low parent consent, from poor communication of information to parents, parents being time-poor and having other higher priorities, mental health stigma, and low mental health literacy. Staff recognized that the limitations of consent are not a problem outside of research trials.

Ideal Implementation

Throughout their general reflections about how the FPP worked within schools, staff identified their “wish list” for ideal implementation. Integration into the school curriculum was consistently identified as necessary for buy-in and engagement because it has the potential to overcome barriers relating to resources, capacity, and coverage of students. Key facilitators for the implementation process identified by staff are presented in Table 2.

Table 2. Ideal facilitators for the implementation process of the Future Proofing Program (FPP).

Facilitators	FPP status[a]
Planning and engaging	
Reputable implementing institution and provision of high-quality resources	Provided
Active leadership support (including recognition of staff input) and school ownership	Encouraged
Counselors involved in decisions about FPP adoption and planning	Encouraged
In-school champion that engages staff and students	Encouraged
Engagement strategy for students and parents to encourage buy-in	Provided
Supportive school implementation team with clear responsibilities to share load	Encouraged
Dedicated staff time for planning and reviewing	Encouraged
Established community support for referrals of high-risk students that are outside the remit or resources of schools	Ideal
Executing	
Flexible delivery of FPP	Provided
Integration into school curriculum as an adjunct program	Ideal
Technology support from implementing institution	Provided
Adequate school-level resources (eg, rooms, Wi-Fi, and laptops)	Encouraged
Standardized risk follow-up and referral processes for counselors	Encouraged
Availability of counselors and provision of adequate time to respond to risk follow-ups	Encouraged
In-school reminders about SPARX[b] completion for students	Encouraged

[a]FPP status indicates whether the named facilitators were provided by the future proofing team, were encouraged by the future proofing team (and therefore adaptable based on school resourcing and preferences), or were outside of scope because of feasibility (and therefore ideal for future implementation).

[b]SPARX: Smart, Positive, Active, Realistic, X-factor thoughts.

Discussion

Principal Findings

This paper reports on the first implementation evaluation embedded into a school-based randomized controlled trial of a smartphone app depression prevention intervention. Four key superordinate themes were identified from qualitative responses provided by school staff involved in implementation delivery. Overall, the FPP added significant value to school approaches to mental health, offering vital resources that schools either did not have or were wanting to strengthen (right place at the right time). Staff agreed that an innovative approach was needed to support student mental health in schools and that a digital approach was generally appropriate within schools (innovative approach). Ease of execution reflected the amount and quality of planning staff engaged in, which was typically dependent on teamwork, communication, and individual capacity and motivation (ways of working within schools). Low student engagement and staffing availability were identified as critical barriers for future adoption and implementation (reflecting on past experiences). The identified themes highlight the importance of school organizational characteristics and staff characteristics in the implementation of digital mental health programs.

A critical point of disagreement in our results was capacity to respond to screening outcomes. Although there was tension for change in schools for new methods of identifying at-risk students and providing support in a timely manner, human resourcing was often a major barrier. Counselors from some schools also noted concerns about high identification rates in the absence of available community supports for referral. School counselors in Australia typically provide short-term reactive care rather than intensive tailored treatment programs for individual students [14,52]. Lack of available and appropriate referral options reflects a failure of the Australian youth mental health system [53] and leaves schools unsupported without the internal capacity to provide care. Our findings show that the implementation of mental health programs in schools, even when delivered digitally, requires careful planning and consideration of how schools intersect with the external health system.

Organizational Change in Schools

An implication of our findings is that school-based implementation of digital mental health programs requires some level of organizational change. Organizational change in schools is any alteration, improvement, or restructuring in the processes or contents of education [54]. There are many organizational change theories, with different assumptions about why, how, and when a change occurs [55]. One perspective suggests the value of a continuous change, that is, ongoing, small-scale change that is embedded in daily practice [56]. Interpersonal relationships, leadership, and continual refinement are essential

for this type of change in organizations [55]. The following sections will discuss these aspects of continuous change in schools in relation to the FPP.

Organizational Change in Schools: Interpersonal Relationships

Change at the school level requires change at the staff level. Prior research has shown that interpersonal process variables such as trust, social interaction, networking, communication, and knowledge sharing directly contribute to continuous change behavior in school teachers [55,56]. These findings align with this study. Working together, adequate communication about roles or tasks and sharing knowledge about the FPP were important for staff in the planning, engaging, and executing phases of implementation. These factors were particularly important for counselors. Some counselors were not ready or prepared to accommodate the new program, leading to significant disruptions to existing responsibilities and caseloads. Overall, working together to create new ways of doing things within the established school system was important to support implementation of the FPP.

Organizational Change in Schools: Leadership

The continuous change approach shifts leadership away from a top-level group (eg, the school executive) to every organizational member (eg, staff members involved in FPP implementation) [56]. This is not to say that the executive has no role; they are still integral in establishing a culture of change [55] and buy-in to the value system of an intervention. Our results showed that staff from most schools acknowledged that the executive and well-being units had cultivated, or were cultivating, a positive mental health culture and that the FPP aligned with this culture.

Distributing leadership practice across schools is needed to facilitate small-scale changes and make these changes a routine part of everyday work. Consistent with this conceptualization of leadership, our results showed the practical value of positioning counselors as critical decision makers in adoption, planning, and execution. Although these processes were encouraged in the FPP, interviews with school staff indicated that they were not put into practice in some schools despite willingness to do so (ie, nonadherence to the implementation strategy). Differences in school-level resourcing of counseling staff might in part explain the difficulties observed with engaging with the counseling unit. For example, counselors often work across multiple schools within a district and have limited availability in any one school. Involvement at critical decision points (eg, school-level adoption, when school visits will be held) may be necessary to ensure feasible involvement of counselors in future implementation efforts of digital mental health programs.

Organizational Change: Continual Refinement

A recent review of organizational change interventions in schools noted that many interventions fail to accomplish their purpose and result in a loss of valued resources [55]. Continuous change is dynamic, and even if change processes are operational, they often need to be refined and adapted to maintain their relevance within a system [55]. One implication, which was evident from staff perspectives about FPP, is that some level of flexibility in the implementation strategy may be necessary to help overcome challenges experienced during rollout of digital programs in schools. This was demonstrated by how schools complied with the strategy of scheduling in-school SPARX sessions to facilitate module completion. Although some staff were unable to do so because of limited staffing capacity and conflicts with other curriculum-based activities, other staff integrated SPARX completion into homeroom periods or scheduled specific SPARX sessions during class time. A flexible implementation strategy may be more feasible than a prescriptive strategy that does not allow adaptation. The need for local variation or tailoring of implementation processes is consistent with evaluations of other nondigital school-based physical activity and suicide prevention programs [31,34].

Practical Recommendations: Implementing Digital Programs in Schools

Available implementation strategies tailored to school contexts have primarily been developed for programs delivered in person and are not specific to digital mental health or scaled prevention programs [40,41]. Drawing from the themes identified in our evaluation and related work [25], we outline recommendations for implementing digital mental health programs at scale in schools. The function of these recommendations is to facilitate organizational change and to help schools to achieve their intended purpose of implementation.

The top evidence-informed recommendation is alignment with and integration into the national school curriculum (eg, health or physical education). Integration would consolidate support from leadership and other staff, therefore facilitating appropriate allocation of resources and coverage of students. Not only does integration into the curriculum overcome time and resourcing barriers but it also aligns with the idea that mental health is a core part of the education and socioemotional development that is fostered by schools. This approach is a core tenet of the Health Promoting Schools framework, a whole-school approach to promoting health that recognizes the link between health and education [57,58].

In the absence of curriculum integration, additional school-level resources are necessary to facilitate buy-in and engagement from all sectors of the school community. We have developed eight evidence-informed recommendations about strategies that school staff can use to support the implementation of adjunct digital programs in schools:

1. Establishment of a multidisciplinary internal implementation team with counselors as critical decision makers in program adoption and planning. It is important to consider both the persons (eg, motivations) and their position (eg, formal responsibilities and capacity) to bring the right players on board.
2. A structured, multipronged approach to communicating information about the program, with a specific component for counselors, to encourage buy-in and engagement. Focusing on core business outcomes (ie, learning) as well as the links between mental health and academic achievement can clearly showcase benefits for schools, staff, students, and their families. School implementation

teams may be best placed to communicate such information within schools.

3. Active internal leadership support for the program including allocation of resources (eg, in school time for planning, engaging, and executing), administration support (eg, to distribute reminders), and recognition of staff input and effort. In-school time for completing the program is essential; however, how this time is provided can be school dependent (eg, during roll call or homeroom and well-being days).
4. In-school champion or implementation lead that engages staff and students in the digital mental health program.
5. Formal meeting times held regularly between the implementing school staff to facilitate communication and review of implementation processes (using checklists to facilitate progress and accountability).
6. Prioritization of evidence-based programs that are engaging for students, with up-to-date graphics and gamification to ensure relative advantage over other programs in the marketplace.
7. Flexible program delivery to allow for adaptation to local contexts including area or region (metropolitan vs rural or regional, high vs low socioeconomic), school type (eg, public, independent, or catholic), or state or territory (eg, different policies and roles or availabilities of counselors). Flexibility is essential for scaled implementation across different types of schools.
8. Students use their own phone or laptop (or school-supplied devices if necessary) to complete the program.

Limitations

Hybrid type 1 implementation effectiveness trials evaluating digital programs in schools have a unique set of challenges. One challenge is differentiating between implementation factors relating to the trial and to the digital program. For example, trial consent processes and other components of data collection related to secondary trial aims likely affected engagement and uptake of the FPP with students. Future hybrid trials should document which factors are research-related and program-related to guide hypothesis testing. In a deviation from the implementation evaluation protocol, we did not formally collect data from intervention schools about adherence to the implementation strategy due to feasibility constraints. The FPP team gained ad hoc information via emails from implementing staff about planning and execution. The data may not have been of sufficient quality to ensure reliability. As a result, objective data from all intervention schools about adherence to the implementation strategy are lacking, and we cannot conclude which strategies were crucial to mobilize staff support and student uptake of SPARX-R. Qualitative inquiry found that implementation teams in some schools did not do what was specified or encouraged. This provides some indication that the strategies were not feasible for all schools, reinforcing the complexity of implementation in schools. Finally, the CFIR covers multiple perspectives. The current evaluation explored reports from a small sample of school staff. Different insights into implementation barriers and facilitators may have been raised by students, parents, education departments, or even community services linked in with schools.

Conclusions

Results from this study showed that interpersonal factors, leadership factors, and flexibility were important for implementing the FPP in schools (according to staff). We also found that implementing digital programs in schools requires significant planning and consideration of specific school environments. In line with our findings, we proposed a select set of recommendations for future implementation of digital prevention programs delivered at scale in schools. These recommendations might facilitate an organizational change and help schools to achieve their intended purpose of implementing digital mental health programs (eg, improved student support and mental health). These recommendations can also be applied beyond the mental health domain to support the scaled implementation of other digital programs in schools.

Acknowledgments

We would like to thank the school communities who participated in this study. This project was funded by a National Health and Medical Research Council (NHMRC) Project Grant awarded to HC (GNT1138405), a Ramsay Health Philanthropic Grant awarded to HC and AWS, an NHMRC Emerging Leader Fellowship awarded to AWS (GNT1197074), an NHMRC Emerging Leader II Fellowship awarded to ALC (GNT 1173146), an SPRF NHMRC Fellowship to HC (GNT 1155614), NHMRC Fellowship 1158707 to PJB, and an NHMRC Emerging Leader II Fellowship awarded to MT (GNT 2007731). RL was funded through the Financial Markets Foundation for Children. The funders had no role in any aspect of the study.

Data Availability

Data generated or analyzed during this study are not available because data are sensitive and sharing does not comply with ethical approvals.

Authors' Contributions

JRB and AWS conceptualized the study, with ongoing support from KMB, RL, ALC, PJB, MT, HC, IZ, and KM. JRB, LB, HF, AB, and MH conducted qualitative coding. JRB organized qualitative themes, interpreted results, and wrote the first draft of the manuscript, and AWS, RL, and KMB provided critical revisions. All authors contributed to and have approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
School Staff Interview Guides.
[DOCX File , 205 KB - pediatrics_v6i1e42349_app1.docx]

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
FPP: Future Proofing Program
SPARX: Smart, Positive, Active, Realistic, X-factor thoughts

Edited by S Badawy; submitted 01.09.22; peer-reviewed by L Martinengo, M van der Burgt; comments to author 15.02.23; revised version received 23.03.23; accepted 18.04.23; published 12.06.23.

Please cite as:
Beames JR, Werner-Seidler A, Hodgins M, Brown L, Fujimoto H, Bartholomew A, Maston K, Huckvale K, Zbukvic I, Torok M, Christensen H, Batterham PJ, Calear AL, Lingam R, Boydell KM
Implementing a Digital Depression Prevention Program in Australian Secondary Schools: Cross-Sectional Qualitative Study
JMIR Pediatr Parent 2023;6:e42349
URL: https://pediatrics.jmir.org/2023/1/e42349
doi:10.2196/42349
PMID:37307051

Exploring the Usability and Acceptability of a Well-Being App for Adolescents Living With Type 1 Diabetes: Qualitative Study

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Abstract

Background: Adolescents living with either type 1 diabetes (T1D) or type 2 diabetes (T2D) have an increased risk of psychological disorders due to the demands of managing a chronic illness and the challenges of adolescence. Psychological disorders during adolescence increase the risk of suboptimal glycemic outcomes and may lead to serious diabetes-related complications. Research shows that digital health interventions may increase access to psychological support for adolescents and improve physical and mental health outcomes for youth with diabetes. To our knowledge, there are no evidence-based, publicly available mental health apps with a focus on improving the psychological well-being of adolescents with diabetes.

Objective: This study aimed to explore the acceptability and usability of our evidence-based well-being app for New Zealand adolescents, *Whitu: 7 Ways in 7 Days* (*Whitu*), to allow us to further tailor it for youth with diabetes. We interviewed adolescents with T1D and T2D, their parents, and health care professionals to explore their views on the *Whitu* app and suggestions for tailoring the app for adolescent with diabetes. We also explored the cultural acceptability of the *Whitu* app for Māori and Pacific adolescents.

Methods: A total of 34 participants, comprising 13 adolescents aged 12-16 years (11 with T1D and 2 with T2D), 10 parents, and 11 health care professionals, were recruited from a specialist diabetes outpatient clinic and Facebook diabetes groups. Each participant attended one 1-hour focus group on Zoom, in person, or via phone. Researchers gathered general feedback on what makes an effective and engaging app for adolescents with diabetes, as well as specific feedback about *Whitu*. Transcribed audio recordings of the focus groups were analyzed using directed content analysis.

Results: Adolescents with T1D, their parents, and health care professionals found *Whitu* to be acceptable and usable. Adolescents with T1D and their parents signaled a preference for more diabetes-specific content. Health care professionals expressed less awareness and trust of digital health interventions and, as such, recommended that they be used with external support. Due to challenges in recruitment and retention, we were unable to include the views of adolescents with T2D in this qualitative study.

Conclusions: There appears to be sufficient openness to the use of an app such as *Whitu* for supporting the well-being of adolescents with T1D, albeit with modifications to make its content more diabetes specific. Based on this qualitative study, we have recently developed a diabetes-specific version of *Whitu* (called *LIFT: Thriving with Diabetes*). We are also planning a qualitative study to explore the views of youth with T2D and their perspectives on the new *LIFT* app, where we are using alternative research approaches to recruit and engage adolescents with T2D and their families.

(JMIR Pediatr Parent 2023;6:e52364) doi:10.2196/52364

KEYWORDS

well-being; digital health interventions; type 1 diabetes; diabetes; diabetic; adolescent; youth; adolescents; young people; parents; parent; mHealth; mobile health; app; apps; application; applications; acceptability; usability; interview; interviews; opinion; opinions; perception; perceptions; perspective; perspectives; acceptance

Introduction

Adolescents living with type 1 diabetes (T1D) and type 2 diabetes (T2D) are at higher risk of psychological disorders, including anxiety, depression and eating disorders, compared to their peers without diabetes [1,2]. Such psychological disorders can increase the risk of suboptimal glycemic outcomes [3] as well as diabetes-related complications and hospitalization [4]. Although not every adolescent living with diabetes experiencing psychological distress will be diagnosed with a psychological disorder, diabetes-related psychological distress

can still significantly impact their self-management and quality of life [4].

Due to factors such as time constraints and limited access to mental health services, routine psychological support is often not undertaken as part of diabetes care. Digital interventions may offer a solution for addressing this clinical gap. Research shows that digital interventions are acceptable to adolescents, cost-effective, and scalable and that they can reach populations that typically have low engagement with traditional services [5,6]. Some have even been found to be as effective as face-to-face psychological therapies [7]. However, a recent systematic review conducted by our team found limited evidence that digital interventions are effective for improving the psychological well-being of adolescents living with diabetes, highlighting the low quality of available evidence and small number of theoretically underpinned interventions [8].

Whitu: 7 Ways in 7 Days (*Whitu*) is a well-being app that contains seven modules to help young people (1) recognize and rate emotions, (2) learn relaxation and mindfulness, (3) practice self-compassion and (4) gratitude, (5) connect with others, (6) care for their physical health, and (7) engage in goal setting. The coping skills included in the app have all previously demonstrated efficacy for improving the well-being of young people (see our protocol paper for further information) [9]. It can be completed within a week or as desired. The app was co-designed and developed by our team together with Māori and Pacific researchers and a group of New Zealand adolescents and young adults. Previous studies with adolescents and young adults living without diabetes found that its use was associated with improved emotional and mental well-being, self-compassion, stress, sleep, depression, and anxiety at 4 weeks, with effects sustained at 3 months [10,11]. Given that *Whitu* might offer a viable solution for improving the well-being of adolescents with diabetes, this study aimed to explore the acceptability and usability of the current version of the app and to explore how it might need to be tailored for use with adolescents with T1D and T2D.

Methods

Study Design

A qualitative study was used. Study results are presented according to the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist [12] (see Checklist 1).

Ethical Considerations

Ethics approval for this study was granted by the Auckland Health Research Ethics Committee (AH21899) on February 23, 2021. All participant data were deidentified after the interviews and focus groups.

Study Participants and Recruitment

This study aimed to recruit 10 participants from each of the following groups: adolescents with T1D, adolescents with T2D, parents, and health care professionals. A total of 15 adolescents with T1D and 4 adolescents with T2D aged 12-16 years were recruited from 2 specialist pediatric diabetes clinics in Auckland, New Zealand, between April and August 2021. In addition, 3 adolescents with T1D were recruited via a Facebook advertisement. A total of 12 parents of adolescents with diabetes were recruited in clinic and 3 were recruited via a Facebook advertisement. A total of 12 health care professionals from 2 Auckland-based specialist diabetes teams were recruited via emails sent out by the first author.

Inclusion criteria for adolescents were being aged 12-16 and having been diagnosed with T1D or T2D more than 6 months ago. Exclusion criteria for adolescents included not being an English speaker or having a serious developmental or psychiatric disorder (eg, psychosis). Parents were eligible for inclusion if they were a parent of an adolescent diagnosed with T1D or T2D more than 6 months ago. Health care professionals were included if they provided care for adolescents with diabetes. During recruitment, 41 adolescents and their parents were approached to take part in the study. Of those, 38 agreed to take part in the study (24 adolescents and 15 parents) and 3 (parents) declined. Of the 20 health care professionals invited to participate via email, 11 agreed to take part in the study and 9 declined due to the lack of interest or time. Overall, 11 of the original 38 adolescents and parents were lost to follow-up, and 4 dropped out after signing informed consent. A total of 34 individuals participated in the focus groups (13 adolescents, 10 parents, and 11 health care professionals). Informed consent or assent (for adolescents aged <16 y) was obtained at recruitment, and participants were asked to fill out a baseline questionnaire regarding basic demographic information, as well as the length of diagnosis and insulin regimen for adolescents. Parents and adolescents completed consent or assent and baseline questionnaires in person at recruitment or on the web if recruited over Facebook. Health care professionals were sent a digital copy of the informed consent and baseline questionnaire.

Focus Groups and Interviews

A total of 9 focus groups, each with 2-4 participants and lasting 30-90 minutes, were conducted over the web using Zoom (Zoom Video Communications) videoconferencing or in person using a semistructured interview schedule. Interviews over Zoom or over the phone were conducted if participants were not able to take part in the focus groups due to scheduling constraints. Adolescents with diabetes, their parents, and health care professionals participated in separate focus groups. Adolescents and their parents did not participate together. One week before the focus groups or interviews, participants received a link to download the *Whitu* app with instructions to familiarize themselves with the app before attending the focus groups or interviews. In the focus groups, the facilitators showed screenshots of each of the modules to remind the participants of the module content. Each focus group was facilitated by 2 of the following researchers: KG (female European health psychology student), Anna Boggiss (female European health psychology PhD candidate), DL (male Asian health psychology student), and Kalolaine Finaulahi (female Tongan psychology student). Six individual interviews were conducted by KG. There was no established relationship with the participants prior to study commencement. During the focus groups and interviews, participants were also asked about previous use of digital interventions. *Whitu* modules were shown to participants, and feedback on the current content, look, and feel of the app

and possible diabetes-related improvements to the app was obtained. Upon completion, participants were thanked for their time and provided a gift voucher worth NZ $40 (~US $25). Audiotaped recordings were then transcribed by the first author.

Qualitative Analysis

Transcripts were analyzed by 2 members of the research team (KG and HT) in NVivo (Lumivero) using directed content analysis, an approach where data exploration is guided by an existing framework or theory [13]. The qualitative analysis was informed by user engagement frameworks, including the Engagement, Functionality, Aesthetics, and Information domains from the user version of the Mobile Application Rating Scale [14], and used a largely deductive approach. The researchers began by independently coding the data, then forming categories, and lastly identifying descriptive themes. Any coding discrepancies were resolved by discussion with a third member of the research team (AS).

Results

Participant Demographics

Characteristics of the study participants can be seen in Tables 1-3 below.

Table . Demographic characteristics of the adolescents (n=13)

Characteristics		Type 1 diabetes (n=11, 85%)	Type 2 diabetes (n=2, 15%)	All adolescents (n=13)
Age (y), mean (SD)		13.6 (1.2)	12.5 (0.5)	13.4 (1.9)
Sex, n (%)				
	Female	8 (72)	1 (50)	9 (69)
	Male	3 (27)	1 (50)	4 (31)
Race and ethnicity, n (%)				
	New Zealand European	10 (91)	0 (0)	10 (77)
	Māori	1 (9)	0 (0)	1 (8)
	Pacific	2 (18)	2 (100)	4 (31)
	Chinese	1 (9)	0 (0)	1 (8)
	Other	1 (9)	0 (0)	1 (8)
Length of diabetes (y), mean (SD)		5.9 (3.52)	1 (0.5)	5.1 (3.68)
Insulin regimen				
	Insulin pump, n (%)	5 (46)	0 (0)	5 (38)
	Insulin injections, n (%)	5 (46)	0 (0)	5 (38)
	Medications	NovoRapid and Lantus	Lantus, NovoRapid, and Metformin	N/A[a]
Comorbidities, n (%)		4 (37)	1 (50)	5 (38)
	Asthma	2 (18)	0 (0)	2 (15)
	Celiac disease	1 (9)	0 (0)	1 (8)
	Graves disease	1 (9)	0 (0)	1 (8)
	High blood pressure	0 (0)	1 (50)	1 (8)

[a]N/A: not applicable.

Table . Demographic characteristics of the parents.

Characteristics		Parents (n=10)
Age (y) mean (SD)		47.4 (5.6)
Sex, n (%)		
	Female	8 (80)
	Male	2 (20)
Race and ethnicity, n (%)		
	New Zealand European	8 (80)
	Māori	1 (10)
	Pacific	1 (10)
	Chinese	1 (10)
Child's type of diabetes, n (%)		
	Type 1	9 (90)
	Type 2	1 (10)
Reported length of child's diabetes (y), mean (SD)		4.8 (2.71)
Reported insulin regimen		
	Insulin pump (children with type 1 diabetes; n=9), n (%)	4 (44)
	Insulin injections (children with type 1 diabetes; n=9), n (%)	5 (56)
	Medications	NovoRapid and Lantus
Reported comorbidities experienced by their children, n (%)		4 (40)

Table . Demographic characteristics of health care professionals.

Characteristics		Health care professionals (n=11)
Age (y), mean (SD)		43.9 (12.5)
Sex, n (%)		
	Female	10 (91)
	Male	1 (9)
Race and ethnicity, n (%)		
	New Zealand European	4 (36)
	Māori	2 (18)
	Pacific	3 (27)
	Chinese	1 (9)
	Indian	1 (9)
	Other	2 (18)
Occupation, n (%)		
	Diabetes nurse specialist	5 (46)
	Health psychologist	2 (18)
	Intern psychologist	1 (9)
	Community coordinator	1 (9)
	Dietitian	1 (9)
	Dietitian's assistant	1 (9)
Years of experience, mean (SD)		12.9 (11.3)

Qualitative Findings

Adolescents

Three main descriptive themes were identified from adolescents: (1) limited use of well-being–related digital interventions, (2) general acceptability of *Whitu*, and (3) a desire for more diabetes-related content to be included in the app.

Theme 1: Limited Use of Well-Being–Related Digital Interventions

Young people reported limited use of digital mental health interventions and reported mostly using digital tools (eg, apps) to improve their physical health and manage their diabetes (6/13, 46%). The most commonly used apps were the Freestyle Libre and xDrip+ apps to manage blood glucose levels. A smaller number (3/13, 23%) used Fitbit and other exercise apps for fitness. Only a few (2/13, 15%) adolescents said they had ever used well-being apps such as Calm and Headspace to help with relaxation and sleep. Those who reported using digital interventions to manage their physical health (6/13, 46%) noted that they were useful for managing their diabetes, fitness, or general health. Most adolescents (11/13, 85%) were open to recommending well-being apps to their friends.

> *I would. To keep me on track of like, just my mental health, to keep on top of it. And like, see where I need to improve myself. [Female adolescent, aged 15 years with T1D]*

However, a few adolescents (3/13, 23%) admitted that they would feel apprehensive about how peers might perceive them. When asked if they would consider using a diabetes-related well-being app, most adolescents (11/13, 85%) agreed that they would be open to using one to improve their diabetes, better manage diabetes-related stressors, and improve their mental health.

Theme 2: General Acceptability of Whitu

Most adolescents (11/13, 85%) liked the look and feel of *Whitu*. Many (10/13, 77%) enjoyed the colors and graphics used in the app, and some (5/13, 38%) noted that they thought the interface was easy to use and relaxing.

> *Yes. I like how it's quite easy to follow and it's got nice neutral colours, nice like relaxing colours. [Male adolescent, aged 15 years with T1D]*

One participant commented on the animated characters being too childish. Participants also provided feedback on ways to change the look and feel by adding more gamification or adding flowers to the *puriri* tree (the tree in the *Whitu* app that grows with each completed module). In terms of usability, most (11/13, 85%) found it easy to navigate and got used to the app quickly. One participant preferred having subtitles in the videos rather than having to play them out loud. Two adolescents said they did not like some of the videos as they were too long and became bored after watching them. Overall, adolescents liked the content of *Whitu* and found the modules and exercises useful and interesting. Some modules were more popular, with module 1 (Feel) being the most liked module and module 7 (Goal Setting) being the least liked. Regarding cultural acceptability, adolescents liked how it was linked to New Zealand and included *te reo Māori* (the Indigenous language of New Zealand). The *karanga* (traditional Māori call of welcome) at the start of the app was a highlight, and 1 participant highlighted that this made the app stand out to her.

> *Yeah, I think it makes it unique and stand out from other apps, I enjoyed that part. [Female adolescent, aged 13 years with T1D]*

Theme 3: Desire for More Diabetes-Related Content

When asked how *Whitu* could be adapted to diabetes, most (11/13, 85%) adolescents wanted to combine diabetes management tools with well-being tools. Suggestions for possible additional content included a blood glucose tracker, dietary education focusing on carb counting, and reminders to take insulin. Many participants (9/13, 69%) also supported using the app to form connections with peers with T1D who might understand their situation and challenges.

> *I think, like being able to chat to people would be quite good because then like, you can kind of relate to things and because like the camps and things those are only like an annual thing, and you don't get to see those people quite often. [Female adolescent, aged 12 years with T1D]*

Some participants (6/13, 46%) found aspects of *Whitu* such as the badges a bit childish and suggested that it would be better to have age-specific content. Others (5/13, 38%) suggested including videos of teenagers sharing well-being or diabetes stories. A few participants (2/13, 15%) suggested that *Whitu* could include more specific information on mental health problems, such as information about self-harm.

Parents

The four main descriptive themes identified from parents were (1) support for the use of a well-being app, (2) general acceptability of *Whitu*, (3) similar desire for more diabetes-related content, and (4) recommendations for parental involvement and support.

Theme 1: Support for the Use of a Well-Being App

Overall, most parents (8/10, 80%) were in favor of using a well-being app to help their children. Some parents (6/10, 60%) said they would find an app that combined diabetes management and well-being improvement highly useful. Parents reported that their kids were not using many well-being apps, if at all. However, parents expressed being willing to recommend apps to their children if they believed the apps could help their child.

> *Yeah, anything like that's going to help them. Yeah, I would definitely encourage for sure. [Male parent of an adolescent with T1D]*

Theme 2: General Acceptability of Whitu

Whitu was found to be acceptable by most parents (8/10, 80%). The app was thought to be relevant and include beneficial coping skills. One parent even described how the app had helped them and their child work through an incident at school by using the traffic light system to rate their feelings.

> *We found that a really good timing and that something had happened at school that day so, especially that feelings one was a really good way of getting him to talk about what had happened. [Female parent of an adolescent with T1D]*

Other parents (4/10, 40%) said that the Relax module would be helpful to ease their child's stress or anxiety. Parents also liked the look and feel of the app and praised the designs and colors used (6/10, 60%). Parents found the lack of subtitles on the videos inconvenient, whereas another parent commented that the app felt too stiff. Parents also reported that module 7 (Goal Setting) was repetitive and not sufficiently engaging.

Theme 3: Similar Desire for More Diabetes-Related Content

Similar to the adolescents, parents reported wanting more diabetes-related examples and information in the *Whitu* modules (8/10, 80%). Some parents (3/10, 30%) suggested adding information about diabetes management, including carb counting and ways to manage or track blood glucose levels. Parents also wanted to see diabetes-related examples of well-being integrated into the modules. One parent suggested that this could be done in the Be Kind to Yourself module, where self-compassion could be tied back to the challenges of diabetes management and not always having "perfect numbers" (ie, optimal hemoglobin A_{1c}).

> *Just making kids realise that they're not failing if they don't quite get it right. It's quite important and she used to get a bit nervous going in to see the doctor because she thought, oh, what if my numbers are high and she's a bit of a perfectionist. [Female parent of an adolescent with T1D]*

Alongside this suggestion, parents recommended the addition of encouraging phrases throughout the app and suggested there should be some way to connect teens with T1D together via the app for peer support. Suggestions to achieve the latter included web-based forums, chat functions, and diabetes groups.

Theme 4: Recommendations for Parental Involvement and Support

Parents noted that there was room for parental involvement in *Whitu*. Some were skeptical that their child would use the app on their own without encouragement.

> *I actually think some of it might still be good with parental involvement, I don't know how much my child would use it on their own without parents sort of instigating it. [Female parent of an adolescent with T1D]*

Others wanted the option to oversee their child's activities on the app to facilitate conversation about areas with which they may be struggling.

Health Care Professionals

Three main themes were identified from health care professionals: (1) limited awareness of well-being–related digital interventions, (2) variable responses to *Whitu*, and (3) some desire for clinician involvement or control.

Theme 1: Limited Awareness of Well-Being–Related Digital Interventions

Overall, health care professionals expressed more interest in improving their patients' diabetes management (blood glucose tracking and diet) than their well-being via the use of digital interventions.

> *Yeah, I think the more generic, the better and then the benefits will flow out into their diabetes management. [Female diabetes nurse specialist]*

Most (7/11, 64%) were unfamiliar with well-being–related and other mental health apps, expressing significant concerns about whether they would be adequate for supporting adolescents with active mental health problems. Their primary interest in well-being apps was to support the identification of "high risk" patients and timely referral for face-to-face support via the in-team psychologist and external mental health services.

Theme 2: Variable Responses to Whitu

Most health care professionals (8/11, 73%) spoke positively about the design and layout of *Whitu*, and many (7/11, 73%) were positive about its content. They noted that *Whitu* could increase young people's exposure to well-being concepts, and some acknowledged the value of guided modules for learning skills such as deep breathing to aid relaxation.

> *It introduces young people who might never be exposed to the possibility of doing these things, to an option where they might try it when they're on their own in their own bedroom. [Female diabetes nurse specialist]*

Some health care professionals (5/11, 45%) were more critical about *Whitu*, especially regarding the content of the Look After Your Body module, which they thought might contradict some of the dietary advice provided to adolescents with diabetes. The Goal Setting module was also questioned as potentially being too complicated for patients to manage. Most health care professionals (8/11, 73%) misunderstood the short-term educative nature of *Whitu* (ie, to learn a suite of new skills within a week, then continue practicing preferred skills as needed) and expressed concerns about whether it would hold users' attention on a long-term basis and be able to longitudinally track users' progress. Finally, health care professionals (5/11, 45%) also raised concerns about discussing coping strategies without acknowledging the barriers brought on by social determinants of health and health inequities for many families living with diabetes.

> *We make a lot of assumption that we all know this, so we're all going to talk about this, but they don't have pots and pans to cook a healthy meal. [Female diabetes nurse specialist]*

Theme 3: Some Desire for Clinician Involvement or Control

Health care professionals expressed some desire for involvement or control in the app. One participant suggested providing face-to-face therapy alongside some *Whitu* modules. In particular, they explained that the Look After Your Body and Goal Setting modules might be more effective if tailored to

patients' diabetes-related needs and expectations by their diabetes team.

> *In terms of what I would use with my patients I would use the first five and it could work really well, alongside delivering therapy. So, you could do the same with this, but I am really worried about the look after your body and the goal setting. [Female health psychologist]*

Discussion

Principal Findings

Qualitative data from adolescents, parents, and health care professionals revealed important insights into perceptions of *Whitu*, and overlapping themes were identified between the 3 groups. Overall, there was sufficient acceptability of an app such as *Whitu* for supporting the well-being of adolescents with T1D. However, some modifications to the current version are required to ensure it is fit for purpose for this audience. Despite efforts to recruit and interview adolescents with T2D, insufficient data were obtained from adolescents with T2D to understand their perspectives. Further work needs to be done to improve the recruitment of this cohort.

Our finding that adolescents in this study had limited prior use of well-being apps is in line with previous research, which found that despite a quarter of adolescents being open to the idea of using mobile health (mHealth) apps, only 7.3% had ever actually used one [15]. It is likely that non–health-related technologies such as games and music are more commonly used to manage mood and stress [16]. However, this does not detract from the appeal of digital technology for digital natives, and therefore, it is encouraging that most participants were supportive of *Whitu* being adapted to be more useful for adolescents with diabetes.

The acceptability of *Whitu* by adolescents with T1D and their parents is in line with its acceptability by participants in previous studies of *Whitu* among young people without T1D [9,10]. It also aligns with previous research findings that clean, symmetrical, and creative apps are associated with better perceptions of app quality [17]. Adolescents and parents also enjoyed the content of *Whitu* and found the modules and exercises helpful and relevant. These findings echo previous qualitative studies where adolescents expressed their desire for mHealth apps to include resources relevant to their needs [16]. Although general well-being information was appreciated by adolescents, more diabetes-related content was also requested by all of them. This combination of views is consistent with previous findings that adolescents with diabetes prefer face-to-face and digital psychosocial interventions to include tailored, diabetes-specific content [18-20] and that adolescents without diabetes want well-being apps to be relevant and based on their specific needs [16]. It was reassuring to see that *Whitu* was perceived as culturally acceptable by adolescents in this study. They expressed their enjoyment of the *karanga* and the fact that the app was congruent with Māori culture and Māori models of mental health and well-being. These results highlight the importance of co-design to build tools that align with the culture and values of the app users.

Adolescents and parents expressed a preference for *Whitu* to help connect adolescents with peers who also live with diabetes. Several qualitative studies have found similar findings, where adolescents have reported that connecting with their peers was an integral part of psychosocial interventions for youth with diabetes [18,19]. This is supported by other studies in digital health where adolescents with diabetes prefer to have some form of social connection in mHealth apps [21]. Although the current version of *Whitu* has not been designed to be externally supported by parents or clinicians, it is interesting to note the findings of recent studies that peer and professional support may increase user engagement with health and well-being apps [22]. It may be that this is of greater relevance for adolescents with T1D who are more used to receiving health support than those without diabetes.

Health care professionals displayed limited familiarity with digital mental health interventions and a greater focus on the identification and management of mental health problems than the preservation or improvement of patient well-being. Given that technology including diabetes pumps and glucose-tracking apps are commonly used these days [23], this may be more a reflection of their limited familiarity with contemporary well-being interventions [24] and anxiety regarding the management of mental health problems during busy medical clinics, rather than their status as "digital immigrants" or the lack of interest in holistic patient care. Given the importance of health care professionals in the implementation of digital interventions and that digital mental health tools in diabetes should support and augment existing psychosocial support, it is essential that further iterations of *Whitu* are closely developed with this group to ensure their acceptability and feasibility within clinical settings. Formal implementation research may also need to be undertaken to maximize the impact of a diabetes-specific version of *Whitu*.

The main strength of this study was the inclusion of multiple perspectives from adolescents living with T1D, parents, and health care professionals, enabling us to gain a rich understanding of how *Whitu* might be adapted to meet the needs of this patient population.

In contrast, a limitation of this study was that we were unable to recruit any endocrinologists to explore their views of the *Whitu* app. This is somewhat mitigated by the fact that the research team includes 2 pediatric endocrinologists; however, endocrinologists represent an important stakeholder group, and their input and support of any future apps is integral to the success and implementation of well-being apps as part of diabetes care. Another limitation was our difficulty in recruiting adolescents with T2D (n=2) and their parents (n=1), which is also an issue faced by previous researchers [25]. As a result, current findings cannot be generalized to those with T2D. Given the high rate of T2D among Māori and Pacific adolescents and the lack of interventions developed for this group [8], this is an urgent gap to address in the literature. Future research in New Zealand should aim to use *Kaupapa Māori* research approaches (Māori research paradigm) that are led or coled by Māori researchers, which have shown to be highly effective for building relationships, engaging and retaining participants, and prioritizing Māori worldviews [26,27]. Other strategies to

increase participant recruitment include using more culturally appropriate recruitment strategies, for example, recruiting through schools with a high percentage of Māori and Pacific students or via Māori and Pacific community groups. Cultural and language support for focus groups and greater use of face-to-face interviews may also yield more useful results. Lastly, future research should also offer adolescents with diabetes the opportunity to have individual interviews, as they may prefer to discuss potentially sensitive topics privately, without their peers present.

Based on the findings from this qualitative study, we have recently adapted *Whitu* to be a diabetes-specific well-being app called *LIFT: Thriving with Diabetes*. We are currently conducting a feasibility study of *LIFT* among youth with T1D and their parents. The adapted version contains the original 7 modules; however, they have all been tailored to be specific to diabetes. We have also added additional content to allow parents to better support adolescents and to improve parental well-being. Importantly, we are also planning a subsequent qualitative study to explore whether the newly adapted *LIFT* well-being app is engaging and useful for youth with T2D. This would allow us to explore whether *LIFT* needs to be further tailored for T2D.

Conclusion

With diabetes-specific modifications, *LIFT* (the newly adapted version of *Whitu*) may be an acceptable digital intervention for improving the well-being of adolescents with T1D. Continued collaborative development of the app with adolescents with T2D, parents, and clinicians will be important to ensure its utility, uptake, and use in clinical care.

Acknowledgments

We thank the study participants for their valuable feedback. This qualitative study was a master's project and was not externally funded. The original Whitu well-being app was funded by the Auckland Medical Research Foundation (grant 1720008), New Zealand. The feasibility study of the newly adapted LIFT well-being app is being funded by the Juvenile Diabetes Research Foundation (grant 3-SRA-2023-1279-M-B). CJ is the recipient of a New Zealand Health Research Council (HRC) clinical practitioner research fellowship (20/026). The intellectual property of the app is owned by the University of Auckland and is not for profit. We thank the adolescents, their families, and the health care professionals who participated in the study. We also thank Anna Boggiss and Kalolaine Finaulahi for helping to facilitate the focus groups.

Authors' Contributions

The study was conceptualized by AS and HT. Participant recruitment was undertaken by KG with assistance from PH and CJ. Data collection was undertaken by KG. Data analysis was undertaken by KG, AS, and HT. The paper was written by KG; edited by DL, AS, and HT; and reviewed by all authors.

Conflicts of Interest

AS and HT are codevelopers of the *Whitu* app.

Checklist 1
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[PDF File, 120 KB - pediatrics_v6i1e52364_app1.pdf]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
mHealth: mobile health
T1D: type 1 diabetes
T2D: type 2 diabetes
Whitu: Whitu: 7 Ways in 7 Days

Edited by S Badawy; submitted 31.08.23; peer-reviewed by K Crosby, L Jesus, W Hansen; revised version received 01.11.23; accepted 03.11.23; published 22.12.23.

Please cite as:
Garner K, Thabrew H, Lim D, Hofman P, Jefferies C, Serlachius A
Exploring the Usability and Acceptability of a Well-Being App for Adolescents Living With Type 1 Diabetes: Qualitative Study
JMIR Pediatr Parent 2023;6:e52364
URL: https://pediatrics.jmir.org/2023/1/e52364
doi:10.2196/52364

Evaluation of Study Engagement With an mHealth Intervention (THR1VE) to Treat Diabetes Distress in Teens With Type 1 Diabetes: Randomized Clinical Trial

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Abstract

Background: Positive psychology interventions demonstrate improvements in diabetes self-management and quality of life among adults with chronic health conditions, but few interventions for adolescents use this approach.

Objective: This study describes engagement with a positive psychology intervention delivered via automated SMS text messages aimed at treating diabetes distress and improving diabetes outcomes. In addition, demographic and clinical predictors of intervention engagement were examined.

Methods: Adolescents with type 1 diabetes (ages 13-17 years) who reported at least moderate diabetes distress were randomized to receive either the education or positive affect + education intervention, comprising 8 weeks of automated SMS text messages. Engagement was assessed as the response to the SMS text messages. Adolescents completed satisfaction surveys 3 months post intervention, and a subset of participants from both intervention groups completed exit interviews.

Results: Adolescents in both groups reported high levels of satisfaction with the study, with 95% (163/172) reporting that they would participate again. Engagement with the SMS text messages was high; on average, adolescents in the positive affect + education group responded to 92.5% of intervention messages, and their caregivers responded to 88.5% of messages. There were no significant differences in rates of engagement related to adolescents' sex, age, device use, or race/ethnicity.

Conclusions: A positive psychology intervention for adolescents delivered via automated SMS text messages was feasible and acceptable across genders, ages, and racial/ethnic groups, suggesting potential for wider dissemination.

Trial Registration: ClinicalTrials.gov NCT03845465; https://clinicaltrials.gov/study/NCT03845465

(JMIR Pediatr Parent 2023;6:e47089) doi:10.2196/47089

KEYWORDS

type 1 diabetes mellitus; positive psychology; adolescents; parental positive messaging; mHealth; engagement; diabetes; distress; teens; chronic health conditions; sex; age; device; race; ethnicity; text; mobile health

Introduction

Many adolescents with type 1 diabetes (T1D) experience high rates of diabetes distress, or the emotional burden of living with diabetes [1], and struggle with diabetes management; in a national sample, only 17% of youth ages 13-17 years were meeting glycemic targets [2]. Interventions targeting family processes and adolescents' coping skills have demonstrated modest effects [3-5]. Recently, behavioral interventions have focused on promoting resilience in youth with T1D [6], reinforcing adolescents' diabetes-related strengths [7], and promoting positive parent-child communication around diabetes management behaviors [6,8] to improve psychosocial and glycemic outcomes. A positive psychology approach, focused on inducing positive affect, is an innovative way to improve outcomes among this high-risk population.

While positive psychology interventions have successfully improved adherence and self-efficacy among adults with chronic health conditions [9], few studies have evaluated this approach in adolescents, and the studies with adults used phone calls to deliver the intervention. The THR1VE intervention used evidence-based components [10] to induce positive affect among adolescents, including self-affirmation, gratitude, and positive parent messages, based on the broaden-and-build hypothesis that increasing positive affect improves people's capacity to cope with stress in adaptive ways [11]. Given established associations between coping and psychosocial outcomes [12], the THR1VE intervention is based on the premise that increasing positive affect will reduce adolescents' diabetes distress and

improve glycemic outcomes. In addition, THR1VE included a caregiver component (providing positive messages) because adolescents' perceptions that parents blame them for glucose levels and worry too much about complications contribute to their diabetes distress [13]. Because this positive psychology approach is relatively novel for adolescents, it is important to evaluate engagement and satisfaction in this age group, and to determine whether SMS text messaging is a feasible method of inducing positive affect.

This study builds on pilot work demonstrating the feasibility and acceptability of a brief positive psychology intervention for adolescents with T1D [14] by expanding the study to two sites and delivering the intervention remotely via Zoom sessions and automated SMS text messages. The intervention is aimed at reducing diabetes distress and improving glycemic outcomes among adolescents with T1D. In the current analyses, we describe the feasibility of intervention delivery, participant satisfaction and experience with the study, and the rates of engagement with the SMS text messaging intervention (response rate to automated SMS text messages), and examine demographic (age, gender, and site) and clinical predictors (baseline hemoglobin A_{1c} and use of diabetes devices) of engagement. In addition, we explore adolescents' and caregivers' experiences participating in the study and their feedback about the intervention. These findings have implications for adapting similar interventions for other pediatric populations.

Methods

Ethics Approval

This study was approved by the Vanderbilt Institutional Review Board (IRB# 191245).

Procedures

This study was a randomized clinical trial (NCT03845465), and details of the protocol are described elsewhere [15,16]. Adolescents were eligible if they were aged 13-17 years, diagnosed with T1D for at least 12 months, had a cellular phone, and reported at least moderate diabetes distress, with a score of ≥34 on the Problem Areas in Diabetes–Teen Version (PAID-T). A score of ≥34 was chosen to screen for adolescents with an indication of moderate diabetes distress while allowing for a higher positive rate to meet recruitment and enrollment goals. Data collection occurred at baseline, 3 months, 6 months, and 12 months corresponding with diabetes clinic visits. After completing baseline measures, adolescents were randomized to receive either the education or positive affect + education (PA + EDU) intervention. Adolescents in the PA + EDU group received SMS text messages 5 days per week for 8 weeks after enrollment. These messages included self-affirmation messages, gratitude messages, and "mood booster" messages, and every 14 days they received a small gift (US $5 Amazon e-gift card code). Mood booster messages were selected based on ratings by 40 adolescents with T1D of inspirational quotes and jokes, and we created separate pools of mood booster messages for younger (ages 13-14 years) or older (ages 15-17 years) adolescents. Caregivers of adolescents in the PA + EDU group received messages once per week, reminding them to praise their child and asking them to reply yes or no if they gave their child a positive message that week. The SMS text messages were tailored to be sent at each adolescent's and caregiver's preferred time, and the start of each exchange asked the participant to "reply to this message with any text." Each week, a research assistant reviewed participants' responses to messages sent the previous week to identify and address system or user problems. If a participant did not respond to any messages within their first week of the intervention, a research assistant reached out to the participant to confirm they had received messages the past week and troubleshoot as needed (eg, participant thought the message was spam or the incorrect phone number was entered into REDCap).

As a measure of intervention acceptability, we examined engagement with the SMS text messaging intervention. We defined engagement as any response to the first message in the exchange. We also explored differences in engagement related to participant demographics.

Measures and Data Collection

As part of the survey administered at the 3-month data collection time point, adolescents completed a brief evaluation survey asking how helpful they found the program (1=not helpful, 2=a little helpful, 3=somewhat helpful, 4=pretty helpful, 5=very helpful). They were also asked if they would recommend THR1VE to their friends, if they would participate again, and if the time spent on the study was worth their time. We considered the intervention acceptable if at least 50% of adolescents provided positive ratings of their perceptions of the intervention. A positive rating was indicated by answering that they found the program at least "somewhat helpful" and responding "yes" to questions about if they would recommend the program, if it was worth their time, and if they would participate again. Finally, they were asked which educational topics were most and least helpful to them.

In addition, we conducted brief qualitative interviews via Zoom (Zoom Video Communications) using purposive sampling (with respect to age, gender, race and ethnicity, site, and diabetes device use). Interviews were optional, and participants who completed them received an additional US $10 gift card. Interviews were recorded and transcribed. Qualitative data were analyzed using a content analysis method [17]. Two trained research staff individually structurally coded transcripts using NVivo software (version 12; QSR International), assigning codes to each caregiver/adolescent statement to capture its meaning. The research staff double-coded 17% of transcripts to review any discrepancies between assigned codes. Once consensus was achieved, the interrater reliability was established using NVivo.

Results

Participants

Participants in the study included 198 adolescents (n=115, 58.1% female; mean age 15.3, SD 1.4 years; n=114, 58% non-Hispanic White) with T1D (mean T1D duration 76.4, SD 44.5 months; mean hemoglobin A_{1c} 9.1%, SD 2.1%) and their

caregivers (n=169, 85.4% female). A subsample of 66 adolescents and 63 caregivers completed a brief qualitative interview assessing study experience and perceptions (Table 1).

Table . Descriptive statistics of study participants and a subsample of participants who completed a brief qualitative interview.

Characteristic		Full sample (N=198)	Completed interview (n=66)[a]
Site, n (%)			
	VUMC[b]	108 (54.5)	29 (43.9)
	CNMC[c]	90 (45.5)	37 (56.1)
Intervention group, n (%)			
	Education	99 (50.0)	37 (56.1)
	Positive affect + education	98 (49.5)	29 (43.9)
Adolescent age (years), mean (SD)		15.3 (1.4)	15.3 (1.3)
Adolescent gender, n (%)			
	Male	83 (41.9)	30 (45.5)
	Female	115 (58.1)	36 (54.5)
Adolescent race, n (%)			
	African American/Black	47 (23.7)	13 (19.7)
	American Indian or Alaska Native	2 (1.0)	1 (1.5)
	Asian	8 (4.0)	4 (6.1)
	Biracial	16 (8.1)	8 (12.1)
	White	123 (62.1)	40 (60.6)
	Other	2 (1.0)	0 (0.0)
Adolescent ethnicity, n (%)			
	Non-Hispanic or Latinx	189 (95.5)	65 (98.5)
	Hispanic or Latinx	9 (4.5)	1 (1.5)
Treatment type, n (%)			
	Insulin pump	116 (58.6)	38 (57.6)
	Injections	82 (41.4)	28 (42.4)
Uses a CGM[d], n (%)		161 (81.3)	54 (81.8)
Diabetes duration (months), mean (SD)		76.1 (44.4)	74.6 (44.2)
Baseline hemoglobin A_{1c} (%), mean (SD)		9.1 (2.1)	8.9 (1.8)
Caregiver gender, n (%)			
	Male	28 (14.1)	8 (12.7)
	Female	169 (85.4)	55 (87.3)
Caregiver education, n (%)			
	High school or less	29 (14.6)	5 (7.9)
	Some college	48 (24.2)	15 (23.8)
	College graduate	120 (60.6)	43 (68.3)
Annual household income (US $), n (%)			
	<50,000	51 (25.8)	13 (19.7)
	50,000-89,999	47 (23.7)	9 (13.6)
	90,000-149,999	42 (21.2)	21 (31.8)
	>150,000	56 (28.3)	22 (33.3)
Caregiver marital status, n (%)			
	Married/partnered	150 (75.8)	48 (76.2)
	Single/divorced/widowed	48 (24.2)	15 (23.8)

[a]The interview was completed by 63 caregiver-adolescent dyads and 3 adolescents (without their caregivers). One adolescent's audio recording failed, and the data were unusable.

[b]VUMC: Vanderbilt University Medical Center.

[c]CNMC: Children's National Medical Center.

[d]CGM: continuous glucose monitor.

Feasibility

Intervention Delivery

Over the active study period (33 months), during which participants received their 8 weeks of study SMS text messages, we identified some instances where messages were not sent or received as expected. For example, if participants did not add the study phone number to their contacts list, some phone carriers blocked the messages as spam. Additionally, there were occasional system-wide glitches that interfered with sent SMS text messages. Overall, approximately 145 messages (n=35 adolescents and n=36 parents) were affected by system errors (out of >4400 scheduled text messages), representing only 3% of messages sent over the duration of the study.

Participant Perceptions

In general, both adolescents and their caregivers described favorable experiences participating in the study. Caregivers frequently noted that participating in the study was easy and was not burdensome:

> *It was easy. It actually wasn't time-consuming. I think the biggest thing was that it didn't put a lot of pressure on me to have to take out a lot of time* [mother of teen girl]

Caregivers found that the study survey questions were thought-provoking and allowed them to reflect on their experiences:

> *The questions I could definitely relate to. It's good for, kind of like, introspection...it kind of makes you think about your situation a lot more and how you can change it or do better you know, how I can do better in helping my daughter be more independent managing her diabetes and maybe get less irritable with her, angry with her about it* [mother of teen girl]

Similarly, adolescents also reported that their study experience was easy and nonintrusive:

> *I liked that it wasn't like too probey. It didn't feel like I was just like a test subject, like the surveys weren't really long or super deep, they weren't bothersome or troublesome* [17-year-old girl]

In addition, teens also appreciated the gift card compensation. Although less common, some caregivers and teens noted that surveys were sometimes long and time-consuming, and a few participants reported that questions were repetitive or unclear.

Barriers to participation were not commonly reported by either caregivers or teens. However, several caregivers acknowledged forgetting to respond to the SMS text messages at times and minor issues with their mobile phones or receiving SMS text messages. Several teens and caregivers also noted that life circumstances occasionally interfered with participation, such as work and school schedules. For example, when asked if anything made it difficult or got in the way of their participation in the study, a mother of a teen girl explained:

> *Just life in general. Just being busy. I would get some of the messages and stuff and I would be in the midst of working or cooking dinner or whatever I was doing...I'm like I didn't get back to that, I forgot about it.*

Acceptability

Study Interest

Both parents and adolescents were generally interested in the study. When asked about their initial interest, one mother said:

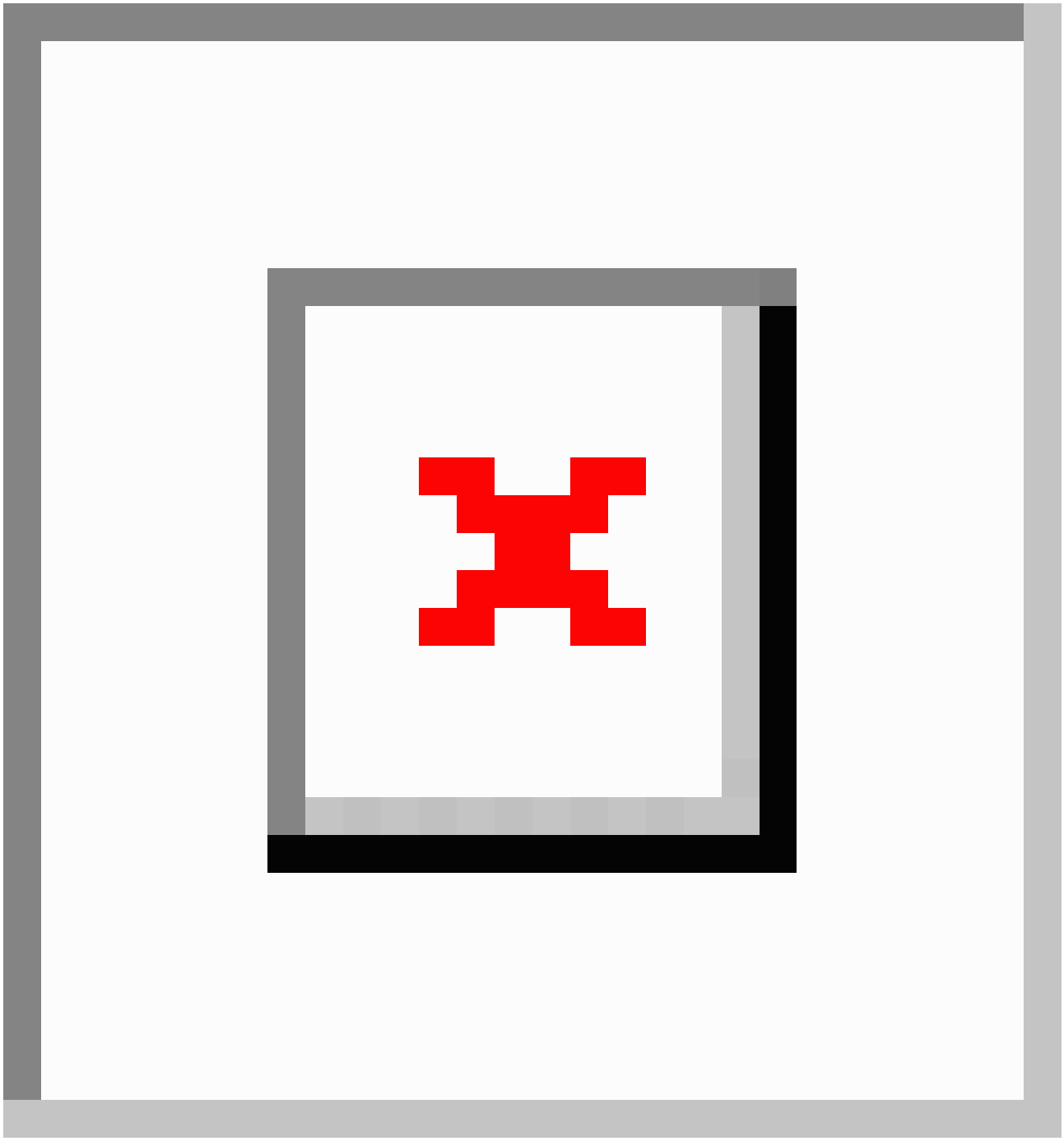
> *I felt that anything that I could do to help [my child], I'm on board for. And if it's going to help another teenager as well, so really for my child and other children.*

A 15-year-old girl stated, "I was interested because I think people need to know more about the emotional effects that type 1 diabetes has on kids." The most common reasons for study interest reported by teens and caregivers included wanting to learn about diabetes and its management, gift card compensation, and wanting to help other people with diabetes.

Engagement With Text Messages

The response rate to SMS text messages was high and remained fairly consistent across the 8-week intervention (Figure 1). Adolescents in the PA + EDU group responded to an average of 92.5% (SD 26.3%) of messages, and caregivers of adolescents responded to an average of 88.5% (SD 32%) of messages. We observed a small but significant decrease in the response rate over 8 weeks, with a high of 96.1% in week 1 and a low of 88.6% in week 8 among the adolescents ($F_{1,95}$=4.27; P<.001); however, there was not a significant change in parents' response over the 8 weeks ($F_{1,86}$=0.99; P=.44).

Figure 1. Average adolescent and parent response rate to automated texts by week.



When we examined the predictors of response rate, we found that the study site was the only significant factor; adolescents from the Vanderbilt University Medical Center site had significantly higher response rates at week 8 as compared to those from the Children's National Medical Center site (no difference in the overall rate of response). Adolescent age, gender, and race/ethnicity were not significantly associated with response rate.

In qualitative interviews, teens in the EDU + PA group reported using the gratitude exercises or noticing things that made them happy, including thinking about family and friends, recent vacations, and activities they enjoy such as art and basketball. Teens reported the exercises were helpful and improved their mood. A 15-year-old girl said:

> *I ride the bus home...I'd be in a grumpy mood and then I'd get a text and it would be asking about [what makes me happy] and so I'd say stuff about my dog. It just makes me happy to think about him sometimes.*

Similarly, a 17-year-old girl said:

> *It was just a good perspective exercise where it just made me think about things more in a good way, not like in a sad way. I like that.*

The majority of teens reported continued use of positive affect exercises at the time of the interview. Caregivers also liked how the study SMS text messages engaged their children and that the study provided an outside source of encouragement and support for them. A mother of a teen girl said:

> *What I liked was her getting text reminders with the positive feedback and kind of reminders and information...[My child] can also feel isolated, and this was like someone looking out for her besides just her family.*

Caregivers and teens in the PA + EDU group also reported positive experiences with using and receiving parental affirmations. Parents valued the teaching exercise and text reminders to give affirmations. A mother of a teen girl stated, "[The teaching exercise] made me really think about what I needed to—what to actually praise her for." She went on to say how the exercise helped "separating diabetes from her and seeing her just as with diabetes...it's been nice." Another parent, a mother of a teen girl, appreciated the weekly reminders:

> *I think it was just the right amount. You expected it every week, you know...it's a good way to reflect on the week and actually wonder, "did I do something good?"*

Participants reported that parental affirmations were often oriented around academic achievements or family responsibilities.

> *We had end-of- testing scores. I did really well on it so my mom was really proud of it* [14-year-old boy]

Although parents received instructions to use affirmations unrelated to diabetes, several teens reported that their parents used diabetes-related affirmations with them, such as praise for checking their blood glucose levels.

Caregivers noted that they provided affirmations to teens face-to-face and through SMS text messages. More than half of caregivers in the EDU + PA group reported that they gave affirmations more frequently than once per week. Most parents described continued use of this strategy even after the weekly study reminders ended.

Study Satisfaction

Adolescents were generally satisfied with the THR1VE program based on survey data completed by 86.9% (172/198) of adolescents, with 83.1% (n=143) reporting that the program was helpful in some way (somewhat helpful: n=65, 37.8%; pretty helpful: n=60, 34.9%; very helpful: n=17, 9.9%; average 3.34, SD 0.98), exceeding our benchmark of 50%. When asked if they would recommend the program to their friends, 87.2% (n=150) said yes, 94.8% (n=163) said that they would participate in it again, and 94.2% (n=162) said it was worth their time.

Discussion

Feedback from participants indicated that a positive psychology intervention to induce positive affect delivered via tailored SMS text messages is feasible and acceptable for an adolescent population. The high rates of response to automated SMS text messages and lack of significant demographic predictors of engagement support that this approach was highly acceptable to adolescents with T1D. The response rate over the intervention period (8 weeks) demonstrates continued engagement, and adolescents and their parents reported continued use of positive affect exercises after the intervention ended.

Evaluating engagement in SMS text messaging interventions is necessary to understand whether this method is a viable option for health behavior change in adolescents. Given the relatively low rates of engagement with app-based interventions to improve diabetes management in youth, other approaches may be needed. For example, a randomized trial evaluating a diabetes management app for adolescents found that only 9% of participants had high engagement (using the app 3-7 days/week) [18], and a study evaluating a parent-developed app for diabetes management excluded 24% of participants from the analysis due to insufficient app use [19]. More recently, an app designed to facilitate positive parent-adolescent communication around diabetes management [8,20] found somewhat higher use; in a randomized pilot, the average app use was 58 out of 84 days for adolescents, but only 23 days for parents [8]. It is also unknown whether these apps would be acceptable for youth from minoritized racial and ethnic groups, as they were tested in predominantly non-Hispanic White youth or did not report on race or ethnicity. SMS text messaging may be a better way to reach adolescent populations, since even adolescents living in rural areas that have spotty Wi-Fi are likely to have access to cell phones [21], and teens report that SMS text messaging is their main source of communication across racial and ethnic groups [22].

The ideal "dose" of SMS text messaging is unclear, but adolescents in our study maintained high levels of response to messages 5 days per week. In interviews, the majority of teens in the EDU + PA group said that the amount of SMS text messaging was "just right," a few teens said it was too many texts, and a few teens said it was too few texts. Most of the parents interviewed who received a weekly reminder, said it was a good amount, but several said they would like more frequent SMS text message reminders, such as a midweek text. By asking teens to report on their own sources of gratitude and personal attributes, we were able to personalize the messages without a lot of extra programming.

The inclusion of feedback from adolescents with T1D prior to starting the trial likely enhanced engagement; the problem we were addressing was meaningful for this population (diabetes distress), the mood booster SMS text messages (selected based on adolescents' ratings) were appealing, and adolescents liked the amount/type of compensation (gift cards). Parents appreciated the reminders to give positive reinforcement/praise messages and that the intervention went beyond the tasks of diabetes management and addressed adolescents' mood. Input from adolescents with T1D was essential in translating the positive psychology protocol developed for adults [9] to a younger population.

This study was limited by the involvement of adolescents with T1D who reported diabetes distress, so it may not be generalizable to other adolescent populations. While we had a relatively representative sample, it is possible that adolescents from different cultures may respond differently to positive psychology approaches, and future studies are needed to determine the amount of cultural tailoring needed to achieve high levels of engagement. Finally, it is challenging to evaluate acceptability versus user engagement for digital health

interventions [23], and future work is needed to establish recognized benchmarks for acceptability.

Findings from this study support that a positive psychology intervention to induce positive affect delivered via automated SMS text messages is highly feasible and acceptable for adolescents and their caregivers. While the integration of feedback from the patient population is critical for a successful protocol, this approach may be translated to improve health outcomes in other pediatric populations.

Acknowledgments

This work was supported by the National Institutes of Diabetes and Digestive and Kidney Diseases (R01DK121316). The manuscript has been seen and reviewed by all authors, and all authors have contributed to it in a meaningful way.

Conflicts of Interest

None declared.

Checklist 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File, 1084 KB - pediatrics_v6i1e47089_app1.pdf]

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Abbreviations

PA + EDU: positive affect + education
PAID-T: Problem Areas in Diabetes–Teen Version
T1D: type 1 diabetes

Edited by S Badawy; submitted 07.03.23; peer-reviewed by A Monzon, K Mitchell; revised version received 06.06.23; accepted 13.07.23; published 05.10.23.

Please cite as:
LeStourgeon L, Bergner E, Datye K, Streisand R, Jaser S
Evaluation of Study Engagement With an mHealth Intervention (THR1VE) to Treat Diabetes Distress in Teens With Type 1 Diabetes: Randomized Clinical Trial
JMIR Pediatr Parent 2023;6:e47089
URL: https://pediatrics.jmir.org/2023/1/e47089
doi:10.2196/47089

Quality of Web-Based Sickle Cell Disease Resources for Health Care Transition: Website Content Analysis

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Abstract

Background: Adolescents and young adults with sickle cell disease (SCD) transitioning from pediatric to adult health care face a high-risk period associated with increased use of acute health care services and mortality. Although 59% of American citizens report using the internet for health care information, the quality of web-based, patient-facing resources regarding transition in SCD care has not been evaluated.

Objective: This study aimed to evaluate the quality and readability of web-based health information on SCD, especially as it pertains to the transition to adulthood for inidividuals with SCD. The study also compared the readability and content scores of websites identified in 2018 to those from 2021 to assess any change in quality over time.

Methods: Keywords representing phrases adolescents may use while searching for information on the internet regarding transition in SCD care, including “hydroxyurea” and “SCD transition,” were identified. A web-based search using the keywords was conducted in July 2021 using Google, Yahoo, and Bing. The top 20 links from each search were collected. Duplicate websites, academic journals, and websites not related to SCD health care transition were excluded. Websites were categorized based on the source: health department, hospital or private clinician, professional society, and other websites. Websites were assessed using Health On the Net Foundation code of conduct (HONcode), Flesch Reading Ease (FRE), Flesch-Kincaid Grade Level (FGL), Ensuring Quality Information for Patients (EQIP), and a novel SCD content checklist (SCDCC). EQIP and SCDCC scores range from 0- to 100. Each website was reviewed by 2 research assistants and assessed for interrater reliability. Descriptive statistics were calculated.

Results: Of the 900 websites collected, 67 (7.4%) met the inclusion criteria: 13 health department, 7 hospital or private clinician, 33 professional society, and 14 other websites. A total of 15 (22%) out of 67 websites had HONcode certification. Websites with HONcode certification had higher FRE and EQIP scores and lower FGL scores than those without HONcode certification, reflecting greater readability. Websites without HONcode certification had higher SCDCC scores, reflecting greater clinical content. Only 7 (10%) websites met the National Institutes of Health recommendation of a seventh-grade or lower reading level. Based on EQIP scores, 6 (9%) websites were of high quality. The mean SCDCC score was 20.60 (SD 22.14) out of 100. The interrater reliability for EQIP and SCDCC ratings was good (intraclass correlation: 0.718 and 0.897, respectively). No source of website scored significantly higher mean EQIP, FRE, FGL, or SCDCC scores than the others (all $P<.05$).

Conclusions: Although seeking health care information on the web is very common, the overall quality of information about transition in SCD care on the internet is poor. Changes to current web-based health care information regarding SCD care transitions would benefit transitioning youth by providing expectations, knowledge, skills, and tools to increase self-efficacy.

(JMIR Pediatr Parent 2023;6:e48924) doi:10.2196/48924

KEYWORDS

sickle cell; health care transition; readability; Flesch Reading Ease; health care information; adulthood; sickle cell disease; online resource; quality; adolescent; transition; health care service; website quality; online information; Ensuring Quality Information for Patients; EQIP; FRE

Introduction

Sickle cell disease (SCD) is a life-threatening and chronic condition characterized by vaso-occlusion, anemia, and hemolysis [1]. The transition from pediatric to adult health care for young adults with SCD is an especially high-risk period [2-4]. One study found a 2-fold increase in the risk of mortality for patients with SCD aged 19-21 years compared to teenagers aged 16-18 years and a nearly 3-fold higher risk of mortality for young adults aged 22-24 years [3]. Another study that reviewed surveys taken by patients with SCD in pediatric clinics found that a barrier to health care for patients in this population was access to a knowledgeable provider [5]. The first 2 years following transition to adult care in the population with SCD are associated with increased health care use and death [4], theorized to be partly due to poor patient knowledge and skills [6]. Thus, providing youth with SCD with adequate skills and knowledge to manage their own health care is important.

Acquiring the knowledge and skills needed for successfully transitioning from pediatric to adult care has historically fallen to patients and families. Today, 72% of internet users have accessed the internet at least once for health information on the web. Additionally, 92% of American youth access the internet daily [7,8]. As of 2017, an estimated 80% of adolescents and young adults (age 16-24 y) have access to the internet via a computer or smartphone [9]. Additionally, a person living with a chronic disease is more likely to access the internet for health information than the general population of e-patients [10]—patients who use the internet for information related to their condition [11]. Accessibility to web-based health information is important, as perceived website information quality is associated with increased trust for users to choose web-based resources as their main source of health information [12].

Despite patients' perception that websites are useful for providing health information, the quality of web-based health information that young adults and adolescents with SCD have access to learn about their chronic condition and transition is unknown. There is a vast amount of freely available health information on the internet regarding chronic conditions such as SCD and general transition from pediatric to adult health care, and there are an increasing number of youth accessing it. However, there has not been a content analysis of web-based health information regarding transition to adulthood for patients with SCD. We defined adolescents and young adults as those aged 16-24 years per prior studies investigating the transition period [6,13]. The aims of this study were (1) to evaluate the readability, quality, and content of patient-facing information on the transition to adulthood for patients with SCD available on the internet; (2) to investigate the impact of website source and internet quality certifications on readability, quality measures, and content; and (3) to assess whether readability, quality, and content have improved over the course of 3 years. We hypothesized that the readability, quality, and content of patient-facing information on the transition to adulthood for patients with SCD available on the internet is above the recommended reading level of health information and is of poor quality. Additionally, we did not expect a change in the readability or quality of SCD websites between 2018 and 2021.

Methods

Website Search and Inclusion

To collect website data, search terms were established by a team of patients with SCD, pediatricians, internists, social workers, and research staff. Initial search terms were compiled by a group of physicians with expertise in caring for patients transitioning from pediatric to adult health systems. Search terms were distributed to SCD clinical teams across 2 distinct health systems for review and feedback. Final searched terms were as follows: "sickle cell," "sickle cell disease," "sickle cell anemia," "sickle cell transition," "sickle cell healthcare transition," "transitional care sickle cell," "sickle cell transition readiness," "sickle cell disease medical transition," "sickle cell anemia resources," "hydroxyurea," "hydroxyurea for sickle cell disease," "sickle cell pediatric to adult care transition," "sickle cell disease medical resources," "sickle cell disease symptoms," and "sickle cell disease treatment." The Keywords Everywhere extension (Axeman Tech Pvt Ltd) [14] was used to validate that these search terms have been used by other Google users. Keywords Everywhere is a program that provides data on the number of times a search term has been searched per month over the past 15 years within the United States. The program is only available on Google Chrome and Firefox web browsers. Because 65% or more of internet searches take place on Google [15], we assumed that web searches validated on Google will be valid on another platform. Websites were collected in July 2021 using the 3 most used search engines in the United States: Google, Yahoo, and Bing. These search engines make up over 95% of internet searches in the United States [15].

Web searches were performed in an incognito tab to prevent cookies from previous searches from influencing the results. An ad blocker was used to prevent ads from appearing in searches. The first 20 websites per search term were collected. Previous studies have shown that internet users tend to not view search results after the second page of a search [16]. The first 2 pages on all 3 search engines, without ads, include 20 websites. Websites were excluded from the study if they were repeated URLs from a prior search, if their focus was not SCD, if the website contained only videos or links to other pages, or if the website is not accessible to the general public such as an academic publication. Additionally, websites were categorized based on their source: hospital or private clinician, professional society, health department, and other websites. The "other" category included databases such as Wikipedia and WebMD. Lastly, each website was assessed for readability, quality, and transition in SCD care–related content.

To investigate the change in the scores regarding the quality of SCD-related websites over the course of 3 years, unpublished data (S Shilly et al) collected in 2018 were included in this study for comparison. The search terms and inclusion and exclusion criteria were the same in 2018 and 2021. In 2018, SCD health care transition websites were collected from the 5 most used search engines at the time (Google, Yahoo, Bing, DuckDuckGo,

and Ask.com), and the data were collected between December 2017 and January 2018.

Website Readability

Website readability was measured using the Flesch Reading Ease (FRE) and Flesch-Kincaid Grade Level (FGL) formulas. The FRE formula uses word length, the number of syllables, sentence length, and other variables to score an article. Higher scores are associated with greater ease of reading [16]. The FRE formula is scored on a scale from 0-100: scores from 0-29 are considered "very confusing," 30-49 as "difficult," 50-59 as "fairly difficult," 60-69 as "standard" (eighth- and ninth-grade level), 70-79 as "fairly easy," 80-89 as "easy," and 90-100 as "very easy" (fifth-grade level) readability [17]. The FGL formula assigns a score that correlates with the US education level a person must achieve to be able to read an article. The National Institutes of Health recommends that medical information should be written at no higher than a sixth-grade reading level, which corresponds to an FGL score below 7 [18,19].

Websites were graded using Microsoft Word, with photographs, figures, and links being removed before being analyzed [20].

The FRE and FGL formulas were chosen as these scores have been used in previous literature to assess health care document readability [21-23]. The scores correspond with a grade level that can be compared to National Institutes of Health recommendations.

Website Quality

Website quality was measured using the Ensuring Quality Information for Patients (EQIP) tool and Health On the Net Foundation code of conduct (HONcode) certification. The EQIP tool is a 20-item validated instrument that has been used in numerous studies to assess health information quality on the web [24]. It can be used to evaluate the content, identification, and structure of each website. The EQIP tool includes a rating scale of 4 options: yes, partly yes, no, and not applicable. EQIP scores range from 0% to 100%, with higher grades indicating better quality [24]. The EQIP tool was applied to the primary website and the links presented to other sources within it. If a link redirected to an external website, it was not assessed to calculate the EQIP score.

EQIP scores are calculated by dividing a website's total score across the 20 items by 20 and multiplying this number by 100%. Website quality was scored by 2 research assistants (TA and TO). Intraclass correlations (ICCs) were calculated to measure the agreement between EQIP scores. No consensual agreement has been made regarding cutoff values of EQIP scores to determine website quality. Based on previous studies, a high-quality website was defined as having an EQIP score of ≥75% in this study [25,26].

The EQIP tool was chosen to assess website quality as it is a comprehensive assessment of written medical information. It has been used previously in peer-reviewed literature to assess the quality of information presented on the web [25-27].

HONcode certification identifies whether websites provide quality, objective, and transparent medical information [28]. The Health On the Net Foundation is a not-for-profit nongovernmental organization affiliated with the World Health Organization (WHO). HONcode certification is obtained through a voluntary application that the owner of the website must apply for [29]. Each website is examined by a review committee for the 8 HONcode ethical principles, which are authority (provide qualifications for authors), complementarity (provide information to support, not replace), confidentiality (respect the privacy of site users), attribution (cite the sources and dates of medical information), justifiability (provide justification of claims or balanced and objective claims), transparency (ensure accessibility and provide valid contact details), financial disclosure (provide details of funding), and advertising (clearly distinguish advertising from editorial content). If a website complies with all 8 principles, the site will be given a HONcode seal to place on their page. In our study, each website was assessed for the presence or absence of the HONcode certification.

The presence of HONcode certification was determined using the HONcode search engine [30,31].

The FRE, FGL, EQIP, and SCD content checklist (SCDCC) scores were compared between websites with HONcode certification and those without certification.

HONcode certification was chosen as a method of assessment as the 8 ethical principles the certification is based on align with the 3 pillars of medical ethics: beneficence, nonmaleficence, and justice. HONcode certification has been used in previous literature as a quality assurance method [32,33].

SCD- and Transition-Related Content

SCD- and transition-related content was assessed using a novel 12-item transition in SCD care-specific content tool (SCDCC), which was produced since no validated tool has been published yet (Textbox 1). The tool was generated using the 6 modifiable factors of transition from the Social-Ecological Model of Adolescent and Young Adult Readiness to Transition [34]. Additionally, items were selected based on the conceptual framework of the chronic care model and the *National Heart, Lung, and Blood Institute SCD Treatment Guidelines* [30,35]. The tool was reviewed by a team of hematologists, psychologists, and other professionals who are experienced and knowledgeable in the transition to adulthood for patients with SCD.

Textbox 1. The 12 categories graded on the sickle cell disease (SCD) content checklist and the description of the criteria used in their assessment.

1. Development: evidence of developmental maturity necessary for success in the adult system
2. Knowledge: knowledge related to disease history, health or status, and needs and benefits of transition
3. Skills/Efficacy: skills and self-efficacy needed to manage personal health and transition
4. Beliefs/Expectations: beliefs and expectations related to the transition process
5. Goals: provides achievable goals related to the transition process
6. Relationships: describes relationships among patients, parents, pediatric providers, and adult providers
7. Psychosocial functioning: describes psychological conditions, family functioning, acute crises, stress, and emotions related to the transition process
8. Mood/Pain: describes symptoms of pain crises and emotions related to pain crises
9. Navigating health systems: provides advice on navigating a health system and establishing care during the transition period
10. Self-management: describes increased accountability of obtaining SCD treatment, finding a provider, and managing one's own health
11. Self-advocacy: describes the need for patient to be involved in their health and aware of their needs
12. Vocational planning: prepares a person with SCD for the workplace

SCDCC scores are calculated by dividing a website's total score across the 12 items by 12 and multiplying this number by 100%. A total score could range from 0 to 100, with higher scores indicating content more consistent with the above validated frameworks. Each item is scored with either a 0 for item not present, 1 for item clearly present, or 0.5 for item not clearly present but alluded to. Website content was scored by 2 research assistants (TA and TO).

The purpose of adding the SCDCC as an analytic tool was to supplement the EQIP score as a method to better assess written SCD material.

Statistical Analysis

The FRE, FGL, EQIP, and SCDCC scores were compared between websites with HONcode certification and those without certification.

Websites were categorized based on their source. Websites ending in ".gov" were designated as health department websites. Websites associated with a hospital or system were designated hospital or private clinician websites. Websites were categorized as professional society websites if they were produced by a medically oriented professional association. Websites designated as "other" did not fit into the aforementioned categories. FRE and FGL scores were calculated by copying and pasting the text on each website into a word-processing program. An extension in the word-processing program that calculates readability was used. EQIP scores were measured using a 20-point scale established by Moult et al [24]. The score out of 20 items was then divided by 20 and multiplied by 100% to get a percentage of EQIP items that the website possessed. Similarly, SCDCC scores were calculated on a 12-point scale, divided by 12 and multiplied by 100%. Google sheets with the *XLMiner ToolPak* (Frontline Systems Inc) was used to assess ANOVA and 2-tailed *t* tests. ANOVA was used to measure statistically significant differences in mean FRE, FGL, EQIP, and SCDCC scores between each website source. *t* tests were used to measure statistically significant differences between the mean scores of websites with and without HONcode certification. *t* tests were also used to measure statistically significant differences in mean FRE, EQIP, and SCDCC scores for websites in 2018 and 2021.

Results

Website Search

In 2021, a total of 900 websites were collected, with 67 (7.4%) meeting the inclusion criteria: 13 health department, 7 hospital or private clinician, 33 professional society, and 14 other websites.

FRE and FGL Evaluation

The mean FRE score among all websites was 54.64 (SD 10.48; range 24.4-78.6), indicating that the websites were difficult to read (the recommended range is >70). There were no significant differences in FRE scores between website sources (F_3=0.262; P=.85; Table 1). The reading difficulty of each website was stratified based on their FRE score. Of the 67 websites, only 7 (10%) were "fairly easy to read" (FRE score 70-79). Of those 7 websites, 1 was a hospital or private clinician website, 2 were health department websites, 2 were professional society websites, and 2 were other websites.

Table . Readability scores.

Score	Website source				
	All sources	Hospital or private clinician	Health department	Professional society	Other
FRE[a], mean (SD)	54.64 (10.48)	54.56 (10.65)	55.55 (9.54)	55.67 (9.47)	56.03 (18.67)
FGL[b], mean (SD)	9.72 (1.96)	9.84 (2.83)	9.54 (1.94)	9.57 (2.17)	8.99 (3.87)

[a]FRE: Flesch Reading Ease.

[b]FGL: Flesch-Kincaid Grade Level.

The mean FGL score among all websites was 9.72 (SD 1.96; range 1.94-19.2), also indicating that the websites were above the recommended seventh-grade reading level. There were no significant differences in FGL scores between website sources (F_3=0.341; P=.69; Table 1). Of the 67 websites, only 8 (12%) had an FGL score in the recommended range of <7. Of those 8 websites, 4 were hospital or private clinician websites, 1 was a health department website, 1 was a professional society website, and 2 were other websites.

EQIP Evaluation

The mean EQIP score was 47.18 (SD 13.00) for all websites. The mean EQIP scores for each website source were as follows: hospital or private clinician, 49.30 (SD 12.32); health department, 52.88 (SD 13.89); professional society, 51.95 (SD 12.45); and other, 59.82 (SD 8.82). There were no significant differences in EQIP scores between website sources (F_3=1.96; P=.12; Table 2). Of the 67 websites, only 1 (1%) achieved an EQIP score over 75. The interrater reliability of EQIP scores calculated using ICC was 0.718, which is considered acceptable for interrater reliability.

Table . Quality scores.

Score	Website source				
	All sources	Hospital or private clinician	Health department	Professional society	Other
EQIP[a], mean (SD)	47.18 (13.00)	49.30 (12.32)	52.88 (13.89)	51.95 (12.45)	59.82 (8.82)
SCDCC[b], mean (SD)	20.60 (22.14)	37.32 (28.48)	26.12 (19.88)	22.79 (17.60)	19.05 (6.74)

[a]EQIP: Ensuring Quality Information for Patients.

[b]SCDCC: sickle cell disease content checklist.

The EQIP items most frequently graded as “yes” or “partly yes” were “Is the tone respectful” and “Is the information presented in logical order.” The EQIP items least frequently graded as “yes” or “partly yes” were “Does the document have a named space for the reader to make notes” and “Does the document say whether patients and/or family members were involved or consulted in its production.”

SCDCC Evaluation

The mean website content score for SCD websites was 20.60 (SD 22.14). The mean SCDCC scores for each website source were as follows: hospital or private clinician, 37.32 (SD 28.48); health department, 26.12 (SD 19.88); professional society, 22.79 (SD 17.60); and other, 19.05 (SD 6.74). The interrater reliability of SCDCC scores calculated using ICC was 0.897. There were no significant differences in SCDCC scores between website sources (F_3=2.32; P=.08; Table 2).

The SCDCC items most frequently graded as “yes” or “partly yes” were “Knowledge” and “Mood/Pain.” The SCDCC items most frequently graded as “no” were “Vocational Planning” and “Goals.” Less than 25% of websites contained information related to “Skills/Efficacy” (16/67, 24%), “Self-Advocacy” (15/67, 22%), “Relationships” (12/67, 18%), “Vocational Planning” (6/67, 9%), “Development” (15/67, 22%), and “Goals” (7/67, 10%).

HONcode Certification

Of the 67 websites reviewed, 15 (22%) had a HONcode certification. Of the 15 websites who had the certification, 3 (20%) were developed by a health department, 2 (13%) were developed by a hospital or private clinician, 4 (27%) were developed by a professional society, and 6 (40%) were developed by other sources.

Websites that were HONcode certified had significantly higher FRE (P=.02) and lower FGL (P=.001) scores (greater readability) and higher EQIP (P=.004) scores (higher quality).

There were no significant differences between the SCDCC scores (range of contents) of websites with HONcode certification versus those without HONcode certification (P=.30; Table 3).

Table . Comparison of the mean FRE[a], FGL[b], EQIP[c], and SCDCC[d] scores for websites with HONcode[e] certification and websites without HONcode certification.

Score	Websites with HONcode certification, mean (SD)	Websites without HONcode certification, mean (SD)	*P* value
FRE	60.37 (11.81)	53.51 (9.90)	.02
FGL	8.12 (1.98)	10.08 (2.40)	.001
EQIP	58.08 (11.59)	48.31 (12.44)	.004
SCDCC	20.56 (10.38)	28.21 (25.50)	.30

[a]FRE: Flesch Reading Ease.

[b]FGL: Flesch-Kincaid Grade Level.

[c]EQIP: Ensuring Quality Information for Patients.

[d]SCDCC: sickle cell disease content checklist.

[e]HONcode: Health On the Net Foundation code of conduct.

Comparison Between 2018 and 2021 Data

In 2018, a total of 1924 websites were collected, with 92 (4.8%) meeting inclusion criteria: 11 health department, 38 hospital or private clinician, 21 professional society, and 22 other websites. In all, 31 websites identified in 2018 were also identified in 2021. When the quality of data was compared between 2018 and 2021, websites still scored poorly for FRE, EQIP, and SCDCC (Table 4). Overall, the quality of websites did not improve between the 2 data collection periods. Compared to 2018, websites in reviewed 2021 had statistically lower EQIP scores (*P*=.006), indicating a slight degradation of website quality over time. In both 2018 and 2021, websites were fairly difficult to read on average as assessed by the FRE formula. There was also a lack of HONcode-certified websites in both 2018 and 2021. Compared to 2021, more websites had HONcode certification in 2018 (2021: 15/67, 22% vs 2018: 26/92, 28%).

Table . Comparison of the mean FRE[a], EQIP[b], and SCDCC[c] scores for websites from 2018 to 2021.

Score	Year, mean (SD)		*P* value
	2018	2021	
FRE	51.8 (13.6)	55.1 (11.1)	.10
EQIP	56.8 (11.0)	51.6 (12.5)	.006
SCDCC	20.8 (18.1)	30.1 (24.1)	.008

[a]FRE: Flesch Reading Ease.

[b]EQIP: Ensuring Quality Information for Patients.

[c]SCDCC: sickle cell disease content checklist.

Similar to the results from 2021, websites with HONcode certification in 2018 were associated with significantly higher FRE scores (*P*=.02). The mean FRE score for websites with HONcode certification was 56.57 (SD 11.12) and the mean FRE score for websites without HONcode certification was 50.01 (SD 14.21). There were no significant differences between EQIP and SCDCC scores (*P*=.18 and *P*=.44, respectively).

Discussion

Principal Findings

This is one of the first studies to conduct a content analysis of web-based health information regarding the transition to adult care for patients with SCD. Previous studies have shown that the quality of health information available on the internet is variable and unregulated [31]. Our study is consistent with this finding. Our study indicated that the overall quality of information on SCD transition to adult care on the internet does not meet the recommended seventh-grade or lower reading level, which is consistent with other studies on SCD websites [36]. On average, websites containing information on the transition in SCD care were fairly difficult to read. These websites also failed to score highly on the EQIP and SCDCC assessments. Website analysis revealed few HONcode certifications, which is consistent with other studies on health information [32,33]; few websites that met the recommended reading level; and few websites of high quality based on EQIP and SCDCC scores. Websites hosted by academic centers, hospitals, or governmental sources were not comparatively better in readability, quality, or content. For the small proportion of websites that obtained HONcode certification, certification is associated with improved readability and quality, without sacrifices in content, although the content based on the SCDCC score was relatively poor overall. HONcode certification may be a helpful check for website readability and quality, given the association of HONcode certification on the measures in our study, and HONcode certification can be obtained for any website by requesting for review over the web.

Furthermore, website quality did not significantly improve between 2018 and 2021. The poor scores for websites in both 2018 and 2021 point to the need for the improvement of web-based health resources for adolescents and young adults

with SCD. We acknowledge that EQIP and SCDCC scores increased between 2018 and 2021; however, the mean scores were of poor quality in both years. Academic centers, governmental agencies, and other organizations should ensure their websites are up to date and comprehensive to increase the readability and quality of content for patients with SCD. The web-based sources that were analyzed in this study lack a well-rounded view of a patient's experience with the SCD health care transition process. Although these websites provide factual information, they are not written to the level of an average reader nor do they provide clear expectations and a holistic view of a patient with SCD. The consequences of poorly designed websites can include decreased patients' perception of usefulness and trust in web-based information and withered patient-physician relationships [12,30,35]. According to previous studies, the quality of health websites remains poor and inconsistent, and web-based information is being used more among patients as it can improve the patient-physician relationship [12,36-39]. It is important for there to be improvements in the quality of the websites that would allow youth with SCD to learn to manage their own health.

The readability of websites can be improved by using shorter sentences and avoiding medical jargon. When medical terms need to be used, they should be explained in terms that can be understood by the average person. The quality of websites can be improved by writers using the EQIP tool as a guideline. Additionally, we believe the SCDCC can act as a guideline for writers to provide well-rounded information regarding the process of transitioning their SCD care. Involving people with SCD in the writing process of these websites can also help to improve the quality of websites [40], as their feedback would be invaluable.

Health information for transitioning patients with SCD needs to be tailored to adolescent and young adult patients by aligning with their cognitive skills and providing well-rounded information [41]. Gaps in adolescent and young adult patients' knowledge pose a threat to their health during the vulnerable transition time period. It has been established that this is a time of increased morbidity and mortality [2-4] and that knowledge about SCD is a barrier to care [5]. We identified that web-based, patient-facing information on the transition of SCD care is, on average, fairly difficult to read and generally of poor quality. Physicians should be knowledgeable that their patients with SCD will likely use the internet to obtain medical information and that there are gaps in web-based information. Reliable, quality websites should be given to patients for reference, and a discussion should be initiated between patients with SCD and their providers to identify the knowledge the patient has and bridge any gaps in their knowledge.

Limitations

Our study only included websites that presented information in English. Future studies should be conducted to evaluate websites in other languages that appear in search results. Additionally, using incognito mode to search for websites does not prevent the location from affecting search results. The websites that were collected may have been influenced by our location in New York state. Websites from other countries and states may have been excluded. A virtual private network can be used in future studies to access websites from other areas of the world. Our study is time sensitive to a single point in time. Websites are updated or changed every 27 months on average, and HONcode certification and FRE, FGL, EQIP, and SCDCC scores are subject to change [42]. HONcode certification is a voluntary process by the site owner, meaning that websites may meet the HONcode criteria but have not been certified due to not applying for certification [29]. Additionally, there is no resource available that lists sites that have applied for HONcode certification but did not meet the criteria. Due to the subjective nature of EQIP and SCDCC scoring, the scores are subject to variation, although no significant variations were seen between the 2018 and 2021 websites. The SCDCC has not been validated as a measure of the quality of SCD-specific information. We believe that the scale offers a valuable insight into SCD-specific, web-based information that the EQIP tool cannot offer. This study investigated the quality of SCD websites and did not investigate other mediums of health information available on the internet such as social media. Future studies investigating the quality of information presented on platforms other than websites would provide valuable information given the popularity of social media. Despite the inherent limitations present in this study, we believe that the observations of the study are significant and show that the quality of web-based information regarding preparation for the transition of SCD care is not satisfactory.

Conclusions

Many websites available for patients with SCD transitioning from pediatric to adult care lack a well-rounded view of the experiences and health care needs of these patients. Additionally, these websites can be fairly difficult to read. Websites can be improved by using shorter sentences, limiting the length of sentences, and providing a more comprehensive view of the SCD transition of care process. With these changes, improvements in self-management of adolescents and young adults with SCD transitioning from pediatric to adult care may be seen.

Acknowledgments

The authors would like to thank Jane Lindahl for her assistance with the website review. We would also like to thank members of the general pediatrics research team at Cohen Children's Medical Center: Telmo Santos, MD, MPH; Abigail Seide, MPH; Arianna Mastrogiannis; Andrea Zuzarte; Michelle Katzow, MD, MS, FAAP; and Shing Ho Cheng.

Conflicts of Interest

None declared.

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Abbreviations

EQIP: Ensuring Quality Information for Patients
FGL: Flesch-Kincaid Grade Level
FRE: Flesch Reading Ease
HONcode: Health On the Net Foundation code of conduct
ICC: intraclass correlation
SCD: sickle cell disease
SCDCC: sickle cell disease content checklist
WHO: World Health Organization

Edited by S Badawy; submitted 15.05.23; peer-reviewed by L Crosby, S Creary; revised version received 27.09.23; accepted 30.09.23; published 13.12.23.

Please cite as:
Annesi T, Steinway C, Oluwole T, Shilly S, Szalda D, Myers R, Chen J, Jan S
Quality of Web-Based Sickle Cell Disease Resources for Health Care Transition: Website Content Analysis
JMIR Pediatr Parent 2023;6:e48924
URL: https://pediatrics.jmir.org/2023/1/e48924
doi:10.2196/48924

Original Paper

Gamification to Support Adherence to a Therapeutic Ambylopia Treatment for Children: Retrospective Study Using a Focal Ambient Visual Acuity Stimulation Game

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Abstract

Background: The gold standard treatment for amblyopia is patching the better eye. Improvement of visual acuity in the amblyopic eye is significantly impacted by the adherence to the patching therapy. It is known that the overall adherence is rather low.

Objective: This retrospective study evaluated whether an updated version of attention-binding digital therapeutic games based on the principle of focal ambient visual acuity stimulation (FAVAS) would result in improved patient adherence in 4- to 16-year-old patients with amblyopia associated with anisometropia or strabismus.

Methods: We analyzed electronically pseudonymized recorded data from patients treated with occlusion therapy and FAVAS therapeutic games. One group used an older version (2015) and the other group used a newer version (2020) that provided more attractive therapeutic games with tablet computer functionality. Objective adherence was calculated by comparing the number of minutes using the therapeutic games as monitored in the automatized logbook versus the prescribed number of minutes for using the games.

Results: Children in group 2015 (n=138) spent on average 2009.3 (SD 1372.1; range 36-5556) minutes using FAVAS; children in group 2020 (n=129) spent on average 2651.2 (SD 1557.1; range 38-5672) minutes using the newer version. Group 2020 spent on average 641.9 more minutes on FAVAS than group 2015 ($t_{255.49}$=3.56, P<.001, d=0.45; 95% CI 0.69-0.20). Although patient adherence was very variable, compared to the 55.0% (SD 29.4%) in group 2015, it significantly improved up to 68.5% (SD 33.7%) in group 2020 ($t_{254.38}$=3.48, P=.001, d=0.44; 95% CI 0.68-0.19).

Conclusions: FAVAS 2020, with improved gamification aspect as well as tablet computer functionality, increased adherence significantly compared to the earlier version of FAVAS 2015, indicating that FAVAS 2020 could be an effective approach to support adherence to amblyopia treatment.

Trial Registration: German Clinical Trials Register (DRKS) DRKS00017633; https://drks.de/search/de/trial/DRKS00017633

(JMIR Pediatr Parent 2023;6:e32282) doi:10.2196/32282

KEYWORDS

amblyopia; children; compliance; adherence; occlusion; patching; therapeutic game; FAVAS

Introduction

Unilateral amblyopia is a developmental disorder resulting in degraded visual acuity in 1 eye. During the developmental phase of vision, degraded stimulation by the weaker eye leads to the underdevelopment of the corresponding cortical visual areas [1]. Amblyopia is associated with poor binocular visual experience in children and has a lasting effect on the individuals' quality of life, while children with amblyopia are impacted in their daily activities and future job selection [2]. It also increases the risk of severe trauma for the fellow sound eye [3]. Occlusion therapy with patching, after optical adaptation with binocular eyeglass correction, has been the gold standard therapeutic approach for forcing the visual development of the amblyopic weaker eye by an input deprivation of the other sound eye since Sattler [4]. However, by patching, a high rate of patients (approximately 25% to 30%) do not show a full recovery of visual function, and some of those patients even show further worsening in visual function [5-8]. Visual acuity improvement in the amblyopic eye is significantly impacted by adherence to patching therapy [9]. For a long time, a system of monocular and binocular visual exercises and stimulation methods (pleoptics and orthoptics) in support of the standard occlusion treatment has been developed, but only with limited success [10-12]. Some perceptual learning treatments of the last few years have been monocular training with grating contrast detection tasks or viewing action movies and video games. Some binocular treatments work by presenting dichoptic, high-contrast stimuli to the amblyopic eye and low-contrast stimuli to the other eye during video games. Other binocular treatments do not involve contrast balancing but instead present dichoptic videos or video games with the background presented to both eyes and foreground elements presented only to the amblyopic eye [13,14].

This study explores the a priori hypothesis that the updated version of monocular focal ambient visual acuity stimulation (FAVAS) therapeutic games has improved patient adherence. To improve adherence to patching therapy, gamification of therapy could encourage the patient to actively use the amblyopic eye. FAVAS therapeutic games are an innovative digital therapeutic designed as a supplementary treatment to patching. A customized moving ambient sinusoidal wave pattern (moving gratings) is presented in the background of focal attention-binding digital therapeutic games, stimulating cortical areas to activate the central perceptive activity of the amblyopic eye again and thus improving visual acuity [15].

At the same time, ambient stimulation is provided in the game's background by a drifting sinusoidal contrast-modulated grating pattern of constant spatial and temporal frequency. Due to its periodicity, the drifting grating stimulus is assumed to induce resonance within and between filter systems of band-pass selective neuronal transmission channels [15-17]. The stimulus is a drifting sinusoidal grating with a spatial frequency of 0.3 and a temporal frequency of 1 cycle per second, reciprocally coordinated with each other to produce a drift of 0.33 degrees per second. The customized pattern takes the axis of astigmatism into account, there are 3 groups of best-corrected visual acuity (BCVA; <0.2, 0.2-0.5, >0.5), and with strabismus there is a circular stimulation. The software-implemented exercises for our visual training are based on a specially developed FAVAS. In the foreground of the screen, a focal computer game demands sensory-motor coordination, visual fixation performance, and adherence from the children. Thus, the gaming activity serves mainly for attention binding, which has been previously proven to be a decisive factor for the success of visual-training exercises. Previously, Kämpf et al [16] showed that FAVAS had a promising effect on the visual acuity of amblyopic eyes in a specific way.

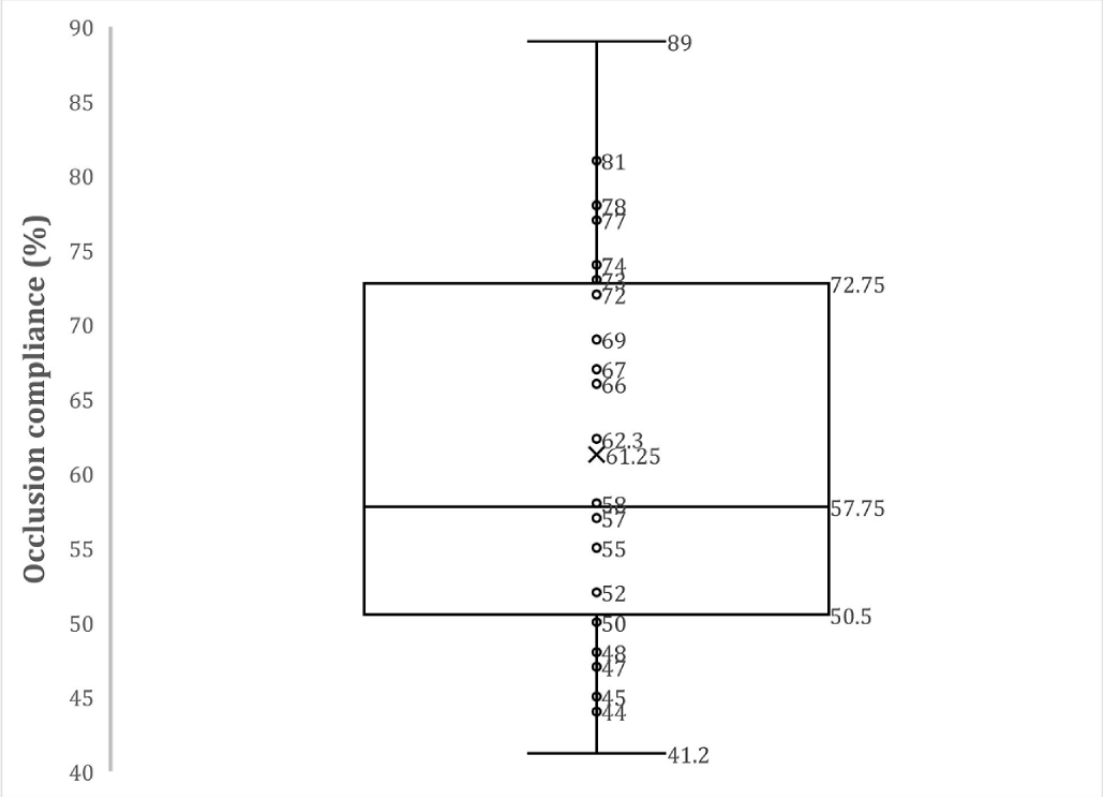
Recently, a new modified version of FAVAS (2020) focused on user-friendliness of touch screen tablet computers, gamification, and attention-binding aspects, which could potentially improve patient adherence. Besides technical updates, later versions of commercially available treatment games could specifically improve engagement. We know from the literature that adherence with prescribed occlusion therapy is 62% (Table 1, Figure 1). However, in our study, we measured adherence to prescribed FAVAS therapy. The goal of this study is to evaluate whether an improved gamification aspect as well as tablet computer functionality of FAVAS therapeutic games would result in higher patient adherence compared to the earlier version. Therefore, we analyzed the electronically recorded data from a commercially available FAVAS system (Caterna Vision GmbH) in 4- to 16-year-old patients, and compared adherence to the earlier version of FAVAS 2015 with adherence to an updated version of FAVAS 2020.

Table 1. Literature overview of 8 papers measuring occlusion compliances in 24 groups with standard regimens to interventions like education, cartoons, and stickers to boost motivation in children and parents [18-26].

Studies and groups in paper	Objective compliance (%)[a]	Age group (years)
Stewart et al [20]	48	3-8
Awan et al [22]		
3-h regimen	57.5	3-8
6-h regimen	41.2	
Loudon et al [21]		
Education intervention group	78	<4
4-6	77	
>6	74	
Control group	57	<4
4-6	52	
>6	55	
Stewart et al [23]		
6-h regimen	66	<4
4-6	72	
>6	69	
12-h regimen	50	<4
4-6	47	
>6	58	
Tjiam et al [24]		
Preimplementation cartoon	52	3-6
Postimplementation	62.3	
Tjiam et al [18]		
Educational cartoon group	89	3-6
Reward sticker group	67	
Parent leaflet group	73	
Control group	55	
Wallace et al [25]	44	3-8
Pradeep et al [26]		
Educational/motivational intervention group	81	3.5-8.9
Control group	45	

[a]Mean 62.33% compliance (SD 13.31%).

Figure 1. Box plot of average occlusion compliance of the meta-analysis of 24 groups from Wang et al 2015 [18-26].



Methods

Ethics Approval

This retrospective study adhered to the Declaration of Helsinki, was conducted at a single center, and was approved by the local ethics committee, Ethikkommission der Ärztekammer des Saarlandes (118/19, trial registration DRKS00017633). Due to the retrospective nature of this study and the pseudonymization at the source, no additional informed consent was required.

Recruitment

We compared pseudonymized electronic user protocols showing the therapeutic game activity time of patients aged between 4 and 16 years; all patients were diagnosed with amblyopia by their ophthalmologist and treated with a combination of occlusion and a commercially available FAVAS therapy (Caterna Vision GmbH). The amblyopia was associated with anisometropia or strabismus. Patients had their current refractive correction worn for at least 16 weeks or until 2 consecutive visual acuity measurements, at least 8 weeks apart, did not improve by more than 1 logMAR line. The amblyopic eye had a BCVA from 20/40 to 20/200; the other eye had a BCVA of 20/32 or better, and the difference between the eyes was ≥3 logMAR lines. Children with proven learning disabilities, known epilepsy, other pre-existing ophthalmic conditions, or deprivation amblyopia (weak vision due to an organic cause) were excluded. All individuals had previous treatment with standard patching that was not successful.

Treatments

All patients had full binocular correction with glasses, prescribed by their local eye doctors. For occlusion therapy, patients used standard eye patches. Every individual got a personalized occlusion rhythm of how many hours per day they had to wear the patch, depending on the visual acuity, fixation site at the fundus, age, and other findings. Each participant was provided with access to a home-based FAVAS, offered by Caterna Vision GmbH. The prescribed FAVAS game therapy was played every day for 30-45 minutes during occlusion time for 90 days. The treatment was reimbursed by the insurance companies. The patching regimen was individual and according to the guidelines provided by the German Ophthalmological Society. Lege artis-FAVAS regimen is standardized for 37.5 minutes per day and is applied in addition to the standard patching. The data about the effectivity in the literature all suggest that this time under FAVAS therapy has the best results. Therefore, this time interval was chosen and was also tested 2 times 20 minutes per day, but adherence with 1 time per day was higher [15,16]. Group 2015 contains a data set of patients who used FAVAS version 1.0 in 2015. They had to read the instructions for the games. For playing therapeutic games, only a keyboard and mouse with a fixed screen size of 15 inches were available. The FAVAS 2015 had a 1024 px max resolution; this has been an Adobe Flash limitation (Table 2). Group 2020 contains a data set of patients receiving therapy in 2020. They were able to play directly with high-resolution graphics and high usability. For playing games, not only a keyboard and mouse but also touchscreens with screens between 10 and 27 inches were available.

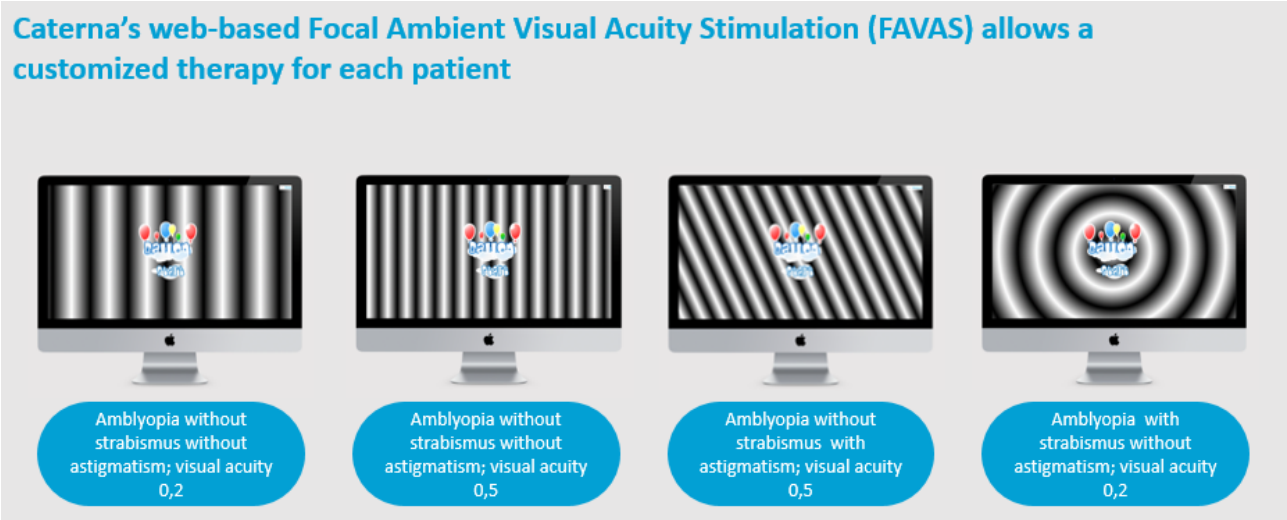
Table 2. FAVAS software differences.

FAVAS-version	2015	2020
Client	Web-based software solution supported by Plugin: Adobe Flash version 10	Web-based software solution
Browser	Usable, for example, with Microsoft Edge, Microsoft Internet Explorer 7, Mozilla Firefox ab 3.5, Google Chrome 3	Usable, for example, with Microsoft Edge, Mozilla Firefox und Google Chrome
Operating system	Windows from XP, or OS X from v10.4 or higher required	Plays a minor role
Stimulus	The stimulus is based on an Adobe Flash implementation	The stimulus is based on an HTML-5 implementation

Modification of Attention-Binding Web-Based Games

The FAVAS 1.0 therapy was modified in a few ways: in terms of technical refinement, a larger selection with a variety of engaging games to attract children's attention and participation was included, resulting in 9 edutainment HTML5 games for children between 4 and 16 years. Rotating gratings were personalized and selected according to the type of amblyopia (mild, moderate, or severe) with or without astigmatism and with or without strabismus. Figure 2 shows a few examples of personalized, selected FAVAS therapy. There was backward compatibility for browser, screen size, and hardware combined with better onboarding (patient manual, frequently asked questions, simplified usability). The majority of children between 4 and 16 years have access to a tablet computer, which makes access to the therapy independent of time and place. Therefore, we focused on making the therapy effective on tablet computers.

Figure 2. Examples of FAVAS 2020 in the customization of vertical rotating gratings according to the type of amblyopia. (A) Vertical moving gratings for anisometropic amblyopia, BCVA=0.2; (B) vertical moving gratings for anisometropic amblyopia, BCVA=0.5; (C) circular moving gratings for strabismic amblyopia, BCVA=0.2; (D) oblique moving gratings for meridional amblyopia, BCVA=0.5. BCVA: best-corrected visual acuity; FAVAS: focal ambient visual acuity stimulation.



Main Outcome Measures

The primary outcome measure was therapy adherence. Objective adherence was defined by comparing the number of minutes spent playing the computer game as monitored in the automatized, electronically recorded logbook versus the prescribed number of minutes.

Statistical Analysis

Sample size estimates were based on data from literature reviews and participants in group 2015 pilot trials who would meet the eligibility criteria for this protocol [2,3,5,6,12]. A 2-tailed independent *t* test was used to compare continuous variables such as age and adherence between the two groups. Pearson chi-square test was used for analyzing categorical variables. *P* values smaller than .05 were considered statistically significant. Adherence over 100% (the patients played more time than prescribed) was cut down to 100% for statistical analysis. Patients in group 2015 as well as in group 2020 are patients who meet the reimbursement criteria of their health insurance. The inclusion and exclusion criteria were the same as for FAVAS 2015, so these cohorts can be carefully considered comparable. This study is a retrospective study using already collected data from patients. Due to these circumstances, a power analysis is not useful because it estimates the necessary sample size before data collection. In our case, data collection already happened, and we cannot collect more or fewer data depending on the power analysis. Following Perugini [27], we provide a sensitivity analysis instead to obtain the smallest effect which can be found using the current sample. Using a conventional power of 80%, the smallest effect which can be found is d=0.34 for a 2-sample t test. The effect size for comparison between the 2015 and 2020 group for adherence (in percent) is d=0.44. Thus, the empirical effect size is far beyond the minimal effect size which can be detected using the current sample and the current sample size is deemed to be

sufficient. Adherence is expressed as a percentage (exercise minutes/maximum minutes).

Results

Overview

As shown in Figure 3, in group 2015, a total of 138 patients were analyzed; in group 2020, a total of 129 patients were analyzed. Basic characteristics of the 2 groups, such as age, sex, BCVA, and types of amblyopia, are shown in Table 3. The mean age was slightly younger in group 2020 than in group 2015, by approximately 0.6 years. Both groups had similar gender ratios and amblyopia type distributions. Patients who trained for less than 200 minutes were excluded. These were due to technical difficulties (ie, slow internet and computer problems). The patients with very little training were called by technicians and reported these problems.

Figure 3. Patient flowchart, with group 2015 having 6 dropouts and group 2020 having 4 dropouts due to technical challenges. FAVAS: focal ambient visual acuity stimulation.

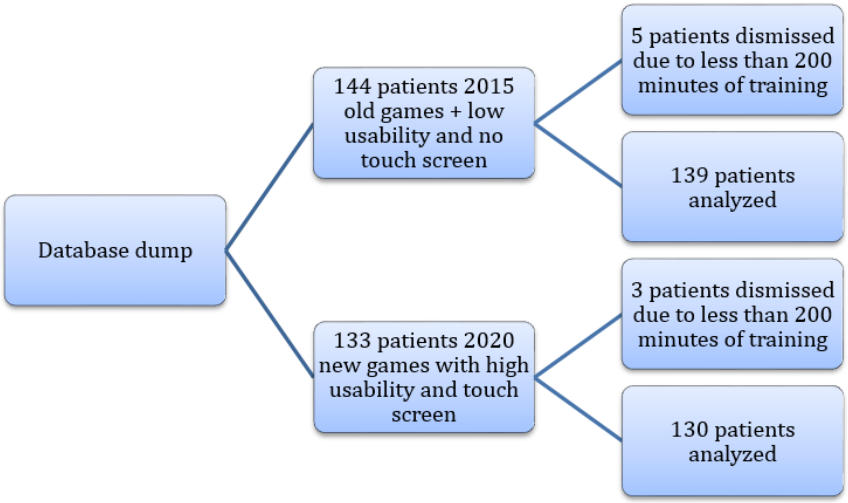


Table 3. Baseline characteristics of the two groups.

	Group 2015 (n=138)	Group 2020 (n=129)	Chi-square or *t* test (*df*)	*P* value
Sex			0.005 (1)[a]	.93
Female, n (%)	70 (50.7)	67 (51.9)		
Male, n (%)	68 (49.3)	62 (48.1)		
Age (years), mean (SD; range)	7.8 (2.1; 4.2-15.6)	7.2 (2.3; 4.3-14.7)	2.22 (265)[b]	.03
Amblyopia types			0.00092[a]	.10
Strabismic, n (%)	65 (47.1)	61 (47.3)		
Anisometropic, n (%)	73 (52.9)	68 (52.7)		
BCVA[c]			N/A[d]	N/A
<0.39	38	29		
0.4-0.69	69	68		
>0.7	31	32		

[a]Chi-square test.

[b]*t* test.

[c]BCVA: best-corrected visual acuity

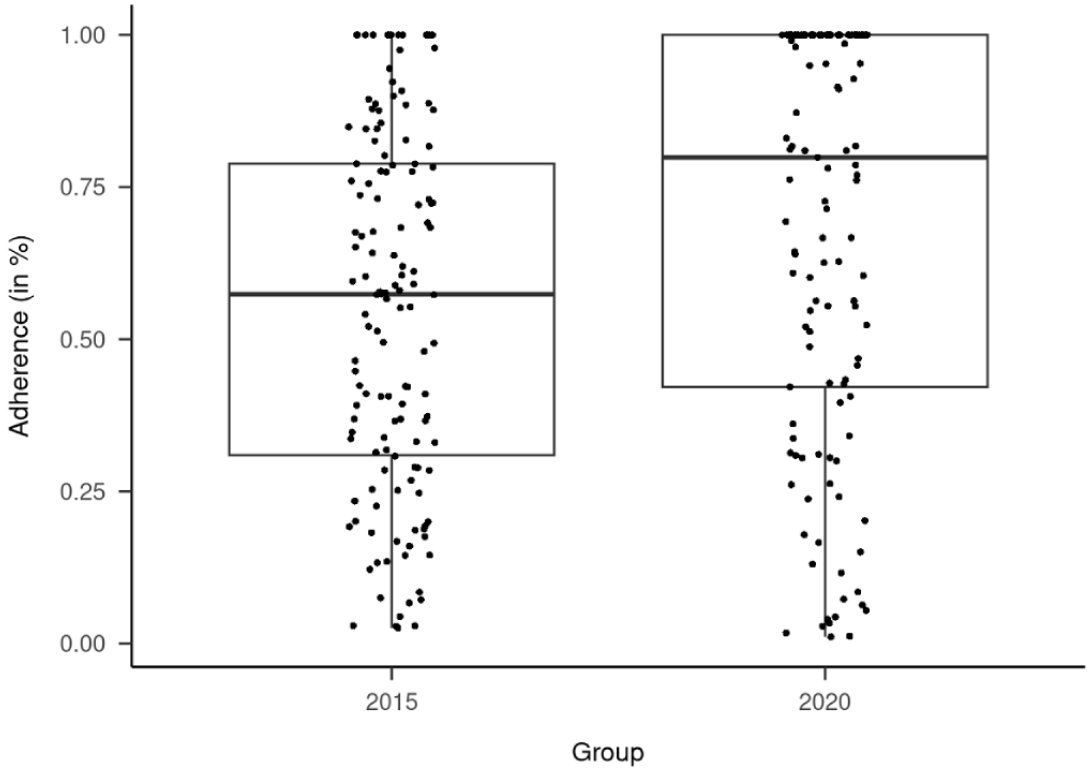
[d]N/A: not applicable.

Adherence

Children in group 2015 spent on average 2009.3 (SD 1372.1; range 36-5556) minutes on FAVAS games; children in group 2020 spent on average 2651.2 (SD 1557.1; range 38-5672) minutes on playing, meaning that group 2020 spent on average 641.9 minutes more time on FAVAS games than group 2015 ($t_{255.49}$=3.56, P<.001, d=0.45; 95% CI 0.69-0.20). In both groups, some patients played longer than 1.5 times of the prescribed time, which indicates that some individuals enjoyed FAVAS treatment (Figure 4). In group 2015, the mean adherence was 55.0% (SD 29.4%) of the prescribed exercise time. Adherence in group 2020 significantly improved up to

68.5% (SD 33.7%) compared to group 2015 ($t_{254.38}$=3.48, P=.001, d=0.44; 95% CI 0.68-0.19).

Figure 4. Box plot of adherence with FAVAS treatment games in group 2015 and group 2020. FAVAS: focal ambient visual acuity stimulation.



Discussion

Comparison With Prior Work

It was shown in earlier studies that adherence to patching is rather low, at only 60% (Table 1 and Figure 1) [2,3,5]. An overview of therapy adherence studies is shown in Table 1 and an average of occlusion compliance is shown in Figure 1. However, Loudon et al [21] and Stewart et al [20] included children younger than 4 years old, which is different from our participants. Manh et al [28] found a poor adherence of participants aged 13 to <17 years old to binocular video game treatment using an iPad at home: only 13% completed more than 75% of the prescribed 1 hour per day treatment. In this study, we showed that improving the gaming aspect and usability of FAVAS therapy can enhance patient adherence, which could possibly improve the overall therapeutic effect. Our data suggest that the new version of FAVAS with a larger selection of games attracts active participation. Backward compatibility for browsers, screen size, and hardware combined with better onboarding (patient manual, FAQ, simplified usability) seems to be a good strategy to improve patient adherence. Previous studies showed that interventions such as education cartoons for children, education flyers for parents, and sticker games have been effective in improving compliance with patching [18]. To the best of our knowledge, this is the first study on the new version of FAVAS web-based treatment games for improving adherence to patching amblyopia treatment. The modifications in this FAVAS therapy could possibly be the reason for better adherence. The reported FAVAS therapy adherence in this study was better (80%) compared to the FAVAS 2015 group, indicating that this might be beneficial for overall treatment adherence, especially for patients with low motivation for patching. However, our data do not give precise information about the rest of the prescribed occlusion time; therefore, this conclusion should be regarded with caution.

The Pediatric Eye Disease Investigator Group concluded that performing common near activities in children from 3 to 7 years old did not improve visual acuity outcomes when treating anisometropic, strabismic, or combined amblyopia with 2 hours of daily patching. The study included near activity tasks that required hand-eye coordination, such as crafts, reading, writing, and computer or video games [13]. These near tasks cannot be compared to the FAVAS game. FAVAS differs in several ways from the known moving grating stimulation Cambridge Stimulator (CAM) treatment. CAM used high-contrast square-wave gratings, which were rotated in front of the amblyopic eye while playing on a transparent cover in front of the stimulator. It was initially reported to improve outcomes when combined with patching but failed to succeed in subsequent prospective randomized controlled studies [29,30]. Beyond CAM treatment, FAVAS relies not only on the spatial frequency selectivity of the ambient background stimulus but also on the interaction of its coordinated temporal frequency parameters with the focal sensory-motoric gaming activity (Kämpf et al) [15-17]. While CAM treatment is a passive treatment, FAVAS is an active treatment because patients have to interact with games. Interactions with FAVAS games require eye-hand coordination. The treatment duration differs. CAM treatment was applied for only 7 minutes, while FAVAS was applied for 30 to 45 minutes for 90 days in this study. During interactive binocular treatment, the participant wears shutter

glasses, and the images are presented to both eyes, but parts of the image are presented only to the amblyopic eye. A fine and movable stimulus is presented to the amblyopic eye, and fixed targets or backgrounds are presented to the dominant eye. Additionally, half of 1 image for each eye is shown simultaneously, and identical images are demonstrated for both eyes with a small retinal disparity [31].

It has been proven before that monocular training improves visual acuity, but contrast sensitivity improves more when grating patterns are used [14,32]. Previous studies had positive results on stereoacuity after monocular training [33]. On the other hand, not all studies show evidence of improved visual acuity after dichoptic treatment [28-34]. It should be evaluated further regarding functional outcomes such as visual acuity, stereopsis, or contrast sensitivity improvement during FAVAS therapy. A recent study showed that near visual acuity was better than distance visual acuity in amblyopic patients, so that near visual acuity tests can be used to increase the sensitivity and specificity of the distance visual acuity tests for screening and diagnosis of amblyopia. However, other studies do not find this difference and think it is likely due to test-retest variability [35,36]. This is also an aspect we have to take into account.

Limitations

Our study has a few limitations. One is that the retrospective character and the fact that data about patching duration were only measured using electronic logbooks during the therapeutic game activity should be regarded critically. During ongoing therapeutic interventions, the adherence to patching is, on average, continuously decreasing the longer the treatment lasts [19]. Thus, our future tasks will not only be increasing average adherence but also changing the current dynamic of adherence by slowing down, maintaining, or reversing the decreasing adherence trend with computer-assisted therapeutic interventions. The results of this study show an attractive option: improving gamification and adding tablet computer functionality increased adherence, which might stop a negative dynamic during a long therapy. However, further studies with automatic occlusion dose monitoring should be added to verify our findings [37]. The long-term compliance of the FAVAS therapy has to be investigated since the binocular treatment of amblyopia using videogames study says that compliance is high early in therapy but begins to fall after 6 weeks if the game is not changed [13]. The strengths of this study are the fact that the data were generated not in an artificial setting of a trial but reflect clinical reality; also, participation was monitored objectively through electronic log files and did not include patient questionnaires regarding adherence.

Conclusions

FAVAS therapeutic game 2020 with an improved gamification aspect as well as tablet computer functionality increased adherence significantly compared to the earlier version of FAVAS 2015, indicating that FAVAS 2020 could be an effective approach to support adherence to amblyopia treatment.

Acknowledgments

All authors contributed to the study's conception and design. All authors read and approved the final manuscript. No funds, grants, or other support were received.

Conflicts of Interest

UK is consulting Caterna Vision GmbH.

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Abbreviations

BCVA: best-corrected visual acuity
CAM: Cambridge Stimulator
FAVAS: focal ambient visual acuity stimulation

Edited by S Badawy; submitted 28.07.21; peer-reviewed by M Piano, S Badawy; comments to author 16.01.22; revised version received 14.06.22; accepted 23.07.22; published 01.02.23.

Please cite as:
Bocqué C, Wang J, Rickmann A, Julich-Haertel H, Kaempf U, Januschowski K
Gamification to Support Adherence to a Therapeutic Ambylopia Treatment for Children: Retrospective Study Using a Focal Ambient Visual Acuity Stimulation Game
JMIR Pediatr Parent 2023;6:e32282
URL: https://pediatrics.jmir.org/2023/1/e32282
doi:10.2196/32282
PMID:36724007

Original Paper

Mediating Role of Treatment Perceptions in the Relationship Between Individual Characteristics and Engagement With a Digital Psychological Intervention for Pediatric Chronic Pain: Secondary Data Analysis

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Abstract

Background: Engagement predicts benefits from self-managed treatments. However, engagement is an important concern in digital interventions, with over 50% of patients being nonadherent to interventions in chronic conditions such as chronic pain. Little is known about the individual characteristics that contribute to engagement with a digital self-management treatment.

Objective: This study tested the mediating role of treatment perceptions (difficulty and helpfulness) in the association between individual baseline characteristics (treatment expectancies and readiness to change) and treatment engagement (online and offline) with a digital psychological intervention for adolescents with chronic pain.

Methods: A secondary data analysis of a single-arm trial of Web-based Management of Adolescent Pain, a self-guided internet intervention developed for the management of chronic pain in adolescents, was conducted. Survey data were collected at baseline (T1), midtreatment (ie, 4 weeks after the treatment started; T2), and post treatment (T3). Online engagement was assessed using back-end information on the number of days adolescents accessed the treatment website, while the offline engagement was assessed with the reported frequency of use of skills (ie, pain management strategies) learned at the end of the treatment. Four parallel multiple mediator linear regression models, using ordinary least square regression incorporating the variables were tested.

Results: In total, 85 adolescents with chronic pain (12-17 years old, 77% female) participated. Several mediation models were significant in predicting online engagement. A significant indirect effect was found for the path expectancies–helpfulness–online engagement (effect 0.125; SE 0.098; 95% CI 0.013-0.389) and for the path precontemplation–helpfulness–online engagement (effect −1.027; SE 0.650; 95% CI −2.518 to −0.054). Fourteen percent of the variance of online engagement was explained by the model including expectancies as a predictor (F_3=3.521; P<.05), whereas 15% was explained by the model where readiness to change was the predictor (F_3=3.934; P<.05). Offline engagement was partially explained in the model including readiness to change as the predictor but with marginal significance (F_3=2.719; R^2=0.111; P=.05).

Conclusions: Treatment perception, specifically, perceived helpfulness, was a mediator of the pathway between both treatment expectancies and readiness to change and online engagement with a digital psychological intervention for chronic pain. Assessing these variables at baseline and midtreatment may help to determine the risk of nonadherence. Further work is needed to confirm these mediation pathways in larger samples.

Trial Registration: ClinicalTrials.gov NCT04043962; https://clinicaltrials.gov/ct2/show/NCT04043962

(JMIR Pediatr Parent 2023;6:e42399) doi:10.2196/42399

KEYWORDS

treatment adherence; treatment perceptions; mediators; pediatric pain; psychological intervention; digital health; treatment; intervention; engagement; self-management; psychological

Introduction

Chronic pain is a burden for patients and their families; it has been declared a global health priority [1]. Multidisciplinary treatments have shown success in improving patient function and quality of life; however, evidence-based interventions are not widely available. The difficulty accessing pain clinics and the long waitlist times [2] call for finding new and complementary approaches to address this problem. The National Pain Strategy [3] recommends promoting and enabling self-management of pain through technology. With the development of technology and digital platforms, self-managed digital interventions are a rising therapeutic approach that can help bring evidence-based interventions to the user [4,5]. By translating validated in-person therapeutic approaches into digital interventions, the number of people with chronic pain that can receive such interventions can be dramatically increased by eliminating important barriers of access such as limited economic resources, distance from the clinics, waitlists, or limited mobility. This may allow for a significant improvement of access to specialized care and help reduce disparities. A meta-analysis on technology-delivered psychological interventions has shown some efficacy across chronic pain conditions including significantly reducing headache intensity and producing satisfaction with treatment for mixed pain conditions [5]. However, there is considerable variability in treatment engagement and treatment response. A call has been made to understand the moderators and mediators involved in predicting benefits from psychological treatments [6], in particular, to determine factors that could be targeted in different or alternative interventions that could be offered to those at risk of low treatment response [7].

Digital health approaches offer several advantages when testing for potential treatment mechanisms, such as exposing all participants to the same intervention, ensuring treatment fidelity, and collecting data prospectively at different points during the intervention in real-time, allowing for better testing of treatment mediators and processes.

On the other hand, patients following self-managed interventions are not closely monitored by their therapists, and engagement with treatment is self-motivated. Consequently, a strong candidate for mediating treatment efficacy is patient engagement, as it has been shown to be associated with treatment outcomes [8]. This is an important concern in digital interventions, with over 50% of patients being nonadherent to interventions in chronic conditions such as chronic pain [9]. Expert consensus on priority topics for future research in engagement with behavior change interventions suggests focusing on “effective engagement” instead of just “more engagement,” that is, sufficient engagement with the intervention in a way that the intended outcomes are achieved [10]. It is also recommended to distinguish between engagement with the digital intervention (online engagement) and engagement with the behavior changes taught by the intervention (offline engagement). For example, a higher use of the digital intervention (eg, more interaction and more hours spent using it) has been traditionally considered a good measure of engagement; however, it is possible that users disengage with the intervention on the web because they have already learnt the skills to change behaviors and continue to engage with those changes offline. Alternatively, users may keep engaging with the intervention digitally because they are struggling to learn the new behavior and are not able to engage with it offline.

One of the factors impacting treatment engagement is motivation. According to the Motivational Model for Pain Self-Management [11], motivation for treatment engagement is often low in people with chronic pain. It varies as a function of the perceived importance of engaging with treatment (eg, expectancies about the treatment benefits). In this study, we consider motivation to engage with the treatment in 2 ways. On the one hand, as expectancies about the treatment benefits and on the other as pretreatment readiness to change (proposed by the Transtheoretical Model of Change [12]), a concept that has been extensively studied in smoking cessation, diabetes treatment adherence, and other fields since the 1980s. In adults, high pretreatment readiness to change is associated with improvements in pain and psychological functioning after behavioral treatment [13-16]. In children, Simons et al [17] found that the strongest predictor of nonresponse after an intensive pain rehabilitation program was low readiness to change. Fortunately, readiness to change is not a trait, but a state, and it has been shown to increase after multidisciplinary pain treatment (for both children and their parents) [18].

Finally, to integrate the effects of those baseline characteristics with treatment processes, we took as a referent the Behavior Change Model for Internet Interventions [19]. This model aims to integrate treatment processes for remotely delivered interventions; one focus of this model is the perceptions patients have of the treatment, as an element that can influence engagement with the intervention. These perceptions can include, for instance, how difficult the treatment is to follow and how helpful the treatment is for coping with symptoms.

In summary, despite engagement being a clearly important variable to consider and understand, little is known about the individual characteristics that contribute to engagement with a digital self-management treatment, especially in adolescents. It is important to better understand how some baseline characteristics are associated with motivation to follow the treatment and with perceptions about it, and whether or not this influences the level of engagement with the intervention. Consequently, the main aim of this study is to examine baseline characteristics (ie, readiness to change and expectancies) as predictors of treatment perceptions (ie, helpfulness of the

treatment and difficulty following the treatment) and adherence to the treatment (both online and offline).

We hypothesized that both online (ie, number of days accessing the treatment website) and offline (ie, reported frequency of use of skills learned at the end of the treatment) engagement will be significantly and independently predicted by (1) low readiness to change, as evidenced by precontemplation scores (negative association) and (2) treatment expectancies (positive association), and they will be mediated by treatment perceptions: helpfulness (positive association) and difficulty following the treatment (negative association). In addition, we expect that individual characteristics will be significantly associated with treatment perceptions, specifically, higher expectancies will be positively associated with higher perceived helpfulness and lower difficulty following treatment recommendations, whereas precontemplation scores will have a negative association.

Methods

Procedures

In order to address our aims, we examined treatment process variables during the participation in a single-arm trial of Web-based Management of Adolescent Pain (WebMAP), a self-guided internet intervention developed for the management of chronic pain in adolescents [20]. A single-arm clinical trial design was chosen to study treatment processes because the efficacy of the intervention has already been proven for several outcome variables [20-24]. Another article has been published about baseline sleep as a predictor of treatment response using data from the same trial [25]; however, the variables studied in the present report and the aims are different.

Ethics Approval

The trial is registered on ClinicalTrials.gov (NCT04043962). The primary study and subsequent modifications were approved by the institutional review board at Seattle Children's Research Institute.

During the study period, participating adolescents had access to Web-based Management of Adolescent Pain (WebMAP), an interactive web-based intervention covering different aspects related to pain self-management and well-being, specifically education, stress and negative emotions, deep breathing and relaxation, coping skills at school, cognitive skills, sleep and lifestyle, staying active, and relapse prevention. There are 8 treatment modules assigned at a pace of completing 1 module per week. Data collection took place using the Research Electronic Data Capture (REDCap, Vanderbilt University [26]) secure system, and in this report, we use data from baseline (T1), midtreatment (ie, 4 weeks after the treatment started; T2), and post treatment (T3). Full details can be found in the main outcomes study description [25].

Participants

Inclusion criteria were (1) being 12-17 years old, (2) diagnosed with a primary pain disorder by a specialty physician in one of the participating clinics, (3) experiencing pain for at least 3 months, and (4) having access to the internet. In total, 85 adolescents with chronic pain participated in the study (12-17 years old). They were recruited from 2 multidisciplinary pain clinics (one specialized in headache and the other in complex chronic pain) at Seattle Children's Hospital from November 2018 to February 2020. The exclusion criteria were (1) presenting another serious health condition (eg, cancer), (2) not speaking English, (3) having active psychosis or suicidal ideation, and (4) having a diagnosis of sleep apnea or narcolepsy (due to the aims of the main study).

Measures

Demographic and Clinical Characteristics

Adolescent's age, sex, race and ethnicity, annual household income, and parents' education were reported by the parents. Pain characteristics (bodily location, intensity, and frequency over the past 3 months) were reported by the adolescents. A 0 to 10 numerical rating scale [27] was used to assess average pain intensity.

Baseline Characteristics (T1, Pretreatment)

Treatment Expectancies

Treatment expectancies were measured with the Treatment Expectancies Questionnaire, which assesses how participants think a treatment that may help adolescents with chronic pain. The 10-item measure assesses how likely it is that a chronic pain internet program may be useful for adolescents with chronic pain and for the management of chronic pain in different ways (eg, having less pain and making better lifestyle choices). Items are rated on a 5-point Likert scale (1="not at all likely" to 5="extremely likely"). Total scores have a possible range of 10-50, with higher scores indicating higher expectancies. This measure has been used in a previous study with pediatric chronic pain populations [28]. Cronbach α was .92 in this study.

Readiness to Adopt a Self-management Approach to Pain

Readiness to change was measured with the 30-item Pain Stages of Change Questionnaire – Adolescent version (PSOCQ-A [29]), which assesses how ready an individual is to practice self-management of pain. The items of the PSOCQ-A assess to what extent someone is ready to act (eg, "I have been thinking that the way I cope with my pain could get better" and "I am developing new ways to cope with my pain."). Items are rated on a 5-point Likert scale (1="strongly disagree" to 5="strongly agree"). The PSOCQ-A consists of 4 factors: precontemplation (in which the individual has little interest in changing their behaviors), contemplation (in which the individual is thinking about the behavioral change but is not likely to change soon), action (in which the individual is considering behavioral change and is likely to engage in change within a month), and maintenance (in which the individual is trying to maintain their behavioral changes). Each factor has a possible range of 1-5, with higher scores indicating a greater likelihood of being in that stage of behavior change. We used the precontemplation scale for this study, as it indicates a low readiness to change, which we identified as important in predicting treatment response. Cronbach α for this scale was .75.

Treatment Perceptions (T2, Midtreatment)

Treatment Helpfulness

Participants were asked to rate on a 4-point Likert scale "How positively is the treatment affecting you?" (0="did not affect me at all" to 3= "completely").

Treatment Difficulty

Participants were asked to rate on an 11-point Likert scale "How difficult are the treatment strategies for you to use?" (0="extremely easy" to 10="impossible to do").

Treatment Engagement (T3, Immediate Post-treatment)

Online Engagement

Online engagement with the treatment was assessed using back-end information from the treatment website. Specifically, the number of modules completed and the number of days adolescents accessed the treatment website were recorded.

Offline Engagement

Offline engagement was assessed with the reported frequency of use of skills learned at the end of the treatment. Participants were first presented with a list of all the skills taught in the treatment and asked to rate, on a 5-point Likert scale "How often are you currently using them?" (0="never" to 4="every day").

Statistical Analysis

Power

As a secondary data analysis study, the sample size was determined by the number of participants (N=85) in the primary trial. That sample size is estimated to be enough to test all the paths of the mediation models proposed for this study, following the recommendations of Hayes and Rookwood [30] of including at least 10 participants per each path to be tested.

Data Analysis Plan

In order to test all the hypotheses, we first computed Pearson correlations between all the relevant variables: precontemplation scores, treatment expectancies, perceptions about the treatment, online engagement, and offline engagement.

We then planned to integrate all the significant associations into 4 parallel multiple mediator linear regression models, using ordinary least-squares regression (model #4 in PROCESS [30]) to test for significant paths. Four models were used instead of 1 large comprehensive model due to the limited sample size that was available to conduct alternative analyses. We used treatment expectancies as the predictor (X) in models 1 and 2, precontemplation scores as the predictor in models 3 and 4, and engagement as the dependent variable (Y): online engagement in models 1 and 3 and offline engagement in models 2 and 4. The mediators (M) for all models were treatment perceptions: helpfulness and difficulty. All data analyses were conducted using SPSS (version 26; IBM Corp) for Mac [31] and the PROCESS 3.5 macro (Hayes et al) [30].

Results

Participant Characteristics

Participants were mostly female (n=65, 77%) and 13 (15%) were Hispanic, with a mean age of 15 (SD 1.5) years. Parents were well educated and with a medium to high income. Regarding the clinical characteristics, average pain intensity in the sample was 5.7 (SD 1.7) out of 10, average number of pain locations was 4 (SD 2.3), and the frequency of pain was daily for over half of the sample (n=57, 67%). See Table 1 for details.

Adolescents completed an average of 7 (SD 2.5) of the 8 modules of the treatment, with 51 (60%) of them completing at least 7 modules. Given the low variability, we decided to use the number of days they logged into the treatment program to compute the amount of online engagement. The two variables (ie, modules completed and days logging in) are moderately correlated (r=0.54; P<.001).

Table 1. Baseline characteristics of the sample (N=85).

Characteristics	Values
Demographic characteristics	
Age (years), mean (SD)	15.5 (1.5)
Sex (female), n (%)	65 (77)
Ethnicity, n (%)	
Hispanic or Latino	13 (15)
Race, n (%)	
American Indian/Alaska Native	5 (6)
Asian	7 (8)
Black	4 (4.6)
Latin American	7 (8)
White	77 (91)
More than one race	16 (18)
Annual household income (US $), n (%)	
<49,999	24 (28)
50,000-99,999	25 (29)
>100,000	35 (41)
Not reported	1 (1)
Parents' education, n (%)	
High school or less	4 (5)
College or vocational school	60 (70)
Graduate or professional school	20 (24)
Not reported	1 (1)
Clinical characteristics	
Usual pain severity (0-10 NRS[a]), mean (SD)	5.7 (1.7)
Pain frequency (past 3 months), mean (SD)	
Daily	57 (67)
Weekly	22 (26)
Monthly	4 (5)
Not reported	2 (2)
Pain locations (0-9), mean (SD)	4 (2.3)

[a]NRS: numerical rating scale.

Bivariate Associations Among Treatment Expectancies, Readiness to Change, Treatment Perceptions, and Engagement With the Intervention

Participants' expectancies were moderately high on average (30.4 out of 50, SD 7.1). Their precontemplation scores were 3.2 (SD 0.9) over 5, indicating a low readiness to change. Treatment perceptions were mixed, as evidenced by a moderate perceived helpfulness score (1.8 on a 0-3 scale; SD 0.9) but also a moderate perceived difficulty score (6.9 out of 10; SD 2.3). Online engagement was adequate, with an average of 12.9 days (over 8 weeks) logging into the treatment, although there was high variability (SD 12.2). Offline engagement was high, with a mean score of 3.1 on a 0-4 scale (SD 0.9).

As shown in Table 2, higher expectancies (T1) were significantly associated with lower precontemplation scores (ie, higher readiness to change; T1), higher perceived helpfulness of the treatment (T2), and higher offline engagement (T3). Offline engagement was also positively associated with the perceived helpfulness of the treatment (T2). Perceived helpfulness was, on the other hand, negatively associated with baseline precontemplation. Finally, online engagement (T3) was only associated with perceived difficulty of the treatment (T2), that is, higher perceived difficulty was associated with more online engagement.

Table 2. Descriptive statistics and correlations between treatment variables.

Variables	Mean (SD)	Expectancies	Precontemplation	Difficulty of treatment	Helpfulness of treatment	Online engagement	Offline engagement
Expectancies	30.4 (7.1)	—[a]					
Precontemplation	3.2 (0.9)	−0.30[b]	—				
Difficulty of treatment	6.9 (2.3)	0.02	0.02	—			
Helpfulness of treatment	1.8 (0.9)	0.32[b]	−0.28[c]	−0.02	—		
Online engagement	12.9 (12.2)	0.02	0.08	0.26[c]	0.22	—	
Offline engagement	3.1 (0.9)	0.24[c]	−0.11	0.19	0.27[c]	0.08	—

[a]Not available.

[b]Pearson correlations significant at $P<.01$.

[c]Pearson correlations significant at $P<.05$.

Mediation Models

Model 1: Mediation Model With Expectancies Predicting Online Engagement

The first model proposes that expectancies would impact online engagement directly and treatment mediators which would, in turn, impact online engagement (see Figure 1).

The full regression model explained 14% of the variance of online engagement (F_3=3.521; R^2=0.14; $P<.05$); however, only some paths of the model were significant. Specifically, as hypothesized, higher treatment expectancies predicted higher perceived helpfulness (path *a*2: B=0.039; SE 0.014; $P<.05$; 95% CI 0.011-0.06), but they did not significantly predict perceived difficulty. Direct effects (Table 3) of treatment perceptions were also significant: higher perceived helpfulness led to more online engagement (path *b*2: B=3.948; SE 1.718; $P<.05$; 95% CI 0.516-7.380), as predicted, and, contrary to the hypotheses, higher perceived difficulty also predicted more online engagement (path *b*1: B=1.468; SE 0.615; $P<.05$; 95% CI 0.240-2.696). The direct effect from expectancies to online engagement was not significant. Finally, regarding the indirect effects (Table 4), the path expectancies–difficulty–online engagement was nonsignificant, as the 95% bootstrap CIs contained zero. On the other hand, the path expectancies–helpfulness–online engagement is statistically significant as the CI did not contain zero (effect=0.125, SE 0.098; 95% CI 0.013-0.389).

Figure 1. Model 1: mediation model with expectancies predicting online engagement.

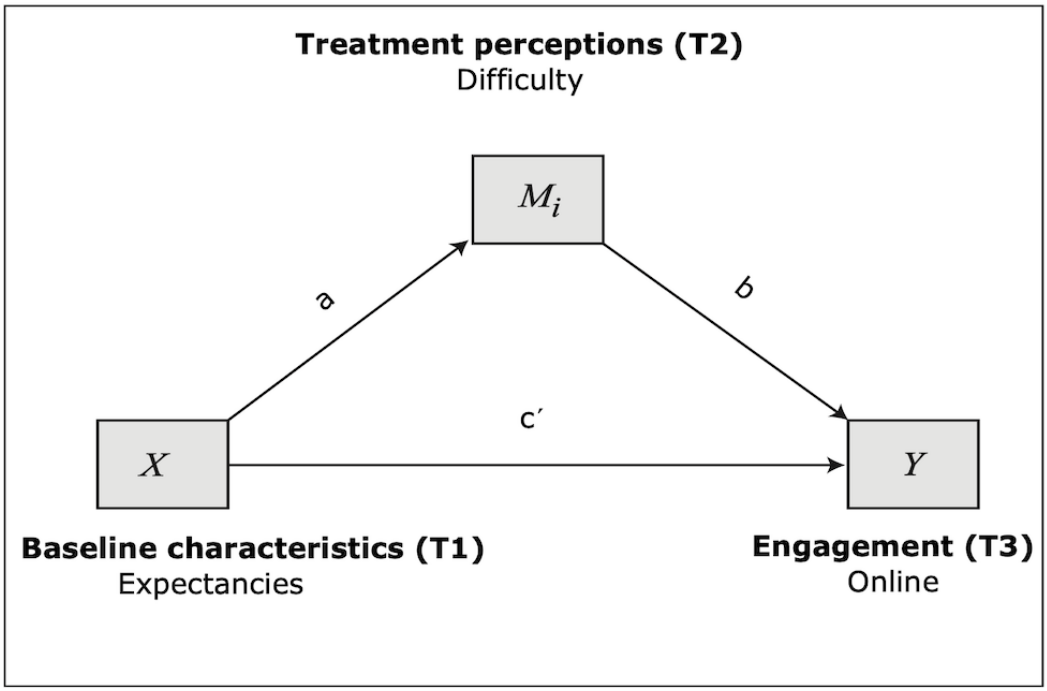

Table 3. Summary of model 1[a]: direct effects.

Direct effects	Path	B	SE	*P* value	95% CI
Expectancies to difficulty	*a*1	0.004	0.038	.923	−0.073 to 0.080
Expectancies to helpfulness	*a*2	0.039	0.014	.007	0.011 to 0.066
Difficulty to online engagement	*b*1	1.468	0.615	.019	0.240 to 2.696
Helpfulness to online engagement	*b*2	3.948	1.718	.025	0.516 to 7.380
Expectancies to online engagement	*c*’	−0.059	0.205	.773	−0.468 to 0.349

[a]R=0.374; R^2=0.140; $F_{3,65}$=3.521; P=.02.

Table 4. Summary of model 1: indirect effects.

Indirect effects	Boot[a] effect	Boot SE	Boot LLCI[b]	Boot ULCI[c]
Expectancies to difficulty to online engagement	0.006	0.069	−0.134	0.147
Expectancies to helpfulness to online engagement	0.152	0.098	0.013	0.389

[a]Boot: statistics for the indirect effects are the result of the bootstrapping method.

[b]LLCI: lower limit 5% CI.

[c]ULCI: upper limit 95% CI.

Model 2: Mediation Model With Expectancies Predicting Offline Engagement

The second model proposes that expectancies would impact offline engagement directly and treatment mediators which would, in turn, impact offline engagement (see Figure 2). That is, the variables are similar to model 1, with the exception of the outcome (offline engagement).

The full regression model was not significant (P=.39). However, some of the paths were significant. Similar to model 1, as hypothesized, higher treatment expectancies predicted higher perceived helpfulness (path *a*2: B=0.032; SE 0.014; P<.05; 95% CI 0.004-0.060), but they did not significantly predict perceived difficulty. Direct effects (Table 5) of expectancies or treatment perceptions on offline engagement were not significant in this model. Finally, indirect effects (Table 6) were not significant.

Figure 2. Model 2: mediation model with expectancies predicting offline engagement.

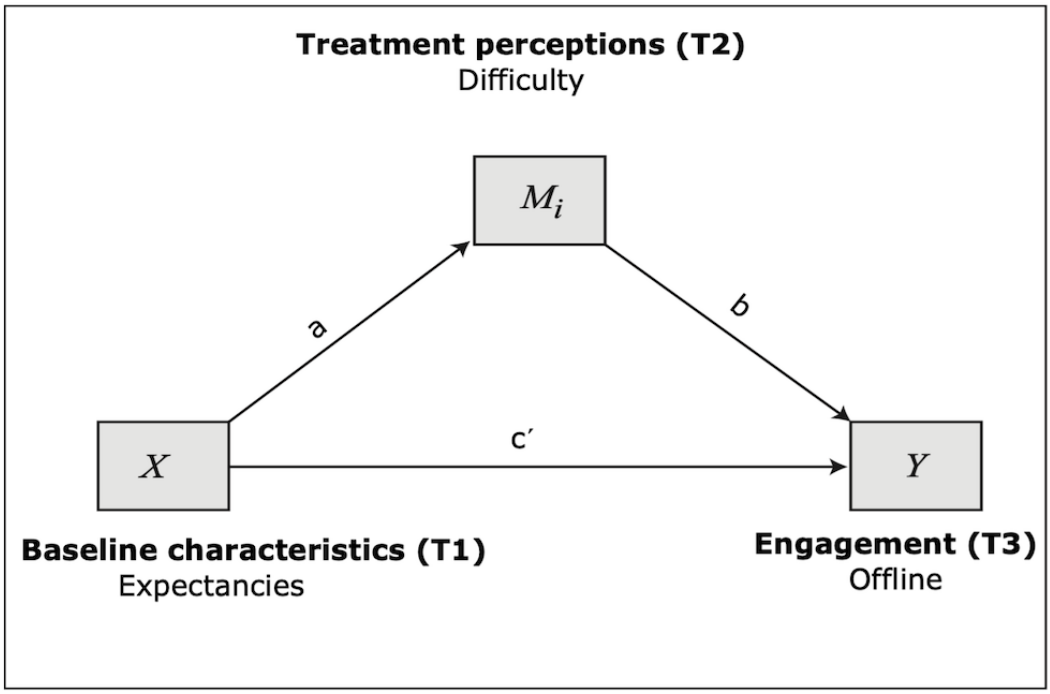

Table 5. Summary of model 2[a]: direct effects.

Direct effects	Path	B	SE	*P* value	95% CI
Expectancies to difficulty	*a*1	0.013	0.039	.743	−0.066 to 0.092
Expectancies to helpfulness	*a*2	0.032	0.014	.025	0.004 to 0.060
Difficulty to offline engagement	*b*1	0.002	0.052	.976	−0.103 to 0.106
Helpfulness to offline engagement	*b*2	0.212	0.147	.153	−0.081 to 0.505
Expectancies to offline engagement	*c*’	0.016	0.164	.325	−0.017 to 0.049

[a]R=0.219; R_2=0.048; $F_{3,61}$=1.025; P=.39.

Table 6. Summary of model 2: indirect effects.

Indirect effects	Boot[a] effect	Boot SE	Boot LLCI[b]	Boot ULCI[c]
Expectancies to difficulty to offline engagement	0.000	0.003	−0.011	0.004
Expectancies to helpfulness to offline engagement	0.007	0.007	−0.003	0.026

[a]Boot: statistics for the indirect effects are the result of the bootstrapping method.

[b]LLCI: lower limit 5% CI.

[c]ULCI: upper limit 95% CI.

Model 3: Mediation Model With Precontemplation Predicting Online Engagement

The third model proposes that readiness to change, precontemplation scores, specifically, would impact online engagement directly and treatment mediators which would, in turn, impact online engagement (see Figure 3). That is, the variables are similar to model 1, with the exception of the predictor.

The full regression model explained 15% of the variance of online engagement (F_3=3.934; R^2=0.154; P<.05); however, only some paths of the model were significant. Specifically, as hypothesized, higher precontemplation scores predicted lower perceived helpfulness (path *a*2: B=−0.254; SE 0.108; P<.05; 95% CI −0.468 to −0.039), but they did not significantly predict perceived difficulty. Direct effects of treatment perceptions were also significant: higher perceived helpfulness led to more online engagement (path *b*2: B=4.047; SE 1.678; P<.05; 95% CI 0.696-7.397), as predicted, and, contrary to the hypotheses, higher perceived difficulty also predicted more online engagement (path *b*1: B=1.457; SE 0.610; P<.05; 95% CI 0.240-2.675). The direct effect (Table 7) from precontemplation to online engagement was not significant. Finally, regarding the indirect effects (Table 8), the path precontemplation–difficulty–online engagement was nonsignificant, as the 95% bootstrap CIs contained zero. On the other hand, the path precontemplation–helpfulness–online engagement is statistically significant as the CI did not contain zero (effect=−1.027; SE 0.650; 95% CI −2.518 to −0.054).

Figure 3. Model 3: mediation model with precontemplation predicting online engagement.

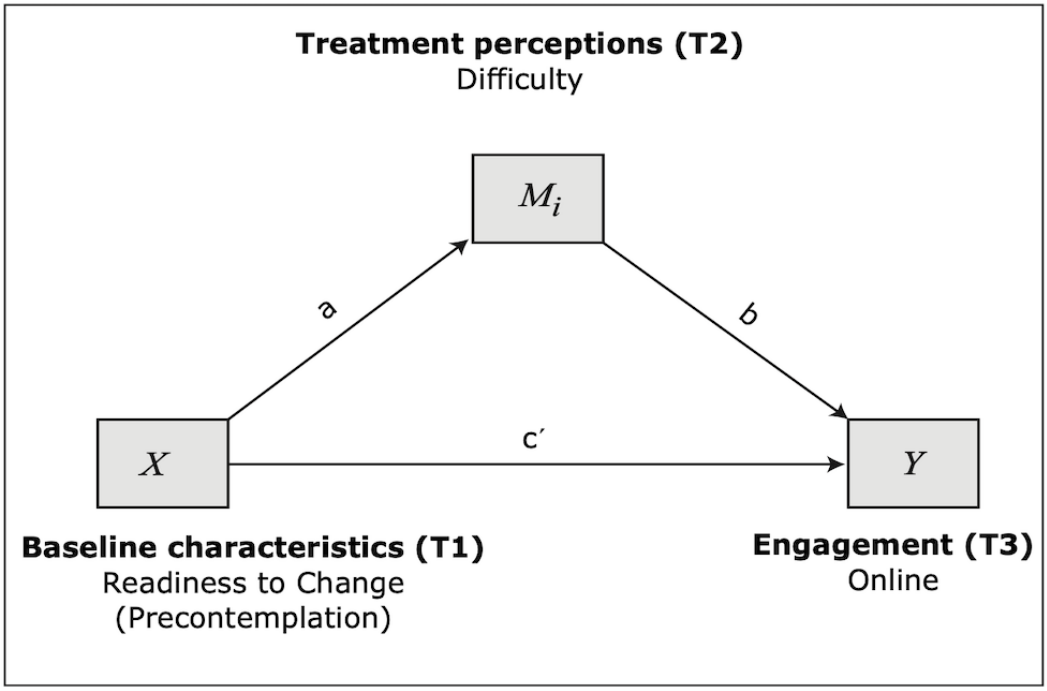

Table 7. Summary of model 3[a]: direct effects.

Direct effects	Path	B	SE	*P* value	95% CI
Precontemplation to difficulty	*a*1	0.012	0.296	.968	−0.579 to 0.603
Precontemplation to helpfulness	*a*2	−0.254	0.108	.021	−0.468 to −0.039
Difficulty to online engagement	*b*1	1.457	0.610	.020	0.240 to 2.675
Helpfulness to online engagement	*b*2	4.047	1.678	.019	0.696 to 7.397
Precontemplation to online engagement	*c*’	1.276	1.572	.420	−1.862 to 4.415

[a]R=0.392; R^2=0.154; $F_{3,65}$=3.934; P=.01.

Table 8. Summary of model 3: indirect effects.

Indirect effects	Boot[a] Effect	Boot SE	Boot LLCI[b]	Boot ULCI[c]
Precontemplation to difficulty to online engagement	0.017	0.437	−0.793	0.964
Precontemplation to helpfulness to online engagement	−1.027	0.650	−2.518	−0.054

[a]Boot: statistics for the indirect effects are the result of the bootstrapping method.

[b]LLCI: lower limit 5% CI.

[c]ULCI: upper limit 95% CI.

Model 4: Mediation Model With Precontemplation Predicting Offline Engagement

The fourth and final model proposes that readiness to change would impact offline engagement directly and treatment mediators which would, in turn, impact offline engagement (see Figure 4). That is, the variables are similar to model 2 with the exception of the predictor (readiness to change).

The full regression model was marginally significant (P=.05), explaining 11% of the variance of offline engagement (F_3=2.719; R^2=0.111). Additionally, some of the paths were significant. Similar to model 3, as hypothesized, lower readiness to change (ie, higher precontemplation scores) predicted higher perceived helpfulness (path *a*2: B=−0.239; SE 0.106; P<.05; 95% CI −0.449 to 0.028), but it did not significantly predict perceived difficulty. Direct effects (Table 9) on offline engagement were only significant for perceived helpfulness in this model (path *b*2: B=0.213; SE 0.104; P<.05; 95% CI 0.006-0.420). Finally, indirect effects (Table 10) were not significant.

Figure 4. Model 4: mediation model with precontemplation predicting offline engagement.

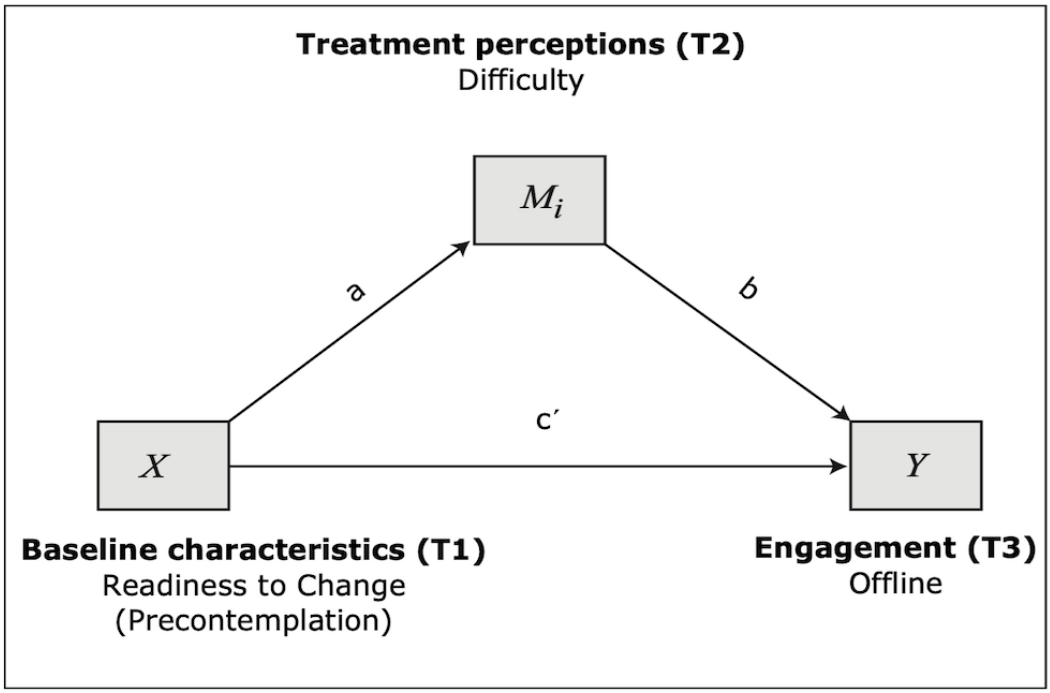

Table 9. Summary of model 4[a]: direct effects.

Direct effects	Path	B	SE	*P* value	95% CI
Precontemplation to difficulty	*a*1	−0.073	.277	.793	−0.625 to 0.479
Precontemplation to helpfulness	*a*2	−0.239	.106	.027	−0.449 to −0.028
Difficulty to offline engagement	*b*1	0.063	.040	.118	−0.016 to 0.142
Helpfulness to offline engagement	*b*2	0.213	.104	.044	0.006 to 0.420
Precontemplation to offline engagement	*c*’	−0.100	.093	.287	−0.285 to 0.086

[a]R=0.333; R^2=0.111; $F_{3,65}$=2.710; P=.05.

Table 10. Summary of model 4: indirect effects.

Indirect effects	Boot[a] Effect	Boot SE	Boot LLCI[b]	Boot ULCI[c]
Precontemplation to difficulty to offline engagement	−0.005	0.024	−0.066	0.035
Precontemplation to helpfulness to offline engagement	−0.051	0.035	−0.131	0.002

[a]Boot: statistics for the indirect effects are the result of the bootstrapping method.

[b]LLCI: lower limit 5% CI.

[c]ULCI: upper limit 95% CI.

Discussion

Principal Results

This secondary data analysis of a single-arm trial of digital psychological intervention for adolescents with chronic pain evaluated individual baseline and psychological variables that predict engagement with the intervention program. For the first time, the concepts of online versus offline engagement were examined separately.

In order to better understand how those variables are related to each other, we built 4 mediation models to test for their interactions, all of them using individual characteristics (T1) as predictors, treatment perceptions (T2) as mediators, and engagement (T3) as outcomes. Two models were built with online engagement as the outcome. Both models predicted a small but significant amount of variance (perceived helpfulness was a mediator of the pathway between the predictors and online engagement). Two models, on the other hand, had offline engagement as the outcome, and these models were not significant.

Specifically, a significant indirect effect was found for the path expectancies–helpfulness–online engagement and for the path precontemplation–helpfulness–online engagement with similar variance of online engagement explained by the model when expectancies was a predictor as when readiness to change was

the predictor. Offline engagement was partially explained in the model including readiness to change as the predictor, but with marginal significance.

Comparison With Prior Work

As proposed by the Motivational Model for Pain Self-Management [11], our results show that readiness to adopt a self-management approach for pain management is key in engagement with a digital psychological intervention for adolescent chronic pain. Prior studies have also shown that individuals with high precontemplation scores tend to believe that pain management is the responsibility of the health care professionals (or of their parents, in the case of adolescents) [29].

Specifically, we found that readiness to change influences treatment perceptions (ie, lower readiness is related with poorer perceptions) and that this, in turn, had an impact on engagement. Similar results were observed in relation to the association between expectancies and engagement. The Motivational Model for Pain Self-Management [11] suggests that pretreatment interventions could be administered before starting treatment, as a "pre-habilitation" intervention, in order to ensure the patient is ready to adopt the treatment recommendations. Hence, assessing the stage of readiness to change and determining whether patients with low versus high levels approach (and perceive) the treatment differently is a relevant aspect to consider when deciding when patients should receive a self-administered treatment. Pretreatment sessions (eg, motivational interviews and psychoeducation) could be implemented to increase readiness to change. For instance, conducting motivational interviewing can help the patient feel heard and validated and to overcome ambivalence about starting the treatment by focusing on their specific goals. Additionally, therapists can provide education on the bio-psycho-social dimensions of pain and how the way patients behave, think, and experience emotions has an impact on subsequent pain and associated symptoms. This may help the patients to better understand how having an active role following an intervention of this kind may be helpful for their pain and increase their expectancies and their willingness or readiness to engage with it.

Focusing on the selected mediators, we found that treatment perceptions, specifically perceived helpfulness of the treatment, predicted engagement. Assessing such perceptions midtreatment, which could be done on the web, using the website or app used to deliver the digital treatment, could be used to trigger warnings for the therapist in charge (in the case of supervised interventions) or to trigger booster modules (in the case of stand-alone interventions). This may also be a criterion for stepping up care to involve human support, especially when the treatment is perceived as difficult to follow, as coaching guidance has been shown to increase adherence to digital treatments in a recent meta-analysis [32]. This could help integrate stand-alone treatments into a stepped model of care, that is, if midtreatment assessment shows high perceived difficulty, the patient may need to move to a supervised intervention with a coach that can review the exercises, discuss difficulties found, and suggest different strategies to overcome such difficulties based on the specific characteristics (eg, skill level and personal preferences) of the patient.

It is noteworthy that participants perceiving the treatment as more difficult logged in significantly more, hence, contrary to the classic concept of engagement, greater online interaction does not necessarily mean participants like the treatment or it is useful for them, but instead, that they may be struggling to understand it or to implement the strategies. This defies the traditional concept of adherence in digital interventions, usually determined by the number of logins or intervention modules completed [33]. This emphasizes the importance of assessing online and offline engagement separately, as it seems that youth in our study who were struggling to understand how to follow the treatment needed to engage with the website more, perhaps to review the instructions provided.

From the 4 models proposed, only 1 predicted offline engagement, and with marginal significance. This may be due to other variables not considered in this study (eg, self-efficacy, pain intensity). However, we indeed observed a direct effect on one path of the model: perceiving the treatment as helpful was directly associated with the frequency of use of the skills. Literature is scarce in this area; nevertheless, some studies have shown that the use of the skills taught in digital interventions is a significant mediator in symptom reduction [34], making it a good candidate to be included in future studies on the efficacy of digital psychological interventions.

Future lines of research could use the models presented here to test engagement with digital interventions addressing mental health problems (eg, depression or anxiety) and other health conditions, such as diabetes or asthma.

Limitations

The findings of this work should be interpreted in light of the following limitations. First, the sample size, although usual for this type of trial, did not allow for subgroup testing or to integrate all the variables of interest in a single, more comprehensive, model. This would have allowed, for example, to test for moderated mediation and to discern the relationship between predictors and mediators. Second, most of the variables were self-reported, which might have led to a reporting bias effect. Finally, the participants lacked racial and ethnic diversity, and most were from a medium-to-high socioeconomic class, limiting generalizability to more diverse groups. Additionally, participants were mostly female, and whereas this is representative of the population with chronic pain, it might limit the generalizability to males.

In spite of the limitations, this study presents some strengths. First, the consideration of online and offline engagement separately is novel and of interest for future research on digital health. Second, the use of a digital intervention whose effectiveness has been well established, and linked to the level of engagement of the participants [21] allows us to develop firmer conclusions on the role of the different variables. Finally, the longitudinal nature of the design provided the opportunity to observe the temporal effects of the predictors on the mediators, the mediators on the outcomes, and the predictors on the outcomes.

Conclusions

In conclusion, both of the studied baseline characteristics (treatment expectancies and readiness to change) and treatment perceptions (helpfulness and difficulty) had different degrees of direct and indirect effects on both online and offline engagement with a digital psychological intervention. Assessing these variables at baseline and midtreatment may help to determine the risk of nonadherence. Future research should include larger samples to allow for the testing of all the variables in a single model.

Acknowledgments

This study was funded by the National Institutes of Health (R21 NR017312, PI: TP) and the Hearst Foundation (PI: RdlV). RdlV's work on this project was supported by the Spanish Ministry of Science and Innovation with a Ramon y Cajal contract (RYC2018-024722-I). The sponsors had no involvement in the study design, collection, analysis, or interpretation of the data, writing the manuscript, or the decision to submit the paper for publication. The authors would like to thank the participating families.

Authors' Contributions

Conceptualization, funding acquisition, formal analysis, writing, review, and editing of the manuscript were performed by RdlV; conceptualization, funding acquisition, project administration, supervision, writing, review, and editing of the manuscript were performed by TP.

Conflicts of Interest

None declared.

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Abbreviations

PSOCQ-A: Pain Stages of Change Questionnaire-Adolescent version
REDCap: Research Electronic Data Capture
ULCI: upper limit 95% confidence interval
WebMAP: Web-based Management of Adolescent Pain

Edited by S Badawy; submitted 02.09.22; peer-reviewed by H Shen, S Althammer ; comments to author 25.12.22; revised version received 16.01.23; accepted 17.01.23; published 06.03.23.

Please cite as:
de la Vega R, Palermo TM
Mediating Role of Treatment Perceptions in the Relationship Between Individual Characteristics and Engagement With a Digital Psychological Intervention for Pediatric Chronic Pain: Secondary Data Analysis
JMIR Pediatr Parent 2023;6:e42399
URL: https://pediatrics.jmir.org/2023/1/e42399
doi:10.2196/42399
PMID:36877543

Original Paper

Long-term Memory Testing in Children With Typical Development and Neurodevelopmental Disorders: Remote Web-based Image Task Feasibility Study

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Abstract

Background: Neurodevelopmental disorders (NDD) cause individuals to have difficulty in learning facts, procedures, or social skills. NDD has been linked to several genes, and several animal models have been used to identify potential therapeutic candidates based on specific learning paradigms for long-term and associative memory. In individuals with NDD, however, such testing has not been used so far, resulting in a gap in translating preclinical results to clinical practice.

Objective: We aim to assess if individuals with NDD could be tested for paired association learning and long-term memory deficit, as shown in previous animal models.

Methods: We developed an image-based paired association task, which can be performed at different time points using remote web-based testing, and evaluated its feasibility in children with typical development (TD), as well as NDD. We included 2 tasks: object recognition as a simpler task and paired association. Learning was tested immediately after training and also the next day for long-term memory.

Results: We found that children aged 5-14 years with TD (n=128) and with NDD of different types (n=57) could complete testing using the Memory Game. Children with NDD showed deficits in both recognition and paired association tasks on the first day of learning, in both 5-9–year old (P<.001 and P=.01, respectively) and 10-14–year old groups (P=.001 and P<.001, respectively). The reaction times to stimuli showed no significant difference between individuals with TD or NDD. Children with NDD exhibited a faster 24-hour memory decay for the recognition task than those with TD in the 5-9–year old group. This trend is reversed for the paired association task. Interestingly, we found that children with NDD had their retention for recognition improved and matched with typically developing individuals by 10-14 years of age. The NDD group also showed improved retention deficits in the paired association task at 10-14 years of age compared to the TD group.

Conclusions: We showed that web-based learning testing using simple picture association is feasible for children with TD, as well as with NDD. We showed how web-based testing allows us to train children to learn the association between pictures, as shown in immediate test results and those completed 1 day after. This is important as many models for learning deficits in NDD target both short- and long-term memory for therapeutic intervention. We also demonstrated that despite potential confounding

factors, such as self-reported diagnosis bias, technical issues, and varied participation, the Memory Game shows significant differences between typically developing children and those with NDD. Future experiments will leverage this potential of web-based testing for larger cohorts and cross-validation with other clinical or preclinical cognitive tasks.

(JMIR Pediatr Parent 2023;6:e39720) doi:10.2196/39720

KEYWORDS

memory; neurodevelopmental disorder; autism spectrum disorder; intellectual disability; developmental delay; hippocampus; recognition; paired association learning; remote testing; autism; disorder; genetics; developmental; developmental disorder; game; remote; testing; diagnose; diagnosis

Introduction

Neurodevelopmental Disorders Are Common

Learning new information by forming associations is at the core of development and daily functioning. Yet, our understanding of how such associations may differ between typically developing individuals and those with neurodevelopmental disorders (NDD) remains insufficient in some important aspects. NDD includes a group of diagnoses, in which the development of typical brain functions, such as attention, cognition, or social functioning, is altered [1]. Examples of common NDDs include attention-deficit/hyperactivity disorder (ADHD), autism spectrum disorder (ASD), and intellectual disability [2]. In the United States alone, approximately 1 in 6 (17%) children between the ages of 3 and 17 years had an NDD, as reported by the parents [3]. This mirrors the rate identified in population studies worldwide [4-10]. Not only individuals with NDD but also their families will experience significant financial and psychological burdens [11-13], necessitating more effort in developing targeted interventions, as most NDD will have lifelong effects [14].

Current Discrepancies in the Memory Type Tested Between Preclinical and Clinical NDD Models

In the last decade, there has been a vast increase in studies identifying genes associated with each neurodevelopmental condition and the development of multiple animal models to study the disorders [15-17]. Nevertheless, there is a disparity between the cognitive testing used in humans and the cognitive measures used in animal models, which may hamper the translation of candidate treatments [18,19].

As many of the genes discovered in NDD belong to signaling pathways that were already investigated in animal models of learning and memory [20,21], many well-established “memory assays” previously used in NDD animal models do not necessarily align with NDD clinical testing. Animal testing has been focusing on studying nonassociative (sensitization and habituation) versus associative memory (fear conditioning, spatial navigation, and olfactory conditioning) [22,23], and short-term memory (STM; training and recall within minutes) versus long-term memory (LTM; 24 hours) [24]. Mutants for NDD gene orthologues and candidate pharmacological interventions have been characterized for their effects on those behaviors [25-27]. The tools to detect memory problems of NDD individuals in clinical settings, however, remain inadequate or rely heavily on self-reports [28,29].

While some of the pioneering work on memory and recall in typical individuals, such as one by Ebinhaus, investigated STM and LTM [30], most of the clinical memory testing has been focusing on STM types, such as working memory [31]. The majority of individuals with NDD, including those with common genetically defined conditions such as Fragile X syndrome [32-35], Down syndrome [36,37], Williams syndrome [38], as well as clinically defined disorders, such as specific language impairment [39,40], ADHD [41-43], ASD [44], and intellectual disability [45-48], have been found to have STM defects. LTM, however, has not been reported, except in 1 study done in the 1990s, showing LTM defects in Down syndrome [49]. We hypothesize that this is partly due to technical and financial limitations that limit the feasibility of developing novel and highly accurate memory testing, and repeated testing in a lab setting. This suggests that web-based or remote testing might be the solution.

Similarly, limitations in the current test design have limited consistent use of memory testing in NDD. Paired association is often employed clinically with the use of picture and name or word-word association [50]. This type of test relies on hippocampal functioning [51-54]. Typically, an individual will learn an association between a person’s picture and their name. At testing time, they will be presented with the photo and 3 names (1 correct and 2 other names of different individuals seen in the training session). Those with NDD can have challenges in reading and have, therefore, not been exposed to paired association testing extensively [55,56]. Nevertheless, picture-based association tasks have been used for children with dyslexia [22,57] and NDD [58] to circumvent issues with language delay [59,60].

A potential issue in remote testing would be to infer the degree of attention of the participants. Control tasks [61], such as recognition of a pair, a less difficult, hippocampal-independent task, have been used to test the ability of an individual to participate and their attention to a task [54,62,63]. In this situation, using flanker images, which have never been seen before, makes recalling the association easier.

Emergence of Web-based and Remote Testing as a Method for Cognitive Assessment in NDD

Touch screen-based testing has emerged as an accurate and engaging tool for testing children and individuals with NDD. Evidently, subtasks of the NIH Toolbox for the Assessment of Neurological and Behavioral Function, such as episodic memory [64] and working memory [65], have been used recently in a clinical trial for Fragile X syndrome [66]. However, those tasks

do not assess associative or LTM skills. Additionally, the NIH toolbox currently needs to be administered locally on tablets, with guidance from trained researchers in a laboratory. Another test that is used for individuals with NDD is the Cambridge Neuropsychological Test Automated Battery, which evaluates working memory, episodic memory, attention, and decision-making [67]. This test is licensed and has been administered in individuals with ADHD using researchers' tablets [68,69]. While being well constructed, these tests currently do not allow for the testing of associative memory at different time points. They are also limited to in situ testing in the laboratory or on researchers' devices, making it expensive and inaccessible to a large number of participants. Testing in traditional laboratory environments can also be challenging for children, especially those with NDD, considering the high prevalence of anxiety [70-76].

Thus, we aim to develop a remote web-based and accessible cognitive test, which could better mirror the type of memory (associative) and the different time points (STM and LTM) used in preclinical models, in hope that this will make preclinical therapies more easily translated into clinical trials. Here, we assessed the feasibility of such testing administered web-based in individuals with typical development (TD) and NDD.

Methods

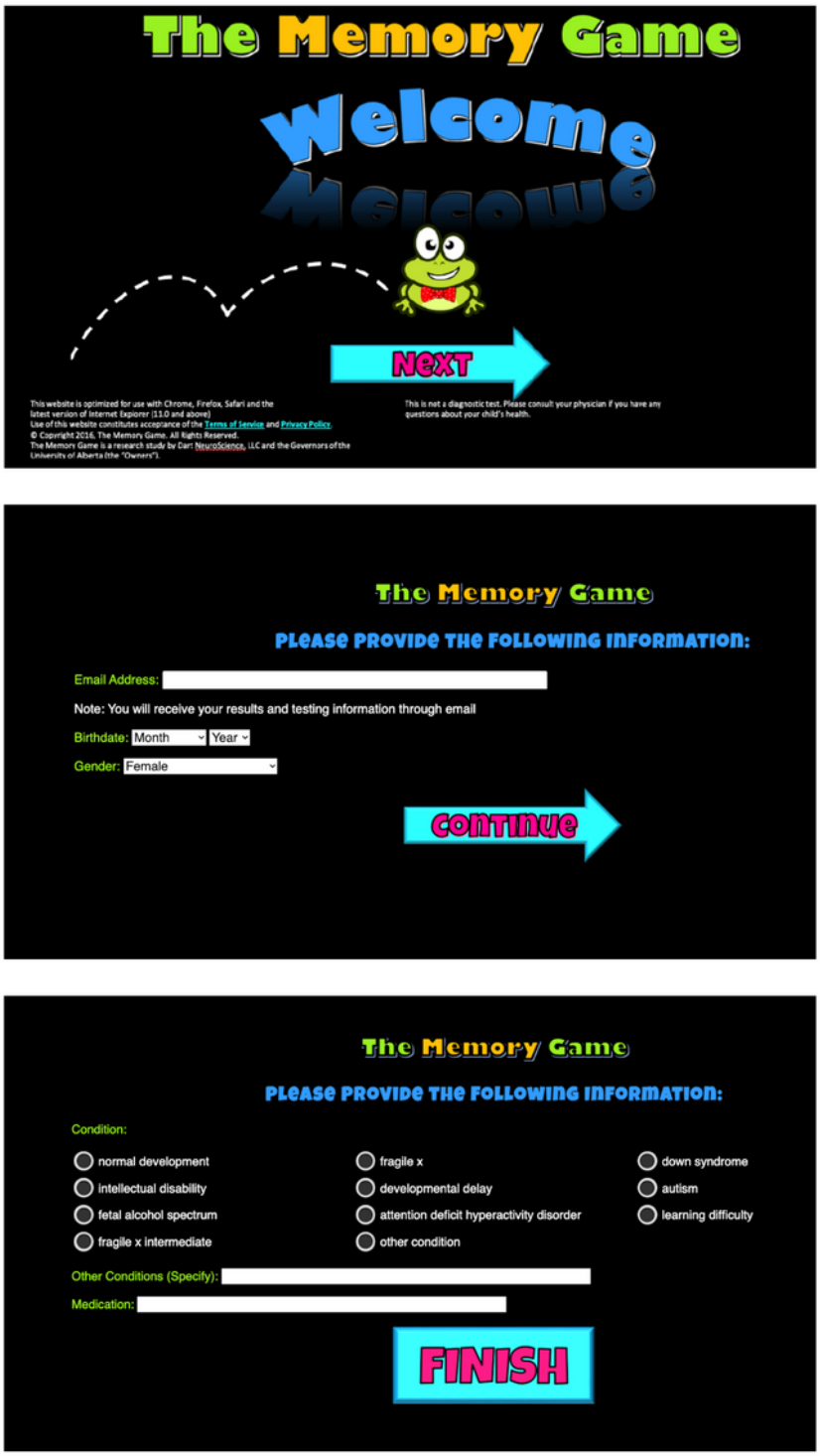
Ethics Approval

The project was approved by the ethics committee at the University of Alberta (Pro00033138).

Informed Consent

Informed consent to participate in the study was sought from the participant's parent or guardian (Multimedia Appendix 1). Next, participants, or parents and caregivers, were asked to provide information about the participant's age, neurological and medical conditions, sex, and current medications (Figure 1).

Figure 1. Registration. Participants or caregivers enter their email addresses (to receive the participant code) and then provide demographic information as well as the diagnosis they have (if applicable).



Participants

In total, 128 individuals with no known neurological conditions and 57 individuals with NDD, including developmental delay, ASD, and intellectual disability participated in the study. Eligible participants' caregivers self-reported their diagnoses or the absence thereof. Table 1 includes the demographic information for the participants. The participants were contacted by their School Board via the Healthy Infants and Children Clinical Research Program (HICCUP) or via family support groups. The access was free of charge to participants. The participants received the URL for the Memory Game.

Table 1. Demographic characteristics of participants.

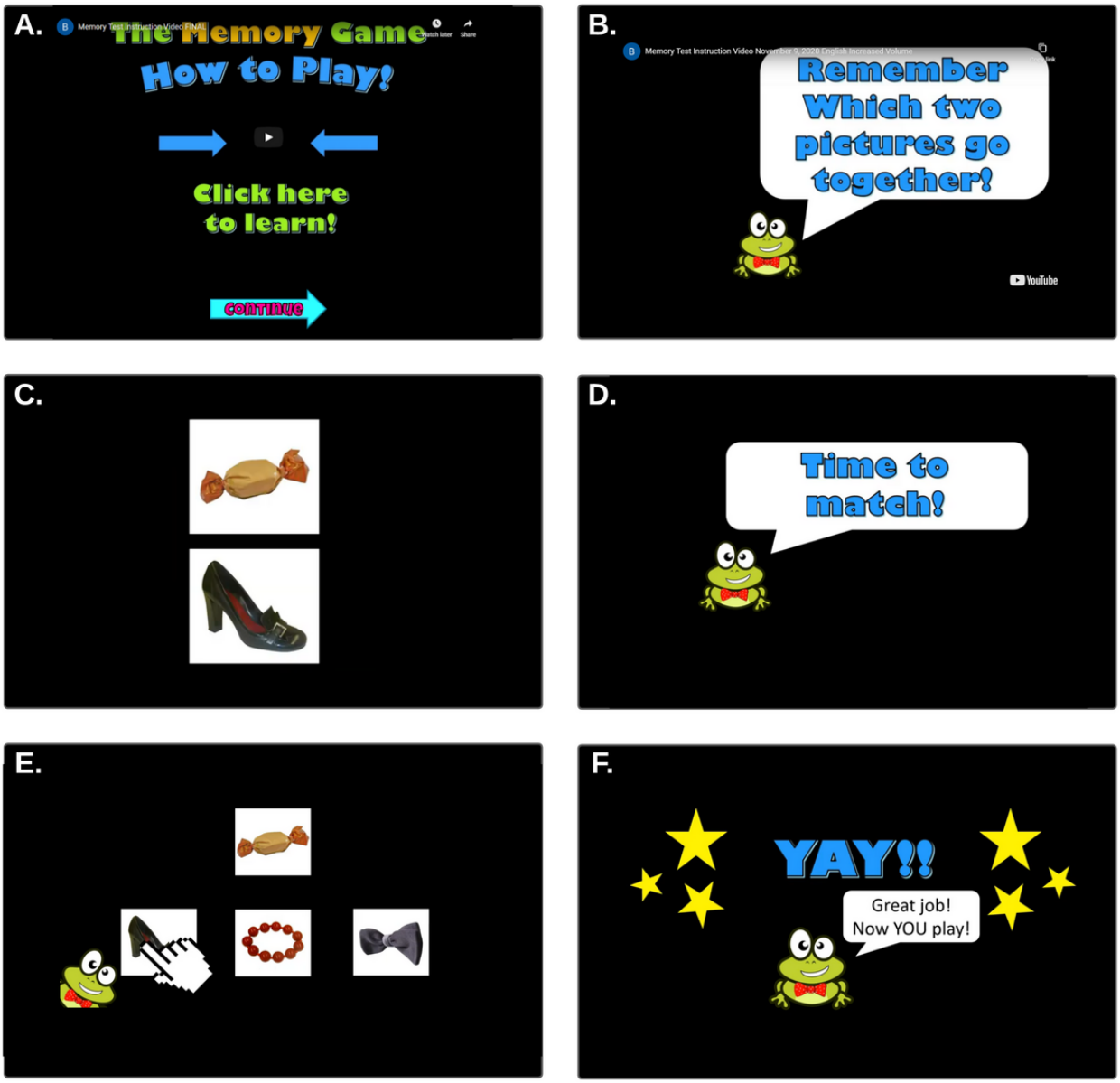
Condition and age group	Day 1, n	Day 2, n
Typical development		
5-9 years	97 (female: 4, male: 4, not available: 89)	56 (female: 4, male: 2, not available: 50)
10-14 years	31 (female: 3, male: 3, not available: 25)	17 (female: 0, male: 2, not available: 15)
Neurodevelopmental disorders		
5-9 years	30 (female: 7, male: 6, not available: 17)	16 (female: 5, male: 4, not available: 7)
10-14 years	27 (female: 3, male: 6, not available: 18)	19 (female: 3, male: 6, not available: 10)

The Memory Game Interface

All participation in the Memory Game was done web-based using a touch screen tablet device (eg, iPad). The procedure has five main components: (1) consent, (2) registration, (3) tutorial video, (4) training phase, and (5) testing phase.

Having completed the consent and registration, participants received a code via email, which allows them to move on to the training and testing components. These occur over 2 days. On day 1, the participants participate in 3 phases of the game: a tutorial phase, a practice phase, and a testing phase. The phases had to be completed to proceed through the test. The tutorial phase consisted of verbal and visual explanations of completing the test by properly matching the pairs. This is in the form of an instructional video to explain how the game works. A cartoon frog demonstrates with examples, while a voiceover explains what to do (Figure 2). The video is followed by the practice phase, in which participants are first shown 6 sets of pairs, followed by 6 questions. In this section, they were given feedback as to whether their response was correct or incorrect. Finally, participants went through the testing phase where they were shown 20 sets of pairs followed by 20 questions, this time without any feedback on their responses. On day 2, the participants were directed to the testing phase (as on day 1) and were not given feedback on their responses.

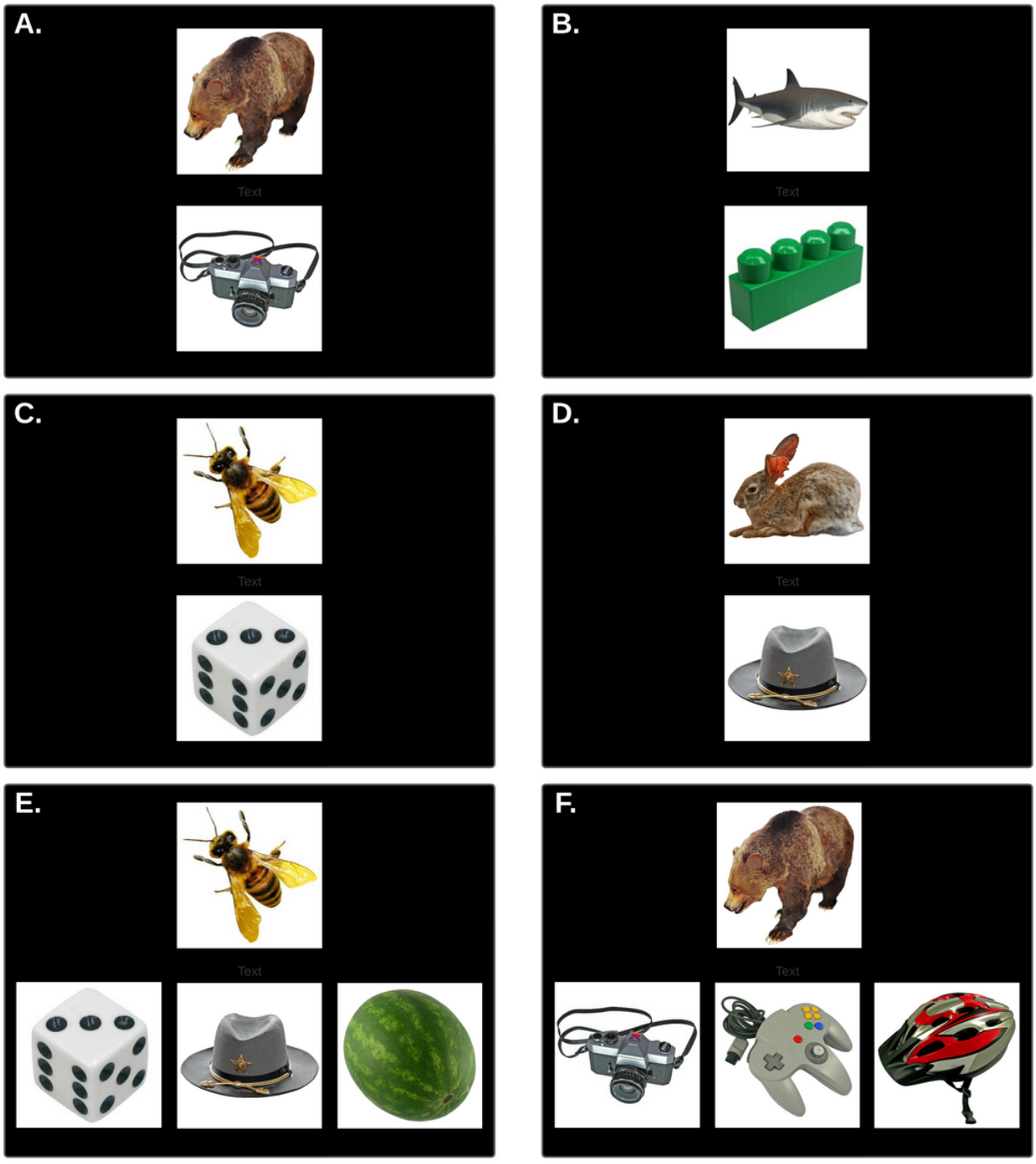
Figure 2. Tutorial video demonstration. In order to explain the task as easily as possible (without direct supervision from the researchers), a tutorial video explaining the procedure to the participants was developed. This includes a voiceover reinforcing the information provided visually about the pictures that go together.



Task Description

The Memory Game includes questions testing both paired association and recognition memory, depending on the distractor photos present (Figure 3). In a recognition question, the 2 distractor photos are not part of any pairs seen in training and have not been previously viewed. In a paired association question, 1 of the distractors will be the matching photo for a prompt not currently being displayed and so will have been previously viewed. The images used have been selected based on their shape and appearance from the Bank of Standardized stimuli (BOSS) database created by Dr Mathieu Brodeur.

Figure 3. Example of stimuli and paradigms used in the Memory Game. (A-D) Representative examples of pairs of images used in the training phase. The testing phase consists of 2 different types of tasks: paired association (PA) and recognition (R). (E) In the PA task, the participant must distinguish the correct association (the bee goes with the dice as seen in training 3C) but with flanker images present that were part of other associations presented in the training phase (hat from training 3D), making the task more difficult. (F) For the R task, the target image from the pair (the camera which goes with the bear) is flanked by 2 pictures, which were not seen in the training phase.



Task Development

We initially developed the Memory Game for testing using E-Prime (Psychology Software Tools) and administered it to children with NDD in our developmental neurology clinic, using a touch screen laptop under the supervision of trained undergraduate neuroscience students. This allowed us to optimize the instruction video and the choice of images, and refine the task. For instance, we found that having a voiceover during the instruction video made it easier for the participants and caregivers to follow. The choice of the pictures used for the paired association and recognition testing, which were standardized in the BOSS database, was reviewed for general understandability and quality assurance with caregivers and for formatting (orientation, color, and shapes) with 2 psychologists from our team (SAW and JP). Similarly, we changed the position of the "correct response" from left, middle, and right to prevent a "false success" if, for instance, an individual always

chose a given position. We also sought feedback from caregivers present in the room during the testing about the flow used and challenges in understandability. In addition to general comments, we ensured that the participants understood the instruction video and the training and testing phases of the Memory Game. Once established in E-Prime software, a widely used program for stimulus presentation [77], the final version of the task was discussed with the programmers (Jeffrey Van Alstine, Arthur Schuiltz, Department of Education from University of Alberta) and developed for web-based testing on tablets. The Memory Game underwent several revisions to optimize responsiveness. While diagnosis and age were included in all versions, sex was added in the second version only.

Coding Approach

The Memory Game consists of 3 parts: the front-end game interface, the researcher interface, and the application programming interface (API) that both communicate with. The front-end game interface is static HTML running a custom web application built with jQuery 1.11 (OpenJS Foundation) and reliant on the YouTube iFrame API. The researcher interface is a small custom PHP 7 application with no dependencies. The API itself is constructed on the PHP Slim framework v3.4, uses PHPMailer v5.3 to send confirmation or reminder emails through a local university SMTP server, and in turn saves the data in a MySQL (Oracle Corporation) database with any identifying information (email addresses) encrypted such that it can only be decoded and read by researchers with the correct key. The Memory Game is web based and can be accessed in [78].

Data Analysis

From the game component, the percentage of correct responses was recorded, as well as the time required to answer each question as reaction time (RT).

The performance of participants with NDD was compared against the corresponding age group of the TD participants. The groups were broken down into 2 age groups: 5-9 years and 10-14 years. The percent correct score is given as a percentage of questions answered correctly. The performance on day 1 and day 2 was plotted. A line joining those 2 was drawn and the slope was used to estimate memory decay. RT is the average time participants took to answer the questions and is given in ms. Unpaired *t* tests with assumed Gaussian distribution (using parametric test), no assumption about consistent SDs (the Welch *t* test), and no correction for multiple comparisons were performed (*P* value * <.05, ** <.01, *** <.001; Cronbach α=.05). Effect sizes between groups were reported as Cohen *d* values. All statistical analyses were run using Prism software (GraphPad).

Outlier Analysis

For RT, any outliers for a participant were detected using a modified Z-score [79], adapted for small data sets, and then removed. This was done on a participant-by-participant basis, with any absolute value greater than 3.5 labeled as an outlier.

Results

Paired Association and Recognition Performance on Day 1

We recruited individuals with TD and individuals with different types of NDD. These were self-reported by the users' parents and included developmental delay, intellectual disability, and ASD (Table 2).

We started by assessing learning performance (day 1) for individuals with NDD compared to individuals with TD. We evaluated both performance and RT for each type of paradigm (paired association and recognition) in the function of age group (5-9 years old and 10-14 years old).

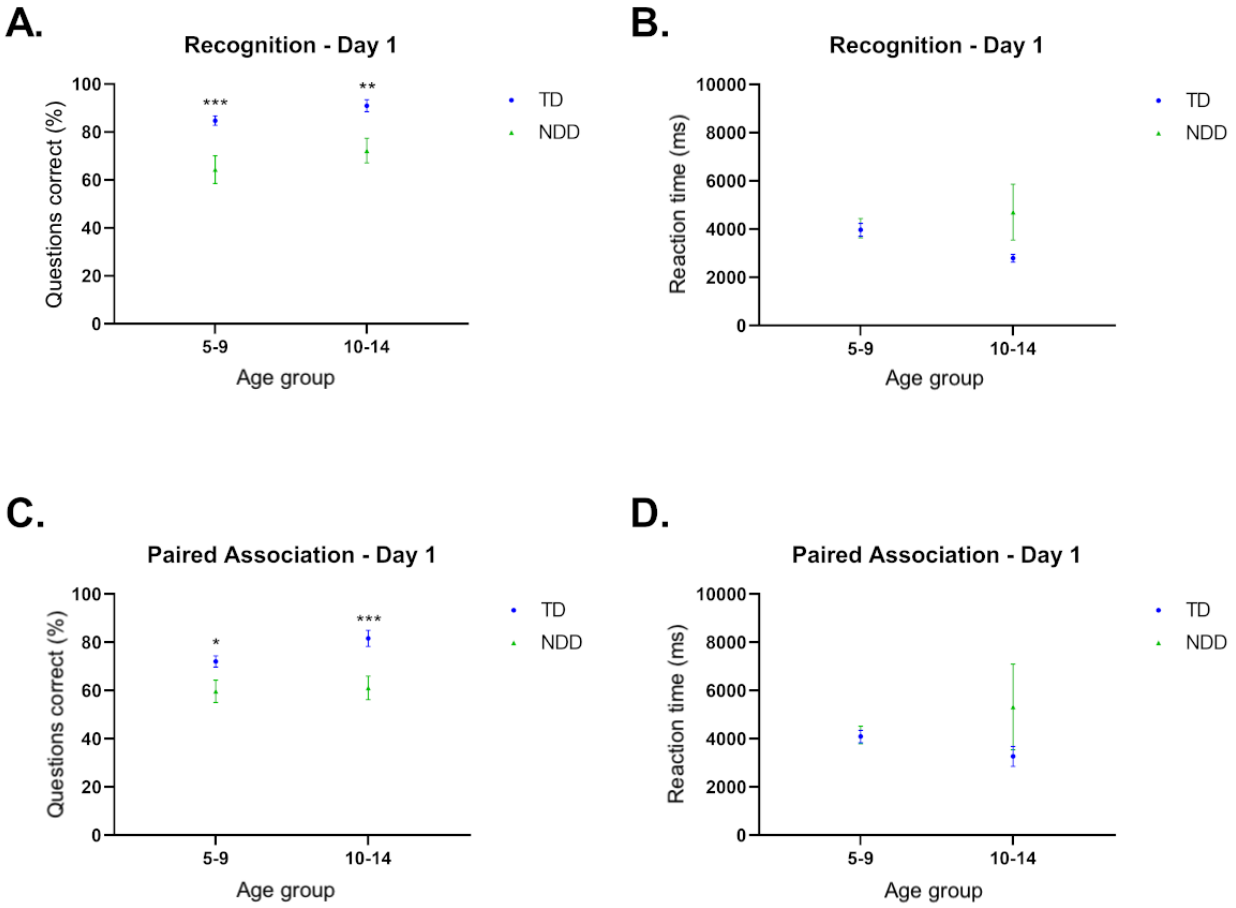
The typical session length ranged from 3 to 6 minutes. Not all participants completed the test on day 1 after initiating it. For day 1, 69 TD and 32 NDD individuals started but did not finish the practice portion, while 32 TD and 14 NDD individuals finished the practice but not the testing portion. For day 2, among participants that completed day 1, 5 TD and 12 NDD started but did not finish the testing.

NDD performance was significantly lower for recognition memory in both age groups (ages 5-9 years, *P*<.001, *d*=0.89; ages 10-14 years, *P*=.001, *d*=0.90) (Figure 4A). We found that RT was not significantly different between TD and NDD individuals (ages 5-9 years, *P*=.90; ages 10-14 years, *P*=.09) (Figure 4B). We observed a trend toward decreased RT from 5-9 to 10-14 years in TD, but we did not observe such a reduction in NDD individuals.

Table 2. Distribution of diagnosis by age and day of memory test performance.

Condition	Day 1		Day 2	
	Ages 5-9 years (n=30), n	Ages 10-14 years (n=27), n	Ages 5-9 years (n=16), n	Ages 10-14 years (n=19), n
Autism	7	3	4	2
Developmental delay	15	12	9	9
Intellectual disability	0	1	0	1
Multiple conditions	8	11	3	7

Figure 4. Performance in recognition (R) and paired association (PA) tasks. (A) Performance of individuals with typical development (TD) and neurodevelopmental disorders (NDD) in the recognition task by age group. (B) Reaction time (RT) in the R task in individuals with TD and NDD by age group. (C) Performance for the PA task in individuals with TD and NDD by age group. (D) RT for the PA task in individuals with TD and NDD by age group. TD ages 5-9 years, day 1: n=97; TD ages 10-14 years, day 1: n=31; NDD ages 5-9 years, day 1: n=30; NDD ages 10-14 years, day 1: n=27. *t* tests were performed to assess differences. **P*<.05, ***P*<.01, ****P*<.001.



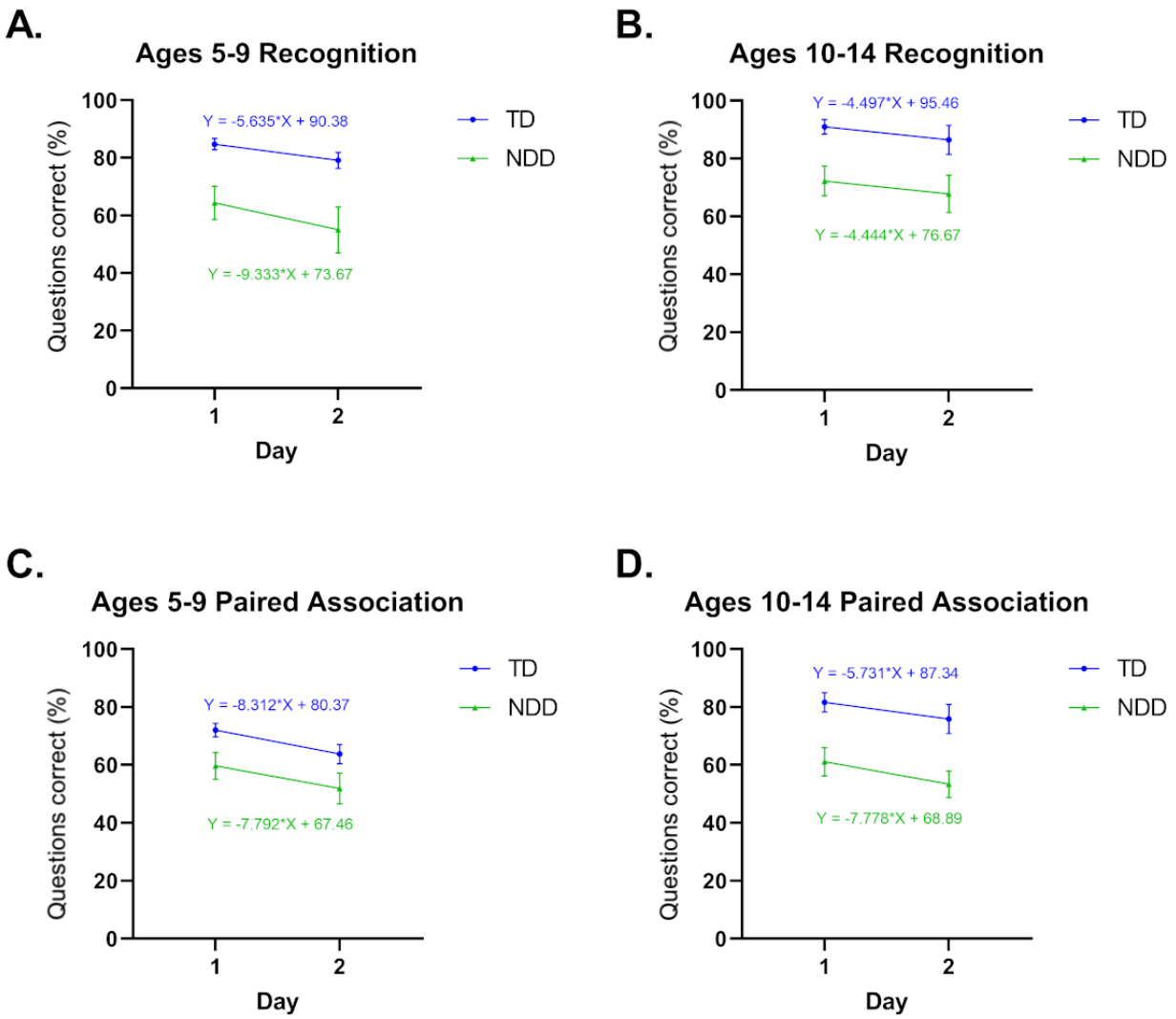
For paired association memory, we found significant deficits in 5-9 years old children (*P*=.01, *d*=0.53) and 10-14 years old (*P*<.001, *d*=0.94) with NDD compared to TD (Figure 4C). RT did not show significant differences (ages 5-9 years, *P*=.91; ages 10-14 years, *P*=.23) but showed a trend for decreased RT in TD (Figure 4D) between the 2 age groups. RT in NDD trended toward increasing when comparing 5-9 years old to 10-14 years old individuals, suggesting that NDD performance potentially requires more cognitive processing, and thus the increased reaction time.

We also found that recognition scores were higher than the paired association. This difference was observed for both groups; however, it was only significant for the TD groups (ages 5-9 years, *P*<.001, *d*=0.60; ages 10-14 years, *P*=.03, *d*=0.57) and not the NDD groups (ages 5-9 years, *P*=.53; ages 10-14 years, *P*=.12).

Memory Decay From Day 1 to Day 2

We found that for the recognition task, 5-9 years old individuals with NDD presented with a faster decay in performance on day 2 (24-hour decay) compared to individuals with TD, as shown by the difference in slope (Y=5.637 in TD vs Y=9.333 in NDD) (Figure 5A). Nevertheless, this was not observed in individuals aged 10-14 years (Figure 5B). Strikingly, the opposite trend was observed for the paired association. Individuals with NDD showed similar decay in the 5-9 years old group (Figure 5C) but had higher decay in 10-14 years old (Figure 5D). No differences were observed in any of the reaction time comparisons (Multimedia Appendix 2). There was similar attrition in participation from day 1 to day 2 at all ages for both TD and NDD groups (41 out of 97 participants [42%] for individuals with TD vs 14 out of 30 [47%] for those with NDD in the 5-9 years old group, and 14 out of 31 participants [45%] in TD vs 12 out of 27 (44%) in individuals with NDD in the 10-14 years old group).

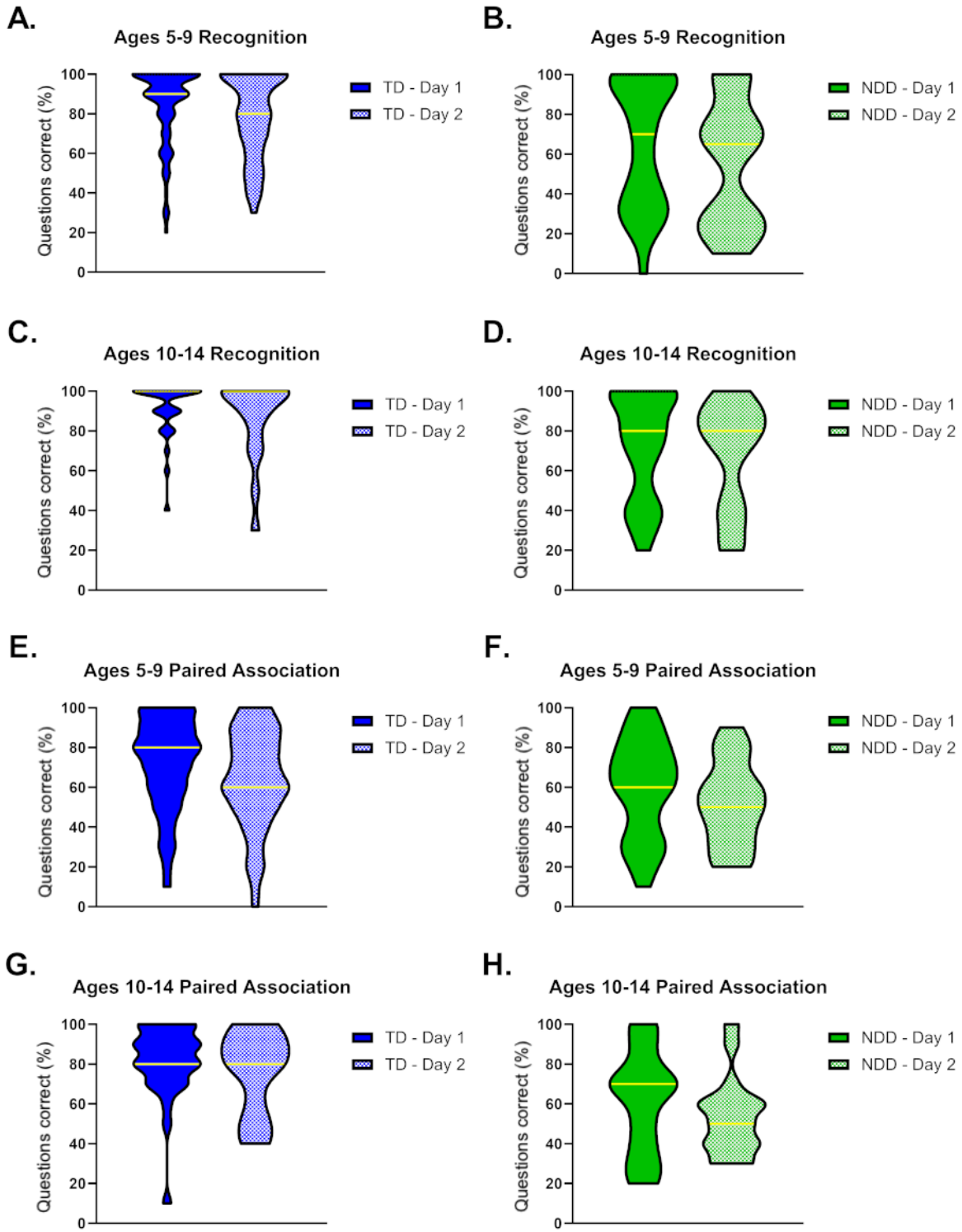
Figure 5. Comparative performance right after training (day 1) compared to performance the day after (day 2). (A) Performance of individuals with typical development (TD) and neurodevelopmental disorders (NDD) in the recognition task by age group. (B) Performance in the recognition (R) task in individuals with TD and NDD by age group. (C) Performance for the paired association (PA) task in individuals with TD and NDD by age group. (D) Performance for the PA task in individuals with TD and NDD by age group. TD ages 5-9 years, day 1: n=97; TD ages 5-9 years, day 2: n=56; TD ages 10-14 years, day 1: n=31; TD ages 10-14 years, day 2: n=17; NDD ages 5-9 years, day 1: n=30; NDD ages 5-9 years, day 2: n=16; NDD ages 10-14 years, day 1: n=27; NDD ages 10-14 years, day 2: n=19.



Performance Distribution Homogeneity Between Groups

We compared individuals from TD and NDD by plotting their performance and RT in both paired association and recognition to demonstrate homogeneity. Several individuals with NDD had mixed diagnoses; hence, we could not plot them by diagnosis individually. We found that those with NDD appeared to have a different group distribution in performance, especially in the younger age group (5-9 years old), with a bimodal distribution for recognition and paired association (Figure 6). On the other hand, RT had a more uniform distribution (Multimedia Appendix 3).

Figure 6. Distribution of performance on day 1 and day 2 for individuals with typical development (TD) and neurodevelopmental disorders (NDD). (A) Memory performance for recognition (R) in individuals with TD of the 5-9 years old group. (B) Memory performance for R in individuals with NDD of the 5-9 years old group. (C) Memory performance for R for individuals with TD of the 10-14 years old group. (D) Memory performance for R for those with NDD of the 10-14 years old group. (E) Memory performance for paired association (PA) for individuals with TD of the 5-9 years old group. (F) Memory performance for PA for individuals with NDD of the 5-9 years old group. (G) Memory performance for PA for individuals with TD of the 10-14 years old group. (H) Memory performance for PA for individuals with NDD of the 10-14 years old group. TD ages 5-9 years, day 1: n=97; TD ages 5-9 years, day 2: n=56; TD ages 10-14 years, day 1: n=31, TD ages 10-14 years, day 2: n=17; NDD ages 5-9 years, day 1: n=30; NDD ages 5-9 years, day 2: n=16; NDD ages 10-14 years, day 1: n=7; NDD ages 10-14 years, day 2: n=19.



Discussion

Feasibility of Remote Web-based Cognitive Testing

Our work shows that remote web-based memory testing is feasible for children with TD (n=128 individuals) and NDD (n=57 individuals), as early as 5 years old. Indeed, using picture matching allowed for the testing of children with NDD. The results are also consistent with a previous report of a progressive increase in performance for recognition tasks in children with TD [80]. Our task also allowed us to measure paired association memory and find significant differences between participants with TD versus NDD.

It also found that children with TD or NDD were able to perform LTM (day 2) testing in the same proportion, supporting further the feasibility of the Memory Game as a tool to probe both STM and LTM. In addition, a significantly decreased performance in individuals with NDD compared to TD was found.

Benefits of Web-based Testing

We believe that the tablet approach makes cognitive testing more engaging for children. Evidently, we observed during our initial pilot testing (done in person) that most children enjoyed the game. In addition, by using pictures, we could help test individuals with limited literacy and language development, who could not perform traditional word-matching tasks. The task could be extended also to individuals using other languages; however, this will require updating the instruction video. Considering the prevalence of anxiety in individuals with NDD [67,81], we propose that remote testing with the Memory Game, being complete in the individual's familiar environment, may better capture the full potential of individuals with NDD.

Web-based testing on participants' devices is important as remote testing has been increasingly considered by researchers to resolve problems with participant compensation for travel, geographical issues in rare disorders, and recruiting large numbers of participants.

While this work focuses on clinical diagnosis (NDD), having access to a larger number of participants will be key in future work focused on specific genes or syndromes. In addition, the closer proximity of the cognitive measures tested by the Memory Game (LTM and paired association) could facilitate the translation of findings from animal models.

Current Limitations

One of the trade-offs of remote web-based testing is in ascertaining the behavior of the participant as one would do with in-person testing. For instance, an individual may be distracted and perform suboptimally. The participant and caregiver may also not understand the instruction video, and thus may not be able to complete the task optimally. While we aimed to develop the instruction video with the feedback of caregivers during the early pilot testing in the clinic, it is possible that some users may not have understood it well. It is also challenging to assess how much and what type of guidance was provided by caregivers. Another important technical improvement to consider would be the flow of the test so that the next step is dependent and determined by the performance of the participant in the practice trial. At the moment, even though the participant receives feedback, they can still proceed to the testing phase regardless of their previous performance. It may be important to redemonstrate to the participant the tutorial or to train them further before they could proceed to the testing phase.

Some aspects of NDD such as repetitive behavior, or motor delay, may also impact the performance and thus, not reflect their memory capacity accurately. In addition, visual impairment could also influence the ability of participants to recognize the pictures and should be included in the future version as an item that would be reported by caregivers. Web-based testing also relies on self-reported diagnosis by caregivers, which might be incorrect. Therefore, future testing will include a correlation with in-person psychometric testing. While testing in larger cohorts may allow limiting the proportion of such outliers, smaller cohorts may be more impacted by such types of limitations. We also proposed an outlier analysis to identify individuals who may have experienced technical difficulties or stopped the test due to lack of attention or compliance, so as not to bias the results. Future research will be needed to develop adjustments for technical aspects, such as internet speed, device types, and browsers, which could also affect the results. Finally, one could also record the individual while performing the task. This has been implemented widely, for instance, during COVID-19 for web-based test administration in universities, but this presents many privacy issues and therefore was not used in the Memory Game.

In addition, despite the Memory Game allowing extensive testing by removing potential physical or geographical barriers, it remains challenging to achieve diversity of age, sex, gender, and diagnosis. Moreover, despite being potentially easier by being image-based rather than text-based paired association tasks, we recognize that many individuals with NDD may still not be able to perform the testing. In order to be of extensive use, the tutorial video will need to be translated, as well as some of the buttons, but the pictures used will be readily reusable.

This study also measured performance across different age groups but does not provide longitudinal data about memory performance in function of previous performance. Therefore, longitudinal follow-up will be important. We also recognize the importance of including individuals with diverse NDD etiology or a larger sample size of individuals, with a given specific NDD diagnosis to further assess diversity in the future and correlate the Memory Game findings with other cognitive tests such as for attention, working memory, intelligence quotient, or simpler form of plasticity (sensitization and habituation).

Future research will be needed to correlate the Memory Game performance with specific diagnoses and identify if the genes involved more specifically in LTM in animal models would affect LTM more than STM. In addition, repeated training has been shown to be important for LTM in typically developing individuals, for instance, when learning a language [82,83]. It will be interesting to evaluate if individuals with NDD would perform similarly on such tasks; however, we did not include those paradigms at this time based on the feedback of families

in our initial development phase mentioning the importance of keeping the task short.

Acknowledgments

We would like to thank Dr Achim and Beaulieu for their help with the BOSS database of pictures. We would also like to thank Drs Tim Tully and Mary Pyc for providing constructive feedback for the design of the Memory Game.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Online consent. The participants (or caregivers) first see the landing page with the Memory Game logo and are then directed to a consent form (approved by the University of Alberta). The participant (or caregiver) can then decide whether to give consent or not.

[PNG File , 186 KB - pediatrics_v6i1e39720_app1.png]

Multimedia Appendix 2

Comparative reaction time right after training (day 1) compared to performance the day after (day 2). (A) Reaction time (RT) of individuals with typical development (TD) and neurodevelopmental disorders (NDD) in the recognition (R) task by age group. (B) RT in the R task in individuals with TD and NDD by age group. (C) RT for the paired association (PA) task in individuals with TD and NDD by age group. (D) RT for the PA task in individuals with TD and NDD by age group. TD ages 5-9 years, day 1: n=97; TD ages 5-9 years, day 2: n=56; TD ages 10-14 years, day 1: n=31; TD ages 10-14 years, day 2: n=17; NDD ages 5-9 years, day 1: n=30; NDD ages 5-9 years, day 2: n=16; NDD ages 10-14 years, day 1: n=27; NDD ages 10-14 years, day 2: n=19.

[PNG File , 125 KB - pediatrics_v6i1e39720_app2.png]

Multimedia Appendix 3

Distribution of reaction time on day 1 and day 2 for individuals with typical development (TD) and neurodevelopmental disorders (NDD). (A) Reaction time (RT) for recognition (R) of individuals with TD of the 5-9 years old group. (B) RT for recognition of individuals with NDD of the 5-9 years old group. (C) RT for R for individuals with typical development of the 10-14 years old group. (D) RT for R for individuals with NDD of the 10-14 years old group. (E) RT for paired association (PA) for individuals with TD of the 5-9 years old group. (F) RT for PA for individuals with NDD of the 5-9 years old group. G) RT for PA for individuals with TD of the 10-14 years old group. H) RT for PA for individuals with NDD of the 10-14 years old group. TD ages 5-9 years, day 1: n=97; TD ages 5-9 years, day 2: n=56; TD ages 10-14 years, day 1: n=31; TD ages 10-14 years, day 2: n=17; NDD ages 5-9 years, day 1: n=30; NDD ages 5-9 years, day 2: n=16; NDD ages 10-14 years, day 1: n=27; NDD ages 10-14 years, day 2: n=19.

[PNG File , 165 KB - pediatrics_v6i1e39720_app3.png]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
API: application programming interface

ASD: autism spectrum disorder
BOSS: Bank of Standardized stimuli
LTM: long-term memory
NDD: neurodevelopmental disorders
RT: reaction time
STM: short-term memory
TD: typical development

Edited by S Badawy; submitted 20.05.22; peer-reviewed by K Shamlian, J Louw; comments to author 24.06.22; revised version received 13.12.22; accepted 20.01.23; published 08.05.23.

Please cite as:
Bui TA, Rosenfelt CS, Whitlock KH, Leclercq M, Weber S, Droit A, Wiebe SA, Pei J, Bolduc FV
Long-term Memory Testing in Children With Typical Development and Neurodevelopmental Disorders: Remote Web-based Image Task Feasibility Study
JMIR Pediatr Parent 2023;6:e39720
URL: https://pediatrics.jmir.org/2023/1/e39720
doi:10.2196/39720
PMID:37155237

Original Paper

Comprehension by Caregivers and Adolescents of Clinical Trial Information Delivered via Multimedia Video Versus Conventional Practice: Nonrandomized Controlled Trial

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Abstract

Background: Research participants often misunderstand the required elements of informed consent information, whether provided in written or oral format. Informed consent instruments with embedded evidence-based learning theory principles administered in multimedia electronic formats may improve comprehension and retention.

Objective: This study aims to determine whether study information comprehension and retention using an interactive multimedia video consent process was noninferior to comprehension and retention after an in-person face-to-face interaction with a conventional written consent document for caregivers and adolescents enrolled in a clinical trial.

Methods: Participants were caregivers and children aged 12 to 17 years who were enrolled in a clinical trial of asthma treatment. Consent information was presented as a multimedia web-based video consent interaction or as a conventional written consent document with in-person interaction between the prospective participants and the study staff. The trial used a parallel nonrandomized noninferiority design that compared the 2 consent methods. Caregivers and adolescents completed a 17-item open-ended comprehension questionnaire (score range 17-51) at enrollment and at the end of the study 20 weeks later. Comprehension and retention were compared between the consent formats. Noninferiority was established if the 95% CI upper bound of the difference in scores (conventional format minus web-based) was less than the noninferiority margin of 2.4; superiority was established if the upper bound of the CI was <0.

Results: In total, 54 caregiver and adolescent dyads completed the interactive multimedia web-based video consent, and 25 dyads completed the conventional consent. Overall, 33% (26/79) of all adolescents were Black, 57% (45/79) were male, and 61% (48/79) had a household income of <US $60,000 per year. For caregivers, the interactive multimedia web-based format was noninferior to the conventional format at enrollment (difference between the conventional and web-based formats: mean −0.30, 95% CI −2.52 to 1.92) and was superior at the end of the study 20 weeks later (mean −2.20, 95% CI −3.9 to −0.5). There was a loss of comprehension over 20 weeks (mean −1.65, 95% CI −3.1 to −0.19) with the conventional format but not with the multimedia web-based format (mean 0.14, 95% CI −0.84 to 1.12). For adolescents, the noninferiority of the multimedia web-based format was not established.

Conclusions: Caregivers who are considering enrolling their adolescent in an asthma clinical trial have similar comprehension of study information when delivered through an interactive multimedia web-based platform, which incorporates evidence-based learning theory principles, compared with having a conventional in-person, face-to-face discussion. The retention of study information over time was better with the multimedia format for caregivers.

Trial Registration: ClinicalTrials.gov NCT02061280; https://clinicaltrials.gov/ct2/show/NCT02061280 and NCT01437995; https://clinicaltrials.gov/ct2/show/NCT01437995

(JMIR Pediatr Parent 2023;6:e44252) doi:10.2196/44252

KEYWORDS

adolescent; clinical trial; comprehension; informed consent; internet; multimedia

Introduction

Background

Obtaining informed consent is one of the main protections of human subject participation in research and must be obtained before any research procedure, unless a waiver is approved by an institutional review board (IRB) [1]. The consent process is characterized by three features: (1) disclosing sufficient information for the participant to make an informed decision, (2) facilitating the understanding of that information, and (3) underscoring the voluntariness of participation in research [1]. Enrolling dependent youth or child participants in research studies adds complexity because of the need to obtain permission from the parent or legal guardian as well as assent from the child (as young as 7 years) who is capable based on age, maturity, and psychological state [2-4]. Federal regulations and guidance documents are silent on the information to be provided during the assent process; however, the assent would be expected to increase in complexity as a child ages. The provision of assent by a child expresses their willingness to participate, although there is no regulatory requirement to ensure that the required elements of consent have been effectively communicated [1,4]. Federal regulations allow informed consent information to be presented in a written or verbal format.

There is ample evidence that research participants have a poor understanding of the federally required elements in informed consent documents, regardless of format [5-15]. The problem is exacerbated by the complexity and length of typical written consent documents that now, because of intensified institutional oversight, have more regulatory requirements that require the inclusion of difficult-to-understand legal language [13,16]. Strategies to promote the understanding of research study information such as modified layouts, lower reading levels, and multimedia presentations have shown mixed results [16]. However, many of these strategies did not incorporate evidence-based learning principles [13,17,18]. Furthermore, studies that measured understanding often used closed-ended questions that primarily test recall versus open-ended questions, which can assess the comprehension of learned information. Few studies have assessed the comprehension of study information in children or adolescents who were actually enrolled in a clinical trial [12-14,19].

Objectives

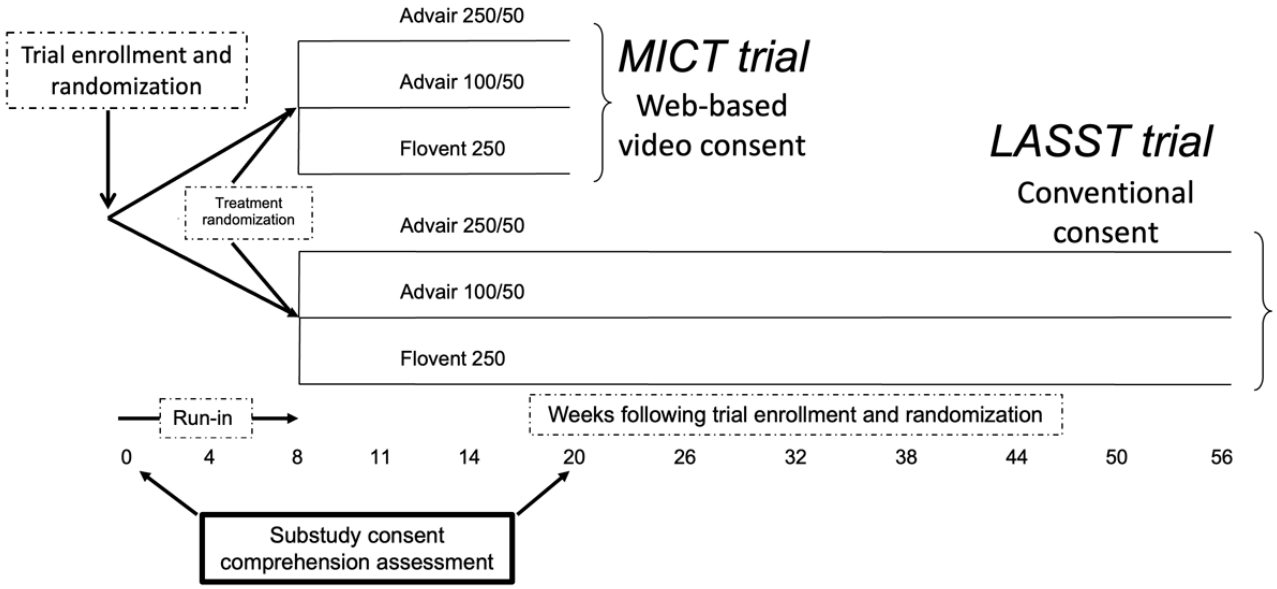
To address these issues, we designed an interactive multimedia video and associated website for caregivers and adolescents considering participation in an asthma clinical trial to compare study comprehension with the conventional in-person face-to-face consent process. The interactive multimedia video and website applied evidence-based learning theory principles designed to enhance learning while reducing cognitive load in participants with varying levels of health literacy [18,20-22]. We hypothesized that study comprehension following multimedia video consent and website interaction would be noninferior to the conventional consent process.

Methods

Overall Trial Design

The study comprehension evaluation by consent format was designed as a substudy nested within 2 asthma clinical trials: one trial using conventional procedures for consent, enrollment, and follow-up (Long-Acting Beta-Agonist Step-Down Study [LASST]) and the other trial using web-based and video procedures for study conduct (Use of Mobile Devices and the Internet to Streamline an Asthma Clinical Trial [MICT]; Figure 1). The LASST clinical trial was a multicenter, double blinded to treatment (Advair 250/50 [GlaxoSmithKline], Advair 100/50 [GlaxoSmithKline], and Flovent 250 [GlaxoSmithKline]) study designed to evaluate de-escalation strategies in participants aged ≥12 years with moderate persistent asthma that was well controlled with a fixed-dose combination of inhaled corticosteroid plus a long-acting β_2-agonist (LASST; NCT01437995) [23]. LASST included an 8-week run-in period before treatment randomization and involved 12 visits over 56 weeks. LASST was conducted from February 2012 to July 2015 at 18 network sites of the American Lung Association Airways Clinical Research Centers (ACRC) network [23]. The ACRC study sites are pulmonology and allergy subspecialty clinics within academic medical centers that have large racially and socioeconomically diverse patient populations.

Figure 1. Study schema for conventional (Long-Acting Beta-Agonist Step-Down Study [LASST]) and web-based (Use of Mobile Devices and the Internet to Streamline an Asthma Clinical Trial [MICT]) trials. Consent comprehension was conducted at enrollment and 20 weeks later.



The web-based trial with video procedures was designed to evaluate methods to reduce the burden of research participation (MICT; NCT02061280), was modeled after LASST with identical treatment groups but with only 2 on-site study visits (to obtain and return study equipment) and 4 web-based visits (using an iPad [Apple Inc] with FaceTime [Apple Inc]) over 12 weeks, and was conducted in adolescents aged 12 to 17 years [20,21]. The MICT trial was conducted in adolescents because the lead site was a pediatric institution. MICT was conducted at 6 of the 18 ACRC network sites that had study coordinators experienced in pediatric clinical trial research from November 2013 to February 2017.

A substudy to evaluate the comprehension of the conventional in-person, face-to-face consent format (in LASST participants) versus the multimedia web-based delivery process (in MICT participants) was conducted among adolescents and their caregivers at the 6 ACRC network pediatric sites by coordinators enrolling participants for both the LASST and MICT trials. Coordinators were trained and knowledgeable in the trial procedures, including obtaining informed consent from parents or guardians (hereafter referred to as caregivers) and adolescents. At the start of enrollment for the substudy, participants were randomized by trial type (LASST or MICT), and caregivers and adolescents were unaware of both trials when randomization was performed. After enrollment was completed in the LASST trial, all eligible participants were then enrolled in the MICT trial.

The details of the LASST and MICT trials and a description of the learning principles used in the development of the interactive multimedia video consent and website for the MICT trial have been previously described [20,21,23]. This paper presents a comparison of the consent procedures with respect to study *comprehension* between the LASST and MICT trials.

Ethics Approval

The LASST and MICT trials were approved by the IRB at Nemours Children's Health as research involving greater than minimal risk but presenting the prospect of direct benefit to the individuals per Code of Federal Regulations 45CFR46.405 and 21CFR50.52. Parental permission and assent were obtained from the legal caregivers and adolescents aged 12 to 17 years, respectively, and informed consent was obtained from adults aged ≥18 years. IRB approval numbers were #288148 (LASST) and #332965 (MICT).

Enrollment and Payment for Participation

Participants enrolled in the LASST and MICT trials had well-controlled asthma (Asthma Control Test score of ≥20) [24], were on a medium dose of fluticasone-salmeterol combination inhaler (Advair, GlaxoSmithKline) for at least 4 weeks, and had less than a 10 pack-year smoking history with no smoking in the previous year [20,23].

On enrollment in the LASST or MICT trial, the participant was assigned a unique alphanumeric code and a name code that used the first and middle initials and the first 3 letters of the last name. The links to the codes were stored in password-protected computer files at the study site institution, with access limited to the research study team at the study sites. Data without personal identifiers were analyzed by the Center for Clinical Trials and Evidence Synthesis at Johns Hopkins Bloomberg School of Public Health.

Participants in the LASST trial were paid up to US $825 prorated over the course of 56 weeks for completing 11 study site visits. Participants in the MICT trial were paid up to US $430 prorated over the course of 20 weeks for completing 6 study visits (remote and on site) and each morning (US $1) and evening (US $1) diary card. Participants in the LASST trial were paid US $50 for the enrollment visit at which informed consent was obtained and study procedures were performed; participants in the MICT trial were paid US $25 for completing the multimedia video consent process (and an additional US $25 at the first on-site visit at which study procedures were conducted). Thus, the payment amount was equivalent between trials for the consent substudy. Payment was issued by a check

from the study site in the LASST trial and by a reloadable debit card in the MICT trial.

Objective

The objective of the consent substudy was to compare the comprehension and retention of informed consent elements using an interactive multimedia web-based delivery of consent information (multimedia method) developed for MICT versus paper consent and assent documents and in-person face-to-face discussions with a study coordinator (conventional method) in LASST. We made comparisons between formats in the caregiver and adolescent participants. We hypothesized that consent comprehension and retention with the multimedia web-based delivery would be noninferior to the conventional in-person, face-to-face consent process.

Interventions

Conventional Informed Consent Document for LASST

Parental permission and adolescent assent documents were developed according to the requirements of the IRB of the study site. Parental permission and assent were 13-page and 2-page single-spaced typed documents, respectively. The Flesch Kincaid Grade Level for the parental permission and assent were 9.8 and 6, respectively.

Conventional Informed Consent Process for LASST

Participants were contacted via the usual processes at the study site (telephone, provider referral, clinic intercepts, and response to flyers). Parental permission and adolescent assent were obtained through a conventional in-person interaction between the caregiver and the study coordinator and between the adolescent and the study coordinator, respectively. During the substudy training, the coordinators were instructed to maintain their usual consenting process for the LASST trial participants to avoid influencing study outcomes. The caregivers and adolescents were provided the consent documents upon arrival at the enrollment visit (or emailed or mailed to the family at their request ahead of the visit) and allowed as much time as needed, generally approximately 20 to 30 minutes, to review the document.

The study coordinator then began audio recording (Audacity) the consent process interaction for later analysis by trained coders [25]. The coordinator reviewed each section of the document with the caregiver and adolescent and answered questions. Once complete, the coordinator conducted the consent comprehension assessment and then administered the Newest Vital Sign (NVS), a health literacy tool, separately with the caregiver privately. The adolescent was then brought into the room for comprehension assessment and NVS administration [20,26-31]. As the caregiver was still in the room with the adolescent, the coordinator instructed the caregiver not to cue the adolescent with answers to the assessment questions. The coordinator reviewed responses that suggested an incomplete understanding of the study information and answered questions before obtaining caregiver and adolescent signatures on the parental permission form and assent documents, respectively.

Interactive Multimedia Informed Consent Video for MICT

The interactive multimedia video and website provided study information, including all the required and supplemental elements of informed consent [8]. The video storyboard and audio script were developed from the content in the 13-page parental permission form used for LASST [23]. The video had 5 sections, each 3 to 4 minutes in length, and was designed using theory and principles to facilitate electronic learning [21,22,32]. Professional video directors and professional actors were used to create the video. A segment of the video was previously published [20,21].

The video was housed within a framework in which a content-related sidebar provided additional study information by the participant selecting a tab that changed color when the video reached a relevant section on the sidebar. Each section had 2 to 3 multiple-choice questions that had to be answered before the next video section became available. The correct response was always provided to reinforce learning. The sections were programmed to be viewed sequentially to ensure that the entire video was watched.

Consent Process for Interactive Multimedia Informed Consent Video for MICT

Participants were contacted via telephone to participate in the MICT trial, and if interested, a private link to the interactive multimedia web-based informed consent video was sent via email to the caregiver and adolescent 4 days before a scheduled consent comprehension assessment; the 4-day period was to allow sufficient time for both the caregiver and adolescent to view the video 1 or more times. The consent comprehension assessment was conducted during a one-on-one audio-recorded call (WebEx, Cisco Systems) with the study coordinator. The audio recordings were saved for later analysis by the trained coders. The caregiver and adolescent comprehension were evaluated separately. Following the assessment, the coordinator reviewed the understanding of the study and answered any remaining questions. The NVS was then administered separately to the caregivers and adolescents. Parental permission and assent signature forms were sent via a secure patient portal from Nemours Children's Health for electronic signatures and stored in the adolescents' electronic health records.

Measurements

Participants' comprehension of the elements of informed consent was measured at enrollment upon study entry and again at study end after 20 weeks of study participation. The NVS was administered to caregivers and adolescents at enrollment only.

Newest Vital Sign

The NVS is validated by a 6-item survey, which measures general health literacy in children and adults and requires 3 to 4 minutes for administration [27]. The survey uses an ice cream nutrition label and incorporates reading, comprehension, and numeracy skills. The instrument was selected over other literacy assessment tools because it is a valid and reliable screening tool for caregivers and adolescents, has no ceiling effect, and can

be administered in person and remotely [20,27,33,34]. The NVS was included as a covariate in the comprehension analysis.

Consent Comprehension Assessment Tool for LASST and MICT

The comprehension assessment tool was developed by the study psychologists and principal investigator as a 17-item open-ended questionnaire designed to assess the knowledge and comprehension of the consent material (Textbox 1). The tool was derived from questionnaires previously developed by coinvestigators in preliminary studies (NCI R03CA133442 and NCI R03CA133419; T Wysocki, PhD, unpublished data, 2010). The tool used in this study was slightly modified from the original tool by replacing 1 question that was considered redundant and adding a question on payment for participation. The psychology staff trained the study coordinators on each interview question and to use nonleading prompts to elicit further knowledge when appropriate. Each consent assessment question was scored by 2 coders as incorrect, partially correct, or correct (scored as 1, 2, and 3, respectively). The possible scores ranged from 17 to 51, with higher scores indicating better comprehension. Scores between coders were reviewed frequently early in the trial, and discrepancies between the coders were resolved by mutual agreement, with input from the principal investigator as needed, to ensure overall consistency in scoring.

Textbox 1. Seventeen-item questionnaire for consent comprehension assessment used for both consent formats.

1. Please tell me the researchers' reasons for doing this study.
2. Please tell me how much of your child's (your) time is required while you are in this study.
3. Please tell me the main things that your child (you) will need to do at each study visit.
4. Please tell me about the study treatments that are being tested.
5. Please tell me what the chances are that your child (you) will get one kind of treatment or another.
6. Please tell me how many other people will be in this study.
7. Please tell me what bad things or risks there could be from being in this study.
8. Please tell me what the good things or benefits there are from being in this study.
9. Please tell me what other choices your child has (you have), aside from being in this study.
10. Please tell me how the researchers will protect your child's (your) privacy while being in this study.
11. Please tell me who's responsible for your child's (your) medical costs if your child gets (you get) hurt or sick while your child is (you are) in the study.
12. Please tell me who you (your parent) should call if your child has (you have) questions about the study.
13. Please tell me what your child (you) should do if your child wants (you want) to stop being in the study.
14. Please tell me if and why the researchers could take your child (you) out of the study without your permission.
15. Please tell me why researchers would give your child (you) new information about this study while your child is (you are) in it.
16. Please tell me what type of payment or rewards your child (you) will get for being in the study.
17. Please tell me why your child is (you are) being asked to be in the study.

Statistical Plan

Sample Size and Power

The hypothesis was that study comprehension following the novel multimedia web-based video consent process would be no worse than that following the conventional process; therefore, a noninferiority design was used. There was no expectation that comprehension would be better with the multimedia web-based consent, even with the incorporated learning principals. For ethical reasons, a noninferiority design was selected to test that the multimedia web-based consent was no worse than, or not inferior to, the conventional in-person consent process and thus is consistent with regulations governing human subjects research [1]. In addition, using a noninferiority analysis allowed for superiority to be tested if noninferiority was established. The sample size determination, using the caregiver comprehension assessment scores from preliminary data obtained in 2 R03 grants (NCI R03CA133442 and NCI R03CA133419; T Wysocki, PhD, unpublished data, 2010), assumed the normalcy of the data and defined the noninferiority margin as 2.4, which corresponds to 0.5 SD units. One-half SD was considered a clinically reasonable margin to consider the interactive multimedia web-based video noninferior to the conventional consent format and is consistent with empirical results on participant-reported outcomes [35]. On the basis of these calculations, the randomization of 120 caregivers and adolescents (60 dyads each for the multimedia web-based video consent and conventional consent process) would provide 85% power to reject the hypothesis that the multimedia web-based video consent process yields statistically significant ($P \leq .05$) lower (worse) scores than the conventional process at a threshold of 2.4 units on the caregiver consent comprehension assessment scale, after allowing for approximately 10% loss to follow-up. Preliminary data indicated a greater noninferiority margin of 3.2 for adolescents. We chose the caregiver margin for sample size determination because, for a typical clinical study, caregivers largely determine whether a child will participate,

and they engage in explaining the study to their child, who is then asked to provide assent.

Data Analysis

Data included in the analysis were from participants randomized to treatment assignments in the LASST or MICT trials. Adolescent characteristics at enrollment were compared using chi-square and Kruskal-Wallis tests for categorical and continuous outcomes, respectively. Unadjusted mean and 95% CI scores were calculated and compared between the consent processes at enrollment using generalized estimating equations. The same methods were used to compare scores at enrollment and at 20 weeks between and within each group to assess the retention of study information. The noninferiority margin was 2.4, that is, the interactive multimedia web-based video consent process was noninferior to the conventional consent process if the upper bound of the 95% CI for the difference (conventional minus multimedia website) was <2.4. The a priori margin of noninferiority was determined from the data using the caregiver consent comprehension assessment tool in the preliminary studies. The same noninferiority margin was used to evaluate adolescent scores. If noninferiority was met, the superiority of the interactive multimedia web-based video consent was evaluated using a conventional cutoff, and the 95% CI for the difference did not include 0. Exploratory univariate regression was conducted to identify the characteristics predictive of the primary outcome, followed by sensitivity analysis to determine the effect on comprehension scores. There was no controlling for multiple comparisons. The data were analyzed using SAS (version 9; SAS Institute) and R (version 4.1.2; The R Project for Statistical Computing).

Results

Overview

The consent substudy in the MICT and LASST trials was conducted from November 2013 to February 2017 at the 6 sites conducting both studies. These trials were conducted concurrently, and randomization across trial types was initially planned; however, rapid enrollment completion in the LASST trial across the 18 ACRC network sites resulted in 37 participants being enrolled in the LASST consent substudy rather than the 60 participants planned. In total, 71 participants were enrolled in the MICT consent substudy.

Characteristics of Adolescent Participants

In the trials, 108 adolescents were enrolled, of whom 79 (73.1%) were allocated to treatment and were included in the analysis (Figure 2). There were no statistically significant differences in baseline characteristics between the groups except for prebronchodilator forced expiratory volume in 1 second: the median values were 90% (IQR 80-97) predicted in the conventional group and 95% (IQR 85-107) predicted in the web-based group (P=.04; Table 1).

Figure 2. Flow of participants by trial type. FU: follow-up; PI: principal investigator.

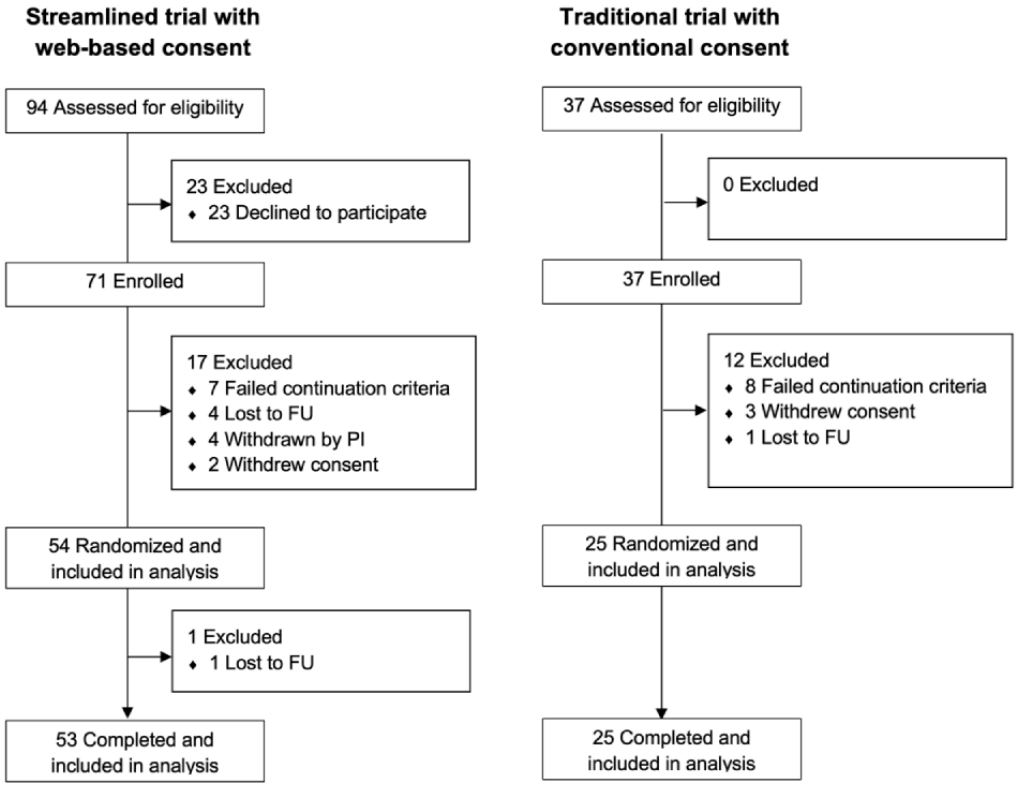


Table 1. Characteristics of caregivers and adolescents at enrollment by consent format.

Characteristic	Total (n=79)	Conventional consent process (n=25)	Interactive multimedia consent video and website (n=54)
Adolescent sex, male (vs female), n (%)	45 (57)	13 (52)	32 (59)
Caregiver sex, male (vs female), n (%)	9 (11)	4 (16)	5 (9)
Adolescent age, median (IQR)	14 (13-15)	15 (13-16)	14 (13-15)
Adolescent race, Black (vs non-Black), n (%)	26 (33)	10 (40)	16 (30)
Income (US $), n (%)			
≤$60,000	48 (73)	14 (70)	34 (74)
>$60,000	18 (27)	6 (30)	12 (26)
Income missing	13 (16)	5 (20)	8 (15)
Asthma characteristics			
Unscheduled health care visit for asthma in prior year (vs none), n (%)	32 (41)	9 (36)	23 (43)
Age of asthma onset, median (IQR)	2 (1-6)	4 (1-7)	2 (1-5)
Secondary smoke exposure, n (%)	15 (19)	6 (24)	9 (17)
Questionnaires, median (IQR)			
Newest Vital Sign			
Adolescent score (range 0-6)[a]	5 (4-6)	5 (3-6)	5 (4-6)
Caregiver score (range 0-6)	5 (3-6)	4 (3-6)	5 (3-6)
Asthma Control Test (range 5-25)[b]	22 (21-24)	22 (21-23)	22 (22-24)
Spirometry, median (IQR)			
Pre-BD[c] percent predicted forced expiratory volume in 1 second	94 (85-102)	90 (80-97)	95 (85-107)
Pre-BD percent predicted forced vital capacity	102 (94-108)	102 (96-106)	102 (93-109)
Peak flow (L)	390 (323-451)	350 (290-425)	398 (343-455)

[a]Newest Vital Sign score: 0 to 1, high likelihood of limited literacy; 2 to 3, possibility of limited literacy; and 4 to 6, almost always adequate literacy.

[b]Asthma Control Test: high scores indicate better health.

[c]Pre-BD: prebronchodilator.

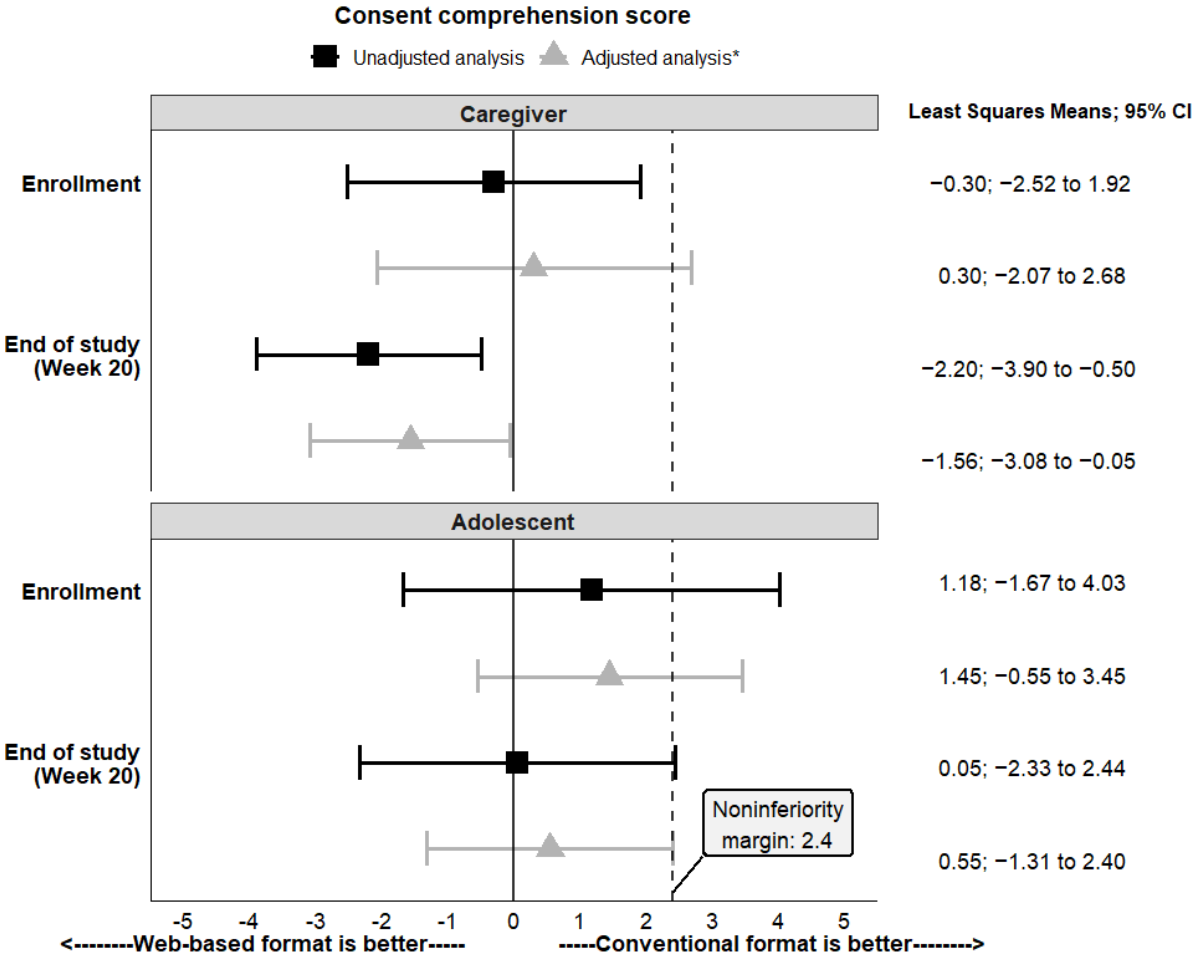
Primary Outcome: Caregiver Comprehension Assessment Score

The unadjusted mean (95% CI) caregiver comprehension score at enrollment was slightly higher with interactive multimedia web-based video consent (better comprehension) than with the conventional consent (Table 2) and met the criteria for noninferiority but not superiority (Figure 3). At the final study visit (20 weeks after enrollment), caregiver scores declined in the conventional group and remained stable in the multimedia web-based video consent group, such that comprehension in the multimedia web-based video consent was superior to conventional consent (Figure 3 and Table 2).

Table 2. Consent comprehension scores for caregivers and adolescents at enrollment and the end of the study (week 20).

	Conventional, mean (95% CI)	Web-based, mean (95% CI)
Caregiver score		
Enrollment	42.90 (41.06 to 44.74)	43.20 (41.96 to 44.45)
End of the study (week 20)	41.08 (39.67 to 42.49)	43.28 (42.33 to 44.23)
Change from enrollment	−1.65 (−3.10 to −0.19)	0.14 (−0.84 to 1.12)
Adolescent score		
Enrollment	42.26 (39.90 to 44.62)	41.08 (39.48 to 42.69)
End of the study (week 20)	41.27 (39.29 to 43.25)	41.22 (39.88 to 42.55)
Change from enrollment	−0.75 (−2.27 to 0.77)	0.16 (−0.86 to 1.18)

Figure 3. Consent comprehension score of caregivers and adolescents at enrollment and at the end of the study (20 weeks after enrollment) for the web-based and conventional consent delivery format. Noninferiority was established if the upper bound of the 95% CI for the difference was below the noninferiority margin of 2.4. Superiority of the format was determined if the noninferiority margin was met and the 95% CI for the difference did not include 0. *Analysis of scores following adjustment for baseline characteristics was not prespecified in the protocol.



Adolescent Comprehension Scores

Among adolescents, the unadjusted mean (95% CI) scores at enrollment were higher in the conventional group. The noninferiority of the interactive multimedia web-based video consent was not established because the upper bound of the CI for the difference in comprehension scores was 4.03, which exceeds the noninferiority margin of 2.4 (Figure 3 and Table 2). At 20 weeks, neither group had a reduction in comprehension, and the difference between the 2 groups of adolescents was less; however, the upper bound of the CI (2.44) exceeded the noninferiority margin.

Exploratory Analysis

In the exploratory analysis, adolescents' race (P=.009), having an unscheduled health care visit in the prior years (P=.02), and NVS scores for caregivers (P<.001) and adolescents (P=.03) were significantly associated with the caregiver's score (all caregivers in both trials) at enrollment (Table 3). Adolescents' sex (P=.008), age (P<.001), and race (P<.001) and both adolescents' (P=.004) and caregivers' (P<.001) NVS scores were significantly associated with adolescents' scores (all adolescents in both trials) at enrollment (Table 3). These same variables were significantly associated with scores for all caregivers and adolescents at week 20, except for having an unscheduled health care visit in the prior year, which was no longer associated with scores for caregivers (data not shown). Our sample was too small to meaningfully assess whether the multimedia video consent had a greater effect on comprehension scores in those with limited health literacy (10 participants from both trials) compared with the conventional consent.

After adjustment for variables identified in the exploratory analysis (participant race, unscheduled health care visit, and caregiver NVS score), comprehension with the multimedia web-based video consent was no longer noninferior at baseline in caregivers but remained noninferior and superior to the conventional consent at 20 weeks after enrollment (Figure 3). There were no significant interactions between the predictors.

Table 3. Univariate association of baseline characteristic with comprehension score in caregivers and adolescents at enrollment (conventional and web-based combined).

Participant characteristics	Outcome: score at enrollment			
	Caregivers		Adolescents	
	Estimate (95% CI)	*P* value	Estimate (95% CI)	*P* value
Sex, male (vs female)	−1.10 (−3.17 to 0.97)	.30	−3.51 (−6.09 to −0.94)	.008
Age (years), anchored at 14 years	0.51 (−0.09 to 1.11)	.09	1.29 (0.56 to 2.03)	<.001
Race, Black (vs non-Black)	−2.83 (−4.93 to −0.72)	.009	−5.87 (−8.39 to −3.35)	<.001
Unscheduled health care visits for asthma in the previous 12 months before enrollment (vs none)	−2.41 (−4.45 to −0.38)	.02	−1.50 (−4.19 to 1.19)	.27
Secondary smoke exposure	−2.52 (−5.09 to 0.05)	.06	−1.26 (−4.65 to 2.12)	.47
Age of asthma onset (years)	−0.01 (−0.27 to 0.26)	.97	0.28 (−0.05 to 0.62)	.09
Per point of caregiver NVS[a] from 0	1.06 (0.49 to 1.64)	<.001	1.14 (0.37 to 1.90)	.004
Per point of participant NVS from 0	0.70 (0.09 to 1.30)	.03	1.74 (1.03 to 2.45)	<.001
Per point in Asthma Control Test from 0	0.01 (−0.69 to 0.72)	.97	0.20 (−0.71 to 1.10)	.67
Pre-BD[b] percent predicted forced expiratory volume in 1 second (per 10% unit difference)	0.01 (−0.74 to 0.76)	.99	0.13 (−0.84 to 1.10)	.80
Pre-BD percent predicted forced vital capacity (per 10% unit difference)	−0.71 (−1.57 to 0.14)	.10	−0.16 (−1.29 to 0.96)	.77
Peak flow (per 100 L)	0.49 (−0.55 to 1.53)	.36	0.91 (−0.42 to 2.24)	.18

[a]NVS: Newest Vital Sign.

[b]Pre-BD: prebronchodilator.

Discussion

Principal Findings

In caregivers, we found that comprehension with the web-based delivery format was noninferior to the conventional format at enrollment and, importantly, that study information was retained better with the web-based delivery when assessed 20 weeks later. With both consent formats in caregivers and adolescents, assessment scores indicated acceptable comprehension at enrollment (approximately 83%) out of the total possible score of 51, and there may have been little room for improvement to demonstrate the superiority of web-based delivery. We intentionally designed the interactive multimedia web-based consent using established principles for web-based learning, which may have facilitated retention. The retention of consent information over the study period with web-based delivery is noteworthy because it is essential that information about the study is understood throughout participation.

In adolescents, the score for the interactive multimedia web-based process did not meet the noninferiority margin at baseline or 20 weeks later. The caregiver score from the preliminary data was used to estimate the sample size and for the primary outcome because caregivers consider their parental permission before the child is presented with the option to assent or dissent from participation. Thus, it is essential for caregivers to have a thorough understanding of the research study to help their children have a meaningful comprehension of the presented information during the assent process. A wider margin of 3.2 from the preliminary data in adolescents may have been more appropriate because adolescent cognitive capacity and attention span are less than what is expected in adults [36]. If a margin of 3.2 was used for adolescents, noninferiority at enrollment would not have been established, although it would have been at the 20-week assessment. This finding suggests that perhaps the experiential component of trial participation aided in retention of study information at the end of the study for adolescents.

Our exploratory analysis suggests that there may be variables associated with adolescents that influence caregiver as well as adolescent consent comprehension. Unsurprisingly, health literacy scores were positively associated with comprehension scores in both caregivers and adolescents. However, larger clinical trials are required to verify the relevance of these findings.

Comparison With Prior Work

Only 2 studies on caregivers and children have incorporated some of the features used in this project, and neither study was enrolling children in an actual clinical trial [13,14,37]. O'Lonergan and Forster-Harwood [38] evaluated study comprehension of hypothetical medical procedures (dual-energy x-ray absorptiometry and ultrasound) delivered by a multimedia PowerPoint (Microsoft Corporation) presentation with video hyperlinks designed with a "learning objective approach" versus a standard IRB templated paper document in caregivers and young adolescents. Both caregivers and adolescents had better comprehension of the medical procedures with the PowerPoint presentation assessed by semistructured interviews. Unlike our study, the caregivers and adolescents read the paper document of the medical procedures without contemporaneous review of content with a study staff member before assessment, which

may have biased comprehension in favor of the PowerPoint presentation.

Tait et al [39] developed a presentation of pictorials and touch-and-drag features to explain research concepts (eg, randomization and blinding) with voice-over on an iPad and compared comprehension with paper-based explanations; the material was not for a clinical trial. Parents demonstrated no difference in comprehension between formats when assessed by semistructured interviews, whereas children had greater comprehension after viewing the iPad pictorials. As with the study by O'Lonergan and Forster-Harwood [38], there was no review of the paper-based material with the parent or child before the interview, which may have influenced the better comprehension scores for the iPad presentation.

In a review of strategies designed to improve consent comprehension through various methods, including multimedia processes, Abdel-Rahman [13] found that recall and comprehension are enhanced by formats that include both audio and video components, even without an interactive component [40]. An evaluation of digital tools for informed consent found that multimedia formats (images, audio, videos, and graphics) had a greater impact on understanding, satisfaction, anxiety, and participation compared with videos (audiovisual) only, perhaps because videos do not enhance information already communicated through in-person interaction [37]. Improvements with multimedia formats have tended to be modest, which may be a function of the characteristics of the format as well as the method for assessing comprehension [13].

In this study, we assessed comprehension using open-ended questions that were graded by a team of trained scorers. A systematic review found that the understanding of study material assessed by closed-ended questions was better than that assessed by open-ended questions [14]. Open-ended questions, as in semistructured interviews, require the comprehension of previously stored information that is more difficult than responding to closed-ended questions, such as multiple choice, which rely on the recall of a correct response out of presented possibilities. The semistructured interviews used in this study elicited a more complete assessment of the learned material.

This is the first study to test consent information comprehension in caregivers and adolescents who experienced an interactive multimedia web-based video consent format versus a conventional written consent document with in-person face-to-face interaction in an actual asthma clinical trial that enrolled adolescents. Our intent was to determine whether interactive multimedia web-based video consent provided clinical trial information and promoted understanding of that information in a manner that was similar or noninferior to a conventional in-person, face-to-face consenting process that included a review of the consent of a study staff member. Our study has important findings that can guide the development of interactive multimedia web-based consent formats for future clinical trials. The platform was intentionally developed using 5 specific theoretically grounded principles of multimedia learning, with an intentional focus on appeal to people with low health literacy [21]. In addition, the quizzes embedded in the consent video reinforced the key study information. We used a semistructured interactive interview to assess and score comprehension at enrollment and again 20 weeks later to assess the retention of study information rather than multiple-choice or true-false questions. This is one of the few studies to address modifying the assent process to improve comprehension in minors [19].

Limitations

Our study has several limitations. First, enrollment by trial type was not randomized as initially intended because of the rapid pace of participant accrual into the conventional trial conducted across the entire network of study sites. As a result, the enrollment goals were not met. However, with the available sample, we were able to demonstrate noninferiority for the interactive multimedia web-based video consent format at enrollment and superiority at study end compared with the conventional consent process in caregivers. Second, we did not have an established noninferiority margin specified for adolescents, and we did not establish noninferiority using the specified margin. However, in pediatric trials, the caregiver is largely the decision maker, with assent or dissent provided by the child participants; thus, the comprehension assessment by the caregiver was considered of principal importance for sample size estimation and outcome analysis. Third, it is possible that the study coordinator's knowledge of the comprehension score being measured may have altered their typical consenting style (known as the Hawthorne effect) to be more thorough or engaging, thus resulting in higher scores for the caregiver and adolescent with the conventional consent format [41]. The coordinators were instructed at the study outset to maintain the consent process used in other clinical trials. In contrast, there was no coordinator interaction with participants who received the web-based format to facilitate comprehension before comprehension assessment. It is possible that the focus on the consent process may have preferentially favored the conventional consent format, thus reducing the score differences. Fourth, this was a pilot study comparing consenting formats in a population with a chronic disease and may not be applicable to patients with cancer or acute illnesses; however, our results need to be replicated in other intervention trials that include children and adolescents with chronic conditions (eg, Crohn disease, allergies, and epilepsy).

It is important to acknowledge that the development of the video and website required resources (videographers, actor talent, website designers, and psychologists) that may not be readily available at an institution planning a small clinical trial. Clinical trials are expensive to perform, with costs for study procedures as well as for less apparent costs of time and effort associated with patient recruitment and retention [42]. Pediatric clinical trials are particularly labor intensive and expensive to perform, and joining a trial is often perceived as inconvenient and time-consuming by families [43-47]. Parents often have to bring siblings to appointments and manage competing after-school priorities to travel to a study site. The interactive multimedia video consent and website were developed for the MICT trial to evaluate the consenting process via the internet to reduce the burden of having an on-site study site visit for the purpose of learning about the study before considering enrollment. Failure to recruit participants can extend trial completion and thus costs

or result in premature trial discontinuation and wasted resources [42]. Therefore, how to effectively spend the limited resources that are needed for recruitment materials, stipends, and retention incentives requires careful consideration that may be study specific or site specific. The development of a video consent with the resources used in this trial may be best suited for large multisite trials; those conducted by the pharmaceutical industry; grants in which funding can be included in a budget proposal; or trials governed by a single IRB process, which is becoming more common. We found that the trial information was effectively conveyed and understood with the multimedia web-based consent designed for this trial.

Looking forward, advancements in artificial intelligence to create or manipulate multimedia content for film production in the absence of videographers and live actors may overcome some of these barriers [48]. Currently, there are software programs geared toward nonprofessionals to create simplified animated videos (Doodly, CreateStudio, and Cinema 4D) that may be suitable for creating consent documents or supplemental consent information [49]. The development of this multimedia platform would not have been possible without considerable dialogue with the IRB of the lead institution.

Conclusions

The new findings resulting from these data are that the comprehension of trial information can be effectively communicated with an asynchronous interactive multimedia web-based consent developed with established principles of learning for caregivers of adolescents with asthma. Embedding these learning principles may aid in the retention of study information over the duration of the study, as we found in this trial. We do not suggest that a participant's trial participation decision should occur in the absence of a discussion with the study staff. However, avoiding a long on-site study appointment to simply learn about the study before deciding to participate may relieve some of the burden of study participation for caregivers and their children and the study staff. Thus, modernizing the consent process to convey necessary clinical trial information in a manner that promotes improved comprehension across ages and sociodemographic groups is essential. Finally, the COVID-19 pandemic has had a substantial impact on the conduct of on-site study visits with participants and institutions alike, redirecting in-person, face-to-face study visits to telehealth. Thus, greater attention to strategies to conduct research in study site–independent venues will likely be a critical consideration in the design of future clinical trials to facilitate trial enrollment.

Acknowledgments

This study was supported by the National Institutes of Health grant 101HL114899 (to KVB) and the American Lung Association Airways Clinical Research Centers network. Publication was made possible in part by support from the Nemours Grants for Open Access from Library Services. Study data were collected and managed using REDCap (Research Electronic Data Capture; Vanderbilt University) tools hosted at Nemours Children's Health. The authors gratefully acknowledge the efforts of Yang Li, Kate Norton, and Ferdie Martinez on the web page design. In addition, the critical evaluation of study logistics provided by Stacey Gray and Nancy Archer, RN, were invaluable during study start-up. The site principal investigators and study coordinators (David Schaeffer, MD; Dale Schrum, MD; Jason Lang, MD; Okan Elidemir, MD; Gary Emmett, MD; Mario Castro, MD; Jenny Batalla; Angela Price, RN; Holly Turner, RN; Dana Geiser; Stephanie Kahn; Sandra Budd; and Jaime Tarsi, MPH) were instrumental in learning and teaching the study technology. Most importantly, these data would not have been possible without the enthusiastic participation of the caregivers and adolescents who participated in this trial.

Data Availability

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

Authors' Contributions

KVB contributed to conceptualization, methodology, investigation, writing the original draft, visualization, supervision, project administration, and funding acquisition. HA and AT contributed to methodology and investigation. HTB contributed to methodology, software, and resources. JH contributed to formal analysis. RH contributed to formal analysis and data curation. JTH and EAS contributed to formal analysis and writing the original draft. SMM contributed to software, resources, and data curation. CP contributed to software and resources. LR contributed to investigation. DS contributed to methodology. RAW contributed to conceptualization, methodology, resources, and funding acquisition. TW contributed to conceptualization and methodology.

Conflicts of Interest

None declared.

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Abbreviations

ACRC: Airways Clinical Research Centers
IRB: institutional review board
LASST: Long-Acting Beta-Agonist Step-Down Study
MICT: Use of Mobile Devices and the Internet to Streamline an Asthma Clinical Trial
NVS: Newest Vital Sign

Edited by S Badawy; submitted 11.11.22; peer-reviewed by H Wang, A Russell, H Veldandi; comments to author 11.01.23; revised version received 27.01.23; accepted 17.02.23; published 22.06.23.

Please cite as:
Blake KV, Antal H, Bunnell HT, He J, Henderson R, Holbrook JT, McCahan SM, Pennington C, Rogers L, Shade D, Sugar EA, Taylor A, Wise RA, Wysocki T
Comprehension by Caregivers and Adolescents of Clinical Trial Information Delivered via Multimedia Video Versus Conventional Practice: Nonrandomized Controlled Trial
JMIR Pediatr Parent 2023;6:e44252
URL: https://pediatrics.jmir.org/2023/1/e44252
doi:10.2196/44252
PMID:37347518

Original Paper

Caregivers' Experiences With a Web- and Mobile-Based Platform for Children With Medical Complexity and the Role of a Live Platform Coach: Thematic Analysis

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Abstract

Background: Children with medical complexity (CMC) are individuals with complex chronic conditions who have substantial health care needs, functional limitations, and significant use of health care. By nature of their health status, they have many care providers across multiple settings, making information sharing critical to their health and safety. Connecting2gether (C2), a web- and mobile-based patient-facing platform, was codeveloped with families to support and empower parental caregivers, improve information sharing, and facilitate care delivery. C2 also provided a live platform coach to conduct parental feedback and coaching sessions, which included answering questions, providing advice on usage, and addressing technological issues.

Objective: This study was conducted to understand the experience of parental caregivers using the C2 platform and the role of the live platform coach. This study is a subset of a larger study assessing the feasibility of C2 in the care of CMC.

Methods: Parental caregivers (n=33) participated in biweekly sessions to provide feedback and receive real-time platform use support from a trained research team member acting as a live platform coach. Parental caregivers were asked about the utility and usability of C2's features. Questions, platform issues, and feedback were recorded on a standardized electronic data collection tool. A thematic analysis was performed to analyze parental comments, and codes were categorized into key themes. The number of comments corresponding with each code was quantified.

Results: A total of 166 parental feedback and coaching sessions were conducted, with an average of 5 sessions per parental caregiver (range 1-7). There were 33 (85%) parental caregivers that participated in at least one coaching session. Technical issues and difficulties navigating C2 were addressed in real time during the sessions to encourage platform engagement. Four key themes were identified: (1) live platform coach, (2) barriers to platform usage and technical challenges, (3) platform requests and modifications, and (4) parent partnership and empowerment.

Conclusions: Parental caregivers describe C2 as a valuable tool, acting as a facilitator for enhanced care coordination and communication. Parental caregiver feedback showed that the live platform coach was a critical tool in educating on platform use

and addressing technological concerns. Further study of the use of the C2 platform and its role in the care of CMC is needed to understand the possible benefits and cost-effectiveness of this technology.

(JMIR Pediatr Parent 2023;6:e43214) doi:10.2196/43214

KEYWORDS

care coordination; care; children with medical complexity; children; chronic condition; electronic data; engagement; health information exchange; medical; patient care planning; pediatrics; usage; utilization

Introduction

Children with medical complexity (CMC) are individuals with complex chronic conditions who have substantial health care needs, functional limitations, and significant use of health care [1]. CMC often require multiple care providers across various settings, including home, hospital, and school [2], and the unique challenges of navigating multiple levels of care often results in fragmented care [3]. Timely access to up-to-date medical information is critical in the care of CMC. However, this information is often challenging to obtain due to electronic medical record (EMR) access limitations and other communication barriers [3,4]. A significant burden is often placed upon parental caregivers to integrate information from various care providers and systems to address their child's needs [5]. Streamlined communication, familial support, and health care team engagement are required to ensure that medical information is available to all members of a child's care team [5].

The use of a shared web- and mobile-based patient-facing platform for CMC [4] may facilitate information sharing, communication, and coordination among parental caregivers and their child's care team [6,7]. Previous research has explored the use of pediatric patient-facing platforms in order to improve patient information access, health outcomes, and communication with care providers [4]. Mobile health apps are positioned to deliver information outside of a clinical encounter [6]. Thus, mobile health apps can positively impact care outside of a health care setting. Studies of mobile health apps efficacy in pediatrics suggest that mobile health apps that involve usage by caregivers may have a more significant impact on health outcomes [8]. However, the use of mobile health apps in the care of CMC has been limited [6,8-11]. The complexity of this pediatric population, alongside previously identified caregiver burden [5], may benefit from a mobile health app with elevated levels of user support to enhance the caregiver experience and obtain maximal benefit from the app itself. Thus, the use of a live platform coach may be necessary to provide parental caregivers with the support required for platform use and accurate assessment of the use of these apps.

The overarching research question is to understand the parental caregiver experience of using Connecting2gether (C2), a web- and mobile-based patient-facing platform for parental caregivers of CMC. The objectives were to (1) identify barriers and challenges to platform uptake, (2) understand facilitators of parental use, and (3) evaluate the role of a live platform coach. This analysis is a substudy of a larger evaluation assessing the feasibility of the C2 platform in caring for CMC.

Methods

Connecting2gether Platform

C2 was developed to facilitate communication, care coordination, and information sharing between parental caregivers of CMC and their child's care team using secure messaging, health tracking, educational resources, a web- and mobile-based schedule, care map [12], and shared care plans [13]. Parental caregivers could invite their child's care team (ie, family members, health care providers, care coordinators, and teachers) to use C2 with them, hereinafter referred to as their "circle of care." Invitations for care team members to join C2 were sent through the platform by parental caregivers upon providing a circle of care member email address. Upon receiving the invitation email, circle of care members were able to set up their profile in C2. Parental caregivers were able to control the ability of each circle of care member to view and edit their child's profile. The live platform coach was able to assist parental caregivers in inviting care team members to the platform if they experienced difficulty with the invitation process. C2 was developed in partnership with a health technology solution company, NexJ Health, which provides evidence-based health solutions to those experiencing chronic conditions [14]. C2 was co-developed in partnership with parental caregivers and circle of care members of CMC. C2 was accessible through desktop, tablet, and mobile (iOS and Android) devices.

C2 also contained an automated points system where points were acquired when features were used (ie, inviting a care team member and sending a message) to enhance engagement.

Live Platform Coach

The team clinical research coordinator (MB) was trained by NexJ Health for the role of live platform coach and was knowledgeable about the care of CMC. The live platform coach engaged in continued, weekly touchpoints with NexJ Health. The term "coaching" henceforth refers to the act of counseling and encouraging parental caregivers on platform use. The purpose of the live platform coach was to empower, support, and educate, building parental self-sufficiency in platform use. Unlike commonly used programmed chatbots or artificially intelligent and programmed helpers, entitled "virtual human assistants" [9], the live platform coach provided a more personalized approach to addressing parental concerns and needs related to the use of the C2 platform. The live platform coach facilitated feedback and coaching sessions with parental caregivers, acting in a role of mentorship and support, as well as gathering feedback comments. Feedback and coaching sessions were designed to collect information about parental

caregivers' perspectives and behaviors related to platform use and utility. The platform coach addressed user concerns, aided with platform navigation, provided suggestions on the use of platform features, and sent a weekly message to all parental caregivers through the secure messaging system. The messages were formulated based on parental caregiver feedback and included a welcome message, helpful platform tips, educational resources, and updates on platform features. Weekly messages were intended to increase parental caregiver engagement, address common usage issues, and bring attention to lesser-used platform features. The platform coach communicated regularly with parental caregivers using the secure messaging system and did not provide medical advice.

Parental caregivers who identified concerns in the web- and mobile-based form were contacted by the live platform coach. Issues were addressed in real time by the live platform coach and tracked throughout the study and were further addressed through regular platform updates by NexJ Health.

Study Design and Population

Parental caregivers of CMC were recruited from the Complex Care Program (CCP) at The Hospital for Sick Children, Credit Valley Hospital, and Royal Victoria Regional Health Center in Ontario, Canada. To be eligible for the CCP, children must meet at least one criterion from each of the following conditions: technology dependence, users of high-intensity care, fragility, chronicity, and complexity [15].

Purposive sampling was used to ensure diversity in participant age, ethnicity, and geographical location. Nurse practitioners within the CCP were asked to draw upon their knowledge of parental caregiver experiences to recommend families for study participation. Primary caregivers of CMC who had been in the CCP for at least three months and had an active care plan were eligible for inclusion in the study. Parental caregivers were excluded if participation in the research study would be an added burden due to challenges including end of life, acute deterioration, hospitalization, parental physical or mental health concerns, or if caregivers did not speak English. English language proficiency was necessary for platform navigation and the use of the educational materials.

Study information was sent by post to eligible parental caregivers. Recruitment was conducted by phone and informed consent was obtained. Parental caregivers were recruited between July and November 2019 and used the C2 platform for 6 months.

Data Collection

Parental caregivers completed a demographics questionnaire at the beginning of the study in person or through REDCap (Research Electronic Data Capture), a web- and mobile-based electronic survey tool [16]. Chart review was conducted by a research team member for participating CMC to obtain additional demographic information regarding the clinical characteristic of the patient sample.

Parental caregivers were asked to participate in biweekly feedback and coaching sessions for the first month and in monthly sessions thereafter. Parental caregivers were given a choice at the study onset of completing the sessions through the phone, in person, or through REDCap, which contained standardized questions with open-ended responses (Multimedia Appendix 1). Parental caregivers were asked about their experience using C2, its usefulness, and each main platform feature such as "If not using any trackers, is there a reason you have not been using the trackers? Is there anything I can help you with?" The web- and mobile-based form was sent at predetermined time points and automatic reminders were sent if the form was not completed within a week. Feedback was collected verbatim for parental caregivers who completed the web- and mobile-based sessions. Telephone and in-person sessions were summarized by the live platform coach through the use of typed notes. All feedback and coaching session data were collected and managed using REDCap.

Participants received a CAD $20 and CAD $40 gift card (a currency exchange rate of CAD $1=US $0.74 is applicable) after completing baseline questionnaires and at the end of the study, respectively. Parental caregivers also received a CAD $5 gift card when they reached point milestones on C2 (1000, 2500, 5000, and 10,000 points).

Data Analysis

Demographic and chart review data were analyzed using descriptive statistics to contextualize the parental caregivers and CMC in the study. Responses from the feedback and coaching sessions were collected and organized based on the interview questions targeted to platform features.

Data from the sessions were analyzed using thematic analysis methods proposed by Braun and Clarke [17] by 3 members of the research team (JO, ACS, and MB). Thematic analysis is flexible, allowing for the production of a robust, nuanced, and detailed account of complex data. Thematic analysis has been successfully used in the analysis of open-ended interview question responses [18-20]. In this study, thematic analysis was chosen as this methodology is able to encompass the breadth of parental caregiver experiences in a complex and diverse population.

In this study, thematic analysis was conducted in alignment with the 6 stages for thematic analysis proposed by Braun and Clarke [17]. In stage 1 of the framework, data were first reviewed to promote familiarization (ACS). In stage 2, codes and subcodes were systematically developed across the entire dataset to categorize feedback based on platform features and parental caregiver experience (ACS). Codes were reviewed by other research team members (JO and MB) to reduce bias. Codes and subcodes were merged and refined to better reflect parental caregiver feedback, and a code tree was synthesized (ACS, JO, and MB). In stage 3, codes were collated into themes. Themes were developed inductively to describe the parental caregiver experience with C2 (ACS). In stage 4, themes were reviewed and amended by all 3 coding members of the research team to reflect the comments provided (ACS, JO, and MB). In accordance with stage 5, ongoing analysis of data was used to develop specific definitions and names for each theme. In stage 6, specific representative examples from the data were chosen to aid in communication of each theme.

The data were analyzed quantitatively to determine the frequency of parental caregiver comments based on each subcode and the number of parental caregivers who provided feedback under each code. The number of sessions completed by each parental caregiver were quantitatively determined.

Ethics Approval

Institutional research ethics approval was obtained at Credit Valley Hospital (REB #973), The Hospital for Sick Children (SickKids, REB1000060804), and Royal Victoria Regional Health Centre (REB #R18-013) in Ontario, Canada. Informed consent was obtained from all participants. Research was conducted in accordance with all applicable guidelines and regulations. Study data were deidentified prior to data analysis. A username and password were required to access C2. C2 is a secure, cloud-based platform. All C2 data were stored on IBM Softlayer servers, which are HIPAA, FedRAMP, PCI, and FISMA certified and fully compliant with ISO 27001, 27017, 27018. All stored data were encrypted and transferred within the system using only secure HTTPS connections.

Results

Platform Usage

A total of 39 parental caregivers consented to participate in the research study, and 37 parental caregivers completed the baseline data questionnaires (Figure 1). Out of these, 36 parental caregivers registered on the platform and 33 parental caregivers participated in at least 1 coaching session, with an average of 5 sessions per parental caregiver (n=33, range 1-7). Of the 3 parental caregivers who did not complete any feedback and coaching sessions, 2 withdrew from the study before completing a session, and 1 could not be contacted. Out of 252 possible parental feedback and coaching sessions, 166 were completed,demonstrating high parental engagement. A total of 42 (25%) feedback and coaching sessions occurred over the phone (range 5-15 minutes in length) and 122 (73%) feedback sessions were completed on the web. A total of 2 (0.01%) feedback sessions occurred in person. CMC and parental caregiver characteristics are included in Tables 1 and 2, respectively.

Figure 1. Flow diagram of parental caregiver recruitment. *These participants were not approached because recruitment had closed.

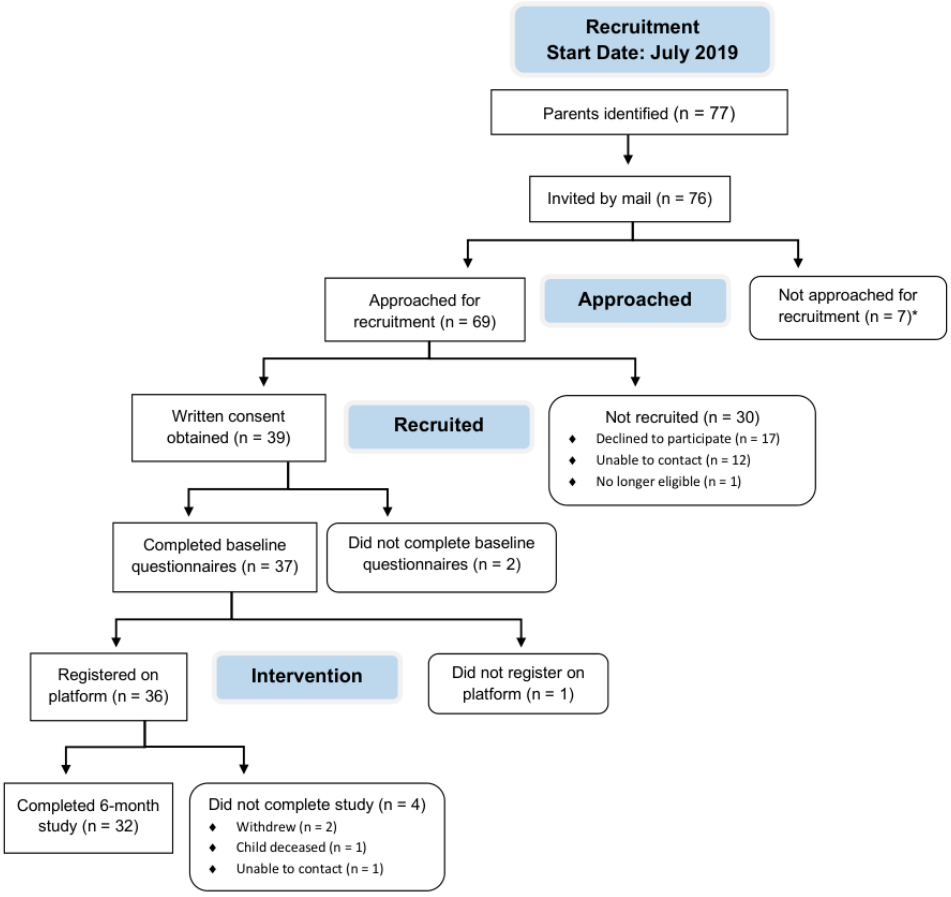


Table 1. Demographic characteristics of children with medical complexity (CMC) (n=37).

Characteristic	Children with medical complexity
Sex, n (%)	
Female	14 (38)
Male	23 (62)
Length of time in complex care program, n (%)	
<1 year	3 (8)
1-3 years	9 (24)
>3 years	25 (68)
Number of diagnoses, n (%)	
1-5	2 (5)
6-10	19 (51)
11-15	15 (40)
>15	1 (3)
Number of medications, n (%)	
1-10	15 (41)
11-20	19 (51)
21-30	3 (8)
Number of technologies, n (%)	
<5	11 (30)
5-10	19 (51)
11-15	7 (19)
Technology devices[a], n	
Feeding technology[b]	45
Respiratory technology[c]	67
Vascular access device[d]	4
Mobility device[e]	111
Communication device[f]	4
Other invasive technology[g]	1
Number of subspecialists[h], n (%)	
<5	1 (3)
5-10	18 (49)
11-15	18 (49)

[a]Each CMC used multiple technologies.

[b]Feeding technology: devices to obtain nutrition (ie, G-J tube, feeding pump).

[c]Respiratory technology: devices to assist with and monitor respiratory function (ie, tracheostomy, nebulizer, oxygen, heated high flow, bilevel positive airway pressure cough assist, oximeter).

[d]Vascular access device: devices for venous access (ie, central venous line and peripherally inserted central catheter).

[e]Mobility device: devices to improve personal mobility and movement (ie, special stroller, specialized wheelchair, walker, stander, portable Hoyer lift, bath chair, tomato chair, shoe lift, and ankle and foot orthotics).

[f]Communication device: devices used for communication purposes (ie, communication systems, cochlear implants, GO Talk board, iPad, and writing aids).

[g]Other invasive technology includes vagal nerve stimulator.

[h]Most used specialist included: neurology, respirology, cardiology, genetics, and hematology.

Table 2. Demographic characteristics of parental caregivers (n=37).

Characteristics	Parental caregivers, n (%)
Role	
Mother	30 (81)
Father	7 (19)
Age (years)	
20-40	19 (51)
>40	16 (43)
Did not answer	2 (6)
Primary language	
English	34 (92)
Other	3 (8)
Ethnic background	
Caribbean	3 (8)
East and South Asian	3 (8)
European ancestry	25 (67)
Latin, Central and South American	1 (3)
Other	2 (6)
Prefer not to answer	3 (8)
Marital status	
Single or divorced	4 (12)
Married or common law	30 (80)
Prefer not to answer	3 (8)
Education	
High school	2 (5)
Postsecondary school	21 (57)
Professional or graduate degree	13 (35)
Prefer not to answer	1 (3)
Employment status	
Employed full-time or part-time	19 (51)
Primary caregiver	12 (32)
Unemployed	3 (8)
Other	2 (5)
Prefer not to answer	1 (3)
Annual household income (CAD $[a])	
0-59,999	9 (24)
60,000-89,999	6 (16)
>90,000	18 (49)
Prefer not to answer	4 (11)

[a]A currency exchange rate of CAD $1=US $0.74 is applicable.

Quantitative Analysis of Functionality and Features

Functionality describes the overall ease of use and visual presentation of the platform. Nonparticipation refers to a lack of platform use and participation by members of the circle of care, including healthcare providers, educators, and parents. Parental caregivers' comments most commonly referred to C2's features (ie, educational resources and secure messaging),

accounting for 65.3% (335/513) of the total comments (Table 3). Of these features, the shared care plans and secure messaging were most frequently discussed (103/513, 20.1% and 82/513, 16%, respectively; Table 3). Parental caregivers provided the fewest comments on platform functionality (2/513, 0.4%) and the schedule feature (8/513, 1.6%; Table 3).

Table 3. Number of items of feedback from parental caregivers by code.

Code	Items of feedback (n=513), n (%)[a]	Parental caregivers who commented (n=33), n (%)[b]
Care plan	103 (20.1)	31 (93.9)
Secure messaging	82 (16)	32 (97)
Health trackers	67 (13)	31 (93.9)
Nonparticipation	63 (12.3)	31 (93.9)
Health library and workbooks	41(8)	26 (78.8)
Other feedback[c]	38 (7.4)	21 (63.6)
Care map	34 (6.6)	25 (75.8)
Live platform coach	32 (6.2)	32 (97)
Platform invitations	24 (4.7)	24 (72.7)
Technical issues	12 (2.3)	12 (36.4)
Schedule	8 (1.6)	8 (24.2)
Questions about research study	7 (1.4)	7 (21.2)
Functionality	2 (0.4)	2 (6.1)

[a]A piece of feedback is defined as a comment from a parental caregiver related to a specific aspect of the platform.

[b]Parental caregivers who provided comments falling under multiple subcodes were counted for each subcode.

[c]Other feedback includes feedback related to concerns about security, learning curve, integration, and positive comments about platform interface and usability

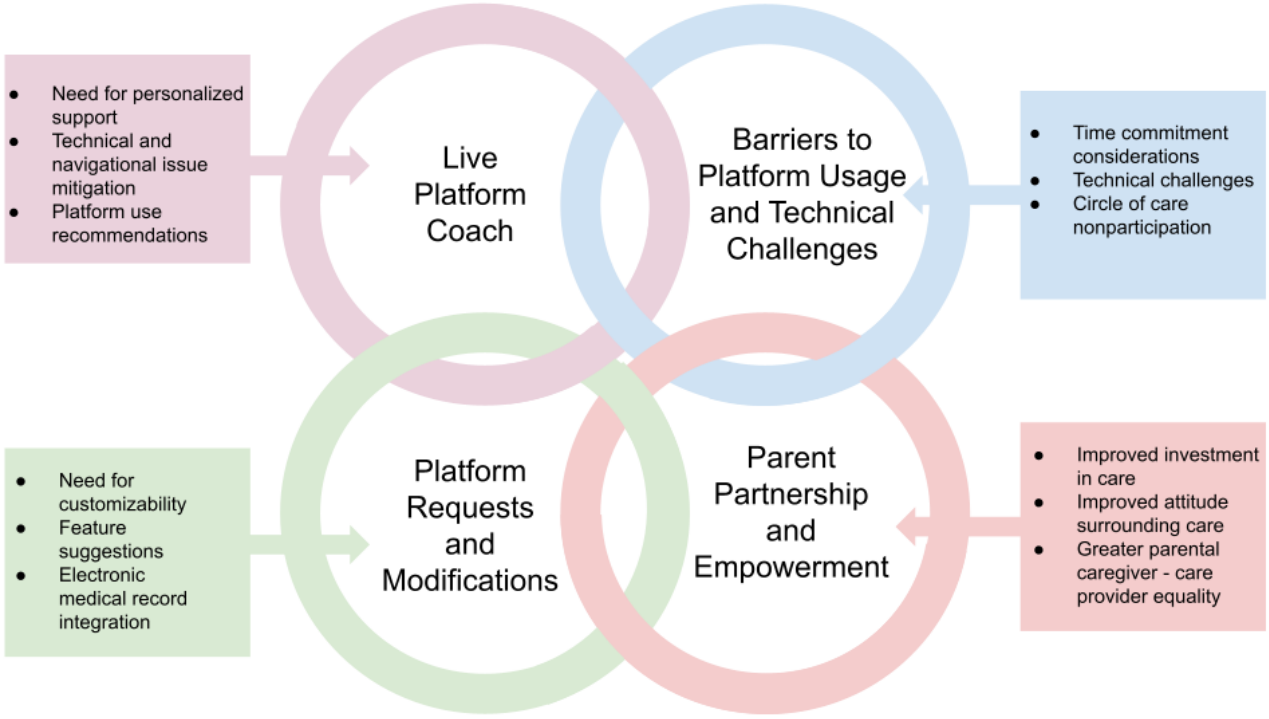
Thematic Summary of Parental Caregiver Feedback

To address the 3 study objectives, parental caregiver feedback was analyzed to identify key themes describing the parental caregiver experience using C2. From the analysis, four key themes emerged: (1) live platform coach, (2) barriers to platform usage and technical challenges, (3) platform requests and modifications, and (4) parental caregiver partnership and empowerment (Table 4 and Figure 2).

Table 4. Demonstration of platform usage and parental feedback relating to each identified theme.

Theme	Parental feedback
Live platform coach	• "I messaged [platform coach] on platform to get help editing a wellness tracker entry." (P16) • "[Platform coach] changed [the weight tracker to kilogram] for [me] and told [me] how to locate units under settings." (P22)
Barriers to platform usage and technical challenges	• "I asked [my] child's school nurses to join in the care circle. They were reluctant to as for their agent's policy." (P14) • "There were parts of the program I wanted to use such as care maps. They just didn't work." (P1) • "This past week has been rough with child, [I] haven't had as much time to go through the platform." (P4)
Platform requests and modifications	• "[I had] trouble adding signs and symptoms tracker–[I] wanted to create own rather than adding from the list." (P16) • "It would be useful to have home care nurses charting on the platform to be able to share with health care providers and nurse practitioners." (P14)
Parental caregiver partnership and empowerment	• "[I] had a meeting with school–printed off the care map and care plan. [I] felt more confident sitting in the meeting with the documents." (P41) • "[Connecting2gether] opened [my] eyes to the possibility to negotiate dialogue with health care team. [I felt] empowered to participate in child's care." (P8)

Figure 2. Themes describing the parental caregiver experience of using Connecting2gether.



Thematic Analysis

Live Platform Coach

Parental caregivers described the emerging role of the live platform coach as a key facilitator of platform use. The role of the live platform coach evolved into assisting with platform navigation, providing suggestions on the use of platform features, addressing technical errors, and gathering parental feedback comments. The live platform coach was able to work with parental caregivers to aid in password retrieval, unit conversions, and technical issue mitigation, potentially enhancing parental engagement. For example, the platform coach helped navigate between metric and imperial conversions for the health trackers, saving parental caregivers time and maintaining a positive experience. Parental caregivers also often asked about how to use specific platform features (ie, care map and care plans). The platform coach was able to provide suggestions as to how the platform could support their individual needs. For example, the platform coach provided suggestions on the use of the care map, such as the type of information that may be useful to add to a care map and who to share it with. The platform coach was also available to field parental caregiver questions and support platform use. A total of 97% (32/33) of parental caregivers commented on their use of the live platform coach, highlighting the importance of this role and parental caregiver support. The majority of these comments described the use of the platform coach in navigating platform use, mitigating technical issues, and suggesting avenues of platform use.

Barriers to Platform Usage and Technical Challenges

Parental caregiver feedback on barriers to platform usage included challenges such as the time commitment to use the platform, circle of care nonparticipation, lack of familiarity with the platform, and a lack of platform usefulness during periods of health stability (Table 3). Of parental caregivers, 24.2% (8/33) reported that platform set-up was a time-consuming process as some of the child's health information had to be manually entered, leading to decreased participation. Lack of engagement of circle of care members was a common barrier reported by parental caregivers and was usually due to organizational policies or lack of familiarity with the platform (Table 3).

Parental caregivers described technical challenges as a significant barrier to platform use. Common technical challenges included the mobile app crashing and a lengthy website loading time. Though only 36.4% (12/33) of parental caregivers discussed technical challenges (Table 3), the parental caregivers who experienced these challenges reported that this had a significant impact on their use of C2. Technical issues were mitigated through contact with the platform developer by the platform coach and the use of periodic software updates. The platform coach advised parental caregivers on simple technical solutions such as updating the app or device software to mitigate some of the technical issues.

Platform Requests and Modifications

Many parental caregivers requested increased customizability on certain aspects of the platform features, such as the secure messaging or shared care plans, and suggested new platform functions, particularly related to the health trackers and the schedule feature. For example, several parental caregivers suggested adding a feature allowing for gaps in sleep to be tracked to reflect the total hours of sleep more accurately. Parental caregivers also requested the ability to sync the web- and mobile-based C2 schedule with their own personal calendars. Parental caregivers also felt that integration of C2 with the hospital's patient-facing EMR would enhance usability and indicated that the lack of integration negatively impacted

their use of C2 as it required multiple platforms to be used for a comprehensive understanding of their child's health care needs.

Parental Caregiver Partnership and Empowerment

A key facilitator of parental caregiver platform use was the feeling of renewed parental caregiver-provider partnership and empowerment. Though feedback and coaching session questions focused on discerning methods of platform use and mitigating issues, roughly one-third of parental caregivers reported feelings of partnership with the medical team and empowerment through an improvement in attitude and investment in their child's care after using C2. Parental caregivers felt more involved in their child's care and as though they were acknowledged by their child's care providers. For example, one caregiver reported that they had felt that the health care team provided information and they received information prior to the study start. They stated that the platform helped to change and equalize that dynamic. Many parental caregivers appreciated the ease of communication with other members of their child's care team. Some parental caregivers indicated interest in C2 being available for a longer duration and to other families of CMC.

Discussion

Principal Results

To our knowledge, this is one of the first studies to assess the feasibility of a web- and mobile-based, patient-facing platform for parental caregivers of CMC. Upon examination of parental feedback data, the parental caregiver perspective on the use of CMC was characterized and organized into four key themes: (1) barriers to platform usage and technical challenges, (2) platform requests and modifications, (3) parental caregiver partnership and empowerment, and (4) live platform coach.

Parental Caregiver Partnership and Empowerment

Some parental caregivers reported renewed feelings of partnership with their child's care team members and a greater ability to participate in their child's care. Parental caregivers of CMC face challenges associated with fragmented care that impacts their partnership with health care providers [4]. This finding replicates previous study findings, where parental caregivers reported that they felt their expertise in their child's care was not acknowledged or valued by members of the medical team [4]. Previous studies have identified a need for family-centered care (FCC), where health care decisions are made based on a partnership between health care providers and families [4,21]. A primary challenge in the implementation of FCC is a lack of communication and collaboration. The outcome of improved parental caregiver empowerment following the use of C2 demonstrates that the use of a web- and mobile-based platform with a live platform coach can be considered as a facilitator of enhanced FCC.

Live Platform Coach

Parental caregivers reported that technical challenges also impacted their use of C2. Previous research on mobile health apps indicates technical challenges, including learnability, system design, and interoperability, affect platform usage [22]. These issues were mitigated in part by using the live platform coach, who provided suggestions to circumvent technical issues. The instrumental nature of the live platform coach to platform use was an unanticipated outcome of this study, thus feedback session questions did not directly target its use. The volume of parental caregiver comments describing the use of the live platform coach indicates the critical nature of this role.

The parental caregiver experience suggests that C2 was a useful tool for parental caregivers in the care of CMC. Though barriers existed, they were partially mitigated by the role of the live platform coach. CMC are a diverse population with a wide variety of needs, thus a human in the role of a platform coach is required to provide a flexible and tailored response to web- and mobile-based patient-facing platforms supporting the needs of parental caregivers of this population. Though the use of virtual human assistants has been described in many web- and mobile-based health platforms in adult populations, the role of a live platform coach has not been studied in pediatric populations. Support implemented in previous web-based health care platforms typically takes the form of an artificially intelligent virtual human assistant, as opposed to a person engaged in the role of platform support and partnership [9]. Unlike the platform coach role used in C2, the role of a virtual human assistant describes programmable features, like chatbots, that have been implemented in some mobile health apps for adult populations [9]. In analyses of the use of a virtual human assistant, more "human-like" characteristics of the avatar used and the programmed response including empathy and self-disclosure result in more positive parental caregiver experiences. A live platform coach may be beneficial over a virtual human assistant, as the live platform coach can provide a greater degree of personalization and specialization necessary for this population where feasible. The results of this study suggest that the live platform coach is a critical component of C2, and that widespread implementation of the platform would require an individual to function in a similar role for improved platform uptake.

Parental Caregiver Use and Platform Integration

Parental caregiver feedback suggests that C2 is a useful tool to have, when necessary, but its daily use is not always feasible or helpful. Caring for CMC is a significant time commitment [5], and a lack of time was reported by parental caregivers to be one of the most significant barriers to platform use (Table 3). Previous studies of adults using mobile health-related interventions identified that health issues often prevented patients from participating due to limitations imposed by the time required to manage their condition or pain, for example [23]. Similarly, several parental caregivers in the study reported decreased platform use due to a lack of time secondary to intensive care provision for their medically complex child. Thus, this study found that lack of time often perturbed the use of C2 from fitting parental caregivers' daily schedules. Parental caregivers found that the platform was most helpful when it could be used as a tool to track health patterns over time as needed instead of being used daily, particularly in establishing timelines during consultation with physicians and other health care professionals.

Previous studies on mobile health platforms showed that a lack of integration with EMR was a barrier as the use of other platforms or EMR themselves was prioritized due to convenience [24]. As reported by parental caregivers in the study, parental caregivers found that C2 was a valuable tool, but that further integration with existing EMR was necessary to improve usefulness. The C2 platform was not embedded within the hospital's EMR; thus, providers and parental caregivers had to manually input changes and log into a separate system. Parental caregivers stated that the integration of MyChart's schedule or results reporting tools would have improved platform usefulness. Due to the nature of the feasibility study, EMR integration was not addressed. Platform efficacy must be determined prior to EMR integration being considered, and a large-scale assessment of feasibility must be performed. Partnership with parental caregivers and a user-centered design approach is crucial to ensure that the future iteration of a web- and mobile-based patient-facing platform for CMC is tailored to parental needs, including increased customizability.

Comparison With Previous Work

Previous studies have identified multiple challenges in care coordination for CMC [4]. The unique complexity of this population requires the investigation of unique solutions. In partnership with NexJ Health, the existing NexJ Connected Wellness (NCW) was adapted to create C2 [14]. Previous studies evaluating the use of NCW have been conducted on adult populations [25]. To adapt to the unique CMC pediatric population, features from NCW including workbooks and health trackers were tailored to the CMC population, providing increased platform adaptability, layout, and functionality. Previous studies on care coordination challenges in CMC identified that the implementation of shared systems that can be accessed by all members of a child's care team in real time may help mitigate these challenges [4]. This study expands upon previous work to evaluate parental caregiver perspectives on a novel technological solution to improve care coordination and information-sharing.

Limitations

Given parental caregiver preference to complete sessions remotely or by phone, data recording methodology for feedback and coaching sessions varied. Summarization and verbatim transcription were both used. The use of summarization is a limitation of this study as it may have resulted in interviewer bias. Further study limitations involve study exclusion criteria. The study population excluded individuals that did not speak English, and future research is needed to understand the feasibility of C2 for families who prefer languages other than English. Further, families involved in the study were approached based on a nurse practitioner's evaluation that they would be able to use the technology and provide constructive feedback, and that it would be appropriate for families to participate, which may have also introduced bias. Additionally, the majority of parental caregivers were of European ancestry and had completed a postsecondary degree, with close to half of participants having an annual household income of more than CAD $90,000. As a result, the breadth of needs of parental caregivers belonging to lower socioeconomic status groups or those from historically marginalized groups may not have been encompassed by the study.

Conclusions

It is well understood that caring for CMC involves communicating with multiple health care providers across a variety of settings and a significant amount of care coordination by parental caregivers, amounting to a large time commitment for families. The C2 platform was described as a useful tool by parental caregivers to enhance communication and information access in the care of CMC. Improved access to information and educational resources, alleviation of caregiver burden, and tracking of health trends may lead to improved health outcomes for this population. The live platform coach facilitated platform use, mitigated technical issues, and enhanced the experience of parental caregivers with C2. Future patient-facing platforms for CMC should consider the use of a live platform coach to provide personalized platform support and improve platform utility.

Acknowledgments

We would like to thank all parental caregivers who graciously donated their time to participate in this study. We would also like to thank the Government of Ontario for funding this study through the Ontario Center of Innovation, a member of the Ontario Network of Entrepreneurs. Lastly, we would like to thank NexJ Health for their partnership over the course of this study.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Parental caregiver online feedback and coaching session questionnaire.
[DOC File , 101 KB - pediatrics_v6i1e43214_app1.doc]

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Abbreviations

C2: Connecting2gether
CCP: Complex Care Program
CMC: children with medical complexity
EMR: electronic medical record
FCC: family-centered care
NCW: NexJ Connected Wellness

Edited by S Badawy; submitted 16.10.22; peer-reviewed by V Gurupur, H Holmen; comments to author 27.01.23; revised version received 18.03.23; accepted 03.04.23; published 05.07.23.

Please cite as:
Shouldice AC, Beatty M, Adams S, Dharmaraj B, Moore C, Stinson JN, Desai A, Bartlett L, Culbert E, Cohen E, Orkin J
Caregivers' Experiences With a Web- and Mobile-Based Platform for Children With Medical Complexity and the Role of a Live Platform Coach: Thematic Analysis
JMIR Pediatr Parent 2023;6:e43214
URL: https://pediatrics.jmir.org/2023/1/e43214
doi:10.2196/43214
PMID:37405834

Original Paper

An After-Hours Virtual Care Service for Children With Medical Complexity and New Medical Technology: Mixed Methods Feasibility Study

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Abstract

Background: Family caregivers (FCs) of children with medical complexity require specialized support to promote the safe management of new medical technologies (eg, gastrostomy tubes) during hospital-to-home transitions. With limited after-hours services available to families in home and community care, medical device complications that arise often lead to increased FC stress and unplanned emergency department (ED) visits. To improve FC experiences, enable safer patient discharge, and reduce after-hours ED visits, this study explores the feasibility of piloting a 24/7 virtual care service (Connected Care Live) with families to provide real-time support by clinicians expert in the use of pediatric home care technologies.

Objective: This study aims to establish the economic, operational, and technical feasibility of piloting the expansion of an existing nurse-led after-hours virtual care service offered to home and community care providers to FCs of children with newly inserted medical devices after hospital discharge at Toronto's Hospital for Sick Children (SickKids).

Methods: This exploratory study, conducted from October 2020 to August 2021, used mixed data sources to inform service expansion feasibility. Semistructured interviews were conducted with FCs, nurses, and hospital leadership to assess the risks, benefits, and technical and operational requirements for sustainable and cost-effective future service operations. Time and travel savings were estimated using ED visit data in SickKids' electronic medical records (Epic) with a chief complaint of "medical device problems," after-hours medical device inquiries from clinician emails and voicemails, and existing service operational data.

Results: A total of 30 stakeholders were interviewed and voiced the need for the proposed service. Safer and more timely management of medical device complications, improved caregiver and provider experiences, and strengthened partnerships were identified as expected benefits, while service demand, nursing practice, and privacy and security were identified as potential risks. A total of 47 inquiries were recorded over 2 weeks from March 26, 2021, to April 8, 2021, with 51% (24/47) assessed as manageable via service expansion. This study forecasted annual time and travel savings of 558 hours for SickKids and 904 hours and 22,740 km for families. Minimal technical and operational requirements were needed to support service expansion by leveraging an existing platform and clinical staff. Of the 212 ED visits related to "medical device problems" over 6 months from September 1, 2020, to February 28, 2021, enteral feeding tubes accounted for nearly two-thirds (n=137, 64.6%), with 41.6% (57/137) assessed as virtually manageable.

Conclusions: Our findings indicate that it is feasible to pilot the expansion of Connected Care Live to FCs of children with newly inserted enteral feeding tubes. This nurse-led virtual caregiver service is a promising tool to promote safe hospital-to-home transitions, improve FC experiences, and reduce after-hours ED visits.

(JMIR Pediatr Parent 2023;6:e41393) doi:10.2196/41393

KEYWORDS

children with medical complexity; technology dependence; medical devices; family caregivers; virtual care; home and community care; emergency department visits; enteral feeding tubes; hospital-to-home transition; feasibility; mixed methods

Introduction

Background

Children with medical complexity (CMC) are known to have multiple and severe chronic health problems, functional limitations, and a dependence on medical technologies (eg, central lines and tracheostomies) with increased caregiver needs [1-4]. CMC may be discharged to home and community care settings on 1 or more medical devices that they depend on to support vital functions, such as eating and breathing. Among the varied medical devices used in home and community care, enteral feeding tubes are one of the most common technologies and have high rates of unplanned hospital visits [5-8]. An enteral feeding tube is a medical device placed in the nose, mouth, or a stoma that is used to deliver liquid nutrition, medications, or fluids directly into the gastrointestinal tract, such as a gastrostomy, gastrojejunostomy, nasogastric, nasojejunostomy, or jejunostomy tube (G tube, GJ tube, NG tube, NJ tube, or J tube, respectively) [9,10]. The typical feeding tube complications that these patients present with to the emergency department (ED) are displacement, blockage, leakage, bleeding, and infection [4,5]. Increased stress associated with managing feeding complications and frequent trips to seek medical care are common challenges family caregivers (FCs) face while caring for children with newly inserted enteral tubes [11].

Although CMC make up less than 1% of children in Canada, they account for nearly 60% of total pediatric hospital care costs [1]. When complications related to medical devices arise, the associated costs tend to be even higher for CMC and those who depend on technology devices (ie, CMC with technology dependence [CMC-TD]), due to their increased utilization of health services and visits to the ED [1,3,4]. To enable safe medical device management during hospital-to-home transitions, CMC-TD often require highly skilled, around-the-clock care from FCs and home and community care providers [12]. In preparing for discharge, it is important that FCs receive specialized education to enable their confidence and competency in pediatric complex care to prevent and troubleshoot medical device complications, while reducing unplanned ED visits [12]. One of the FCs noted as follows:

> *My daughter was diagnosed with a rare genetic illness and spent the first year of her life at the hospital. Six years ago, when she was first discharged from the hospital, we had limited support managing her G tube and oxygen therapy. A home care nurse was sent to visit her, but they did not arrive until three days after discharge, so my only option was to call the in-patient unit to ask for their support. Again, more recently, I had an incident in 2020, where my daughter's G tube had fallen out. I had inserted her emergency catheter but was not able to pull back gastric fluid to get a pH reading. I tried calling the hospital but realized the clinic team was only available during office hours. Then, I called the physician on-call at the hospital, who told me they could not see the G tube, so it was best I came into the hospital. I ended up taking my daughter to the emergency department for a complication that could have been avoided entirely and virtually managed at home with video calling support.*

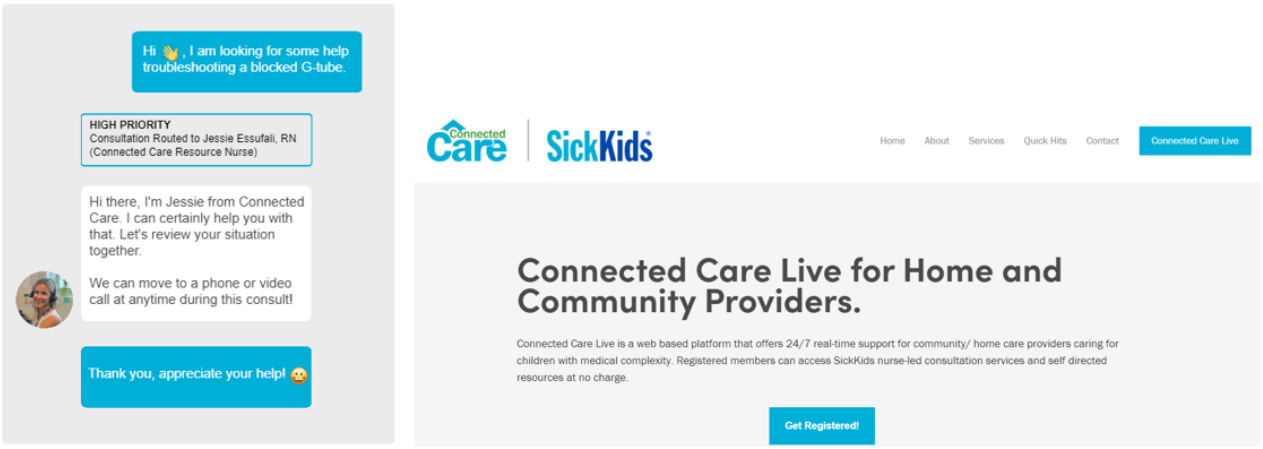
About the Program and Service

At the Hospital for Sick Children (SickKids), Canada's largest pediatric hospital, over 3000 CMC-TD are discharged each year to home who have an ongoing need for specialized home and community care [13,14]. SickKids partners with home and community care providers to support the unique needs of this population, drive system integration, and promote seamless hospital-to-home transitions through their Connected Care program [14]. Connected Care provides specialized medical device training through an annual program comprising over 2000 in-hospital and virtual family education sessions before discharge, along with more than 1000 education modules tailored for home and community care providers, such as nurses from home care agencies, across Ontario [14]. Home and community care providers can access 24/7 real-time virtual care support through the Connected Care Live service. This support is available via text, phone call, or video call and is provided by an interprofessional team of SickKids clinicians, primarily registered nurses, who are experts in the use of home care technologies (Figure 1) [14]. This web-based service, accessible via smartphones/tablets and PC/laptop, is device agnostic and supports over 1000 providers across the Greater Toronto Area [15]. Connected Care Live consultations are typically used to help users troubleshoot medical device complications; reinforce specialized education and skills; and clarify patient medical orders, care plans, or medications [15]. Currently, this service is exclusively available to regulated care providers in home and community care settings who care for CMC-TD.

After discharge, FCs at SickKids cannot access the Connected Care Live service but are offered specialized support through scheduled virtual visits arranged by Connected Care staff within a week of discharge, self-directed online AboutKidsHealth resources, email and telephone office-hours contact with specialized medical device teams (eg, G-Tube Resource Team), and home and community care provider services [14]. However, virtual visits cannot be initiated by FCs and are not accessible

in real time. Besides, many specialized medical device teams are not available after-hours, further limiting support available to FCs during this time. In addition, not all CMC-TD are eligible for home and community care provider services and significant reductions have been seen across home and community care services because of major health human resource shortages, fears of COVID-19 transmission, and greater desire among FCs to increase self-efficacy [16]. With limited access to specialized medical device support during after-hours, a more sustainable strategy is required to support FCs of CMC-TD beyond discharge.

Figure 1. The Connected Care Live virtual care service on mobile and desktop.



Study Goal

This study aims to establish the economic, operational, and technical feasibility of piloting the expansion of Connected Care Live to FCs of CMC-TD with newly inserted enteral feeding tubes (ie, G, NG, and GJ tubes) after discharge from SickKids, to ensure the sustainability of a nurse-led after-hours virtual care service for this high-needs population.

Methods

Study Design

An exploratory study was conducted from October 2020 to August 2021 using mixed data sources to evaluate the service expansion. A total of 30 semistructured interviews were conducted with key informants including FCs of CMC-TD, nurses, and hospital leadership to assess the risks, benefits, and technical and operational requirements of the service expansion. Economic feasibility was assessed by considering anticipated risks and benefits, which were determined through interviews. We estimated time and travel savings for families, clinicians, and the hospital by comparing the existing state of after-hour services with the anticipated future state following the implementation of Connected Care Live. Similarly, previous studies have used time invested in implementing new technologies as a measure of economic value to establish feasibility [17]. Operational feasibility was assessed by identifying the resources and workflow changes required for service expansion. Technical feasibility was assessed by identifying the technical requirements for delivering the service.

Semistructured Interviews

A mix of virtual and in-person semistructured interviews was conducted with FCs, nurses, and hospital leadership. Interview participants were self-selected in response to an email and were purposively recruited to ensure the breadth of perspectives was reflected across individuals that had relevant experience with the identified challenges, type of project, or proposed service. The sample size was determined by considering the segmentation of leader viewpoints, diversification of the participants, and saturation achieved through iterative data analysis. A semistructured interview guide informed by principles of child and family-centered care was developed iteratively by the study team [18]. Interview guides were sent out 24 hours in advance of each meeting to promote readiness and respect for participant's time. At the start of each interview, participants were informed about the purpose and that observational notes would be taken to support the feasibility assessment.

A qualitative content analysis of all interviews was conducted using a conventional approach. This analysis included 3 steps: (1) familiarization with the data through manual reading of text from observational notes taken in response to open-ended questions; (2) identification of key categories related to risks, benefits, and operational and technical requirements described by participants; and (3) selection of quotes and examples [19]. The preliminary analysis of interview content was completed sequentially after data collection by the primary author (KB), which was followed by a secondary analysis performed by 2 coauthors (KK and JE). The identification of categories was driven by quantity and relative importance as expressed by the most common and greatest challenges (eg, gap in after-hours support) identified across interview participants.

Economic Feasibility

ED visits and after-hours medical device inquiries data were used to estimate the cost of inaction for the time and travel savings analysis. Before data extraction, hospital approval was obtained to extract relevant data from the SickKids' Epic electronic medical record team. Over a 6-month period from September 1, 2020, to February 28, 2021, data on all ED visits with a chief complaint of "medical device problems" were

extracted from the Epic electronic medical record. Variables that were analyzed from these data included type of medical device, reason for visit, and number of hours in ED. The study team also examined and classified each ED visit to identify those that were likely "avoidable" had there been access to a virtual care solution for these FCs. The criteria for visits that could not be managed virtually were developed in consultation with subject matter experts from the Connected Care and G-Tube Resource Team (Textbox 1).

To estimate the time spent managing after-hours emails and voicemails, over a 2-week period from March 26 to April 8, 2021, data on medical device inquiries by FCs to the G-Tube Resource Team were collected. The analyzed variables were mode of contact, date of contact, reason for contact, and disposition. The study team also examined and classified each inquiry, identifying those that could be managed by the Connected Care Resource Nurses. The criteria for Connected Care manageable inquiries were also developed in consultation with subject matter experts from the Connected Care and G-Tube Resource Team (Textbox 2).

Textbox 1. Exclusion criteria for virtually manageable emergency department visits.

- Obtained imaging (eg, x-rays, ultrasound for tube placement) and tests (eg, nasopharyngeal swabs).
- Required intravenous access or medications not part of the home care plan.
- Obtained blood work (not including blood sugar levels checked for missed feeds).
- Dispositioned to hospital admission.

Textbox 2. Exclusion criteria for medical device inquiries manageable by Connected Care Resources Nurses.

- Appointment-related questions
- Serious and life-threatening conditions that require immediate medical attention
- Gastrojejunostomy tube dislodgement–specific questions

Operational Feasibility

ED visits and after-hours inquiries data were used to forecast the volume and timing of Connected Care Live consultation service demands. We measured the service's operational requirements in hours, using service demand data to estimate the annual nursing full-time equivalents needed for pilot service expansion. This also included the hours required for specialized G tube training for Connected Care Resource Nurses, quality assurance, and administrative tasks before and during the initial pilot. Estimated service demands were compared with existing scheduling and human resource capacity to determine the impact on workflows.

Technical Feasibility

We assessed technical feasibility by identifying the technical requirements for delivering the service in consultation with internal subject matter experts, including those from Connected Care, privacy, legal, risk, and information security functional departments, during semistructured interviews.

Ethics Consideration

Ethics approval was not sought for this study, given the minimal risk posed to participants. In its entirety, it is compliant with the Tri-Council Policy Statement (TCPS2 2022 [20]) on research ethics. Participation in data collection was completely voluntary. Before observational notes were taken during interviews, all research participants provided informed consent and were briefed on their right to opt out of the data collection process at any time.

Results

Overview of Study Participants

A total of 30 participants were interviewed in this feasibility study. The participants represented a variety of roles that directly and indirectly provide support to CMC-TDs, including FCs, nurses, and hospital leadership (Table 1). All FCs interviewed had experience caring for their children with newly inserted enteral tubes, nurses had anywhere from 5 to 16 years of clinical experience managing medical device complications, and hospital leadership had previous experience supporting the implementation of virtual care services.

Table 1. Participants interviewed from SickKids (N=30).

Participant group	Participants, n
Family caregivers	
Parents of children with medical complexity from the SickKids' Patient and Family Advisory Network	2
Nurses	
Emergency department	2
Connected Care Program	4
Gastrostomy Tube Resource Team	3
Hospital leadership	
Connected Care Program leadership and administrative staff	4
Clinical directors and managers	5
Functional department leads for privacy, information security, legal, and risk, information management, and technology	6
Quality and education leads	2
Project managers	2

Economic Feasibility

Results of the Risk-Benefit Analysis From Interviews With Families, Nurses, and Hospital Leadership

The risks of service expansion identified by interview participants are shown in Table 2. These included service demand, legal, privacy, technical, nursing practice, and purpose of service. The benefits of service expansion identified by interview participants are shown in Figure 2. These included safer and more timely management of medical device complications, improved caregiver and provider experiences, strengthened partnerships, and significant annual time and travel savings for FCs, SickKids' ED, and G-Tube Resource Nurses.

Table 2. Risks of service expansion to families identified among interview participants.

Risk category	Participants impacted	Risk description
Service demand	• Connected Care Resource Nurses • Connected Care Leadership	• Risk of high-volume and long-duration consults • Risk of inadequate staffing and health human resources
Legal	• Connected Care Resource Nurses	• Risk of providing recommendations that result in potential or actual harm to patients
Privacy	• Patients, family caregivers, and Connected Care Resource Nurses	• Risk of difficulty verifying end users (authorized family caregivers) to protect personal health information; risk of lost or stolen devices
Technical	• Family caregivers and Connected Care Resource Nurses	• Risk of having technical issues or service interruptions during consults
Nursing practice	• Connected Care Resource Nurses	• Risk of errors; concern for gaps in knowledge when supporting family consults
Purpose of service	• Patients • Connected Care Resource Nurse	• Risk of harm for delayed emergency department visits if the family caregiver misunderstands the purpose of the service • Risk of increased time and resources spent redirecting family caregivers

Figure 2. Value emerging from Connected Care Live service expansion to families. CC: Connected Care; CCRN: Connected Care Resource Nurse; ED: emergency department; FC: family caregiver; GTRN: Gastrostomy Tube Resource Nurse.

Emerging Themes

Addresses Patient Safety and Gap in the After-Hours Support to Family Caregivers

Many interview participants emphasized the limited follow-up and lack of real-time support available to FCs beyond discharge to enable safe after-hours management of their child's medical device. Participants highlighted the value that the Connected Care Live service would bring to support families after-hours on weekends, weekday evenings, and statutory holidays.

> *A home care nurse may be worried about making a mistake that upsets a parent, but a parent is worried about making a mistake that impacts the safety of their child. We want to know how to solve problems to avoid going to the emergency department, but also how can we stay away from calling [the hospital] again or prevent future ED visits. How can we become more independent.* [FC, Patient and Family Advisory Network]

> *Parents would have ongoing support after discharge. Right now, our follow up is limited.* [Experienced registered nurse]

> *Having this service would be a huge help to our families overnight and over the weekend.* [Experienced registered nurse]

Participants also highlighted the need for a service like Connected Care Live to prevent after-hours ED visits and how valuable it is to be able to access video-calling features in addition to text or calling to feel more confident about caring for their child at home.

> *If I had this service, I'm 99.9% sure, it would have prevented an ED visit.* [FC, Patient and Family Advisory Network]

> *Especially for new families, this service would be invaluable. Even just over the phone it can be difficult to walk you through what needs to be done but having the option of the video makes a huge difference to see what you are referring to. To have equipment and supplies available through Connected Care Live and physically see what needs to be done.* [FC, Patient and Family Advisory Network]

Supports Caregiver After-Hours Stress and Strengthens Partnerships

Participants further voiced that having a gap in after-hours services available to FCs has contributed to increased caregiver stress when caring for their child's medical device at home. By expanding Connected Care Live to families, they described how it would not only help alleviate stress but also enhance existing partnerships with SickKids' providers.

> *A lot of the concern I have as a parent to deal with at home is the anxiety of not knowing if you're doing the right thing or not.* [FC, Patient and Family Advisory Network]

> *With each consult encounter, it would strengthen the partnerships we have with our families.* [Experienced registered nurse]

Improves Provider Satisfaction and Reduces Workflow Interruptions

Nurses are often responding to FC inquiries to ensure that they receive the high-quality specialized support that they need to manage their child's medical devices at home. However, in the absence of formal channels to support families after-hours, nurses voiced the increased workflow interruptions they were experiencing, highlighting the need for a service like Connected Care Live. Particularly, the G-Tube Resource Nurses mentioned that they frequently deal with a large volume of after-hours emails upon returning from the weekend. Because of limited capacity, they are then required to schedule fewer patients and specialized wait-listed procedures on Mondays

> *Right now, we see many backdoor consults through emails. The increasing number of emails are difficult*

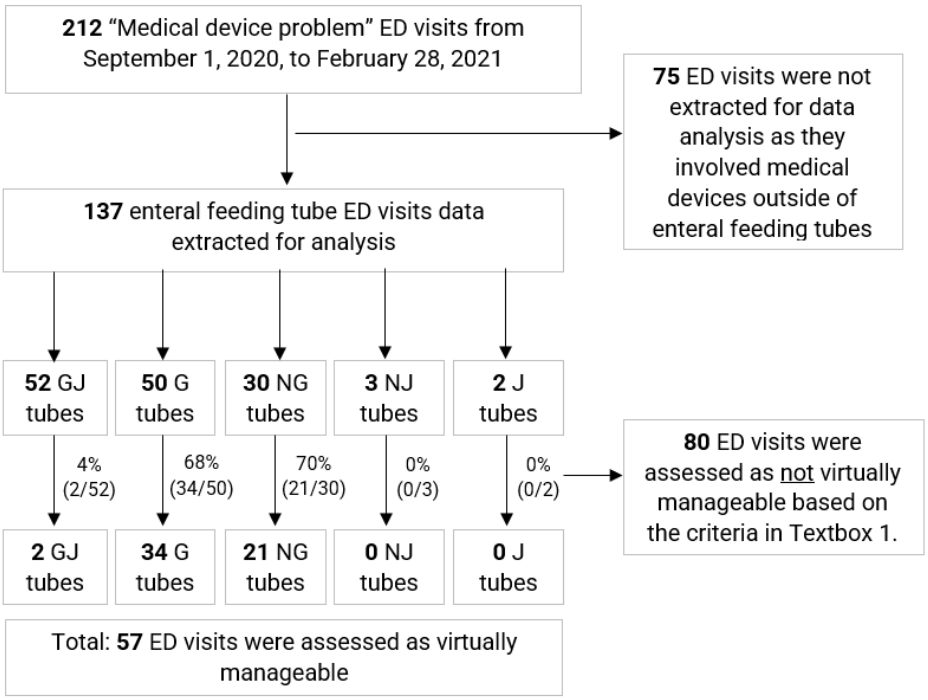
to organize and manage, but families show a lot of appreciation of this support. This service will provide a more formal structure and secure pathway for us to provide recommendations. [Experienced registered nurse]

We often book less patients on Mondays because we are so busy responding to after-hours emails. [Experienced registered nurse]

ED Visit Data Results

Figure 3 presents a flowchart depicting the findings from the extraction of Epic ED visit data. Of the 212 ED visits categorized as "medical device problems," enteral feeding tubes accounted for nearly two-thirds (n=137, 64.6%). Across these visits, patients and FCs spent an average of 4.2 hours in the ED. Dislodgment (92/137, 67.2%), blockage (19/137, 13.9%), and stoma issues (8/137, 5.8%) were the top 3 reasons for visits. Among the 137 enteral feeding tube visits, 37.9% (52/137) were related to GJ tubes (with 4%, 2/52, assessed as virtually manageable), 36.5% (50/137) were related to G tubes (with 68%, 34/50, assessed as virtually manageable), 21.9% (30/137) were related to NG tubes (with 70%, 21/30, assessed as virtually manageable), 1.5% (2/137) were related to jejunostomy tubes (with 0%, 0/2, assessed as virtually manageable), and 2.2% (3/137) were related to nasojejunal tubes (with 0%, 0/3, assessed as virtually manageable). Across all the ED visits related to enteral feeding tubes, 41.6% (57/137) were assessed as virtually manageable (see Textbox 1 for exclusion criteria).

Figure 3. Flow diagram showing EPIC emergency department (ED) visits from September 2020 to February 2021. G tube: gastrostomy tube; GJ tube: gastrojejunostomy tube; NG tube: nasogastric tube; NJ tube: nasojejunal tube; J tube: jejunostomy tube.



After-Hours Medical Device Inquiries to G-Tube Resource Team Data Results

Out of 192 enteral tube insertions (ie, G and G-J) performed each year by SickKids' image-guided therapy (n=170) and general surgery (n=22) teams, 47 after-hours emails and voicemails inquiring about 35 different patients to the G-Tube Resource Team were documented over a 2-week period. The results are presented in Table 3. Approximately three-quarters (33/47, 70%) of inquiries were initiated by FCs, nearly all via email (45/47, 96%), and over two-thirds occurred during the first day of the week (33/47, 70%). Note this "first day" includes 1 Tuesday after a statutory holiday with the highest volume of inquiries addressed after a long weekend (13/47, 28%); 35/47 (75%) inquiries were for G tubes and the rest were for either a GJ tube (9/47, 19%) or not stated (3/47, 6%). The top 3 reasons for contacting the team were appointment related (13/47, 28%), stoma or granulation tissue (11/47, 23%), or dislodgement (3/47, 6%). Over one-half of the issues were considered manageable by the Connected Care team (24/47, 51%; see Textbox 2 for exclusion criteria).

Table 3. After-hours medical device inquiries to G-Tube Resource Team results from March 26, 2021, to April 8, 2021, out of 192 new insertions each year.

Variable	Inquiries (N=47), n (%)
Mode of contact	
Email	45 (96)
Voicemail	2 (4)
Individual/group initiating contact	
Family caregiver	33 (70)
Point-of-care team	9 (19)
Other (group home, image-guided therapy team)	5 (11)
Type of medical device	
Gastrostomy tube	35 (75)
Gastrojejunostomy	9 (19)
Not stated	3 (6)
Reason for contact	
Appointment related	13 (28)
Stoma/granulation tissue	11 (23)
Dislodgement	3 (6)
Other (stoma output, tube size/fit, primary insertion, adaptors and catheters, balloon volume, leakage, old blood from tube, blood work follow-up, re-siting tube, routine follow-up)	20 (43)

Time and Travel Savings Analysis Results

Our study forecasted an annual savings of 478.3 hours for SickKids' ED, 74.4 hours for G-Tube Resource Nurses, and 890.7 hours and 22,740 km (travel) for families. The estimated total annual time and travel savings are presented in Table 4. To calculate travel savings for families, we estimated the average round-trip distance per hospital visit, the average number of visits per year, and the total number of patients based on the ED visit data.

Table 4. The estimated total annual time savings for SickKids Emergency Department, family caregivers, and the Gastrostomy Tube Resource Nurses.

Estimation	SickKids Emergency Department	Family caregivers	Gastrostomy Tube Resource Nurses
The calculation to determine the total number of hours per year (eg, number of visits in a year × hours/visit)	• 137 enteral medical device EDa visits in 6 months × 2 • 4.2 hours on average/ED visit	• 2 hours of estimated total travel time/ED visit • 4.2 hours on average/ED visit • 3 ED visits/year on average • 94 families in 6 months × 2	• 5 minutes/email 47 emails on average every 2 weeks × 2 × 12 months • 1 hour blocked off Monday mornings (or Tuesdays if holidays) from clinic visits to respond to after-hours inquiries × 52 weeks
Total number of hours per year	• 1150	• 3497	• 146
Percentage of virtually manageable visits	• × 41.6% (57/137) virtually manageable visits including all enteral feeding tube types (see Figure 3)	• × 41.6% (57/137) virtually manageable visits including all enteral feeding tube types (see Figure 3) • 564 hours for estimated Connected Care Live consults (3 consults per year/1 hour per consult/94 families in 6 months × 2)	• × 51% (24/47) Connected Care Resource Nurse manageable visits
Estimated total annual time savings (hours)	478.3	890.7	74.4

[a]ED: emergency department.

Operational Feasibility

The estimated program service operational requirements are shown in Table 5. These include approximately 0.1 nursing full-time equivalents for supporting the pilot service expansion and 60 hours for initial-year activities such as professional development training workshops, project management, auditing, quality assurance, and administrative tasks before pilot implementation. Service demand was estimated based on ED visits and after-hours inquiries data. Almost 95.6% (131/137) of consults resulting from enteral feeding tube ED visits and after-hours inquiries occurred within the established Connected Care service hours, which are from Mondays to Thursdays, 7 AM to 11 PM, and Fridays to Sundays, 7 AM to 7 PM.

Table 5. Connected Care operational requirements for gastrostomy/gastrojejunostomy tube pilot expansion.

Initial annual operational requirements[a]	Ongoing operational requirements[a]	Annual required FTE[b,c]
• 274 (137×2) enteral ED[d] visits/year • 41.6% (57/137) virtually manageable (includes all enteral feeding tube types shown in Figure 3) • 1 hour on average/consult • 53 hours of emails • 60 hours (project management, payroll, benefits, professional development training, administrative costs, auditing, and quality assurance)	• 274 (137× 2) enteral ED visits/year • 41.6% (57/137) virtually manageable • 1 hour on average/consult • 53 hours of emails • 40 hours (payroll, benefits, ongoing professional development training, administrative costs, auditing, and quality assurance)	• FTE = 37.5 hours/week • 1950 hours/year • (274×41.6% [57/137] = 114 × 1 hour consult + 53 hours of emails) = 167 Connected Care Resource Nurse hours/year • 167/1950=0.085

[a]The total time requirement for initial annual operational and ongoing operational requirements was 228 and 208 hours, respectively.

[b]Approximately 0.1 nursing FTEs are required to support the pilot service expansion.

[c]FTE: full-time equivalent.

[d]ED: emergency department.

Technical Feasibility

We identified minimal technical requirements in consultation with the Connected Care leadership team by leveraging existing platforms and job aids (eg, practice toolkits and quality assurance procedures). Discussion with privacy, legal, information security, and risk functional department leads identified the following requirements before piloting the service expansion to families: best practices for end user verification methods, password updates, revised terms of use, user agreements, and legal disclaimers before piloting the service.

Overall Feasibility

Results across the economic, operational, and technical assessments all suggest the pilot service expansion of Connected Care Live to FCs of the enteral feeding tube (ie, G, GJ, NG tubes) population to be a feasible virtual care solution to improve FC experiences, support safer hospital-to-home transitions, and reduce after-hours ED visits. All 3 data sources, ED visits, after-hours inquiries, and semistructured interviews, highlighted the gap in after-hours services available to FCs of CMC-TD after discharge to support medical device prevention and management of complications. However, to successfully launch this pilot with the enteral feeding tube population, we acknowledge the need to ensure that robust practice development and privacy, security, and legal best practices are implemented in advance. Service volumes and timing must also be measured throughout to ensure the current on-call operational model is sustainable and cost-effective for future program operations.

Discussion

Principal Findings

This study suggests that Connected Care Live is feasible to pilot with FCs of children with newly inserted enteral feeding tubes (ie, G, GJ, and NG tubes), given the significant time and travel savings forecasted, widespread benefits identified during interviews, and minor operational and technical program changes required to support this population. Although limited in scale, this study addresses an important gap in the delivery of nurse-led virtual care services that are specifically offered after-hours and to FCs of the enteral feeding tube pediatric population. Other studies have highlighted the value of nurse-led virtual care services and increasing after-hours access to adult patients to reduce low-acuity ED visits, but only a few studies have investigated after-hours support available to FCs of the pediatric complex care population, a group known for being the highest users of pediatric health care resources [21,22].

During our semistructured interviews, FCs described the increased stress they experienced after-hours beyond discharge, the guilt they felt for interrupting hospital operations when calling in-patient clinical staff, and their dependence on visiting the ED to ensure the safety of their children. Similar findings have been noted in other studies exploring the health and well-being of caregivers for CMC-TD, demonstrating a high level of mental health burden among this population, particularly in the first few weeks following medical device insertions [23,24]. Our interview results also suggest that having 24/7 real-time virtual access to trusted providers to support troubleshooting medical device complications would be valuable for improving hospital-to-home transition experiences, reducing FC after-hours stress, and preventing ED visits. This finding was consistent with other studies, where having 24/7 real-time virtual support and access to trusted providers led to reduced ED utilization rates and high levels of caregiver satisfaction [2,25]. FCs expressed that one of the appealing aspects of real-time virtual support through Connected Care Live was its video-calling feature, which provided visual cues for medical device management. This was seen as an advantage over existing email and phone services. Similarly, an Ontarian telehome care study indicated that parents of CMC-TD had a strong preference

for and satisfaction with videoconferencing provider visits to support hospital-to-home transitions [26].

Interview results further highlighted the significant workflow interruptions nurses experienced for nonurgent cases, by either responding to FC after-hours inquiries or ED visits. During an interview with clinicians in the G-Tube Resource Team, they mentioned that they routinely set aside the first hour of every Monday morning, dedicating it to addressing medical device inquiries from families instead of seeing patients in the clinic. This finding suggests that introducing Connected Care Live offers the potential to offset workload and increase capacity to support additional clinic visits during this time. Our interviews with ED nurses demonstrated how frequently parents would arrive at the ED with their children for minor and non–life-threatening enteral feeding tube complications. These visits often required consultation from Connected Care and the G-Tube Resource Team or minimal intervention, which in both cases constrained resources and delayed care of other higher-acuity cases in the ED. This finding was consistent with other studies in which increased waiting times, overcrowding, and reduced quality of care were seen across EDs with a high census of low-acuity patients [27].

In our ED visits analysis, high economic feasibility was established among the enteral feeding tube population, as they accounted for the largest proportion of patients presenting with medical device complications (137/212, 64.6%), with 41.6% (57/137) of these visits assessed as virtually manageable or considered “avoidable.” Of the 137 enteral feeding tube visits, the largest proportion of visits was found among patients with G tubes (50/137, 36.5%) and GJ tubes (52/137, 37.9%), whereas the highest percentages of visits assessed as virtually manageable were found with G tubes (34/50, 68%) and NG tubes (21/30, 70%). These findings are consistent with G tube insertions being one of the most common pediatric surgeries [28] and enteral feeding as one of the most commonly performed procedures by FCs of CMC-TD at home [7]. Given this large volume of potentially virtually manageable visits, we anticipate that more than half of enteral feeding tube complications would not require ED provider intervention and could be successfully troubleshooted at home with video-enabled access to expert support that builds confidence and competence for FCs [4]. This finding was comparable with other studies, which highlight that pediatric patients with newly inserted G tubes typically present to the ED with low-acuity complications that do not require admission and can often be supported in home and community care settings by specialized family education and reassurance [4,5,29].

In this study, the question of which types of ED visits were potentially avoidable and otherwise virtually manageable was explored to prepare an iterative plan for safe and impactful service expansion. G tube complications were identified as highly preventable and virtually manageable at home based on well-established practice standards amenable to virtual care. GJ tubes had a low percentage of visits assessed as suitable for virtual management; however, they accounted for the highest proportion of ED visits related to enteral feeding tube complications. Previous studies have demonstrated similar findings in which GJ tubes accounted for some of the highest proportions of device-related ED encounters requiring hospitalization, with reductions in complications over time with additional supports (eg, complex care program enrollment) [4,30]. NG tubes were identified as highly preventable; however, existing literature demonstrates an increased risk for complications and a lack of confidence in best practices associated with managing complications in home and community care settings compared with G tubes [31]. This finding suggests the need for after-hours support to reduce preventable visits. In addition, with recent professional practice guidelines limiting the requirement for imaging of NG tubes, suitability for virtual care services is anticipated [32].

The operational requirements identified by study participants indicated that minimal program changes would be required to support the service expansion. Based on the consultation volume and timing estimates, the Connected Care program could support the pilot study with existing clinical staff, who would already be familiar with navigating this online platform. However, future specialty training for Connected Care Resource nurses would be required to reinforce education on the management of enteral feeding tubes, while mitigating risks to nursing practice with gaps in knowledge as identified during interviews. Having ongoing professional development training opportunities for nurses is widely recognized to improve the quality of care and patient safety needed to promote best practices among FCs [33]. As highlighted above, across the different enteral feeding tube types, there is the highest feasibility to pilot the service initially with G and GJ tube patients, given the existing support available from the G-Tube Resource Team and the quality of evidence–based resources. This team plays a critical role in the success of this pilot through their support for building content for training workshops in collaboration with Connected Care Resource Nurses, and for providing expertise as needed throughout the pilot Go-Live period.

While many CMC-TD receive home and community care services from regulated care providers to support medical device management, these services are often not delivered around the clock. To ensure the continuing safety and quality of care provided at home, unregulated care providers including FCs play an important role in filling this service gap and building competencies in caring for their child’s home care technologies [34]. In acknowledging these legal implications, during our technical feasibility assessment and semistructured interviews discussing the risks of the proposed service, we identified the need to update language around accountability for care in the Connected Care Live Terms of Use to better reflect both regulated (home and community care providers) and unregulated care providers (FCs). For example, when outlining the purpose of the service intended to aid and support users, both health care providers and FCs were separately addressed to highlight that information shared through the service is not a substitute for neither professional judgment nor services delivered by health professionals within a patient’s circle of care [35].

Overall, the study findings demonstrated a significant gap in after-hours resources available to FCs of CMC-TD beyond discharge. This real-time nurse-led virtual care service offers a valuable approach to improving FC after-hours experiences and reducing avoidable health care encounters. In the future, upon

successful pilot study and evaluation of Connected Care Live with the G and GJ tube population followed by that with the NG tube population, this service holds the potential to be scaled to a much larger group of medical devices and families spanning beyond the Greater Toronto Area.

Strengths and Limitations

The greatest strength of this study was the widespread commitment and interest on behalf of FCs, nurses, and hospital leadership to establish the feasibility of piloting the Connected Care Live service expansion. Although a small sample of FCs and nurses were interviewed, the results signaled the need for additional after-hours support. Some of the study limitations were that time and travel savings data may have been impacted by the COVID-19 pandemic and seasonality with variable ED visit volumes; however, other factors were considered, such as pandemic-related decreases in home care visits further straining FC support at home. In addition, manual data extraction and collection of ED visits and after-hours inquiries data were required to ensure timely access to data. For the after-hours medical devices inquiries, we would also like to acknowledge that the G-Tube Resource Team primarily supports the G and GJ tube population, thus excluding the NG tube population from this portion of this analysis.

In addition, semistructured interviews were focused internally across SickKids stakeholders, and future studies would largely benefit from including external perspectives, such as home and community care providers. While the primary focus for service expansion in this study was FCs, future studies would also benefit from interviewing patients with new medical technologies themselves to better understand the direct impact this type of service has on their hospital-to-home transition and after-hours experiences. Some of the unaccounted time savings for the economic feasibility analysis included the amount of time spent by Connected Care leadership on the feasibility study, pilot project planning and evaluation, and redundant resourcing for safety and practice development during the initial pilot Go-Live period. Other considerations for the time savings calculations are identifying the number of nurses required in the G-Tube Resource Clinic during their first hour of work and the number of patients that can be seen in an hour.

Conclusions

The findings from this study were successful in demonstrating the economic, operational, and technical feasibility before launching the pilot expansion of Connected Care Live initially to FCs of children with newly inserted G and GJ tubes, followed by NG tubes. This nurse-led virtual care consultation service for families serves as a promising tool to promote safe and positive hospital-to-home transition experiences, while reducing after-hours ED visits. In future studies, further investigation will be needed to establish the feasibility of scaling such a service to other medical devices (eg, central lines, tracheostomies) and geographic areas across Ontario.

Acknowledgments

The authors thank the participants of this study (families, nurses, and hospital leadership) including the Connected Care Live for Family Caregivers Advisory Group members. Without added compensation, they were all willing to invest their time in this study to improve the after-hours care experiences and health outcomes for FCs and CMC-TD. The authors also thank Helen Edwards, the former Chief Nursing Informatics Officer at SickKids, and faculty members of the Executive Master of Health Informatics at the University of Toronto for their esteemed mentorship and support throughout this graduate student health informatics study. The Connected Care Live for Family Caregivers Advisory Group members are as follows: Sophia Lawson, SickKids Patient and Family Advisory Network; Francine Buchanan, SickKids Patient and Family Advisory Network; Wayne Lee, SickKids Director of Diagnostic Imaging; Holly Norgrove, SickKids G-Tube Resource Nurse; Silvana Oppedisano, SickKids G-Tube Resource Nurse Practitioner; Amanda Li, SickKids G-Tube Resource Nurse Practitioner; Reenu Chokar, Connected Care Resource Nurse; Melissa Carr, Connected Care Resource Nurse; Danielle Loveland, Connected Care Resource Nurse; Janice Tang, Connected Care Resource Nurse; Adal Bahlibi, Connected Care Program Coordinator; Delaney Ward, SickKids Emergency Department Nurse; and Anjelica Guytingco, SickKids Emergency Department Nurse.

Conflicts of Interest

None declared.

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Abbreviations

CMC-TD: children with medical complexity and technology dependence
ED: emergency department
FC: family caregiver
FTE: full-time equivalent
GJ tube: gastrojejunostomy tube
G tube: gastrostomy tube
NG tube: nasogastric tube
NJ tube: nasojejunal tube
J tube: jejuonostomy tube

Edited by S Badawy; submitted 24.07.22; peer-reviewed by J Quet, M Bird; comments to author 29.12.22; revised version received 11.01.23; accepted 04.03.23; published 08.11.23.

Please cite as:
Babayan K, Keilty K, Esufali J, Grajales III FJ, Connected Care Live for Family Caregivers Advisory Group
An After-Hours Virtual Care Service for Children With Medical Complexity and New Medical Technology: Mixed Methods Feasibility Study
JMIR Pediatr Parent 2023;6:e41393
URL: https://pediatrics.jmir.org/2023/1/e41393
doi:10.2196/41393
PMID:37938869

Original Paper

Evaluation of a Mobile-Based Immunization Decision Support System for Scheduling Age-Appropriate Vaccine Schedules for Children Younger Than 2 Years in Pakistan and Bangladesh: Lessons From a Multisite, Mixed Methods Study

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Abstract

Background: Missed opportunities for vaccination (MOVs), that is, when children interact with the health system but fail to receive age-eligible vaccines, pose a crucial challenge for equitable and universal immunization coverage. Inaccurate interpretations of complex catch-up schedules by health workers contribute to MOVs.

Objective: We assessed the feasibility of a mobile-based immunization decision support system (iDSS) to automatically construct age-appropriate vaccination schedules for children and to prevent MOVs.

Methods: A sequential exploratory mixed methods study was conducted at 6 immunization centers in Pakistan and Bangladesh. An android-based iDSS that is packaged in the form of an application programming interface constructed age-appropriate immunization schedules for eligible children. The diagnostic accuracy of the iDSS was measured by comparing the schedules constructed by the iDSS with the gold standard of evaluation (World Health Organization–recommended Expanded Programme on Immunization schedule constructed by a vaccines expert). Preliminary estimates were collected on the number of MOVs among visiting children (caused by inaccurate vaccination scheduling by vaccinators) that could be reduced through iDSS by comparing the manual schedules constructed by vaccinators with the gold standard. Finally, the vaccinators' understanding, perceived usability, and acceptability of the iDSS were determined through interviews with key informants.

Results: From July 5, 2019, to April 11, 2020, a total of 6241 immunization visits were recorded from 4613 eligible children. Data were collected for 17,961 immunization doses for all antigens. The iDSS correctly scheduled 99.8% (17,932/17,961) of all age-appropriate immunization doses compared with the gold standard. In comparison, vaccinators correctly scheduled 96.8% (17,378/17,961) of all immunization doses. A total of 3.2% (583/17,961) of all due doses (across antigens) were missed in age-eligible children by the vaccinators across both countries. Vaccinators reported positively on the usefulness of iDSS, as well as the understanding and benefits of the technology.

Conclusions: This study demonstrated the feasibility of a mobile-based iDSS to accurately construct age-appropriate vaccination schedules for children aged 0 to 23 months across multicountry and low- and middle-income country settings, and underscores its potential to increase immunization coverage and timeliness by eliminating MOVs.

(JMIR Pediatr Parent 2023;6:e40269) doi:10.2196/40269

KEYWORDS

missed opportunities for vaccination; mobile-based immunization decision support system; catch-up immunizations

Introduction

Background

Routine childhood immunization is the cornerstone of an efficient public health system and childhood disease prevention. Despite progress in improving routine immunization coverage, in 2022, 17% and 7% of children aged 0 to 23 months in Pakistan and Bangladesh, respectively, did not receive the third dose of the diphtheria-tetanus-pertussis vaccine [1]. The problem is further exacerbated for children who do visit health facilities in low- and middle-income countries (LMICs), but the immunization system fails to provide all age-appropriate vaccines to one in every 3 of these children [2]. This creates missed opportunities for vaccination (MOVs), where despite being eligible for vaccination, a child is not administered one or more of the vaccine doses [3]. MOVs remain a rampant problem in many LMICs [4,5], leading to underimmunization and delayed vaccination of children.

A systematic review of MOVs across LMICs showed a pooled MOV prevalence of 32.2% (95% CI 26.8%-37.7%) among children and 46.9% (95% CI 29.7%-64.0%) among women of childbearing age [2]. MOV prevalence estimates are even higher for some countries, ranging from 42% to 89% [6,7]. A study from Pakistan reported that despite being eligible for the pentavalent vaccine (Penta) at the measles vaccine visit, 34% of children did not receive the required dose of Penta even though they visited the immunization clinic and were vaccinated for measles [8]. Lack of awareness among parents and providers is one of the primary causes of MOVs, with vaccinator confusion about contraindications and the immunization schedule being the main factors [2,9]. In the absence of frequent refresher training, improper health care worker practices lead to repeated MOVs in LMICs and high-income countries [10,11]. However, regardless of the amount of training, scheduling age-appropriate vaccinations, especially catch-up schedules (when the child has missed or delayed one or more vaccines), is a complex task [12,13]. A study from Illinois showed that 33% of all health workers constructed incorrect hypothetical catch-up schedules in a survey designed to determine health workers' knowledge of catch-up immunizations [10]. In LMICs, where vaccinators are more likely to be overburdened and pressed for time [14], the likelihood of making errors in scheduling is even higher.

Decision support systems have proven to be powerful tools for improving clinical care and patient outcomes across various domains [15,16]. They have contributed to improving evidence-based medical practices, reducing medical errors, and improving adherence to standard care practices [17,18]. At the basic level, an immunization decision support system (iDSS) provides patient-specific vaccination recommendations at each immunization visit, considering the child's date of birth and vaccination history and ensuring the appropriate scheduling of feasible doses.

Currently, examples of iDSS deployment are limited and almost exclusively constitute complex systems from high-income country settings. For example, in the United States, clinical decision support systems based on national standard guidelines for immunization are embedded in regional immunization information systems [19] or web-based immunization forecasting services accessible by various electronic health records [20]. There is a dearth of literature on contextually appropriate, efficient, and practical mobile-based iDSS that is easily implementable within LMICs.

Objective

We aimed to analyze the diagnostic accuracy of an innovative mobile-based iDSS in an LMIC setting to construct age-appropriate vaccination schedules for children aged 0 to 23 months and compared with the gold standard of evaluation (World Health Organization [WHO]–recommended Expanded Programme on Immunization [EPI] schedule constructed by a vaccines expert). We also aimed to generate preliminary evidence for MOVs among visiting children (caused by inaccurate vaccination scheduling by vaccinators) that could be reduced through iDSS by comparing the manual schedules constructed by vaccinators with the gold standard. Finally, we reported the findings on the vaccinators' understanding, perceived usability, and acceptability of the iDSS.

Methods

Study Design

We implemented a sequential exploratory mixed methods study design with a quantitative component preceding the qualitative interviews. In the quantitative component, the children's demographic details and immunization history were recorded by trained study staff using iDSS. The iDSS used this information to formulate an age-appropriate immunization schedule for the children, and it was recorded on the back end and was not visible to the study staff (or vaccinators). Simultaneously, the study staff also captured the manually constructed immunization schedules determined by the vaccinators as indicated on the child's government-issued immunization cards. Through this process, we were able to capture both the iDSS and vaccinator schedules simultaneously for the same child (antigen doses). We used this information to assess the diagnostic accuracy of the iDSS algorithm by comparing the age-appropriate immunization schedules constructed by the iDSS for children aged 0 to 23 months with the gold standard of evaluation (WHO-recommended EPI schedule constructed by a vaccine expert). We also independently compared the vaccine schedules constructed manually by the vaccinators for the same children with the gold standard. This allowed us to generate preliminary evidence of MOVs resulting from inaccurate vaccination schedules constructed by vaccinators. This phase was followed by a qualitative phase in which the vaccinators were provided with iDSS-enabled study phones. After vaccinators had a chance to use the iDSS, we conducted in-depth interviews with vaccinators at the participating immunization centers regarding their

experience of using the iDSS, its perceived utility, and acceptability.

Study Sites

We conducted a multicountry study at 6 immunization centers, 3 each in Pakistan and Bangladesh. Both countries vary in terms of full immunization coverage rate (Pakistan 66%; Bangladesh 84%) and infant mortality rates (81/1000 live births in Pakistan; 43/1000 live births in Bangladesh) [21,22]. Immunization centers were selected based on the influx of children, availability of vaccines and vaccinators, and absence of any kind of decision support system at these sites. The selected study sites had high penetration of mobile phones (>90%) and the presence of cellular networks (data connectivity) among the population [23,24].

Two of the selected immunization centers in Pakistan were located in Gilgit district in Gilgit Baltistan territory, which had a full immunization coverage rate of 57% among children aged 12 to 23 months in 2018 [21]. The third selected immunization center in Pakistan was a private center located in the Rahim Yar Khan district in Punjab province, with a full immunization coverage rate of 65% in 2019 [23].

In Bangladesh, all 3 immunization centers were located in Dhaka city in Dhaka district. The district had a full immunization coverage rate of 85% among children aged 12 to 23 months as of 2019 [25].

Study Population

The inclusion criteria for the study were as follows: children must be aged <2 years, visiting any of the 6 selected immunization centers for routine vaccination, and presenting with an immunization card. Exclusion criteria were as follows: children visiting for immunization campaigns and those who did not receive vaccination during their visit. We obtained verbal consent from the caregivers of the eligible children before enrollment.

For the qualitative component, our study population included all vaccinators from the participating immunization centers who used iDSS app during the study. We obtained written consent from the study participants before the interviews.

Ethics Approval

Ethics approval for the study was obtained from the Institutional Review Boards of the Interactive Research and Development (Pakistan; IRD_IRB_2019_01_010) and Building Resources Across Communities James P. Grant School of Public Health (Bangladesh).

Vaccination Schedule

Pakistan's routine EPI schedule in 2019 included BCG (bacille Calmette-Guérin) vaccine and oral polio vaccine (OPV) at birth; 3 doses of Penta (containing diphtheria-tetanus-pertussis, hepatitis B, *Haemophilus influenzae* type b vaccine), pneumococcal vaccine (PCV10), and OPV at 6, 10, and 14 weeks; 2 doses of rotavirus vaccine (Rota) at 6 and 10 weeks; a single dose of inactivated polio vaccine (IPV) at 14 weeks; and 2 doses of measles vaccine at 9 and 15 months.

For Bangladesh, the EPI schedule included BCG vaccine at birth; Penta, PCV, and OPV at 6, 10, and 14 weeks; IPV at 6 and 14 weeks; and measles-rubella (MR) vaccine at 9 and 15 months.

Development of the iDSS

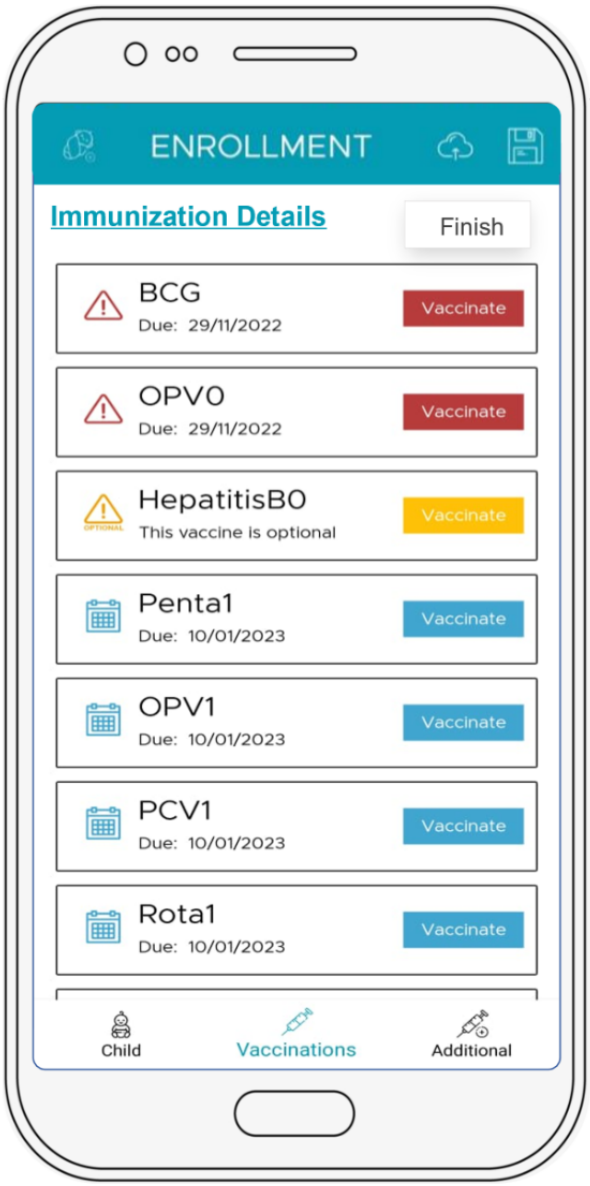
We developed an android-based iDSS designed for mobile-based deployment, packaged in the form of an application programming interface (API) to function both as a stand-alone module and interoperable with other digital applications or platforms, such as web-based or mobile-based electronic immunization registries (EIRs).

The iDSS was formulated as a 2-step process comprising a data entry form and display interface showing the proposed vaccination schedule. In the first step, the details of the child, including the date of birth and immunization history, are entered in the data entry form of the iDSS. The algorithm uses this information to construct an age-appropriate immunization schedule (including the vaccines due at the current visit and those to be scheduled) tailored to the child and the respective country's EPI schedule.

iDSS automatically reformulates the child's immunization schedule after every visit, adjusting for missed appointments and delayed vaccinations and considering the birth date, previous vaccines, standard interval based on live or inactivated vaccines and interdosing schedule, without the need for any manual calculation by the vaccinators. Changes in the EPI schedule and new vaccines are also incorporated into the iDSS algorithm. The results (current and scheduled vaccines) are instantly displayed on the iDSS interface through a color-coded system that allows for straightforward interpretation, especially by low literacy and overburdened vaccinators (Figure 1). The iDSS proposes the dates for scheduled vaccines (accounting for public holidays and vaccine-specific days at centers) and prompts the vaccinator through warning messages if vaccines are being administered out of schedule to ensure that interdose gap guidelines are followed.

In addition, the iDSS algorithm can be customized to the needs of the country, according to the respective EPI schedule. The iDSS is also multilingual and is developed as open-source software for easy integration and interoperability across a variety of settings and systems. As part of the iDSS development, the module was pretested in-house for quality assurance and with randomly selected vaccinators (outside the study site) for limited field deployment. A detailed overview of the iDSS is provided in Multimedia Appendix 1.

Figure 1. A screenshot showcasing features of the immunization decision support system app. BCG: bacille Calmette-Guérin; HepB: Hepatitis B; OPV: oral polio vaccine; PCV; pneumococcal vaccine; Penta: pentavalent vaccine; Rota: rotavirus vaccine.



Study Procedures and Data Collection

We enrolled eligible children whose accompanying caregivers provided verbal consent for participation. At enrollment, a unique study identifier was allocated to each child, and each follow-up visit by the child to the participating immunization center was recorded as a unique visit. Trained study staff used the iDSS installed on study mobile phones to record the demographics and immunization history of the enrolled children to enable iDSS to schedule their current and future vaccination visits. This information was recorded at the back end of the iDSS, and both the study staff and vaccinators were blinded to it. Simultaneously, the study staff also recorded the vaccination schedules determined by the vaccinators as per routine, which were obtained from the child's immunization cards. Vaccinators did not use the iDSS during the quantitative phase of the study. The iDSS app was linked to a web-based dashboard that allowed the real-time downloading of data for further analysis.

For the qualitative component of the study, we interviewed 16 vaccinators (11 from Pakistan and 5 from Bangladesh) after obtaining written consent. These vaccinators were provided with mobile phones with iDSS that they could use to schedule current and future vaccinations. Before using the iDSS, vaccinators were given a 2-day training by the study staff on using the iDSS module as part of their daily immunization activities. At the end of the period when the vaccinators had used the iDSS for at least 4 weeks, the study team interviewed the vaccinators. In-person interviews were conducted by Project Managers at both sites, who were qualified public health researchers with a medical background. The interviews were facilitated by Research Associates, who helped to take notes. We used a 16-item semistructured interview guide covering user experience, acceptability, and feasibility of the iDSS feature, and suggestions for improvement. Demographic indicators, including age, education, gender, and years of experience, were also collected from the participants. Each interview lasted between 25 and 40 minutes and was audio-recorded and transcribed for further analysis.

Study Outcomes

Our primary study outcome was the diagnostic accuracy of the iDSS in constructing age-appropriate vaccination schedules as per the WHO-recommended EPI guidelines. In addition, we examined the vaccinators' perceived usability and acceptability of the iDSS. A secondary outcome included preliminary estimates of the number of MOVs among children aged 0 to 23 months visiting study immunization centers for routine immunization visits.

Data Security

The phones used for data collection by the field staff and vaccinators had password locks with an additional level of protection through software sign-in passwords. Data collected through iDSS were uploaded to a secure database server. All the data sent from the phones to the server and back were encrypted in transit using the PBKDF2 algorithm (an industry standard). Access to data on the server was through a password-protected web dashboard interface, and only those involved with the project had access to the data for research purposes.

Statistical Analysis

Quantitative Analysis

For descriptive analysis, we used frequencies and percentages for categorical data and means and SDs for continuous data. We compared the age-appropriate immunization doses scheduled by the iDSS and vaccinator with the gold standard. The latter helped determine the evidence for MOVs caused by inaccurate vaccination schedules constructed by vaccinators. To determine the gold standard vaccination schedule, an expert epidemiologist and practicing pediatrician reviewed the immunization history and date of birth or age of the child to determine the age-appropriate immunization doses due at each visit as per the WHO-recommended EPI schedule for the respective country. Summary statistics for the diagnostic tests were calculated using the *diagt* command package. Forest plots for sensitivity and specificity were generated using the *metan* command. The accuracy of the iDSS was determined along with the area under the receiver operating characteristic curves and their range. Analyses were performed using STATA software (version 17.0; StataCorp LLC).

Qualitative Analysis

The recordings of the qualitative data collected through the in-depth interviews were first transcribed and then translated into English. Transcriptions were coded by 2 researchers separately, who were public health practitioners, trained and experienced in performing qualitative analysis. The researchers extensively discussed and scrutinized the results to ensure the trustworthiness and comprehensiveness of the analysis. The final coding was shared with a third researcher to resolve any inconsistencies in the codes. Using a thematic analysis approach, the codes were sorted into categories to converge toward key overarching themes. Data were analyzed using NVivo qualitative data analysis software (version 12, 2018; QSR International).

Results

Quantitative Analysis

From July 5, 2019, to April 11, 2020, a total of 6241 immunization visits were recorded from 4613 eligible children. A total of 73% (4557/6241) of visits were recorded from 3 immunization centers in Pakistan, and 27% (1684/6241) of visits were recorded from 3 immunization centers in Bangladesh (Figure 2).

The proportion of male children (2435/4613, 52.8%) enrolled in the study was slightly higher than that of female children (2178/4613, 47.2%) across both the sites (Pakistan: 1720/3197, 53.8%) and Bangladesh (715/1416, 50.5%; Table 1). Most (3348/4613, 72.6%) children enrolled in the study were aged ≤6 months at the time of enrollment, both in Pakistan (2423/3197, 75.8%) and Bangladesh (925/1416, 65.3%).

Table 2 shows the age-appropriate immunization doses scheduled by both the iDSS and vaccinators compared with the gold standard. In Pakistan, we collected data on 13,039 immunization doses for all antigens. The iDSS correctly scheduled 99.8% (13,015/13,039) of all age-appropriate immunization doses that should have been administered at the current visit compared with the gold standard, ranging from 99.2% to 100% for BCG vaccine, OPV-0 to 3, Penta-1 to 3, PCV-1 to 3, Rota-1 to 2, measles vaccine 1, and IPV vaccine doses. Of all the antigens, the proportion of correctly scheduled doses by iDSS was the lowest at 96.7% (202/209) for the measles-2 vaccine. In comparison, the vaccinator correctly scheduled 96.2% (12,545/13,039) of all the immunization doses that should have been administered on the current visit compared with the gold standard, ranging from 97% to 100% for BCG vaccine, OPV-0 to 3, Penta-1 to 3, PCV-1 to 3, Rota-1 to 2, and measles-2. However, the proportion of correctly scheduled doses by vaccinators due on the current visit decreased to 94.5% (362/383) and 66.3% (653/985) for measles-1 and IPV vaccine doses, respectively. Owing to errors in the vaccination schedules constructed by vaccinators, 3.8% (494/13,039) of all due immunization doses were missed by the vaccinators. Among the age-eligible children, the highest proportion of MOVs was for the polio and measles vaccines, where 33.7% (332/985) and 5.5% (21/383) of all due immunization doses, respectively, were missed by vaccinators.

In Bangladesh, we recorded data on 4922 immunization doses. The iDSS correctly scheduled 99.9% (4917/4922) of the age-appropriate immunization doses that should have been administered on the current visit compared with the gold standard, with the lowest proportion of correctly scheduled doses for the measles-2 vaccine (196/201, 97.5%). In comparison, the vaccinator correctly scheduled 98.2% (4833/4922) of all immunization doses that should have been administered on the current visit, ranging from 97.5% to 100% for BCG vaccine, OPV-1 to 3, Penta-1 to 3, PCV-1 to 3, IPV-1, and measles-rubella-2, but dropped to 95.1% (137/144) for measles-rubella-1 and 87.4% (355/406) for IPV-2 vaccine doses. Owing to errors in the vaccination schedules constructed by vaccinators, 1.8% (89/4922) of all due immunization doses were missed by the vaccinators. Similar to the findings in Pakistan,

the highest proportion of MOVs was for polio and measles-1 vaccines, where 12.6% (51/406) and 4.9% (7/144) of all due immunization doses, respectively, were missed by vaccinators.

Compared with the gold standard, in Pakistan, the accuracy of the iDSS varied between 94.5% and 100% across vaccines versus 88.5% to 99.4% for the immunization doses scheduled by the vaccinator. The iDSS demonstrated a sensitivity of 97.1% to 100%, whereas the sensitivity of the vaccinator's scheduling was between 66.3% and 100%. The estimated specificity for iDSS compared with the gold standard was 92.6% to 100%, whereas the specificity for vaccinator scheduling was 84.1% to 100%. The results were similar for the Bangladesh site, with iDSS demonstrating a higher accuracy (97.9%-100%) and a higher sensitivity of 100% compared with the gold standard, whereas estimates of accuracy and sensitivity for vaccinator scheduling were 89.4% to 99.8% and 87.4% to 100%, respectively. The iDSS had a specificity of 97.6% to 100% compared with the gold standard, whereas the specificity for the vaccinator's scheduling was 83.2% to 100% (Figures 3 and 4).

Across both the sites, receiver operating curve analysis showed that the iDSS had high overall accuracy of scheduling age-appropriate immunization doses (area under the curve ranging from 99%-100% across antigens), whereas for vaccinator schedules, estimates for area under the curve ranged between 88% and 100%.

On the basis of the findings of the diagnostic accuracy of the iDSS in which the sensitivity and specificity were <100% for selected antigens, we updated the iDSS algorithm by fixing the errors related to the vaccine intervals and recommended age for administering the vaccines based on the WHO guidelines.

Figure 2. Study participant flow for all enrolled children and subsequent immunization visits from July 5, 2019, to April 11, 2020, in Pakistan and Bangladesh.

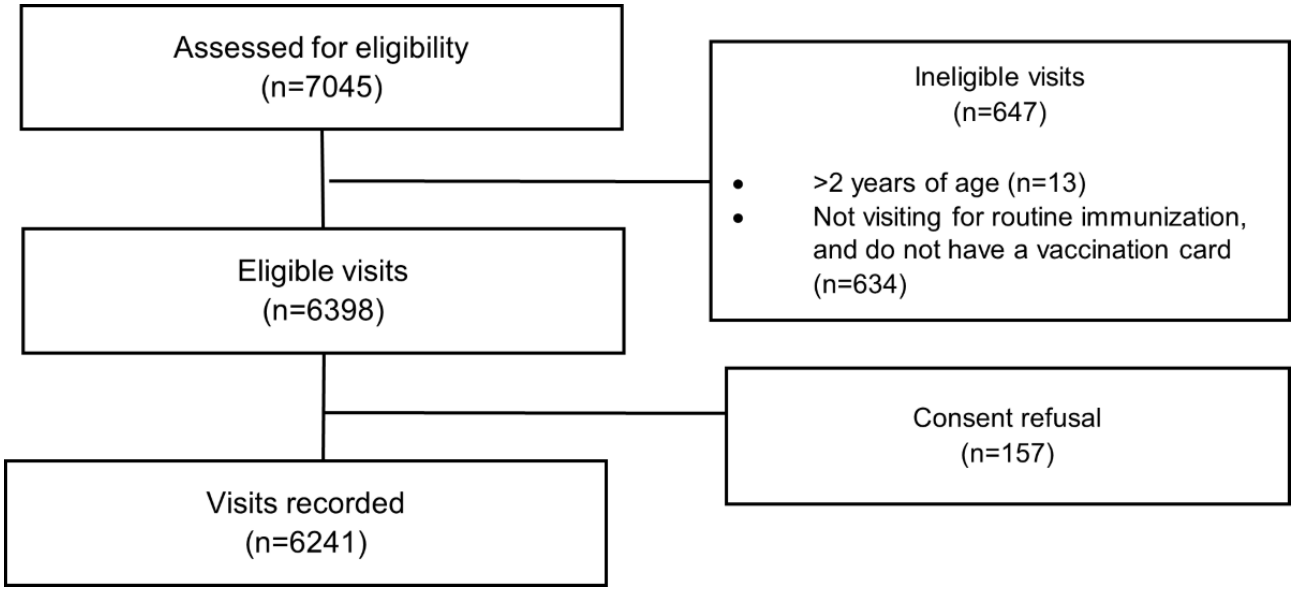


Table 1. Characteristics of study participants enrolled in Pakistan and Bangladesh sites[a].

Characteristics	Participants in Pakistan (n=3197)	Participants in Bangladesh (n=1416)	Total (N=4613)
Female, n (%)	1477 (46.2)	701 (49.5)	2178 (47.2)
Enrollment age (months), n (%)			
≤6	2423 (75.8)	925 (65.3)	3348 (72.6)
6 to ≤12	462 (14.5)	235 (16.6)	697 (15.1)
12 to ≤18	284 (8.9)	242 (17.1)	526 (11.4)
18 to ≤24	28 (0.9)	14 (1)	42 (0.9)
Father's age (years), mean (SD)	32.7 (6.6)	33.3 (5.6)	32.9 (6.3)
Father's education (years), n (%)			
0	571 (17.9)	19 (1.3)	590 (12.8)
1-5	180 (5.6)	169 (11.9)	349 (7.6)
6-10	1018 (31.8)	289 (20.4)	1307 (28.3)
11-12	486 (15.2)	249 (17.6)	735 (15.9)
>13	942 (29.5)	690 (48.7)	1632 (35.4)
Father's occupation, n (%)			
Government employee	1048 (32.8)	162 (11.4)	1210 (26.2)
Self-employed	821 (25.7)	518 (36.6)	1339 (29)
Daily wage earner	678 (21.2)	40 (2.8)	718 (15.6)
Private employee	337 (10.5)	689 (48.7)	1026 (22.2)
Others	313 (9.8)	7 (0.5)	320 (6.9)
Mother's age (years), mean (SD)	26.3 (5.0)	26.4 (4.8)	26.3 (4.9)
Mother's education (years), n (%)			
0	820 (25.6)	5 (0.4)	825 (17.9)
1-5	177 (5.5)	176 (12.4)	353 (7.7)
6-10	1024 (32)	373 (26.3)	1397 (30.3)
11-12	473 (14.8)	395 (27.9)	868 (18.8)
>13	703 (22)	467 (33)	1170 (25.4)
Mother's occupation, n (%)			
Home maker	2806 (87.8)	1151 (81.3)	3957 (85.8)
Private employee	118 (3.7)	128 (9)	246 (5.3)
Government employee	115 (3.6)	97 (6.9)	212 (4.6)
Other	158 (4.9)	40 (2.8)	198 (4.3)
Ethnicity, n (%)			
Gilgiti	2700 (84.5)	N/A[b]	2.700 (58.5)
Saraiki	173 (5.4)	N/A	173 (3.8)
Balochi	94 (2.9)	N/A	94 (2)
Bangal	N/A	1413 (99.8)	1413 (30.6)
Other	230 (7.2)	3 (0.2)	233 (5.1)
Household income (US $ per month), mean (SD)	267.3 (620.3)	442.8 (453.9)	321.1 (580)
Enrollment vaccine, n (%)			
BCG[c]	1125 (35.2)	367 (25.9)	1492 (32.3)
OPV-0[d,e]	4 (0.1)	N/A	4 (0.1)

Characteristics	Participants in Pakistan (n=3197)	Participants in Bangladesh (n=1416)	Total (N=4613)
Penta-1[f,g]	484 (15.1)	107 (7.6)	591 (12.8)
Penta-2[h]	480 (15)	228 (16.1)	708 (15.3)
Penta-3[i]	381 (11.9)	247 (17.4)	628 (13.6)
IPV[j]	1 (0)	N/A	1 (0)
Measles-1	428 (13.4)	226 (16)	654 (14.2)
Measles-2	294 (9.2)	241 (17)	535 (11.6)
Age at enrollment vaccine (weeks), mean (SD)			
BCG	2.1 (3.2)	6.7 (2.9)	3.2 (3.7)
OPV-0	0.2 (0.2)	N/A	0.2 (0.2)
Penta-1[g]	9.0 (4.4)	8.2 (7.6)	8.8 (5.2)
Penta-2[h]	15.2 (5.8)	12.6 (4.1)	14.4 (5.5)
Penta-3[i]	21.3 (7.0)	18.8 (8.5)	20.4 (7.7)
IPV	35.1 (0.0)	N/A	35.1 (0.0)
Measles-1	42.0 (7.4)	41.2 (5.6)	41.7 (6.8)
Measles-2	68.1 (6.6)	67.6 (5.2)	67.9 (6.0)

[a]Number of children enrolled in the study. A total of 4557 immunization visits were recorded from the Pakistan site and 1684 visits were recorded from the Bangladesh site.

[b]N/A: not applicable.

[c]BCG: bacille Calmette-Guérin.

[d]OPV: oral polio vaccine.

[e]Schedule for polio vaccine is different at both sites. Pakistan: OPV0-3 doses at birth, 6, 10, and 14 weeks and single IPV dose at 14 weeks; Bangladesh: OPV1-3 doses at 6, 10, and 14 weeks and 2 IPV doses at 6 and 14 weeks.

[f]Penta: pentavalent vaccine.

[g]Administered with PCV-1 and OPV-1 and Rota-1 and IPV-1 vaccines.

[h]Administered with PCV-2 and OPV-2 and Rota-2 vaccine.

[i]Administered with PCV-3 and OPV-3 and IPV-2 vaccine.

[j]IPV: inactivated polio vaccine.

Table 2. Antigen-wise doses scheduled by the gold standard (World Health Organization [WHO]–recommended Expanded Programme on Immunization [EPI] schedule)[a], immunization decision support system (iDSS), and vaccinator for Pakistan and Bangladesh sites.

Vaccines	Pakistan (n=13,036)					Bangladesh (n=4920)					Total (n=17,956)[b]				
	Due as per gold standard, n	Due as per iDSS, n (%)		Vaccinated by vaccinator, n (%)		Due as per gold standard, n	Due as per iDSS, n (%)		Vaccinated by vaccinator, n (%)		Due as per gold standard, n	Due as per iDSS, n (%)		Vaccinated by vaccinator, n (%)	
	Yes	Yes	No	Yes	No	Yes	Yes	No	Yes	No	Yes	Yes	No	Yes	No
BCG[c]	1505	1505 (100)	N/A[d]	1477 (98.1)	28 (1.9)	372	372 (100)	N/A	369 (99.2)	3 (0.8)	1877	1877 (100)	N/A	1846 (98.3)	31 (1.7)
OPV-0[e]	1212	1212 (100)	N/A	1210 (99.8)	2 (0.2)	N/A	N/A	N/A	N/A	N/A	1212	1212 (100)	N/A	1210 (99.8)	2 (0.2)
Penta-1[f]	924	923 (99.8)	1 (0.2)	898 (97.2)	26 (2.8)	425	425 (100)	N/A	419 (98.6)	6 (1.4)	1349	1348 (99.9)	1 (0.1)	1317 (97.6)	32 (2.4)
OPV-1	924	923 (99.8)	1 (0.2)	896 (97)	28 (3)	424	424 (100)	N/A	420 (99.1)	4 (0.9)	1348	1347 (99.9)	1 (0.1)	1316 (97.6)	32 (2.4)
PCV-1[g]	924	923 (99.8)	1 (0.2)	898 (97.2)	26 (2.8)	423	423 (100)	N/A	419 (99.1)	4 (0.9)	1347	1346 (99.9)	1 (0.1)	1317 (97.8)	30 (2.2)
Rota-1[h]	924	923 (99.8)	1 (0.2)	898 (97.2)	26 (2.8)	N/A	N/A	N/A	N/A	N/A	924	923 (99.9)	1 (0.1)	898 (97.2)	26 (2.8)
IPV-1[i]	N/A	N/A	N/A	N/A	N/A	425	425 (100)	N/A	420 (98.8)	5 (1.2)	425	425 (100)	N/A	420 (98.8)	5 (1.2)
Penta-2	786	785 (99.8)	1 (0.2)	786 (100)	N/A	347	347 (100)	N/A	347 (100)	N/A	1133	1132 (99.9)	1 (0.1)	1133 (100)	N/A
OPV-2	785	784 (99.8)	1 (0.2)	785 (100)	N/A	347	347 (100)	N/A	347 (100)	N/A	1132	1131 (99.9)	1 (0.1)	1132 (100)	N/A
PCV-2	785	784 (99.8)	1 (0.2)	785 (100)	N/A	346	346 (100)	N/A	346 (100)	N/A	1131	1130 (99.9)	1 (0.1)	1131 (100)	N/A
Rota-2	784	783 (99.8)	1 (0.2)	784 (100)	N/A	N/A	N/A	N/A	N/A	N/A	784	783 (99.9)	1 (0.1)	784 (100)	N/A
Penta-3	635	634 (99.8)	1 (0.2)	635 (100)	N/A	354	354 (100)	N/A	352 (99.4)	2 (0.6)	989	988 (99.9)	1 (0.1)	987 (99.8)	2 (0.2)
OPV-3	637	636 (99.8)	1 (0.2)	635 (99.7)	2 (0.3)	354	354 (100)	N/A	353 (99.7)	1 (0.3)	991	990 (99.9)	1 (0.1)	988 (99.7)	3 (0.3)
PCV-3	637	636 (99.8)	1 (0.2)	635 (99.7)	2 (0.3)	354	354 (100)	N/A	353 (99.7)	1 (0.3)	991	990 (99.9)	1 (0.1)	988 (99.7)	3 (0.3)
IPV-2	985	982 (99.7)	3 (0.3)	653 (66.3)	332 (33.7)	406	406 (100)	N/A	355 (87.4)	51 (12.6)	1391	1388 (99.8)	3 (0.2)	1008 (72.5)	383 (27.5)
M-1[j,k]	383	380 (99.2)	3 (0.8)	362 (94.5)	21 (5.5)	144	144 (100)	N/A	137 (95.1)	7 (4.9)	527	524 (99.4)	3 (0.6)	499 (94.7)	28 (5.3)
M-2[k]	209	202 (96.7)	7 (3.3)	208 (99.5)	1 (0.5)	201	196 (97.5)	5 (2.4)	196 (97.5)	5 (2.5)	410	398 (97.1)	12 (2.9)	404 (98.5)	6 (1.5)
Total	13039	13015 (99.8)	24 (0.2)	12545 (96.2)	494 (3.8)	4922	4917 (99.9)	5 (0.1)	4833 (98.2)	89 (1.8)	17961	17932 (99.8)	29 (0.2)	17378 (96.8)	583 (3.2)

[a]WHO-recommended EPI schedule constructed by a vaccine expert, using the following criteria: BCG at ≤1-year age; OPV-0 at ≤28 days; Penta-1, OPV-1, PCV-1, Rota-1, and IPV-1 at ≥6 weeks; Penta-2, OPV-2, PCV-2, and Rota-2 at ≥10 weeks and >28 days after vaccination with Penta-1, PCV-1, OPV-1, and Rota-1; Penta-3, OPV-3, and PCV-3 at ≥4 weeks age and >28 days after vaccination with Penta-2, PCV-2, and OPV-2; IPV-2 at ≥14 weeks age (for Bangladesh, >28 days after IPV-1); measles-1 at 9 months; measles-2 at 15 months and >28 days after measles-1 vaccine (source: WHO-2020, Expanded Program on Immunization, Pakistan; WHO-2019, Fact sheet Bangladesh).

[b]n is the number of doses due for each antigen for the 6241 immunization visits recorded for 4613 children from both Pakistan and Bangladesh sites.

[c]BCG: bacille Calmette-Guérin.

[d]N/A: not applicable.

[e]OPV: oral polio vaccine.

[f]Penta: pentavalent vaccine.

[g]PCV: pneumococcal vaccine.

[h]Rota: rotavirus vaccine.

[i]IPV: inactivated polio vaccine.

[j]M: measles vaccine.

[k]In Bangladesh, measles-rubella combined vaccine is administered.

Figure 3. Diagnostic accuracy of vaccine schedules constructed by the immunization decision support system compared with the gold standard presented as a forest plot. BCG: bacille Calmette-Guérin; CI: Confidence Interval; FN: false negative; FP: false positive; LCL: lower confidence level; OPV: oral polio vaccine; PCV: pneumococcal vaccine; Penta: pentavalent vaccine; ROC: receiver operating curve; Rota: rotavirus vaccine; TP: true positive; TN: true negative; UCL: upper confidence level.

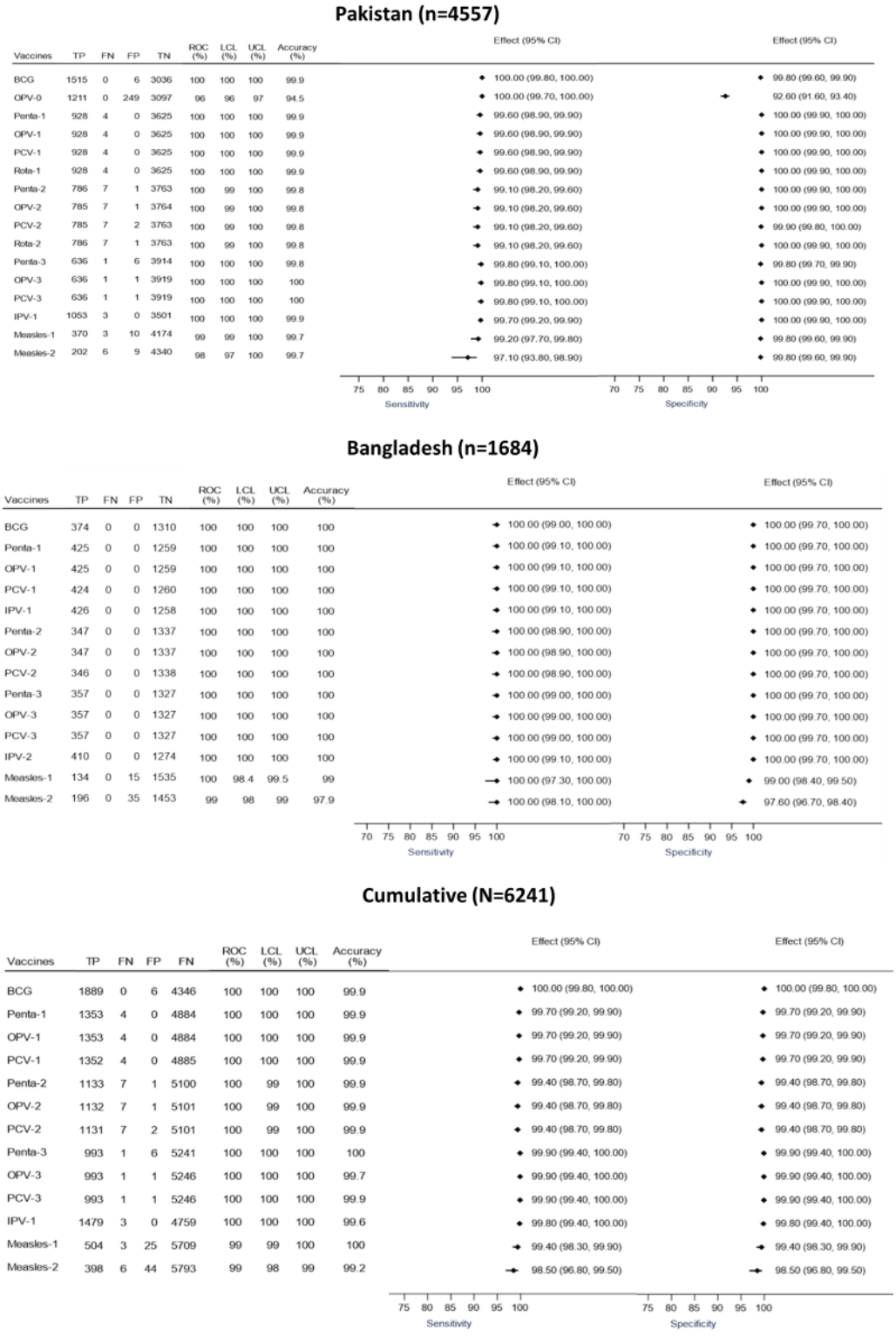
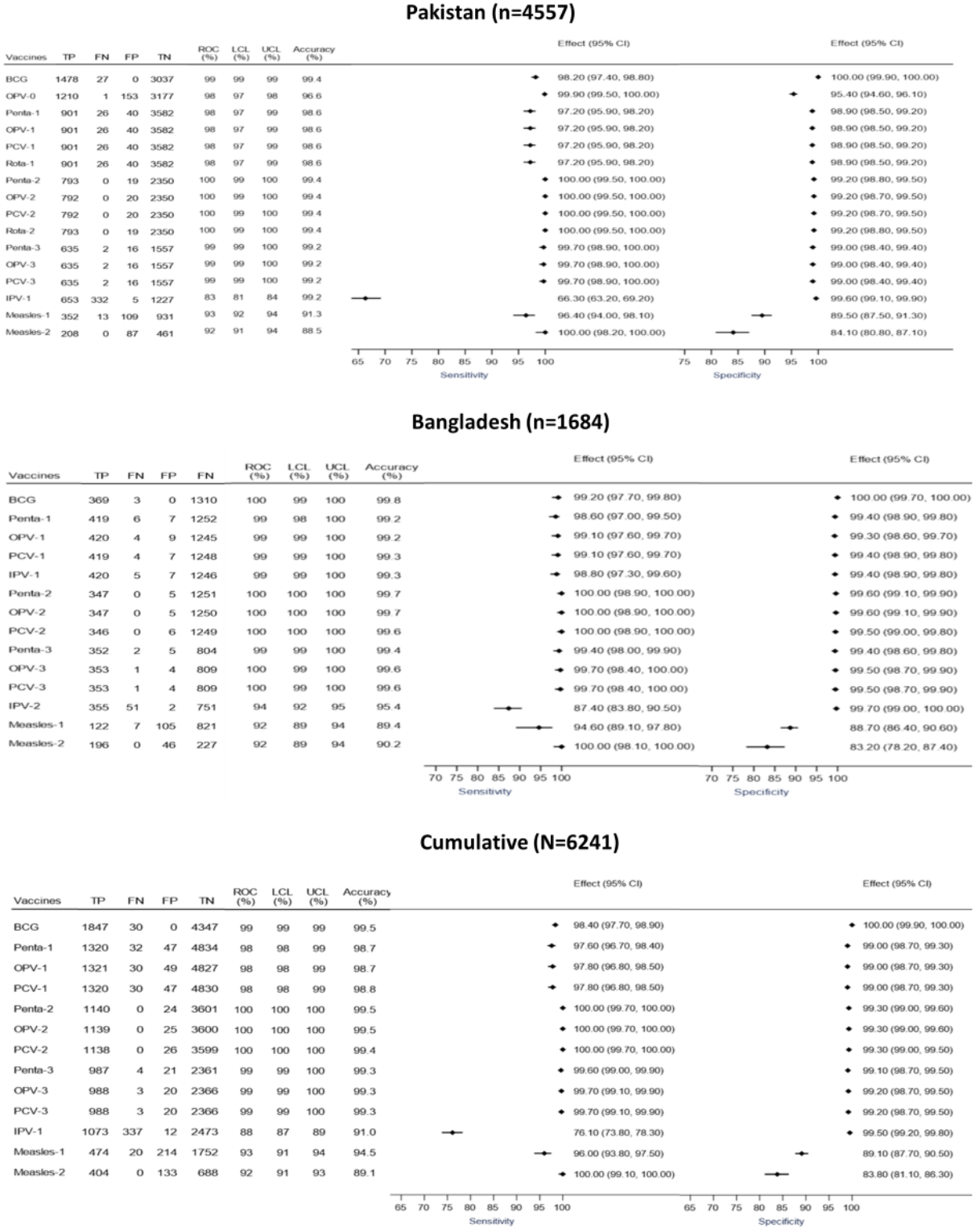


Figure 4. Diagnostic accuracy of manual vaccine schedules constructed by vaccinators compared with the gold standard presented as a forest plot. BCG: bacille Calmette-Guérin; CI: Confidence Interval; FN: false negative; FP: false positive; LCL: lower confidence level; OPV: oral polio vaccine; PCV: pneumococcal vaccine; Penta: pentavalent vaccine; ROC: receiver operating curve; Rota: rotavirus vaccine; TP: true positive; TN: true negative; UCL: upper confidence level.



Qualitative Analysis

Participant Characteristics

A total of 16 vaccinators participated in the key informant interviews (Table 3). In Pakistan, 1 (9%) vaccinator out of 11 was female, whereas in Bangladesh, the proportion of female vaccinators was 80% (4/5). On average, the participants had been working as vaccinators for 7.6 (SD 8.4) years, and the mean age was 32 (SD 9.3) years. In Pakistan, nearly half (6/11, 54%) of all the vaccinators interviewed had >12 years of education, whereas in Bangladesh, this proportion was 100% (5/5).

We extracted 3 major themes through thematic analysis of in-depth interviews conducted with the vaccinators.

Table 3. Characteristics of vaccinators interviewed in Pakistan and Bangladesh.

Characteristics	Participants		
	Pakistan (n=11)	Bangladesh (n=5)	Total (N=16)
Female, n (%)	1 (9.1)	4 (80)	5 (31.3)
Years of education, n (%)			
≤12	5 (45.5)	N/A[a]	5 (31.3)
>12	6 (54.5)	5 (100)	11 (68.8)
Age (years), mean (SD)	32.0 (9.0)	32.2 (11.1)	32.0 (9.3)
Years of experience, mean (SD)	8.1 (9.8)	6.6 (4.7)	7.6 (8.4)

[a]N/A: not applicable.

Theme 1: Understanding of iDSS

All (16/16, 100%) vaccinators appreciated the iDSS module for calculating the age-appropriate vaccine schedules for each visit. They relayed good knowledge of iDSS functionality and 69% (11/16) believed that they could effortlessly explain the app features to their fellow colleagues. Furthermore, most (13/16, 81%) vaccinators were aware of the color scheme and were able to interpret it correctly:

> *The color codes give us indications; vaccines that are supposed to be administered on current visit have different color codes, and already vaccinated have a different color code.* [Vaccinator 3]

On assessing the knowledge about key variables on which the iDSS algorithm functions, very few vaccinators (6/16, 37%) were aware that the iDSS predicted future dates using the variables of date of birth, age, and immunization history.

Theme 2: Functionality of iDSS

Automatic Construction of Age-Appropriate Vaccine Schedules

All the vaccinators (16/16, 100%) appreciated the instantaneous calculation of age-appropriate schedules using the iDSS. They noted and were able to explain the significance of dates that appeared against each vaccine that was due on the current visit, given previously, or needed to be scheduled for an upcoming visit:

> *When we enroll a child, it automatically tells which vaccine has to be administered and the dates are same as the dates we used to calculate manually.* [Vaccinator 10]

> *iDSS is an easy app to use. Precisely I can say, I don't need to think about dates or about weekend. It automatically generates dates, and we can update our record book and EPI card easily without error.* [Vaccinator 13]

Accuracy in Generating Age-Appropriate Vaccine Schedules

The vaccinators conveyed mixed responses regarding the perceived accuracy of the iDSS algorithm across both the sites. Less than half (7/16, 44%) of the vaccinators stated that they found no discrepancies in the schedules constructed by the iDSS, whereas others stated discrepancies that contradicted their routine practices.

Despite endorsing the accuracy, 62% (10/16) participants across both sites were confused about the age-appropriate administration of IPV and measles vaccines. For instance, 54% (6/11) vaccinators in Pakistan were unsure about administering the IPV vaccine due at the age of 14 weeks according to the national immunization schedule. Some vaccinators believed that IPV should be administered with the third dose of Penta, irrespective of the age of the child, and hence considered iDSS to have scheduled the IPV dose inaccurately:

> *It happens that if a child's age is let's say 3 months or 3.5 months and he comes in for BCG, application shows IPV to be given as well at 3.5 months, but we don't do so and schedule IPV for future.* [Vaccinator 1]

One of the participants from Pakistan (1/11, 9%) also questioned the interval between the 2 doses of measles, particularly for children who were behind their routine schedules:

> *We have some confusions, for example if a child's age is 12 months, then it (iDSS) gives date randomly and does not keep a gap of 3 months between two doses.* [Vaccinator 8]

Vaccinators in Bangladesh (3/5, 60%) were unsure about the scheduling of upcoming vaccines that are not dependent on previous doses (for instance, the first dose of measles vaccine is not dependent on pentavalent-3 dose and should be administered when a child turns 9 months). Vaccinators believed that the measles vaccine should be "locked" on the iDSS (ie, not allowed to be given) until the child receives the pentavalent-3 dose. The same logic was applied for the IPV-2 dose due at the age of 14 weeks in Bangladesh:

> *Why do I have to schedule Measles and Rubella during Penta-2 vaccination? Isn't it supposed to be given only after Penta-3–IPV 2 schedule?* [Vaccinator 14]

Theme 3: Usability of iDSS

Utility of the iDSS for Vaccinators

More than half (9/16, 56%) of the vaccinators stated that the iDSS is easy to use and 69% (11/16) emphasized its need as it accurately constructs age-appropriate vaccine schedules quickly,

saving time. Vaccinators highlighted that the iDSS facilitates decisions regarding whether the child should receive vaccination or not, eventually reducing MOVs:

> *Best thing are the dates/schedules that are automatically generated. It is less time consuming and the vaccines that are needed to be administered are ticked.* [Vaccinator 1]

> *Initially, we were tallying dates that we predicted with the dates shown in iDSS. We found some mismatch in the dates, but it was our mistake mostly, because we did not do [the calculations] properly. Some days were missed by us.* [Vaccinator 9]

Almost one-fifth (3/16, 19%) of the vaccinators thought that iDSS would be more useful for outreach activities in which they often encounter children who have missed their routine vaccination doses:

> *Though our country has a wide range of EPI centers, during our outreach activities we try to reach defaulter children and ensure to give them all required vaccines displayed as due vaccines on this app [iDSS].* [Vaccinator 13]

Vaccinators (6/16, 37%) also suggested that iDSS should serve as a channel to digitalize immunization information systems and replace the conventionally used manual calculation methods for constructing vaccine schedules:

> *Our country is going to digitalize the vaccination system and we are still dependent on the old hardcopy methods. It was needed in the past since we have started EPI activity. It will assist in data centralization.* [Vaccinator 13]

Overall Feedback on iDSS

Overall, the vaccinators were satisfied with the app functionality and provided positive feedback about the app:

> *In my experience iDSS is far better than our current system. Moreover, auto generation of vaccine schedules helps us to enter data within no time.* [Vaccinator 14]

Vaccinators (7/16, 44%) suggested that the color scheme should be reconsidered:

> *There are no issues with color scheme and its well understood; however, if red could be replaced by any other color it makes us feel better. You know red is used to indicate danger.* [Vaccinator 4]

All vaccinators admired the current iDSS interface in terms of color scheme, text font and size, and design. Vaccinators mentioned that there was room for improvement, but they did not provide specific details of the features that needed to be changed:

> *No this is okay, we don't have any issues in that, the design is okay and so is the text.* [Vaccinator 8]

Theme 4: Challenges With the Manual Calculation of Catch-up Schedules

As part of their routine work, vaccinators were mainly dependent on vaccination cards or parental recall to infer the date of birth of children and their vaccination history to manually calculate immunization schedules:

> *If someone has lost the EPI card then we try to figure out through a recall method and ask the parent to tell us when the child gets the first vaccine. Then we ask for the date of birth, which they usually don't know, and tell us the age of the child. In this way, based on verbal discussion and age of child, for example, they say 2 or 3.5 months, we take the risk and vaccinate the child for 2nd or 3rd dose accordingly.* [Vaccinator 11]

For follow-up visits, vaccinators mentioned that the usual practice was to provide a calendar date with a 1-month gap for the next dose instead of following the standard 28-day interval between scheduling future doses as per the WHO-recommended EPI schedule guidelines. Vaccinators mentioned that to schedule doses with a 28-day interval, they had to refer to calendar and count the days to find the exact dates. A few times, they did not account for weekends when scheduling the subsequent visits. Vaccinators found iDSS useful in providing schedules automatically for subsequent visits that were in line with the WHO EPI guidelines:

> *Previously, we had to see the dates one by one and calculate it, now the benefit is we just enter data and get dates automatically. It also shows the schedule for my next visit.* [Vaccinator 5]

Discussion

Principal Findings

Our study has demonstrated the diagnostic accuracy and feasibility of iDSS to accurately schedule age-appropriate vaccination doses across a multicountry LMIC setting. We also demonstrated the potential of iDSS to reduce MOVs caused by poor vaccinator adherence to standard immunization schedules and the interpretation of complex immunization schedules. Our study reports positive feedback received from a diverse set of vaccinators with varying levels of education and experience on the usability and acceptability of the iDSS.

Overall, the iDSS had higher accuracy in constructing age-appropriate immunization schedules as per the WHO-recommended EPI guidelines compared with vaccinators. Our study highlights the issue of missed vaccine doses despite children making contact with vaccinators. Reducing MOVs caused by complexity and changes in EPI schedules can improve immunization coverage, timeliness, and equity [14]. One study from the United States estimated that the potentially achievable vaccination coverage for 4+Diphtheria, tetanus, and acellular pertussis vaccine, 4+PCV, and full series of *Haemophilus influenzae* type b for children aged 19 to 35 months would have been 90% if missed opportunities in the administration of these vaccines were eliminated [26]. From an equity perspective, iDSS can enable children from disadvantaged backgrounds,

who are already delayed on their vaccination, to catch-up with the rest through accurate administration of all due vaccine doses when they encounter a vaccinator.

Our findings show that the highest MOVs across Pakistan and Bangladesh sites were for polio and measles vaccines, as 27.5% (383/1391) and 5.3% (28/527) of all due immunization doses, respectively, were missed by vaccinators. A systematic review of MOVs across LMICs also reported the prevalence rate of MOVs with regard to polio vaccines to range from 13.4% to 46.7% [2]. According to the WHO-recommended EPI schedule, Pakistan and Bangladesh administer the IPV vaccine to all children at 14 weeks. However, feedback from vaccinators across both sites revealed that vaccinators considered it to be given alongside vaccines administered with Penta-3 (irrespective of age). This practice delayed the IPV vaccination, as the Penta, OPV, and PCV vaccines depend on previous doses and are often administered beyond 14 weeks of age [27]. These MOVs, especially for polio vaccines, are alarming, as they impede global efforts to eradicate polio. Pakistan remains one of the last 2 polio-endemic countries with a substantial surge in the number of polio cases since 2017 (147 cases in 2019 vs 8 in 2017) [28], putting the country on a failing trajectory and the broader Global Polio Eradication Initiative at risk. Similarly, the measles incidence in the country increased from 24.6 cases per million to 80.4 per million between 2000 and 2018 [29].

Although previous studies have reported examples of EIR in LMIC settings [30,31], not all of them have an in-built immunization scheduling or decision support system [32-34]. Our study adds to this important area by providing evidence of the diagnostic accuracy of a stand-alone mobile-based iDSS implemented across a multicountry LMIC setting. Our results are in line with findings reported from high-income countries where iDSS has improved the scheduling of vaccinations. A hospital-based study in the United States that implemented a computer-based clinical decision support algorithm demonstrated an increase in the tetanus, diphtheria, pertussis vaccination in postpartum women [35]. Our results corroborate this finding, making a strong case for high diagnostic accuracy of iDSS technology in LMIC settings. In addition, the end-user feedback from a diverse set of vaccinators, who varied in terms of gender, education, age, and experience, also confirms the utility and functionality of iDSS, its acceptance, and user satisfaction; however, interviews with vaccinators in our study did reveal that only about half (9/16, 56%) of them found the iDSS easy to use, presumably because of maintaining paper-based and electronic records simultaneously in the study. Switching to electronic records completely is likely to address this concern [14].

In contrast to most web-based iDSS developed and used in high-income countries, the iDSS in this study is packaged in the form of an API that is interoperable with health information systems and allows flexibility of deployment. As EIRs continue to be adapted, incorporating iDSS through APIs should be considered, in line with established standards such as the Pan American Health Organization EIR guidelines [36]. API-based iDSS such as the one used in this study also allows flexibility to adjust to multicountry EPI schedules that change frequently and can also adapt to cosmetic user interface changes such as varying languages and displays.

Integration of an iDSS module in LMIC Immunization Programs can, therefore, yield enormous benefits, not only in terms of reducing MOVs but also in designing accurate catch-up regimens to ensure universal immunization. This is particularly relevant in the context of the huge numbers of children who have missed their vaccine doses during the COVID-19 pandemic and associated lockdowns [18]. Equipping vaccinators with iDSS technology can help ensure that these children are effectively immunized for all due vaccines at subsequent visits, thereby maintaining optimal immunity levels and reducing the likelihood of secondary vaccine-preventable disease outbreaks.

Strengths and Limitations

A major strength of our study was the demonstration of the feasibility of the iDSS across 2 different LMIC settings, with varying EPI schedules, infrastructure, coverage levels, vaccinator education, experience, demographics, and immunization-related challenges. One limitation of our study was that the evidence of MOVs generated in this study only accounted for MOVs because of inaccurate vaccination schedules constructed by vaccinators and hence would be an underestimation of the overall MOV prevalence in our study sites.

Conclusions

The iDSS has high diagnostic accuracy for scheduling age-appropriate vaccinations and reducing MOVs; and high acceptability among vaccinators regardless of gender, education, and experience. The iDSS boasts a variety of features for easy adaptability and replicability across LMIC settings. The evidence generated from this study demonstrates the prevalence of MOVs, especially for measles and polio vaccines. iDSS can increase immunization coverage, timeliness, and equity by eliminating these MOVs and help design accurate catch-up regimens to ensure universal immunization, especially in the aftermath of the COVID-19 pandemic. The findings from this study provide the impetus for rigorously evaluating the impact of iDSS through a randomized controlled trial and paving the way for a scaled implementation of this tool across LMICs.

Acknowledgments

The authors would like to thank Zahid Hossain, Jobaer Faruque, and Farzana Hossain for their support in implementing this study at the Bangladesh site. The authors extend their gratitude to the Expanded Programme for Immunization—Gilgit Baltistan, Pakistan and Expanded Programme for Immunization-—Bangladesh for their support throughout the study and thank the front-line health workers for their cooperation during implementation. This study was funded by the Bill & Melinda Gates Foundation (ID:

OPP1199224). The funding source had no role in study design, data collection, data analysis, data interpretation, or manuscript writing. The corresponding author has full access to all the study data and the final responsibility to submit for publication.

Data Availability

Deidentified participant data and data dictionary are available to any researcher upon reasonable request.

Authors' Contributions

SC conceptualized the study. SC and DAS designed the study and acquired the funding. SC, RFA, and DAS developed the study protocol and methodology. SC, DAS, RFA, MTS, and VKD supervised the development of the immunization decision support system software. RFA, MTS, and VKD implemented the project and curated the data under the supervision of SC, DAS, and TR. RFA and AAK conducted statistical analyses with input from SC and DAS. DAS and RFA interpreted the data and wrote the original draft, which was revised through technical input provided by SC. All authors contributed to and reviewed the final submitted manuscript. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Immunization decision support system supplementary information.
[DOCX File , 511 KB - pediatrics_v6i1e40269_app1.docx]

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Abbreviations

API: application programming interface
BCG: bacille Calmette-Guérin
EIR: electronic immunization registry
EPI: Expanded Programme on Immunization
iDSS: immunization decision support system
IPV: inactivated polio vaccine
LMIC: low- and middle-income country
MOV: missed opportunity for vaccination
MR: measles-rubella
OPV: oral polio vaccine
PCV: pneumococcal vaccine
Penta: pentavalent vaccine
Rota: rotavirus vaccine
WHO: World Health Organization

Edited by S Badawy; submitted 29.06.22; peer-reviewed by M Das, M Yakum; comments to author 29.09.22; revised version received 22.11.22; accepted 25.12.22; published 17.02.23.

Please cite as:
Siddiqi DA, Ali RF, Shah MT, Dharma VK, Khan AA, Roy T, Chandir S
Evaluation of a Mobile-Based Immunization Decision Support System for Scheduling Age-Appropriate Vaccine Schedules for Children Younger Than 2 Years in Pakistan and Bangladesh: Lessons From a Multisite, Mixed Methods Study
JMIR Pediatr Parent 2023;6:e40269
URL: https://pediatrics.jmir.org/2023/1/e40269
doi:10.2196/40269
PMID:36800221

Review

The Effectiveness of mHealth Interventions Targeting Parents and Youth in Human Papillomavirus Vaccination: Systematic Review

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Abstract

Background: The prevalence of human papillomavirus (HPV) and its related cancers is a major global concern. In the United States, routine HPV vaccination is recommended for youth aged 11 or 12 years. Despite HPV being the most common sexually transmitted infection and the vaccine's proven efficacy, the vaccination rate among US youth remains below the recommended 80% completion rate. Mobile health (mHealth) interventions have demonstrated promise in improving health. Examining and synthesizing the current evidence about the impact of mHealth interventions on vaccination coverage in youth and intervention characteristics could guide future mHealth interventions aimed at mitigating the vaccination gap and disease burden.

Objective: This study aims to conduct a systematic review to assess the effectiveness of mHealth interventions on parental intent to vaccinate youth against HPV and youth's vaccine uptake.

Methods: We searched empirical papers through databases including Google Scholar, PubMed, CINAHL, PsycINFO, and Cochrane Library. The inclusion criteria were the following: (1) published between January 2011 and December 2022; (2) using mHealth aimed to improve HPV vaccination rate; (3) targeted unvaccinated youth or their parents; and (4) measured HPV-related knowledge, vaccination intention, or vaccine uptake. Overall, 3 researchers screened and appraised the quality of the eligible papers using the Melnyk Levels of Evidence and the Cochrane Grading of Recommendations Assessment, Development, and Evaluation methodology. Disagreements in search results and result interpretation were resolved through consensus.

Results: Overall, 17 studies that met the inclusion criteria were included in the final review. Most studies were conducted in the United States (14/17, 82%), used a randomized controlled trial design (12/17, 71%), and adopted behavior change theories or a culture-centric approach (10/17, 59%). mHealth interventions included SMS text message reminders, motivational SMS text messages, computer-tailored or tablet-tailored interventions, smartphone apps, web-based tailored interventions, social media (Facebook) campaigns, digital videos, and digital storytelling interventions. Approximately 88% (15/17) of the mHealth interventions demonstrated positive effects on knowledge, intention, or behaviors related to HPV vaccination. Overall, 12% (2/17) reported limited or no intervention impact on vaccine uptake or vaccine series completion. Effective vaccine uptake was commonly seen in interventions based on behavior change theories and those that provided culturally relevant information.

Conclusions: This systematic review identified the impact of mHealth interventions among unvaccinated youth and their parents, which showed improvement in HPV-related knowledge, vaccination intention, or vaccine initiation. The interventions that incorporated theories and culture-centric approaches revealed the most promising results. Although these outcomes are encouraging, future studies are needed to investigate factors associated with the success of interventions using SMS text messaging or social media. More studies are also needed for a better understanding of the intervention elements that boost the responses of age-specific and ethnicity-specific populations.

(JMIR Pediatr Parent 2023;6:e47334) doi:10.2196/47334

KEYWORDS

human papillomavirus; mobile health; mHealth; parents; systematic review; vaccination; youth; mobile phone

Introduction

Background

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States and globally. In the United States, the overall prevalence of HPV infection was estimated at approximately 40%, with the incidence of disease-associated HPV infection of 6.9 million and 6.1 million among men and women, respectively [1]. Each year, approximately 13 million individuals including adolescents were found infected with the virus [2]. Individuals who are infected with the virus could be asymptomatic, which makes the diagnosis of the disease difficult [3]. With the potential to cause genital warts and cancers in the cervix, penis, anus, and oropharynx, the considerable disease burden attributable to HPV infections remains as a global concern.

The HPV vaccine could reduce the risk of developing HPV-related infections and cancers, making it a critical tool for protecting individuals from these potentially life-threatening diseases. The prevention and control of the disease could be more difficult to manage owing to the low vaccination rate [4-6]. Since the introduction of the first HPV vaccine in 2006, the Advisory Committee on Immunization Practices has recommended starting the vaccination at age 9, with routine vaccination by age 11 or 12, to ensure protection before potential virus exposure. However, despite these guidelines, the current vaccination rate among US youth stands at only 58.6%—lagging behind the 80% target set by the Healthy People 2030 initiative, which aims to promote health and well-being of well-being of individuals, organizations, and communities across the United States [7,8].

Role of Mobile Health

Mobile health (mHealth), as part of digital health interventions, uses mobile, wireless technologies to deliver information [9]. Previous studies have found this approach to be promising for closing gaps in health systems by facilitating the successful delivery of various health services or interventions and improving the quality of care. For example, mHealth apps facilitated point-of-care diagnostics, tracked crucial events, and contributed to data collection and decision-making among health care providers [9]. Using mHealth was also found to be beneficial in supporting patients with cancer throughout their disease journey, improving their quality of life, and promoting overall patient well-being [10]. Nevertheless, previous studies have shown the inconsistent effectiveness of mHealth in promoting youth vaccination. For instance, a review paper examining the effectiveness of mHealth solutions in facilitating vaccination campaigns for unvaccinated children living in low-income and middle-income countries has suggested a promising impact on vaccine uptake [11]. However, an mHealth intervention using SMS reported no improvement in polio vaccination [12]. Factors such as health literacy and gender difference in the response to interventions could potentially influence their effectiveness [11,13].

Research Gap

Although numerous studies have been conducted to assess the potential of using mHealth in vaccination programs, to the best of our knowledge, there is no comprehensive review that has assessed the effectiveness of mHealth interventions targeting parents and children worldwide to address the HPV vaccination gap. The current limitations in our understanding of how mHealth could affect HPV vaccination intentions among unvaccinated, US children and their parents and its impact on actual vaccine uptake highlight an urgent need for studies in this area to better inform and refine the intervention strategies.

Objective

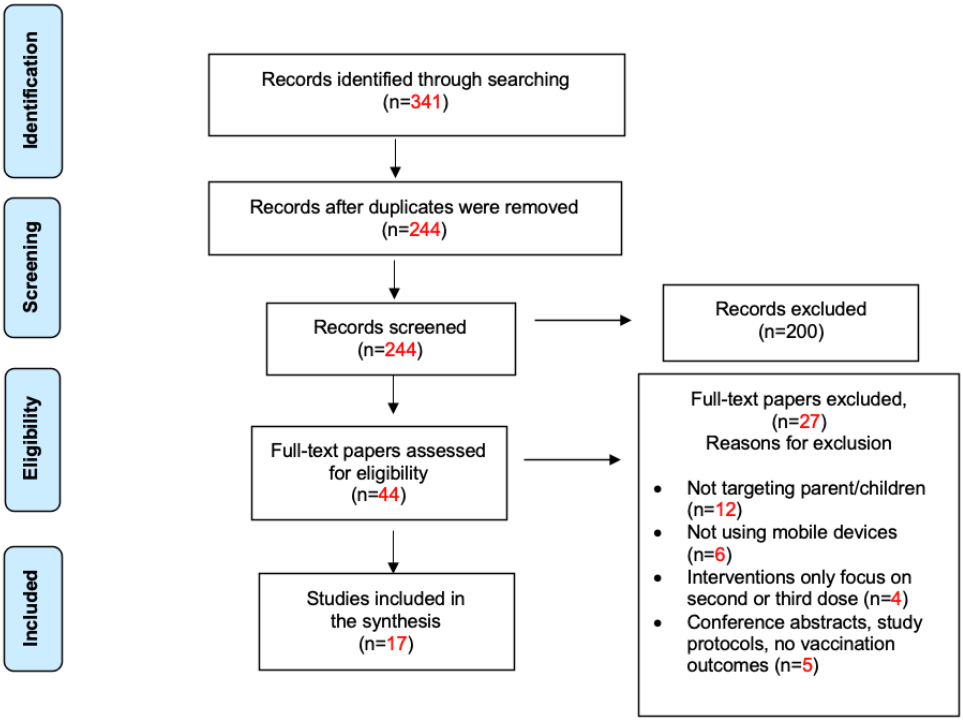
This systematic review was conducted to describe, assess, and synthesize the effectiveness of mHealth interventions in promoting HPV-related knowledge, vaccination intentions, and behaviors (uptake) among unvaccinated children and their parents. In the context of this study, “effectiveness” was measured based on the intended outcomes of the intervention, which included promoting HPV-related knowledge and increasing the vaccination intention or actual vaccine uptake among parents or youth. The findings will inform directions for developing effective mHealth interventions to mitigate HPV-related cancers through vaccination.

Methods

Study Design

The authors of this paper conducted a comprehensive literature search and gathered and appraised empirical evidence from databases including Google Scholar, PubMed, CINAHL, PsycINFO, and Cochrane Library. Specifically, the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement guided this review process. The PRISMA flow diagram (Figure 1) illustrates the study selection process, reasons for study exclusion, and number of papers obtained and retained. Refer to Multimedia Appendix 1 for the PRISMA checklist.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of the study selection process.



Inclusion Criteria

Inclusion criteria were as follows: (1) peer-reviewed studies published in English from January 2011 to December 2022; (2) mHealth interventions aimed to improve youth's HPV vaccination rates; (3) targeted parents of unvaccinated youth or unvaccinated youth alone; and (4) measured HPV-related knowledge, HPV vaccination intention, or vaccine uptake. Conference abstracts, letters to the editor, and study protocols were excluded.

Search Strategy

Overall, 3 researchers independently conducted the review and identified potential eligible studies. The title, abstract, and full text of the studies were assessed for inclusion. The reference lists of the included studies were also screened. Medical Subject Heading terms and keywords of the potential eligible papers were both used for the search. Words used for the search were: ("Mobile health" or "mHealth" "eHealth" or "mobile application"), ("Human Papillomavirus" or "HPV"), ("Human Papillomavirus vaccination" "Human Papillomavirus intervention" or "HPV vaccination" or "HPV intervention), ("HPV vaccination intention" or "HPV vaccine uptake"), ("parents" or "caregivers" or "mother" or "father"), and ("children" or "adolescent" or "youth" or "teenager"). Searching strategies for searched databases are presented in Multimedia Appendix 2.

Evidence Assessment and Synthesis

The level of evidence of the included studies was assessed using the modified Melnyk Levels of Evidence [14]. In addition, each study was assessed for its risk of bias and level of certainty in evidence using the Cochrane Grading of Recommendations Assessment, Development, and Evaluation methodology [15]. The risk of bias was categorized into 3 levels: high, low, or unclear. These were determined based on limitations in the body of evidence, which could subsequently downgrade the quality of evidence from high to very low. Disagreements among the 3 researchers were resolved with discussions until 100% consensus was achieved. Owing to heterogeneity across the studies and variations of evaluated outcomes, a meta-analysis was not performed for the included studies. Thus, we synthesized the evidence by analyzing and comparing the characteristics of these studies and the effectiveness of the mHealth interventions on youth's HPV vaccination intentions and vaccine uptake and discussed the factors associated with the intervention impacts. Specifically, a narrative approach was used, in which the results from individual studies were described and discussed. Details of the studies, intervention characteristics, and findings of each included study are presented in table format to facilitate a clear visual assessment. Studies were grouped according to factors including the study location, design, types of the intervention, outcomes measured, evidence level, and quality of evidence.

Ethical Considerations

Ethics approval was not required for this systematic review as it involves the analysis of previously published data. No new primary data were collected or used for this study.

Results

Included Studies

The search initially obtained 341 papers, of which 97 (28.4%) were duplicates. After removing the duplicates, the remaining 71.6% (244/341) of the papers were further screened. The primary reason for exclusion at the screening stage was that the study did not focus on HPV vaccination (141/341, 41.3%) or mHealth interventions (59/341, 17.3%). Overall, 44 papers were included for the subsequent full-text review, and 27 (61%)

papers were excluded with reasons after assessing the eligibility. Specific reasons for study exclusion included the following: mHealth interventions not targeting parents or children (12/27, 44%); interventions not using mobile devices (6/27, 22%); interventions only focused on the second or third dose of the HPV vaccine uptake (4/27, 15%); and conference abstracts, study protocols, or studies that did not measure vaccination outcomes (5/27, 19%). Overall, 39% (17/44) of the papers were included in the final review.

Study Characteristics

The characteristics of the 17 included studies are described in Table 1. Most studies (14/17, 82%) included in the review were conducted in the United States [16-29]. The remaining 18% (3/17) of the studies were conducted in the Netherlands, Australia, and Japan, respectively [30-32]. Regarding study settings, 59% (10/17) of the studies recruited the study participants from clinical settings including primary care practice, public health clinics, vaccine clinics, family medicine, pediatric and adolescent clinics, and outpatient clinics [16-19,21,24,25,27-29]. Of the 17 studies, 2 (12%) used both clinic and community recruitment [22,23]; 1 (6%) collaborated with secondary schools to implement the intervention [31]; and 4 (24%) relied on web-based outlets for participant enrollment, with 2 (12%) referring to the National Immunization Register and Surveys [26,30] and 2 (12%) using designated web pages [20,32].

Regarding the target population, of the 17 studies, 9 (53%) comprised diverse racial and ethnic participants [16,19-21,23,25,26,28,29]; 5 (29%) specifically focused on 1 racial and ethnic group, such as African Americans, Vietnamese Americans, Asian participants, or participants of Mexican heritage [17,18,22,24,32]; and 3 (18%) did not specify the racial and ethnic groups they included [27,30,31]. Furthermore, of the 17 studies, 13 (76%) targeted parents [16,18,19,22-32], with 15% (2/13) of them specially focused on mothers [26,30]. A study solely included youths aged 12 years [30], and 76% (13/17) of the other studies involved adolescents aged between 10 and 18 years [16-21,24-29,31]. For the 41% (7/17) of the studies that reported information about the parents' ages, the average age spanned from 38 to 48 years [18,22,23,26,28,29,32].

Among the 17 studies, initiation of at least 1 dose of HPV vaccine was measured as the primary outcome in 12 (71%) interventions [16-21,24,25,27,29-31], and 3 (18%) of the studies also assessed the completion of the vaccine series [17,21,27]. The intention of parents to vaccinate their children against the virus, which was found in 35% (6/17) of the studies, was the second most frequently measured outcome [22-24,26,28,32]. Apart from the 35% (6/17) of studies that examined HPV-related knowledge [18,21-23,28,29], 29% (5/17) of studies also evaluated other determinants of the vaccination, such as attitudes and beliefs toward the vaccine, normative beliefs, facilitators of and barriers to vaccination, perceived susceptibility, and severity of the infection [17,18,22,23,30]. Regarding the study design and quality of the design, of the 17 studies, 12 (71%) used randomized controlled trials [16,17,19,21-27,29-32], 4 (24%) were quasi-experiments [18,20,22,23], and 1 (6%) used a mixed methods approach [28].

Following the Melnyk Levels of Evidence approach, among the 17 studies, 13 (76%) were of level-2 evidence including the mixed methods study [16,17,19,21,24-32] and 4 (24%) quasi-experimental studies [18,20,22,23] were of level-3 evidence [14]. The quantitative elements contained in the mixed methods study were used to determine the level of evidence. Moreover, of the 17 studies, 13 (76%) were found to be of moderate risk of bias [16,18-23,25,26,28-30,32] and 4 (24%) were of high risk [17,24,27,31]. The downgrade in evidence quality was owing to inadequate descriptions of allocation concealment, blinding procedures, and psychometrics of outcome measures.

Table 1. Summary of studies included in the review.

Study, year	Location	Design	Intervention	Outcome measures	Evidence level	Quality of evidence
Rand et al, 2015 [16]	New York, United States	Randomized controlled trial	Centralized Managed Care Organization–generated text message reminders	The receipt of the first and subsequent doses of the HPV[a] vaccine	2	Moderate
DiClemente et al, 2015 [17]	Atlanta, United States	Randomized controlled trial	Computer-delivered presentation and motivational keychains with vaccine reminders	Perceived susceptibility and severity of contracting HPV and initial HPV vaccine uptake and dosage compliance	2	High
Chen et al, 2017 [18]	Arizona, United States	Quasi-experimental design	Bilingual, tablet-tailored intervention	HPV-related knowledge, cultural norms, facilitators of and barriers to HPV vaccination, parental intention to vaccinate their children, and the receipt of the first dose of vaccine	3	Moderate
Pot et al, 2017 [30]	Dutch	Randomized controlled trial	Website with web-based assistants	HPV vaccination uptake, mothers' degree of informed decision-making, decisional conflict, and critical determinants of vaccination uptake	2	Moderate
Hofstetter et al, 2017 [19]	New York, United States	Randomized controlled trial	Automated text reminders with educational messages	The receipt of the first dose of HPV vaccine and missed vaccination opportunity by 4, 12, and 24 wk after the initial reminder	2	Moderate
Mohanty et al, 2018 [20]	Philadelphia, United States	Quasi-experimental design	Facebook vaccination campaign	The receipt of the first, second, and third doses of the HPV vaccine through the Facebook page, 3 for ME	3	Moderate
Ortiz et al, 2018 [21]	Southeastern Cities, United States	Randomized controlled trial	Social media health intervention	Knowledge related to HPV and its vaccine, interpersonal discussions about HPV and its vaccine, and HPV vaccine immunization status	2	Moderate
Tull et al, 2018 [31]	Victoria, Australia	Randomized controlled trial	Motivational and self-regulatory SMS	The receipt of the HPV vaccine (any dose) and completion of the HPV vaccine schedule	2	High
Chen et al, 2019 [22]	Arizona, United States	Quasi-experimental design	Tablet-tailored intervention	HPV-related knowledge, perceived risk of having HPV, facilitators of and barriers to HPV vaccination, cultural norms, parental intention to vaccinate their children, and the receipt of the first dose of vaccine	3	Moderate
Chen et al, 2019 [23]	Arizona, United States	Quasi-experimental design	Digital storytelling	HPV-related knowledge, attitudes, and beliefs and mothers' intent to vaccinate their children against HPV	3	Moderate
Dempsey et al, 2019 [24]	Colorado, United States	Randomized controlled trial	Web-based, individually customizable intervention	The HPV vaccination intention among parents, receipt of any needed dose of the HPV vaccine, and initiation and completion of the vaccine series	2	High
Dixon et al, 2019 [25]	Indiana, United States	Randomized controlled trial	Tablet-based educational intervention	The changes in HPV vaccine status, including the first dose (initiation), second dose, and third dose (completion) of the vaccine series	2	Moderate
Panozzo et al, 2020 [26]	27 states in the United States with the lowest HPV vaccine coverage	Randomized controlled trial	Web-based digital videos with tailored messages	Mothers' intent to vaccinate their children and the changes in the strength of the main HPV vaccine concern	2	Moderate

Study, year	Location	Design	Intervention	Outcome measures	Evidence level	Quality of evidence
Szilagyi et al, 2020 [27]	New York, United States	Randomized controlled trial	Auto dialer centralized reminder and recall	The initiation and completion of the HPV second or third dose of the vaccine series	2	High
Suzuki et al, 2021 [32]	Tokyo, Japan	Randomized controlled trial	Web-based educational intervention	HPV awareness, attitudes toward the HPV vaccination, and willingness of adults to consider children's vaccination	2	Moderate
Becker et al, 2022 [28]	Texas, United States	Mixed methods study	Smartphone app	Awareness, attitudes, and knowledge regarding HPV and the vaccine; intentions to vaccinate their child; and communication with the child's pediatrician about the vaccine	2	Moderate
Shegog et al, 2022 [29]	Texas, United States	Randomized controlled trial	Smartphone app	Knowledge about HPV and the HPV vaccine and HPV vaccination initiation rates	2	Moderate

[a]HPV: human papillomavirus.

Intervention Characteristics

This review encompassed a range of mHealth interventions. Of the 17 studies, 5 (29%) examined the impact of tailored educational information regarding the HPV vaccine, with 60% (3/5) of them using web-based interventions to deliver the messages [24,30,32] and 40% (2/5) using tablet computers [18,23]. Messaging services were used in 24% (4/17) of the studies [16,19,27,31], 75% (3/4) of which featured SMS text messages with embedded educational and customized content [19,27,31]. Digital videos were used in 18% (3/17) of the studies, 67% (2/3) of which incorporated customized messages to address the vaccination concerns of parents or guardians [25,26], whereas the other study used personal stories from mothers of vaccinated adolescents sharing their experiences with HPV and the vaccine [22]. In 12% (2/17) of the studies, Facebook pages were used to reach the targeted adolescents for the intervention [20,21]. Of the 17 studies, 2 (12%) studies used smartphone apps to support parents in making decisions regarding HPV vaccination [28,29]. A study used the combination of a computer-delivered presentation on HPV vaccination, vaccine appointment cards, and keychains with motivational health messages [17].

In addition, the interventions in 18% (3/17) of the studies incorporated culturally tailored and gender-tailored messages addressing cultural beliefs pertinent to HPV vaccination [17,18,22]. Of the 17 studies, 4 (24%) indicated that the development of their interventions was informed by multiple sources. These included key informants; significant community and end user input; and insights from adolescents, parents, and health care providers. This comprehensive approach aimed to capture each individual's unique questions, experiences, attitudes, and beliefs [21-24].

The duration of the intervention was reported in 35% (6/17) of the studies, and it varied depending on the type of intervention, ranging from <50 seconds to 30 minutes [17,18,22,23,25,26]. The delivery frequency of message reminders also varied, with some interventions providing reminders once [31], and others providing up to 4 [16] or 5 weekly messages [19]. However, 18% (3/17) of the studies did not specify the duration of their interventions [24,30,32]. In 18% (3/17) of the studies, only the total duration of the study period was reported, with 2 Facebook-based vaccination campaigns lasting 1 year and 3 months, respectively [20,21], and a study exploring the use of phone reminders lasting 2 years [27]. Another 12% (2/17) of the studies used apps that were assessed by logging data over 5 months [28,29].

Among the 17 studies, 10 (59%) incorporated theories into their interventions. Theories of behavior change were used in 53% (9/17) of the studies to guide the development of the interventions [17,18,20-23,27-29,32], including the Information-Motivation-Behavioral Skills model, PRECEDE-PROCEED Model, Health Belief Model, Theory of Planned Behavior, Social Cognitive Theory, and Theory of Reasoned Action. A study of digital storytelling used the Model of Culture-Centric Narratives in Health Promotion as the guiding theoretical framework [22].

Measured Outcomes

HPV-Associated Knowledge, Attitudes, and Beliefs

Of the 17 studies, 6 (35%) that used educational interventions found that the interventions positively influenced HPV-related knowledge, with knowledge scores showing improvement after the intervention [18,21-23,28,29]. The knowledge was assessed through various measures, specifically covering topics including the recognized risk factors for HPV infection, associated diseases, and methods for HPV detection [18]; information about how HPV is sexually transmitted, its symptoms, prevalence, potential to lead to cancer and genital warts in both sexes, and vaccination requirements for both boys and girls [21]; notion of selective vaccination of boys and girls [22]; and HPV risks in teenagers, its ties to different diseases and cancers, preventive approaches, recommended vaccine doses, and its safety [23]. A study assessed different health conditions that the HPV vaccine could prevent and people at risk for HPV infection [29], and another study solely measured the increase

in knowledge about HPV and its vaccine using a 4-point agreement scale [28]. In several papers (4/17, 24%) [22,28,29,32], favorable changes in belief and attitude toward HPV vaccination and its safety and effectiveness were also found among parents who had been enrolled in and completed the intervention.

Facilitators of and Barriers to HPV Vaccination

Among the 17 studies analyzed, 2 (12%) [18,23] noted a significant rise in parents' perception of facilitators for HPV vaccination between the preintervention and postintervention phases, with *P* values of .008 and .007, respectively. Several factors facilitating vaccination behavior change were identified and assessed regarding the intervention effectiveness, such as suggestions or recommendations from health care providers or religious leaders, positive attitudes toward the vaccine, support from significant others, and beliefs about vaccine benefits.

In the 12% (2/17) of studies mentioned previously, perceived barriers to vaccination were also compared before and after the intervention. Nevertheless, there was no statistically significant association identified. Factors examined included concern about vaccine safety, lack of health insurance or provider recommendation, language barrier between patients and providers, and worries that the vaccination would encourage early sexual activity.

Moreover, in a study [17], perceived susceptibility or severity of HPV and perceived risk of HPV developing into cervical cancer served as motivating factors for HPV vaccination. The findings indicated that participants exposed to the media intervention had a high level of perceived susceptibility or severity of HPV and HPV ‐ attributable cancers compared with those in the control group. The difference in perceived susceptibility between the 2 study conditions was statistically significant (*P*=.03).

Cultural Norms or Beliefs

Of the 17 studies, 4 (24%) evaluated culturally congruent interventions [17,18,22,23], whereas only 2 (12%) of them specifically included cultural beliefs or cultural norms in the outcome measures [18,23]. Despite the computer-tailored intervention using information from sources such as focus groups with parents and health care providers and targeting HPV knowledge and awareness among the youth, the results found no significant difference in cultural norms among parents with unvaccinated adolescents before and after the intervention [23]. However, significantly decreased scores of vaccination-related cultural beliefs (*P*<.001) and more favorable attitudes toward the vaccine were identified among Mexican-heritage participants in the study [18].

Parental Intention and Vaccine Decision-Making

Of the 17 studies, 8 (47%) [18,22-24,26,28,30,32] evaluated changes in participants' intention or willingness to vaccinate after the intervention. Of the 8 studies, 3 (38%) [18,22,23] revealed that the parents' intention to vaccinate their youth was ranging from 95% to 100% during the postintervention period. Of the remaining studies, 63% (5/8) included at least one comparison group. All of these (5/5, 100%) demonstrated a positive intervention impact, showing a significantly higher intention to vaccinate children compared with the control group, with *P* values ranging from .002 to <.001. A study [30] found that the tailored intervention, where messages were customized to mother participants' preferences and needs for HPV vaccine decision-making, was particularly useful for them when in doubt, as they experienced less decisional conflict relating to a lack of information after the intervention. However, a study [26] found that the average strength of the main concern about the HPV vaccine among mothers remained high even after receiving the intervention messages tailored to reduce the concerns.

Vaccine Uptake and Completion

Of the 41% (7/17) studies discussing mHealth's impact on youth's HPV vaccine initiation and completion of HPV vaccine, all tracked this over time, offering data up to 7 months after intervention [16,20,21,24,25,27,31]. Overall, 29% (5/17) of the studies [16-18,25,31] reported notable increases in HPV vaccination rates and vaccine series completion rates. Of these 5 studies, 3 (60%) assessed youth participants' receipt of the initial HPV vaccine dose [16,18,25] and 2 (40%) evaluated youth participants' adherence to the second and third doses of the HPV vaccine series [17,31]. Study [19] noted that after 12 weeks of plain text reminders, there was a significant increase in vaccine uptake among those aged 11 to 12 years (*P*=.07), but this was not observed in the 13 to 17 age group.

In contrast, the findings of 29% (5/17) of the studies suggested no difference in youth vaccine uptake between the intervention and control groups. Of the 17 studies, 3 (18%) [21,27,30] found no significant difference in the vaccination uptake and completion rates across the intervention and control groups. A study [24] found that the HPV vaccine uptake among Latino adolescents and young adults did not differ significantly across the groups receiving tailored educational messages, nontailored interventions, and usual care despite their improved vaccination intention. The Facebook-based vaccination campaign successfully reached and engaged >12,000 adolescents, whereas only 73 of them received the first dose of the vaccine [20].

Intervention Engagement

In 24% (4/17) of the studies that evaluated intervention fidelity and engagement, several methods were used. For a smartphone app, qualitative feedback was collected and revealed that participants preferred push notifications for HPV facts and suggested that the app could incorporate broad topics, be more interactive, and contain adolescent-friendly elements such as animations and games [28]. User interactions, such as clicks, likes, comments, and shares, on a vaccine campaign Facebook page were analyzed to determine whether youth participants preferred advertisements highlighting immediate risks (eg, HPV-related infections) as opposed to long-term consequences (eg, HPV-induced cancer). The findings suggested that youth participants might be more responsive to content that focuses on immediate risks; however, further analysis was not conducted to identify how this reception might influence vaccination intent and uptake [20]. Another study of educational messaging intervention proposed an approach to assess the time users engaged with web-based intervention pages to evaluate their

involvement, with results still under analysis [24]. Moreover, a review was conducted to assess both recall and intervention fidelity, where participants were asked to identify which notifications and specific pieces of information from the Facebook-based intervention they remembered. However, there was no improvement in HPV knowledge or vaccination rates among those using the intervention [21].

Discussion

Summary

As of 2022, the HPV vaccination has been introduced in >120 countries worldwide; however, challenges for youth vaccination remain [33]. Digital technologies such as mHealth could be applied to address this global public health concern. This systematic review explored the effectiveness of 17 mHealth interventions in improving the HPV vaccination among unvaccinated youth. The included mHealth interventions used various technologies, including SMS text message reminders, smartphone apps, computer or web-based tailored interventions, social media campaigns, digital videos, and digital storytelling. The findings of the review suggested that mHealth intervention was a promising approach to improving the low HPV vaccination rates among youth. Specifically, these mHealth interventions could effectively enhance knowledge, attitudes, and beliefs related to HPV and its vaccine and motivating factors including perceived susceptibility or severity of HPV infections and its related cancer, which in turn, assisted in making vaccination decisions and promoting the vaccine uptake.

Tailored interventions, which considered the unique needs and concerns of specific groups or individuals, were developed using theoretical components and messaging that resonated with participants in a context-specific manner, such as through cues related to age, gender, race and ethnicity, or culture. These efforts made them more effective in addressing facilitators of and barriers to vaccination and eliciting positive responses for health behavior change compared with the information-only approach [34]. Consistent with previous studies, we found that tailored messages within successful mHealth interventions in this review addressed the knowledge gaps regarding HPV and its vaccine. The customized educational messages were designed with consideration of a variety of factors, including previous empirical evidence; theoretical concepts in the guided framework (eg, knowledge, attitudes, beliefs, perceived risk, barriers, and facilitators); age, gender, ethnicity, race, and cultural beliefs of the children regarding HPV vaccination; youth's current knowledge about the disease and vaccine based on assessment results; feedback from parents in the clinic network obtained through focus groups; inputs from youth advisory board meetings; and insights from other important sources such as health care providers and religious leaders [18,21-23,28,29].

Although it is noteworthy that tailored information is crucial for enhancing the uptake of HPV vaccination among unvaccinated youth and their parents, tailored education that addressed all the concerns of parents was found to be more effective in improving their intentions to vaccinate children than focusing solely on their primary concerns [26]. The results aligned with those of previous studies indicating that parents who had vaccine hesitancy were more likely to refuse the HPV vaccine owing to a range of concerns related to the importance of the vaccine for both the child and community health, vaccine safety, potential side effects, and overall benefits [35]. Boosting parents' confidence in the HPV vaccine by addressing their concerns and discussing the benefits of the vaccination could lead to a reduction in their hesitancy toward the vaccine [36].

Cultural norm was also found to be associated with the HPV vaccine administration. Parental and youth reluctance to seek the HPV vaccine may be influenced by their traditional beliefs, such as cultural norms that advocate sexual abstinence until marriage [37]. A previous study conducted among ethnic minority parents revealed concerns about the vaccine, stemming from fears that it might encourage risky sexual behavior and promiscuity [38]. Although this study was specifically centered on the ethnic minority population, similar views could also be prevalent among other groups that upheld beliefs valuing a woman's purity and reputation, especially in sexual or relational contexts [39]. These attitudes, in turn, could influence the perceptions about and use of health care services and their self-reported health, health behaviors, and health outcomes [40,41]. Nevertheless, providing relevant and reliable information about the HPV vaccine to parents could help to drive positive change in their attitudes toward the vaccination [18,23,37]. Both religious beliefs and cultural views may influence vaccine decision-making [37]. Hence, engaging spiritual organizations and religious authorities in the design of interventions aimed at increasing HPV vaccination rates among unvaccinated youth could be essential.

Of the 17 studies, 3 (18%) [20,21,30] found that web-based interventions or interventions using social media had limited effects on increasing the actual uptake of the HPV vaccine, despite improved knowledge about the virus and vaccine and vaccination intention among the participants. Although social media platforms such as YouTube, Facebook, Instagram, and Twitter could be a feasible and effective tool with expansive reach and be useful for disseminating health information about the vaccine, providing practical information about how and where to receive the vaccine, and addressing public shared concerns or questions, these interventions may not be sufficient on their own to promote vaccination behavior change among adolescents [42]. The information that individuals receive through social media is not always complete or favorable. To gain a deep understanding of how unvaccinated youth and their parents perceive and trust the information, it is important to explore the factors that influence strategic messaging. This could provide valuable insights into what types of information could be useful and credible for this population.

Although the use of SMS text message interventions had been shown to have a small impact on vaccine uptake and completion among eligible adolescents, positive outcomes varied among states and regions even when using identical messages, regardless of the number of messages sent [27]. These message reminders may only serve as an additional stimulus for those who have already decided to vaccinate [19]. Factors such as timing and setting for the message sent and easy access to vaccination may also be critical to consider in reducing the

vaccination gap. To improve youth attendance and stay on track to complete the vaccine schedule, integrating SMS reminders with vaccine appointment alerts could be beneficial. In addition, incorporating secondary school–based vaccination programs, where parents were provided with consent cards and informational booklets and were reminded of upcoming vaccination sessions through school newsletters or a web-based portal, could further increase vaccine completion rates for the second and third doses in the HPV vaccine series [31]. These findings were in accordance with previous studies showing that vaccination interventions were more effective when framed as reminders to receive the vaccine that had already been prescheduled for the message receivers. Moreover, SMS text messages integrated with behavior change theories and sent before health care visits had the potential to significantly boost vaccination rates ($P<.05$) [43]. The effectiveness of messaging interventions and the direction of the effect may vary based on context. Further studies are needed to determine how successful SMS text message interventions could be adapted across subpopulations and different settings.

The improved HPV vaccination intention among parents may not necessarily translate well into youth HPV vaccine use as suggested by Dempsey et al [24]. Involving youth in vaccination decision-making and addressing their needs in the process may help them take responsibility for their health. In addition, adolescents aged as young as 9 to 12 years may already have the capability to make informed medical decisions [44]. Nonetheless, the review revealed that there was a lack of mHealth interventions that targeted unvaccinated adolescents, with only 4 studies focused on this population. The understanding of successful interventions that could help improve youth vaccination rates could be limited owing to the lack of research in the area. Further studies that investigate adolescent vaccination decision-making and its changes before and after interventions could provide valuable insights into the factors that contribute to effective interventions. These insights could then be used to facilitate the translation of improved vaccination intentions into actual increases in vaccination rates among youth.

Other aspects such as participants' satisfaction and experience with the intervention (utility, usefulness, and quality of the mobile app) were critical to assess [28]. In 24% (4/17) of the studies, the acceptability of the interventions by parents and youth was evaluated. This assessment addressed various aspects of the interventions, including the appropriateness of content and wording, graphic design and color choices, intervention length, the likelihood of recommending the intervention, and discussions about the intervention [18,21,23,30]. These evaluations allowed for a comprehensive assessment of the intervention and provided areas for ongoing improvements to the technology-mediated, tailored intervention for the HPV vaccination. The findings may also help to inform how to link intervention engagement to youth vaccination and uncover motivational factors that could influence significant vaccination behavior change and adherence.

This systematic review expands the current understanding regarding the use of mHealth interventions and their impact on unvaccinated youth and their parents. It adopted multiple search strategies and was not limited to randomized controlled trials; such inclusion could help gain a more comprehensive understanding of the strengths and limitations of the available evidence. Although this review could be a useful reference to guide the future development and evaluation of mHealth interventions targeting the improvement of HPV vaccination decisions and behaviors among youth, it is essential to note that the studies of moderate quality included in the review may have the potential to compromise the generalizability and transferability of the findings.

Limitations

The review also has some limitations, including the limited number of databases searched; exclusion of non–English language studies; and a narrow geographical focus, with most studies conducted in the United States, which could all lead to selection and reporting biases. The evidence presented in the review could not represent all the current mHealth interventions for HPV vaccination as only parents and adolescents were targeted. Moreover, a meta-analysis could not be conducted because of the heterogeneity of the studies and measured outcomes. Finally, the dynamics surrounding HPV vaccine decision-making might be different in various regions outside the United States. For instance, the accessibility or availability of the HPV vaccine might be a predominant factor affecting vaccine decisions in some other countries or regions [45,46]. Although this study sheds light on the situation within the United States, further studies are necessary to explore the nuanced interactions between mHealth tools and vaccine decision-making in diverse international settings.

Conclusions

This review synthesized the available evidence for mHealth interventions designed to promote HPV vaccination among youth. mHealth has shown promising results in improving youth and their parents' HPV-related knowledge, attitudes, and beliefs toward the vaccine and addressing the barriers to vaccination, vaccination intention, and vaccine uptake. Future studies should examine the factors that could increase the quality of the study evidence and the complexity of the use of mHealth vaccination interventions, as its impact could differ depending on the platforms used, populations involved, settings of the app, and any additional efforts used to encourage the vaccination.

Authors' Contributions

LO, ACCC, and AA conceived the study topic and designed the review protocol. LO and ACCC screened the studies. LO conducted the data extraction and risk of bias assessment, which were validated by ACCC. The systematic review was written by LO, with revisions from ACCC and AA.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[PDF File (Adobe PDF File), 105 KB - pediatrics_v6i1e47334_app1.pdf]

Multimedia Appendix 2
Searching strategies for searched databases.
[PDF File (Adobe PDF File), 59 KB - pediatrics_v6i1e47334_app2.pdf]

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Abbreviations

HPV: human papillomavirus
mHealth: mobile health
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Edited by S Badawy; submitted 17.03.23; peer-reviewed by KL Mauco, A Teitelman; comments to author 30.08.23; revised version received 18.09.23; accepted 12.10.23; published 21.11.23.

Please cite as:
Ou L, Chen ACC, Amresh A
The Effectiveness of mHealth Interventions Targeting Parents and Youth in Human Papillomavirus Vaccination: Systematic Review
JMIR Pediatr Parent 2023;6:e47334
URL: https://pediatrics.jmir.org/2023/1/e47334
doi:10.2196/47334
PMID:37988155

Digital Technology Characteristics and Literacy Among Families With Children With Asthma: Cross-Sectional Study

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Abstract

Background: The use of digital technology in pediatric asthma management has emerged as a potential tool for improving asthma management. However, the use of digital tools has the potential to contribute to the inequitable delivery of asthma care because of existing social factors associated with asthma disparities. Our study focused on parents' chosen language and sociodemographic factors that might shape the use of digital technology in asthma self-management.

Objective: This study aims to estimate and compare patient, family, and technology-related characteristics by parents' chosen language (English or Spanish) and compare a digital literacy measure by sociodemographic factors.

Methods: Survey data were collected from July to December 2021 from parents of children with asthma who were seen by a Chicago pediatric health system pulmonary provider. Questions assessed patient and family characteristics, digital technology use, and digital literacy, measured using the validated eHealth Literacy Scale (eHEALS). Chi-square tests and multivariable logistic regression were used for comparisons, and Kruskal-Wallis tests were used for comparing median eHEALS scores by social characteristics.

Results: Of the 197 parents surveyed, 24.4% (n=49) of parents identified as a race categorized as other, 37.1% (n=67) as White, and 38.6% (n=75) as Black; 47.2% (n=93) identified as Hispanic/Latino/Latina. Additionally, 79.7% (n=157) of parents preferred English, and 20.3% (n=40) preferred Spanish. English-speaking parents were more likely to report having a data plan for their smartphone (117/157, 74.5%) or high-speed internet (138/157, 87.9%) compared to Spanish-speaking parents (smartphone: 23/40, 58%; *P*=.03; internet: 27/40, 68%; *P*=.002). Compared with Spanish-speaking parents, English-speaking parents were less likely to report having a lot or some concern about paying for internet (28/40, 70% vs 83/157, 52.9%; *P*=.046) or about data privacy (35/40, 88% vs 105/157, 67.5%; *P*=.01). Digital literacy scores differed significantly by race, income, education level, and language. In a multivariable model, language was not a significant factor for having high-speed internet service (*P*=.12) or concern about paying for internet at home (*P*=.60), but it was a significant factor for concerns about data privacy (*P*=.04).

Conclusions: The significant differences in technology-related characteristics suggest that digital connectivity, affordability, and data privacy may also be important factors in considering digital technology use in asthma care.

(JMIR Pediatr Parent 2023;6:e48822) doi:10.2196/48822

KEYWORDS

pediatric asthma; digital literacy; health equity; equity; asthma; respiration; respiratory; pulmonary; child; children; youth; survey; surveys; disparity; disparities; socio-demographic; sociodemographic; use; technology use; self-management; family

Introduction

Digital technology is emerging as a tool to help manage pediatric chronic disease. Studies have shown that disease self-management is improved by the use of smartphone apps and remote monitoring devices, as evidenced by increased medication adherence, improved attendance at medical appointments, and improved measures of quality of life [1,2].

There are similarly promising findings for pediatric asthma management with digital technologies; however, the availability and use of digital technology in asthma care could be inequitable [3-5]. Asthma disparities due to sociodemographic factors, including low socioeconomic status, race, ethnicity, and household language, are well-described [6-9]. Implementing digital technology in the context of existing disparities could potentially widen disparities already experienced in asthma

care. For example, previous studies of general digital technology use have found that Black patients reported using mobile technology for social activities, but fewer used it for health-related information or communication [10]. Furthermore, a study of a large urban area found disparities in digital connectivity for Hispanic populations [11]. Thus while digital health care may have advantages for tailoring health information and education, an intentional design to meet the linguistic, cultural, and literacy needs of specific populations is necessary [12]. Implementation without attention to these known social determinants of health, associated with disparate asthma care, could lead to unintentional perpetuation, or even worsening, of disparities.

In partnership with pediatric pulmonary providers that serve a primarily low-income and racial-ethnically diverse population, our study team examined key characteristics that might influence families' digital technology use for asthma care. In particular, we highlighted the differences in technology-related characteristics between English-speaking and Spanish-speaking families with children with asthma. Language-concordant care is an essential component of high-quality health care in the United States [13,14]. Studies have typically focused on the use of medical interpreters in care delivery, and only a few studies have compared the use of digital health technology among patients with a non-English preference [15]. They found that Spanish speakers tend to have lower digital literacy than English speakers and that there are cultural differences in what they want from health tools [16,17].

Health systems and clinicians need to understand how to support the equitable delivery of digital health for families with children with asthma as digital engagement expands in health care delivery [18]. To inform those efforts, we surveyed parents/caregivers about their digital technology access, use, and preferences at home and in their community. Our study focuses on parent language and other sociodemographic factors that might shape the use of digital technology in asthma self-management.

Methods

Study Procedures and Participants

For this cross-sectional study, data collection occurred from July 2021 to December 2021. A convenience sample of parents/caregivers (henceforth, parents) of patients with an asthma diagnosis, managed by pediatric pulmonology providers at a single pediatric hospital system, were recruited by email and in person at a clinic. If the child (ie, patient) was seen by a pediatric pulmonology provider during the study period, then their parent was invited to fill out the survey by email. For patients approached at the pediatric asthma clinic, a research staff member asked parents while they were waiting to be seen by their pulmonary provider if they were interested in completing the survey. If they agreed, then the unique survey link was opened on a tablet for completion. The pediatric asthma clinic was located in Chicago, Illinois, whereas other pulmonary clinics, which manage all pulmonary conditions, were located in Chicago and the surrounding suburbs. The characteristics of participants who completed the web-based survey versus the in-person survey are included in Table S1 in Multimedia Appendix 1. We recruited by email and in person to ensure that our sample was not biased toward only those who felt comfortable participating by email. In our previous research, patients expressed that meeting research staff in person was an important component of study participation. While the overall response rate was 47.2% (197/417 participants approached), the response rate was higher in a clinic (81/100, 81% of participants approached) than by email (116/317, 36.6% of participants emailed). During the study period, approximately 1000 unique pediatric patients with asthma were managed by pulmonary providers in our health system, so our sample size represented 20% of that patient population.

To be eligible, the parents had to complete the survey in English or Spanish and have a child with an asthma diagnosis who was younger than 18 years. Parents were excluded if their child had a comorbidity, making the management of asthma different from typical asthma management per the pulmonology provider's clinical judgment (eg, ventilator dependent or interstitial lung disease).

Asthma diagnosis was retrieved from the pulmonology visit's associated *International Classification of Diseases, Tenth Revision* (*ICD-10*) code in the patient's chart from the electronic health record. Participants were compensated with a US $10 electronic gift card. Language preference for survey participation was indicated by selecting English or Spanish when asked "What is your preferred language of communication?" [15].

Ethical Considerations

The Lurie Children's Hospital of Chicago Institutional Review Board deemed the study exempt from review (2021-4330).

Instrument

The survey was developed with pediatric primary care and pulmonology expertise. Questions evaluated patient and family characteristics [19,20] (parent and child gender, race, and Hispanic/Latino/Latina ethnicity; household income; child grade; and perceived burden from asthma) and digital technology access and use (devices [21], activities on devices, type of internet access [21], concern paying for internet, concern about data privacy, and interest in technology for asthma management; the survey is available in Multimedia Appendix 2 [19-21]). Questions were pretested with research staff, not affiliated with the study, and parents to ensure clarity and reliability regarding the function of the questions before dissemination.

Additionally, digital literacy was measured in the survey using the validated eHealth Literacy Scale (eHEALS), which was developed from social cognitive theory and self-efficacy theory, and is the most commonly used assessment of an individual's ability to use digital resources for health [22-26]. The eHEALS is composed of 8 items measured using a 5-point Likert scale, varying from "strongly agree" (5 points), "agree" (4 points), "neutral" (3 points), "disagree" (2 points), and "strongly disagree" (1 point). The total eHEALS score for a participant completing all items ranged from 8 to 40 by a summation of every item's score, and a higher score meant better digital literacy. The English- and Spanish-validated versions of eHEALS were used.

Statistical Analysis

Descriptive statistics of key sociodemographic factors and survey responses included frequencies and proportions. Based on distribution for self-identified race, there was further categorization into 3 major groups: Black or African American, White, or other (Asian, American Indian/Alaskan Native, Hawaiian/Pacific Islander, or preferred to self-describe). The child's race was categorized similarly. The estimated household income variable was dichotomized (ie, <US $50,000 or ≥US $50,000) at approximately 200% of the federal poverty level of an annual 2022 income for a household of 4 persons (US $55,500) in the United States [27]. Parent education was dichotomized into two categories: high school education or less and any college education or more, including graduate-level education. Child grade was dichotomized from early child education (kindergarten) to the end of middle school (eighth grade) and high school (ninth to 12th grade). Asthma diagnosis was determined by the *ICD-10* code associated with the pulmonary clinic visit and categorized into mild, moderate, or severe based on the visit's coding.

Chi-square tests were used for bivariate comparisons for categorical variables unless there was a small response size, then Fischer exact tests were used. A multivariable logistic regression with parent language (ie, English as the referent group vs Spanish) and dichotomized household income, as defined above, was used to look at three dichotomized dependent variables: has high-speed internet (0 was no and 1 was yes), concern about paying for internet at home during the COVID-19 pandemic (0 for "Not too much/at all/do not have to pay" and 1 for "A lot/Some"), and concern about data privacy (0 for "Not too much/at all/do not have to pay" and 1 for "A lot/Some"). Kruskal-Wallis tests were used for comparing median eHEALS scores by categorical variables. Nonparametric statistical tests were used for the analysis given the small sample size. Results are reported as significant for 2-sided *P* values <.05. Analyses were performed using SPSS, Version 28 (IBM Corp).

Results

Characteristics of Parent and Child

Of the 197 parent-child dyads surveyed, 89.1% (n=172) were female parents, and 10.4% (n=20) were male parents (Table 1). The median age was 37 (IQR 32-43) years. Surveyed parents identified their race as other (n=49, 24.4%), White (n=67, 37.1%), or Black or African American (n=75, 38.6%), and 47.2% (n=93) identified their ethnicity as Hispanic/Latino/Latina. By language, there were statistical differences in parent education level and income. While 68.8% (108/157) of English-speaking parents reported having at least some college education, only 18% (7/40) of Spanish-speaking parents reported similar education levels (*P*<.001). Further, 33.1% (48/157) of parents who preferred English and 9% (3/40) of parents who preferred Spanish reported estimated household incomes greater than US $50,000 (*P*=.004).

Table . Characteristics of parent and child by language (N=197).

	Overall sample (N=197)	English (n=157)	Spanish (n=40)	*P* value
Parent age (years; n=181), median (IQR)	37 (32-43)	35 (31-42)	41 (37-45)	.04
Parent gender [a] (n=193), n (%)				.26
Male	20 (10.4)	14 (9.2)	6 (15.4)	
Female	172 (89.1)	139 (90.8)	33 (84.6)	
Parent race (n=191), n (%)				<.001
Black or African American	75 (38.6)	75 (49.0)	0 (0.0)	
White	67 (37.1)	52 (34.0)	15 (39.5)	
Other (Asian, American Indian/Alaskan Native, Hawaiian/Pacific Islander)	49 (24.4)	26 (17.0)	23 (60.5)	
Parent ethnicity, Hispanic/Latino/Latina (yes), n (%)	93 (47.2)	54 (35.3)	39 (97.5)	<.001
Parent education, n (%)				<.001
High school or less	82 (41.6)	49 (31.2)	33 (82.5)	
Any college or more	115 (58.4)	108 (68.8)	7 (17.5)	
Estimated annual household income (US $; n=180), n (%)				.004
<50,000	129 (65.5)	97 (66.9)	32 (91.4)	
≥50,000	51 (25.9)	48 (33.1)	3 (8.5)	
Child gender, n (%)				.12
Male	124 (62.9)	103 (65.6)	21 (52.5)	
Female	73 (37.1)	54 (34.4)	19 (47.5)	
Child race (n=191), n (%)				<.001
Black or African American	79 (40.1)	79 (52.0)	0 (0.0)	
White	75 (38.1)	51 (33.6)	24 (61.5)	
Other (Asian, American Indian/Alaskan Native, Hawaiian/Pacific Islander)	37 (18.8)	22 (14.5)	15 (38.5)	
Child ethnicity, Hispanic/Latino/Latina (yes), n (%)	92 (46.7)	54 (34.8)	38 (97.4)	<.001
Child grade (2021-2022; n=196), n (%)				.78
Kindergarten to 8th grade	174 (88.8)	138 (88.5)	36 (90.0)	
9th to 12th grade	22 (11.2)	18 (11.5)	4 (10.0)	
Difficulties caused by asthma, n (%)				.02
Minor	63 (32.0)	43 (27.4)	20 (50.0)	
Moderate	73 (37.1)	60 (38.2)	13 (32.5)	
Severe	61 (31.0)	54 (34.4)	7 (17.5)	
Asthma diagnosis (n=196), n (%)				.77
Mild	27 (13.8)	22 (14.1)	5 (12.5)	
Moderate	51 (26.0)	42 (26.9)	9 (22.5)	
Severe	118 (60.2)	92 (59.0)	26 (65.0)	

[a]One participant selected "other/preferred not to answer."

Among the 197 children, 88.8% (n=174) of them were between kindergarten and eighth grade, and 11.2% (n=22) were between ninth and 12th grade (Table 1). When evaluating the self-reported burden experienced by the family from their child's asthma, 32% (n=63) reported minor, 37.1% (n=73) reported moderate, and 31% (n=61) reported severe difficulties. The asthma severity diagnosis distribution, however, was 13.8% (n=21) mild, 25.9% (n=51) moderate, and 60.2% (n=118) severe. While there were statistical differences in the perceived difficulties caused by asthma by language participation (42/157, 27.4% of English-speaking parents and 50% (20/40) of Spanish-speaking parents reported minor difficulties; *P*=.02), there were no differences in asthma severity diagnosis by language (*P*=.77).

Technology-Related Characteristics

Most of the 197 parents reported having a smartphone (n=181, 91.9%), with 68.5% (n=135) reporting having a desktop or laptop and 63.5% (n=125) reporting having a tablet computer at home (Table 2). Parents mostly reported that the devices were used for entertainment by their child (n=170, 86.3%); 71.1% (n=140) of parents reported having a cell phone data plan, and 83.8% (n=165) reported having high-speed internet service. More English-speaking parents, compared to Spanish-speaking parents, reported having a cell phone data plan (117/157, 74.5% vs 23/40, 58%; *P*=.03) or having high-speed internet service (138/157, 87.9% vs 27/40, 68%; *P*=.002).

Table . Technology-related characteristics by language (N=197).

		Overall sample (N=197), n (%)	English (n=157), n (%)	Spanish (n=40), n (%)	*P* value
Devices at home (yes)[a]					
	Desktop or laptop	135 (68.5)	110 (70.1)	25 (62.5)	.85
	Smartphone	181 (91.9)	146 (93.0)	35 (87.5)	.26
	Tablet or other portable wireless computer	125 (63.5)	104 (66.2)	21 (52.5)	.11
Child activities on devices (yes)[a]					
	Remote learning	122 (61.9)	97 (61.8)	25 (62.5)	.93
	Entertainment (eg, YouTube, games)	170 (86.3)	136 (86.6)	34 (85.0)	.79
	Communication with family and friends	121 (61.4)	98 (62.4)	23 (57.5)	.57
Types of internet access at home (yes)[a]					
	Cell phone data plan for a smartphone or other mobile device	140 (71.1)	117 (74.5)	23 (57.5)	.03
	High-speed internet service (eg, cable, fiber optic, DSL[b] service)	165 (83.8)	138 (87.9)	27 (67.5)	.002
	Satellite internet service[c]	16 (8.1)	9 (5.7)	7 (17.5)	.02
	Some other service[c]	5 (2.5)	2 (1.3)	3 (7.5)	.06
Concern about paying for internet at home during the COVID-19 pandemic					.046
	A lot/some	111 (56.3)	83 (52.9)	28 (70.0)	
	Not too much/not at all	77 (39.1)	68 (43.3)	9 (22.5)	
	Do not have to pay for internet	9 (4.6)	6 (3.8)	3 (7.5)	
Concern about data privacy					.01
	A lot/some	141 (71.6)	106 (67.5)	35 (87.5)	
	Not too much/not at all	56 (28.4)	51 (32.5)	5 (12.5)	
Interest in technology for managing your child's asthma (n=196)					.29
	A lot/some	154 (78.6)	125 (80.1)	29 (72.5)	
	Not too much/not at all	42 (21.4)	31 (19.9)	11 (27.5)	

[a]These questions asked participants to select all that apply.

[b]DSL: digital subscriber line.

[c]Fisher exact test was used for comparing English- and Spanish-speaking participants due to the small sample responses.

English-speaking parents (68/157, 43.3%) were less likely to have concerns about paying for internet and cell phone service during the pandemic than Spanish-speaking parents (9/40, 23%; *P*=.02). English-speaking parents (106/157, 67.5%) were also less likely to have concerns about data privacy than Spanish-speaking parents (35/40, 88%; *P*=.01). There were no statistically significant differences by language in interest in technology use in asthma care (*P*=.29). In multivariable regression, the associations between having high-speed internet service (adjusted odds ratio [aOR] 0.5, 95% CI 0.2-1.2; *P*=.12) and concern about paying for internet at home (aOR 1.2, 95% CI 0.5-2.8; *P*=.60) with parent language were not significant after adjusting for household income (Table 3). Concerns about data privacy by language remained statistically significant after adjusting for household income (aOR 3.2, 95% CI 1.0-9.7; *P*=.04).

Table . Associations between technology-related perceptions and language (adjusted for income status).

	Spanish, adjusted odds ratio (95% CI)	*P* value
Has high-speed internet service (eg, cable, fiber optic, or DSL[a] service)	0.5 (0.2-1.2)	.12
Concern about paying for internet at home during COVID-19 pandemic[b]	1.2 (0.5-2.8)	.60
Concern about data privacy	3.2 (1.0-9.7)	.04

[a]DSL: digital subscriber line.

[b]The answers were coded as 0 for "not too much/at all/do not have to pay" and 1 for "a lot/some." The referent group for language was English.

Digital Literacy

In an assessment of digital literacy, many of the parents knew how to find helpful health resources on the internet (86/194, 44.3%) and used the internet to answer their health questions (83/196, 42.4%), but only 26.8% (52/194) felt that they could identify high-quality resources from low-quality ones on the internet, and 20.4% (40/196) of respondents felt confident using the information to make health decisions (Figure 1). When examining median eHealth scores, they were significantly different by parent race ($P<.001$), income (categorized as those above and below an estimated annual household income of US $50,000; $P<.001$), education level ($P<.001$), and parent language ($P<.001$; Table 4).

Figure 1. Participant responses to digital health literacy items (N=197).

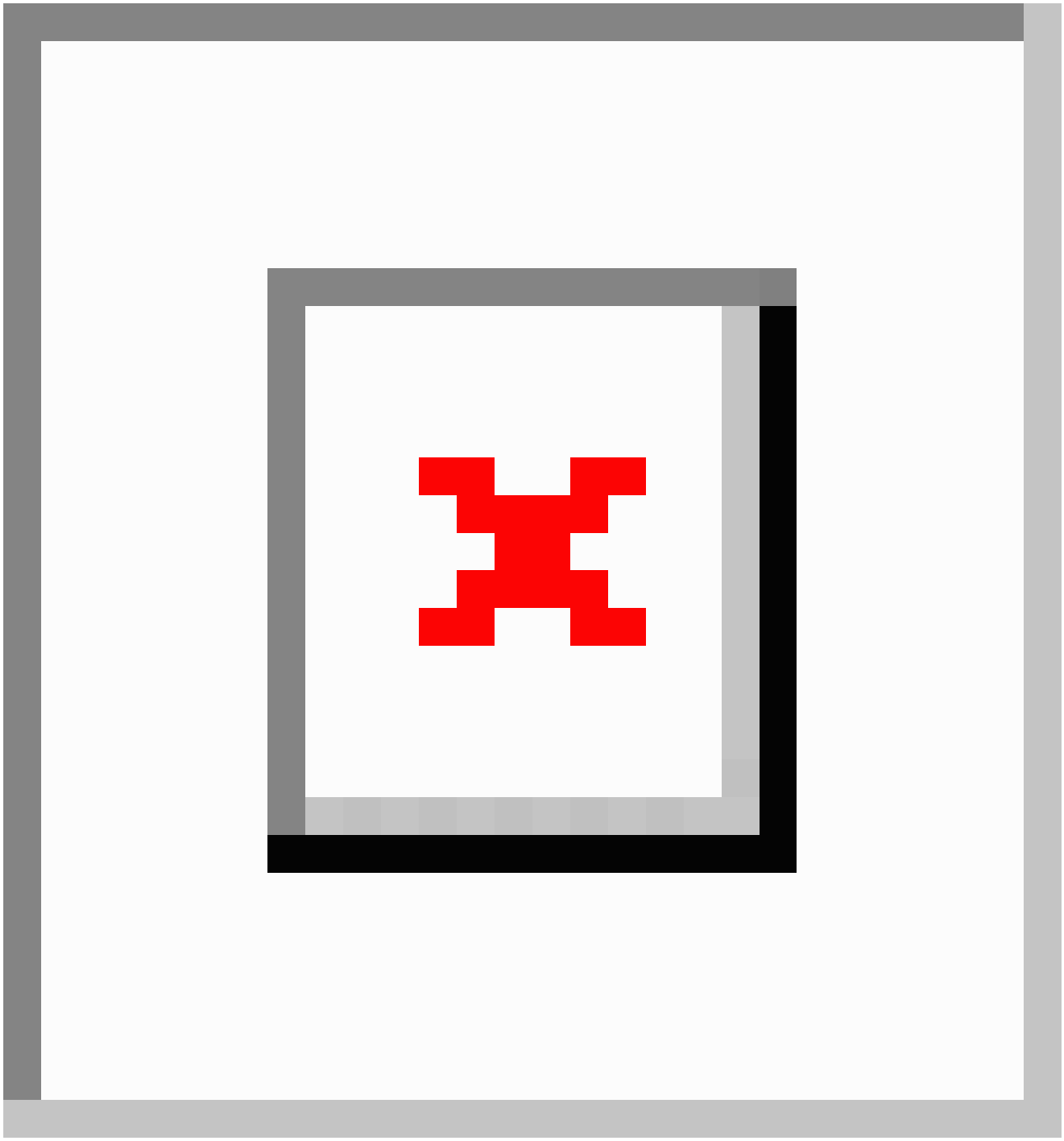

Table . Association between digital literacy and race, ethnicity, income, education level, and language.

		eHealth score, median (IQR)	*P* value
Overall sample		32 (26-37)	N/A[a]
Parent race			<.001
	Black	32 (27-38)	
	White	33 (29-39)	
	Other (Asian, American Indian/Alaskan Native, Hawaiian/Pacific Islander)	30 (24-33)	
Parent ethnicity Hispanic/Latino/Latina			.09
	Yes	31 (25-35)	
	No	32 (27-38)	
Income (US $)			<.001
	<50,000	31 (25-37)	
	≥50,000	33 (30-40)	
Parent education			<.001
	High school or less	28 (24-32)	
	Any college or more	33 (30-39)	
Parent language			<.001
	English	32 (28-38)	
	Spanish	26 (18-31)	

[a]N/A: not applicable.

Discussion

Principal Findings

This exploratory descriptive study uniquely examined and highlighted the significant differences in technology-related characteristics between English- and Spanish-speaking parents among households with children with asthma. Spanish-speaking parents were less likely to report having high-speed internet and had higher concerns about paying for the internet during the pandemic, although these findings were not significant when adjusted for income status. In the adjusted models, Spanish-speaking parents remained more likely to report concern about data privacy when using technology for their child's health. These findings are crucial in aiding the design and implementation of digital health care for pediatric patients and for prioritizing resources and the concern of parents to ensure the equitable use of these tools by families.

Although some technology differences might be related to economic status, they might be also associated with other important factors that shape families' interests and capacity to use digital tools in asthma management [28-30]. The differences in digital connectivity in the household, internet affordability, perceptions of data privacy, and digital literacy have a potential influence on how families might engage with asthma digital technology. The findings emphasized the need for understanding which characteristics might be potential facilitators or barriers to using digital tools in pediatric asthma clinical care.

Knowing the household resources for digital connectivity was critical for understanding families' access to digital health tools. Asthma predominantly affects those in low socioeconomic statuses, and digital health equity has become an increasing issue for those in historically marginalized communities as technology use has expanded [12,18]. Our results were similar to national trends that found nearly 90% of households possessed a smartphone, and there were no significant differences between households for smartphone and tablet ownership [31]. However, racial and ethnic disparities in the types of internet access, reported by the Pew Research Center, were also evident in the parent's chosen language in our results. The national survey in 2021 found that Hispanic adults were less likely to have a home broadband connection and more likely to report smartphone-only internet [31]. Since most Spanish-speaking parents also identified as Hispanic or Latino/Latina in our study, we found similar patterns of fewer Spanish-speaking parents owning a smartphone data plan or high-speed internet service at home than English-speaking parents. The differences in digital connectivity by parent language could be related to affordability and income; although for parents with school-aged children in public schools, there was a program for no-cost internet [32]. Another barrier might also be the lack of high-speed broadband services in neighborhoods where these families live [33,34].

An additional factor shaping differing technology characteristics might be digital literacy. The "digital literacy" term has been interchangeably used with eHealth literacy but was broadly defined as "an individual's ability to access, understand, and engage with digital healthcare materials or technology to

contribute to quality of life." [23,24] The eHEALS is the most widely used eHealth literacy measurement available in different languages and for different age groups [22,35].

Our findings showed significant associations with socioeconomic status and other social determinants of health, like race, income level, education level, and preferred parent language. Since eHealth, or digital literacy, has theoretical foundations in health literacy and self-efficacy, these findings were not surprising. The eHEALS scores mostly varied in the 30s within a potential range of 8 to 40. The differences in median eHEALS scores were largest by parent education level and preferred language in our study, but the aggregate eHEALS scores were similar to previous studies of older adults with chronic disease who had familiarity with health care or with using web-based resources [25,36,37]. While the variation of eHEALS scores was minimal in our study, other literature has emphasized the eHEALS' use longitudinally to evaluate whether exposure to digital health interventions improves participants' scores. Using eHEALS or other assessments of digital literacy might be a helpful way to prioritize resources for supporting patients' use of technology in clinical care [38].

The findings' implications for our clinical population are important. While having high-speed internet and concerns about paying for internet were no longer significant in the adjusted model controlling for household income, concerns about data privacy remained significant by language. Aside from access barriers to digital engagement, patients might have differing views on why they find using digital tools valuable in health care and their comfort with what, how, and why health information is shared. For example, in an SMS text message–based mental health intervention, researchers found that English speakers reported increased introspection with the intervention, but Spanish speakers highlighted feelings of social support [17]. While we did not evaluate motivations for engaging in digital health tools in this study, ensuring that our digital interventions align with why patients might engage with them is necessary for sustaining digital health approaches [39].

Limitations

There are limitations to this study. This was a single health system study of patients recruited from pediatric pulmonary clinics and may not be generalizable to patients with asthma at other institutions or patients not managed by a specialist. Although eHEALS is the most used validated measure for digital literacy, the questions focus on a person's familiarity with internet use and navigation, which may not be indicative of other skills around digital literacy that have evolved with the use of smartphones and mobile apps. Given the limited sample size, we also could not use a multivariable model to evaluate for confounding between parent language, income level, and parent education level in our study population.

Conclusions

Our study found that the integration of digital tools into health care will potentially require adaptations to improve access to digital devices, resources for high-quality digital connectivity, and assistance for navigating digital tools for this patient population. Examining and comparing these factors to support the equitable use of digital tools in asthma care is necessary to ensure that our socioeconomically and language-diverse populations with asthma receive high-quality asthma care and support for self-management.

Acknowledgments

We are grateful to the patients, clinic staff, and health providers who supported this study. This study was supported by the Agency for Healthcare Research and Quality (3K12HS026385-03S1). The content is solely the responsibility of the authors and does not necessarily represent the official views of the Agency for Healthcare Research and Quality.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Characteristics of parent/caregiver and child by survey participation type (N=197).
[DOCX File, 18 KB - pediatrics_v6i1e48822_app1.docx]

Multimedia Appendix 2
Survey instrument.
[DOCX File, 23 KB - pediatrics_v6i1e48822_app2.docx]

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Abbreviations

aOR: adjusted odds ratio
eHEALS: eHealth Literacy Scale
***ICD-10*:** *International Classification of Diseases, Tenth Revision*

Edited by S Badawy; submitted 24.05.23; peer-reviewed by IJ Wang, K Kostyrka-Allchorne; revised version received 27.09.23; accepted 16.10.23; published 29.11.23.

Please cite as:
Kan K, Morales L, Shah A, Simmons E, Barrera L, Massey L, List G, Gupta RS
Digital Technology Characteristics and Literacy Among Families With Children With Asthma: Cross-Sectional Study
JMIR Pediatr Parent 2023;6:e48822
URL: https://pediatrics.jmir.org/2023/1/e48822
doi:10.2196/48822

Caregivers' Perceptions, Needs, and Data Sharing Concerns in mHealth Research on Pediatric Asthma: Cross-Sectional Survey Study

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Related Article:

This is a corrected version. See correction statement: https://pediatrics.jmir.org/2024/1/e56046

Abstract

Background: Pediatric asthma is the most common chronic respiratory disease of childhood. Caregivers often report lacking knowledge in several aspects of asthma management at home. Although the use of mobile health (mHealth) tools, such as mobile apps, could facilitate asthma self-management and, simultaneously, the collection of data for research, few studies have explored the features that caregivers would like to see in such a tool and their perceptions on data sharing.

Objective: This study evaluates caregivers' perceived knowledge gaps in asthma management; their perceptions of certain features and resources that should be included in a potential mobile app; and any concerns that they may have regarding data sharing for research, including privacy and security concerns.

Methods: In this cross-sectional study, we surveyed 200 caregivers of children (aged 1-13 y) with asthma who were followed at a pediatric tertiary care center in Montreal, Canada. Anonymous data were collected through the institutional web-based survey platform. We collected the participants' answers by using a 5-category Likert scale ("completely agree," "agree," "neither agree nor disagree," "disagree," and "completely disagree"), multiple-choice questions, and free-text questions on the abovementioned topics. Descriptive statistics were performed, and answers were compared between caregivers of preschool-aged children and caregivers of school-aged children.

Results: Participating children's mean age was 5.9 (SD 3.4) years, with 54% (108/200) aged ≤5 years and 46% (92/200) aged >6 years. Overall, caregivers reported having adequate knowledge about asthma and asthma self-management. Nonetheless, they identified several desirable features for a mobile app focused on asthma self-management. The most frequently identified features included receiving alerts about environmental triggers of asthma (153/199, 76.9%), having videos that demonstrate symptoms of asthma (133/199, 66.8%), and being able to log children's asthma action plans in the app (133/199, 66.8%). Interestingly, more caregivers of preschool-aged children preferred textual information when compared to caregivers of school-aged children (textual information for explaining asthma: P=.008; textual information for the symptoms of asthma: P=.005). Caregivers were generally highly in favor of sharing data collected through a mobile app for research.

Conclusions: Caregivers of children with asthma in our study identified several desirable educational and interactive features that they wanted to have in a mobile app for asthma self-management. These findings provide a foundation for designing and developing mHealth tools that are relevant to caregivers of children with asthma.

(JMIR Pediatr Parent 2023;6:e49521) doi:10.2196/49521

KEYWORDS

asthma; mHealth; mobile health; app; application; apps; applications; pediatrics; caregivers; knowledge translation; cross-sectional; survey; surveys; respiratory; pulmonary; lung; pediatric; data sharing; information sharing; privacy; usability; confidentiality; child; children; caregiver; caregiving; patient knowledge

Introduction

Asthma is a chronic pulmonary inflammatory disorder that affects more than 262 million people of all ages around the world [1], imposing a great burden on patients and society. Among all individuals with asthma, children have the highest rates of asthma-related emergency department visits [2]. Furthermore, asthma can persist until adulthood and has been associated with reduced long-term lung function [3,4]. Therefore, the importance of early diagnosis and management lies in the potential maximization of lung function and reduction of asthma-related morbidity [5]. Moreover, optimal asthma self-management can help prevent unscheduled care, symptom exacerbations, and school and work absences, in addition to helping improve the overall quality of life.

One aspect of optimal asthma self-management is having the necessary knowledge and ability to recognize symptoms. Several studies have explored parents' perceptions of their children's asthma and the gaps in their knowledge of the pathology and management of asthma [6-9]. Although targeted education is delivered by asthma educators and health professionals, several gaps remain in caregivers' knowledge of their children's asthma, which have resulted in many caregivers believing myths about asthma, such as the long-term usage of corticosteroids having a negative impact on cardiac function and dependence [10]. Parents also feel a psychological weight as the caregivers and are often hypervigilant due to the unpredictability of the symptoms of asthma exacerbation [11].

There is thus a need for an effective and accessible tool that can support caregivers in the management of their children's asthma, particularly in between visits with their health professionals. Information-based technologies can serve as good tools for enhancing parents' knowledge of their children's asthma, thereby enabling them to better manage the condition [12]. In particular, the omnipresence of mobile and wireless technologies has driven changes not only in society's daily life but also in the health care system. In 2017, health apps were downloaded about 3.7 billion times [13], with more than 325,000 health apps available across mobile platforms. *Mobile health* (mHealth) is a term that refers to the "use of mobile phones and other wireless technology in medical care" [14]. Since its introduction into the health care system, many studies evaluating the effects of mHealth have mostly reported positive results with regard to the promotion of self-management, though most of these studies focus on adult patients. For example, a study that was conducted in adult outpatient asthma clinics showed that mobile-based interactive intervention improves pulmonary function, quality of life, asthma symptoms, and treatment adherence while reducing rates of acute exacerbations [15]. mHealth technologies can also help health professionals track patients' progress and symptoms in order to adapt treatment plans, which can in turn reduce adverse outcomes. mHealth benefits have also been studied for nonrespiratory chronic conditions; such studies demonstrated that mHealth technologies were mostly positively rated in terms of usefulness in the management of the condition, as they increased the patients' autonomy by making them actors in their own health [16,17].

Although mHealth is already serving a large population, pediatric conditions, including childhood asthma, are commonly neglected when it comes to mHealth technology [18]. Furthermore, the needs of caregivers of children with asthma and whether these needs differ across children of different ages are unknown. Additionally, we could not identify existing mHealth apps for pediatric asthma that explicitly mention that caregivers' perceptions and needs were taken into account during app development. In order to develop a useful tool for caregivers, it is important to explore the gaps that they believe are present in their knowledge or in their daily routine (ie, those that prevent them from achieving optimal asthma management).

In this study, we assessed caregivers of children (aged 1-13 y) with asthma and their perspectives on using mHealth to facilitate asthma management. Specifically, we surveyed caregivers on their perceived knowledge gaps in asthma management, their perceptions of certain features and resources that should be included in a potential mobile app, and any concerns that they may have regarding data sharing specifically for research. This study provides a foundation for designing and cocreating future mHealth tools for childhood asthma self-management.

Methods

Study Design

We conducted a cross-sectional survey of caregivers of children with asthma who were followed at the Centre Hospitalier Universitaire (CHU) Sainte-Justine in Quebec, Canada. This study was conducted from September 1, 2019, to July 1, 2020.

Ethical Considerations

This study was approved by the CHU Sainte-Justine Research Ethics Board (project number: 2020-2664). Informed consent was obtained with a research information and consent form, which was administered to and signed by participants at the beginning of the survey. Submitted data were anonymous.

Participants and Procedures

We included the caregivers of (1) children aged 1 to 13 years, inclusively, and (2) children with physician-diagnosed asthma or suspicion of asthma. There were no exclusion criteria. We identified eligible patients from the respiratory medicine and asthma clinics, inpatient units, and pulmonary function test laboratory of the CHU Sainte-Justine. Eligible families were approached in person or contacted by phone, and they were asked to fill in the web-based survey.

Data Collection and Questionnaire

The survey was administered via the CHU Sainte-Justine LimeSurvey platform (LimeSurvey GmbH). We asked participants to fill in a questionnaire to assess the caregivers' (1) knowledge on asthma pathogenesis, symptom recognition, and controller and rescue medication use; (2) perceptions on features that they would like to see in a mobile app for facilitating asthma self-management; and (3) openness to using a mobile app for research purposes and their concerns. We constructed the survey based on the themes we identified as important in the mHealth and asthma fields (knowledge gaps, desirable features, mHealth use in research, and data sharing

concerns). These themes were based on existing literature and the gaps we identified. We collected the participants' answers by using a 5-category Likert scale ("completely agree," "agree," "neither agree nor disagree," "disagree," and "completely disagree"), multiple-choice questions, and free-text questions. We also collected data on the children's age, sex, and previous asthma history (hospitalizations and emergency department visits in the past year).

Sample Size and Data Analysis

Our target sample size was 200 caregivers, which would allow for the description of responses with a 7% margin of error at a 95% confidence level. We performed a descriptive analysis of the participants' baseline characteristics and each item in the questionnaire, using frequencies and percentages. Additionally, we compared the perceptions and needs of caregivers of preschool-aged children to those of caregivers of school-aged children, using the chi-square test for proportions and the nonparametric Kolmogorov-Smirnov test for distributions, such as Likert scale distributions.

Results

Participants

A total of 200 caregivers completed the survey, although some questions were left unanswered by some participants. The mean age of the children for whom the parents answered the survey was 5.9 (SD 3.4) years, and most children were male (142/200, 71%)—a proportion that reflects the sex distribution of pediatric asthma in the general population (Table 1). The majority of children were not hospitalized over the past year (146/199, 73.4%), but more than half reported at least 1 asthma-related emergency department visit over the past year (106/199, 53.3%).

Table . Baseline characteristics of children for whom the parents answered the survey (N=200).

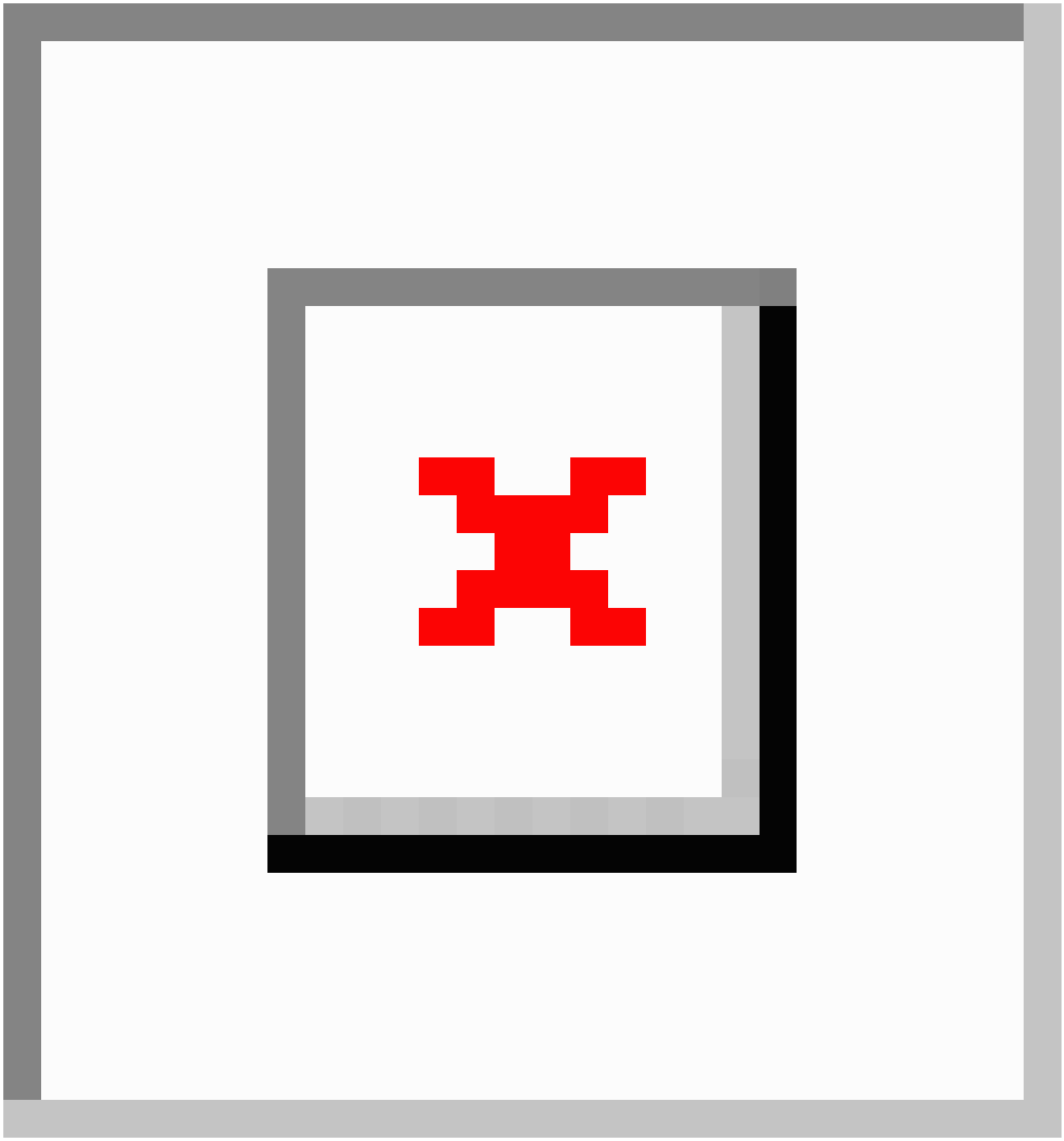
Participant characteristics		Value
Age (y), mean (SD)		5.9 (3.4)
Age category, n (%)		
	Preschool-age (≤5 y)	108 (54)
	School-age (6-13 y)	92 (46)
Sex, n (%)		
	Male	142 (71)
	Female	58 (29)
Number of asthma-related emergency department visits in the past year, n (%[a])		
	None	93 (46.7)
	1	38 (19.1)
	2	28 (14.1)
	≥3	40 (20.1)
Number of asthma-related hospitalizations in the past year, n (%[a])		
	None	146 (73.4)
	1	31 (15.6)
	2	14 (7)
	≥3	8 (4)

[a]Percentages were calculated with a denominator (N) of 199, as 1 caregiver did not answer the question.

Caregivers' Perceived Asthma Knowledge

We first assessed the caregivers' perceived knowledge on asthma and asthma management (Figure 1). The majority of caregivers strongly agreed or agreed that they understood the purpose of asthma medication (191/197, 97%), could explain what asthma is (168/197, 85.3%), and could recognize asthma symptoms (181/196, 92.3%). Caregivers reported that they remembered to give their children's medicine on time (176/194, 90.7%), renewed their prescriptions (176/196, 89.8%), and knew the steps to follow during an asthma exacerbation (157/196, 80.1%). In terms of asthma management, most participants reported that they would be able to identify the triggers of their children's asthma (150/196, 76.5%). Caregivers were comfortable with the methods of administration of their children's treatment (182/200, 91%) and believed that their children's asthma was well controlled (155/200, 77.5%). Interestingly, a big proportion of caregivers were curious about whether there were alternative therapies for asthma (151/200, 75.5%), such as homeopathy and acupuncture. As expected for this study's sample of young children, few children managed their asthma on their own.

Figure 1. Caregivers' perceived asthma knowledge. N/A: not applicable.



Desirable Features in a Mobile App Focused on Asthma Self-Management

We asked caregivers to identify mobile app features that would be helpful in managing their children's asthma and would address their needs (Table 2). Several options were listed (more than 1 could be chosen), along with a free-text option. Receiving alerts about environmental triggers of asthma, such as excessive heat and high pollen levels, was the most frequently identified feature (153/199, 76.9%). Caregivers were also interested in videos demonstrating the symptoms of asthma (133/199, 66.8%) and in the personalization of the app to their own children's situations, which included logging their children's asthma action plans in the app (133/199, 66.8%). Other features that caregivers perceived as useful were charts of their children's symptoms (131/199, 65.8%), a short questionnaire that could be completed regularly to monitor asthma symptoms (123/199, 61.8%), information on new asthma studies (121/199, 60.8%), and reminders to renew inhalers (116/199, 58.3%). Less commonly identified app features among caregivers were textual information that explains inhaler techniques (66/199, 33.2%) and what asthma is (71/199, 35.7%) and a platform to interact with other parents of children with asthma (77/199, 38.7%).

Table . Desirable features in a mobile app for asthma self-management identified by caregivers (N=199).

Features[a]	Caregivers, n (%)
Alerts about asthma triggers in the environment (eg, excessive humidity, high pollen count, etc)	153 (76.9)
Video demonstrating the symptoms of asthma (indrawing, wheezing, etc)	133 (66.8)
The ability to log children's asthma action plans in the app	133 (66.8)
Charts of children's asthma symptoms	131 (65.8)
A questionnaire (5-7 questions) to be completed regularly in order to be able to monitor children's asthma symptoms	123 (61.8)
Information on new studies on asthma	121 (60.8)
Reminders to renew pumps	116 (58.3)
Symptom diary (to be completed manually)	113 (56.8)
Reminders to administer the pumps every day	106 (53.3)
Text explaining the symptoms of asthma	99 (49.7)
Video demonstrating the techniques of pumps' usage	85 (42.7)
Video explaining what asthma is	83 (41.7)
Internet links for more information on asthma	78 (39.2)
A platform to interact with other parents of children with asthma	77 (38.7)
Text that explains what asthma is	71 (35.7)
Text explaining the techniques of pumps' usage	66 (33.2)

[a]More than 1 feature could be chosen by caregivers.

Participants also suggested other needs that were not included in the questionnaire, notably the need for a mobile app adapted to older children and adolescents that could help them develop skills for managing their own asthma and medications. Other caregivers also mentioned the need for a reminder system for upcoming medical appointments.

Stratifying the answers as those from caregivers of preschool-aged children (≤5 y) and those from caregivers of school-aged children (>5 y) showed differences that were statistically significant (Table 3). Specifically, more caregivers of preschool-aged children with asthma than caregivers of school-aged children deemed that a symptom diary (to be completed manually; P=.04), text that explains what asthma is (P=.008), and text that explains the symptoms of asthma (P=.005) would be useful in a mobile app.

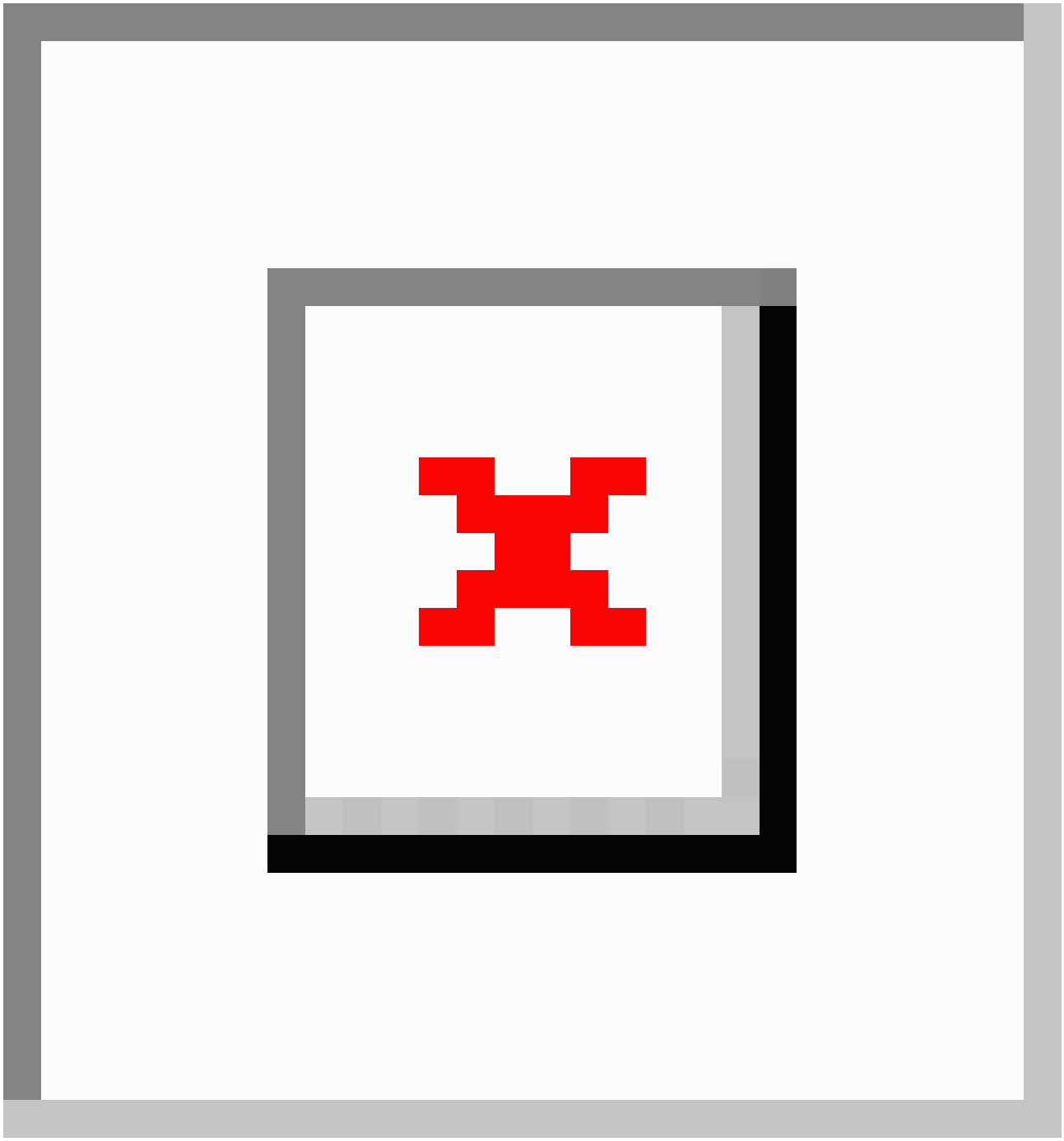
Table . Desirable mobile app features identified by caregivers of preschool-aged children (≤5 y) and school-aged children (>5 y).

Feature	Caregivers of preschool-aged children (n=108), n (%)	Caregivers of school-aged children (n=92), n (%)	*P* value
Questionnaire to be completed regularly to monitor children's asthma symptoms	72 (66.7)	51 (55.4)	.16
Symptom diary	69 (63.9)	44 (47.8)	.04
Charts of children's asthma symptoms	70 (64.8)	61 (66.3)	.86
Reminders to administer the pumps every day	58 (53.7)	48 (52.2)	.99
Reminders to renew pumps	65 (60.2)	51 (55.4)	.66
Text that explains what asthma is	48 (44.4)	23 (25)	.008
Text explaining the symptoms of asthma	64 (59.3)	35 (38)	.005
Text explaining the techniques of pumps' usage	40 (37)	26 (28.3)	.27
Video explaining what asthma is	46 (42.3)	37 (40.2)	.90
Video demonstrating the symptoms of asthma	77 (71.3)	56 (60.9)	.19
Video demonstrating the techniques of pumps' usage	47 (43.5)	38 (41.3)	.91
The ability to log children's asthma action plans in the app	75 (69.4)	58 (63)	.48
Alerts about environmental asthma triggers	83 (76.9)	70 (76.1)	.99
Internet links for more information on asthma	44 (40.7)	34 (37)	.73
Information on new studies on asthma	70 (64.8)	51 (55.4)	.26
Platform to interact with other parents of children with asthma	46 (42.6)	31 (33.7)	.28

Using Personal Data Through mHealth for Research

We evaluated the caregivers' perceptions on sharing personal data, that is, those entered into a mobile app, with researchers via a secure portal, prefacing that the data would be used to create a database that would allow researchers to carry out projects that aim to improve the management of asthma in children (Figure 2). Most caregivers understood the usefulness of sharing their data for research purposes (186/200, 93%). The majority were comfortable with their data being used by researchers (180/200, 90%) and reported that they would agree to share their data anonymously for research purposes (175/200, 87.5%). Most caregivers were also interested in participating in asthma research projects (151/200, 75.5%) and reported that they would like to be informed of research projects using their data through the app (148/200, 74%). Few caregivers deemed data breach possibilities (58/200, 29%) and the fact that their data would be used for research purposes (11/200, 5.5%) as deterrents for using the mobile tool. We also compared caregivers' perceptions on the use of personal data for research between caregivers of school-aged children and caregivers of preschool-aged children, which did not show statistically significant between-group differences (*P* values for all responses were <.05).

Figure 2. Caregivers' perceptions on the use of data through mHealth for research. N/A: not applicable.



Discussion

Principal Results

Our study identified features that caregivers of children with asthma would like to see in an mHealth tool, specifically a mobile app, for asthma management despite their perception of having good knowledge about many aspects of asthma. The highly desirable features have personalizable or interactive components. Additionally, we found that some desired features differed between caregivers of preschool-aged children and caregivers of school-aged children. We also found that the use of data collected through a mobile app for research was highly acceptable among caregivers.

Comparison With Prior Work

Previous studies documented that caregivers perceived lacking knowledge about asthma pathogenesis [6-8], the medications used in their children's asthma plans [8], the main triggers of asthma [9] and how to avoid them, and recommended changes that they should make at home and in their children's environment to avoid any exacerbations [9]. The perception of lack of knowledge can lead to suboptimal adherence [9], which can result in adverse health events. Our study contrasts with previous literature, as most caregivers reported having good knowledge of asthma. This contrast may be related to the nature of our sample, which consisted of caregivers of children who were followed at a tertiary pediatric care center. However, the caregivers still identified several educational features that they

would like to see in a mobile app for asthma. For example, while 92.3% (181/196) of caregivers strongly agreed or agreed that they could recognize asthma symptoms when their children exhibited them, 66.8% (133/199) reported that they would like to have a video explaining asthma symptoms in the mobile app. This discordance suggests that in addition to identifying knowledge gaps, studies should directly assess caregivers' perspectives on their needs and their proposed solutions.

Interestingly, a majority of caregivers wanted information on alternative therapies for the management of asthma (151/200, 75.5%). This corroborates the existing literature; one study found that parents who wanted to explore alternative therapies denoted that health care professionals had little or no knowledge of them [19]. Although there is currently no evidence-based alternative therapy for asthma, our findings highlight that this is an important asthma management–related issue to discuss with caregivers.

Few mobile apps target caregivers of children with asthma or the pediatric population. Although mHealth can be useful in improving health outcomes in the pediatric population, interventions produce larger changes when caregivers are involved rather than when only children are targeted [20]. Thus, it is essential to assess the caregivers' needs when designing a mobile tool to ensure its relevance. In a study on parents' and clinicians' preferences for a mobile app focused on asthma self-management in adolescents, parents identified the ability to input symptoms into a diary and the ability to generate reports for the physician as the most useful features [21]. Reminder messages for medication and prescription renewals were also features that were appreciated by parents, as they encouraged medication adherence. Although the app targeted adolescents, the study gave an overview of parental needs. In our study, several desirable features were identified by caregivers for an app that would target them. These included reminders for medication administration and renewal, environmental alerts that are relevant to asthma, the ability to log symptoms and children's asthma action plans, and evaluations of asthma control. Many of these features can only be integrated in a mobile or digital tool and cannot be made available through traditional educational sessions or paper materials, underlining the potential usefulness of an mHealth tool. One common theme across these features is the desire for interactivity, which is a key component of mHealth. A second theme is improving asthma management by tracking symptoms and being aware of potential triggers. mHealth tools can readily respond to these needs by providing real-time alerts and feedback to caregivers and by sending programmed medication-related reminders.

Interestingly, we found that some desired features differed between caregivers of preschool-aged children and caregivers of school-aged children, mostly with regard to the mode of education information delivery. More caregivers of preschool-aged children reported that they would like to see textual information on asthma. Although we could not find existing literature to explain this difference in asthma or chronic disease education, our findings suggest that the mode of knowledge transmission is important and has to be considered while creating a mobile tool.

In addition to facilitating knowledge sharing and tracking health, mHealth can be a powerful tool for research. With the user's consent, information entered into an app can provide valuable, real-world, longitudinal data on patients with different conditions. For example, these data can be used to conduct observational studies on predictors of adverse outcomes, which in turn could result in targeted interventions and improved management. Our findings suggest that caregivers welcomed research projects that are conducted through a mobile app and were open to sharing their data for research. The majority of caregivers were not deterred by a fear of a possible data breach (142/200, 71%) and were comfortable with sharing data with industrial researchers (156/200, 78%). These perspectives can be leveraged to design research projects around patient-centered or caregiver-centered mobile tools.

Strengths and Limitations

The relatively large sample size of our study allowed us to capture a variety of opinions accurately. Additionally, by including caregivers of preschool-aged children and caregivers of school-aged children, we were able to compare the needs of different populations. Our study also has noteworthy limitations. First, our study surveyed caregivers of children who were followed or treated at a tertiary care center, which may limit the generalizability of our results to children with milder asthma. However, this study population also represents the sickest children with asthma, who may benefit the most from achieving improved self-management through a mobile tool. Second, we assessed only the caregivers' perceptions of asthma knowledge. Caregiver knowledge gaps have been extensively documented in the literature. Although this was not within the scope of this study, these knowledge gaps should be also be addressed when creating an educational tool. Third, given the lack of a standardized survey for assessing parental perceptions of mHealth in asthma management, we constructed our survey based on the knowledge gaps that we identified based on existing literature and our team's clinical experience. Although we checked survey responses for errors and consistency (eg, between items such as "I understand the purpose of asthma medication" and "I know the role of the different medications my child takes for asthma"), the psychometric properties of the survey have not been formally evaluated, and some specific topics may not have been addressed (eg, the use of graphical information). Fourth, given the design of this study, we did not conduct qualitative interviews with the parents, which could have provided a more complete understanding of parental perceptions and concerns. Finally, we did not assess the preferences and needs of adolescents. As they represent a distinct population and are more likely to independently self-manage their asthma, it is important to assess their needs through a survey that specifically targets them.

Conclusions

Our study found that despite caregivers perceiving that they have good knowledge of asthma and its management, they still identified several desirable educational and interactive features that they wanted to have in a mobile app for asthma self-management. This highlights the potential role that mHealth can play in asthma self-management. Additionally, caregivers

were enthusiastic about sharing their data through a mobile app for research. By identifying these preferences and needs, our findings provide a foundation and starting point for co-designing and codeveloping mHealth tools, so that they are relevant to caregivers of children with asthma.

Acknowledgments

We would like to thank the caregivers who participated in this survey.

Authors' Contributions

GM contributed to the analysis and drafted the manuscript. MJA contributed to the study design and data collection. SMT contributed to the study design, data analysis and interpretation, and manuscript edits. All authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CHU: Centre Hospitalier Universitaire
mHealth: mobile health

Edited by S Badawy; submitted 15.06.23; peer-reviewed by J Hamid, P Singh; revised version received 11.10.23; accepted 12.10.23; published 19.12.23.

Please cite as:
Meng G, Jan Ali M, Tse SM
Caregivers' Perceptions, Needs, and Data Sharing Concerns in mHealth Research on Pediatric Asthma: Cross-Sectional Survey Study
JMIR Pediatr Parent 2023;6:e49521
URL: https://pediatrics.jmir.org/2023/1/e49521
doi:10.2196/49521

Original Paper

The Acceptability of Using Augmented Reality as a Mechanism to Engage Children in Asthma Inhaler Technique Training: Qualitative Interview Study With Deductive Thematic Analysis

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Abstract

Background: Inhaled medications or inhalers provide first-line pharmacotherapeutic treatment for patients with asthma for both acute symptomatic relief and long-term management to keep symptoms under control. A good technique requires only basic instruction and training; however, a recent study identified that 92% of children do not follow all correct steps when using inhalers. There is a growing interest in technology-enhanced asthma education, with evidence demonstrating improvements in knowledge and treatment adherence. Subsequently, there are calls to explore the role of technology-based solutions in improving asthma management and disease outcomes from public health experts, health professionals, and patients with asthma. Augmented reality (AR) technology is an information delivery mechanism with proven efficacy in educational settings. AR displays digital content in a real-world environment using the camera on a smartphone or tablet device to create an immersive learning experience.

Objective: The study aimed to evaluate the acceptability of AR as a mechanism for delivering asthma inhaler technique education from the perspective of children with asthma and their parents and health professionals, examined through the theoretical framework of acceptability (TFA).

Methods: An asthma education resource enhanced with AR technology was created to provide inhaler technique education to children. An iterative co-design process was undertaken with target end users for a qualitative evaluation. The participants were 8 to 12 years old with asthma, their caregivers, and health professionals who had experience in managing asthma. Qualitative data were obtained through semistructured one-on-one interviews. Deductive thematic analysis using TFA was undertaken using NVivo software 2020 to assess the acceptability of AR as a delivery modality for asthma inhaler technique education.

Results: Overall, 6 health care professionals, 5 asthmatic children, and 5 caregivers of children with asthma totaled a sample of 16. The use of AR in the asthma inhaler resource was found to be acceptable when responses were examined in accordance with TFA. Each of the 7 component constructs of TFA was coded throughout the 16 interviews, with *perceived effectiveness* (157 times) and *affective attitude* (63 times) coded most frequently. Positive responses included the intervention being accessible, easy to use, interesting, and fitting within the users' value systems. Negative responses included the need to maintain an interest in children and concerns about the loss of face-to-face interaction with health professionals.

Conclusions: AR appears to be an acceptable modality for delivering asthma education to children when explored using TFA constructs. Although some challenges were identified with the use of AR, the results were predominantly positive. Future designs

of asthma education interventions involving AR should consider the results of this study, and further research should focus on the feasibility, usability, and barriers and facilitators of behavior change to ensure the successful implementation and uptake of AR into clinical settings.

International Registered Report Identifier (IRRID): RR2-10.1177/16094069211042229

(JMIR Pediatr Parent 2023;6:e40231) doi:10.2196/40231

KEYWORDS

asthma; asthma education; pediatric asthma; augmented reality; mobile phone

Introduction

There are over 260 million cases of asthma worldwide, with the incidence and prevalence being higher in children than in adults [1,2]. Susceptible individuals can have symptoms of wheezing, coughing, and breathlessness [3,4]. If symptoms are poorly controlled in young people, it can lead to long-term effects, with the potential for pathological airway remodeling, impaired airway development, and possible reductions in maximal attainable lung function than those without asthma [2,5,6]. To minimize long-term airway damage, the use of inhaled medications (ie, inhalers) is the first-line treatment for both acute symptomatic relief and long-term asthma control in both children and adults [7,8]. Current guidelines state that inhaler technique education must be provided with satisfactory techniques demonstrated before the prescription of inhalers with the efficacy of education and training in improving techniques supported by a Cochrane systematic review [7,9].

Despite this, in recent studies where the asthma inhaler technique has been assessed in children, 42% of hospitalized patients have missed a critical step, and 92% of children aged 8-16 years do not properly follow all correct steps when using their inhaler [10-12]. This highlights the need to consider new approaches for educational interventions on inhaler techniques in young people. A recent nationwide survey of over 20,000 young Australians identified a 10 times greater likelihood of seeking web-based support over health professional advice to manage their stress, indicating their penchant toward technology-based solutions [13]. This preference for technology combined with the growing body of evidence suggesting that technology-delivered interventions and asthma education programs can improve knowledge, treatment adherence, and health outcomes in children with asthma highlights the need for using technology-based solutions for inhaler technique education in children to improve engagement and uptake and health outcomes [14-16]. The use of mobile technology–based solutions such as smartphones and tablet devices to deliver asthma education and self-management has also been explored in adults, with systematic reviews identifying improved quality of life and asthma control compared with routine care [17,18].

One relatively new digital solution is augmented reality (AR) defined as *technology which is able to superimpose computer-generated objects into a real-world setting so that the computer-generated objects seem to coexist in the same space in real time* and is one of the top novel technological innovations in the medical and health care industry [19,20]. They can be delivered via smartphones or tablets. It has the benefits of already having proven efficacy in other educational settings and as a behavioral change tool and would allow asthma inhaler technique education to be delivered via smartphones or tablets through videos and animations [21-26]. Given that more than 80% of children aged 5-17 years own at least one screen-based device in Australia, this suggests an appropriate and accessible delivery modality for asthma inhaler technique education [27]. Apart from 1 study showing an improved asthma inhaler technique limited by evaluation among a pediatric cohort without asthma, AR has not yet been explored in asthma education for children [28]. Research on the acceptability and awareness of this technology is paramount to informing future asthma educational interventions and their successful uptake. To address these gaps, this study aimed to evaluate the acceptability of AR as a mechanism for delivering asthma inhaler technique education.

Methods

Overview

An asthma inhaler technique education resource enhanced by AR technology delivered by a smartphone was co-designed for children with asthma, their caregivers, and health care professionals (HCPs) who treat asthma. Qualitative interviews based on the theoretical framework of acceptability (TFA) evaluated the acceptability of AR as a delivery mechanism. The development of TFA was described in 2017 by Sekhon et al [29] to address the lack of consistent definitions and measurements for acceptability, despite recommendations by the United Kingdom Medical Research Council that it be assessed in health care intervention development [30-33]. Acceptability has since been defined as "multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention" [34]. Since its development, TFA has been used in multiple studies and is an accepted framework for assessing the acceptability of health care interventions [29,35-40]. A prespecified protocol for this study was published in the Australian New Zealand Clinical Trials Registry (Trial ID: ACTRN12621000306819).

AR Intervention Development Process

To establish context for the acceptability evaluation of AR as a delivery mechanism for asthma education, a brief summary of its development is provided. The full development process will be discussed in more detail in future studies.

An iterative co-design process with target end users was undertaken to provide a deeper understanding of their

requirements for technology use and enable improvements in the prototype asthma inhaler technique resource [41,42]. The first cohort of participants interacted with an existing cystic fibrosis–enhanced AR educational resource to provide an example of how AR functions. Their feedback was used to create an asthma-specific AR-enhanced poster to provide education on inhaler techniques. This poster was used to trigger digital educational content through the smartphone or tablet app (Figure 1). This resource was presented to the next cohort of participants who provided feedback, which was again used to enhance the intervention before being presented to the final cohort for feedback. Co-design processes optimize the uptake of digital interventions in children; therefore, this process has been used for intervention development [43-45].

Figure 1. Paper-based poster triggering digital content on smartphone.

Participants and Recruitment

The participants included HCPs who managed asthma, children with asthma, and caregivers of children with asthma.

The inclusion criteria for HCPs included having worked in their profession (nursing, pediatric general medicine medical officers, general practitioners, respiratory specialists, pharmacists, and asthma educators) and having treated patients with asthma regularly for more than 12 months in the previous 5 years. The inclusion criteria in the prespecified protocol for children and adolescents with asthma were having a clinical diagnosis of asthma and being aged between 8 and 17 years. Parents and guardians of children with asthma were included if their child had a clinical diagnosis of asthma and was aged 8 to 17 years. Participants who were unable to provide consent or were non–English-speaking were excluded.

Recruitment was within a South Australian pediatric tertiary hospital, conducted by the primary investigator of the study who approached potential participants for screening. Participants were invited to participate in the study if they met the inclusion criteria and provided informed consent.

Participants were recruited from July 2021 until April 2022. Purposive sampling was intended; however, during recruitment, it became evident that this approach could not be strictly adhered to for representation across the age spectrum. This was owing to a combination of the demographics of children hospitalized for acute asthma treatment and minimization of face-to-face appointments or allowance of patients to attend hospital unless deemed medically necessary during the SARS-CoV-2 pandemic. This substantially diminished the available sample pool of older children. The inclusion criteria were changed halfway through the recruitment to children aged 8 to 12 years.

A target sample size of 15 to 20 participants was determined to achieve a large enough size to ensure sufficient breadth and depth of data but small enough to achieve meaningful analysis, which was a similar approach to other qualitative studies [46].

Interviews and Data Collection

Qualitative data were obtained through one-on-one interviews conducted with a trained interviewer. Semistructured moderator guides were used based on TFA to aid in specifically assessing acceptability within each group of participants. The beginning of the interview explored previous experiences with asthma education, the use of smartphone and tablet apps for health, and AR. Once previous awareness and experience were assessed, the interviewer demonstrated the AR intervention to the participants and allowed them to use it themselves. Further interview questions were then asked based on the participants' experiences of using it.

The interviews took approximately 20 to 40 minutes per participant and were audio-recorded. All the interviews were deidentified and transcribed using an automated transcription service. Interviews were check-backed and corrected by the primary investigator to ensure that they were verbatim. Transcripts were sent back to the participants to validate the content if required.

Statistical Analysis

Using TFA as a coding framework, deductive thematic analysis was performed using the NVivo software (QSR International) [47]. Two researchers (AO and either AH or DC) jointly coded the data into NVivo to improve interrater reliability, with any disagreements resolved through discussion. The 7 component constructs of TFA consisted of an informed coding scheme. The seven constructs and their definitions are as follows: (1) affective attitude—the individuals' feelings of the intervention; (2) burden—the amount of effort required to participate in the intervention; (3) perceived effectiveness—the extent to which the intervention is perceived as likely to achieve its purpose; (4) ethicality—the extent to which the intervention has a good fit with an individual's value system; (5) intervention coherence—the extent to which the participant understands the intervention and how it works; (6) opportunity costs—the extent to which benefits, profits, or values must be given up to engage in the intervention; and (7) self-efficacy—the participant's confidence that they can perform the behavior required to participate in the intervention. Affective attitude, burden, perceived effectiveness, and opportunity cost were also coded as *anticipated* or *experienced* on the basis of whether interview questions had been asked before the use of the intervention or after.

Ethics Approval

Ethics and governance approval was obtained from the Women's and Children's Hospital Human Research Ethics Committee on August 21, 2020 (HREC/20/WCHN/74), and acceptance of approval was obtained from the University of Adelaide on October 20, 2021. Informed consent was obtained from all participants before the interviews were taken.

Results

Participant Characteristics

Of the 16 potential participants, all were recruited and analyzed. There were 6 HCPs, 5 children with asthma, and 5 caregivers (Table 1).

HCPs were split equally among medical officers and nursing staff who had treated patients with asthma for at least 12 months in the previous 5 years. Two of the participants also had a previous asthma educator role, whereas the other had a pediatric medicine educator role within the ward in which they were working. Overall, 66% (4/6) of the HCPs were female, and the remaining were male. All HCPs reported treating asthma across multiple settings, including within the community, inpatient care, outpatient care, and the emergency department.

Patients with asthma and their caregivers mostly live in metropolitan settings. All patients with asthma were diagnosed by either a respiratory specialist or a general pediatrician. Sixty percent of patients with asthma were male, and 40% were female. All caregivers were female with a range of educational levels.

Table 1. Participant characteristics.

Characteristics	Health care professionals (n=6)	Children with asthma (n=5)	Caregivers of children with asthma (n=5)
Age (years), mean (SD)	34.33 (4.32)	9.8 (1.10)	41.8 (2.79)
Female sex, n	4	2	5
Mean duration of asthma diagnosis (years)	N/A[a]	4.77[b]	N/A
Metropolitan vs remote, n (reference: metropolitan)	N/A	4	4
Highest level of education of caregiver (tertiary:high school)	N/A	N/A	1:1[c]
Mean duration of treating asthma for health care professionals (years)	11.68	N/A	N/A
Occupation (medical professionals:nursing:other)	1:1:0	N/A	N/A

[a]N/A: not applicable.

[b]One unknown.

[c]One participant not disclosed.

Coding Results

Overview

All 7 TFA component constructs were coded throughout the 16 transcripts. The most frequently coded construct was *perceived effectiveness*, which was coded over double the number of occasions as the second most coded construct of *affective attitude*, which was coded 63 times. The remaining constructs were coded between 21 and 52 times (Figure 2).

Our findings are reported through a narrative synthesis with representative quotes for the 7 constructs of TFA. Quotes are followed by participant ID in parentheses (AC, asthmatic children; CG, caregivers of children with asthma; HP, health professionals). Table 2 expands the illustrative quotes for each construct.

Figure 2. Coding frequency. TFA: Theoretical framework of acceptability.

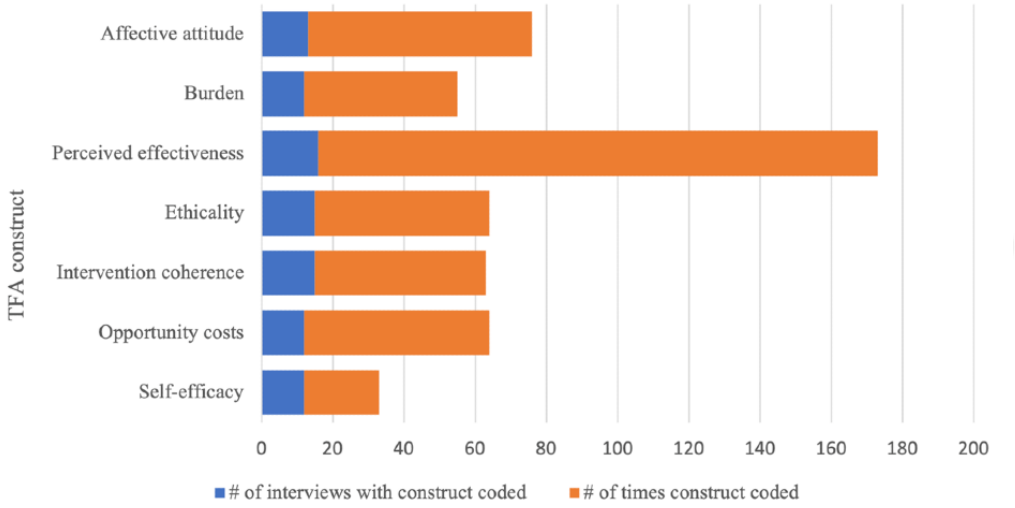

Table 2. Theoretical framework of acceptability (TFA) construct illustrative quotes from interviews.

TFA construct	Illustrative quotes
Perceived effectiveness	• Education in a different form, sort of like an interactive education or a, um, video setting, which might make it more engaging for the patient as well. [HP001] • I think it'll definitely add a component of something different and new to get them involved rather than just watching a video on a screen. [HP006] • It was very informative. [PA004]
Affective attitude	• Like if a kid's looking at a piece of paper and then you put your smartphone over it and it comes to life, that's pretty awesome. [HP002] • Pretty good, actually interesting. Cause, um, it would take a lot of coding and stuff to actually work on it. [CH002] • I used to think it…health apps are like boring and that stuff but virtual [augmented] reality is cool. [CH004] • Um, I think it's, it's, uh, it's a fantastic idea, uh, to present the information, um, in that format. Um, I think, I think the, uh, use of augmented reality is a novelty that kids would really connect with. [HP005]
Intervention coherence	• Um, it was just different to how I envisioned. Um, cool that you can hover over the, the images and then it triggers where you want to learn more from. [HP003]
Ethicality	• Obviously I would certainly be happy to show people how to access it and, um, you know, just show them that it is something fun and exciting to at least get them excited to then take home and, and be involved with at home. [HP006] • It would be really good if it goes ahead and it's become something that we can use…[HP002]
Self-efficacy	• Pretty easy to use. [CH001] • Easy to do, Just click. [PA003] • Easy to use. [CH003] • I think it was easy yeh. [HP006] • Um, definitely good that it's not hard to use. You kind of just go into the portal and then the videos come up, I kind of like that you have to move the phone. Um, and yeah. Seems to be pretty easy to use. [PA005]
Burden	• Um, I do wonder if like, especially for littler kids, if it wouldn't be exciting enough or interesting enough, like as an adult and probably as a teenager as well, that would be fine, but for the little ones it could potentially be boring. [HP001] • Also when it does slip back to the menu, not making them sit through it again cause they'll be like, if we want them to watch all of them. Then they'll be like 'oh we've seen this bit.' And then they'll just lose focus. [HP004] • I do wonder because um, you have, you have to hold the, uh, the, the phone or tablet up to review the video if, um, um, you know, if, if a kid's not able to do it for that long, that might affect your, uh, ability to educate. [HP005]
Opportunity cost	• Being able to actually have a hands-on with the puffer and spacer or, your airways or something like that. [HP003] • You haven't got someone there to answer your questions. So if like we, we are thinking of things and, and the feedback is there and whatever, and the parent, everyone's individual and everyone's got different backgrounds and different levels of understanding. And I guess the difference with education being provided here before you go home, 'have you got any questions?' We can answer them. [HP004] • I guess that's the only negative, is it's not real life. Like it's not, it is augmented reality, not reality. And so, and there are times when you get to the end of asthma education and you go, 'you got any questions?' And they say no, and I go, 'so can you talk to me at what point you would come back to hospital?' I guess you can check their knowledge rather than just assumed. [HP004] • Um, it's I guess if we, if we are using this tool, it really, it relies on, um, the family having a device that you can use. Uh, which is probably okay here in Adelaide, but I know that other places I've worked, um, yeah, lots of families don't have smartphones or tablets, so yeah. I guess your uptake is limited by that. [HP005]

Perceived Effectiveness

Overall, perceived effectiveness from participants was positive and was coded in all interviews.

Before the intervention, all 16 participants indicated that asthma education delivered via smartphone or tablet apps or by using AR as a delivery mechanism would be a useful modality for asthma inhaler technique education (ie, anticipated effectiveness). When asked why this might be the case, patients with asthma elaborated that they *understand more with technology* [AC004], and both caregivers and HCPs described the possibility of improving accessibility to education through use of a smartphone or tablet—*It's right there, you can just go have a look if it's got information on it* [CG002]; *it's something that it's all part of our life, day-to-day* [HP003]. HCPs also described the possibility of it being a more engaging modality compared with paper-based resources:

> *Kids are obsessed with devices for starters, not always for a good reason, but I feel like they would, um, they would enjoy accessing this information because it is on a device, and they seem to be very device focused. Um, so it might actually capture their attention and then hopefully that would make it sink in.* [HP002]

After using the AR intervention, all 16 participants reported that AR delivered via a smartphone or tablet was a useful modality for asthma education (ie, experienced effectiveness). As postulated, the use of a smartphone or tablet device was described as being accessible—*something like this seems it could be much more easily incorporated into sort of home-based education* [HP001] and AR thought to add a novelty factor for children to aid in engagement—*I think it'll definitely add a component of something different and new to get them involved rather than just watching a video on a screen* [HP006]; *It was, it was new. It was good* [CG001].

Affective Attitude

Affective attitude involved participants' feelings about the use of the AR intervention. Experienced affective attitude was coded more frequently than anticipated affective attitude (55 and 8 times, respectively), which would likely reflect unknown feelings toward an intervention before experiencing it. Affective attitude was predominantly positive for both anticipated and experienced affective attitude, with participants describing AR as *cool* [AC004, HP003], *fun* [AC004] and a *great* concept [HP004]. The ability to immerse participants within the educational resource was also described:

> *I think it's like, it feels more, I know that information is probably, the information that's being delivered is the same, but you feel, feel like you're being interacted with, rather than just...there's the info.* [HP004]

One child with asthma, however, did describe having negative feelings of having too much knowledge with the use of the intervention—*...I could start worrying about my asthma. Get more worried* [AC002] and some participants had concerns over the intervention being boring—*I think they are okay. But some people might not. Just sit there and go 'Oh this is boring, I don't want to listen to this'* [AC002]; *I thought it was very clever. Just potentially, just boring for little ones* [HP002].

Intervention Coherence

Intervention coherence was defined as the extent to which participants understood the intervention and how it worked. Before the use of the intervention, many of the participants did not know what AR was; however, after experiencing the AR intervention, despite describing AR as different to what they expected—*different to how I envisioned* [HP003]; *I didn't think people would be talking to me. I actually thought it was going to be more reading* [CG003], most understood the intended purpose of using AR and smartphone or tablet technology to improve asthma inhaler technique and increase engagement and accessibility for asthma education:

> *So then I could read up from the information and, you know, explain it to her and explain it to others.* [HP001]

> *I like the fact that it's just a piece of paper, um, and they can use their own smartphone…this is so simple, like it's just a piece of paper and your own smartphone, and I'm assuming it works with like Android or apple or whatever. So it's really, it's very accessible.* [HP002]

Ethicality

Ethicality described the extent to which AR and the use of smartphone or tablet technology would be a good fit within the value system of the participants. It was coded in 15 transcripts and was predominantly coded when participants were questioned about their personal views on the use of this technology in asthma education. All HCPs reported that they would use a similar intervention with AR technology if existed:

> *It would certainly be something that I would involve in my day to day practice if that was available to, um, show to patients, some parents.* [HP006]

> *I would, I would love to have something like this to be able to use, especially in a time pressured world. So yeah. Yeah. I'd be very happy for this to be mainstream.* [HP005]

All caregivers of children with asthma, and 4 out of 5 children with asthma also reported that they would use the intervention if they were available to them.

Self-efficacy

Self-efficacy was described predominantly when participants were discussing the ease of use of the AR intervention and access to smartphones or tablets, and it was coded in 12 transcripts. One hundred percent of children with asthma had access to a smartphone or tablet (either their own individual device or the one within the household), and most participants were confident in their own ability to use the intervention with the description of it being *easy* to use [AC001, AC003, AC004, AC005, CG001, CG002, CG003, CG005, HP003, and HP006]. All coding related to self-efficacy was positive, with no concerns raised about the difficulty or inability to use AR via a smartphone or tablet app for asthma inhaler technique education.

Burden

Despite the ease of use of the intervention reported by many participants in the self-efficacy construct, there was still a burden of using the AR educational intervention described above. Burden is the perceived effort required to participate in an intervention.

Burden, which was described by participants, included the inability to hold the attention of children through the educational videos alone—*It'd be good if it was more interactive* [AC002]; *I do wonder if like, especially for littler kids, if it wouldn't be exciting enough or interesting enough* [HP002] and technical aspects of the initial iterations of the intervention—*it looked like there was a little bit of lag sometimes* [HP001]; *I guess just working out those little things, like going back to the menu or like, how do you get back to that home page?* [HP003].

The requirement of the paper-based poster required to trigger the digital educational content by holding the phone over it was

also described as a burden—*It would be, it would be good if once it started playing it, you didn't have to hold it there.* [HP004]; *if you need the paper to use the app and if patients lose the paper, then it…has some issues* [HP001].

Opportunity Cost

Opportunity cost, defined as the extent to which benefits, profits, or values must be given to engage in the intervention, was coded in 12 interviews. Opportunity costs were not necessarily explicitly stated, but concerns regarding parents being required to give up their values surrounding screen time if engaging in the intervention were voiced by some HCP participants—*sometimes…parents are concerned regarding screen time* and *some parents may also not like their children using a smartphone, so that might be restrictive to certain patients* [HP001]; *I think, I think there's, um, I think there's negatives to screens. Um, when it's unsupervised prolonged use that becomes an addiction* [HP003]. Interestingly, this was not reported by any of the caregivers.

The concern that the use of the intervention would mean the loss of the face-to-face interaction between families and their HCPs was also expressed as was the concern that for the intervention, access to a smartphone or tablet was necessary, and so people with asthma in a lower socioeconomic status may be missed:

> *You haven't got someone there to answer your questions…and I guess the difference with education being provided here before you go home, 'have you got any questions?' We can answer them.* [HP003]
>
> *Some patients and their families may not have access to a smartphone, so that provides limitations in terms of a socioeconomic point of view.* [HP001]
>
> *Downsides I guess, is, um, you obviously have to have access to the internet and things like that. So I suppose some disadvantaged people might not have a smartphone or wifi, et cetera.* [HP006]

Discussion

Principal Findings

This qualitative study evaluated the acceptability of AR as a delivery mechanism for asthma inhaler technique education through a robust framework of acceptability, which has been used in the evaluation of other health care interventions [29,35-40].

Overall, participants positively reported the use of AR as a delivery mechanism for asthma inhaler technique and found it to be an acceptable intervention. This is in line with other studies that have examined the acceptability of the use of digital technologies for children and adolescents with asthma who have also indicated generally positive findings regarding the acceptability of interventions [48-50].

The TFA construct of perceived effectiveness was the most coded and reported by all participants. Participants found AR to be new and interesting for children, which would allow for increased engagement in inhaler technique education and the use of smartphones and tablets as an accessible modality for many communities with asthma. In recent years, challenges from the SARS-CoV-2 pandemic have highlighted the need for alternative health care education delivery mechanisms [51-53]. Therefore, the ability of this intervention to be delivered at home or in other nonclinical settings is advantageous.

The ease of use of a digital health intervention is also important with regard to acceptability. A recent pilot study by Davis et al also discussed the importance placed by participants on the ease of use of a co-designed goal-setting asthma app for young people with asthma [44]. The ease of AR use was highlighted in the TFA construct of self-efficacy, in which participants reported simplicity of the intervention and the ability to confidently use AR technology independently via a smartphone device. Other forms of modern technologies, including virtual reality, may require additional equipment such as head-mounted displays or headphones to create a fully immersive experience, highlighting the relatively uncomplicated nature of AR as a benefit in this investigation [54-56].

The challenges to acceptability included the perceived burden of maintaining the attention of the children through educational videos alone, with suggestions such as increased gamification and animation provided by participants to try to combat this. Recently, multiple publications and systematic reviews have provided evidence of the potential of gamification to improve learning outcomes and promote positive behavioral change in various health care or educational settings [57-63]. Similarly, the impact of animation on visual attention has recently been studied in a systematic review that reported the positive influence animation has on viewers' attention and learning skills [64]. Regarding asthma specifically, smartphone apps such as *AsthmaXcel Adventures*, which use gamification and animation have been shown to improve asthma control and knowledge and reduce morbidity such as emergency department visits in pediatric patients with asthma, strengthening the case to incorporate these into developing AR interventions [65]. Technical difficulties of the intervention and the use of the paper-based resource requirement to trigger digital content also provided challenges for the use, which in further iterations will be ironed out to minimize this as a barrier for uptake. The opportunity cost of the lack of face-to-face interaction with HCPs was also identified with the use of AR via smartphone or tablet technology. It is possible this may be overcome via incorporation of a *chat* function with HCPs within the digital intervention, such as in the mobile health app designed by Kosse et al, who also showed improved adherence to asthma medication in adolescents with asthma who used this function [66].

Strengths and Limitations of the Study

The strengths of this study include the recruitment of likely end users for the intervention of participants to ensure optimization of information-rich data and the rigorous qualitative methodology applied to this evaluation. The gold-standard methodology included a prespecified published protocol, qualitative interview training, transcription of audio files, 2 coders to reduce interpretation bias and use of a well-established theoretical framework. The use of TFA allowed interview questions to be formed with a theoretical basis and allowed for

comparison with other studies that use TFA to explore similar themes.

This study has several limitations, including generalizability, limitations of AR technology, and a purely deductive analysis. Generalizability was limited because patients with asthma were excluded if English was not their first language. This precluded the evaluation of acceptability in other ethnic backgrounds, particularly in Aboriginal and Torres Strait Islander children in Australia, who have approximately 2 times the asthma prevalence than children who are non-Indigenous [67]. Participants were also unable to use the intervention if they had any visual or hearing impairment. As mentioned in the Methods section, the recruitment inclusion criteria were also changed during the study owing to the restrictions of the COVID-19 pandemic and the diminished sample pool of older children (>12 years). To ensure that we adhered to purposive sampling, we could have increased the sample size or adjusted the parameters of our age inclusion criteria. After careful consideration and consultation with both asthma clinical care experts and experts in technological innovation design, it was decided that targeted, more meaningful information would be more likely to be obtained if only the younger cohort was included. It was also felt that the older cohort would have different design and content requirements. Therefore, we did not review the acceptability of AR in the adolescent age group but will do so in a future study. Other aspects of purposive sampling such as representation of the 3 different participant groups and gender were achieved. Purposive sampling is commonly used in qualitative research; however, there is an inherent risk of selection bias, which is another limitation of this study. Recruitment was also only undertaken at a single site—a tertiary pediatric hospital—indicating that the sample pool may not have had widely differing opinions. Patients and parents recruited may have had poorer control or more severe asthma, and HCPs may have been more experienced in managing asthma and providing education to this specific subpopulation. The AR intervention itself also had limitations owing to the availability of only a small amount of funding to design and develop the software, content, and scope of information. This may have affected the feedback received from the participants, especially in terms of the burden of use. This study also used a purely deductive approach for data analysis, which meant that there may have been data that did not fall within TFA and hence possibly missed. However, as TFA was also used as the basis for interview questions within the semistructured moderator guides, the data generated predominantly fell within the TFA constructs. We did not identify any key outliers or recurring themes outside TFA.

Implications for Future Research and Clinical Practice

AR is a relatively novel technological innovation; only 1 previous study has explored its use as a delivery mechanism in asthma inhaler techniques in children, and no qualitative research on its acceptability has been undertaken [28]. Although there have been multiple studies evaluating the acceptability of mobile apps and other digital interventions in patients with asthma, to the best of our knowledge, this is the first study to evaluate the acceptability of AR for asthma inhaler technique education [68-70].

Our findings can inform future designs that should consider incorporating features such as gamification to further increase engagement and ensure a streamlined design with minimal technical difficulties to decrease the perceived burden of use. The possibility of including interactions with health care professionals may also be beneficial to decrease the perceived opportunity cost of loss of the ability of caregivers and children to ask questions, provide feedback, and knowledge *check back*.

To ensure successful uptake and implementation in the clinical setting and for broader generalizability, future research should focus on barriers and facilitators to change the usability of such interventions, feasibility (by focusing on areas such as practicality and efficacy testing), and exploration of the use of AR in other groups who may have suboptimal engagement in asthma inhaler technique education, such as adolescents.

Conclusions

AR appears to be an acceptable modality for the delivery of inhaler education to children with asthma, their caregivers, and HCPs who provide care to young people with asthma. This evaluation provides important findings to inform further development, expansion, and upscaling of the AR education resource to address issues around inhaler technique education and potential beyond this specific issue. It also identified an appetite for novel technology-based health interventions to deliver best-practice self-management and education within the asthma community. The findings may also be used to inform the design of future interventions using AR-enabled smartphone or tablet apps to deliver health care education.

Acknowledgments

The authors would like to thank the children, their families, and health care professionals who participated in this study.

Conflicts of Interest

KCC is a cofounder of a start-up company that includes augmented reality technology as one of the functions in a smartphone app to support smoking cessation attempts. At the time of manuscript submission, personal financial interests have yet to be attained.

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Abbreviations

AR: augmented reality
HCP: health care professional
TFA: theoretical framework of acceptability

Edited by S Badawy; submitted 12.06.22; peer-reviewed by T Risling, B Nievas Soriano; comments to author 26.09.22; revised version received 08.11.22; accepted 09.11.22; published 13.01.23.

Please cite as:
O'Connor A, Tai A, Brinn M, Hoang ANTH, Cataldi D, Carson-Chahhoud K
The Acceptability of Using Augmented Reality as a Mechanism to Engage Children in Asthma Inhaler Technique Training: Qualitative Interview Study With Deductive Thematic Analysis
JMIR Pediatr Parent 2023;6:e40231
URL: https://pediatrics.jmir.org/2023/1/e40231
doi:10.2196/40231
PMID:36637889

Original Paper

Co-design of an Augmented Reality Asthma Inhaler Educational Intervention for Children: Development and Usability Study

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Abstract

Background: Smartphone and tablet apps that deliver health care education have been identified as effective in improving patient knowledge and treatment adherence in asthma populations. Despite asthma being the most common chronic disease in pediatrics, there are few apps that are targeted specifically for children. Only half of children with asthma have acceptable control of their symptoms, and 40%-98% do not use their inhalers correctly. With children being increasingly connected to technology, there is an opportunity to improve asthma inhaler technique education by delivery via smartphone or tablet apps. Augmented reality (AR) technology was used in this study to capitalize on growing technological innovations. Digital health interventions that use a co-design process for development have the highest likelihood of successful uptake and effectiveness on their intended outcomes. Perceived usability also has been shown to improve the effectiveness of education as well as the acceptance of the intervention.

Objective: The aims of this study were to describe the co-design process, development, and design outcomes of a smartphone or tablet app that incorporates AR technology to deliver asthma inhaler technique education to children with asthma. This study also aimed to provide a usability evaluation, using the System Usability Scale to inform our work and future research, and recommendations for others performing similar work.

Methods: The development of the AR asthma inhaler technique education app was based on an iterative co-design process with likely end users (children with asthma, their caregivers, and health care professionals). This involved multiple stages: recruitment of end users for qualitative interviews and usability testing with a previously designed educational intervention, which used an AR-embedded smartphone or tablet app; ideation of content for a specific asthma inhaler technique education intervention with end users; development of the specific asthma inhaler intervention; and 2 further rounds of interviews and usability testing with the redesign of the initial prototype.

Results: We included 16 participants aged 9-45 years. Using the co-design process, the AR asthma inhaler technique education app was designed, incorporating the preferences of end users. After iteration 1, animation was included based on the feedback provided. Iteration 2 feedback resulted in increased AR experiences and the removal of the requirement of a paper-based resource to trigger AR in the third iteration. Throughout all rounds, the ease of use of the app and the novel nature of the intervention were frequently described. The usability of the intervention overall was perceived to be excellent, and the mean System Usability Scale score of the intervention was found to be highest in the final round of evaluation (90.14).

Conclusions: The results from this co-design process and usability evaluation will be used to develop a final AR asthma inhaler technique educational intervention, which will be evaluated in the clinical setting.

International Registered Report Identifier (IRRID): RR2-10.1177/16094069211042229

(JMIR Pediatr Parent 2023;6:e40219) doi:10.2196/40219

KEYWORDS

asthma; asthma education; pediatric; pediatric asthma; co-design; usability; development; smartphone; tablet; augmented reality; health education; mobile app; mobile phone

Introduction

Background

There are currently over 6 billion smartphone users worldwide, with a 50% increase in the number of users over the last 5 years [1]. With the abundance of smartphone users and over 50,000 health care or medical apps available, the ease of access and convenience of such apps became clear during the SARS-CoV-2 pandemic, during which surveys found that 40% of respondents trialed new health care apps for monitoring their health [2,3]. Systematic reviews of health care education delivered via smartphone or tablet apps have identified effectiveness for outcomes such as improved knowledge, adherence to medications or treatment, and improved clinical care [4]. For asthma self-management, health care apps have also shown positive effects, with improvements in quality of life and asthma control [5,6].

Despite asthma being more prevalent in the pediatric population and only 50% of this population having acceptable control of their asthma symptoms, only 5% of the almost 150 apps available related to asthma are targeted specifically toward children [7-9]. This subgroup of patients with asthma is increasingly connected to digital technology, with the age of introduction continually dropping and research suggesting that some children are more familiar with devices, such as smartphone and tablets, than with books [10]. It is clear that smartphone and tablet-related apps should be designed for this population.

Smartphone and tablet apps that use augmented reality (AR) technology may provide a novel, generation-appropriate delivery mechanism for asthma self-management education in children. Using smartphone and tablets as viewing devices, AR technology has the ability to superimpose digital information over real-world objects, giving the impression of coexistence within the same space [11]. AR is one of the leading novel technological innovations in the medical and health care industry, with their adoption into medical education and training, diagnostic imaging, and patient management already being prominent [12-14]. While research of AR in asthma education is scarce, it has been shown in other sectors to have proven efficacy for behavior change [11,15]. AR has yet to be explored in an asthma pediatric cohort, with only 1 study to date reporting on the use of AR in inhaler education for children without asthma [16].

Although still described as a relatively new process [17], the co-design of digital health interventions facilitates active collaboration between intended end users, key stakeholders, and software developers to build a program with the highest likelihood of successful uptake and effectiveness on intended outcomes [18,19]. There is growing awareness about the importance of consumer co-design for tech-based health interventions among youth and the need to publish specific details of the consumer engagement process, enabling reproducibility and scientific rigor [18-22]. The risk of inadequate engagement is inferior and less appealing products and can lead to low uptake and effectiveness [22]. In 2016, Schneider et al [23] highlighted the importance of developing an app in collaboration with a cohort of young people with asthma. However, to our knowledge, few studies since then have been published on a user-centered design process in asthma [23-27].

In addition to co-design with potential end users and stakeholders, the usability of an intervention should also be evaluated through the design process. The International Organization of Standardization defines usability as “the extent to which the intervention or product can achieve specified goals by specified users with effectiveness, efficiency and satisfaction” [28]. Perceived good usability has been shown to improve the effectiveness of the education from the intervention as well as improve productivity and end user well-being in health-related apps [29,30]. Good usability perceived by clinicians is also vital for increasing the likelihood of successful uptake of the intervention within clinical settings, with poor perceived usability of technology-based systems, such as electronic health systems, linked to increased workload and lower acceptance of the system [31-34].

With the asthma inhaler technique having been well studied to be frequently performed incorrectly, with errors in 40%-92% of children, there is a clear ongoing need for alternative methods to deliver asthma inhaler technique education to this cohort [35-37]. Given the popularity of smartphones among young people and their increasing use, a smartphone or tablet app that uses AR may be an effective way to address this. With the small number of apps available for young people with asthma but the growing popularity of their usage, there is a need to co-design a smartphone or tablet app for this cohort. To maximize effectiveness, a co-design process that focuses on usability is necessary.

Objectives

Our main objective was to undertake a co-design process for a smartphone or tablet app that uses AR technology to deliver asthma inhaler technique education, to capitalize on growing technological innovations in children with asthma and address the paucity of co-designed apps. Our secondary objective was

to evaluate the usability of the AR smartphone or tablet app. As AR is a novel technology for delivering asthma education, the co-design process of an intervention and evaluation of its usability are necessary. Our aims were to describe the process, development, and design outcomes and perform usability evaluation to inform our work and future research, as well as to provide recommendations for others performing similar work.

Methods

Overview

We created an AR-enabled smartphone or tablet app to address the 40%-92% of children who have incorrect asthma inhaler technique. Development of the AR asthma inhaler technique education intervention was based on an iterative co-design process [38]. This involved 3 rounds of semistructured one-on-one interviews with likely end users to ideate content for the asthma inhaler technique education intervention initially and then obtain feedback to inform subsequent iteration development. Evaluation of the usability was performed in each round, using the System Usability Scale (SUS) questionnaire [39].

Qualitative evaluation based on the Theoretical Framework of Acceptability and Theoretical Domains Framework was obtained through interviews and questionnaires, with these results presented in separate papers [40,41]. In brief, the Theoretical Framework of Acceptability is a validated framework for the assessment of the acceptability of health care interventions to aid the identification of any characteristics that may be improved [41,42]. The Theoretical Domains Framework is also a validated framework that is used for the investigation of the barriers and facilitators of health behavior change interventions [43]. This paper will focus only on the iterative co-design process and usability, which are important to publish to enable reproducibility and scientific rigor.

Ethics Approval

Ethics and governance were approved on August 21, 2020, after the study was reviewed by the Human Research Ethics Committee of the study site (approval number HREC/20/WCHN/74). Participants were provided with participant information sheets prior to enrollment, and written informed consent or oral assent was obtained from participants prior to interviews being conducted.

Recruitment and Participants

An approximate total sample size of 15-20 participants was determined, prior to recruitment, for 3-4 usability testing rounds. This sample size was based on previous usability studies and experts of usability testing advocating that 5 users be involved per round, as 80% of usability problems can be found within these 5 users [44]. Five users per round was not a strict rule; however, as Faulkner [45] suggested, increasing the numbers tested can improve data confidence.

Purposive sampling was planned for recruitment to ensure adequate diversity of likely end users for maximal transferability of the intervention. Likely end users were children with asthma; their caregivers, who would likely be involved in the supervision and delivery of the intervention; and health care professionals (HCPs), who had experience in the management of children with asthma and would be those who introduced the intervention to children and their families. HCPs were also thought to be imperative in the co-design process and usability testing, as they would allow for knowledge and feedback on how the intervention would be able to complement standard care and be successfully integrated within the relevant settings. Purposive sampling was also used to ensure that a broad range of experiences, backgrounds, and opinions could be obtained from participants.

Inclusion criteria for children were an age of 8-17 years and a clinical diagnosis of asthma among those who were able to give assent. Inclusion criteria for caregivers were those who were the primary caregivers for children with a clinical diagnosis of asthma and were able to give consent. With purposive sampling intended to gain good representation of end users, it was identified midrecruitment that predominantly younger children were presenting to the hospital during the SARS-CoV-2 pandemic when recruitment was occurring, and there were minimal face-to-face outpatient clinic appointments also affecting recruitment from the older cohort. The decision was made halfway through recruitment to change the inclusion criteria to children aged 8-12 years, in consultation with experts in clinical care and technological innovation design.

Inclusion criteria for HCPs were nursing professionals, pediatric general medical doctors, respiratory doctors, pharmacists, asthma educators, or general practitioners who had treated and managed children with asthma regularly for over 12 months in the previous 5 years.

Potential participants who were non-English speaking were excluded. Participants were recruited by the primary investigator, starting from July 2021, at a tertiary pediatric hospital within Australia. Potential participants were approached and screened for inclusion and provided with patient information sheets. Potential participants were given time to review the information sheets and given the opportunity to decline participation.

Data Collection and Analysis

Co-design data were obtained through one-on-one interviews, using semistructured moderator guides, by the primary investigator who had received interview training. Focus groups had been initially planned for the co-design process; however, due to the SARS-CoV-2 pandemic, this changed to one-on-one interviews. Interviews took approximately 20-40 minutes per participant and involved four components: (1) exploring the participants' previous experiences with asthma and asthma education (specifically inhaler technique education), experiences with smartphone and tablet apps in health care, and experiences with AR; (2) being shown the intervention by the interviewer; (3) being able to use the intervention as a one-off; and (4) exploring participants' views and experiences of the trialed intervention.

All interviews were audio-recorded, auto-transcribed, and check-backed by the primary investigator to ensure all data were verbatim. Feedback from each iteration was consolidated by

the primary investigator and discussed with the project team, which resulted in an agreed set of changes over subsequent iterations. The evidence underpinning these recommendations has been presented in the results with supporting evidence from the quotes. We prioritized changes where there was some consensus by participants that a change was needed and changes that were within the scope of our budget and time.

Usability data were collected via the SUS questionnaire. The SUS is a common, simple, standardized questionnaire for perceived usability, which has been used since the 1980s [39,46]. It was chosen for this study due to its known suitability in the evaluation of computer systems, medical systems, and mobile devices; its relatively simple ease of administration; its ease of interpretation with known reference standards; and its suitability with small sample sizes [47]. Participants were asked to complete the questionnaire once the interview had been completed.

The standard approach for scoring the SUS was used, in which the 10 questions were answered based on the 5-point scale, odd-numbered items had 1 subtracted from the raw score, and even-numbered items had the raw score subtracted from 5, with the sum of the adjusted scores multiplied by 5 for the standard SUS score [39]. If a participant did not score an item, it was given a raw score of 3 [39]. The standard SUS scores were entered into Microsoft Excel to determine the mean, median, and SD for all participants. The higher the score, the better the usability, with Bangor et al [48] suggesting a system needs to score above 70 to be considered at least passable, and better systems will score in the high 70s to high 80s, with scores over 90 indicating a truly superior system. The SUS, which was supplied for children, had small wording modifications (Table 1).

Table 1. SUS[a] for children.

Item	SUS statement	Modified statement for children
1	I think that I would like to use this system frequently.	I think that I would like to use this resource often.
2	I found the system unnecessarily complex.	I found the resource unnecessarily complicated.
3	I thought the system was easy to use.	I thought the resource was easy to use.
4	I think that I would need the support of a technical person to use this system.	I think that I would need the support of a technical person to be able to use this resource.
5	I found the various functions in this system were well integrated.	I found the various functions in this resource were put together well.
6	I thought there was too much inconsistency in this system.	I thought there were too many differences in this resource.
7	I would imagine that most people would learn to use this system very quickly.	I imagine that most people would learn to use this resource very quickly.
8	I found the system very cumbersome to use.	I found the resource very difficult to use.
9	I felt very confident using the system.	I feel very confident using the resource.
10	I needed to learn a lot of things before I could get going with this system.	I needed to learn a lot of things before I could get going with this resource.

[a]SUS: System Usability Scale.

Results

Participant Characteristics

A total of 16 participants were recruited between July 2021 and April 2022. This included 5 children with asthma, their 5 caregivers, and 6 HCPs who had experience in managing patients with asthma. There were 3 rounds, with 4 to 6 new participants per round (Table 2).

HCPs (n=6) included respiratory and general pediatrics doctors and nursing staff who had backgrounds of working within inpatient settings, emergency departments, and intensive care units, as well as educator roles within the hospital. Children (n=5) and their caregivers (n=5) with asthma had been predominantly diagnosed by a general pediatrician or respiratory specialist and were recruited while admitted into the hospital for the treatment of asthma exacerbations. All caregivers were female, and there was a broad range of educational levels, from not having completed year 12 to the completion of tertiary education.

Table 2. Number of participants per round of interviews.

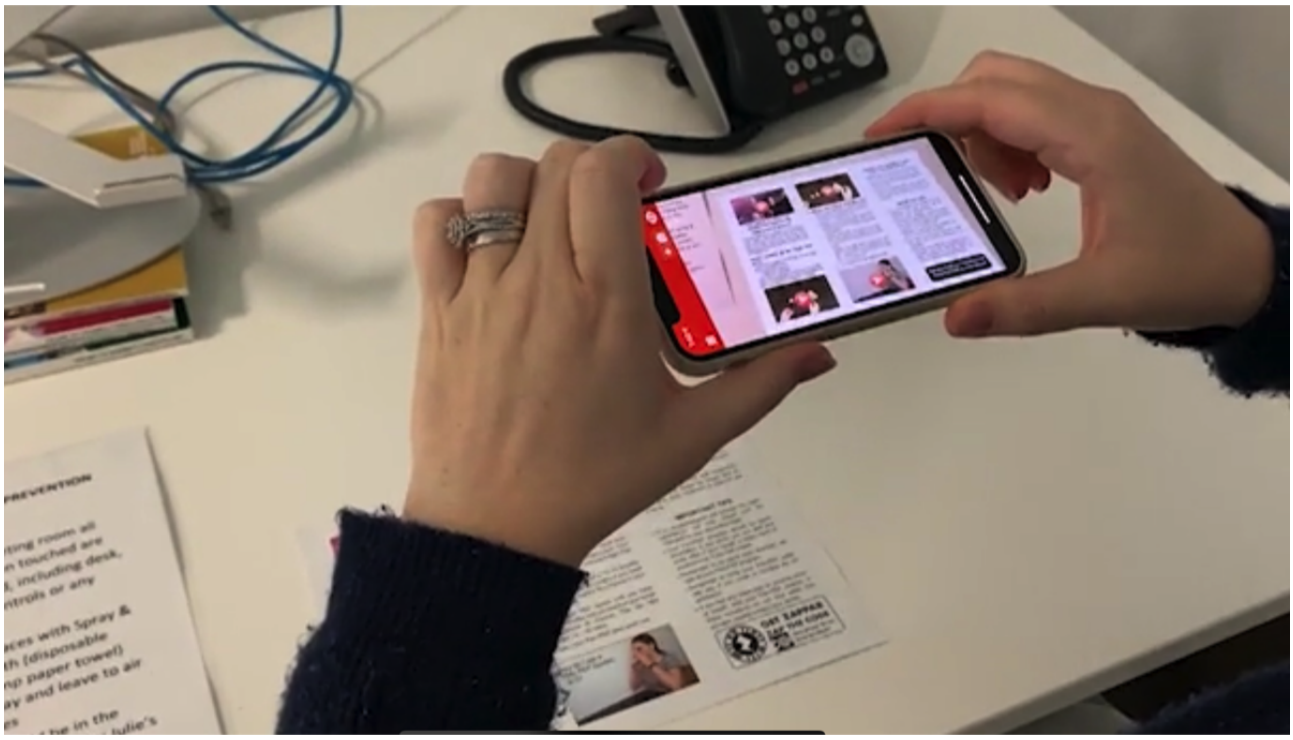
	First iteration (N=4)	Second iteration (N=6)	Third iteration (N=6)
Health care professionals, n	2	2	2
Children with asthma, n	1	2	2
Caregivers of children with asthma, n	1	2	2
Sex (males:females)	0:4	1:5	4:2

Co-design Process and Intervention Feedback

Iteration 1: Interviews and Feedback

Participants were initially shown an educational intervention, which incorporated AR to deliver education via a smartphone or tablet app on physiotherapy in cystic fibrosis. This was undertaken to provide a basic demonstration as to how AR-enabled technology delivered via a smartphone or tablet app works. The first round was aimed at the general concept of AR, as end-user input for a specific asthma inhaler educational intervention was wanted from the outset, with no previous published qualitative research, usability testing, or design processes for AR interventions in asthma education for children to form a precedence. The activation of digital content on physiotherapy equipment education was triggered (via pattern recognition) when the app was open and the smartphone or tablet hovered over a paper pamphlet. This allowed the user to have a direct view of video demonstrations on their smartphone or tablet device, giving the impression of the images on the paper "coming to life" (Figure 1). Participants were then given time to use the smartphone or tablet to trial the use of the intervention themselves, provide feedback on their experiences with the AR technology, and generate ideas on content specifically for an asthma inhaler technique educational intervention that used AR.

Figure 1. Iteration 1 demonstrated and used by participants in the first round.



During the first round of interviews (N=4), the use of AR technology was found to be novel, interesting, and easy to use:

> *It was, it was new. It was good* [caregiver, female]
>
> *It's like really being in the future…Like I wouldn't have ever, if you look at this piece of paper, you wouldn't expect that to kind of come to life. So I think that will be like the surprise factor as well, make it interesting for them and yeah. Get their attention* [health professional, female]
>
> *[it was] pretty easy to use* [child, female]
>
> *I liked it [augmented reality]* [child, female]

All participants reported that the use of an AR intervention would be a useful mechanism for delivering education to children and teenagers, including the child participant who answered "yeah" to the question "Do you think it would be useful for…learning about your asthma?" [child, female].

Suggestions and ideas for content were recommended through the interviews for the provision of education on all asthma inhaler devices as well as education on the asthma disease process itself:

> *It would good to have one, I guess, I mean, for each of the puffers or each of the puffer types like a metered dose inhaler and a spacer, and then like your, um, elliptas and kind of going through all of them with how to use them, that would be good* [health professional, female]
>
> *So particularly, um, use of inhalers, um, reliever and preventer, and sort of, um, a video representation to children of how they should use their preventer or their reliever* [health professional, female]
>
> *I guess that would be good to have a broad overview of asthma and what asthma is* [health professional, female]

To create content that younger people were more likely to engage with, the addition of animation and the need to improve relatability to children were suggestions that were provided to ensure that the content was more age appropriate:

> *somehow you have to make it sound exciting rather than just so factual* [health professional, female]
>
> *So I don't know if younger ones potentially, um, like cartoony...* [health professional, female]

The use of the paper pamphlet to trigger the AR and the digital educational content itself was also raised as a potential burden:

> *I guess the paper based resource has limitations in terms of, if you need the paper to use the app and if patients lose the paper, then it makes, has some issues…* [health professional, female]

Iteration 2: Interviews and Feedback

A second iteration, which was designed specifically for asthma inhaler technique education and used the same AR technology as iteration 1, was created (Figures 2 and 3). This iteration used the same paper-based mechanism to activate educational digital content, for which a poster of 3 children was created. When the smartphone or tablet app was open and hovered over the asthma-specific poster, the digital content—the 3 children "coming to life" and speaking on asthma and asthma inhalers—was triggered, with users being able to view this through the screen of their device, which superimposed the web-based educational content onto the real world. Users were given the option to click on signs being held by each child to view educational content on general asthma information, asthma reliever inhalers, or asthma preventer inhalers. If users chose to view content on asthma inhalers, further videos that demonstrated the steps on inhaler use were provided as options, with users being able to choose which inhalers they would like to learn more about (Figures 2 and 3). Due to time constraints, a purely app-based intervention was unable to be developed for iteration 2 (this was achieved by iteration 3), and hence, the same paper-based trigger mechanism was used. Components of feedback from participants that were addressed in this iteration included education on multiple inhaler devices and a broad overview of asthma, the use of animation, and the use of peer role models to improve relatability to young children. Multiple videos were created to demonstrate the use of the different types of inhalers, with users prompted to click on the inhaler that they wished to learn about. Scripts were written based on Lung Foundation inhaler technique videos, reviewed by asthma educators within the pediatric hospital, and had "readability" scores generated via Grammarly to ensure they were age-appropriate [49,50].

In the second round of interviews (N=6), participants received a demonstration of the AR asthma intervention and were then invited to use it themselves. After testing the intervention, feedback was again provided, and suggestions were made for improvements.

The technical functional aspects of the app were commented on, in regard to both the ease of use and the burden of the paper-based requirement for triggering and launching the app. The ease of the launch of the app was commented on by most participants (eg, "Easy to do, Just click" [caregiver, female]). However, technical issues related to functionality features of the paper-based resource were highlighted, which created difficulty in its use at times:

> *It would be, it would be good if once it started playing it, you didn't have to hold it there. Once you click out of the main menu* [health professional, female]
>
> *Maybe that once it's on, maybe it'll lock…because it's not comfy putting it over [the paper]* [child, female]

Asthma education delivered by children actors was received positively and thought to be a relatable means to deliver information:

> *my first thought is, oh, this is cool. It's actually kids doing it, which would really target kids. So I was like, oh, that's nice. It just makes it really relatable* [health professional, female]
>
> *as a kid with asthma, I think it makes it very relatable because you've got kids talking about it, kids demonstrating* [health professional, female]

Feedback and suggestions were also provided to improve engagement and decrease boredom for children. This was predominantly reflected in suggestions of animation incorporation, increased AR use, and gamification:

> *I do think that you have to [include] a game…just to teach them.* [caregiver, female]
>
> *It'd be good if it was more interactive because some people might have trouble listening to things.* [child, female]
>
> *Maybe you could like, have, um, maybe cartoon people next to them.* [child, female]
>
> *Just add a little bit more to the actual product…Come to life a little bit more then it grabs the kids* [health professional, female]

More components of asthma education were also requested in regard to content, such as expanding on asthma symptom triggers and the addition of asthma action plans:

> *One of the things that I think you should put on it is triggers* [caregiver, female]
>
> *you could go through steps of even like your asthma action plan* [health professional, female]

Figure 2. Iteration 2 demonstrated and used by participants in the second round.

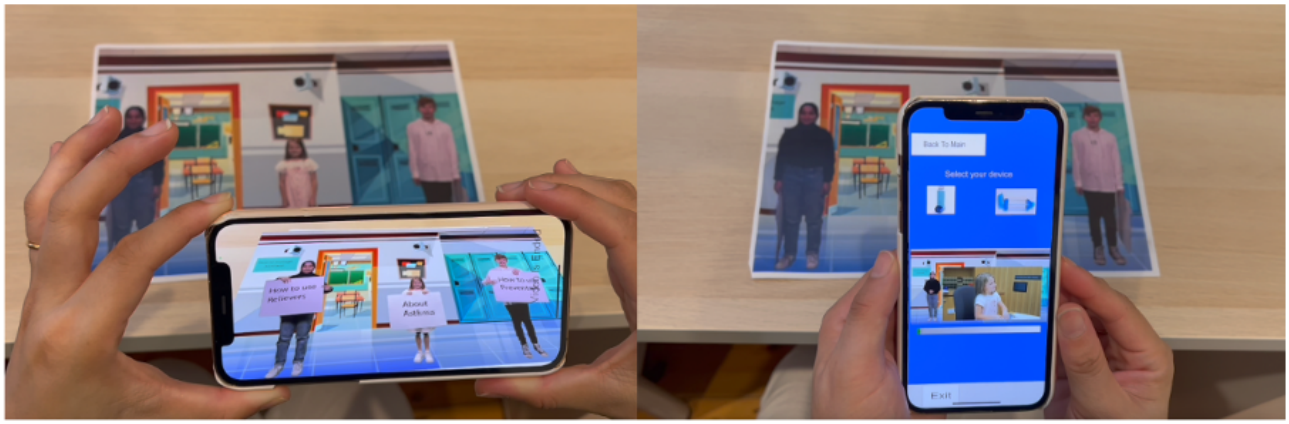


Figure 3. Iteration 2 demonstrated and used by participants in the second round - digital educational content for multiple asthma inhaler devices.

Iteration 3: Interviews and Feedback

The third iteration of the AR asthma inhaler educational intervention was devoid of the paper-based trigger and modified, with additional major changes being the expansion of animation and the pivoting of the users' AR experience through the smartphone to increase interaction of the app with young people. With the removal of the piece of paper required to trigger the smartphone or tablet app, an area of homogenous ground was used to trigger digital content instead. Once the app was opened,

the user scanned any area of homogenous ground. This prompted the participant to place a "portal" onto the ground, which then allowed the participant to enter the "portal" and go into a room, which they could view on their smartphone or tablet. Asthma inhaler educational videos and animations were available on the walls of the room for participants to watch (Figures 4 and 5, Multimedia Appendix 1). This included educational content on general asthma information (eg, "What is asthma"), inhaled asthma reliever medications, inhaled asthma preventer medications, and the correct steps in the use of inhalers. Additional educational content on triggers was also added based on feedback; however, gamification was not yet incorporated into this iteration due to limitations on funding and the time it would take to create appropriate gamification for this particular intervention.

Figure 4. Iteration 3 demonstrated and used by participants in the third round—images after having entered a room through the portal and screens shown on the walls of the room with an asthma inhaler educational video.

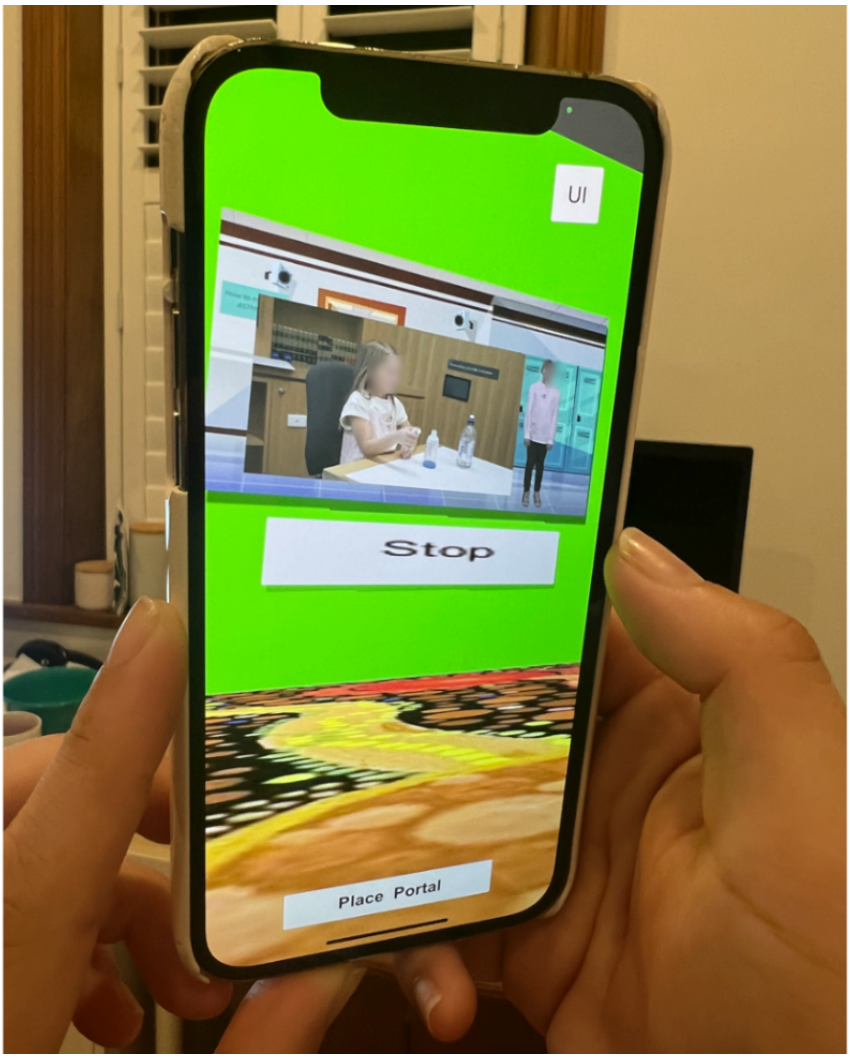
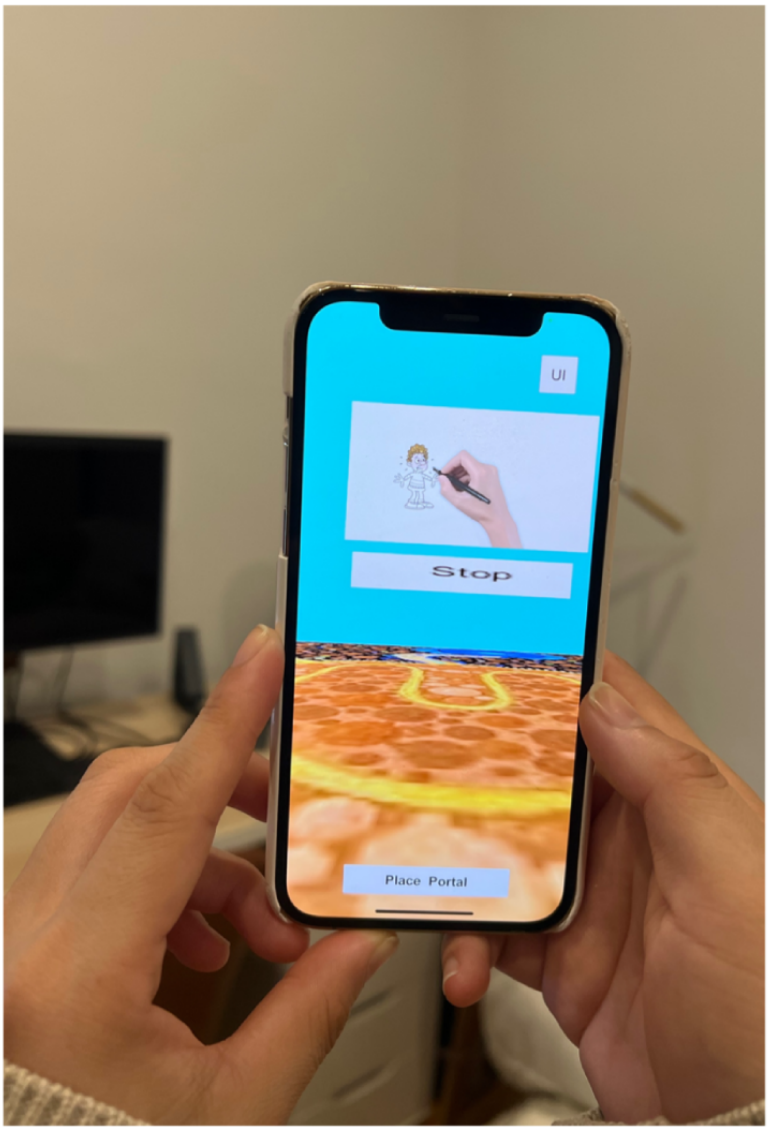


Figure 5. Iteration 3 demonstrated and used by participants in the third round—images after having entered a room through the portal and screens shown on the walls of the room with a whiteboard animation.



Six participants provided feedback in the third round of interviews after testing the AR smartphone or tablet intervention. An animated introduction using whiteboard animation was well received by all participants, as was the increased AR experience via the use of the portal and room:

> *The introduction was kind of fun. The playground and that stuff* [child, male]
>
> *the use of the drawings in the intro video, uh, was a great idea* [health professional, male]
>
> *You kind of just go into the portal and then the videos come up, I kind of like that you have to move the phone* [caregiver, female]
>
> *I liked the drawings* [caregiver, female]

Having children involved as the actors was once again highlighted as a positive to the intervention, as were the use of AR as a novelty technology and increasing the AR experience, which was suggested in iteration 2 to increase interactivity:

> *I think, I think the, uh, use of augmented reality is a novelty that kids would really connect with. Um, and the use of children delivering the education is also really good* [health professional, male]
>
> *I think it'll definitely add a component of something different and new to get them involved rather than just watching a video on a screen (regarding AR technology) [health professional, male];*
>
> *it's interesting (regarding AR technology)* [child, male]
>
> *I used to think health apps are like boring and that stuff but...reality is cool* [child, male]

Suggestions for improvement included incorporation of gamification again from children participants, as well as more animation within the intervention:

> *Animation? (when asked about how the intervention could be improved)* [child, male]
>
> *Little games and stuff? (when asked about how the intervention could be made more interesting or fun)* [child, male]

A lot of drawing animation is always, always good [caregiver, female]

Results of Usability (SUS)

All 16 participants who were recruited completed the usability questionnaire. Only 1 participant did not score all 10 items, and as described in the methods, these items were allocated a raw score of 3. SUS scores provided from participants ranged from 60 to 100, with an average of 87.65 (SD 16.96) and median of 88.75, indicating that the system was acceptable (scores of >70) and that the perceived usability of the intervention was excellent overall, with mean SUS scores between 85.5 (SD 12.17) and 90.4 (SD 11.7) considered within the "excellent" range when SUS scores have an adjective rating applied [51]. While in iteration 2, a child recorded an SUS score of 60; on review of raw data, this identified inconsistent scoring and responses (eg, scoring "agree" for both "I found the resource unnecessarily complicated" and "I thought the resource was easy to use"). This was also inconsistent with their interview transcript, with the participant reporting that the intervention was "easy to use," suggesting that the scoring was likely incorrect.

When SUS scores were compared across the 3 rounds, the mean SUS score was lowest for iteration 2, and the highest mean SUS score was for iteration 3 (ie, the final round). Per Bangor et al [48], based on the SUS mean score, iteration 3 was classified as a truly superior system (Multimedia Appendix 1).

When SUS scores were compared across the 3 participant groups (children with asthma, their caregivers, and health professionals), health professionals scored the intervention highest in terms of perceived usability, with a mean score of 89.58 (SD 5.34), and caregivers scored it the lowest, with a mean score of 85.5 (SD 12.17) (Table 3). Of note, all scores were still within the "excellent" usability range across the 3 participant groups.

Table 3. SUS[a] scores per participant group.

Participant group	SUS, mean (SD)	SUS, median (IQR)
Children with asthma	87.5 (16.96)	95 (60-100)
Caregivers of children with asthma	85.5 (12.17)	92.5 (70-97.5)
Health professionals	89.58 (5.34)	87.5 (85-100)

[a]SUS: System Usability Scale.

Discussion

Principal Results

This paper is the first to describe the co-design process of an AR asthma inhaler educational intervention for children. End users were engaged in the development from the beginning of the process, which allowed for a user-centered design. Participants had mostly favorable views of the AR intervention, with the ease of use of the technology and the novel nature of AR being able to capture the attention of children for inhaler technique education in all 3 iterations. Through the use of the iterative co-design process, the preferences of end users were also able to be incorporated with key suggestions, such as the addition of animation and increased interactivity with AR included to later iterations. With this process, it was possible to identify areas that required improvement or were perceived to not be necessary (such as the use of the paper-based resource to trigger the AR intervention) and provide information on the preferences of end users to inform further development of the intervention. The use of an iterative co-design process was particularly important for the development of this AR intervention in children for two main reasons: (1) the novel nature of AR as an educational delivery mechanism in health care education, especially for asthma in children, and (2) evidence showing that these design processes increase the efficacy and uptake of the intervention by end users [25].

Through use of the SUS, this intervention was found to have excellent perceived usability, with an overall mean of 87.6. The third iteration had the highest mean of 90.14, indicating a truly superior system, providing encouraging evidence that with the iterative co-design process, the intervention can continue to be improved on throughout subsequent rounds.

Comparison With Prior Work

This paper aimed to describe a user-centered design and the usability of an AR intervention, which was delivered via a smartphone or tablet. To date, there have been no studies identified that describe a co-design process for asthma educational interventions that use AR or the usability of such developed interventions, as in this study.

Smartphone apps, which have poor usability and do not use this design process, have lower adoption rates, and despite the increasing use of mobile apps for health care education, only a small number of papers recently have described a co-design process or usability testing for asthma apps for children and young people [52]. Sonney et al [25] recently described, in 2022, using a "human-centered design" for refinement of an app, which was designed for asthma monitoring and as a behavioral intervention to promote shared asthma management between a parent and child with asthma. While children and their parents were involved in the process, their involvement from the outset in the design of the app was not apparent [53]. Mayoral et al [54] also recently described end-user involvement in the development of a mobile health app for children with asthma; however, children and adolescents were not involved until the later stages of its development. Other studies, such as one by Davis et al [24], described using a participatory approach from the preintervention development phase for an asthma self-management smartphone app; however, this was targeted at people aged 15-25 years with asthma, who would likely have differing preferences compared to our patient cohort. In regard to usability testing for asthma apps for children, Mayoral et al

[54] also used the SUS for usability testing; however, Schneider et al [23] used semistructured interviews by a research assistant. While there is more recent literature on usability testing for asthma apps aimed at adults and adolescents with asthma, usability testing in children remains scarce [55-57].

Limitations

Limitations for this study first lie with the limited generalizability of the intervention. Participants were only recruited if they were primarily English-speaking and were recruited from a tertiary pediatric hospital. Children and their caregivers were recruited during a hospital admission, indicating that the end users recruited were predominantly children who may have had more severe or more poorly controlled asthma and may have had a stronger desire for interventions to improve their asthma education. Similarly, health professionals were also recruited within the tertiary hospital setting, which may have led to the recruitment of health professionals who see and manage patients with asthma who have poorer control and are on the more severe end of the spectrum. In addition, 11 of 16 participants were female (69%); it is possible that feedback and app development would have been different with a more even distribution of genders. Although we had intended on purposive sampling, we were limited to the demographic of patients presenting to the site. During the recruitment phase, it was noted that children who were younger were presenting to the site and recruited. To ensure that purposive sampling was completely adhered to, a decision had to be made as to whether to try and increase the sampling size by adding a second site or adjusting the parameters of the age inclusion criteria. Following consultations with experts in clinical care and experts in technological innovation design, it was decided that we would have more targeted information if we focused on the younger cohort alone, and it was likely that the intervention would have had different requirements and feedback from older children (13-17 years inclusive). Another study for the older cohort is planned.

The small sample size of our study also limited the interpretation of the SUS; however, the usability evaluation of this study was for hypothesis-generating purposes. More research is required with a larger sample size to evaluate the intervention's usability in the clinical setting. Another limitation in the evaluation of usability was that while the SUS can be used as an aid for understanding the overall level of the usability of an intervention, it does not necessarily identify detailed information on the intervention's effectiveness or efficiency, which may be able to provide more information for improvement on subsequent iterations [58]. Lastly, while the wording of our SUS instrument was modified slightly for improved understanding among children, this had not been tested or validated previously, decreasing its reliability.

Not all feedback from interview rounds were able to be incorporated into the subsequent iterations, which is a further limitation to our study. Due to time constraints, we were not able to make adjustments to a paper-free version until iteration 3, so during iteration 2, we continued with the paper-based triggering model. There still might be advocation for a paper-based resource however, such as within hospital settings where pamphlets for education are predominantly used or for people who are reluctant to rely solely on technology-based resources. The incorporation of gamification was also not achieved during this study due to time and funding constraints; however, it should be strongly considered for smartphone or tablet asthma education app developers to increase engagement and interactivity with children with asthma. It is possible that had we been able to act on all identified feedback themes, SUS scores may have been higher.

Lastly, this study reports on only the design process and usability, but for the successful uptake and implementation of an intervention on a larger scale, other aspects of the intervention must also be evaluated, such as the acceptability of its use, the barriers and facilitators to its use, the feasibility of the intervention, and its efficacy. These will be addressed in future papers and studies.

Conclusions

Not only is published research on the use of AR for asthma educational interventions in children scarce, the use of a co-design process in the development of smartphone or tablet asthma educational intervention apps, as well as the usability of such apps, is also infrequently reported. This contributes to the literature by identifying and incorporating the preferences of intended end users. The key recommendations found in our work, which should be considered by others in the design of similar interventions, are the inclusion of animation, increased interactivity, and gamification. This paper highlighted the importance of co-design and showed the improvement in usability scores with the incorporation of end user feedback through subsequent iterations of design. The results from this process are now being used to develop the final AR intervention for evaluation in the clinical setting.

Acknowledgments

The authors would like to thank the participants of this study, including the children with asthma, their families, and the health care professionals who care for these patients.

Conflicts of Interest

KCC is cofounder of a start-up company that will include augmented reality technology as one of the functions in a smartphone app to support smoker quit attempts. At the time of manuscript submission, personal financial interest has yet to be attained.

Multimedia Appendix 1

Video demonstration of augmented reality intervention.
[MP4 File (MP4 Video), 5909 KB - pediatrics_v6i1e40219_app1.mp4]

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Abbreviations

AR: augmented reality
HCP: health care professional
SUS: System Usability Scale

Edited by S Badawy; submitted 11.06.22; peer-reviewed by D Drummond, J King; comments to author 21.07.22; revised version received 22.12.22; accepted 15.04.23; published 25.07.23.

Please cite as:
O'Connor A, Tai A, Brinn M, Hoang ANTH, Cataldi D, Carson-Chahhoud K
Co-design of an Augmented Reality Asthma Inhaler Educational Intervention for Children: Development and Usability Study
JMIR Pediatr Parent 2023;6:e40219
URL: https://pediatrics.jmir.org/2023/1/e40219
doi:10.2196/40219
PMID:37490325

Usability and Perception of a Wearable-Integrated Digital Maternity Record App in Germany: User Study

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Abstract

Background: Although digital maternity records (DMRs) have been evaluated in the past, no previous work investigated usability or acceptance through an observational usability study.

Objective: The primary objective was to assess the usability and perception of a DMR smartphone app for pregnant women. The secondary objective was to assess personal preferences and habits related to online information searching, wearable data presentation and interpretation, at-home examination, and sharing data for research purposes during pregnancy.

Methods: A DMR smartphone app was developed. Key features such as wearable device integration, study functionalities (eg, questionnaires), and common pregnancy app functionalities (eg, mood tracker) were included. Women who had previously given birth were invited to participate. Participants completed 10 tasks while asked to think aloud. Sessions were conducted via Zoom. Video, audio, and the shared screen were recorded for analysis. Task completion times, task success, errors, and self-reported (free text) feedback were evaluated. Usability was measured through the System Usability Scale (SUS) and User Experience Questionnaire (UEQ). Semistructured interviews were conducted to explore the secondary objective.

Results: A total of 11 participants (mean age 34.6, SD 2.2 years) were included in the study. A mean SUS score of 79.09 (SD 18.38) was achieved. The app was rated “above average” in 4 of 6 UEQ categories. Sixteen unique features were requested. We found that 5 of 11 participants would only use wearables during pregnancy if requested to by their physician, while 10 of 11 stated they would share their data for research purposes.

Conclusions: Pregnant women rely on their medical caregivers for advice, including on the use of mobile and ubiquitous health technology. Clear benefits must be communicated if issuing wearable devices to pregnant women. Participants that experienced pregnancy complications in the past were overall more open toward the use of wearable devices in pregnancy. Pregnant women have different opinions regarding access to, interpretation of, and reactions to alerts based on wearable data. Future work should investigate personalized concepts covering these aspects.

(JMIR Pediatr Parent 2023;6:e50765) doi:10.2196/50765

KEYWORDS

maternity log; maternity logbook; log; logbook; experience; experiences; attitude; attitudes; opinion; opinions; perception; perceptions; perspective; perspectives; pregnancy record; personal health record; PHR; health records; health record; feature; features; develop; development; maternity record; electronic; digital; paper hand-held record; mHealth; mobile health; app; apps; application; applications; smartphone; smartphones; wearable; wearables; usability; pregnant; pregnancy; maternal; maternity; electronic maternity record; pregnancy app; data sharing; privacy; online search; searching; information behavior; information behaviour; information seeking

Introduction

Home-based maternal records, also referred to as pregnancy logs, maternity records, or hand-held paper records, store women’s medical information during pregnancy. These records contain various information, for example, about vaccinations, blood pressure, or ultrasound examinations [1]. They are used in more than 163 countries and greatly vary in design and content [2]. Home-based maternal records have been shown to provide advantages. They establish a better connection between caregivers and pregnant women, an improved sense of women’s

empowerment, increased knowledge, family involvement, and continuity of care [3,4].

Digitalization has the potential to alleviate existing pitfalls of home-based maternal records. In a previous study, 36% of women involved in one trial stated that they forgot their records during at least one visit to their caregiver [5]. This and other problems can be solved by digital maternity records (DMRs). DMRs can improve information transfer between general practitioners, gynecologists, midwives, and hospitals [6]. Furthermore, clarity and documentation efforts can be improved while avoiding media discontinuities, that is, changes between communication media, such as (manual) data transfer from fax to paper or digital [7].

Several studies have implemented and investigated the effect of DMRs: Providing maternity data to pregnant women on flash drives resulted in advances in patient empowerment, satisfaction, and safety [8]. A digital pregnancy information and journaling tool could increase patient activation [9], although this may decrease over time compared to paper-based tools [10]. DMRs are mostly perceived as positive [11,12], although confidentiality, privacy, and data control are of concern [13]. A study in the Netherlands [14] found no effect on quality of care or outcomes.

The openness toward the use of wearable devices in maternal care is mixed [15,16]. Motivation to use wearable devices increases if the use is associated with positive outcomes [16]. At the same time, pregnant women state that incorrect or out-of-normal measurements from wearables can be a source of anxiety [16]. A trial that integrated wearables into routine maternal care reported that most participants continued to use the devices through pregnancy and after birth [17].

Patient-centered design transfers the principles of user-centered design (UCD) to the health care domain. UCD aims to increase the chance of user acceptance through regular and iterative inclusion of users in the development process [18,19]. Evidence on usability is crucial for the implementation of new apps in maternal health care [20].

Some studies on DMRs have investigated usability: Shaw et al [21] provided pregnant women with access to websites containing antenatal health information. One group received access to their individual antenatal health record, the other to general pregnancy health information. Users provided with personalized information logged in 6 times as often as users receiving general antenatal health information. Participants in both groups were highly satisfied with the website itself. Chang et al [22] developed a system integrating web-based maternity records, including explanations about individual tests; self-care journals for weight, blood pressure, movement and contraction tracking; and educational features. A survey administered to 68 pregnant participants revealed that the pregnancy calculator, estimated date of birth, and body calculator were particularly relevant for pregnant women, and 80.9% of participants stated the system was useful for their pregnancy. In a previous study, we investigated the use of a DMR interface by physicians and midwives [23]. The completion time for DMR data entries was about 30% higher, while the average number of errors was lower, compared to the analogue version.

However, most studies investigating usability aspects in DMRs have used postuse questionnaires. While this provides general usability metrics, it provides no insights on users' thought processes and behavior. To date, no study has examined the use of a DMR app for pregnant women with live user testing. The effect of displaying wearable data in a pregnancy app has also not been investigated to date. Thus, this work aimed to investigate the usability and perception of a medically guided DMR integrating wearable data by conducting a usability study using a DMR prototype app, think-alouds, and semistructured questionnaires.

Methods

This work used a mixed methods approach consisting of think-alouds during several usability tasks followed by a semistructured interview.

Ethical Considerations

The study was approved by the ethics committee of Friedrich-Alexander Universität Erlangen-Nürnberg (106_13 B). The participants provided informed consent to participate.

Concept and Features

A novel DMR app was developed jointly by obstetricians, ethicists, and computer scientists. This app combined four aspects: (1) DMR functionality, that is, providing users with their personal antenatal care data, (2) the integration of wearable devices, (3) medical trial functionality to deliver questionnaires for this study and other prospective mobile and ubiquitous health studies, and (4) additional features known from commercial pregnancy apps (general information section, week-by-week information, mood tracker).

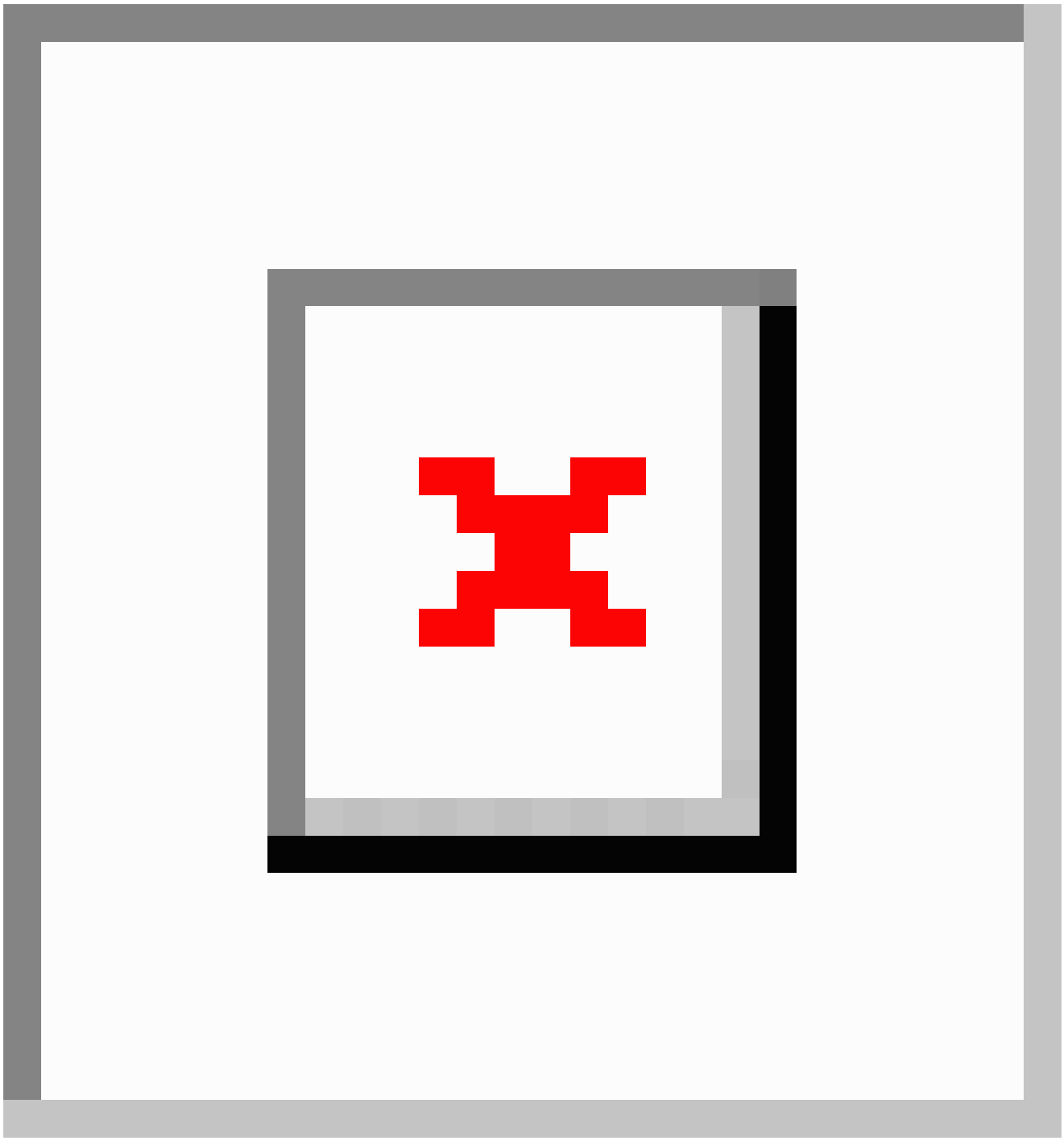
First, the DMR functionality was developed in close alignment with the official and standardized paper-based German home-based maternal record (Mutterpass). For each section of the Mutterpass, a respective digital page was created ("Lab results," "Previous pregnancies," "Consultation," "Anamnesis," "Special findings," "Date estimation," Gravidogram," "Hospitalizations," "Cardiotocography," "Ultrasound," "Epicrisis"). We refrained from implementing potential improvements related to digitalization or making other major changes, as the official German DMR (E-Mutterpass) currently rolled out is in line with our approach [24]. Second, wearable devices are integrated by displaying heart rate, sleep, and blood pressure data. Third, study functionality is organized around a "My tasks" page. Each category offers visualization options for all data, as well as monthly, weekly, and textual representations. Fourth, the implementation of selected functionalities typically found in pregnancy apps, including a mood tracker, information section, and week-by-week information, aims to improve the overall attractiveness of the app.

Development

The app is a progressive web app (PWA) developed using ReactJS (Facebook Inc) as frontend framework. The user interface uses components from MUI (Material-UI SAS). The backend uses the *carecentive* framework [25]. *Carecentive* is implemented using Node.js (OpenJS Foundation), relying on

Express.js (OpenJS Foundation) for web server functionality and MySQL (Oracle Corp) as the database. Screenshots of the developed app are shown in Figure 1. The app was developed in German.

Figure 1. Example screenshots of the developed app. (A) "Start," (B) "My tasks," (C) "Mapi questionnaire," (D) "Installation guide," (E) "My measurements," (F) "Main menu," (G) "Ultrasound section," and (H) "Information" sections. The app is intended for a German audience and was thus developed in German. A retrospectively translated English version of these screenshots is provided in Multimedia Appendix 1.



Recruitment

A flyer for participant recruitment was designed and was distributed using the local university department's mailing list, student Facebook groups, local businesses displays, and personal contacts. The flyer included information about the prerequisites for participation. These included having reached the legal age of maturity (18 years), having had one or more pregnancies in the recent past, and having German and English language skills. We did not use a fixed time threshold for the time since the last pregnancy, as participant recruitment for similar studies with such fixed constraints proved to be difficult in the past. Interested individuals were asked to contact the study advisor by email or phone; this contact information was also included in the flyer.

Study Setup

The study was conducted from December 7, 2021, to January 11, 2022. Germany experienced a significant number of COVID-19 infections during this timeframe. After careful

evaluation, we determined that conducting a lab study with in-person attendance was unreasonable, as our study aims could still be achieved through virtual meetings. Zoom (version 5.8.1; Zoom Video Communications, Inc) was used for this purpose.

Procedure

After expressing their interest in the study, participants were sent a Zoom link along with the respective consent forms. After participants provided informed consent, the study advisor started audio and video recording. Following this, participants received study instructions as a PDF document by email. This document led participants through the procedure alongside the study advisor. It comprised questionnaires and instructions for individual tasks.

Afterward, a PDF questionnaire for demographic data (age, number of previous pregnancies, months since last pregnancy, education level, household income, high-risk pregnancy, and familiarity with the German Mutterpass) and technical affinity [26] (enthusiasm, expertise, and positive and negative attitude) was filled out. A short video about pregnancy in gestational week 25 was shown to increase participants' pregnancy immersion [27].

The study advisor shared the screen of a smartphone (Huawei Y7 2017; Android 7.0) via Zoom. A tool that mirrors a smartphone screen on the computer was used for this purpose (Scrcpy version 1.21; Genymobile). Participants were able to control the full mobile phone (not only a browser), including the ability to change phone settings or install apps. The screen was shared with the participant, and interactive use of a keyboard and mouse was enabled. Participants were now able to interact with the app in the same way as if it was used on their computers. This was necessary to record the interactions of the participant with the app for later evaluation. The installation of screen recording software and consecutive transfer of files to the study coordinators was previously deemed unfeasible due to the required technical expertise and significant effort of participants.

Participants were asked to complete 10 tasks and asked to freely express their feelings and thoughts during app use (eg, provide "think-alouds"). The tasks and their respective aims are shown in Table 1. Example screenshots for each task can be found in Multimedia Appendix 2. Following this, users completed the User Experience Questionnaire (UEQ) [28] and System Usability Scale (SUS) [29] in a digital form directly in the app. A semistructured interview about perceptions and personal preferences regarding information search in pregnancy, wearable device use, integration into maternal care, digitalization potential, and research data sharing concluded the study.

Table . List of study tasks.

Task ID	Description	Specific aim(s)	Evaluation of success, time, and errors?
1	Create a new user and login	Test login and registration procedure	Yes
2	Install the app on the mobile phone	Test progressive web app installation	Yes
3	Free exploration	Assess general perception and initial thoughts	No
4	Complete Multivariable Apnea Prediction Index [30]	Test questionnaire interface by using a specific questionnaire as an example	Yes
5	Explore ultrasound section	Test ultrasound section, particularly the Material-UI tabs	No
6	Find remarks on second ultrasound checkup	Test design of digital maternity record section	Yes
7	Explore visualization options	Test wearable data display and presentation	No
8	Find a heart rate value	Test wearable data display and presentation	Yes
9	Find depression information	Test design of information section	No
10	Enter and save information in mood journal	Test design of mood journal	Yes

Evaluation

SUS, UEQ, and think-aloud remarks were used to evaluate usability. General perception was assessed through the think-aloud and semistructured interview at the end. Personal preferences and habits on online information searching, wearable data presentation and interpretation, at-home examination, and willingness to share data for research purposes were also assessed through the semistructured interviews at the end of the study.

Task completion times (TCTs), task success, errors, and self-reported (free text) feedback were recorded to assess effectiveness and efficiency. TCTs were extracted from video recordings. Task success was defined as all actions being clearly

identified and completed, while failure was defined as at least one of the actions composing the task failing once. Errors were categorized as slips (unintended actions such as typos or accidental clicks) and mistakes (wrong actions thought to be correct, such as clicking on a nonclickable item) [31]. GOMS (Goal, operators, methods, and selection rules) modeling using Cogulator (Mitre Corp) was used to estimate reference times. GOMS modeling analyzes and aims to predict user interaction with computer systems. It helps designers, developers, and researchers to understand user behavior. User tasks are divided into goals. Each of the goals is achieved by solving subgoals in a divide-and-conquer approach [32]. In the context of this work, a reference time was estimated by dissecting each task into different subtasks. Each of these subtasks (eg, typing a text, pointing and clicking on an item, processing information) was associated with a certain time.

Oral remarks and comments were aggregated into 3 categories: feature requests, comments about user experience, and identified bugs.

Results

Participants

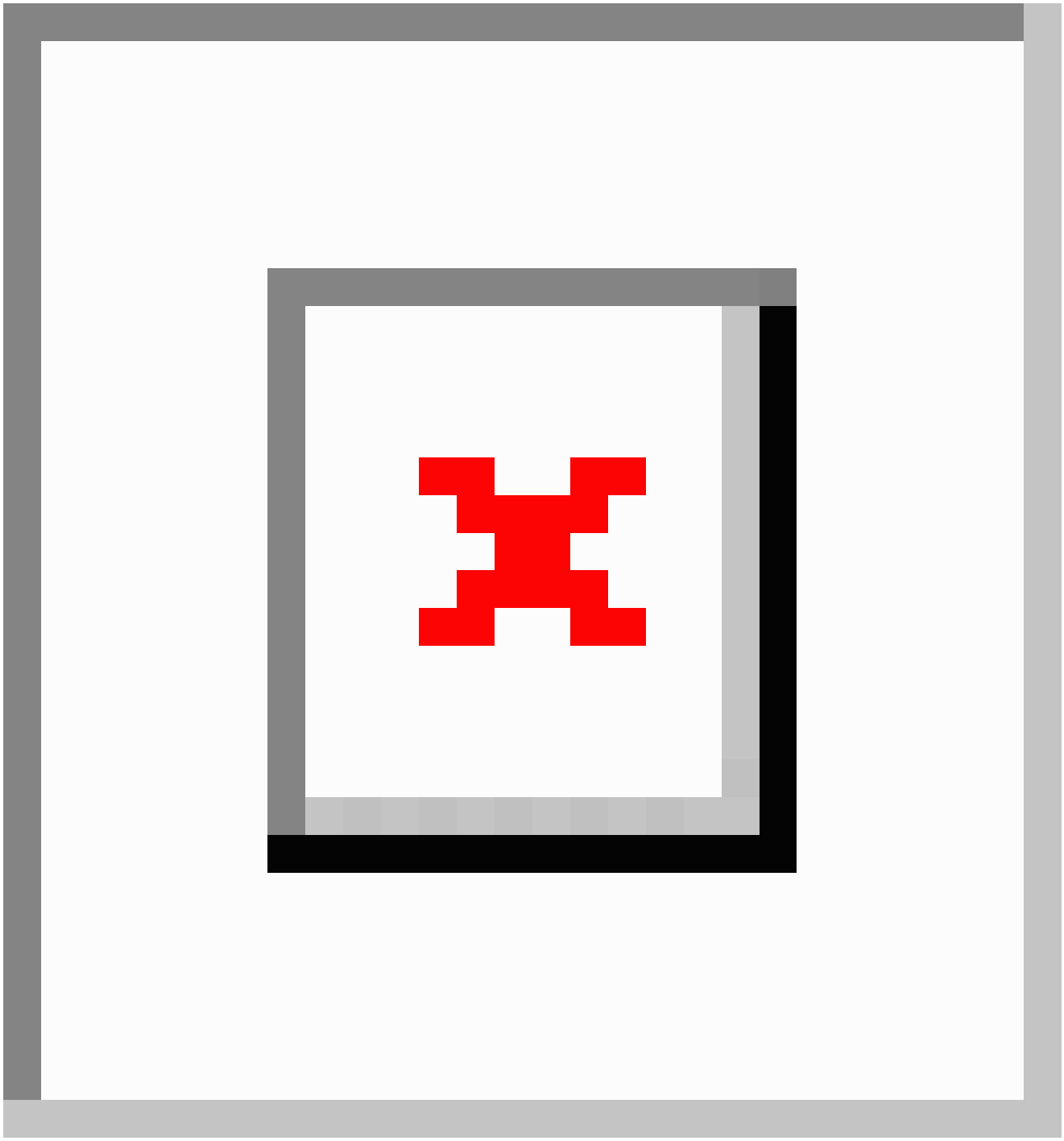
A total of 14 participants scheduled appointments for study participation. Two (P6, P7) did not fulfill the inclusion criteria. The screen-recording data of one participant (P3) could not be saved due to technical issues. This participant was thus excluded. Finally, 11 participants were included in the evaluation.

Participants were aged 34.6 (SD 2.2) years, had 1.8 (SD 0.98) previous pregnancies, and had their last delivery 33.2 (SD 24.5) months previously. Education level (n=1: job training; n=3: bachelor's degree; n=1: master's degree; n=6: PhD) and monthly household gross income varied (n=1: €3000-€6000; n=3: €6000-€9000; n=3: €9000-€12,000; n=4: >€12,000; a conversion rate of €1=US $1.13 applies). Most participants were native German speakers (n=9). The remaining 2 participants reported basic (n=1) and advanced (n=1) German language skills.

Task Completion Time

The task completion times and GOMS reference times of each task are shown in Figure 2. As outlined in Table 1, no times were measured for explorative tasks.

Figure 2. Task completion times for each task. See Table 1 for details on the individual tasks. GOMS (goal, operators, methods, and selection rules) modeling using Cogulator was performed to estimate reference times. No times were measured for explorative tasks (tasks 3, 5, 7, 9).



Errors and Task Success

Recorded errors per task and overall task success rates are shown in Table 2.

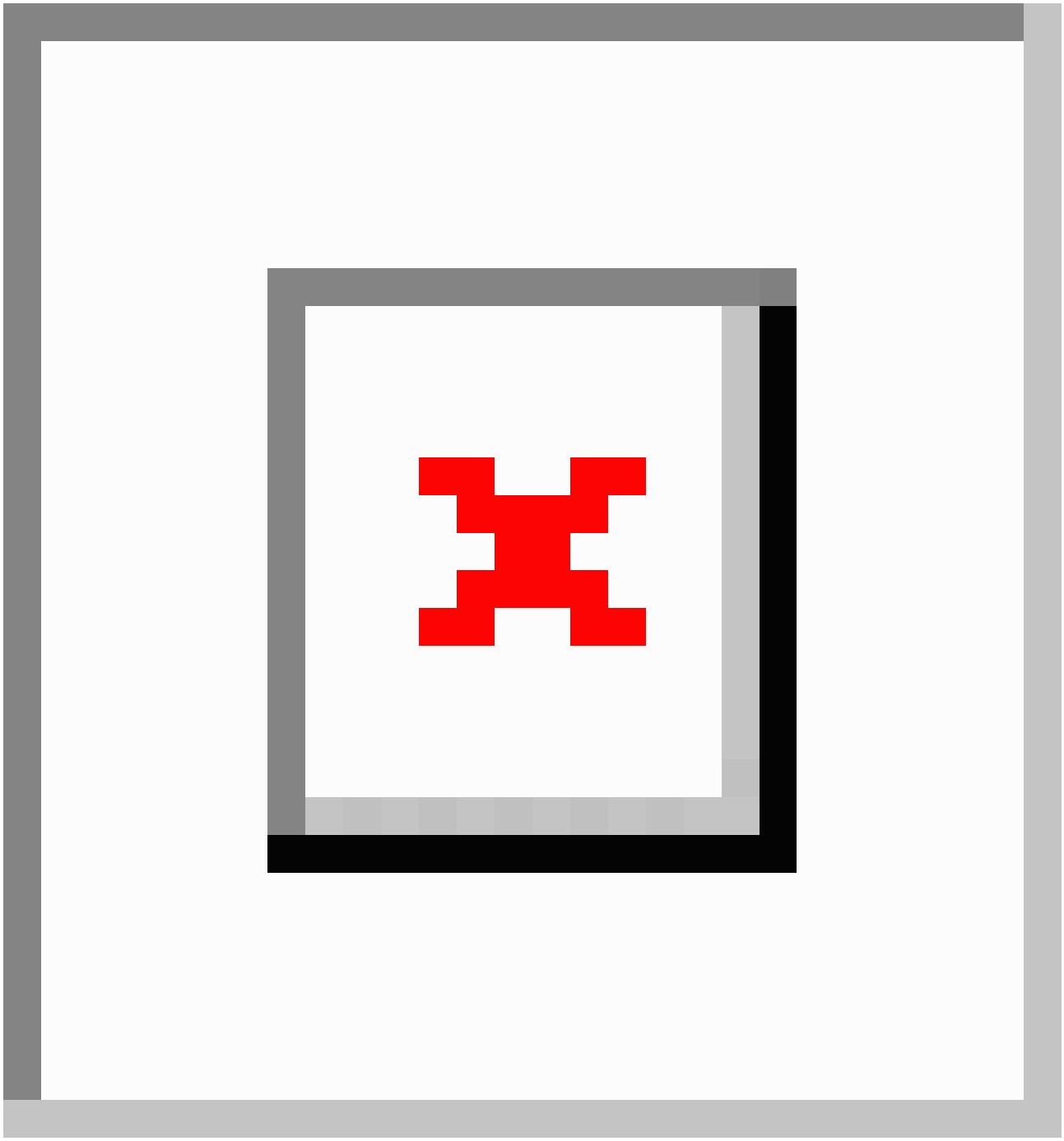
Table . Total error count and task success per task. No times were measured for explorative tasks (tasks 3, 5, 7, and 9).

Task ID	Errors, n	Successfully completed tasks (n=11), n (%)
1	1	2 (18)
2	17	11 (100)
4	1	11 (100)
6	4	11 (100)
8	8	5 (46)
10	3	11 (100)

Usability Questionnaires

The app received a mean SUS score of 79.09 (SD 18.38). According to the UEQ, participants rated the app's attractiveness, perspicuity, efficiency, and stimulation as "above average." It was rated as "good" in dependability and "below average" in novelty (Figure 3).

Figure 3. User Experience Questionnaire (UEQ) results. The app was rated as "above average" in most areas. The UEQ scales range from −3 to +3. The graphic was derived from the official UEQ evaluation benchmark tool, which crops ranges to improve readability.



Oral Think-Aloud Remarks and Comments

Participants requested a total of 23 features, of which 16 were unique (Table 3). The study identified 6 unique bugs (Table 4). Participants made 35 additional usability-related comments regarding 25 unique items (Table 5).

Table . Feature requests as stated by users during the study.

Description	Context	Users, n
Interactive graphs: zoom, pan, hover	Data visualization	4
Upload ultrasound picture	Ultrasound	3
Emergency contact phone numbers	General	2
Send recommendations based on mood trend	Journal	2
Gravida and para values updated automatically	Maternity logbook	1
Contextual explanation of concepts that appear in the app	General	1
Contextual explanation of pregnancy concepts in the app	General	1
Provide information about size and weight of the baby	General	1
Information about items needed when giving birth	Information	1
Information on health professionals involved during pregnancy	Information	1
Reuse information from previous pregnancies	Maternity logbook	1
Overview of scheduled appointments as in the paper version	General	1
Show a questionnaire to enter basic data at first app use	General	1
Show visualization of mood trend	Journal	1
Support multiple pregnancies	Maternity logbook	1
Ultrasound curves	Ultrasound	1

Table . Bugs encountered by users during the study.

Description	Users, n
Automatic logout after some time	7
Scrolling up to the top refreshes the app	6
Installation did not work	1
Opening tasks menu does not delete completed tasks	1
Page reload for unknown reason	1
Questionnaire was not sent	1

Table . Other usability-related comments made by users during the study.

Description	Context	Users, n
Show meaning of abbreviations	General	4
Too much scrolling in the app	General	3
Side menu: too much information	General	3
Unclear why the app needs to be installed	App installation	2
Confusing that the Mutterpass data is editable	Maternity logbook	2
Side menu: avoid scrolling up each time to access side menu	General	2
Heart frequency plots without labels	Data visualization	1
Show the gravidogram version in a user-friendly way	Maternity logbook	1
Visualization options: not easy to find	Data visualization	1
Side menu: use collapsible structure	General	1
Side menu: make it sticky to avoid scrolling up to open it	General	1
Side menu: colors make it unclear which parts are clickable	General	1
Show time estimated to finish a questionnaire	General	1
Show previous ultrasound examinations first by default	Ultrasound	1
Show reference values in plot	Data visualization	1
Heart frequency plots without legends	Data visualization	1
Reduce the amount of information on each screen	General	1
Reduce number of needed clicks in questionnaires	General	1
Horizontal scrolling tabs not discoverable	General	1
Hide technical information from the Mutterpass by default	Maternity logbook	1
Color code open tasks if done or in progress	Open tasks	1
Use smaller icons in main screen to reduce scrolling	General	1
Due date estimation: too much information	Maternity logbook	1
Journal option not discoverable	Journal	1
Visualization options: text would look better as a table	Data visualization	1

Semistructured Interviews

The following paragraphs summarize the findings from the semistructured interviews. A more detailed tabular summary is provided in Multimedia Appendix 3.

Information Seeking and Online Research

Participants were initially asked about their preferred information depth for medical pregnancy information. For example, they were asked whether they preferred only basic information, as they may feel overwhelmed, or wanted to know "all pregnancy details." Participants answered either that they had no problem during their pregnancy and thus could not answer the question (1/11), did not prefer deep information (1/11), relied on their physician to deliver adequate information (3/11), felt overwhelmed by information when things were not in order (1/11), or wanted to know all information (5/11). Almost half (5/11) of the participants searched online for information. Three explicitly mentioned that they do not perceive online forums or blogs as trustable. Apps were mentioned 3 times, although one participant said that she ultimately did not use them, as she did not want to pay for them. The reliability of sources, such as apps officially published by a government authority, was a reoccurring topic (4/11). Some participants stated they used books or scientific papers (3/11).

Wearables and Wearable Data Interpretation

Participants were invited to discuss the use of wearables during pregnancy, as well as the resulting data presentation (such as vital parameters) and interpretation. Two participants stated they would use wearables as part of regular prenatal care, with one having had a situation in the past where the technology would have been helpful. Almost half (5/11) mentioned that they would only use wearables if required to do so by their physician. One participant mentioned that the use of wearables might be helpful if risk factors were present (such as underweight or obesity). Two participants explicitly stated that they would not use wearable devices. Privacy and cyberchondria concerns were mentioned by 2 participants each.

Regarding the presentation and communication of data-derived information in the app, 1 participant stated that the full data must be accessible to the women. On the contrary, 2 mentioned that the data should only be interpreted by the physician. When asked about how users should be informed about detected anomalies in the recorded data, 6 women stated that they would like to receive a notification in these cases. Out of these 6, 1 said that a physician visit should be enforced after receiving such a notification, another requested immediate feedback to assist with the problem (eg, breathing exercises), 1 stated that data should be generally hidden as she did not understand it, and 2 stated that these notifications should only appear upon severe anomalies.

In terms of data visualization, 2 participants mentioned that this should be organized in a way that a summary or interpretation is first shown before displaying detailed data. One participant mentioned that she could not give any suggestion about how to display the data or whether notifications are useful, as the app or its algorithm may not be trustable in the first place.

At-Home Examinations and Current Practice

Participants were asked whether they could imagine replacing a limited number of in-person obstetrician-gynecologist visits by conducting at-home measurements. One participant agreed with this idea but mentioned that it depended on the pregnancy and potential complications. One stated that fewer appointments could be convenient when a long drive to the doctor's office is necessary. Another participant mentioned that she overall liked the appointments, but those where the physician was not involved could be potentially replaced. A total of 4 of 9 participants mentioned that they preferred the appointments, as they felt safer (1/4) and were able to ask questions (2/4). The question was not asked in 2 interviews as a result of the semistructured approach.

Data Donation: Sharing Data for Research Purposes

Lastly, data sharing for research purposes was discussed with participants. All but one woman stated they would share their data for research purposes, and 6 of 11 explicitly mentioned that the data should be anonymized. Several additional points were discussed by participants: security was perceived as important (1/11); the study and ethics committee should be named (1/11); participants would not share data if the data were invasive (1/11); a clear data protection policy is important (1/11); and data users must follow regulatory recommendations (1/11). One participant stated that she is privacy aware in everyday life but does not have these concerns regarding maternal record data.

Discussion

This work aimed to assess usability and perceptions of a wearable-integrated DMR smartphone app. A user study was conducted for this purpose.

Key Results

The app's SUS score was a mean 79.09 (SD 18.38). This is in the 85th percentile compared to literature benchmarks and represents above average usability [33]. The app scored "above average" in all categories but "novelty." We believe this is attributable to our close copy of the analogue (paper) version of the German maternity record (Mutterpass). It was not our aim to redesign the document, as this is outside the scope of this work. Therefore, we closely copied the document in the maternity record section of our app but did not explore all benefits for the health care setting of a digital redesign.

TCTs in all tasks were higher than those modeled with GOMS, with the highest differences in tasks 1, 2, and 8. The long time taken for task 2 can be attributed to the atypical app installation process. As the app is a PWA, it is installed by using browser-delivered functionality as opposed to an app store. The respective instructions are lengthy and require participant effort. In task 8, users were able to choose different visualization options through a "slide-to-the-side" bar on top of the page. This functionality and the choice of visualization options was not obvious to users. The visualization options were presented using a "slide-to-the-right" bar, also resulting in user experience problems. Users performed think-alouds throughout the tasks. This may also have had a negative effect on task completion time.

Most errors occurred in task 2 (ie, app installation, during which 17 errors occurred; Table 2). The menu button was placed on the top left of the page. It was thus not visible unless users scrolled to the top of the page, which resulted in corresponding errors. Task 1 (user creation and login; 2/11, 18%) and task 8 (find heart rate value; 5/11, 46%) had low task success rates. In the first task, users tried to log in without having previously registered an account, which can be ascribed to poor study instructions. Task 8 suffered from the presentation of visualization options, as explained in the previous paragraph. The study was overall very helpful in finding usability problems in our app, which we continue to improve for future use. This equally applies to the feature requests made by participants.

The trustworthiness of pregnancy apps was considered as important by several women, which favored apps from official sources. This underlines our overall concept.

Interviews provided insights into the perception of individual aspects of our DMR concept. Opinions regarding the overall concept of a wearable-integrated DMR app were mixed. Participants stated that a clear benefit must be communicated, and this benefit should be communicated by the caretaking obstetrician-gynecologist. Participants that experienced

pregnancy complications in the past were overall more open toward the idea.

Comparison With Prior Work

To the best of our knowledge, previous work, including think-aloud usability sessions or studies focusing on wearable integration in maternity care, is limited to date. Our work is the first to examine usability in a DMR environment using the think-aloud method and the first overall to investigate aspects of usability when integrating wearable data into a DMR app.

Usability is often reported as a secondary element or through postuse surveys or questionnaires [21,22,34]. Scott et al [35] analysed commercial pregnancy apps and found that only 2 of 10 apps had full usability. An online tool for gestational diabetes reached a SUS score of 70.9 [36]. The only study we identified that used think-aloud sessions investigated an app for pregnancy-related work advice [37]. A total of 82 usability problems were identified, and the overall mean SUS score was 68. In light of these findings from the literature, we believe our app (mean SUS score 79.09, SD 18.38) overall has high usability compared to its peers. It furthermore benefited and will continue to benefit from our UCD approach.

Our results from the semistructured interviews are overall in line with previous work. Groenen et al [38] found that users do not start a DMR if they feel it has no perceived value and that physicians play a key role in the adoption of technology. In this previous work, participants similarly stated that pregnancy complications increase the value of technology. Other work confirms these findings [15,16].

Strengths, Weaknesses, and Contribution

Several limitations apply to our work. Participants did not conduct the study on their phones, but instead used a phone interface on their desktop computers. This was necessary due to COVID-19–related restrictions. Usability problems related to the actual end device and its use (eg, smartphone or tablet) cannot be discovered in such a setting. The SUS score was shown as a questionnaire in the app. We used a vertical instead of a horizontal layout for the Likert questions, which could influence results. Overall, participants had a both a comparably high education level as well as household income. Women with low digital affinity may be less likely to participate in a study such as ours, and could thus be underrepresented. Interviews may have been biased in the sense that not every participant was asked every question, as they were designed as semistructured sessions to catch overall perceptions and impressions. The semistructured interviews conducted as part of our study design could benefit from additional participants. We did not use a fixed threshold since the last pregnancy as an inclusion criterion. Thus, the time since the last pregnancy varied between participants. This may have influenced participants' responses.

Our study combines several strengths: Regarding the usability study and think-alouds, a sufficient number of women with previous pregnancy experience participated, and the participant size was adequate for the proposed study design [39,40]. We are the first to explicitly conduct an observational usability study of pregnancy mobile health, compared to previous work that relied on postuse questionnaires. Furthermore, we are the first to evaluate several mobile health and ubiquitous health concepts, including the use of wearables in care practice, in one single prototype. We believe this descriptive prototype makes it easier for participants to understand the underlying concepts and the potential impact on their personal life. Additionally, we evaluated several connected topics of high importance in the realm of mobile and ubiquitous health in maternal care, particularly regarding information research, health anxiety, reaction to potential alerts, and data sharing for research.

Future Work and Areas for Innovation

We propose several areas for future work. These proposals are based on statements of the participants, the literature, experiences during app development, and lessons learned from conduct of this study. They target both industry innovation and future scientific work.

Participants stated that they would appreciate additional explanations within the DMR section of the app. The existing German paper-based hand-held maternity record largely relies on medical terms and abbreviations. Based on the interviews and our clinical experience, these are not understood by many women. The DMR has the potential to provide understandable additional information in close proximity to the respective fields. This can include easy-to-understand explanations and expert videos; it could even be tailored to individual measurement values or findings.

The visualization and communication of recorded and potentially automatically assessed wearable data must be considered in future work. There was no consensus on whether data should be completely accessible by or hidden from the user. Some participants were aware of potential risks such as cyberchondria and preferred not to view the full data in the first place.

An important related question is the reaction to abnormal measurements. Should the user or the physician be notified? Participants were equally split regarding this question. One way to address these mixed opinions could be a user-controlled setting.

DMRs have the potential to alleviate media discontinuties [23]. They can improve information flow from women to caregivers as well as between caregivers. Thus, DMRs may be a tool to improve overall care.

Recommendations for the use and application of wearables in routine care may be helpful for both pregnant women and caregivers. An important question for future discussion is the measurement reliability of devices and interpretation of the generated data. The latter is relevant as data are generated "in the field" outside the supervision of medical professionals and could be of lower quality and reliability.

Sharing data for research was favored by most participants, although this finding may be biased given that we only interviewed participants that decided to take part in a scientific study in the first place.

Our work only investigated usability, perception, and opinions on several related topics among women who had been pregnant in the past. Longitudinal studies during pregnancy may be

helpful to examine how app interaction, opinions, and related phenomena (such as cyberchondria) change throughout pregnancy.

Conclusion

We were the first to assess the concept of a wearable-integrated DMR app in terms of usability and overall perception. The app combined several concepts: the maternity record itself, information sections, selected consumer pregnancy app functionalities, and the integration of wearable data. Semistructured interviews on online information research, the use of wearable devices, integration into routine care, and data sharing for research completed the study.

Our work found good overall usability and was helpful in identifying usability problems as well as errors. Participants were of mixed opinions regarding the integration of wearable technology into prenatal care. Clear benefits of such devices must be communicated to prospective users to ensure user acceptance. Pregnant women rely on the opinion and guidance of their caretakers, particularly gynecologists and midwives, who thus play a key role in the adoption of mobile and ubiquitous health technology such as wearables in maternal care.

Opinions on the display of wearable data, its evaluation, alert levels, and handling of potential alerts were mixed and highly individual. Some women preferred to see all data, while others explicitly did not want access to it. Future work should thus investigate different personalized options for wearable data display, interpretation, automated evaluation, and potential reaction to alerts.

Acknowledgments

This work was supported by the Federal Ministry of Health on the basis of a decision by the German Bundestag (grant 2519DAT400). BME gratefully acknowledges the support of the German Research Foundation within the framework of the Heisenberg professorship program (grant ES 434/8-1). We acknowledge financial support from Deutsche Forschungsgemeinschaft and Friedrich-Alexander-Universität Erlangen-Nürnberg within the funding program Open Access Publication Funding.

Authors' Contributions

MN conceived the study, developed the app and study design, analyzed data, assisted in interviews, and wrote the manuscript draft. CA Perez assisted in app development, developed the study design, conducted interviews, and analyzed data. All authors reviewed the final manuscript. KMJ, HB, and MF assisted in writing the manuscript. HB provided ethical expertise and assisted in developing the study design. HH, ND, AT, CA Pontones, PAF, and MWB provided clinical expertise and requirements for app development. PAF, MWB, BME, and HL initiated and supervised the project. All authors reviewed the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Retrospectively translated English version of example screenshots of the developed app (from top left to bottom right): “Start,” “My tasks,” “MAPI questionnaire,” “Installation guide,” “My measurements,” “Main menu,” “Ultrasound section,” and “Information” section. The app is intended for a German audience and was thus originally developed in German. This version was not used in the study but is provided for reference and clearer presentation.
[PNG File, 391 KB - pediatrics_v6i1e50765_app1.png]

Multimedia Appendix 2
Example app walkthrough based on the study procedure.
[PDF File, 1414 KB - pediatrics_v6i1e50765_app2.pdf]

Multimedia Appendix 3
Tabular overview of participants’ responses during the semistructured interviews.
[PDF File, 239 KB - pediatrics_v6i1e50765_app3.pdf]

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Abbreviations

DMR: digital maternity record
GOMS: goal, operators, methods, and selection rules
PWA: progressive web app
SUS: System Usability Scale
TCT: task completion time
UCD: user-centered design
UEQ: User Experience Questionnaire

Edited by S Badawy; submitted 12.07.23; peer-reviewed by G Colonna, M Gong; revised version received 20.09.23; accepted 02.10.23; published 15.12.23.

Please cite as:
Nissen M, Perez CA, Jaeger KM, Bleher H, Flaucher M, Huebner H, Danzberger N, Titzmann A, Pontones CA, Fasching PA, Beckmann MW, Eskofier BM, Leutheuser H
Usability and Perception of a Wearable-Integrated Digital Maternity Record App in Germany: User Study
JMIR Pediatr Parent 2023;6:e50765
URL: https://pediatrics.jmir.org/2023/1/e50765
doi:10.2196/50765

Original Paper

Evaluating the Impact of an App-Delivered Mindfulness Meditation Program to Reduce Stress and Anxiety During Pregnancy: Pilot Longitudinal Study

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Abstract

Background: Stress and anxiety during pregnancy are extremely prevalent and are associated with numerous poor outcomes, among the most serious of which are increased rates of preterm birth and low birth weight infants. Research supports that while in-person mindfulness training is effective in reducing pregnancy stress and anxiety, there are barriers limiting accessibility.

Objective: The aim of this paper is to determine if mindfulness meditation training with the Headspace app is effective for stress and anxiety reduction during pregnancy.

Methods: A longitudinal, single-arm trial was implemented with 20 pregnant women who were instructed to practice meditation via the Headspace app twice per day during the month-long trial. Validated scales were used to measure participant's levels of stress and anxiety pre- and postintervention. Physiological measures reflective of stress (heart rate variability and sleep) were collected via the Oura Ring.

Results: Statistically significant reductions were found in self-reported levels of stress (P=.005), anxiety (P=.01), and pregnancy anxiety (P<.0001). Hierarchical linear modeling revealed a statistically significant reduction in the physiological data reflective of stress in 1 of 6 heart rate variability metrics, the low-frequency power band, which decreased by 13% (P=.006). A total of 65% of study participants (n=13) reported their sleep improved during the trial, and 95% (n=19) stated that learning mindfulness helped with other aspects of their lives. Participant retention was 100%, with 65% of participants (n=13) completing about two-thirds of the intervention, and 50% of participants (n=10) completing ≥95%.

Conclusions: This study found evidence to support the Headspace app as an effective intervention to aid in stress and anxiety reduction during pregnancy.

(JMIR Pediatr Parent 2023;6:e53933) doi:10.2196/53933

KEYWORDS

mindfulness app; pregnancy; pregnant; maternal; obstetric; obstetrics; stress; anxiety; heart rate variability; mindfulness; mHealth; mobile health; app; apps; applications; mental health; meditation; mind-body; complementary; alternative; heart rate; sleep; mobile phone

Introduction

Overview

Stress and anxiety during pregnancy are extremely prevalent, where an estimated 58% of people who are pregnant experience prenatal stress [1], and 25% experience anxiety [2]. Stress and anxiety during pregnancy are associated with numerous poor outcomes, among the most serious are increased rates of preterm birth [3] and low birth weight infants [4]. According to the World Health Organization (WHO), preterm birth is the leading cause of infant morbidity and mortality in children worldwide [5], with an estimated 15 million preterm infants born annually [6]. In the United States, approximately 11% of infants are born preterm [7], leading to societal costs of US $26 billion each year [8].

Mind-body practices like yoga and mindfulness meditation are becoming increasingly popular to manage stress and anxiety. Mindfulness is the awareness that arises through paying attention, on purpose, in the present moment, nonjudgmentally [9]. There is evidence that mindfulness meditation training can have a beneficial impact on reducing perinatal stress [10] and anxiety [11]. However, in-person instruction has barriers including accessibility, availability, cost, and time.

Internet mindfulness-based interventions (iMBIs), including computer and app-based resources, provide a convenient alternative to traditional mindfulness classes. Studies examining the impact of iMBIs during pregnancy found a reduction in stress [12,13] and anxiety [14,15]. However, limitations included high attrition, poor adherence, and lack of objective or physiological measures of stress, like heart rate variability (HRV) and sleep. Research supports that HRV is an objective, reliable measure of stress [16]. Sleep is also reflective of stress, where improved sleep reduces stress [17]. None of the reviewed studies used top-rated iMBIs like the Headspace app. Headspace is among the highest-scoring mindfulness apps based on the Mobile Application Rating System [18]. The purpose of this study was to determine if a more accessible form of mindfulness meditation training, specifically Headspace, can help reduce stress and anxiety during pregnancy.

Theoretical Framework

The theoretical framework for this study is based on the polyvagal theory [19], which postulates that the vagus nerve has two branches that regulate different physiological states: the dorsal vagal complex, associated with immobilization behaviors (rest or digest and shutdown or freeze), and the ventral vagal complex, associated with social engagement, calm, and safety [19]. Relaxation practices like meditation activate the ventral vagal complex, reducing stress [20], and improving HRV [21]. Various HRV metrics, which are reflective of vagus nerve activity, can be extracted. For example, the HRV metric the root-mean-square of successive differences between adjacent normal heartbeats (RMSSD) is mediated by the vagus nerve [22], with higher values indicating relaxation and lower mental stress [23]. The HRV metric low-frequency (LF), reflects a mix of the sympathetic and vagal influences on HRV [24], and lowers with relaxation practices, like mindfulness [25,26].

HRV Changes in Pregnancy

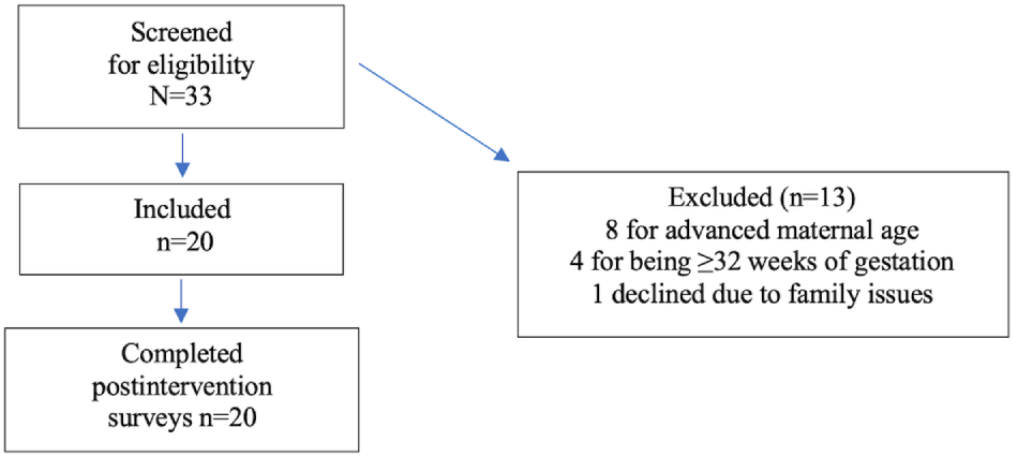
Most HRV metrics decrease throughout pregnancy [27,28]. A recent study, which evaluated HRV changes during pregnancy against age-matched nonpregnant controls, found that there was reduced HRV in the pregnant groups for all trimesters [29]. A more recent systematic review evaluating 8 research studies measuring HRV trends across gestation in healthy pregnant women found further evidence that HRV decreases across gestation for all HRV metrics but 2. The LF and the LF per high-frequency (HF) ratio showed an ascending trend from early to late pregnancy [28]. Despite the variations in HRV observed during pregnancy as compared to the nonpregnant population, several studies have used HRV as a physiological measure of stress during pregnancy [26,30-32].

Methods

Participants

The study sample consisted of 20 study participants to achieve 80% power with a moderate effect size (0.35) and α of .05. The inclusion criteria were (1) pregnant people residing in San Diego County; (2) age 18-35 years; (3) between 10 and 32 weeks gestation; (4) able to read and understand English; and (5) access to a smartphone, Wi-Fi, email, and able to download apps. Exclusion criteria were (1) people who regularly (≥3× per week) engaged in other mindfulness practices like yoga, (2) concurrent enrollment in a mindfulness meditation class, (3) hearing impairment, (4) cognitive impairment, (5) chronic health or pregnancy-related medical condition causing “high risk” pregnancy, (6) current psychotherapy, (7) current psychoactive medications, and (8) severe depression or anxiety. A total of 33 people were screened for eligibility, with 8 excluded for advanced maternal age, and 4 were excluded because they had passed 32 weeks of gestation (Figure 1).

Figure 1. CONSORT diagram. CONSORT: Consolidated Standards of Reporting Trials.



Ethical Considerations

After the institutional review board approval from the University of California, Irvine (HS# 2021-6664), recruitment flyers were posted at maternity clinics, describing the study, and providing contact information. Once contacted, potential participants were sent a recruitment email containing further study details and instructions to contact the investigator if they met eligibility criteria. Next, a phone conversation was scheduled to further assess eligibility, provide details, and answer questions. During the call, potential participants were asked to give their verbal consent for the investigator to further assess their eligibility, and screen them for severe anxiety and depression. Participants were informed that all records would be kept confidential and stored in REDCap (Research Electronic Data Capture; Vanderbilt University), a Health Insurance Portability and Accountability Act of 1996 (HIPAA)–compliant web-based app for managing clinical research data.

Design and Procedure

Potential participants were screened for severe depression using the Edinburgh Postnatal Depression Scale (EPDS) [33] and severe anxiety using the Generalized Anxiety Disorder Scale (GAD-7) [34]. EDPS scores of ≥19 and GAD-7 scores of ≥15 rendered potential participants ineligible. Next, a meeting was arranged for consent, completion of baseline measures, and assistance with study apps and materials (Multimedia Appendix 1). Participants were loaned an Oura Ring to wear nightly during the study period. Participants wore the ring for 4 days (2 workdays and 2 days off) prior to starting the intervention to get a baseline HRV reflective of their stress levels. The researcher monitored the Oura Ring server throughout the experiment to assess participant compliance with wearing the Oura ring, and that data were recorded. Surveys and measures of stress and anxiety were completed at baseline and study completion, and measures for anxiety were additionally collected at the study midpoint (Multimedia Appendix 2).

Incentive

As a study incentive, participants each received a 6-month subscription to the Headspace app, as well as US $50. Once mid-study surveys were completed, participants received a US $15 gift card incentive by email. At study completion, once the participants finished the final study measures, they were contacted by the investigator to arrange a meeting time and place to return their Oura Ring and charger and receive their remaining financial incentive (US $35 gift card).

Materials: Headspace

Participants were instructed to practice meditation with Headspace twice daily during the month-long trial, starting with “Basics,” followed by “Pregnancy.” “Basics” contained 30 meditations, between 3 and 20 minutes long, introducing the essentials of mindfulness meditation. Next, participants were instructed to complete 30 meditations in the “Pregnancy” course, between 10 and 20 minutes long, which focused on the development of favorable conditions for pregnancy and birth. The total intervention was 60 meditations for a range of 530-1050 minutes.

Measures

Screening Measures

Screening Tool

A screening tool was used to assess eligibility via the inclusion and exclusion criteria.

Severe Depression

Potential study participants were screened for severe depression using the EPDS [33]. The EDPS has been validated against both the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) and the International Classification of Diseases, Tenth Revision (ICD-10), with high sensitivity and specificity [35]. Scores of this 10-item scale range from 0 to 30, with higher scores indicating the presence of depressive symptoms.

Severe Anxiety

Potential study participants were screened for severe anxiety using the GAD-7 [34]. The GAD-7 assesses the most prominent diagnostic features from the DSM-5 for generalized anxiety disorder [36]. The GAD-7 asks respondents to rate how often they experienced the survey anxiety symptoms within the last 2 weeks. Scores range from 0 to 21, and scores of 5, 10, and 15 are the respective cut-off points for mild, moderate, and severe anxiety [34]. The GAD-7 has demonstrated good reliability

(Cronbach α=.89) and validity in the pregnant population [37]. This measure was additionally used as an anxiety assessment at baseline and study completion.

Other Baseline Measure: Social Support

Social support was assessed using the Multidimensional Scale of Perceived Social Support (MSPSS) [38]. The MSPSS consists of 12 questions using a 7-item Likert scale for participant responses, ranging from "very strongly disagree" (1) to "very strongly agree" (7), with higher numbers indicating greater social support. The MSPSS has shown good-to-excellent internal reliability with a Cronbach α of .81-.98, and test-retest reliability of 0.92-0.94 [38].

Physiologic Measures and Dependent Variables

Heart Rate Variability

HRV data were collected by the Oura Ring, which wirelessly syncs data to the Oura app and server. The Oura Ring uses photoplethysmography for HRV monitoring, a commonly used signal in wearable technology designed for stress measurement. Oura Ring measurements of HRV are highly accurate [39]. Various HRV metrics were extracted and analyzed, with each metric correlating with a physiological representation of stress, depending on whether their values are low or high. To evaluate the impact of an intervention on these metrics, we can observe if the values increase or decrease. As the most accurate HRV assessments are recorded with the participant at rest in the supine position [40], HRV data were collected during participant sleep hours.

Sleep

Sleep data were collected by the Oura Ring, which analyzes sleep by measuring the following: resting heart rate (HR), body temperature, time spent in specific sleep stages (including light, deep, and rapid eye movement), and movement [41] via actigraphy, a validated method of measuring sleep via an accelerometer [42]. Oura's algorithms combine the measurements, yielding a sleep score ranging 0-100, with higher scores indicating better sleep. Oura Ring measurements of sleep are highly accurate [43].

Self-Report Measures

General Anxiety and Pregnancy Anxiety and Dependent Variables

To evaluate anxiety, the GAD-7 (see above) and the Pregnancy-Related Anxiety Scale (PRAS) [44] were used. PRAS is a measure specific to pregnancy anxiety (eg, worries about health during pregnancy and childbirth). This 10-item instrument used a Likert scale, where participants answered questions with options ranging from "never or not at all" (1) to "a lot of the time or very much" (4). Scores range from 0 to 30, with higher scores indicating greater anxiety. This scale has good internal reliability, with a Cronbach α of .78 [44].

Stress, Dependent Variable

Stress was measured using the Perceived Stress Scale (PSS) [45], a questionnaire that was designed to measure how uncontrollable and overloaded participants perceive their lives to be [45]. The PSS-10 is a 10-item, 5-point Likert scale assessment, which asks participants questions based on their thoughts or feelings over the previous month. Scores range from 0 to 40, with higher scores indicating higher stress. The PSS has good psychometric qualities [45,46], with good internal consistency and a Cronbach α of .89 [46].

Investigator-Developed Items

Investigator-developed items were collected at baseline and study completion to assess potentially confounding lifestyle information (medications, substance use, and exercise). An example Likert-style question used in the exit survey was "My exercise level increased during this trial" with answers ranging from "strongly disagree" to "strongly agree," and an open-ended question asking how learning and practicing mindfulness meditation helped with other aspects of their life.

Data Analysis

HRV and sleep data were obtained from the Oura dashboard and analyzed. To extract HRV features, we used the interbeat interval (IBI) data. Oura calculates HR and IBI using the optical photoplethysmography sensor embedded in the Oura Ring. Time-domain variables (HR, RMSSD, and SD of the IBI of normal sinus heartbeats, with "normal" referring to the removal of artifact [SDNN]) were extracted through statistical analysis, and frequency domain variables (LF, HF power bands, and LF per HF ratio) were extracted and analyzed by fast Fourier transform and power spectral density algorithms [16,22]. To assess potential physiological changes reflective of reduced stress (HRV and sleep changes over time), hierarchical linear modeling (HLM) was used.

To evaluate subjective changes in stress, anxiety, and pregnancy anxiety, the self-report measures (PSS, GAD-7, and PRAS) were assessed at baseline and study completion. Paired 1-tailed *t* tests compared the before and after observations on the same subjects. Subjective sleep was assessed with a Likert scale prompt on the postintervention questionnaire: "My sleep improved during this trial," with options ranging from "strongly disagree" to "strongly agree."

Results

Participants

Most study participants were White (n=16, 69.6%), educated (n=18, 90% completed college), with high social support (n=18, 90%), married (n=15, 75%), working full-time (n=14, 70%), and an average age of 29.45 years (Table 1). Data on exercise were collected as an increase in exercise level during the trial could have been a potential confounder. At baseline, 50% (n=10) of the women reported exercising regularly. Use of certain medications, alcohol, tobacco, recreational drugs, and excessive caffeine can impact HRV [47], so baseline data on participant usage were collected. All participants denied taking medications that are known to impact HRV, and 100% (n=20) of the participants denied use of alcohol, recreational drugs, tobacco, and vaping. All participants indicated they consumed low-to-no caffeine (≤1-2 cups per day). At baseline, 60% (n=12) of participants reported regular stress-management activities (eg, prayer and massage). Participants' baseline stress and anxiety levels were low-to-moderate. Baseline stress (PSS) levels were

as follows: 50% (n=10) had low, 45% (n=9) had moderate, and 5% (n=1) had high stress. Baseline general anxiety (GAD-7) levels were as follows: 65% (n=13) had mild, 25% (n=5) had moderate, and 10% (n=2) had severe general anxiety. Baseline pregnancy anxiety (PRAS) was interpreted as mild to moderate (mean score 10.84, SD 5.2).

Parity and gestation trimester can impact HRV [27]. Most study participants were primiparous (n=12), while the remainder were multiparous. At the start of the study, 30% of participants (n=6) were in their first trimester, 55% (n=11) were in their second trimester, and 15% (n=3) were in their third trimester. During the month-long trial, all participants stayed within a week range of their original trimester, except for 3 who changed, 1 from first to second and 2 from their second to their third trimester. At study completion, 25% (n=5) were in their first trimester, 50% (n=10) were in their second trimester, and 25% (n=5) were in their third trimester (Table 1).

Table 1. Sample baseline characteristics.

Characteristics	Values
Age, mean (SD)	29.45 (3.27)
Race or Ethnicity (including dual ethnicity identity), n (%)	
White or European American	16 (69.6)
Hispanic or Latino	4 (17.4)
Asian or Pacific Islander	2 (8.7)
Black or African American	0 (0.0)
Other	1 (4.3)
Parity, n (%)	
Primiparous	12 (60)
Multiparous	8 (40)
Trimester of gestation, n (%)	
First trimester	6 (30)
Second trimester	11 (55)
Third trimester	3 (15)
Education, n (%)	
Completed master's degree or higher	6 (30)
Completed bachelor's degree	8 (40)
Completed associate degree	4 (20)
Completed high school or equivalent	2 (10)
Relationship type, n (%)	
Married	15 (75)
Cohabitating	3 (15)
Single	2 (10)
Employment status, n (%)	
Full-time	14 (70)
Part-time	3 (15)
Unemployed	3 (15)
Exercise, n (%)	
Regular exercise	10 (50)
No regular exercise	10 (50)
Denied alcohol, recreational drugs, or vaping	20 (100)
Caffeine, n (%)	
Denied caffeine use	7 (35)
Drank 1-2 cups of caffeinated drinks per day	13 (65)
Regular stress-management activities, n (%)	
Yes	12 (60)
No	8 (40)
Social support, mean (SD)	6.14 (0.73)
High social support	18 (90)
Moderate social support	2 (10)
Low social support	0 (0)

HRV

The HLM analysis of the physiological data showed changes in HRV reflective of reduced stress (Table 2). A total of 1 of 6 HRV metrics, LF, changed in the direction of reduced stress, lowering by 13% (P=.006). The LF per HF ratio changed in the direction of reduced stress, decreasing by 2% and trending toward significance (P=.09). The statistically significant results in 2 additional HRV metrics, HR and RMSSD, moved in the opposite direction of what was hypothesized, with minimum or resting HR increasing by 2.3% (P=.007), and RMSSD decreasing by 9% (P=.007). SDNN (P=.09) and HF (P=.07) both decreased, moving opposite of the hypothesized direction.

Table 2. Results of physiological stress outcome measures.

Monitoring parameter or metric	Expected direction of change indicating reduced stress [26]	% change in 4 weeks	*P* value
HRV[a] metric			
Min HR[b] (resting)	↓	Increased by 2.3	.007
RMSSD[c]	↑	Decreased by 9	.007
SDNN[d]	↑	Decreased by 7	.09
HF[e]	↑	Decreased by 11	.07
LF[f]	↓	Decreased by 13	.006
LF per HF ratio	↓	Decreased by 2	.09
Sleep metric			
Sleep score	↑	Increased by 2	.09

[a]HRV: heart rate variability.

[b]HR: heart rate.

[c]RMSSD: the root mean square of successive differences between adjacent normal heartbeats.

[d]SDNN: SD of the IBI of normal sinus heartbeats, with “normal” referring to the removal of artifact.

[e]HF: high-frequency.

[f]LF: low-frequency.

Stress

Paired *t* test analysis yielded statistically significant reductions in stress (P=.005) from baseline to postintervention (Table 3).

Table 3. Pre- and postintervention mean comparisons for self-report variable.

Measure	Pre, mean (SD)	Post, mean (SD)	*P* value
PSS[a]	14.4 (5.83)	10.25 (5.4)	.005
GAD-7[b]	4.65 (3.25)	2.6 (2.93)	.01
PRAS[c]	10.84 (5.2)	5.9 (3.99)	.0001

[a]PSS: Perceived Stress Scale.

[b]GAD-7: General Anxiety Disorder Scale.

[c]PRAS: Pregnancy-related Anxiety Scale.

General Anxiety and Pregnancy Anxiety

Paired *t* test analysis yielded statistically significant reductions in anxiety (P=.01) and pregnancy anxiety (P=.0001) from baseline to postintervention (Table 3).

Sleep

HLM analysis of sleep indicated that sleep score increased by 2%, trending toward significance (P=.09; Table 2), which reflects decreased stress. On the exit survey, 13 (65%) participants reported their improved sleep during the trial.

Other

Regarding potential confounders, none of the study participants were on medications or used substances that may have impacted their HRV. A total of 9 study participants indicated that their level of exercise increased during the study period. Of the 13 participants who reported improved sleep during the trial, 6 reported increased exercise.

An exit survey question asked, “Did learning/practicing mindfulness meditation help with other aspects of your life?” The overwhelming majority, 19 participants, answered “yes.” A total of 17 participants provided narrative details, and a

quasi-qualitative thematic evaluation identified that learning and practicing mindfulness meditation helped study participants with the following: improved patience, improved perspective, improved focus, improved conflict management, reduced emotional reactivity, and a greater focus on self-care. All participants completed the postintervention assessments, received their financial incentive, and returned the Oura Rings and chargers, indicating a 100% retention rate, with no attrition.

Discussion

Principal Findings

This study found evidence to support that the Headspace app is an impactful mindfulness meditation intervention to aid in stress and anxiety reduction for the pregnant population. Study results indicated that LF, 1 of 6 HRV parameters evaluated in this study, decreased significantly by 13% (*P*=.006). LF reflects both sympathetic nervous system (SNS) and parasympathetic activity, with the SNS and baroreceptor activity playing a large role in generating this frequency [22]. A recent systematic review which included 8 studies analyzing HRV among healthy pregnant women found that LF showed an ascending trend from early to late pregnancy, indicating that an increase in sympathetic activity is common in pregnancy [28]. As lower levels of power in the LF band indicate relaxation and low mental stress [48], the reduced levels of LF in this trial support the efficacy of the intervention for stress reduction among study participants. Another HRV metric, LF per HF ratio, decreased by 2%, trending toward significance (*P*=.09). The LF per HF ratio is a commonly used index of sympatho-vagal balance and generally increases with stress [23,48]. Therefore, the decreased value suggests reduced mental stress for study participants.

In the literature using HRV metrics as outcome variables, when one of the metrics changed in the direction expected for a stress-reducing intervention, the findings were reported as evidence that the intervention was effective [30,31]. Therefore, the HRV results in this study follow current reporting trends.

In this trial, the HLM analysis indicated that the participants' HR measure changed in the opposite direction of what was hypothesized, increasing by 2.3% (*P*=.007). For the general population, it is expected that a stress-reducing intervention would cause a decrease in HR. However, during pregnancy, there is an expected increase in HR. A recent meta-analysis evaluating trends in HR among 8317 pregnant women found that on average, the HR during pregnancy increased by 10% (7.6 beats per min) [49]. As the increase in HR for this pilot study population was 2.3% (*P*=.007), it is possible that the intervention impacted the participant's HR, potentially causing a smaller increase than would have been expected without a stress-reducing intervention. It could be that the impact was less pronounced due to the normal physiological pregnancy changes impacting HR.

The remaining HRV results in this pilot study were consistent with current research findings regarding the expected direction of HRV metrics during pregnancy. A recent study examining HRV trends across pregnancy compared to unpregnant matched controls found that SDNN, RMSSD, LF, and HF metrics decreased significantly during the second trimester [27]. Half of the women in this pilot study were in their second trimester, which could explain the decreased levels of these metrics observed in this experiment. Furthermore, it has been found that HRV reduction in pregnancy is more marked for primiparous versus multiparous women [29]. A total of 12 (60%) of the women in this pilot study were primiparous, which may have contributed to the study findings.

A total of 13 (65%) participants reported an improvement in their sleep during the trial, and the physiological data analysis found that sleep improved by 2%, trending toward statistical significance (*P*=.09). Exercise may have been a confounder, as exercise is associated with improved sleep and reduced stress [10] and anxiety [50]. Given that 9 (45%) study participants reported increased exercise during the trial, there is a question as to whether the improvement in their stress, anxiety, and sleep could have been related to exercise. A narrative review which included 13 studies evaluating mindfulness interventions during pregnancy noted that none of the studies evaluated sleep and asserted that it is imperative to evaluate sleep in this population [51]. This study contributes to the literature by including sleep as an outcome variable and by providing preliminary data that practicing mindfulness meditation with the Headspace intervention may improve sleep during pregnancy.

Participants were asked to complete 60 meditations, for a total range of 530-1050 minutes of meditation. A total of 13 of 20 participants completed ≥65% of the intervention, with 10 of those participants completing ≥95% of the intervention. This supports the acceptability and feasibility of Headspace as a mindfulness meditation intervention for this population.

Conclusion, Study Strengths, and Limitations

The use of technology via the Oura Ring and Headspace enabled the collection of objective data (HRV, sleep, and intervention-time usage), which contributed to validity. Using the Oura Ring to collect HRV data yielded approximately 3000 data points per individual, reducing the standard error in the results, and contributing to the overall study strength. The study design included best practices related to HRV collection, and the inclusion of recommended HRV variables [52]. That the study participants did not partake of potentially confounding substances (eg, alcohol and tobacco) was a strength, as was the collection of data that were potential confounders. There was a 100% participant retention rate, and adherence to the intervention was very good, providing support for the feasibility of this study design, and the usability and feasibility of the intervention.

The study may have been underpowered due to the sample size and potential lack of time engaging with the intervention to achieve significant findings in some HRV metrics. The sample population was homogenous, consisting of predominantly White, educated, women of low to moderate stress, and who self-selected to participate, which limits the generalizability of study results. Future research needs to be done with a more diverse study sample. Participants may have been influenced by the recommendations provided by the Oura Ring app. Subjective sleep was not evaluated with a validated scale and the qualitative analysis may have been biased as the investigator

was the sole interpreter. The GAD-7 assesses anxiety within the past 2 weeks. Recommendations for future research include a stronger study design, such as a randomized controlled trial (RCT) with a mixed methods component; for the RCT to have controls that are matched by factors that impact HRV (parity, gestational age, and maternal age); inclusion of a validated self-report sleep measure; objective collection of exercise data; and having a large enough sample size to independently analyze HRV trends per trimester. This study adds to the body of scientific knowledge supporting that mindfulness meditation, and specifically the Headspace app, is an effective iMBI for stress and anxiety reduction among the pregnant population. While future research is necessary, this pilot study showed promising initial results.

Acknowledgments

We thank Headspace, the study participants, and the dedicated librarian at the University of California, Irvine, Stephen Clancy, for their support. We would also like to thank the providers at West Coast Obstetrics and Gynecology, Best Start Birth Center, and Inge Taylor, Certified Nurse-Midwife for assistance with recruitment. With gratitude for the analytical support provided by Salar Hashemitaheri, and for the financial support received from emeritus faculty member at San Diego State University, Dr Betty L Broom, the California State University Chancellor's Doctoral Incentive Program, the University of California, Irvine Graduate Division, and the Sue & Bill Gross School of Nursing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Instructions and product information.
[PDF File (Adobe PDF File), 75 KB - pediatrics_v6i1e53933_app1.pdf]

Multimedia Appendix 2
Study timeline.
[PDF File (Adobe PDF File), 39 KB - pediatrics_v6i1e53933_app2.pdf]

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Abbreviations

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
EPDS: Edinburgh Postnatal Depression Scale
GAD-7: Generalized Anxiety Disorder Scale
HF: high-frequency
HIPAA: Health Insurance Portability and Accountability Act of 1996
HLM: hierarchical linear modeling
HR: heart rate
HRV: heart rate variability
IBI: interbeat interval
ICD-10: International Classification of Diseases, Tenth Revision
iMBI: internet mindfulness-based intervention
LF: low-frequency
MSPSS: Multidimensional Scale of Perceived Social Support

PRAS: Pregnancy-Related Anxiety Scale
PSS: Perceived Stress Scale
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture
RMSSD: root mean square of successive differences between adjacent normal heartbeats
SDNN: SD of the IBI of normal sinus heartbeats, with “normal” referring to the removal of artifact
SNS: sympathetic nervous system
WHO: World Health Organization

Edited by G Eysenbach, S Badawy; submitted 31.10.23; peer-reviewed by W Duan, F Sarhaddi; comments to author 18.11.23; revised version received 05.12.23; accepted 06.12.23; published 25.12.23.

Please cite as:
Balsam D, Bounds DT, Rahmani AM, Nyamathi A
Evaluating the Impact of an App-Delivered Mindfulness Meditation Program to Reduce Stress and Anxiety During Pregnancy: Pilot Longitudinal Study
JMIR Pediatr Parent 2023;6:e53933
URL: https://pediatrics.jmir.org/2023/1/e53933
doi:10.2196/53933
PMID:38145479

Implementation of a Web Camera System in an Australian Neonatal Intensive Care Unit: Pre- and Postevaluation of the Parent and Staff Experience

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Abstract

Background: Admission to a neonatal intensive care unit (NICU) for prematurity or illness is necessary for approximately 20% of newborns in Australia, resulting in parent-infant separation. Web cameras in the NICU provide a virtual link for parents to remain remotely connected to their infant during admission. Web camera use is increasing; however, there is limited evidence on the impact of web cameras on parents, infants, and neonatal staff.

Objective: There were two objectives: (1) to determine the attitudes of parents and staff toward web cameras in the NICU and (2) to compare parental depression, anxiety, and stress levels using validated scales before and after web camera implementation in the NICU.

Methods: A pre- and postevaluation survey was administered before and after implementation of the NICVIEW camera system in a tertiary NICU in Sydney, Australia. The NICVIEW camera system provides secure real-time viewing of infants and can be accessed from any device with an internet connection. Surveys were administered to parents of inpatients and staff, and included open- and closed-ended questions and Likert scales. Survey questions aimed to determine parent and staff attitudes and use of web cameras before and after implementation. In addition, pre- and postimplementation parental levels of depression, anxiety, and stress, as measured by the 21-item version of the Depression Anxiety Stress Scale (DASS-21) and Parental Stressor Scale: Neonatal Intensive Care Unit, were recorded.

Results: In total, 94 parents and 109 staff members completed the pre- and postimplementation surveys. Post implementation, 43 of 44 (98%) parents supported web cameras, and 40 of 42 (95%) parents stated that they used web cameras. The most common reasons for support from parents included web cameras making parents feel more at ease, facilitating parent-infant bonding, increasing parental confidence in staff, and allowing others to see infants. There was no significant difference between the parental groups for the depression, anxiety, or stress scales measured by DASS-21. Staff support for web cameras increased significantly from 34 of 42 (81%) participants before to 64 of 67 (96%) participants after implementation (P=.01). Following implementation, there was a resolution in staff concerns about web cameras having an adverse impact on staff roles and privacy and security concerns.

Conclusions: Web camera use in a tertiary Australian NICU was strongly supported by parents and staff and may reduce parental stress, facilitate parent-infant bonding, and encourage positive parent-staff engagement. Web cameras are a feasible method of providing continuity of care for families and should be considered as a standard of care in similarly resourced settings.

(JMIR Pediatr Parent 2023;6:e47552) doi:10.2196/47552

KEYWORDS

web camera; telehealth; telemedicine; neonate; neonatology; NICU; virtual visitation; implementation; Australia; prematurity; illness; newborns; parent-infant separation; stress; parental; engagement; neonatal intensive care unit

Introduction

In Australia, approximately 1 in 5 babies require admission to a special care nursery or neonatal intensive care unit (NICU) [1], resulting in parent and infant separation. Advances in telecommunication and internet accessibility have allowed the implementation of web cameras into neonatal care units to facilitate virtual visitation. Web cameras are being increasingly used and provide parents with images, videos, or a live stream of their infant, accessible from any device with internet connectivity. Videophones were first used to connect parents remotely with their infants in 1983 [2], and the first internet web camera system Baby CareLink [3] was evaluated using a randomized trial in the late 1990s. Global uptake of the technology followed, with the first installation in Australia in 2009 [4]. Despite their widespread acceptance and use, there is limited evidence of the impact of web cameras on infants, families, and neonatal staff.

Bonding and attachment between parents and their infant may be interrupted when a neonatal admission occurs. An infant may need to stay in a neonatal unit geographically distanced from the family home for a period that may extend for months. Factors related to the NICU that may interfere with attachment and bonding include physical and logistical barriers to visiting, the physical environment of the NICU, parental stress, separation, and the intermittent sense of parenthood [5,6].

Web cameras provide one way for parents to remain connected to their infant when they are unable to be at the bedside and, thereby, mitigate factors that may disrupt bonding. This concept is supported by Dunham and Marin [7] who incorporated virtual visitation as a modifiable variable into a conceptual model describing the NICU maternal-infant bonding process. A recent systematic review found that web cameras may be helpful to reduce parent stress and anxiety, and enhance parental responsiveness and feelings of closeness with their infant, increasing emotional attachment [8]. This is supported by findings of reduced parental stress when given access to web cameras [9,10] and positive parental perceptions in the evaluation of a web camera system [9]. Web cameras are reported to be associated with improved breast milk–pumping experiences, increased motivation for mothers [11], and improved rates of breast milk feeding at the time of discharge from the NICU [12]. Other literature describes positive perceptions before the implementation of a web camera system [13] and the role of web cameras in assisting fathers in visiting their infants [14].

While attitudes toward web cameras are largely positive, staff working with web cameras have described increased workloads [15,16], disruptions to usual duties, and potential negative impacts on the quality of care [16]. Kubicka et al [9] did not find a significant difference in work-related burnout for staff who work with web cameras but described staff perceptions of increased nursing and parental stress, and no improvement in the quality of care provided to infants.

The Family Integrated Care (FICare) model of incorporating parents into caring for their infants in the NICU has demonstrated positive outcomes for infants [17] and reduced parental stress and anxiety [17,18]. Web cameras could be considered an extension of FICare for providing continuity for parents and virtual access to infants for other family and friends. The COVID-19 pandemic and its challenges, including limitations on visiting the NICU, have made it pertinent for NICUs to provide alternative ways for families and infants to remain connected.

This study aimed to determine parental and staff attitudes before and after the implementation of a web camera system in an Australian neonatal unit. A secondary aim was to determine parental depression, anxiety, and stress levels using validated scales before and after web camera implementation.

Methods

Design

The study is a pre- and postintervention evaluation survey administered to parents and staff before and after the installation of the NICVIEW camera system in one neonatal unit.

Setting

The study was conducted in a tertiary neonatal unit located in a large metropolitan hospital in Sydney, Australia. The neonatal unit is an open-plan design of 10 intensive care beds and 24 beds for high- to low-dependency care. There are approximately 1000 admissions per year, of which approximately 50 are transferred from other hospitals.

Intervention

The NICVIEW camera system was installed in June 2018. Above each bed space, a camera is located on an adjustable arm. The cameras provide secure real-time viewing of infants from any device with internet access. There is no audio component or storage of video footage. Parents are provided with verbal and written information, and are required to sign a consent form and accept the terms and conditions before use. Parents receive an email with unique log-in credentials to access the website. Log-in details can be shared with others at the parents' discretion. Cameras are on 24 hours per day but turned off for episodes of care, procedures, and the relocation of patients to another area in the unit.

Survey Instrument

Parent and staff surveys were developed by the authors for data collection. The parent survey included closed- and open-ended questions exploring demographics, visiting patterns (including barriers to visiting), camera use, and attitudes toward cameras. Parent data was collected in 5-year epoch categories. Gestational age at birth was converted from a continuous variable into categorical data consistent with stages of prematurity. As outlined below, validated scales were incorporated into the survey. The survey design was pragmatic, limiting the number of additional questions to minimize the survey burden. The staff survey included closed- and open-ended questions and Likert scales for exploring demographics, staff experience in using cameras, the cameras' impact on their role, and staff support for or against cameras. The surveys were pilot-tested with a multidisciplinary group to ensure functionality and assess the timing for completion.

Outcome Measures

The secondary aim was to assess parental depression, anxiety, and stress before and after web camera implementation; therefore, additional scales were used in the parent survey.

The 21-item version of the Depression Anxiety Stress Scale (DASS-21) [19] was administered to parents in the pre- and postimplementation surveys. The DASS-21 was used as a measure of the psychosocial impact of having an infant in the neonatal unit. It is a self-report instrument consisting of 3 scales of 7 items, measuring the emotional states of depression, anxiety, and stress. Respondents read each item and recorded their answers using a Likert scale ranging from 0 (did not apply to me at all) to 3 (applied to me very much or most of the time). Answers were summed to generate a total score for the depression, anxiety, and stress scales, and then stratified into mild, moderate, severe, and extremely severe categories. It has been validated for use in the general population, among pregnant women, and in the postpartum period [20-22].

Following analysis of the preimplementation results, the Parental Stressor Scale: Neonatal Intensive Care Unit (PSS:NICU) [23] was included in the postimplementation survey to gather comprehensive NICU-specific information about stress. The revised PSS:NICU was administered, consisting of 17 items in the "Looks and Behavior of the Infant" and 11 items in the "Parental Role" subscales. The "Looks and Behavior" subscale variables include parental perception of stress based on the appearance of the baby such as color, breathing, movement, and size; the use of equipment including intravenous lines; and behaviors of the baby, including crying and appearing to be sad or in pain. The "Parental Role" subscale variables include parental perception of stress to being separated from their baby; their role as a caregiver including feeding, touching, and providing care; and feelings of helplessness and of staff being closer to their baby. The camera system does not have audio; therefore, the "Sights and Sounds" subscale was omitted. All items were answered with a response scale of 1 (not stressful) to 5 (extremely stressful). PSS:NICU results were scored according to metric 2 (overall stress level), which considers all items to calculate the overall stress score. Items not experienced by the respondent were given a score of 1.

Sample Size

The primary purpose of the study was to determine the attitudes of parents and staff before and after web camera implementation, with a secondary aim to determine any effect on DASS-21 and PSS:NICU scores. At the time of the study design, there were no data available to determine an expected estimate of the effect of DASS-21 or PSS:NICU scores in a population following web camera implementation. Therefore, a sample size was unable to be predetermined. We aimed to collect approximately 100 survey responses in both the parent and staff groups.

Eligibility

All parents with an infant admitted to the neonatal unit during the preintervention (November 2017 and February 2018) and postintervention (July 2020 and May 2021) survey administration periods were eligible for inclusion. Parents of infants who had been discharged but admitted to the neonatal unit during the postimplementation period were eligible for inclusion in the postimplementation survey. There were no exclusion criteria based on gestation or multiple births or whether infants were inborn or transferred from other facilities.

All staff, including medical, nursing, allied health, and administrative staff, employed to work in the neonatal unit during the survey administration periods were eligible for inclusion.

Parent and staff surveys were only available for completion in the English language.

Recruitment and Data Collection

The preimplementation parent survey was distributed to parents of infants admitted to the NICU between November 2017 and February 2018. The postimplementation survey was distributed to parents of infants admitted between July 2020 and May 2021 following camera installation. Surveys were distributed using flyers with QR codes or website links, and paper copies were available for parents to complete at a convenient time. During their infant's admission, parents of inpatients were approached once by designated staff not providing clinical care to the infant to request survey completion. As the postimplementation surveys were distributed during the COVID-19 lockdown, which affected the number of visitors to the NICU, the QR code and website links to the postimplementation survey were published in a newsletter distributed to parents of infants who were recently discharged from the neonatal unit but admitted during the postimplementation period.

The staff survey was distributed for completion between August and September 2017 before camera installation and between July and November 2020 after installation. Surveys were distributed using flyers with QR codes and a website link, emails with a website link, and paper copies. Staff were approached by authors and designated staff to request survey completion in person and by email during the study period.

Data Analysis

Study data were collected and managed using REDCap, an electronic data capture tool hosted at Sydney Local Health District [24,25]. REDCap is a secure web-based software platform designed to support data capture for research studies. Results were exported from REDCap into Excel version 16.49 (Microsoft Corporation) for provisional analysis, and descriptive statistics were generated using SPSS Statistics 27 (IBM Corp). Parent and staff demographic and web camera characteristics were described using proportions and compared using chi-square and Fisher exact tests. DASS-21 ordinal scores were assessed for distribution and investigated using the Mann-Whitney *U* test. *P* values less than .05 were considered statistically significant. We planned to perform a multivariate analysis if any univariate associations were significant; however, no significant associations were noted in the univariate analysis.

Ethical Considerations

Consent was implied by survey completion following an introductory consent statement. Surveys could be discontinued at any stage. All surveys were anonymous unless parents or

staff chose to provide details. No respondents received compensation for participation in the survey.

The study was approved by the Ethics Review Committee (Royal Prince Alfred Hospital Zone) of the Sydney Local Health District (protocol X16-0298 & HREC/16/RPAH/381).

Results

Overview

A total of 125 parents and 110 staff members commenced the surveys. Data analyses were possible for ~94 parents and 109 staff members with complete responses. The exact response rate for the survey is uncalculable as the survey was anonymous, and twins and multiple parents of the same infant are unable to be accounted for. In addition, families who declined or were not offered a web camera in the postimplementation period were not documented. A total of 301 babies were admitted in the preimplementation and 941 in the postimplementation period.

Parents

Demographics

Parent demographic characteristics for parents who completed the survey are presented in Table 1. There was no significant difference between groups. We also compared parent demographic characteristics for parents who did not complete the survey and noted no differences (Multimedia Appendix 1).

Table . Characteristics of parents in the pre- and postimplementation web camera groups.

Characteristic		Preimplementation (n=43), n (%)	Postimplementation (n=51), n (%)	*P* value
Gender				.63
	Female	34 (79)	38 (75)	
	Male	9 (21)	13 (26)	
Age (years)				.24
	20-24	2 (5)	2 (4)	
	25-29	4 (9)	3 (6)	
	30-34	13 (30)	25 (49)	
	35-39	12 (28)	14 (28)	
	40-44	9 (21)	7 (14)	
	≥45	3 (7)	0 (0)	
Marital status				.43
	Married or de facto	37 (86)	46 (90)	
	Never married	3 (7)	3 (6)	
	Separated	0 (0)	2 (4)	
	Widowed	0 (0)	0 (0)	
	Did not answer	3 (7)	0 (0)	
Country of birth				.22
	Born in Australia	29 (67)	28 (55)	
	Born overseas	14 (33)	23 (45)	
Language spoken				.35
	English only	34 (79)	36 (71)	
	Additional language	9 (21)	15 (29)	
Highest level of education				.29
	Postgraduate degree	15 (35)	16 (31)	
	Bachelor’s degree	15 (35)	21 (41)	
	Certificate, diploma, or advanced diploma	6 (14)	6 (12)	
	Graduate certificate	1 (2)	4 (8)	
	High school	6 (14)	2 (4)	
	Did not finish high school	0 (0)	2 (4)	
Employment status				.11
	Full-time	21 (49)	29 (57)	
	Part-time	11 (26)	3 (6)	
	Do not have a job	2 (5)	5 (10)	
	On paid leave	4 (9)	13 (26)	
	Other	4 (9)	1 (2)	
	Did not answer	1 (2)	0 (0)	
Place of birth				.10
	Inborn	35 (81)	48 (94)	
	Ex utero transfer	8 (19)	3 (6)	
Gestation (weeks)				.21
	24-25	2 (5)	2 (4)	

Characteristic		Preimplementation (n=43), n (%)	Postimplementation (n=51), n (%)	*P* value
	26-27	4 (9)	2 (4)	
	28-31	22 (51)	17 (33)	
	32-36	12 (28)	22 (43)	
	37-42	3 (7)	8 (16)	

Parental Visiting and Barriers

Most parents reported that they visited their infant daily. A higher proportion of parents experienced barriers to visiting after web camera implementation (13/43, 30%) compared to preimplementation (7/42, 17%). There was a reduction from pre- to postimplementation in the proportion of parents who stated they would feel better if they could visit for longer. Detailed results for parental visiting and barriers are outlined in Table 2.

Table . Parental visiting and barriers for the pre- and postimplementation web camera groups.

		Preimplementation, n (%)	Postimplementation, n (%)	*P* value
Visiting frequency				>.99
	Daily	34 (92)	38 (93)	
	3-5 d/wk	3 (8)	3 (7)	
	Total	37	41	
Time (hours/visit)				.99
	>8	8 (21)	7 (17)	
	5-8	17 (44)	20 (48)	
	3-4	11 (28)	13 (31)	
	1-2	3 (8)	2 (5)	
	<1	0 (0)	0 (0)	
	Total	39	42	
Would you feel better if you could visit for longer?				.01
	Yes	33 (81)	23 (55)	
	No	8 (20)	19 (45)	
	Total	41	42	
Barriers to visiting experienced				.14
	Yes	7 (17)	13 (30)	
	No	35 (83)	30 (70)	
	Total	42	43	
Barriers identified				N/A[a]
	Personal health	1 (14)	3 (23)	
	Lack of transport	3 (43)	6 (46)	
	Financial	1 (14)	1 (8)	
	Caring for other children	3 (43)	7 (54)	
	Distance required to travel	0 (0)	5 (39)	
	Work commitments	1 (14)	0 (0)	
	COVID-19 reasons	0 (0)	5 (39)	
	Other	0 (0)	2 (15)	
	Total	7	13	

[a]N/A: not applicable.

Parental Web Camera Use and Attitudes

Web cameras were reported to be used by the majority of parents (40/42, 95%), and most parents (30/42, 71%) stated that their family used the web camera. The most common viewing times were in the evening and overnight. Almost all parents were supportive of web cameras before (37/40, 92%) and after (43/44, 98%) implementation. The most common reason for support in both groups was that the web camera helped parents feel at ease when they were unable to visit their infant. After implementation, one parent was not supportive of web cameras, identifying that they made them feel anxious or stressed. Concerns regarding privacy and security were not cited as reasons against support after implementation. Detailed results for parental views are outlined in Table 3, and free-text comments from parents in the postimplementation survey are included in Multimedia Appendix 2.

Table . Parental views on web cameras in the pre- and postimplementation groups.

		Preimplementation, n (%)	Postimplementation, n (%)	*P* value
Support web camera use				.34
	Yes	37 (93)	43 (98)	
	No	3 (7)	1 (2)	
	Total	40	44	
Reasons for web camera support				N/A[a]
	Parent-infant bonding	16 (43)	21 (49)	
	Help parents feel at ease if unable to visit	36 (97)	37 (86)	
	Allow others to see infant	27 (73)	29 (67)	
	Increase confidence in staff	20 (54)	23 (54)	
	Positive staff engagement	18 (49)	17 (40)	
	Breastfeeding/expressing	0 (0)	3 (7)	
	Transition to home	0 (0)	1 (2)	
	Other	3 (8)	1 (2)	
	Total	37	43	
Reasons against web camera support				N/A
	Compromise parental care	1 (33)	0 (0)	
	Privacy concerns	3 (100)	0 (0)	
	Security concerns	1 (33)	0 (0)	
	Distraction from care	1 (33)	0 (0)	
	Increase anxiety or stress	3 (100)	1 (100)	
	Witness adverse event or infant distress	2 (67)	1 (100)	
	Total	3	1	

[a]N/A: not applicable.

Parental Depression, Anxiety, and Stress

There were no significant differences between the groups for the DASS-21 depression, anxiety, or stress scales (Table 4). However, there was a nonsignificant trend toward lower stress scales as measured by DASS-21 in the postimplementation group. The PSS:NICU scores were collected for the postimplementation group (Table 4) and provided NICU-specific information regarding stress for parents.

Table . Parent Depression Anxiety Stress Scale (DASS-21) scores for the pre- and postimplementation web camera groups and Parental Stressor Scale: Neonatal Intensive Care Unit (PSS:NICU) mean scores for the parent postimplementation group.

		Preimplementation	Postimplementation	*P* value
DASS 21, n (%)				
Depression				.83
	Normal	34 (79)	40 (78)	
	Mild	4 (9)	7 (14)	
	Moderate	5 (12)	3 (6)	
	Severe	0 (0)	1 (2)	
	Extremely severe	0 (0)	0 (0)	
	Total	43	51	
Normal vs any depression				.94
	Normal	34 (79)	40 (78)	
	Any depression	9 (21)	11 (22)	
	Total	43	51	
Anxiety				.42
	Normal	29 (67)	35 (69)	
	Mild	8 (19)	8 (16)	
	Moderate	1 (2)	5 (10)	
	Severe	0 (0)	1 (2)	
	Extremely severe	5 (12)	2 (4)	
	Total	43	51	
Normal vs any anxiety				.90
	Normal	29 (67)	35 (69)	
	Any anxiety	14 (33)	16 (31)	
	Total	43	51	
Stress				.48
	Normal	28 (65)	37 (73)	
	Mild	9 (21)	8 (16)	
	Moderate	3 (7)	4 (8)	
	Severe	2 (5)	2 (4)	
	Extremely severe	1 (2)	0 (0)	
	Total	43	51	
Normal vs any stress				.44
	Normal	28 (65)	37 (73)	
	Any stress	15 (35)	14 (28)	
	Total	43	51	
PSS:NICU, mean (SD)				N/A[a]
Looks and behavior (n=47)		N/A	2.65 (1.50)	
Parental role (n=49)		N/A	2.74 (1.35)	

[a]N/A: not applicable.

Staff

Staff characteristics are shown in Table 5. Staff support for web cameras significantly increased from 34 of 42 (81%) participants supporting before implementation to 64 of 67 (96%) participants after implementation (*P*=.01). There was a reduction in staff concerns regarding the web cameras having an adverse impact

on their role in the postimplementation survey. The main areas for staff concern included the web cameras taking time away from patient care, technical or equipment issues relating to web cameras, phone calls from parents, and parental anxiety. A total of 15 staff members identified that they would prefer restrictions on the time the web cameras can be turned on, with the majority stating that cameras should be turned off during procedures or caring routines. The majority of staff members (54/67, 81%) found current web camera resources adequate. Staff suggested additional support resources including a guideline or mobile app. Staff views on the web cameras and their impact on the staff's role are outlined in Table 6.

Table . Characteristics of staff in the pre- and postimplementation web camera groups.

		Preimplementation, n (%)	Postimplementation, n (%)	*P* value
Role				.60
	Administration	1 (2)	1 (2)	
	Nursing	37 (88)	63 (93)	
	Medical	4 (10)	3 (4)	
	Allied health	0 (0)	1 (2)	
	Total	42	68	
Time worked in a tertiary neonatal setting (years)				.24
	<1	2 (5)	5 (8)	
	1-5	10 (24)	25 (37)	
	6-10	6 (14)	12 (18)	
	>10	24 (57)	25 (37)	
	Total	42	67	
Time worked at study site (years)				.24
	<1	3 (7)	9 (13)	
	1-5	11 (26)	25 (37)	
	6-10	5 (12)	10 (15)	
	>10	23 (55)	24 (35)	
	Total	42	68	
Age (years)				.33
	<25	1 (2)	3 (5)	
	25-35	16 (38)	37 (55)	
	36-45	12 (29)	12 (18)	
	46-55	5 (12)	8 (12)	
	>55	8 (19)	7 (10)	
	Total	42	67	
Born in Australia				.20
	Yes	24 (59)	46 (71)	
	No	17 (42)	19 (29)	
	Total	41	65	
Area worked				.98
	Intensive care	37 (88)	56 (82)	
	High dependency	37 (88)	59 (87)	
	Special care nursery	36 (86)	51 (75)	
	Outpatients	3 (7)	5 (7)	
	Total	42	68	
Previous web camera experience				.67
	Yes	3 (7)	3 (4)	
	No	39 (93)	65 (96)	
	Total	42	68	

Table . Staff views on web cameras in the pre- and postimplementation web camera groups.

		Preimplementation, n (%)	Postimplementation, n (%)	*P* value
Support web cameras				.01
	Yes	34 (81)	64 (96)	
	No	8 (19)	3 (5)	
	Total	42	67	
Reasons for support				N/A[a]
	Parent-infant bonding	17 (50)	47 (73)	
	Reduce parental anxiety	31 (91)	59 (92)	
	Allow others to see infant	24 (71)	58 (91)	
	Increase confidence in staff and the unit	16 (47)	26 (41)	
	Positive parental-staff engagement	20 (59)	31 (48)	
	Other	4 (12)	4 (6)	
	Total	34	64	
Reasons against support				N/A
	Physically impede access	3 (38)	1 (33)	
	Compromise care	1 (13)	1 (33)	
	Privacy concerns	8 (100)	0 (0)	
	Security concerns	5 (63)	0 (0)	
	Distraction from care	5 (63)	3 (100)	
	Staff anxiety/stress	4 (50)	0 (0)	
	Parents witness adverse event or infant distress	5 (63)	2 (67)	
	Reduced parental visiting	4 (50)	0 (0)	
	Other	6 (75)	2 (67)	
	Total	8	3	
Adverse impact on staff role				N/A
	Strongly agree	2 (5)	1 (2)	
	Agree	7 (17)	7 (10)	
	Unsure	10 (24)	13 (19)	
	Disagree	16 (39)	34 (51)	
	Strongly disagree	6 (15)	12 (18)	
	Total	41	67	

[a]N/A: not applicable.

Discussion

Principal Results

Our pre-post implementation study found that web camera use in an Australian tertiary neonatal unit was strongly supported by both parents and staff, and that web cameras were well used following installation. Web cameras may assist with reducing parental stress and facilitating parent-infant bonding while not increasing parental reported depression or anxiety. Initial staff concerns about web cameras were largely alleviated following their implementation. Parent confidence in staff and positive staff engagement were common reasons cited for web camera support from parents in both the pre- and postimplementation periods.

Comparison With Prior Work

This study simultaneously examines parent and staff perceptions, and the impact of web cameras on parent depression, anxiety, and stress in neonatal care. Our findings support the existing conclusion that web cameras are an acceptable and feasible intervention to facilitate virtual visitation and support families during a neonatal admission [26-28].

DASS-21 scores demonstrated that the implementation of web cameras did not increase parents' levels of depression, anxiety, or stress in this study. There was, however, a nonsignificant trend in reducing any stress on DASS-21 post implementation (15/43, 35% preimplementation to 14/51, 28% postimplementation). We investigated this trend further by comparing the mean PSS:NICU subscale scores (collected in the postimplementation survey) with scores from a published comparison population group enrolled in the FICare intervention trial. This trial, completed in Canada, Australia, and New Zealand, aimed to identify how FICare affects maternal stress and anxiety, and has published baseline data from similar neonatal units. Our study's PSS:NICU scores for "Looks and Behavior" (mean 2.65, SD 1.50 vs mean 2.78 [18], mean difference −0.13, 95% CI −0.23 to −0.02; *P*=.02) and "Parental Role" (mean 2.74, SD 1.35 vs mean 2.98 [18], mean difference −0.23, 95% CI −0.35 to −0.12; *P*<.001) were significantly lower when compared to the group in Cheng et al [18]. This comparison, although not within our setting, supports the concept that a web camera service within a NICU may reduce parental stress. This result is further supported by recent findings by Kubicka et al [9] who found a reduction in PSS:NICU scores comparing an "on web camera" to an "off web camera" group.

Reasons for web camera support identified by parents included that web cameras help with bonding, make parents feel more at ease, and allow others to see the infant. Kubicka et al [9] discussed similar findings, with 86% of parents reporting that watching their baby on the web camera made them feel better. These findings are further supported by Kerr et al [28] who highlighted the positive parental perceptions of web cameras, including enhanced feelings of closeness, emotional well-being, and the involvement of family and friends. A small number (n=3) of parents in this study identified that web cameras helped with breastfeeding and expressing. A sustained intention to breastfeed or provide breast milk to the baby and an improved expressing experience has been described in recent literature [11,12], which provides a positive direction for future research.

Our findings indicate that, following implementation, most staff support the use of web cameras. This finding is in contrast to those by Kubicka et al [9] who reported that 86% of the nursing staff did not believe that web cameras improved infants' quality of care. Our findings suggest that initial staff concerns regarding web cameras are balanced by experience and the identified benefits for families, a sentiment previously discussed by Joshi et al [16]. Furthermore, staff should be reassured that many parents identified that web cameras increased their confidence in and had positive effects on their engagement with staff. This was also the case for the Baby CareLink intervention group, which reported higher overall quality of care [3], and for Kubicka et al [9], who reported that 83% of parents were reassured about their infant's nursing care. The hesitations regarding the privacy and security of web cameras were not sustained following implementation. However, a small number of staff reported that web cameras may have an adverse impact on their role, highlighting that support for and provision of adequate resources for staff are imperative for the ongoing success of a web camera service.

Strengths and Limitations

Strengths of our study included the pre-post implementation approach, the inclusion of both parents and staff, and the use of validated scales to assess depression, anxiety, and stress. Our NICU is located in a large Australian city and services a culturally diverse population, increasing the generalizability of results to other tertiary neonatal units. The separation in periods between the pre- and postsurvey administration allowed for web cameras to be well integrated within the culture of the neonatal unit. A study limitation was the absence of preimplementation PSS:NICU results. This scale was added to the postimplementation survey, as the analysis of the preimplementation DASS-21 scores suggested a reduction in stress, and the PSS:NICU collects NICU-specific stress information. We addressed this limitation by using a large comparison cohort that was generalizable to our study population [18] to compare our scores. Additional limitations include the absence of a prespecified sample size specifically for the DASS-21 outcomes for parents and the unlikely but possible potential for duplicate survey responses. The timing of survey completion by parents during their infant's admission was not collected and may be a confounder. There is potential reporter bias, as those parents completing the survey may be more likely to use and be supportive of the cameras; however, our respondents appeared to be representative of our unit's parent population. The postimplementation survey was administered during the COVID-19 pandemic when restrictions limited visits to one parent at a time. We hypothesize that support for web cameras will inevitably increase during a period where visiting is limited, and this may potentially reduce the generalizability of results.

Conclusions

This study contributes to the growing body of evidence on the impact of web cameras in NICUs. Web cameras were strongly supported by parents and staff, and may reduce parental stress, facilitate parent-infant bonding, and encourage positive parent-staff engagement.

Web cameras are a feasible and acceptable method of providing support and continuity of care for families during neonatal unit admission and should be considered as a standard of care in similarly resourced settings.

Acknowledgments

The NICVIEW camera system was purchased and installed using funds generously donated by the Australian Stockbrokers Foundation, Annette Olle, and the many donors who have contributed to the Neonatal Unit in Sydney Local Health District.

Data Availability

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

Authors' Contributions

AG was responsible for the study concept and design, and for ethics approval. AG and SR were responsible for the preimplementation survey design, development, and administration. AAL contributed to the postimplementation survey development, administration, and data collection. JLM assisted with the postimplementation survey administration and data collection. AG and AAL performed the data analysis. AAL drafted the first version of the manuscript. AG and SR contributed to writing and editing the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Characteristics of parents for complete and incomplete surveys for the pre- and postimplementation of web camera groups.
[DOCX File, 21 KB - pediatrics_v6i1e47552_app1.docx]

Multimedia Appendix 2
Free-text parent comments from the postimplementation survey.
[DOCX File, 14 KB - pediatrics_v6i1e47552_app2.docx]

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Abbreviations

DASS-21: 21-item version of the Depression Anxiety and Stress Scales
FICare: Family Integrated Care
NICU: neonatal intensive care unit
PSS:NICU: Parental Stressor Scale: Neonatal Intensive Care Unit

Edited by S Badawy; submitted 11.04.23; peer-reviewed by J Marcin, T Marin; revised version received 04.09.23; accepted 18.09.23; published 22.11.23.

Please cite as:
Legge AA, Middleton JL, Reid S, Gordon A
Implementation of a Web Camera System in an Australian Neonatal Intensive Care Unit: Pre- and Postevaluation of the Parent and Staff Experience
JMIR Pediatr Parent 2023;6:e47552
URL: https://pediatrics.jmir.org/2023/1/e47552
doi:10.2196/47552

Original Paper

Iterative Development, Validation, and Certification of a Smartphone System to Assess Neonatal Jaundice: Development and Usability Study

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Abstract

Background: Medical device development is an area facing multiple challenges, resulting in a high number of products not reaching the clinical setting. Neonatal hyperbilirubinemia, manifesting as neonatal jaundice (NNJ), is an important cause of newborn morbidity and mortality. It is important to identify infants with neonatal hyperbilirubinemia at an early stage, but currently there is a lack of tools that are both accurate and affordable.

Objective: This study aimed to develop a novel system to assess the presence of NNJ. The device should provide accurate results, be approved as a medical device, be easy to use, and be produced at a price that is affordable even in low-resource settings.

Methods: We used an iterative approach to develop a smartphone-based system to detect the presence of NNJ. We performed technical development, followed by clinical and usability testing in parallel, after which we initiated the regulatory processes for certification. We updated the system in each iteration, and the final version underwent a clinical validation study on healthy term newborns aged 1 to 15 days before all documentation was submitted for conformity assessment to obtain Conformité Européenne (CE) certification. We developed a system that incorporates a smartphone app, a color calibration card, and a server.

Results: Three iterations of the smartphone-based system were developed; the final version was approved as a medical device after complying with Medical Device Regulation guidelines. A total of 201 infants were included in the validation study. Bilirubin values using the system highly correlated with total serum or plasma bilirubin levels (r=0.84). The system had a high sensitivity (94%) to detect severe jaundice, defined as total serum or plasma bilirubin >250 µmol/L, and maintained a high specificity (71%).

Conclusions: Our smartphone-based system has a high potential as a tool for identifying NNJ. An iterative approach to product development, conducted by working on different tasks in parallel, resulted in a functional and successful product. By adhering to the requirements for regulatory approval from the beginning of the project, we were able to develop a market-ready mobile health solution.

(JMIR Pediatr Parent 2023;6:e40463) doi:10.2196/40463

KEYWORDS

neonatal jaundice; neonatal hyperbilirubinemia; newborns; mobile app; design; validation; regulatory processes; mobile health; mHealth; mobile phone

Introduction

Background

Medical devices are a central part of medicine today and can be defined as any "products or equipment intended for a medical purpose" [1]. The development of novel medical devices is an area facing multiple barriers [2]. These include time for development, strict regulatory requirements, and financial aspects along with unknown market potential, limiting the number of devices reaching the clinical setting. Furthermore, numerous devices fail to scale up [3]. For the development of medical devices for infants and children, the challenges are even larger [4,5].

The field of eHealth and mobile health (mHealth) services has been rapidly developing, with technological advances opening new avenues for delivering health care, including point-of-care services. The expectations of this field have been high, especially in traditionally underserved areas [6]. Although many mHealth developments have shown promise, a key obstacle has been extending innovations from pilot projects and ideas to clinical implementation, a problem described as *pilotitis* [7]. Several factors have been linked to this phenomenon, such as regulatory requirements, lack of user perspective and engagement during development, and an absence of sustainable financial models in place, resulting in short-lived software applications and devices not tailored to the actual needs of the target population and users [8-10].

Neonatal jaundice (NNJ) is a common condition among newborns because it affects 60% of all term newborns and 80% of all preterm newborns [11]. Neonatal hyperbilirubinemia (NHB) is one of the leading causes of readmission to the hospital after discharge [12]. Although most cases are self-limiting, the condition could lead to severe consequences such as brain damage, sensory defects, or even death if not detected and treated in a timely fashion, and globally NHB remains an important cause of neonatal mortality [13-15]. Most of the severe cases occur in low- and middle-income countries. In addition, shortened stays at maternity wards after delivery are shown to increase the risk of hospital readmission for NNJ, which was further exacerbated during the COVID-19 pandemic [16,17]. To reduce the adverse consequences of NHB, timely detection of infants with the condition is important [18]. NHB can be detected in multiple ways, but the currently available methods all have specific limitations. Visual assessment is shown to be unreliable; transcutaneous bilirubin (TcB) measurements are too expensive for many settings; and measurement of total serum or plasma bilirubin (TSB) requires training and an invasive blood draw, in addition to having the necessary equipment. There is clearly a pressing need for novel detection technologies [19-21].

Development of a Smartphone-Based System

On the basis of the need for novel technologies for NNJ detection, we developed a smartphone-based system with the following properties:

1. It provides accurate results.
2. It has been approved as a medical device.
3. It is easy to use.
4. It is affordable.

To achieve this, we (1) explored methods that could be adapted to our system, (2) tested and evaluated prototypes, and (3) developed a final product for formal validation before submission for conformity assessment.

In this paper, we describe our complete developmental process: going from product idea to a Conformité Européenne (CE)–marked medical device, which we call the *Picterus Jaundice Pro*.

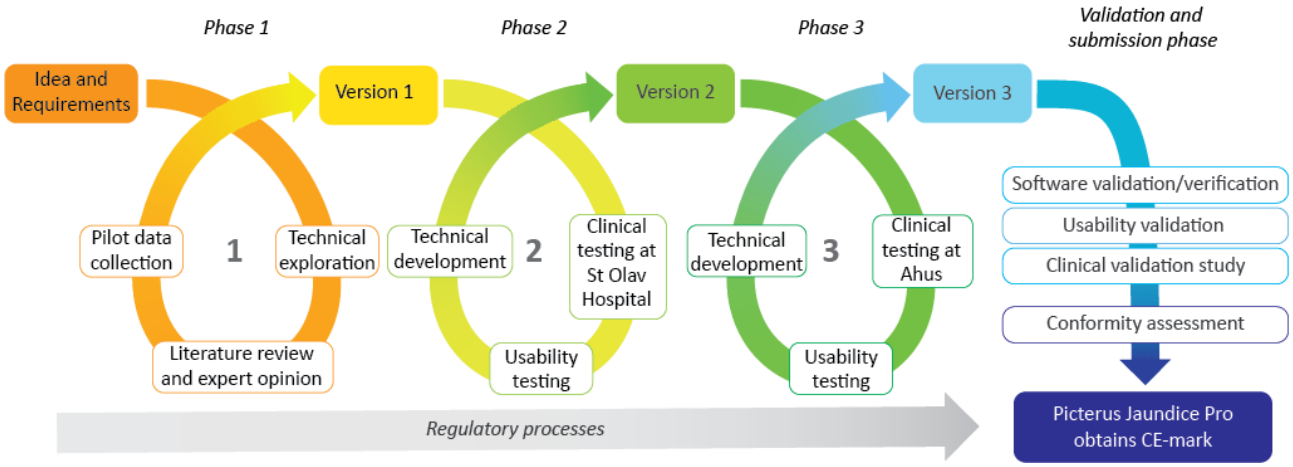
Methods

Project Overview

We worked on this project from January 2014 to October 2021 in 3 different developmental phases before entering the final phase to obtain CE approval. We used an iterative approach that enabled us to work on different aspects of the product in parallel. The different stages included development of software and algorithms for bilirubin measurements, usability evaluations, product development, and collection of clinical data. An overview of the different stages is shown in Figure 1. All phases were carried out in compliance with the General Data Protection Regulation [22].

This project was initiated as a research project at the Norwegian University of Science and Technology and St Olav Hospital, both in Trondheim, Norway, and continued later in collaboration with the spin-off company Picterus AS.

Figure 1. Overview of the development phases. Ahus: Akershus University Hospital; CE: Conformité Européenne.



Phase 1

In the first developmental phase, we developed skin simulations to mimic the bio-optical properties of newborn skin and explored the technical properties of digital cameras used in smartphones [23].

The skin simulations were based on how light interacts with varying levels of the most important compounds that make up skin color, that is, melanin, blood, and bilirubin [24]. Each simulation resulted in a color. By running many simulations, we were able to generate a large database of bilirubin level–color pairs. We then compared the ability of different smartphone cameras to distinguish among colors in relation to different levels of bilirubin.

As color analysis of digital images depends on accurate color detection, we explored several ways of obtaining colors relevant for bilirubin detection. First, we tested a paper-based foldable spectrometer that was attached over the camera lens (Foldable Mini-Spectrometer; Public Lab) to separate the light into different wavelengths. Second, we attached band-pass filters (FB450-40 and FB550-40; Thorlabs Inc) over the camera lens that only allowed transmission of bilirubin-specific wavelengths. Finally, we obtained digital images using the standard camera on the smartphones of a fixed color reference, a MacBeth ColorChecker (X-Rite Inc). This ColorChecker is a reference card with different color samples with known properties and is commonly used by photographers to calibrate photographs [25].

A clinical pilot study was then performed to obtain sets of skin images of the chests of newborns. Thirty infants, dressed only in a diaper, were placed on their backs on a standard examination table, and 6 images were captured, 3 with flash and 3 without. A MacBeth ColorChecker was placed on the side of each infant's chest. Images were taken at a distance of 40 cm from the chest using the built-in camera on a Samsung Galaxy S3 smartphone. TSB and TcB levels were measured for each infant within 60 minutes before or after image capture. The images were uploaded to a server and skin colors analyzed. The skin colors were first calibrated using the ColorChecker and then converted into bilirubin values based on our skin simulations. We then compared these values with the TSB values.

The results from the technical work and analyses of the newborns' images were supplemented with input from clinical experience of jaundice assessment and literature searches on NHB. On the basis of published literature, we chose the best measurement site on newborns' bodies to test our prototype system [26]. Version 1 of the system was then developed based on these findings (Figure 1).

Regulatory Processes

We performed an initial assessment of whether a potential final product would be considered a medical device in accordance with European regulations [27,28]. On the basis of this assessment, a regulatory process for approval was initiated [29].

First, a quality management system in accordance with International Organization for Standardization 13485 standards was initiated. Thereafter, we conducted a comprehensive analysis of potential risks related to the product and created a risk management file. All risks related to the use of the product were evaluated and classified based on severity, risk of occurrence, and probability of intervention.

Definitions of the intended user and intended use as well as specifications of customer requirements were developed, which defined the criteria for technological development. All documentation of the product, including manufacturing, was incorporated into a technical file. We developed a clinical evaluation plan based on the relevant risks for the use of the product.

With regard to fulfilling regulatory requirements as a medical device, it should be noted that all the described regulatory processes do not have an end point but are continually updated throughout the lifetime of the medical device. The described regulatory documents in development phase 1 were continually updated during all phases of the project, and all involved participants were trained.

Phase 2

In phase 2, we evaluated version 1 of the system.

Clinical Study

A clinical study was performed at St Olav Hospital, and relevant data were published in 2020 [30]. A cross-sectional study compared bilirubin levels from digital images, obtained with a

smartphone together with a calibration card, with TcB and TSB levels. Four images from different distances were captured in a standardized setting. Infants were placed on a white cloth on an examination table under illumination provided by halogen light bulbs. All sunlight was blocked out with dark curtains.

Usability Testing

We used different methods to assess user experience of the system. First, a method known as guerrilla testing was applied [31]. This method provides rapid insights into how a system is perceived and involves little effort from test users. Nurses, midwives, and physicians at St Olav Hospital were asked to participate. This user group was chosen based on experience with handling newborns and knowledge of NHB. They were presented with version 1 of the system and asked to perform a supervised test on a baby doll. They were encouraged to express their opinions and experience while using the system.

Second, during the clinical study phase, research assistants who helped with data collection provided feedback on the system. This yielded additional insights because the research assistants used the system on live newborns and not on a doll. The images collected during the clinical study not only revealed technical issues but also provided insights into how the user captured the images.

Technological Development

Image sets with corresponding TSB levels from 34 randomly selected newborns in the clinical study were chosen and used to adjust the skin simulation models. We examined all collected images visually for quality and developed a method for an automated analysis of the image sets. Images that did not fulfill the quality criteria were excluded. To be included in the next phase of the analysis, the following criteria needed to be met: all color patches on the calibration card had to be clean and present in the image, there should be no major shadows over the skin or card, no object should have covered the lens, and the images should have been captured from the correct distance. For a set of images to be included, 3 out of the 4 images had to fulfill the quality criteria.

This procedure was then used to determine bilirubin levels in the remaining image sets (n=101). These levels were compared with TSB and TcB levels and evaluated using Pearson correlations and Bland-Altman plots.

A bench study was performed using version 1 of the system under different illumination conditions and with different smartphones. Skin phantoms were created by mixing gelatin with varying concentrations of bilirubin. Images of these phantoms were obtained under a standardized setting where the illumination could be altered. Four different smartphones were used, and 3 images for each phantom were obtained. The smartphones were placed on a stand to enable the capturing of stable images from the same distance and angle. A color calibration card, which was developed in phase 1, was used as a fixed reference for each image. The colors in the images before and after color calibration were compared, both under different light sources and among different smartphones.

The clinical study, bench testing, and usability studies resulted in an improved version of the system (version 2).

Phase 3

In the third development phase (Figure 1), we tested and evaluated version 2 of the system and developed the final product.

Clinical Testing

Version 2 of the system was evaluated in a clinical study at the Akershus University Hospital, Lørenskog, Norway, and relevant data have been published [30]. We used inclusion criteria and methods that were similar to those used in the phase 2 clinical study. However, the illumination was not standardized, and images were captured under ambient light conditions to evaluate the performance in settings closer to those in which the final product would be used.

Usability Testing

Usability testing in phase 3 was also conducted by applying the guerrilla method using a doll as well as by recording the experiences of research assistants taking part in data collection.

Technological Development

Images collected in the clinical study of phase 2 were used for evaluating the clinical performance of the system, as well as for developing a method for automated quality checks of the images. Moreover, a method for checking the quality of the calibration card was developed. We set up the server to perform automated bilirubin measurements from approved image sets, and we developed a communication module that would report the result back to the app on the user's smartphone.

To ensure safe storage and transport of the cards, we designed special packaging for the calibration cards in compliance with regulatory requirements. Instructions for use were provided in both paper and web-based formats, as well as an in-app teaching module. The results from usability testing were used to improve the design of the calibration card as well as the smartphone app.

The combined findings in the third phase of the development led to version 3 of the system.

Validation and Submission Phase

In the last phase, we aimed to finalize a fully tested system that was ready for certification as a medical device. To achieve this, we performed validation and verification tests of the software and hardware, as well as formal usability testing, and executed a clinical validation study of version 3 of the system.

Software and Hardware Validation and Verification

We developed validation and verification tests of the software and hardware of version 3 to prove that the system meets user needs and intended use criteria, as well as system requirements and specifications [32]. These tests are based on the needs and requirements of users, as well as risks identified in the risk assessment.

Usability Validation

To be in accordance with regulatory requirements, a formal usability study was performed. Sixteen health care workers were

recruited and shown the system with the app, instructions for use, and calibration card. The risk analysis identified potential misuse of the product, and the users were presented with 10 different test cases that simulated scenarios where such misuse could happen. Tests were performed on a baby doll lying on an examination table. The test cases included basic tests to assess the ease of downloading and installing the app, as well as the users' understanding of the intended use of the product. Specific pass or fail criteria for each test case were defined in advance.

Clinical Validation Study

Study Design

We conducted a cross-sectional prospective study in the maternity ward and a breastfeeding outpatient clinic at St Olav Hospital. Data collection took place from September 5, 2019, to September 9, 2020.

Study Participants

Newborns were selected for the study if they were aged 1 to 15 days, born at term (37 weeks of gestation or more), and with birth weights ranging from 2500 g to 4500 g. Newborn infants with signs of disease or skin conditions other than jaundice and who received advanced medical treatment or phototherapy were excluded.

Recruitment

To include newborns with a wide range of bilirubin levels, we recruited them from 3 different groups: newborns at the maternity ward who needed a TSB determination for clinical purposes, newborns without visible jaundice but whose parents were willing to let them undergo a TSB sample drawn during their newborn screening when they were aged approximately 48 hours, and newborns brought to the breastfeeding clinic for follow-up care and who needed TSB determination for clinical purposes. The parents were asked to participate in the study, and informed written consent was obtained.

Data Collection

For each newborn, the following variables were collected: day and time of birth, birth weight, gestational age, sex, and feeding type, as well as mother and newborn blood type and Rh type. A blood volume of 600 µL was obtained by heel prick or venipuncture and stored in light-protected containers. The blood samples were analyzed at St Olav Hospital by applying the vanadate oxidation method using the Advia Chemistry XPT system (Siemens Healthcare GmbH). Within 60 minutes of blood collection, each newborn was placed on an examination table, and a measurement using the Picterus Jaundice Pro was performed. A color calibration card was placed over the sternum, and an image set, consisting of 3 images with flash and 3 without, was collected using a Samsung Galaxy S7 smartphone with version 3 of the Picterus Jaundice Pro. For each image, color correction was carried out and bilirubin levels determined. Bilirubin assessment using a TcB-measuring device (Jaundice Meter JM-105; Dräger) was performed immediately thereafter. All measurements were performed by the same trained person following hospital routines and instructions from the manufacturer.

Statistical Analysis

Bilirubin measurements using the different methods were analyzed using the Kruskal-Wallis test with the Dunn multiple comparison post hoc test. The correlations between Picterus Jaundice Pro bilirubin levels and TSB levels were evaluated using Pearson *r*. Bland-Altman plots were performed to determine the mean bias and 95% CIs between Picterus Jaundice Pro and TSB levels. Receiver operating characteristic curves were constructed to determine the sensitivity and specificity to detect severe jaundice, defined as TSB >250 µmol/L (14.6 mg/dL). Analyses were performed using MedCalc (version 20.109; MedCalc Software Ltd).

Submission for Conformity Assessment

A notified body was contracted to perform the conformity assessment and collect all documents to comply with Medical Device Regulation (MDR) approval. The documents included the technical file describing all components of the product, a clinical evaluation report, a plan for postmarket surveillance and clinical follow-up to capture user feedback and confirm safety of the product, the risk analysis, and the quality management system.

Ethics Approval and Study Registration

The clinical studies were approved by the Regional Committee for Medical and Health Research Ethics of Southeast Norway (2014/618) and by data protection officers at both St Olav Hospital and Akershus University Hospital. The validation study was approved by the Norwegian Medicines Agency as a study of a non–CE-marked medical device. The clinical studies were registered in ClinicalTrials.gov (NCT03007563 and NCT04182555).

Results

The development of the Picterus Jaundice Pro involved 3 phases before the final version was approved for CE certification as a medical device (Figure 1). The 3 phases produced 3 iterations of the calibration card (Figure 2) and 3 iterations of the image capture interface of the app (Figure 3).

Figure 2. Versions of the calibration card. (A) Phase 1. (B) Phase 2. (C) Phase 3 (final version).

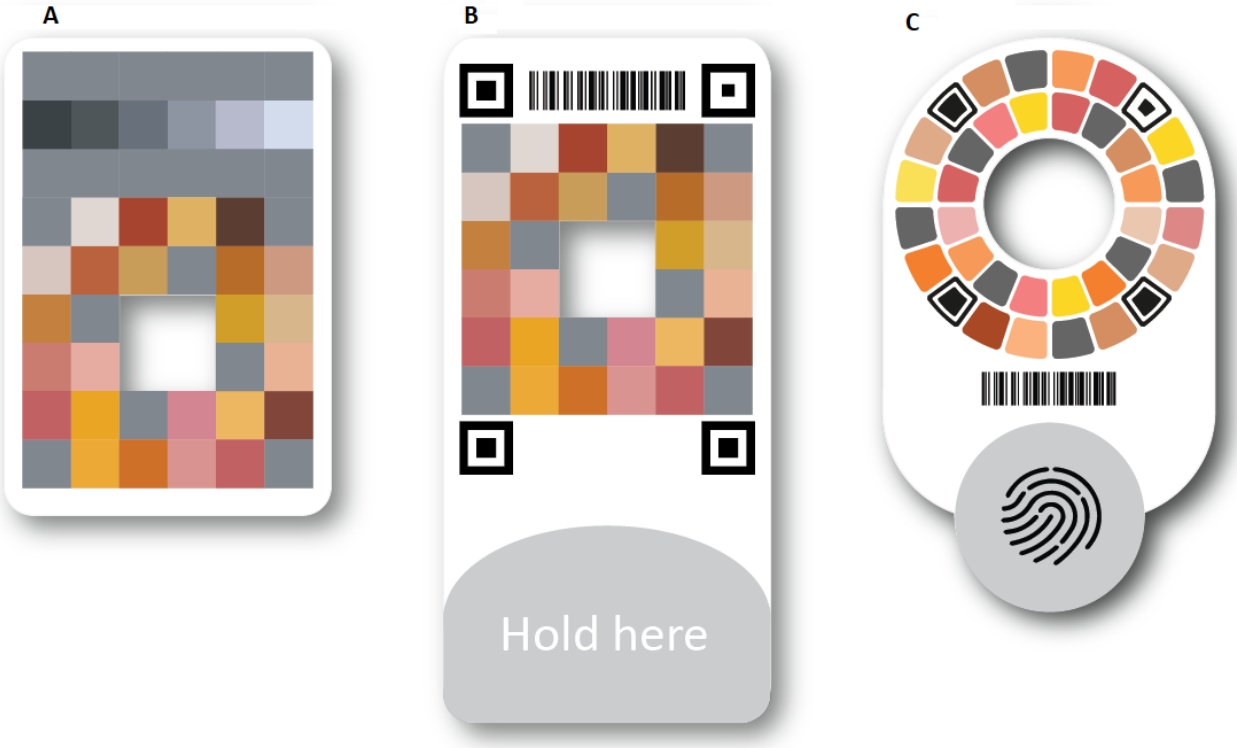
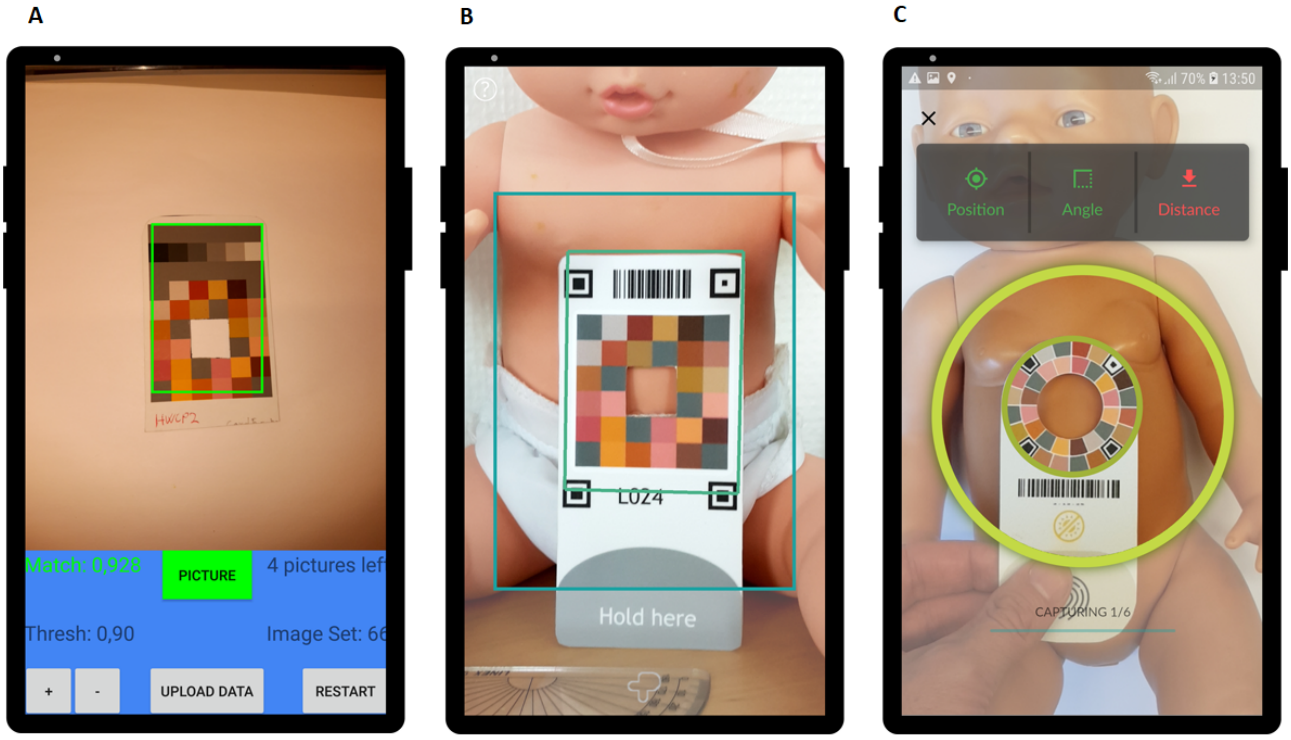


Figure 3. Versions of the app slides of the image capture module. (A) Phase 1. (B) Phase 2. (C) Phase 3 (final version).



Phase 1

System With 3 Major Components

In phase 1, we developed a system consisting of 3 major components: an app to collect and upload images of the skin of newborns, functionality to accurately calibrate the colors in the images, and a server that could communicate with the smartphone and where images could be stored and analyzed.

Initial assessment of the smartphone cameras revealed that they were able to distinguish among colors reflecting different levels of bilirubin [23]. However, under varying illumination conditions, using a fixed reference in the images in the form of the color calibration card was the only way to detect colors with

the needed accuracy; accordingly, other methods of color detection were abandoned. This resulted in a system consisting of a color calibration card, an app, and a server.

In the pilot testing in phase 1, the newborns had a mean TSB level of 166 (SD 74) µmol/L (mean 9.71, SD 4.33, mg/dL) and a mean TcB level of 150 (SD 120) µmol/L (mean 8.78, SD 7.02, mg/dL). The bilirubin measurements from the images had a mean level of 190 (SD 119) µmol/L (mean 11.1, SD 6.96, mg/dL). The TSB and TcB levels were highly and significantly correlated (Pearson r=0.92; P=.005). Comparison of bilirubin values from the images with TSB and TcB levels revealed no significant correlation (Pearson r=0.04; P=.23).

On the basis of these findings, we identified several areas for improvement, with *how* images were captured being most essential. The design of the ColorChecker [25] was not optimal for color calibration of images of newborns' skin, and the ColorChecker needed to be positioned closer to the measurement site.

As a result, we developed the first version of the color calibration card (Figure 2A). This card consisted of various color and gray patches. To get these patches close to the measuring site, the card had a hole in the center showing where to perform skin measurements. We implemented a spectral printing method, which makes colors consistent when exposed to different illuminations [33]. We printed the cards using an inkjet printer and standard photo paper (HP DesignJet Z7300 printer and HP Premium Matte Photo Paper; HP Inc), which made it possible to print these cards at a low price. To ensure color consistency, all cards were measured with a spectrophotometer after printing.

Although image standardization with regard to distances and angles among the newborns was attempted, the built-in camera app of the smartphones was not adequate for this purpose. We therefore developed an app with an image capture module (Figure 3A) to standardize how images were obtained. The app was developed for an Android operating system. We included functionality to store and upload images. In addition, we set up a server that could communicate with the app and link image sets to unique identity numbers for each newborn.

All implemented features of version 1 of the app, color calibration card, and server are described in Textbox 1. The color calibration card of version 1 is shown in Figure 2A, and the app slide of the image capture module is presented in Figure 3A.

Textbox 1. Description of version 1.

- App
  - Functionality to take sufficient images for clinical study
  - Communicates with server to upload images
  - Software for recognizing card
  - Takes images from different distances
  - Takes images with and without flash
  - Image sets coded to unique ID
  - Indicates to user when to take photographs
  - Indicates to user how to position smartphone
  - Crops image
- Calibration card
  - 24 color and 8 gray patches
  - Strip of 6 different gray tones
  - Hole for skin analysis
  - Colors close to hole
  - Opaque
  - Matte surface to reduce reflections
  - Size that fits on infant's chest
  - Safe for the newborn: biocompatible material and no sharp edges
- Server
  - Receives and stores images with unique ID for later analysis

Regulatory Compliance

The initial assessment of the final system concluded that the system could be considered class 1 medical device software according to the Medical Device Directive [27]. Through the timeline of the development, European regulations regarding medical devices changed, with the MDR replacing the Medical Device Directive [28]. A new assessment of the final system according to the updated regulations classified the system as a class 2a medical device. The color calibration card had been classified as a class 1 medical device accessory, and this classification remained the same after the change to the MDR.

The intended users of the system were defined as health care personnel, with intended use at hospitals, clinics, health stations, or during home visits. The system was identified as a screening system that assists health care workers in their assessment of NNJ and not as a stand-alone diagnostic tool. According to MDR specifications, the device was to be used on newborns born at term, with normal birth weight, and not showing signs of pathologic jaundice.

During the risk assessment, we found 3 risks that needed to be mitigated by a clinical evaluation: confirmation of a relationship between bilirubin levels in the skin and in blood, verification that bilirubin measurements in digital images in general correlate to bilirubin levels in blood, and demonstration to prove that bilirubin measurements using our system are correlated to bilirubin levels in blood. The first and second risks were resolved by reviewing published papers, but for the third risk we had to gather our own clinical data to have the system approved as a medical device.

To be compliant with the General Data Protection Regulation, all images were cropped so that no identifiable features of the newborns were visible.

Phase 2

In phase 2, we tested, evaluated, and improved upon the first prototype of the system (version 1).

During the clinical study of phase 2, a total of 181 newborns were recruited: 36 (19.9%) had image sets that had technical errors or were completely missing, another 10 (5.5%) had missing blood samples or were excluded because of miscoding or not meeting our inclusion criteria, and a subset of 34 (18.8%) newborns who were used to calibrate our model were also excluded from further analysis, leaving 101 (55.8%) image sets available for final analysis. Bilirubin values from the images were highly and significantly correlated to TSB values (Pearson r=0.83; P<.001) and TcB values (Pearson r=0.85; P<.001) [30].

An analysis of the image sets with technical errors revealed several weaknesses with version 1, and usability testing showed that the method of obtaining images was inadequate. The technical errors in the 36 rejected image sets included images where the infants' clothes covered portions of the color calibration card or the fingers of the researcher covered the lens, as well as image sets where the color calibration card or the infant was not captured in the image.

The software for recognizing the calibration card did not perform as intended, and there was an unwanted delay between the time that the app judged that conditions for capturing an image were met and the time that the actual images could be obtained. After testing different methods, we added 4 QR position codes to the calibration card and implemented updated software to recognize these position codes (Figure 2B). The position codes served as distinct and easily recognizable features on the card and made sampling of the color patches from the images more stable and easier to automate.

In version 1, the user had to press a button to capture images, which made it difficult to hold the smartphone steady. We implemented automated image capturing and added a camera shutter sound as well as a progress bar indicating the progress of the image capture operation.

Images from different distances did not improve correlations, added complexity, and reduced usability; therefore, a standard distance of 25 cm was chosen. Testing on live newborns showed that it was challenging to have the color calibration card stay in place during image capture, and we increased the size of the card, adding a section where the user could hold the card without affecting the color patches or the QR position codes (Figure 2B).

Analysis of the images of the skin phantoms showed that the method of color calibration was able to correct for changes in illumination as well as differences among the cameras in the 4 different smartphones that we tested. The analysis further showed that some of the patches on the calibration card were not needed and were therefore removed (Figure 2B).

All implemented features in version 2 of the app, color calibration card, and server are described in Textbox 2. The color calibration card of version 2 is shown in Figure 2B, and the image capture interface is presented in Figure 3B. The implementation of the combined findings from the second phase led to version 2 of the system with an updated interface for the app and a new version of the color calibration card.

Textbox 2. Description of version 2.

- App
  - Updated software for recognizing calibration card
  - Takes images from fixed distance
  - Takes images from same angle
  - Takes images automatically
  - Only takes images when conditions are met
  - Plays shutter sound when taking images
  - Displays a frame of the calibration card to ease positioning of the phone
  - Illustrates progress of image capture operation
  - Collects data on gestational age, birth weight, and current age
- Calibration card
  - Flap to hold the card
  - Barcode to identify unique card
  - QR position codes to improve card detection
- Server
  - Receives and stores images with unique ID for later analysis

Phase 3

In phase 3, we tested and evaluated version 2 and developed a final product (version 3) that was ready for formal validation before submission for conformity assessment.

During the clinical study of phase 3, a total of 161 newborns were recruited, of whom 3 (1.9%) had been miscoded and were excluded. Updating of the software and calibration card resulted in improved image capture quality: no image set had to be excluded. We determined a bilirubin value in the remaining 158 infants, of whom 84 (53.2%) had a TSB test performed, and the bilirubin measurements from our system were highly and significantly correlated to the TSB values (Pearson r=0.85; P<.001) and TcB values (Pearson r=0.79; P<.001) [30].

Usability tests and the experience of the research assistants showed that the image capture process was still not optimal, and it was difficult to align the smartphone and the card. We changed the design of the calibration card to a circular layout that reduced the need for this alignment and changed the user interface accordingly (Figures 2C and 3C). Another challenge was that users had to hold the card in place with one hand and then position the smartphone with the other. This was especially difficult when the newborn was moving. Therefore, we added double-sided medical tape, intended for use on newborn skin, on the back of the card to hold it in place while capturing images. To help new users, we developed a training module and implemented this in the app (Figure 4).

On the basis of the outcomes of the clinical study, we developed multiple quality checks for both the calibration card and the images. Inputs to these quality checks were based on continually updated risk analysis. The quality checks for the calibration card included tests to ensure that there were no shadows over the card, the card was not manipulated, nothing was spilled on the card, and the card was not damaged in other ways. The quality checks of the skin patch included checks to determine that the test area only captured human skin, that the skin had no rash, and that there were no shadows in the area chosen for analysis.

To maintain the colors on the calibration card, we designed special packaging that would protect the card from exposure to sunlight. Finally, instructions for use, terms and conditions, and a privacy policy were developed in accordance with relevant requirements.

All implemented features of version 3 of the app, the color calibration card, and the server are described in Textbox 3. The color calibration card of version 3 is shown in Figure 2C, and the image capture interface is presented in Figure 3C.

Figure 4. App slides of the training module.

Textbox 3. Description of version 3.

- App
  - Gives immediate result
  - On-boarding sequence
  - Learning module
  - Shows terms and conditions
  - Instructions for use
  - Stores latest measurement results
  - Reduces need for user input
  - Shows user whether position, angle, and distance are within required levels
  - Developed using software that would enable use of both Android and iOS smartphones
  - Includes functionality to translate app text into multiple languages
- Calibration card
  - Safe packaging of card
  - Circular design to ease alignment with the smartphone
  - Sticker to hold the card in place on the chest
  - Increased size of hole for skin analysis
  - Separate version for multiple use and possible to sanitize card
  - Multiple-use card (laminated)
- Server
  - Performs automated bilirubin assessment from images
  - Communicates result to app
  - Rejects image sets if quality requirements are not met
  - Calibration card present in the image
  - All color patches (colors and gray) on the calibration card present
  - Barcode present in all images
  - Colors in the card hole for the skin within normal range for skin colors (meaning no object other than human skin is being evaluated)
  - Cross validation of colors
  - Checks whether card is damaged

Validation and Submission Phase

In the final phase, we demonstrated that the system was ready for approval as a medical device. Using version 3, we performed validation and verification tests of the software and hardware and also conducted formal usability testing and a clinical validation study.

Software and Hardware Validation and Verification

Validation and verification tests of version 2 were developed and executed, and the system passed all the tests.

Usability Validation

During formal usability testing, one of the test participants failed in 1 of the 10 test cases regarding the definition of the intended users of the system. This was not considered critical, and no risk mitigation was required.

Results of Clinical Validation Study

A total of 248 newborns were recruited in the study, of whom 201 (81%) met the inclusion criteria for the intended use of the system and were included for data analysis. Birth weight, gestational age, and TSB and TcB levels as well as bilirubin measurements from the Picterus Jaundice Pro system are shown in Table 1. Thirty-four newborns were classified with severe hyperbilirubinemia, defined as TSB >250 µmol/L (14.6 mg/dL).

The scatterplot (Figure 5A) shows a significant positive correlation between TSB and Picterus Jaundice Pro values (Pearson r=0.85; P<.001). Correlations between TcB and Picterus Jaundice Pro values showed similar results (Pearson r=0.85; P<.001). The mean difference between Picterus Jaundice Pro values and TSB levels was –9.7 µmol/L (95% CI –89.9 to 70.6 µmol/L; –0.57 mg/dL, 95% CI –5.26 to 4.13 mg/dL). No systematic overestimations or underestimations of bilirubin

levels were observed (Figure 5B). Receiver operating characteristic curve (Figure 5C) analysis of data from newborns with severe hyperbilirubinemia, defined as TSB >250 µmol/L (14.6 mg/dL), showed an area under the curve value of 0.89 and a Youden index with cutoff at >214 µmol/L (12.5 mg/dL), resulting in a sensitivity of 94.1% and a specificity of 70.7%.

Table 1. Clinical characteristics of the included newborns (N=201).

Characteristics	Values, mean (SD; range)
Birth weight (g)	3642 (460; 2510-4830)
Gestational age (weeks)	39.7 (1.4; 37-42)
Bilirubin levels	
µmol/L	
Picterus Jaundice Pro	186.6 (66.5; 1-322)
TSB[a,b]	178.2 (76.5; 13-367)
TcB[c,d]	156.7 (70.4; 0-304)[e]
mg/dL	
Picterus Jaundice Pro	10.9 (3.9; .1-18.8)
TSB[b]	10.4 (4.5; 0.8-21.5)
TcB[d]	9.2 (4.1; 0-17.8)[e]

[a]TSB: total serum bilirubin.

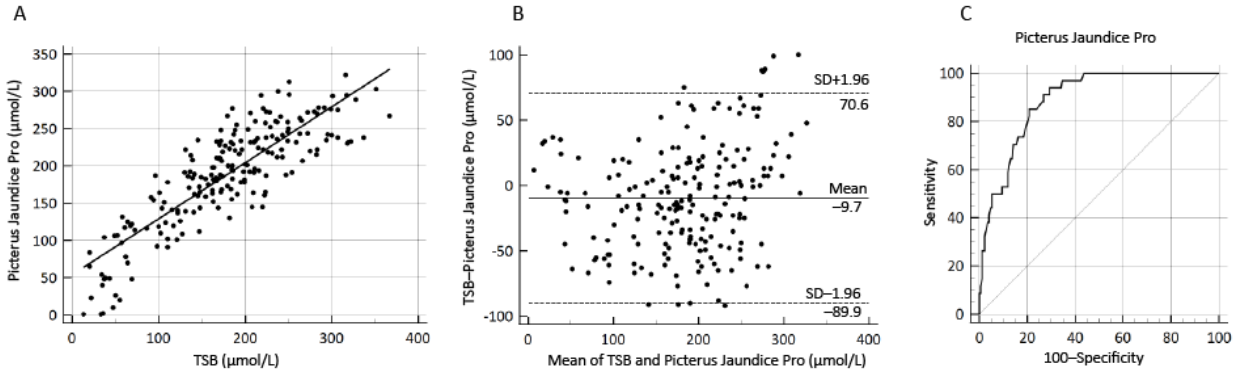
[b]Total serum bilirubin and transcutaneous bilirubin levels and bilirubin measurements from the Picterus Jaundice Pro system were analyzed with the Kruskal-Wallis test with the Dunn multiple comparison post hoc test.

[c]TcB: transcutaneous bilirubin.

[d]Information from 2 newborns is missing.

[e]*P*<.05 versus total serum bilirubin.

Figure 5. Correlation between Picterus Jaundice Pro and total serum bilirubin (TSB) levels illustrated in (A) a scatterplot, (B) a Bland-Altman plot, and (C) a receiver operating characteristic curve.



Submission for Conformity Assessment

On the basis of the risks outlined in the results of phase 1, a literature review was performed by searching PubMed, MEDLINE (via Ovid), and Scopus databases. Relevant information from 59 articles was included in the review.

Our own clinical data were insufficient to claim that the device could be used on newborns born to parents with the darkest skin types, defined as type 5 and 6 on the Fitzpatrick scale, and this limitation was added to the intended use of the product. A notified body reviewed all documentation of our system and performed 2 on-site audits before the certificate of the CE mark for the device was issued on October 22, 2021 [34]. For the calibration card, which was classified as an accessory, a self-declaration was sufficient to obtain the CE mark.

Discussion

Summary

In this paper, we have described the development of a new digital system for screening of NNJ using a CE-certified medical device. By working in parallel along technical, clinical, usability, and regulatory axes, we developed iterations of the system that progressively resulted in a medical device that was approved as a CE-marked medical device. Clinical validation studies demonstrated that the Picterus Jaundice Pro bilirubin measurements highly correlated with TSB levels with a high sensitivity to identify newborns with severe hyperbilirubinemia.

For the development of this system, we set 4 objectives:

- First, we wanted to create a device that provides accurate results. The clinical validation study demonstrated a strong correlation between Picterus Jaundice Pro and TSB measurements. This objective was, however, only partially met because validation for all skin types was not yet demonstrated.
- Second, the system had to be approved as a medical device, and this was achieved by obtaining the CE mark. The CE mark is only valid in the region where this mark is accepted; however, this proves that our system will fulfill safety requirements, and adaptation to regulatory requirements in other regions will be easier.
- Third, the system should be easy to use. This is a necessity for lowering the threshold for using the system and making it accessible even for users with limited experience in using digital tools. Through usability testing and iterative development, we received feedback on different versions of the system and gradually improved it to meet the needs of the intended users.
- Fourth, we aimed to create a system that would be affordable even in low-income settings. A key advantage of digital solutions is the relatively low costs of scaling up the solution. However, maintenance costs will still apply as will costs involved in product approval. Furthermore, regulatory requirements result in continuous costs incurred on safety and clinical performance follow-up. The costs of production of the calibration card are low, but distribution costs will increase the cost for the user. Nonetheless, compared with other relevant medical devices for NHB, the total costs are substantially lower.

Strengths

From the initial phase of the project onward, the overarching goal was to convert our work into actual improvement in newborns' health by creating a product ready for users and also to develop the technology. The iterative approach combining usability and clinical testing in parallel with technological development enabled us to gradually develop a product that fulfilled our objectives. The guerrilla testing method is easy to conduct and made it possible to reach the intended users despite their busy clinical work.

Regulatory compliance work has been a substantial part of this development and included tasks that are often seen as cumbersome, expensive, and challenging. The rationale behind these processes is to prevent unsafe devices from reaching patients and to ensure that the benefits of a device can justify any remaining risks related to it. In this development, we identified potential risks from the beginning and evaluated and mitigated the risks when needed. Implementing the regulatory processes from the beginning ensured feasibility of the actual product in terms of increased patient safety, which will lead to increased acceptance of the product by users.

Compared with projects that are a result of technology discoveries, an advantage of this project is that it originates from a clinical need. This factor, often called "the why," has been highlighted as key to scaling and spreading innovations [3].

Limitations

Although we developed, user-tested, validated, and obtained regulatory approval for a novel system fulfilling a clinical need, further development is needed to ensure successful implementation of the innovation [3,35].

Although we performed usability testing of the device, at this stage we were not able to test the system in clinical practice. We need to understand how this system will fit into the daily workflow of delivery of health care and how users will experience added value [10]. Use in clinical practice would further contribute to understanding which other features the system should include; for instance, the system currently provides no interpretation of the results, and this could be an important feature for further development. The largest burden of NHB today is experienced in low- and middle-income countries, and a limitation of this project is that we did not perform usability testing with users in such settings. Although the usability experience regarding the image capture module is likely to be similar, implementation of new features must be adapted to specific contexts, especially because many newborns in low-resource settings are seen by health care workers with less education.

Moreover, the ability to scale up the innovation is required to ensure successful implementation. The system was approved and tested for a limited set of smartphones, but to scale up the system, it must work and be approved for use on most smartphones. The calibration cards are currently being printed on a small scale, and a system for mass production needs to be developed. The system further requires connectivity, and for remote and less developed areas this would be a limiting factor. As sub-Saharan Africa and South Asia are among the regions experiencing the largest burden of NNJ, it will be important to have the system approved for newborns with all skin pigmentations.

Finally, sustainability of innovations includes financial sustainability, with appropriate business models generating revenue. Development of such models has been part of our work but is not included in this paper. In general, the organization of a health care system is complex and differs from country to country, and our business models will need to be adjusted depending upon how health services are financed within each specific market.

Conclusions

In conclusion, we have described the development of a novel system for screening of NNJ from conceptualization to a CE-certified medical device. By following an iterative approach and by working along different axes in parallel and with considerations given to requirements for regulatory approval from the beginning, we developed a market-ready mHealth solution.

Acknowledgments

The authors thank Professor Lise L Randeberg for her contribution to this project, all health personnel at St Olav Hospital and Akershus University Hospital who contributed to data collection and usability testing, and finally all parents who allowed their infants to take part in this development study. This project has received funding through an individual PhD grant from the Norwegian University of Science and Technology to the first author as well as from the European Union's Horizon 2020 research and innovation program (946013).

Authors' Contributions

AA and GV were responsible for the initiation of this project. AA, GV, GJD, and LMG were responsible for system development. AA, GJD, HB, and ED collected the clinical data. AA, GV, GJD, and LMG carried out usability testing. AA, GV, LMG, HB, and ED performed data analysis. All authors contributed to the drafting and revision of the final manuscript, and all authors approved the final version of the manuscript.

Conflicts of Interest

AA and GV are both employed at, and shareholders of, Picterus AS, which is currently commercializing the Picterus Jaundice Pro app. GJD and LMG are both employed at Picterus AS.

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Abbreviations

CE: Conformité Européenne
MDR: Medical Device Regulation
mHealth: mobile health
NHB: neonatal hyperbilirubinemia
NNJ: neonatal jaundice
TcB: transcutaneous bilirubin
TSB: total serum bilirubin

Edited by S Badawy; submitted 28.06.22; peer-reviewed by M Mirro, T Parikh, RJ Wong; comments to author 18.11.22; revised version received 16.12.22; accepted 16.01.23; published 28.02.23.

Please cite as:
Aune A, Vartdal G, Jimenez Diaz G, Gierman LM, Bergseng H, Darj E
Iterative Development, Validation, and Certification of a Smartphone System to Assess Neonatal Jaundice: Development and Usability Study
JMIR Pediatr Parent 2023;6:e40463
URL: https://pediatrics.jmir.org/2023/1/e40463
doi:10.2196/40463
PMID:36853753

Original Paper

The Effectiveness of Interactive Text Messaging and Structured Psychosocial Support Groups on Developmental Milestones of Children From Adolescent Pregnancies in Kenya: Quasi-Experimental Study

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Abstract

Background: In sub-Saharan Africa, one-quarter of all pregnancies occur in adolescents. Children born to adolescent mothers have poorer physical and socio-cognitive development. One reason may be inadequate knowledge on childcare and psychosocial support during pregnancy and post partum, since adolescent mothers have less antenatal care attendance and overall interaction with the health care system. Mobile health technology has been used to relay health information to special groups; however, psychosocial support commonly requires physical interaction.

Objective: We aimed to assess the efficacy of an interactive mobile text messaging platform and support groups in improving adolescent mothers' knowledge and practices as well as infant growth and development.

Methods: This was a quasi-experimental study, conducted among adolescent mothers with infants younger than 3 months, in Homa Bay County, Kenya. Five of the 8 subcounties in Homa Bay County were purposively selected as study clusters. Four subcounties were assigned as intervention clusters and 1 as a control cluster. Adolescent mothers from 2 intervention subcounties received interactive text messaging only (limited package), whereas those from the other 2 subcounties received text messaging and weekly support groups, moderated by a community health extension worker and a counselor (full package); the control cluster only received the end-line evaluation (posttest-only control). The follow-up period was 9 months. Key outcomes were maternal knowledge on childcare and infant development milestones assessed using the Developmental Milestones Checklist (DMC III). Knowledge and DMC III scores were compared between the intervention and control groups, as well as between the 2 intervention groups.

Results: We recruited 791 mother-infant pairs into the intervention groups (full package: n=375; limited package: n=416) at baseline and 220 controls at end line. Attrition from the intervention groups was 15.8% (125/791). Compared with the control group, adolescent mothers receiving the full package had a higher knowledge score on infant care and development (9.02 vs 8.01; *P*<.001) and higher exclusive breastfeeding rates (238/375, 63.5% vs 112/220, 50.9%; *P*=.004), and their infants had higher average DMC III scores (53.09 vs 48.59; *P*=.01). The limited package group also had higher knowledge score than the control group (8.73 vs 8.01; *P*<.001); this group performed better than the full package group on exclusive breastfeeding (297/416, 71.4%

vs 112/220, 50.9%; *P*<.001) and DMC III scores (58.29 vs 48.59; *P*<.001) when compared with the control group. We found a marginal difference in knowledge scores between full and limited package groups (9.02 vs 8.73; *P*=.048) but no difference in DMC III scores between the 2 groups (53.09 vs 58.29; *P*>.99).

Conclusions: An interactive text messaging platform improved adolescent mothers' knowledge on nurturing infant care and the development of their children, even without physical support groups. Such platforms offer a convenient avenue for providing reproductive health information to adolescents.

Trial Registration: Pan African Clinical Trials Registry PACTR201806003369302; https://tinyurl.com/kkxvzjse

(JMIR Pediatr Parent 2023;6:e37359) doi:10.2196/37359

KEYWORDS

text messages; adolescent pregnancy; milestones; mHealth; psychosocial support; Kenya; nurturing care

Introduction

The World Health Organization (WHO) estimates that 23 million girls younger than 20 years of age become pregnant in low- and middle-income countries (LMICs) every year [1]. The burden of adolescent pregnancies is the highest in Sub-Saharan Africa, where one-quarter of all pregnancies occur in adolescents [2]. In Kenya, the adolescent pregnancy rate is 96 per 1000 births, with some counties having a higher burden [3].

Adolescent pregnancies are associated with poorer physical and socio-cognitive development during infancy and early childhood, partly due to inadequate knowledge on infant care [1]. Children born to mothers younger than 20 years of age have a 50% higher chance of being born as stillbirths, dying within the first few weeks after birth or being born with low birth weight; they also have a higher risk of long-term effects, behavioral problems in childhood, poor cognitive development, and worse educational outcomes [4-9]. Adolescent mothers have higher rates of depression, poverty, and poor economic development since the majority are forced to drop out of school [5,10].

Adolescent mothers show less sensitive and more intrusive, hostile interactive behaviors and less frequently engage in direct interactions with their children [11]. Maternal sensitivity has also been shown to be of major significance for children's attachment and socio-emotional development as well as cognitive development [12,13]. Another study showed that cognitive developmental differences in 3-year-old children of adolescent and adult mothers were indirectly mediated by maternal parenting behaviors [14]. Some of these behaviors among adolescent mothers may arise from the lack of knowledge on proper infant feeding and care practices. Socioeconomic problems such as economic deprivation, which accompany many adolescent pregnancies, are associated with negative developmental outcome in the offspring [15]. This may be due to low cognitive stimulation in the home, including toys, books, and learning opportunities that shape the developing brain [16].

Adolescent mothers have less knowledge on infant care and development compared with their older counterparts [17,18]. Antenatal care (ANC) offers an opportunity for the provision of information and advice for a healthy pregnancy, safe childbirth, and postnatal recovery; care of the newborn; and promotion of early, exclusive breastfeeding [19]. However, adolescent mothers also attend ANC less often than recommended [20]. Therefore, a different approach is necessary for ensuring that these mothers receive this vital information. Identifying adolescent pregnancies early on and offering a specialized package of care involving education, counseling, and support together with nutritional supplementation can reduce neurocognitive underdevelopment at minimal cost in LMICs [21,22]. Mobile health (mHealth) technology has been applied in various settings in LMICs to motivate positive health behaviors and improve health outcomes, including HIV testing [23], antiretroviral treatment adherence [24-26], postoperative clinic follow-ups [27], malaria treatment [28], immunization [29], and postnatal care and follow-ups [30]. Such innovations have been shown to be cost-effective in improving maternal, newborn, and child health outcomes [31,32].

The WHO Nurturing Care Framework identifies the formation of parent groups, counseling, and support as a model for achieving responsive care giving [33]. We sought to test the efficacy of interactive mobile text messaging on childcare and development, with or without psychosocial support groups, among adolescent mothers in improving maternal knowledge and early infant development.

Methods

Study Design and Population

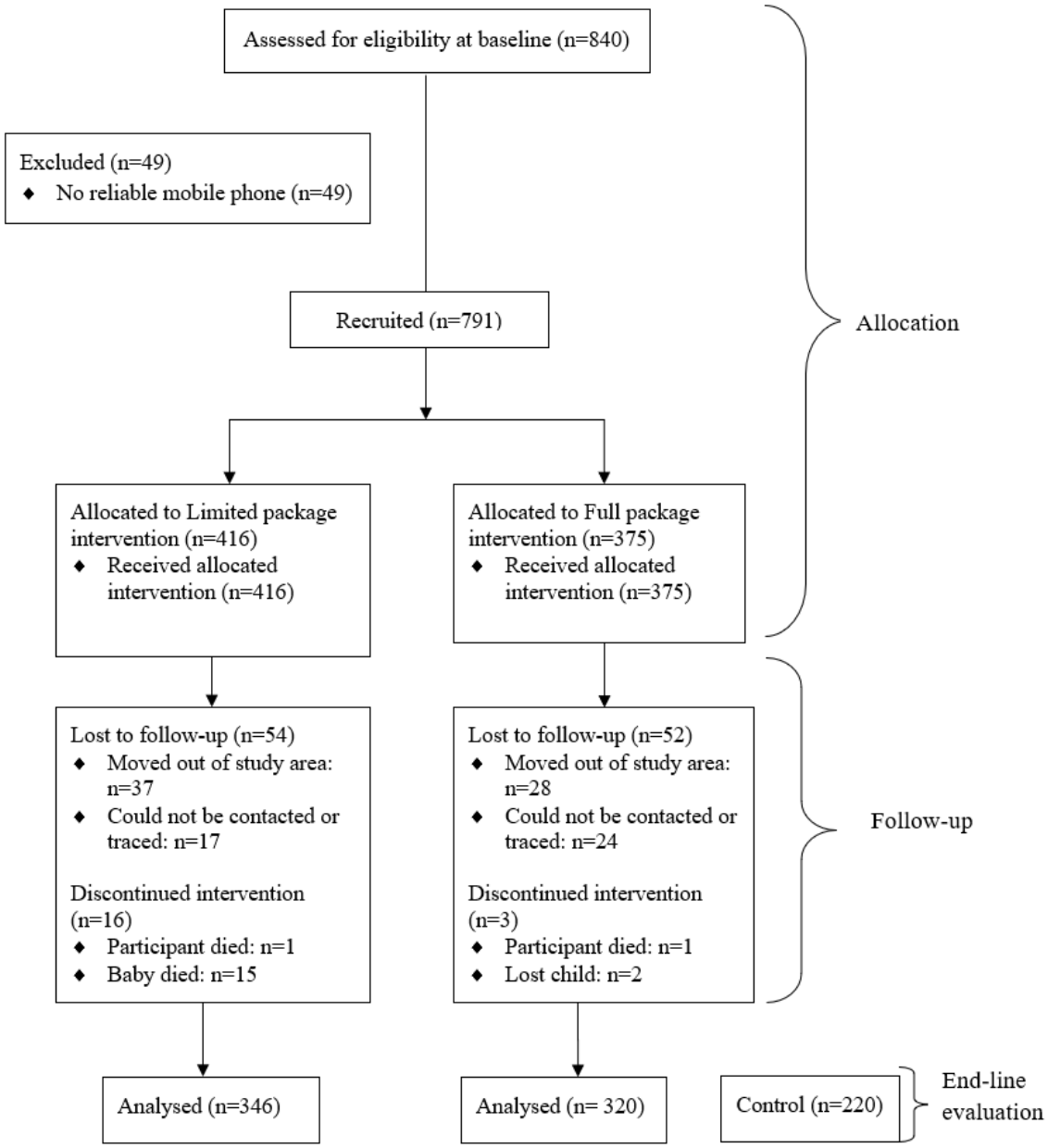
This was a quasi-experimental study to assess the efficacy of a nurturing care package delivered through mHealth and psychosocial support on the development of children born to adolescent mothers. The study was conducted in 5 subcounties purposively selected from the 8 subcounties in Homa Bay County, Kenya. Homa Bay County has the second highest prevalence of adolescent pregnancies in Kenya, at 33.3% in 2019 [34].

The study population was adolescent mothers and their infants. The minimum sample size required per cluster was 200, based on a 22% expected difference in exclusive breastfeeding rates between adolescent and mature mothers [35]. Adolescent mothers (aged younger than 20 years) with a child younger than 3 months of age at recruitment, who are residents of 1 of the selected subcounties, were eligible for inclusion. We excluded those who did not have access to a mobile phone within the family setup. Written consent was obtained from all the participants; for those younger than 18 years of age, a guardian had to give consent before inclusion.

Sampling Procedures

We adopted a cluster-sampling method, with the subcounty representing a cluster. Four subcounties were randomly selected from the 8 in Homa Bay County and assigned to 1 of the 2 study arms: full package intervention or limited package intervention (2 subcounties each). Eligible adolescent mothers were recruited by community health extension workers working in each of the subcounties. A baseline survey was conducted, collecting key variables including age, education, occupation, telephone number, and knowledge and practices on infant care and development. A total of 791 adolescent mothers were recruited into the study at baseline. We did not recruit a no-intervention control group at baseline due to 2 reasons. First, the community health extension workers in the study locations felt that recruiting a control group and then following up with them until the final evaluation with no intervention may be difficult to explain to the adolescents and their guardians. On the contrary, a control group at end line would be packaged as a health promotion activity in the community. Second, since the study team would still need to do community tracking of the adolescents in the control group, it would be difficult to avoid providing information similar to our interventions if specifically asked by the participants; this would result in contamination risk. Therefore, we adopted a pretest-posttest design with a posttest-only control [36]. We recruited a control group with comparable key characteristics (maternal age younger than 20 years with a child between the age of 9-12 months) from a different subcounty in Homa Bay County at end line. A total of 220 adolescent mothers were recruited in the control group (Figure 1).

Figure 1. Study CONSORT (Consolidated Standards of Reporting Trials) flow diagram.



Intervention

The intervention consisted of (1) the delivery of targeted messages on childcare and nurturing through an interactive text messaging platform and (2) psychosocial support groups for the adolescent mothers, moderated by trained personnel. This was based on the WHO Nurturing Care Framework, which emphasizes health, nutrition, early learning, and responsive care giving through parent groups, counseling, and support [33]. By delivering a package of targeted interventions to the adolescent mothers, we expected to improve their knowledge and practices in childcare, which would translate to better development of their children. We hypothesized that although an mHealth platform could provide an avenue for health education, psychosocial support for the adolescent mothers may still need a physical interaction. The interventions were implemented in 4 subcounties: 2 received text messaging only and 2 received the full package of text messaging and psychosocial support groups. The text messaging intervention consisted of the transmission of text messages, arranged in themes each week, at a rate of 5-10 key messages per week. These themes included feeding at every age (including during diarrhea and other illnesses), breastfeeding, immunization, danger signs in infants and young children, general childcare and safety, developmental milestones, and when to seek care. The interactive feature allowed the adolescent mothers to engage experts on the platform to seek clarification, ask questions, or obtain guidance on various aspects of their health or that of their children, at no cost on their side. The psychosocial support groups consisted of 5-10 adolescent mothers, grouped by the ward of residence. Each group held weekly meetings, with a community health extension worker and a counselor moderating the discussions. Discussion topics were based on the themes addressed by the text messages transmitted that week. Meetings were usually held during weekends, to accommodate adolescent mothers who were in school. The total follow-up period was 9 months; the interventions were conducted from October to December 2019, and the postintervention follow-up was conducted from January to June 2020.

Data Collection

A baseline questionnaire was administered, documenting the demographic and contact information of the eligible participants. Key information at baseline included the ages of the mother and infant, residence, and mobile telephone number. Data were collected by community health extension workers. Development assessment used the Developmental Milestones Checklist (DMC III) [37], with questions from the checklist matched with the age of the infant at final evaluation. The DMC III items had 3 likely responses: milestone observed continually (score 2), milestone observed occasionally (score 1), and milestone not observed at all (score 0). The DMC III evaluation involves both interviewing the mother as well as observing and assessing the infant. Data were collected electronically using Android tablets. A survey questionnaire was administered to the adolescent mothers at end line, measuring knowledge (12 items) and practices in feeding, vaccination, growth monitoring, breastfeeding, hygiene, and milestones in a child's development. Each of the survey questions was scored as either 0 if the mother did not know the correct response or 1 for correct responses. For the DMC III checklist, the gross motor component had 25 items, the fine motor component had 12 items, and the language component had 18 items. Each item was either scored 0 (caregiver has not observed that milestone in the previous 4 weeks), 1 (the milestone item has been observed but not continuously), or 2 (the milestone had been observed continuously in the previous 4 weeks). In addition to the questionnaire administered to the mother, other assessments on the infants included weight, midupper arm circumference, head circumference, and height or length.

Study Outcomes

The primary outcomes were (1) maternal knowledge and practices (exclusive breastfeeding, immunization, feeding, and stimulation) on childcare and development and (2) infant developmental milestones at end line as assessed by the DMC III. The secondary outcomes were (1) the incidence of diarrhea and respiratory illnesses and (2) anthropometric measurements. The secondary outcomes are not reported in this paper.

Data Management and Statistical Analysis

We first explored the descriptive analysis using independent sample 2-tailed *t* test to compare mean estimates of the outcomes between study arms and by survey period. The study end points were analyzed at end line only, comparing the 2 interventions against the control, as well as against each other (full package vs control, limited package vs control, and full package vs limited package). Development milestones were summed to generate continuous variables representing knowledge, fine motor, gross motor, and language scores. These were considered normally distributed variables, and hence, means and SDs were used to compare the significant differences. Independent sample *t* tests were then used to test the hypothesis that the mean differences in DMC III scores were similar for those participants who received the full package intervention compared to controls. To account for cluster effects and probability sampling weights and to assess the effectiveness of the interventions at the same time, we fitted a generalized estimating equations (GEE) model with a linear model for a continuous outcome. The GEE model was used with a small-sample correction, due to the small number of clusters [38]. The dependent variables were knowledge, language, gross motor, and fine motor scores. The effect factor was a binary variable representing either full package versus control, limited package versus control, or full package versus limited package. Results with P values <.05 were considered statistically significant results. The analysis was done using Stata (version 15; StataCorp), and effects were reported with 95% CIs. Data management was carried out by a statistical team that was independent from the main study group.

Ethics Approval

Eligible study participants were given the rationale and aims of the intervention study. Written informed consent was then obtained from all enrolled adolescent mothers. The protocol was approved by the African Medical Research Foundation Ethics and Scientific Review Committee (protocol ESRC P589/2019). We also obtained approval of local authorities, at the county and subcounty levels, and community strategy coordination before the implementation of the study. The study

protocol was registered at the Pan African Clinical Trials Registry (PACTR201806003369302).

Results

Baseline Sociodemographic Characteristics of the Study Population

A total of 1011 adolescent mothers were recruited: 416 in the limited package arm, 375 in the full package arm, and 220 in the control group. The majority of the participants (873/1011, 86.4%) were between the ages 16 and 19 years, and 61.6% (623/1011) were students. Only 10% (101/1011) had completed secondary school. One-quarter (265/1011, 26.2%) were married, and only 16.4% (166/1011) were involved in any form of income-generating activity (business, employment, casual labor, or farming). Antenatal clinic attendance for at least 1 visit was high for all the groups (370/375, 98.7% for the full package group; 396/416, 95.2% for the limited package group; and 215/220, 97.7% for the control group). The comparison of the various parameters across the 3 groups is shown in Table 1.

At end line, 666 adolescent mothers in the intervention groups were still active in the study, translating to an overall attrition rate of 15.8% (125/791; 70/416, 16.8% in the limited package intervention group vs 55/375, 14.7% in the full package intervention group). The mean age of the children at the end-line evaluation was 11.8 (SD 2.5) months for the full intervention group, 12.4 (S.D 2.8) months for the limited intervention group, and 11.0 (S.D 4.2) months for the control group. Exclusive breastfeeding rates were higher in the full package intervention group compared with the control group (238/375, 63.5% vs 112/220, 50.9%; P=.004); the difference was even higher for the limited package intervention group (297/416, 71.4% vs 112/220, 50.9%; P<.001).

Table 1. Sociodemographic characteristics of study population[a].

Characteristics	Full package (n=375), n (%)	Limited package (n=416), n (%)	Control (n=220), n (%)
Age range (years)			
12-15	64 (20)	63 (15.1)	11 (5)
16-19	311 (82.9)	353 (84.9)	209 (95)
Education level			
Primary, incomplete	134 (38.7)	163 (39.2)	83 (37.5)
Primary, completed	38 (10.1)	59 (14.2)	27 (12.3)
Secondary, incomplete	156 (41.6)	162 (38.9)	88 (40.2)
Secondary, completed and above	47 (12.5)	32 (7.7)	22 (10.1)
Occupation			
Business	8 (2.1)	32 (7.7)	11 (5)
Casual laborer	6 (1.6)	7 (1.7)	4 (1.6)
Farming	24 (6.4)	50 (12)	20 (9.3)
Formal employment	0 (0)	2 (0.5)	0 (0)
Housewife	68 (18.1)	72 (17.3)	39 (17.9)
Student	260 (69.3)	227 (54.6)	136 (61.7)
Other	9 (2.4)	26 (6.3)	10 (4.5)
Marital status			
Married	84 (22.4)	123 (29.6)	58 (26.4)
Single	291 (77.6)	292 (70.2)	162 (73.6)
Other[b] (separated, divorced, or widowed)	0 (0)	1 (0.2)	0 (0)
Source of family income			
Agriculture	128 (34.1)	286 (68.8)	115 (52.3)
Business	195 (52)	75 (18)	75 (34.1)
Employment	30 (8)	14 (3.4)	12 (5.6)
Others	22 (5.9)	41 (9.9)	18 (8)
Religion			
Christian	375 (100)	409 (98.3)	218 (99.1)
Muslim	0 (0)	7 (1.7)	2 (0.9)
ANC[c] attendance at least 1 visit			
Yes	370 (98.7)	396 (95.2)	215 (97.7)
No	5 (1.3)	20 (4.8)	5 (2.3)

[a]This includes the number of participants as at recruitment—the intervention groups at baseline and the control group at end line.

[b]Other includes those who are separated, divorced, or widowed; these were combined since the numbers were very small.

[c]ANC: antenatal care.

Change in Maternal Knowledge on Infant Care and Developmental Milestones at End Line

Compared with the control group, adolescent mothers who received the full package had a higher knowledge score on infant care and development (9.02 vs 8.01; $P<.001$); the same was observed for those who received the limited package (8.73 vs 8.01; $P<.001$), as shown in Table 2.

The infants of mothers in both intervention groups also had higher average scores on the DMC III in developmental milestones (Figure 2).

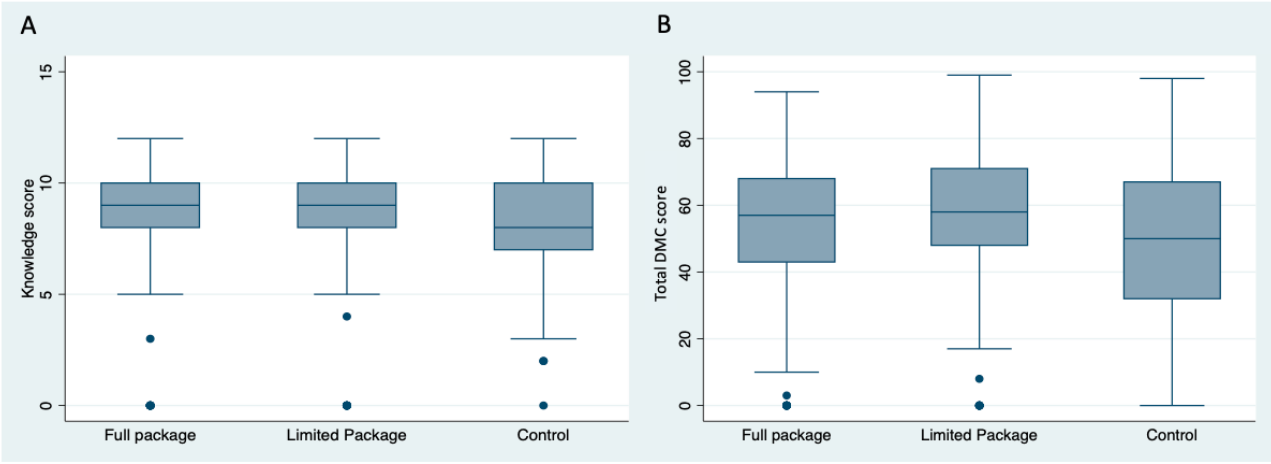
Table 2. Comparison of maternal knowledge score between the 2 interventions groups and the control group at end line[a].

Package	Intervention		Control		Knowledge score, mean difference	*P* value (*t* test)
	Participant, n	Knowledge score, mean (SD)	Participant, n	Knowledge score, mean (SD)		
Full package	307	9.02 (2.19)	199	8.01 (2.07)	1.01	<.001[b]
Limited package	297	8.73 (2.22)	199	8.01 (2.07)	0.73	<.001[b]

[a]The n values differ from the numbers analyzed from the CONSORT (Consolidated Standards of Reporting Trials) diagram due to records with missing key variables that were dropped from the model.

[b]Significant results at *P*<.05.

Figure 2. Comparison between groups in (A) maternal knowledge and (B) infant developmental milestones at end line. (A) Full package vs control: *P*<.001; limited package vs control: *P*<.001; full package vs limited package: *P*=.01. (B) Full package vs control: *P*=.01; limited package vs control: *P*<.001; full package vs limited package: *P*=.003. DMC: Developmental Milestones Checklist.



Differences in Developmental Milestones at End Line for the Intervention Groups and the Control Group

Compared with the control group, participants who received the full package had significantly higher gross motor (26.55 vs 23.50; *P*<.001), fine motor (12.97 vs 11.41; *P*<.001), as well as overall DMC III score (53.09 vs 48.59; *P*=.01). However, there was no significant difference in language scores between those who received the full package of interventions and the control group (13.57 vs 13.68; *P*=.56; Table 3).

Participants who received limited package also had significantly higher scores in fine motor (12.59 vs 11.41; *P*=.002), gross motor (27.95 vs 23.50; *P*<.001), and also language (17.75 vs 13.68; *P*<.001) scores compared with the control group. Overall DMC III scores were also significantly higher for those who received limited package compared with control (58.29 vs 48.59; *P*=.002; Table 3).

Table 3. Comparison of mean Developmental Milestones Checklist (DMC III) scores between the intervention groups and the control group.

Score	Full package (n=307), mean (SD)	Control (n=199), mean (SD)	*P* value	Limited package (n=297), mean (SD)	Control (n=199), mean (SD)	*P* value
Fine motor	12.97 (4.80)	11.41 (5.09)	<.001[a]	12.59 (4.02)	11.41 (5.03)	<.001[a]
Gross motor	26.55 (9.52)	23.50 (10.60)	.56	27.95 (9.33)	23.50 (10.60)	<.001[a]
Language	13.57 (8.20)	13.68 (9.18)	.01[a]	17.75 (7.91)	13.68 (9.18)	<.001[a]
Total DMC III score	53.09 (20.02)	48.59 (23.32)	<.001[a]	58.29 (19.28)	48.59 (23.32)	.002[a]

[a]Significant results at *P*<.05.

Comparison of Mean Developmental Milestone Scores Between the Full and Limited Package Groups

Overall, there was no statistical difference in developmental milestones between those who received the full package and those that received the limited package (*P*>.99; Table 4). However, the full package group had higher knowledge scores than the limited package group (9.02 vs 8.73; *P*=.048).

Table 4. Comparison of knowledge and mean Developmental Milestones Checklist (DMC III) scores between the full and limited package groups.

Score	Full package (n=307), mean (SD)	Limited package (n=297), mean (SD)	*P* value
Knowledge	9.02 (2.19)	8.73 (2.22)	.048[a]
Fine motor	12.97 (4.80)	12.59 (4.02)	.15
Gross motor	26.55 (9.52)	27.24 (9.44)	.97
Language	13.57 (8.20)	17.75 (7.91)	>.99
Total DMC III score	53.09 (20.02)	58.29 (19.28)	>.99

[a]Significant results at $P<.05$.

Discussion

Key Findings

In this study, using an interactive text messaging service to provide information and support to adolescent mothers improved their knowledge on nurturing infant care and the developmental milestones of their children at 1 year of age. Adding psychosocial support groups did not have superior impact on maternal knowledge nor infant developmental milestones compared with the interactive text messaging alone.

Comparison With Other Studies

Other studies have showed mixed findings on the impact of providing information and psychosocial support to mothers; most showed improvement in some but not all of the growth and developmental parameters of the children. A cluster intervention trial in Zambia evaluating home visits and parenting groups found an improvement in some anthropometric measures (stunting) as well as language but no effects on motor skills, cognitive, or socio-emotional development [39]. In Uganda, an intervention to reduce maternal depression and improve child development through group education on feeding, hygiene, and stimulation improved the cognitive and language development of the children [40]. Other interventions in mothers that provide information and support have been shown to improve various nutritional parameters [41]. A randomized trial in Ethiopia found improvement in socio-emotional and language development after an intervention consisting of play stimulation during home visits [42]. However, a home-based parenting support program delivered until 6 months post partum in South Africa found no impact on the cognitive development of the infants [43]. Our study found improvements in both maternal knowledge and infant development parameters. One possible reason for this may be because we were intervening among adolescent mothers only, whereas the other studies were among mixed-age mothers. Adolescent mothers are at a very high risk of maternal depression due to the lack of familial social support and socioeconomic hardships; any intervention in a convenient approach therefore could have higher impact [44]. Most of the studies mentioned above had a component of home support visits; however, we found no added benefits of home visits or psychosocial support groups to either maternal knowledge or infant growth and development outcomes. A possible explanation is since we were using an interactive text messaging platform, the adolescent mothers were able to access both information and sense of support from the platform, similar to what they would have acquired through home visits or support groups, but with an added advantage of privacy and convenience. An expansion of such a platform to include peer-to-peer interaction can further changes, knowledge, and behavior on nurturing infant care [45]. Interactive mHealth solutions that give users the opportunity to ask question or seek clarifications are more acceptable and effective than one-way platforms and can increase access to health information, especially to special populations, in an equitable and cost-effective way [46-49]. This would be valuable in providing adolescent mothers with information and support on reproductive health, which are services traditionally offered at health facilities. Interestingly, ANC attendance was high for all the groups in this study; this implies that the main limiting factor may not be the lack of interaction with the health care system but the provision of tailored, adolescent-responsive reproductive health information conveniently.

Limitations and Strengths

The findings of this study should be interpreted in consideration of some limitations. First, the study had a limited number of clusters. To minimize the likely effect on the type 1 error rate, the GEE model with a small-sample correction was performed. Due to reservations of community stakeholders on recruiting vulnerable adolescent mothers with no planned interventions, we were not able to recruit a control group at baseline. The control group was recruited during the end-line survey, in a different subcounty in the study county, among adolescent mothers with infants between the ages of 9-12 months (similar to the intervention groups at the end of follow-up). Therefore, uncontrolled differences between the intervention groups and the control group could have contributed, in part, to the observed differences in developmental outcomes. Studies with posttest-only controls also have a weakness in that they may not adequately measure the change brought about by maturation (threats to validity that happen over time during follow-up) or sensitization (the impact of the intervention groups being exposed to the survey at baseline) [36]. Additionally, the groups had significant differences in socioeconomic variables at recruitment, which could have influenced the outcomes due to residual confounding. Due to the COVID-19 pandemic, we were not able to conduct assessments at 6 and 12 months but had our final evaluation after 9 months of follow-up.

Our study also has several strengths. Our target population was a vulnerable segment of the female reproductive population, which is a leading contributor to maternal and infant morbidity as well as mortality. Since the lack of information on reproductive health among adolescents is a key causative factor,

out study provides evidence on how such information and support can be availed efficiently to this vulnerable demographic. Second, other than the information itself, our implementation approach was to use currently available structures (mobile phones and community health strategy) to make available information and support to adolescent mothers. Only 5.8% (49/840) of eligible participants were excluded due to the lack of a reliable mobile phone. This can make scaling up both feasible and sustainable. The mHealth strategic framework and electronic community health information system by the Kenya Ministry of Health are some of the pathways through which our findings can be adopted into policy, to drive interventions targeted at adolescent mothers and their children.

Conclusion

In this study, an interactive text messaging platform among adolescent mothers in rural Kenya improved both the knowledge of mothers on infant nurturing care and the development milestones of their infants. These findings, if replicated in other studies in different settings, can provide a mechanism of improving the overall reproductive health of adolescents in LMICs. Although the addition of support groups in such interventions has been adopted before, we did not find any additional benefit in improving developmental outcomes. Therefore, an interactive mHealth solution could serve as a minimum intervention package among this vulnerable group to improve health outcomes.

Acknowledgments

We wish to thank the Homa Bay County Department of Health and the Field Epidemiology Society of Kenya team, for their support and facilitation during the conduction of this study.

This study was funded by Grand Challenges Canada, under the Saving Brains Initiative (grant SB-POC-1810-19773).

Authors' Contributions

VM conceived and provided leadership in the execution of the study; IM led the monitoring and evaluation component; VO and VW performed the data processing, analysis, and reporting; and JO coordinated the study fieldwork. All the authors led and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1116 KB - pediatrics_v6i1e37359_app1.pdf]

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Abbreviations

ANC: antenatal care
DMC III: Developmental Milestones Checklist
GEE: generalized estimating equations

LMIC: low- and middle-income country
mHealth: mobile health
WHO: World Health Organization

Edited by S Badawy; submitted 17.02.22; peer-reviewed by T Zan, T Tigest, D Linde, K Uludag; comments to author 19.04.22; revised version received 23.07.22; accepted 23.08.22; published 01.05.23.

Please cite as:
Mwenda V, Makena I, Ogweno V, Obonyo J, Were V
The Effectiveness of Interactive Text Messaging and Structured Psychosocial Support Groups on Developmental Milestones of Children From Adolescent Pregnancies in Kenya: Quasi-Experimental Study
JMIR Pediatr Parent 2023;6:e37359
URL: https://pediatrics.jmir.org/2023/1/e37359
doi:10.2196/37359
PMID:37126373

Original Paper

A Mobile Self-Management App (CanSelfMan) for Children With Cancer and Their Caregivers: Usability and Compatibility Study

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Abstract

Background: Despite the increasing development of different smartphone apps in the health care domain, most of these apps lack proper evaluation. In fact, with the rapid development of smartphones and wireless communication infrastructure, many health care systems around the world are using these apps to provide health services for people without sufficient scientific efforts to design, develop, and evaluate them.

Objective: The objective of this study was to evaluate the usability of CanSelfMan, a self-management app that provides access to reliable information to improve communication between health care providers and children with cancer and their parents/caregivers, facilitating remote monitoring and promoting medication adherence.

Methods: We performed debugging and compatibility tests in a simulated environment to identify possible errors. Then, at the end of the 3-week period of using the app, children with cancer and their parents/caregivers filled out the User Experience Questionnaire (UEQ) to evaluate the usability of the CanSelfMan app and their level of user satisfaction.

Results: During the 3 weeks of CanSelfMan use, 270 cases of symptom evaluation and 194 questions were recorded in the system by children and their parents/caregivers and answered by oncologists. After the end of the 3 weeks, 44 users completed the standard UEQ user experience questionnaire. According to the children's evaluations, attractiveness (mean 1.956, SD 0.547) and efficiency (mean 1.934, SD 0.499) achieved the best mean results compared with novelty (mean 1.711, SD 0.481). Parents/caregivers rated efficiency at a mean of 1.880 (SD 0.316) and attractiveness at a mean of 1.853 (SD 0.331). The lowest mean score was reported for novelty (mean 1.670, SD 0.225).

Conclusions: In this study, we describe the evaluation process of a self-management system to support children with cancer and their families. Based on the feedback and scores obtained from the usability evaluation, it seems that the children and their parents find CanSelfMan to be an interesting and practical idea to provide reliable and updated information on cancer and help them manage the complications of this disease.

(JMIR Pediatr Parent 2023;6:e43867) doi:10.2196/43867

KEYWORDS

Digital health; eHealth; Telehealth; mHealth; Mobile app; self-management; cancer; child; parent; caregiver; usability evaluation

Introduction

Recent advances in smartphone technology have made a wide variety of apps available to the public [1] that have multiple uses in health care, such as supporting patients and providing medical services [2,3]. Since children and teenagers are active users of this technology, smartphones can be an acceptable social tool to provide education and self-management to these groups [4,5]. Studies show that the rate of learning, use, and satisfaction was high in children with technological tools such as smartphones, and this group has no problem using these tools [6]. This provides a suitable opportunity for a wide population of children and adolescents to access support, assessment, and treatment of disease-related symptoms over the internet [7-9]. Despite there being many different smartphone apps in this field, most lack proper evaluation. In fact, with the rapid development of smartphones and wireless communication infrastructure, many health systems around the world are using these apps to provide health services for people without sufficient scientific efforts to design, develop, and evaluate them [10]. A review of over 75 clinical trial studies related to mobile health showed that most of these interventions, although they were conducted in high-income countries, were of low quality, and the results were far from expected. For example, as Free and colleagues [11] reported, “Our meta-analyses show that, to date, mobile technology–based interventions for diabetes control that have statistically significant effects are small and of borderline clinical importance.”

Therefore, to facilitate an increase in effectiveness, satisfaction, and trust of users, a suitable standard method should be used to evaluate the intervention [12,13]. A usability test is one of the best ways to ensure that a product meets the users’ needs [14]. According to the International Standard Organization, usability refers to “the extent to which a product can be used by a specific user to achieve specific goals with effectiveness, efficiency, and satisfaction” [13]. Moreover, usability refers to users’ satisfaction and level of engagement with the system’s user interface, ease of use, and simplicity of learning [1] Therefore, an evaluation of usability is an important step in health interventions. Additionally, a review of the final product based on the end users’ opinions provides valuable information about the quality and usability of the product for the developer [15]. This issue is influential because usability is a key factor in the acceptance and use of any new technology in the health industry, and it can have a direct impact on users’ satisfaction. [16,17]

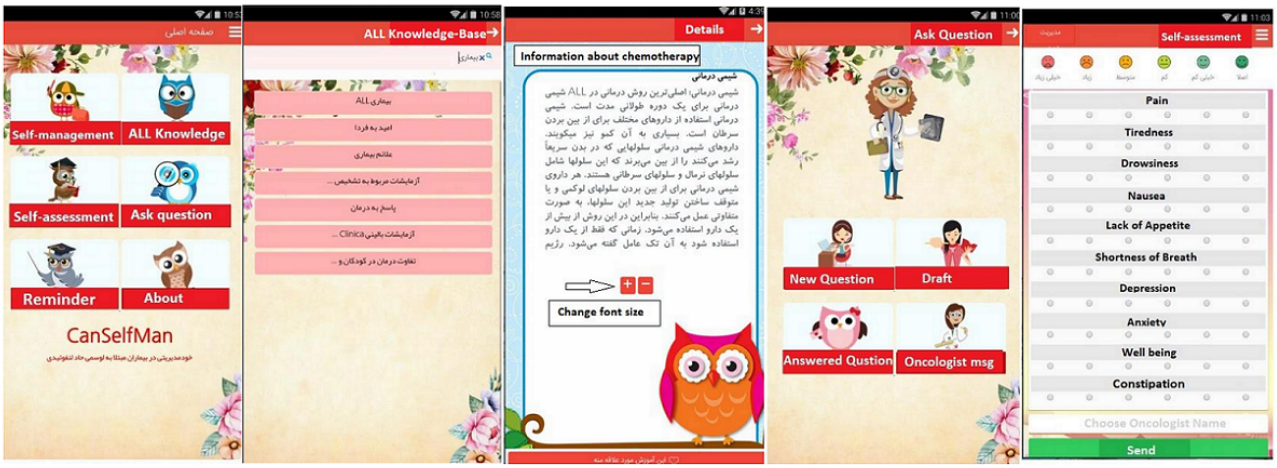
Thus, it seems obvious that usability testing should be a common step in the development process, even for small-scale systems [16,18]. Studies show that products with higher scores in usability evaluation tests are more desired and used, while low usability has a negative effect on user acceptance [19,20]. Without considering usability and user satisfaction, no app can expect long-term use by users. For example, most users usually spend less than 30 seconds working with a new app, and if not satisfied within that time frame, they will delete it and use other alternative apps [21]. Therefore, to ensure that the product meets user needs, its usability must be evaluated. For this purpose, we aimed to evaluate the usability of CanSelfMan, a self-management system for children with cancer and their families (which we covered in another report [22]), via the User Experience Questionnaire (UEQ) questionnaire (Multimedia Appendix 1).

Methods

System Description

CanSelfMan is a self-management system for children with cancer that includes a web-based dashboard for oncologists and an Android app for the children and their parents/caregivers. In the initial version of CanSelfMan, there were 2 distinct versions for parents/caregivers and children. In the final iteration, a single app was made for both children and their parents/caregivers. The final version of the app had 5 modules, which included (1) cancer knowledge (ie, information about the definition of the disease, causes of the disease, treatment methods, and complications), (2) self-management recommendations (ie, recognition of symptoms, control of symptoms, physical activities, and nutritional information), (3) symptom management, (4) self-assessment questionnaire of symptoms, and (5) questions from the physician and reminders. Additionally, the oncologists’ dashboards included parts to see the results of patient assessments, questions, and answers to patients’ questions (Figure 1).

Figure 1. CanSelfMan app screenshots. ALL: acute lymphoblastic leukemia.



Usability Tests

Performance and Compatibility Test

After we completed the steps related to coding and developing the final prototype, we performed a debugging test to evaluate app performance and identify possible errors. The process of finding and fixing errors in a software or app is called debugging, and it includes detecting codes that cause problems in app execution or performance. A debugger is a tool that helps you find and fix errors. Debugging can be done manually or through a debugger [23]. In this study, the debugging process was carried out by the principal researcher (HM) with an Android debugger.

Following this, a compatibility test was done in a simulated environment to ensure the final version of the app could run properly on different phones with different hardware and software capabilities. This test was done to check the compatibility of the app on smartphones produced by different manufacturers and with different screen sizes. For this simulation, the pCloudy [24] platform was used. This test evaluates how a mobile app performs in terms of battery consumption, memory, processor, and network data usage. It also checks how the app performs with the different smartphone brands and presents the results.

UEQ Evaluation

Next, to evaluate usability and user satisfaction, we used a questionnaire. After reviewing similar studies and based on the opinions of research team members, we decided to use the standard UEQ, a free questionnaire that measures usability and user experience. It has been described as a "fast and reliable questionnaire to measure the user experience of interactive products [that is] available in more than 30 languages [and is] easy to use due to rich supplementary material" [25]. It has been widely used in human-computer interaction research, and along with other qualitative evaluation methods like Think Aloud [22], it can accurately identify the weak and strong points of a product. In our previous report, we explained the results obtained from the Think Aloud evaluation [22].

The UEQ is filled out by the user after they use the product to measure its effectiveness [25]. Usually, it takes between 3 and 5 minutes to complete this questionnaire. Therefore, it is one of the most efficient methods to measure users' opinions about a software product. The official version of this questionnaire has been translated into over 20 different languages, including Persian. It has 26 questions that include 6 measures, namely, (1) attractiveness, (2) perspicuity, (3) efficiency, (4) dependability, (5) stimulation, and (6) novelty in the 2 axes of design quality and use quality. Additionally, it measures both usability and user satisfaction with the product [26]. Textbox 1 briefly explains each of these 6 measures.

The remaining 5 scales have an impact on the attractiveness scale, which measures the user's overall impression of the app. While stimulation and novelty describe hedonic (non–goal-directed) quality criteria, the scales of perspicuity, efficiency, and dependability provide information about pragmatic (goal-directed) quality aspects. Each item is a pair of opposites with a 7-point Likert scale, which is the form of a semantic differential. [27]. Multimedia Appendix 1 shows the UEQ items.

The UEQ has a tool designed in Microsoft Excel (Microsoft Corp) to calculate and interpret the results, as well as a database containing the results of previous studies, allowing us to compare our results with those of 246 previous studies [25,28]. The answer to each question is on a 7-point Likert scale ranging from −3 (completely agree with the negative conditions) to +3 (completely agree with the positive opinion), with 0 being neutral. If the total score of each measure is less than −0.8, it means unacceptable or weak, −0.8 to +0.8 means acceptable, and +0.8 to 3 is considered good and excellent.

Textbox 1. The 6 measures of the User Experience Questionnaire (UEQ).

1. Attractiveness: Do users like or dislike the app?
2. Perspicuity: Is it easy to get used to and understand how to use the app?
3. Efficiency: Can users get their work done quickly and efficiently?
4. Dependability: Are interactions with the app safe and predictable?
5. Stimulation: Is using the app enjoyable and motivating?
6. Novelty: Do users feel motivated to continue using the app?

Ethics Approval

This study received ethical review approval from Shahid Beheshti University of Medical Sciences (IR.SBMU.RETECH.REC.1396.1316).

Study Setting and Population

After compatibility and technical testing, the final version was provided to end users to evaluate usability. For this purpose, a banner was placed in the outpatient department of MAHAK's Pediatric Cancer Treatment and Research Center inviting people to participate in the study. The inclusion criteria for entering this study for children were (1) children with acute lymphoid leukemia referred to MAHAK who were in the phase of chemotherapy treatment (ie, at least 1 year had passed since the start of treatment), (2) at least 7 years of age, and (3) can work with a smartphone. For parents/caregivers, the inclusion criteria were (1) having at least 1 child with cancer that has been diagnosed for a year and is currently undergoing active treatment with chemotherapy, (2) having the ability to read and write in Persian, and (3) having an Android smartphone (version 8 to 11). The exclusion criteria were patients who were in the end stages of cancer and those struggling with their mental health

and parents/caregivers who did not know how to work a smartphone and could not read or write. In addition, 4 oncologists participated in this study to answer patients' questions.

Before initiating the study, we presented information about the study to the participants in a 30-minute session. In this session, the principal researcher (author HM) explained the app to the participants and the purpose of this study in plain language. Following that, another researcher (author AM) obtained permission from the children's parents/caregivers to participate in this study and then from the children themselves. After this, the parents signed the consent form.

We explained to all participants that they could withdraw at any stage of the study without providing a reason. After this, the CanSelfMan app was installed on their smartphones, and they were shown how to use the app. After 3 weeks of use, the participants returned to MAHAK in person and completed a questionnaire related to demographic information including age, sex, place of residence, and education, along with the UEQ.

Results

CanSelfMan Compatibility Test

At this stage, to ensure that the final app was functioning correctly, a compatibility test was performed using a simulation with the pCloudy service. The results are shown in Figure 2.

One of the important issues in the compatibility test included installing, running, and uninstalling the app, which was done on 10 different brands of smartphones in the pCloudy platform.

The app was installed and run on all the desired phones without any errors. Then, the app was examined from compatibility and applicability aspects on different smartphones with different screen sizes. Again, it was executed without any problems. Next, 4 features, namely, memory, processor, network data, and battery consumption, were examined. Based on the results of this simulation, CanSelfMan acquire scored 7.9 out of 10 possible points in the battery consumption section, which is considered a good score and indicates an optimal consumption of battery and memory. Moreover, in the network exchange data evaluation, it obtained a score of 9.6, which is a very high score (Figure 2).

Figure 2. CanSelfMan app results for the compatibility test. CPU: Central Processing Unit; mAh: milliampere hour.

Usability and User Satisfaction

During the 3 weeks of app use, 270 symptom evaluations and 194 questions were recorded in the system by children and their parents/caregivers and answered by oncologists. After the end of the 3-week period, 44 users completed the UEQ. Respondents included 25 parents who had a child under the age of 7 years with cancer.

The age range of the parents/caregivers in this phase was between 27 and 48 years, with an average age of 32 years, and most (n=16, 64%) were female. Table 1 shows the participants' demographic information.

A total of 19 children with cancer ranging in age from 7 to 14 years, with an average age of 12 years, completed the UEQ. The majority (11/19, 58%) of the children were female. The range of points that can be obtained in UEQ is from −3 (the lowest possible point) to +3 (the maximum point that can be obtained). The results are interpreted based on average values, and there is no unique score. In addition, the CI of the measurements refers to the level of accuracy in estimating the average. As a result, the smaller the CI, the higher accuracy and reliability of the obtained results. Since each of the 6 measures in UEQ includes a set of items, none of the items can be interpreted alone. Therefore, for each measure, the total score of the related items was calculated.

Table 1. Participants' demographic information.

Participants	Parents (n=25)	Children (n=19)
Age (years), mean (SD; range)	32 (2.1; 27-48)	10 (1.7; 7-14)
Gender, n (%)		
Female	16 64))	11 (58)
Male	9 (36)	8 (42)
Residence, n (%)		
Urban	14 (56)	13(68)
Rural	11 (44)	6(32)
Education level, n (%)		
Secondary school	1 (4)	9 (47)
College diploma	13 (52)	N/A[a]
Junior college	3 (12)	N/A
Bachelor's degree and above	8 (32)	N/A

[a]N/A: not applicable.

The results showed the measures of transparency, motivation, and attractiveness had the highest possible points, respectively. Table 2 shows the average score and SD of each measure for both groups (ie, parents/caregivers and children). According to the children's evaluations, attractiveness (mean 1.956, SD 0.547) and efficiency (mean 1.934, SD 0.499) achieved the best results compared with novelty (mean 1.711, SD 0.481). Parents/caregivers rated efficiency at a mean of 1.880 (SD 0.316) and attractiveness at a mean of 1.853 (SD 0.331). The lowest score was reported for novelty (mean 1.670, SD 0.225). In addition, to determine the app quality, the UEQ shows the overall performance of the product with 3 measures (attractiveness, quality of use, and quality of design) [25].

UEQ parameters can also be divided into 2 general groups: pragmatic quality (perspicuity, efficiency, dependability) and hedonic quality (stimulation and originality). Table 3 shows the app's pragmatic and hedonic quality scores. Pragmatic quality describes task-related quality aspects, and hedonic quality describes non–task-related quality aspects [25].

According to the obtained results, CanSelfMan scored above +0.8 in all measures, which is above the average score of 1.5, thus falling in the good category. The results of the evaluation showed that the CanSelfMan app ranked highest in attractiveness and efficiency and lowest in novelty, which indicates a high level of user satisfaction with the app's quality and user interface. One of the reasons for the app's attractive user interface could be the use of graphic elements and gamification, which attracted children's attention and subsequently increased scores in the efficiency and app usage scales. In addition, the low score on the novelty scale may be because new apps do not evoke a sense of innovation and novelty for young users due to the increasing number of apps that are designed for this age group.

For the parents/caregivers, the app scored highly for efficiency and attractiveness and lowest for novelty. Obtaining a high score in efficiency indicates the app's quality and the high satisfaction of users regarding the use of the app. One of these reasons for this can be the integrated and modular design of the app, which, by separating the functions of each part and reducing the complexity of the app as much as possible, has made it easy for users to perform tasks and use the app. Accordingly, a high score in the attractiveness category for parents can also be a sign of the quality of the app's user interface design, which led to high user satisfaction. The low score for novelty could be attributed to the increase in health apps in this domain available through app stores; thus, a new app like CanSelfMan may not excite or delight users enough.

The UEQ also provides a calculation tool that includes evaluation data from previous studies. Therefore, the results obtained in each evaluation can be compared with previous studies. To provide a better overall picture of the app quality, the results were compared with the benchmark data set of the UEQ. The data set was collected for 246 studies evaluating various products, including, web pages, mobile apps, social networks, and so forth. A comparison of the results of this study with those of previous studies indicates the relative quality of CanSelfMan on an international scale. Figure 3 shows the CanSelfMan results compared to those of 246 previous studies conducted with the UEQ.

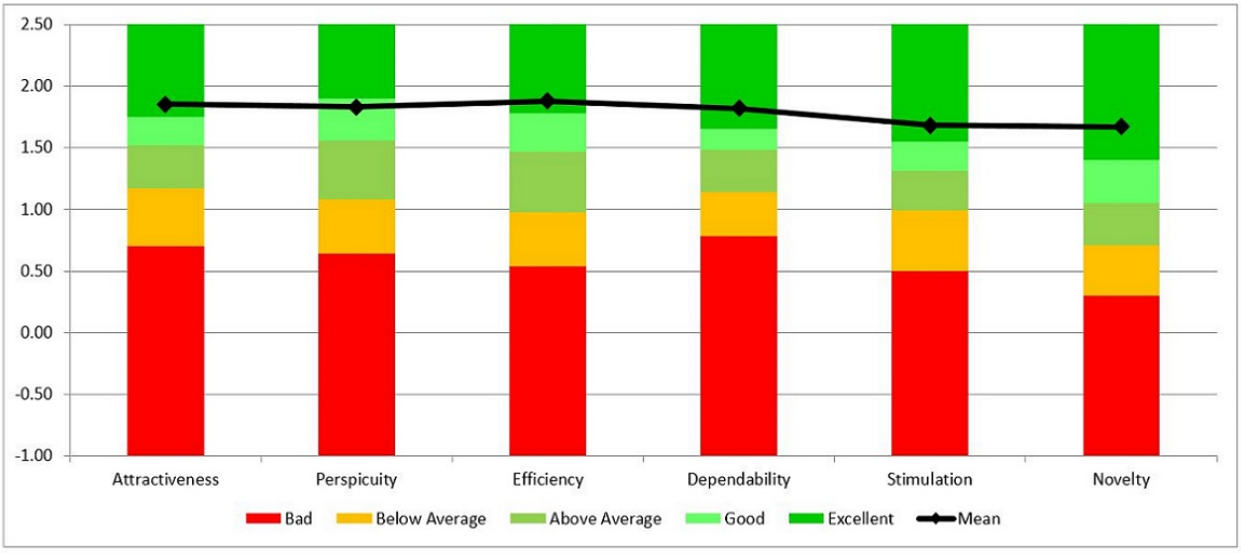
Table 2. Results of the User Experience Questionnaire (UEQ) for both study groups (parents/caregivers and children).

Measures	Children (n=19)		Parents/caregivers (n=25)	
Scales	Mean (SD)	95% CI	Mean (SD)	95% CI
Attractiveness	1.956 (0.547)	1.710-2.202	1.853 (0.481)	1.724-1.983
Perspicuity	1.895 (0.668)	1.594-2.195	1.830 (0.481)	1.678-1.982
Efficiency	1.934 (0.668)	1.710-2.159	1.880 (0.316)	1.756-2.004
Dependability	1.803 (0.668)	1.567-2.038	1.820 (0.255)	1.720-1.920
Stimulation	1.776 (0.399)	1.597-1.956	1.680 (0.223)	1.593-1.767
Novelty	1.711 (0.481)	1.494-1.927	1.670 (0.225)	1.582-1.758

Table 3. The CanSelfMan app's pragmatic and hedonic quality scores.

Study groups	Children	Parents/caregivers
Attractiveness	1.96	1.85
Pragmatic quality	1.88	1.84
Hedonic quality	1.74	1.68

Figure 3. Comparison chart of the CanSelfMan app's usability results and those of previous studies.



Discussion

Principal Findings

Information systems researchers [1] have confirmed the importance of evaluating product usability. In this study, we evaluated the usability of CanSelfMan from the aspects of technical performance and usability. CanSelfMan is an educational self-management app aimed at supporting children with cancer and their parents/caregivers, which provides access to up-to-date and reliable information about cancer and information on how to deal with and manage symptoms related to cancer.

In the first step, the technical performance of the app was examined. In general, issues such as screen size, screen resolution, processing ability, and the amount of system resource usage are considered common problems and limitations of smartphones [13]. These limitations, especially frequent outages in communication or connection to the network, variable

bandwidth, and high-energy consumption can have negative effects on app quality, especially on usability and reliability [29]. Various studies have been conducted that focus on the challenges related to the usability of these tools, including the ability to run on devices with different screen sizes and the consumption of system resources including the processor, battery, system memory, and connection speed [30]. The results of these studies show that well-designed apps increase app usage and user satisfaction [31]. On the other hand, considering that different phone manufacturers make smartphones with different technical features [32], ensuring the optimality of the apps and their ability to run on and adapt to a wide range of devices with different technical characteristics is essential. Therefore, we tried to ensure the optimality of CanSelfMan via a simulation, thereby reducing the negative effects on the usability of the final version.

Since one of the limitations of smartphones is the limited amount of battery or charge maintenance, one of the most important issues relating to apps is the optimal use of this limited energy [32]. The results of the simulation and the score of 7.9 out of 10 possible points for battery consumption in different devices indicated an acceptable overall score. These features indicated that the app operated correctly, with the absence of additional load in terms of energy consumption and overall device memory usage. Moreover, this simulation provided information about the optimal execution of the app on devices with different screen sizes and showed that it was compatible with screens of different sizes and ran without any issues.

After the performance evaluation, we evaluated the CanSelfMan app from the usability aspect. Usability measurement studies can facilitate a better understanding of user interactions with the final product and help determine the strengths and weaknesses of the product according to different user groups. The results obtained from these evaluations can provide important information about user behaviors and tendencies when it comes to new technologies, thereby providing a better understanding of user acceptance for the developer [33]. As such, app developers, especially those in the health care domain, should focus on users' needs and ensure the practicality and effectiveness of the product [34]. To this end, it is essential to perform usability tests to ensure that the final product meets the users' needs [35]. Accordingly, we used the UEQ to evaluate the app's usability.

The results of the UEQ provided useful information about various aspects of the app. We were also able to compare various aspects of our app relating to design and performance with other similar software. This questionnaire has been widely used in human-computer interaction studies and is considered an efficient and accurate method of measuring users' feelings toward software products. The validity and reliability of this questionnaire are very high, and it helped us obtain a comprehensive evaluation of the feelings and experiences of the users toward the CanSelfMan app. Similarly, Salari and colleagues [36] used this questionnaire to evaluate an educational and self-management app designed to support people with type 2 diabetes.

Subsequently, the final evaluation of the CanSelfMan was carried out by the children with cancer and their parents/caregivers. For both groups, attractiveness, motivation, and efficiency scales scored higher than others, indicating their satisfaction with the user interface and graphic elements used in the app, which could motivate them further to use the app. Additionally, the high scores on the efficiency, transparency, and reliability scales indicate the app's quality and high user satisfaction. Similarly, MacPherson and colleagues [37] designed a mobile app called C-SCAT to measure and report symptoms related to chemotherapy in children and adolescents with cancer. It also provided information about symptoms, possible causes, mitigating or aggravating factors, and self-management tips to control symptoms. The results related to the usability evaluation indicated the ease of use, applicability, and high satisfaction of users of the C-SCAT app.

In another study, Wang and colleagues [38] developed a mobile app to collect, record, and assess symptoms in children with cancer and their families. The user interface of this app was designed appropriately for children, and animation and attractive colors were used. The results of the evaluation showed that children and parents felt that the app was easy to use.

However, this may raise the question of whether children have the competence and ability to evaluate app usability. The answer is yes. Currently, there are many apps designed specifically for children, and due to the increasing use of tablets and smartphones, children have a high ability to use these tools [39,40]. Moreover, based on the studies conducted in this field, children between the ages of 6 and 10 years can understand and follow instructions—skills that they learn in school. Therefore, they can complete the evaluation without any challenges. This also extends to children aged 11 to 14 years, who also have no issue in this regard due to their familiarity with computers and digital devices. [41,42]. Moreover, having children evaluate usability can be a valuable problem-solving process for app designers and help them understand how children use the product. In a study similar to ours, Massoud and colleagues [39] evaluated the usability and user interface of an educational app aimed at 4- to 5-year-old preschool children. In another study, Brown and colleagues [43] evaluated the usability of an educational app about nutrition and diet called Foodbot Factory. In their study, children aged between 9 and 12 years evaluated the app's usability, and the results showed that the majority of them found the app easy to use and fun.

In another study, Grasaas and colleagues [6] investigated the usability of the iCanCope app, which was designed to teach adolescents with cancer self-management and pain control. It was evaluated via the System Usability Scale, with the results showing that iCanCope scored high in usability and user satisfaction. Cheng and his colleagues [44] evaluated a mobile app aimed at supporting families and children with complex conditions and family-delivered enteral tube care. In this study, the children and their families completed a questionnaire to evaluate the app's usability. The level of user satisfaction and app usability was high, and users declared that they would recommend this app to others. In our study, both groups of users (children and their parents/caregivers) were generally satisfied with the quality of CanSelfMan.

Weaknesses, Strengths, and Limitations

This study had several limitations. These include the small sample size and the low diversity of participants (all participants were from the same treatment center) in the evaluation stages, which makes it impossible to generalize the results of this study. However, small sample sizes in early evaluation studies usually provide adequate information about implementations. Another limitation of this study was that the usability test was conducted with the participation of elementary school children. To create a sense of confidence and facilitate cooperation, the children were accompanied by 1 parent. Additionally, while the children were completing the UEQ, one of the researchers (authors HM or AM) was present with them and explained all the options to them so that they could answer the questions. Finally, although this study was able to collect useful data on the app usability and user satisfaction through the questionnaire, the next step for future research could be to assess additional indicators such as the level of digital health literacy, the level of access to technology, and the clinical outcomes related to using this app.

Conclusions

In this study, we described the evaluation process of CanSelfMan, a self-management app designed to support children with cancer and their families. We adopted a user-centered strategy and involved end users at every stage of app development and evaluation to ensure it was in line with the users' requirements. To this end, the usability evaluation was carried out with the aim of solving potential issues with the app to develop a final product that would be user friendly and acceptable. The results of this study show that we were successful in achieving this goal.

Based on the feedback and the scores obtained from the usability evaluation, the children and their parents/caregivers found CanSelfMan to be an appealing and practical tool to provide reliable, up-to-update information on cancer and help them manage the complications of this health condition. However, because our small sample size prevents the generalization of our study results, other studies are needed to evaluate the usability of this app with a larger population. In future studies, we plan to investigate the clinical outcomes and the effects of the short versus long-term use of this app.

Authors' Contributions

HM conceptualized and designed the study. All authors were involved in the app development, data extraction, and evaluation process. All authors critically reviewed, provided comments on, and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
User Experience Questionnaire (UEQ) items.
[DOCX File , 15 KB - pediatrics_v6i1e43867_app1.docx]

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Abbreviations

UEQ: User Experience Questionnaire

Edited by G Eysenbach, S Badawy; submitted 27.10.22; peer-reviewed by K Butten; comments to author 26.11.22; revised version received 28.02.23; accepted 04.03.23; published 30.03.23.

Please cite as:
Mehdizadeh H, Asadi F, Nazemi E, Mehrvar A, Yazdanian A, Emami H
A Mobile Self-Management App (CanSelfMan) for Children With Cancer and Their Caregivers: Usability and Compatibility Study
JMIR Pediatr Parent 2023;6:e43867
URL: https://pediatrics.jmir.org/2023/1/e43867
doi:10.2196/43867
PMID:36995746

Original Paper

Characteristics of Inclusive Web-Based Leisure Activities for Children With Disabilities: Qualitative Descriptive Study

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Abstract

Background: The participation of children with disabilities in leisure activities is a key determinant of their physical and mental health. The COVID-19 pandemic has limited participation in leisure activities for all children, particularly those with disabilities. As a result, children with disabilities may be less active while feeling more isolated and stressed. Web-based communities and activities have become increasingly important. Understanding how web-based activities include or exclude children with disabilities can contribute to the development of inclusive communities that may support participation after the pandemic.

Objective: This study aimed to identify factors that may facilitate or prevent the participation of children with disabilities in web-based leisure activities.

Methods: We adopted a qualitative descriptive interpretative methodology and conducted interviews with 2 groups of participants: service providers offering inclusive web-based leisure activities and parents of children with disabilities who have engaged in web-based leisure activities during the COVID-19 pandemic. A semistructured interview format was created based on the Theoretical Domains Framework. The questions focused on the description of the web-based activities offered by the service provider (eg, age range, frequency, cost, target population, and type of activity offered) and any adaptations to make the web-based activity accessible to children and youth with disabilities, and their perceptions and beliefs about what supported or deterred participation in the activities.

Results: A total of 17 participants described their experiences in participating in and creating web-based leisure programs and the factors preventing or facilitating children's participation in web-based activities. Environment and context factors included accommodations, the format of activities and the web-based setting, stakeholder involvement, and materials and resources available. Activities that had flexible schedules, both recorded and live options for joining, and that provided clear instructions and information were perceived as more accessible. Beliefs involved the characteristics of the child and the family environment, as well as the characteristics of the organizations providing the activity. Activity facilitators who were familiar with the web-based environment and knew the specific characteristics of the child facilitated their participation. Engagement in community champions and respect for children's individual preferences were perceived as positive. Access to technology, funding, and caregivers' ability to facilitate child engagement are crucial factors that must be considered when offering web-based programs.

Conclusions: Web-based environments offer an accessible and safe option for leisure participation when public health conditions prevent children with disabilities from participating in in-person activities. However, to make web-based activities accessible to children with a variety of disabilities, there needs to be a clear plan toward universal web-based accessibility that accounts for individual needs and collective approaches to web-based leisure. Future work should consider developing and testing guidelines for web-based accessibility, equity, public policy, and programming considerations in offering these activities for all children.

(JMIR Pediatr Parent 2023;6:e38236) doi:10.2196/38236

KEYWORDS

children with disabilities; social inclusion; participation; accessibility; leisure; web-based activities; pandemic

Introduction

Background

Participation in leisure activities is a human right as per the United Nations Conventions on the Rights of the Children statement that "accessible and inclusive environments and facilities must be made available to children with disabilities, to enable them to enjoy their rights" (Article 31; page 5) [1]. In addition, it is indicated by the United Nations Conventions on the Rights of Persons with Disabilities to "ensure that children with disabilities have equal access with other children to participation in play, recreation and leisure and sporting activities, including those activities in the school system" [2].

Leisure refers to the time designated for freely chosen activities performed outside self-care or work (school) [3]. Participation in leisure activities is a key determinant of the physical and mental health of children with disabilities, essential in developing skills and competencies, socializing with peers, exploring personal interests, and improving their quality of life [4-7]. However, children with disabilities are at a higher risk of exclusion from several forms of participation in leisure activities. Children with disabilities and their families face challenges in engaging in different activities and accessing essential services throughout their lives [8]. A Canadian national survey demonstrated that among children with disabilities in Canada aged 0-4 years, 69.7% reported mild or moderate difficulty while playing, and 8.8% reported severe difficulty while playing. Among children aged 5-14 years with disabilities, 44.3% reported disadvantages in transportation or leisure, illustrating the many barriers that exist for children with different disabilities in engaging in leisure environments [9].

With the rapid spread of COVID-19 the World Health Organization declared the outbreak a public health emergency of international concern on January 30, 2020; and on March 11, 2020, it was declared a global pandemic [10]. Countries worldwide, including Canada, began massive health campaigns to protect the public through prevention protocols and control interventions to limit the spread of the virus. These measures include self-isolation, social distancing, and stay-at-home recommendations. Accordingly, public and private facilities were obligated to close, which also led to a sudden change in the availability of leisure activities, programs, and all other essential forms of socialization for children [5].

The challenges faced by all children during the pandemic, including social isolation and disruption of daily activities, have been exacerbated in children with disabilities and their families [11]. For instance, approximately 45% of children with disabilities did not have access to in-clinic services for mental or physical health, and approximately 40% did not benefit from telehealth services for mental or physical health during the pandemic [12]. Only a minority (30%) had access to individualized educational plans [13]. Studies during the pandemic have found that lockdown restrictions have had considerable negative effects on physical activity levels and the mental and behavioral health of children with disabilities [14]. According to Statistics Canada, 50% of parents were concerned about their children's physical activity levels. In addition, more than 60% of parents reported concerns about a lack of opportunities for their children to socialize [15].

Objective

Technology and web-based environments were essential for optimizing communication and socialization during the COVID-19 pandemic. Adults and children shifted to web-based environments to learn, stay connected with their peers, and maintain their physical, social, and mental health [16]. Many organizations that previously led in-person leisure activities quickly pivoted to web-based platforms to continue offering options for activities such as sports, music, arts, camps, and life skills programs [15]. Allen et al [17] found that during the pandemic, parents with young children acknowledged the importance of physical activity for their children but questioned the suitability of web-based leisure activities as an option for young children. The same issue was raised by parents of children with disabilities in web-based forums and support groups during the pandemic period. Although web-based activities present as a positive alternative for maintaining physical activity, socializing, and receiving health and education services [18], little is known about the characteristics of web-based activities that can enhance inclusion and accessibility for children with different disabilities. Therefore, the objective of this study was to identify factors that may facilitate or prevent the participation of children with disabilities in web-based leisure activities and to inform the development of future inclusive web-based environments.

Methods

Overview

We developed an interview guide using the Theoretical Domains Framework (TDF), which was created to identify barriers and facilitators in clinical practice [19]. The TDF identifies areas that can act as barriers or facilitators to implement a certain type of intervention. For instance, it suggests individual (eg, service provider perceives their role as responsible to implement the web-based program) and organizational (eg, the organization has a culture of innovation) factors that promote or hinder the implementation of practices or programs. In this case, we applied the TDF to understand the barriers and facilitators to participation of children with in web-based leisure activities. Examples of the interview questions and their corresponding TDF domains are listed in Table 1. Multimedia Appendix 1 provides the full interview guide.

Table 1. Examples of interview questions and corresponding Theoretical Domains Framework (TDF) domains.

TDF	Questions
Social or professional role and identity	• *Service providers*: did you consult with an expert (eg, accessibility consultant, web-based platform consultant, occupational therapist) on how to make your web-based program accessible before introducing your programs?
Beliefs about capabilities	Question to both *service providers* and *parents*: • In your opinion, how accessible is the program to individuals with different activity limitations? • Parents: what were the main challenges that your child faced in the web-based activities in which your child participated?
Beliefs about consequences	• *Service providers*: in an ideal world, what would make this web-based activity more accessible or fully accessible or more inclusive?
Environmental context and resources	Question to both *service providers* and *parents*: • Is it free or is there a fee? • Requires registration or anyone can join? • Is it open to "new" members or only for people who participated before COVID?

We adopted a semistructured interview format to facilitate dialogue between the researcher and participants to collect open-ended qualitative data. The questions focused on the description of the web-based activities offered by the service provider (eg, age range, frequency, cost, target population, and type of activity offered) and any adaptations that were implemented to make the web-based activity more accessible to children and youth with disabilities. Follow-up questions were asked as needed to explore participants' thoughts and insights on the topic of inclusive web-based activities to provide the opportunity to discuss personal experiences [20].

Participants and Procedures

Participants were selected from organizations listed as offering web-based leisure activities to children with disabilities on the Jooay App. These activities were added to the App by the Jooay App team through extensive web-based searches during the pandemic. The Jooay App is a free mobile and web app (Jooay [21]) created in Canada in 2015 [22]. It is a resource platform on which children with disabilities and their families, clinicians, educators, and others can locate leisure opportunities that are close to where they live, accessible, suit their needs and abilities, and match their preferences.

We used a convenience, purposeful maximum representation sample to recruit two distinct groups of participants: (1) service providers offering inclusive web-based leisure activities and (2) parents of children with disabilities who participated in web-based leisure activities during the pandemic. These 2 groups were selected to identify the structural and experiential aspects of the programs, representing different types of activities (eg, sports and arts) and activities tailored to different types of disabilities (eg, physical disabilities, autism spectrum disorders, and visual impairments). Children and youth were considered for interviews, but because of limitations in the ethics review board procedures during the pandemic, they were excluded from the study.

Recruitment of Service Providers

A recruitment email, including information about the Jooay App, the objective of the study, and the steps required for participation in the study, was sent to the service providers of inclusive web-based activities in Canada, which were listed as "Online" activities on the Jooay App. The email was followed by a phone call to the publicly available phone number if no email response was received.

Recruitment of Parents

A recruitment flyer was posted multiple times on Jooay social media platforms including Facebook, Instagram, and Twitter. Interested participants were contacted via email to schedule an interview at their convenience (phone or videoconference on Zoom platform), in their preferred language (English or French), using accessibility options, if desired. Once the interview was scheduled, the participant received both a consent form and a demographic form to be returned before the scheduled interview. The interviews took approximately 30 to 45 minutes, and each interview was led by 1 of 3 members of the research team. The interviews were recorded and transcribed verbatim for qualitative analyses.

Data Analysis

Interview transcripts were imported into NVivo 12 (QSR International) [23], a qualitative data management software. An interpretative descriptive analysis methodology was applied to analyze the data collected in this study to understand the factors that may facilitate or hinder participation in web-based leisure activities for children with disabilities in web-based activities. First, the research team developed an initial coding scheme, based on a sample analysis of the 2 interviews. The initial themes were identified deductively (through the questions or answers, based on the TDF) and then inductively (distancing from the questions to interpret what the participants were bringing to the discussion, generalizing and creating new themes based on the interpretation gained beyond the direct questions). Two members of the team analyzed the remaining interview transcripts to refine the codebook and complete the analysis. The research team met regularly to discuss points of disagreement in the analysis and salient content emerging from the iterative analysis. Descriptive analysis of the participants' sociodemographic characteristics was conducted using IBM SPSS Statistics 24 [24].

Ethics Approval

This study was approved by the Institutional Review Board of the Faculty of Medicine and Health Sciences, McGill University (A00-B67-16B). All the participants provided informed consent form before the interviews. The contact information of the team members conducting the interviews was provided on the consent form, and there were any questions or concerns. The interviewer was also mindful of participants' concerns or discomfort. Finally, the participants' names and affiliations were removed from the analysis to ensure confidentiality.

Results

Participants' Characteristics

A total of 15 interviews were conducted with a total of 17 participants (12 service providers and 5 parents; 2 interviews had 2 individuals from the same organization responding together). The sociodemographic characteristics of the participants and their children (parents of children with disabilities) are presented in Tables 2 and 3.

Table 2. Sociodemographic characteristics of organization representatives.

ID	Age	Education	Position	Work status
1	30	University—postgraduate degree	Recreation therapist	Full-time
2	45	University degree	Executive director	Full-time
3	52	__[a]	Executive director	Part-time
4	31	University—postgraduate degree	Teacher; therapist	Part-time
5	43	University degree	Regional manager	Full-time
6	28	Some high school education	Program's coordinator	Full-time
7	57	University—postgraduate degree	Executive director	Full-time
8	66	University—postgraduate degree	Executive director	Full-time
9	22	University degree	Community engagement coordinator	Full-time
10	31	University—postgraduate degree	Founder; Executive Director	Part-time
11	44	University degree	Director of Operations	Full-time
12	42	University degree	Founder; Executive Director	Full-time

[a]Missing data as the participant preferred not to answer the question.

Table 3. Sociodemographic characteristics of parents and their children[a].

ID	Parent's age	Education	Annual family income	Child's age	Type of disabilities
13	45	University degree	Between CAD $40,000 and CAD $60,000	11	Autism spectrum disorder
14	54	High-school diploma	Between CAD $20,000 and CAD $40,000	21	Intellectual + physical + Autism spectrum disorder
15	47	University degree	__[b]	11	Intellectual
16	51	University degree	Between CAD $60,000 and CAD $80,000	19	Intellectual
17	43	Postsecondary or professional degree	Between CAD $40,000 and CAD $60,000	4	Physical

[a]CAD $1 was about US $0.77 at the time of interviews.

[b]Missing data as the participant preferred not to answer the question.

The age range of children with disabilities whose parents participated in this project was 4-21 years, with a mean age of 13 (SD 6.8) years, with 3 (60%) of them being female. The types of disabilities in children included intellectual disabilities, physical disabilities, and autism spectrum disorders. Most of the organization representatives who participated in the study had more than 10 years of experience working with children with disabilities, with only 2 having between 5 and 10.

Programs' Characteristics

The web-based programs provided were categorized into multiple types (art, music, sports, camps, and others). Examples of web-based leisure programs included web-based zoo and museum tours, book clubs, life skills groups, and youth leadership development programs. The activities included a vast age range and types of disabilities (Table 4). The activities described were offered 1 to 5 times a week for groups of 3-10 participants with 30-90–minute duration.

Table 4. Characteristics of web-based leisure programs (n=34).

Characteristics of programs	Values, n (%)
Activity type	
Art	2 (6)
Music	3 (9)
Sport	7 (21)
Camp	3 (9)
Others	19 (56)
Age range[a]	
Preschool (0-5 years old)	2 (6)
School age (5-18 years old)	25 (71)
Young adult (>18 years old)	8 (23)
Types of disabilities accommodated[a]	
Intellectual	3 (7)
Physical or motor	7 (16)
Autism spectrum disorder	7 (16)
Visual	0 (0)
Hearing	0 (0)
Behavioral or mental health	1 (2)
Communication	3 (7)
Chronic illnesses	4 (9)
Others	
Attention-deficit hyperactivity disorder	1 (2)
Cerebral palsy	8 (19)
Developmental coordination disorder	6 (14)
Fetal alcohol spectrum disorder	3 (7)

[a]Some programs were provided to more than 1 age group or types of disabilities; therefore, the total number in these 2 categories were more than 34.

Factors Influencing Participation in Web-Based Activities

The interpretative descriptive analysis yielded 7 main themes under the 2 broad TDF categories of Environmental context and Resources and Beliefs as factors associated with participation of children with disabilities in web-based leisure activities. These are discussed in the following sections. These factors were divided into several subcategories, as listed in Table 5.

Table 5. Factors influencing participation in web-based leisure activities.

Category and subcategory	Summary points
Environmental context and resources (TDF[a] domain)	
Accommodations	
Individual	• Individual activities • Individual adaptations made in group activities
General	• Strong collaboration with children and families • Adequate activity duration with time for engagement
Format or setting	
Sensory considerations	• Close captioning and sign language for live and prerecorded videos
Accessible platforms and formats	• Live stream with recorded option • Structured activity sequence, flexible schedule options
Environment	• Simple background • Platform safety (logins and password required, advertising free)
Setup	• Objects needed for the activities at hand
Variety of programs	• Different options of programs offered to meet child's preferences
Stakeholder involvement in program development	
Opportunities to socialize and connect with others	• Family involvement in planning • Collaboration with community organizations
Material resources	
Activities	• Appropriate for the child's age, ability, and skill level • Cost of activities and materials, funding options
Information	• Clear and provided in advance
Technology and equipment	• Verification of equipment requirements in advance
Beliefs (TDF domain)	
Characteristics of children	• Limited attention span to focus on the screen • Individualized needs known to activity provider
Characteristics of the home environments and families	• Parents availability to support or participate in the activity • Familiarity with web-based environments
Characteristics of the organizations	• Collaborations with other organizations • Interprofessional support • Staff training and retention • Readiness to change or respond • Staff knowledgeable about activity and about individual needs of participants

[a]TDF: Theoretical Domains Framework.

Environmental Context and Resources

Accommodations

Accommodations are considered as the features that help making web-based activities inclusive. Individual accommodations were those made to address specific needs of children, as described by a service provider:

> *We're looking at everybody that we're supporting on a very individual basis. So, you know, it really depends on who we're serving.* [ID#12]

The participants suggested that service providers must *establish a strong collaboration* with children and parents in advance. This included incorporating input from parents about program options and their child's needs and creating space for parents to give feedback and request specific accessibility accommodations. Examples of how this was done include creating a registration form or making individual phone calls

to collect information and interact with parents before the activity. Service providers also modified their activities based on participants' characteristics, including allowing extra time between activities so that all children could be prepared for the next activity or providing extra guidance to help a child get a movement done right. Other accommodations included *providing options for modifications*, such as the design of a standing or sitting form for a given movement. For example, one service provider mentioned as follows:

> *So, if I know that we are going to be doing something that is a little bit more challenging, give some form of modification so that it is all inclusive. I will demonstrate in the way that I believe everybody could potentially have the ability to do it.* [ID#5]

Families also contributed accommodations to facilitate their child's participation; for example, parents used a larger screen to help the child focus and identify the optimal duration of the activity to sustain the child's attention. Service providers in our study described *program durations* ranging from 20 minutes to 1.5 hours. A shorter duration was often preferred for children, especially in younger age groups, because of the limited attention span on a screen. It was also noted that short breaks during activities helped maintain participation.

Format or Setting

Participants noted how the format and setting of the web-based environment contributed to or hindered participation. Some participants indicated that live, synchronous sessions were more engaging, whereas others mentioned the benefits of recorded programs. Recorded programs allowed families to follow the program at times that might be more convenient for them, alleviating the competing demands during the pandemic:

> *They had shown us the super simple songs on YouTube where they have 2 to 30 minute engaging songs and videos about counting and numbers and alphabets and colors and all that type early learning stuff that I could set (my daughter) up with one of those and I could get a few things done or answer emails or do paperwork...So, that was a good one for us for me to get a break.* [ID#17]

Having both synchronous and asynchronous options available seemed to be the preferred format for families:

> *It was a Facebook live event. But if you weren't able to make it for that time, you could go back and watch it later, which was really a big deal for us because morning is a hard time for us to get going, so we were always able to go and watch these little videos and sort of put them in throughout our day for like a little break.* [ID#17]

Many parents noted that web-based programs offered more flexibility than in-person activities, avoiding commute time and other accessibility issues such as parking or facing treacherous weather conditions:

> *Outside the pandemic, I would sign up for some of these things again. During cold and flu season in the winter when we don't want to drag the wheelchair outside to go to a class..., like not having to move the chair in and out or clean it off the snow when you get to the place that you're going to it was. It's a pretty big deal.* [ID#17]

However, the web-based format also presents an inherent barrier to participation, for instance, parents' familiarity with the web-based platform—*"The technology requires a certain amount of know-how" (ID#11)*—and physical presence requirements during the activity to facilitate their children's participation. Strategies to overcome the accessibility issues in the web-based environment included offering the families a brief training on how to use the platform before the activity and sending a preactivity survey to identify, whereas participants had the technology required for participation. It also included considering the background of the program to be simple and conducive to facilitating focus on the staff facilitating the activity with few elements that could be distracting for participants.

The characteristics of the activities provided by organizations played an important role in the participation of children with disabilities. The opportunity for the child to choose from a *variety of activities* that aligned with their preferences and interests was a key motivator for participation. Parents and organizations noted that leisure and recreation activities were the activities that children enjoyed the most. Leisure provided opportunities to stay active and allowed social connections that were critical during the COVID-19 pandemic. The *appropriateness of the activity* to the child's age and skill level was also essential for the success of the activity. In addition, participants noted that having a regular, predictable, and consistently *structured program* facilitated children's participation:

> *It's really engaging. It goes by super-fast. She doesn't get bored, and by the time like half an hour's long for a 4.5-year-old on the computer, right, she's happy to be done, but they do a hello song and a goodbye song, so the kids know what's coming at the beginning and the end.* [ID#17]

Stakeholder Involvement in Program Development

Web-based activities became a platform for children to socially connect and build communities for children and parents alike when they connect with other families. *Family involvement* in the planning and migration of activities from the in-person to the web-based environment was fundamental to facilitating participation. The web-based format was accommodating for parents and siblings to participate with the child. This family involvement created a familiar environment for the child to feel safe, where the parent can help if and when the child is "having a hard time self-regulating or with coping strategies" (ID#12), as mentioned by a service provider.

Family involvement was encouraged by the organizations by *collecting and incorporating feedback and suggestions provided by children and families* into the activities, as illustrated by a service provider:

> *I say, what do you want to learn? What do you feel like doing or how do you want me to help you get stronger? So, it's a very open dialogue.* [ID#10]

This information was collected before the development of the program and after a few sessions. The children's preferences were also considered, as they often determined what activity was done that day and informed further program development in a client-centered approach to service delivery as presented by a service provider: *"We always plan our activities around what our clients want to do" (ID#5)*. In addition, *collaboration with external organizations and stakeholders* was also important in designing and creating activities or programs. For instance, organizations collaborated with recreation specialists and camp directors, whereas others partnered with para-athletes to share their experiences participating in a sport and answer participants' questions. Indeed, collaboration with other organizations was perceived as contributing to better program and activity development and helped create a more engaging environment. This was illustrated by a service provider who mentioned the following:

> *We have often paired with other organizations...we've been doing lots of partnership and so a lot of new program ideas come from what they are hopeful to see as well for their families.* [ID#12]

Material Resources

The resources described by the study participants can be divided into *financial, information, technology, and equipment*. Financial resources were a main barrier for service providers to offer quality and accessible programs and for parents to register their children. Financial support by governmental or nongovernmental organizations was a facilitator of participation; nevertheless, free activities may have reduced families' commitment to participate. This was illustrated by one parent:

> *I really appreciated the fact that they were free. It gave you the option to go on, but with free programming, like someone was obviously paying for it out of a resource fund that they had, but I find that you as a participant don't have to pay even a token 5$ or whatever it is towards it, but since you're not paying and it's not out of pocket for you, your level of responsibility is very low, your accountability.* [ID#15]

Another concern for parents was information about appropriate activities. Families highlighted the importance of clearly identifying which demographic activity was tailored to assess the fit of the activity for their child. A parent mentioned the following:

> *It's been hard to figure out and navigate new programming and things that are accessible for her.* [ID# 15]

Another parent indicated that:

> *We were really, really happy with the different things that were available to us, but we are also super connected in our community and with our recreation therapists. So, I think if parents don't have connections, they're not gonna realize what's out there, so they obviously need to advertise it a little bit more too. I mean, we do a lot of things by word of mouth as well.* [ID#17]

Adequate technology available, including a computer and reliable internet for the use of the child, was essential to engage with the web-based programs, and acted as a barrier for participation if those resources were not available, as indicated by a service provider:

> *One of our regular families through the years has four kids so they would send four at a time, but they don't have four computers so they would send two at a time for virtual programs.* [ID#8]

Beliefs

Beliefs about capabilities—what one knows and how it is applied into the program, and about consequences—the understanding about what happens if certain information or knowledge is used or not, were also part of how study participants described the actions taken in the web-based programs to facilitate participation in the activities.

Characteristics of Children

Participants expressed several challenges that were unique to their child's condition, and how the pandemic exacerbated ongoing problems, such as finding leisure activities that are suitable for their child's needs. For example, one parent mentioned that the following:

> *My daughter has cerebral palsy, she's nonverbal, and has a seizure disorder and also a cognitive delay. So, finding activities appropriate for her is very very challenging.* [ID#15]

However, parents' beliefs on the importance of leisure, and the outcomes to their child, motivated them to make the necessary efforts to have their child engaging:

> *"I have two daughters with special needs. It's been challenging, but as I said, before the pandemic, she was very social, she has lots of friends, but one of the main problems, the friends that she need, she does end up connecting with them a lot online, through Facebook and other social media, because they live all over the city"* [ID#16]

and that despite parents' own experience in navigating web-based activities, *"We are a bit zoomed-out" (ID#16)*.

In addition, as the pandemic situation evolved rapidly, it was challenging for children to clearly understand the situation and why they had to switch to web-based activities instead of in-person settings. For children with intellectual disabilities and younger children, parents mentioned that limited attention span to focus on the screen and lack of understanding that other people on the screen were engaging in the activity with them in real time were barriers to engagement. For example, one parent mentioned the following:

> *The second session he started having a tantrum because he didn't understand what was going on, why I was keeping him in front of the screen.* [ID#13]

Parents suggested that the activity should be very stimulating and adopt different formats to help the child stay focused. However, parents noticed an improvement over time as their child adjusted to the web-based format, demonstrating increased confidence in the program as familiarity with the format grew.

Characteristics of the Home Environment and Families

Parents reported that their child's experience of the activity was influenced by the *presence of parents, siblings* or other support workers with the child during the activity. Adult involvement included facilitating the use of technology, creating space for the child to perform physical activity, and communicating with the activity facilitator on behalf of the child. For activities targeted at younger children, parents felt it was helpful to have activities in which they had a specific role, similar to the therapist's role during an in-person activity. Although *willing to engage* and believing in the value of providing these activities for their children, parents were juggling multiple roles during the pandemic; therefore, the need to be present at the child's web-based activity was sometimes perceived as an added stressor, whereas in-person activities were seen as opportunities for respite:

> *Parents have to be a lot more hands-on. It is a burden on us as parents.* [ID#14]

Activity providers supported parents' beliefs in their limited capabilities and created resources in response:

> *What we've done is we've taken videos of kids doing activities so that we can then share them so that families can imitate it 'cause obviously parents are facilitators in these activities. They are there with the child to manage the technology but also to make sure the kid stays put. So, the way we're presenting it is trying to engage parent and child together in the activity, just as if it would be a therapist and a child.* [ID#11]

Characteristics of the Organizations

For organizations, the impact of COVID-19 was reactionary in nature. Although some web-based activities existed before the pandemic, organizations either started promoting the existing web-based activities more actively, added more features to these web-based activities, or began offering web-based activities in response to restrictions and closures. For some organizations, this shift to a web-based environment was quick, as children with multiple disabilities were considered particularly susceptible.

It was evident that organizations had different levels of readiness to switch from in-person to web-based activities during the COVID-19 lockdown. The presence of an interdisciplinary team of health professionals and educators, such as recreational, occupational, and music therapists and early child educators, facilitated a quicker transition into web-based sessions. A *multidisciplinary team* accelerated planning for activities that were most appropriate for the organization's clientele, accommodating individual needs and sustaining participation throughout the program season. For example, a service provider indicated as follows:

> *Everyone in the team that we have has different expertise, and also is an artist themselves, so that was never lost. They're always thinking like how we can still make this you know, creative and fun.* [ID#4]

Organization leadership that also resourced into volunteers and had a wider community support had positive experiences to report:

> *These are university students for the most part, they know some of the kids 'cause they've worked with them in the previous summer and they're just their camp counselors, so they're creative and flexible and motivated and enthusiastic, and that's been a real asset to the program.* [ID#2]

Certain organizations hired staff who were once participants in their activities themselves. Having the participants come back as camp leaders ensured that the personnel working at the organizations were very familiar with the environment. Perceived benefits were participants reporting a feeling that this was a safe environment, and people with disabilities were represented as leaders.

Organizations readiness to change was also reflected in their ability to navigate web-based environments and resources. Organizations that felt familiar with their clientele did not undergo formal training to make the web-based activities accessible but rather gathered tips on how to make the web-based version of their activities accessible. Other service providers received training specific to group facilitation through Zoom to tailor activities using that platform, communicate in a text-based environment, and prompt the children to interact in specific ways to ensure flow during the activity. Nevertheless, the abrupt transition to a web-based environment was challenging for all organizations. They had to mobilize resources quickly and take considerable time and effort. These challenges were overcome through a firm belief in the organization's missions and value of the services provided to maintain children's health and well-being:

> *It's not camp at all, and we've been very forward and upfront with our community that this is not what we do, but we want to stay connected and build community and build those connections. It's crucially important. It is a challenging time for mental health and depression and social isolation and anxiety. And so, if we can bring a teeny tiny little bit of the Magic of camp into their [kids] homes and also encourage them to like get outside, get active, make some new friends...People are making new friends and we're getting some of the benefits, we are fulfilling our mission just in a very, very different way.* [ID#2]

Staff knowledge of the activity and about the child's and families' needs contributed to creating programs that were trusted by parents and perceived as beneficial by the organization. Service providers described strategies they believed helped maintain attention and facilitate engagement such as understanding children's cues, knowing when to take a break, or including extra breaks in a program when there were many participants who found it challenging to stay focused. *Making information available* for families and sending related

resources (eg, links to samples of the web-based activity or related videos to gauge children's interest in the activity, instructions for the session, and lists of required materials) to parents ahead of time helped parents adjust their child's expectations and structure the home environment to optimize participation. This was accomplished by email, posting on the organization's website, social media, or mail. Some organizations used mobile apps, where the list of resources and calendar of events were updated regularly and categorized by the type of activity, as illustrated by one parent:

> *They provide a calendar of events that they are having every month and things that repeat every month. That's something that's really handy when you are now planning extracurricular activities,..., it's very important to have access to what's available.* [ID#15]

Staff's attitudes that supported inclusion included acknowledging the presence of all participants, ensuring that everyone felt included, and ensuring a good connection with all participants. Some service providers recruited student volunteers to cofacilitate and support the lead instructor during the program. One parent mentioned the following:

> *So, they really just make an effort to acknowledge that he's there and it's a really interesting skill to be able to speak to him as though he can speak but at the same time understanding that he's not going to speak. That's actually a pretty good skill to have.* [ID#14]

In addition, *collaborations among organizations* allowed for extended access to programs for clients and enhanced the belief in staff's capabilities by creating leadership, mentorship, interprofessional support, and knowledge sharing opportunities for staff across organizations:

> *We would often partner with organizations that would recruit us to help them develop more inclusive programming, implement the programming and then train their staff.* [ID#12]

Discussion

Principal Findings

The COVID-19 pandemic has increased barriers to participation in leisure activities and other essential activities for children with disabilities [14,25,26]. The lack of access to facilities and in-person activities rapidly increased the demand for the creation of web-based communities, activities, and programs to promote health and well-being during these challenging times [16,18]. This study underscored the importance of web-based activities in promoting and maintaining physical and mental health during the COVID-19 pandemic and identified key environmental and contextual factors contributing to the participation of children with diverse disabilities in web-based programs, as well as parents' and service providers' beliefs that contribute to child participation in these programs. These characteristics included staff training and preparedness, use of accessible technology and provision of information for participants, variety of offers of activities with a structured and familiar sequence, ability to integrate children's individual needs into group settings, inclusion of parents and other caregivers in program development, and interprofessional and cross-organization collaborations.

This study also showed that although organizations and parents struggled with the abrupt migration from in-person to web-based environments because of the pandemic, there was also a perceived advantage of these programs. Web-based environments can contribute to increased participation by providing community building and socialization opportunities without the physical and social accessibility barriers of in-person activities. Previous studies have demonstrated the positive influence of web-based peer mentorship programs on social engagement and participation in life situations for children with disabilities [27]. However, many web-based resources designed for children are usually not accessible to children with disabilities and require close supervision by a parent or caregiver, thus limiting participation [14]. Despite the benefits and inevitable need to develop web-based activities during the pandemic, this format is not always preferred by youth who desire social connection and have functional limitations that may limit their written or verbal communication that is prioritized in web-based environments [28]. This study confirmed this through parents' concerns over the need for adult mediation and limited socialization opportunities in web-based activities.

Staff training and the ability to respond to children's evolving needs have been identified as crucial aspects of inclusive leisure programing [29] and were perceived as an essential component for program creation during the COVID-19 pandemic. Client-centered activities and programs are crucial for creating inclusive web-based environments. This includes considering child and family preferences in relation to leisure participation, while considering the context of a family's values and other personal and environmental factors related to the child [25,30]. Service providers should ensure that every activity is prepared so that participants can meaningfully engage with encouragement and support through a clear description of the activity and instructions provided in advance. The duration of the activities should be adjusted to the web-based format, age group of the children, and number of children partaking. Our results suggest that the optimal duration of activities involves an interplay between the activity type, the skill level of the child, the familiarity of the moderator (staff) with the web-based environment, and the characteristics of participants, the platform used, and the presence or absence of other facilitators who are physically with the child. In line with a previous study, our participants suggested that smaller groups of participants in each program could help children engage more meaningfully in activities [31].

Access to information about programs and dissemination of information to potential users are known determinants of participation [32,33]. During the pandemic, families dealt with a large amount of evolving information about public health measures and updates. The amount of information, coupled with the disruption in daily routines, lockdowns, and reduced social support and services, were a major source of distress for all, but particularly for families of children with disabilities [13,15]. Families can benefit from clear information tailored to their

needs and from trusted sources, so they do not need to rely on generic search sites for accurate information. Leisure is often perceived by families as a source of well-being for their children and respite for parents [4], but these effects may be extinguished if they cannot access the necessary information to allow for their child's participation and face technological barriers such as inaccessible platforms or no access to the internet. A collaborative approach to equitable access to technology that forms partnerships across sectors—education, health, community serving persons with disabilities, and web-based and mobile app listings—is an essential step for service providers and governments to be aware of [34]. In a separate study, we found that listing detailed information about existing web-based leisure activities increased the search for these activities after an all-time low search for this information during the first weeks of lockdowns in Canada [22]. We can infer that families are seeking opportunities to maintain their child's health under all circumstances, and programs are continuously adapting and providing services that match their mission, but all operate under limited resources and strenuous circumstances. Therefore, public health initiatives are needed to bridge these resources and make information available to those who need it.

Sociodemographic and equity considerations cannot be overlooked when discussing web-based programs. Participants in this study emphasized the challenges of having technology equipment available exclusively for their child when parents were often working from home and the lack of other support that would allow for participation. In a recent study in Canada, we identified a decreased number of offerings of in-person community leisure activities in neighborhoods with higher social and material deprivation [35]. Web-based activities require access to technology and the internet. Canada has recently acknowledged a "national connectivity gap" where rural Canadians face the daily challenge of slower, less reliable internet access than those in urban centers [36]. Only 37% of rural households have access to internet speeds necessary for contemporary use, whereas only 24% of households in indigenous communities have access to such speeds. Furthermore, it was found that those from lower socioeconomic backgrounds were less likely to have a computer at home [37]. Although this finding was from 2003, it raised the ongoing concern for sufficient technology or devices or both for current internet use, particularly when there are multiple users at once. In our study, families with 1 device in their home had to share and allocate time for its use for each member of the family, which means that use is limited for each member of the household, including the child who wishes to participate in web-based leisure activities.

Limitations and Directions for Future Research

In this study, we used a small convenience sample of Jooay App users, which limits the generalizability of our findings. As is the case for qualitative studies, however, we preconize an in-depth depiction of web-based leisure experiences to gain perspectives on characteristics that can foster reflection on the context and beliefs surrounding the creation of these programs and promote greater participation of children with disabilities in leisure and the web-based world. Furthermore, as mentioned, interviews with children and youth were not feasible because of delays in the ethics review board procedures during the pandemic. Future studies should obtain the perspectives of children and youth with a variety of disabilities and age groups and in different types of programs. The information obtained in this study can guide future studies on making web-based leisure activities more inclusive for children with disabilities, developing universal accessibility guidelines for web-based activities, and, in particular, structured evaluations of the impact of universal accessibility and client-centered web-based programs on children's participation in leisure activities. Future studies should also consider the equity and socioeconomic factors related to the growing provision of web-based services, proposing a critical reflection on who benefits from these programs and the groups that may be further marginalized through its creation.

Conclusions

This study identified the important characteristics of inclusive web-based activities for children with disabilities and provided suggestions on how to make future web-based activities inclusive. Despite the unprecedented nature of the pandemic and the challenges faced by engaging in web-based activities, our study also revealed that there is a strong willingness to cope, adapt, and succeed in the implementation of these programs, which also testifies to the value of these activities for children with disabilities and their families. Similarly, an organization's readiness to change and the propensity to continue offering programs they believe were essential for the vulnerable population they serve was primordial in making these programs possible.

Although our study highlighted the willingness of organizations to adapt themselves to web-based activities, their capacities, strategies, and knowledge of how to make their programs accessible to children with disabilities varied. It is conceivable that organizations offer a blend of in-person and web-based leisure activities postpandemic to maximize accessibility and flexibility. This study can inform the development of resources aimed at promoting inclusive web-based activities that can be used by both service providers and parents of disabled children in collaborative programming.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview questions.

[DOC File , 57 KB - pediatrics_v6i1e38236_app1.doc]

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Abbreviations

TDF: Theoretical Domains Framework

Edited by S Badawy; submitted 24.03.22; peer-reviewed by A Joseph, N Yu; comments to author 25.08.22; revised version received 07.11.22; accepted 25.12.22; published 04.05.23.

Please cite as:
Movahed M, Rue I, Yoo PY, Sogomonian T, Majnemer A, Shikako K
Characteristics of Inclusive Web-Based Leisure Activities for Children With Disabilities: Qualitative Descriptive Study
JMIR Pediatr Parent 2023;6:e38236
URL: https://pediatrics.jmir.org/2023/1/e38236
doi:10.2196/38236
PMID:36668903

Original Paper

Prospective Association Between Video and Computer Game Use During Adolescence and Incidence of Metabolic Health Risks: Secondary Data Analysis

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Abstract

Background: Video and computer games are popular activities, with 72% of adolescents aged 13 to 17 years reporting video game use on either a computer, game console, or portable device. Despite high levels of video and computer game use in adolescence, relatively little scientific literature exists examining the association and effects of video and computer games on adolescents.

Objective: The objective of this study was to examine the prevalence of video and computer game use among US adolescents and rates of positive screens for obesity, diabetes, high blood pressure (BP), and high cholesterol.

Methods: A secondary data analysis was conducted using the National Longitudinal Study of Adolescent to Adult Health (Add Health) data, including adolescents aged 12 to 19 years between 1994 and 2018.

Results: Respondents (n=4190) who played the most video and computer games had a significantly (*P*=.02) higher BMI and were more likely to self-report having at least one of the evaluated metabolic disorders: obesity (BMI >30 kg/m^2), diabetes, high BP (BP >140/90), and high cholesterol (>240). With increased video or computer game use, there was a statistically significant increase in high BP rates in each quartile, with those with more frequent use also having higher rates of high BP. A similar trend was observed for diabetes, though the association did not reach statistical significance. No significant association was observed between video or computer game use and diagnoses of dyslipidemia, eating disorders, or depression.

Conclusions: Frequency of video and computer game use is associated with obesity, diabetes, high BP, and high cholesterol in adolescents aged 12 to 19 years. Adolescents who play the most video and computer games have a significantly higher BMI. They are more likely to have at least one of the evaluated metabolic disorders: diabetes, high BP, or high cholesterol. Public health interventions designed to target modifiable disease states through health promotion and self-management may support the health of adolescents aged 12 to 19 years. Video and computer games can integrate health promotion interventions in gameplay. This is an important area for future research as video and computer games are integrated into the lives of adolescents.

(JMIR Pediatr Parent 2023;6:e44920) doi:10.2196/44920

KEYWORDS

video games; obesity; pediatrics; computer games; portable device; teenager; adolescents; health data; BMI; diabetes; high blood pressure; high cholesterol; metabolic disorder

Introduction

Video and computer games are popular activities, with 72% of adolescents aged 13 to 17 years reporting video game use on either a computer, game console, or portable device [1]. Despite high levels of video and computer game use in adolescence, relatively little scientific literature exists examining the association of the effects of video and computer games on health risks in adolescents. With video and computer games being traditionally sedentary behaviors, the increase in video and computer game use is concerning. However, sedentary behavior is one of the leading modifiable risk factors for noncommunicable diseases. As video and computer games are commonplace in daily life, more research is needed to assess the association between video and computer games and chronic health conditions.

Sedentary behavior throughout the lifespan increases one's risk for all-cause and cardiovascular disease (CVD) mortality, incident CVD, and type 2 diabetes [2]. Sedentary behavior is also associated with multiple forms of cancer [2]. Sedentary behavior may be associated with disease states due to hemodynamic, inflammatory, and metabolic processes resulting in impaired arterial health [3]. Similarly, systematic reviews have focused on the relationship between screen time in general and children's adiposity measures (ie, BMI, percentage body fat, and waist circumference). For example, a systematic review examining 40 studies from 2010 to 2017 shows a positive association of screen time (ie, time spent on screen devices) with adiposity in children and adolescents (5 to 19 years old) in 85% of the studies [4].

In addition to being associated with chronic health conditions, sedentary screen time is related to psychological conditions. In a study of youth aged 11 to 20 years (n=2282), sedentary screen time (ie, time spent doing sedentary screen-based activities) was associated with the severity of depression (β=.23, P<.001) and anxiety (β=.07, P<.01) [5]. In particular, video game playing (β=.13, P<.001) and computer use (β=.17, P<.001) were associated with more severe depressive symptoms, and video game playing (β=.11, P<.001) was associated with the severity of anxiety [5].

This study aimed to examine the prevalence of video and computer game use among US adolescents and rates of positive screens for obesity, diabetes, high blood pressure (BP), and high cholesterol. Video and computer games are defined as electronic games played on either a personal computer or a video screen. This does not include smartphone games. The research question that guided this secondary data analysis was the following: To what extent is the frequency of video games and computer game use associated with self-reported chronic health conditions (ie, conditions that last a year or more and require ongoing medical attention, or limit activities of daily living, or both)?

Methods

Overview

A secondary data analysis was conducted in 2022 using the National Longitudinal Study of Adolescent to Adult Health (Add Health) 1994-2018. Add Health was a longitudinal study of US adolescents aged 12 to 19 years, starting in the 1994-1995 school year. This cohort was interviewed in 5 waves between 1994 and 2018. Waves 1 through 5 were collected in 1994-1995, 1996, 2001-2002, 2008-2009, and 2016-2018, respectively.

Data Collection

Data were collected from the Add Health longitudinal study, in which all respondents who recorded data for both wave 1 (1994-1995) and wave 5 (2006-2018) were considered eligible. Add Health data came from 80 high schools selected from a sample frame of 26,666. Prior to sampling, schools were sorted by size, school type, census region, level of urbanization, and percent White race. Of the 80 selected, 52 were eligible and agreed to participate. Participating high schools then identified their feeder middle schools, resulting in one school pair. Parental consent was required for students to participate in the study. Some schools required passive consent (assuming parents granted permission for students to participate unless otherwise indicated), and others required active consent (a parental signature had to be returned before a student could participate). Data were collected from respondents using a combination of physical measurements, biospecimens, and self-reported surveys.

Demographic information was collected from the master data set, and exposure and outcome-specific variables were recorded from the respective wave data sets. Video game use variables were collected from wave 1 to capture video and computer game use while in adolescence (all wave 1 data were collected when the respondents were in grades 7-12). Outcome variables were recorded in wave 5 (21-23 years later), including outcomes related to health conditions. Any chronic conditions reported in a previous wave were recorded in wave 5. This allowed for maximum follow-up time through adulthood to capture as many conditions as possible.

Variables

Variables in the data set were identified as exposures (video or computer game frequency) and outcomes (health outcomes). Wave 1 data were used at the exposure, and wave 5 data were used at the outcome. The exposure variable included self-reported video or computer game play duration and was measured in hours per week. Outcome variables included obesity (BMI >30 kg/m^2), diabetes, high BP, hyperlipidemia, depression, and eating disorders. Obesity was measured using weight and height to calculate BMI, with BMI >30 kg/m^2 indicating obesity. Hyperlipidemia was measured using a biospecimen. High BP was measured using physical measurements. Diabetes, depression, and eating disorders were measured by a self-reported survey of whether or not each participant had been

diagnosed with the disorder. Self-reported measures of diabetes, depression, and eating disorders have been found to be reliable and valid in other studies [6-8]. Additionally, lifestyle variables were assessed. Lifestyle variables included self-reported measures of dairy, fruit, vegetable, grain, and pastry intake, as well as smoking, drinking, drug, and exercise habits.

Statistical Analysis

The exposure of interest was split into quartiles to better understand the effects of none, low, moderate, and high video game use. All those in the lowest quartile were nonusers, and those in the remaining quartiles were evenly distributed. All baseline and demographic features listed above were evaluated across all quartiles for baseline differences in video and computer game use at the start of the study. Similarly, lifestyle characteristics were also evaluated across all quartiles at baseline. The relationship between video or computer game use at enrollment (baseline: wave 1) and reported metabolic and health outcomes at wave 5 was examined using logistic regression using the following four models: (1) the first model was an unadjusted crude model; (2) the second model adjusted for sociodemographics (ie, age, race, and sex); (3) the third model, in addition to sociodemographics, adjusted for socioeconomic characteristics (ie, public assistance and money for bills); and (4) the final model adjusted for sociodemographics, socioeconomic characteristics, and current lifestyle behaviors (ie, cigarette smoking, alcohol consumption, sedentariness, and fast food intake at wave 5), accounting for sampling weight and cluster sampling. Additionally, the exposure variable (duration of video or computer game played) was investigated as both a categorical value and a continuous variable in all models. All data were analyzed in 2022.

A supplementary analysis was carried out to evaluate the relationship between video or computer game use at enrollment (baseline: wave 1) and reported metabolic and health outcomes at wave 5 while adjusting for current BMI at wave 5 to account for the role of obesity in the development of other metabolic risks.

Only cases with complete data at both waves were used for statistical analysis, with no imputation of missing values required. A total of 6504 completed respondent records were identified in wave 1. Of these 6504 records, 6390 were completed through wave 5. Those respondents without complete wave data were removed from our analytic sample, for a total of 114 respondents (1.75%) at this point. Additionally, any records that contained incomplete data for any metric included in this study at any timepoint or wave were also removed. This removed 2200 respondents (33.83%) from our analytic sample. Due to a large amount of missing data across this longitudinal panel, we decided to use listwise deletion to avoid any bias or influence introduced with imputation. Our final analytic database included 4190 respondents.

Statistical analysis was performed using SPSS (version 25.0; IBM Corp).

Ethical Considerations

This study did not require ethics approval as it involved secondary analysis of data available in the public domain.

Results

Video Games and Computer Game Use Among the Respondents

A total of 4190 respondents were included in this analysis. The median (range) hours spent by the respondents on video games and computer games was 1 (0-99) hours per week. Approximately 47% of the respondents did not play video games. The distribution of socioeconomic characteristics of respondents by quartile of the duration of video game played per week is shown in Table 1. Respondents who did not play any video games or computer games were typically older (16-17 years) and predominantly female (1440/4190, 72.5%) versus respondents in the other quartiles. While respondents who identified themselves as White were more likely to be represented in the lower quartiles (Q1 and 2), African American respondents had a higher likelihood of being in the higher quartiles (Q3 and 4) of duration spent playing video or computer games per week. A U-shaped association of the quartiles of the duration of video games and computer games played per week was observed with the location of residence and indicators of socioeconomic status, with urban residents and those receiving public assistance more likely to be in the extreme quartiles.

Table 1. Socioeconomic characteristics of all respondents by quartile of the duration of gameplay at enrollment. Values in the same row or category not sharing the same superscript are significantly different at $P<.05$ in the 2-sided test of equality for column proportions. Values with no superscript letters were not included in the test. Tests assume equal variances. Tests are adjusted for all pairwise comparisons within the rows in each subcategory using Bonferroni correction.

	Quartile of the duration of video games played per week				*P* value
	1 (n=1986)	2 (n=672)	3 (n=720)	4 (n=812)	
Duration of video games played (hours/week), median (95% CI)	0 (0-0)	1 (1-1)	2 (2-3)	7 (7-8)	<.001
Age (years), median (95% CI)	16 (16-17)[a]	15 (15-16)[b]	15 (15-16)[b]	15 (15-16)[b]	<.001
Age range (years)	13-18	12-18	12-18	13-18	
Male, %	27.5[a]	49.7[b]	52.1[b]	67.5[c]	<.001
Race, %					<.001
White	68.7[a]	75.0[b]	66.1[a,c]	61.8[c]	
Black or African American	20.4[a]	15.5[b]	20.8[a,b]	28.1[c]	
American Indian or Native American	1.1[a]	1.9[a]	1.9[a]	1.4[a]	
Asian or Pacific Islander	3.2[a]	4.0[a]	3.5[a]	3.2[a]	
Other	6.5[a]	3.6[b]	7.6[a]	5.5[a,b]	
Completely urban residence, %	52.1[a]	44.9[b]	51.3[a,b]	52.2[a]	.01
Receiving public assistance, %	8.5[a]	4.2[b]	7.7[a,b]	9.4[a]	.002
Having enough money for bills, %	81.0[a]	84.8[a,b]	86.2[b]	82.3[a,b]	.01

Duration of Video or Computer Game Use and Lifestyle Characteristics

The distribution of lifestyle characteristics of respondents by quartile of the duration of video games played per week is shown in Table 2. Respondents in the higher quartiles of the duration spent on video or computer games more frequently reported consuming dairy products (54.6%); bread, pasta, or rice (65%); and pastry products (25.6%) on the previous day. They were also less likely to report not consuming fruit juice the previous day (49%). No association was found with vegetable consumption. Compared to those who reported playing video games, those who reported not playing them were more likely to report smoking (22%) and drug use (29%). No association was observed between video or computer gameplay and participation in a school club or physical education classes (proxy indicators of physical activity).

Table 2. Lifestyle characteristics of respondents by quartile of the duration of gameplay at enrollment. Values in the same row or category not sharing the same superscript are significantly different at $P<.05$ in the 2-sided test of equality for column proportions. Values with no superscript letters were not included in the test. Tests assume equal variances. Tests are adjusted for all pairwise comparisons within the rows in each subcategory using Bonferroni correction.

	Quartile of the duration of video game played per week				*P* value
	1	2	3	4	
Ate dairy products yesterday					<.001
Did not eat	19.3[a]	14.3[b]	12.8[b]	15.0 [b]	
Ate once	35.0[a]	26.9[b]	31.5[a,b]	30.3[a,b]	
Ate twice or more	45.6[a]	58.8[b]	55.7[b]	54.6[b]	
Ate fruit or fruit juice yesterday					.03
Did not eat	23.6[a]	17.4[b]	20.8[a,b]	20.1[a,b]	
Ate once	30.3[a]	32.6[a]	32.6[a]	30.9[a]	
Ate twice or more	46.2[a]	50.0[a]	46.5[a]	49.0[a]	
Ate vegetables yesterday					.08
Did not eat	32.5[a]	26.8[b]	31.4[a,b]	30.2[a,b]	
Ate once	39.1[a]	44.0[a]	37.5[a]	40.9[a]	
Ate twice or more	28.4[a]	29.2[a]	31.1[a]	28.9[a]	
Ate bread, pasta, or rice yesterday					.004
Did not eat	8.9[a]	6.7[a,b]	7.1[a,b]	5.1[b]	
Ate once	31.2[a]	27.4[a]	29.6[a]	30.0[a]	
Ate twice or more	59.9[a]	65.9[b]	63.3[a,b]	65.0[a,b]	
Ate pastry products yesterday					<.001
Did not eat	50.7[a]	42.0[b]	40.6[b]	41.7[b]	
Ate once	30.6[a]	36.5[b]	37.2[b]	32.7[a,b]	
Ate twice or more	18.7[a]	21.6[a,b]	22.2[a,b]	25.6[b]	
Regular cigarette smoking	22.0[a]	15.0[b]	16.8[b]	17.6[a,b]	<.001
Drink alcohol >2-3 times	59.4[a]	49.0[b]	50.1[b]	48.6[b]	<.001
Drug use	29.0[a]	22.2[b]	22.5[b]	23.5[b]	<.001
Participation in any sports-related clubs at school	100.0	100.0	100.0	100.0	N/A[c]
Days or week of physical education classes					.07
0 days	43.7[a]	36.7[a,b]	34.57[a,b]	33.9[b]	
1 day	1.5[a]	2.7[a,b]	4.4[b]	1.6[a,b]	
2 days	5.4[a]	7.0[a]	6.8[a]	4.4[a]	
3 days	9.6[a]	9.4[a]	8.4[a]	10.4[a]	
4 days	1.7[a]	1.2[a]	1.2[a]	2.0[a]	
5 days	38.0[a]	43.0[a,b]	44.6[a,b]	47.8[b]	

[c]N/A: not applicable.

Duration of Video or Computer Game Use and Health

The distribution of metabolic and health indicators among respondents by quartile of the duration of video game played per week is shown in Table 3. Quartile 4 respondents had a significantly higher BMI and were more likely to report having at least one of the evaluated metabolic disorders (obesity (BMI >30 kg/m^2), diabetes, high BP, and high cholesterol). The trend for an increased prevalence of high BP with increasing quartiles of video or computer game use was significant. A similar trend was observed for diabetes, though the association did not reach statistical significance. No significant association was observed between video or computer game use and the diagnosis of dyslipidemia, eating disorders, or depression.

Table 3. Metabolic and health indicators at wave 5 by quartile of the duration of gameplay at enrollment. Values in the same row or category not sharing the same superscript are significantly different at $P<.05$ in the 2-sided test of equality for column proportions. Values with no superscript letters were not included in the test. Tests assume equal variances. Tests are adjusted for all pairwise comparisons within the rows in each subcategory using Bonferroni correction.

	Quartile of the duration of video game played per week				*P* value
	1 (n=1986)	2 (n=672)	3 (n=720)	4 (n=812)	
BMI (kg/m^2), median (95% CI)	28.4 (28.2-29.1)[a]	27.5 (27.3-28.3)[a]	28.1 (27.4-29.0)[a]	29.5 (29.1-30.1)[b]	<.001
BMI >30 kg/m^2, %	42.8[a]	37.2[a]	38.3[a]	47.1[b]	<.001
Any one metabolic disorder, %	54.2[a]	50.7[a]	52.8[a]	60.3[b]	.001
Ever diagnosed with diabetes, %	5.5[a]	5.2[a]	6.3[a]	7.4[a]	.20
Ever diagnosed with high BP, %	16.8[a]	19.9[a,b]	21.7[b]	22.5[b,c]	.001
Ever diagnosed with hyperlipidemia, %	16.6[a]	17.8[a]	17.7[a]	19.7[a]	.28
Ever diagnosed with depression, %	26.8[a]	23.5[a]	23.8[a]	23.7[a]	.14
Ever diagnosed with eating disorder, %	2.2[a]	1.2[a]	1.0[a]	1.5[a]	.08

Relationship Between Duration of Video or Computer Game Use and Health Indicators

In brief, the odds for the presence of any metabolic abnormality, obesity, or diabetes were significantly higher in the highest quartile compared to the lowest quartile of video and computer game use at enrollment. Quartile 4 (highest duration spent) compared to quartile 1 (lowest duration; this quartile reportedly did not play these games) had 23%, 27%, and 63% higher odds of reporting or having a metabolic abnormality, obesity, or diabetes, respectively.

Video or Computer Game Use and Metabolic Abnormalities

In the unadjusted model, every additional hour reportedly spent playing video games per week increased the odds of metabolic abnormalities by 1% (odds ratio [OR] 1.014, 95% CI 1.004-1.025). The relationship remained significant when adjusted for sociodemographic variables (age, sex, and race; OR 1.016, 95% CI 1.005-1.028) and additionally for socioeconomic indicators (OR 1.015, 95% CI 1.003-1.028). However, the association was not significant in the fully adjusted model.

Video or Computer Game Use and Obesity

In the unadjusted model, every additional hour reported to have been spent on playing video games per week increased the odds of obesity by approximately 1% (OR 1.013, 95% CI 1.003-1.023). When adjusted for sociodemographic variables (age, sex, and race), the strength of the association increased (OR 1.019, 95% CI 1.008-1.030). On additional adjustments for factors such as socioeconomic indicators, the association remained significant (OR 1.017, 95% CI 1.005-1.029). The relationship remained statistically significant even when the current lifestyle of the respondents and cluster sampling were accounted for (OR 1.016, 95% CI 1.003-1.029). However, such a significant association was not found with quartiles of video game playing duration in the final model.

Video or Computer Game Use and Diabetes

In the crude model, the duration of playing video games was not associated with diabetes incidence. However, when adjusted for sociodemographic variables (age, sex, and race; OR 1.020, 95% CI 1.004-1.037) and additionally for socioeconomic indicators (OR 1.019, 95% CI 1.002-1.037), the associations became significant. The association was attenuated and no longer statistically significant when the final model estimates were adjusted for current lifestyle (OR 1.011, 95% CI 0.991-1.031). Similarly, no significant association was found between quartiles of video game playing duration and the incidence of diabetes in the final model.

Video or Computer Game Use, High BP, and High Blood Cholesterol

The associations between video or computer game use, high BP, and high blood cholesterol were much less evident. While compared to those in Q1 (those who did not play the games), Q2, 3, and 4 had higher odds of reporting high BP or high blood cholesterol, a linear dose-response relationship was absent.

Video or Computer Game Use and Chronic Disease

Chronic disease was described as reporting any one of the following conditions: heart disease, kidney disease, stroke, and heart failure at wave 5. No association was observed between

the risk for the prevalence of a chronic disease and the duration of video or computer game use (Table 4).

A supplementary analysis that adjusted for current obesity in evaluating the association between video or computer game use and cardiometabolic risks is presented in Multimedia Appendix 1. The results remained unaltered in this analysis.

Table 4. Association between duration of gameplay in adolescence (wave 1) and subsequent metabolic abnormality diagnosis (wave 5).[a]

Diagnosis and duration of video game use (hours/week)	Model 1	Model 2	Model 3	Model 4
Any one of the metabolic disorders				
Quartile 1	1.000	1.000	1.000	1.000
Quartile 2, OR (95% CI)	0.871 (0.731-1.038)	0.897 (0.745-1.080)	0.845 0.692-1.031)	1.348 (1.087-1.671)
Quartile 3, OR (95% CI)	0.945 (0.797-1.121)	0.963 (.802-1.155)	1.015 (0.833-1.237)	1.111 (0.879-1.404)
Quartile 4, OR (95% CI)	1.287 (1.090-1.519)	1.315 (1.094-1.580)	1.240 (1.018-1.510)	0.941(0.735-1.205)
P value	.001	.002	.03	.70
R^2	0.005	0.017	0.013	0.063
Continuous, OR (95% CI)	1.014 (1.004-1.025)	1.016 (1.005-1.028)	1.015 (1.003-1.028)	1.012 (0.998-1.026))
P value	.006	.005	.01	.09
R^2	0.003	0.015	0.024	0.060
Obesity				
Quartile 1	1.000	1.000	1.000	1.000
Quartile 2, OR (95% CI)	0.792 (0.660-0.950)	0.856 (0.706-1.037)	0.818 (0.664-1.007)	0.736 (0.594-0.911)
Quartile 3, OR (95% CI)	0.831 (0.697-0.990)	0.871 (0.722-1.050)	0.892 (0.729-1.092)	0.857(0.679-1.083)
Quartile 4, OR (95% CI)	1.189 (1.008-1.403)	1.319 (1.098-1.585)	1.263 (1.037-1.539)	1.144 (0.897-1.460)
P value	<.001	<.001	.002	.88
R^2	0.006	0.014	0.021	0.076
Continuous, OR (95% CI)	1.013 (1.003-1.023)	1.019 (1.008-1.030)	1.017 (1.005-1.029)	1.016 (1.003-1.029)
P value	.009	.001	.004	.02
R^2	0.002	0.011	0.019	0.073
Diabetes				
Quartile 1	1.000	1.000	1.000	1.000
Quartile 2, OR (95% CI)	0.792 (0.660-0.950)	0.856 (0.706-1.037)	0.818 (0.664-1.007)	1.155 (0.620-2.152)
Quartile 3, OR (95% CI)	0.831 (0.697-0.990)	0.871 (0.722-1.050)	0.892 (0.729-1.092)	1.278(0.806-2.026)
Quartile 4, OR (95% CI)	1.189 (1.008-1.403)	1.319 (1.018-1.585)	1.263 (1.037-1.539)	1.356(0.823-2.235)
P value	<.001	<.001	.002	.46
R^2	0.006	0.014	0.021	0.023
Continuous, OR (95% CI)	1.015 (0.999-1.031)	1.020 (1.004-1.037)	1.019 (1.002-1.037)	1.011 (0.991-1.031)
P value	.06	.02	.03	.29
R^2	0.002	0.007	0.008	0.022
High BP				
Quartile 1	1.000	1.000	1.000	1.000
Quartile 2, OR (95% CI)	1.229 (0.983-1.537)	1.178 (0.926-1.499)	1.158 (0.892-1.504)	1.114(0.827-1.502)
Quartile 3, OR (95% CI)	1.372 (1.109-1.698)	1.319 (1.048-1.661)	1.419 (1.108-1.817)	1.291(0.924-1.806)
Quartile 4, OR (95% CI)	1.432 (1.169-1.755)	1.217 (0.967-1.531)	1.145 (0.891-1.471)	0.969(0.723-1.289)
P value	.001	.09	.05	.92
R^2	0.006	0.023	0.027	0.047
Continuous, OR (95% CI)	1.013 (1.002-1.024)	1.007 (0.995-1.019)	1.006 (0.993-1.019)	1.002(0.982-1.023)
P value	.01	.27	.38	.84
R^2	0.002	0.021	0.024	0.044

Diagnosis and duration of video game use (hours/week)	Model 1	Model 2	Model 3	Model 4
High blood cholesterol				
Quartile 1	1.000	1.000	1.000	1.000
Quartile 2, OR (95% CI)	1.090 (0.865-1.373)	1.059 (0.827-1.357)	1.027 (0.785-1.343)	1.024(0.751-1.397)
Quartile 3, OR (95% CI)	1.079 (0.861-1.351)	1.052 (0.825-1.339)	1.096 (0.845-1.420)	1.152)
Quartile 4, OR (95% CI)	1.232 (0.998-1.520)	1.139 (0.900-1.441)	1.164 (0.904-1.498)	1.197(0.882-1.624)
P value	.28	.76	.67	.76
R^2	0.001	0.012	0.013	0.017
Continuous, OR (95% CI)	1.004 (0.992-1.016)	1.002 (0.989-1.016)	1.005 (0.991-1.018)	1.007(0.989-1.026)
P value	.48	.73	.48	.44
R^2	0.000	0.011	0.012	0.017
Chronic disease				
Quartile 1	1.000	1.000	1.000	1.000
Quartile 2, OR (95% CI)	0.842 (0.441-1.610)	0.889 (0.442-1.785)	1.045 (0.499-2.191)	0.820(0.306-2.199)
Quartile 3, OR (95% CI)	1.044 (0.583-1.870)	1.093 (0.583-2.050)	1.198 (0.606-2.366)	0.933 (0.432-2.014)
Quartile 4, OR (95% CI)	1.529 (0.931-2.511)	1.493 (0.837-2.662)	1.538 (0.815-2.904)	1.050 (0.428-2.575)
P value	.26	.46	.59	.06
R^2	0.05	0.008	0.023	0.050
Continuous, OR (95% CI)	1.025 (1.005-1.044)	1.028 (1.007-1.048)	1.039 (1.014-1.066)	1.014(0.975-1.054)
P value	.01	.007	.003	.48
R^2	0.006	0.012	0.041	0.052

[a]The multivariate logistic regression (enter) method was applied. Metabolic abnormality was defined as having been diagnosed with any one of the following: obesity, diabetes, high BP, and high cholesterol at wave 5. Metabolic disease was defined as having been diagnosed with any one of the following: heart disease, kidney disease, stroke, and heart failure at wave 5. Model 1 was an unadjusted model; model 2 was adjusted for demography (age, race, and sex); model 3 was adjusted for demography and socioeconomic characteristics (public assistance and money for bills); model 4 was adjusted for demography, socioeconomic characteristics, current lifestyle (cigarette smoking, alcohol consumption, sedentariness, and fast food intake at wave 5) and the clustering effect. No interaction or collinearity between covariates were found.

Discussion

Principal Findings

The objective of this study was to examine the prevalence of video and computer game use among US adolescents and assess its association with obesity and associated metabolic disorders longitudinally. Respondents who played the most video and computer games at enrollment had a significantly higher BMI and were more likely to report having at least one of the evaluated metabolic disorders (obesity, ie, BMI >30 kg/m^2; diabetes; high BP; and high cholesterol) than those who did not report playing games over the 2 decades of follow-up. No significant association was observed for diabetes, hypertension, dyslipidemia, eating disorders, or depression.

The associations between video and computer game use and obesity are of public health importance. The raw mean difference in BMI between the lowest and highest quartiles of video game use was approximately 1 kg/m^2. It is estimated that the odds of developing type 2 diabetes per unit increase in BMI (kg/m^2) range between 1.19 and 1.38 [9]. Possible explanations for the relationship between video games and a significantly higher BMI include sedentary behavior, increased food intake during video game sessions, and insufficient sleep [10,11]. However, current literature suggests there is an inconsistent relationship between video games and obesity [12]. We acknowledge that obesity has a multifactorial etiology and requires a multipronged approach to effectively prevent and manage the epidemic in several populations [13,14]. The fully adjusted model evaluating the association between the duration of video game use (hours/week) and obesity accounts for approximately 7% of the variation in the outcome. While each factor may account for a small variance, identifying variables that are associated with the long-term development of obesity will aid in individualizing strategies for the prevention and treatment of obesity. Further research is needed on the role video games play in obesity-related behaviors.

It is noted that obesity usually precedes the development of metabolic abnormalities. This could explain why the association of video and computer game use with obesity was statistically significant, but the trend did not reach statistical significance for other metabolic disorders. The trend for an increased prevalence of high BP with increasing video or computer games aligns with current literature [15]. Elevated BP as an adolescent

is associated with CVD outcomes as an adult [16]. Similar to the association between video games and BMI, video games may increase BP through increased food intake while playing and a lack of sleep [10,11]. Further, BP may be elevated due to the excitement, stress, and concentration needed for effective gaming [15]. Further research is needed on separating obesity-related behaviors from the stress-inducing behaviors of video and computer game play.

Similarly, there was an observed potential for an increased likelihood of diabetes, which did not reach statistical significance. Current literature suggests inconsistent findings exist on the relationship between video games and diabetes. One cross-sectional study of adolescents aged 14-18 years (n=307) found no association between video games and an elevated risk of diabetes [17], and another pilot study (n=12) found video games to induce a state of excitation sufficient to activate the sympathetic system and alter the course of glycemia in children with type 1 diabetes [18]. Similar to an increase in BP, excitation, leading to mental and physical stress, may contribute to the increase in blood glucose. Due to the inconsistency in the findings, more research is needed to determine the direction of the association between diabetes and video and computer games.

No significant association was observed between video or computer game use and the diagnosis of dyslipidemia, eating disorders, or depression. Current literature has mixed findings on the relationship between video and computer games and depression. One study (n=126) found mobile phone and TV viewing were associated with higher levels of depression a year later [19]. However, video game play was unrelated. Another study found video game playing (β=.13, P<.001) and computer use (β=.17, P<.001) were associated with more severe depressive symptoms [5]. No known studies are looking at the association of video game play with eating disorders (anorexia nervosa or bulimia). However, one study looks at the use of video games to treat bulimia. There are no studies currently associating dyslipidemia and video games, however, there is evidence that dyslipidemia is observed in obese and overweight youth [17].

Limitations

The Add Health study is robust, yet the limitations of large databases and secondary data analyses are present. First, the quantification of exposures and outcomes is accurate within the limitations of the self-reported nature of this data. Second, the long retrospective period of this study is both to its benefit and a potential limitation. With more than 20 years between exposure (wave 1) and outcome (wave 5), there is adequate time to assess the development of the outcomes of interest into adulthood; however, this also opens the study up to more than 20 years of unmeasured confounding and loss to follow-up. However, this does not diminish the observed association. Third, in our categorization of video game use, quartile 1 included all respondents who reported that they did not play video games at enrollment. This approximately represented 48% of the respondents. The rest of the respondents were distributed between the remaining quartiles, resulting in a skewed distribution of respondents among the quartiles. We also acknowledge that the available data does not allow for a trajectory analysis of important confounders such as diet and physical activity. Thus, this analysis assumes that these variables were stable during the course of the follow-up and that residual confounding cannot be discounted. Finally, video game technology as well as social understanding around the topic has greatly changed in the past 20 years. These limitations, however, highlight areas for future study, as the vast majority of them are related to the secondary data source used. A purpose-built study design and data collection would address these limitations and help to examine the relationship found.

Conclusions

The frequency of video and computer game use in adolescents aged 12 to 19 years is longitudinally associated with obesity, with trends for higher prevalence of diabetes, high BP, and high cholesterol after 20 years of follow-up. Adolescents who play the most video and computer games have a significantly higher BMI in adulthood. They are more likely to have developed at least one of the evaluated metabolic disorders: diabetes, high BP, and high cholesterol. Obesity, diabetes, high BP, or high cholesterol are all modifiable health conditions. As such, public health interventions designed to target modifiable disease states through health promotion and self-management may support the health of adolescents aged 12 to 19 years. Potentially, video and computer games can integrate health promotion interventions into gameplay. This is an important area for future research as video and computer games are integrated into the lives of adolescents.

Acknowledgments

KLF was funded by a National Institute of Mental Health K01 award (K01MH117496).

Conflicts of Interest

KLF offers consulting services through Social Wellness and partners with Emissary Health, Inc.

Multimedia Appendix 1
Association between duration of gameplay in adolescence (wave 1) and subsequent metabolic abnormality diagnosis (wave 5), controlling for current BMI.
[DOCX File , 24 KB - pediatrics_v6i1e44920_app1.docx]

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Abbreviations

Add Health: Adolescent to Adult Health
BP: blood pressure
CVD: cardiovascular disease
OR: odds ratio

Edited by S Badawy; submitted 08.12.22; peer-reviewed by T Baranowski, A Sevic; comments to author 27.01.23; revised version received 20.03.23; accepted 03.04.23; published 06.07.23.

Please cite as:
Lebby SR, Shyam S, Ramadas A, Bohm AR, Hill JC, Fortuna KL, Zoltick SR
Prospective Association Between Video and Computer Game Use During Adolescence and Incidence of Metabolic Health Risks: Secondary Data Analysis
JMIR Pediatr Parent 2023;6:e44920
URL: https://pediatrics.jmir.org/2023/1/e44920
doi:10.2196/44920
PMID:37410530

Original Paper

An Individualized Postoperative Pain Risk Communication Tool for Use in Pediatric Surgery: Co-Design and Usability Evaluation

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Abstract

Background: Risk identification and communication tools have the potential to improve health care by supporting clinician-patient or family discussion of treatment risks and benefits and helping patients make more informed decisions; however, they have yet to be tailored to pediatric surgery. User-centered design principles can help to ensure the successful development and uptake of health care tools.

Objective: We aimed to develop and evaluate the usability of an easy-to-use tool to communicate a child's risk of postoperative pain to improve informed and collaborative preoperative decision-making between clinicians and families.

Methods: With research ethics board approval, we conducted web-based co-design sessions with clinicians and family participants (people with lived surgical experience and parents of children who had recently undergone a surgical or medical procedure) at a tertiary pediatric hospital. Qualitative data from these sessions were analyzed thematically using NVivo (Lumivero) to identify design requirements to inform the iterative redesign of an existing prototype. We then evaluated the usability of our final prototype in one-to-one sessions with a new group of participants, in which we measured mental workload with the National Aeronautics and Space Administration (NASA) Task Load Index (TLX) and user satisfaction with the Post-Study System Usability Questionnaire (PSSUQ).

Results: A total of 12 participants (8 clinicians and 4 family participants) attended 5 co-design sessions. The 5 requirements were identified: (A) present risk severity descriptively and visually; (B) ensure appearance and navigation are user-friendly; (C) frame risk identification and mitigation strategies in positive terms; (D) categorize and describe risks clearly; and (E) emphasize collaboration and effective communication. A total of 12 new participants (7 clinicians and 5 family participants) completed a usability evaluation. Tasks were completed quickly (range 5-17 s) and accurately (range 11/12, 92% to 12/12, 100%), needing only 2 requests for assistance. The median (IQR) NASA TLX performance score of 78 (66-89) indicated that participants felt able to perform the required tasks, and an overall PSSUQ score of 2.1 (IQR 1.5-2.7) suggested acceptable user satisfaction with the tool.

Conclusions: The key design requirements were identified, and that guided the prototype redesign, which was positively evaluated during usability testing. Implementing a personalized risk communication tool into pediatric surgery can enhance the care process and improve informed and collaborative presurgical preparation and decision-making between clinicians and families of pediatric patients.

(JMIR Pediatr Parent 2023;6:e46785) doi:10.2196/46785

KEYWORDS

eHealth; risk communication; decision aid; pain; individualized risk; surgery; anesthesia; postoperative; risk; co-design; focus group; requirement definition; prototyping; usability; prototype; child; pediatric; decision support; iterative

Introduction

Surgery poses a substantial risk for postoperative pain, with roughly 1 in 5 children experiencing pain 12 months following surgery [1], which can have detrimental consequences on their long-term well-being and future care-seeking behaviors [2]. The discovery of factors that increase the risk of postoperative pain (eg, anxiety, poor pain coping skills, and pain catastrophizing) [1-6] and the development of prehabilitation plans (eg, improved nutrition and exercise) [7-11] presents an opportunity to improve postoperative outcomes (eg, reduced length of stay [12] and reduced pain [13]). However, these risk factors and potential mitigation are not always communicated clearly and consistently in line with the information needs of the patients and their families [14]. Consequently, researchers are developing a risk identification and communication tools to improve information-sharing with patients and to improve care [15], with some initial success (eg, improved comprehension of procedure-associated risks) [16]. This work has all been focused on adult patients, but there is a clear need to extend this approach to pediatric surgery [14].

Furthermore, the development of health risk communication tools has typically not applied user-centered design principles [16,17]. Participatory design techniques, such as co-design focus groups, can directly incorporate stakeholders throughout development and ensure end user needs are addressed in the design process [18]. Engaging end users has several benefits: access to tacit knowledge and improved knowledge generation [19]; more profound understanding of user needs through examining visual overviews and written communication between users [20-22]; improved design of research materials; and improved quality of service, including a better fit between user needs and the service provided, and increased trust during participation in clinical trials [23,24]. These benefits can all potentially increase the generalizability of results [25]. Hence, incorporating primary end users' feedback into the development process is imperative to creating easy-to-use and effective risk communication tools and their successful uptake in clinical practice.

Aligned with the BC Children's Hospital's (BCCH) continued priority of improving pediatric pain management [3] and patient-centered care [4], our research program aims to (1) contribute to the efforts to minimize postoperative pain and to reduce pain medication requirements, specifically opioids and (2) generalize from the specific use case of pediatric postsurgical pain to develop a range of risk prediction communication tools pertinent to other clinical scenarios. In a previous study, we established the design requirements for a pediatric postoperative pain risk visualization tool, which guided the development of the initial prototype for an easy-to-use tool targeted at clinicians and family users [26]. Our preliminary prototype design was guided by our expected end users' requirements and included the nonthreatening and multimodal presentation of risk, an estimation of risk factors' contribution, and mitigation strategies to decrease the patient's level of risk [26].

The purpose of this study was to further develop and evaluate our preliminary pediatric postoperative pain risk communication prototype before implementing it into clinical practice. Hence, we aimed to (1) acquire additional design requirements from both sets of expected end users (clinicians and family members) through a critique of our preliminary design and a series of co-design activities and (2) evaluate the usability of the redesigned prototype through role-play based on low- and high-risk clinical scenarios and follow-up with standardized usability questionnaires.

Methods

Study Design and Approval

We conducted a two-stage study: (1) small group co-design over 2 sessions, followed by (2) individual usability evaluation sessions. Both stages were conducted with BCCH clinicians and family participants, including parents whose children had previously undergone surgery and adults with lived pediatric surgical experience.

Participants

We recruited BCCH attending physicians and nurse practitioners via departmental email distribution lists, parents via BCCH patient experience email lists and in-person invitations in the anesthetic care unit, and adults with previous childhood surgery via a provincial research network platform (REACH BC). A trained research team member described the study in detail and acquired written informed consent or web-based informed consent using Research Electronic Data Capture (REDCap, Vanderbilt University) [27,28]. In our report, parents and adults with pediatric surgical experience are collectively referred to as "family participant(s)" to protect their privacy. All participants were remunerated CAD $25 (US $19.50) per hour for their expertise and time. The co-design sessions included a mixture of family participants and clinicians. Usability evaluation sessions were individual, and participants in these sessions had not previously participated in co-design.

Data Collection

Overview

A brief prestudy questionnaire, administered via REDCap, collected participants' demographic information. A total of 2 research team members with expertise in qualitative methods conducted 5 web-based co-design and 12 usability testing sessions between December 2021 and August 2022 using Zoom (Zoom Video Communications); 2 researchers cofacilitated each session (MDW along with CF or YC). The researchers briefly introduced the session, including an overview of the

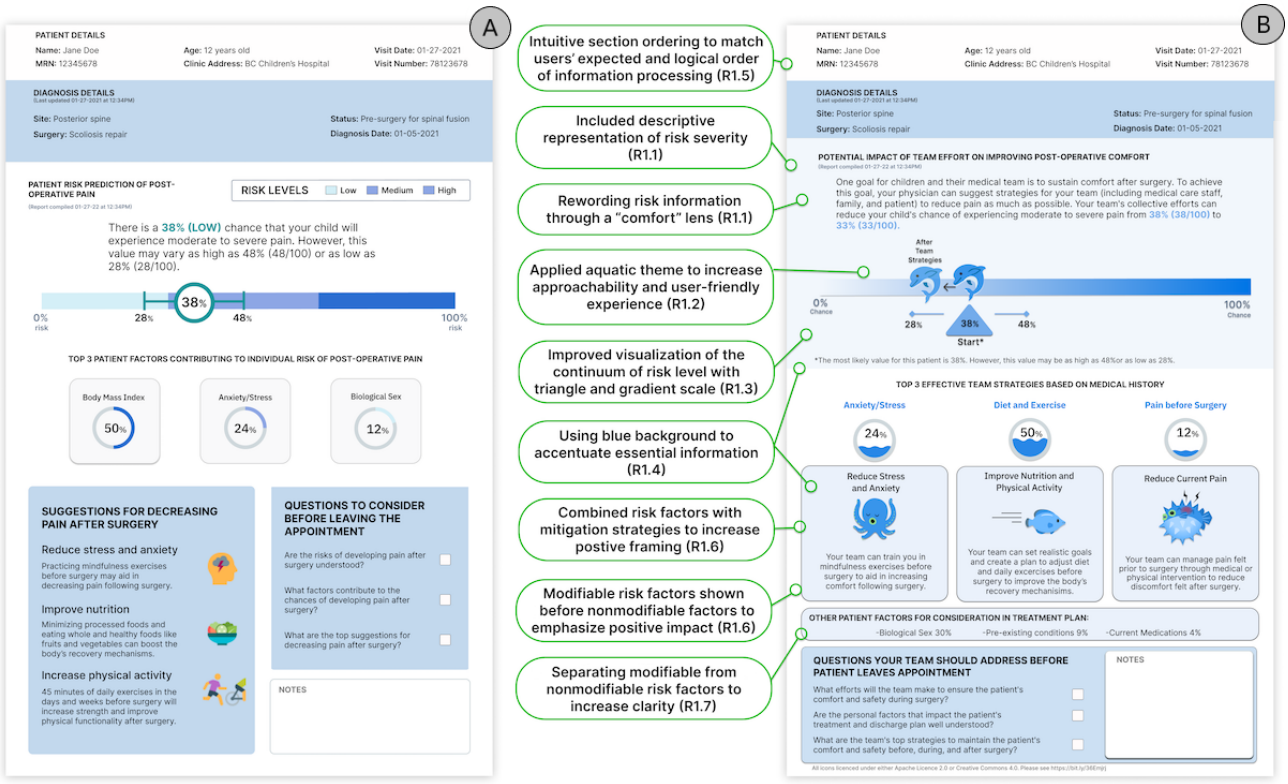
research program, described the co-design or usability evaluation process to illustrate the intended purpose of each activity, and conducted an icebreaker activity to increase participant comfort. Panels of approximately 3-5 family participants or 3-5 clinicians were targeted for each co-design session; usability evaluation sessions had 1 participant each.

All sessions were conducted web-based, so participants were required to have an internet connection, access to an electronic device with a camera, and proficiency in English. Co-design sessions lasted approximately 60 minutes each, were audio-recorded, and digitally transcribed; usability testing sessions lasted approximately 45 minutes each. Participant names were replaced by sequential identifiers, and transcripts were verified by a research team member (CF or YC).

Co-Design Iteration 1

Participants were given 4 minutes to rapidly sketch 4 distinct pain risk scores to evaluate potential design approaches and visualization strategies. Next, each participant completed a wireframing exercise in turn, in which each participant was presented with empty rectangular text boxes indicating the prototype sections (demographics, risk factors, and mitigation strategies) and risk score examples (bar chart, pie chart, line plot, people count arrays, thermometer, or fuel gauge). They were then instructed to place the 3 prototype sections and 1 risk score into an empty canvas to indicate their preferences for placement, positioning, and sizing of each section. Finally, participants were shown our initial prototype [26] (Figure 1A) and prompted to critically evaluate the design. Data from the first round of co-design sessions were used to generate redesign themes and requirements.

Figure 1. Redesign of the risk score prototype from requirements identified during the first co-design session. (A) The initial prototype [26]. (B) The redesigned prototype. Text in green boxes describes key design requirements identified from thematic analysis (see Table 1).



Co-Design Iteration 2

Participants were invited to return for a second co-design session to elicit additional design requirements and visualization preferences to inform iterative prototype development. They were also asked to provide feedback on low- and high-risk clinical scenarios (including the corresponding risk score visualization) to be used during the usability evaluation sessions, specifically to comment on the scenario's accuracy, understandability, realistic representation of patient risk, and whether they had any final suggestions.

Usability Evaluation

Pilot usability testing sessions were conducted to confirm the applicability and feasibility of using the proposed low- and high-risk scenarios and to ensure the appropriateness of the interview questions before formal testing sessions. Then, an additional cohort of family participants and clinicians, who did not participate in any previous session, was recruited for usability evaluation.

Each participant was asked to identify information in the various prototype sections, for which we recorded time and accuracy. Specifically, they were asked to complete four tasks: (1) identify key demographic information (patient's visit number and diagnosis date), (2) report the patient's likelihood (and uncertainty) of developing postoperative pain if they did not adopt any team strategies to reduce its risk, (3) identify the patient's risk factor that has the highest contribution to the patient's overall chance of developing postoperative pain, and

(4) indicate what the patient's chance of developing postoperative pain is if the patient adopts the identified team risk-reduction strategies. This list of tasks was informed by the design team and our patient and clinical partners and was confirmed with study participants during the second co-design session.

Participants were then asked to role-play and "think aloud" through both the low-risk (inguinal hernia) and high-risk (scoliosis correction) scenarios (see Multimedia Appendix 1). Clinicians were asked to state how they would use the tool to communicate risk scores and team risk-reduction strategies to the patients' families; family participants were asked to state how they would explain their child's condition to their spouse or child. The order in which the low- and high-risk scenarios were presented to participants was alternated to minimize order effects. Task completion time, the accuracy of prototype interpretation, and the participants' decision-making processes were recorded and analyzed. At the end of each session, we measured participants' mental workload with the National Aeronautics and Space Administration (NASA) Task Load Index (TLX) [29] and user satisfaction with the Post-Study System Usability Questionnaire (PSSUQ) [30]. Both were administered via REDCap [28].

Data Analysis

Session transcripts were analyzed with NVivo, and results were summarized using a thematic analysis [31]. The 2 research team members (MDW along with CF or YC) independently reviewed the 2 transcripts. They used inductive coding [32] to develop a preliminary list of thematic codes organized by theme, subtheme, and participant type [33]. These researchers then compared interpretations and developed consistent codes, which were applied to the remaining 3 transcripts using deductive coding [32]. The 3 researchers discussed additional themes that emerged after coding these remaining transcripts, resolved any discrepancies, and modified the coding framework to ensure that the key concepts were captured. For co-design, a saturation criterion was implemented [34]; specifically, the 2 research team members (MDW along with CF or YC) determined that similar comments and concerns were repeatedly discussed and that data saturation had occurred.

Our prototype was developed using an iterative process in which the research team created, discussed, and revised the prototype using Figma (Figma Inc). Prominent themes emerging from co-design sessions were then used to generate design themes and requirements for prototype redesign.

For the usability evaluation, quantitative data for task completion times, workload, and user perceptions were summarized as median (IQR) values using R (R Core Team). Task accuracies and requests for assistance were summarized as counts and percentages.

Ethical Considerations

Ethical approval was obtained from the University of British Columbia or Children's & Women's Health Centre of British Columbia Research Ethics Board (H20-00613; date of approval 2020-10-20; Principal Investigator: MG). Findings are reported following the Consolidated Criteria for Reporting Qualitative Research checklist [35].

Results

Participant Demographics

A total of 12 participants, including 8 clinicians (3 nurse practitioners and 5 anesthesiologists) and 4 family participants attended 5 co-design sessions with a mix of 3-5 clinical and family participants in each session; 12 participants, including 7 clinicians (1 registered nurse, 5 anesthesiologists, and 1 surgeon) and 5 family participants evaluated the usability of our prototype. Family participants were: 6/9 (67%) female; 3/9 (33%) over the age of 49; and 6/9 (67%) with either a certificate (university or nonuniversity) or university degree, and 3/9 (33%) with a high school diploma (or equivalent). Clinicians were female (8/15, 53%), older than 49 years (7/15, 47%), in practice for more than 5 years (10/15, 67%), and clinical fellows (2/15, 13%).

Co-Design Sessions

Overview

Through 2 rounds of co-design sessions, we identified requirements for (1) presentation and usability of the visualization tool, (2) identifying and categorizing risks and mitigation strategies, and (3) supporting collaboration and communication. We present them in detail below.

Presentation and Usability of the Visualization Tool

The key themes from the first co-design sessions were that the tool should (A) present risk severity descriptively and visually and (B) ensure that the appearance and navigation are user-friendly (Table 1). Most participants strongly preferred including a descriptive representation of risk severity (from "low" to "high"; design requirement R1.1, Table 1). To represent risk graphically, family participants typically drew child-friendly symbols and real-world objects, such as traffic lights or a race car on a track (R1.2). At the same time, clinicians preferred more traditional graphical representations, such as bar or pie charts (R1.3). This conflict was resolved by incorporating both views in the final set of requirements (R1.2 and R1.3). We were encouraged to change our original circular charts for risk factors and mitigation strategies (Figure 1A) to "fishbowls" for a more child-friendly tone, with the water level representing risk percentage (R1.2; Figure 1B).

Table 1. Summary of design requirements obtained from iterative co-design sessions.

Design requirement theme	Requirements elicited during the first co-design session		Requirements elicited during the second co-design session	
	ID	Specific design requirement	ID	Specific design requirement
(A) Present risk severity descriptively and visually				
	R1.1	Communicate risk severity descriptively (eg, "low" or "high")	N/A[a]	N/A
	R1.3	Visualize continuum of risk level		
(B) Ensure appearance and navigation are user-friendly				
	R1.2	Use real-world symbols to increase user-friendliness	R2.7	Add page numbers to encourage users to review both pages
	R1.4	Use color to highlight essential information		
	R1.5	Order sections to match users' intuitive information processing expectations		
(C) Frame risk identification and mitigation strategies in positive terms				
	R1.6	Reduce patient and family anxiety by emphasizing positive impact risk mitigation strategies can provide	R2.3	Maintain positive framing of optimizing comfort; include pain terminology in relevant sections
			R2.4	Separate risk scale into before and after to highlight the effect of mitigation strategies
			R2.5	Emphasize mitigation strategies and subsequent effects on reducing the risk of pain
(D) Clearly categorize and describe risks				
	R1.7	Increase clarity by improving categorization of risk factors	R2.1	Reword textual risk statements to increase readability and reduce anxiety
(E) Emphasize collaboration and effective communication				
	N/A	N/A	R2.2	Emphasize collaboration of cross-functional care teams
			R2.6	Create a separate page for the checklist and notes section

[a]N/A: not applicable.

Participants suggested emphasizing the risk score visualization as it represented essential information. Similarly, the elements for successful risk reduction and the change in risk score "after team strategies" (see also R2.4) were deemed essential and should be emphasized with color (R1.4). The wireframing exercise established an expected ordering of sections (Figure 1B). To accentuate the risk score, most participants enlarged the visualization, placed it centrally in the frame, and placed risk factors and mitigation strategies adjacently (R1.5).

Identifying and Categorizing Risks and Mitigation Strategies

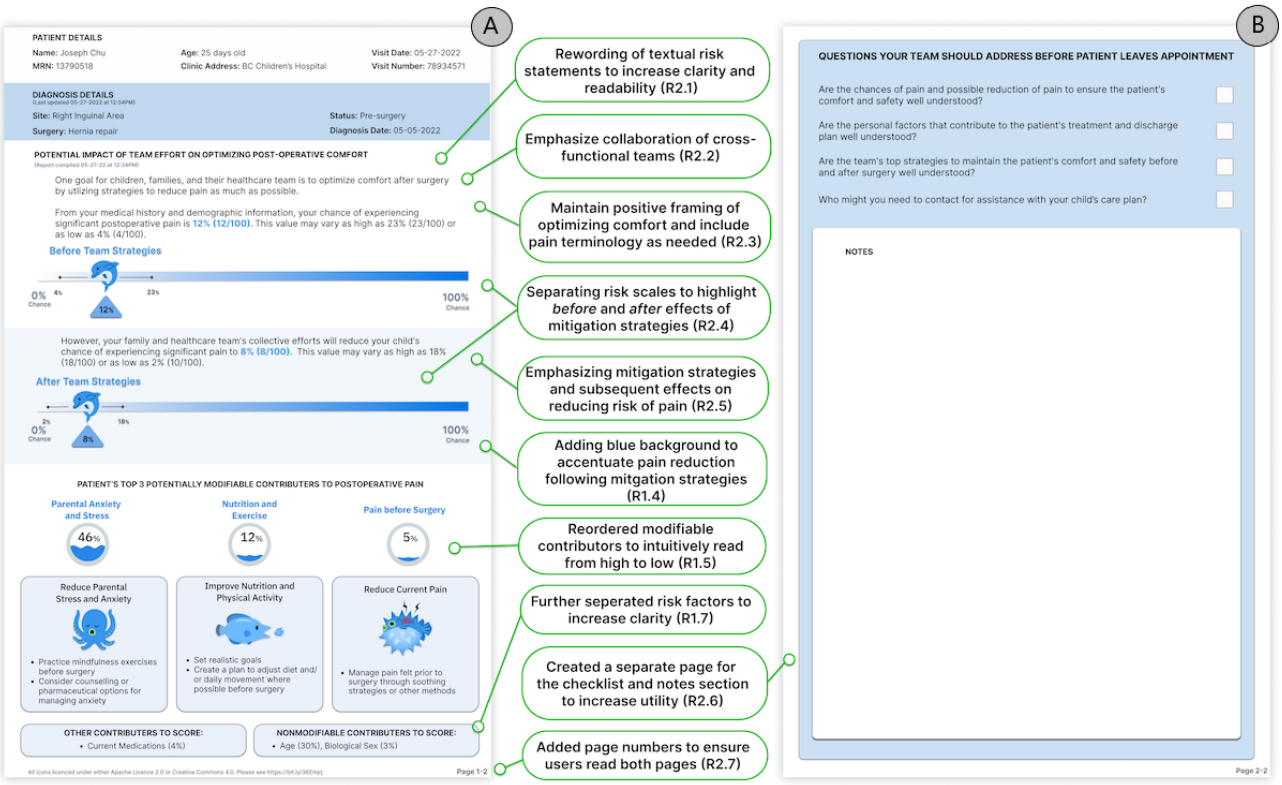
Further themes derived from a critical examination of the existing prototype were that the tool should (C) frame risk identification and mitigation strategies positively and (D) clearly categorize and describe risks (Table 1).

Most participants approved of using a risk score's range with uncertainty, as "it shows that there is always a margin of error" (family participant 2), and showing risk factors with percentages. However, some clinicians insisted that risk information be presented in a way that reduces anxiety, for example, displaying "non-modifiable [risk factors], such as biological sex, might distress the patient" (clinician 7), and "presenting families with a risk assessment of the potential pain after surgery could cause unintended adverse effects…you may be inducing pain by showing patients how much pain they might feel" [Clinician 4].

By "focusing on the possibility of mitigation, clinicians can focus the conversation on discussing pre-habilitation" (clinician 5) to reduce their risk score (R1.6). Separating risk factors that are "modifiable from non-modifiable" (clinician 1) and prioritizing modifiable factors may emphasize positive aspects of improving outcomes (R1.7).

Following a critical review of the revised prototype in the second co-design session, participants suggested we clarify some textual statements, such as changing "improving comfort" to "optimizing comfort" (R2.1; Figure 2A; for a higher-resolution version, see Multimedia Appendix 2).

Figure 2. Prototype redesign following the second co-design session. (A) Demographic and clinical information, risk score before and after team strategies, and targeted strategies to reduce risk. (B) Comprehension checklist and expanded notes section on a second page. Text in green boxes describes fundamental redesign changes (see Table 1). For a higher-resolution version of the figure, Multimedia Appendix 2



Clinicians remained concerned that a patient's level of pain "is highly influenced by consultation dialogue" (clinician 2) and thus favored using positive framing of risk around the concept of comfort; on the other hand, some family participants insisted that "using comfort/discomfort in a pain management tool confuses the goal of the tool for patients and families" (family participant 4). A clinician noted that "there is a lot of evidence that suggests the language we use can change people's perception of pain" but acknowledged that some "pain language must be there" (clinician 5). This conflict was resolved by balancing both viewpoints equally in our design requirement; that is, we determined that we should maintain the positive framing of "optimizing comfort" but include pain terminology, such as "significant postoperative pain," where relevant (R2.3).

Both clinicians and family participants needed clarification about the percentage changes associated with risk reduction (Figure 1B). They suggested we separate our risk score into 2 components: "Before team strategies" and "After team strategies" (R2.4 and see also R1.4). Most participants did not identify the asterisk footnote about the statistical uncertainty of the risk score (Figure 1B), which suggested we move this detail to the textual risk statement (R2.1).

Clinicians and family participants recommended "focusing families on the mitigation strategies" (clinician 2) and their ability to reduce the risk of pain following surgery; that is, we should emphasize how much risk reduction the cross-functional teams can achieve in the "After Team Strategies" risk score (R2.5; Figure 2A). Finally, it was suggested that we reorder the modifiable contributors to read from high to low, reflecting how users would process the information (reinforcing R1.5).

Some participants were confused about whether the risk factor percentages (Figure 1) were population-based or personalized and recommended "stressing that the percentages are individualized" (clinician 4; Figure 2A). Similarly, separating "Other contributors to score" (eg, medication) from "Nonmodifiable contributors to score" (eg, age and biological sex) would improve clarity (reinforcing R1.7).

We were asked to update "Diet" to "Nutrition" to emphasize nutrient intake rather than food quantity (Figure 2A), and a family participant noted that diet and exercise "might be the hardest to implement in your daily life if you have disabilities, live in poverty, and/or a pre-existing condition(s)" (family participant 4). It was suggested that we change the section title to "Potentially Modifiable Contributors" and list the strategies in point form to increase ease of readability (R2.1).

Supporting Collaboration and Communication

The final theme from the co-design sessions was that the tool should (E) emphasize collaboration and effective communication (Table 1). Following a critical review of the revised prototype in the second co-design session, participants suggested it should emphasize the collaboration of cross-functional care teams (patient's family, nurses, and physicians) by changing "your physician" to "your health care team" (R2.2).

Our original notes section was too small; it needed sufficient space for participants to write and draw essential information from the consultation (R2.6) and thus was separated and placed on a separate numbered page (see also R2.7; Figure 2B). Participants approved the checklist questions as reminders of topics to discuss during the consultation (Figure 1B). However,

several participants stated the importance of knowing who to contact to assist with their child's care (see also R2.1). Some insisted that the questions should be connected to the information shown and not require complex answers (see also R2.1; Figure 2B).

Usability Evaluation

Potential Use of the Tool in Practice

During low- and high-risk clinical role-play, participants typically said they would use the tool by comparing the risk scores before and after risk reduction strategies to demonstrate the proposed benefits to motivate positive change. Participants typically said they would describe the top 3 modifiable contributors and ensure the family could implement the targeted strategies. Most participants thought that the comprehension checklist was a helpful reminder and that the notes section was beneficial to document clinical information, such as targeted strategies, referral contacts, aftercare instructions, and questions arising during the consultation.

Most participants agreed that the child would benefit from seeing the tool, at least for older children (>12 years of age), though some felt it would benefit children as young as 5 years of age. There were conflicting views on the use of the tool in practice: some clinicians would not focus on discussing low-risk pain with the patient, or if only a small risk mitigation was anticipated, as it may increase patient anxiety; however, family participants all agreed that the risk score should be used in both low- and high-risk scenarios as any decrease in postoperative pain would be meaningful for a child's surgical experience. All participants recognized that nonmodifiable contributors, such as biological sex and age, provided context but would not discuss these with the child.

Task Completion, Usability Ratings, and Workload

Completion time across tasks varied, but tasks were largely completed quickly (median time to complete each task ranged from median 5.0, IQR 2.9-6.8 seconds to median 16.6, IQR 10.9-34.3 seconds) and accuracy ranged from 11/12 (92%) correct to 12/12 (100%) correct, with only 2 requests for assistance and no evidence for substantial differences between clinicians and family participants (Table 2).

Table 2. Participant speed, accuracy, and requests for assistance while identifying essential personalized risk information during usability evaluation.

Task	Time (seconds), median (IQR)		Accuracy (n=12), n (%)	Requests for assistance
	Clinicians (n=7)	Family participants (n=5)		
Task 1: demographics	11.8 (7.5-20.9)	11.4 (9.2-17.4)	11 (92)	0
Task 2: risk of pain	16.5 (7.2-25.3)	16.6 (15.6-34.3)	11 (92)	1 Family participant
Task 3: main risk factor	7.0 (3.4-10.7)	6.9 (4.0-9.3)	11 (92)	1 Clinician
Task 4: effect of team strategies	6.1 (3.0-7.3)	4.3 (2.9-6.1)	12 (100)	0

Median (IQR) PSSUQ scores [30] (on a 1-7 scale) across all participants were 2.0 (IQR 1.5-2.2) for system usefulness, 2.5 (IQR 1.9-3.0) for information quality, 2.0 (IQR 1.8-2.7) for interface quality, and 2.1 (IQR 1.5-2.7) for overall score, which are within typical ranges of acceptability [36]. The scores were similar between clinicians and family participants, but there was some evidence for differences in their levels of satisfaction with information quality and interface quality (Table 3), which may reflect conflicting views on the use of this tool in all scenarios.

Table 3. Post-Study System Usability Questionnaire scores[a].

PSSUQ[b] factor	Composite score, median (IQR)		Composite score of ≤3 equating to strongly agree, agree, or somewhat agree, n (%)	
	Clinicians (n=7)	Family participants (n=5)	Clinicians (n=7)	Family participants (n=5)
System usefulness	2.0 (2.0-2.4)	1.3 (1.0-1.5)	7 (100)	5 (100)
Information quality	3.0 (2.7-3.4)	1.7 (1.0-2.0)	4 (57)	5 (100)
Interface quality	2.7 (2.3-3.2)	1.5 (1.0-2.0)	5 (71)	4 (100)[c]
Overall	2.6 (2.2-2.9)	1.4 (1.4-1.5)	5 (71)	5 (100)

[a]Composite scores are the mean of subcomponent scores on a 1-7 scale, with lower numbers indicating greater agreement.

[b]PSSUQ: Post-Study System Usability Questionnaire.

[c]One family participant answered not applicable for all "interface quality" questions.

Median (IQR) NASA TLX subcomponent scores [29] suggested that participants generally felt they were able to perform the tasks required of them, though clinicians scored this subcomponent lower than family participants. Mental demand and effort to achieve their performance contributed the most to the overall workload; scores for temporal demand, physical demand, and frustration were low (Table 4).

Table 4. National Aeronautics and Space Administration Task Load Index scores[a].

TLX[b] subcomponent	Score, median (IQR)	
	Clinicians (n=7)	Family participants (n=5)
1. Mental demand	27 (19-34)	16 (15-23)
2. Physical demand	12 (0-12)	0 (0-2)
3. Temporal demand	15 (14-18)	3 (1-6)
4. Performance	67 (64-79)	96 (82-97)
5. Effort	50 (17-56)	48 (21-50)
6. Frustration	13 (8-23)	2 (1-3)

[a]Scores are given on a sliding scale from 0=very low to 100=very high.

[b]TLX: Task Load Index.

Discussion

Principal Results

In this user-centered study, 5 outline design requirements for a pediatric postoperative pain risk visualization tool were identified during co-design focus group sessions, which built on previously published work [26]: (A) present risk severity descriptively and visually, (B) ensure appearance and navigation are user-friendly, (C) frame risk identification and mitigation strategies in positive terms, (D) categorize and describe risks clearly, and (E) emphasize collaboration and effective communication. A revised risk communication prototype based on these requirements was used by both clinical and family participants quickly and accurately. Only minor frustration was reported during the usability evaluation, and user perception of the tool was acceptable.

Comparison With Prior Work

Development and Use of Risk Communication Tools

Personalized risk communication tools have yet to be widely implemented in clinical practice and have not yet been studied in the context of pediatric pain risk following surgery. However, in preliminary studies previously conducted with adult patients, participants have largely rated personalized risk communication tools as easy to use [37,38], helpful [39], and beneficial to patients [40]. Participants believed that personalized risk communication might result in increased patient engagement [41], increased awareness and understanding of potential surgical complications, and deeper discussion with providers [42]. Participants who were presented with a personalized risk score while consenting for surgery, in particular, agreed that they had received adequate time discussing surgical risks, felt more comfortable with their procedure, had decreased anxiety [43], were significantly more satisfied with the consent process [40,43], and had increased knowledge about the risks associated with their surgery [40]. These other studies explicitly support the motivation behind our research program and the development of a perioperative pediatric risk communication tool. Our usability data mirror some of these findings.

In previous studies, patients also preferred the visual consent tool to text-based documents [42], found personalized surgical risk communication tools helpful for informed decision-making [39], indicated that they would use a personalized risk tool again before a future procedure [40], and believed sharing personalized risk information should be a universal requirement during surgical consultations [44]. Clinicians also highlighted that identifying modifiable risk factors was more important than nonmodifiable ones; thus, separating their contributions was critical [38]. On viewing their risk of postsurgical complications, most patients said they would consider participating in a structured prehabilitation program to decrease their risk and improve postsurgical outcomes [44]. These results are promising and broadly consistent with our findings. However, these previous studies were conducted only with adult participants. While they helped inspire our design decisions, their detailed recommendations can only be fully translated by reevaluating how this approach should be applied in the pediatric surgical setting, as we have done in this study.

Personalized and Contextualized Risk Scores

Other studies have shown that data-driven personalized risk calculations can perform significantly better than physicians in predicting patient outcomes in the perioperative domain, and exposure to the calculated risk scores can improve physicians' prediction accuracy [37]. Patients with low-risk may be more likely to overestimate their surgical risk [39,44], and patients with high-risk may be more likely to underestimate their risk [44], highlighting the importance of improving patient understanding of potential postsurgical complications through supported communication. As we discovered during our usability testing sessions, a point of conflict between patients and health care professionals is that patients typically prefer to be shown their personalized risk scores even when they are low-risk, while some health care professionals felt that this might result in a misuse of clinic time (as was also found in other previous studies [39,41]) or unnecessarily increase anxiety; our family participants universally agreed the risk tool should be used in low- as well as high-risk situations, explaining that any opportunity to decrease postoperative pain, no matter how small, would be beneficial to their child. This further highlights the benefit of involving family participants in the design process to ensure effective use by expected end users.

Essential Design and Feature Considerations

Where patients and health care professionals have provided input to the design and feature considerations of personalized

risk score tools, their requirements echo the findings from this study. For example, other studies also identified simplicity and clarity as essential characteristics to facilitate shared decision-making [45,46], and to ensure that risk information does not overwhelm patients [45-47]. Other focus group studies have also suggested including less complex language for risk severity, such as "low," "medium," and "high" [44], and that simplistic visualizations and language are crucial to understanding—patients have been confused by highly interactive visualizations and better comprehended static charts [45]. These previous findings are similar to the design requirements we established for this prototype.

Patients and care providers have previously indicated that a multimodal risk score supports the learning styles and preferences of various users [40,46]. Furthermore, continuing to engage stakeholders, educating staff, and allowing smooth integration into workflows have previously been noted as important implementation success factors [40]. The findings from these other studies are broadly reflected in our participants' comments during our co-design sessions and usability evaluation.

Differences Between Clinical and Family Participants' Design Requirements

While addressing user needs overall is critical, we must acknowledge some differences between clinicians' and family participants' perceptions of the risk communication tool in our usability testing. While clinicians were satisfied with the tool overall, their lower levels of satisfaction with information and interface quality (as evidenced by their lower PSSUQ scores for these components) may have reflected concerns about what information is presented; clinicians also felt less able to perform the tasks required of them (as evidenced by their lower NASA TLX performance scores). These differences may reflect clinicians' concerns about the potential adverse effects of communicating risk to patients via the "nocebo effect" [48], which should be recognized and addressed, particularly in the pediatric setting. We incorporated this clinical guidance into the final iteration of our prototype to provide the risk information through a "comfort" lens; that is, we aimed to focus the efforts of the clinician and family team on "maintaining comfort" rather than "reducing pain," while still acknowledging the risk of pain inherent in their surgical procedure. This approach is consistent with international initiatives aimed at prioritizing compassionate approaches to the recognition, prevention, and treatment of children's pain (eg, ChildKind International [49]) as well as our own institution's recommended approach [50]. It seems these changes may not have been sufficient to address the concerns of our clinical participants in usability testing. Importantly, however, other research has shown that, while increased risk has been correlated with patients wanting to discuss the procedure in more detail with their providers [37], presenting patients with their personalized risk has not been associated with canceling procedures or changes in the decision to undergo surgery [39,43,44].

Limitations and Future Work

We must acknowledge several limitations in our study. First, our study participants included no surgeons during the requirements gathering phase and only 1 surgeon in the usability testing phase; however, all clinician participants were anesthesiologists or nurses with expertise and regular involvement in predicting, diagnosing, treating, and offering families guidance on managing postoperative pain. Second, we did not include children or adolescents. Future work may involve evaluating the benefit of developing a child-centered version of the tool. At this stage, we adopted the strategy of developing a family-centered tool, but we aim to expand this idea to a tool targeted at adolescents. We have begun this process with a perioperative survey of our adolescent surgical population, which evaluates potential preoperative risk factors and postoperative recovery indicators. If successful, we can expand this work to younger children. Participants in this study echoed this aim: most agreed that children older than 12 years of age would benefit, and some felt we could consider including children between the ages of 5 and 11 years.

Third, our focus group sizes were relatively small (3-5 participants per session), typically due to the challenges of scheduling time with clinicians and family participants. While this could have avoided "group think," it may have hindered collaborative idea generation. Furthermore, we did not use a dynamic prototyping tool in our co-design sessions with participants working collaboratively on a shared resource, which may have enhanced the design process; in pilot-testing, this had been found to be a barrier to participation. However, our patient partners suggested that screen sharing the exercises would increase accessibility as it may be challenging to teach participants of various education and language proficiencies to use a prototyping tool in real time or if they were using a small screen (eg, cell phone) and could not easily complete each exercise, or had a disability that might limit motor function and participation. Fourth, conducting co-design sessions over Zoom rather than in-person may have biased our sample. On the one hand, the requirement for an internet connection may have prevented participation by some families, which may have impacted the social equity of our findings and on the other hand, it may have facilitated participation for some people who would otherwise have been able to contribute due to travel or time constraints.

Finally, our usability evaluation provides only limited evidence of the tool's readiness for implementation. Although its intended real-world use is as a shared clinician-family resource, we evaluated with individuals (either a clinician or family participant but not both at the same time), using a static prototype, with tasks that may have been too simple to evaluate the usability effectively. That said, the tool is not designed to be a complex, dynamic tool, but rather to communicate a fixed set of information personalized to each clinician-family presurgical encounter.

Future work will involve implementing the design in digital form, which will first be evaluated with a range of clinical scenarios and take account of the need for joint clinician-family evaluation. We are also collecting data in a separate study to generate a risk prediction model, which will supply the personalized risk predictions and proposed prehabilitation strategies that the tool is designed to present [51]. A key point that should be addressed ideally before implementation is how

widely the tool should be used in practice: in all cases, as our family participants suggested; only in cases with a high risk of pain; or where team mitigation strategies are expected to make a significant difference.

Conclusions

This user-centered co-design study identified essential requirements for a pediatric postoperative pain risk visualization tool to present risk severity descriptively and visually, to ensure that appearance and navigation are user-friendly, to frame risk identification and mitigation strategies in positive terms, to categorize and describe risks clearly, and to emphasize collaboration and effective communication. The usability of the resulting paper prototype was positively evaluated by both clinical and family participants suggesting that it is ready to be implemented as a digital prototype that can be tested in a clinical setting to establish its efficacy in supporting communication about postoperative pain risk.

Acknowledgments

This work was supported, in part, by a University of British Columbia Canada's Digital Technology Supercluster expansion research grant and a BC Children's Hospital Research Institute Evidence to Innovation Research Theme seed grant. MG holds a Michael Smith Health Research BC scholar award; MDW holds a Mitacs postdoctoral fellowship. The authors thank the participating families and BC Children's Hospital staff for their time and insights. The authors would also like to thank Kim Correa for her help in conducting the initial co-design sessions and verifying transcripts and Rama Sreepada for assisting with recruitment and providing content expertise to study implementation. Finally, they would like to thank Amanda Ross-White (Queen's University) for lending her librarian expertise to assist in searching and identifying literature relevant to study preparation. The authors thank the BC Children's Hospital Foundation for its support.

Authors' Contributions

MDW, CF, and YC participated in study design, data collection, qualitative analysis, prototype design, and paper drafting and editing. EPC, KCL, and SDW participated in study design, designing of the prototype, and paper drafting and editing. NCW and KC participated in the study design, paper drafting, and editing. MG participated in study design, data collection, designing of the prototype, and paper drafting and editing.

Conflicts of Interest

We disclosed our redesigned prototype for Intellectual Property protection to the University of British Columbia University-Industry Liaison Office (2022-07-29).

Multimedia Appendix 1
Low- and high-risk scenarios for role-play and "think aloud."
[PDF File (Adobe PDF File), 101 KB - pediatrics_v6i1e46785_app1.pdf]

Multimedia Appendix 2
Higher-resolution version of the risk communication tool prototype following the second co-design session.
[PDF File (Adobe PDF File), 31596 KB - pediatrics_v6i1e46785_app2.pdf]

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Abbreviations

BCCH: BC Children's Hospital
NASA: National Aeronautics and Space Administration
PSSUQ: Post-Study System Usability Questionnaire
REDCap: Research Electronic Data Capture
TLX: Task Load Index

Edited by S Badawy; submitted 24.02.23; peer-reviewed by H Yang, D Nakikj; comments to author 06.06.23; revised version received 07.07.23; accepted 23.10.23; published 17.11.23.

Please cite as:
Wood MD, West NC, Fokkens C, Chen Y, Loftsgard KC, Cardinal K, Whyte SD, Portales-Casamar E, Görges M
An Individualized Postoperative Pain Risk Communication Tool for Use in Pediatric Surgery: Co-Design and Usability Evaluation
JMIR Pediatr Parent 2023;6:e46785
URL: https://pediatrics.jmir.org/2023/1/e46785
doi:10.2196/46785
PMID:37976087

Original Paper

Exploring Social Media Preferences for Healthy Weight Management Interventions Among Adolescents of Color: Mixed Methods Study

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Abstract

Background: Social media holds promise as an intervention platform to engage youths in healthy weight management and target racial inequities in obesity.

Objective: This mixed methods study aimed to examine social media habits, preferences, and obesity-related behaviors (eg, diet and physical activity) among adolescents of color and understand preferences for healthy weight management interventions delivered via social media.

Methods: This mixed methods study is comprised of a cross-sectional web-based survey and a series of digital focus groups. Study participants (English-speaking youths of color ages 14-18 years) were recruited from high schools and youth-based community settings in Massachusetts and California. For surveys, participants were invited to complete an anonymous web-based survey assessing self-reported sociodemographics, social media habits and preferences, health behaviors (diet, physical activity, sleep, and screen time), and height and weight. For focus groups, participants were invited to participate in 45- to 60-minute web-based group discussions assessing social media habits, preferred social media platforms, and preferences for physical activity and nutrition intervention content and delivery. Survey data were analyzed descriptively; focus group transcripts were analyzed using a directed content analysis approach.

Results: A total of 101 adolescents completed the survey and 20 adolescents participated in a total of 3 focus groups. Participants reported most frequently using TikTok, followed by Instagram, Snapchat, and Twitter; preference for platform varied by purpose of use (eg, content consumption, connection, or communication). TikTok emerged as the platform of choice as an engaging way to learn about various topics, including desired health information on physical fitness and diet.

Conclusions: Findings from this study suggest that social media platforms can be an engaging way to reach adolescents of color. Data will inform future social media–based interventions to engage adolescents of color in healthy weight management content.

(JMIR Pediatr Parent 2023;6:e43961) doi:10.2196/43961

KEYWORDS

social media; adolescents of color; obesity disparities; disparity; disparities; healthy weight management; health education; child health; mHealth; mobile health; weight; obese; obesity; child; pediatric; adolescent; adolescence; preference; health behavior; mobile phone

Introduction

The high rates of adolescent obesity in the United States remain a significant public health concern. Nearly 1 in 4 (22.2%) adolescents aged 12-19 years in the United States had obesity from 2017 to 2020 [1]. Youths of color experience disproportionately higher rates of obesity, with 26.2% of Hispanic and 24.8% of non-Hispanic Black youths ages 2-19 years with obesity, compared to 16.6% of their non-Hispanic White peers [1]. Given the adverse effects associated with adolescent obesity, including elevated risk for diabetes, heart disease, and shorter life expectancies, developing intervention strategies with a health equity lens to prevent and treat obesity, particularly among youths of color who face disproportionately higher rates, is critical [2-4].

Digital or mobile health interventions, defined as health services delivered electronically through formal or informal care, hold promise as a modality to engage adolescents in improving obesity-related health behaviors, such as diet and physical activity [5-8]. Studies to date that have evaluated digital health interventions as a primary or supplemental tool within behavior change obesity interventions have primarily targeted adults or have assessed programs that jointly engage adolescents and their parents or guardians [6,9,10]. Prior digital health interventions targeting adolescents have largely focused on chronic disease management (eg, type 1 diabetes) rather than health behavior change related to obesity prevention and treatment [7,11]. Further, research on digital health interventions targeting obesity-related behaviors with content and strategies tailored for adolescents of color is limited.

Given the high prevalence of smartphone and social media use among adolescents, social media–delivered health interventions are a promising approach to engage adolescents in healthy weight management [12]. In 2021, 84% of adolescents 13-18 years of age reported ever using social media [13]. Social media use among this age group increased during the COVID-19 pandemic, with an average of 1 hour and 27 minutes per day spent on social media in 2021, up from 1 hour and 10 minutes in 2019 [13]. A 2018 Pew Research study found that 95% of 13- to 17-year-olds reported having access to a smartphone and nearly half reported being on the internet almost constantly, with over 70% of Black and Latine youth participants reported using at least 1 social media platform [14]. The Pew study also reported gender differences in social media platform preference among adolescents, with females more likely to prefer Snapchat than males and males more likely to prefer YouTube than females. The prevalent use of social media platforms among all adolescents, including those of color, highlights the potential of social media as a vehicle to deliver accurate and engaging health content to promote healthy weight management behaviors.

The limited literature on adolescents' exposure to and consumption of health information, particularly related to healthy weight management, through social media platforms has produced mixed findings. A small pilot study evaluating the consumption of health- and fitness-related social media content among adolescent females found that participants did not follow health-related pages or accounts and did not actively search for health content on social media [15]. A systematic review of social media interventions with content targeting nutrition and obesity among adolescents and young adults found that two-thirds of such interventions were associated with at least 1 clinical nutritional or dietary behavioral improvement [16]. However, none to our knowledge have specifically examined the efficacy of such interventions among adolescents of color.

This mixed methods study aims to (1) examine social media habits, preferences, and obesity-related behaviors (eg, diet and physical activity) among adolescents of color and (2) understand intervention preferences to inform the development of future healthy weight management behavioral intervention delivered via social media through cross-sectional surveys and focus groups among a sample of adolescents of color.

Methods

Design

This study collected quantitative and qualitative data from high school students aged 14-18 years who identified as people of color in order to assess adolescents' weight management behaviors, attitudes, practices, and social media preferences. Participants were asked to answer questions related to their social media habits, preferences for physical activity and nutrition intervention content and delivery, preferred social media platform, self-reported measures of obesity-related behaviors (eg, diet and physical activity), and height and weight via an anonymous cross-sectional web-based survey and web-based focus groups.

Ethics Approval

Study procedures were approved by the Institutional Review Board of Boston University Medical Campus (IRB # H-40968).

Recruitment, Setting, and Procedures

The investigative team contacted youth-based or youth-affiliated organizations in their network, including the Massachusetts Alliance of Boys & Girls Clubs (BGC), high schools in California, and community partners in Massachusetts and California to recruit participants. BGC staff, high school administrators, and community partners in Massachusetts and California were informed of the purpose and methods of the study. In total, 3 BGCs in Massachusetts and 2 high schools in southern California indicated interest in participating and were asked to share physical recruitment flyers with adolescents of color ages 14-18 years. Adolescent participants were also invited

to share the survey with their social networks. Survey recruitment and administration took place from March 2021 to April 2022 with interested and eligible participants provided with a web-based QR code to access and complete the 1-time web-based survey. Focus group recruitment and facilitation took place from April 2021 to September 2021. Study staff contacted interested and eligible focus group participants to identify a date and time for a web-based 1-hour meeting (6-8 participants per group). Focus groups were conducted by a trained facilitator using Zoom, lasted 45-60 minutes in duration, and were recorded and transcribed.

Participants

Inclusion criteria for survey and focus group participants included 14-18 years of age; self-identification as a person of color (African American or Black, Latine or Hispanic, Native American or American Indian, Native Hawaiian or Pacific Islander, Asian, other, or Multiracial); and able to read and communicate verbally in English. Survey participants were asked to provide electronic consent. Focus group participants were recruited from the sample of survey participants. Focus group members provided verbal consent. Participants were offered a US $25 gift card for participating in the study survey and US $50 for participating in the study focus group.

Measures

Survey Measures

Web-based survey questions measured self-reported sociodemographics, health behaviors, height and weight, and social media habits and preferences. Sociodemographics included gender (male, female, or nonbinary); age (years); grade level; Hispanic or Latine ethnicity; race (White, Black or African American, Asian, American Indian or Alaskan Native, Native Hawaiian or Pacific Islander, other, or multiracial) with more than one response permitted; and state or territory of residence in the United States. Items from the 2019 Youth Risk Behavior Surveillance Survey were used to assess health behaviors, including number of servings of fruit, vegetables, and sugar-sweetened beverages (SSBs) on a typical day in the past week [17]; number of days engaged in at least 60 minutes of physical activity per day over the past week; number of hours slept on an average school day and a weekend day over the past week; and number of hours engaged in screen time (nonschoolwork) on an average school day.

Survey items on social media habits and preferences assessed current use of major platforms (TikTok, Instagram, Twitter, Facebook, Snapchat, YouTube, Tumblr, Reddit, and Pinterest) as well as asked participant to identify their single most-used platform. Participants reported usage frequency (several times a day, once a day, 3-5 times per week, 1-2 times per week, every few weeks, and less often) for each platform of interest and were asked to identify their preferred platform to receive health information and connect with other adolescents of color on health behaviors.

Focus Group Measures

A trained facilitator asked a series of open-ended questions assessing social media usage and preferences, health-related concerns, and design and content preferences for a social media intervention to address obesity risk behaviors (see Multimedia Appendix 1 for guide).

Data Analysis

Quantitative Survey Data Analysis

Descriptive statistics were compiled to characterize the study population according to sociodemographics, health behaviors, social media usage, and age- and gender-adjusted BMI-based weight status categories. Race and Hispanic or Latine ethnicity were combined into mutually exclusive race and ethnicity categories: Hispanic or Latine; non-Hispanic Black; non-Hispanic Asian; or non-Hispanic other or multiple races. BMI was computed from self-reported height and weight and classified based on age- and gender-specific percentiles as follows: underweight (<5th percentile), healthy weight (5th-84th percentile), overweight (85th-94th percentile), and obese (>95th percentile), with missing or implausible responses excluded. Average daily screen time combined the number of hours watching television and using video games and computers.

For participants who did not respond to the question on single most-used social media platform (n=23), a most-used platform was imputed based on their reported usage frequency of each platform, resulting in 93 responses for this measure. Overall social media usage frequency (several times a day, once per day, or less than once per day) combined the reported frequency of use for each individual platform and was defined as frequent usage if the frequency exceeded once per day.

Differences in health behaviors, social media habits, and covariates of interest by gender (male vs female) and weight status (underweight or healthy weight vs overweight or obese) were explored using chi-square tests. Data presented in the tables were not stratified by gender or weight status as the study was not powered to detect differences by these characteristics, and data were not compared by race or ethnicity, state of residence, or social media usage frequency because the sample lacked sufficient distribution across subgroups. All analyses were conducted using SAS (version 9.4; SAS Institute).

Focus Group Data Analysis

Focus group audio was transcribed verbatim and thematically analyzed by study staff. The analysis used a directed content analysis approach, where common themes were identified by a study staff member and used to formulate an initial codebook [18]. Two independent coders reviewed the transcripts and codes and revised the codebook to incorporate additional themes as needed. Initial interrater agreement of coding was 85.7%; discrepancies were resolved via discussion until 100% consensus was reached. The 2 coders also identified quotes that represented themes from focus group discussions.

Results

Survey Results

A total of 101 adolescents of color (mean age of 16.4, SD 1.3 years) completed the survey. An equal proportion (48.5%) identified as male and female, and 3.0% identified as nonbinary. The majority of respondents indicated Hispanic or Latine

ethnicity (79.0%) and California residence (63.4%). Over half of the participants (53.6%) had BMI in the healthy weight category, followed by overweight (25.8%) and obese (17.5%). Social media usage frequency exceeded once per day for 88.1% of survey participants (see Table 1 for additional characteristics). The top most-used social media platforms included TikTok (40.9%), Instagram (17.2%), Snapchat (11.8%), and Twitter (8.6%; Table 2). The majority of survey participants reported some use of TikTok (80.2%) and Instagram (71.3%). TikTok was also the most frequent response for preferred platform to receive health advice (55.4%) and connect with others (44.0%).

Table 1. Characteristics of 101 adolescents of color in a mixed methods social media study (2021).

Characteristics	Values
Gender, n (%)	
Male	49 (48.5)
Female	49 (48.5)
Nonbinary	3 (3.0)
Age, mean (SD)	16.4 (1.3)
Race and ethnicity[a], n (%)	
Hispanic or Latine	79 (79.0)
Non-Hispanic Black or African American	12 (12.0)
Non-Hispanic Asian	3 (3.0)
Non-Hispanic other or multiple races	6 (6.0)
State of residence[b], n (%)	
California	63 (63.4)
Massachusetts	28 (28.3)
Other states	8 (8.1)
Social media usage frequency, n (%)	
Once per day or more	89 (88.1)
Less than once per day	8 (7.9)
BMI[c], mean (SD)	24.6 (5.2)
Underweight or healthy, n (%)	55 (56.7)
Overweight, n (%)	25 (25.8)
Obese, n (%)	17 (17.5)
Health behaviors	
Number of days engaged in moderate to vigorous physical activity at least 60 minutes per day over the past 7 days, mean (SD)	4.1 (2.2)
Engaged in daily moderate to vigorous physical activity at least 60 minutes per day, n (%)	27 (26.7)
Number of fruit and vegetable servings consumed per day, mean (SD)	4.3 (2.5)
Consumed at least 5 servings of fruits and vegetables on a typical day over the past 7 days, n (%)	44 (43.6)
Number of sugar-sweetened beverage servings consumed per day over past 7 days, n (%)	1.8 (1.4)
Consumed 0 or 1 servings of sugar-sweetened beverages per day on a typical day over the past 7 days, n (%)	54 (53.5)
Screen time (hours per day) over the past 7 days, mean (SD)	4.4 (2.8)
Hours slept per night on a typical school night over the past 7 days, mean (SD)	7.2 (1.3)
Slept at least 8 hours per night on a typical school night over the past 7 days, n (%)	39 (38.6)

[a]Race or ethnicity information was missing for 1 respondent.

[b]State of residence was missing for 2 respondents.

[c]BMI was calculated based on self-reported height and weight. Height or weight data for BMI were missing or implausible for 4 respondents.

Table 2. Social media platform usage among 101 adolescents of color in a mixed methods study (2021).

	Ever used platform (N=101), n (%)	Most used platform (N=93), n (%)	Preferred platform for advice on health behaviors (N=101), n (%)	Preferred platform to connect with others on health behaviors (N=100), n (%)
TikTok	80 (80.2)	38 (40.9)	56 (55.4)	44 (44.0)
Instagram	72 (71.3)	16 (17.2)	17 (16.8)	22 (22.0)
YouTube	70 (69.3)	7 (7.5)	2 (2.0)	4 (4.0)
Snapchat	65 (64.4)	11 (11.8)	4 (4.0)	7 (7.0)
Twitter	41 (40.6)	8 (8.6)	10 (9.9)	8 (8.0)
Pinterest	35 (34.7)	3 (3.2)	N/A[a]	N/A[a]
Facebook	32 (31.7)	6 (6.5)	6 (5.9)	10 (10.0)
Reddit	17 (16.8)	2 (2.2)	1 (1.0)	0 (0.0)
Tumblr	3 (2.97)	0 (0.0)	0 (0.0)	1 (1.0)
Other or none	N/A	2 (2.2)	5 (5.0)	4 (4.0)

[a]N/A: Not applicable; Pinterest was not offered as a survey choice for this question.

Compared to males, female adolescents were less likely to engage in 60 minutes or more of moderate to vigorous physical activity daily (16.3% vs 38.8%; *P*=.01) and consumed more daily servings of SSBs (mean 2.0, SD 1.4 vs mean 1.4, SD 1.3; *P*=.04; results not shown in tables). No other significant differences were found between male and female participants in terms of age, social media usage frequency, screen time, BMI, fruit and vegetable intake, or sleep measures. Participants with overweight or obesity were significantly more likely than those with healthy weight or underweight to report consuming more than one daily serving of SSBs (66.7% vs 45.5%; *P*=.04; data not shown in tables). No other significant differences in health behaviors by weight status were observed. We were unable to assess whether weight status or health behaviors varied by frequent social media usage due to an insufficient number of respondents (n=12) reporting usage frequency of once per day or less (Table 1).

Among the 93 participants with data on a single most-used platform (TikTok, Instagram, Snapchat, Twitter, or all other platforms combined), a significant difference was found in the distribution of most-used social media platform by gender (*P*=.03). Among males, TikTok was the most-used platform for 40.0% of respondents, followed by Instagram (22.2%) and Twitter (15.6%). Only 4.4% of males reported Snapchat as their most-used platform. Female respondents also reported TikTok as their most-used platform (41.3%), followed by Snapchat (19.6%) and Instagram (13.0%), with only 2.2% of females reporting Twitter as their most-used platform. The distributions of the most-used social media platform, preferred platform to receive health advice, and preferred platform to connect with others did not vary significantly by weight status (data not shown in tables).

Focus Group Results

Overview

A total of 20 adolescents of color ages 14-18 years (80% female) from 8 youth-based settings participated in 1 of 3 web-based focus groups for the qualitative portion of this study. Using a directed content analysis approach, 4 themes were identified and coded based on the focus group guide: preferred social media platform, purpose of platform use, satisfaction and engagement with platform, and preferences for healthy weight management content and delivery. These themes are summarized in Table 3 and presented alongside illustrative quotes.

Table 3. Illustrative quotes by theme from focus groups with 20 adolescents of color in a mixed methods social media study (2021).

Themes	Illustrative quotes
Preferred social medial platform (overall)	
TikTok	• "TikTok [has] a lot of versatility to it…there's more than one thing you can do…you can watch videos, or you can make them, and it's just fun to do." • "TikTok would be my favorite app… you can meet new people through comments and stuff like that, so I think that's fun about it." • "TikTok literally has everything you can search… all the other social media [platforms] keep up with people's [lives] instead of learning stuff."
Instagram	• "I use Instagram because I like seeing what's going on in the world." • "There's like a lot of pages, especially on Instagram…that show appreciation for having darker skin or…having a certain type of body."
Platform preference use by purpose or function	
Variety and entertainment	• "[TikTok] is just nonstop content…literally never ending…it'll just make you laugh the whole time." • "Tik tok literally has everything…you can search for [dance, art, health]…for other social media platforms, you [see] other people's loves."
New content and information	• "[On TikTok] there's always something new…give you new ideas." • "If you ever want to learn something…there's multiple creators [on TikTok] who are specifically posting content about that topic." • "TikTok has taught me…a lot of stuff that they don't teach you in school." • "If I can't find it [on TikTok]…then I will go on on YouTube and find it because YouTube has a lot of various options as well."
Messaging and communication	• "I use Instagram a lot to message my friends and family members because we all use Instagram to message each other." • "[For Snapchat], you can communicate a message directly with friends, and then you can post stories to it as well." • "I usually use Snapchat to…connect with friends and see what my friends are doing…on a daily basis." • "Snapchat [is] the way I can talk to people without having their contact information."
Maintaining real-life connections	• "Snapchats [are] the main communication when I talk to my friends." • "I use Facebook to reach out to people, mostly to stay connected with my family, my friends, because it's very easy to tag people."
Satisfaction and engagement with platform	
TikTok	• "TikTok would be my favorite app… you can meet new people through comments and stuff like that, so I think that's fun about it." • "Time goes by so fast and you're laughing…you just keep scrolling and clicking…it kind of like changes your mood."
Preferences for health weight intervention content and delivery	
TikTok as platform for health content; Instagram for live engagement	• "I like to follow a lot of health content [on TikTok]." • "I prefer TikTok…they do help videos [that you can] incorporate with your life and…the things you do daily." • "Instagram and TikTok are the ones to go to because those are the ones that platforms that spread the most information." • "Instagram Live is…more popular…. getting questions from [the] audience really helps because a lot of people [can] relate… … they're asking different questions that you might have thought of, or you haven't [thought of]." • "Instagram…[is] a good one would where everyone could interact."

Themes	Illustrative quotes
Content on physical and mental health	• "I think that people could benefit [from nutrition and exercise content] because we're young…and it's easier for us to lose weight…when you're an adult, it's a lot harder to lose weight. So you can start making a change now so you can be better off in the future." • "[Content on] physical and mental health….because you got to be mentally motivated for a physical kind of thing." • "Promoting mental health more…nobody actually talks about their emotions [or] problems, they keep it inside and hide it." • "[Content on] my mental health and also my physical health, like my diet and my weight in particular. I'm very conscious about it."
Peer messengers and trusted sources	• "[On TikTok] we see…people who work in the medical field…who have training." • "[On] Tik Tok…you can follow certain creators for the content that you want to see like…like an OB/GYN I know…I follow [her]." • "[I want to hear from] people our age…because they know what we are going through and have the same mindset." • "[It] felt good, very good to see somebody like in your shoes, and then see them get better, because it's very encouraging." • "I know I'm like not the only one… finding people that are like relatable to me would help..."
Relatable posts and users on healthy eating and physical activity	• "[It's] very good to see somebody in your shoes, and then see them get better, because it's very encouraging…[you realize] it's not just me, I could do it too." • "…People relate more when they see people [who] look like them talking about [health information]…people of all different races and all different body shapes, all different sexes…"
Frequent microhealth tips	• "I like when people give out a little tip… little steps to help you get through the day…those are really helpful." • "if you keep seeing it over and over…it's going to motivate you even more." • "…it helps when the [creator] is consistent or the page is consistent with new content."
Design methods to enhance engagement	• "try to include [the post] with new songs today…songs that we all know…it [makes it] more pleasing to look at instead of somebody's just talking to you about it."

Preferred Social Media Platform (Overall)

TikTok emerged among focus group participants as the overall preferred platform of choice generally and with respect to health content. Most participants preferred TikTok due to its versatility, tailored content for the individual user, and options for multiuse engagement (watching, making videos, and interacting with other users through comments, liking, sharing, and dueting). The majority of participants also described initiating use or engaging in more frequent use of TikTok as a result of being isolated from their peers during the first year of the COVID-19 pandemic. Instagram emerged as the second most preferred platform with ease of being able to visually share information and updates, follow and engage with people outside of one's personal network (eg, influencers and celebrities), and connect with real-life network members (eg, family members, friends, and classmates).

Platform Preference by Purpose or Function

Participants discussed using multiple social media platforms for different purposes. With respect to obtaining new content or information and entertainment, TikTok emerged as the preferred platform. With respect to frequent (eg, daily and weekly) messaging and engaging in conversation with others, including interfacing with new individuals or accounts, Snapchat and Instagram were identified as the preferred platforms. In terms of maintaining real-life connections (eg, longer-term updates) with family members and friends, participants identified using Snapchat, Instagram, and Facebook.

Satisfaction and Engagement With Platforms

The majority of focus group participants discussed TikTok as yielding the highest amount of satisfaction and engagement. Participants reported that often learning or being exposed to something uplifting, positive, or humorous (resulting in improved mood) on TikTok and that this platform offered a variety of content that was constantly tailored to user preferences. Participants also valued TikTok as a platform for its novelty ("always something new to see") and relatability ("can always find something [or someone] to relate to"). The second most preferred platform was Instagram, where participants enjoyed viewing updates, viewing inspirational content, and seeing representation of other peers.

Preferences for Weight Management Content and Delivery

Key suggestions and preferences for healthy weight management content and delivery via social media that participants voiced included content that addressed the intersection of mental and physical health (eg, body image and the types of strategies to engage in healthy eating and physical activity that also improve mental well-being); peer messengers and information from trusted sources (eg, health care providers and health experts); posts or content that were relatable (eg, information, strategies, and stories from people going through similar experiences); and consistency and frequency in posting content on small, attainable behavioral goals (eg, frequent micro tips on healthy eating or exercise routines). Participants' views on the ideal source for

health-related content were mixed; some participants wanted to see content from health professionals only, whereas other participants preferred to view content from peers with the same everyday, lived experiences.

Discussion

Principal Findings

This mixed methods study is the first to our knowledge to examine social media platform use, design, and content preferences for social media–delivered weight management interventions among adolescents of color. Participants in our study reported most frequently using TikTok, followed by Instagram, Snapchat, and Twitter, and preference for platform varied by purpose of use. Participants reporting using TikTok primarily for entertainment, consumption, and creation of content, Snapchat and Instagram for frequent communication or messaging, and a variety of platforms (Snapchat, Instagram, and Facebook) to stay connected with family, friends, and peers. These findings are similar to a small pilot study conducted among adolescent girls aged 12-18 years who reported using Snapchat and Instagram as ways to communicate and stay connected with friends [15].

In concordance with recent trends on social media use among US teens ages 13-17 years from a 2022 Pew Research Center report, TikTok was the most popular social media platform reported by our sample of adolescents of color aged 14-18 years, followed closely by Instagram and Snapchat [14]. These patterns were reflected in both the study's survey and focus group data. Findings from our study are also in line with 2022 Pew data indicating higher shares of Black and Hispanic teens reporting usage of TikTok, Instagram, and Twitter compared with White teens. Focus group data from our study also support prior research findings that while adolescents are often exposed to health information via social media, they more frequently turn to websites versus social media when proactively searching for health information and are aware of the need to evaluate the accuracy and trustworthiness of health information obtained on the internet [19-21].

Importantly, our study added to the literature by examining adolescents' preferred platform by function (information vs connection) in the context of a healthy weight management intervention and solicited open-ended input from adolescents of color on their preferences for health intervention content, design, and delivery. Quantitative and qualitative data from this study highlighted TikTok as one of the top preferred platforms of choice for learning new information on healthy weight management, and TikTok and Instagram as preferred platforms for connecting with others (eg, live discussion, commenting, and supporting) on healthy weight management behavioral changes. This study additionally identified adolescents' specific healthy weight intervention design preferences, such as trusted sources for health information (health professionals and peers), consistency and high frequency of content exposure, importance of being able to relate to others through content (creator or story is one that they can identify with) or connection (engaging with other viewers going through similar experiences), and priority topics they would find engaging and relevant (intersection of physical and mental health).

Compared to national estimates, the prevalence of certain health behaviors among our target sample of adolescents of color (majority Latine) differed; 44% of our study sample reported consuming 5 or more servings of fruits and vegetables daily and 39% reported sleeping 8 or more hours per night compared to 15% and 26% of adolescents from the 2017 Youth Risk Behavior Surveillance Survey, respectively [22]. With respect to interest in intervention content on physical fitness, diet, and mental health, our study findings were consistent with a prior study on social media use and mental well-being among participants aged 14-22 years that reported fitness, nutrition, stress, anxiety, and depression as the top 5 topics searched on social media platforms [23].

To date, there is a lack of research on healthy weight management or obesity interventions delivered via social media among adolescents in the United States. A few studies have examined the efficacy of mobile health interventions targeting diet, physical activity, and BMI among adolescents with promising improvements in certain health behaviors, though the vast majority of these interventions are app or text-based, are not delivered via social media, and lack adequate representation of participants of color [24-26]. One pilot intervention study targeting weight-related behaviors among primarily White adolescents aged 14-18 years incorporated social media (Facebook) as an intervention component to enhance engagement [27]. Participants in the aforementioned study experienced an average increase in steps, though the majority of participants reported preferring other social media platforms such as Instagram over Facebook for intervention purposes. This body of literature combined with findings from this study highlights gaps in the field in leveraging social media as an intervention modality to promote healthy eating and physical activity among adolescents, particularly those of color.

Given the high rates of social media use among adolescents and the prevalence and fast spread of inaccurate health information on social media, the following design considerations, based on our results, may be helpful to guide the development of social media–delivered interventions targeting healthy weight management behaviors among adolescents of color [28]. These include designing content that can be readily disseminated via multiple platforms to reach multiple audiences; matching intervention activities with platforms that are most suited to meet the activity's purpose (eg, knowledge transfer, connect with others, and sustain motivation); collaborating with adolescent peer leaders to co-design and deliver content to enhance engagement and relatability of content; incorporating frequent microhealth tips; and integrating discussion of physical and mental health topics.

Study strengths include the recruitment of adolescents of color who experience disproportionately higher rates of obesity and are underrepresented in health research and the use of quantitative survey and qualitative focus group methodology to understand patterns and preferences for a social media–based intervention targeting healthy weight management behaviors. Qualitative data provided additional context of the reasons

behind participants' preferences of certain social media platforms over others, why certain platforms were preferred for a social media–based intervention targeting healthy weight management, and what respondents felt should be included in such an intervention. Study limitations include a relatively small sample size of 101 survey respondents and 20 focus group respondents (compared to larger polls or cohort studies), where most focus group respondents were female (thus limiting the male perspective); cross-sectional assessments, which limit our ability to examine changes over time; the use of self-reported measures, which may be subject to recall and social desirability bias; selection bias (eg, participants with greater interest in healthy eating and physical fitness may be more likely to participate in this study than those who did not); and convenience sampling, which resulted in a majority Latine sample recruited from Massachusetts and California, thus limiting generalizability of study findings.

Conclusions

Given the near ubiquity and high prevalence of social media use among adolescents and adolescents of color, a social media–delivered intervention has a high potential to reach and engage adolescents of color in healthy weight management behaviors. Findings from this study, along with further partnership with adolescent peer leaders, can be used to begin to inform the choice of platform and development of content and strategies for future social media–delivered interventions for youths of color and subsequent efficacy trials of intervention approaches tailored for this population.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Focus group guide for 20 adolescents of color participating in a mixed methods pilot social media study.
[DOCX File , 16 KB - pediatrics_v6i1e43961_app1.docx]

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Abbreviations

BGC: Massachusetts Alliance of Boys & Girls Clubs
SSB: sugar-sweetened beverage

Edited by S Badawy; submitted 31.10.22; peer-reviewed by M Katzow, D Young; comments to author 24.01.23; revised version received 21.03.23; accepted 10.04.23; published 08.05.23.

Please cite as:
Alatorre S, Schwarz AG, Egan KA, Feldman AR, Rosa M, Wang ML
Exploring Social Media Preferences for Healthy Weight Management Interventions Among Adolescents of Color: Mixed Methods Study
JMIR Pediatr Parent 2023;6:e43961
URL: https://pediatrics.jmir.org/2023/1/e43961
doi:10.2196/43961
PMID:37155230

Review

Social Media Interventions for Nutrition Education Among Adolescents: Scoping Review

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Abstract

Background: Adolescence is a critical period for reinforcing healthy dietary behaviors and supporting the development of cooking skills. Social media may be an avenue for supporting these behaviors, as it is popular among adolescents and can improve access to nutrition education interventions. This study sought to understand the optimal implementation of effective social media–based nutrition education interventions to inform the implementation of future social media–based nutrition education interventions.

Objective: A scoping review of the characteristics, feasibility, effectiveness, and factors influencing social media–based nutrition education interventions for adolescents was conducted.

Methods: We searched MEDLINE, Embase, CINAHL, Web of Science, and PsycINFO databases using a predefined search strategy. Primary research articles were independently screened and included if they involved adolescent populations (10-18 years old) and delivered nutrition education through social media. The information on intervention characteristics, feasibility, effectiveness, and factors influencing social media–based nutrition education interventions was extracted.

Results: A total of 28 publications out of 20,557 met the eligibility criteria. Twenty-five nutrition interventions were examined by 28 studies. Fourteen interventions used homegrown social media platforms, 8 used Facebook, and 2 used Instagram. Feasibility outcomes were infrequently reported, and the cost of intervention delivery was not reported. Engagement with interventions was variable; high engagement was not required to elicit significant improvements in dietary behaviors. Tailoring interventions, offering practical content, meaningful peer support, and involving families and communities facilitated successful interventions. Strategies to address engagement and technical issues were varied.

Conclusions: Emerging evidence demonstrates that social media interventions for adolescent nutrition are acceptable and improve nutrition outcomes. Future interventions should strengthen peer support components and tailor delivery to specific populations. Further research should examine engagement, adherence, and the impact of interventions on behavioral and physical outcomes. This review is the first to examine the use of social media as the primary medium for nutrition education for adolescent populations. The analysis used in this review argues the importance of peer support in social media–based nutrition interventions and the need for user-centered design of the interventions.

(JMIR Pediatr Parent 2023;6:e36132) doi:10.2196/36132

KEYWORDS

adolescents; digital health intervention; food literacy; health literacy; nutrition; peer education; peer support; social media

Introduction

Poor nutrition, such as the consumption of highly processed foods and infrequent consumption of vegetables, is directly linked to a multitude of preventable chronic illnesses, including ischaemic heart disease, diabetes, cancer, and poor mental health [1]. Dietary behaviors are influenced by a complex set of factors, including food security, social environments, attitudes and beliefs about food, and nutrition and food literacy [2-11]. Food and nutrition literacy are the skills and knowledge that allow individuals to prepare and eat good-tasting, healthy, and affordable foods on a daily basis and are linked to improved diet quality in adolescence [12,13]. Rates of preventable chronic illness will continue to increase, particularly in young people, if modifiable factors influencing nutrition are not addressed [14].

Cooking skills during adolescence also track into adulthood and are predictive of diet quality (eg, vegetable consumption) and confidence in cooking abilities in adulthood [15,16]. Behavioral patterns established during adolescence influence adolescents' risk of developing chronic illnesses during adulthood and their current health. However, opportunities for learning cooking and food preparation skills have decreased in school and at home, and family meals have decreased due in part to parental precarious work, poor housing conditions, and the use of devices and media during mealtimes [17-20]. Thus, promoting food and nutrition literacy during adolescence is an important component of a multipronged chronic illness prevention strategy [21,22].

Interventions for food and nutrition literacy have positive impacts on adolescents' nutrition knowledge, self-efficacy in cooking skills, and dietary behaviors [13,23-26]. Technology-based interventions, especially social media, are recommended to effectively engage adolescents, especially older adolescents [23,24]. Adolescents are especially sensitive to their social environments (eg, peers and social media) and use social media to socialize and learn new information, making social media an important avenue for health promotion [27,28]. Irrespective of income level, 95% of adolescents today use mobile phones, and upwards of 70%-80% of adolescents use social media (eg, Instagram or Snapchat) [28].

However, the effective design and implementation of social media interventions for nutrition in adolescents remain unclear [29]. One review of social media interventions for nutrition in adolescents and young adults found some positive impacts on BMI and dietary intake. However, the components of the interventions eliciting positive impacts, especially for adolescents from low socioeconomic status (SES) communities, remained unclear [29]. Adolescents from low SES communities are at the highest risk of poor nutrition due to food insecurity, uncertain or limited access to healthy foods, and lower food and nutrition literacy due to poor housing conditions and parental precarious working conditions [7,15-20,30-39]. To inform the development and evaluation of a social media–based food literacy intervention for adolescents from low SES settings, we sought to conduct a scoping review of the evidence on social media–based interventions for nutrition outcomes among adolescents. This review differs from previous reviews in several ways: we focused on adolescent populations as there are several implementation issues (eg, privacy and consent) and differences in food environments for this population (eg, living with parents or guardians); we used a broader search strategy and inclusion criteria, including earlier studies (2000 onward) and qualitative and quantitative studies, and we sought to identify any barriers and facilitators to the interventions and highlight factors that were specific to adolescents from low SES communities. Our research questions were:

1. What are the characteristics (eg, platform or frequency) of social media interventions used to address nutrition outcomes in adolescents?
2. What is the feasibility (eg, dropout rates or cost) of delivering interventions using social media for improving nutrition outcomes in adolescents?
3. What is the effectiveness of social media interventions in achieving positive changes in nutrition outcomes (eg, attitudes about nutrition, BMI, or dietary intake) among adolescents?
4. What factors influence the implementation and success of social media interventions for nutrition outcomes?

Methods

We conducted a scoping review, as articulated by Arksey and O'Malley [40]. We chose a scoping review over a systematic review methodology due to our broader research questions and overarching aim to inform the development and evaluation of a social media–based food literacy intervention for adolescents from low SES settings [40].

Literature Sources and Search Strategy

The search strategy was developed in collaboration with a medical library information specialist. It combined subject headings and text words relating to the main concepts using "AND" and "OR." The search concepts were (1) social media, (2) children or adolescents, and (3) nutrition-related interventions. Searches of relevant electronic bibliographic databases (MEDLINE, Embase, CINAHL, PsycINFO, and Web of Science) for published work meeting the inclusion criteria were conducted, restricted to the years 2000 to April 7, 2022, with no language restrictions. We limited searches to the years 2000 and onward, corresponding with the emergence of social media for public use. We chose to include earlier studies with the earliest forms of social media because the essence of social media, which is peer-to-peer sharing and user-generated content, has remained consistent irrespective of the changes in platforms and technology over time. Reference lists of primary studies included in the review and of any relevant, previously published reviews were hand-searched. We initially reviewed the gray literature but decided not to include it to maintain the feasibility of the review. The gray literature we reviewed did not include evaluations of the interventions that were not already published in a peer-reviewed journal. A search strategy is available on request.

Selection Criteria and Screening Process

We included publications in peer-reviewed journals meeting the following criteria: (1) population ages of 10-18 years old,

as consistent with previous literature in this area and World Health Organization definitions of adolescence or described as adolescents; (2) social media as the primary intervention or a component of a complex intervention; (3) primary intervention provided nutrition education; and (4) conducted an evaluation of the social media intervention. All empirical study designs were included. Conference abstracts, guidelines, protocols, editorials or commentaries, dissertations, and reviews were excluded. Relevant reviews were examined for any potentially eligible studies, and dissertations were used to identify peer-reviewed publications. Social media was defined as electronic communications allowing for the creation of user-created communities and the sharing of information, personal messages, ideas, and audiovisual content [41]. Examples of social media include applications and websites such as Facebook, TikTok, and Instagram; forums (eg, Reddit); microblogging (eg, Twitter); and social bookmarking (eg, Pinterest) [42].

A calibration exercise was completed to ensure screening consistency and agreement; a random 10% subset of references was screened by 2 review authors (YK and BP), achieving an initial agreement of 97%. Any disagreements were resolved by discussion to achieve 100% agreement. Following the calibration exercise, the titles and abstracts of retrieved studies were screened independently by at least one review author (YK or BP) to identify studies that potentially met the selection criteria. The same exercise was completed again for full-text screening, achieving 95% agreement initially and 100% agreement following discussion. The screening was conducted using Covidence systematic review software [43].

Data Extraction

Data extraction was conducted on Excel (Microsoft Corp) using a prepiloted form developed by the review authors to independently extract data [44]. Extracted information included: study context (eg, country and setting); intervention characteristics (eg, platform and content); population demographics (eg, ages and gender); study methodology (eg, study design); quantitative and qualitative study results; and study discussion and conclusions.

Data Synthesis

We descriptively summarized study characteristics, intervention characteristics, and feasibility outcomes that were extracted from the included studies. Qualitative results from studies were analyzed using qualitative content analysis to identify and summarize factors influencing the implementation and success of the intervention. Data included in qualitative analyses included survey data, focus group discussions, individual interviews, and observation and field notes made by research staff during programs.

Results

Study Characteristics

A total of 20,557 unique references were retrieved through database searches and screened for inclusion based on the selection criteria. Of these, 28 studies of 25 distinct interventions met the inclusion criteria and were included in the review. See Multimedia Appendix 1 for the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram, including reasons for exclusion at the full-text screening stage. Fourteen studies were from the United States, 3 from Spain, 2 from Malaysia, 2 from Canada; and the remainder were from Brazil, Denmark, France, Indonesia, Portugal, and South Korea. Eleven studies were randomized controlled trials, 3 of which were cluster randomized controlled trials; 8 studies were pre-post designs, 2 of which were feasibility studies; 4 studies were quasi-experimental pre-post with control group designs; 2 studies were process evaluations; 2 studies were qualitative evaluations; and 1 study was a usability study. See Table S1 in Multimedia Appendix 2 for the characteristics of the included studies.

Study Participant Characteristics

Total sample sizes ranged from 13 participants to 2001 participants. Four interventions were for females only; 11 studies had mostly female participants (60% or more); and 2 studies did not report the sex or gender of participants. Sixteen studies reported on race or ethnicity, 13 of which were from the United States, 1 from Malaysia, 1 from Canada, and 1 from Spain and Mexico. Of the 13 studies from the United States, 7 had mostly (50% or higher) Caucasian participants, 9 studies reported a proportion of African American participants (mean 22%; range 1.4%-46.2%), 7 studies reported a proportion of Latino or Hispanic participants (mean 20%; range 7.3%-43.5%), 1 study reported 16% of Asian participants, 1 study reported 4.9% American Indian or Alaska Native participants, 1 study targeted only Korean American participants, and 8 studies reported proportion of other or multiethnic categories (mean 17.6%; range 7.6%-46.7%). Four studies reported on the SES of participants using varying definitions and categorizations of SES, summarized in Table S1 in Multimedia Appendix 2. Eleven studies targeted adolescents who were considered overweight or obese. See Table S1 in Multimedia Appendix 2 for characteristics of included studies.

Social Media Interventions

Intervention durations were between 6 weeks and 2 years with the most common length being 12-16 weeks (9/22, 41%; 3 studies did not report length). Most interventions used homegrown websites with social networking functions (10/25, 40%), 4 (16%) interventions used homegrown mobile phone apps, 8 (32%) used Facebook, 2 (8%) used Instagram, and 1 (4%) used an unspecified social networking service. Homegrown platforms included discussion forums, chat functions, resource centers, games, and education modules. Thirteen studies involved additional intervention components (17/25, 68%), including attendance at a weight management clinic, intermittent face-to-face group meetings or meetings with a health professional, text message reminders, weekly newsletters, weekly quizzes, web-based rewards for healthy goal setting, informational websites, changes to the school curriculum, a food diary, exergaming, and a new food labeling system at the school cafeteria. In addition to nutrition education, 16 interventions addressed physical activity and exercise; 7 interventions addressed weight management, weight loss, and obesity; 5 interventions addressed eating disorders, body image,

or related symptoms and behaviors; and 2 interventions addressed stress management. Nine interventions (9/25, 36%) involved parents, with parent-specific websites or newsletters, or providing intervention access to parents. Ten interventions (10/25, 40%) reported how they were developed, 8 used feedback from or the involvement of adolescents to design the intervention, and 2 used an iterative user-centered design process. Four interventions were designed by educators or health care providers. No interventions reported including a cooking skills component to the intervention. See Table S2 in Multimedia Appendix 3 for a summary of social media intervention characteristics.

Feasibility

Most studies did not report recruitment rates (17/25, 26%), while 3 (16%) recruited participants in a short period of time (eg, 1-3 weeks) at the start of the intervention. Twelve studies reported dropout rates, ranging from no dropouts to 68% dropout; however, most (7/12) were between 0% and 22%. Eight studies (8/24, 33%) reported some program costs: 5 gave participants gift certificates or compensation (US $20 to US $50) for outcome measures or study completion; 2 used prize contests to motivate increased participation; 2 provided participants with equipment (eg, iPhone and digital food scale) to participate in the intervention; 1 allowed participants to "cash in" points from adhering to the intervention to redeem at local merchants; and 1 provided a US $25 monthly incentive to assist participants with mobile data costs [45]. See Table S3 in Multimedia Appendix 4 for a summary of feasibility outcomes.

Factors Influencing Implementation and Success of Interventions

Overview

Factors influencing the implementation and success of interventions were categorized into the following themes: role of families and communities, tailoring interventions for the target population, engagement, technical and logistical issues, and peer support. See Table S4 in Multimedia Appendix 5 for a complete summary of categories.

Role of Families and Communities

Studies reported that parents' inclusion in programs elicited positive impacts on participants, irrespective of their level of involvement, and that positive behavior changes among participants diffused to their families and peers [46-53]. When considering parents' inclusion in programs, studies suggested that parental digital literacy needed to be considered as well as whether their involvement would detract from the independence adolescents would be attempting to achieve during this period of development [47,53,54]. Conversely, the positive impact of including families in interventions needed to be balanced with intervention content that addressed interpersonal barriers to healthy eating, such as peer and family pressure, lack of parental support for healthy eating, lack of control over food at home and in social settings, and tensions with cultural foods and healthier food choices [52,55,56]. Designing interventions in concert with community partners aided in the planning and delivery of the intervention, identifying improvements, and ensuring intervention sustainability [48,57-62].

Tailoring for Target Population

Studies recommended selecting social media platforms according to the target population, as differences in usage of platforms may exist between genders, SES levels, age groups, and countries [47,48,52,54,55,63]. Adolescents preferred content presented in actionable terms; frequent opportunities for peer interaction; examples of good-tasting healthy food; minimal, low-cost ingredient simple recipes; and culturally relevant content [48,52,55,59,61,64,65]. Studies found that content should be reviewed ahead of delivery to avoid stigmatizing messaging and encourage healthy lifestyles [52,63,64,66-69]. Finally, including adolescents' feedback at all stages of the research was effective in ensuring the relevance of interventions to youths [47,51,56,59,62,64].

Engagement

Participants were more motivated to engage with interventions when they were involved in existing peer networks and peer support and used social media platforms that they already use [48,57,59,63,64,68-70]. Strategies, such as notifications and message prompts; adjunct in-person meetings; peer leaders, educators, and mentors; and greater intervention guidance, facilitated engagement [45,48,57,58,64,67-70]. Low or passive engagement may be enough to elicit preliminary improvements in dietary behaviors [54,58]. However, for future interventions, dynamic and responsive social media environments similar to media that adolescents already engage with would be essential to maintain adolescents' engagement in the intervention and nutrition education more broadly [48,67,71].

Technical and Logistical Issues

To ensure the success of interventions, studies recommended using platforms that participants already use, adapting to changes in social media, testing social media functionalities regularly, counseling participants on privacy and safety on the internet, creating privacy and safety contingency plans, and ensuring access to devices and the internet [45,48,52,59,62,65,70,72].

Peer Support

Nutrition education delivered through social media needed to involve meaningful peer support to facilitate sustainable changes in health behaviors [45,48,52,61,63,67-69]. Effective peer support was drawn from participants' existing social networks, from individuals whose opinions and judgments they valued, and from those who were from similar backgrounds [45,48,52,61,63,67-69]. Several mechanisms of influence explain the role of peer support in health behavior change using social media [48,49,52,68,69]. Thus, studies reported some uncertainty regarding how interventions should be designed to facilitate health behavior change [48,49,52,68,69].

Discussion

Summary

We sought to review the literature on social media interventions for nutrition in adolescent populations. Twenty-eight studies met our eligibility criteria and were included in the synthesis. The interventions were highly varied, although generally, they used similar social media platforms (eg, Facebook, homegrown

websites, or apps) and duration (12-16 weeks). The feasibility of interventions could not be adequately assessed due to a lack of reporting and varied dropout rates, engagement, and reported costs. Of the studies examining the effectiveness of interventions, improvements in BMI and dietary behaviors typically occurred between 6 and 9 months of follow-up. Finally, factors influencing interventions suggested that effective interventions must be tailored to populations, offer peer support, and be dynamic and responsive, similar to existing social media environments.

Principal Results

Social media interventions varied in the platform, length, theoretical foundation, format, and content, similar to previous review findings [73,74]. Trends, such as the use of Facebook and websites, reflect the dominant social media platforms from 2007 to 2014 when the top social media platform used by adolescents was Facebook [75]. Yet, the trend in the use of homegrown apps and websites continued into later studies included in this review. This may be due in part to concerns regarding the safety of adolescents when using popular social media, which remains a challenge in delivering these interventions. Today, adolescents report using platforms such as Instagram and Snapchat exclusively on mobile phones [28]. Reviews of social media interventions for child health, HIV treatment and prevention, and smoking, and studies in this review suggest that the best practice is to use existing social media platforms that adolescents already use to increase ease of use and accessibility and reduce costs [76-79]. New platforms may be adopted according to current trends and the target population's usage [76-79]. However, irrespective of technology and platform, studies reported challenges in maintaining adequate peer-to-peer sharing and support. Many studies reported using interpersonal-level theories to inform the design of interventions since a key feature of social media is peer-to-peer sharing. However, few interventions centered on using peer support to achieve behavior change, and the peer educators or mentors had a limited role in the few interventions where they were involved.

There was limited information on feasibility in the included studies. Dropout rates and engagement varied widely when reported, and recruitment rates and cost information were seldom reported. The promise of social media–based health interventions lies in their assumed ability to reach broader geographic regions, increase accessibility, be cost-effective, and effectively engage adolescents; however, no studies have examined the extent to which this occurs. Many existing nutrition education programs are delivered by dieticians or other licensed health professionals or by teachers in schools, have limits on the number of participants they may reach, and vary in terms of their ability to provide tailored content to adolescents, reach broader geographic regions, effectively engage adolescents, and achieve improvements in dietary behaviors [13,23-26]. A clearer understanding of the costs and benefits of the different types of programs can aid decision makers in determining appropriate interventions and sustainability.

The data on the effectiveness of interventions was variable. Some studies demonstrated effects on BMI and dietary behaviors up to a 6- to 9-month follow-up. Similar improvements in dietary behaviors were found in a review of social media interventions for diet and exercise [80]. However, our ability to conclude effectiveness is limited due to the heterogeneity of social media interventions and the presence of multicomponent interventions. While these findings suggest some positive impact of social media interventions on nutrition outcomes in adolescent populations, without an appropriate understanding of dose-response, it is difficult to generalize the findings of these studies to other interventions or populations. Future definitive trials focused on examining effectiveness and dose-response will be needed to better understand these interventions.

We grouped factors influencing interventions into several categories, including the role of families and communities, tailoring for population characteristics, engagement with the intervention, technical and logistical issues, and peer support.

A few studies examined the role of parents in the intervention and suggested that they facilitated engagement with the intervention. Studies that involved parents found that they were facilitators regardless of how involved they were [48-51,81]. Even the act of parents providing consent for adolescents to participate in the intervention had an effect on improving participation [48]. These findings suggest significant involvement among parents may not be an essential component of programs for adolescents and can reduce some of the challenges when targeting low-income or ethnic minority youths, where parental time constraints, language, digital literacy, and other barriers may prevent parents from being involved in the intervention.

Several studies emphasized the role of involving communities in ensuring engagement, sustainability, and success of the intervention. Evidence from a range of health promotion interventions suggests that community-based interventions are most successful in improving nutrition [77,82]. Community partners can continue to deliver successful programs after studies end, streamline recruitment, and increase the acceptability of the program as participants are more likely to participate in a program delivered by familiar people and organizations.

Studies unanimously recommended more tailored approaches to program delivery. However, there was limited information regarding the tailoring of interventions to low SES and ethnic minority populations. Many US-based studies mainly targeted White participants, and others did not report the race or ethnicity of participants, similar to the findings of the systematic review of social media for diet and exercise by Williams et al [80]. However, studies such as Januraga et al [52] reported that interventions need further modifications to resolve participants' tensions between family and culture-centered values, their desire to make healthy changes to their diets, and the interpersonal barriers that adolescents face in advocating for their healthier choices to parents and peer circles. A US study that targeted Korean-American adolescents also reported a need for more culturally tailored information [56]. Evidence on health behavior change in ethnic minority populations suggests that culturally tailored and facilitated interventions are more likely to achieve

improvements in health outcomes [83]. Social media interventions have an opportunity to address these gaps, as official and national dietary guidelines may not address the breadth of diverse populations to the same extent as social media [84]. Among studies designed with youths' involvement, none reported the extent to which youths' preferences for nutrition education content were included. Nutrition education in the interventions was developed based on a variety of sources. Due to the scope of this review, we were unable to contact the authors of studies for further information regarding the nutrition curriculum used for each intervention and examine whether it was evidence-based.

Many studies targeted female participants and had higher female participation than male participation. The focus on adolescent females may be because several studies had the concurrent aim of eating disorder prevention, which affects girls and women at higher rates [85]. However, poor dietary behaviors and obesity affect males at higher rates than females, and males are less likely to engage with health services or be targeted by programs or services than females [86-88]. Furthermore, no studies in this review addressed adolescents who identify along the continuum of gender identity or sexual orientation, despite these adolescents being at greater risk of poor dietary behaviors, obesity, and disordered eating [89].

Engagement with interventions was often reported as a challenge, and several strategies were suggested for improving engagement. Challenges with engagement are frequently reported in other social media–based health interventions, and strategies, such as end user involvement in intervention design and financial incentives for participation, are suggested as potential ways to improve engagement [80]. However, despite involving end users in intervention design and financial incentives, studies in this review still found difficulties in engagement. Instead, feedback from adolescents suggested that leveraging existing friendships and social networks would increase engagement. Furthermore, most interventions in this review were static, with intervention content developed and then delivered with no further changes. Interventions are often "competing" with social media and adolescents consume on a regular basis that involve real-time responsiveness to participant engagement and feedback and tailoring content as social media users interact with it. Social media–based interventions for HIV treatment and prevention that involve dynamic and responsive content and peer-to-peer interaction have found fewer challenges with engagement [76].

Where peer support was active and engaged, participants reported positive experiences and a preference for more opportunities for peer support, a preference that is in line with previous reviews of social media for adolescent health [77]. Reviews of social media interventions for HIV treatment and prevention find that those that involved significant peer or social support components (eg, mentors or the primary aim of peer-to-peer communication) had high participant satisfaction with peer and social support and were linked to higher testing rates [76,90]. The role of peer mentors or educators was minimal in most interventions in our review, with few offering formal training to peer mentors. However, should future interventions incorporate peer mentors or leaders, formal training may ensure the effectiveness of mentor support by providing mentors with appropriate skills and strategies to deliver interventions [91].

Several studies discussed the role of technical issues and the need for them to be solved in real time and addressed ahead of or during the intervention in usability testing. A few studies discussed issues related to privacy and consent for studies. As many studies used homegrown websites and applications, the study teams were able to have greater control over intervention privacy. Studies that used Facebook asked adolescents to create new accounts for the study itself or used private, anonymized pages or groups. This issue requires further attention to ensure the successful implementation of social media–based nutrition education for adolescents without increasing barriers to participation [74].

This review highlighted several potential areas for future research on social media interventions for adolescent nutrition to explore. First, given that the aim of social media is to promote peer-to-peer sharing and communication, interventions should ensure peer and social support remain central to the intervention and are measured as part of outcomes. Second, in the literature reviewed, few described tailoring to ethnic minority populations or targeting populations most vulnerable to poor nutrition. Addressing these issues will be important to reduce health inequities and ensure effectiveness among diverse populations. Many of the studies had a focus on adolescent females or generally had higher rates of adolescent females participating. The risk of overweight, obesity, and dietary behaviors tends to be higher in males versus females; thus, ensuring interventions are accessible and effective for different sexes and genders is crucial to reducing health disparities. Third, examining dose-response and essential components of interventions will improve estimates of improvements in outcomes and the successful implementation of programs. Identifying the appropriate length, frequency, and engagement with the intervention will improve program rollout and allow interventions to be replicated accordingly based on evaluations of dose-response of interventions. Last, none of the included studies examined the cost-effectiveness or cost of the intervention. Examining cost-effectiveness will be important for policy makers and decision makers.

Strengths and Limitations

One of the strengths of this review was the inclusion of both qualitative and quantitative data, allowing them to be interpreted in context with one another. Examining both types allowed us to identify factors influencing social media interventions for nutrition among adolescents. The second was the comprehensive search strategy we developed in collaboration with a medical library information specialist. The search strategy ensured we addressed a broad range of social media and varieties of interventions addressing nutrition in adolescent populations and addressed several gaps in previous reviews. Third, our focus on adolescents allowed us to examine specific issues related to consent, privacy, and safety, as well as the role of parents and communities. Previous reviews of social media interventions for health have combined adolescents with young adult populations [29,42]. Finally, our focus on the peer-to-peer sharing aspects of social media allowed us to gain an

understanding of the unique role of social media in nutrition and health promotion for adolescents.

The results of this scoping review must be interpreted in context with its limitations. Due to resource constraints, the authors of included studies were not contacted for missing or unpublished data which may have yielded potential information to address our research questions. This review did not examine in depth the nutrition education provided in the interventions as it was beyond the scope of the review; however, summaries of the nutrition education are provided in Table S2 in Multimedia Appendix 3. Studies came from different fields interested in nutrition education interventions, such as eating disorder prevention, weight management, and healthy eating promotion. Thus, the outcomes measured in certain studies are less applicable to other fields, and intervention design, development, and content focus differ depending on the health concern.

Conclusions

Accessible and cost-effective health promotion targeting adolescents' nutrition is an important component of a multipronged strategy for the prevention of chronic illnesses. Social media interventions are essential components of effective health promotion, as social media are ubiquitous among adolescents and afford the ability to provide education and psychosocial support in developing healthy eating. The results of this review demonstrate that social media interventions for adolescents' nutrition are acceptable and demonstrate promising impacts on dietary behaviors. Further research is required to understand the dose-response of interventions, the role of parents in interventions, the design of programs tailored to ethnically diverse adolescents and adolescent males, the role of peer leaders and peer support in programs, the impact on health-related outcomes, and cost-effectiveness.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Prisma flow chart.
[DOCX File , 42 KB - pediatrics_v6i1e36132_app1.docx]

Multimedia Appendix 2
Table S1. Characteristics of included studies.
[DOCX File , 296 KB - pediatrics_v6i1e36132_app2.docx]

Multimedia Appendix 3
Table S2. Summary of social media intervention characteristics.
[DOCX File , 289 KB - pediatrics_v6i1e36132_app3.docx]

Multimedia Appendix 4
Table S3. Feasibility outcomes.
[DOCX File , 288 KB - pediatrics_v6i1e36132_app4.docx]

Multimedia Appendix 5
Table S4. Factors influencing implementation and success of interventions.
[DOCX File , 285 KB - pediatrics_v6i1e36132_app5.docx]

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Abbreviations

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SES: socioeconomic status

Edited by S Badawy; submitted 29.06.22; peer-reviewed by E Hohman, S Hewko; comments to author 05.09.22; revised version received 27.01.23; accepted 08.06.23; published 20.07.23.

Please cite as:
Kulandaivelu Y, Hamilton J, Banerjee A, Gruzd A, Patel B, Stinson J
Social Media Interventions for Nutrition Education Among Adolescents: Scoping Review
JMIR Pediatr Parent 2023;6:e36132
URL: https://pediatrics.jmir.org/2023/1/e36132
doi:10.2196/36132
PMID:37471119

Original Paper

Parents' Perceptions of the Factors Influencing the Uptake of Remote Pediatric Hearing Aid Support: Development of a Conceptual Framework

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Abstract

Background: To achieve effective integration of virtual care into family-centered audiology practices, participatory research methods, including parents as vital participants in the delivery of pediatric audiology care, should be considered. A better understanding of the barriers and facilitators influencing the adoption of virtual care for families is warranted.

Objective: This study aimed to develop a conceptual framework of the factors perceived to influence the adoption of remote pediatric hearing aid support among the parents of children with hearing loss.

Methods: A total of 12 parents of children who wear hearing aids, between the ages of 0-17 years, were recruited to participate in group or individual interviews as part of the 6-step participatory-based concept mapping (CM) process. Data collection was specific to parents in a Canadian context. Analyses included multidimensional scaling and hierarchical cluster analysis.

Results: The CM process resulted in 6 main themes, displayed in a cluster map according to their order of importance. These themes include access to timely, consistent care; technology considerations; convenience; child engagement; cost; and partnership considerations. Key underlying statements and subthemes are highlighted per theme.

Conclusions: Findings from this study demonstrate the use of CM in participatory research with parents and as part of a family-centered care model. Future research should aim to investigate the factors that influence the uptake of remote hearing aid support in different contexts, for example, in low- to middle-income countries versus those in high-income countries.

(JMIR Pediatr Parent 2023;6:e47358) doi:10.2196/47358

KEYWORDS

audiology; care; child engagement; children; concept mapping; cost; hearing aid; hearing loss; hearing; integration; parents; pediatric audiology; pediatric; remote hearing aid support; support; virtual care

Introduction

Clinical interactions occurring remotely have been slowly increasing in audiology practice over the past few decades, with a rapid increase observed since the onset of the COVID-19 pandemic to improve access to audiological services [1-3]. Remote delivery of hearing health care services can be accomplished using a virtual care delivery model. Within this study, virtual care describes interactions among families, patients, and audiologists delivering follow-up hearing aid

services remotely using any forms of communication or information technologies with the aim of facilitating or maximizing the quality and effectiveness of the care process [4]. According to recent survey findings reported by Eikelboom and colleagues [2], international audiologists exhibit more positive attitudes toward and a greater use pattern around virtual audiology care following COVID-19, pointing to the need to integrate virtual care as part of the new normal. This study aimed to contextualize virtual care within Canadian hearing health care, with a focus on the provision of family-centered care.

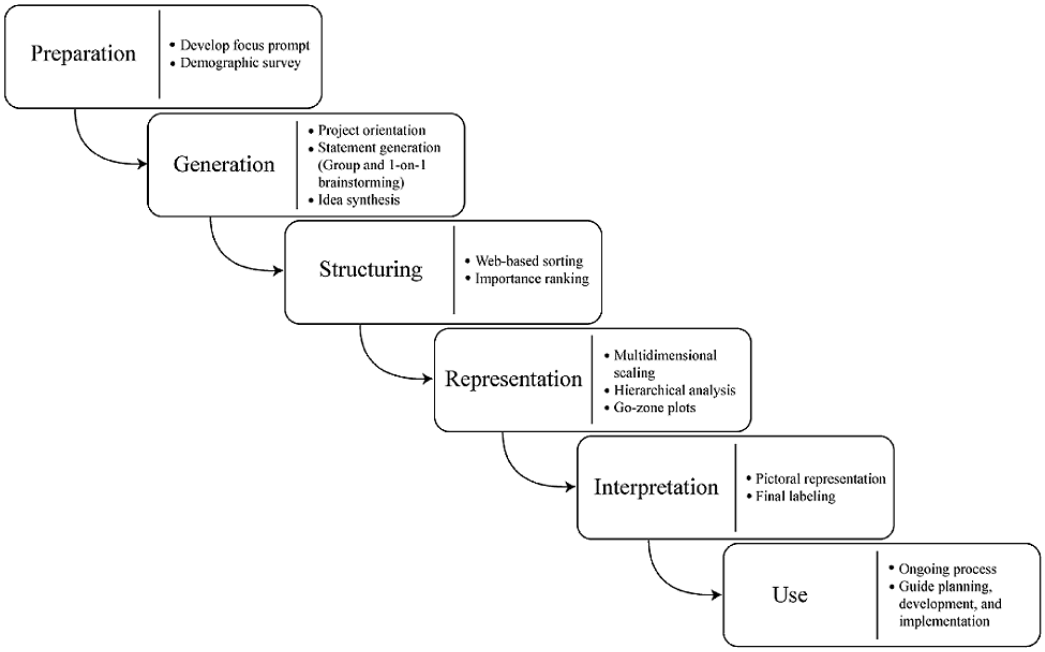
For young children, early intervention for hearing loss significantly improves speech and language development trajectories, helping to ensure that children are ready for school entry [5]. Limited access to early hearing detection and intervention services may negatively impact speech, language, and other important early developmental milestones [6]. For families of children with hearing loss, virtual care has been shown to reduce the rate of loss due to early hearing loss detection follow-up appointments without affecting level of satisfaction with service delivery [7]. Family members are often included in virtual care appointments as patient-site facilitators with varying roles [8]. The benefits of family-centered engagement in virtual care are starting to appear in the hearing health care literature. For example, Muñoz et al [9] reported improved parental knowledge, confidence, and abilities to manage their child's hearing aid following a randomized control trial on the topic of eHealth parent education specific to hearing aid management intervention. The literature also reported positive parent experiences with virtual support interventions, indicating that the sessions they were provided with were effective for supporting their partnership with service providers [10]. Overall, virtual care can benefit families through the provision of flexible and timely access to support, and as part of pediatric hearing aid management care, it has been reported to improve hearing aid use [11].

Central to the development of listening and spoken language is the use of hearing aid technology to support child development. Within virtual environments, barriers still exist when it comes to the effective integration of hearing technology, calling for a better understanding of the implications for parents and families and the range of support required to facilitate virtual care [10]. From the clinician perspective, barriers to effective virtual care delivery may include the quality of the patient-provider relationship, technology limitations at the patient or remote site, digital literacy, and the need for additional training as significant barriers to the delivery of virtual audiology [12,13]. When it comes to technology-related considerations, key clinical factors influencing the use of virtual care include the integration of accessible and easy-to-use technology, a robust internet connection, and the provision of support around the setup and maintenance of equipment [14]. There is a gap in the literature around the key factors perceived to influence family-centered virtual care, including remote hearing aid support.

Engaging families and community partners in the research process have been identified as a feasible and effective tool for obtaining a broad range of input to identify priorities in intervention approaches [15]. Concept mapping (CM) is emerging as an increasingly useful methodology for implementation science and participatory-based research [16]. This collaborative approach to research can be useful to ensure successful integration of novel intervention procedures by identifying barriers to uptake [17-19]. Within the field of communication sciences and disorders, CM has been used to better understand the barriers and facilitators associated with the uptake of evidence-based services [14,20]. Recently, Glista et al [14] used CM to help identify factors perceived by audiologists to be significant in the adoption of remote hearing aid support services, as a sister project to the study presented within this paper. One of the inherent strengths of CM is that participants are directly involved in the data analysis process, helping to drive the interpretation of findings and discussions [21,22]. The structured process of CM helps to produce results that directly reflect the thoughts and ideas of the participants, with a focus on 1 topic of interest and the integration of participant input to produce an interpretable graphic view of interrelated ideas [21,23,24]. Traditionally, CM involves a 6-step mixed methods process; this process, as well as description of all related tasks per step as implemented in this study, are depicted in Figure 1.

To date, there have been few studies conducted with parents that examine their perspective of virtual audiology services as well as a knowledge gap specific to remote hearing aid support. This study aims to fill this knowledge gap to help guide family-centered virtual hearing aid care, an integral part of early hearing detection and intervention programs, by examining the factors that influence Canadian parents' use of remote hearing aid support. This work is timely as virtual hearing aid services are continuing to expand globally, and it is incumbent that we understand how to achieve effective delivery in family-centered care models.

Figure 1. The 6-step concept mapping process as integrated in this study.

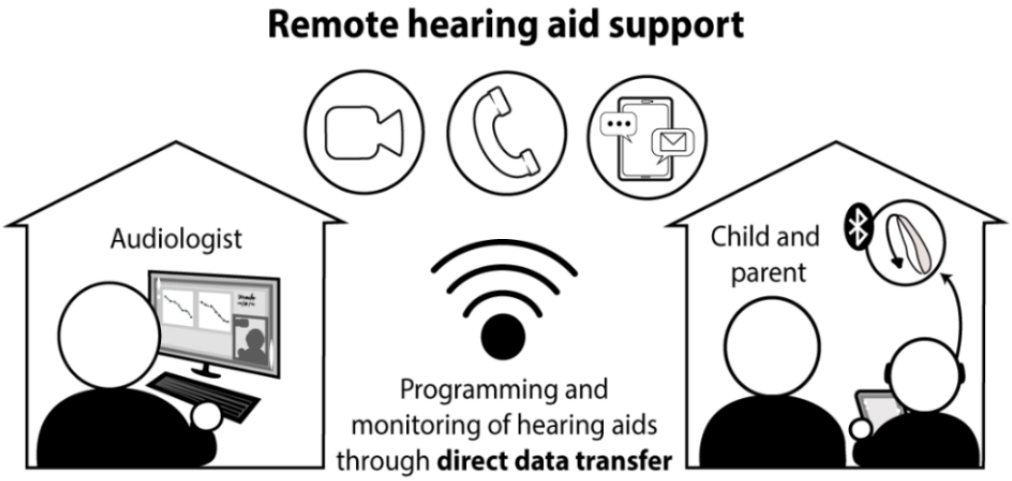


Methods

Study Design

In this study, CM methodology was used to develop a conceptual framework of the factors that influence adoption of virtual audiology practices by parents of children with hearing loss and the provision of follow-up hearing aid support. Figure 2 illustrates this application of virtual care and a typical interaction that can result between an audiologist at a clinic-site and a family (eg, child and parent) at their home location.

Figure 2. An illustration of remote hearing aid support, connecting an audiologist at a clinic site to a family at home.



Participants

The participant recruitment process was guided by selecting appropriate study participants based on the research goals [22,25]. Convenient purposive sampling was used to recruit parent participants until no new statements were generated during the brainstorming phase. Details added to Methods section: there is no specific number of participants recommended for a CM study [26]. Kane and Trochim [27] suggest that least 5 participants can produce meaningful data. Parents of children aged 0-17 years who have hearing loss, who were fitted with hearing aids, and who reside in the province of Ontario, Canada, were included. Parents were required to have had experience participating in audiology appointments related to their child's hearing aid fittings; have access to a computer and the internet at home; and be proficient in English. Parents were recruited from a database within Western University's National Centre for Audiology or through professional networks. Recruiting audiologists were given a letter of information to pass on to potential parent participants. Interested parents were asked to contact either the principal investigator or another member of the research team. Parents were invited to participate in a face-to-face group setting (n=3) or as part of a 1-on-1 telephone interview (n=9) during the timeline of June 2018 to June 2019. Participant characteristics are summarized in Table 1, including information related to the audiology care setting experienced by the family and parent-specific technology use.

Table 1. Participant characteristics as reported by the parents.

Participant characteristics	Participants (N=12), n (%)
Parent age (years)	
30-49	9 (75)
50-64	3 (25)
Parent gender	
Male	0 (0)
Female	12 (100)
Audiology care setting	
Private practice	2 (17)
Hospital	4 (33)
College or University	8 (67)
Mobile clinic	1 (8)
Technology owned	
Smartphone	12 (100)
Tablet	10 (83)
Desktop	5 (36)
Laptop	12 (100)
Computer knowledge level	
Beginner	1 (8)
Average	8 (67)
Advanced	3 (25)
Expert	0 (0)
Ability to use smartphones or tablets	
Beginner	1 (8)
Average	10 (83)
Advanced	1 (8)
Expert	0 (0)
Ability to download “apps” on a smartphone or tablet	
Beginner	2 (17)
Average	7 (58)
Advanced	3 (25)
Expert	0 (0)
Current use of virtual care	
Yes	2 (17)
No	10 (83)
Child age (years)	
0-3	0 (0)
4-7	1 (7)
8-11	5 (36)
12-17	8 (57)
Child identity	
Male	8 (67)
Female	4 (33)

Participant characteristics	Participants (N=12), n (%)
Child attendance in care appointments	
Yes	12 (100)
No	0 (0)
Child-led technologies	
Smartphone	8 (57)
Tablet	11 (92)
Desktop	4 (33)
Laptop	10 (83)

Ethics Approval

This study was part of a sister project also exploring the factors that influence the uptake of remote hearing aid follow-up support by clinicians [14]. Both studies were approved by the Health Sciences Research Ethics Board of the University of Western Ontario (approval number 109403). All participants provided written consent to participate in either a face-to-face session or a telephone interview, as well as several follow-up web-based tasks using a personal computer.

Procedures

Participants completed web-based tasks, including sorting and rating, using the Concept Systems Global Max software [28]. The Concept Systems Global Max software uses CM methodology with a web-based interface and is based on group process techniques [29]. To enable web-based tasks, participants were invited through email, in which a weblink to the CM software was provided. A paper record of a unique login and password was provided to each participant.

Preparation

All participants were asked to complete a short demographic survey that was delivered in person for face-to-face session attendees and over the phone for telephone interviews. Focus prompt development was consistent with that of the sister project, using expert opinion in the development [14].

Brainstorming and Idea Synthesis

Each face-to-face session began with a brief orientation presentation on the topic of remote support in audiology, sample applications, the use case of interest (follow-up hearing aid support), as well as a summarization of the study methods. Before telephone sessions, the orientation step was delivered using a short, animated 4-minute video created in VideoScribe. The video was accessed by the participants through an emailed weblink. During all sessions, participants were asked to develop as many statements as possible to complete the CM focus prompt: “One thing that may influence my use of teleaudiology for remote follow-up hearing aid support is…” A synthesis step was used by the investigators to combine the final statements into 1 large data set and eliminate redundancies. The decisions made during the synthesis step were manually recorded by the investigators, resulting in a list of key statement synthesis decisions. The face-to-face sessions and phone interviews were also audio-recorded.

The researchers compiled all the statement sets into 1 large set that was then edited and synthesized by the research team to eliminate redundancies and refine statements to ensure clarity and comprehension. Statements that were unrelated to the prompt were removed; statements were also merged or split to ensure that each statement had 1 clear meaning [25]. The statement synthesis steps were recorded to create an audit trail of the consolidated set of 125 statements. The final (synthesized) set included 107 unique parent statements related to the focus prompt.

Structuring

Participants were contacted twice through email to complete web-based follow-up tasks. Overall, 8 participants completed the web-based sorting task and 9 completed the importance ranking task. A web link to the Global Max software was sent in the first follow-up email. Instructions were given within the software to facilitate the sorting of the final set of statements into piles and the ranking of the statements based on perceived importance. The importance-ranking instructions provided to the participants were as follows: “Please rate each statement on a scale of 1 to 5 where; 1=relatively unimportant; 2=somewhat important; 3=moderately important; 4=very important; 5=extremely important. To complete each rating, type a number next to each statement.”

Following analyses, the research team conducted a final review of the statements, clusters (which are resultant categories of similar ideas generated in the brainstorming phase), and corresponding names of each cluster, with the end goal of achieving group consensus on acceptable labels for each cluster and number of clusters. This final step was mainly driven by the research team due to the outbreak of the global COVID-19 pandemic, which limited contact with the participants.

Results

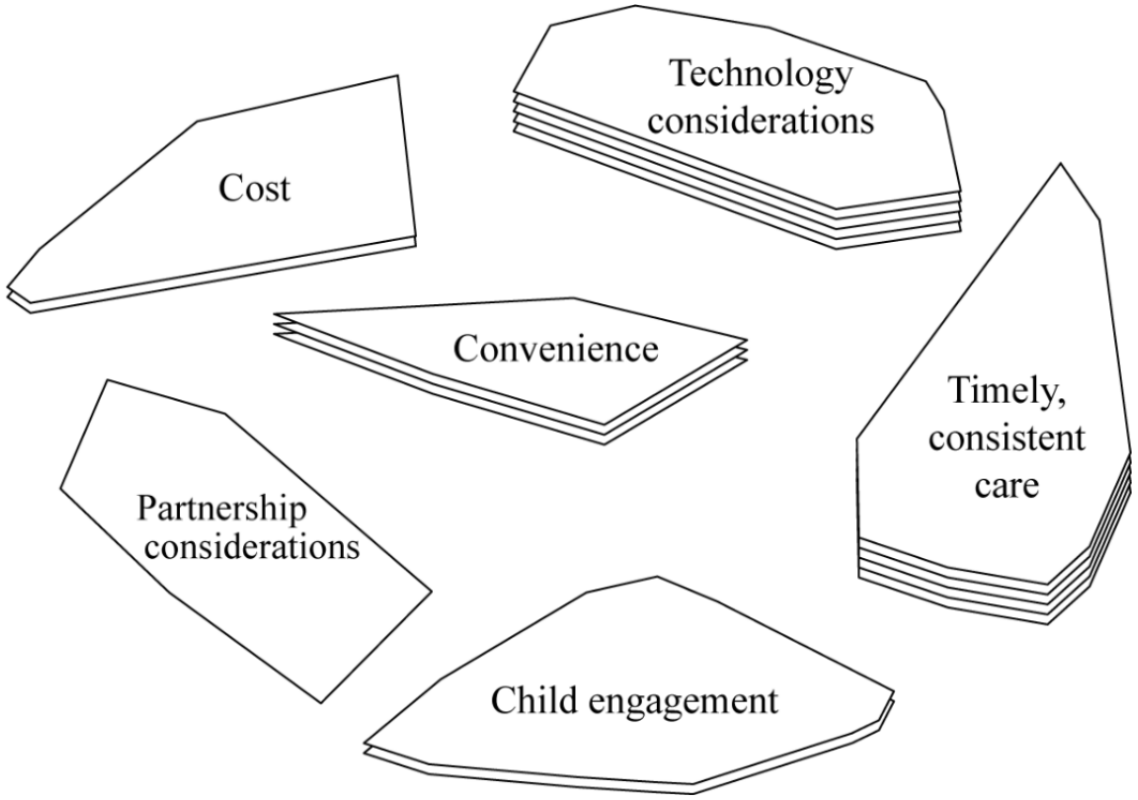
Representation

The representation of results was enabled using the Global Max software and used 2 types of analyses: multidimensional scaling and hierarchical cluster analysis. Details regarding the production of the final concept map are described in the representation section. Multidimensional scaling was used to locate each parent statement in a 2D space to display on a point map, following a 2-step process from Kane and Trochim [27]: (1) A similarity matrix, using a similarity cutoff of 3 to filter

out false relationships between statements, was generated by pairing the 107 statements with one another and assigning a numerical value indicating the number of parents who put that pair of statements in the same pile; and (2) A 2D solution was used to produce x- and y-coordinates for each statement, following a bivariate distribution. These steps resulted in the generation of a point map that was used to yield a 6-cluster configuration; this cluster map is illustrated in Figure 3. Each point on the point map represents 1 statement. Statements that were sorted together more often by the participants appear as points closer together; statements that were less often sorted together appear further apart [30]. A stress value is a statistic routinely generated and reported in multidimensional scaling analyses, indicating how well the statement configuration matches the data [21]. The final stress value of 0.34 falls within the normal and acceptable range for CM research, indicating that the map appropriately represents the sorting data [27]. Also known as a concept map, the resulting cluster map helps to depict a group-level conceptualization of parent-generated ideas around the factors influencing the uptake of remote hearing aid support. The final stress value of 0.34 falls within the normal and acceptable range for CM research, indicating that the map appropriately represents the sorting data [27].

Hierarchical cluster analyses, using input from multidimensional scaling, mathematically grouped each statement into adjustable cluster configurations, based on how parents rated and sorted the data. Each cluster represents a unique theme on the resulting map (Figure 3). The selection of the final number of clusters included in the CM required both software and researcher input to yield an optimal solution. The recommendation is for researchers to examine a range of possible clusters suggested by the software program, consider the statements included within the cluster, and use this information to formulate a cluster configuration [27]. Possible cluster configurations were considered and discussed by the research team (DG, SM, and RO) and a final configuration of 6 clusters was selected.

Figure 3. Six-cluster map of the 107 statement point map, of factors influencing the uptake of remote hearing aid support by parents labeled by importance rating.



Interpretation

Final cluster labels reflect the general theme for each cluster of statements. The layers per cluster indicate the level of importance rating provided by the parents for their statements per cluster. A greater number of layers represents greater importance for the group of statements included within the cluster, as judged by individual parents. For example, access to timely, consistent care was rated by the parents as more important when compared to partnership considerations.

A list of the main themes, subthemes, and example statements were generated using single cluster go-zone plots, allowing for visualization of the relationship between participant ratings with respect to the concept map (Table 2). The example statements presented by theme included those that received high overall average ratings of importance. Table 3 provides a count of the total number of statements that appear in each cluster, along with the mean importance values for each cluster. Mean cluster values are presented in order of importance from most to least important and correspond to responses collected using the 5-point scale.

Table 2. Concept mapping clusters, subthemes, and example statements created using the prompt: "One factor that will influence my uptake of remote hearing aid follow-up support is..."

Cluster	Overall subthemes	Example statements
Access to timely, consistent care	Participation of relevant stakeholders and consistent access to remote audiological services	• "Ability to troubleshoot remotely in listening environments important to my child." • "The ability to access remote fitting support in times of need (eg, during extracurricular activities, hearing aid emergencies)."
Technology considerations	Access to stable and consistent technology (equipment and internet access); training and support available	• "Access to a phone/tablet that is current enough to be used for remote fitting appointments." • "The learning curve associated with remote hearing aid appointments."
Convenience	Traveling distance; time taken off from work and school	• "If I don't have to miss work for an appointment." • "If my child doesn't have to miss school for an appointment." • "If it eliminates the need to arrange for child-care at the time of an appointment."
Child engagement	Child's, parent's, and audiologist's confidence and involvement in appointments	• "If it builds/maintains a positive relationship between my child and his/her Audiologist." • "If it addresses my child's need for frequent follow-up appointments following a new hearing aid fitting."
Cost (financial and otherwise)	Costs associated with the appointment in terms of equipment and traveling	• "If the cost of a remote appointment is the same or less than a face-to-face appointment." • "The need to negotiate with family members to use a phone/tablet for a remote appointment."
Partnership considerations	Privacy considerations; participation of family members and other health care professionals in the appointment	• "The ability to have other healthcare professionals participate in an appointment." • "The quality of the services being delivered remotely, in comparison to face-to-face."

Table 3. Clusters and corresponding total statement numbers arranged by importance level, along with the overall mean importance values.

Cluster	Statements, n	Importance values, mean (SD; range)
Access to timely, consistent care	22	4 (0.51; 3.1-4.9)
Technology considerations	24	3.93 (0.57; 2.2-4.7)
Convenience	13	3.71 (0.68; 2.3-4.6)
Child engagement	23	3.65 (0.69; 2.6-4.8)
Cost (financial and otherwise)	11	3.55 (0.67; 1.8-4.2)
Partnership considerations	14	3.41 (0.96; 1.3-4.7)

Discussion

Overview

This study demonstrates how CM was used to develop a conceptual framework in collaboration with parents of children wearing hearing aids to explore factors that may influence the adoption of remote follow-up hearing aid support services delivered through teleaudiology. A total of 12 parents of children who have hearing loss and reside in Ontario, Canada, were recruited to participate in this study. Overall, 6 themes were developed to form the final conceptual framework of the perceived factors that influence the uptake of remote hearing aid support by parents of children with hearing loss. These 6 themes, in order of overall level of importance, were (1) access to timely, consistent care; (2) technology considerations; (3) convenience; (4) child engagement; (5) cost; and (6) partnership considerations.

Access to timely, consistent audiological care was rated by the parents as the most important factor in delivering remote hearing aid support to their children. Subthemes in this cluster highlighted that parents value the ability to access hearing aid support remotely in times of hearing aid emergencies or during extracurricular activities where listening demands are different. Virtual audiological consultations with parents and families of children who have hearing loss have shown benefits in terms of flexibility and timely access to support [10,11]. Furthermore, increased access to audiological care can result in direct, collaborative problem-solving between the parents and the

audiologist, which could lead to increased hearing aid use and better hearing outcomes.

Technology considerations were ranked as the second most important factor in the uptake of pediatric remote hearing support. Technological barriers (such as consistent internet connection and availability of training and support) have been cited in the literature as one of the main reasons why remote hearing aid support is not readily adopted worldwide [31]. The top-rated overall statements by parents regarding technological considerations and infrastructure pertained to accessibility of phones or tablets that are up-to-date to support remote hearing aid fitting appointments and the learning curve associated with remote hearing aid appointments. Confidence is a key aspect when considering engagement in remote hearing aid support, and additional support can guide patients in their ability to manage remote technology [32]. Additionally, the technical knowledge of audiologists who engage in remote hearing aid support has emerged as an important factor in the uptake of remote support by pediatric audiologists [14]. This theme highlights the need for developing clinical guidelines to support both parents of children who have hearing loss and pediatric audiologists in the clinical implementation of remote hearing aid support services and clinical resources to assess and guide family-centered training around virtual care.

Patient- and family-centered factors pertaining to service accessibility were also deemed important by parents. These include convenience (traveling distance, time taken off from work and school, and the need to arrange for childcare), cost (related to traveling and equipment needed for remote support), and child engagement (addressing the 'child's need for frequent follow-up appointments following a new hearing aid fitting). Teleaudiology has been reported as a cost-effective manner of service provision [33]. In addition, increased convenience and decreased cost could lead to fewer missed appointments [14]. Access to more frequent remote follow-up appointments for the pediatric population could, in turn, minimize the detrimental effects of hearing loss on speech and language development in children [34].

The final cluster pertained to participation and the collaboration between the professional, the parents, and their family members. Audiologists play a vital role in partnering with parents and families to provide the support needed for the effective day-to-day management of their child's hearing aids [11]. Building a trusting parent-professional partnership helps to implement and sustain consistent daily hearing aid use, which can support developmental outcomes for children.

Usage

The use step in a CM framework is an ongoing process related to the study objectives and involves working with the stakeholder team to determine the best ways to use the maps and reports produced as part of the CM procedures [30]. A total of 6 main themes and related subthemes emerged from this study, which focused on parent-perceived factors influencing the uptake of remote hearing aid support for their children with hearing loss. Recommendations arising from the identified themes will ultimately be used to help guide the planning, development, and implementation of teleaudiology services, such as remote hearing aid support, into pediatric clinical practice. Planning and implementation of pediatric remote audiological care should be tailored according to a parent and family focus. Results of this CM study reinforce the need for standardized pediatric telehealth protocols and procedures to facilitate remote audiological follow-up care for children [35]. In addition, the CM framework in this study will be used to support future research, including development of best-practice guidelines and training documents to assist in the uptake of remote hearing aid support services for parents and families of children with hearing loss.

Limitations and Future Research

Study limitations include the use of nonrandom sampling, which results in a sampling bias; a small sample size, which limits generalizability; the labor-intensive process of creating a CM framework; and the personal attributes of the participants, which likely shaped the resulting themes in the framework of this study [36]. Furthermore, no parents of very young children (0-3 years of age) and only 1 parent with a child in the 4-7 years of age category participated in this study, which limits understanding of parent perspectives across the age spectrum. For example, parents typically need educational and management support when hearing aids are first fitted, but this theme was not identified by the participants in this study. A possible reason for this could be that the parents in this study had more experience and were focused on how virtual care could currently help them. Another limitation for this study was that the final member–checking step (usually done by the participants in a CM study) was not completed due to the outbreak of the global COVID-19 pandemic; this was due to an inability to recruit parents to participate in additional steps during this time. Therefore, the final resultant clusters in the CM framework were not reviewed by the parent participants to obtain feedback.

Results of this study demonstrate the benefit of CM methodology in facilitating parent engagement in research. Through the inclusion of parent participants, greater value is added when considering family-centeredness in the context of virtual audiology care. Future research could use a similar approach to investigate factors that influence parental uptake of remote hearing aid support in different contexts and across different languages, for example, in low- to middle-income countries versus high-income countries, as well as in populations for whom English is not the predominant language.

Acknowledgments

This project was supported by a research grant awarded by Sonova to D Glista. The authors are thankful for data management support provided by Ben Tran throughout this project.

Authors' Contributions

Following the Contributor Roles Taxonomy (CRediT), authorship contributions were collated to provide visibility and recognition for all team members (Allen et al [37]). SM and DG were involved in conceptualization. SM, KK, RO, and DG performed data curation. SK, SM, RO, and DG contributed in formal analysis. DG and SM were involved in funding acquisition. SK, SM, KK, and RO performed the investigation. SM and DG were involved in methodology. SM, KK, and DG contributed in project administration. SM, KK, and DG were involved with resources. SM and DG performed supervision. SK, SM, RO, and DG contributed in visualization. SK, SM, and DG were involved in writing of original draft. SK, SM, KK, RO, and DG contributed in revision and editing.

Conflicts of Interest

None declared.

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Abbreviations

CM: concept mapping

Edited by S Badawy; submitted 17.03.23; peer-reviewed by K Munoz, L Coco; comments to author 10.04.23; revised version received 27.04.23; accepted 11.05.23; published 06.06.23.

Please cite as:
Kuschke S, Moodie S, Kirubalingam K, O'Hagan R, Glista D
Parents' Perceptions of the Factors Influencing the Uptake of Remote Pediatric Hearing Aid Support: Development of a Conceptual Framework
JMIR Pediatr Parent 2023;6:e47358
URL: https://pediatrics.jmir.org/2023/1/e47358
doi:10.2196/47358
PMID:37279061

Original Paper

Feasibility of Video Consultation for Preterm Neurodevelopmental Follow-up Care During the COVID-19 Pandemic: Cohort Study

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Abstract

Background: During the COVID-19 pandemic, parents of infants born very preterm or at risk were exceptionally worried about being infected. The only means of protection during the onset of the pandemic was social distancing. Video consultations for neurodevelopmental follow-up care were offered as an alternative way to stay in contact with patients and their families, to provide expert support, and to monitor and assess children's development.

Objective: To assess the feasibility of and family satisfaction with video consultations, interviews were conducted after video and in-person consultations.

Methods: An interview with 28 questions was created to evaluate parental satisfaction with the consultations (eg, their confidentiality and the children's behavior). A total of 93 interviews with parents were conducted between March 2020 and February 2021 and compared (58 after video consultations and 35 after in-person consultations). The interviews were conducted at the end of the consultations by a trained professional. The video consultations were conducted using a certified platform created by Zava Sprechstunde Online, maintaining data protection with end-to-end encryption. Follow-up consultations (video or in-person) were performed at corrected ages of 3, 6, and 12 months as well as 2, 3, 4, and 5 years. The rate of total follow-up appointments attended during the survey period was evaluated and compared with the previous year.

Results: There were no significant differences between the video and in-person consultation groups in satisfaction, attitudes on the confidentiality of the consultation, or discussion of private and sensitive information. Following video consultations, parents were significantly more likely to report that they were avoiding contact with medical professionals during the pandemic (P=.045; Shapiro-Wilk W=1094.5, Cohen d=–0.1782146) than the in-person consultation group. Parents in the video-consultation group stated that performing a guided examination on their child was comfortable and helped them understand their child's development. In fact, they agreed to take advantage of future video consultations. The rate of total follow-up appointments increased compared to the previous year. Between March 2019 and February 2020, 782 of 984 (79.5%) children born at Essen University Hospital attended a follow-up appointment. During the survey period, between March 2020 and February 2021, a total of 788 of 1086 children (73%) attended a follow-up appointment, of which 117 (14.9%) were video consultations.

Conclusions: The feasibility of attending video consultations for follow-up care of very preterm or at-risk infants and parental satisfaction with these consultations were as high as for in-person consultations. Parents rated video consultations as being as

confidential as in-person appointments. Telemedicine can be offered as an equivalent alternative to in-person consultations and is particularly useful under certain circumstances, such as for very sick children who require assistive devices or respiratory support and oxygen or for those living a long distance away.

(JMIR Pediatr Parent 2023;6:e40940) doi:10.2196/40940

KEYWORDS

COVID-19; very preterm infant; video consultation; follow-up care; COVID-19 pandemic; neurodevelopmental outcome

Introduction

Approximately 15 million newborns are born preterm worldwide each year, which is more than 1 in 10, and this rate is increasing in almost every country. Substantial progress in perinatal care has significantly increased survival rates over the past 3 decades. However, long-term morbidity remains a concern [1,2]. Approximately 14% of newborn infants (preterm and term-born infants) need postnatal care in Germany, and 8.6% of infants are born preterm [3,4]. Therefore, follow-up care for these patients at risk is an important part of a safe transition from the neonatal intensive care unit (NICU) to home care, and it is crucial for long-term monitoring and support of these infants' neurodevelopment [5]. For early detection and intervention, international guidelines recommend follow-up examinations at defined times, starting with discharge management and support during the transition to school age [6]. The use of standardized tests is advisable, as well as assessment of the physical and mental health of both children and parents. Other important aspects of follow-up consultations are to support parent-child interactions, provide information on how parents can promote their child's development, and give practical recommendations about the challenges of daily life, such as feeding, sleeping, dealing with behavioral problems, and monitoring and administering drugs [5,7].

Whereas follow-up care in very preterm children can detect severe motor and cognitive impairment for up to 2 years, long-term follow-up care, until school age, is recommended to detect more subtle development disorders [8]. Regular follow-up appointments enable early intervention in children who have previously demonstrated age-appropriate development, but later show development disturbances. However, during the COVID-19 pandemic, appointments may have been missed at critical periods of development. The reasons for this are manifold: symptoms of infection, quarantine and hygiene restrictions, and fear of infection.

At the onset of the COVID-19 pandemic, neither vaccination nor adequate therapies were available, and the only means of protection was social distancing. To reach out to patients and their families who would not or could not attend regular follow-up appointments, video consultations were offered. This method provided several opportunities: it allowed health care providers to stay in contact with patients and their families, provide expert support and information, and keep track of the children's development. However, there were potential challenges, such as a lack of confidentiality, the discussion of private and sensitive information, technical issues, accessibility, and acceptance of this new digital tool. To assess the feasibility of this method and family satisfaction, we conducted interviews after video and in-person consultations. The rate of total follow-up appointments attended during the period of the survey, which took place during the COVID-19 pandemic, was evaluated and compared with the previous year.

Methods

Subjects

A total of 93 interviews were conducted with parents (58 after a video consultation and 35 after an in-person outpatient appointment) between March 2020 and February 2021. On average, parents of the participants were aged 33.45 (SD 5.11) years in the video-consultation group and 31.40 (SD 5.86) years in the in-person group. Inclusion criteria for participation in the video-consultation group were sufficient language skills in German, English, or Turkish and the possession of the minimum required technical equipment, such as a mobile phone. Interviews were conducted at the end of the in-person or digital appointment by a professionally trained neurodevelopmental psychologist. The video consultations were conducted on a certified platform developed by Zava Sprechstunde Online that maintained data protection with end-to-end encryption.

Ethics Approval

The investigation was approved by the ethics committee of the Medical Faculty of the University Hospital Essen (20-9319-BO) and adhered to the Declaration of Helsinki.

Planning and Implementation of Digital Consultations at the Onset of the COVID-19 Pandemic

Starting on March 13, 2020, the German federal states ordered the closure of schools and kindergartens, postponed semester breaks, and banned visits to nursing homes to protect the elderly [9]. Two days later, the borders with Austria, Denmark, France, Luxembourg, and Switzerland were closed. By March 22, curfews had been imposed in 6 states, while others prohibited physical contact with more than one person outside the household [10]. To protect the most fragile patients, such as follow-up groups of premature or high-risk infants, the department of neurodevelopmental follow-up care at our institution sought an alternative as soon as possible to protect patients and their families from the unknown COVID-19 virus. All high-risk patients and families already scheduled for in-person appointments were contacted and asked if they would be willing to change to a video consultation. If they declined, the in-person appointment was performed wearing protective equipment and was scheduled so that patients did not meet each other. If a family agreed to hold the scheduled appointment as a video consultation, they received an email in advance with the necessary technical requirements and items to have ready

for the appointment (eg, an ID card to identify themselves, an internet-enabled device with a camera, and toys). After the video consultation and outpatient appointment with the staff, an interview (described in the Measurements section of this paper) was conducted with the same staff member to compare the quality of the appointment to an in-person consultation. This was highly important to the department of neurodevelopmental follow-up care, as it was crucial to know whether digital appointments via video consultation were feasible during this time of uncertainty in the pandemic. The participants in the video interviews could decide whether they wanted to take part or not. They had the option to cancel the interview and recall their data at any time. Due to the completely anonymous collection of the data, no conclusions can be drawn about the families, the age of the patients, or whether the same families participated in multiple video consultations.

Video Consultation Procedure

Follow-up care, both via video consultation and in person, was performed by authors BMH, BA, and SG (who are medical doctors), LJC (a psychologist) AKD (an occupational therapist) and UT (a physiotherapist). During the in-person visits, a detailed medical history was taken with the parents, and the child was then examined by the various professionals. During video consultations, a detailed medical history was also taken, but the camera was pointed at the child so that he or she could be observed in his or her home environment. After the medical history was taken, parents were subsequently instructed to position the child and the camera. The parents were guided with a mannequin through different positions of the infant, such as a traction attempt, held seat and held stand, the axillary hanging position, the floating stomach position, and the passive rotation and stomach position. The spontaneous movements of the infant in these different positions were observed. Preschool-age children were instructed to perform fine and visual motor tasks, including copying forms; using scissors to cut along a line; and grasping, transferring, and releasing paper clips into a match box, to test precise finger coordination. Gross motor functions were tested using regular neurological examinations, such as the finger-nose test, walking in tandem, and the stance and gait test.

While guiding parents, the examiner explained all observed items and findings. In addition, questions regarding the examination, as well as everyday life issues, were answered, including questions related to weight gain, feeding, developmental steps, and self-regulation. Physicians were able to assess fine and gross motor skills, as well as cognitive function, in the children through visual observation, for example, by observing how a toddler explored and handled items.

Measurements

To determine the parents' perspectives on video and in-person consultations at the follow-up outpatient clinic for preterm and high-risk infants during the COVID-19 pandemic, an interview with 26 questions was created based on a questionnaire by Rutherford et al [11] (Multimedia Appendix 1). Questions 1 to 5 related to demographic information and distance from the outpatient clinic. Questions 6 to 20 (for the in-person appointment interviews) and 6 to 26 (for the video consultation interviews) related to parents' satisfaction with the appointments. Parents' satisfaction was reported on a Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). The 6 additional questions in the interviews after the video consultations were related to technical implementation and feasibility (eg, the kind of device used, satisfaction with the video and audio quality, self-examination of the child, instructions on position changes and explanations of development, differences with in-person appointments, and likelihood to use future video consultation).

To evaluate the total attendance rates for follow-up appointments (for both in-person appointments and video consultations) for the children, the total number of consultations was compared with the number of scheduled appointments for preterm infants born at University Hospital Essen and also compared with the previous year.

Data Analysis

Statistical analyses were conducted using the R environment for statistical computing and graphics with the RStudio integrated development environment. All data were tested for normal distribution using the Shapiro-Wilk test. The distribution was not normal, so all comparisons between groups (ie, the video consultation and in-person appointment groups) were calculated using the Mann-Whitney *U* test. In cases with significant differences, the effect size was calculated with the Cohen *d*.

Results

Between March 2020 and February 2021, 93 interviews were conducted and analyzed. There were no significant differences between the video and in-person consultation groups in satisfaction or attitudes toward confidentiality and discussion of private and sensitive information. Parents in the video-consultation group were significantly more likely to agree (mean Likert score 4.82, SD 2.26) that they were avoiding contact with medical professionals during the pandemic than the in-person consultation group (mean score 3.89, SD 2.25; Shapiro-Wilk W=1094.5; P=.045; d=–0.1782146). Furthermore, parents in the video-consultation group agreed that they would take advantage of future video consultations (mean score 6.49, SD 1.09). Parents reported being empowered by the self-examination of their child (mean score 6.53. SD 1.39) and learning more about their neurodevelopment. All children were calm and cooperative (mean score 6.45, SD 1.17) in their home setting with only familiar people.

Significant differences between the groups were found in parental age (Figure 1), estimates of waiting time before the appointment (Figure 2), belief in safety from pathogens, and avoidance of contact with medical professionals (Figure 3).

Parents who attended a video consultation were significantly older on average (mean age 33.45, SD 5.11 years) than parents who attended an in-person appointment (mean age 31.4, SD 5.86 years; Shapiro-Wilk W=1043; P=.044; d=–0.1767638). The video-consultation group made estimates of the potential waiting time at the clinic that were significantly longer (mean 23.58, SD 27.75 minutes) than estimates of the potential waiting

time at the clinic made by the in-person group (mean 11.39, SD 17.6 minutes; Shapiro-Wilk *W*=1387.5; *P*<.001; *d*=–0.3633795). Parents reported feeling safer from pathogens at home (mean score 6.78, SD 0.76) after a video consultation than after an in-person appointment (mean score 6.37, SD 1.09; Shapiro-Wilk W=1060.5; *P*=.02; d=–0.2577713).

Parents were on average very satisfied with the video and audio quality of the video consultations (mean score 6.29, SD 1.26); they considered examining their children themselves under supervision was on average beneficial (mean score 6.53, SD 1.39) and allowed them to better understand their development (mean score 6.57; SD 1.36); they considered that the video consultations were implemented similarly to in-person appointments (mean score 5.67, SD 1.84); and they accepted video consultations as an alternative in the future and wished to use them again (mean score 6.49; SD 1.09).

Between March 2019 and February 2020, 782 of 984 (79.5%) children born at Essen University Hospital attended a follow-up appointment. During the survey period between March 2020 and February 2021, a total of 788 of 1086 children (73%) attended a follow-up appointment, of which 117 (14.9%) were video consultations.

Figure 1. Mean age in years of the parents (*P*=.044 between groups). The bars indicate mean values and tails indicate SD.

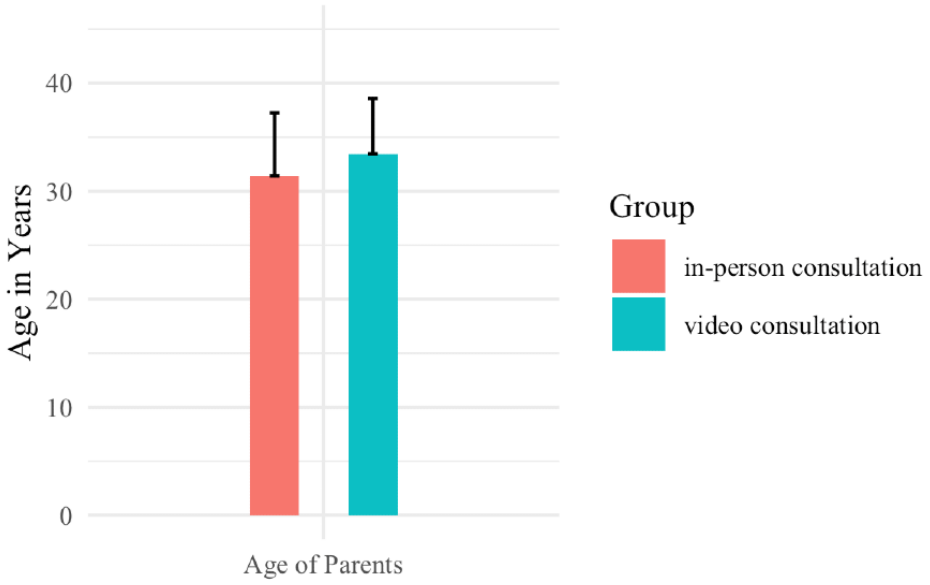


Figure 2. Mean estimates of potential waiting time in minutes for in-person appointments (*P*<.001 between groups). These estimates were made after either an in-person consultation or a video consultation. The bars indicate mean values and tails indicate SD.

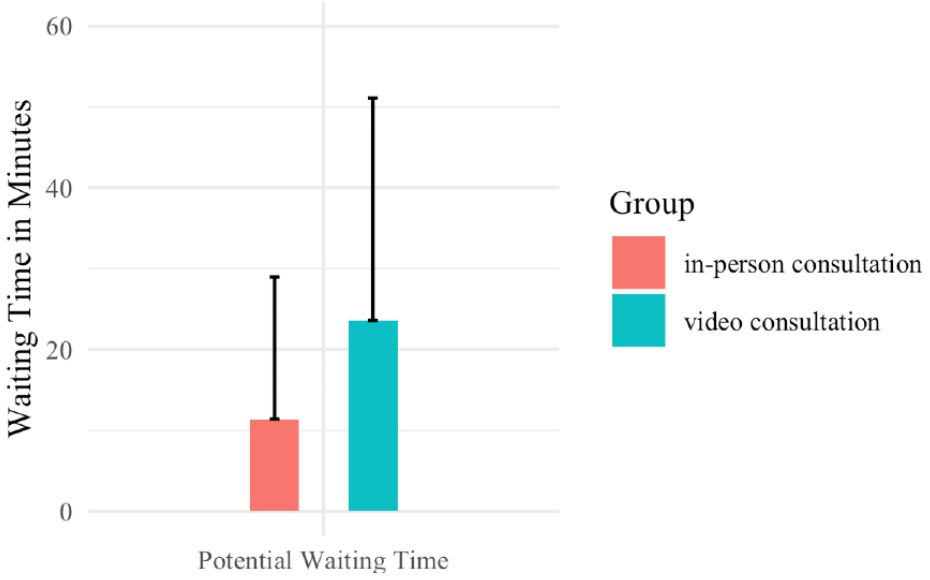
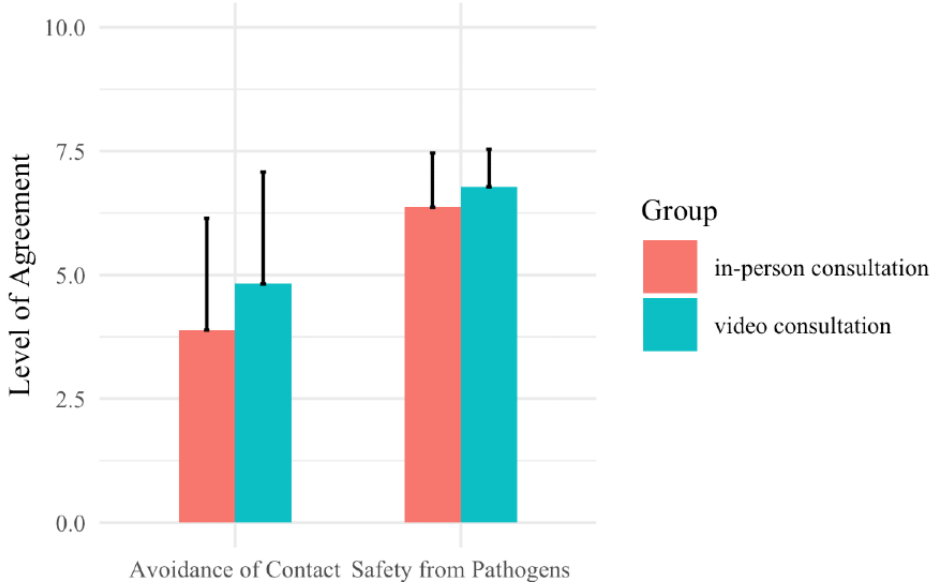


Figure 3. Level of agreement with statements on avoidance of contact with medical professionals during the pandemic (*P*=.045 between groups) and belief in safety from pathogens at home (*P*=.02 between groups). Higher numbers indicate stronger agreement. All ratings were made after either an in-person consultation or a video consultation. The bars indicate mean values and tails indicate SD.



Discussion

Principal Results

The subjective satisfaction of families attending video consultations for follow-up care for their very preterm or at-risk infants was as high as in-person consultations. Parents found the video consultations to be as confidential as in-person appointments. In addition, parents felt comfortable and self-confident performing the guided examinations of their children by themselves during video consultations. Parents indicated that performing the examinations of their children gave them a better understanding of their development. During video consultations, the parents rated the children as being as calm and cooperative as at in-person appointments. Parents rated the feasibility of the video consultations as very high and similar to in-person appointments. Acceptance of the video consultations was considered high, as the parents agreed to choose video consultations again.

During the COVID-19 pandemic, cancellation of in-person appointments due to symptoms of infection with SARS-CoV-2, other viral infections, or quarantine of family members was frequent. However, missed appointments often could not be made up in a timely manner. Dayal et al [12] compared an in-person visit cohort with a telemedicine visit cohort in their outpatient pediatric neurology clinic and reported that telemedicine visits were more likely to be completed versus cancelled or missed compared to in-person visits. The authors concluded that telemedicine could serve as an equal supplement to in-person visits.

Feasibility of Video Consultations

Parents strongly considered video consultation as an equal alternative for keeping scheduled follow-up appointments. The acceptance of the video consultations by parents and their positive evaluations of the confidentiality of the conversations suggests the possibility of using this modality beyond the pandemic.

Offering video consultations from the beginning of the COVID-19 pandemic was a rapid, adaptive response to meet the needs of the patient population. According to Chew et al [13] the successful deployment of digital tools is dependent on patient willingness to use the tools, provider acceptance, and quality of hardware infrastructure [14].

It is much more difficult for highly complex patients, such as those receiving home oxygen therapy or those who live far away from the hospital, to attend in-person appointments. However, keeping track of patients with ongoing medical and therapeutic requirements reduces the rate of hospitalization. This also holds true for neonatal patients. Robinson et al [15] showed that telemedicine for follow-up care of infants after discharge from the NICU reduced emergency visits to the hospital. Furthermore, it has been reported that 26% of parents receiving telemedicine felt they had more scheduled appointments than necessary, which increased their level of satisfaction [16]. Gund et al [17] showed that telemedicine could reduce the need for home visits among parents practicing neonatal home care. There are examples of randomized controlled trials with promising outcomes for digital tools with ecological validity. The SAVED (Safety and Efficacy of Follow-up for Patients With Abdominal Pain Using Video Consultation) study [18], a randomized controlled trial, showed that video consultation was a safe and efficient tool for follow-up care in patients presenting with acute abdominal pain in the emergency room. Richards et al [19] showed that digital intervention for patients with depression and anxiety was therapeutic and cost-effective and could be a strong tool to counter or account for the treatment gap in mental health. With time- and cost-effective digital tools, diagnosis and treatment may be offered significantly earlier to patients in distress.

Neurodevelopmental follow-up in preterm infants aims to identify children at risk early, in order to initiate intervention

to best promote development. De Kleine et al [7] investigated long-term follow-up care of preterm children up to the age of 5 years and revealed a large group of children with developmental disturbances who were previously considered developmentally appropriate. Video consultations offered an opportunity in this study to evaluate development of the children and consult parents about all developmental domains of their child. Gavazzi et al [16] showed the feasibility of video consultations for standardized measurement instruments, such as the Gross Motor Function Measure–88, in a pediatric group with chronical neurological disease. Li et al [20] showed that a combination of follow-up visits that were face-to-face and via video allowed a follow-up rate that was as high during the first wave of the COVID-19 pandemic in April 2020 as in the previous year. In this study, due to the additional offer of a video consultation, the rate of follow-up appointments decreased slightly, but the total number of consultations increased.

During the first 3 infectious peaks of the COVID-19 pandemic in Germany (March 2020-January 2021), there were several weeks when planned in-person appointments for medical causes that were not urgent were prohibited by social distancing rules. This study showed that parents who preferred follow-up care via video consultation were significantly more afraid of an infection and were significantly more likely to avoid contact with medical professionals. Parents of very preterm children have been exceptionally worried about being infected due to the fact that preterm children suffer from respiratory infections more often and have an increased risk of rehospitalization, especially during the first 2 years of life [1]. Brasseler (personal communication, July 8, 2022) showed that parents with preterm infants had more anxiety during the COVID-19 pandemic than parents of infants born at term. Furthermore, participants in the video-consultation group in this study were significantly older than those in the in-person appointment group. A great deal of research has shown that higher maternal age, among other factors, is correlated with higher compliance to follow-up care among very-low-birth weight infants and infants discharged from the NICU [21,22].

In the outpatient clinic, 3 follow-up visits are scheduled in the first year of life and annually until school age (6 years in Germany). The video consultations for follow-up care in this study included patient-reported medical history and a guided examination of the patients by the parents. Observing children in their home environment following parental instructions provided an opportunity to gain insight into the family environment. Standardization was a challenge, and only individual items could be measured. Muscle tone and muscle strength were difficult to examine via video consultation. Nevertheless, observation of the infant's spontaneous motor skills is one of the most important examinations and is easy to perform via video consultation in most cases. In toddlers and children, an overview of developmental domains in fine and gross motor skills, language and speech, cognition, performance and reasoning, sensory skills, and social-emotional behavior was obtained [7]. The subjective impression of the examiners was also that the children were calmer and more relaxed in their home environment.

Limitations

This study used a nonrandomized cohort design as the onset of the pandemic required rapid adaptation for developmental neurological follow-up care due to contact restrictions. Due to the completely anonymous collection of the data, no conclusions can be drawn about the families retrospectively. Nevertheless, additional variables would have been of interest from the current perspective, such as the age of the children or the frequency of participation in video consultations. Furthermore, the interviews were conducted after the appointments or consultations and were thus not anonymously registered.

Parents in the in-person appointment group estimated the potential waiting time as being shorter than parents in the video-consultation group. However, technical problems (eg, not enough mobile data available or insufficient battery) also often led to waiting times before video consultations. The actual waiting time was not recorded in either group. Similarly, parents who were offered video consultations but did not accept the offer were not included or evaluated in this study.

Future Perspectives

The examiners' perspectives were not elicited but might have revealed valuable new approaches for further research. There appears to be a lack of evidence from research in digital health, which in turn hinders implementation, and vice versa. Future randomized controlled studies are needed for the evaluation of digital tools in medical services offered to chronically ill children [23]. Future studies should also address technological considerations, such as the devices used, data volume, and signal strength.

In developing countries with low incomes and high rural populations, telemedicine could offer, on one hand, opportunities to bring a higher level of health service to patients in isolated regions [12,15], but on the other hand, they might be limited by the supply of hardware and software, as well as by data volume and signal strength; these are issues that should be investigated.

Independent of the pandemic, video consultation has been developed as a low-threshold service to bring medical care closer to the patient. It serves patients very well who live far away from specialists or who have greater logistical challenges, such as children on ventilators [24]. Telemedicine significantly reduces health service use and may therefore reduce health service costs [15,25,26]. Parents feel secure and adequately supported in their own home with their preterm infants and children. This generation of parents has an innate understanding of digital devices and services [27,28]. They feel well informed about the neurodevelopment of their children at risk of neurodevelopmental difficulties. Being closely involved in the examination of their infants during video consultations as part of follow-up care gives parents a better understanding of the neurodevelopment of their children and empowers them as caregivers. Offering follow-up care as a multi-professional team with a combination of in-person visits and interactive media may have the potential to improve the compliance of families and lengthen the period of follow-up care [28]. Overall, telemedicine and video consultations may be used as

supplementary tools in medical and follow-up care in the twenty-first century for chronically ill patients and children with the need for continuous attendance and surveillance. The opportunities certainly outweigh the challenges in times such as the COVID-19 pandemic.

Conclusion

The feasibility of video consultations for follow-up care of very preterm or at-risk infants and parental satisfaction with the consultations was as high as for in-person consultations. Parents rated video consultations as being as confidential as in-person appointments. Telemedicine can be offered as an equivalent alternative to an in-person consultation and is particularly useful under certain circumstances, such as care for very sick children who require assistive devices, such as respiratory support and oxygen, or for children living a long distance away.

Acknowledgments

The authors wish to thank the Stiftung Universität Essen foundation, which started this trial as part of its COVID-19 projects (20204699123), and the University Medicine Essen Clinician Scientist Academy, which funded author BA. We also sincerely thank the children, parents, and other participants for their contribution to this trial.

Data Availability

All data presented in this article and the code for reproducing the statistical results and figures are available in Multimedia Appendix 2.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interviews to evaluate the video or in-person consultation of follow-up care of premature infants.
[DOCX File , 19 KB - pediatrics_v6i1e40940_app1.docx]

Multimedia Appendix 2
Video consultation in preterm follow-up care during the COVID-19 pandemic -opportunities and challenges.
[PDF File (Adobe PDF File), 953 KB - pediatrics_v6i1e40940_app2.pdf]

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Abbreviations

NICU: neonatal intensive care unit

Edited by S Badawy; submitted 10.07.22; peer-reviewed by D Gunasekeran, M Silva; comments to author 22.10.22; revised version received 11.11.22; accepted 17.11.22; published 25.01.23.

Please cite as:
Albayrak B, Cordier LJ, Greve S, Teschler U, Dathe AK, Felderhoff-Müser U, Hüning BM
Feasibility of Video Consultation for Preterm Neurodevelopmental Follow-up Care During the COVID-19 Pandemic: Cohort Study
JMIR Pediatr Parent 2023;6:e40940
URL: https://pediatrics.jmir.org/2023/1/e40940
doi:10.2196/40940
PMID:36409307

Original Paper

Understanding Transgender and Gender-Diverse Youth's Experiences Receiving Care via Telemedicine: Qualitative Interview Study

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Abstract

Background: Access to virtual care has increased since the beginning of the COVID-19 pandemic, yet little is known about transgender and gender-diverse (TGD) youth's experiences and perspectives on receiving care via telemedicine.

Objective: The purpose of this study was to explore these experiences to (1) inform necessary changes to the provision of pediatric gender-affirming care and (2) help providers and health systems determine if and how telemedicine should be made available post pandemic.

Methods: Youth (aged 14-17 years) who completed a telemedicine visit in the Seattle Children's Gender Clinic were invited to participate in a semistructured interview exploring perceived advantages or disadvantages of telemedicine and preferred visit modalities. Interview transcriptions were analyzed by 2 research team members using an inductive thematic analysis framework.

Results: A total of 15 TGD youth completed an interview. Commonly cited advantages of telemedicine were convenience and comfort with having visits in their own environments. Reported disadvantages included technical issues, discomfort with the impersonal nature, lack of familiarity with the platform, and privacy concerns. Overall, slightly more youth preferred in-person visits over telemedicine, referencing both specific characteristics of the clinical visit (ie, initial vs return and complexity) and proximity to the clinic as reasons for this preference. Although a plurality of TGD youth preferred in-person visits, they also recognized the value of telemedicine and the impact it may have in facilitating access to care.

Conclusions: Given the variations in needs and visit complexity, our study supports the provision of both in-person and telemedicine modalities as options for pediatric gender-affirming care.

(JMIR Pediatr Parent 2023;6:e42378) doi:10.2196/42378

KEYWORDS

transgender and gender diverse youth; adolescent; telemedicine; gender-affirming care; qualitative methods; COVID-19; pandemic; youth; gender; care; technical; implementation; transgender; telemedicine; gender diverse; complexity

Introduction

Telemedicine provides a means for 2-way, real-time, synchronous communication between a health care provider and a patient, who are not in the same physical location, using audio or video technology [1]. Although telemedicine has been available for a number of years, it has primarily been used to support populations who experience geographic barriers to

specialty health care (eg, rural settings and health professional shortage areas) [1]. However, the COVID-19 pandemic has recently forced health care systems to rapidly implement or scale up the availability of telemedicine visits to continue serving patients, resulting in increased focus on optimizing these platforms for broader use [2,3].

Even before the pandemic, work was in progress to expand telemedicine for the provision of subspecialty care to other vulnerable populations, including children and youth [4]. This was also true for transgender and gender-diverse (TGD) youth seeking access to gender-affirming care, which may include social or psychological supports and medical care that affirms an individual's gender identity. Telemedicine represented an important mode of care delivery for TGD youth, given that many experience substantial barriers to receiving gender-affirming care due to the limited number of clinics across the United States that deliver this care and the fact that few providers outside of these clinics have received formal training in this area [5-7]. However, few guidelines were in place for the provision of these services [3], and little research had been conducted regarding youth's needs and preferences with this modality of care delivery [8,9].

More recent research during the pandemic with a nationally representative sample of youth has shown that young people see value in telemedicine for minor concerns or follow-up care, but that most still prefer in-person visits [10]. Similarly, research conducted before the pandemic showed that just under half (47%) of TGD youth were interested in telemedicine, but they, too, preferred to use this modality for follow-up care [9,11,12]. However, telemedicine interest was especially high among TGD youth who had less parental support for their identities [11]. Such unique experiences illustrate the importance of understanding diverse patient perspectives as health care systems make decisions about whether and how to provide telemedicine services moving forward. As such, now that telemedicine services are more widespread, more research is needed to understand TGD youth's perspectives on receiving gender-affirming care via telemedicine and whether this could be a way to improve access and help overcome the unique barriers to care faced by this population [5,6,13].

Therefore, the purpose of this study was to further explore TGD youth's experiences receiving gender-affirming care via telemedicine, with the broader goals of (1) informing necessary changes to the provision of pediatric gender-affirming care and (2) helping gender-affirming care providers and health systems determine if and how this modality should continue to be made available following the COVID-19 pandemic.

Methods

Participants and Recruitment

Youth aged 14-17 years who completed a telemedicine visit with a Seattle Children's Gender Clinic physician or nurse practitioner to discuss or receive gender-affirming medical care within the last 6 months were invited to complete a screening survey, and if eligible, to participate in a semistructured, one-on-one Zoom interview. For the purpose of this study, the term "telemedicine" was defined as any visit that occurred using real-time video and audio technology from a location outside of the clinic.

For initial recruitment, members of the research team reviewed electronic medical records to identify patients who met initial inclusion criteria to contact by email or during an in-person visit to the clinic. All prospective participants were directed to a Research Electronic Data Capture (REDCap) [14] screening survey to determine eligibility and to provide additional information about the study. Eligible participants were then contacted by a member of the research team to schedule an interview over Zoom [15].

Ethics Approval

Due to the low-risk nature of this study and to avoid excluding participants who may not have disclosed their gender identity to a parent, a waiver of parental consent was granted by the Seattle Children's Hospital Institutional Review Board (STUDY00002873), and all participants provided verbal assent to participate prior to the start of the interview. Each interview participant received a US $20 Amazon e-gift card. All study procedures were approved by the Seattle Children's Institutional Review Board.

Measures

Screening Survey

Demographic information regarding age, gender identity, ethnicity, and race were self-reported on the REDCap screening survey.

For gender identity, respondents could select all that applied from the following: transmale or transmasculine, transfemale or transfeminine, nonbinary, genderqueer, genderfluid, gender questioning, gender nonconforming, agender, demigender, gender variant, androgyne, two spirit (or other identity of indigenous origin), cisgender male, cisgender female, and other.

Respondents were also asked about travel time to the clinic, how supportive their most supportive parent or legal guardian was of their transition on a scale from 1 to 10, and whether a parent had participated in their telemedicine visit with the gender clinic.

Interview

The first part of the semistructured interview included open-ended questions related to participants' experiences receiving gender-affirming care via telemedicine. The second half of the interview focused on their attitudes toward receiving gender-affirming care in the primary care setting. This paper focuses on the first half of the interview, which asked the following open-ended questions:

- "How did you feel about doing a gender clinic visit using telemedicine?"
- "Were there particular aspects of the telemedicine visit you liked or didn't like? Why?"
- "If you had the option of doing a visit over telemedicine vs in-person, what would you choose and why?"

Interview questions were reviewed by members of a TGD youth advisory board for clarity and applicability prior to implementation.

Analyses

Interview transcripts were automatically generated by the Zoom computer program [15] and reviewed by members of the research team for clarity and accuracy. Transcripts were then analyzed by 2 members of the research team using an inductive thematic analysis framework [16] and Dedoose qualitative analysis software (SocioCultural Research Consultants) [17]. Specifically, 2 members of the research team ("coders") used an initial codebook that was generated collaboratively with TGD youth, parent, and primary care provider stakeholders to analyze the data. The coders then met weekly to discuss disagreements and to add codes iteratively as other key themes emerged from the interviews until thematic saturation was achieved. The final results were triangulated with members of a TGD youth advisory board who were provided with a list of themes and examples to ensure they agreed with the quote categorizations.

Results

Participant Characteristics

Of the 45 TGD youth who completed the screening survey, 29 (64%) were deemed eligible and invited for an interview, of which 15 (52%) agreed to participate (Table 1). The mean age of interview participants was 15.7 years (SD 1.1). The majority (n=11, 73%) identified as transmale or transmasculine, and one-third (n=5, 33%) selected more than one gender identity (range: 1-8). Most of the interviewed youth (n=12, 80%) completed their first gender-clinic visit in person, while 3 (20%) youth had completed their first gender-clinic visit via telemedicine. Nearly all of the interviewed TGD youth lived within an hour from the clinic (n=14, 93%). Overall, youth indicated high levels of support for their transition from a parent (mean 8.5, SD 1.9), and 12 (80%) youth had a parent join for a telemedicine visit. Interviews ranged in length from 20 to 45 minutes.

Table 1. Demographic characteristics of screening survey and interview participants.

Variables	Screened (n=45)	Interviewed (n=15)
Age (years), mean (SD)	16.2 (1.2)	15.7 (1.1)
Gender identity[a], n (%)		
Transmale or male	30 (62.5)	11 (73.3)
Transfemale or female	11 (22.9)	3 (20.0)
Nonbinary	14 (29.2)	6 (40.0)
Genderqueer	5 (10.4)	3 (20.0)
Genderfluid	2 (4.2)	2 (13.3)
Gender questioning	0 (0.0)	0 (0.0)
Gender nonconforming	3 (6.3)	3 (20.0)
Agender	4 (8.3)	1 (6.7)
Demigender	4 (8.3)	2 (13.3)
Gender variant	1 (2.1)	1 (6.7)
Androgyne	0 (0.0)	0 (0.0)
Two spirit (or other identity of indigenous origin)	1 (2.1)	0 (0.0)
Cismale	0 (0.0)	0 (0.0)
Cisfemale	0 (0.0)	0 (0.0)
Bigender	2 (4.2)	1 (6.7)
>1 gender identity (range: 1-8)	15 (33.3)	5 (33.3)
Ethnicity or race[a], n (%)		
Hispanic	9 (18.8)	2 (13.3)
American Indian or Alaska Native	2 (4.2)	0 (0.0)
Asian	5 (10.4)	2 (13.3)
Black or African American	3 (6.3)	1 (6.7)
Native Hawaiian or Pacific Islander	2 (4.2)	1 (6.7)
White	37 (77.1)	13 (86.7)
Distance to clinic, n (%)		
≤30 minutes	10 (20.8)	5 (33.3)
31 minutes to 1 hour	25 (52.1)	9 (60.0)
1 to 2 hours	4 (8.3)	0 (0.0)
2 to 3 hours	0 (0.0)	0 (0.0)
3 to 4 hours	2 (4.2)	1 (6.7)
>4 hours	2 (4.2)	0 (0.0)
First visit, n (%)		
In person	29 (60.4)	12 (80.0)
Telemedicine	14 (29.2)	3 (20.0)
Parental support for transition (mean; 1-10)	8.2 (2.1)	8.5 (1.9)
Parent at telemedicine visit, n (%)	38 (79.2)	12 (80.0)

[a]Youth could select more than one gender identity and ethnicity or race.

Advantages and Disadvantages of Telemedicine Modality for Gender-Affirming Care

Key themes of the TGD youth's responses regarding the aspects that they liked and disliked about telemedicine with representative quotes are shown in Table 2.

Table 2. Advantages and disadvantages of telemedicine for gender-affirming care (n=15).

Themes and subthemes	Quotations
Advantages	
Convenience (n=13, 87%)	
Travel time	• *"I do like that it's more convenient. Like you just don't have to, like, drive out or get your parents to drive you out to a specific location."* • *"I especially appreciated that for very short check-in visits. That was, like, super easy to do via telemedicine. That would have taken up a big portion of my day if we'd had to drive down."*
Efficiency	• *"There is also no wait time. I had some long waiting in the office times with the gender clinic. But with telemedicine, it's just like, you log on and they're right there. So, it's very, very efficient."* • *"I think for like just checkups and stuff and general symptoms it's good for telehealth because you can just call and make it happen instead of having to drive over."*
User-friendly	• *"It's very like easy to use the telemedicine videos like you can, like it's very like easy to learn like it's not really complicated like you can just, press on the Zoom link and then go on and then, if you have to put your password or your name you just click enter and then and it's super reliable too, so I like it."* • *"Telemedicine is easy, you can do it at your house, in your bed, you don't really have to do much, you just tap a few buttons."*
Comfort (n=10, 67%)	
Own environment	• *"Well, I mean it's nice to do visits from my house. It's like being in my home is a little bit more comforting because you know, when I go to [CLINIC NAME] I'm in a hospital."* • *"Um, for me, it's mostly the environment around me because when I'm actually in clinic it doesn't really have that same feeling that at home it does, cuz that's home…it's home. But the clinic, it feels like there's a bunch of doctors and nurses and it just doesn't have that same comfort that it would be at home."*
Social anxiety	• *"It might be scary you're going to in person, because they've never had to, cause gender is, like a really touchy subject and, like it can be a little bit uncomfortable sometimes, so I think having the screen in between can sometimes make it a little bit less scary."* • *"For me, especially back then, before I started hormones, I was a very socially anxious person. So, it's always a little daunting going in and sitting face to face with somebody for an hour and you're just looking at a doctor and I feel like through telemedicine it kind of broke that weird barrier there. Like I wasn't as anxious going into it and it was a really good introduction into my care there."*
Avoiding COVID-19	• *"Personally, I like it just because like especially right now, because, like COVID and, like the delta variant and all that stuff going on, I don't feel super comfortable going in, even though I am vaccinated like fully but I do like in this current time, the distance because of the health precautions and stuff."* • *"especially with COVID it- it's it it's a lot safer"*
Disadvantages	
Technical issues (n=9, 60%)	
Bad connection	• *"Occasionally it's annoying if like, connections are bad and it's hard to understand people, technology issues, that sort of thing. But that's about it. That's pretty much the only issues I've had."* • *"It's not really the telemedicine, like visit. It's more like the, like if you live somewhere like, where the Internet is weird like, sometimes the connection is like, unstable."*
Difficulty using platforms	• *"I think, I think it's a bit difficult sometimes because of planning around it and about environment. Because it can be stressful to figure out how to set up something like Zoom or Teams if you haven't before."* • *"I don't personally have any concerns but I know that some people might struggle with a public video call software via the platform that we use. It might be more comfortable for some people to be able to do theirs through something that can be assured as limited access and very secure. Like a [HOSPITAL NAME] run portal type thing."*
Discomfort (n=8, 53%)	
Impersonal	• *"There is kind of more of a personal aspect to sitting with somebody. You kind of get to be with them and it's more of a close connection you have with them."* • *"I just think sitting in a room with someone and seeing them right there kind of helps you get more of a feeling of 'this is a real person.' Because sometimes, looking at a screen, it's just 'this is my computer.' There's just this barrier in between you and the other person."*

Themes and subthemes	Quotations
Unfamiliar	• *"It's just a different environment and it changes how you feel about a certain area."* • *"I think at first it was very unfamiliar to me and kind of hard to adjust with talking to someone on a screen instead of in person. Especially about kind of personal things, but that wasn't an issue much as I got more used to doing that."*
Privacy (n=7, 47%)	
	• *"Some of the things that I don't really like is because everybody's at home, I feel like people will overhear me because the walls aren't that thick and, or like they'll come up to me and say like, 'hey I heard you say this over your interview' or like, 'during your visit.'"* • *"Like the contrast between being in person and being like, through Zoom - when you're in person you're in an office or you're in a room somewhere and it's just the two of you, and you know that it's private. But then when you're not, on their end it's private but also like, on your end, you can be anywhere."*

Advantages

The 2 main themes that emerged regarding the advantages of telemedicine included *convenience* (n=13, 87%) and *comfort* (n=9, 60%). Regarding convenience, participants appreciated not having to commute to the clinic, the efficiency of their visit, and the user-friendliness of the web-based platform. Regarding comfort, TGD youth liked being in their own environment to conduct the visit, not having to deal with social anxiety surrounding their gender identity when visiting the clinic, and avoiding exposure to COVID-19.

Disadvantages

The most commonly reported disadvantage of conducting the visit over telemedicine was *technical issues* (n=9, 60%). Specifically, TGD youth cited unreliable internet connections and difficulty navigating a new or different platform to engage with their providers. Just over half of the TGD youth also reported *discomfort* (n=8, 53%) using telemedicine, indicating that these visits felt impersonal and were an unfamiliar way of engaging with their providers. Finally, participants frequently voiced concerns about *privacy* (n=7, 47%), explaining that they felt more likely to be overheard by family or others while connecting with their providers from home.

Preferred Modalities for Receiving Gender-Affirming Care

A slight majority of the interviewed youth (n=7, 47%) indicated that they preferred in-person visits compared to telemedicine (n=5, 33%), while the remaining 3 (20%) youth said it would depend on certain characteristics of the visit. Interestingly, although most youth had a specific preference for either in-person or telemedicine modality, it became clear through further discussion that their preferred modality could vary based on certain characteristics of the visit (Table 3).

Specifically, youth indicated that their first visit to the gender clinic would be better done in person, but for return or follow-up visits, they preferred telemedicine. In fact, of the 5 youth who preferred telemedicine visits, 3 (60%) indicated wanting their first visit to be in person. Regarding the first visit, participants cited wanting to build rapport with their provider and have their initial conversations occur face-to-face. Participants who preferred telemedicine for follow-up or return visits most often indicated that this was due to the simplicity of the visit and the frequency with which they occur.

Another main theme was visit complexity. Participants suggested that complex visits, including those that involved procedures or major changes to their care, were better done in person. Conversely, participants indicated that less complex visits, including verbal check-ins with a provider, could be easily completed via telemedicine.

Finally, youth cited distance to the clinic as an important factor in deciding when to use telehealth services. Specifically, youth suggested that in-person visits were better for those who lived closer to the gender clinic, while telemedicine were better for those who lived further away or with other transportation barriers.

The following quote from a study participant illustrates this interplay between these characteristics:

> *My first visit with the gender clinic was definitely better in person, but many consecutive appointments after that, I would have absolutely done telemedicine. Because there was my first appointment, I was prescribed something out the gate and that's, you know, I would prefer that to be in person. But every subsequent appointment besides that wasn't talking about starting a new medication. It was definitely like, I'm here for 10 minutes and I'm out. All right, well goes back to convenience, where I don't really want to hear the same thing, I don't want to go drive half an hour and then hear the same thing that I heard last appointment then drive away…I guess it depends on the subject matter and the duration of the visit...But yeah, yeah it's not, it, I feel like, ironically, despite my stance on telemedicine, like, as in, like, it's probably my least preferred way of communicating medical ideals, it's, I also believe that it's the future of medicine, because it's so convenient.*

Table 3. Reasons for in person versus telemedicine care.

Themes	Visit description and quotations	
	In-person	Telemedicine
Visit type	• First visit • *"I personally would prefer the first appointment to be in person, just so it's easier to connect."* • *"I think maybe go in person, just for like a big initial visit, and then after that I would have just been comfortable with telemedicine."*	• Return visit • *"I think follow ups it really makes sense to do them virtually because you're gonna have so many of them."* • *"I honestly think that telemedicine makes a lot more sense than in person, especially for follow ups"*
Complexity	• More complex visit • *"If we were going to talk about doing something new or making a big change to the stuff I'm already doing, I think that's something that would be better done face-to-face."* • *"If they need to, you know, run tests, draw blood or whatever like that, then I would rather come in then, be in person, because I feel like that's harder to do virtually."*	• Less complex visit • *"It kind of depends what the subject of the visit would be, but for the normal check-ins I do, I think telemedicine is preferable."* • *"I think it depends on what needs to be done at my visit, because for just an average 'how are you doing on your hormones' kind of talking thing, I would prefer telemedicine."*
Distance	• Closer proximity to clinic • *"I don't think, there's no challenges or obstacles because like, we live like, really close to her like, well, to the hospital."* • *"I guess if you're closer to [CITY] and, and would, you would be, different reasons."*	• Further distance from clinic • *"Personally, I thought it was a lot easier because I live a few hours away."* • *"I think time is a big part of it…Like, for me, I prefer telemedicine because it's a long time to drive."*

Discussion

Principal Findings

The purpose of this study was to better understand TGD youth's perspectives and preferences regarding how they receive gender-affirming care services in order to inform and improve future care delivery. Our results support those of past surveys and quantitative research, which have shown that youth prefer in-person visits to telemedicine [8-11]; however, our qualitative discussions regarding benefits and drawbacks of each modality further indicate that the choice is not so simple. Although a plurality of TGD youth in our study indicated a preference for in-person visits, they also recognized the value of telemedicine to themselves and others for less complex or follow-up visits and the impact it may have in facilitating access to care [12]. Given variations in needs and visit complexity, our results suggest that both in-person and telemedicine modalities should be options for the provision of gender-affirming care, and that patient needs and constraints should be considered as these services become more widely implemented.

Although the rapid implementation and scale-up of telemedicine options resulting from the COVID-19 pandemic have allowed health care systems to continue serving patients remotely, any such rapid change also brings growing pains [2,3]. Some of these may be remediable with time. For example, certain disadvantages cited by the youth in our study, including discomfort with the new modality and certain technical issues, may improve as patients become more familiar with the visit process and platforms used. Other disadvantages, such as feeling impersonal, may also be helped by additional provider training on building rapport virtually. However, there are some disadvantages, such as privacy issues, which may be more difficult to change given the different environments where youth engage in their telemedicine visits. National guidelines emphasize the importance of confidential health services for adolescents, which allow for private discussion of sensitive health topics and encourage adolescent responsibility for their own health care [18,19]. This may be even more important for TGD youth who are not open about their gender identity to all of the individuals with whom they live or those who have limited parental support [11,20]. Additional changes to virtual care provision (eg, room scans, use of headphones, asking whether the patient is alone or if they can be overheard at the start of the visit) may help to alleviate some of these privacy concerns, but further solutions to ensure access to confidential care via telemedicine are warranted [21].

Strengths and Limitations

An important strength of this study is our use of qualitative methods to engage more deeply with end users. Existing stakeholder-engaged research mechanisms have allowed for patient-centered discussions regarding their needs and expectations around their health care [22]. However, youth, and particularly TGD youth, are rarely included in these conversations [23]. Thus, engaging with youth in this way represents an important first step toward developing more youth-friendly health information technology, which will not only make these services more responsive to the unique needs of youth but will likely also increase patient satisfaction and engagement with health care [23-26]. Given the current generation's access to and familiarity with technology [27], such adolescent-informed platforms may also have additional benefits as they relate to promoting adolescent autonomy over

their health care and facilitating their successful transition to adult care [28-30].

A critical limitation of our study is sample size, as the experiences of this small group of youth cannot be interpreted as representative of the broader population of TGD youth. Similarly, rates of perceived parental support among participants in our sample were quite high, which can be attributed to our recruitment strategy that focused on TGD youth who had already completed a telemedicine visit at the Seattle Children's Gender Clinic. Care must therefore be taken not to generalize these findings to youth who may have lower rates of perceived parental support. Our study is also limited by a relative lack of diversity, which is not uncommon in clinic-based studies of TGD youth, [30] but reflects the characteristics of populations with greater access to gender-affirming care services [31]. That said, it is critically important to recognize how intersectional identities and experiences—such as those who identify as gender diverse and are Black, Indigenous, and people of color or live rurally—can further exacerbate barriers to care [31]. Furthermore, additional barriers that may disproportionately impact TGD youth, such as parent or caregiver dependence for access to care and consent to services, should also be considered when developing pediatric gender-affirming care services [6,32].

Relatedly, since we interviewed youth via Zoom and only interviewed those who had participated in a telemedicine visit, we did not hear the perspectives of youth who experience barriers to accessing these services. Specifically, those who live in areas where internet access is unavailable or less reliable may still have disproportionately less access to health care and other services. Despite the often-cited advantage of increasing access to health services among those living in medically underserved areas, we must remain aware of the fact that the rapid implementation of telemedicine could exacerbate existing disparities [33].

Conclusions

Overall, our study supports the provision of both in-person and telemedicine modalities as options for pediatric gender-affirming care. Moreover, the benefits and drawbacks identified by TGD youth in this study can be used to inform new and developing telemedicine programs for adolescent health care as well as future work focused on building adolescent-friendly and responsive health systems.

Acknowledgments

This project was supported by the Seattle Children's Research Institute and the Agency for Healthcare Research and Quality (AHRQ; K12HS026393-03; principal investigator: GMS) and Pivotal Ventures.

Thank you to the Seattle Children's Gender Clinic TGD youth advisory board for their review of the interview questions and results. Thank you to Elsie Rockers for her assistance with data collection.

Authors' Contributions

NFK drafted the initial manuscript, carried out initial analyses, and reviewed and revised the manuscript. YHA assisted with drafting the initial manuscript, collected data, carried out the initial analyses, and reviewed and revised the manuscript. KMB collected data and reviewed and revised the manuscript. DAC and LPR assisted in conceptualizing and designing the study and critically reviewed and revised the manuscript. WP critically reviewed and revised the manuscript. GMS conceptualized and designed the study and data collection instruments, supervised data collection, and reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Conflicts of Interest

The author GMS has received consultative compensation from Pivotal Ventures and the Fenway Institute.

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Abbreviations

REDCap: Research Electronic Data Capture
TGD: transgender and gender diverse

Edited by S Badawy; submitted 01.09.22; peer-reviewed by K Braune, L Thurston, M Mars; comments to author 29.01.23; revised version received 01.02.23; accepted 04.02.23; published 14.02.23.

Please cite as:
Kahn NF, Anan YH, Bocek KM, Christakis DA, Richardson LP, Pratt W, Sequeira GM
Understanding Transgender and Gender-Diverse Youth's Experiences Receiving Care via Telemedicine: Qualitative Interview Study
JMIR Pediatr Parent 2023;6:e42378
URL: https://pediatrics.jmir.org/2023/1/e42378
doi:10.2196/42378
PMID:36745775

Review

Satisfaction With Telehealth Services Compared With Nontelehealth Services Among Pediatric Patients and Their Caregivers: Systematic Review of the Literature

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Abstract

Background: Telehealth refers to the use of technology to deliver health care remotely. The COVID-19 pandemic has prompted an increase in telehealth services.

Objective: This study aimed to review satisfaction with pediatric care in studies that had at least one group of pediatric patients and their caregivers receiving telehealth services during the COVID-19 pandemic and at least one comparison group of those receiving nontelehealth services.

Methods: We searched for peer-reviewed studies published in the English language that compared the satisfaction with pediatric care between pediatric patients and their caregivers receiving telehealth services during the COVID-19 pandemic and those receiving nontelehealth services. Owing to stay-at-home orders, studies with comparison groups for nontelehealth services that took place either before or during the pandemic were eligible. We searched the PubMed, Embase, CINAHL, and PsycINFO databases on January 5, 2023. We followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. A total of 2 reviewers independently screened the titles and abstracts before reviewing the full text of the remaining articles. The following information was extracted from each eligible study: country, participant characteristics by comparison group, study design, telehealth approach, measurement tools to assess satisfaction, and findings by comparison group.

Results: All 14 eligible studies assessed satisfaction among caregivers and pediatric patients participating in video or telephone visits during the COVID-19 pandemic compared with those having in-person appointments either before or during the pandemic. In 5 of the 14 studies, a comparison of nontelehealth services took place before the pandemic, and in the remaining 9 investigations, nontelehealth services took place during the pandemic. A total of 13 studies were observational investigations with different designs, and 1 study was a quasi-experimental intervention with 3 comparison groups for video, in-person, and hybrid visits. In 9 of the 14 studies, satisfaction with telehealth services was higher than during in-person visits. Caregivers were satisfied with video visits for the ease of use and reduced need for transportation. Reasons caregivers were not satisfied with remote care included limited personal interaction with the provider, technological challenges, and a lack of physical examination. Those participating in nontelehealth services expressed that in-person interactions promoted treatment adherence. Only 1 study assessed satisfaction where adolescent patients completed their own surveys; a higher percentage of adolescents using telehealth services reported effective communication with the provider compared with patients using in-person visits.

Conclusions: In most studies, telehealth services received more favorable or comparable satisfaction ratings than in-person visits. Needed improvements in telehealth services included strategies to address technological challenges and develop better rapport among the patient, caregiver, and medical provider. Interventions may investigate the influence of telehealth services on access to and quality of care.

(JMIR Pediatr Parent 2023;6:e41554) doi:10.2196/41554

KEYWORDS

satisfaction; pediatrics; telehealth; telemedicine; virtual care; caregivers; patients; children; COVID-19; coronavirus; SARS-CoV-2; technology use; caregiver; adolescent; youth; satisfaction survey; health outcome; review methodology; systematic review

Introduction

Background

Many health care providers switched from using in-person to remote care for medical visits to adhere to federal, state, and local stay-at-home orders during the COVID-19 pandemic. A 154% increase in the use of telehealth services occurred in March 2020 compared with March 2019 [1]. Telehealth is defined as "the remote provision of health care services through telecommunication technologies for prevention, diagnosis, and treatment" [2].

Telehealth can be synchronous care, asynchronous care, and remote monitoring [3]. Synchronous care entails a direct conversation between the patient and health care provider using telecommunication technology to complete a health care appointment. Asynchronous telehealth involves patient-provider interactions via email, text messaging, or patient portals, where medical questions, photographs, test results, reminders, and medical history are exchanged [3]. Remote monitoring can include receiving frequent vital signs and photographs from patients for detection and intervention [4].

The use of telehealth services has limitations. Previous studies indicated that technological issues [5], incomplete appointments [5], the lack of in-person and personable interaction [5-7], linguistic barriers to access [6], and lower compassion in care [5] were areas of concern in the use of telehealth services. To improve these downfalls in telehealth care, understanding satisfaction with pediatric telehealth services compared with pediatric nontelehealth services provides insight into health care enhancements.

The literature surrounding the use of telehealth services during the COVID-19 crisis is growing, but to the best of our knowledge, no systematic review assessed satisfaction with pediatric care comparing separate groups of participants, where at least one group received telehealth services and another group received nontelehealth services during the time frame of the pandemic. In one published scoping review focusing on both adult and pediatric care during the COVID-19 pandemic, satisfaction was mentioned briefly, stating that there was insufficient information on that topic and proposed researching satisfaction in the future [7]. In a systematic literature review of pediatric randomized controlled trials (RCTs) conducted before the COVID-19 pandemic, telemedicine interventions resulted in slightly better or comparable satisfaction with care and health outcomes compared with control groups in all 10 included studies [8].

Objective

Our study sought to investigate satisfaction with telehealth during the COVID-19 pandemic compared with nontelehealth use among caregivers and pediatric patients. Our systematic literature review included only studies that compared satisfaction in separate groups of participants (ie, caregivers and pediatric patients), where at least one group participated in telehealth services and 1 group received nontelehealth services. Because of stay-at-home orders, studies with comparison groups for nontelehealth services that took place either before or during the pandemic were eligible.

Methods

Research Question, Review Design, and Eligibility Criteria

Overview

The review question was as follows: what is the satisfaction of pediatric patients and their caregivers involved in telehealth compared with those involved in nontelehealth services? We followed the 2020 PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [9]. The page numbers where different elements of the PRISMA are included in this study are in the completed PRISMA 2020 checklist in Multimedia Appendix 1. Before conducting the literature search, the review protocol was registered in the International Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY; registration 202290067) [10].

One of the PRISMA 2020 checklist items is "Describe and explain any amendments to information provided at registration or in the protocol" [9]. In the original registered review protocol, the intent was to not restrict to only studies with comparison groups. Owing to the large number of studies with no comparison groups (ie, 187 studies), we restricted our search to only studies with comparison groups. Initially, the study included pediatricians along with pediatric patients and caregivers as participants; as we were reviewing studies, we realized that the same pediatricians were asked to compare their in-person and telehealth visits without separating medical providers into comparison groups. In addition, our search was initially conducted without the guidance of a librarian, resulting in 13 eligible studies. As a manuscript focusing on how to conduct literature searches following PRISMA guidelines states, guidance provided by librarians can result in reproducible searches [11]. Revising the search strings through the collaboration of a librarian resulted in 1 additional article or a total of 14 studies. Thus, the review protocol was revised to include a comparator, exclude pediatricians as part of the participants (ie, exclude pediatricians describing their satisfaction and only include pediatric patients and their caregivers), and revise the search strategy by using Medical Subject Headings (MeSH) words as described below based on the suggestions of a librarian [10]. The Populations, Interventions (or Exposures), Comparators, Outcomes, and

Study designs or Settings (PI(E)COS) structure used in this review is as follows:

- Outcome: satisfaction
- Participants: pediatric patients and their caregivers
- Intervention or exposure: telehealth
- Comparison group: a group not participating in telehealth services, such as a group receiving in-person services
- Time frame: COVID-19 pandemic

Language and Study Designs

The inclusion criteria were peer-reviewed studies with full text in the English language seeking to gain perspectives on satisfaction among pediatric patients and their caregivers involved in telehealth services compared with pediatric patients and their caregivers involved in nontelehealth services. Conference abstracts and dissertations were also excluded.

There were no restrictions on the study design because of the limited number of studies with comparison groups. The 2020 PRISMA guidelines state that checklist items "are applicable to systematic reviews with objectives other than evaluating interventions" [9]. All intervention designs were included specifically randomized RCTs, quasi-experimental studies with control or no control groups, and qualitative studies. In addition to interventions studies, observational cross-sectional, cohort, and case-control studies involving surveys and interviews assessing satisfaction among those participating in telehealth services compared with those participating in nontelehealth services were also included in the study. Both prospective and retrospective analyses were eligible for inclusion in the study.

Health Conditions

Pediatric patients aged between 0 and 18 years could be seen for any physical or mental health condition in this review. No restrictions on the type of condition were placed. Studies on satisfaction during pregnancy were also excluded.

Time Frame

Telehealth services that occurred during the COVID-19 pandemic were also included. As at times, only telehealth services may have been allowed because of stay-at-home orders, studies with comparison groups for nontelehealth services that took place either during or before the pandemic were included. As search words for the COVID-19 pandemic were used, the search was not restricted by date. Interventions and observational studies with published dates occurring after the onset of the pandemic were excluded if they did not address the implications of the COVID-19 crisis or if the study period occurred before the pandemic. Studies from the period when the COVID-19 crisis had not yet been defined as a pandemic were excluded.

Participants

Patients (ie, children and adolescents aged 0-18 years) and caregivers (eg, family members, parents, mothers, or fathers) were included. Studies in which adults discussed experiences with their own health care and nonpediatric care were excluded.

Intervention or Exposure

Studies in which participants received telehealth services such as video and telephone visits and remote monitoring were included. No restrictions were imposed on the type of telehealth.

Intervention or Exposure Comparator

Studies in which there was at least one comparison group of participants who were receiving nontelehealth services, such as in-person visits, were included. Studies comparing telehealth services and nontelehealth services in the same group of participants (such as in studies where the same patients were asked to compare their experiences with telehealth services and nontelehealth services) were excluded.

Outcome

No standard measurement of satisfaction was included in the study. Studies that created their own measurements, as well as studies that used reliable or valid or other measurements, were included.

Databases and Search Strategy

Literature review searches were performed in the PubMed, CINAHL, Embase, and PsycINFO databases on January 5, 2023. The search strings were developed with the guidance of a librarian from the University of Michigan—Flint library, as stated in the *Acknowledgments* section. The search strings in Multimedia Appendix 2 were used in each database. Multimedia Appendix 2 also lists the specific steps of the search, such as a description of whether an advanced search was used and in what box or field the strings were entered so that one could reproduce the searches.

As different countries may use different synonyms for keywords, we sought to use various synonyms. Synonyms for exposure were "telehealth," "telemedicine," "video consultation," and "remote consultation." Synonyms of the outcomes were "patient satisfaction," "satisfaction," "perception," and "attitude." Synonyms for the type of care and population included "pediatrics," "paediatric," "pediatric," "baby," "infant," "child," "teen," and "adolescent." Synonyms for the time frame were "Covid-19," "SARS-CoV-2," "sars-cov-2," "sars-cov-2," "Severe Acute Respiratory Syndrome Coronavirus," "NCOV," "2019 NCOV," and "coronavirus."

PubMed and Embase allowed for the use of MeSH and explosion (marked by /exp) terms, respectively, which used their own synonyms as part of the search. In PubMed, the following MeSH terms were entered: "pediatrics," "child," "infant," "adolescent," "telemedicine," "remote consultation," "patient satisfaction," "COVID-19," "sars-cov-2," and "coronavirus." Telemedicine is a MeSH term introduced in 1993 that is associated with the following synonyms: "telehealth," "tele-referral," "virtual medicine," "tele-intensive care," "tele-ICU," "mobile health," "mHealth," and "eHealth."

Essential keywords were entered both as MeSH words or expanders and separately with truncations; therefore, the search allowed the inclusion of more relevant articles. Specifically, "pediatric," "paediatric," "child," "adolescent," "attitude," and "perception" were entered as MeSH/explosion terms and separate words with truncations. The symbol for truncation is

the asterisk (*), which allows for the retrieval of all words that contain the part of the term preceding the asterisk. Truncations in all databases were as follows: “pediatric*,” “paediatric*,” “child*,” “adolescen*,” “attitude*,” and “perception*.” MeSH words and expanders must be entered without truncations.

Data Extraction and Synthesis

After using the search words in Multimedia Appendix 2 in each database, all articles were uploaded to EndNote Basic (Clarivate), where duplicates were removed using automation tools. Following the removal of duplicates, 2 authors (GDK and TC) reviewed all the remaining titles and abstracts. If the title and abstract did not clearly indicate whether the study met or did not meet the inclusion criteria, the reviewer opened the full text of the article. Each reviewer made notes about why the study fit the inclusion or exclusion criteria in a separate Excel file. The 2 reviewers resolved disagreements after reviewing the full text of the article. A consensus was reached between the reviewers on the items when there were differing opinions on inclusion in the literature review.

The final studies were categorized based on the participant group whose satisfaction was assessed. Information was extracted on the location, sample size by comparison group, mean and median age of participants or other information provided on age, pediatric health condition, telehealth and comparison group definitions, assessment of satisfaction, and findings by comparison group. Some studies used the term “telehealth” and others used “telemedicine.” The terms referred to in these studies were used.

If the article did not specify the type of study design used, we made decisions on what the study design was based on descriptions in the text. Owing to the many satisfaction findings in most studies, not all outcomes were extracted in tables. Findings representative of the overall study results were extracted; for example, for studies that concluded that patients were more satisfied with in-person visits than telehealth visits, representative findings showing lower satisfaction with telehealth visits were extracted. If a study used both close-ended and open-ended items, the key results for both types of items were presented. Findings extracted were not based on the same measures because the studies used various definitions of satisfaction. Risk ratios, mean differences, and P values, if any, were reported as the key results. GDK conducted data extraction. TC reviewed the extracted data. GDK and TC reviewed the final data and resolved any disagreements through discussions.

Quality of Evidence or Risk of Bias

The quality of evidence in the studies was independently evaluated by 2 reviewers (GDK and TC) using 2 methods: the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach [12] and the Joanna Briggs Institute (JBI) critical appraisal tools [13].

The GRADE approach involves assigning a quality level rating to a study based on the study design [12]. According to the GRADE approach, RCTs receive a high rating, and observational studies receive a low rating [12]. In this review, the ratings based on study design were as follows: RCTs, high; quasi-experimental pretest and posttest study, moderate; cohort study (prospective) and case-control study (retrospective), low to moderate; and analytic cross-sectional study (retrospective), low. Similarities and differences in sociodemographic characteristics of participants in comparison groups and validity and reliability of data collection tools were reviewed in more detail in a narrative table to assess limitations in the study design and execution of the study in Multimedia Appendix 3 [14-27].

In addition, to assess specific limitations in the study design and execution of the studies, scores were assigned based on answering common questions across study types on JBI forms [13] in Multimedia Appendix 4 [14-27]. In total, 2 independent reviewers (GDK and TC) used the forms separately with JBI assessment form questions for each study including the following:

- Were the criteria for inclusion in the sample clearly defined?
- Were the study participants and setting described in detail?
- Were the comparison groups (telehealth and nontelehealth) comparable in terms of sociodemographic characteristics?
- Was the period (such as months and years) of the study periods for each comparison group clearly defined?
- Was satisfaction measured in the same way in the comparison groups?
- Were satisfaction outcome measures valid and reliable?
- Were appropriate statistical analyses used?

A score of 1 for the above questions meant “yes,” a score of 0.5 signified “partially,” and a score of 0 meant “no or unclear.” The scores were summed up for each question for each study. Higher total scores indicated higher study quality and a lower risk of bias. Disagreements in GRADE quality levels and JBI critical appraisal forms scores were resolved through discussion between the 2 reviewers.

Results

Literature Search

Figure 1 illustrates the flow of the systematic review in selecting articles. A total of 14 manuscripts met the inclusion criteria [14-27].

Of the 959 articles following the original search, 382 (39.8%) were removed using automation tools because they were duplicates. A total of 355 articles were removed during title or abstract review. Among the 219 full-text articles assessed, 187 (85.3%) were excluded because they focused on satisfaction in pediatric care during the pandemic but did not have a comparison group. An example of a study that was excluded was that from Zambia, in which 1 group of adolescents answered questions about experiences and perceptions related to telephone visits without comparing the results with a group of adolescents having nontelehealth visits [28]. Of the 187 articles, only 14 (7.4%) assessed satisfaction with health care among pediatric patients and their caregivers participating in telehealth services compared with those participating in nontelehealth services.

Among the 14 studies [14-27], 13 (93%) assessed satisfaction among caregivers by asking them about the health care of their children [14-26] and 1 (7%) [27] assessed satisfaction by asking caregivers and adolescents (ie, patients) about their satisfaction

separately. Furthermore, 1 study compared video, in-person, and hybrid visits [14], and 1 study compared telephone visits with in-person visits [25]. Another study compared video, telephone, and in-person visits [24]. All others compared video and in-person visits.

Table 1 provides the location, number of participants, number of visits, mean and median age of participants or other information provided on age, and the pediatric health condition within each study. Table 2 includes information on the telehealth and comparison group definitions, assessment of satisfaction, and findings for telehealth and nontelehealth groups.

Figure 1. Identification of studies through the systematic review process.

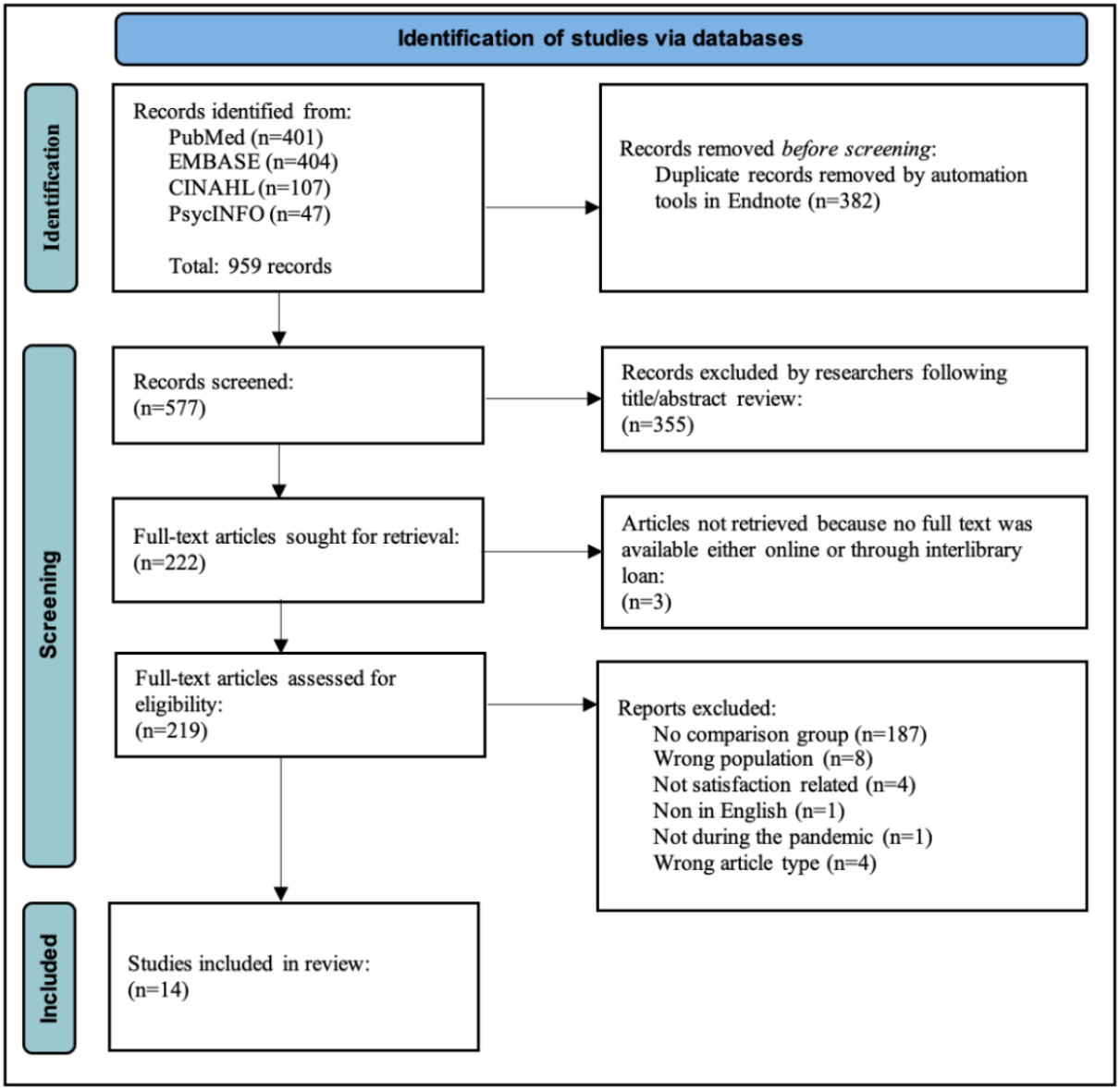

Table 1. Location, number, age, and condition among participants in the 14 included studies.

Study	Country	Number of participants or number of visits	Mean or median age of participants or other information provided on age	Pediatric health condition
Caregivers or patients: caregivers completed survey items on behalf of children or adolescents; results for caregivers and patients were presented together without presenting separate results for patients				
Corona et al [14], 2021	United States	• Total: 95 patients • Video visit patients: 46 • In-person visit patients: 49	• Video visits patient mean age: 28.17 months • In-person visits patient mean age: 27.96 months	Autism spectrum disorder
Hoi et al [15], 2022	United States	• Total: 21,592 visits • Telemedicine visits: 2051 • In-person visits: 19,541	• Telemedicine visits patient mean age: 7.2 years • In-person visits patient mean age: 7.3 years	Otolaryngology
Holzman et al [16], 2021	United States	• Total: 153 patients • Telemedicine visit patients: 51 • In-person visit patients: 102	• Telemedicine visits patient median age: 8.0 years • In-person visits patient median age: 7.5 years	Urology
Johnson et al [17], 2020	United States	• Total: 15,562 visits • Telemedicine visits: 11,192 • In-person visits: 4370	• Not stated	A variety of pediatric specialties, such as attention-deficit hyperactivity disorder, adolescent health, developmental and behavioral, cystic fibrosis

Katz et al [18], 2021	United States	• Total: 150 patients
		• Telemedicine visit patients: 23
		• In-person patients: 127
			• Telemedicine visits patient age distribution:
			  • <1: 0%
			  • 1-4: 17.39%,
			  • 5-10: 39.13%
			  • 11-14: 30.43%
			  • ≥15: 13.04%
			• In-person visit patient age distribution:
			  • <1: 29.13%
			  • 1-4: 33.07%
			  • 5-10: 25.2%
			  • 11-14: 8.67%
			  • ≥15: 3.94%
				Primary care

Kennelly et al [19], 2021	United States	• Total: 1514 visits • Telemedicine visits: 688 • In-person visits: 826	• Not stated	Development pediatrics and autism

Love et al [20], 2022	United States	• Total: 232
		• Telemedicine visit patients: 156
		• In-person visit patients: 76
			• Telemedicine visits patient age distribution:
			  • <1: 6%
			  • 1-10: 44%
			  • ≥10: 50%
			• In-person visit patient age distribution:
			  • <1: 1%
			  • 1-10: 51%
			  • ≥10: 47%
				Pediatric gastroenterology

Mahmoud et al [21], 2022	Egypt	• Total: 1928 patients • Telemedicine visit patients: 1056 • In-person visit patients: 874	• Telemedicine visits patient mean age: 1.2 • In-person visits patient mean age: 1.6	Ambulatory surgery

Study	Country	Number of participants or number of visits	Mean or median age of participants or other information provided on age	Pediatric health condition
Marques et al [22], 2020	United States	• Total: 9392 visits • Telemedicine visits: 2960 • In-person visits: 6362	• Not stated	Ambulatory care
McCoy et al [23], 2022	United States	• Total: 172 patients • Telemedicine visit patients: 59 • In-person visit patients: 113	• Telemedicine visits patient mean age: 4.99 • In-person visits patient mean age: 6.15	Otolaryngology
Mustafa et al [24], 2021	United States	• Total: 401 patients • Video visit patients: 98 • In-person visit patients: 303	• Video visits patient mean age: 29 (range 11-52.5) years • In-person visits patient mean age: 20 (range 6-52.5) years	Allergy or immunology
Ragamin et al, 2021 [25]	The Netherlands	• Total: 144 patients	• Patient median age: 6 years	Atopic dermatitis
Summers et al [26], 2022	United States	• Total: 817 patients • Video visit patients: 674 • In-person visit patients: 143	• Not stated	Ophthalmology
Satisfaction assessed separately for adolescents and caregivers: adolescents answered at least some satisfaction surveys items separately; results were presented separately for adolescents and caregivers				
Troncone et al [27], 2022	Italy	• Total: 610 patients • Video visit patients: 305 • In-person visit patients: 305 • Video visit caregivers: 305 • In-person visit caregivers: 305	• Video visits patient mean age: 12.17 years • In-person visits patient mean age: 12.12 years	Type 1 diabetes

Table 2. Telehealth approach, assessment of satisfaction, and findings among the 14 included studies.

Study	Telehealth approach and comparison groups	Satisfaction data collection tool examples	Findings
Caregivers or patients: caregivers completed survey items on behalf of children or adolescents; results for caregivers and patients were presented together without presenting separate results for patients.			
Corona et al [14], 2021	Video sessions between March 2020 and August 2020 compared with in-person visits between July 2019 and March 2020	• A 14-item closed-ended survey developed by the authors, including items, such as "I would recommend these services to other families," "My child's behavior and skills improved during this service," and "I am pleased with the outcome of services for me and my child."	• 89% of caregivers participating in telehealth service strongly agreed that they were pleased with the outcome of the visit compared with 87% of caregivers participating in in-person visits.
Hoi et al [15], 2022	Telemedicine visits consisting of 352 new patient video visits, 1548 return video visits, 109 phone visits, 41 nonportal video visits for caregiver without portal access, and 1 patient education video visit compared with in-person visits consisting of new patient visits, return visits, preoperative visits, and postoperative visits between April 1, 2020, and April 30, 2021	• Surveys with closed-ended and open-ended items. • Surveys asked respondents to express a positive or negative sentiment with the visit as well as to provide narrative comments on the experience with the visit.	• 96% of caregivers or patients reported positive experiences with the in-person visit compared with 100% with the telemedicine visit. • An example of a positive comment regarding the in-person visit was, "All of my concerns about my son's health have been listened to." • An example of a positive comment regarding the in-person visit was, "The video visit saved us a 10-h drive."
Holzman et al [16], 2021	Video visits between April 2020 till 2020 compared with in-person visits between January 2019 and March 2020	• Survey with a close-ended question on satisfaction: "using a number from 1 to 10, where 1 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?"	• 92% of caregivers and patients participating in telemedicine visits reported high satisfaction with the provider compared with 87% of caregivers and patients participating in in-person visits (odds ratio 1.7, 95% CI 0.53-5.7).
Johnson et al [17], 2020	Video visits compared with in-person visits between April 2020 and May 2020	• Survey with a closed-ended question on satisfaction: "using a number from 1 to 10, where 1 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?"	• 97.9% of caregivers and patients participating in telemedicine visits reported high satisfaction with the provider compared with 83.9% of caregivers and patients participating in in-person visits (P=.07).
Katz et al [18], 2021	Video visits compared with in-person visits between March 10 and June 29, 2020	• Survey with closed-ended questions on satisfaction, such as "Provider explained problem or condition" and "Provider made efforts to include us in decisions"	• In 91.25% of telemedicine visits, caregivers indicated the provider provided a very good explanation of the problem or condition compared with 84.57% of in-person visits. This difference was not statistically significant. The mean visit satisfaction scores were 92.25% for in-person visits and 95.37 for telemedicine visits.
Kennelly et al [19], 2021	Telemedicine visits for caregivers between June 2020 till July 2021 compared with in-person visits for caregivers/patients between June 2019 and May 2020	• Press Ganey survey consisting of 21 items; 7 items not relating to telemedicine were excluded. • A closed-ended item on overall assessment of care included likelihood of your recommending our practice to others.	• 87.25% of caregivers and patients participating in telemedicine visits were likely to recommend practice to others compared with 85.76% of caregivers and patients participating in in-person visits (P<.99).

Study	Telehealth approach and comparison groups	Satisfaction data collection tool examples	Findings
Love et al [20], 2022	In-person visits compared with video visits between May 2020 and June 2020	• Oral telephone survey with questions 2 weeks after the visit on reasons for preferring the type of visit. The specific questions asked were not included. It appeared from the descriptions that the questions were closed ended.	• Among those in the telemedicine group, the reasons for preferring the visit were time savings associated with less driving and reduced cost. • Among those in the in-person group, the reasons for favoring the visit were having a preferred physician and wanting a physical examination.
Mahmoud et al [21], 2022	Video visits between April 2020 till May 2020 compared with in-person visit between January 2020 and February 2020	• Patient experience assessment survey with closed-ended items, such as "overall the service was excellent and it met my expectations." • Caregivers were asked for the reasons, if any, why they were dissatisfied with the visit experience.	• 92% of caregivers and patients participating in telemedicine visits were satisfied with the visit compared with 63% of caregivers and patients participating in in-person visits (P=.04). • 8% of all caregivers and patients participating in telemedicine visits were dissatisfied with the visit because of not being persuaded by the video visit, having internet problems, and having a time that interfered with their schedule. • 37% of all caregivers and patients participating in in-person visits were dissatisfied with the visit because of issues related to parking, cleanliness, wait time, and provider and reception office attitudes.
Marques et al [22], 2022	In-person visits compared with video visits between January 2020 and December 2020	• A 16-item closed-ended patient experience survey with items, such as how well the nurse listened to you; likelihood of recommending the practice to others; our concern for your privacy. Each question had ratings of 1-5. A rating of 5/5 was considered "top box."	• No statistically significant differences in satisfaction (as assessed by top box percentages) existed between caregivers participating in in-person and those participating in telemedicine visits.
McCoy et al [23], 2022	Video visits for the first 6 weeks when telemedicine was implemented compared with in-person visits for the 6 weeks before telemedicine was implemented	• Closed-ended items, such as: "How would you rate the following aspects of your child's experience:" ability to communicate with the physician and the overall outpatient experience.	• The ability to communicate with the physician was rated higher (mean 4.6) in the in-person group compared with the telemedicine group (mean 4.4; P<.01)
Mustafa et al [24], 2021	Video new and follow-up visits compared with in-person new and follow-up visits from June 26, 2020, to July 31, 2020	• Closed-ended items, such as, "Overall, I was satisfied with my in-person/video encounter; my in-person/video encounter resulted in a complete evaluation; in the future, I would prefer the following visit type: in-person, video etc." • Open-ended items, such as, "What is the most important reason you would prefer an in-person encounter?"	• 81.5% responded that they strongly agreed that they were satisfied with the in-person visit compared with 72.7% with the video visit. • The most frequently mentioned reason caregivers were satisfied with an in-person visit was to have a physical examination. Another theme was "in-person care allows for a more personal interaction and more questions." Reasons why respondents were satisfied with video visits included: frequent follow-up, convenience, and COVID-19 safety.
Ragamin et al [25], 2021	New and follow-up in-person consultations compared with new and follow-up telephone consultations from March 2020 to July 2020. Telephone consultations could be with or without shared imagines via email to aid the visit.		

Study	Telehealth approach and comparison groups	Satisfaction data collection tool examples	Findings
		• Closed-ended items, such as, "What is your general satisfaction with received care?" and "Assess your patient satisfaction in these areas: information provided, active involvement, needs addressed, emotional support, interaction in general" • Open-ended items on reasons why caregivers preferred face-to-face or remote consultations.	• 34.7% of caregivers who received face-to-face consultations were very satisfied compared with 12.1% of caregivers who received remote consultations (P<.001). • Caregivers who received face-to-face consultations were significantly more satisfied on the emotional support scale compared with those who received remote consultations (P=.039). • Reasons why caregivers preferred face-to-face consultations included "face-to-face examination is important"; "face-to-face consultations raise treatment adherence"; "face-to-face consultations are more efficient."
Summers et al [26], 2022	In-person visits compared with telehealth visits completed by caregivers and patients between March 2020 and July 2020	• Patient satisfaction survey administered by an outside company with items, such as: "How likely would you be to recommend this facility to your family and friends?" with a score of 0 being not all likely and 10 being extremely likely.	• The satisfaction survey scores for "recommend institution" and "recommend provider" were 79.6 and 86.4, respectively, for in-person visits and 81.4 and 92.3, respectively, for telehealth visits.
Satisfaction assessed separately for adolescents and caregivers: adolescents answered at least some satisfaction surveys items separately; results were presented separately for adolescents and caregivers.			
Troncone et al [27], 2022	Video visits between April 2020 and May 2020 compared with in-person visits between June 2020 and July 2020	• Patients themselves completed the JSPPPE[a]. • Caregivers completed the CASC[b]. Examples of CASC items included "I would like to see improvement in the comfort and support the provider gave to the child: yes/no."	• Adolescents: the mean JSPPPE score was 28.92 for video consultations and 27.82 for the in-person visits showing slightly higher satisfaction with the video visit, which was not statistically significant (P=.096). • Caregivers: there were no statistically significant differences in responses to items as part of CASC. For example, 83% of caregivers participating in video visits answered no to, "I would like to see improvement in the comfort and support the provider gave to the child" compared with 81% of caregivers participating in in-person visits (P=.597).

[a]JSPPPE: Jefferson Scale of Patient Perceptions of Physician Empathy.

[b]CASC: comprehensive assessment of satisfaction with care.

Study Characteristics

In total, 11 studies were conducted in the United States [14-20,22-24,26] and 1 each was conducted in Egypt [21], the Netherlands [25], and Italy [27] (Table 1). Some studies provided information only on the number of visits and other studies provided information on the number of participants. The sample sizes of the participants ranged from 23 to 1056 telehealth visit patients and from 49 to 874 in-person visit patients.

Table 2 includes the periods for telehealth and nontelehealth services. In all 14 studies, telehealth services were provided during the pandemic. In 5 of the 14 studies [14,16,19,21,23], nontelehealth services were provided before the pandemic, and in the remaining 9 investigations, nontelehealth services were provided during the pandemic. In the 5 studies where nontelehealth services were provided before the pandemic, satisfaction was higher with remote compared with in-person visits in 4 studies [14,16,19,21], whereas it was higher with in-person than remote visits in 1 study [23].

Quality and Risk of Bias Assessment

Overview

Multimedia Appendix 3 includes information related to quality including study design, quality of evidence rating, similarities and differences in sociodemographic characteristics among the comparison groups, and validity and reliability of the data collection tools. Multimedia Appendix 4 includes the risk of bias scores based on the common questions of the JBI critical assessment tools.

Study Design

Among the 14 studies, there was 1 intervention: a pretest-posttest 3-group intervention [14] (Multimedia Appendix 3). In the pretest-posttest 3-group intervention, the 3 comparison groups were families who received behavioral and support sessions through telemedicine only, families who received sessions through in-person interaction only, and families who received the intervention in a hybrid mode [14].

Of the 14 studies, 5 were prospective cohort investigations [15,20,23,24,27]. In these prospective cohort studies, investigators classified individuals as participating in nontelehealth or telehealth services and then followed them over time to assess their satisfaction. In addition, 1 study was a retrospective case-control investigation that used propensity score matching to match individuals who had in-person and telehealth services in the past [16]. Furthermore, 7 studies used retrospective analyses in which answers to satisfaction surveys between individuals participating in telehealth and nontelehealth services were compared at certain periods in the past [17-19,21,22,25,26]. On the basis of the types of design according to the GRADE approach, the distribution of gradings were 7 studies with a low grading, 6 studies with a low to moderate grading, and 1 study with a moderate grading.

Similarities and Differences in Participants Between the Nontelehealth and Telehealth Groups

In 6 studies, there were no sociodemographic comparisons of participants between telehealth and nontelehealth groups [17,19,20,22,25,26] (Multimedia Appendix 3). In most studies that reported sociodemographic characteristics of telehealth and nontelehealth groups, there were both similarities and differences between the groups. For example, in 1 study, the 2 groups (telehealth and in-person) were similar in terms of race and ethnicity (94.7% of White participants in the in-person group and 94.9% of White participants in the telehealth group) but not in terms of sex (61.9% of male participants in the in-person group and 49.2% of male participants in the telehealth group) [23]. In another study, the 2 groups (telehealth and in-person) were similar in terms of sex but not in terms of residence (66.4% of participants in the remote care group were rural residents compared with 47.7% of participants in the in-person group) [21]. In a study with propensity score matching to separate patients seen in the past into 2 groups, the telehealth and in-person groups were similar in terms of age, language, and type of visit but not in terms of sex [16].

Outcome Variable (ie, Satisfaction) Reliability and Validity

Some authors have used reliable and valid surveys (Multimedia Appendix 3), such as the Jefferson scale of patient perceptions of physician empathy (Cronbach α=.896) [26]. A total of 8 studies provided no information regarding the reliability and validity of the satisfaction survey [14,15,17,20,21,23,24,26]. In 1 study, the authors specified that they developed their own satisfaction survey [14]. Satisfaction was measured in the same way in all studies, except for in 1 [20], in the telehealth and nontelehealth groups.

Quality of Evidence Scores Based on JBI Critical Assessment Tool Common Questions

The total scores among the 14 studies are included in Multimedia Appendix 4. The reasons for decreased scores included limited description of the participants and settings, differences in sociodemographic characteristics between participants in the comparison groups, the lack of valid and reliable measures of satisfaction, and not using the same questions for participants in the telehealth and nontelehealth groups.

Satisfaction Among Caregivers Completing Survey Items on Behalf of Children and Adolescents

In 13 studies focusing on caregiver satisfaction [14-26], caregivers completed the survey items (Table 2). The results for caregivers and patients were presented together without presenting separate results based on the patient perspective in the 13 studies. Examples of close-ended survey items to assess satisfaction were as follows: “My child’s behavior and skills improved during this service” [14], “I am pleased with the outcome of services for me and my child” [14], “Overall the service was excellent and it met my expectations” [21], and “How would you rate your child’s ability to communicate with the physician?” [23]. Of the 13 studies, 4 involved the use of open-ended items in addition to close-ended items to assess satisfaction in surveys [15,21,24,25]. Examples of open-ended questions as part of the surveys (not interviews) were as follows: “Provide narrative comments on your experience with the visit” [15], “What were the reasons you were dissatisfied with the visit experience?” [21], and “What is the most important reason you would prefer an in-person/telehealth encounter?” [24,25].

In 8 of the 13 studies on caregivers, participants in telehealth services were more satisfied with care compared with participants in nontelehealth services. For example, in the study of Holtzman et al [16], 92% of caregivers and patients participating in telemedicine visits reported high satisfaction with the provider compared with 87% of caregivers and patients participating in in-person visits (odds ratio 1.7, 95% CI 0.53-5.7). In the study of Johnson et al [17], 97.9% of caregivers and patients participating in telemedicine visits reported high satisfaction with the provider compared with 83.9% of caregivers and patients participating in in-person visits (P=.07).

In 1 out of the 13 studies focusing on caregivers, satisfaction levels in people receiving telehealth services and those receiving in-person visits were very similar. Specifically, no statistically significant differences in satisfaction (as assessed by top box percentages) existed between in-person caregivers and those participating in telemedicine visits [22].

In 4 of the 13 studies focusing on caregivers, satisfaction tended to be higher with in-person visits compared with telehealth visits. For example, 34.7% of caregivers who received in-person consultations were very satisfied compared with 12.1% of caregivers who received remote consultations (P<.001) [25]. In a study by Mustafa et al [24], 81.5% responded that they strongly agreed that they were satisfied with the in-person visit compared with 72.7% with the video visit. In a study by McCoy et al [23], the ability to communicate with the physician was

rated higher (mean 4.6, SD 0.8) in the in-person group compared with the telemedicine group (mean 4.4, SD 0.7; P=.01).

Open-ended items offered more specific information on why the participants were satisfied with the visit. The strengths of the visits indicated by caregivers using telehealth included time savings [15], convenience [24], frequent follow-up [24], and protection from COVID-19 [24]. The limitations indicated by caregivers using telehealth included poor technological access and connectivity [21], limited personal connection with providers [24], and the lack of laboratory testing and physical examination [24]. The strengths of nontelehealth services indicated by caregivers using in-person visits included being listened to [15], having opportunities for personal interactions and questions [24], and ensuring treatment adherence [25].

Satisfaction Among Patients and Caregivers

Overall, both pediatric patients and caregivers participating in telehealth appointments in separate surveys noted higher satisfaction when talking to their provider than patients and caregivers having in-person visits, although these findings were not statistically significant [27]. Specifically, among adolescents, the mean satisfaction score was 28.92 for video consultations and 27.82 for the in-person visits showing slightly higher satisfaction with the video visit, which was not statistically significant (P=.096) [27]. In the same study, there were no statistically significant differences in responses to items as part of the caregiver satisfaction survey. For example, 83% of caregivers participating in video visits answered no to "I would like to see improvement in the comfort and support the provider gave to the child" compared with 81% of caregivers participating in in-person visits (P=.597) [27].

Discussion

Principal Findings

The 14 included studies focused on satisfaction among caregivers and patients in a variety of pediatric care needs and specialties, including allergy and immunology, developmental and behavioral health conditions, concussion, type 1 diabetes, otolaryngology, ophthalmology, urology, gastroenterology, primary care, and ambulatory care. This literature review focused only on studies in which there was at least 1 comparison group of participants (ie, pediatric patients and caregivers) for telehealth and 1 comparison group of participants for nontelehealth services. Although the literature search resulted in 187 studies focusing on satisfaction with pediatric telehealth in general, only 14 studies included a comparison group for nontelehealth services. A reason for the limited number of articles with comparison groups may be that there were periods during the pandemic when patients relied only or mostly on remote care for their health care needs.

Most studies compared video and in-person visits. Only 1 of the 14 studies was an intervention (pretest-posttest quasi-experimental with 3 comparison groups) [14]. Previous literature reviews did not focus on comparison groups of telehealth and nontelehealth services in pediatric care [29-32].

In this review, a trend of overall higher or comparable satisfaction with telehealth compared with in-person visits in a pediatric setting was observed in most studies. Open-ended items were especially helpful in understanding the reasons for the satisfaction ratings. High satisfaction ratings with telehealth were commonly because of convenience and health benefits. The benefits of telehealth included not requiring transportation, ease of use, ability for frequent follow-up, and reduced likelihood of contracting the COVID-19 virus.

Only 1 study in which adolescents completed their own surveys on satisfaction was included in this review. The study found higher satisfaction with video visits compared with in-person visits among adolescents, although the difference was not statistically significant [27]. In an investigation conducted before the pandemic, adolescents and their caregivers were randomly assigned to an in-person visit and a video visit [33]. The mean for positivity for the telehealth visit was slightly higher at 5.53 compared with 5.37 for the in-person visit among adolescents [33].

One finding in this review was the concern for the lack of physical examination of patients during telehealth visits. In 1 study included in this review, 48% of caregivers having remote visits noted that the lack of physical examination was the greatest limitation of telehealth services [20]. Therefore, the ability to undergo physical examination is vital to the participants. Home-monitoring equipment may supplement remote appointments and prevent misdiagnoses [34]. To make monitoring equipment available and equitable, health care entities may offer these devices as loans for patients to use during remote appointments through mail-in programs, thus reducing disparities in telehealth use among patients.

Another key finding was the concern that telehealth appointments were less personalized compared with in-person appointments. For example, in 1 reviewed study, a theme based on responses to open-ended items was that in-person visits offered opportunities for personal interaction and asking more questions [24]. In another study, caregivers who received in-person consultations were significantly more satisfied with the emotional support scale compared with those who received remote consultations (P=.039) [25]. A prior study that asked open-ended questions of 105 caregivers similarly found that a lack of in-person interaction was a challenge for telehealth use [35]. Caregivers stated that they lost the feeling that the provider was compassionate during remote care [35]. To increase empathetic care during telecare, health care providers may look straight at the camera; offer verbal cues when needing to look away; start appointments with mutual agenda and goal setting; avoid the use of medical terminology; ask how the health condition affects the daily life of the patient; express knowledge of the patient's history by mentioning prior visits; and, if possible, suggest in-person visits to supplement remote appointments [36].

Studies have identified issues with technology during telehealth appointments. Quality and affordable internet access is essential, and a lack of technological services should not prevent pediatric patients from receiving the care they need. To improve satisfaction in this area, we propose continued support in making access to internet services and technological products more readily available and equitable to families of different racial

and ethnic and socioeconomic groups. In the United States, a federal program plans to cover 85% of the costs associated with broadband connectivity and network equipment needed to support connected care in selected locations by allocating over US $100 million over 3 years through competitive funding processes [37].

Limitations of Reviewed Studies

Limitations included a nonrandomized design, small sample size, low generalizability beyond a specific health care setting or group, sampling method (ie, convenience sampling), limited diversity in backgrounds or no information on sociodemographic characteristics among participants, and the lack of reliable and valid satisfaction assessment tools. Among studies that presented sociodemographic characteristics of participants, differences in the comparison groups may have affected the findings. For example, in 1 study, 66.4% of participants in the telehealth group were rural residents, compared with 47.7% in the in-person group [21]. Rural participants may be more likely to have favorable views toward telehealth compared with urban residents because of transportation barriers associated with attending in-person visits in remote locales.

Most studies assessed satisfaction related to videoconferencing in a telehealth setting. Few studies have assessed satisfaction with telephone appointments [24,25]. In a study comparing telephone and in-person visits, telephone consultations could be conducted with or without shared images via email to aid the visit [25]. Another limitation is that in some studies, video visits were conducted using different technologies, such as FaceTime and Skype [24,27]. Time constraints and lack of assessment of longitudinal changes were other limitations of the reviewed studies. Another limitation is that most studies did not survey adolescents on their own opinions.

Limitations of This Review

Represented in this review were peer-reviewed articles in the English language only. More eligible articles may have been published after the search date. Only the studies in the databases that were searched were included in this review. Other synonyms for the main keywords may have yielded additional eligible results. The use of additional or shorter truncations in all the databases may have resulted in more eligible articles.

Lower income or developing countries may use other terms to describe telehealth not included within the umbrella of the MeSH or explosion terms. We located studies without comparison groups in countries classified as lower income or developing, specifically Argentina [38], Brazil [39,40], India [41-44], Jordan [45], North Macedonia [46], Philippines [47], Saudi Arabia [48,49], and Zambia [28], which used the terms telehealth, telemedicine, and remote consultation. Therefore, we believe that this review allowed for various countries to be included. Still, although the review did not place restrictions on country, 13 of the 14 included studies were from developed nations. It is possible that studies in developing nations did not have as many resources to conduct studies with comparison groups, which may be more costly. The results were mostly applicable to higher income countries because the characteristics of telehealth in lower income countries may be distinct.

Another limitation was the inclusion of different populations (such as by age and type of condition). Owing to stay-at-home orders, in some studies, nontelehealth services were conducted before the pandemic when telehealth services were not as widespread. Participants in comparison groups for nontelehealth services before and during the pandemic may have had different perceptions of in-person visits. Given the different designs and measurements among the studies, we did not perform a meta-analysis.

Future Research

Much prior research has focused on satisfaction with telehealth services without including a comparison group for nontelehealth services [44,50-70]. Additional research comparing satisfaction with telehealth and nontelehealth pediatric services during the same timeframe will be beneficial. Such research provides insight into the type of support patients and caregivers need to access and use for telehealth and in-person visits. RCTs may compare the influence of telehealth and nontelehealth services on medical and pharmacy costs, the accuracy of the patient and caregiver recall, quality of health care, and pediatric health. In addition, comparing satisfaction with in-person laboratory visits and mobile laboratory visits is innovative.

Future studies involving focus groups and interviews with health care providers may offer insight into how telehealth and nontelehealth services influence a provider's ability to conduct all the necessary examinations for a patient. Interventions may assess the influence of education for health care providers in strategies for personable interactions during telehealth appointments on patient and caregiver satisfaction with pediatric care. Education should provide information on how communication during telehealth visits can be tailored to the different cultural and linguistic groups of patients and caregivers.

Conclusions

Telehealth visits were comparable or superior in terms of patient and caregiver satisfaction compared with in-person visits in most of the reviewed studies. This review identifies potential weaknesses of telehealth services that need improvement such as problems with technology connectivity, limited ability to undergo a physical examination, difficulty in having personable interactions with the medical provider, and lower adherence to treatment. Health care providers may develop strategies to overcome these weaknesses and improve telehealth during the pandemic and beyond.

Acknowledgments

The authors are immensely grateful to Emily Newberry, Senior Associate Librarian, University of Michigan, Flint, for guiding them in the development of search strings for the 4 databases. GDK was supported by the Frances Willson Thompson Fellowship.

Authors' Contributions

GDK contributed to conceptualization. TC, BK, and KC contributed to literature search. GDK, TC, BK, and KC contributed to synthesis of information in tables. GDK and TC contributed to analyses of information in articles. TC and GDK contributed to manuscript writing. GDK, TC, BK, and KC contributed to final approval of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 checklist.
[DOCX File , 33 KB - pediatrics_v6i1e41554_app1.docx]

Multimedia Appendix 2
Search strings by database.
[DOCX File , 16 KB - pediatrics_v6i1e41554_app2.docx]

Multimedia Appendix 3
Quality of evidence based on design, sociodemographic participant characteristics, and tool reliability and validity.
[DOCX File , 17 KB - pediatrics_v6i1e41554_app3.docx]

Multimedia Appendix 4
Quality of evidence scores based on Joanna Briggs Institute critical assessment tool common questions.
[DOCX File , 17 KB - pediatrics_v6i1e41554_app4.docx]

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Abbreviations

GRADE: Grading of Recommendations, Assessment, Development, and Evaluation
INPLASY: International Platform of Registered Systematic Review and Meta-analysis Protocols
JBI: Joanna Briggs Institute
MeSH: Medical Subject Headings
PI(E)COS: Populations, Interventions (or Exposures), Comparators, Outcomes, and Study designs or Settings
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial

Edited by G Eysenbach, S Badawy; submitted 12.08.22; peer-reviewed by T Parikh, M Anderson; comments to author 07.09.22; revised version received 10.11.22; accepted 27.03.23; published 27.04.23.

Please cite as:
Kodjebacheva GD, Culinski T, Kawser B, Coffer K
Satisfaction With Telehealth Services Compared With Nontelehealth Services Among Pediatric Patients and Their Caregivers: Systematic Review of the Literature
JMIR Pediatr Parent 2023;6:e41554
URL: https://pediatrics.jmir.org/2023/1/e41554
doi:10.2196/41554
PMID:37000504

Original Paper

Remote Recruitment Strategy and Structured E-Parenting Support (STEPS) App: Feasibility and Usability Study

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Abstract

Background: The Structured E-Parenting Support (STEPS) app provides support for parents of children with elevated hyperactivity, impulsivity, inattention, and conduct problems who are awaiting clinical assessment. STEPS will be evaluated in a randomized controlled trial (RCT) within the Online Parent Training for the Initial Management of ADHD Referrals (OPTIMA) research program in the United Kingdom. Phase 1 of the OPTIMA tested the feasibility of participants' recruitment and the app's usability.

Objective: This study aimed to adapt a digital routine clinical monitoring system, myHealthE, for research purposes to facilitate waitlist recruitment; test using remote methods to screen and identify participants quickly and systematically; pilot the acceptability of the recruitment and assessment protocol; and explore the usability of STEPS.

Methods: myHealthE was adapted to screen patients' data. Parents' and clinicians' feedback on myHealthE was collected, and information governance reviews were conducted in clinical services planning to host the RCT. Potential participants for the observational feasibility study were identified from new referrals using myHealthE and non-myHealthE methods. Descriptive statistics were used to summarize the demographic and outcome variables. We estimated whether the recruitment rate would meet the planned RCT sample size requirement (n=352). In addition to the feasibility study participants, another group of parents was recruited to assess the STEPS usability. They completed the adapted System Usability Scale and responded to open-ended questions about the app, which were coded using the Enlight quality construct template.

Results: Overall, 124 potential participants were identified as eligible: 121 (97.6%) via myHealthE and 3 (2.4%) via non-myHealthE methods. In total, 107 parents were contacted, and 48 (44.9%) consented and were asked if, hypothetically, they would be willing to participate in the OPTIMA RCT. Of the 28 feasibility study participants who provided demographic data, 21 (75%) identified as White. Their children had an average age of 8.4 (SD 1.7) years and 65% (31/48) were male. During the primary recruitment period (June to July 2021) when 45 participants had consented, 38 (84%) participants agreed hypothetically to take part in the RCT (rate of 19/mo, 95% CI 13.5-26.1), meeting the stop-go criterion of 18 participants per month to proceed with the RCT. All parents were satisfied or very satisfied with the study procedures. Parents (n=12) recruited to assess STEPS' usability described it as easy to navigate and use and as having an attractive combination of colors and visual design. They described the content as useful, pitched at the right level, and sensitively presented. Suggested improvements included adding captions to videos or making the recorded reflections editable.

Conclusions: Remote recruitment and study procedures for testing a parenting intervention app are feasible and acceptable for parents. The parents felt that STEPS was a useful and easy-to-use digital parenting support tool.

International Registered Report Identifier (IRRID): RR2-10.1186/s40814-021-00959-0

(JMIR Pediatr Parent 2023;6:e47035) doi:10.2196/47035

KEYWORDS

parenting intervention; mobile app; attention-deficit/hyperactivity disorder; ADHD; behavior problems; mobile health; mHealth; children; usability; mobile phone

Introduction

Background

Attention-deficit/hyperactivity disorder (ADHD) is a neurodevelopmental condition with an estimated prevalence of between 2% and 7% of children worldwide [1,2]. It is manifested by symptoms of inattention, impulsivity, and hyperactivity and is associated with impairment across multiple life domains [3-6]. Over 40% of children with an ADHD diagnosis also display oppositional, disruptive, or defiant behaviors and meet the criteria for an oppositional defiant disorder (ODD) diagnosis [7,8]. Managing this combination of ADHD and ODD is a major challenge for parents [9]. For many parents, it is this combination that motivates them to seek help through a clinical referral to pediatric clinics or child and adolescent mental health services [10]. Parent training as recommended by the National Institute for Health and Care Excellence is the most common evidence-based intervention used to help parents manage their children's disruptive and defiant behaviors [11].

The Structured E-Parenting Support App

Parent training is traditionally delivered in person by clinically trained professionals. However, universal shortages in health care workforces combined with financial challenges facing public health services mean that parents face substantial waiting times in accessing this kind of support [12]. These considerable delays in access to parent training increase the risk of further deterioration of the parent-child relationship and the escalation of their the children's problems. We have developed a digital mobile phone app to address this problem. Structured E-Parenting Support (STEPS) [13] was designed to help parents manage the disruptive and defiant behaviors of their children with elevated levels of hyperactivity, impulsivity, and inattention symptoms. In comparison with in-person support, STEPS is a low-cost, easy, and quick-to-access parenting support intervention, which provides evidence-based advice and support. Its design was inspired by an in-person parent training program, the New Forest Parenting Programme [14], with its content reflecting many years of research about parenting and child behavior [11,15-17]. Using audio-visual and graphic elements, STEPS aims to increase parents' knowledge of children's behavior problems, build children's confidence, facilitate effective communication between parents and children, and provide parents with strategies and skills to better manage their children's challenging behavior.

STEPS is currently being evaluated in a large-scale multicenter randomized controlled trial (RCT) as a way of delivering support to the families of children referred to clinical services who are on the waiting list for specialist assessment and treatment. The RCT represents the second phase of the Online Parent Training for the Initial Management of ADHD Referrals (OPTIMA; funder reference number RP-PG-0618-20003) program. Phase 1 of the OPTIMA program had 4 objectives to help the study team prepare for the future RCT, which was prospectively registered on November 18, 2021 (registration number ISRCTN16523503).

The first objective was to adapt and implement a digital platform, myHealthE, for the remote identification and screening of recently referred families [18]. This is an essential part of OPTIMA, as it ensures rapid and systematic screening of ADHD and ODD symptoms in children accepted by clinical services for a wide range of problems and from different referral sources. We asked the following question: how should myHealthE be adapted so that it can be implemented across a variety of clinical services to support OPTIMA recruitment? Objective 2 was to test the feasibility of a remote recruitment strategy incorporating myHealthE. Objective 3 was to test the wider feasibility of the full-scale trial [13]. To achieve objectives 2 and 3, we conducted a single-arm nonrandomized study. We asked two questions: (1) can the necessary number of eligible families be recruited using our remote identification and screening strategy within the planned time frame to meet the sample size requirements and provide sufficient power in the planned RCT? and (2) is the proposed RCT recruitment and assessment approach acceptable to participants? Objective 4 was to make the final,

minor updates required to optimize the value of the STEPS app for families. To achieve this objective, we conducted a separate mixed methods usability evaluation of the STEPS app with a different group of parents of children aged 4 to 11 years. We asked the following questions: (1) what is the experience of parents using the STEPS app? and (2) are there ways in which they think it can be improved?

Methods

Adaptation of myHealthE for OPTIMA (Objective 1)

Adaptation of the platform was done based on anecdotal feedback from parents, clinicians, service managers, and research governance teams from the participating organizations. This feedback was collected through (1) group meetings with the professionals and the myHealthE team to review the plans and resources required to support implementation and (2) individual interviews with parents who are members of the OPTIMA Patient and Public Involvement and Engagement panel. The initial plan was to integrate myHealthE into local digital platforms. However, after extensive consultation with these stakeholders, it was decided that myHealthE would work better if it was a stand-alone web application. Depending on the organization's preference, the flow of patients' personal and clinical information between myHealthE and clinical records would occur either via manual data entry or a process of robotic process automation. Through a set of programmed instructions, the robotic process automation process allows a software robot to mimic human front-end tasks, such as manual referral data entry into myHealthE, with high efficiency [18]. This change also enhanced functionality for myHealthE users (ie, clinicians and clinical administrators) by allowing the use of a report button to generate caregiver and teacher response outcome reports, whenever needed. This new report can also be manually uploaded to the patient's electronic clinical notes. Further, the central myHealthE team can provide group clinical outcome data as an extract on a periodic basis to support business intelligence work, such as outcome submission to the Mental Health Services Data Set, a repository of information collected via different clinical systems as part of routine patient care, and for local commissioners. Each organization received the National Health Service Digital Technology Assessment Criteria pack for myHealthE, which included data privacy impact assessment, and signed the information processing agreements with the lead organization. The success of myHealthE implementation as a gateway to STEPS access was measured in terms of the number of services that adopted the platform and five additional key performance indicators: (1) the number of parents who were onboarded onto the platform (ie, their contact details were logged, which triggered the invitation to register with myHealthE); (2) the number of those who then registered with the platform; (3) the number of those who completed the routine Strengths and Difficulties Questionnaire (SDQ) and (4) provided consent for research contact; and, finally, (5) the number of children whose parents provided consent for research contact were flagged up as *OPTIMA eligible* based on their age, referral date, and SDQ subscale scores for hyperactivity and conduct problems.

Ethical Considerations

The observational feasibility study received ethics approval from London–Riverside Research Ethics Committee on November 17, 2020 (reference 20/LO/1173). There was no financial incentive for taking part. The STEPS app usability assessment study was approved by King's College London PNM Research Ethics Panel (reference LRS-20/21-21359). Each participant provided written consent on the web and was given a £30 (US $38.1) shopping voucher to thank them for their time.

Observational Feasibility Study (Objectives 2 and 3)

Design and Setting

This was a single-arm observational feasibility study conducted remotely [13]. Clinical recruitment sites were in England, in urban areas with catchment populations from a wide range of ethnic and socioeconomic backgrounds. The overall recruitment period lasted for 2.5 months from mid-May to the end of July 2021, with the primary recruitment period restricted to June and July 2021. The participants completed the study questionnaires and accessed the STEPS app using their private devices in their preferred setting.

Participants

The participants of this study were parents and teachers. Parents were recruited from 4 recruitment sites. Of these sites, 3 adopted myHealthE to facilitate trial recruitment. The fourth site used nondigital methods (not myHealthE) to obtain consent for research contact and screen for ADHD- and ODD-type symptoms. One further site agreed to support the pilot and feasibility study but did not recruit any participants. Inclusion criteria specified that participants were parents of new referrals (on waitlist no longer than 6 calendar months; the initial definition for "new referrals" referring to children being on the waitlist for less than 3 months was modified during the study, and this modification was approved on June 25, 2021) aged 5 to 11 years who passed the initial triage and had been accepted onto the assessment waiting list but had not yet received a diagnosis of ADHD. The parent had to have rated their child as having a high level of ADHD symptoms (a score≥8) and conduct problems (a score≥4) during routine clinical screening with the SDQ, a brief questionnaire used to measure symptoms of psychopathology in children and adolescents [19]. Following an initial conversation with researchers, parents were excluded if they lacked access to a suitable electronic device, had an insufficient level of English language, or if their child was under local authority care. Parents who met the eligibility criteria were invited to participate in the study. Parents who agreed to participate provided written web-based consent, including, in most cases, consent for the team to contact their child's general practitioner and school. Reasons for not enrolling in the study were recorded by the study team.

There were no inclusion or exclusion criteria for teachers, but researchers were required to obtain parents' permission for contacting teachers.

Testing the Feasibility of Remote Recruitment

The feasibility of recruiting a sufficient number of participants for the RCT was assessed by asking each study participant a *feasibility question*. More specifically, participants who consented to take part in the observational feasibility study were read a script explaining the proposed design and procedures of the phase 2 OPTIMA RCT and how it would differ from the current feasibility study. It was explained to participants that taking part in the phase 2 RCT would involve a longer time commitment than the current feasibility study and that they would be randomly assigned to either a group that received the STEPS app straight away or a group that remained on the waitlist without access to the app. Following this explanation, participants were asked to respond "yes" or "no" to whether they would be willing to participate in such a study *in principle*.

Power calculations for the planned RCT in phase 2 of the OPTIMA program indicated that 13 participants per month would need to be recruited to the trial over the 27-month recruitment period (n=352) for the trial to have sufficient power to test for hypothesized differences in the primary outcome. A more conservative stop-go requirement of recruiting 18 participants per month was adopted in the observational feasibility study to consider the potential differences between agreeing in principle in the current feasibility study and actually consenting to take part in the OPTIMA RCT. The rate of participants agreeing per month was calculated as the number of participants agreeing in principle to take part in the RCT during the primary feasibility study recruitment period (June to July 2021) with the associated 95% Poisson CI (using an immediate CI command in Stata [version 17; StataCorp] specifying a Poisson distribution). We also calculated the proportion of participants who agreed by dividing the number of participants who agreed by the number of participants who were recruited and then multiplying the resultant value by 100.

Piloting the Acceptability of the Recruitment and Assessment Protocol

The acceptability of the recruitment and assessment protocol was evaluated by asking parents to provide ratings of satisfaction with the consenting procedures and web-based data collection via the exit questionnaire. In addition, we measured the following: (1) the time taken to complete the remote consenting procedures; (2) the proportion of participants who completed all outcome questionnaires within 7 days of receiving a link to the web-based questionnaires out of the number of participants who were in the study; (3) the number of reminder emails about completing the outcome questionnaires sent to parents by the research team; (4) the proportion of participants who completed the adverse event questionnaire within 7 days of receiving a link to the web-based questionnaire out of the number of participants who were in the study; and (5) the mean number of reminder emails about completing the adverse events questionnaire sent to parents by the research team. We also assessed the feasibility of collecting data from children's teachers by measuring the time needed to identify teachers and the proportion of teachers who returned the outcome questionnaire within 7 days of receiving a link to the web-based questionnaire out of the number of teachers who were recruited.

The piloted measures included parent-completed questionnaires, specifically prebaseline measures to characterize the sample and outcome measures, and a teacher-completed questionnaire. The prebaseline measures included the Eyberg Child Behavior Inventory [20]; Social Communication Questionnaire [21]; and ADHD subscale of the Swanson, Nolan, and Pelham Rating Scale [22]. The outcome measures included the O'Leary Parenting Scale [23,24]; the ODD subscale of the Swanson, Nolan, and Pelham Rating Scale [22]; the Parental Sense of Competence Scale [25]; the Caregiver Strain Questionnaire [26]; and a demographic questionnaire, which asked questions about the parent's gender, educational level, employment status, income, ethnicity, and relationship status and the number and ages of other children in the household and whether they had received an ADHD diagnosis. Finally, parents were also asked whether they had received parent training of any type or had any mental health difficulties that required clinical treatment in the previous 6 months. The teachers completed only the ODD subscale of the Swanson, Nolan, and Pelham Rating Scale [22].

Procedure

Information on the child's age, sex, ADHD symptoms, and conduct problems was derived from the existing referral information. Parents completed questionnaires on the web using Qualtrics (Qualtrics International Inc), a secure web-based data collection platform. Each participant was enrolled in the study for approximately 4 weeks. Those who completed the baseline questionnaires were then emailed instructions on how to access the STEPS app. Importantly, they were informed that the use of the app was optional and were not prompted to use it (the plan for the definitive trial was to monitor and prompt use). Two weeks after the baseline questionnaires were completed, parents were sent a link asking them to complete an adverse events questionnaire on the web. Four weeks after the baseline questionnaires were completed, parents were debriefed and asked to complete an exit questionnaire assessing satisfaction with the remote consenting process and the web-based outcome and adverse events data collection procedures. Parents who consented to have their child's teacher contacted provided the teacher's contact information so that a teacher information sheet and consent statement could be sent to the teacher, along with a link to the web-based teacher questionnaire.

Data

We recorded baseline demographic information, scale scores from the prebaseline and baseline outcome questionnaires, the time taken to complete the study procedures, the number of reminder emails sent, satisfaction survey responses, and the number of participants who completed all web-based questionnaires within 7 days (as a proportion of the number of participants who were given access). The number of people who took up the invitation to download the app was also recorded. Safety data were summarized as the number of adverse events and the number of people who experienced adverse events. The prebaseline and baseline questionnaire score summaries are presented in Multimedia Appendix 1.

STEPS App Usability Assessment (Objective 4)

Participants

Participants were 12 parents (all female) of children aged 4 to 11 years recruited from the general population through advertisements on social media, as well as through the OPTIMA Patient and Public Involvement and Engagement panel. One further parent took part in the initial session but did not complete the entire study and was, therefore, subsequently excluded from the sample.

Measures

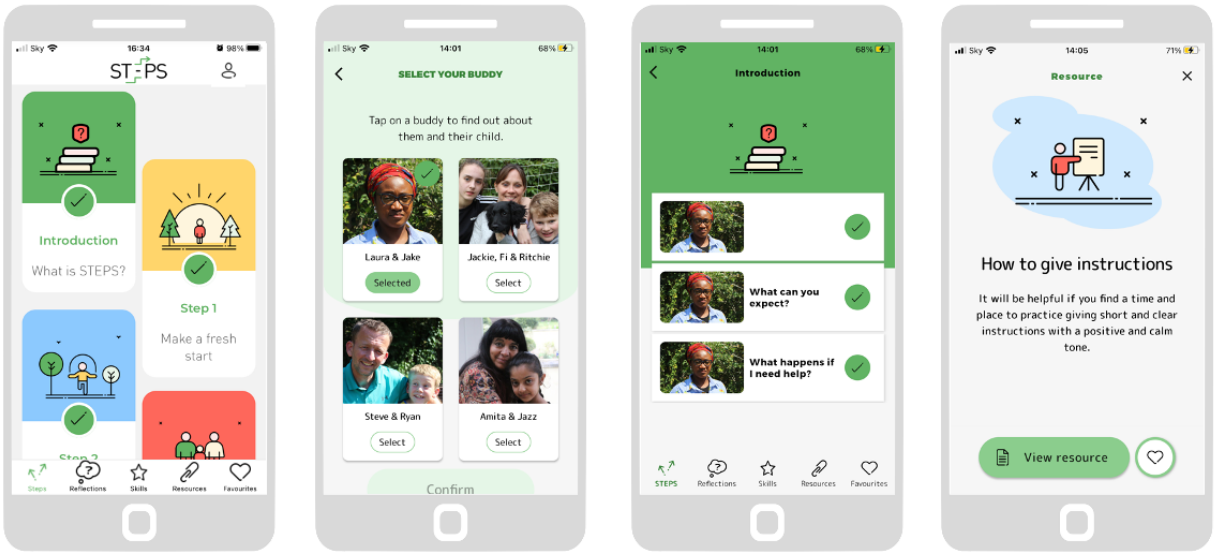
The measures used to fulfill objective 4 were an adapted System Usability Scale [27] and open-ended questions asked in a think-aloud session and follow-up semistructured interviews. The System Usability Scale is a 10-item questionnaire that uses a mix of positively and negatively worded items designed to assess the usability of a digital tool (eg, the ease of use, a user's confidence in using the tool, and the perceived amount of technical support that would be required to use the tool). Responses were made on a 5-point scale ranging from 1 ("strongly disagree") to 5 ("strongly agree"). To calculate the overall usability score, 1 is subtracted from the score of each positively worded item and the score of each negatively worded item is subtracted from 5 to give a score ranging from 0 to 4 for each item, where higher scores reflect more positive responses. These item scores are then summed and multiplied by 2.5 to give a total score ranging from 0 to 100.

Open-ended questions probed the participants' first impressions about the app, including its look, feel, and navigation, as well as elicited more detailed views on the overall experience of using the app and on each of the elements contained within the app.

The STEPS App

A detailed description of the STEPS app is provided in Multimedia Appendix 2. Because of the unguided nature of the STEPS app, several design features were implemented in it to improve engagement. First, a "Buddy," a parent played by an actor, accompanies the user on their journey through STEPS. Upon registering with the app, each user is directed to a screen that provides brief video vignettes of the 4 available Buddies (Figure 1) and is asked to select 1. Buddies can be changed an unlimited number of times during subsequent use of the app. Within each module, the selected Buddy provides an overview of the content and then recaps the key points covered. Second, a brief introductory module needs to be completed, where the selected Buddy provides a brief overview of the content and gives advice on how to use STEPS (eg, take a break for a few days between the modules and record reflections). Third, the app has a linear structure to allow users to build up their parenting skills, with a clear visual distinction between the completed modules (and components within each module; Figure 1) and those that are yet to be completed. Users can also make a note of the content that they particularly like or would like to revisit for quick access by including it among their favorites. Finally, the content is delivered in short, accessible, and "bite-size" pieces, that is, individual videos or audio clips are not longer than 3 minutes to keep users engaged and avoid overwhelming them with too much information.

Figure 1. Examples of the Structured E-Parenting Support (STEPS) app screens: (A) Home screen. (B) Buddy selection screen. (C) Introduction screen. (D) Resources screen.



(A) STEPS home screen (B) Buddies screen (C) Introduction screen (D) Resources screen

Procedure

Each participant took part in 2 remote video sessions facilitated by a trained researcher. In the first, think-aloud, session, participants were asked to download the app, complete a few simple navigation tasks (eg, select and change a Buddy, watch a video, record a reflection, and save an item to favorites), and speak out loud what came to their mind as they completed these tasks. They also answered questions regarding their first impressions of STEPS. The second, follow-up, session was scheduled approximately a week later, and the participants were instructed to use the app as much as they could during the intervening period. In the second session, participants were first asked questions about their general mobile phone use and then

asked more detailed questions about their views on the STEPS app. All sessions were audio and video recorded. The automatically generated transcripts were checked, and any identifying information was removed. The participants were also emailed a link asking them to complete the System Usability Scale on the web via Qualtrics.

Data Analyses

The total System Usability Scale and individual item scores were summarized using means and SDs. Qualitative data from the think-aloud and follow-up sessions were analyzed using the template analysis method [28]. This is a style of thematic analysis that requires the development of a structured coding template. To align with the themes discussed in previous relevant studies, we adopted a prespecified coding template. Specifically, responses were coded using the Enlight quality construct template developed by Baumel et al [29]. This template was derived from a systematic review of quality rating criteria for digital health interventions, tested with both mobile phone–based and web-based interventions, and includes the following core constructs:

1. Usability: the ease of learning how to use the app and the ease of using it properly
2. Visual design: the look and feel of the app
3. User engagement: the extent to which the app's design attracts users to use it
4. Content: the content provided or learned while using the app
5. Therapeutic persuasiveness: the extent to which the app is designed to encourage positive behavior changes
6. Therapeutic alliance: the ability of the app to create an alliance with the user to motivate change
7. Potential: a subjective evaluation of the app's potential to benefit its target users

Results

myHealthE Adaptation (Objective 1)

myHealthE was used by 2 child and adolescent mental health services and 1 local authority early behavioral help service. At the end of the overall feasibility recruitment period (July 31, 2021), a total of 1024 patients were onboarded onto the platform, including 952 (92.97%) new referrals and 72 (7.03%) existing patients. Of the 952 new referrals, 768 (80.7%) registered with the platform, 649 (68.2%) completed the routine SDQ, and 308 (32.4%) provided consent for research contact. Finally, 121 children whose parents provided consent for research contact were flagged up as *OPTIMA eligible*.

Observational Feasibility Study

Participant Characteristics

Of the 107 eligible referrals, who were approached with an invitation to participate in the study, 104 (97.2%) were identified by myHealthE, and the remaining 3 (2.8%) were identified via non-myHealthE methods. Of the 107 referrals, 48 (44.9%) consented to participate in the study (Figure 2). All 48 participants answered the feasibility question about willingness to participate in principle in an OPTIMA RCT and were given access to the prebaseline questionnaires, which were completed by 34 (71%) participants. Then, 38 participants received access to the baseline questionnaires (4 participants were incorrectly given access), which were completed by 25 (66%) participants. These 25 participants were provided with access to the STEPS app (1 was given access erroneously). Of the 25 people who were given access to the app, 21 (84%) downloaded it. Of the 24 participants provided with the adverse events questionnaire about medical and psychological events and difficulties (1 was not provided with the questionnaire owing to the recruitment site closure), there were 15 (62%) completers. Information about the adverse events reported in the study is included in Multimedia Appendix 3. The same 24 participants were provided with exit questionnaires, with 9 (38%) completers. Only 1 (2%) participant out of the total 48 formally withdrew from the feasibility study owing to a house move. Of the 48 parents, 40 (83%) provided teacher information, and 37 (92%) teachers were contacted. A total of 8% (3/40) of teachers were not contacted (2/40, 5% owing to school holidays preventing contact and 1/40, 2% owing to a parent requesting a delay to search for an email address of the teacher, which was never provided). Only 7 (19%) out of the 37 teachers completed the questionnaire within the 1-week response window.

The mean age of the children in the feasibility participant sample (n=48) was 8.4 (SD 1.7) years, and 31 (65%) out of 48 were male. The mean SDQ hyperactivity subscale score was 9.5 (SD 0.7), and the mean conduct problem subscale score was 6.2 (SD 1.7). Of the 28 parents who provided responses on the demographic questionnaire, 21 (75%) were White. Of the 28 parent respondents, 16 (57%) were married or in a long-term relationship and 16 (57%) had completed General Certificate of Secondary Education, Certificate of Secondary Education, Ordinary Level, or equivalent qualifications. All participants' demographic information and children's ADHD symptoms and conduct problems scores are presented in Table 1. A summary of the clinical outcome measure scores is provided in Multimedia Appendix 1.

Figure 2. Observational feasibility study CONSORT (Consolidated Standards of Reporting Trials) flowchart. AE: adverse event; MHE: myHealthE; STEPS: Structured E-Parenting Support.

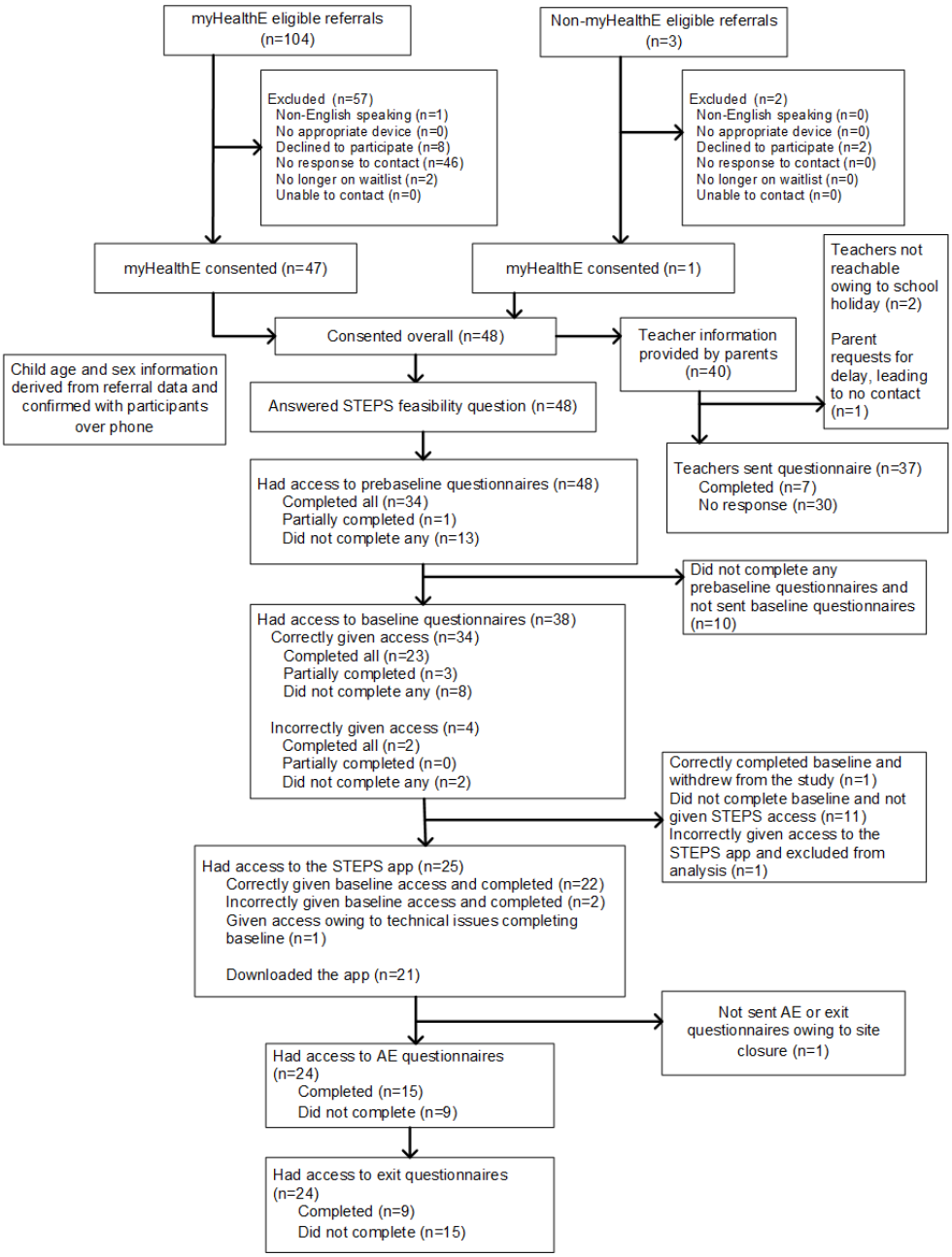


Table 1. Characteristics of the observational feasibility study participants.

Characteristic	Values
Children (n=48)	
Age (years)	
Mean (SD)	8.4 (1.7)
Median (IQR)	9 (7-10)
Sex, n (%)	
Female	17 (35)
Male	31 (65)
SDQ[a] hyperactivity subscale score	
Mean (SD)	9.5 (0.7)
Median (IQR)	10 (9-10)
SDQ conduct problem subscale score	
Mean (SD)	6.2 (1.7)
Median (IQR)	6 (5-7)
Parent participants (n=28)	
Ethnicity, n (%)	
Black or Black British	6 (21)
White British, Irish, or other	21 (75)
Mixed race White and Black or Black British	1 (4)
Sex, n (%)	
Female	28 (100)
Education, n (%)	
No formal qualifications	9 (32)
Completed GCSE[b] or CSE[c] or O-levels[d], equivalent	16 (57)
Completed post-16 vocational course	2 (7)
Undergraduate or professional qualification	1 (4)
SES[e] (£[f]; annual income levels), n (%)	
<16,000	9 (32)
16,000-29,999	7 (25)
30,000-59,999	11 (39)
≥60,000	1 (4)
Marital status, n (%)	
Single (never married)	9 (32)
Married or in a long-term relationship	16 (57)
Widowed	1 (4)
Divorced	1 (4)
Separated	1 (4)

[a]SDQ: Strengths and Difficulties Questionnaire.

[b]GCSE: General Certificate of Secondary Education.

[c]CSE: Certificate of Secondary Education.

[d]O-levels: ordinary level.

[e]SES: socioeconomic status.

[f]£1=US $1.27.

Findings

Can We Recruit a Sufficient Number of Participants Using Our Remote Strategy to Meet the Power Needs of the OPTIMA RCT?

All 48 participants answered the feasibility question, with 41 (85%) agreeing in principle to take part in an RCT. Focusing on the primary recruitment period (June to July 2021), 38 (84%) out of 45 participants agreed in principle to take part in an RCT. This was a rate of 19 (95% CI 13.5-26.1) participants per month, which exceeded the conservative stop or go criterion of 18 participants per month set a priori. We note that the lower limit of the CI excludes 13 per month, that is, the less conservative estimate of the number needed from the power calculation. This suggests we will likely be able to recruit >13 families per month.

Is the Recruitment and Assessment Protocol Acceptable?

The mean time from a service accepting a referral onto a waitlist to the completion of remote consenting by the participant was 51 (SD 40) days. The mean parent rating of satisfaction with consenting procedures was 4.6 (SD 0.5) out of 5; a total of 4 (44%) out of 9 parents were "satisfied," and 5 (56%) out of 9 were "very satisfied."

Of the 38 parents who provided baseline outcome data, 23 (61%) completed all the questionnaires within 7 days. The mean number of reminder emails about web-based data completion sent to parents was 1.1 (SD 1.6; median 0, IQR 0-3). The mean parent rating of satisfaction with web-based data collection was 4.4 (SD 0.7) out of 5; overall, 1 (11%) out of 9 participants selected a "neutral" response, 3 (33%) out of 9 participants were "satisfied," and 5 (56%) out of 9 participants were "very satisfied." Finally, 9 (38%) out of 24 parents completed adverse event questionnaires within 7 days, and the mean number of reminder emails about adverse event questionnaire completion sent to parents was 0.67 (SD 0.70). The average time from the date when participants consented to the date when teachers were identified was 1.5 (SD 6.3; median 1, IQR 0-1) days, and 7 (19%) out of the 37 teachers returned questionnaires within 7 days.

STEPS Usability Evaluation

Participant Characteristics

Of the 12 participants who were recruited specifically for the STEPS usability study, 8 (67%) worked part time or full time, and 4 (33%) were stay-at-home parents. All participants reported using mobile phones frequently for various purposes, such as communication, leisure, banking, navigation, or shopping. None of them reported any general difficulties with using mobile phone technology. Overall, 33% (4/12) of participants reported lesser mobile phone use on weekends than on weekdays. The main reason cited for reduced weekend mobile phone use was "family time."

Findings

System Usability Scale Analysis

Parents rated the app's usability as very high; the overall STEPS usability score on the System Usability Scale was 94.8 (SD 4.8) out of 100. Individual item responses also showed that participants' experience of using STEPS was positive (Multimedia Appendix 4).

Template Analysis of Open-Ended Questions About the App

Usability: all participants found the app simple to use and straightforward to navigate. Many commented that the app was "intuitive" and that navigation was "obvious" and "self-explanatory." Detailed quotes are presented in Multimedia Appendix 5. Some participants attributed the ease of use to the fixed linear structure of the app. However, 1 parent found the need to complete the modules in a fixed order frustrating. Participants found the clear visual distinction between completed and not-completed steps helpful in navigating the app and commented that simple language also improved the usability of the app. Participants made suggestions for improvements, for example, providing captions for videos and transcripts and making the recorded reflections editable. Some also wanted to receive more information about Buddies and their roles.

Visual design: the parents provided very positive feedback about the look and feel of the app. In particular, they commented on the attractive combination of colors and visual design features:

> *I really like the look of it, I really like the design and the graphics, they look really classy, but they also just look very professional.*

Some participants used the word "friendly" to describe the look and feel of the app:

> *It's simple to use and kind of feels nice and modern and friendly.*

Finally, 1 participant's comment also suggested that the structure of the app created very positive first impressions about the look and feel:

> *I found it made sense and it flowed well. I like the way it's laid out. I think it's going to be easy to use on my first impression, it's certainly not daunting, it's quite clear to understand.*

User engagement: comments from several participants suggested that receiving information in short "bite-size" pieces was the key to successful engagement with the app:

> *...and it was also bite-sized amount of information which I liked. It wasn't throwing loads of information at you at once, because obviously that's just overloads yourself [sic], especially if you're busy. I found that quite useful.*

Parents also mentioned that receiving a notification from their Buddy (push notification) served as a useful reminder to log back into the app:

> *If I had like a really busy day and I hadn't looked at it [the app] and then I got a notification from my buddy that said about Steps, it was like a little reminder, oh yes, I need to log on and do that and that was actually was [sic] really helpful. It's quite motivating that you've got that little prompt.*

The variety of formats, including videos, audio clips, and text resources, made the app more engaging:

> *I liked that there was [sic] different elements, it wasn't all just videos, there was some audio. I like the versatility of it and just that there was [sic] different elements, it wasn't just consistently the same thing.*

Although the possibility of accessing the app at any time and at any place is created by general smartphone affordances rather than benefits specifically limited to STEPS, users highlighted such accessibility as an important feature:

> *I think it's really useful just to kind of have it in your pocket all the time and to have it readily available.*

Several participants wanted to receive more information regarding the Reflections feature of the app, specifically, in relation to the privacy and confidentiality of what is recorded there by users. One of the participants said that they would "filter" what they would record in Reflections, rather than freely express their thoughts, if these recordings would be shared with others. Suggestions were also made that although some reflections should be private, it would be useful to be able to choose to share some of the recordings, for example, with a clinician or another professional as "evidence of the child's behaviour or reflections on what's worked well."

Content: participants commented that the content was pitched at the right level and presented in a sensitive way:

> *I liked the content I thought it [expert videos] was really well written in that it gave you the information that you needed, but it was in a very understandable format and I like again the fact it was a video very relatable, not patronising, I thought it was good.*

The variety of examples included in the app made the content applicable to a wide range of parents, as one participant noted:

> *It's quite nice when you first open it [examples] that you can just see a range of children and a range of problems of looking like a menu for things and you can sort of spot which ones.*

The participants highlighted the importance of including children's perspectives in the examples and provided further suggestions on how to give children more presence in the app. For example, this could be achieved by including real stories of children whose parents used the app successfully or by creating sections within the app that could be completed by both a parent and child.

Therapeutic persuasiveness: participants commented that the aims of STEPS were realistic and that the advice was straightforward to implement:

> *I like the fact that it starts at the very beginning and about reconnecting with your child and your relationship with your child and that it works through. I thought the aims were also realistic.*

One participant provided an example of how working through the STEPS resources motivated them to reflect on their own situation and to act to effect change:

> *I did find them [resources] useful. Oh yeah, it was the making quality time for yourself. So, reading through that I actually bought myself a yoga mat in the week 'cause I thought, ok I'm going to sit with my headphones on, forget everything and do that. So yeah, reading through that has made me realise if I'm not at my best because I'm always busy and I'm always doing everything.*

Including children's perspectives in the app's examples was also noted as a factor that may help motivate change:

> *Examples from the children and giving their perspective on things, and I wasn't expecting that, and actually I found that really useful and quite kind of it's almost moving, going and I'm not doing it on purpose and generally don't hear when my mum is telling me to turn off my gaming and that I thought was really, really kind of makes you go oh gosh, yeah [sic]. So, that I think was brilliant having those little bits in, because they are only very short aren't they? I think really quite powerful in a way.*

Finally, one of the parents suggested how reflections could be used to motivate changes by giving users space to write an action plan which advice or skills they want to implement:

> *The other thing I thought is, the reflections bit at the moment is just getting you to think about stuff but, I wondered from a kind of behaviour change perspective, if whether sometimes that could be used to prompt people to commit to things that they want to try, like what are you going to try this week? Which of these suggestions would be good for you? And how and when are you going to try them out? 'Cause that would then act as something to stop it just being something that you spent 10 minutes having a quick listen to or look at and then don't do anything with.*

Therapeutic Alliance

Therapeutic alliance: several participants commented that their Buddies managed to create a sense of personal connection and relatability:

> *I think the buddy system is probably my favourite. I've never come across anything like that before...It makes it easier to connect I think with the buddies.*

They also commented that the inclusion of various examples helped demonstrate that the app's aims were achievable, and the context was relatable:

> *I thought they [examples] were really good because they were very accurate and they also made it easier to relate to the Steps programme, because the examples were realistic and were quite common problems that parents would be going through.*

The expert videos also came across as friendly and knowledgeable, and the content was delivered using an accessible language:

> *That's really good. I like that, she's a great speaker. She's very calm. She's not overcomplicating. She's not using loads of jargon and everything which I hate when you start getting into these sorts of things.*

However, the comment from one of the parents highlighted an important risk that is inherent to unguided parenting

interventions, that is, working through the app may create uncomfortable reflections about one's parenting and lead to the feeling of self-blame:

> *I think the lady, the doctor that was describing it she was fantastic and she kept it very simple, but sometimes when I was listening to it I felt like oh, not I know that [sic], but it felt like a bit like ok, so everything that's happening in my life...it felt like it's my fault, like I've not been the best parent up to now.*

Potential: participants noted the gap in the provision of help and support for parents and thought that the app could help address some of those unmet needs:

> *I think it's a great idea. I have to say I think there is really a gap in parental support. So actually, to have something that is available absolutely all the time at any point when you need it, I think is really good. I think it's a great way to try and support parents' cause.*

They commented that the app could be helpful to a wide range of parents, regardless of whether their child has received a diagnosis or is on the waitlist:

> *I know a lot of parents who've already had their diagnosis and have literally just been given a diagnosis and said congratulations off you go now and that's it [sic]. With no help or support. Just there you go, and they would really benefit from this. So, it would be great if it was more widely available. But also, yes for that for that waiting period it's horrendous and you do know nothing.*

Finally, the app could also be helpful to parents of children who do not have clinical-level needs:

> *I think every parent is looking for something like this, because we all struggled. And of course, parenting is such a difficult thing and there is lots of scope in it, you know to improve yourself, so I think it is giving me a very positive vibe [sic]. In helping myself and my child to manage the behaviour and the steps don't look complicated.*

Discussion

Principal Findings

This paper reported on phase 1 of the OPTIMA research program. It had 4 objectives concerning the adaptation and testing the feasibility of the screening and waitlist recruitment strategy facilitated by the myHealthE platform, piloting the acceptability of the proposed remote recruitment and assessment protocol, and exploring the usability of the STEPS mobile app to optimize its functionality for parents. Overall, our findings were positive and demonstrated that the planned recruitment strategy and assessment protocol were feasible and acceptable to participants. Usability data also supported the use of STEPS to provide support for families on the child health services waitlist and provided useful recommendations for minor modifications to the app.

Our findings showed that myHealthE can be successfully adapted and used across the 3 different child health services in the United Kingdom. To support timely implementation, the original plan to make the platform interoperable with the local clinical patient records systems had to be modified, and myHealthE was implemented as a stand-alone desktop application that could be accessed via a web browser. This adaptation did not compromise the platform's clinical utility in terms of monitoring patient-reported outcomes, as individual reports could be easily generated by the clinic staff. Crucially, myHealthE provided a systematic and efficient way for researchers to screen and identify eligible families from the waitlist of the participating services without the need to involve members of the clinical care team. Traditional approaches require that a patient's (or, in the case of patients aged <16 years, their parent's) consent for research contact be obtained by a clinician and recorded in clinical notes. These notes are subsequently manually screened to identify potentially eligible participants. Such a process not only is time consuming, resulting in delays in contact, but also means that clinicians act as the main gatekeepers to providing access to research opportunities. For families on the waitlist who have very limited or no contact with clinicians until their first assessment appointment, this could be a substantial barrier to being involved in research. Compared with these traditional approaches, myHealthE permitted a straightforward and convenient way of obtaining consent for research contact and facilitated the timely and efficient recruitment of participants from the service waitlist into the study.

Our remote recruitment strategy was also successful. During the primary feasibility study recruitment period, 45 participants consented to take part in the study, and 38 (84%) of them agreed *in principle* to take part in the RCT, exceeding our conservative assumption of 18 participants per month. This suggests that we should comfortably achieve our planned RCT recruitment target of 13 participants per month. This finding is important for 2 reasons. First, meeting trial recruitment targets is essential to ensuring the success of a trial. Second, recruitment from health services can be very challenging (even more so when participants are recruited from the waitlist), and a substantial proportion of trials either experience delays leading to higher research costs or are stopped owing to poor recruitment [30]. It could be that using remote approaches, such as the one adopted in this study, which give participants the maximum flexibility of completing consenting procedures at the time and place that are convenient to them, helps overcome some of the key barriers to successful recruitment. Importantly, remote recruitment and assessments were also acceptable to parents. Those who provided exit questionnaire data were either satisfied or very satisfied with the study procedures. In addition, the feasibility study provided an important learning opportunity for the research team. We uncovered some errors in the study procedures, such as participants receiving access to web-based questionnaires or the app when they should not have. Becoming aware of these potential issues during the feasibility study will help us to develop clear operating procedures to minimize the risk of making errors in the RCT.

Finally, the STEPS app received high usability ratings, and parents provided very positive feedback about the app. Participants found the app easy to navigate (mainly owing to its clear linear structure) and visually attractive. They appreciated the easy-to-understand language used in the app, which was clear of psychological jargon, and found it useful to have information presented in varied formats (ie, text, video, and audio). Many parents emphasized that it was helpful to have information presented in short, "bite-size" pieces that could be accessed when they had a few spare minutes (eg, when waiting to collect their child after school). Although some parents found the functionality that allowed them to record reflections useful, a few expressed concerns about the confidentiality of recording their private thoughts within the app. The key recommendations for enhancing the app included making improvements to the process of app registration, making resources shareable, improving video playback, and adding captions to videos.

The use of digitally mediated approaches to identification, recruitment, and data collection is efficient from the researchers' point of view and convenient for many participants. We established that myHealthE provided an effective method for screening and identifying participants and that our remote recruitment and assessment strategy was feasible and acceptable. However, adopting digital methods may have resulted in a sample that overrepresented individuals with a high level of digital skills. Moreover, access to myHealthE and the STEPS app relies on having access to a device that is connected to the internet, which some families may not have. Ultimately, these families would not be able to access and potentially benefit from the intervention. Research suggests that it is often those already at a disadvantage because of education and employment opportunities, income, disability, or geographic location who are most likely to be excluded from digital access [31]. If not managed carefully, this may further widen existing health inequalities. Furthermore, we should acknowledge that the eligibility requirement that study participants have a reasonable understanding of English has inevitably led to the exclusion of parents from linguistically (and culturally) diverse backgrounds. Researchers adopting digital recruitment methods and those developing mobile phone interventions should consider the impact of digital competence and language exclusion on the generalizability and reach of their findings.

Conclusions

This study demonstrated that digital screening and remote recruitment from child clinical services' waiting lists are feasible. They are also timely and efficient and minimize the burden on clinical teams, which are typically substantially involved when nondigital recruitment methods are used. Such procedures are also acceptable to participants. Usability data indicate that STEPS has the potential to deliver parenting support to parents of children with ADHD-type symptoms.

Acknowledgments

Online Parent Training for the Initial Management of ADHD Referrals (OPTIMA) is funded by the National Institute for Health Research (NIHR) Programme Grants for Applied Research (RP-PG-0618-20003). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care. The funding body played no role in the study design and conduct.

This paper represents an independent research project part funded by the NIHR Maudsley Biomedical Research Centre at South London and Maudsley National Health Service Foundation Trust and King's College London and the NIHR Applied Research Collaboration South London at King's College Hospital National Health Service Foundation Trust. The views expressed are those of the authors and not necessarily those of the National Health Service, NIHR, or Department of Health and Social Care.

CLH acknowledges support from the NIHR Nottingham Biomedical Research Centre and NIHR MindTech MedTech Co-operative. KS is an NIHR Senior Investigator.

The authors would like to thank the parents who are members of the OPTIMA Patient and Public Involvement and Engagement panel for their continuous support, advice, and involvement in the project.

Authors' Contributions

EJSS-B is the Online Parent Training for the Initial Management of ADHD Referrals (OPTIMA) chief investigator and led the original study conceptualization, the design of phase 1 of OPTIMA, and the writing of the paper with KK-A. KK-A was responsible for coordinating the observational feasibility and usability studies and analyzed the usability study data. CB, BF, and EH were responsible for enrolling participants, administering outcome measures, and coordinating recruitment in the observational feasibility study. CB cocoordinated the usability study with KK-A. ES, SC, DD, and JD contributed to the conception and design of the study and were responsible for liaising with clinical services. JD led the adaptation and implementation of myHealthE. JK contributed to the conception and design of the observational feasibility study and was responsible for overseeing research activities in the Southampton trial center. KS and CLH were responsible for overseeing research activities in the Nottingham trial center. NL provided administrative support for the project and for patient and public involvement activities. KG contributed to the conception and design of the observational feasibility study and supervised the feasibility study data analyses. PC conducted the feasibility study data analyses. SB contributed to the conception and design of the observational feasibility study and was responsible for the design and implementation of the economic component of the overall research program. JS contributed to the design of the economic component of the overall research program, including the design of the economic measure of service use.

MT contributed to the conception and design of the observational feasibility study and the Structured E-Parenting Support (STEPS) app development. HK and CG contributed to the conception and design of the observational feasibility study. All authors have read and approved the final version of the manuscript.

Conflicts of Interest

SC declares honoraria and reimbursement for travel and accommodation expenses for lectures from the following nonprofit associations in the last 3 years: Association for Child and Adolescent Central Health, Canadian ADHD Alliance Resource, the British Association of Pharmacology for educational activity on attention-deficit/hyperactivity disorder. DD declares educational talks for Medice, and Takeda, advisory board attendance for Takeda, and educational travel from Takeda and Medice. He has also received royalties from the sale of a self-help version of the New Forest Parenting Programme, on which STEPS is based, payments for providing training on New Forest Parenting Programme, nonmonetary support from Qbtech, and research funding from National Institute for Health Research. EJSS-B declares speaker fees and conference support from Takeda and Medice, honoraria from the Journal of Child Psychology and Psychiatry and Aarhus University, and research support from Qbtech, Medical Research Council, Economic and Social Research Council, National Institute for Health Research, Waterloo Foundation, and Shanly Foundation.

Multimedia Appendix 1
Prebaseline and baseline questionnaire score summaries.
[DOCX File , 14 KB - pediatrics_v6i1e47035_app1.docx]

Multimedia Appendix 2
The Structured E-Parenting Support app.
[PDF File (Adobe PDF File), 385 KB - pediatrics_v6i1e47035_app2.pdf]

Multimedia Appendix 3
Adverse event and serious adverse event summary metrics.
[DOCX File , 18 KB - pediatrics_v6i1e47035_app3.docx]

Multimedia Appendix 4
The System Usability Scale individual item scores.
[DOCX File , 15 KB - pediatrics_v6i1e47035_app4.docx]

Multimedia Appendix 5
Additional quotes from the usability interviews.
[DOCX File , 17 KB - pediatrics_v6i1e47035_app5.docx]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
ODD: oppositional defiant disorder
OPTIMA: Online Parent Training for the Initial Management of ADHD Referrals
RCT: randomized controlled trial
SDQ: Strengths and Difficulties Questionnaire
STEPS: Structured E-Parenting Support

Edited by S Badawy; submitted 14.03.23; peer-reviewed by V Prasad, K Kan; comments to author 14.06.23; revised version received 19.07.23; accepted 20.07.23; published 11.09.23.

Please cite as:
Kostyrka-Allchorne K, Chu P, Ballard C, Lean N, French B, Hedstrom E, Byford S, Cortese S, Daley D, Downs J, Glazebrook C, Goldsmith K, Hall CL, Kovshoff H, Kreppner J, Sayal K, Shearer J, Simonoff E, Thompson M, Sonuga-Barke EJS
Remote Recruitment Strategy and Structured E-Parenting Support (STEPS) App: Feasibility and Usability Study
JMIR Pediatr Parent 2023;6:e47035
URL: https://pediatrics.jmir.org/2023/1/e47035
doi:10.2196/47035
PMID:37695667

Dropout or Drop-In Experiences in an Internet-Delivered Intervention to Prevent Depression and Enhance Subjective Well-Being During the Perinatal Period: Qualitative Study

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Abstract

Background: The perinatal period is a vulnerable time when women are at increased risk of depression. “Mamma Mia” is a universal preventive internet-delivered intervention offered to pregnant women, with the primary goals of preventing the onset or worsening of depression and enhancing subjective well-being during the perinatal period. However, treatment dropout from internet-delivered interventions is often reported.

Objective: The study aim was to acquire an understanding of the different experiences among participants who dropped out of the Mamma Mia intervention during pregnancy, compared to participants who dropped out during the postpartum follow-up phase.

Methods: A total of 16 women from a larger randomized controlled trial (Mamma Mia) participated in individual semistructured interviews following a strengths, weaknesses, opportunities, and threats format. Of the 16 participants included, 8 (50%) women dropped out early from the intervention during pregnancy (pregnancy group), whereas 8 (50%) women dropped out later, after giving birth (postpartum follow-up group). Data were analyzed using the framework approach.

Results: The results showed that there were differences between the groups. In general, more participants in the postpartum follow-up group reported that the program was user-friendly. They became more aware of their own thoughts and feelings and perceived that the program had provided them with more new knowledge and practical information than participants in the pregnancy group. Participants in both groups suggested several opportunities for improving the program.

Conclusions: There were differences between women who dropped out of the intervention during pregnancy and the postpartum follow-up phase. The reported differences between groups should be further examined.

(JMIR Pediatr Parent 2023;6:e46982) doi:10.2196/46982

KEYWORDS

perinatal depression; internet intervention; dropout; well-being; perinatal period

Introduction

Mental health problems are one of the leading causes of disability worldwide. In particular, depression constitutes a major public health problem [1]. Women are particularly susceptible to depression throughout the perinatal period [2]. During this period, between 10% to 15% of women experience moderate to severe depressive symptoms [3,4]. Depression is commonly associated with a range of negative consequences for the woman (eg, reduced life quality and social functioning); it may also affect the mother-infant relationship and have long-term consequences for their child [5-10] and partner [11,12].

Despite the availability of different types of traditional treatments for mental health problems, help-seeking behavior among women with perinatal depression remains low (ie, 17%-25% [13-15]). The negative consequences of maternal depression for the child and the whole family highlight the importance of adequate and timely treatment [8]. Internet-delivered interventions have emerged as an innovative approach to prevent and treat depression. Recent studies have demonstrated their usability, feasibility [16-18], and effectiveness in reducing depressive symptoms [19-24]. However, treatment dropout is often reported, both in unguided and guided internet-delivered interventions [25,26]. Dropout is often preceded by missed sessions or ending without completing the treatment components [27]. Research considers a lower

treatment completion rate as a moderator of treatment effect size [28]. It is important to understand participants' reasons for dropout. Exploring and comparing dropout at different stages helps researchers identify and understand the underlying causes of dropout at different stages of intervention. Researchers have previously found that baseline symptoms of depression, depression with comorbid anxiety symptoms, lower educational levels, interventions without guidance, and gender are risk factors for dropout from psychological web-based interventions for depression [29-31]. Dropout is also frequently cited as being caused by the perception of lengthy and time-consuming content, social changes, the demands of caring for a newborn, a lack of motivation to begin the intervention, engagement with the content and relationship with technology, and feelings of benefits from the intervention [26,32,33].

A qualitative systematic review and meta-synthesis across 24 quality studies was aimed at exploring the views of people who had been invited to participate in digital health interventions for depression [34]. Three themes emerged regarding acceptability and usability: initial motivations and approaches to digital health interventions, the personalization of treatment, and the value of receiving personal support in digital health interventions. The meta-synthesis suggests that participants' initial beliefs about digital health interventions can have an important effect on their engagement with these types of interventions.

In this study, we focused on an internet-delivered, unguided self-help program for depression ("Mamma Mia"), to achieve a deeper understanding of user experiences. Mamma Mia is designed as a universal preventive intervention that can be offered to all pregnant women. Its' primary goals are to prevent the onset or development of depression and enhance subjective well-being during the prenatal and postnatal periods. Examining participants' experiences from a qualitative perspective can provide more in-depth answers about the complexity of treatment dropout. The study aim was thus to acquire an understanding of the different experiences among participants who dropped out of the intervention during pregnancy, compared to participants who dropped out during the postpartum follow-up phase.

Methods

Study Design and Participants

This study used a qualitative design with individual semistructured interviews following a strengths, weaknesses, opportunities, and threats (SWOT) format. Participants were recruited through the Mamma Mia randomized controlled trial [20,35], where pregnant women in Norway were invited to participate between December 2013 and February 2015. They were recruited at well-baby clinics, during routine prenatal care, and via hospitals in Eastern Norway during regular ultrasound imaging (gestational wk 18-20). Eligible participants had to be pregnant (up to gestational wk 25), 18 years or older, able to read and write Norwegian, and have access to the internet and an email account. All participants were enrolled for the study, enrolled in the intervention, and invited for an interview, consecutively. Inclusion criteria for being invited to an interview were either (1) completing the intervention, (2) having no program activity during the last 4 weeks, or (3) lagging 3 or more sessions behind the prescribed intervention schedule. Participants fulfilling the 2 latter criteria were defined as dropouts.

In this study, 16 interviews were conducted. Respondents were women who were either pregnant or had given birth at the time of the interview. Of the 16 participants included, 8 (50%) women dropped out early in the intervention during pregnancy (pregnancy group), whereas 8 (50%) women dropped out later, after giving birth (postpartum follow-up group). Participants in the pregnancy group had completed between 3 to 15 sessions out of a total of 44 sessions. At the time they were invited to interview, these 8 women had no program activity during the last 4 weeks or were lagging 3 or more sessions behind the prescribed intervention schedule. They had left the program before it ended at session 44 (after birth). Participants in the postportum follow-up group had completed between 25 to 38 sessions out of a total of 44 sessions. They had followed the intervention from session 1 (during pregnancy) to sessions 25-38 (after birth); however, they did not complete the intervention, and at the time they were invited to the interview, they had had no program activity during the last 4 weeks or were lagging 3 or more sessions behind the prescribed intervention schedule.

Mamma Mia

Mamma Mia is a universal internet-delivered intervention developed with the primary goals of improving or maintaining subjective well-being and preventing the onset of or reducing depressive symptoms during pregnancy up to 6 months after birth. Overall, Mamma Mia consists of 44 sessions over 11 months in 3 phases, starting from pregnancy between gestational weeks 17 and 24 and lasting into the postpartum period 6 months after childbirth. The first phase, the pregnancy phase, consists of 16 sessions, which starts at gestational week 21 and ends at week 40. The second phase is the maternity phase, which starts when the infant is 2-3 weeks old and lasts for 6 weeks. Sessions are delivered 3 times a week, for a total of 18 sessions. The final phase is the low-intensity follow-up phase, consisting of 10 sessions over 18 weeks. These sessions are delivered with some variation (weekly at first and then biweekly). All sessions include themes specific to the perinatal period. Mamma Mia was deployed as an unguided, universal intervention with a tunneled design to guide women through the program in a step-by-step fashion, in accordance with the psychological preparation of becoming a mother. Each session was designed to take 10-15 minutes. Mamma Mia has a website that could be use on tablets and mobile devices, and the intervention is delivered through email and interactive websites that include text, pictures, prerecorded audio files, and user feedback [36]. In the Mamma Mia randomized controlled trial, the total number of respondents in the total sample was 1342 at baseline; 1117 (83.2%) at gestation week 37; and 962 (71.7%), 886 (66%), 847 (63.1%) at 6 weeks, 3 months, and 6 months post partum, respectively.

Interviews

The semistructured interviews followed the theory-neutral SWOT framework, focusing on participants' spontaneous and

open appraisals of Mamma Mia. Each participant was asked questions about what they perceived to be the SWOT to Mamma Mia. During the first part of the interview, participants spoke freely about the different SWOT. In the second part of the interview, a more exploratory approach was used to obtain additional information and a richer description of the SWOT described in the first part of the interview. The SWOT format can be helpful to understand the intervention better and provide potentially more accurate perspectives on the intervention.

The interviews were conducted from March 2014 to April 2015 and were carried out at the Regional Centre for Child and Adolescent Mental Health. All interviews were recorded electronically and transcribed verbatim. The length of the interviews ranged from 48 to 110 (mean 75.8) minutes.

Analysis

Descriptive statistics and frequencies were used to describe the characteristics of the sample. Interviews were analyzed using the framework approach as suggested by Gale et al [37]. The framework approach consisted of 5 phases: familiarization, identification of a thematic framework, indexing, charting, and mapping and interpretation. Familiarization involved immersion in the data by reading the transcripts several times. In developing the thematic framework, we identified themes from issues that the participants raised themselves. Indexing involved systematically applying the thematic framework to all interview transcripts. During the charting phase, we lifted data from their original context and rearranged them according to theme. We identified themes and patterns within and between the 2 different groups of participants: the pregnancy group and the postpartum follow-up group. In the mapping and interpretation phase, we reviewed the charts, compared and contrasted the data, and sought patterns and explanations within the data. NVivo (version 12; Lumivero) was used to structure the condensed meaning units and group differences. The final interviews did not reveal new information or insights, and it was considered that data saturation had been reached. To contribute to reflexivity in the research, continuous reflection was applied throughout the research processes on the researcher's role, biases, values, and relationships.

Frequency labels were used to characterize the data. The "general" label corresponds to all or all but 1 case (n=7-8); the "typical" label corresponds to more than half of the cases up to the cutoff point for the "general" label (n=5-6); and the "some" label corresponds to 2 cases up to the cutoff point for the "typical" label (n=2-4). When comparing the 2 groups, we defined the results as different if they varied by at least 2 frequency labels [38].

Ethical Considerations

The study has been performed in accordance with the Declaration of Helsinki and has been approved by an appropriate ethics committee, the Norwegian Regional Committees for Medical and Health Research Ethics (project REK-SØ 2012/1716). The study was conducted in line with the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist to promote transparency. Written informed consent was obtained from all participants upon recruitment. The Regional Centre for Child and Adolescent Mental Health, Eastern and Southern Norway, has granted permission to access and use the data set. The participants did not receive financial compensation.

Results

Participants

In the pregnancy group, the age ranged from 26 to 40 years, with a mean age of 31 years. One of the participants in this group was not a native Norwegian. In the postpartum follow-up group, the age ranged from 21 to 33 years, with a mean age of 29 years, and all the women were native Norwegians. In both groups, all women were married or cohabitating. They were highly educated—in both groups, 38% (3/8) had 1-3 years of college or university education, and 62% (5/8) had ≥4 years of college or university education—and all were currently employed. They had few symptoms of depression as measured by the Edinburgh Postnatal Depression Scale [39]; mean scores were 6.8 (SD 5.1) and 6.1 (SD 5.9) in the pregnancy and postpartum follow-up groups, respectively. At baseline in the pregnancy group, the mean Satisfaction With Life Scale [40] score was 21.1 (SD 3.2), mean positive affect score was 37.0 (SD 6.7), and mean negative affect score was 18.50 (SD 7.3). At baseline in the postpartum follow-up group, the mean Satisfaction With Life Scale score was 21.5 (SD 3.9), mean positive affect score was 31.8 (SD 3.06), and mean negative affect score was 22.25 (SD 10.12).

Table 1 shows the 4 primary themes that emerged from the interviews in the 2 groups: user-friendliness, awareness, learning, and adaption.

Table . Perceived experiences of the Mamma Mia intervention as reported by participants in the pregnancy and postpartum follow-up groups.

Themes		Pregnancy group	Postpartum follow-up group
User-friendliness			
	Similarities in subthemes	• Easy to use • Technical problems • Time-consuming to follow up	• Easy to use • Technical problems • Time-consuming to follow up
	Differences in subthemes	• N/A[a]	• Accessibility • Simple design • Weekly reminders • Positive repetition of information • Difficult to catch up
Awareness			
	Similarities in subthemes	• Relationship to the partner	• Relationship to the partner
	Differences in subthemes	• Awareness of the pregnancy phases	• Conscious of thoughts and feelings • Connection to the baby • Normalization of emotions • Reflection
Learning			
	Similarities in subthemes	• Evidence-based information	• Evidence-based information
	Differences in subthemes	• Instructive exercises	• New knowledge • New tools
Adaptation			
	Similarities in subthemes	• Follow-up	• Follow-up
	Differences subthemes	• Adaptation to the target group • Relevant information	• Flexibility in the program • More information or links to external sources

[a]N/A: not applicable.

User-Friendliness

There was a group difference in the perceived user-friendliness of the program. Only some of the women in the pregnancy group mentioned that the program was easy to use, whereas women in the postpartum follow-up group generally reported that the program was user-friendly. When they reported that the program was user-friendly, they highlighted the accessibility of the program, the design, the weekly reminders, and the repetition of information to increase usability. They emphasized that the intervention contained brief, relevant information and appropriate reminders for the user. They also favored the program over other websites or web-based sources of information.

> *It was very easy to log in, click on the links, and follow the program. It was also very easy to use...There was an okay amount of information. [Respondent 238]*

> *I appreciate that the program is friendliness. You click on the E-mail, and you don't need a password. It is an advantage with weekly reminders. [Respondent 8]*

> *It is very easy to use. I have it on my phone, an email comes up. So, it is very user-friendly. [Respondent 173]*

At the same time, participants in both groups typically experienced technical challenges with the program. They reported that the program did not always work well on mobile phones and tablets. It was also difficult to store and retrieve information and videos in the program, especially when using a mobile phone. As 1 woman in the pregnancy group said: "The program did not work very well on my phone. It should be easier to follow the program if it had worked on my mobile" (respondent 327)

In general, participants in both groups also reported that the program was time-consuming with frequent emails and many program days. They did not always have time to complete the sessions according to the prescribed program schedule, especially if they had other children to care for. When they fell behind schedule, it felt difficult to catch up again, and for some women, this was perceived as stressful. A participant in the postpartum follow-up group said: "It's challenging to spend so much time with your PC. Before I had the baby, it was nice to

get an email and pay attention to the program. But after having the baby, I simply did not have the time" (respondent 8).

A participant from the pregnancy group said: "I used the program more actively in the beginning. I had decided to prioritize it" (respondent 248).

Awareness

After participating in Mamma Mia, participants in the postpartum follow-up group generally reported that they had become more aware of their own thoughts and feelings than participants in the pregnancy group.

> *I became more aware of my own thoughts, feelings, and moods...It made me aware of processes in myself. [Respondent 238]*
>
> *I'm more aware of all these emotions, and became a little more...[have] gotten more in touch with myself. [Respondent 279]*

Some participants in the pregnancy group talked about awareness in relation to the phases of pregnancy and in their relationship with their partner. In contrast, women in the postpartum follow-up group typically talked about the changes that occurred during the transition to motherhood, as well as how the information in the program created awareness and self-reflection and contained important reminders that facilitated attachment and bonding with the baby. They emphasized that themes containing information about the baby were one of the strengths of the program.

> *You feel like you are better able to connect with your baby. It strengthens the bond with the baby...and the connection is something that comes gradually. [Respondent 155]*
>
> *I can now see how my baby responds to different things. [Respondent 218]*

The postpartum follow-up group also mentioned the ways in which the program helped them in their daily life by looking at things more positively. In addition to normalizing feelings, during pregnancy or in situations where it was difficult to comfort the child, they gained a greater understanding that they were not alone in experiencing such situations.

> *It is useful to learn that people may have the same kind of challenges with the child as you. I became aware that some situations are normal, and I am not the only one who has these experiences. [Respondent 202]*
>
> *Many people, my-self included, have concerns. When you are told that, for example, negative thoughts are normal, it feels good. [Respondent 251]*

Learning

There was a difference between the groups in terms of learning outcomes. Learning was not to any great extent reported in the pregnancy group, whereas respondents in the postpartum follow-up group generally reported that the program had provided them with new knowledge and practical information that were useful. However, in the pregnancy group, relaxation exercises, such as mindfulness exercises, were perceived as pleasant and instructive by some respondents. Participants in the postpartum follow-up group typically reported that they had gained knowledge through information and interactivity in the program. They highlighted knowledge such as how to comfort the child, the stages of infant sleep-wake cycles, and how to manage conflicts in their relationship with their partner. This was useful because they used it in their interaction with their child and partner.

> *There is a lot of practical information that you need as a new parent. I learned a few techniques, for example, to distinguish between the different stages of sleep. I learned a lot from that. [Respondent 155]*
>
> *I learned a lot of things that I wasn't fully aware of, such as comforting the child. [Respondent 279]*
>
> *I really think that the whole program was very educational. [Respondent 238]*

In general, participants in the postpartum follow-up group described that they changed their thoughts, feelings, and ways of interacting with their child and partner by acquiring new knowledge. They received practical strategies that influenced how they adapted to different requirements and environments, whether this applied to their child or partner. Participants said that they have been given new useful tools. For example, methods such as "gradual comforting" and managing infant sleep-wake cycles were mentioned as useful tools that were translated into practical strategies, helping them consider "what should be done" and "how it should be done."

> *It was very exciting...You don't necessarily solve all problems, but you get some tools that can be used to solve problems constructively. [Respondent 155]*
>
> *When a situation gets difficult, I now have a strategy to use. [Respondent 238]*

They appreciated that the content provided in the program was quality assured, in contrast to other information found on the web. They described the information that was given as trustworthy, and a couple of participants in both groups highlighted that the information in the program was evidence based. However, although the content was relevant, some of the participants also said that some exercises were difficult to implement. Difficult exercises that were mentioned were techniques intended to improve communication skills and facilitate conflict resolution with their partner.

Adaptation

Participants in both groups suggested several opportunities for improving the program. Women in the pregnancy group typically suggested that the content of the program should be better adapted. They perceived that the content of the program was aimed at first-time mothers and suggested that the program should also be addressed to a greater extent to multiparous women. Some respondents also reported that some of the content in the program was familiar or not very relevant. Some sessions were considered too brief, and they emphasized the lack of depth and relevance of the information as central weaknesses. Furthermore, they suggested a parallel program dealing with problems concerning difficulties relevant to multiparous women.

> *The challenge is that...there are people with different personalities and situations in one program. It is difficult to find a program that could be adapted to everyone. [Respondent 248]*
>
> *The fact that I am a third-time mother may have affected me in the way I perceive Mamma Mia...It could have been divided into first- and second-time mothers, and asked questions about how the current pregnancy is different from the previous pregnancy. [Respondent 32]*

It was, in general, more pronounced in the postpartum follow-up group that they wanted more flexibility in the program. They reported dissatisfaction with the tunneled sequence—having to complete 1 module before starting the next one. A better adaptation of the program, where participants can drop some of the modules or reenter the program later, may help them perceive the program as being less stressful. The lack of flexibility was also mentioned with regard to subjects the women wanted to learn more about. Some sessions were considered too brief and superficial. Therefore, participants suggested links to web portals or other sources to retrieve more information of interest. The participants expressed a desire to go deeper into 1 subject of interest. Specifically, a link to more information about practical care for the infant and sleep was mentioned.

> *It's really about making suggestions about where to find more information, quality-assured information. [Respondent 255]*
>
> *Access to resources, libraries or something where you have the opportunity to find out more. [Respondent 155]*

Some respondents in both groups, regardless of how long they had used the program for, wanted further follow-up when something was difficult.

> *…that I get further help to figure out what to do next when I'm very depressed, or something is wrong. A description of how to proceed to get help. [Respondent 8]*

Discussion

Principal Findings

This study aimed to acquire an understanding of the participants' experiences of a universal, internet-delivered intervention offered to all pregnant women, with the primary goals of preventing the onset or worsening of depression and enhancing subjective well-being during the perinatal period. We compared the experiences between participants who dropped out during the pregnancy phase to participants who dropped out during the postpartum follow-up phase. The analysis resulted in 4 themes, each relating to different experiences with the intervention. The results showed that there were similarities but also differences between the groups. The postpartum follow-up group had a larger proportion of participants who reported that the program was user-friendly. They also became more aware of their own thoughts and feelings and perceived that the program had provided them with more new knowledge and practical information than participants in the pregnancy group. However, respondents in both groups suggested several opportunities to improve the program. Although women in the pregnancy group typically suggested that the content of the program should be better adapted to the target group, it was generally more pronounced in the postpartum follow-up group that they wanted more flexibility.

Despite these findings, Mamma Mia was described as a positive and credible intervention in both groups. The main different between the group was that, in general, more women in the postpartum follow-up group reported that the program was user-friendly; emphasized the accessibility of the program; and indicated that the intervention containing brief, relevant information and reminders suitable for the user. They reported that the presentation and navigation in the program was easy to use and understand and was aesthetically pleasing, which was mainly due to the design. The experiences of user-friendliness may have contributed to the fact that women in the postpartum follow-up group followed the intervention longer than women in the pregnancy group. Users of internet-delivered interventions often experience barriers and difficulties when using new technology [26,41], but a design that is easy to use and perceived as user-friendly can reduce this burden [42]. It can thus contribute to maintaining engagement and achieving benefits from digital health interventions [43-45]. However, technical challenges with the program were mentioned by participants in both groups. They reported that the program did not always work well on mobile phones and tablets and that it sometimes was difficult to store and retrieve information and videos in the program, especially when using a mobile phone. This issue is important since previous research has shown that improving the convenience of internet programs improves usability and reduces attrition [26,41]. Our findings add to this evidence, indicating that there is still great potential for improvement in the design of eHealth products to provide technology that users will participate in and use.

Women in both groups also typically reported that the program was time-consuming and that they did not always have time to complete the sessions as prescribed according to the program schedule. Giving birth and caring for a new infant mark an important transition in life. Although this transition is often exciting and rewarding, it also leads to a multitude of new responsibilities, often alongside a range of physical, psychological, and social changes [46]; this may have made it difficult to follow the program on a weekly basis post partum. However, adaptation to a maternal role is affected by individual factors, such as educational background, their partner, and psychological state (eg, depression) [47-49]. The literature has previously documented the influence of external factors on treatment dropout [50,51], stating that the demands these factors place on the individual will lead to dropout if they are viewed as an obstacle to the individual's daily life [51]. Lagging behind may result in perceiving the program as stressful, and the demands of motherhood may directly interfere with their ability to complete the program [52].

Differences between the groups were also found in relation to awareness and learning outcomes. In general, more women in the postpartum follow-up group reported how the information in the program had created awareness and self-reflection and

contained important reminders that facilitated attachment and bonding with the baby. These findings are in line with previous research showing that many noncompleters also experience the clinical benefit of programs [53] and that the greatest benefits of interventions can be observed among those with a completion rate in the top quartile [28]. However, the postpartum follow-up group dropped out later and thus may have found the program more beneficial or positive in general. From a prevention and treatment perspective, these findings are important because the intervention was designed to prevent the onset or worsening of perinatal depression among pregnant and postpartum women and, thus, negative consequences for the child as well [6,54]. Our findings of different learning and awareness experiences in the 2 groups could be contributed to both individual differences between the participants and factors related to the intervention. However, there were no differences between participants in the groups in terms of marital status, education, or employment. Participants in both groups also had few symptoms of depression, and there were no differences in quality of life or negative affect scores between the participants before they started the intervention.

Opportunities for improving the program were mentioned by both groups. Although women in the pregnancy group typically suggested that the content of the program should be better adapted to the target group, women in the postpartum follow-up group emphasized that they wanted more flexibility in the program. Although participants in internet-delivered interventions usually can choose where and when they want to work with the program, they requested more flexibility and suggested links to more information on some subjects. This is in line with previous research, showing that inflexibility is a common experience among participants in internet-delivered treatment that can lead to nonadherence [55].

Some important limitations should be noted when interpreting the results of this study. First, the women who participated were typically living with a partner, well educated, and employed. They also scored low on depressive symptoms and high on subjective well-being. Thus, a limitation of this study is the potential of sampling bias. Maternal mental health can change during pregnancy and the postpartum period, and therefore, universal health programs must reach as many women as possible, including those who are doing well. However, future research should include a more diverse sample of women, for example, women with lower socioeconomic status, a history of depressive disorders, or current mild to moderate symptoms of depression (ie, Edinburgh Postnatal Depression Scale score≥10). Despite these limitations, the result of this study adds to the literature on user experiences with dropout from a universal internet-delivered program in the perinatal period.

Conclusion

The results of this study showed that there were differences between women who dropped out of the intervention during pregnancy and the postpartum follow-up phase. In general, more women in the postpartum follow-up group reported that the program was user-friendly. They became more conscious of their own thoughts and feelings and perceived that the program had provided them with more new knowledge and practical information than participants in the pregnancy group. However, women in both groups suggested several opportunities to improve the program. Although women in the pregnancy group typically suggested that the content of the program should be better adapted to the target group, it was in general more pronounced in the postpartum follow-up group that they wanted more flexibility in the program. The reported differences between groups should be further examined.

Acknowledgments

We are grateful to all the women who took part in this study.

Data Availability

The data that support the findings of this study are available from Regional Centre for Child and Adolescent Mental Health, Eastern and Southern Norway, Oslo, Norway, but restrictions apply to the availability of these data, which were used under license for the current study and so are not publicly available. Data are however available from the author upon reasonable request and with permission of the Regional Centre for Child and Adolescent Mental Health, Eastern and Southern Norway.

Authors' Contributions

LV participated in the study design and contributed to the interpretation. LV was responsible for the analytic framework of the study and writing of the manuscript. SMH participated in the study design, conducted the interviews, participated in the analytic framework of the study, and critically revised the manuscript for important intellectual content. SG-N critically revised the manuscript for important intellectual content. FD was responsible for the study design; conducted the interviews; and participated in the analytic framework of the study, data interpretation, and in the writing of the manuscript. All authors have given their final approval of the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
SWOT: strengths, weaknesses, opportunities, and threats

Edited by S Badawy; submitted 04.03.23; peer-reviewed by A Reupert, J Scott, LL Leng, M Gonzalez; revised version received 24.10.23; accepted 06.11.23; published 22.12.23.

Please cite as:
Valla L, Haga SM, Garthus-Niegel S, Drozd F
Dropout or Drop-In Experiences in an Internet-Delivered Intervention to Prevent Depression and Enhance Subjective Well-Being During the Perinatal Period: Qualitative Study
JMIR Pediatr Parent 2023;6:e46982
URL: https://pediatrics.jmir.org/2023/1/e46982
doi:10.2196/46982

Review

Digital Behavioral Activation Interventions During the Perinatal Period: Scoping Review

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Abstract

Background: Pregnancy is a complex period that implies many biopsychosocial changes, and the way women adapt to these changes impacts their well-being and the chances of developing mental health problems. During the perinatal period, women have expressed a preference for support delivered on the web. In this regard, interventions such as behavioral activation (BA), which are brief and structured psychosocial interventions, seem particularly suited to be delivered through digital solutions.

Objective: This study aimed to map the literature investigating digital BA interventions deployed during the perinatal period. We paid particular attention to the methodological underpinnings of the studies, the potential impact of BA interventions on symptoms other than depression, and the existence of differences occurring when these interventions were administered during pregnancy versus the postpartum period.

Methods: A systematic search compliant with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews) guidelines was conducted considering 5 bibliographic databases; reference lists and key journals were also screened by 2 independent authors following a double-blind approach.

Results: A total of 7 studies published between 2013 and 2022 were included. In total, 2 studies were protocols for randomized controlled trials, 5 were empirical studies, and 1 was a qualitative study. All studies focused on the postpartum period, except for 1 that focused on the broader perinatal period. Promising effects on depression symptoms were reported but not on other psychosocial symptoms. Low intervention adherence has emerged, whereas the usability associated with the digital means used to deploy interventions was scarcely addressed; moreover, information on the digital platforms used was poorly reported overall.

Conclusions: Our findings highlight the scarcity and preliminary nature of digital BA interventions deployed during the perinatal period, where the focus seems more on treatment rather than prevention. Moreover, future studies should also consider and address usability and user engagement, given their relevance to intervention efficacy.

(JMIR Pediatr Parent 2023;6:e40937) doi:10.2196/40937

KEYWORDS

behavioral activation; eHealth; perinatal care; depression symptoms; scoping review; mobile phone

Introduction

Background

The transition to motherhood is a life-changing experience entailing a series of social, psychological, and hormonal changes, which may be challenging to adapt to and often cause exhaustion, a sense of overwhelm, and fatigue [1,2], thereby directly impacting pregnant and postpartum women's quality of life and overall well-being. Taken together, these factors define the perinatal period as a high-risk period for women's mental health [3,4]. The literature provides plenty of evidence

on this matter, highlighting how pregnancy is often associated with mood instability [5] and common mental disorders (1%-37%) [6] as well as depression (approximately 25.3%) [6,7] and anxiety (1%-26%) [6]. Depression symptoms during pregnancy, in particular, are among the main predictors of postpartum depression [8]. From a clinical viewpoint, depression during the perinatal period is described as peripartum depression, which consists of an episode of major depression with peripartum onset, satisfying the criteria for either major depression or persistent depressive disorder [9]. The direct association of peripartum depression with the peculiar challenges and bodily changes intrinsic to the perinatal period makes the condition peculiar, thereby determining the need to consider it as a stand-alone disorder [10]. Accordingly, a recent review concluded that peripartum depression "may be distinct from major depressive disorder with respect to symptom severity, hormone contributions, heritability, epigenetic mechanisms, and response to standard and novel treatment interventions" [10].

Considering the detrimental effects that depression symptoms, together with the often associated anxiety and stress symptoms, have on the physical and psychological well-being of both mothers and children [4], it is paramount to take prompt action and minimize the incidence of adverse effects. In this regard, it is important to emphasize that in the present age, beside the abovementioned challenges, the perinatal period can be experienced very differently by women. Physiological pregnancies and artificially induced ones, that is, pregnancies reached through assisted reproductive techniques (ARTs; eg, in vitro fertilization and intracellular sperm injection), can particularly be distinguished between in this regard. As a matter of fact, ARTs are infertility treatment that determine a series of specific challenges that differentiate them from physiological pregnancies, such as increased psychological distress, loss of self-esteem, relationship problems, disruption in personal life, and even economic problems linked to the substantial expenses they entail [11-14]; this determines a greater psychological toll compared with physiological pregnancies. Moreover, ART are associated with an increased risk of miscarriage [15,16], which could further hinder women's adaptation capacities; although having reached pregnancy, many women might still be mourning their previous interrupted ones [17]. For these reasons, physiological pregnancies, ART-induced pregnancies, and consequent postpartum periods must be deemed as very different experiences. Accordingly, it is paramount to account for their peculiarities in clinical practice by tailoring interventions specifically to their respective needs.

In this regard, contrary to women undergoing ART who are kept under greater clinical scrutiny by default, access to mental health care for women at large going through the perinatal period is severely limited by a series of logistic challenges; for instance, time constraints, lack of information about services, and social stigma are indicated by women themselves as the main obstacles hindering their ability and willingness to seek help [18-20]. However, such barriers can be overcome through the implementation of digital interventions; the literature not only highlights a clear preference for support delivered through a web-based format expressed by women experiencing mental health issues during the postpartum period [21-23] but also underscores how such treatments are effective in decreasing the severity of mood disorders, both during pregnancy and the postpartum period [24-26].

In this regard, behavioral activation (BA) interventions, which in their modern protocols can be counted among the so-called "third wave" cognitive and behavioral therapies [27], seem particularly suited to be implemented digitally. BA is a brief, structured, and empirically supported psychotherapeutic approach developed as a stand-alone treatment for depression [28]. Laying its foundation on the behavioral model, it is mainly aimed at increasing engagement in adaptive and pleasurable activities and decreasing engagement in maladaptive behaviors through the systematic targeting of patients' escape and avoidance strategies [29,30]. The focus is exclusively on the promotion of behavioral change, stimulated by using a series of different strategies such as self-monitoring, activity scheduling, values and goals assessment, and skills training. The ultimate goal is to encourage patients to act in line with their values, allowing them to reconnect with sources of positive reinforcement and fostering a sense of well-being, agency, and mastery through the reconstruction of a routine [30]. Both the efficacy and effectiveness of in-person BA as a treatment specific for depression have been widely proven [31], and the literature also provides promising evidence regarding its efficacy in perinatal depression, both in terms of improved outcomes [29,32] and of engagement and satisfaction [33]. The distinctive features of BA render it a parsimonious, transportable, simple to implement, and cost-effective treatment, suitable to be administered by both specialists and generic mental health professionals [34] in a wide range of formats such as web-based interventions or self-guided smartphone apps [29]. Encouraging findings already exist on the feasibility of internet-based BA interventions for adults with symptoms of depression [35]; therefore, it seems appropriate to further investigate the topic within the context of perinatal care. Nonetheless, it is worth mentioning that evidence on the efficacy and specific features of BA interventions during the perinatal period is still scarce and inconspicuous. For instance, there is some initial evidence highlighting that the effect of in-person BA on depression symptoms might also generalize to other symptoms, thereby leading to the simultaneous reduction of the highly associated anxiety and stress [29,30,32]. However, studies investigating the efficacy of BA interventions have classically focused on the mere reduction of depression symptoms; thus, further research is needed to deepen our knowledge and provide solid evidence on its effects on other concurrent mental health conditions. Similarly, although as previously mentioned, existing studies regarding digital interventions show promising results, and it must be noted that it is a fairly new field and is still under development; therefore, further studies are needed in this area as well [35,36]. Accordingly, this scoping review aimed to map the available literature on digital BA interventions administered specifically during the perinatal period. Scoping reviews serve to bring together "literature in disciplines with emerging evidence, as they are suited to addressing questions beyond those related to the effectiveness or experience of an intervention" [37]. Indeed, this methodological approach to literature review allows us to map the range, nature, and extent

of existing research evidence on a given topic regardless of the specific study design while also allowing the identification of gaps within the available literature [38]. Accordingly, this scoping review intended to investigate how BA interventions have been deployed through digital solutions, paying particular attention to their methodological underpinnings; a further aim was to assess if studies have considered the potential of digital BA interventions to influence symptoms and conditions other than depression (eg, anxiety and stress symptoms, overall quality of life, and well-being). This was expected to provide insights useful for refining the existing digital BA interventions. Moreover, it was also expected to support the further development of effective prevention and intervention programs divulged through digital solutions for women in the perinatal period, thereby supporting both their own and their children's well-being.

Objectives

The specific research questions guiding this scoping review were as follows: (1) How have BA interventions been structured (eg, intervention length, number of modules, topics considered, and guided vs unguided interventions) to be administered through digital means? (2) Has a specific BA protocol been followed? If so, on what BA protocol were the interventions based? [39] (3) What were the main barriers, including both participants' concerns and issues given by the digital tool itself, in implementing BA interventions through digital means? (4) Were digital BA interventions able to influence psychosocial symptoms other than depression? (5) Have they willingly been used to influence symptoms other than depression? and (6) Are there differences in the BA interventions administered during the antenatal period versus the postnatal period?

Methods

This scoping review was conducted in compliance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews) guidelines (refer to Table S1 in Multimedia Appendix 1 [40-47]).

Eligibility Criteria

The inclusion criteria for this study were as follows: (1) considering BA interventions administered through digital means (web-based, smartphone-based, telehealth, etc), (2) inclusion of women aged ≥18 years, (3) focusing on the peripartum period (both antenatal and post partum), (4) inclusion of women who were experiencing or had experienced a physiological pregnancy (up to 1 year post partum), and (5) being written in English.

The exclusion criteria were as follows: (1) being a review article, (2) focusing on or including women who were experiencing or had experienced artificially induced pregnancy, and (3) focusing on or including women with preexisting medical conditions.

In line with the intent of scoping reviews, that is, mapping the available literature regardless of its specific study design [38], no restrictions were imposed on the study design. Accordingly, any type of study satisfying the criteria mentioned above was included, as the intent was to provide an overview of existing literature that is informative of what has already been done (eg, already published studies), what is expected to be done in the near future (eg, study protocols), and what is still lacking entirely or needs further investigation (ie, literature gaps). For the same reason, studies relying on secondary data were also included if they provide information that adds up to the primary analysis, thereby allowing a more in-depth understanding of the intervention evaluated and, more broadly, of the state of the art.

Search Strategy

A total of 5 electronic bibliographic databases, namely, Web of Science, PubMed, PsycINFO, Embase, and CINAHL, were screened in April 2022 to identify studies that met the eligibility criteria. No search restrictions were applied. Reference lists were also scanned, and a handsearching of key journals (ie, *Journal of Medical Internet Research* and *Telemedicine and e-Health*) was performed to ensure a comprehensive literature search. Studies were identified using the following search strings: (behavioral activation OR behavioral activation OR activity scheduling OR pleasant events OR pleasant event) AND (digital interventions OR telehealth OR telemedicine) AND (perinatal depression OR antenatal depression OR postpartum depression OR perinatal mental health); (behavioral activation) AND (web-based interventions OR e-health OR internet-based interventions) AND (perinatal OR postnatal OR prenatal OR antenatal OR postpartum OR maternal OR pregnant OR pregnancy).

Study Screening and Data Charting Process

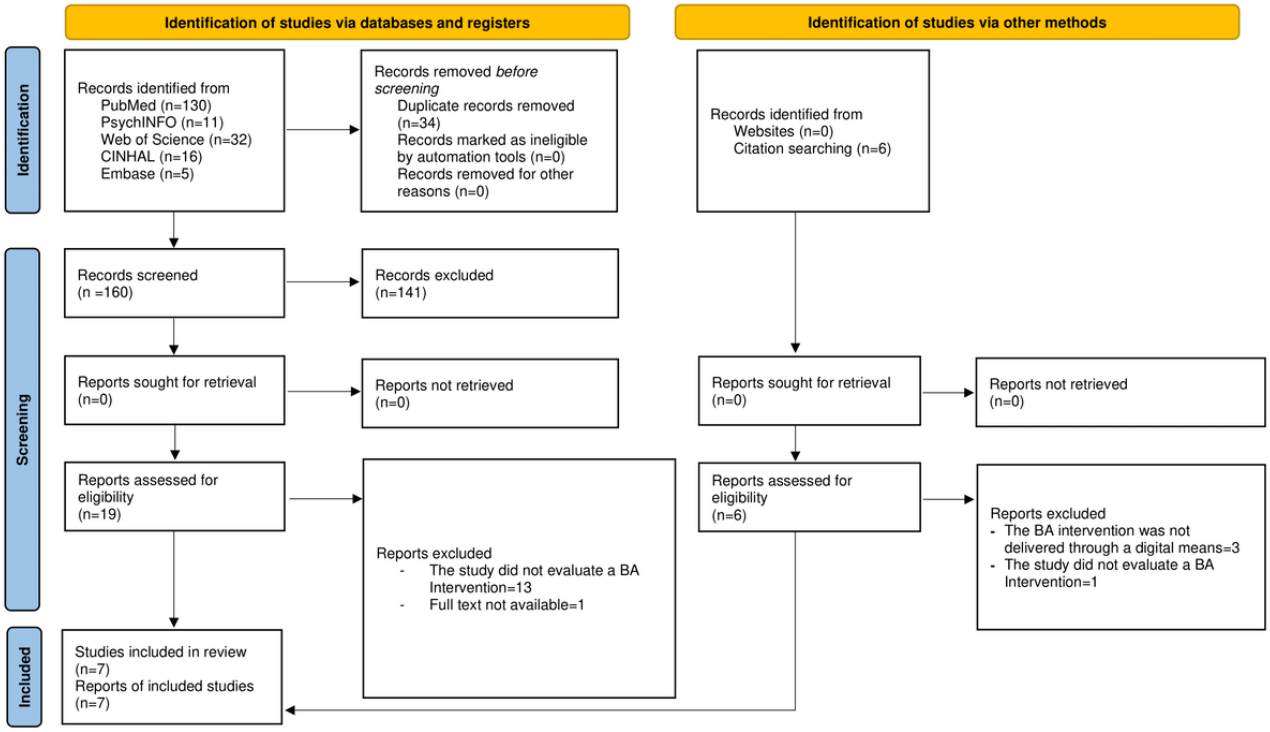
A double-blind screening of titles and abstracts was performed using the ASReview Lab software [48] by 2 authors (EM and DP), who also manually inspected the software results and then performed the subsequent full-text screening in a double-blind fashion. Any doubts or disagreements were resolved by consulting a third author (SS). Similarly, 2 independent authors (EM and DP) performed the data extraction in a double-blind fashion. Any disagreement was resolved by consulting a third author (SG). The extracted data, collected in an Excel (Microsoft Corporation) sheet, were as follows: *study characteristics* (digital object identifier; first author's name; publication year; country of origin; study design; study aim; time points for data collection; outcomes considered by the included study; measurement tools used to evaluate the outcomes; main results; reason for dropout, if applicable; participants' feedback on the intervention, if present; and type of comparator, if present), *sample characteristics* (sample size, age, ethnicity, occupation, marital status, educational level, income, clinical characteristics, gestational week or postpartum period, and inclusion and exclusion criteria for the participants), and *BA intervention characteristics* (description of the BA protocol, original BA protocol from which the new one was derived, if and how the protocol was modified, intervention length and structure, digital means used to administer the BA, and intervention delivery format).

Results

Search Results

The database search yielded 194 studies (Figure 1). Following duplicate removal, the titles and abstracts of 160 studies were screened; 141 studies were removed, resulting in 19 studies whose full text was screened in accordance with the inclusion and exclusion criteria. Of these 19 studies, 5 (26%) were eventually included. The database search was integrated with a manual search of key journals and the screening of reference lists, through which 7 more studies were identified for full-text screening; only 2 studies complied with the inclusion criteria. Taken together, 7 studies were ultimately included in this scoping review. Excluded studies with reasons for exclusion are reported in Tables S2, S3, and S4 in Multimedia Appendix 1.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 flow diagram, including searches of databases, registers, and other sources. BA: behavioral activation.



Studies' Characteristics

The aims and design of the studies are reported in Table 1, and the studies' main outcomes are summarized in Figure 2. The included studies were published between 2013 and 2022, of which 2 are randomized controlled trials (RCTs) [41,42] and 2 are protocols for RCTs [43,44]. Moreover, 2 studies are secondary analyses conducted on the RCT by O'Mahen et al [42], 1 is a secondary analysis focused on a subsample of the original sample [45], and 1 is a secondary analysis focused only on follow-up data of the total sample [46]. Finally, 1 is a qualitative study, which included participant-level analyses as well as 2 case studies [47]. Both the studies by Singla et al [44,47] relate to the same broad ongoing study. Only the 2 protocol studies [43,44] preregistered their clinical trials. All included studies were focused on evaluating the efficacy or effects of a digital BA intervention, except for 1 study [45], which investigated the processes underlying digital BA's efficacy. The outcomes considered by the included studies are summarized in Figure 2. Although all interventions were developed to target depression symptoms, coherently with the intents of BA, studies have also marginally considered other maternal variables such as anxiety symptoms (n=3) [43,44,46], parental stress (n=1), quality of life (n=1) [43], social support (n=4) [42,44,46], work and social functioning (n=3) [42,45,46], and mother-child bonding (n=3) [42-44]. Moreover, only Obikane et al [43] and Singla et al [44] included child-related variables in their protocol study, such as maternal psychological and physical aggression toward the child (n=1) [43], the child's physiological (n=1) [43] or mental development (n=1) [44], and the level of health care services used for the child (n=2) [43,44] (Figure 2; Table S5 in Multimedia Appendix 1). The included studies also marginally evaluated the intervention-related outcomes. Specifically, 1 study protocol [44] reported that they will evaluate therapy quality as well as homework completion and the frequency with which the intervention sessions are followed. Instead, 3 studies [44-46] evaluated intervention adherence, operationalized as the number of intervention modules opened and completed [45,46]. Only 2 studies specifically considered interventions' feasibility (ie, if the intervention is feasible for further testing) and acceptability (ie, how well the intervention meets the needs of the target population) [41,43]. Finally, only 1 study [43], a study protocol, reported that the assessment of usability will be conducted through the System Usability Scale [49].

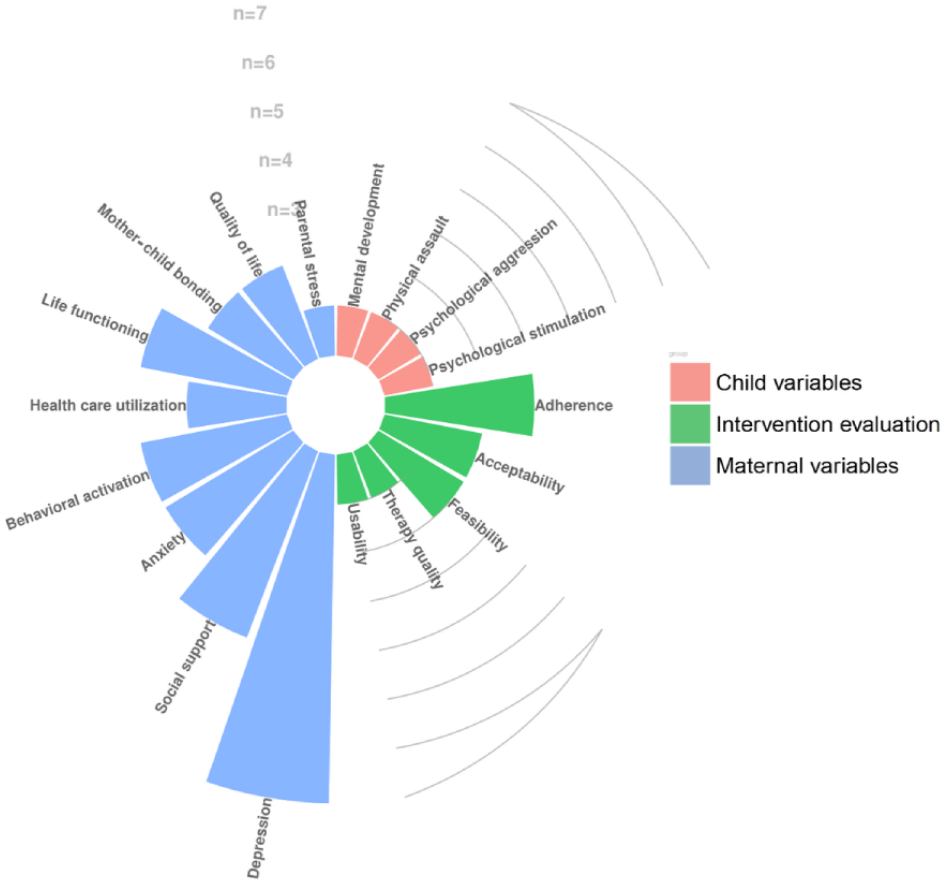
Table 1. Aims and characteristics of the studies.

Study	Study type	Study aim
Bagnall [46], 2014	Long-term follow-up of RCT[a] (doctoral dissertation)	1. To collect 16-month follow-up data of postnatal women who participated in a feasibility RCT investigating an internet-based BA[b] [42] 2. To investigate intervention efficacy at a 16-month follow-up 3. To investigate the intervention adherence and predictors of intervention outcomes 4. To investigate the predictive role of psychological or demographic factors of attrition throughout the study and at follow-up
Obikane et al [43], 2021	Protocol for RCT	1. To investigate the efficacy of a postnatal internet-based BA program targeting postpartum depression in reducing depression symptoms (primary aim) as well as mother-child bonding, parental stress, and quality of life 2. To investigate the program's efficacy in preventing child psychological and physical abuse and to evaluating the associated child developmental measures 3. To investigate the program's acceptability, feasibility, and appropriateness and their association with the participants' medical and social characteristics
O'Mahen et al [41], 2014	RCT	1. To investigate the feasibility (primary aim), assessed as treatment adherence, of an internet-based BA program targeting postpartum depression 2. To investigate the program's efficacy in reducing depression symptoms compared with usual care
O'Mahen et al [42], 2014	RCT	1. To investigate the feasibility, assessed as treatment adherence, and to identify adherence predictors (primary aims) of an internet-based BA program targeting postpartum depression 2. To investigate the program's efficacy in reducing depression and anxiety symptoms as well as functional impairment, perceived support, and mother-child bonding
O'Mahen et al [45], 2017	Secondary analysis from the study by O'Mahen et al [42]	1. To investigate the participants' processes referred to sudden gains and depression spikes associated with an internet-based BA program targeting postpartum depression [42] 2. To investigate the association between participants' sudden gains and therapists' actions
Singla et al [44], 2021	Protocol for 4-arm RCT (noninferiority trial)	1. To investigate if a BA intervention targeting postpartum depression can be delivered by nonspecialists (primary aim) 2. To compare the efficacy of a BA intervention in reducing depression symptoms delivered through telemedicine versus delivered in person (primary aim) 3. To investigate the efficacy of the BA intervention in reducing anxiety symptoms 4. To investigate the comparative effectiveness of the BA intervention delivered antenatally versus postnatally 5. To investigate whether the timing of the BA intervention administration differently influences the child's mental development 6. To investigate barriers, facilitators, and processes subsuming the BA intervention efficacy in reducing depression and anxiety symptoms
Singla et al [47], 2022	Qualitative study	1. To qualitatively investigate the barriers and facilitators of BA intervention delivered through telemedicine from both participants' and intervention providers' perspectives (ongoing trial)

[a]RCT: randomized controlled trial.

[b]BA: behavioral activation.

Figure 2. Circular bar plot of the main outcomes of the studies. n=frequency of the outcomes reported by the included studies.



Sample Characteristics

The sample characteristics and studies' sample-related inclusion criteria are summarized in Table 2. All participants were postpartum women, except for those in the study by Singla et al [44,47], which focused on both antenatal and postnatal women. All studies used the Edinburgh Postnatal Depression Scale to include women in their study, albeit relying on different cutoff values. Moreover, in their 2014 study, O'Mahen et al [42,45,46] had supplemented the Edinburgh Postnatal Depression Scale with a telephone interview aimed at ensuring that women satisfied the criteria for major depressive disorder according to the International Classification of Diseases, Tenth Revision. With regard to demographic information (Table S6 in Multimedia Appendix 1), information on the sample's age was reported by only 2 studies [42,47], the sample's ethnicity by 3 studies [42,44,45], occupation by 4 studies [41,42,45,47], educational level by 3 studies [41,42,45], income by 2 studies [42,45], marital status by 4 studies [41,42,45,47], and the total number of children by 3 studies [41,42,45]. Finally, with regard to the studies' sample sizes, the 2 protocol studies included [43,44] stated that they will include samples whose numerosity will be based on preliminary power analyses, and all the other included studies reported small sample sizes. Only 1 study [41] reported a larger sample size (<150); nonetheless, changes in the sample's numerosity from baseline to intervention end point and follow-up are unclear.

Table 2. Sample characteristics.

Study	Sample, N	Perinatal period	Inclusion criteria	Exclusion criteria
Obikane et al [43], 2021	Over 75 per group (4 groups: estimated)	Post partum	• Aged ≥20 years (adult age in Japan) • Having given birth within the past 10 weeks • Available internet-access • Living with the newborn baby • Fluent in Japanese	• Suicidal intent • Receiving public livelihood assistance
O'Mahen et al [41], 2013	EG[a]: 164; CG[b]: 134	Post partum	• Aged ≥18 years • EPDS[c] >12 • Having given birth within the past 12 months • Being a member of Netmums	• Not reported
O'Mahen et al [42], 2014; Bagnall [46], 2014	EG: 41; CG: 42	Post partum	• Aged ≥18 years • Having given birth within the past 12 months • EPDS >12 • MDD[d] (International Classification of Diseases, Tenth Revision criteria)	• Substance abuse • Psychosis
O'Mahen et al [45], 2017	32 (subsample of the study by O'Mahen et al [42])	Post partum	• As per the study by O'Mahen et al [42]	• As per the study by O'Mahen et al [42]
Singla et al [44], 2021	342 per group (4 groups; estimated)	Perinatal	• Aged ≥18 years • EPDS ≥10 • Pregnant up to 36 weeks or 4-30 weeks post partum • Speaks English or (US sites) Spanish	• Suicidal intent • Active symptoms of psychosis or mania • Taking psychotropic medication • Change of medication 2 weeks before enrollment • Ongoing psychotherapy • Substance abuse • Severe fetal anomalies, stillbirth, or infant death for pregnant participants
Singla et al [47], 2022	23	Perinatal	• As per the study by Singla et al [44]	• As per the study by Singla et al [44]

[a]EG: experimental group.

[b]CG: control group.

[c]EPDS: Edinburgh Postnatal Depression Scale.

[d]MDD: major depression disorder.

Digital Interventions' Characteristics

The characteristics of the different interventions are reported in Table 3 and Table S7 in Multimedia Appendix 1. All interventions were based on validated BA protocols (ie, validated and manualized intervention protocols); however, none extensively explained the changes made to adapt the intervention to either the population or the digital setting. Studies' intervention content structuring is quite consistent, with differences given mainly by the inclusion of optional modules [42,46] or the possibility to customize sessions [41]. Furthermore, in the qualitative study by Singla et al [47], the intervention protocol deployed during the COVID-19 lockdown was adapted to account for pandemic-related stressors and participants' perceived racial injustice in a subsample of ethnic minority participants.

All interventions were guided, except for an unguided one [41] that, nonetheless, included a sort of "technical" support, whereby psychologists or specialized health visitors gave advice for homework completion and answered participants' questions on the program material; no further information was reported. With regard to guided interventions, only O'Mahen et al [42] and Singla et al [44,47] reported information on how supporters guiding them had been trained and monitored through supervision by expert clinicians. Moreover, in the studies by Singla et al [44,47] and O'Mahen et al [42], authors monitored and evaluated supporters through independent fidelity raters who listened to recordings of the sessions. All 3 studies by O'Mahen et al [41,42,45] and the related secondary analysis by Bagnall [46] considered the web-based Netmums BA program; both the studies by Singla et al [44,47] relied on telemedicine, whereas only Obikane et al [43] reported the development of a web-based BA intervention that can be deployed through

smartphones. Obikane et al [43] further reported that they will ensure data confidentiality by temporarily storing data in the Amazon Elastic Compute Cloud system and will only later move them in a password-protected computer. No other study reported information referred to data privacy and storage.

Table 3. Characteristics of the interventions.

Study	Intervention name	Length (weeks), total number of sessions	Guided versus unguided	Guided—description	Digital means	Intervention delivery format
Obikane et al [43], 2021	SmartMama	12, 12	Guided (psychotherapists)	• Provided participants with feedback • Answered participants' questions about the intervention	Web-based app for smartphones	• Not reported
O'Mahen et al [41], 2013	Postnatal iBA[a]	15, 11	Unguided	• N/A[b]	Web based (Netmums site)	• Multimedia presentations • Web-based materials • Web-based homework • Possibility to access weekly web-based real-time "clinics" • Web-based chat room moderated by parent supporters
O'Mahen et al [42], 2013; O'Mahen et al [45], 2014; Bagnall [46], 2014	NetmumsHWD	17, 12	Guided (mental health workers)	• Answered participants' questions about the intervention • Support the overcoming of barriers to the implementation of the intervention	Web based (Netmums site)	• Multimedia presentations • Web-based materials • Web-based homework • Possibility to access weekly web-based real-time "clinics" • Web-based chat room moderated by peer supporters
Singla et al [44], 2021	Behavioral activation	6-8, 6-8	Guided (nonspecialists and specialists)	• Delivers the intervention • Addresses treatment barriers and facilitators	Telemedicine	• Zoom (Zoom Video Communications Inc.) or WebEx video calls
Singla et al [47], 2022	Behavioral activation	Not reported, 8	Guided (trained psychologists)	• Delivered the intervention • Addresses treatment barriers and facilitators • Accounted for COVID-19 and racial injustice worries	Telemedicine	• Zoom or WebEx video calls

[a]iBA: internet-based Behavioral Activation.

[b]N/A: not applicable.

Results of Individual Evidence and Overall Synthesis

The main results of the studies, referring to both clinical outcomes and intervention-related outcomes, are summarized in Table 4. Overall, these studies consistently showed a significant intervention effect on depression symptoms. However, following multiple imputation analyses, the results of the study by O'Mahen et al [42] showed that such differences were not significant between the intervention and control groups. The same authors reported a trend for reduced anxiety symptoms and improved work and social functioning compared with the control condition at the intervention end point; however, this trend was not statistically significant. Accordingly, in the secondary follow-up analysis by Bagnall [46], the intervention effect was not significantly different between groups at any time point. Notwithstanding, the 2 case studies reported by Singla et al [47] were useful in highlighting the subjective experience of participants and their perceived benefits of the interventions. In both case studies, participants reported an improvement in communication skills that favored the support between them and their husbands by sharing child-related responsibilities. Moreover, at the end of the intervention, participants reported better associating their mood with what was happening in their lives, thereby voluntarily redirecting their attention toward value-based activities that would improve their mood. At the intervention end point, one of the women self-reported remission in both depression and anxiety symptoms, whereas the other

reported that she was then able to embrace her past traumas, triggered by postpartum-related stressors, and thereby requested a referral to a clinical professional. The secondary analysis performed by O'Mahen et al [45] was also useful in highlighting the relevant processes underlying the intervention that were associated with its efficacy. Specifically, the authors observed that slightly more than half of the sample (18/32, 51%) showed at least one sudden improvement or gain in depression symptoms, even though these were often followed by a depression spike; however, participants showing these sudden improvements reported much reduced depression symptoms at intervention end point and also reported having followed more web-based intervention modules compared with those who had not reported such improvements. The same participants had also talked about more specific and concrete topics during the telephone sessions preceding the sudden gains [45].

Regarding the interventions' feasibility, acceptability, and overall intervention adherence, the available information is limited. However, although studies explicitly evaluated these factors, their results on dropout rates and adherence seemingly suggest reduced acceptability. The studies by O'Mahen et al [41,42] provided information in this regard, reporting that dropouts were quite high and that there was limited participation in the real-time "online clinics" as well as in the chat rooms made available for mums to talk with each other. Moreover, limited intervention adherence was highlighted by the modest median completion rate of the intervention sessions. In this regard, it is noteworthy that reduced adherence was associated with women's lower socioeconomic level, reduced social support as well as reduced work and social functioning, and with attending school or working [42]. Nonetheless, based on participants' feedback, what had favored acceptability and adherence was the convenient delivery of the intervention's content and the ease experienced in following the program; however, the latter is hindered when interventions include large number of sessions and activities that women are requested to follow [41]. Accordingly, O'Mahen et al [41,42] had simplified their intervention from their 2013 versus 2014 study. Moreover, contrary to what was reported by O'Mahen et al [42] regarding the predictors of intervention adherence, the study by Bagnall [46] did not identify any significant predictors (ie, depression symptoms level, level of BA, social support, and household income) of intervention adherence or the predictive role of assessments' adherence to the intervention outcomes (eg, depression symptoms). The latter study was primarily focused on investigating participants' adherence to follow-up assessments (which might thus better fit within the broader construct of "intervention feasibility" more than within that of "adherence"). In this regard, they reported that outreach helped improve participation in the follow-up assessments. No study investigated the programs' usability; however, 1 of the included study protocols [43], as previously reported, is expected to provide further information in this regard.

Table 4. Main results of the studies.

Study	Assessment time points	Clinical outputs	Intervention-related outputs
Bagnall [46], 2014	• T0[a]: baseline • T1[b]: intervention end point • T2[c]: follow-up, 10 months from intervention end point • T3[d]: follow-up, 16 months from intervention end point	• No significant reduction in depression and anxiety symptoms or improvements in work and social functioning as well as the level of BA[e] emerged, at any time point, among participants from the intervention group compared with participants in the usual care condition	• Intervention adherence was not associated with depression symptoms at any time point following the intervention • Household income, relationship status, depression symptoms, and level of BA and social support at baseline were predictive of attrition
Obikane et al [43], 2021	• T0: baseline • T1: intervention end point • T2: follow-up, 12 weeks from intervention end point	• N/A[f]	• N/A
O'Mahen et al [41], 2013	• T0: baseline • T1: intervention end point	• Significant reduction in depression symptoms among participants from the intervention group compared with participants in the usual care condition	• Appreciation for the program's flexibility and convenient delivery • Difficulty in keeping up with the program requirements • Low participation in the chat rooms with other mothers and in the web-based clinics • Drop in the sessions' adherence following the second session
O'Mahen et al [42], 2014	• T0: baseline • T1: intervention end point • T2: follow-up, 6 months from intervention end point	• Trend of greater reduction in depression and anxiety symptoms and improvement in life function in the intervention group compared with participants in the usual care condition • Significant greater chances of clinically improved depression symptoms (odds ratio 0.26, 95% CI 0.10-0.71) in the intervention group compared with the control condition	• Modest intervention adherence overall • Reduced intervention adherence among women (1) working or attending school, (2) with less social support, (3) reduced life functioning at baseline, and (4) with a lower socioeconomic status • Only 5% completed ≥8 sessions, of which 5 completed all 12 sessions • Most chosen optional module was the one on motherhood (chosen by 22% of participants)
O'Mahen et al [45], 2017	• As per the study by O'Mahen et al [42]	• Overall fast initial improvement in depression symptoms (particularly among women with higher baseline symptoms), which slowed down over time • In total, 51% of the sample had a sudden gain (ie, clinically relevant improvement in depression symptoms); associated with reduced depression symptoms overall at the intervention end point • In total, 19% of the sample showed depression spike • In total, 75% of the sample that had experienced a depression spike and also showed a sudden gain, with the latter preceding the depression spike • Women showing more sudden gains had completed more web-based modules but not more telephone sessions	• N/A
Singla et al [44], 2021	• T0: baseline • T1: 3 months from randomization • T3: 6 months from randomization • T4[g]: 12 months from randomization	• N/A	• N/A

Study	Assessment time points	Clinical outputs	Intervention-related outputs
Singla et al [47], 2022	• N/A	• The 2 case studies highlighted the intersection between depression symptoms during the postpartum period, public health responses, pandemic-related interpersonal consequences, and the awareness of racial responses • The qualitative participant-level results highlighted that among women receiving the intervention during the pandemic, the main facilitators were (1) the provision of creative problem-solving to attend the intervention, (2) BA helped deal with pandemic-related distress, (3) BA provided connection and support during the pandemic, and (4) telemedicine. The main barriers were (1) privacy, (2) greater pandemic-related stressors, and (3) limited activity owing to the pandemic	• N/A

[a]T0: Time 0.

[b]T1: Time 1.

[c]T2: Time 2.

[d]T3: Time 3.

[e]BA: behavioral activation.

[f]N/A: not applicable.

[g]T4: Time 4.

Discussion

Principal Findings

This scoping review aimed to map the available literature on digital BA interventions administered during the perinatal period. The research questions guiding this work have focused on the interventions' methodological underpinnings as well as on the interventions' targets, referring to the specificities of the population considered as well as to the symptoms experienced by the latter.

Regarding research questions (4) *Were digital BA interventions able to influence psychosocial symptoms other than depression?* and (5) *Have they willingly been used to influence symptoms other than depression?* in line with expectations, they seem to be overall promising in reducing depression symptoms among postpartum women; however, owing to the limited literature available, it is not possible to draw definitive conclusions in this regard. Moreover, although an in-person BA intervention administered to pregnant women was effective in reducing anxiety symptoms [32], the sole concluded trial included in this review that had evaluated anxiety symptoms [42,46] reported no significant intervention effect. Accordingly, to date, it is not possible to draw complete conclusions on the generalizability of the efficacy of digital BA interventions on psychosocial variables (eg, anxiety and stress symptoms and quality of life) other than depression symptoms. This is mostly owing to the above-mentioned marginal investigation of these symptoms.

Referring, instead, to research question (6) *Are there differences in the BA interventions administered during the antenatal period versus the postnatal period?* it is noteworthy that of all the included studies, most [41-43,45,46] focused solely on the postnatal period by considering women who had recently given birth, whereas none specifically focused on pregnant women and, therefore, on the antenatal period. However, one of the included protocol studies [44] reported that it foresees the future inclusion of both antenatal and postnatal women to compare intervention efficacy as a function of the perinatal period during which it is deployed. Thus, overall, it is not possible to answer the research question focused on the efficacy of digital BA interventions deployed during the antenatal period versus the postnatal period. The lack of digital interventions administered during the antenatal period represents a limitation of the available literature in terms of both evidence-based treatments and prevention programs. This is relevant, especially considering the high prevalence of depressive symptoms during pregnancy (between 15% and 65% [50]) and of the interrelated [51,52] anxiety (between 18% and 24% [53]) and stress symptoms (low-moderate symptoms level 78% [54]). Altogether, these hinder women's quality of life [55], with repercussions on the child's development and well-being [56-58], while further significantly increasing the risk of postpartum depression [8,59]. These results might be particularly insightful if read through the lens of the Stepped Care model [60]. This specific approach to health care advocates for a highly collaborative approach among primary and secondary mental health services to choose and deliver the most appropriate treatment, ranging from primary low-burden care to more intensive and specialized care on the basis of patients' specific level of need and distress, which should ultimately improve access to health care for patients on one hand and, on the other hand, the efficiency and cost-effectiveness of treatments themselves [60]. Within this theoretical framework, prevention programs can be regarded as primary health services; therefore, research on the feasibility and effectiveness of digital interventions within the perinatal

period should be encouraged; such treatments are expected to be of great benefit for both women in the perinatal period and the health care system on the whole, as they should foster scalability and thereby reduce health care costs [61,62].

Similarly, with regard to overcoming the broader barriers already reported in the literature, limiting access to mental health care programs (eg, time constraints, lack of information about services, and social stigma [18-20]), the creation and implementation of acceptable and effective digital interventions would also be advantageous in terms of both time and expenses for both the patients and the health care specialists. Moreover, through the advent of social media platforms and the possibility to create ad hoc websites, digital interventions can be made known and spread with greater ease, thereby allowing the extension of care to patients living in hard-to-reach areas. These same premises might also be associated with a reduction in the social stigma surrounding health care seeking by, on the one hand, normalizing the reliance on psychological programs and, on the other hand, allowing the maintenance of privacy within one's social environment. This review also attempted to identify the logistic, social, and pragmatic barriers specifically associated with digital BA interventions. Focusing, instead, on research question (3) *What were the main barriers, including both participants' concerns and issues given by the digital tool itself, in implementing BA interventions through digital means?* the data reported here do not allow to gather insights or formulate suggestions regarding the existence and potential overcoming of barriers within the context of digital BA interventions during the perinatal period. In fact, only 1 study [47] specifically addressed the intervention's barriers, raising some concerns about the maintenance of privacy during the intervention; however, this might be strictly linked to the use of telemedicine in general rather than on digital BA interventions specifically.

Regarding the remaining research questions, namely, (2) *Has a specific BA protocol been followed? if so, on what BA protocol were the interventions based? [39]* and (1) *How have BA interventions been structured (eg, intervention length, number of modules, topics considered, and guided versus unguided interventions) to be administered through digital means?* it is worth highlighting that all interventions were based on validated BA protocols [63], but no extensive explanation of the changes made to the original protocols were reported. Similarly, scarce information was reported on the role of the guidance in the guided interventions as well as on the specificities of the digital means used to administer the interventions. This limits the reproducibility of studies as well as the advancement of the matter, as it restricts the possibility of identifying the benefits and limitations of the different digital BA interventions. Likewise, all the included studies reported limited information on how the interventions' content and home assignments were implemented and deployed. However, a thorough reporting of the choices made on the intervention content and structuring, of the specificities of the technological components used to implement the intervention, and of the potential drawbacks that might have emerged from the trials is needed to foster information exchange within the scientific community. This is particularly relevant, considering their value for the feasibility and efficacy of the intervention as well as for overall usability. Including such information in trial reports would ultimately contribute to the broader research field. In line with this thought, the work by O'Mahen et al [41,42] is noteworthy with regard to the investigation of the feasibility of interventions, as they reported refining their intervention structuring in line with participants' feedback and then retesting its efficacy. In this regard, although none of the studies provided reasons for choosing a certain number of sessions composing the interventions, O'Mahen et al [41,42] reported reducing the number of core sessions while including some optional modules [42]—a decision based on participants' feedback stating that they could not "keep up" with the intervention [41]. This particular mode of action is what seems to be lacking and should instead be promoted, as it provides information on the interventions' specific structures, thereby favoring scientific exchange and, ultimately, the advancement of the matter. Future studies might benefit from including qualitative evaluations of the interventions' experience and overall usability, for instance, by foreseeing the use of semistructured interviews at the end of the intervention [64]. In this regard, it should be stressed that usability was not evaluated by any of the concluded research studies included in this review, although the criticality of adherence to interventions was highlighted as it emerged in previous studies [65,66]. Usability is conceptualized as the output of the interaction between the user and the tools (eg, website) used [67] and includes 5 main concepts [68]: ease of use, intended as learnability, experienced by users learning how to use a digital tool; the efficiency with which users interact with the digital tool; the memorability of how to use a digital tool to which the user has been already exposed; the errors users make, intended as the number of trials needed to make a certain action correctly; and the perceived users' satisfaction with the user experience. The latter further includes aspects relevant to user engagement, including the affective, cognitive, and behavioral response of the user to the digital tool [69]. In this regard, Bagnall [46], referring to the nonpredictive effect of intervention adherence on the intervention outcomes, discussed that beyond adherence, it might indeed be the level of engagement with the intervention, intended as behavioral participation, to be particularly relevant in influencing intervention efficacy. In line with this, O'Mahen et al [42] highlighted that intervention acceptability as well as adherence, as reported by women, was favored by the convenient delivery of the intervention's content and the ease felt in following the program, which are all aspects relevant to usability. This further highlights the importance of accounting for usability facets when investigating the efficacy of digital interventions, which emerged in this review as a strong limitation of the literature on digital BA interventions deployed during the perinatal period. Future studies should, therefore, more carefully and consistently account for and thoroughly explain the results of the user experience while also accounting for user engagement [70].

Overall, the information retrieved through this scoping review does not allow to provide specific suggestions for the implementation of interventions. However, the gaps identified in the available literature can be useful for refining existing protocols and supporting the design of future interventions. Specifically, there has emerged a need to substantially investigate both the usability and user engagement associated

with these digital interventions to better understand and refine them. The human-computer interaction aspects of these interventions, as of today, seem only marginally considered but should instead be central in future research, as they define the "setting" in which interventions take place. It should be noted that the existing literature does provide guidelines [70] or models [71] that should be followed in future trials to support adherence and engagement, as they are pivotal for the efficacy of interventions. Moreover, greater flexibility in the structuring of interventions (ie, the number of sessions and time required to complete each session) is recommended, as it would support acceptability. These aspects might be particularly valuable, considering the high attrition rate of these interventions, which had already been pointed out by existing literature and was coherently reported by the included studies as well [66].

Conclusions

Taken together, the available literature examined was useful in highlighting the potential, and also the immaturity, of the research field on digital BA interventions, while promptly stressing the need to develop interventions specifically targeting pregnant women. To address this gap, future research should focus on addressing such limitations, paying particular attention to the investigation of the feasibility, acceptability, and usability of interventions. Moreover, future studies should invest in the development and evaluation of digital prevention programs deployed during pregnancy.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary materials.
[DOCX File , 286 KB - pediatrics_v6i1e40937_app1.docx]

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Abbreviations

ART: assisted reproductive technique
BA: behavioral activation
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews
RCT: randomized controlled trial

Edited by T Leung, G Eysenbach; submitted 10.07.22; peer-reviewed by MP Gagnon, A Coe; comments to author 23.09.22; revised version received 07.12.22; accepted 03.01.23; published 28.02.23.

Please cite as:
Mancinelli E, Dell'Arciprete G, Pattarozzi D, Gabrielli S, Salcuni S
Digital Behavioral Activation Interventions During the Perinatal Period: Scoping Review
JMIR Pediatr Parent 2023;6:e40937
URL: https://pediatrics.jmir.org/2023/1/e40937
doi:10.2196/40937
PMID:36853756

Original Paper

A Family-Based Collaborative Care Model for Treatment of Depressive and Anxiety Symptoms in Perinatal Women: Results From a Pilot Study

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Abstract

Background: Untreated perinatal depression and anxiety can have detrimental consequences on family function. Logistical barriers prevent many perinatal women from accessing treatment, and these barriers are compounded for women residing in rural areas. This paper describes a Family-Based Collaborative Care Model (FBCCM) that is designed to bypass barriers to increase access to care for depressed and anxious perinatal women in rural regions of the United States. The FBCCM includes the following two components: (1) a 10-session video-delivered family therapy treatment for perinatal depression and anxiety and (2) a video-delivered infant care provider training on addressing the parenting needs of depressed and anxious mothers.

Objective: This paper describes the feasibility of implementing the FBCCM with families and infant care providers. Findings are presented on the preliminary effectiveness of the video-delivered family therapy treatment in reducing maternal depressive and anxiety symptoms, and family conflict.

Methods: This pilot study was carried out using an implementation-effectiveness hybrid trial design without a comparison group. Changes in maternal depressive symptoms, maternal anxiety symptoms, and family conflict were measured at posttreatment, 3 months, and 6 months later.

Results: On average, mothers (n=24) attended 9.79 (SD 1.02) sessions. On average, their family members (n=24) attended 9.42 (SD 1.28) sessions. A total of 31 infant care providers attended the training on addressing the parenting needs of depressed and anxious mothers. Mothers reported a significant reduction in depressive symptoms (P<.001) and anxiety symptoms (P<.001) from baseline to the 6-month follow-up. Mothers reported a significant reduction in conflict (P<.001), and their family members also reported a significant reduction in conflict (P=.007) from baseline to the 6-month follow-up.

Conclusions: The findings from this study provide support for the feasibility and preliminary effectiveness of the FBCCM. The findings will be used to inform a larger study of the FBCCM.

(JMIR Pediatr Parent 2023;6:e45616) doi:10.2196/45616

KEYWORDS

anxiety; depression; family treatment; infant care; maternal health; parenting; pediatric primary care; perinatal anxiety; perinatal care; perinatal depression; video therapy; women's health

Introduction

Background

Perinatal depression and anxiety are increasing in the United States with prevalence rates ranging from 10% to 23% for depression [1-3] and 11% to 20% for anxiety [4,5]. Although the United States Preventative Task Force recommends for providers to screen women for perinatal depression and refer them for treatment [1], barriers (eg, no childcare or transportation) prevent women from getting treatment and under 25% initiate treatment [6,7]. These barriers are compounded for perinatal women in rural regions.

There is growing recognition that technology-based interventions for depression and anxiety bypass logistical barriers for pregnant and postpartum women [8-14]. Further, research has shown that technology-based interventions for perinatal depression and anxiety are feasible for use within routine perinatal care [8,9]. For example, MomMoodBooster2 has been shown to be an effective treatment option within routine perinatal care, especially when combined with universal depression screening and referral [8]. Although some technology-based treatments include some strategies to address instrumental support and relational health (ie, partner support website), the primary focus is cognitive-behavioral individual-level treatment for perinatal depression and anxiety [8,11-14].

Untreated perinatal depression and anxiety are precipitants and consequences of family conflict that worsens these symptoms [15-18]. Since mothers with perinatal depression tend to experience a mix of depressive and anxiety symptoms, the current COVID-19 pandemic has exacerbated their symptoms [19,20]. Perinatal depression and anxiety in combination with the current pandemic place demands on families that they are unprepared to meet, which can increase family conflict. Despite this, no evidence-based family therapy treatment exists for perinatal depression and anxiety [15,21,22].

This study was conducted during the COVID-19 pandemic and explored the feasibility and preliminary effectiveness of a Family-Based Collaborative Care Model (FBCCM) to address perinatal depression and anxiety. The FBCCM includes following two components: (1) a video-delivered family therapy treatment for depressed and anxious perinatal women receiving obstetrics care in rural clinics and (2) training for infant care providers on addressing the parenting needs of depressed and anxious mothers. The FBCCM uses technology to increase access to treatment for perinatal depression and anxiety and training for infant care providers in rural areas.

Objectives

This paper has 2 objectives. The first objective is to present findings on the feasibility of the FBCCM for use with families and infant care providers. The second objective is to present findings on the preliminary effectiveness of the video-delivered family therapy treatment in reducing maternal depressive symptoms and anxiety symptoms, and family conflict. We hypothesized that (1) perinatal women will report significant reductions in depressive symptoms and anxiety symptoms from baseline to the 6-month follow-up, and (2) families will report a significant reduction in conflict from baseline to the 6-month follow-up.

Methods

Study Design

This implementation effectiveness hybrid trial, without a comparison group, tested both clinical interventions and implementation strategies [23]. The first objective pertains to implementation aspects of the design and reflects strategies to explore the feasibility of implementing the FBCCM with families receiving routine care in obstetrics clinics and infant care providers. The second objective pertains to clinical effectiveness aspects of the design to explore preliminary impacts on maternal and family outcomes.

Ethics Approval

This study has been approved by an institutional review board (IRB) at an academic medical center in New England (02000646).

Framework of FBCCM

Our research on perinatal depression guided the development of the FBCCM that includes 2 components. The first component is a video-delivered family therapy treatment (Resilience Enhancement Skills Training [REST]) [24-26] that is summarized in this section. REST is informed by Dialectical Behavior Therapy (DBT) Skills Training [27] and includes systemic interventions [28] to address conflict. Standard DBT is based on cognitive-behavioral therapy and includes individual therapy, skills training, and coaching, and it is effective for use in populations with severe depressive symptoms [29-31]. DBT skills training targets cognitive, emotional, and behavior regulation [27]. REST includes a total of 10 weekly, 30-minute interactive sessions that are delivered by a clinician using Health Insurance Portability and Accountability Act–compliant video technology (VCT) to families. Families attend sessions by clicking links on their cell phones, tablets, or computers from home. To date, REST has been delivered using 2 types of Health Insurance Portability and Accountability Act VCT: Vidyo [32] and WebEx [33].

The results of the preliminary pilot study of REST with home-visited families showed that it significantly reduced maternal depressive symptoms and family conflict [24]. Although the participants in this study had an overall higher level of education and greater financial security than those who participated in other studies of REST [24-26], the severity levels for maternal depressive symptoms and family conflict are similar. This study expands the existing research on REST to explore its impact on perinatal anxiety.

The first author delivered REST to families in this study using Vidyo [32] and Cisco WebEx [33]. The selection of VCT was dependent on the participant's bandwidth consumption limits. This study used the same technology training procedures for REST participants that were used in other studies [24-26].

The second component of the FBCCM is a 1-hour video-delivered training session provided by the second author

to infant care providers on addressing the parenting needs of depressed and anxious mothers within the context of well-child visits. The training was offered during lunchtime to increase the likelihood of provider attendance. The training used elements of the second author's guide on addressing maternal depression in primary care [34], cited by the American Academy of Pediatrics [35,36]. The established training was expanded to include guidance on addressing the parenting needs of anxious mothers. The training primarily focused on expanding maternal knowledge of developmentally appropriate expectations, validating parenting efforts, and responding to infant fussiness.

Eligibility Criteria

The study population included mothers at least 18 years of age in any trimester of pregnancy and up to three months postpartum, and their adult family members receiving perinatal care in 2 participating obstetrics clinics in rural regions of New England. This study included a 2-phase eligibility screen process for mothers. Mothers routinely complete the *Patient Health Questionnaire-2item* [37] and *Generalized Anxiety Disorder-2 item* [38,39] in the patient portal on electronic tablets when they check in for perinatal care appointments. In phase 1, mothers with *Patient Health Questionnaire-2item* scores of ≥2 [40] or *Generalized Anxiety Disorder-2 item* scores of ≥3 [39] were automatically directed to an IRB-approved study information sheet (included an overview of the study goals, video-delivered family therapy treatment, and potential benefits and risks) to read that was followed by a question on whether or not they wanted to be contacted by the first author to learn more about the study. Mothers who selected "Yes" to the question entered their contact information in a textbox. The electronic medical record system automatically sent the first author a notification with the contact information of mothers who requested to be contacted about the study. Mothers who did not want to be contacted about the study received standard services (eg, referral to mental health provider) through the obstetrics clinic where they were receiving perinatal care.

The first author called mothers within 48 hours of receipt of their requests to provide more details on the study and ask if they wanted to proceed with the phase 2 eligibility screen. The first author secured electronic consent for the phase 2 eligibility screen from mothers and administered the measures. Each mother was asked to select a "family member" (defined as her adult relative or current intimate partner) with whom she had conflict who could potentially participate with her in the study. The Family Environment Scale-Conflict (FES-C) subscale [41] was administered to mothers to assess the level of conflict between the mother and the selected family member. Mothers with FES-C scores of at least four (indicative of moderate to high conflict) without domestic violence as measured by the Abuse Assessment Screen [42] were eligible for participation. The Beck Depression Inventory-Second Edition (BDI-II) [43] and State-Trait Anxiety Inventory-State Anxiety (STAI-S) scale [44] were administered to mothers to detect severity of symptoms. Mothers with BDI-II scores below 54 without suicidal ideation were eligible for study participation. Participants had to be fluent in English since the intervention materials were written in English. Participants had to have consistent internet access (ie, subscribe to an internet service provider without weekly disruptions in service) on a cell phone, tablet, or computer equipped with a camera and microphone to participate in sessions. Mothers on stable doses (eg, at least 3 months) of psychiatric medications were eligible for study participation. Mothers with current individual therapy or a history of DBT were not eligible for study participation. The first author referred ineligible mothers to appropriate services in the community.

Infant care providers, willing physicians, resident physicians, and nurse practitioners who provided infant care at participating pediatric and family medicine clinics were eligible for study participation. The second author used video communication technology (Zoom) to deliver presentations to infant care providers that included an overview of the study goals, study participation, and description of the FBCCM (infant care provider training and family therapy treatment) potential benefits and risks. Infant care providers were informed that mothers, some of whom were served by their clinics, would be recruited for study participation and this confidential information could only be shared with them by the mother. Infant care providers were informed that the training would be provided to help mothers who are participating in the study and any other mothers with depression and anxiety who are served in their clinics.

Recruitment and Consent Procedures

The first author secured electronic consent of the IRB-approved consent form for the phase 2 eligibility screen from 89 willing mothers. Of these 89 screened mothers, 29 of them were ineligible (n=16 low family conflict; n=7 receiving therapy; n=5 inconsistent internet access; and n=1 upcoming move to another state). The first author referred ineligible mothers to appropriate services in the community. Of the 60 eligible mothers, 21 of them decided not to enroll in the study due to busy schedules.

The first author secured electronic consent of the IRB-approved consent form for study enrollment from 39 willing mothers and their 29 willing family members. It is important to note that 10 mothers enrolled in the study without family members, and we plan to prepare a separate paper with the data on this subgroup of the sample. Of the 29 families who enrolled in the study, 3 of them dropped out before the first session due to busy schedules.

Infant care providers from 5 participating clinics were invited to attend the training. The second author secured electronic consent of the IRB-approved consent form for study enrollment from 9 willing infant care providers to complete a survey prior to the training. The 9 infant care providers were from 3 of the clinics.

Data Collection

Participants completed a web-based baseline questionnaire in research electronic data capture [45]. The maternal and family member questionnaire included demographic items (eg, age, race, gender, highest level of education, and employment). The infant care provider questionnaire included demographic items (eg, age and gender). It also included items that pertained to current clinic practices for screening for maternal depression and anxiety with response options of "yes" or "no." It included

items on perceived job responsibilities for addressing maternal depression and anxiety within the context of well-child visits with response options that ranged from 1 “strongly disagree” to 4 “strongly agree.”

Feasibility

The first author calculated the number of REST sessions attended by each participant and the number of families who completed REST. The second author recorded the number of infant care providers who attended the training.

The first author closely monitored maternal depressive and anxiety symptoms (safety) and family conflict (tolerability) during the treatment phase. Mothers completed the BDI-II [43] after session numbers 2, 4, 6, and 8. The time points for the BDI-II align with standard guidelines for monitoring moderate to severe perinatal depression during treatment [46,47]. Since this was the first REST study that enrolled perinatal women with moderate to severe anxiety, the STAI-S [44,48,49] was also administered to mothers at these 4 time points in the treatment phase to closely monitor anxiety symptoms. The safety protocol outlined referral procedures for mothers with increased BDI-II or STAI-S scores from baseline, indicative of increased moderate to severe symptoms, for more intensive treatment services. The protocol specified that mothers with suicidal ideation were immediately connected to emergency services. The first author administered the FES-C subscale [41] to each mother and her family member separately after session numbers 4 and 8 to assess tolerability. The FES-C is designed to measure conflict in the past month [41]. Each respondent was directed to respond to the items based on experiences that occurred within the past month with the family member who participated in the study. The tolerability protocol outlined referral procedures to services in the community for families with increased conflict or sustained high conflict from baseline. This protocol also specified safety planning and referral procedures if domestic violence was reported by a mother or her family member.

Preliminary Effectiveness of REST

Mothers and family members completed web-based measures in research electronic data capture at baseline, postintervention (within a week after the final session), and 3-month and 6-month follow-ups.

The STAI-S [44] was used to measure maternal anxiety in this study. It is a reliable and valid measure in perinatal women [48,49]. It includes 20 items that are rated by symptom intensity. STAI-S scores range from 20 to 80, and scores of at least 38 indicate moderate to high anxiety in perinatal women [50-52].

The BDI-II [43] was used to measure maternal depression in this study. It has established reliability and validity in perinatal women [53-55]. It includes 21 items to assess depressive symptom severity by intensity and frequency, including suicidal ideation. The BDI-II scores range from 0 to 63, and scores of at least 20 indicate moderate to severe depressive symptoms [43].

The NIH Toolbox *Perceived Hostility Survey Ages 18+* (PHS) [56] was used as the family conflict outcome measure in this study. It is a reliable and valid measure for conflict-based communication [56]. It includes 8 items, each have a 5-point scale with response options that range from 1 “never” to 5 “always” [56]. PHS scores range from 8 to 40, and scores of at least 16 indicate moderate to high conflict in perinatal women [57]. Each respondent was directed to respond to the items based on experiences in the past month with the family member who participated in the study.

Statistical Methods

Participant Characteristics

Univariate statistics were used to characterize families at baseline and infant care providers.

Feasibility

Ratios for actual to expected number of sessions (10 sessions) were calculated for each family in REST. Means and SDs were calculated for sessions attended by mothers and family members. High retention was defined as families attending ≥80% of sessions. The number of infant care providers who attended the training session was calculated.

For safety of REST for mothers, means and SDs were calculated for the BDI-II and the STAI-S from baseline through each clinical monitoring time point (session numbers 2, 4, 6, and 8). Wilcoxon signed rank tests were used to assess changes in BDI-II and STAI-S scores from baseline through session number 8. For tolerability of REST for families, means and SDs were calculated for the FES-C from baseline through each clinical monitoring time point (session numbers 4 and 8). Maternal and family member scores were calculated separately for the FES-C at each clinical monitoring time point. Wilcoxon signed rank tests were used to assess changes in FES-C scores from baseline through session number 8 for mothers and family members separately.

Preliminary Effectiveness of REST

Given the small sample size of mothers, the Friedman test was used to assess changes in maternal depressive symptoms (BDI-II scores) and maternal anxiety symptoms (STAI-S scores) from baseline to the follow-up time points (postintervention, 3-month follow-up, and 6-month follow-up). For significant results, post hoc pairwise comparison analyses were conducted using the Wilcoxon signed rank test with a Bonferroni correction applied, resulting in a significance level set at P=.008. Evidence of effectiveness will be demonstrated at the 6-month follow-up by significant reductions in maternal depressive symptoms on the BDI-II and maternal anxiety symptoms on the STAI-S.

Family conflict was analyzed in mothers and their family members separately. Given the small sample size of mothers and small sample size of family members, the Friedman test was used to assess changes (PHS scores) from baseline to the follow-up time points (postintervention, 3-month follow-up, and 6-month follow-up). For significant results, post hoc pairwise comparison analyses were conducted using the Wilcoxon signed rank test with a Bonferroni correction applied, resulting in a significance level set at P=.008. Evidence of effectiveness will be demonstrated at the 6-month follow-up by significant reductions in family conflict on the PHS.

Results

Participant Characteristics

Of the 26 families who started REST, 24 families contributed follow-up data. The baseline characteristics for these 24 families are included in Table 1. Mothers' ages ranged from 26 to 40 years old. Mothers either selected their partners or spouses to participate with them in the study; 88% (21/24) of mothers were married. Family members' ages ranged from 27 to 49 years old. About 96% (n=23) of mothers were pregnant at baseline. About 63% (n=15) of mothers were in the second trimester of pregnancy, and the remainder of them were in the third trimester. Half were first-time mothers. About 46% (n=11) of mothers had moderate to severe anxiety symptoms and moderate to severe depressive symptoms. Half of mothers had moderate to severe anxiety symptoms and mild depressive symptoms. One mother had severe depressive symptoms and mild anxiety symptoms.

The characteristics for the 9 infant care providers are included in Table 2. All providers identified as pediatricians, and 44% (4/9) of them were resident physicians. Prior to the training, one-third of providers reported they had not received sufficient education about maternal depression and how to address it in practice. Over half of providers (56%, 5/9) reported they had not received sufficient education about maternal anxiety and how to address it in practice. About 78% (7/9) of providers agreed that family social determinants of health limited what they could do to help depressed mothers and anxious mothers.

Table 1. Family baseline characteristics.

	Mothers (N=24)	Family members (N=24)
Age (years), mean (SD)	32.79 (3.08)	34.13 (4.84)
Race, n (%)		
Asian	2 (8)	0 (0)
More than one race	1 (4)	1 (4)
White	21 (88)	23 (96)
Highest level of education, n (%)		
High school diploma or General Educational Diploma	1 (4)	2 (8)
College degree	8 (33)	11 (46)
Graduate school degree	15 (63)	11 (46)
Employed, n (%)	18 (75)	22 (92)
Family conflict score[a], mean	55.8	54.4
Maternal depression score[b], mean (SD)	20 (7.62)	N/A[c]
Maternal anxiety score[d], mean (SD)	43.63 (7.37)	N/A

[a]Perceived Hostility Survey Ages 18+ (PHS) [56] uncorrected T-Score from the NIH Toolbox Raw Score to T-Score Conversion Table.

[b]Beck Depression Inventory-Second Edition (BDI-II) scores of 20-28 indicate moderate depressive symptoms [43].

[c]N/A: not applicable.

[d]State-Trait Anxiety Inventory-State Anxiety (STAI-S) [44] scale scores of at least 38 indicate clinically significant anxiety [50].

Table 2. Infant care provider characteristics.

	Infant care providers (N=9)
Age (years), mean (SD)	35.56 (7.49)
Female, n (%)	7 (78)
Race, n (%)	
More than one race	1 (11)
White	8 (89)
Clinic implements postpartum depression screens, n (%)	6 (67)
Job responsibilities for maternal depression, n (%)	
Recognition of postpartum depression	
Strongly agree	6 (67)
Agree	3 (33)
Addressing parenting issues that pertain to maternal depression	
Strongly agree	6 (67)
Agree	3 (33)
Clinic implements postpartum anxiety screens, n (%)	2 (22)
Job responsibilities for maternal anxiety, n (%)	
Recognition of postpartum anxiety	
Strongly agree	4 (44)
Agree	5 (56)
Addressing parenting issues that pertain to maternal anxiety	
Strongly agree	5 (56)
Agree	4 (44)

Feasibility

Of the 26 families who started REST, 2 families dropped out prior to the third session due to busy schedules. One family attended 5 sessions, reported they resolved their conflict, and they did not need more sessions. Nearly all mothers (96%; 23/24) attended all 10 sessions. On average, mothers attended 9.79 (SD 1.02) sessions. A few family members had to miss sessions due to work commitments. On average, family members attended 9.42 (SD 1.28) sessions. Overall, 83% of participants attended all 10 sessions.

The training on addressing maternal depression and anxiety in well-child visits was offered to infant care providers at 5 participating clinics. A total of 31 infant care providers attended the training.

The results indicate that REST is safe for mothers. Mothers reported a significant reduction in depressive symptoms (Z=–3.95, P<.001) and a significant reduction in anxiety symptoms (Z=–3.49, P<.001) from baseline through session 8. No mothers required referrals to intensive mental health services. Figure 1 shows the changes in maternal depressive symptoms and maternal anxiety symptoms from baseline through the treatment phase.

The results indicate that REST is well tolerated by families. No families were removed from the study due to increased family conflict on the FES-C or domestic violence. Mothers reported a significant reduction in family conflict on the FES-C (Z=–4.16, P<.001) and their family members also reported a significant reduction in family conflict on the FES-C (Z=–2.42, P=.02) from baseline through session number 8. Figure 2 shows the changes in family conflict in mothers' FES-C scores and family members' FES-C scores from baseline through the treatment phase.

Figure 1. Changes in maternal depressive and anxiety symptoms from baseline through the treatment phase. BDI-II: Beck Depression Inventory-Second Edition; STAI-S: State-Trait Anxiety Inventory-State Anxiety scale.

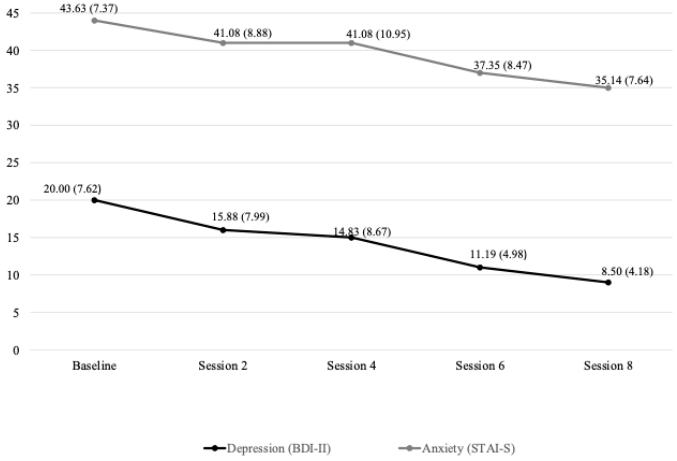
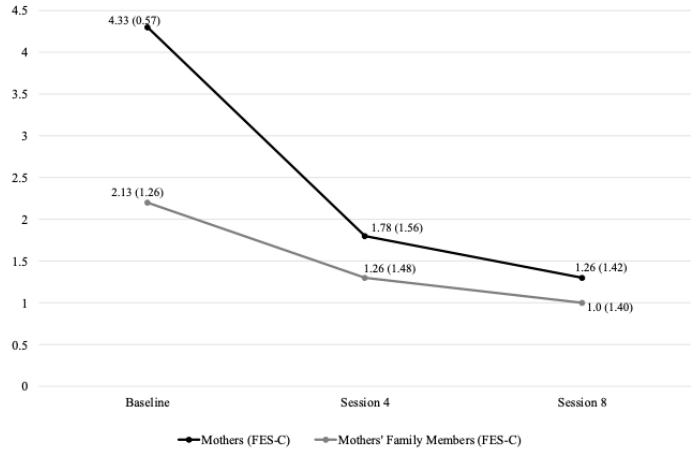


Figure 2. Tolerability of Resilience Enhancement Skills Training. FES-C: Family Environment Scale-Conflict subscale.



Preliminary Effectiveness of REST

Of the 48 participants who completed the baseline measure, 47 of them also completed the postintervention measure. One mother's family member was unable to complete the postintervention measure but completed the 3-month and 6-month follow-up measures. Two couples (n=4 individuals) were lost to follow-up after completing the postintervention measure.

Table 3 includes the changes in maternal depressive and anxiety symptoms from baseline to each of the 3 follow-up time points. Mothers reported a significant decrease in depressive symptoms over time ($\chi^2_{3,22}$=27.26, *P*<.001). There were statistically significant reductions in maternal depressive symptoms from baseline to postintervention (*Z*=–4.06, *P*<.001), baseline to the 3-month follow-up (*Z*=–3.87, *P*<.001), and baseline to the 6-month follow-up (*Z*=–3.82, *P*<.001). Although the significant reduction in maternal depressive symptoms was sustained at the 6-month follow-up, there were no significant differences in maternal BDI-II scores from postintervention to the 3-month follow-up (*Z*=–1.15, *P*=.25), postintervention to the 6-month follow-up (*Z*=–1.22, *P*=.22), and the 3-month follow-up to the 6-month follow-up (*Z*=–0.61, *P*=.54).

Table 3. Changes in maternal depressive and anxiety symptoms by time point.

	Baseline (N=24)	Postintervention (N=24)	*P* value	3-month follow-up (N=22)	*P* value	6-month follow-up (N=22)	*P* value
BDI-II[a], mean (SD)	20 (7.62)	6.96 (2.77)	<.001	8.46 (4.19)	<.001	8.27 (5.11)	<.001
STAI-S[b], mean (SD)	43.63 (7.37)	33.17 (6.94)	<.001	33.73 (7.97)	<.001	33.77 (7.56)	<.001

[a]BDI-II: Beck Depression Inventory-Second Edition scores.

[b]STAI-S: State Trait Anxiety Inventory- State Anxiety scale.

Mothers reported a significant decrease in anxiety symptoms over time ($\chi^2_{3,22}$=25.29, *P*<.001). There were statistically significant reductions in maternal anxiety symptoms from baseline to postintervention (*Z*=–4.03, *P*<.001), baseline to the 3-month follow-up (*Z*=–3.67, *P*<.001), and baseline to the 6-month follow-up (*Z*=–3.81, *P*<.001). Although the significant reduction in maternal anxiety symptoms was sustained at the 6-month follow-up, there were no significant differences in maternal STAI-S scores from postintervention to the 3-month follow-up (*Z*=–0.42, *P*=.68), postintervention to the 6-month follow-up (*Z*=–0.15, *P*=.88), and the 3-month follow-up to the 6-month follow-up (*Z*=–0.14, *P*=.89).

Table 4 includes changes in family conflict, measured separately using mothers' PHS scores and their family members' PHS scores, from baseline to each of the 3 follow-up time points. Mothers reported a significant decrease in conflict with their participating family members over time ($\chi^2_{3,22}$=26.66, *P*<.001). There were statistically significant reductions in mothers' PHS scores from baseline to postintervention (*Z*=–3.90, *P*<.001), baseline to the 3-month follow-up (*Z*=–2.98, *P*=.003), and baseline to the 6-month follow-up (*Z*=–3.41, *P*<.001). Although the significant reduction in maternal reported family conflict was sustained at the 6-month follow-up, there were no significant differences in maternal PHS scores from postintervention to the 3-month follow-up (*Z*=1.31, *P*=.19), postintervention to the 6-month follow-up (*Z*=–0.79, *P*=.43), and the 3-month follow-up to the 6-month follow-up (*Z*=–0.57, *P*=.57).

Family members also reported a significant decrease in conflict with mothers over time ($\chi^2_{3,21}$=17.65, *P*<.001). There were statistically significant reductions in family member reported conflict from baseline to postintervention (*Z*=–2.81, *P*=.005), baseline to the 3-month follow-up (*Z*=–3.32, *P*<.001), and baseline to the 6-month follow-up (*Z*=–2.67, *P*=.007). Although the significant reduction in family member reported conflict was sustained at the 6-month follow-up, there were no significant differences in family member PHS scores from postintervention to the 3-month follow-up (*Z*=–1.42, *P*=.16), postintervention to the 6-month follow-up (*Z*=–0.16, *P*=.88), and the 3-month follow-up to the 6-month follow-up (*Z*=1.44, *P*=.15).

Table 4. Changes in family conflict by participant type and time point.

	Baseline (N=48)	Postintervention (N=47)	*P* value	3-month follow-up (N=44)	*P* value	6-month follow-up (N=44)	*P* value
Maternal PHS[a], mean	55.8	48.1	<.001	49.8	.003	48.1	<.001
Family member PHS[a], mean	54.4	51.4	.005	48.1	<.001	49.8	.007

[a]Perceived Hostility Survey Ages 18+ uncorrected mean T-Score from the NIH Toolbox Raw Score to T-Score Conversion Table.

Discussion

Principal Results

The findings from this study support the feasibility and preliminary effectiveness of REST in reducing maternal depressive symptoms, maternal anxiety symptoms, and family conflict from baseline through the 6-month follow-up. Mothers reported a significant reduction in depressive symptoms (*P*<.001) and a significant reduction in anxiety symptoms (*P*<.001) from baseline to the 6-month follow-up. This study is the first to explore REST's potential effectiveness in reducing maternal anxiety. We plan to conduct more research to determine REST's effectiveness in reducing maternal anxiety.

Mothers reported a significant reduction in conflict with their family members (*P*<.001) from baseline to the 6-month follow-up. Family members reported a significant reduction in conflict with mothers from baseline to the 6-month follow-up (*P*=.007). More studies are needed to show that REST is an effective treatment, especially in ethnically diverse families. A preliminary pilot study of REST showed that it was feasible and acceptable for socioeconomically disadvantaged families [24]. A pilot randomized trial is currently underway that is testing REST's impacts on depression and family function in a more diverse population of families [26], and the results will be published in a subsequent journal paper.

A total of 31 infant care providers attended the training on addressing the parenting needs of depressed and anxious mothers. Given that the providers are overburdened with clinical responsibilities that have multiplied due to the current pandemic, it is not surprising that only 9 of them agreed to complete the questionnaire prior to the training. Of these 9 infant care providers, 67% (n=6) of them reported that mothers are screened for depression at their clinics, and 22% (n=2) of them reported that mothers are screened for anxiety at their clinics. Although the infant care providers acknowledged that it is important to screen mothers for anxiety; the lack of available treatment resources in rural regions has likely inhibited clinic managers' decisions to require routine screening procedures for maternal depression and anxiety. Regardless of clinic decisions to implement routine screening procedures, mothers may still disclose depressive symptoms and anxiety symptoms during well-child visits and infant care providers need to know how to best help them. This study offered these providers convenient and easily accessible training on addressing the parenting needs of depressed and anxious mothers.

Comparison With Prior Work

The current findings for REST can be compared to those of previous research [24]. The feasibility results that pertain to family retention, session attendance, safety, and tolerability of REST are consistent with those of previous research on REST [24]. REST was primarily developed for use with families

enrolled in early childhood home visiting programs. Although the sample of families in this study was not enrolled in home visiting, the findings on REST's impacts on maternal depression and family conflict are consistent with the findings for the home visited families [24]. The current and previous results [24] showed that mothers experienced significant reductions in depressive symptoms, and families experienced significant reductions in conflict. The current findings strengthen the previous findings in that the current findings show that REST's impact was sustained for 6 months after the final session.

The characteristics of the infant care providers who completed the questionnaire prior to the training are similar to those who participated in the second author's previous research [58]. The study took place during the COVID-19 pandemic and many of the participating clinics were rapidly transitioning to electronic administration of patient clinical screening measures and video-delivered services, which required providers to quickly adjust to these new practices. Although infant care providers were very busy adapting to these new changes, they prioritized the training in an effort to increase their knowledge on addressing the parenting needs of depressed and anxious mothers. The training time and duration, 1 hour at lunchtime, and video-based format likely made it convenient and easy for them to attend it.

Limitations

This study is not without limitations. First, the sample sizes were small for families and infant care providers. For this reason, the findings should be interpreted with caution. Second, few ethnically diverse families and infant care providers participated in the study. Thus, the results may not be generalizable to more diverse populations. Although rural areas of the United States are less ethnically diverse than urban areas [59], we plan to conduct future research on the effectiveness of FBCCM with ethnically diverse populations. Third, this pilot study did not include a comparison group. It was not feasible to include a comparison group in this study. We plan to conduct a larger study that will include comparison groups in order to assess differences in outcomes for FBCCM participants.

Conclusions

This paper included findings that support the feasibility of the FBCCM and preliminary effectiveness of the family therapy treatment component of this model. These findings are important in justifying a larger study. Our future research will focus on testing the impact of the FBCCM in improving outcomes for families and infant care providers.

Acknowledgments

This study was funded by the Couch Family Foundation.

Conflicts of Interest

None declared.

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Abbreviations

BDI-II: Beck Depression Inventory-Second Edition
DBT: Dialectical Behavior Therapy
FBCCM: Family-Based Collaborative Care Model
FES-C: Family Environment Scale-Conflict
IRB: institutional review board
PHS: Perceived Hostility Survey Ages 18+
REST: Resilience Enhancement Skills Training
STAI-S: State-Trait Anxiety Inventory-State Anxiety scale
VCT: compliant video technology

Edited by S Badawy, G Eysenbach; submitted 10.01.23; peer-reviewed by A Woolard, P Watson; comments to author 01.02.23; revised version received 06.02.23; accepted 07.02.23; published 13.04.23.

Please cite as:
Cluxton-Keller F, Olson A
A Family-Based Collaborative Care Model for Treatment of Depressive and Anxiety Symptoms in Perinatal Women: Results From a Pilot Study
JMIR Pediatr Parent 2023;6:e45616
URL: https://pediatrics.jmir.org/2023/1/e45616
doi:10.2196/45616
PMID:37052997

Original Paper

Novel At-Home Mother's Milk Conductivity Sensing Technology as an Identification System of Delay in Milk Secretory Activation Progress and Early Breastfeeding Problems: Feasibility Assessment

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Abstract

Background: Prolonged exclusive breastfeeding is a public health priority and a personal desire by mothers; however, rates are low with milk supply challenges as a predominant cause. Early breastfeeding management at home is key. Milk electrolytes, mainly sodium ions, are accepted as biomarkers of secretory activation processes throughout the first weeks after birth and predictors for prolonged breastfeeding success, although they are not incorporated into routine care practice.

Objective: The aim of this study was to test the feasibility of a novel handheld smartphone-operated milk conductivity sensing system that was designed to compute a novel parameter, milk maturation percent (MM%), calculated from milk sample conductivity for tracking individual secretory activation progress in a real-world home setting.

Methods: System performance was initially evaluated in data collected from laboratory-based milk analysis, followed by a retrospective analysis of observational real-world data gathered with the system, on the spot in an at-home setting, implemented by lactation support providers or directly by mothers (N=592). Data collected included milk sample sensing data, baby age, and self-reported breastfeeding status and breastfeeding-related conditions. The data were retroactively classified in a day after birth–dependent manner. Results were compared between groups classified according to breastfeeding exclusivity and breastfeeding problems associated with ineffective breastfeeding and low milk supply.

Results: Laboratory analysis in a set of breast milk samples demonstrated a strong correlation between the system's results and sodium ion levels. In the real-world data set, a total of 1511 milk sensing records were obtained on the spot with over 592 real-world mothers. Data gathered with the system revealed a typical time-dependent increase in the milk maturation parameter (MM%), characterized by an initial steep increase, followed by a moderate increase, and reaching a plateau during the first weeks postpartum. Additionally, MM% levels captured by the system were found to be sensitive to breastfeeding status classifications of exclusive breastfeeding and breastfeeding problems, manifested by differences in group means in the several-day range after birth, predominantly during the first weeks postpartum. Differences could also be demonstrated for the per-case time after birth–dependent progress in individual mothers.

Conclusions: This feasibility study demonstrates that the use of smart milk conductivity sensing technology can provide a robust, objective measure of individual breastfeeding efficiency, facilitating remote data collection within a home setting. This system holds considerable potential to augment both self-monitoring and remote breastfeeding management capabilities, as well as to refine clinical classifications. To further validate the clinical relevance and potential of this home milk monitoring tool, future controlled clinical studies are necessary, which will provide insights into its impact on user and care provider satisfaction and its potential to meet breastfeeding success goals.

(JMIR Pediatr Parent 2023;6:e43837) doi:10.2196/43837

KEYWORDS

breastfeeding; feasibility; human milk; biomarker; remote sensing technology; mobile health; retrospective; secretory activation; lactogenesis; milk supply; milk; sensing technology; monitoring tool; lactation; exclusive breastfeeding; breastfeed; maternal health; maternal and infant health; infant health; maternal and child health; prolactin; lactation consultant; lactation support provider; mother; milk maturation

Introduction

Despite the growing body of knowledge regarding breastfeeding benefits for both the mother and baby [1,2] and efforts of national and international health organizations to promote and support breastfeeding, exclusive breastfeeding rates remain low [3]. While breastfeeding initiation rates are relatively high (>80%), use of commercial milk formula (hereafter referred to as "formula") is high [4]. There is a sharp drop where a third of mothers stop breastfeeding within the first month after birth [5,6], with insufficient milk supply being the most prevalent self-reported contributing factor [4,7].

Postglandular (or secondary) lactation insufficiency, caused by ineffective or infrequent milk removal, is reportedly the most common cause of inability to support an exclusively breastfed infant's optimal growth and development [8]. Early proactive and corrective care, when the lactation process is most amenable to positive manipulation, can have a great impact on milk supply in the short and long term [4,9].

Lactogenesis, the process by which the mammary glands develop and regulate milk secretion, is a complex physiological process involving an orchestrated series of endocrine and autocrine/paracrine hormonal changes. The secretory activation stage (known as lactogenesis II) is tightly related to effective breastfeeding with frequent and adequate milk removal from the breast [10]; therefore, this stage can be dramatically perturbed by the introduction of nonmother's milk feeds [4]. Inadequate secretory activation progress constitutes a higher risk for insufficient subsequent milk production, leading to excessive infant weight loss and early exclusive and/or any breastfeeding cessation [11,12]. Thus, objective assessment tools for monitoring an individual's lactogenesis progress warrant attention.

Researchers over the past 70 years have identified a variety of components in human milk indicative of mammary gland progress toward the production of copious mature milk, including electrolytes such as sodium, potassium, and chloride ions, alongside lactose, protein, and citrate [13-18]. Electrolytes, mainly sodium ions, and related measures, including milk conductivity, show unique dynamics over the first weeks postpartum. These factors have been demonstrated to serve as useful biomarkers for successful or failed secretory activation, as a potential measure of increased risk for early breastfeeding cessation [19-24], and were recently assessed as a potential care support tool [25-28]. Early and frequent breast stimulation and efficient emptying were shown to improve marker dynamics and milk supply. Milk electrolyte balance was also shown to be affected by breast inflammation, a well-reported obstacle to breastfeeding success [29,30]. However, the main testing methods available for these biomarkers to date require laboratory-based approaches, hindering their large-scale practical use.

Breastfeeding is managed by the mother at home. Early education and support by lactation consultants via home visits or remotely via telehealth, especially in the first 4 weeks after birth, were shown to impact the success and maintenance of exclusive breastfeeding [31-34]. In recent years, mobile health apps have been paving the way toward more personalized self-care. Breastfeeding tracking and support apps have increasingly been adopted both in nonclinical and clinical contexts [35]. Augmenting health tracking tools with sensor technologies operated in the home setting has the potential to advance our understanding of the dynamics of breastfeeding physiology and low supply etiologies, demonstrating potential for future clinical care implementation.

We here describe the development and early real-world evidence from the use of a novel milk conductivity sensing system designed for tracking individual mothers' milk secretory activation progress at home. The handheld milk conductivity sensing device and a mobile app were designed for an instant computation of a milk maturation percent (MM%) parameter that is computed from milk sample conductivity measured by the device, reflecting sample maturation status in percentages within the full dynamic range from initial colostrum to fully mature milk; the lower the MM%, the less advanced the mother is in her lactogenesis phase progress and supply process.

The aim of this study was to test the feasibility of this smartphone-operated milk conductivity sensing system to track individual secretory activation progress in a real-world home setting and its ability to identify different breastfeeding classifications associated with milk supply in a diverse set of real-world users.

Methods

Research Design

This retrospective study was based on a data set gathered by real-world users of a novel milk conductivity sensing system with the purpose of assessing individual secretory activation progress at home. The study objective was to assess feasibility of the novel system for remotely tracking secretory activation status at home. We referred to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for reporting cross-sectional observational data and also to the Guidelines and Checklist for the Reporting on Digital Health Implementations, when applicable.

System performance was initially evaluated in data collected from laboratory-based milk analysis, followed by a retrospective analysis of observational real-world data gathered with the system implemented by lactation support providers and directly by mothers in the home setting.

The available data set in the company's database allowed for a cost-effective analysis in studying the relationship between milk maturation progress and breastfeeding exclusivity and related problems, which can provide insight for the design of future prospective and randomized trials.

Users joined the technology assessment on their sole discretion; downloaded the app; and consented before use to terms of use, privacy policy, and data usage for anonymous research purposes (see Multimedia Appendix 1). Users' data were adequately secured according to the organization's privacy policies designed for maintaining confidentiality and privacy, and the study data set was deidentified at extraction for analysis.

The system was not intended for diagnosing or treating a medical condition but rather as an informational/educational, noninvasive, and low-risk tool for promoting a healthy lifestyle. This was clearly indicated at all steps of registration. The system was implemented in a nonclinical nonacademic setting; any and all system interaction was at the sole discretion of users.

Ethical Approval

This study was approved by the Institutional Ethics Committee of Ariel University (approval number AU-HEA-AN-20221220).

Setting and Context

This retrospective analysis observed data records from breastfeeding mothers in the state of Israel. According to formal figures published by the Israel Ministry of Health, the breastfeeding initiation rate in Israel is 93% and exclusive breastfeeding rates drop to 55% by 1 month and to 20% at 6 months (data collected by the software "Healthy thinking" within "Tipat Halav" national well-baby visit centers [36]).

Sample

The study population included users registered between July 2018 and October 2020. A total of 592 mothers were included in the retrospective analysis (555 recorded by lactation support providers and 37 self-recorded directly). Users were not compensated for participation. Several users covered shipment costs. Sample demographics, including data on birth weight, gestational week at birth, parity, age, sex of the infant, and more, can be found in Multimedia Appendix 2. The study set was not controlled and was subjected to selection bias, and therefore cannot and is not intended to represent the general population.

Measurement Apparatus and Software

The milk conductivity sensing system comprised a handheld device for sensing the conductivity of small human milk samples and a smartphone app for data recording, computation of MM%, and user output.

The device included a sample cell for holding a small milk sample with two fixed electrodes (cell constant K=1) and a temperature probe. The electronic board featured a microprocessor, LCD display, and was powered by two 1.5-V batteries. Sample conductivity was computed from measured conductance, corrected to 25°C, and calibrated per device using potassium chloride standard solutions. The device's laboratory performance was tested for linearity, precision, accuracy, repeatability, and stability using standard solutions and frozen breast milk specimens (see Multimedia Appendix 2), and was compared with a lab-grade conductivity analyzer (LAQUAtwin, EC-33 HORIBA).

Several milk sample cell configurations were tested to minimize sample size. Comparable results were observed for sample volumes of 0.2 ml, 0.5 ml, 1 ml, and 2 ml, leading to the selection of minimal volume cells of 0.5 ml and 0.2 ml for device assembly (see Multimedia Appendix 2 [37]).

Electrical conductivity, a measure of a fluid's current conduction capability, is linked to the concentration and mobility of ions. The charged particles in body fluids are primarily sodium, potassium, and chloride. The relationship between breast milk conductivity and specific electrolyte concentrations has been previously reported [17].

We investigated sodium ion (Na^+), a well-studied breast milk electrolyte linked to lactogenesis [14,15,38] and lactation adequacy [19,22,23], in relation to the measurements obtained with our apparatus. We used a large set of breast milk samples (n=79) for this lab-based test, plotting the measured relative conductivity against the sodium concentration, as assessed by a lab-grade ion-selective electrode analyzer (Roche/Hitachi Cobas 6000 c501 system, ISE module) and a portable Na^+-selective electrode instrument (LAQUATwin, NA-11 HORIBA) that was previously validated for human milk [37]. The results showed a strong correlation, suggesting Na^+ ion as a key factor in milk conductivity (see Multimedia Appendix 2 [15,29]). No correlation was found with Na^+ or conductivity and certain milk components demonstrating significant interindividual variability (fat; vitamins A, B1, B2, B6, and B12; and caffeine; for details see Multimedia Appendix 2 [39]). However, protein levels, which show similar dynamics to Na^+ in lactogenesis [15] and little interindividual difference in mature milk, positively correlated with both conductivity and Na^+. Postpartum day-specific conductivity patterns mirrored Na^+ trends, similar to the results reported by Neville et al [15], and mirrored Na^+ trends in certain inflammation-associated breast pain cases, confirming previous reports [29,30] (see Multimedia Appendix 2 [19,22,23]).

MM% was calculated from device-measured conductivity using a predefined equation, based on an empirical data set of 625 breast milk samples from the first 10 days postpartum (detailed in Multimedia Appendix 2). The result was computed for each breast, saved, and displayed on the user interfaces in seconds.

Two apps were developed: a user-friendly app for mothers to record and track daily inputs, complemented by educational materials (iOS-compatible; see Multimedia Appendix 2) and a separate app for lactation support providers to manage records of different mothers (iOS- and Android-compatible; Multimedia Appendix 2).

System-recorded data included the baby's birth date and time, birth weight, sex, breastfeeding exclusivity, and milk sample measurements. Users could self-report additional data, including conditions (low milk supply, slow weight gain, tongue-tie, latch problem, breast pain, and nipple pain), baby weights, mother's

age, birth type, preterm birth, and obstetrics/gynecology history. The mother-facing app allowed for calculating a self-assessment LATCH score [40], breastfeeding confidence score (adapted from the Mother Infant Breastfeeding Satisfaction Scale subscale of the Hill & Humenick lactation scale [41]), daily diaper counts, and a pain scale scored from 0 to 5. The questionnaire format was not independently validated.

Data were stored in separate secure cloud-based data storage servers for each app (AWS and Google Cloud). The system was established for investigational use only was not intended to diagnose or treat any medical condition nor to serve as a substitute for medical advice or guide medical care. Data confidentiality was maintained according to user consent and usage terms (see Multimedia Appendix 1).

Data Collection

This study utilized a data set collected from July 2018 to October 2020 by lactation support providers (n=30), including International Board-Certified Lactation Consultants, that used the system at routine home visits, as well as mothers joining in their third trimester who voluntarily used the system for repeated self-assessment starting soon after birth. An additional data set used for milk sample analysis in our laboratory from 2015 to 2023 was also included for system performance assessment (for details see Multimedia Appendix 2). Participation and use were optional, and the informed consent form explained system use, system limitations, and data handling (see Multimedia Appendix 1).

For analysis, data were anonymized, manually organized, and combined from the two app data storage servers. Specific records missing vital classification data or flagged as system failures or misuse were excluded. The unstructured data collection schedule, optional data tags, data merging from two participant groups, and reliance on self-reported data present study limitations. To offer comprehensive group-level analysis, all scans were treated as independent, including multiple-day scans from the same mother, presenting a possible bias toward mothers who scanned more frequently.

Data Analysis

We defined exclusive, full, and partial breastfeeding as previously described [42].

For data set analysis, data points were retrospectively categorized into three types of breastfeeding—"normal," "low supply," and "breastfeeding problems"—based on system interactions by the lactation support provider or mother. These categories reflected reported breastfeeding exclusivity and problem severity.

The "normal" classification included either exclusive breastfeeding, full breastfeeding, full mother's own milk (as described by Labbok and Starling [42]), or predominant mother's milk (≥80% of daily feeds, also referred to as high partial mother's milk feeding) at the time of the scan, with no indicated problems associated with low milk supply.

The "low supply" classification included lactation support provider's reports of formula feeding (defined as nonexclusive breastfeeding since birth and formula feeding during the 24 hours prior to the scan; also referred to as low or medium partial feeding) that were also tagged with problems associated with ineffective breastfeeding and/or low milk supply, or mothers' reports of indirect indicators of low milk supply and slow baby weight gain or significant formula feeds (over 20% of daily feeds and up to mainly formula as the nutrition source of the baby at the time of the report). Importantly, milk supply was not directly evaluated.

The "breastfeeding problems" classification included nonexclusive, partial breastfeeding (any formula at 34 hours prior to the scan) but with no obvious tagging of problems, or predominant breastfeeding (≥80% mother's milk at scan) also tagged with problems associated with ineffective breastfeeding and/or low milk supply (latch problems, 32.9%; tongue/lip-tie, 23.9%; low weight gain, 18.7%; and/or low milk supply, 5.2%).

Group names do not imply either a diagnosis or a confirmed clinical condition. This study is limited by the fact that classification was based on subjective user-reported suspected status, with no direct measurements of milk volumes or per-feed milk transfer by the authors. For ease of reporting, throughout this article, the short descriptors are used as noted above.

Statistical Analysis

Statistical analysis was conducted using JASP Graphical Statistical Software Version 0.17.1.0 (JASP Team, University of Amsterdam, Amsterdam, the Netherlands). Descriptive statistics included mean, median, standard error, coefficient of variation, minimum/maximum percentiles, and quartiles. A two-factor ANOVA was used to estimate the mean change in MM% based on feeding and days after birth, followed by a Tukey test for multiple comparisons. Scatter and interval plots are used to represent numeric variables and 95% CIs, respectively. For percentile analysis, a ±24-hour smoothing window was applied for the first 3 days and a –24-hour window was applied thereafter. Data set distributions were visualized with raincloud plots and quantile limits were visualized with boxplots.

Results

For Visual Abstract see Multimedia Appendix 3.

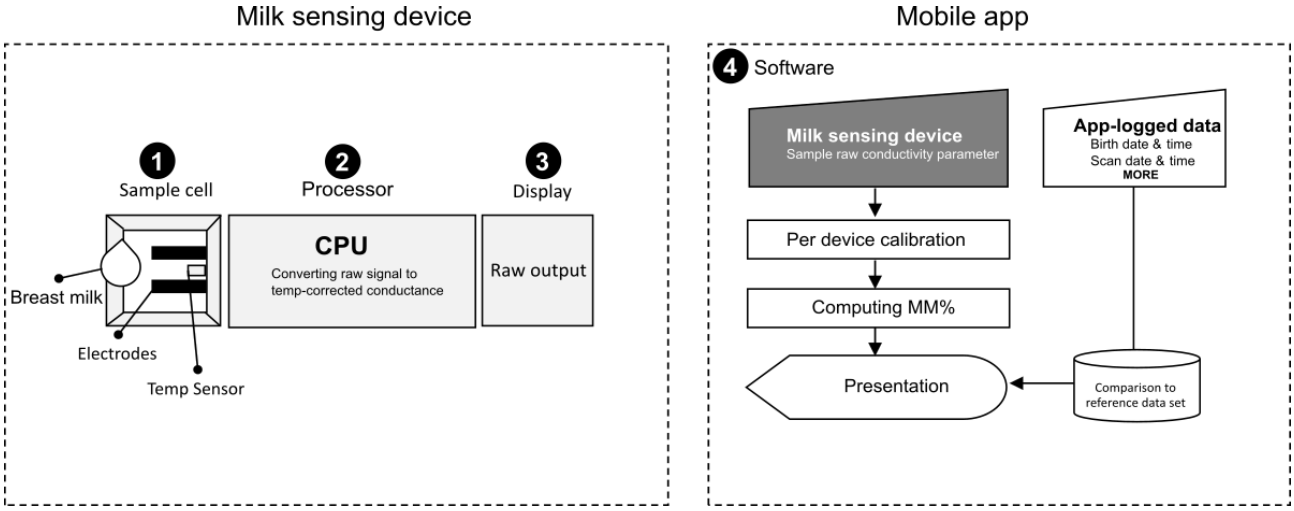
Milk Sensing Device and App

The milk electric conductivity sensing apparatus used to collect data presented in this manuscript was initially tested for laboratory performance in a series of breast milk samples. Results obtained with the apparatus were found to strongly correlate with milk sodium (Na^+), a well-studied electrolyte with regard to lactation state [14,15,19,22,23] (see Figure S1 in Multimedia Appendix 2). In our records, both the apparatus results and Na^+ showed a strong day-after-birth–dependent dynamic change, previously linked to secretory activation [15,38], and both presented a similar association with inflammation-associated breast pain, as previously reported [29,30] (Figure S2 in Multimedia Appendix 2). Although in the scope of this study not all possible contributors can be ruled out, no such correlation was found to a set of milk components

with large interindividual variability in mature milk (Figure S3 Multimedia Appendix 2).

The system (Figure 1) was designed to reliably sense conductivity in a small (200 µl) human milk sample (see Figure S4 in Multimedia Appendix 2) and instantly computes MM% by a proprietary equation defined based on an empirical data set of breast milk samples (detailed in the Methods section). MM% was designed to intuitively follow the directional progress of mother's milk on a continuous 0% to 100% scale determined empirically. The system was operated by the user via a mobile app for data recording and presentation. The lactation support provider app was designed as a dashboard to manage records of different mothers, while the mother-facing app was designed to follow individual mothers' day-to-day milk maturation progress and allow for additional voluntary data recording (see Figure S5 in Multimedia Appendix 2).

Figure 1. Schematic illustration of the milk sensing system. The system is composed of a milk sensing device and smartphone app. The milk sensing device design consists of (1) a sample cell with two electrodes and temperature (temp) sensor, (2) a firmware processor converting raw measurements to temp-corrected conductance, and (3) a display output. On the smartphone app side, (4) a software applies a per-device calibration on the measurable conductivity and computes the milk maturation percent (MM%) parameter. Computation is based on an empirical breast milk history data set.



Participants

A group of 30 professional lactation support providers were voluntarily enrolled and equipped with systems for use as an informational tool in their routine face-to-face home visits. A separate group of 37 expecting mothers (third trimester) were voluntarily enrolled for self and repeated use of the system at their home, starting early after birth. The intended use of the system was informational only and was not intended for diagnosing or treating any medical condition nor to substitute any medical advice. A retrospective analysis was performed on the observational data set recorded in the system data store between July 2018 and October 2020 as part of rolling continued data gather using the system by real-world users, mostly in the home setting.

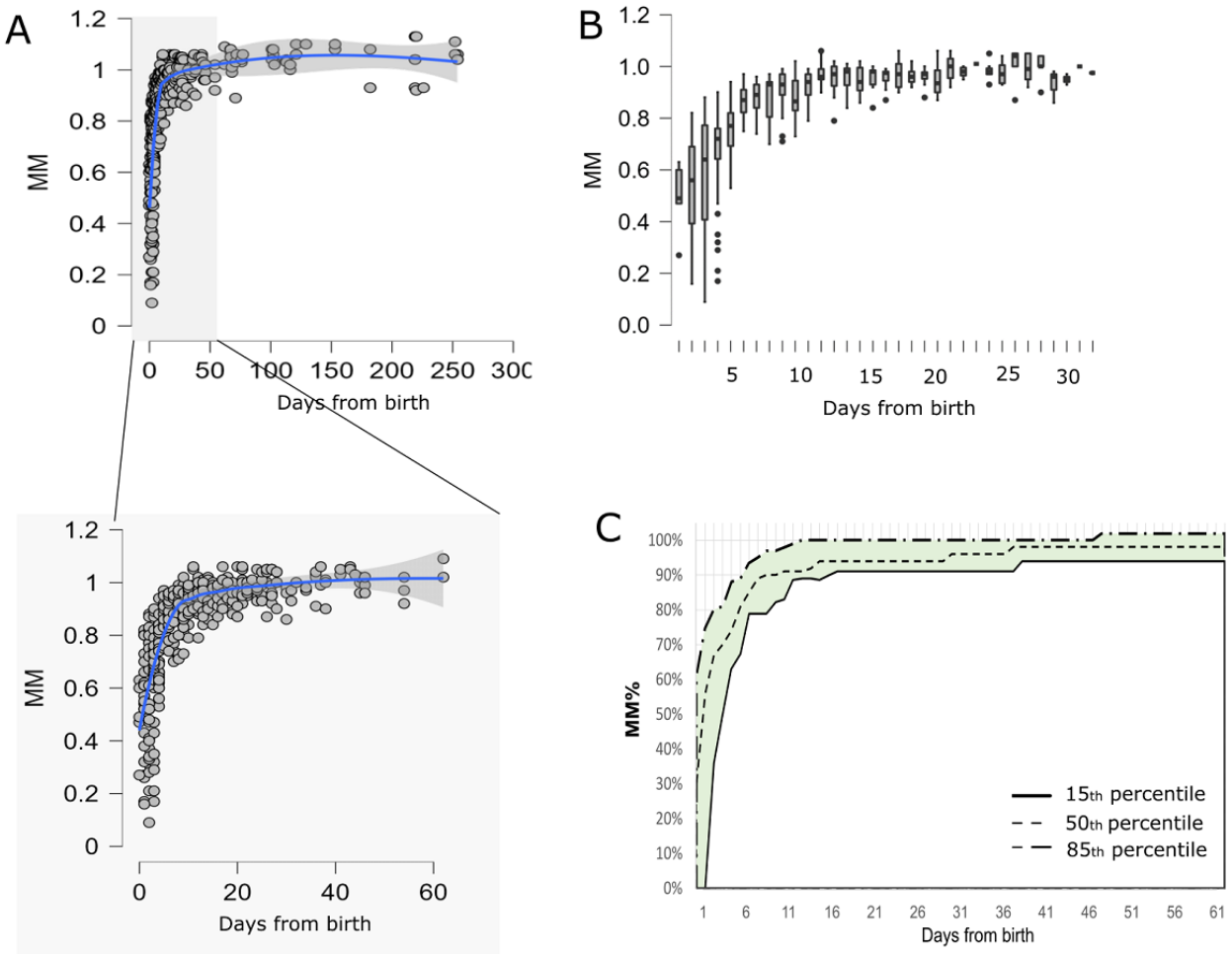
The data set included 1511 scans, including 1098 scans recorded at 593 appointments of professional lactation support collected from 555 mothers and 421 scans recorded on the mother-facing app from mothers that used the system for repeated self-home-tracking. At the stage of analysis, the lactation support providers–derived data set included 555 mothers, with an average maternal age of 30 (SD 5.7) years, reported infant sex of 278 girls and 276 boys, average birth weight of 3224 grams, and average child number 2.2 (out of 519 records, 53% 1st, 18% 2nd, 11% 3rd, and 13% 4th+ child). Infant age at the scan ranged from 0 to 1051 days with a median of 26.6 days. The self-enrolled mother group included 37 mothers; the average baby birth weight was 3103 grams, average child number 1.8, and average gestational week at birth was 37; see detailed sample demographics in Multimedia Appendix 2. As the participating population was not controlled and was subjected to selection bias, the results of the current analysis are not intended to and cannot provide insight into distributions in the general population.

Milk Maturation Progress in Exclusive Breastfeeding

Analysis from home use of the device demonstrated that MM% in exclusive normal breastfeeding progressed steeply throughout the first days and then gradually increased to reach a plateau within 2-3 weeks postpartum.

We analyzed a data set of scan records tagged as exclusive breastfeeding, full breastfeeding (as previously defined [42]), and predominant mother's own milk (≥80% of daily feeds, also referred to as high partial breastfeeding) at the time of the scan, with no breastfeeding problems indicated at the time of the reporting by either the lactation support provider face-to-face evaluation or by the mother (collectively referred to as the "normal" data set). A total of 507 scans fit these criteria. Data analysis revealed rapid elevation in the MM% parameter in the first days from birth that continued to increase slowly along 2 and 3 weeks postpartum, reaching a stable plateau of approximately 100% (Figure 2A-C). High variability was noted in the first days; however, the cofactors contributing to this variation were not assessed in the current study design. We next set per-day MM% "normal" percentiles, defined at the 15th, 50th, and 85th percentiles for each day/day range (daily in the first 21 days postpartum and at 7-10–day intervals at days 21-60 and >60 postpartum) (Figure 2C). These calculations and visualizations were further used as references for single or multiple sets of measurements.

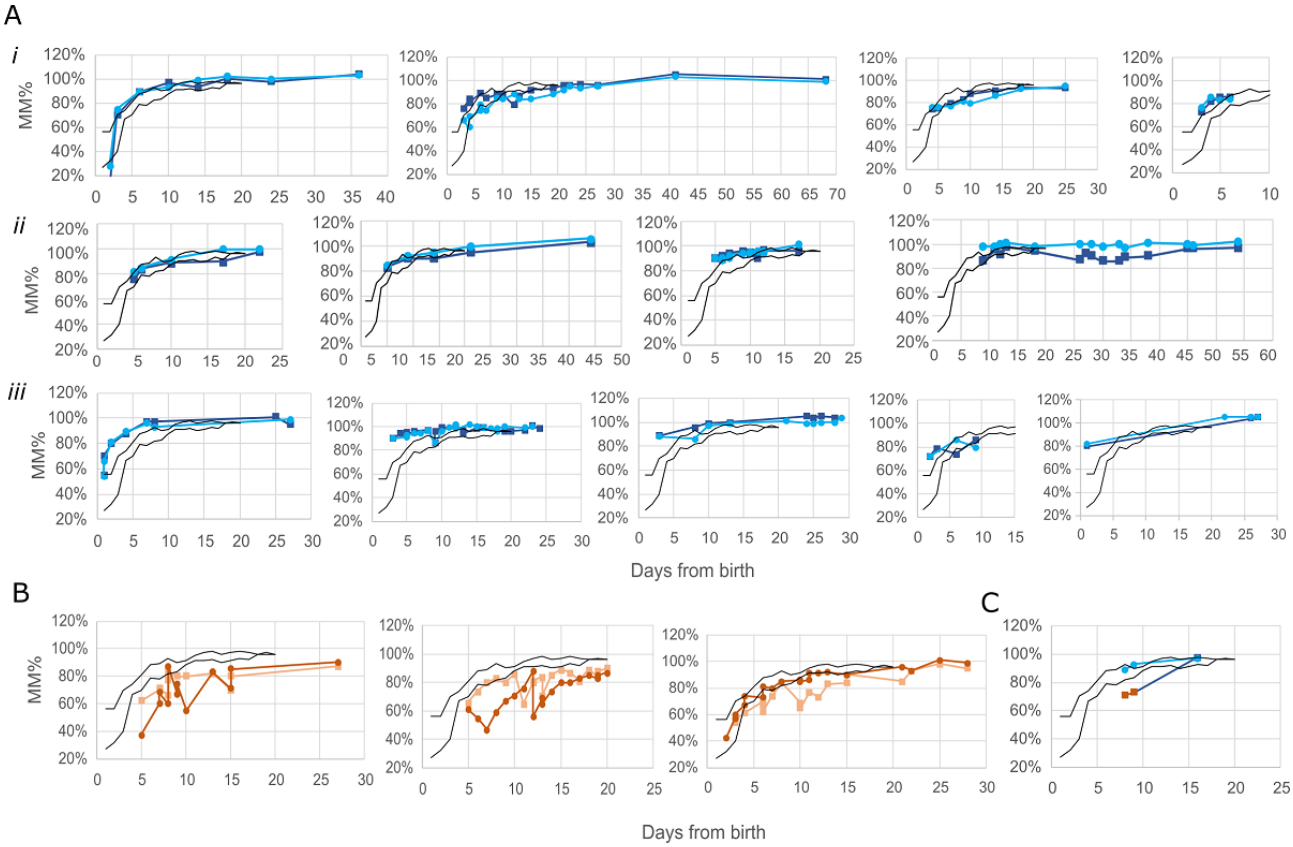
Figure 2. Milk maturation percent (MM%) distribution in a data set of a predominant breastfeeding population. A data set of 507 scans recorded from exclusive breastfeeding or predominant mother's milk (≥80% daily feeds), with no problems at the time of the scan were included. (A) Dot plot chart of MM% to day from birth at scanning. The upper chart shows the full scale up to 300 days (N=507); the lower chart enlarges the 0-60 days snapshot (n=463). (B) Box plot presentation of the data distribution and quantile limits (+1.5 IQR) for each day postbirth (0-60 days). (C) MM% to day postbirth (0-60 days) chart with ranges set by the data set percentile array, where the lower full line depicts the 15th percentile, the middle dashed line depicts the 50th percentile, and the upper dotted-dashed line depicts the 85th percentile.



Individual Mother's Milk Maturation Parameter Dynamics

Next, we assessed the dynamics of MM% in individual mothers who used the system repeatedly in a home setting (712 scans from 17 mothers that used the system on at least 4 separate occasions). The frequency of use of the device was at the mother's sole discretion (varied between 8 and 42 scans for each mother). MM% for each breast was analyzed separately. The plot of per-mother MM% versus day (Figure 3A) revealed similar dynamics to the population medians, where MM% values increased sharply within the first days after birth and continued to change gradually within the second week, eventually reaching a plateau. Records of mothers with no apparent breastfeeding complications tended to have MM% values above the "normal" group's 15th percentile line, often very close to the 50th percentile line (Figure 3A, i-ii). Several records presented more rapid dynamics (Figure 3A iii), reaching full (100%) maturation faster within several days from birth. In contrast, the records from selected individuals with reported breastfeeding problems associated with low milk supply reflected slower MM% versus days dynamics, where MM% values were below the 15th percentile norm line (or close to) from the early days after birth and for a period of time thereafter (Figure 3B). One record presents MM% records of exclusive breastfeeding with reported differences in milk production between breasts, with one side initially below the 15th percentile, demonstrating possible independent dynamics between sides (Figure 3C).

Figure 3. Per-case milk maturation percentage (MM%)-to-day from birth charts in individual mothers. The data set comprised 712 scans recorded by a group of 18 mothers who used the system independently at their homes. Right and left scans are depicted by separate lines. Black lines represent the 15th percentile and 50th percentile data array generated in the "exclusive" reference group. (A) MM% records from 14 exclusive breastfeeding mothers with no indications of breastfeeding problems (blue), showing similar dynamics (i, ii) or advanced (iii) relative to the 50th percentile line. (B) Three individual breastfeeding mothers with indications of breastfeeding problems of low milk supply (orange), showing slower MM%-to-day dynamics below the 15th percentile line. (C) MM% records from exclusive breastfeeding mother with delayed milk production on one side that was balanced.

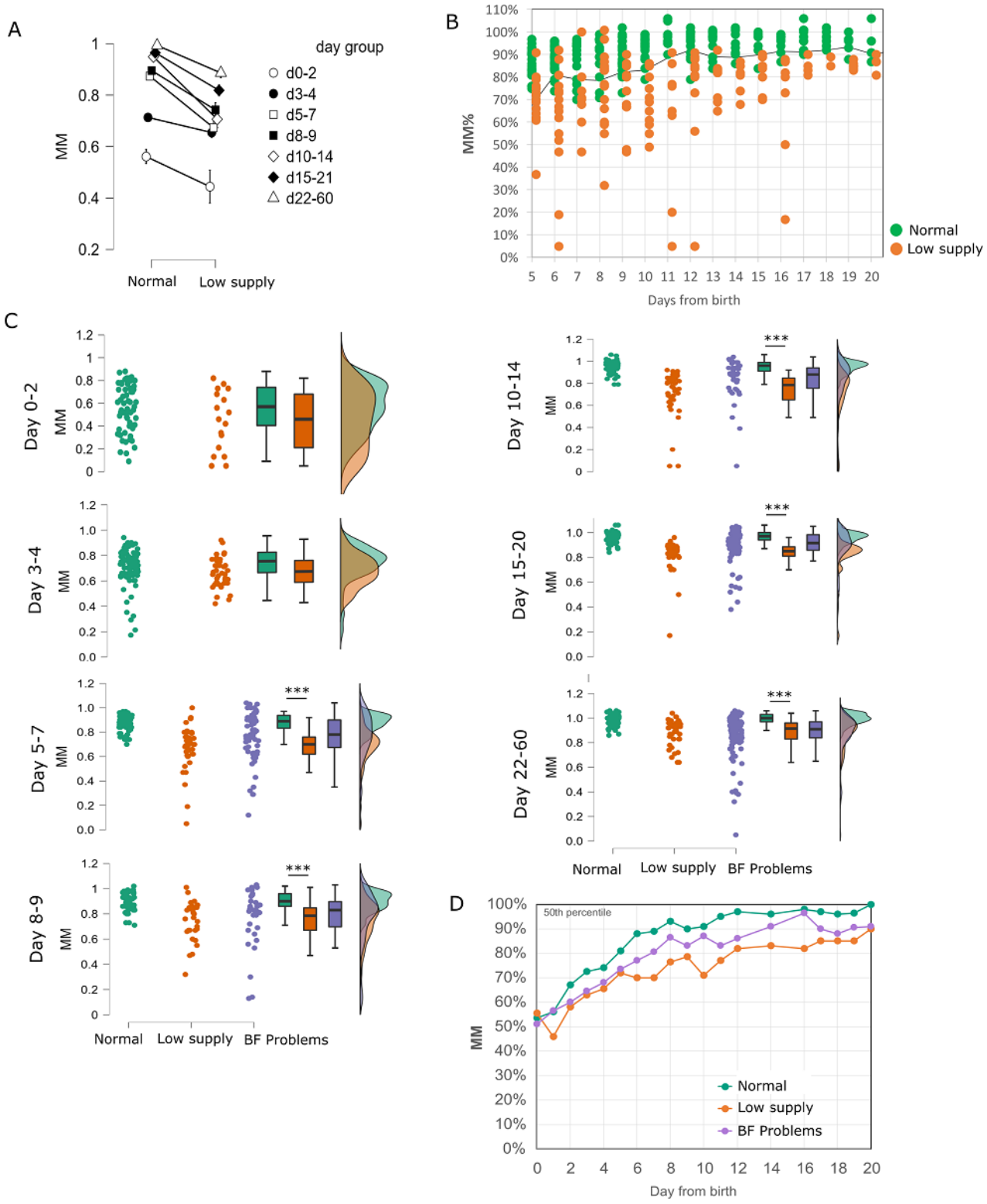


Milk Maturation Dynamics in Ineffective Breastfeeding

Analysis of data from home use of the device showed that lower MM% values are associated with early breastfeeding problems indicative of a low milk supply.

We aimed to test if reported early ineffective breastfeeding status and milk supply problems are associated with different MM% dynamics. The data set was retrospectively classified into one of three breastfeeding classes based on user records of breastfeeding exclusivity and reported breastfeeding problems as "normal," "breastfeeding problems," and "low supply," representing the "severity" of milk supply problems (see detailed data classification and limitations in the Methods). We performed a retrospective analysis in which we compared the "normal" data set as described above to the data set of records classified as "low supply" (n=253 scan records). The low supply MM% array revealed a tendency toward lower values compared to the "normal" predominant exclusive breastfeeding classification, with lower group median, quartiles, and mean MM% for the "low supply" group compared with those of the "normal" group throughout the full period (Figure 4A-D). Per-day range analysis revealed a lower mean MM% in the "low supply"–classified records compared with that of the "normal"-classified group in every day range analyzed (Figure 4B, two-factor ANOVA P<.001; Tukey test for breastfeeding classification P<.001). Posthoc analysis showed strong statistical significance between data sets at day 5 onward after birth (days 5-20 P<.001; days 20-60 P=.002) (Figure 4C).

Figure 4. Milk maturation percentage (MM%) in population groups of low milk supply and breastfeeding problems. Analysis of scans' MM% recorded from breastfeeding women with indication of a low milk supply, as reported by face-to-face evaluation by lactation support provider or mother self-report ("low supply," n=253), compared to "normal" group of exclusive/predominant (≥80% mothers' own milk) breastfeeding ("exclusive," n=463) and a third group of diverse breastfeeding problems ("BF Problem"; n=569, purple). (A) Dot plot presentation of MM% to day from birth at day 6-20: "exclusive," green; "low," orange; the black line is the MM% 15th percentile from the norm array. (B) Per-day range comparison analysis of MM% records between the two factors "low supply" and "exclusive." Two-factor ANOVA *P*<.001, Tukey BF *P*<.001; posthoc comparisons for the interaction BF×day is statistically significant Tukey *P*<.001 at day 5 (d5) to day 20 (d20). (C) Raincloud plot visualization ("exclusive," green; "low supply," orange; "BF Problems," purple) at day ranges, showing group separation at 5-20 days from birth. Box plot presenting quantile limits (Q1, median, Q3, and ±1.5 IQR). (D) MM% group moving median per-day range at 0-20 days. Data set of days 20-60 grouped at day 20.



For the day range 6-20 after birth, 110 out of 135 records classified as “low supply” showed MM% under the 15th percentile threshold line, suggesting a potential preliminary sensitivity of 81% for using the daily 15th percentile of the

"normal" predominant exclusive breastfeeding class as a potential reference threshold (see the detailed analysis in Table S1 of Multimedia Appendix 2). Future controlled prospective pilots and implementation studies, with population representative samples, direct milk supply measurements, and prolonged outcome evaluation, are required for validation of the usefulness and diagnostic capabilities of the system.

The intermediate data set, including scan records with indication of varying milder breastfeeding problems (see data classification in the Methods; n=569 scan records), showed persistent intermediate MM% median values, which were higher than those of the "low supply" group and lower than those of the "exclusive" norm values, most noticeably between days 5 and 19 (Figure 4D), with extended distribution over the full range defined by the two other groups (Figure 4C). As expected in this nonhomogeneous data set, some individual MM% records presented intermediate values in line with intermediate breastfeeding problem severity, while others were either more similar to the "exclusive" data set or to the "low supply" data set. Further metadata analysis and follow-up studies may highlight cofactors involved and their impact on the recorded MM% and possible subclassifications within and between groups.

Discussion

Principal Findings

Here, we present the first real-world data collected in real time using a newly developed human milk conductivity sensing system in the most intensive postnatal period and in a natural home setting. The real-world data design enabled a large, diverse, unique data set, including the MM% parameter alongside unique mother-baby data from numerous heterogeneous cases.

Retrospective analysis of the data demonstrated a typical "normal" MM% progress at the group level and in individual repeated measurements over the first days and weeks postpartum, and demonstrated that the system described is sensitive to breastfeeding exclusivity and milk supply problem severity at multiple and ongoing time frames after birth.

While randomized controlled clinical studies are warranted for evaluating the clinical usefulness compared to current practice and for validating the diagnostic capabilities of the new tool, the benefit of collecting real-time, real-world evidence in a natural setting is powerful. This can promote our understanding of breastfeeding physiology, low milk supply risks, and etiology, and serve as a step toward practical care insights.

Building on Prior Work

Milk electrolytes are used in research as biomarkers of secretory activation, which have been highlighted as predictors of successful or failed breastfeeding [15,18,20,27]. Although precluded from routine practice, previous studies by Humenick [43], Humenick et al [23], and Morton [19] have identified the potential use of milk secretory activation biomarkers for clinicians' per-case evaluation, suggesting that early assessment of secretory activation biomarkers can be used for early evaluation of the adequacy of lactation and the effectiveness of suckling, assist the optimal timing for a follow-up visit, enable the evaluation of progress, and evaluate the cause of inadequate lactation. A recent study validated the use of a portable instrumentation for sodium measurement directly by clinicians [44]. The system we described herewith enabled taking this theory out of the controlled setting into practice in a natural home setting, with an easy-to-operate, immediate, handheld, relatively low-cost technology, well-correlated with prior findings. The described milk conductivity sensing technology may be influenced or correlated with additional factors beyond those assessed in the scope of this study. Future controlled studies assessing various population subsets will assist in defining system usability and limitations, alongside driving further algorithm improvements.

Most studies evaluate individual data relative to a single cutoff criterion for a secretory activation biomarker level (particularly sodium). We argue that with the attempt to translate a gradually changing biomarker to a meaningful tool, an improved methodology can be to compare individual data to day-from-birth matched references. Our preliminary sensitivity assessment using per-day references in the exclusive breastfeeding "norm" population shows promise. Further studies are needed to validate norm values for a large and variable population and to evaluate or adjust the percentiles depicted in this study.

Future Directions

Although preliminary, limited, and out of the scope of the current analysis, in a small-scale user survey, lactation support provider users verbally indicated that the system was valuable for their case assessment and follow-up (see representative quotes in Multimedia Appendix 2), raising the potential of a milk biomarker measuring system to support data-powered and remote care. The current system is built as an informational tool, not intended to diagnose or treat a medical condition and secondary to any professional care. Future studies are warranted to validate the usability and usefulness of the system and for assessing the diagnostic capabilities of the tool.

The system did not distinguish all "low supply" cases. This can be linked to primary lactation insufficiency, hypoplasia, or levels of insufficient glandular tissue [22]; cases where first use of the system was relatively late; or cases of perceived insufficient milk supply. There are certain additional conditions such as mastitis, breast inflammation, and milk stasis that are also reflected in abnormal levels of milk electrolytes [29,30]. Preliminary data suggest the ability of the system to differentiate the above cases (data not shown) and additional research is warranted for validating system use for specific intended uses.

Low milk supply is often diagnosed and managed late [9,45,46]. Insufficient lactation can reflect a variety of cases with different underlying contributing factors that can all benefit to a significant extent from as-early-as-possible preventative and corrective management. Use of the described system may assist in understanding the efforts required to increase supply. The lower the MM%, the less advanced the mother is in her milk supply establishment process, but this can also indicate that the mother's supply can still be significantly increased with frequent and effective milk removal. Early and repeated system use can

reflect day-to-day progress and may assist in evaluation of the effectiveness of management.

Using the daily milk maturation parameter and its dynamic progress throughout the postpartum period, easily measured by the mother at home with minimal effort, combined with additional data on mother and baby harbor the potential to enable (1) the classification of cases to those with lower and higher risk for a breastfeeding problem; (2) evaluating the efforts required for enhancing milk supply and to assess intervention efficiency; (3) differentiating between problems that originate in maternal physiology (glandular) to problems originating in inefficient breastfeeding (postglandular, whether it stems from the baby physiology, breastfeeding management routine, or latch); and (4) structuring a tailor-made care practice accordingly on a case-by-case basis.

A mother-facing system that will include result interpretation and enhances the milk measurement with data-tracking tools, personal insights, and educational materials, tailored to the baby age and to the milk status, may enable personal, comprehensive, empathetic, and practical guidance, and has the potential to drive a mother's early proactivity. This was not directly evaluated in this study and should be addressed in future research, along with assessing the system's benefits beyond the current standard of care.

Limitations

This study was designed as a retrospective descriptive analysis of the data recorded in real-world use by early adopters assessing the technology. First, as the real-world data were not collected as part of a structured research, study limitations include potential selection bias, data inconsistency, confounding factors, and quality assessment challenges. Second, system usage was not routinely controlled and self-reported records were subjective and not complete, limiting data analysis capabilities. In an effort to minimize biases caused by these factors, we chose to include a relatively large data set in this feasibility study.

Third, the app was available only in English and only for iPhone, and the population was not randomized nor controlled but rather included a self-volunteered population that are in favor of the solution; therefore, the data set cannot and is not intended to represent the general population. Future large-scale controlled studies on a representative sample will help in addressing some of these limitations.

Conclusions

This novel mother's milk conductivity sensing technology used by real mothers provides a proof of concept for real-time self and remote reliable assessment of individual milk secretory activation progress in a home setting. Bringing a milk assessment technology for self and remote tracking to the hands of mothers and lactation support providers for use at home, the place where breastfeeding is normally managed in real life, and at the most sensitive and critical period of breastfeeding establishment harbor future research and care potential.

Adoption of secretory activation biomarkers sensing solutions, even as an informational-only tool, could be potentially leveraged into promoting breastfeeding rates and maternal well-being.

Acknowledgments

We want to thank all of the curious women, mothers, and lactation support providers that have taken part in the evaluation of the technology and contributed to data collection.

Data Availability

The data sets generated during and/or analyzed during this study are not publicly available due to data privacy and intellectual property reasons, but are available from the corresponding author on reasonable request.

Conflicts of Interest

SH, RS, and AF have financial disclosures related to MyMilk Laboratories Ltd. SH and RS are cofounders of MyMilk Laboratories Ltd and own stock options in the company. AF is an employee of MyMilk Laboratories Ltd. MyMilk Laboratories is a commercial company in the breastfeeding and human milk analysis and support space. The milk sensing device described in this manuscript is in the research and development stage and not commercially available. DAN has no conflicts to declare.

Multimedia Appendix 1
Privacy policy and consent wording.
[PDF File (Adobe PDF File), 172 KB - pediatrics_v6i1e43837_app1.pdf]

Multimedia Appendix 2
Description of the device and laboratory testing data (Figure S1), milk biochemical correlation analysis (Figures S2-S3), sample size and stability testing (Figure S4), calculation of MM%, app screenshots (Figure S5), sample demographics, predictive analysis of MM% (Table S1), representative quotes of feedback from lactation consultant users.
[PDF File (Adobe PDF File), 1217 KB - pediatrics_v6i1e43837_app2.pdf]

Multimedia Appendix 3
Visual Abstract.
[PDF File (Adobe PDF File), 202 KB - pediatrics_v6i1e43837_app3.pdf]

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Abbreviations

MM%: milk maturation percentage
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

Edited by S Badawy; submitted 26.10.22; peer-reviewed by A Finny, S Sulaiman; comments to author 17.04.23; revised version received 01.06.23; accepted 18.07.23; published 22.08.23.

Please cite as:
Haramati S, Firsow A, Navarro DA, Shechter R
Novel At-Home Mother's Milk Conductivity Sensing Technology as an Identification System of Delay in Milk Secretory Activation Progress and Early Breastfeeding Problems: Feasibility Assessment
JMIR Pediatr Parent 2023;6:e43837
URL: https://pediatrics.jmir.org/2023/1/e43837
doi:10.2196/43837
PMID:37464893

Original Paper

The Effectiveness of an After-school Sport Sampling Intervention on Urban Middle School Youth in the Midwest: Posttest-Only Study

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Abstract

Background: Effective and scalable interventions are needed to combat chronic low levels of youth physical activity. After-school sport sampling programs may be vital interventions for teaching sports and increasing physical literacy and physical activity, which result in healthy lifelong habits that are maintained into adulthood.

Objective: The purpose of this study was to test the effectiveness of an after-school sport sampling intervention among underserved youth in the Midwest.

Methods: Youth (n=81) in 3 middle schools within a large Midwest city participated in an 8-month, after-school physical activity intervention that aimed to increase moderate- and vigorous-intensity physical activity, improve physical literacy, and decrease BMI. Difference scores for this 2-group, posttest-only design were calculated. A series of 2-tailed *t* tests were conducted to assess between-group differences.

Results: The intervention group had significantly better physical literacy (t_{115}=7.57; *P*=.004) and engaged in more moderate- and vigorous-intensity physical activity minutes per week (t_{115}=4.28; *P*=.04) and steps per day (t_{115}=4.29; *P*=.03).

Conclusions: An after-school sport sampling program may be an effective solution for combating youth physical inactivity. Future research should assess the scalability of this intervention with larger populations and in different areas.

International Registered Report Identifier (IRRID): RR2-10.2196/37126

(JMIR Pediatr Parent 2023;6:e42265) doi:10.2196/42265

KEYWORDS

physical activity; adolescent; sport sampling; physical literacy; BMI; health intervention; parenting; healthy lifestyle; youth; health inequality; underserved population

Introduction

Nationally, 71.3% of middle schoolers do not meet physical activity recommendations [1]. Low levels of physical activity have contributed to increased rates of poor health, chronic disease, and obesity [2]. Obesity rates among youth have risen by nearly 7% in the last 20 years [3]. In 2018, over 1 in 5 youth (21.2%) were obese. Racial and ethnic minority youth are disproportionately affected by weight status. In 2017, it was reported that 37.7% of Black youth and 38.8% of Hispanic youth were overweight or obese, whereas 27.7% of White youth were overweight or obese [1]. Similarly, concerning trends are seen in physical activity rates. Physical activity rates have decreased by 5.5% among adolescents in the last 8 years alone, with only 21.1% of Black youth, 20.9% of Hispanic youth, and 25.6% of White youth engaging in at least 1 hour of moderate to vigorous physical activity (MVPA) per day in 2019 [4].

Evidence suggests that sports participation is associated with increased physical activity [5,6]. Therefore, playing sports outside of school hours is a promising strategy for physical activity interventions. However, sports participation differs by race, ethnicity, gender, and socioeconomic status [7,8]. Racial and ethnic minority students, as well as those who are socioeconomically disadvantaged, have lower rates of participation in sports [7]. Adolescent girls also participate less in sports teams than adolescent boys [8]. To increase participation, middle schoolers recommend that programming should incorporate a variety of sports in noncompetitive environments [9].

A barrier to sports participation is lacking the skills to be able to have fun and enjoy playing sports [10]. The "motivation, confidence, physical competence, knowledge, and understanding to value and take responsibility for engagement in physical activities for life" are determinants of physical literacy [11]. Physical literacy is increasingly recognized as a core construct in physical activity interventions and sports programming [12-14]. Overall, children have low levels of physical literacy, with 85% demonstrating inadequate levels [15]. Little is known about the relationship between physical literacy and long-term health outcomes, but emerging evidence suggests that physical literacy is related to physical activity levels and other health outcomes [16]. Although there has been a robust scientific conversation around the concept of physical literacy, more research is needed to explore relationships among physical literacy, physical activity, and health outcomes [17].

Sport sampling interventions may be a potential mechanism for increasing physical activity and physical literacy among youth. However, to date, a school-based, culturally tailored, participant-informed sport sampling intervention has not been evaluated for effectiveness. Therefore, the purpose of this study was to examine the effectiveness of an after-school, culturally tailored, participant-informed sport sampling program on physical activity, physical literacy, and BMI among underserved racial and ethnic minority youth in the Midwest.

Methods

Study Design, Settings, and Participants

The *Move More, Get More* study was conducted as a 2-group, posttest-only study. A total of 3 middle schools with grades 6 to 8 in the Kansas City Public School District (KCPS) participated in this study. All participating schools were public, but one was classified as a KCPS signature school that focuses on college preparation. All students at the three schools were eligible to participate in the intervention. Schools were recruited through the school district and identified as schools in the most need of programming to increase physical activity. The KCPS is the 12th largest school district in Missouri and primarily serves ethnic minority, low-income, and inner-city youth [18]. Over 36 languages are spoken in the schools, with 22% of students receiving English language learner services. All students qualify for free lunches or lunches at reduced costs [18]. Due to the nature of this study, we were unable to collect baseline physical activity data because students began the intervention on the day that they were provided with accelerometers. Therefore, we used end point assessments to compare the intervention group to the control group.

Ethics Approval

All procedures of this study were approved by the University of Missouri-Kansas City Institutional Review Board (protocol number: 2017528).

Intervention

The intervention aimed to increase the overall physical activity levels of middle school youth. Each school had a minimum of 2 trained sport instructors for leading after-school sport sampling sessions. Youth were not separated by gender, and youth only attended activities at their school. Table 1 shows the activities provided. The activities included equipment-based sports (basketball, soccer, football, etc), dance, yoga, and team-based games. The activities were selected and adapted based on student interest, culture, available facilities, instructor expertise, and available equipment. Sessions were held in a variety of settings at the school, including outdoor fields, indoor gymnasiums, hallways, and classrooms. Session locations varied depending on weather conditions and availability, which was based on other after-school programming.

The dose of the intervention was adapted for each school based on the schools' release times and bus schedules. The first school hosted two 1-hour sessions each week. The second school hosted three 1-hour sessions each week. The third school hosted three 2-hour sessions each week. After-school sessions were held from September 2021 through May 2022 and aligned with the KCPS academic calendar. No COVID-19 restrictions (eg, social distancing), other than masking, were imposed by schools or public health agencies. Masking requirements ended in March 2022.

Table 1. Activities by school.

Study week	School 1 activities	School 2 activities	School 3 activities
1	Basketball	Basketball	Basketball
2	Basketball	Basketball and flag football	Basketball
3	Flag football	Basketball and flag football	Flag football
4	Flag football	Basketball	Flag football
5	Soccer	Dodgeball and basketball	Softball and baseball
6	Soccer	Basketball	Basketball
7	Capture the flag	Kickball	Yoga and aerobics
8	Games (red light, green light; shark and minnows; and tag)	Basketball	Yoga and aerobics
9	Games (red light, green light; shark and minnows; and tag)	Basketball	Frisbee, jump rope, and dance
10	Dodgeball and soccer	Flag football and kickball	Frisbee, jump rope, and dance
11	Games (red light, green light; shark and minnows; and tag)	Lacrosse and kickball	Soccer, frisbee, and dance
12	Mini-competition of basketball, soccer, football, and frisbee	Lacrosse and kickball	Soccer, frisbee, and dance
13	Mini-competition of basketball, soccer, football, and frisbee	Yoga, jump rope, and dodgeball	Free play
14	Canceled by school	Canceled by school	Canceled by school
15	Jump rope	Indoor games and trashball	Canceled by school
16	Jump rope and jump rope games	Indoor games and trashball	Aerobics, dance, and yoga
17	Basketball	Soccer	Aerobics, dance, and yoga
18	Basketball	Soccer	Jump rope and jump rope games
19	Flag football and basketball	Basketball	Kickball and basketball
20	Flag football	Basketball	Relay races
21	Basketball	Flag football	Basketball
22	Basketball and kickball	Flag football	Basketball
23	Circuit training and basketball	Badminton	Soccer and handball
24	Soccer	Volleyball	Soccer and handball
25	Soccer	Volleyball	Olympics week
26	Kickball	Kickball	Olympics week
27	Kickball	Kickball	Football
28	Ultimate frisbee	Ultimate frisbee	Football
29	Ultimate frisbee or dodgeball	Ultimate frisbee	Dodgeball and volleyball
30	Free play or review of sports	Free play or review of sports	Dodgeball and volleyball
31	Free play or review of sports	Free play or review of sports	Free play or review of sports

Recruitment and Enrollment

Participants were recruited in August and September 2021 during multiple school events, such as the district enrollment fair, school lunches, and parent-teacher conferences. Parents provided written consent for students to participate in this study. Students also provided written and verbal assent before participating in this study. Participants completed a web-based questionnaire and an objective physical literacy assessment at baseline.

Incentives

Participants received a US $25 gift card upon completion of their enrollment and follow-up data collection. A Garmin Vivofit 4 (Garmin Ltd) was provided as an incentive at baseline. Participants were also entered into a raffle giveaway for a US $150 gift card.

Measures

Physical Activity

Physical activity was assessed with Garmin Vivofit 4 accelerometers throughout the study period. Daily steps and active minutes data were aggregated at the week level. To account for nonwear days, a daily mean was calculated based on a given week. Detailed accelerometer procedures can be found in the previously published protocol [19]. Similar accelerometer procedures were used in previous studies [20].

Physical Literacy

Physical literacy was assessed objectively by trained research assistants using the PLAYbasic instrument [21]. PLAYbasic assesses the physical abilities of participants in the following four domains: locomotor, throwing, kicking, and balance. Research staff set up a course in a school gymnasium where participants were asked to perform the following five tasks: (1) run to a cone approximately 5 m away, turn around, and run back to the starting point; (2) hop to the same cone on 1 leg and hop back to the starting point; (3) throw a tennis ball overhand to a wall 1.5 m away and have it bounce back over their head; (4) kick a ball to a wall 4 m away over a line 1 m from the ground; and (5) walk toe-to-heel in a straight line for 2 m. The tasks were assessed on a scale ranging from 1 to 100, with 0 to 25 representing *initial ranking*, 25 to 50 representing *emerging*, 50 to 75 representing *competent*, and 75 to 100 representing *proficient*. Final scores were calculated by adding section totals to obtain a total score and then dividing by 5, according to the scale's instructions [21].

BMI Assessment

Height and weight were assessed objectively by trained research staff using a validated scale [22] and stadiometer [23]. BMIs were calculated with the following formula:

$$\text{BMI} = \text{weight (kg)}/\text{height (m)}^2$$

Demographics

Age, race, ethnicity, and sex were assessed by using questions from the Youth Risk Behavior Surveillance System [1].

Statistical Analysis

Univariate statistics were conducted for all study variables. Chi-square difference tests were conducted on demographic variables between groups. Mean difference scores for each outcome variable were calculated. A series of 2-tailed *t* tests were conducted to assess between-group differences. All analyses were conducted in SPSS (IBM Corp) [24]. An α level of 95% was used for all analyses. All self-report data were collected in Qualtrics (Qualtrics International Inc) [25]. Accelerometry data were collected from the Garmin application programming interface.

Results

Of the 179 intervention youths that initially consented to participating in this study, 42 were excluded, and 56 were lost to follow-up, resulting in 81 intervention youths being included in the analyses. Of the 50 control youths that initially consented to participating in this study, 15 were lost to follow-up, resulting in 35 control youths being included in the analyses (Figure 1).

Table 2 presents demographic information on the intervention and control participants. In the intervention group, participants were aged 13.4 (SD 1.0) years and distributed among the sixth (31/81, 38%), seventh (26/81, 32%), and eighth (24/81, 30%) grades. Further, 64.2% (52/81) reported being male, 76.5% (62/81) reported being African American or Black, 15% (12/81) reported being Hispanic or Latinx, and 19% (15/81) reported being White. In the control group, participants were aged 13.8 (SD 0.97) years, and more participants were in the eighth grade, with 11% (4/35), 31% (11/35), and 57% (20/35) in grades 6, 7, and 8, respectively. Moreover, 49% (17/35) reported being male, 51% (18/35) reported being African American or Black, 9% (3/35) reported being Hispanic or Latinx, and 11% (4/35) reported being White.

Chi-square difference tests were conducted for all categorial variables to understand if there was a difference in demographic variables between the intervention and control groups. There were no significant differences among demographic variables between groups.

Table 3 presents differences in BMIs, physical literacy, and accelerometry-measured physical activity between the intervention and control groups. The mean BMI was 23.37 (SD 5.91) kg/m^2 for intervention participants and 25.19 (SD 7.10) kg/m^2 for control participants. The small difference in BMIs between groups was not statistically significant (t_{115}=1.41; P=.90).

Physical literacy was statistically different between the intervention and control groups (t_{115}=7.57; P=.004). Participants in the intervention group had an average physical literacy score of 75.62 (SD 14.13), indicating a proficient ranking, while the participants in the control group had an average physical literacy score of 50.71 (SD 19.73), indicating a competent ranking. The mean difference in physical literacy between groups was 24.91 on the 100-point scale.

Minutes per week of MVPA (t_{115}=4.28; P=.04) and steps per day (t_{115}=4.29; P=.03) were statistically different between groups. On average, participants in the intervention group engaged in 107.01 (SD 34.94) minutes of MVPA per week and 10,847.11 (SD 3758.33) steps per day. Participants in the control group engaged in 53.01 (SD 11.17) minutes of MVPA per week and 5030.09 (SD 1128.24) steps per day. The mean differences between groups were 53.99 minutes of MVPA per week and 5817.01 steps per day.

Figure 1. Flowchart of participants in this study.

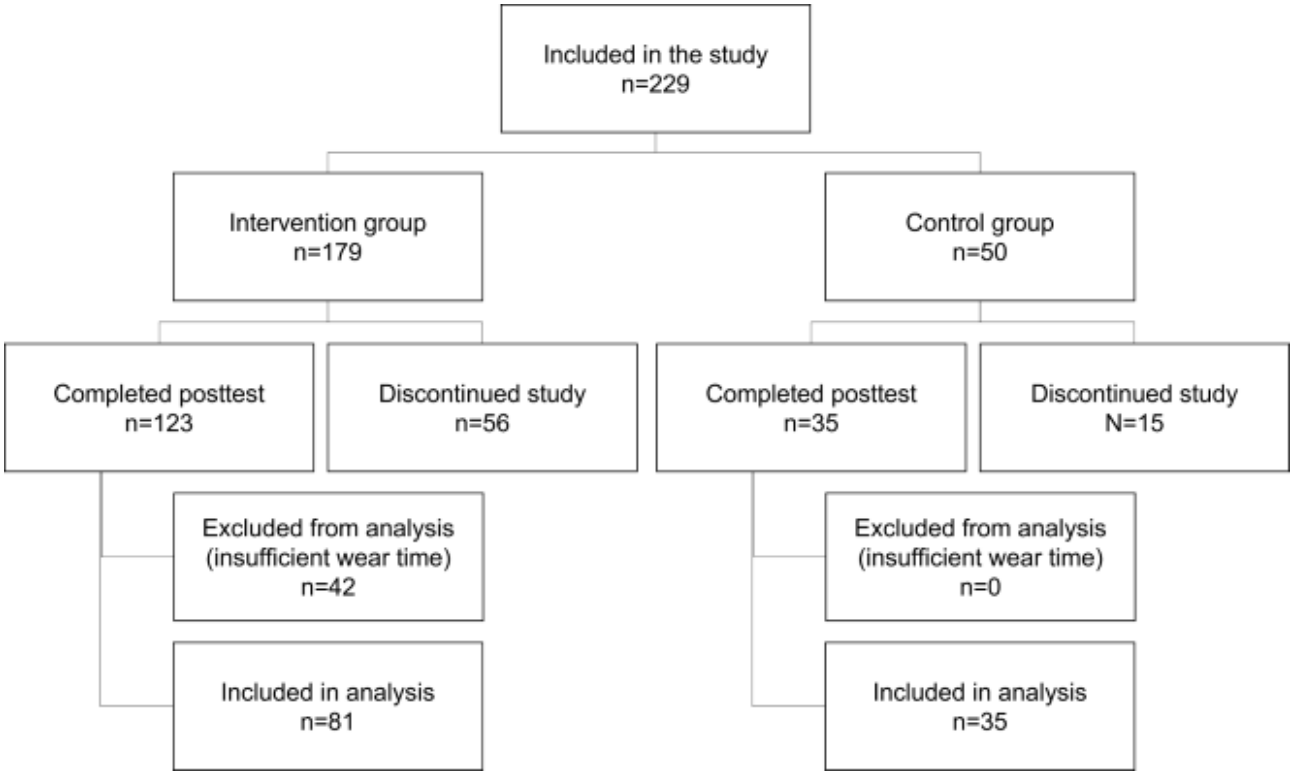

Table 2. End point univariate statistics.

Characteristic	Intervention group (n=81)	Control group (n=35)	Chi-square (*df*)	*P* value
Age (years), mean (SD)	13.4 (1.0)	13.8 (0.97)	7.61 (115)	.11
Grade in school, n (%)			3.06 (115)	.22
Sixth grade	31 (38)	4 (11)		
Seventh grade	26 (32)	11 (31)		
Eighth grade	24 (30)	20 (57)		
Sex, n (%)			1.95 (115)	.38
Male	52 (64)	17 (49)		
Female	28 (35)	18 (51)		
Prefer not to say	1 (1.2)	0 (0)		
Race[a], n (%)			15.63 (115)	.11
African American or Black	62 (77)	18 (51)		
Hispanic or Latinx	12 (15)	3 (9)		
White, Non-Hispanic	15 (19)	4 (11)		
Asian	5 (6)	1 (3)		
Native Hawaiian or Other Pacific Islander	3 (4)	0 (0)		
American Indian or Alaska Native	3 (4)	4 (11)		

[a]Participants were able to choose multiple racial categories.

Table 3. Differences between the intervention and control groups.

Outcome	Intervention group, mean (SD)	Control group, mean (SD)	Mean difference (95% CI)	*t* test (*df*)	*P* value
BMI (kg/m^2)	23.37 (5.91)	25.19 (7.10)	1.82 (−4.60 to 0.96)	1.41 (115)	.90
Physical literacy score	75.62 (14.13)	50.71 (19.73)	24.91 (18.39 to 31.43)	7.57 (115)	.004
Moderate to vigorous physical activity (minutes per week)	107.01 (34.94)	53.01 (11.17)	53.99 (28.45 to 79.54)	4.28 (115)	.04
Steps per day	10,847.11 (3758.33)	5030.09 (1128.24)	5817.01 (3073.15 to 8560.88)	4.29 (115)	.03

Discussion

The purpose of this study was to examine the potential effectiveness of an after-school sport sampling program on physical activity, physical literacy, and BMI among underserved racial and ethnic minority youth in the Midwest. Overall, intervention participants had significantly higher physical literacy scores (*P*=.004) and engaged in more MVPA (*P*=.04) and steps (*P*=.03) than youth in the control group after the intervention. This study aids in the understanding of physical activity for youth in a large, urban Midwest city and provides some evidence that a participant-informed, culturally tailored sport sampling intervention may be a mechanism for increasing physical activity and physical literacy among youth.

This study observed significant differences in MVPA between the intervention and control groups. This difference is consistent with past research that found that after-school programming is an effective strategy for increasing physical activity [26,27]. This study also adds important evidence on the use of sport sampling interventions to potentially reduce health inequality for Black and Hispanic youth.

Move More, Get More allowed youth to provide input on which sports they wanted to learn and practice. By incorporating youths' preferences for which sports they want to engage in, we are potentially better able to maintain their interest in sports and physical activity. Future research should empirically examine if this participant-led approach results in maintained engagement in sports and physical activity for the long-term.

Physical literacy was significantly better in the intervention group compared to that in the control group (*P*=.004), indicating that a sport sampling intervention may be a good strategy for increasing physical literacy. Rajabiyan and Talebi [28] similarly found that an intervention of selected sports was effective in improving physical literacy. More broadly, a recent systematic review found that physical literacy–related interventions can be successful [29]. Evidence supports that physical literacy is associated with physical activity [17] and is believed to contribute to lifelong physical activity [16]. Future research should examine the long-term impacts of physical activity interventions on physical literacy and related health outcomes.

Unexpectedly, there was no significant difference in BMIs between youth in the intervention group and youth in the control group at posttest (*P*=.90). The Centers for Disease Control and Prevention recommend increasing BMI cutoff points for youth until the age of 20 years [30]. Although increases in BMI are usually indicative of poorer health behaviors, as middle school students grow and mature, increases in BMI may be an expected part of normal development. Future studies may consider alternative measures to assess body composition for this age group.

There are several strengths to this study. First, this study was conducted in an urban environment where 100% of the school districts' students qualify for free lunches or lunches at reduced costs and schools serve predominantly racial and ethnic minority individuals. Second, this study adds to the limited research on the effectiveness of sport sampling interventions on physical literacy and physical activity. Additionally, this study assessed physical activity via accelerometry and objectively measured physical literacy and BMIs by using reliable and validated tools.

This study however relies on a posttest-only design that may contribute to type 2 error. A posttest-only design is one way to assess differences among groups while also delivering a needed intervention for underserved populations. Although not ideal, several physical activity studies have used a posttest-only design to increase the external reliability of real-world interventions [31-33].

Over 10 million youths participate annually in after-school programming [26]. These programs have the potential to provide a unique opportunity to help millions of youths become more active and improve MVPA. Although limited, our study and other evidence suggest that after-school sport sampling interventions are effective strategies for increasing physical literacy and physical activity among underserved racial and ethnic minority youth. Future research needs to be conducted on the best way to scale such interventions to board populations of youth to improve physical activity, physical literacy, and health equity.

Acknowledgments

We would like to thank our many community partners that assisted with this study, including University Health's Mobile Market; Mattie Rhodes Centers; Kansas City Parks and Recreation; Kansas City Public Schools; Children's Mercy Hospital (Shelly Summar, Dr Jordan Carlson, Dr Robin Shook, and Dr Emily Hurley); and the team of undergraduate researchers at the University

of Missouri, Kansas City (Niveen Al-Saoudi, Victor Arellano, Macy Hornosky, Tra Statler, Maya Baughn, Denise Dean, and Cynthea Thompson).

Authors' Contributions

JL and AG are joint senior authors. KE and EV are joint junior authors who assisted in the data collection, analysis, and writing of this manuscript. BW led the data collection and project implementation.

Conflicts of Interest

None declared.

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Abbreviations

KCPS: Kansas City Public School District
MVPA: moderate to vigorous physical activity

Edited by S Badawy, G Eysenbach; submitted 30.08.22; peer-reviewed by A Chwałczyńska, M Kapsetaki; comments to author 10.09.22; revised version received 18.10.22; accepted 10.01.23; published 25.01.23.

Please cite as:
Lightner J, Eighmy K, Valleroy E, Wray B, Grimes A
The Effectiveness of an After-school Sport Sampling Intervention on Urban Middle School Youth in the Midwest: Posttest-Only Study
JMIR Pediatr Parent 2023;6:e42265
URL: https://pediatrics.jmir.org/2023/1/e42265
doi:10.2196/42265
PMID:36696161

Original Paper

Supporting Children's Social Connection and Well-Being in School-Age Care: Mixed Methods Evaluation of the Connect, Promote, and Protect Program

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Abstract

Background: School-age care, such as outside school hours care (OSHC), is the fastest-growing childhood education sector in Australia. OSHC provides a unique opportunity to deliver programs to enhance primary school–age children's social, emotional, physical, and cognitive well-being.

Objective: This study aimed to pilot the co-designed Connect, Promote, and Protect Program (CP3) and conduct formative and process evaluations on how well the CP3 achieved its intended aims, ascertain areas for improvement, and determine how the CP3 model could be better sustained and extended into OSHC settings.

Methods: A naturalistic formative and process evaluation of the CP3 implementation was undertaken at 1 and then 5 OSHC sites. Qualitative and quantitative feedback from stakeholders (eg, children, OSHC educators, volunteers, and families) was collected and incorporated iteratively for program improvement.

Results: The formative and process evaluations demonstrated high program engagement, appropriateness, and acceptability. Co-design with children was viewed as highly acceptable and empowered children to be part of the decision-making in OSHC. Feedback highlighted how the CP3 supported children in the 4 CP3 domains: Build Well-being and Resilience, Broaden Horizons, Inspire and Engage, and Connect Communities. Qualitative reports suggested that children's well-being and resilience were indirectly supported through the Broaden Horizons, Inspire and Engage, and Connect Communities CP3 principles. Matched-sample 2-tailed *t* tests found that children's prosocial behaviors increased (mean difference=0.64; *P*=.04; t_{57}=−2.06, 95% CI −1.36 to −0.02) and peer problems decreased (mean difference=−0.69; *P*=.01; t_{57}=2.57, 95% CI 0.14-1.13) after participating in the CP3. Program feasibility was high but dependent on additional resources and CP3 coordinator support.

Conclusions: To our knowledge, the CP3 is the first co-designed well-being program developed and evaluated specifically for OSHC services. This early evidence is promising. The CP3 may provide a unique opportunity to respond to the voices of children in OSHC and those that support them through creative and engaging co-designed activities. Our research suggests that CP3 provides OSHC with a framework and high-quality program planning tool that promotes tailored interventions developed based on the unique needs and preferences of those who will use them.

(JMIR Pediatr Parent 2023;6:e44928) doi:10.2196/44928

KEYWORDS

participatory design; evaluation; children; school-age care; after-school care; health; well-being; program development; community consultation

Introduction

Background

Approximately, 1 in 5 primary school–age children in Australia are vulnerable to developmental delay, which can affect well-being (social, emotional, and physical), language, and cognitive skills [1]. Furthermore, the second Australian Child and Adolescent Survey of Mental Health and Wellbeing (Young Minds Matter) found that, among primary school students, an estimated 18.2% of boys and 12.4% of girls had experienced a mental health–related disorder in the previous 12 months [2]. To address childhood vulnerability, the Organization for Economic Co-operation and Development [3,4] calls for increasing focus on child well-being programs and optimizing educational environments. A critical strategy includes harnessing existing educational structures and broadening the scope of educational curricula to target children's health and well-being. Importantly, this includes delivering programs not only during formal school hours but also in school-age care, which encompasses outside school hours care (OSHC), before- and after-school care, vacation care, and leisure-time centers [3].

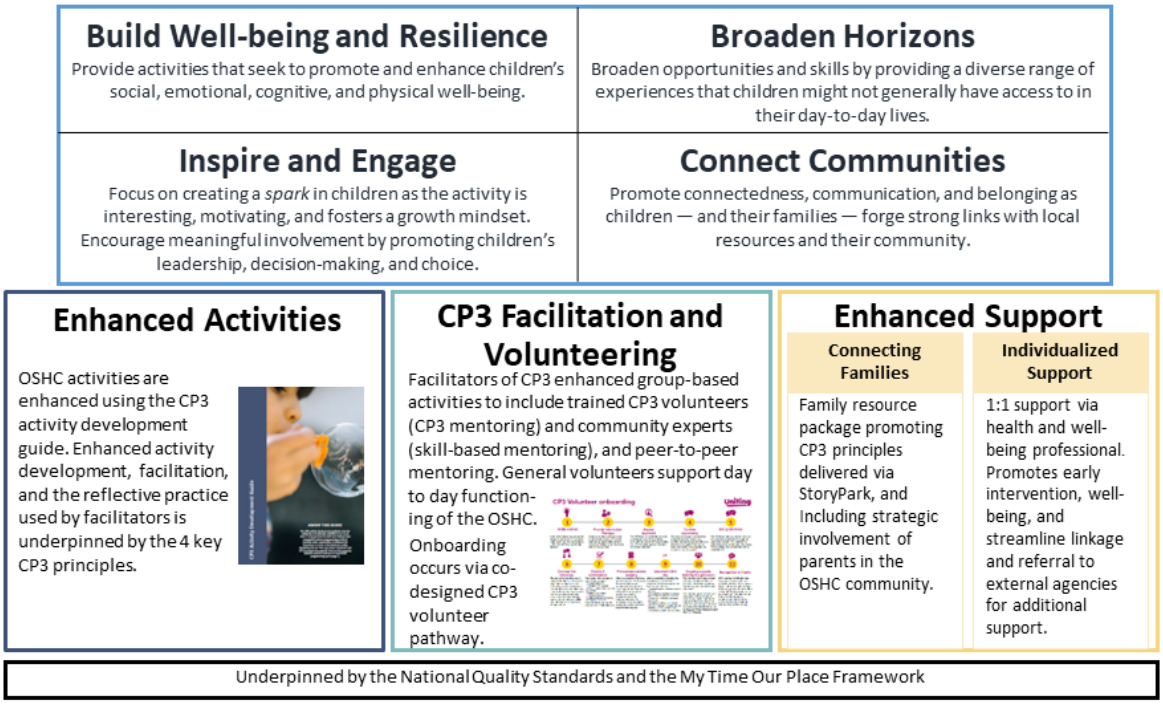
School-age care, such as OSHC, is the fastest-growing childhood education and care sector in Australia [5]. In 2020, the Productivity Commission reported 5000 OSHC sites supporting 460,000 Australian children. OSHC services offer a secure and supervised environment for primary school–age children before and after school, generally for 2 to 3 hours a day during the school term [6], and offer vacation care during school holidays. In Australia, school-age care services can be provided in schools or community facilities by for-profit and not-for-profit organizations and are regulated by the National Quality Framework and National Quality Standard of the Australian Children's Education and Care Quality Authority (ACECQA) [7,8]. School-age care services such as OSHC provide an essential service for many families by enabling parents and primary caregivers to achieve a balance between childcare, social responsibilities, and work beyond regular school hours [9]. However, a recent New South Wales (NSW) Department of Education review reported that the standard of well-being–focused initiatives in the OSHC sector needed improvement [5]. The review's recommendations called for OSHC sites to extend beyond providing "convenient care" [5] and, instead, be a place where children's well-being is actively supported. Indeed, OSHC offers a unique opportunity to implement prevention and early intervention programs designed to multidimensionally enhance children's health and well-being [10].

As such, there has been increased attention from researchers, educators, the government, and the broader community toward how specific well-being–focused programs delivered during OSHC could be better used to support children's learning and growth. Such programs need to be researched, and the OSHC community should be an active research partner [5], through co-design. This is important as OSHC services differ considerably in geography, community context, educator expertise, and the number and characteristics of the children who attend. Programs that are suitable for one OSHC service may not be feasible or appropriate for another [6].

The only known well-being–focused OSHC program that has been developed in Australia through the use of co-design is the Connect, Promote, and Protect Program (CP3) [6]. Co-design, also known as participatory design, places stakeholders at the center of the design process [11,12]. It enables a paradigm shift toward collaborative bottom-up engagement whereby stakeholders (eg, OSHC children, educators and volunteers, and parents or guardians) jointly explore and create solutions for program design and service delivery [6]. Essentially, participatory design allows programs to be co-designed with the people who use them.

CP3 is a structured method for co-designed OSHC activity program development and delivery. It provides opportunities for social connection, child leadership, and engagement and delivers activities that broaden children's experiences, opportunities, and well-being. As shown in the CP3 model (Figure 1) and discussed in previous co-design research [6], the CP3 has four guiding programming principles: (1) Build Well-being and Resilience, (2) Broaden Horizons, (3) Inspire and Engage, and (4) Connect Communities. CP3 is the only cited example of co-designed research in the OSHC space in the Department of Education review of OSHC services [5].

Figure 1. Connect, Promote, and Protect Program (CP3) model. OSHC: outside school hours care.



Objectives

This study reports on the formative and process evaluation of the CP3 model through a partnership between the University of Sydney's Brain and Mind Centre (an Australian multidisciplinary research institute focusing on conditions that affect child development, youth mental health, and brain aging) and Uniting (formally Uniting Care NSW.ACT, a large provider of children's services, including before- and after-school care, vacation care, occasional care, long-day care, and preschool in NSW, Australia). The main objective of this study was to pilot the co-designed CP3 in real-world school-age care services to conduct a formative and subsequent process evaluation. The purpose of the evaluation was to establish how well the CP3 achieved its intended aims, ascertain areas for improvement, and determine how the CP3 model could be better sustained and extended to OSHC settings. Therefore, the research questions were as follows: (1) How well did the CP3 achieve its intended aims in terms of engagement, appropriateness, acceptability, feasibility, and preliminary effectiveness? and (2) What were the barriers, facilitators, and areas for improvement regarding CP3 implementation to inform future program delivery?

Methods

Ethics Approval and Compliance With Ethical Standards

This study was approved by the University of Sydney Human Research Ethics Committee (protocol 2018/832). All procedures were performed in accordance with the with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. All data, including the images and figures in this publication, are presented in nonidentifiable formats.

Study Design

This study was a naturalistic formative evaluation and subsequent process evaluation of the CP3 model in OSHC services. The CP3 model was developed with local stakeholders in 2017 using participatory design and is reported elsewhere [6]. A mixed methods evaluation was used in this study, including the collection, analysis, and interpretation of quantitative and qualitative data [13]. The overarching CP3 research is based on the Medical Research Council guidelines for developing complex interventions [14], which use an iterative research design cycle of development, feasibility, evaluation, and implementation.

Participants and Setting

In both the formative and process evaluations, participants comprised three stakeholder groups: (1) children attending OSHC, (2) OSHC volunteers (ie, CP3 principle mentors and CP3 skilled mentors, defined in the *CP3 Roles* section) or educators (including managers), and (3) parents or guardians of children attending OSHC. The inclusion criteria were (1) being identified as belonging to one of the stakeholder groups, (2) ability to participate in English, and (3) the provision of written informed consent to participate. For a child to participate in any evaluation, both parental or guardian and child written consent were obtained. For the formative evaluation, participants were both children and adults recruited from an OSHC site in the Illawarra region of NSW, Australia, between July 2019 and June 2020. For the subsequent process evaluation, participants were both children and adults recruited from 5 OSHC sites in

the Sydney region of NSW, Australia. The CP3 was implemented at these sites in 2020 (term 4) and 2021 (term 2) over a 10-week period.

CP3 Roles

There are multiple CP3 roles andCP3 personnel who support CP3 delivery, and they will be discussed throughout the reporting of the evaluation findings. This includes the roles outlined in Textbox 1.

Textbox 1. The roles in the Connect, Promote, and Protect Program (CP3).

CP3 coordinator

- This is the overarching coordinator of the CP3, who supports sites implementing the CP3 through resourcing, training, activity planning, delivery, and evaluation.

CP3 site champion

- This is the nominated educator who is responsible at a site level for supporting CP3 delivery.

CP3 skilled mentors

- Skilled mentoring complements the range of activities that can be provided as part of the CP3. These champions are mentors with specialized skills that can facilitate activities in their areas of expertise—whether it be movie making, martial arts, or community advocacy. Depending on their availability, skilled mentors can help facilitate one-off sessional activities or a full CP3 activity program or they may simply offer outside school hours care (OSHC) sites the use of specialized resources.

CP3 principle mentors

- These mentors are trained in and have an in-depth understanding of the

  CP3 principles

  (ie, Build Well-being and Resilience, Broaden Horizons, Inspire and Engage, and Connect Communities). Their role is to support the CP3 activities each week to ensure that the CP3 principles are being delivered in each session.

CP3 peer champions

- These are children attending OSHC sites who are particularly interested in the CP3. These peer champions can play a variety of roles depending on the OSHC. For example, they might lead CP3 announcements in the OSHC community meetings or buddy up with other children who might need additional support during CP3 workshops or CP3 activities.

Recruitment and Informed Consent

Electronic and paper-based advertising materials were used to notify potential participants (as well as students' parents or guardians) of the study. Recruitment was passive so that participants (or their parents or guardians) initially volunteered by contacting researchers to participate, or they could directly take part by completing the survey (paper-based or web-based depending on participant preference). After parental consent was obtained, children went through a consent and a subsequent assent process immediately before the activity. All individuals completed an informed consent process before participating in this research. All participants were reassured of the voluntary nature of participation and that they could stop at any time. Participants did not receive any compensation or reward for taking part in the research; however, all workshops were catered.

Outcomes

For the formative evaluation, a survey collected details such as gender, age, postcode, language spoken at home (children only), year at school (children only), relationship with OSHC site (adults only), satisfaction with the OSHC service, social connectedness (measured using the 1-item Inclusion of Community in Self scale [15]), and quality of life (measured using the Personal Wellbeing Index [16,17]). For the process evaluation, the primary outcome was measured using changes in Strengths and Difficulties Questionnaire (SDQ) [18] scores from baseline to the end of the CP3. The SDQ was already used by OSHC educators for routine monitoring and, thus, aligned with naturalistic service delivery and minimized additional administrative burden. The SDQ is a 25-item behavioral screening questionnaire with 5 scales (emotional symptoms, conduct problems, hyperactivity or inattention, peer relationship problems, and prosocial behaviors). The SDQ has sound psychometric properties in Australian samples of children (aged 4-9 years) [19]. Demographic details such as child gender and age were also available from OSHC routine data monitoring. For both stages of the evaluation, qualitative data related to CP3 acceptability and feasibility were gathered through surveys, participatory design workshops, and routine data outcome monitoring interviews.

Data Analysis

Qualitative

Qualitative data sources and artifacts from participatory design workshops and interviews included detailed notes from workshops by the research team, deidentified transcription notes from routine data outcome monitoring, and notes written by participants on handouts and worksheets. Qualitative data were analyzed using a six-step qualitative thematic analysis [20]: (1) data familiarization; (2) generating initial codes; (3) searching for themes and subthemes; (4) reviewing themes; (5) refining, defining, and naming themes; and (6) report writing. This

stepwise process provides a flexible and accessible way of analyzing qualitative data and enables iterative exploration of patterns and relationships between different themes while ensuring research rigor. All qualitative data sources from the workshops and interviews were reviewed by 3 researchers (KB, ZM, and AM), who noted relevant points and key concepts across all participants to develop an initial coding framework. The pattern of themes generated from the data was mapped back to the CP3 principles (Build Well-being and Resilience, Broaden Horizons, Inspire and Engage, and Connect Communities), program satisfaction, program challenges, and educator and volunteer outcomes. This became the framework matrix used for coding the data [21]. Notes were then coded in the NVivo software (version 11; QSR International) [22] using this framework by 2 researchers per transcript (SH and LBR), and any discrepancies were discussed with a third researcher (AM). Coding followed an iterative process of reading, coding, and discussing the pattern and content of the coded data.

Quantitative

Owing to the small number of participants in the formative evaluation, statistical analysis of the quantitative data generated from the child and adult evaluation surveys was descriptive only. For the process evaluation, SDQ scores from routine data outcome monitoring were used. SDQ scores from scales 1 to 4 were added to obtain a total difficulties score. The SDQ recommends a four-fold classification: (1) close to average, (2) slightly raised or lowered, (3) high or low, and (4) very high or very low. Analysis of SDQ data was performed using SPSS (version 28; IBM Corp). Participant data were matched across baseline and follow-up data. After a 1-sample *t* test (2-tailed) was performed to ensure that there was no difference between the matched and full sample in baseline emotional and behavioral difficulties SDQ scores, a matched-sample *t* test was performed to analyze the mean difference (MD) between baseline and follow-up scores. The post hoc calculation for the matched sample indicated that we could detect a small to medium effect size (0.38) at 80% power (2-tailed; Cronbach α=.05) with the achieved sample (n=58).

Results

Formative Evaluation

Implementation Phases

The CP3 model and implementation process (stages 1 to 3) were tested during the formative evaluation.

Stage 1: Consult and Create

During the first school term, CP3 implementation commenced with initial community consultation to provide information about the CP3 and obtain an early understanding of the needs and wants of the OSHC community. This was followed by CP3 training and participatory design workshops with educators or volunteers (n=6 in 1 workshop) and then 90-minute participatory design workshops with a proportion of the OSHC children (n=16 in 3 workshops) who had parental consent to co-design the CP3 activities for planned delivery. These were facilitated by a psychologist with support from the CP3 site champion (an OSHC educator) and the CP3 coordinator, who took detailed session notes. The main purpose of the child workshops was to engage children in decision-making and planning for the upcoming CP3 enhanced activities. This consisted of four stages: (1) discovery: exploring the children's activity interests; (2) evaluation: understanding children's preferences for the different enhanced activity ideas that had been cocreated in previous workshops with children and educators; (3) mapping: obtaining further information on how children think the activities are linked to the 4 CP3 principles; and (4) prototyping: encouraging children to cocreate their own CP3 activity. The outcome of the *consult and create* phase was 3 activities focusing on promoting physical activity, creative pursuits, and skill development, which were further enhanced by educators and children during the participatory design sessions to align with the CP3 principles. An example activity is provided in Textbox 2.

Textbox 2. Example activity.

Example

- A popular activity co-designed in the *consult and create* stage that was highly acceptable to children was Woodwork Café. Regarding Connect, Promote, and Protect Program principles, children envisioned that the activity would make them feel connected to their families as it was an activity they could do with them; children could give (or sell) the things they built to others in the community (*Connect Communities*); the activity could be a cognitive challenge for their brain and fun and, therefore, make them happy (*Build Well-being and Resilience*); and the activity would be exciting and fun to do (*Inspire and Engage*) and allow them to build things they had not made before and use their imaginations (*Broaden Horizons*).

Stage 2: Test and Refine

Ideas generated in the *consult and create* phase were actively applied via a taste-tester program. All the children attending the OSHC site were able to participate in this program during the second school term. Multiple co-designed activities generated in stage 1 (Woodwork Café, Movie Maker, Get Active, and Art Space; Textbox 3) were tested, and feedback from children, volunteers, educators, and families was collected.

Textbox 3. Connect, Promote, and Protect Program (CP3) implementation stages.

Stage 1: activities co-designed by children and educators—term 1 (Figure 2)

- Woodwork Café: this was a program focused on developing woodworking skills.
- Movie Maker: this was a program focused on script writing, performance, and film production.
- Get Active: this was a program focused on physical activity.
- Art Space: this was a program focused on well-being and creative expression through art.
- Science Sparks: this was a program focused on engaging Science, technology, engineering, mathematics (STEM) activities.
- The Zen Den: this was a program focused on mindfulness and nature.
- Farm to Fork: this was a program focused on gardening and cooking skills.

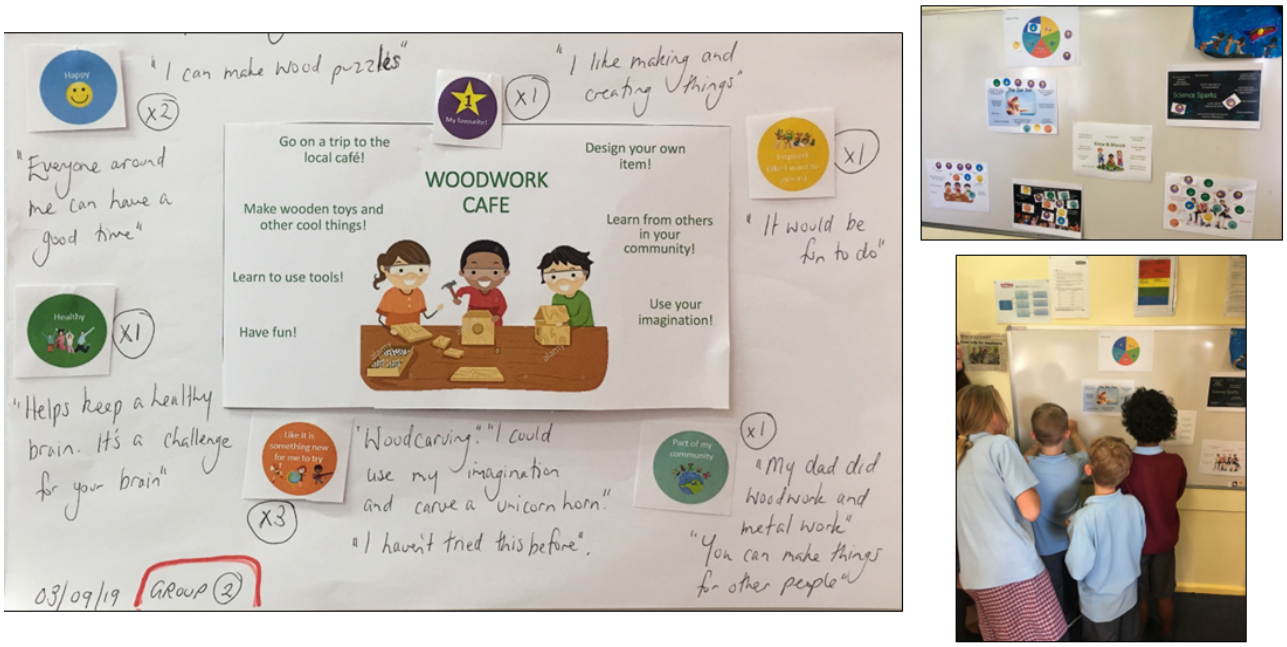
Stage 2: co-designed activities selected and trialed in taste-tester sessions at the outside school hours care (OSHC) site—term 2

- Woodwork Café: volunteers (trained as CP3 principle mentors) supported children to learn to use tools to build 2 go-carts for the OSHC. The children then raced the go-carts in teams at a community event. The program built their planning and communication skills, fine and gross motor skills, and teamwork and community connection.
- Movie Maker: the children taste-tested drama sessions with a volunteer drama teacher (a CP3 skilled mentor) to build their confidence in acting and speaking in public and community links with the local drama school.
- Get Active: the children taste-tested lawn bowls with local volunteers (trained as CP3 principle mentors) at the local community club, building community connection, intergenerational bonds, teamwork, and gross and fine motor skills.
- Art Space: a young local person and artist (CP3 skilled mentor) volunteered to run an art class with the children, and peer-to-peer mentoring also took place with older children (CP3 peer mentors) supporting younger ones. Children worked collaboratively to create an art project that was based on their own choosing for exhibition at the OSHC.

Stage 3: co-designed activities selected and implemented as a full program—term 3

- Woodwork Café was selected by children and educators to continue as a larger program in the final CP3 term. Children, educators, parents, and volunteers collaboratively contributed and co-designed what the program would look like and how it met the CP3 principles. In brief, for this full-term CP3 activity, volunteers (trained as CP3 principle mentors) from the local community supported children in building their own chicken coop at the OSHC site. A volunteer brought a chicken for an OSHC site visit so children could interact with and learn about chickens before baby chickens arrived on-site. Furthermore, an OSHC family provided the CP3 with 2 baby chickens and an incubator to hatch the eggs to live in the coop. Children could engage on the web as well as on-site to see the chickens hatching. The process was documented from beginning to end with updates and photos, which could be shared in paper-based and web-based formats with the OSHC community, enhancing children and their family's engagement and excitement. The co-designed program connected children with their community, broadened their horizons through skill development, and fostered child leadership and well-being. For example:
  - Cognitive well-being: through active collaborative planning—the children actively researched how to care for chickens and the best options for chicken coops.
  - Physical well-being: fine and gross motor skills were developed through learning to use tools.
  - Social well-being: children worked as a team and communicated with each other about the planning and the building of the chicken coop, and intergenerational connections were made with the community volunteers and another local preschool (the children shared resources and ideas about chickens and coops with younger children).
  - Emotional well-being: information about the well-being benefits of animals (eg, companionship, soothing capacity, and happiness promotion) was discussed with children and families verbally and via a web-based communication platform. Well-being resources were shared with families related to strategies for managing anxiety and boosting resilience.

Figure 2. Participatory design artefact—Woodwork Café.



Stage 3: Implement and Evaluate

This last phase involved the implementation and evaluation of a full-length CP3 activity program after incorporating feedback from the *test and refine* phase delivered over a full school term with the full cohort of children attending the OSHC site. In stage 3, the children and educators collaboratively selected which co-designed program they would like to undertake from the taste testers, and they subsequently participated in the third consecutive school term. Examples of the co-design and implementation of the activities over all 3 stages are presented in brief in Textbox 3.

CP3 Formative Evaluation Feedback

Engagement with the CP3 formative evaluation pilot program was high, with educators reporting that most children at the pilot site engaged in the program, including children with additional support needs. Participation rates were an average of 10 to 15 children per session throughout CP3 implementation.

The *appropriateness and acceptability* of the CP3 formative evaluation pilot program were rated as very high based on child, educator, and CP3 volunteer (ie, CP3 principle mentors and CP3 skilled mentors) feedback (demographics are presented in Multimedia Appendix 1). Specifically, the average endorsement by children on CP3 target areas (feeling happy and talking about feelings, staff listening, having fun and making their own choices, and learning and trying new things) across all time points was high—ranging from 84% (16/19) of the children agreeing that they could make their own decisions in OSHC to 100% (22/22) agreeing that the CP3 at the OSHC site was fun.

Table 1 summarizes adult participant endorsement rates (agree to strongly agree) with the CP3 principles demonstrated over the program timeline.

To assess CP3 *feasibility*, workplace-related satisfaction questions were presented to educators and volunteers at time point 3 (Multimedia Appendix 2), and a focus group was run. Volunteers were satisfied or very satisfied with all the items. Educators were satisfied to very satisfied with most items, with paperwork and being part of the decision-making at the OSHC site receiving the lowest satisfaction scores (3/5, 60% of the educators being satisfied or very satisfied). The workshop yielded highly positive feedback on the CP3. Ideas were collated from this to form a CP3 implementation guide for future implementation and the process evaluation at additional OSHC services.

Table 1. Adult participant endorsement rates (agree to strongly agree) with aggregated Connect, Promote, and Protect Program (CP3) principle evaluation items.

CP3 principle	Items	Baseline (before CP3 engagement; n=5), item endorsement rate, n/N (%)	Time point 2 (after CP3 taste-tester activity; n=9), item endorsement rate, n/N (%)	Time point 3 (end of CP3; n=18), item endorsement rate, n/N (%)
Build Well-being and Resilience	• Social well-being • Emotional well-being • Cognitive well-being • Physical well-being • Resilience	20/50 (40)	38/42 (90)	87/90 (97)
Broaden Horizons	• Broaden children's skills • Diverse range of experiences	4/10 (40)	18/18 (100)	35/36 (97)
Inspire and Engage	• Interesting • Motivating • Believing that their skills and talents can grow • Part of the decision-making • Leadership skills	13/25 (52)	39/44 (89)	83/90 (92)
Connect Communities	• Strong links with local resources • Strong links with local community • Connectedness and belonging of children and their families • Communication with children and their families	8/20 (40)	29/35 (85)	65/71 (92)

Process Evaluation

The number of returned SDQs completed by educators for each participating OSHC site is presented in Multimedia Appendix 3. Site 5's follow-up data collection was affected considerably by the COVID-19 lockdown (7/32, 22% completion rate), and site 1 did not collect SDQ data because of workforce capacity issues. The SDQ scores for all participants at all sites are presented in Multimedia Appendix 4.

Of the 88 students who had SDQ data collected at follow-up, 58 (66%) could be matched. A total of 81% (47/58) of these students were female and had a mean age of 7.9 (SD 1.9) years. The baseline total emotional and behavioral difficulties SDQ scores for the matched-sample subset did not differ significantly from those of the full baseline sample in the 1-sample *t* test (8.95 vs 9.08; *P*=.28; t_{89}=1.08, 95% CI −0.09 to 0.32). A matched-sample *t* test analysis of matched students found that prosocial behaviors significantly increased (MD=0.64; *P*=.04; t_{57}=−2.06, 95% CI −1.36 to −0.02) and peer problems significantly decreased (MD=−0.69; *P*=.01; t_{57}=2.57, 95% CI 0.14-1.13) after participating in the CP3 (Table 2). All other changes in SDQ items (emotional symptoms, conduct problems, and hyperactivity) were not statistically significant (all *P*>.05; Table 2).

Table 2. Changes in Strengths and Difficulties Questionnaire items for the matched sample (n=58).

	Mean difference (SD; 95% CI)	*t* test (*df*)	*P* value (2-tailed)
Emotional symptoms	−0.10 (1.71; −0.55 to 0.35)	−0.46 (57)	.65
Conduct problems	0.22 (1.95; −0.29 to 0.74)	0.87 (57)	.39
Hyperactivity	0.38 (2.43; −0.26 to 1.02)	1.19 (57)	.24
Peer problems	0.64 (1.89; 0.14 to 1.13)	2.57 (57)	.01
Prosocial behaviors	−0.69 (2.55; −1.36 to −0.02)	−2.06 (57)	.04

Qualitative Evaluation

Overview

In total, 24 adults provided qualitative evaluation feedback (n=3, 12% parents or guardians; n=2, 8% volunteers; n=15, 62% educators; and n=4, 17% coordinators or managers) in interviews and focus groups. In total, 2 child workshops with 11 children also took place after the CP3 process evaluation. The pattern of themes from the data was mapped back to the original CP3 principles and, therefore, was used in a framework analysis approach alongside reporting program satisfaction, program barriers, and impact on educators and volunteers.

Program Satisfaction

Child Satisfaction

Child satisfaction with the CP3 was very high, with children describing it as a "more fun than normal OSHC day" (child; workshop 2). A number of children recognized that other children also enjoyed the CP3—"when you do this activity everyone is running to do it" (workshop 1)—and expressed a desire for more CP3 activities:

> *I wish I could do CP3 more often.* [Workshop 2]
>
> *...make OSHC better by having more stuff to do like this.* [Workshop 1]

Adult participants echoed that children thoroughly enjoyed and looked forward to OSHC when the CP3 was on, particularly because of differentiation from normal OSHC days:

> *Oh, she loves it very much. She really looks forward to going to it...she enjoys the different activities and she really likes [educator name], and the educators, and she really enjoys spending time with them.* [Parent; P10]

Family Satisfaction

The CP3 was seen as strengthening the relationship between families and OSHC, enabling families to be more involved in decision-making, and increasing awareness of their children's talents and capabilities:

> *It leads to happy parents. Parents are happy to see the different, the new, the challenging activities. Children learning a different sport or a different skill or giving back to the community, which, that feedback gets fed through to the provider, to the service.* [OSHC manager; P7]

Volunteer and Mentor Satisfaction

CP3 volunteers and mentors relayed that they benefited personally, felt proud of what they had achieved, developed new skills, and felt more connected to their community. Volunteering had a ripple effect in the community, where what volunteers taught children was then passed on to others, such as family and friends:

> *For me as a businessman, it was nice to just sort of be out and about in a different world. It broke up the daily activity. I felt like I was making a difference, which is something is important to me. Anyway, obviously I understand the kids probably don't get this access. Because that's why they're doing after school care, I suppose. They're not getting the sporting opportunity. So they're not missing out...at times, like,...giving back in some way, at some point in my life, this was a good engagement for me to see where I'm at as a person, I suppose to start doing that, give back process.* [CP3 volunteer; P24]

Educator Satisfaction

Educators and OSHC coordinators described the CP3 as a highly positive experience as the CP3 was inclusive, unique, innovative, and community-minded. The CP3 supported best-practice program planning and OSHC community engagement and encouraged collaboration and teamwork. The CP3 provided the OSHC with additional resources, equipment, and personnel, which was highly valued. The CP3 principles were reflected in the outcomes for educators personally, which supported their workplace well-being and increased their levels of job satisfaction:

> *I just think it was a great experience...Yeah. I enjoyed it, and I know the kids enjoyed it, so. No, I don't think there's anything much you have to change at all.* [Educator; P11]

Child-Focused CP3 Outcomes

Build Well-being and Resilience

The CP3 was described as supporting and building children's resilience and well-being:

> *CP3 has been good for the children's social, emotional, physical wellbeing. They talk a lot about CP3. They enjoy doing it with their friends.* [Educator; P1]

The CP3 also enhanced well-being indirectly during activities so that children were building skills to support their well-being in a natural and authentic way, including those with underlying challenges or vulnerabilities:

> *...the kids...struggle with...their emotional regulation...initiating play and interacting with each other is really challenging...Robotics and coding program, they were all initiating in play together, sharing their experience...but also working together as a group and learning through play how to connect with each other through their interests.* [OSHC coordinator; P21]

Gaps in regular OSHC delivery were highlighted, and the need to scale programs such as the CP3 was suggested:

> *...there is a definite need and gap in the mental health space for children...I've seen it in children as young as five, trying to end their lives...a program like CP3 provides connection, support, acceptance, all these things, the sense of belonging that these children clearly aren't feeling, and at the age of five that's heart-breaking. And so, I think CP3...captures those children, that everyone else is missing. The schooling system doesn't work for them. For some reason, home life isn't what they want it to be or need it to be. And there's not a lot we can do about that, but we can create a space in an OSHC through CP3 that supports...and engages those children. It gives them a sense of belonging and so that they know that they matter.* [OSHC manager; P7]

Most child feedback did not identify well-being directly but, rather, indirectly from other CP3 principles related to learning new things, social connection, helping others, and having fun.

Broaden Horizons

One of the most consistent themes was that the CP3 broadened the children's experiences by creating opportunities to learn

new skills or expand their knowledge. The CP3 provided a vast range of new experiences as children were "being exposed to things that just generally wouldn't be exposed to" (OSHC manager; P7) and facilitated the engagement of children who did not usually participate in OSHC:

> *The children are excited..."Hey, we're doing this next week." It's supported children in a different sense, where we're seeing children showing us more of their skills...children who don't normally participate in activities...we're actually seeing them participate...* [OSHC coordinator; P2]

The exposure to new activities fostered future hobbies and interests. Child– and community–co-designed CP3 activities ranged from European handball, cooking, Diwali (festival of lights) celebrations, dancing, soccer, build a bear, woodworking, coding and robotics, crafts, gardening, knitting, and visiting a farm. As activities were co-designed by each OSHC community to uniquely meet their own identified needs and goals, "no two services have been the same" (OSHC manager; P7).

Children commented that "I like it because it's different" (workshop 1), "It's different to normal OSHC" (workshop 1), "It means we do new things" (workshop 1), and it "helped me learn how to make things" (workshop 2).

Inspire and Engage

The CP3 principle Inspire and Engage aims to create a "spark" in children with interesting activities that motivate and foster growth mindsets. Meaningful involvement in the CP3 is encouraged by promoting children's leadership, decision-making, and choice:

> *Child engagement has been fantastic. The children have been so excited to tell us what they want to do at their OSHC. Educators are learning from that too...they say, "Oh, I didn't know that they were interested in that." So child engagement and having the child's voice heard has been very successful.* [CP3 coordinator; P4]

Each OSHC site varied in how they engaged children in the CP3 decision-making process. Child-led decision-making processes included "using a voting system which kept activities relevant and maintained children excitement" (educators; P13 and P6), "asking the students what they want to do, [and then] incorporating that into [their] program" (educator; P3), using a book in which children could "write down their ideas," and conducting a survey to decide what activities to do (educator; P8).

An educator highlighted the following:

> *It was an excellent way of looking at things, seeing what they would like to do in a different way than just asking them, "what's your interests?"* [P14]

This made the activities more personally meaningful to the children and resulted in high levels of child engagement and enthusiasm for the CP3. An educator noted that the children selecting the activity and it subsequently being implemented "was a meaningful experience for them because they felt heard" (P13).

Children felt empowered to communicate their opinions:

> *...we've seen children now taking ownership of setting out programs that they want to participate in, really speaking up about what they wanted to do. For example, saying "this is how I feel, I'm not having a turn, I would like more of a turn, or I really want to do this"...We've really seen that change in dynamic of that communication now, what I want to do this in taking the ownership of, "Hey, this is my OSHC. This is the program that I want to do."* [Educator; P17]

Children mostly reflected the Inspire and Engage theme through their enthusiasm for the program, describing it as "...so much fun. Normal OSHC is boring, and school is really boring but CP3 made OSHC a fun thing."

Connect Communities

Connect Communities was the most prominent theme identified in the interviews. Participants said that the CP3 helped build children's relationships and improved their sense of belonging and the way they socialized:

> *They were all initiating in play together, working together as a group and learning through play how to connect with each other through their interests.* [Educator; P18]

> *When they come here to OSHC, it's all together. We're all sitting down, we're all socializing. I think it just brings us all together...and there's a community spirit.* [Educator; P16]

This was especially important for children who struggled with emotional regulation and initiating play with others. Multiple participants highlighted that, instead of solitary or small-group play, CP3 activities encouraged purposeful mingling of larger groups:

> *...this year I can see a change in that child, they are playing in a group now, rather than solitary play.* [Educator; P8]

Furthermore, the program "provides connection, support, acceptance, all these things, the sense of belonging" (educator; P18).

Children actively developed their interpersonal, collaboration, and teamwork skills by navigating ways to work together and be respectful of each other's needs and ideas in an inclusive space:

> *It's about the safe space, knowing the kids, doing the activities together, finding your own wavelength...everyone working together and sharing their views and just talking to each other and talking your ideas through. It's just self-confidence...you might not have the right solution, or the right idea, but it's okay. And being patient to hear each one out as well.* [Parent; P19]

During CP3 activities, peer-to-peer learning and support occurred organically, whereby children with different skill levels supported each other:

> *I think the other big part would be the peer-to-peer learning...by the children. I'm thinking of the soccer activity. There were some children who are obviously very skilled in soccer and some that weren't and the children who were skilled supporting those that weren't.* [CP3 coordinator; P4]

At the community level, participants emphasized that the CP3 benefited children by building their relationships with educators through enhanced communication skills, which in turn improved the educator-student relationship (educator; P20).

The CP3 also helped link children to their local community—examples included a partnered senior school or local sporting group. It was viewed as extremely important in supporting a child's well-being, encouraging a sense of belonging (CP3 coordinator; P4), forging new and important relationships for the future, and being a source of inspiration for the children (educators; P5, P15, and P16). This connection to the community could also make children more aware of their world, have a greater understanding of their community, and feel more like active and connected citizens (OSHC coordinator; P21). Furthermore, the CP3 created an opportunity for children to build a trusting relationship with an adult outside of their immediate family:

> *It's another adult in the children's eyes that they can trust and go to. And if they ever need help, it's having that relationship there. Which you don't get, unless you put effort and time into it, which CP3 encourages, in again, that fun setting.* [OSHC manager; P7]

Children commented on how they enjoyed involving their family and friends:

> *I like baking and love chocolate, so the cooking was my favourite and my family loved it too. It was more exciting and more fun because I was doing it with my sister and families and friends.* [Workshop 2]

Helping others in the wider community was also reflected, with a child commenting that "we will help charity" by knitting and "donating [beanies] to other people who need them" (workshop 1) and another child stating that they enjoyed the CP3 as they made "a house for animals affected by the bush fire" (workshop 2).

Educator and Volunteer Outcomes

The CP3 was described as a "professional development opportunity" (OSHC manager; P7) that could enhance their engagement and interaction skills with children and make them actively consider child well-being in their practice. A coordinator (P4) reported that educators "definitely gain a lot more depth and understanding on what they [the children] want, need, what makes them tick and how we as a service can best support them." Many comments from service providers indicated that educators connected with children in new and improved ways:

> *I really connected in a different way or for the first time.* [Educator; P6]

Another educator (P20) highlighted that the CP3 provided "such a joyful experience" as it enabled educators "to see children in a different way, being able to see them become stronger individuals, learning, taking that opportunity, being motivated." Educators had a greater desire to pay attention to, understand, and act upon children's wants and needs, which increased their connection with the children.

Job satisfaction and well-being were positively reported:

> *There's also been an increased happiness with the educators when they're participating in the program.* [Educator; P22]

A CP3 activity that celebrated the Diwali festival of lights resulted in 2 educators feeling proud to share their culture with the children.

Educators also described that CP3 volunteer mentors were "feel[ing] proud" that they "[had come] here as a volunteer and they [taught] something new to the children." This volunteering had a ripple effect on the local community as they came in to teach something that resulted in "children are teaching their families and cousins and siblings" (educator; P23). Although a volunteer CP3 mentor reported that the CP3 had been a challenging but highly enjoyable experience, helping him "grow further understanding different of things in life with regards to communities and all that sort of stuff," he emphasized that, through the CP3, "I felt like I was making a difference, which is something important to me" (P24).

Challenges to CP3 Implementation

A major challenge to CP3 implementation highlighted by educators was related to the administration of CP3 activities, potentially causing heavier workloads:

> *...it is a lot of work for us educators. On top of what we already have to do.* [Educator; P1]

This included engaging in the research (eg, completing SDQ assessments) and sourcing volunteers. Although some OSHC sites delivering the CP3 reported that finding volunteers was an easy process, 20% of the educators advised that sourcing appropriate volunteers from the community was a major barrier. A coordinator described that "the most challenging thing was trying to find volunteers to come in and do activities free of charge" and "it was a challenge to arrange a time that suited both people, especially if it was a teacher or a parent because parents send their kids to OSHC because they work...So not all people are willing to come after they've worked to come to OSHC to participate" (P21). Participants highlighted the critical role of a person dedicated to supporting the implementation of the CP3 (the CP3 coordinator) and that this role needed to continue to be embedded in the program.

Some participants reported that educators who were not directly involved in CP3 delivery struggled to explain the CP3 to parents and guardians:

> *Yeah, how is it valuable, and then that can help them explain it to parents and carers as well because they were struggling to explain, I guess, how the program was going to be...[the CP3 Coordinator] explained it, but they were struggling to deliver that to parents and carers.* [CP3 coordinator; P21]

Family engagement varied across the participating OSHC sites; some reported excellent engagement, whereas others identified challenges. This was attributed to parents being busy or at work, hence their use of OSHC in the first place. In total, 13% of the educators highlighted that more families at their center wished to be involved, but COVID-19 restrictions prevented engagement. Furthermore, the CP3 coordinator suggested that it may have been a result of "educators not understanding why, how we're doing this, and prioritizing time" (P4), so further educator training may assist in addressing this.

The level of engagement of the OSHC coordinator was another factor that influenced the success of CP3 implementation:

> *...the coordinator seems to be the gateway to the inspiration of CP3 within the team...When I was working alongside an engaged, motivated coordinator, it was really, really easy to implement CP3. They put the time and the effort in...Whereas if the coordinator was a bit more distant, a bit more challenging to communicate with, it was more challenging definitely to do...The sparkle wasn't there. The magic was lost a little.* [CP3 coordinator; P4]

One of the most cited challenges to CP3 implementation and engagement with the program related to external factors that were beyond OSHC control. This was identified as an issue by many participants and included the COVID-19 pandemic, regional natural disasters, and school protocols in response to such events:

> *I think out of [OSHC site], we had the fires, then we had poor air quality, then there was flooding. We've also had COVID-19...we had some volunteers from the local church congregation who were in their senior years and we weren't able to re-engage those volunteers as a result of COVID. We sourced volunteers from within the immediate community. So it was educators who might have had a family member, for example. And at [another OSHC site], we had an educator who had a family member who was a soccer coach, so we engaged that person. They were part of the existing community, so we weren't actually introducing anybody from outside of the immediate community to the space. Schools were quite strict with who came onto the grounds during COVID-19, so that impacted community connections again.* [CP3 coordinator; P4]

Some OSHC sites were agile and used creative engagement strategies; for example, in response to COVID-19 restrictions, an educator (P22) described purposely setting up the CP3 activities in front of the parent sign-in area so that parents could still engage in some capacity. She also ensured that parents were able to see photos of the activities "so, as much as families couldn't come in and be involved, they were still involved in a different way." Other educators (P11 and P12) sought volunteers through family connections and teachers from a linked school.

Discussion

Principal Findings

To our knowledge, the CP3 is the first co-designed social connection and well-being program model for primary school–age children (aged 5 to 12 years) specifically for OSHC settings in Australia. Our study used a 2-stage mixed methods formative and process evaluation to assess the acceptability and feasibility of the CP3. These evaluation stages of research are crucial as research suggests that many mentor-style programs are pursued without any supporting evidence from reliable or valid process or outcome evaluations [23,24].

Our evaluation highlights the high level of satisfaction and engagement with the CP3 and demonstrates promising preliminary findings in terms of the positive impact of the CP3 principles (ie, *Build Well-being* and *Resilience*, *Broaden Horizons*, *Inspire and Engage*, and *Connect Communities*). The process evaluation reported significant positive impacts of the CP3 on prosocial behaviors and reducing peer-related problems in children, as measured using the SDQ. These are important findings, especially as the research was conducted from 2019 to 2020 through unprecedented events such as fires, floods, and the COVID-19 pandemic where it was expected that children's well-being would be negatively affected. Our planned next stage of research is to consolidate these findings by conducting an evaluation of the CP3 using a stepped-wedge cluster randomized controlled study.

Co-design With Children and Their Communities at the Heart of CP3

The qualitative findings demonstrated the positive flow on the effect of children making active decisions about the service where they play, learn, and grow. Research highlights that central to achieving a shift in OSHC service delivery is the need to listen to children's voices [25,26]. As highlighted by Flückiger et al [27] and echoed in Australian research [28], educators need to be able to listen to children to develop policies and practices that directly respond to their needs and perspectives. This process of enabling OSHC services and their educators to listen and respond to children's voices is structurally supported through the CP3 as a best-practice programming tool.

The wider OSHC community (including educators and CP3 volunteer mentors) also described benefiting from the CP3 co-design process. Research highlights that, for educators, having a voice in service delivery is critical in addressing workforce issues that have arisen in recent years [29]. The educator voice is recognized in the Australian National Quality Standard [7], which emphasizes the need for democratic practices and collaborative decision-making across all aspects of service delivery. The qualitative results from this process evaluation indicate a positive impact of the CP3 on educator well-being and sense of community. This warrants further quantitative research to understand whether the CP3 providing a framework for such collaborative decision-making practices influences educators' workplace well-being.

Creative Engagement

Past Australian qualitative research has highlighted that, when asked, children emphasize the importance of friendship, play, and choice of specific activities in OSHC [28]. All these ideas are echoed in the CP3 principles of Broaden Horizons, Inspire and Engage, and Connect Communities. Creative engagement through these channels is a way of directly and indirectly enhancing child social, emotional, physical, and cognitive well-being. The qualitative findings of this study highlighted that more susceptible children were more likely to engage positively with CP3 activities as compared with regular OSHC. There was a distinct change in how they engaged socially and emotionally, forming positive connections through play via the CP3 activities they had themselves co-designed. This high-quality programming process through the CP3 is important as there is research evidence suggesting that, in other childcare settings, those that are most likely to benefit from high-quality programming are children who experience circumstances of disadvantage [30].

The Reality of CP3

The main criticism of the CP3 relates to its potential to add to the workload of OSHC service providers if not properly resourced. For example, the level of paperwork was a concern raised in our formative and process evaluation findings. Although this may have been because educators had conflated research-related paperwork with the CP3 itself, this aspect remains important. Research in the early childhood education sector has highlighted that issues such as paperwork are a major impediment to workplace well-being and the educational effectiveness of educators [31], which can, in turn, influence the quality of OSHC service provision and child outcomes [32,33]. The digitization of CP3 implementation and support tools is planned to minimize the administrative burden of the CP3. This is also intended to augment the CP3's reach to OSHC services located in regional and rural areas.

In line with the "Shaping our Future" strategy, which focuses on supporting Australia's childcare workforce over the next decade [34], if the CP3 is to be successful in the future, it needs to positively affect educator well-being and not be a source of burden. Thus, the CP3 coordinator and CP3 training infrastructure being in place to support OSHC services to deliver, fully resource, and upskill the workforce will be essential to the ongoing success of the CP3. Workforce issues are currently of major concern across the childcare sector, and these types of well-being–focused programs can only be implemented and provide value if funding and resources are sufficient to ensure effective implementation.

Another concern was that the quality of the program could fluctuate depending on the CP3 champion at the OSHC service. This could be attributed to some of the aforementioned workforce issues. However, this may also be because implementation practices differed between services. To understand and be able to support services with this variability, a CP3 fidelity tool is being developed. It is envisaged that a CP3 fidelity tool will (1) provide a structured framework for quality assurance and quality improvement of CP3 delivery; (2) allow services to identify and address any implementation or resourcing issues early; and (3) provide a means for researchers to identify components of the CP3 model, if any, that are critical for positive outcomes.

Strengths and Limitations of the Research

For the first formative evaluation, the CP3 was piloted at 1 OSHC site only, which meant that the sample numbers for the child and educator surveys were very small and may be biased toward the specific sociocultural-economic aspects of that area. The CP3 was subsequently rolled out across an additional 5 sites for the process evaluation so as to gather further evidence in more diverse settings and with a larger sample size. In this evaluation phase, mixed methods data were gathered from children, but only qualitative data could be gathered from educators given funding constraints and the fact that the primary target of the intervention were children. For the process evaluation preliminary effectiveness, only 58 children could be matched across the 2 time points for the SDQ surveys. This was due to children at each time point either joining or leaving the service or the service not completing the routine data outcome monitoring at the time because of unforeseeable circumstances (eg, fires, floods, and COVID-19–related lockdowns). The average attrition rate across all sites from baseline to follow-up was 33.8% (88/122), which increased to 52.5% (58/122) in the matched sample. This attrition is high and poses a threat to the validity of the findings; thus, statistical testing must be interpreted with caution. A real-world randomized cluster stepped-wedge trial is being carried out at regional and urban OSHC sites in NSW, Australia, and will provide more comprehensive evidence for the CP3 model from both a child and an educator perspective.

A critical strength of the CP3 model is that it has undergone iterative development following recommendations of the Medical Research Council guidelines for developing complex interventions [14]. After the initial co-design of the CP3 model [6], the use of a 2-step formative and process evaluation enabled further program design to be agile and actively respond to the identified needs as they arose, for example, the development of a fidelity measure and additional resources to support educators in explaining the CP3 to the community. By using this approach, the CP3 model can grow and be improved upon in real time as a program and service improvement process.

Conclusions

There is strong academic evidence for the developmental effectiveness of providing high-quality programming (intellectually stimulating, emotionally supportive, and providing socially engaging learning experiences) in early childcare settings [29]. This should be extended to OSHC in the primary school years. Providing high-quality OSHC programming is an investment in children's futures given that OSHC is the fastest-growing childhood education and care sector in Australia [5]. OSHC sites need to extend beyond simply existing as "convenient care" and be valued as a place where children's well-being is supported [5]. The early evidence for the CP3 is promising and may provide a unique opportunity to listen and respond to the voices of children in OSHC and those that support them. To ensure future sustainability and scalability, there must be sufficient resources to ensure that such programs do not

burden an already overstretched workforce. The CP3 provides OSHC with a much-needed framework and high-quality program planning tool, which promotes the development of tailored interventions depending on the unique needs and preferences of those who will use them.

Acknowledgments

This study was funded by a benevolent grant from Uniting. Ongoing Connect, Promote, and Protect Program research and write-up of the manuscript were funded by a partnership grant from the University of Sydney Brain and Mind Centre. In addition, ACM was supported partially by the Australian Government through the Australian Research Council Centre of Excellence for Children and Families over the Life Course (project ID: CE200100025). The authors acknowledge all the members of the Uniting NSW.ACT out of school hours care community, including the children, families, educators, and volunteers who participated in and supported this research. In particular, they would like to thank Rod Nadwie-Smith, Melisa Giles, Sophie Fraser, Madonna Lee, and Haley La Monica.

Conflicts of Interest

IH was an inaugural commissioner on Australia's National Mental Health Commission (2012-2018). He is the codirector of Health and Policy at the Brain and Mind Centre, University of Sydney. The Brain and Mind Centre operates early-intervention youth services at Camperdown under contract to the 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 has been formed by the University of Sydney and PwC to deliver the Aus $30 million (US $19.9 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. The Connect, Promote, and Protect Program has an executed intellectual property agreement between the University of Sydney (ACM and IH) and Uniting. All other authors declare that they have no conflicts of interest.

Multimedia Appendix 1
Child and adult formative evaluation demographics.
[DOCX File , 16 KB - pediatrics_v6i1e44928_app1.docx]

Multimedia Appendix 2
Staff (n=5) and volunteer (n=2) satisfaction with Connect, Promote, and Protect Program items during term 1 in 2020.
[DOCX File , 17 KB - pediatrics_v6i1e44928_app2.docx]

Multimedia Appendix 3
Number of completed Strengths and Difficulties Questionnaires at baseline and follow-up by outside school hours care site.
[DOCX File , 14 KB - pediatrics_v6i1e44928_app3.docx]

Multimedia Appendix 4
Educator baseline and follow-up results for each Strengths and Difficulties Questionnaire (SDQ) scale by 4-fold SDQ categories.
[DOCX File , 17 KB - pediatrics_v6i1e44928_app4.docx]

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Abbreviations

ACECQA: Australian Children's Education and Care Quality Authority
CP3: Connect, Promote, and Protect Program
MD: mean difference
NSW: New South Wales
OSHC: outside school hours care
SDQ: Strengths and Difficulties Questionnaire

Edited by S Badawy, G Eysenbach; submitted 08.12.22; peer-reviewed by K Lim, K Hopps; comments to author 25.03.23; revised version received 27.03.23; accepted 28.03.23; published 25.07.23.

Please cite as:
Milton AC, Mengesha Z, Ballesteros K, McClean T, Hartog S, Bray-Rudkin L, Ngo C, Hickie I
Supporting Children's Social Connection and Well-Being in School-Age Care: Mixed Methods Evaluation of the Connect, Promote, and Protect Program
JMIR Pediatr Parent 2023;6:e44928
URL: https://pediatrics.jmir.org/2023/1/e44928
doi:10.2196/44928
PMID:37490323

Viewpoint

Designing an App for Parents and Caregivers to Promote Cognitive and Socioemotional Development and Well-being Among Children Aged 0 to 5 Years in Diverse Cultural Settings: Scientific Framework

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Abstract

Recent years have seen remarkable progress in our scientific understanding of early childhood social, emotional, and cognitive development, as well as our capacity to widely disseminate health information by using digital technologies. Together, these scientific and technological advances offer exciting opportunities to deliver high-quality information about early childhood development (ECD) to parents and families globally, which may ultimately lead to greater knowledge and confidence among parents and better outcomes among children (particularly in lower- and middle-income countries). With these potential benefits in mind, we set out to design, develop, implement, and evaluate a new parenting app—Thrive by Five—that will be available in 30 countries. The app will provide caregivers and families with evidence-based and culturally appropriate information about ECD, accompanied by sets of collective actions that go beyond mere tips for parenting practices. Herein, we describe this ongoing global project and discuss the components of our scientific framework for developing and prototyping the app's content. Specifically, we describe (1) 5 domains that are used to organize the content and goals of the app's information and associated practices; (2) 5 neurobiological systems that are relevant to ECD and can be behaviorally targeted to potentially influence social, emotional,

and cognitive development; (3) our anthropological and cultural framework for learning about local contexts and appreciating decolonization perspectives; and (4) our approach to tailoring the app's content to local contexts, which involves collaboration with in-country partner organizations and local and international subject matter experts in ECD, education, medicine, psychology, and anthropology, among others. Finally, we provide examples of the content that was incorporated in Thrive by Five when it launched globally.

(JMIR Pediatr Parent 2023;6:e38921) doi:10.2196/38921

KEYWORDS

early childhood development; digital technology; health information technology; mHealth; smartphone; neuroscience; pediatrics; mobile app

Introduction

The first 5 years of human life are a remarkable period of cognitive, social, and emotional change. Before modern neuroimaging technologies, it was an open question as to how and to what extent the brain matures during childhood. Our understanding of this phenomenon is now much clearer, with a growing literature demonstrating large-scale structural and functional changes in the brain across childhood, starting from the very first months of life [1-6]. The development of the brain and its cognitive, social, and emotional functions during early life is critical for lifelong health and well-being. Levels of cognitive, social, and emotional functioning during childhood are associated with a variety of adult social, economic, and health outcomes [7-9], and children who struggle with some of these abilities (eg, self-control) when they are young are at elevated risk for negative outcomes as adults (eg, criminality) [9,10]. The degree to which child-rearing practices influence the development of these abilities during early childhood is of great interest.

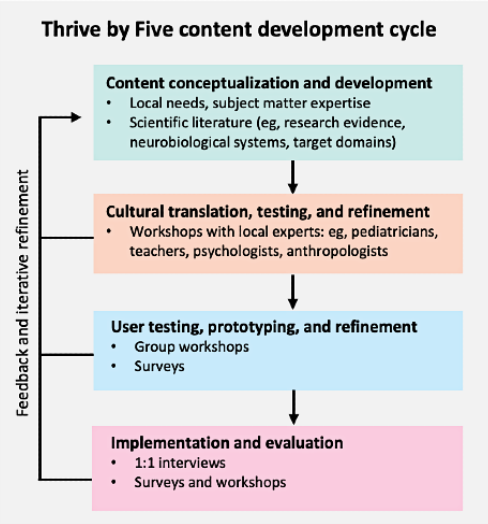
Behavior genetics has demonstrated complex gene-environment interactions that, beyond a simple nature-nurture dichotomy [11,12], contribute greatly to how people differ in terms of cognitive, social, and emotional functioning. Notably, potentially modifiable environmental factors, such as what parents and families do with children, have a substantial influence on these differences. For example, a recent meta-analysis of twin studies estimated that around 40% of individual differences in self-control are attributable to environmental effects [13]. Twin studies have shown the contribution of the shared (family) environment to individual differences in language ability [14], empathy [15], and cognitive school readiness [16], among other traits. Epidemiologic studies have also revealed the need to protect children from harmful environments to ensure optimal cognitive, social, and emotional development [17,18]. Critically, exposure to certain harms (eg, chronic stress and abuse) might be avoided by educating parents and by equipping them and their children with protective strategies. Altogether, we now know that childhood cognitive, social, and emotional traits are malleable. Improving children's functioning in early life via parental behaviors may optimize development and prevent poor outcomes in adulthood, ultimately resulting in lifelong health and well-being.

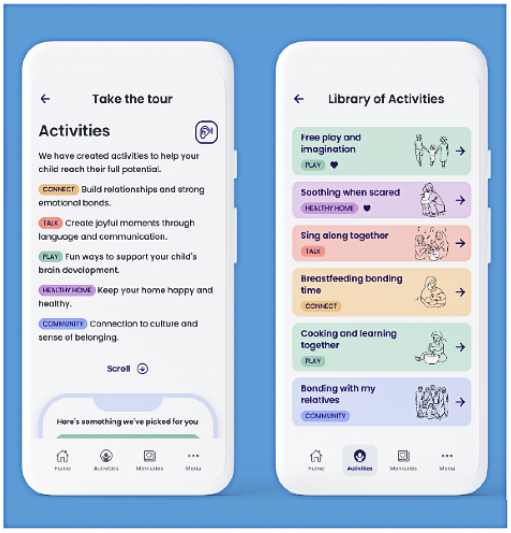
Modern digital technologies (eg, smartphone apps) offer a highly scalable platform for delivering health information across a range of settings (eg, low- and middle-income countries), purposes (eg, education and prevention), and health conditions [19-22]. In an increasingly web-based world, app-based technologies offer the potential to address ethnic, racial, socioeconomic, and regional disparities in access to health information and may represent an effective means of delivering information about early childhood development (ECD) to parents and caregivers globally. Realizing these opportunities hinges on investigating and interrogating the social, cultural, and political dimensions of digital technology use [23], as well as conducting detailed examinations of how users of digital technologies perceive a specific platform's usability (eg, user-friendliness), acceptability (eg, cultural appropriateness), and feasibility (eg, ease of use in daily life) [24].

With the goal of meeting these challenges and opportunities, we partnered with a philanthropic organization—Minderoo Foundation—in 2021 to develop, implement, and evaluate an app that aims to provide parents from approximately 30 countries with science-based and culturally relevant information about ECD. At the time of writing, the app—Thrive by Five—has been launched as 5 localized, country-specific versions. A key difference between Thrive by Five and other popular parenting apps is our focus on combining scientific knowledge with a cultural and anthropologic analysis of each country's local context (eg, approaches to child-rearing, gender roles, and the position of the child in the family; Figure 1). Moreover, rather than focusing only on 1 parent and 1 child, we broadened the scope of the app's child-rearing tips to draw in wider family and community networks, with the goal of exposing children to a wider set of cultural and traditional practices (eg, folk stories; myths; and traditional songs, music, and dance). Accordingly, we refer to the activities in the app as *collective actions*.

The objective of this paper is to describe this project's scientific framework. By *scientific framework*, we refer to the project's basic conceptual and pragmatic approach, including *what* we are targeting (ie, cognitive, social, and emotional well-being); *why* these targets are of interest (ie, the empirical, scientific rationale); and, critically, *how* users can engage with specific practices to potentially drive their children's development in these target areas in ways that are culturally relevant. As our approach to integrating science, culture, and anthropology within a co-design context is novel, the rationale of describing our scientific framework is to provide a road map that other projects with similar aspirations may find useful, as well as a transparent description of the process underlying the design and development of the Thrive by Five app.

Figure 1. Overview of our scientific framework for developing the Thrive by Five app. We combine cultural and anthropological analyses and scientific knowledge to develop and iterate country-specific practices for parents and significant others (collective actions).





Methods

Scientific Framework Overview

In the following sections, we elaborate on this project's scientific framework. First, we describe 5 conceptual domains that are used to organize the content and goals of the information about ECD and child-rearing and outline 5 neurobiological systems that can be behaviorally targeted to influence social, emotional, and cognitive development (*Scientific Framework Part 1*). Second, we discuss our approach to developing an understanding of each country through the cocreation of a cultural framework that summarizes various literature regarding factors that may impact child-rearing and child development (*Scientific Framework Part 2*). Third, we introduce the concept of collective actions as an alternative to parenting tips, emphasizing the strengths of involving wider family and community networks in child-rearing (*Scientific Framework Part 3*). Fourth, we discuss our iterative approach to localizing the app's content for each country, which involves holding collaborative workshops with in-country partner organizations; subject matter experts in ECD, education, medicine, psychology, and anthropology, among other disciplines; and potential users of the app in each country (*Scientific Framework Part 4*). Finally, we provide examples of the content (ie, collective actions) that was included in the app when it launched internationally in 2022 (the first full version of the app was implemented in Indonesia).

Scientific Framework Part 1—Linking Content Development to 5 Thematic Domains and 5 Neurobiological Systems

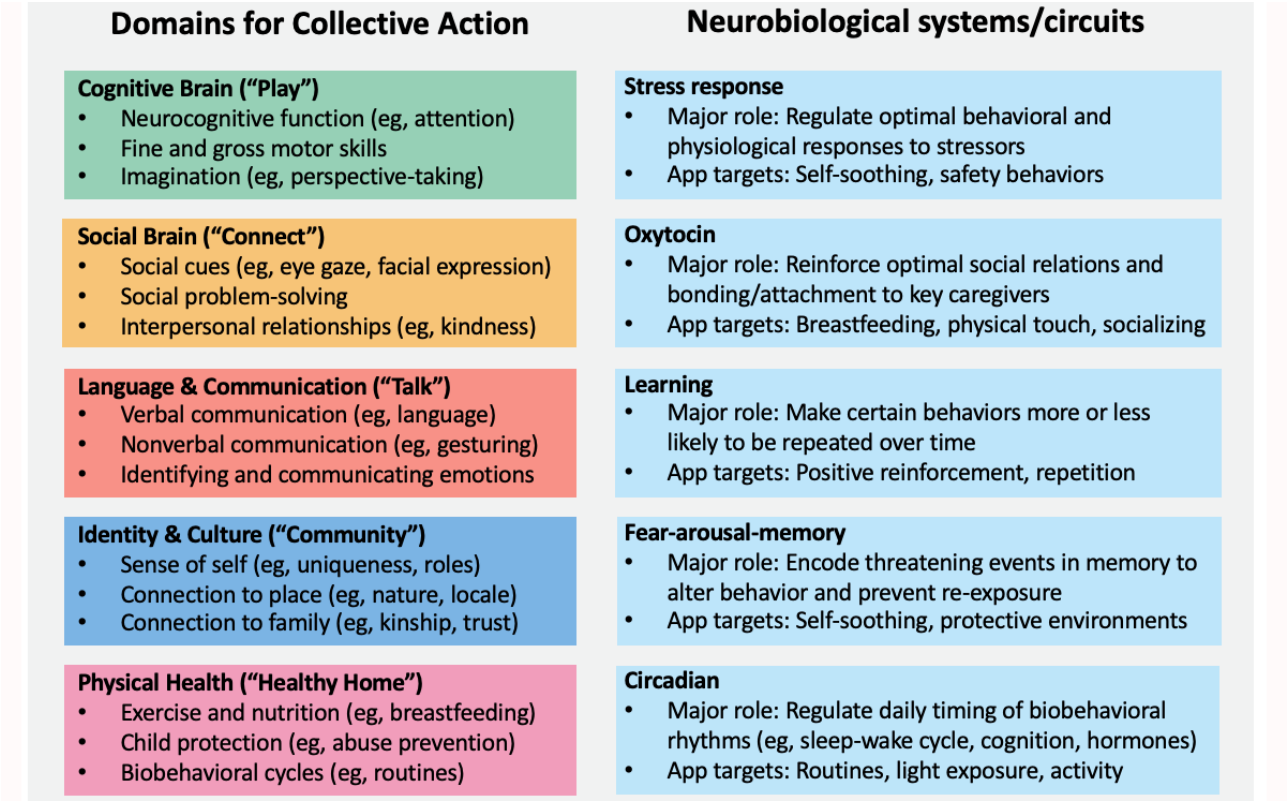
Before developing the app's content, we agreed on 5 thematic domains that are relevant to children's social, emotional, and cognitive development and 5 neurobiological systems that are involved in social, emotional, and cognitive development. These domains and neurobiological systems (Figure 2) guide the development of the app's content, are used to categorize the content within the app, and provide the scientific rationale for encouraging parents to engage with the practices promoted by the app.

The thematic domains are based broadly on the Bright Tomorrows project (developed by Minderoo Foundation and Telethon Kids Institute), with the Brain and Mind Centre team mapping new domains. The domains and the broad types of content included in each domain are (1) the *Cognitive Brain* domain, which includes content about broad cognitive processes (eg, attention, learning, memory, visual and auditory processing, motor skills, and imagination); (2) the *Social Brain* domain, which includes content about social interaction and the sociocognitive processes involved in recognizing, interpreting, and responding to social cues (eg, eye gaze, joint attention, and facial expressions); (3) the *Language and Communication* domain, which includes content about processing, understanding, and using verbal and nonverbal language and signals (eg, gestures); (4) the *Identity and Culture* domain, which includes content about the development of a sense of personal, social, and community identity and the roles that culture and place play in identity development (eg, customs, festivals, and folk stories); and (5) the *Physical Health* domain, which includes content about physical health, growth, and development and physical protection from harm and abuse (eg, harsh discipline).

The neurobiological systems that we focus on and an outline of their relevance to early child development are shown in Figure 2. These five systems and their main functions include (1) the stress response system, which creates a hormonal response to stress (prolonged activation of the stress response system is associated with negative emotional, behavioral, and physical health outcomes); (2) the oxytocin system, which regulates social, behavioral, and emotional processes (eg, smiling, attention to eye gaze, and breastfeeding), of which many are fundamentally important for early child-caregiver bonds and other social bonds; (3) the learning system, which assigns value to objects and behaviors (in childhood, this is fundamental for motivation creation, social behaviors, and associative learning); (4) the fear-arousal-memory system, which encodes and maintains memories of fearful stimuli and the contexts in which they are experienced; and (5) the circadian system, which orchestrates the daily rhythmic timing of almost all physiological processes and behaviors (eg, sleep and

wakefulness, appetite, mood, and cognitive function). Other publications provide more details about these systems and their relevance to early child development [25-38].

Figure 2. The five domains for collective action and the five neurobiological systems/circuits used to guide the conceptualization and development of the app's content.

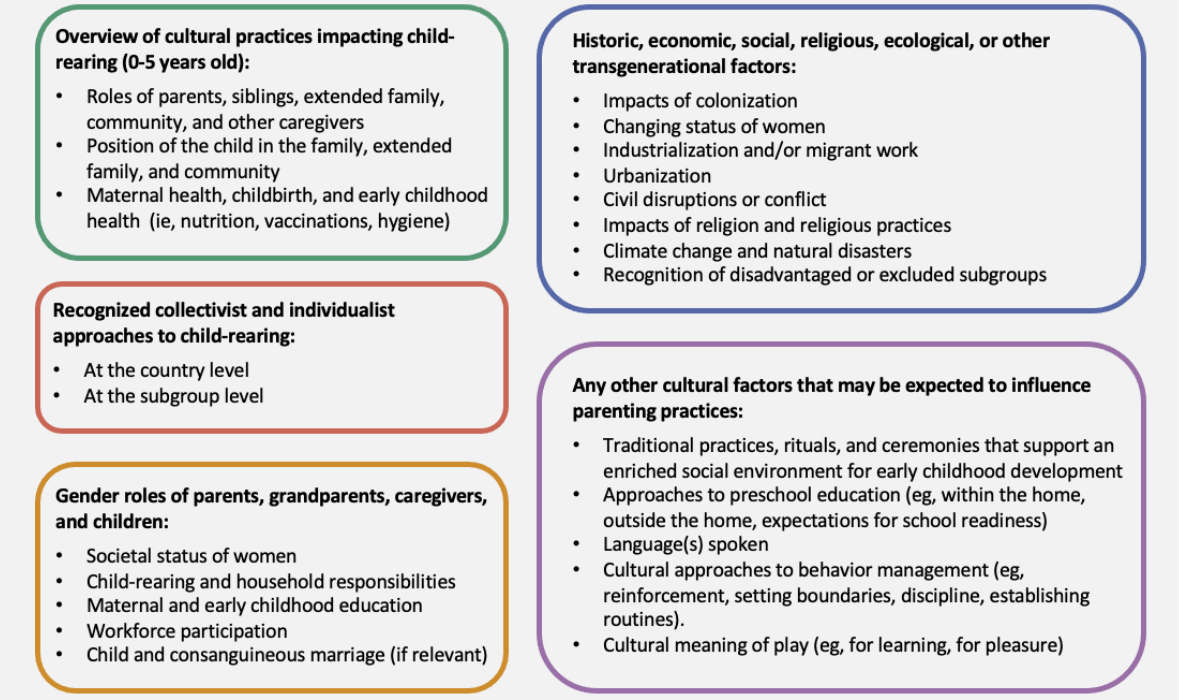


Scientific Framework Part 2—Development of Cultural Frameworks to Localize Content

For each country, a cultural framework is developed collaboratively with the research team and a nominated country-specific expert. This framework is used to guide the first draft of the app's content for each local context. The cultural framework summarizes information from a variety of published literature (eg, government reports, journal articles, and textbooks) that is relevant to child-rearing; family environments; and broader social, economic, and political factors that may influence family functioning and early child development. For each country, we follow a dedicated pro forma that covers the topics presented in Figure 3.

Concurrently, the research team prepares a literature summary that presents the strengths (eg, transgenerational family networks; the empowerment of women; and the cultural celebration of art, music, and dance) and challenges (eg, high rates of childhood mortality, obesity, and exposure to corporal punishment) of each country, which are considered when developing the app's content. The content aims to celebrate the cultural strengths and practices of each country by highlighting how they align with the scientific evidence about childhood development while also considering the various challenges that may impede these practices and how these challenges may be mitigated. Once complete, the cultural framework and literature summary are reviewed and approved by an in-country partner organization.

Figure 3. Components of the cultural framework prepared for each country.



Scientific Framework Part 3—Conceptualizing the App's Content as Collective Actions and Not Just as Parenting Tips

Many available parenting apps adopt a narrow focus in their content, encouraging activities to be completed by 1 parent (typically a mother) with 1 child. Although these activities are well-meaning and are still of potential benefit, their dyadic structure is limiting. Such activities reduce exposure to a variety of social interactions with different people; lack the richness of multigenerational and extended family structures; and narrow the bounds of the complexity and variety of children's social, emotional, and cognitive experiences. Therefore, we conceptualize the content in the app not as parenting tips but as collective actions.

These collective actions broaden the scope of the child-focused activities to include a significantly larger network of individuals in a child's life. As well as mothers, fathers, uncles, aunts, siblings, cousins, grandmothers, and grandfathers (Figure 4), we also encourage families to bring in other trusted adults from their communities and social networks to engage in these actions. We believe that this wider circle of interactions with and around a child may drive greater gains in cognitive, social, and emotional development (by increasing the varieties of experiences, stimuli, and interactions), in addition to increasing the opportunities for a child to be exposed to and embedded within the rich tapestries of their extended family's culture and history (eg, rituals; folk stories; myths; and traditional songs, music, and dance).

In the Thrive by Five app, the primary content (collective actions) comprises 2 components (Figure 5). First, "The Why" provides the scientific background that supports a particular activity (eg, the importance of breastfeeding for a baby's social, cognitive, emotional, and physical development and health outcomes) [39,40]. Second, the "Activity Pop Up" provides a practical activity in which parents, siblings, grandparents, other extended family members, and trusted community members could participate with the child. "The Why" and the "Activity Pop Up" are available both in text form and in audio form.

Figure 4. Our approach to content: collective actions, not just parenting tips. As opposed to a set of child-rearing practices that encourage simplistic parent-child interactions, our concept of collective actions encourages involvement from many family members (eg, grandparents, siblings, and cousins) and trusted community members in interactions with the child. Although we have placed the child at the center of this network, we also recognize the child as an "actor," as children often initiate interactions with others, and that these communications represent interactive loops rather than a unidirectional interaction.

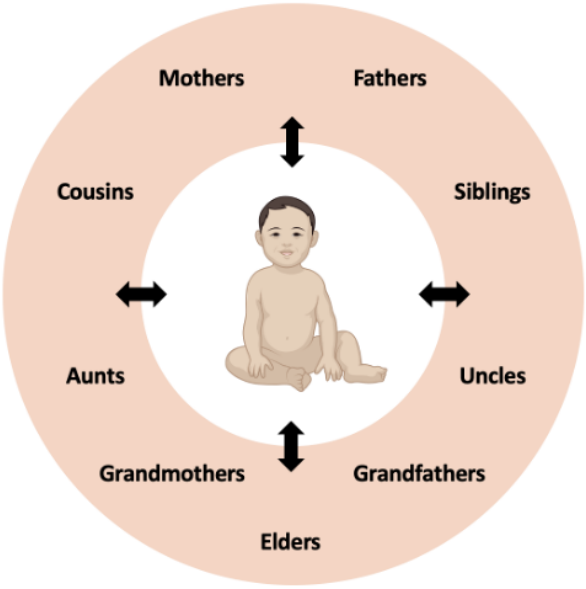


Figure 5. An example of a collective action, including "The Why" and "Activity Pop Up" components in English (top row) and Bahasa Indonesia (bottom row).

Scientific Framework Part 4—The Iterative Process of Localizing Content to Each Country

Over the course of this 3-year project, the Thrive by Five app will be implemented in 30 countries. A unique feature of this project is that for each country, we are actively considering how we can integrate cultural practices into the collective actions as a way of strengthening connections across families and communities and connections to places, cultural traditions, and values. To ensure that the app's content is culturally acceptable, usable, relevant, and engaging, we developed a 4-stage process for developing and prototyping the country-specific collective actions (Figure 1) in partnership with local and international experts in ethnography, anthropology, ECD, medicine, psychology, and other disciplines.

The first phase of development is the conceptualization of the initial library of collective actions for a given country. This process is guided by the research team's expertise and an examination of published research in areas that are relevant to the five domains and the five neurobiological systems that we previously described (Figure 2). The cultural framework (Figure 3) is used concurrently to highlight topics regarding local needs (eg, hygiene and distress management).

In the second phase of development and prototyping, the research team—in cooperation with a nominated in-country partner and representatives from the Minderoo Foundation—holds a series of co-design workshops with local subject matter experts (eg, educators, pediatricians, and psychologists) to examine the acceptability, feasibility, and relevance of the draft content (more details are provided elsewhere [41]). Similarly, in the third phase of development and prototyping, the research team holds a series of workshops with in-country parents, using a beta version or clickable demonstration version of the app to further examine the acceptability, usability, and relevance of the content. Based on the data that emerge from the co-design workshops, the drafted content is iteratively revised.

Finally, the last phase of development and prototyping includes the implementation of the app in the given country, after which an evaluation phase is conducted that examines the impacts of the Thrive by Five app on several factors, including parent-level confidence and self-efficacy (more details are provided elsewhere [41]). Importantly, at any one of the phases that involve communication with in-country partners, experts, and parents, ideas for subsequent collective actions may emerge.

Results and Discussion

The international launch of the Thrive by Five app was in March 2022, marked by the implementation of the first full version of the app in Indonesia. Further, 4 other versions of the app (with localized country-specific content) have been successfully implemented in Afghanistan, Namibia, Kyrgyzstan, and Uzbekistan as of November 2022, and 5 other country-specific libraries of localized content have already been codeveloped and are awaiting implementation. As this project continues to progress, the team will codevelop 20 country-specific libraries and implement the app in 25 countries (bringing the total to 30 countries).

A series of evaluation studies will investigate the parent-level, family-level, and system-level impacts of the app on several factors, including the perceived connection between parents and children and between children and the community, parents' confidence in their caregiving abilities, and knowledge gain with regard to positive child-rearing practices [41]. These evaluations will include a mix of quantitative and qualitative designs and a mix of country-specific investigations and larger cross-country investigations. We anticipate the first empirical reports from this program to be submitted for publication in early 2023.

We acknowledge several limitations of our approach. First, while we are co-designing each of the collective actions (collaborating with potential users and local experts) and the aspects of the app's design (eg, illustrations) [41], several of the features and functions of the app were developed before the co-design phase. Second, in some instances, we have had strong feedback from co-design workshop participants about the relative lack of content related to religious practices. Although obviously culturally relevant, we decided that many of these suggestions would not be included in the app's content, as we could not be confident about their relationships with the cognitive, emotional, and social outcomes of this project. Third, we recognize that while some of our team members have personal experiences with the countries for which we are developing the app, we cannot truly understand the nuances, particularities, and meanings of each country's cultural practices (A Poulsen et al, unpublished data, 2022) [42]. In these instances, we adopt a position of cultural humility and rely more heavily (and modestly) on collaboration with our in-country partners and workshop participants. We hope that we can learn and understand enough to make each app feel authentic and relevant to the users.

Our approach to developing the Thrive by Five app—combining science with cultural and anthropological knowledge—is highly original, and we hope that it will produce a useful, relevant, and engaging resource for parents and families around the world. The first outcomes from this work are expected to be published in early 2023. In closing, this global project brings together cutting-edge knowledge from neuroscience, ECD, digital technology, and anthropology, with the major goal of empowering families around the world with new tools and practices for shaping their children's futures.

Acknowledgments

This research is being conducted by the University of Sydney's Brain and Mind Centre, pursuant to a 3-year agreement between the university and Minderoo Foundation Limited (Minderoo). Minderoo's Thrive by Five international app targets parents and

caregivers of children aged 0 to 5 years to support the cognitive, socioemotional development and well-being of young children across diverse cultures.

Conflicts of Interest

IBH is the codirector of health and policy at the Brain and Mind Centre, University of Sydney. The Brain and Mind Centre operates an early intervention youth service at Camperdown, under contract to headspace. He is the chief scientific advisor to and a 5% equity shareholder in InnoWell Pty Ltd. InnoWell was formed by the University of Sydney (45% equity) and PwC (Australia; 45% equity) to deliver the Aus $30 million (Aus $1=US $0.70), Australian government–funded Project Synergy program (2017-2020; a 3-year program for the transformation of mental health services) and to lead the transformation of mental health services internationally through the use of innovative technologies. MT and NF are employed by Minderoo Foundation (funder). VL is a board member for Matana Foundation, a philanthropic organization that provides funding to programs for disadvantaged young people in Australia. She does not receive any financial benefit for this role. The other authors have no disclosures.

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Abbreviations

ECD: early childhood development

Edited by S Badawy; submitted 06.05.22; peer-reviewed by B Nievas Soriano, K Lawrence; comments to author 29.10.22; revised version received 02.11.22; accepted 28.12.22; published 13.02.23.

Please cite as:
Crouse JJ, LaMonica HM, Song YJC, Boulton KA, Rohleder C, DeMayo MM, Wilson CE, Loblay V, Hindmarsh G, Stratigos T, Krausz M, Foo N, Teo M, Hunter A, Guastella AJ, Banati RB, Troy J, Hickie IB
Designing an App for Parents and Caregivers to Promote Cognitive and Socioemotional Development and Well-being Among Children Aged 0 to 5 Years in Diverse Cultural Settings: Scientific Framework
JMIR Pediatr Parent 2023;6:e38921
URL: https://pediatrics.jmir.org/2023/1/e38921
doi:10.2196/38921
PMID:36780220

Associations Between Patient-Reported Outcome Measures of Physical and Psychological Functioning and Willingness to Share Social Media Data for Research Among Adolescents With a Chronic Rheumatic Disease: Cross-Sectional Survey

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Abstract

Background: Social media data may augment understanding of the disease and treatment experiences and quality of life of youth with chronic medical conditions. Little is known about the willingness to share social media data for health research among youth with chronic medical conditions and the differences in health status between sharing and nonsharing youth with chronic medical conditions.

Objective: We aimed to evaluate the associations between patient-reported measures of disease symptoms and functioning and the willingness to share social media data.

Methods: Between February 2018 and August 2019, during routine clinic visits, survey data about social media use and the willingness to share social media data (dependent variable) were collected from adolescents in a national rheumatic disease registry. Survey data were analyzed with patient-reported measures of disease symptoms and functioning and a clinical measure of disease activity, which were collected through a parent study. We used descriptive statistics and multivariate logistic regression to compare patient-reported outcomes between youth with chronic medical conditions who opted to share social media data and those who did not opt to share such data.

Results: Among 112 youths, (age: mean 16.1, SD 1.6 y; female: n=72, 64.3%), 83 (74.1%) agreed to share social media data. Female participants were more likely to share (*P*=.04). In all, 49 (43.8%) and 28 (25%) participants viewed and posted about rheumatic disease, respectively. Compared to nonsharers, sharers reported lower mobility (T-score: mean 49.0, SD 9.4 vs mean 53.9, SD 8.9; *P*=.02) and more pain interference (T-score: mean 45.7, SD 8.8 vs mean 40.4, SD 8.0; *P*=.005), fatigue (T-score: mean 49.1, SD 11.0 vs mean 39.7, SD 9.7; *P*<.001), depression (T-score: mean 48.1, SD 8.9 vs mean 42.2, SD 8.4; *P*=.003), and anxiety (T-score: mean 45.2, SD 9.3 vs mean 38.5, SD 7.0; *P*<.001). In regression analyses adjusted for age, sex, study site, and Physician Global Assessment score, each 1-unit increase in symptoms was associated with greater odds of willingness to share social media data, for measures of pain interference (Adjusted Odds Ratio [AOR] 1.07, 95% CI 1.001-1.14), fatigue (AOR 1.08, 95% CI 1.03-1.13), depression (AOR 1.07, 95% CI 1.01-1.13), and anxiety (AOR 1.10, 95% CI 1.03-1.18).

Conclusions: High percentages of youth with rheumatic diseases used and were willing to share their social media data for research. Sharers reported worse symptoms and functioning compared to those of nonsharers. Social media may offer a potent information source and engagement pathway for youth with rheumatic diseases, but differences between sharing and nonsharing youth merit consideration when designing studies and evaluating social media–derived findings.

(JMIR Pediatr Parent 2023;6:e46555) doi:10.2196/46555

KEYWORDS

patient-reported outcomes; PROM; outcome measure; outcome measures; patient reported; patient data; social media; sharing; personally generated data; chronic illness; quality of life; rheumatic disease; rheumatic; rheumatoid; adolescent; adolescents; youth; research involvement; privacy; confidentiality; confidential; personal

Introduction

Nearly 1 in 4 US youths are growing up with a chronic illness [1]. Many experience significant levels of disease and treatment burden (eg, pain and medication side effects) that undermine well-being, leading to frequent and costly health care utilization and family financial problems [2]. By adulthood, youth with a chronic illness face increased risks of poor educational, relationship, economic, and health outcomes [3,4]. Life-course risks reflect the complex interplay of disease and treatment experiences and the cumulative effects of social isolation, victimization, school disruption, psychological injury, and home life strain that can accompany chronic illness [5]. Capturing patients' perspectives about these issues is vital to creating supportive interventions. This is especially true for adolescents, as the biopsychosocial processes of puberty, maturation, and development can impact the course and experience of chronic illness just as chronic illness experiences can impact these processes [6,7]. Patient-centered research with adolescents may advance understanding of these issues [8-10].

Psychosocial factors contribute to disease symptoms, such as pain and fatigue, among adolescents with a chronic illness [11]. However, we do not know, with regard to the day-to-day lives of adolescents, what issues are the most important to address to disrupt feedback between disease activity and psychosocial health [12-14]. For example, the experience of pain may be exacerbated by feelings of stress and isolation related to a chronic illness, which can be missed by clinicians when making a treatment decision. Discordance between a young patient's disease experience, including their sense of well-being, and clinical manifestations of disease can stymie and misdirect treatment. This is important for chronic relapsing conditions that may have an unpredictable disease course with periods of flare and dormancy, such as pediatric-onset rheumatic diseases [15-18], which affect 1 in 250 US children younger than 18 years and account for an estimated US $8.3 billion in annual hospital charges [19,20]. Juvenile idiopathic arthritis (JIA) and systemic lupus erythematosus (SLE) are two common forms of pediatric-onset rheumatic disease. JIA is the most common cause of acquired disability in the United States and the fifth most common chronic childhood disease [21]. Youth with JIA report poorer health-related quality of life than that of their peers, even in the setting of low disease activity and after treatment with biologic agents [22-24]. The impacts of JIA persist into adulthood, by which time nearly half of affected youth still experience recurrent or ongoing disease activity, active arthritis, progressive joint destruction, and decreased health-related quality of life [22,25-28]. SLE is a lifelong, chronic, multisystem autoimmune disease; around 15% of persons with SLE developed it in childhood [29], and these persons typically experience severe phenotypes, including organ disease. Youth with SLE may experience secondary morbidities and psychosocial difficulties (eg, mood disorders, body image problems, and academic and social challenges [30]) because, in addition to life-threatening disease manifestations, treatment includes exposure to high doses and prolonged courses of glucocorticoids, as well as cytotoxic agents [31-33].

Patient-reported outcome (PRO) measures that capture dimensions of well-being can inform understanding of treatment experience and efficacy [33], and studies on the clinical validity of PROs are underway among youth with rheumatic diseases and other conditions [10,33]. Data gleaned from youths' social media use may serve as an additional source of information about young patients' experiences of disease and treatment.

Engaging youth with JIA and SLE in reporting about their health via social media and in sharing their social media data with investigators may provide a channel for learning about youth psychosocial status and physical functioning to complement clinical observations and PROs. Social media data may be obtained passively or actively. In the passive case, social media data may be obtained without youths' permission or even without their awareness (as when data are programmatically collected and even sold by social media platforms). Additionally, social media data may be obtained actively via approaches that involve permissioned sharing, opt-in settings, and explicit notifications [34-38].

Regulatory efforts are being enacted to protect the privacy and autonomy of youth in web-based spaces [39,40]. As such, it is vital to understand whether young cohorts are willing to actively share their social media data for health research and whether health status differs between sharing and nonsharing groups [41]. Such insight would (1) clarify the feasibility of engaging youth with rheumatic diseases in sharing social media data for research and (2) help to quantify biases that could arise when relying on active models of collecting data from web-based cohorts. We sought to describe social media use among a clinically characterized cohort of youth with rheumatic diseases and to understand their passive (reading and viewing activities) and active (posting text or images) social media use in relation to these diseases. We further sought to quantify willingness to share social media data for health research and associations between willingness to share and patient-reported experiences of disease symptoms and functioning. We hypothesized that there would be equivalent percentages of youth who would and youth who would not agree to share their social media data for health research under a model of direct observation (ie, friending or otherwise providing access to social media data). Additionally, we hypothesized that the sharing cohort would report fewer symptoms and better functioning compared to those of the nonsharing cohort, potentially reflecting a greater sense of comfort and ease with their health and activities and fewer inhibitions about revealing any vulnerabilities. To date, few studies have been able to link personally generated data from social media with PROs and clinical data [42] to elucidate biases relevant to establishing the validity of social media data for health research—a recognized need [43,44].

Methods

Overview

Among adolescents with JIA or SLE who were members of the Childhood Arthritis and Rheumatology Research Alliance (CARRA) Registry [45,46] and enrolled in a prospective multisite study to clinically validate PRO measures [33], we investigated associations between social media use and

willingness to share social media data for research. Survey reports were collected via a tablet computer by using the REDCap (Research Electronic Data Capture; Vanderbilt University) secure web application [47,48] at regularly scheduled clinics visits, during which PRO and clinical data were also collected.

Ethical Considerations

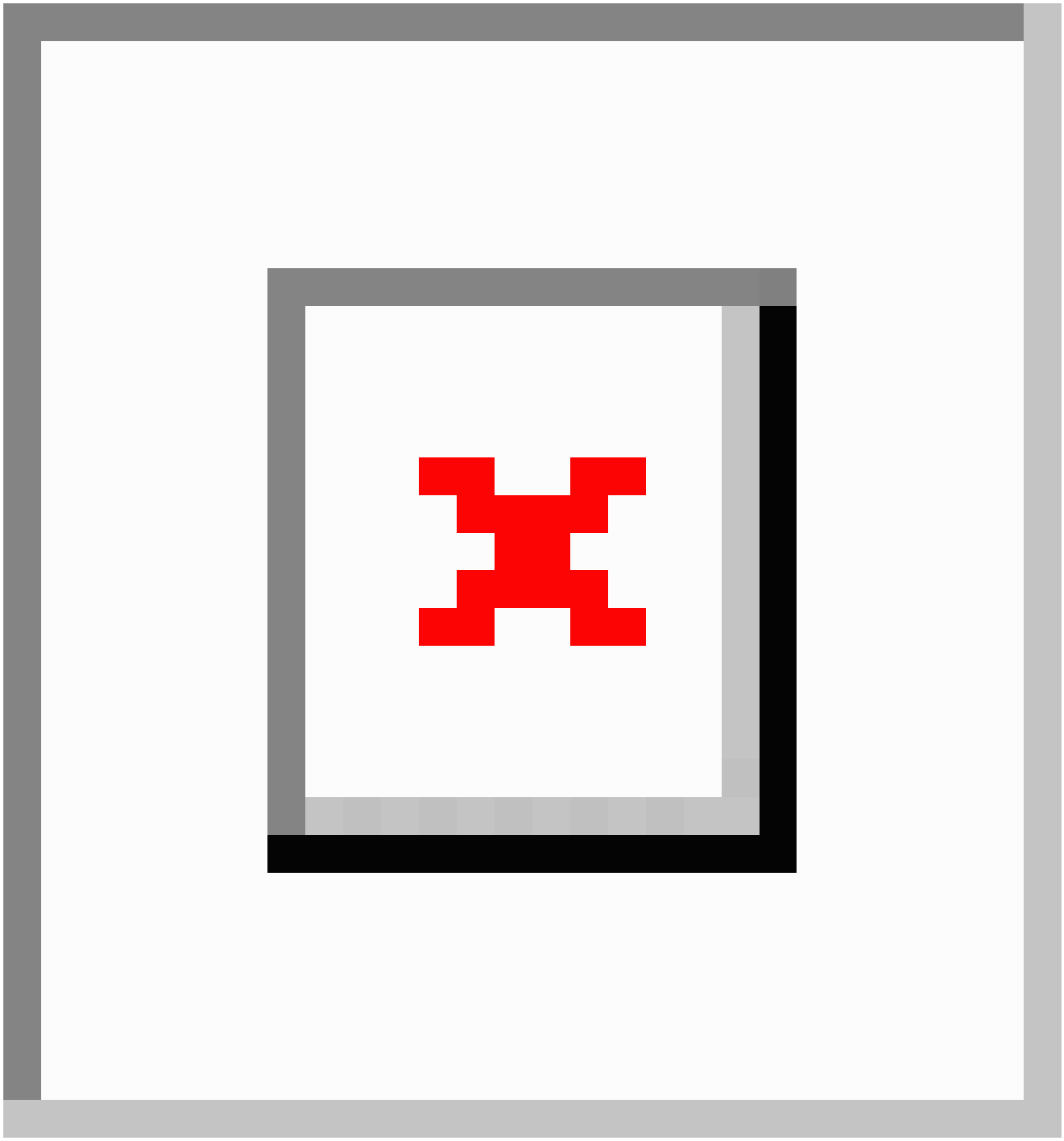
A small stipend was provided to participants in the form of a US $20 gift card. Trained research assistants obtained in-person informed assent and assigned participants a unique study ID that was linked to the ID used for the clinical validation study and registry to ensure confidentiality. The study protocol was reviewed and approved by the Boston Children's Hospital institutional review board (protocol number: IRB-P00025665).

Setting and Sample

Adolescents were eligible if they were members of the CARRA Registry, were diagnosed with JIA or SLE, enrolled in the parent prospective clinical validation study [33], and were at 1 of 3 validation study sites that participated in this substudy. Additional eligibility criteria were an age of 13 to 18 years, the ability to complete the survey in English on a tablet computer, and the reported use of at least 1 of 4 popular social media platforms (Facebook, Twitter, Instagram, or Snapchat) in the past 30 days. Patients were ineligible if they were medically or emotionally unstable or were otherwise unable to assent, as determined by a clinician or site research team member; were unable to speak or read English at an eighth-grade reading level; or did not attend the data collection visit (absent at recruitment).

Of the 145 patients approached, 123 consented (84.8%), of whom 6 were excluded because they were absent during data collection or reported Patient-Reported Outcomes Measurement Information System (PROMIS) measures at a time that did not overlap social media data collection. Of the remaining 117 patients, 5 did not use Facebook, Twitter, Instagram, or Snapchat and were excluded, leaving an analytic sample of 112 (91.1%; Figure 1).

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) diagram of study sample.



Sources of Study Data and Measures

Clinical and demographic data were drawn from the CARRA Registry. PRO and social media survey data were collected electronically by using wireless touch screen tablets during the clinic visit. Social demographic measures included race, Hispanic ethnicity, sex at birth, date of birth, insurance status, and the highest education attained by a parent. Clinical characteristics included the study recruitment and treatment site, the Physician Global Assessment (PGA) score [49], a 10-point visual analog scale score (a value of ≥1 represented active disease), BMI, and disease duration in months.

PROMIS Pediatric measures [50,51] included short-form measures of fatigue, mobility, pain interference, depressive symptoms, anxiety, and meaning and purpose, which were administered by using computer-assisted technology [10,33]. Higher PROMIS symptom T-scores reflect worse symptom levels, and higher functioning scores reflect better functioning. PROMIS measures are designed such that the mean score of the relevant reference population (ie, healthy youth) is 50, with an SD of 10 [52]. A 3-point difference in the PROMIS Pediatric T-score metric is considered a minimally important difference [53].

Willingness to share social media data via direct observation by the research team was assessed for Facebook, Instagram, Twitter, and Snapchat. Willingness measures are summarized in Table 1, along with related measures of motivation to share

social media data, reasons for not sharing, and passive and active use patterns.

Table . Measures of willingness to share social media data.

Question	Response options	Answers
Willingness to share social media		
"Are you willing to share your social media posts from the following site(s) for the two-week time interval around this study visit and your next study visit? This involves 'friending' the study account so the study team can view your posts. We will not message, 'like,' post on, or interact with your accounts"	• Facebook • Twitter • Instagram • Snapchat	1. Yes 2. No 3. Prefer not to answer
"(If YES to sharing any SM with the study) How much do you agree with the following statements regarding your motivations for sharing your social media data with this study?"	• I will be able to help other patients with rheumatic conditions • I am interested in research • I am interested in social media and technology • Participating in this research makes me feel valued • The $20[a] gift card incentivized me to participate in this research • I have some other motivation for sharing my social media data with this study	1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Prefer not to answer
Frequency of social media use		
"About how often do you visit OR use the following social media sites?"	• Facebook • Twitter • Instagram • Snapchat	1. Several times a day 2. About once a day 3. A few times a week 4. Every few weeks 5. Less often 6. I do not use this site 7. Prefer not to answer
"How often do you VIEW/READ about other people who have a rheumatic condition on any of the following sites?"	• Facebook • Twitter • Instagram • Snapchat	1. Often 2. Sometimes 3. Rarely 4. Never 5. Prefer not to answer
"Have you ever POSTED about your rheumatic condition on social media?"	• N/A[b]	1. Yes 2. No 3. Prefer not to answer
Benefits of viewing/reading about others with RD[c]		

Question		Response options	Answers
	"VIEWING/READING about other people who have a rheumatic condition on social media…"	• Helps me to feel less alone with my rheumatic condition • Helps me to talk to my friends about my rheumatic condition • Helps me to feel more prepared when talking to my doctor/care team about my rheumatic condition • Provides me with information about my condition that I can understand • Helps me to talk to my parents or guardians about my rheumatic condition • Provides me with information about treatments for my rheumatic condition • Provides me with health information that my doctors/care team cannot provide • Provides me with health information that I cannot find anywhere else	1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Prefer not to answer
Motivations for posting			

Question		Response options	Answers
	"How much do the following reasons motivate you to POST/SHARE about your condition on social media?"	• I want to feel understood • I want to help or provide support to other people living with a rheumatic condition or any chronic health condition • I want to connect with others living with a rheumatic condition or any chronic health condition • I want to share my experiences with a community that believes me • I want to update my friends/family members about my rheumatic condition • I want to get help or support from others who are living with a rheumatic condition or any chronic health condition • I want to share my thoughts/feelings when my rheumatic condition is under good control • I want to share my thoughts/feelings when I am experiencing disease symptoms	1. A great deal 2. Somewhat 3. Very little 4. Not at all 5. Prefer not to answer
	"How important to you are the following reasons when you are making decisions NOT to POST/SHARE about your rheumatic condition?"	• My rheumatic condition does not define me • I do not want others to feel bad for me because of my rheumatic condition • I do not want to disclose my diagnosis public on the internet • My rheumatic condition is not serious enough for me to post about it on social media • I worry about others knowing too much about my health • I do not want my friends to find out how I am feeling or doing • People might make fun of me, or I might get teased/bullied • I do not want my parents or guardians to find out how I am feeling or doing	1. A great deal 2. Somewhat 3. Very little 4. Not at all 5. Prefer not to answer

[a]US $20.

[b]N/A: not applicable.

[c]RD: rheumatic disease.

Data Analyses

Summary statistics were computed to characterize the study sample overall and by willingness to share social media data for research. The differences in demographic characteristics based on willingness to share social media data were analyzed by using appropriate statistical tests, including the Kruskal-Wallis test, 2-tailed *t* test, 2-sided Fisher exact test, and chi-square test. For 2 participants with JIA and 1 patient with SLE, we imputed missing values on the PGA by using the median score for their disease group and similarly imputed missing BMI values for 2 participants with JIA. In separate multivariable logistic regressions, we assessed the associations between willingness to share social media data for research (the dependent variable) and each PROMIS measure. All models controlled for age, biological sex, study site, and PGA score. The analyses were conducted by using SAS 9.4 (SAS Institute) [54]. Statistical significance was considered at $P<.05$.

Results

Sample Characteristics

Of the 112 participants, 98 (87.5%) were persons with JIA and 14 (12.5%) were persons with SLE. Overall, participants were

aged 13 to 18 (mean 16.1, SD 1.6) years, 72 (64.3%) were female, 86 (76.8%) were White, 105 (93.8%) were non-Hispanic, and 101 (90.2%) had private insurance. For all, the average BMI was 23.2 (SD 4.3) kg/m^2, and the average PGA score was 0.8 (SD 1.5), indicating inactive disease.

Willingness to share social media data was reported by a majority (83/112, 74.1%) of participants. In all, 43.8% (49/112) reported viewing or reading about others with rheumatic diseases on social media, and 25% (28/112) reported posting about rheumatic disease (Table 1).

Association Between Willingness to Share Social Media Data and Health Status

Willingness to share social media data was associated with female sex (*P*=.04) and greater disease activity (*P*=.04), which was measured as a mean PGA score (Table 2). Compared to nonsharers, sharers reported lower mobility (T-score: mean 49.0, SD 9.4 vs mean 53.9, SD 8.9; *P*=.02), greater pain interference (T-score: mean 45.7, SD 8.8 vs mean 40.4, SD 8.0; *P*=.005), more fatigue (T-score: mean 49.1, SD 11.0 vs mean 39.7, SD 9.7; *P*<.001), more depression (T-score: mean 48.1, SD 8.9 vs mean 42.2, SD 8.4; *P*=.003), and greater anxiety (T-score: mean 45.2, SD 9.3 vs mean 38.5, SD 7.0; *P*<.001).

In logistic regression analyses that controlled for age, sex, study site, and PGA score, each 1-unit increase in symptoms was associated with greater odds of willingness to share social media data, for measures of pain interference (Adjusted Odds Ratio [AOR] 1.07, 95% CI 1.001-1.14), fatigue (AOR 1.08, 95% CI 1.03-1.13), depression (AOR 1.07, 95% CI 1.01-1.13), and anxiety (AOR 1.10, 95% CI 1.03-1.18; Table 3).

Table . Characteristics of the sample by willingness to share social media.

Characteristics	All participants (N=112)	Social media sharing		*P* value
		Yes (n=83, 74.1%)	No (n=29, 25.9%)	
Age (years), mean (SD)	16.1 (1.6)	16.2 (1.6)	15.9 (1.5)	.34
Biological sex, n (%[a])				.04
Male	40 (35.7)	25 (30.1)	15 (51.7)	
Female	72 (64.3)	58 (69.9)	14 (48.3)	
Race, n (%[a])				.51
White	86 (76.7)	65 (78.3)	21 (72.4)	
Asian	5 (4.5)	2 (2.4)	3 (10.3)	
African American	2 (1.8)	2 (2.4)	0 (0)	
Mixed race	4 (3.6)	3 (4.6)	1 (3.4)	
Other race[b]	6 (5.4)	5 (6)	1 (3.4)	
Unknown	9 (8)	6 (7.2)	3 (10.3)	
Ethnicity, n (%[a])				.67
Hispanic	7 (6.3)	6 (7.2)	1 (3.4)	
Non-Hispanic	105 (93.8)	77 (92.8)	28 (96.6)	
Parental education, n (%[a])				.10
Less than a college degree	2 (1.8)	0 (0)	2 (6.9)	
College degree or higher	39 (34.8)	29 (34.9)	10 (34.5)	
Prefer not to answer or missing	71 (63.4)	54 (65.1)	17 (58.6)	
Insurance, n (%[a])				.15
Private health insurance	101 (90.2)	77 (92.8)	24 (82.8)	
Government insurance or other	11 (9.8)	6 (7.2)	5 (17.2)	
Rheumatic disease diagnosis, n (%[a])				.19
Systemic lupus erythematosus	14 (12.5)	8 (9.6)	6 (20.6)	
Juvenile idiopathic arthritis	98 (87.5)	75 (90.4)	23 (79.3)	
Health characteristics, mean (SD)				
BMI (kg/m^2)	23.2 (4.3)	23.3 (4.3)	22.7 (4.6)	.39
Disease duration (months)	84.6 (53.8)	84.2 (52.9)	85.6 (57.1)	>.99
Physician Global Assessment (score)	0.8 (1.5)	1.0 (1.6)	0.5 (1.1)	.04
PROMIS [c] Pediatric measure (T-score)				
Mobility	50.3 (9.5)	49.0 (9.4)	53.9 (8.9)	.02
Pain interference	44.3 (8.9)	45.7 (8.8)	40.4 (8.0)	.005
Fatigue	46.7 (11.4)	49.1 (11.0)	39.7 (9.7)	<.001
Depressive symptoms	46.6 (9.1)	48.1 (8.9)	42.2 (8.4)	.003
Anxiety	43.5 (9.2)	45.2 (9.3)	38.5 (7.0)	<.001
Meaning and purpose[d]	47.4 (8.3)	47.4 (8.6)	47.2 (7.4)	.91
Passive social media use, n (%[a])	49 (43.8)	39 (47)	10 (34.5)	.24
Active social media use, n (%[a])	28 (25)	23 (27.7)	5 (17.2)	.26

[a]Column percentages are shown (ie, the percentages were calculated by using the n values presented in the “All Participants” [N=112], “Yes” [n=83],

and "No" [n=29] headings as the denominators).

[b]Includes Middle Eastern or North African, Native American, American Indian, Alaska Native, Native Hawaiian, or other Pacific Islander.

[c]PROMIS: Patient-Reported Outcomes Measurement Information System.

[d]PROMIS measures for meaning and purpose were assessed among a total of 105 participants, including 80 (76.2%) in the "Yes" social media sharing group. Out of 112 total participants, 7 were not administered the PROMIS Meaning and Purpose survey during the parent study visit for reasons of timing.

Table . Associations between PROMIS[a] Pediatric measures of physical functioning, symptoms, and psychosocial well-being and social media sharing (N=112).[b]

PROMIS Pediatric measure	Adjusted odds ratio[c] (95% CI)
Mobility	0.95 (0.89-1.003)
Pain inference	1.07 (1.001-1.14)
Fatigue	1.08 (1.03-1.13)
Depressive symptoms	1.07 (1.01-1.13)
Anxiety	1.10 (1.03-1.18)
Meaning and purpose[d]	1.01 (0.95-1.07)

[a]PROMIS: Patient-Reported Outcomes Measurement Information System.

[b]Outcome: sharing social media contents (reference: not sharing social media); exposure: 1-unit increase in the PROMIS.

[c]Adjusted models controlled for the participants' age, sex, study sites, and Physician Global Assessment score. The reference group for the model is the participant group that was not willing to share the contents of any of their social media platforms with the researchers for this study. For each model, each individual PROMIS measure was entered independently, so these estimates do not reflect adjustment for other PROMIS measures.

[d]PROMIS measures for meaning and purpose were assessed among a total of 105 participants, including 80 (76.2%) in the "Yes" social media sharing group. Out of 112 total participants, 7 were not administered the PROMIS Meaning and Purpose survey during the parent study visit for reasons of timing.

Social Media Use and Value for Youth With Rheumatic Disease

The use of Instagram, Snapchat, Facebook, and Twitter was reported by 94.6% (106/112), 83.9% (94/112), 42.9% (48/112), and 31.3% (35/112) of participants, respectively, and poly-platform use was reported by 84.8% (95/112) of participants. More than two-fifths of participants (49/112, 43.8%) reported passive social media use, that is, reading about others with rheumatic diseases, while one-quarter (28/112, 25%) reported active social media use, that is, posting about rheumatic disease. Passive and active use patterns did not differ by age or by diagnosis; however, larger percentages of female participants than male participants reported both passive and active rheumatic disease–related social media activity (Table 4).

Table . Sample characteristics by passive or active social media use.

Characteristics	All participants (N=112)	Read about others with RD[a] on SM[b]			Post about RD on SM		
		Yes (n=49, 43.8%)	No (n=63, 56.3%)	*P* value	Yes (n=28, 25%)	No (n=84, 75%)	*P* value
Age (years), mean (SD)	16.1 (1.6)	16.3 (1.6)	16.0 (1.6)	.32	16.3 (1.6)	16.1 (1.6)	.61
Biological sex, n (%)							
Male	40 (35.7[c])	9 (22.5[d])	31 (77.5[d])	<.001	2 (5[d])	38 (95[d])	<.001
Female	72 (64.3[c])	40 (55.6[d])	32 (44.4[d])	N/A[e]	26 (36.1[d])	46 (63.9[d])	N/A
Rheumatic disease diagnosis, n (%)							
Systemic lupus erythematosus	14 (12.5[c])	9 (64.3[d])	5 (35.7[d])	.10	5 (35.7[d])	9 (64.3[d])	.33
Juvenile idiopathic arthritis	98 (87.5[c])	40 (40.8[d])	58 (59.2[d])	N/A	23 (23.5[d])	75 (76.5[d])	N/A
BMI (kg/m^2), mean (SD)	23.2 (4.3)	23.3 (4.3)	23.0 (4.4)	.78	24.4 (4.8)	22.7 (4.1)	.12
Disease duration (months), mean (SD)	84.6 (53.8)	76.9 (49.2)	90.5 (56.7)	.21	83.2 (48.7)	85.0 (55.6)	.96
Physical Global Assessment (score), mean (SD)	0.8 (1.5)	0.8 (1.2)	0.8 (1.7)	.23	0.6 (0.7)	0.9 (1.6)	.99

[a]RD: rheumatic disease.

[b]SM: social media.

[c]This percentage was calculated by using the total number of participants (N=112) as the denominator.

[d]A row percentage is presented (ie, the n value in the corresponding "All Participants" row total was used as the denominator).

[e]N/A: not applicable.

Among 49 youths who reported passive disease-related use of social media, there were high levels of agreement that such use is helpful for observational learning from others and for alleviating feelings of isolation (Figure 2). Similarly, many reported that passive use increases their access to understandable information and helps them feel prepared in speaking with family and their care team about rheumatic disease. Of the 28 social media users who reported that they use social media actively to post about rheumatic disease, many reported doing so to feel understood, support and connect with others with rheumatic diseases, and share experiences with family and the rheumatic disease community (Figure 3). Among all social media users, a plurality endorsed the importance of not defining themselves by their condition and not wanting others to feel badly for them because of their condition, reporting these as reasons for *not* posting about their condition. Others refrained from posting about their condition to avoid public disclosure, retain privacy, and protect themselves from others' attention or because they considered their condition insufficiently serious to merit attention (Figure 4). Finally, participants who shared their social media data reported they were motivated to do so because they were interested in research or technology, out of altruism toward other patients with the same conditions, to feel valued, and to receive a stipend (Figure 5).

Figure 2. Responses for the following measure: “VIEWING/READING about other people who have a rheumatic condition on social media.” RD: rheumatic disease.

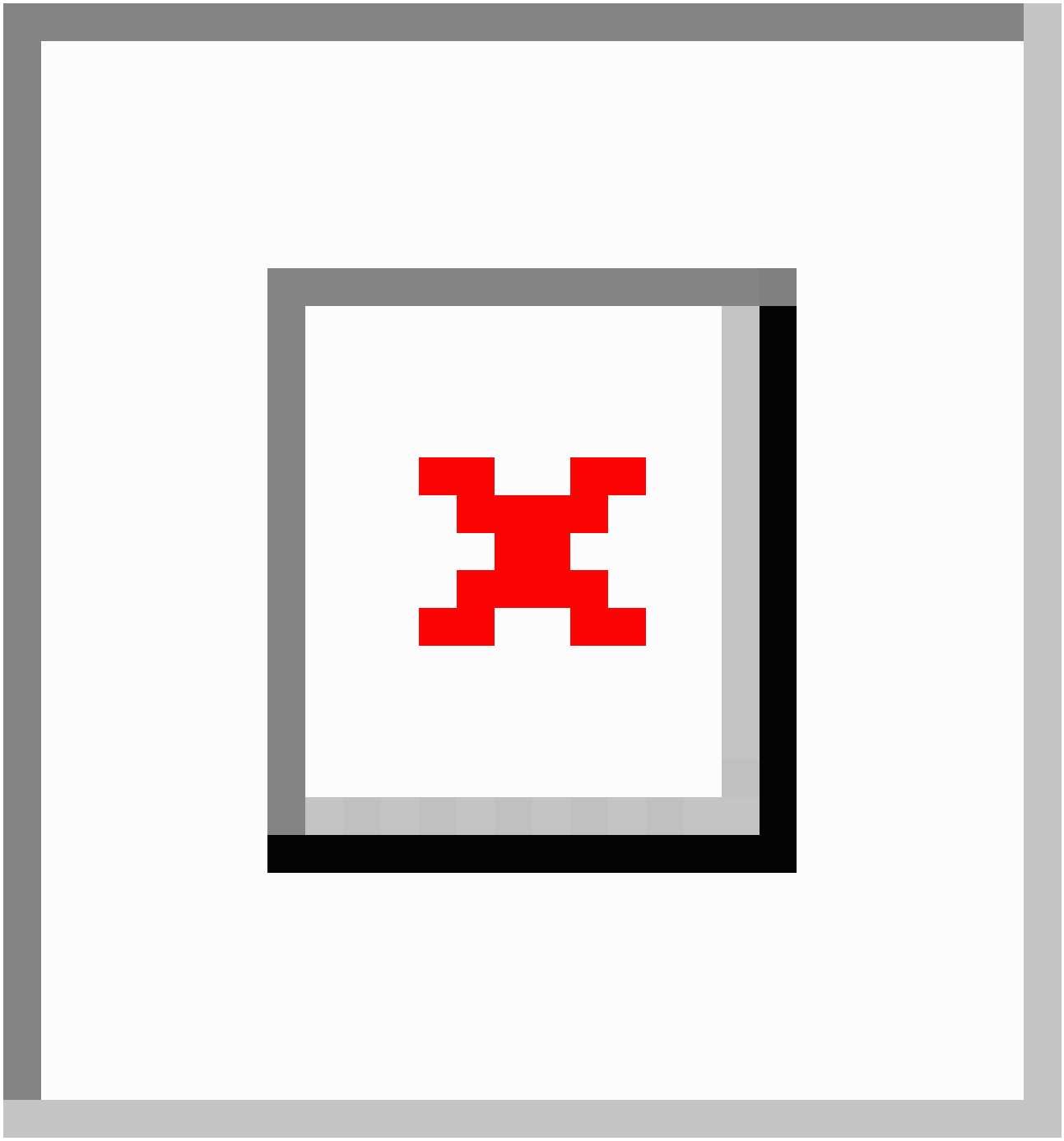


Figure 3. Responses for the following measure: “How much do the following reasons motivate you to POST/SHARE about your condition on social media?” RD: rheumatic disease.

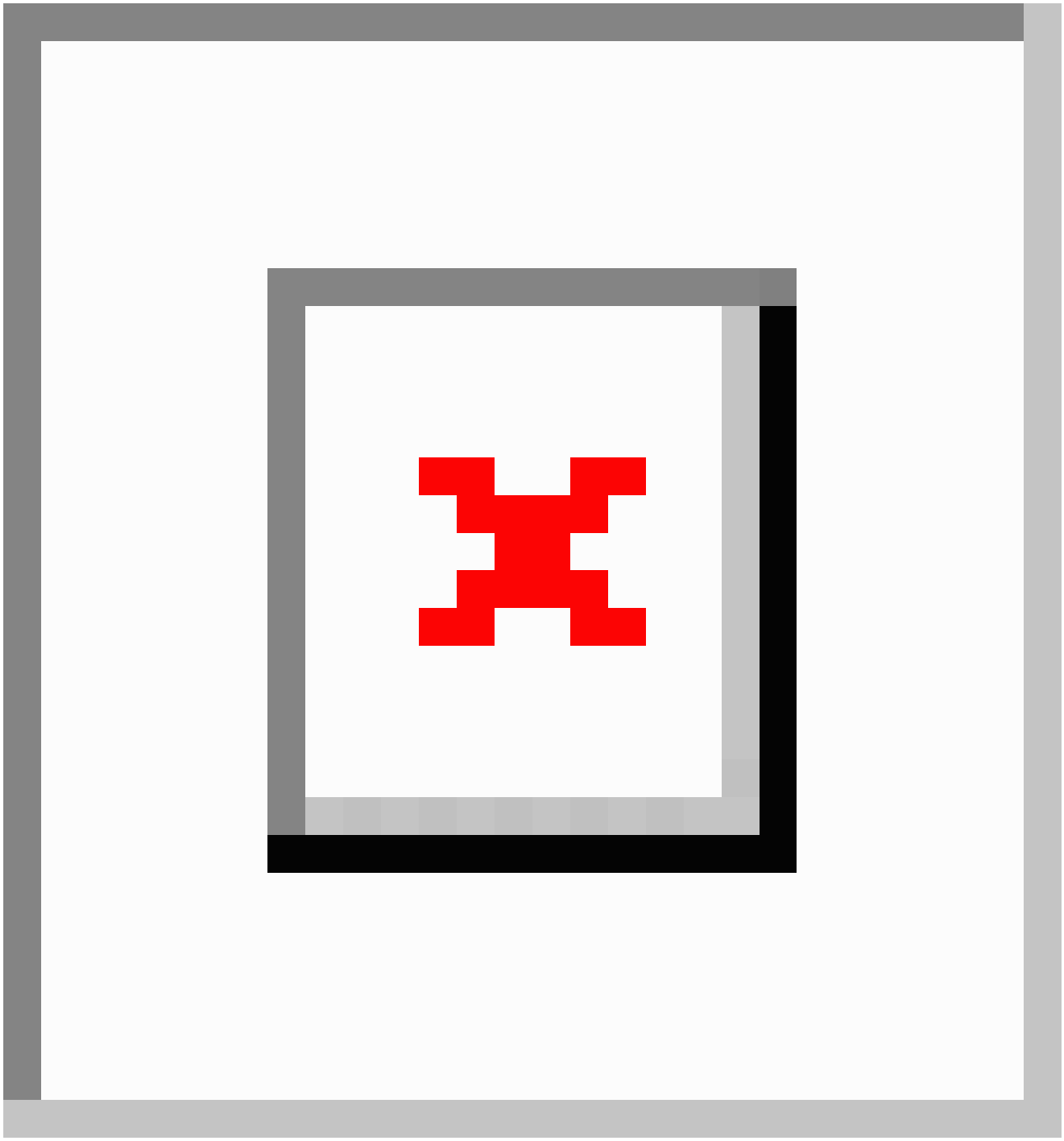


Figure 4. Responses to the following measure: “How important to you are the following reasons when you are making decisions NOT to POST/SHARE about your rheumatic condition?” RD: rheumatic disease.

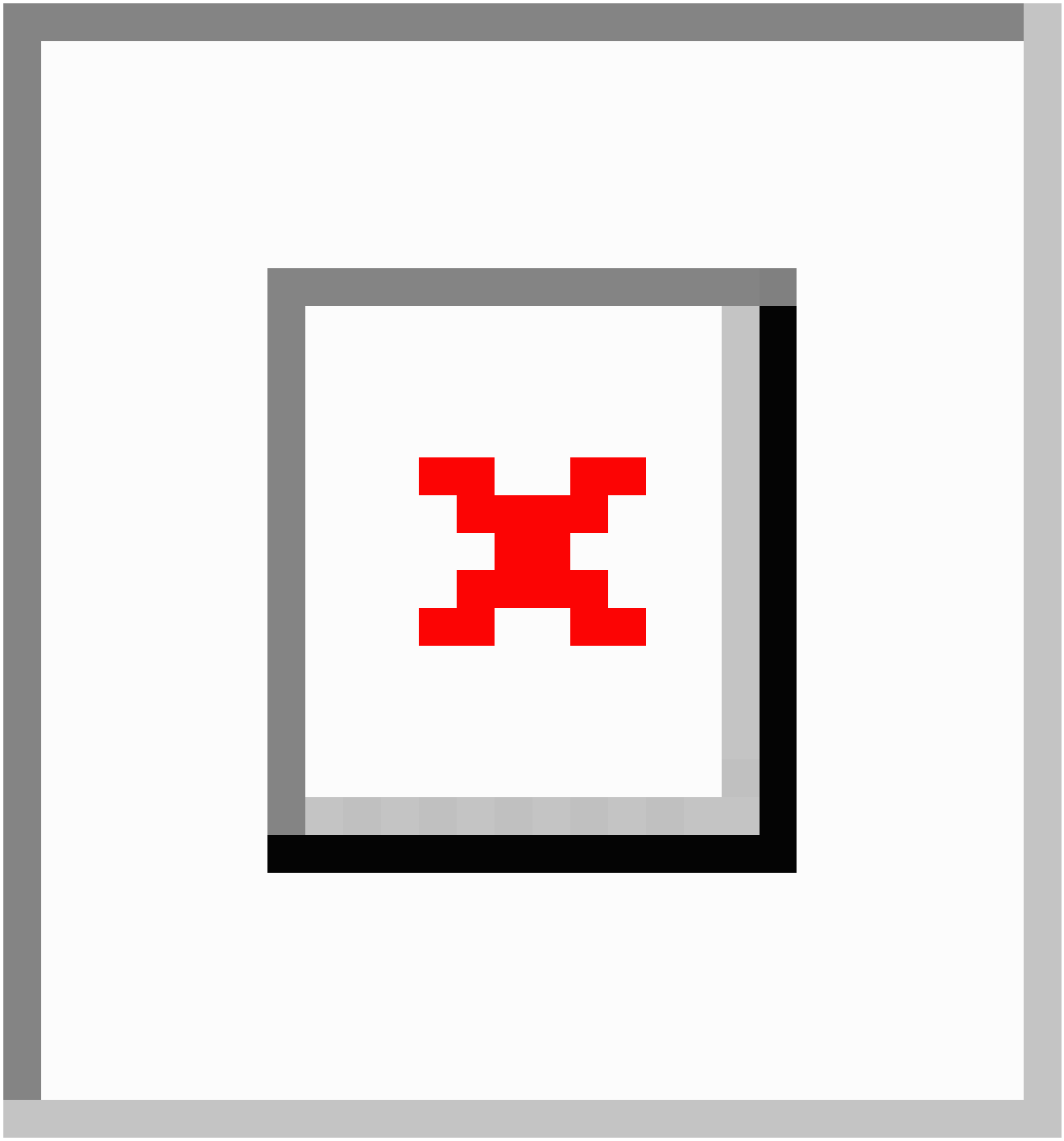
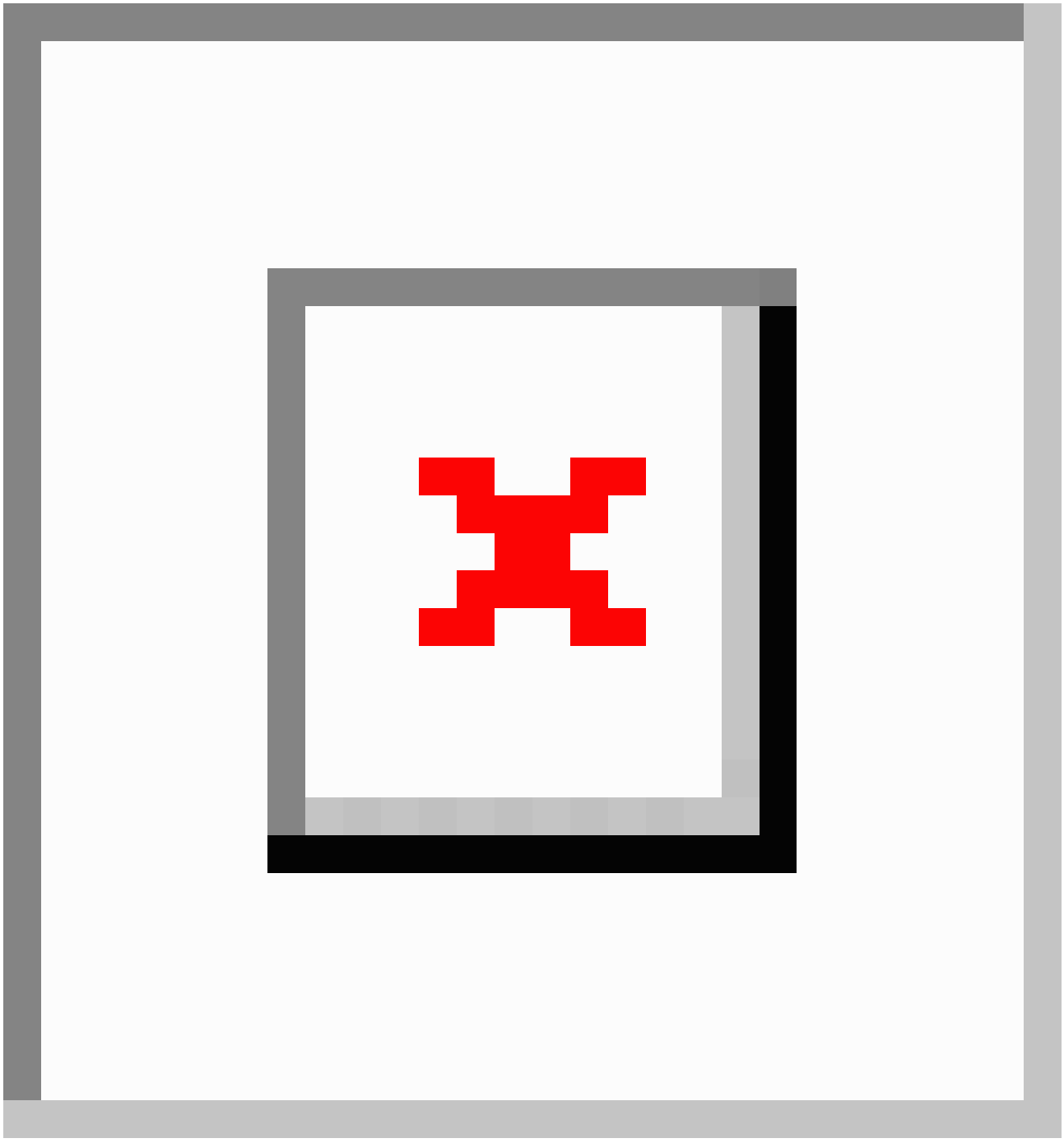


Figure 5. Responses to the following measure: "How much do you agree with the following statements regarding your motivations for sharing your social media data with this study?" RD: rheumatic disease.



Discussion

Principal Findings

In this multisite cohort study centered on adolescents with rheumatic diseases, we found high levels of willingness to share social media data for health research. Contrary to our original hypothesis that willingness to share would be associated with lower levels of symptoms and better psychosocial status, sharing was associated with higher levels of disease-related symptoms, specifically pain interference and fatigue, and higher levels of depression and anxiety. Both passive and active disease-related use of social media were reported, and larger percentages of female participants than male participants engaged in these activities. Passive and active social media use patterns were motivated by participants' goals regarding observational learning about their condition and connection to others with similar conditions, as well as by the exchange of social support. Motivations to refrain from posting about rheumatic disease reflected participants' goals of wanting to avoid having their condition define them, remaining private, and protecting against disclosure and ridicule. Among participants who agreed to share their social media data for research (n=83), almost all did so out of interest in research (83/83, 100%), to help others with a rheumatic condition (80/83, 96%), and because they felt it was of value personally (70/83, 84%) and financially (ie, for compensation; 59/83, 71%).

A growing body of research indicates the potential for improving adolescent and young adult health behaviors and outcomes (eg, health food consumption, reduced BMI, and reduced tobacco use) through engagement with social media and related features for peer groups and messaging [55-57]. Nevertheless, understanding of the potential for using social media as a source of health information and as a platform for research engagement is constrained by the lack of insight into the differences in health status between persons who are and persons who are not willing to share their data. For participatory surveillance models, some evidence shows that greater sharing and openness exist among early adopters of research apps and among persons whose disease is better controlled [58]. Other studies have found less reticence to share digital health data for care improvement among technology users who report lower incomes when compared to those who report higher incomes [59].

This study adds to what is known about willingness to share social media, with the added advantage of assessing reports from a clinically characterized cohort whose actual sharing was directly observed, differing from studies on hypothetical willingness, which are more common [60-62]. Few studies of social media use and social media data sharing provide access to linked clinical data [42] or structured PROs, and to our knowledge, none have been undertaken among youth with rheumatic diseases. Research with teenagers is vital, since this group is assuming control over their own health care, health information, and social media, and as a group, teenagers are both heavily engaged with social media [63] and uniquely vulnerable to social influences communicated through web-based channels [58,59,64,65].

Our findings of differences between sharing and nonsharing cohorts have implications for the use of personally generated data from web-based cohorts. In this study, sharing was associated with worse health. It is not clear what explains differences in health status between sharing and nonsharing youth. It may be that youth with rheumatic diseases who are unwilling to share their social media data are more socially engaged in ways that they consider unsuitable or too sensitive to allow sharing. Alternatively, they may be less desirous of research attention if they feel well and are able to satisfy their social needs through offline means. Future work may help elucidate reasons for observed differences. Similarly, future work with youth affected by other conditions is merited to understand whether differences between sharing and nonsharing groups hold.

The findings from this study have larger implications for social media–related research. First, investigators who use social media platforms to engage adolescents in health research should be explicit about the potential for biases related to inferences when denominators are poorly specified or are unknown [41,66]. The results from this study suggest that observations about the health of youth with rheumatic diseases drawn from social media–engaged cohorts may be skewed toward describing youth with greater symptoms and worse psychosocial health. This is a limitation when the goal of a study is to understand the entirety of a patient population but may be an advantage when the aim of a study is to engage youth who are struggling. The internet and social media serve important supportive functions for youth with a chronic illness, of whom many have been disproportionately adversely affected by social isolation and the hardships of the recent COVID-19 pandemic [67]. Second, findings regarding the high value placed by youth with rheumatic diseases on obtaining social and informational support related to their condition from others on the web is revealing of the seriousness of the gaps in support available from organized health care systems, as others have reported [68]. As youth turn to social media for support to fill these gaps, it remains important to consider the accuracy and safety of information offered by web-based peers, accessibility to youth across a range of health literacy and technology access levels, and the potential for harm from exposure to misinformation. Steps for detecting and addressing this during clinical visits might include asking young patients about their need for information and support and their ability to access web-based resources, as well as providing links and pointers to reliable, vetted sources of web-based guidance. These “low-tech” strategies can be implemented among even more computationally sophisticated systems for evaluating and improving the quality and accuracy of web-based information.

Limitations

This report draws from a convenience sample of youth, and generalizability is limited by several factors, including the focus on youth with rheumatic diseases who have access to and use the internet and social media. The study cohort consisted of youth who were previously enrolled in research, and our findings may not generalize to youth who refrain from or have limited access to research opportunities. Sociodemographic diversity is also limited. However, the clinical confirmation of disease status and availability of validated health measures (eg, PROMIS measures) are strengths. Nevertheless, the results may not generalize to youth at other clinical sites, a broader sample of youth with rheumatic diseases, youth with other chronic conditions, or youth who do not use social media. This study did not assess participants’ understanding of health information or their ability to discern information quality or misinformation. The cross-sectional nature of this study precludes causal interpretation.

Conclusions

We found high willingness to share social media data for health research among a clinically characterized cohort of adolescents with rheumatic diseases and substantial use of social media for disease-related observational learning and social connection. Differences in health status between sharing and nonsharing youth (as well as between social media users and nonusers) underscore the importance of considering the potential for biases in research results that rely on social media data and the importance of identifying opportunities to engage and improve the health of youth who may be on the web and in need of support.

Acknowledgments

The authors would like to acknowledge Kara Magane and Alexandra Marin for help with study planning and Sydney Pierce and Laura Blakemore for help with manuscript preparation. We thank Dr Fatma Dedeoglu, Dr Bryce B Reeve, Dr Sarah Ringold, Dr Laura E Schanberg, Dr Richard Vehe, and Dr Emily von Scheven for providing access to study registry and patient-reported outcome data. The authors wish to acknowledge the Childhood Arthritis and Rheumatology Research Alliance (CARRA) and the ongoing Arthritis Foundation financial support of CARRA. This work was funded by the National Institute of Arthritis and Musculoskeletal and Skin Diseases/National Institutes of Health (NIAMS/NIH; R21AR070944-01A1).

Conflicts of Interest

None declared.

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Abbreviations

AOR: adjusted odds ratio
CARRA: Childhood Arthritis and Rheumatology Research Alliance
JIA: Juvenile Idiopathic Arthritis
PGA: Physician Global Assessment
PRO: Patient-Reported Outcome
PROMIS: Patient-Reported Outcomes Measurement Information System
REDCap: Research Electronic Data Capture
SLE: systemic lupus erythematosus

Edited by S Badawy; submitted 30.03.23; peer-reviewed by K Allen, M Kwon; revised version received 27.07.23; accepted 15.08.23; published 06.12.23.

Please cite as:
Weitzman ER, Minegishi M, Cox R, Wisk LE
Associations Between Patient-Reported Outcome Measures of Physical and Psychological Functioning and Willingness to Share Social Media Data for Research Among Adolescents With a Chronic Rheumatic Disease: Cross-Sectional Survey
JMIR Pediatr Parent 2023;6:e46555
URL: https://pediatrics.jmir.org/2023/1/e46555
doi:10.2196/46555

A Web-Based Intervention to Address Risk Factors for Maternal Morbidity and Mortality (MAMA LOVE): Development and Evaluation Study

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Abstract

Background: Maternal mortality in the United States is a public health crisis and national emergency. Missed or delayed recognition of preventable life-threatening symptoms and untimely treatment of preventable high-risk medical conditions have been cited as key contributors to the nation's worsening mortality rates. Effective strategies are urgently needed to address this maternal health crisis, particularly for Black birthing populations. Morbidity and Mortality Assessment: Lifting Outcomes Via Education (MAMA LOVE) is a web-based platform that focuses on the identification of maternal morbidity and mortality risk factors.

Objective: The purpose of this paper is to present the conceptualization, development, heuristics, and utility evaluation of the web-based maternal mortality risk assessment and educational tool MAMA LOVE.

Methods: A user-centered design approach was used to gain feedback from clinical experts and potential end users to ensure that the tool would be effective among groups most at risk for maternal morbidity and mortality. A heuristic evaluation was conducted to evaluate usability and need within the current market. Algorithms describing key clinical, mental health, and social conditions were designed using digital canvas software (Miro) and incorporated into the final wireframes of the revised prototype. The completed version of MAMA LOVE was designed in Figma and built with the SurveyJS platform.

Results: The creation of the MAMA LOVE tool followed three distinct phases: (1) the content development and creation of an initial prototype; (2) the feedback gathering and usability assessment of the prototype; and (3) the design, development, and testing of the final tool. The tool determines the corresponding course of action using the algorithm developed by the authors. A total of 38 issues were found in the heuristic evaluation of the web tool's initial prototype.

Conclusions: Maternal morbidity and mortality is a public health crisis needing immediate effective interventions. In the current market, there are few digital resources available that focus specifically on the identification of dangerous symptoms and risk factors. MAMA LOVE is a tool that can address that need by increasing knowledge and providing resources and information that can be shared with health care professionals.

(JMIR Pediatr Parent 2023;6:e44615) doi:10.2196/44615

KEYWORDS

maternal mortality prevention; mobile technology; pregnancy; Black women; maternal; pregnant; mortality; web-based; utility; usability; mHealth; mobile health; algorithm; development; design; software; risk assessment; patient education

Introduction

Maternal mortality in the United States is a public health crisis and national emergency [1-3]. According to the Centers for Disease Control and Prevention (CDC), US maternal mortality rates (defined as the number of maternal deaths/100,000 live births) worsened from 2019 (20.1) to 2020 (23.8) [3]. Stark racial disparities persist in maternal mortality, with rates highest among Black women (55.3) as compared to White (19.1) and Hispanic (18.2) women. Missed or delayed recognition of preventable life-threatening symptoms and untimely treatment of preventable high-risk medical conditions have been cited as key contributors to the nation's worsening mortality rates [3,4]. Effective strategies are needed to address this maternal health crisis, particularly for Black birthing populations [5].

The leading pregnancy-related causes of death among Black populations include cardiovascular conditions, hypertensive disorders, hemorrhage, and infection, conditions in which the timeliness of patient reporting and subsequent medical intervention are critical [3,4,6]. Additionally, mental and social

conditions such as postpartum depression and psychosis as well as accidental death from violence, suicide, and opioid overdose increase the risk for self-harm; however, these factors have been largely overlooked in the evaluation of risk factors contributing to maternal death [6-11]. The risk for maternal mortality and poor health outcomes are also influenced by larger systemic, economic, and societal factors including lack of access to resources, racism, and bias [12-15].

Black women consistently report feeling ignored and unheard by providers when expressing concerns about health symptoms and the necessary resources to address them [16,17]. The development of interventions that not only improve the effectiveness of maternal mortality risk assessment but also provide ways to elevate the patient perspective and communication with providers may prove effective in combating the rising maternal morbidity and mortality rates. Technology-based health communications have proven to be effective tools to increase knowledge and improve communication activity among black populations engaged in mobile health (mHealth) research for people with other medical conditions [18,19]. Innovative strategies are needed that empower birthing people to overcome concerns of feeling unheard and disrespected in the birthing setting while ensuring that high-risk symptoms are addressed effectively.

There is limited research on the development, testing, and use of maternal mHealth apps that specifically address serious maternal morbidity and mortality risk for birthing people of color [20]. However, one study evaluated commercially available mHealth apps and the quality of the maternal health information content, app usability, and the inclusion of representation of people of color, who are those at the highest risk of serious maternal morbidity and mortality [20]. The authors screened over 300 mHealth apps, and only 25 met the inclusion criteria. The study found that most mHealth apps addressed peripartum behaviors but not health symptoms or risk factors, and most did not include adequate representation of birthing people of color [20]. Additionally, a meta-analysis of 15 randomized controlled trials implementing mobile technology to address perinatal mental and physical health showed moderate to large effect sizes in measured outcomes related to maternal physical and mental health and knowledge about pregnancy; however, there was no discussion on the impact on communities of color [20]. Other platforms focused on addressing maternal health issues in Black pregnant populations exist but are focused on topics related to weight management, gestational diabetes, and breastfeeding [21-24].

Taken together, these findings suggest that mHealth apps, when developed in collaboration with target demographic communities, appear to be an effective way to communicate information related to knowledge about maternal physical and mental health to birthing people. However, existing platforms do not currently address symptoms related to the high-risk conditions that contribute most to maternal morbidity and mortality, and those that do are not tailored toward communities of color, the population at greatest risk of experiencing adverse perinatal outcomes.

We conducted a market analysis in October 2021 looking at the availability and quality of evidence-based tools that provide customized symptom resources for Black female peripartum consumers. The market analysis was performed through a keyword search of the Apple App Store and Google Play Store, public websites, and PubMed. Our main findings included the Believe Her app (a CDC black mental health clinicians' platform for peer-support and resource access) [25], the Irth app (crowdsourced reviews of health care providers from Black and Indigenous women of color) [26], and several web-based applications, such as Wolomi, Mahmee, and Mae (pregnancy and postpartum resources) [27-29]. These findings provide valuable insights into the market for evidence-based tools that cater to the specific needs of peripartum Black women consumers. While these platforms are important, it becomes apparent that there are a limited number of resources available that specifically address the needs of peripartum Black women consumers specifically related to risk factors for maternal morbidity and mortality [30]. Despite an increasing number of contributions to the field, there remains a critical gap in our understanding of how to best meet these unique health care needs of women of color during the peripartum period.

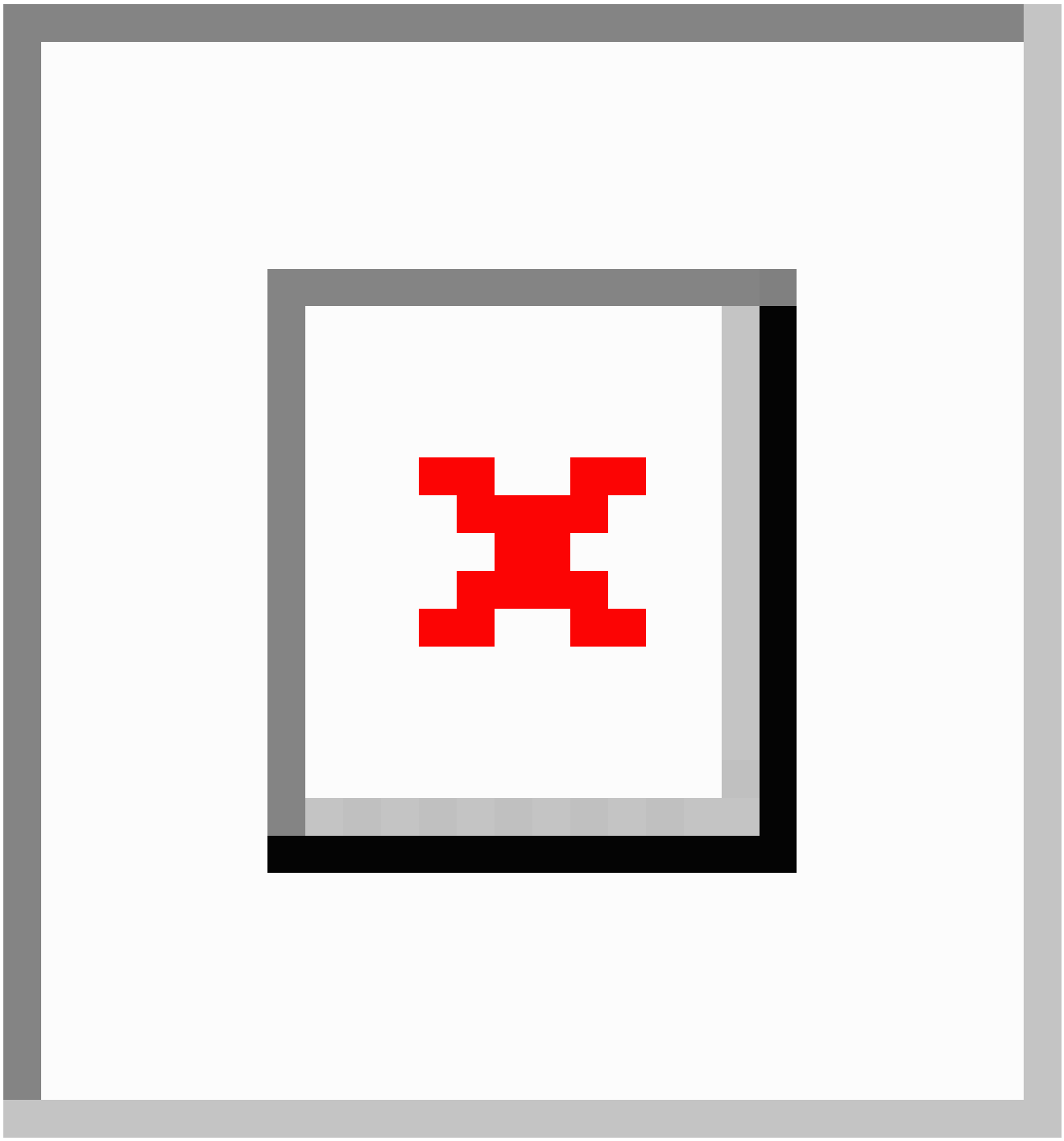
Morbidity and Mortality Assessment: Lifting Outcomes Via Education (MAMA LOVE) is a web-based platform that focuses on the identification of maternal morbidity and mortality risk factors, a feature not identified during our market search. The platform has been designed to address the leading medical conditions associated with maternal morbidity and mortality with an additional focus on mental health conditions and social determinants of health. Specifically, the platform provides the following: options for users to select symptoms associated with each category (physical, mental health, and social); feedback and recommendations on follow-up timelines for selected symptoms; tailored educational and resource links for selected symptoms; and a downloadable document of all physical, mental health, and social factors selected, which can be presented to health care providers as a communication tool. Tools that provide education for birthing people on perinatal urgent warning signs are needed to equip and empower them to seek care and communicate effectively with care providers. A key benefit provided by MAMA LOVE is the ability to tailor resources based on user-entered information, as evidenced by the market analysis. Given this capability, there may be regulatory implications in future versions of the tool. For example, Food and Drug Administration clearance would be required if the app were to make clinical recommendations based on the results of the survey.

The purpose of this paper is to present the conceptualization, development, heuristics, and utility evaluation of the web-based maternal mortality risk assessment and educational tool, MAMA LOVE. Specifically, in this paper, a detailed description of the content development process, feedback and end user recommendations, heuristic evaluation of the platform components, and final tool are presented along with a discussion about implications for future directions.

Methods

The creation of the MAMA LOVE tool followed three distinct phases (Figure 1): (1) the content development and creation of an initial prototype; (2) the feedback gathering and usability assessment of the prototype; and (3) the design, development, and testing of the final tool. In this section, we further describe the methods for each of these phases.

Figure 1. Flowchart of the study's methodology. HE: heuristic evaluation; MAMA LOVE: Morbidity and Mortality Assessment: Lifting Outcomes Via Education.



Phase 1: Content Development

Physical Indicators

The initial conceptualization of the tool was guided by information identified in clinical practice guidelines, publicly available data, and maternal mortality review reports related to the leading maternal health conditions contributing to morbidity and mortality, both in the United States and globally [7,8,31-33]. Epidemiologic-level data and factors identified in the literature were used to ensure that the most common high-risk physical conditions were included [3,7,9]. The CDC has leveraged administrative hospital discharge data and *International Statistical Classification of Diseases, Tenth Revision* (*ICD-10*) diagnosis and procedure codes to create a list of the 21 most common severe maternal morbidity conditions; these created the foundation for the symptom screening component of the app [33].

Additionally, the World Health Organization's *The WHO Application of ICD-10 to Deaths During Pregnancy, Childbirth and the Puerperium: ICD-MM* report was consulted as a resource to ensure that the full range of most common causes of maternal death were incorporated into the physical screening portion of the tool [34].

Mental Health and Social Indicators

Health disparities are driven by multiple interrelated medical, social, and societal factors that promote susceptibility to disease [3,12-14]. Within the context of maternal mortality identification, medical conditions and their risks are well documented. However, less has been published on the relationship between maternal mental health conditions that increase the risk for self-harm and maternal mortality rates [35]. Additional content on maternal mental health conditions as well as social determinants were added given that the data on the leading causes of maternal death and severe illness include many of these factors as potential contributors [4,10-15,15]. The options available for selection by end users incorporate terminology that captures both the user experience as well as symptoms listed in clinical guidelines related to the conditions.

Resources

Educational resources were collected on each associated physical condition from reputable academic (ie, Mayo Clinic and University of California, San Francisco), governmental (ie, CDC), and nonprofit/community-based organizations (ie, Pre-Eclampsia Foundation, National Blood Clot Alliance, and Black Mamas Matter Alliance) to create customized educational reports based on the symptoms selected by the user.

Prototype

From the information identified in the literature, clinical practice guidelines, and public reports about the leading contributors to maternal morbidity and mortality, a prototype was built. This initial prototype of the tool (not shown) was developed via a collaboration between nurse midwifery researchers, community experts, and a software engineer at a private institution in Atlanta, Georgia. The initial prototype was developed with a third party with the guidance of the clinical authors over a period of 1 year. The format of the tool included an introduction to the MAMA LOVE platform; sociodemographic questions; symptom options for physical, mental health, and social factors; sample recommendations for a course of action options; and examples of resources that could be included. The goal of the prototype design was to validate whether the tool captured the most common symptoms and risk factors associated with high-risk perinatal conditions and to explore if the conditions and resources included in the tool were relevant to end users. Due to limitations in the software, the inability to make changes easily, and difficulty in addressing the heuristic evaluation results, a second tool was developed that allowed for more robust algorithm development and seamless transition between selected items, recommendations, and resources.

Phase 2: Feedback and Usability Evaluation

Focus Group Sessions

Given the persistent racial and geographic disparities in maternal mortality risk, a robust approach inclusive of the community and social environment in which Black women reside may prove effective in ameliorating maternal mortality risk. As such, five focus group sessions (n=19) were conducted on the initial prototype with a mix of Black birthing parents (n=3) as well as doulas (n=6), community organization representatives (n=4), and health care providers (n=6) to assess initial impressions of the tool and to validate the concept. A rapid analysis of the focus group sessions was conducted to quickly identify key areas for feedback and revision of the tool [36]. The Emory University Institutional Review Board approved the study.

Heuristic Evaluation Methods

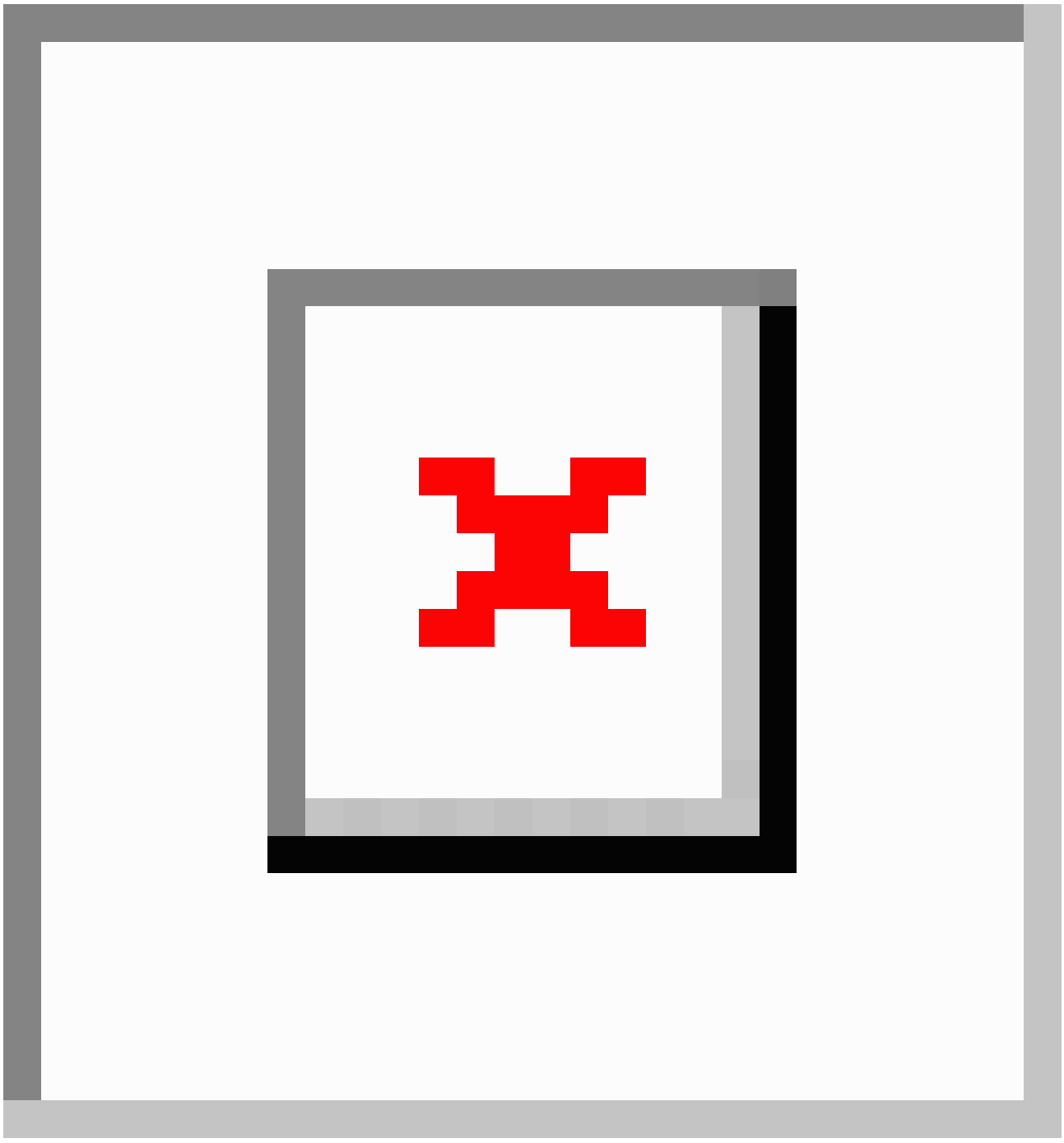
A heuristic evaluation is a qualitative assessment in which a usability expert measures a user interface against a set of principles to find usability issues. The heuristic evaluation was conducted on the initial prototype independently by five experts using Nielsen and Norman's 10 Usability Heuristics, and the number of evaluators was determined using heuristic evaluation principles [37]. The experts responsible for conducting the heuristic evaluation consist of three graduates and two current students of the Masters in Human Computer Interaction program at the Georgia Institute of Technology, in collaboration with digital health developers at the AppHatchery at Emory University.

Phase 3: Design, Development, and Testing

Algorithm Design

The algorithm development followed an iterative approach in the translation from the clinicians to the developers. First, the clinician would list the symptoms related to a given condition and the suggested recommendation for the user. The developer partners would then review that representation and, with the clinicians, verify that the symptoms map properly to the condition. Common computer nomenclature was used to facilitate implementation and testing. Due to the algorithm's complexity and many mappings between symptoms and conditions, a visual approach to organizing the information was used. Miro is a digital canvas tool that allows for real-time collaboration and facilitates mind mapping, which made it ideal for this use case. Symptoms in the algorithm were arranged head to toe and then mapped to select conditions (see Figure 2). Lastly, the language of the symptoms was carefully crafted to be understood by Black birthing parents, incorporating both the feedback from the focus groups as well as the authors' experiences hearing patient questions in clinics.

Figure 2. Visual representation of the algorithm for the head. Symptoms are represented in the turquoise, blue, and yellow sticky notes depending on the symptom category (main or additional). Conditions are in purple diamonds. The recommended course of action is outlined in the textboxes on the right-hand side. HELLP: hemolysis-elevated enzymes and low platelets.



Tool Design and Development

Limitations in the first prototype tool related to software, the inability to make changes easily, and difficulty in addressing the heuristic evaluation results prompted the development of a second and final tool that allowed for more robust algorithm development and seamless transition between selected items, recommendations, and resources.

The second tool was designed in Figma (Adobe), developed with the SurveyJS framework, and carried out by AppHatchery. AppHatchery is a National Institutes of Health–funded team part of the Georgia Clinical and Translation Science Alliance that creates patient-centered digital tools for health care through strategy, user research, design, software development, and clinical studies. The design and development of the tool took 6 months from August 2022 to January 2023, during which weekly meetings were held between the AppHatchery team and the clinical experts. Additionally, the collection of use metrics (Pendo.io) and survey responses (Firebase) was set up to validate the tool's usability and intervention's feasibility; this will be reported in a future paper.

Beta Testing

Once the tool was finalized and made available on MAMA LOVE, it was tested by the authors and 3 nurse midwifery

experts from Emory University prior to public promotion of the platform. The aim was to find issues with the algorithm recommendations and to ensure the data collection was accurately capturing users' behavior in the tool and their submitted responses. During this iterative testing process, inaccuracies were identified and corrected.

Ethics Approval

Ethical considerations and safety were evaluated and approved via the Emory Institutional Review Board's review process (IRB STUDY00002618).

Results

Phase 1: Content Development

Overview

The tool was primarily developed to screen for symptoms related to the most common conditions associated with severe maternal morbidity and mortality. From this list of conditions, clinician experts created symptom panels that map a user's reported symptom experiences to a list of potential health conditions. Symptoms were arranged head to toe and then mapped to potential conditions that include the symptoms selected. Additionally, mental health conditions were included in the design prototype to further contextualize risk factors that may increase the risk for maternal morbidity or mortality. Recent findings indicate that mental and social conditions such as substance use disorder, suicide, and homicide are the leading contributors to serious maternal morbidity, particularly in the later postpartum period [11,35,38]. Overwhelmingly, mental health has been overlooked in the context of maternal mortality risk, but data suggest that more screening and attention to mental health are needed.

When ascertaining which social determinants of health to include in the tool, several modalities were leveraged. The first was expert clinician brainstorming sessions to identify the most common social determinants of health that have the potential to contribute to maternal morbidity and mortality. The search was then expanded to include, from an epidemiological perspective, the social determinants of health found to most commonly predict maternal morbidity and mortality at a large scale. The final conditions included in the tool were determined by the clinical authors in consultation with health care providers who participated in focus group sessions to assess the initial features of the tool. Additional feedback was gathered from other end users including community organizations, doulas, and Black women with experiences of high-risk morbidity conditions who participated in focus group sessions. The Area Deprivation Index was found to be a strong predictor of adverse perinatal outcomes [39-41]. Thus, the potentially modifiable components used to calculate this index were built into the tool, including housing, employment, and access to transportation. Finally, an extensive literature search was performed to further inform the selection of social determinants of health to ensure the most important factors were incorporated, including housing instability, intimate partner violence, rural location or transportation difficulties, and food insecurity [15,38,42-44].

Resources

Delayed reporting of concerning symptoms can result in ineffective and untimely management of potentially deadly conditions. The development of interventions that empower and educate pregnant populations to accurately recognize life-threatening symptoms, provide access to necessary resources, and promote effective communication with providers are needed to mitigate the maternal mortality risk among high-risk populations. It is essential that users are directed to reliable educational resources that consistently use the most up-to-date available evidence. Additionally, resources for mental health and other social determinants of health were included with a particular focus on including culturally focused content from groups like the Black Mamas Matter Alliance and Every Mother Counts organizations. Mental health resources were obtained primarily from Postpartum Support International (PSI), which is a leading nonprofit organization with a focus on perinatal mental health conditions [45]. In addition to educational information on perinatal mood disorders, users can access a PSI-sponsored 24-hour emergency crisis hotline for immediate support and a directory with mental health providers in their area. State- and national-level resources to address food insecurity, housing instability, insurance enrollment information, and transportation resources are also included.

Phase 2: Feedback and Usability Evaluation

Focus Group Sessions

To ensure that MAMA LOVE would be effective, feedback on the first prototype was sought from Black birthing people and community stakeholder experts (comprised of doulas, community organizers, and health care providers). Key aspects identified in the rapid analysis of the focus group sessions included simplification of the terminology used across the platform, incorporation of examples to describe conditions, features to show the end user how far along they are in the platform, grouping of demographics questions, use of more images and fewer words, and expansion of resources lists to include more content from diverse groups that serve Black pregnant populations. A more robust thematic analysis of the focus group sessions is reported elsewhere (manuscript in submission). These preliminary findings were used to inform the development of the second tool.

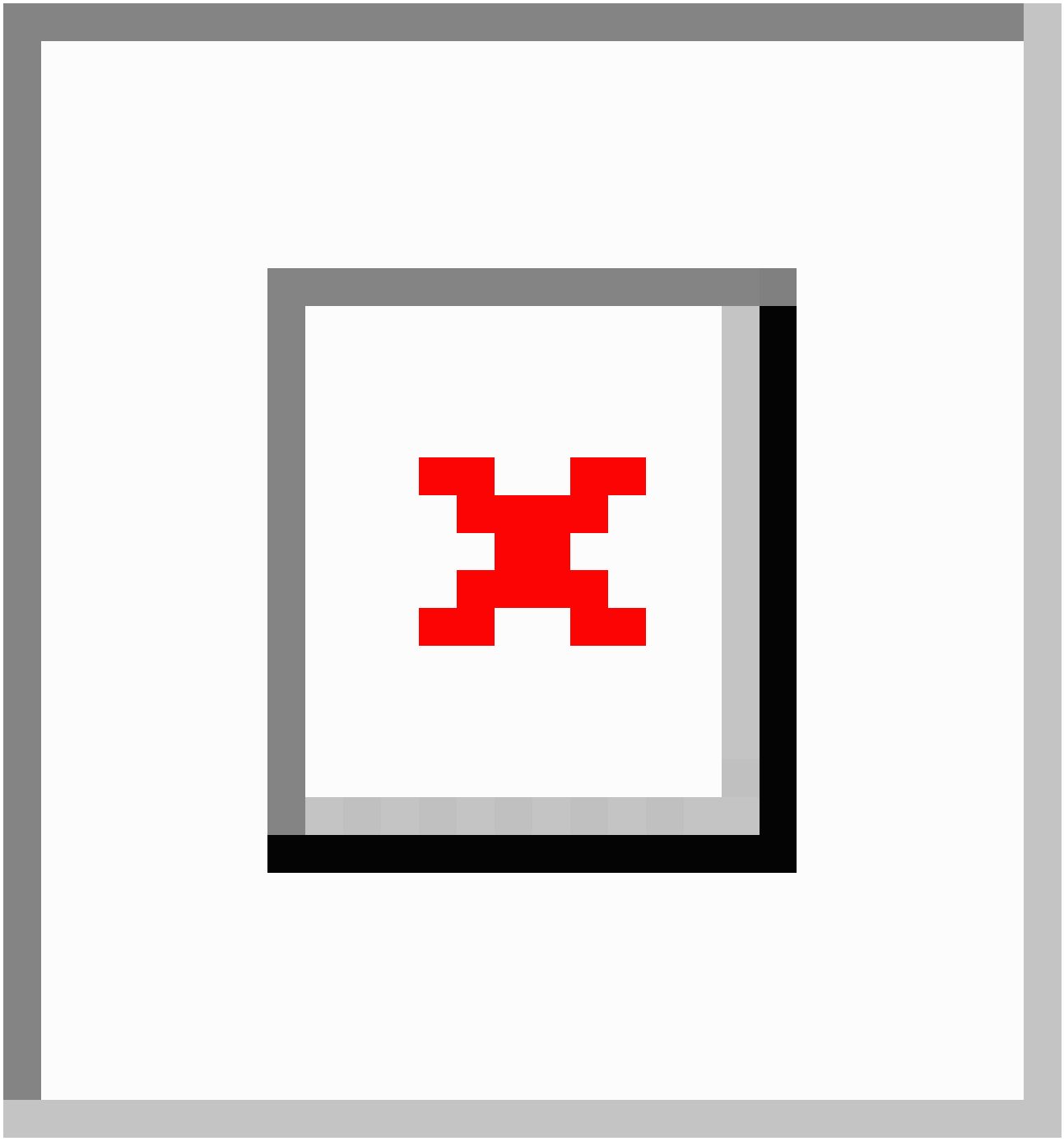
Heuristic Evaluation Results

Following a heuristic evaluation with 5 usability experts, a total of 38 issues were found in the initial prototype of the web tool. Sample comments for each usability factor related to the website are reported in Table 1. The newer version of the tool implemented changes to tackle the major usability issues such as navigation (allowing the user to move freely back and forth through the survey), mobile responsiveness (text and content should scale accordingly to the device type being used), and the consistent use of standard button and interaction paradigms throughout the tool. For the purposes of providing context, a visual example of the changes implemented between the prototype and the final tool is shown in Figure 3.

Table . Heuristic evaluation results and changes.

Heuristic principle	Sample quote	Design alterations
Visibility of system status	• "After selecting symptoms on the cards themselves, the user doesn't see what those selections were."	• Text with a time estimate for completion of the survey was included. • The section the user is on was highlighted on a navigation menu.
Match between system and the real world	• "It might be better to put some illustration of the body parts."	• Images were not included as part of the new design due to time constraints on the construction of the second version of the tool.
User control and freedom	• "Users are not allowed to go back to change their answer."	• A back button on all pages and a navigation bar were incorporated to allow user mobility through the different sections of the tool.
Consistency and standards	• "After selecting a symptom type, the questionnaire changes style into a popup window, and each category (which was not clear they were categories vs. answers) is scrollable into expanded choices- different from the first half."	• The format of web elements such as hyperlinks, buttons, and banners followed standards. • A visual style was applied to the tool to improve consistency from page to page.
Help users recognize, diagnose, and recover from errors	• "Clicking save & continue button without clicking the checkbox doesn't prompt the user with any messages nor visual feedback of what is missing."	• An error message pops up indicating to the user that they must select an answer to proceed.
Error prevention	• "On mobile, the selection boxes are really close together."	• Larger checkboxes or tappable targets were used. • Allowing the user to go back to verify what symptoms they have selected can prevent a wrong assessment.
Recognition rather than recall	• "Unclear that if you are answering age, if it's your own or the person you are filling this out for. The language for the questions doesn't remind the user to answer for another person if this was their choice."	• User selections are saved from page to page so that going back does not require them to remember what they selected.
Flexibility and efficiency of use	• "It asks what type of delivery the user had, although I selected 'No' in the question about giving birth in the last year." • "Symptoms related to a cesarean infection showed up although I did not select cesarean birth."	• Conditional logic was applied so that questions or symptom selections that are irrelevant for the user do not appear. • A tappable area was added to the selection text in addition to the checkbox or radio button to improve speed of use.
Aesthetic and minimalist design	• "Pages are not responsive for mobile, text doesn't scale, and information is very hard to read." • "All questions have the label Question."	• Mobile responsiveness was incorporated to allow text and content to scale properly. • Redundant text and information was removed to reduce visual cognitive load.
Help and documentation	• "It is unclear what the user should do on the category selection page. The 'Save & Continue' button appears only when you select items in each category. This is not obvious to the user."	• Instructions were included throughout the tool to support the users in areas where confusion may arise, such as symptom selection.

Figure 3. Comparison of the results page after addressing issues described in the heuristic evaluation. Left: old; right: new.



The annotations in Figure 3 indicate the changes that were made to the updated version of the tool. These changes aimed to improve the user experience and make the tool more user-friendly:

1. The addition of a navigation menu allowed users to easily navigate to any section of the tool they want to revisit. This provides users with more freedom and improves the visibility of system status by highlighting the section they are currently on.
2. Removal of redundant elements, such as empty content, and the reorganization of the information architecture helps visually prioritize urgency. This means that potential conditions are listed first, so users can immediately see what is important without having to scroll.
3. Changing the format of the download button and presenting it by itself can help users locate the button and avoid confusion over its purpose.
4. The resource section only includes necessary information, and URL links are formatted following web standards to improve user understanding and expectations of their behavior.
5. The addition of a back button allows users to go back and change their choices if they wish, while the finish button ensures that the user knows there is no more content to interact with.

Overall, the changes made to the tool were designed to make it more user-friendly and improve the user experience. The annotations on the figure provide a clear visual representation

of the changes that were made, making it easy for readers to understand how the updated version of the tool differs from the original version. However, there were more changes that were implemented to improve usability, such as saving user selections on previous pages, using consistent colors and standards, increasing the tapping targets so clicking is easier, reducing the amount of text on the screen to the strictly necessary, and making the website mobile responsive.

Phase 3: Design, Development, and Testing

Algorithm Design

The tool determines the corresponding course of action using the algorithm developed by the authors. Following the decision to create a second tool, the algorithm to determine the corresponding course of action was developed between the clinician and developer partner. Examples of algorithms from each of the three categories included in MAMA LOVE are outlined in Figures 4, 5, and 6. Figure 4 outlines the pathway that could lead to pre-eclampsia or eclampsia in a setting where a client would not have access to measure their blood pressure. Figure 5 outlines the pathway related to antenatal or postpartum depression. Figure 6 outlines experiences of racism and mistreatment in the perinatal setting and the pathway to self-advocacy resources.

Figure 4. An example of a user with symptoms associated with pre-eclampsia (not able to measure blood pressure). If a user indicated they have a headache that gets worse over time and they are having confusion or trouble speaking, the tool would predict they have pre-eclampsia. Additionally, if the user is having seizures, the tool will predict eclampsia. It is worth noting that if the user is having seizures, the tool will predict eclampsia immediately without needing the other symptoms. Depending on the predicted condition, the tool would provide a recommended course of action tailored to the severity of the condition (ie, pre-eclampsia: contact your health care provider; eclampsia: go to the hospital). However, a user could arrive at these conditions through different symptom paths (refer to other paths in the diagram and to Figure 1 for an expanded view of more symptoms). HELLP: hemolysis-elevated enzymes and low platelets.

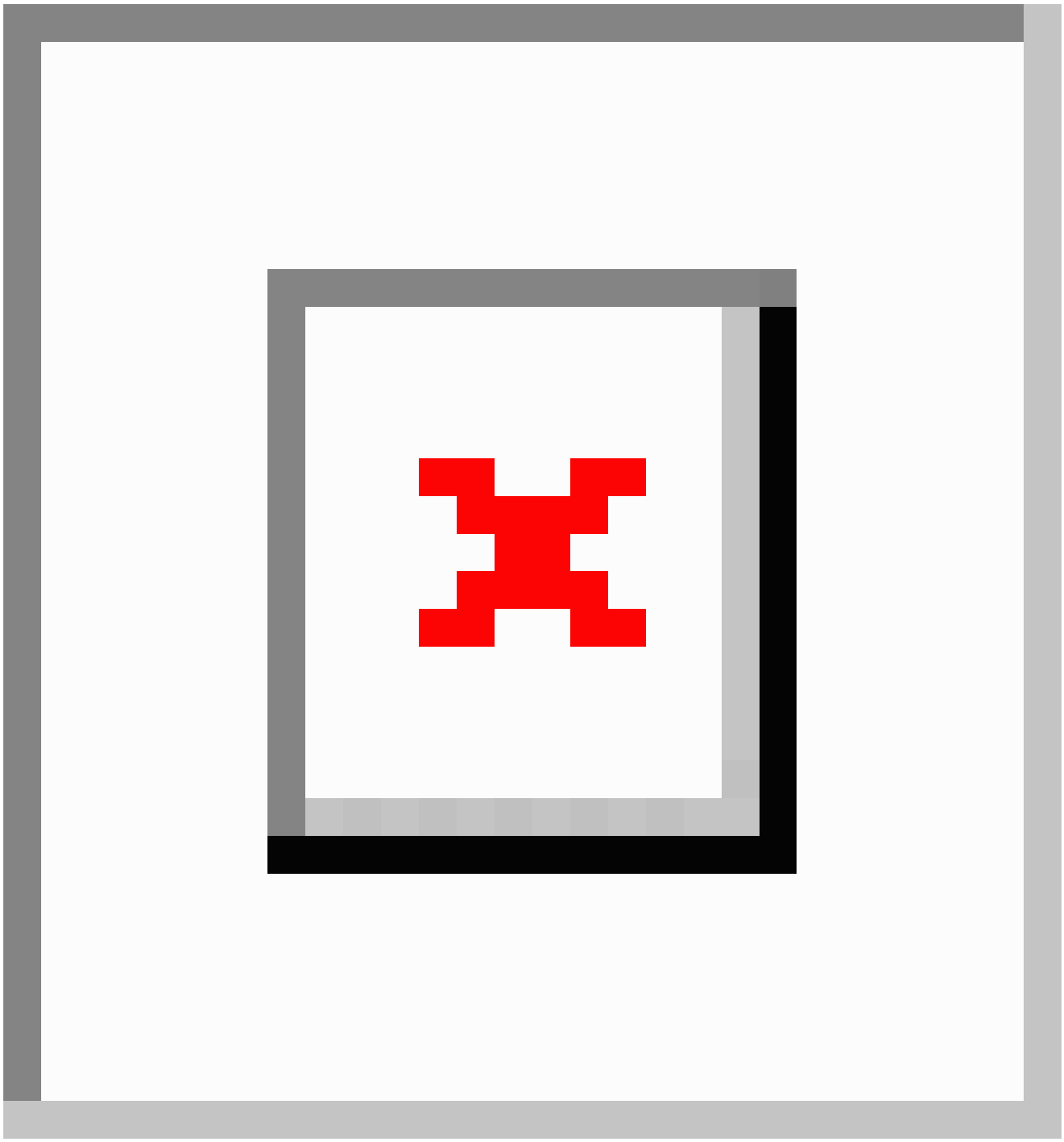


Figure 5. An example implementation of the algorithm for mental symptoms. If a user indicated they have a lasting sad, depressed, or “empty” mood; feelings of irritability; or restlessness while they are pregnant, the tool would predict they have antenatal depression. Alternatively, if the user is 0-2 weeks post partum, the tool will predict baby blues, and if greater than 2 weeks post partum, it will predict potential postpartum depression. Depending on the predicted condition, the tool would provide a recommended course of action tailored to the severity of the condition; in this case, all three possible conditions suggest calling the nurse or provider to discuss the symptoms.

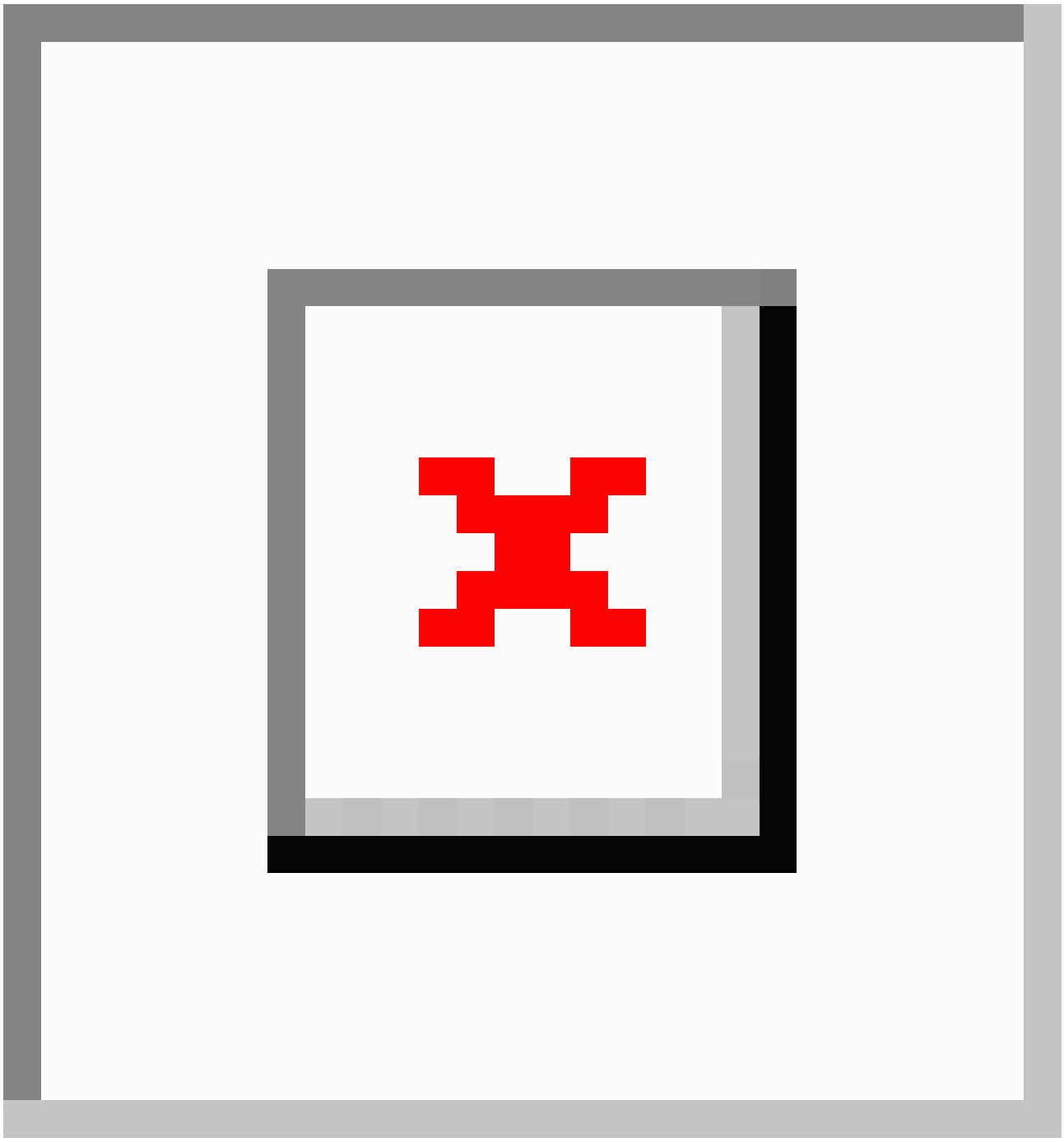
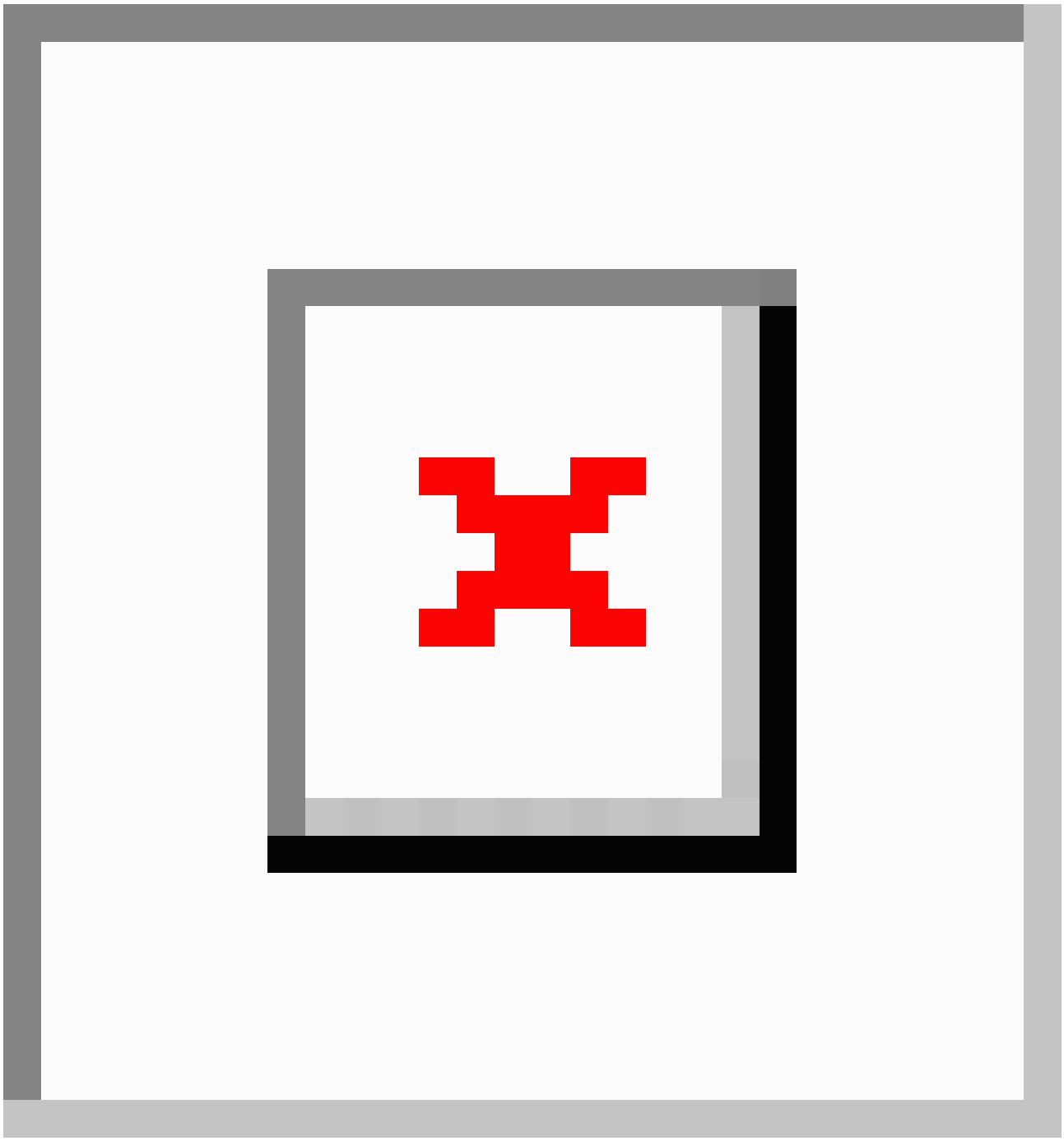


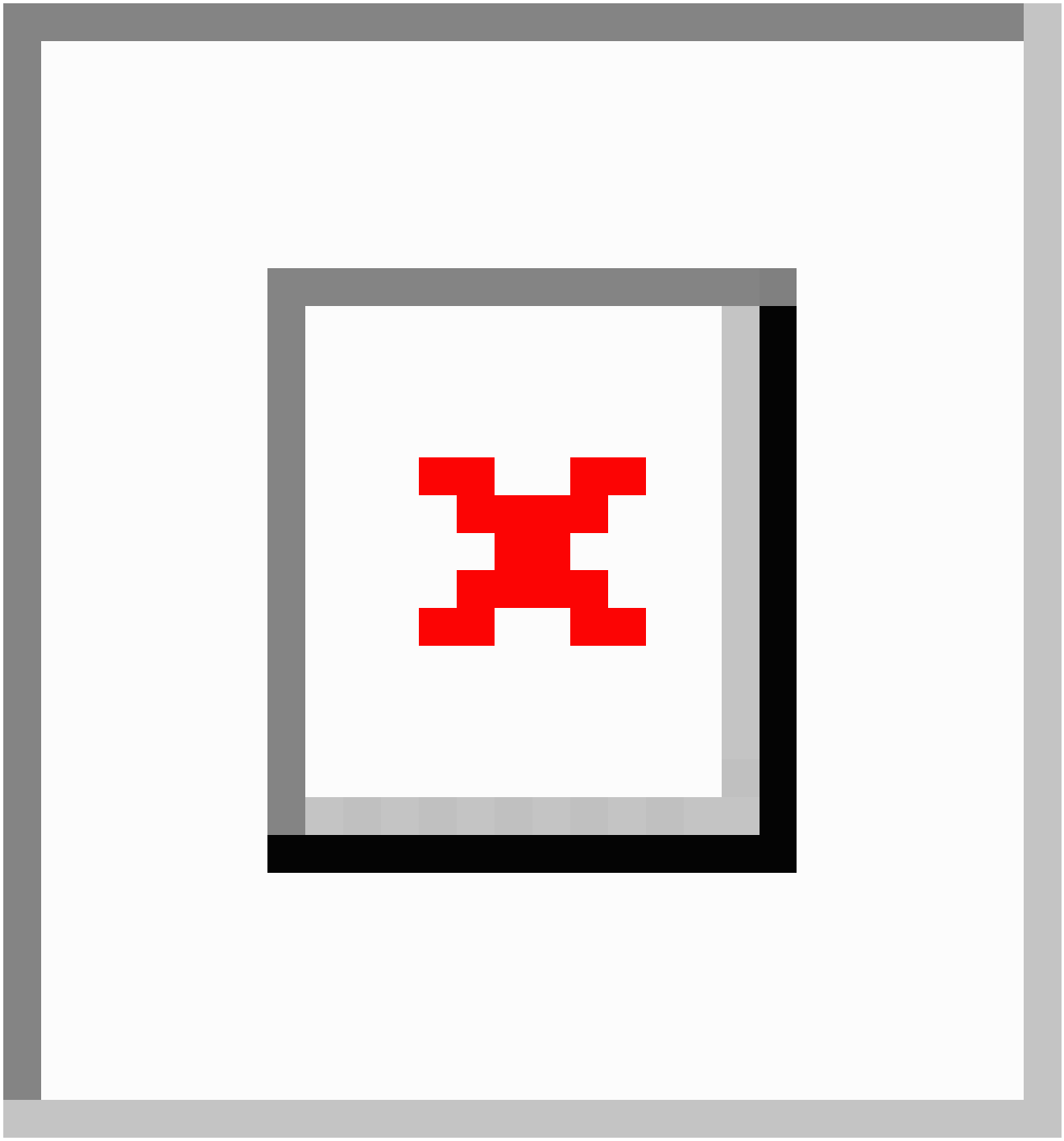
Figure 6. An example implementation of the algorithm for social risk factors. If a user indicated they felt unheard or mistreated by their OBGYN (medical doctor) the tool would recommend them to explore a list of self-advocacy resources including but not limited to the Black Mamas Matter Alliance, which is a holistic care for Black women resource. Depending on the predicted need (self-advocacy, prenatal resources, etc) the tool would provide a list of recommended resources. In this case, all social risk factors displayed map to a recommended need for self-advocacy. OBGYN: obstetrics and gynecology.



Final MAMA LOVE Design and Development

MAMA LOVE is a web-based tool designed to support Black birthing populations by providing guidance and resources on the leading high-risk conditions. The tool follows a survey structure (Figure 7). It begins with a brief introduction explaining the purpose of the tool, questions, and information being collected. It then moves on to a series of simple questions to collect demographic information and the stage of pregnancy or postpartum course. The user can then select whether they have any specific physical symptoms, mental health symptoms, or social risk factors. The final page includes a recommended course of action based on the user's selected symptoms as well as a list of recommended resources based on reported risk factors.

Figure 7. Screenshots of the final version of Morbidity and Mortality Assessment: Lifting Outcomes Via Education (MAMA LOVE). (A) Stage of pregnancy. (B) Physical symptoms selection page. (C) Results page.



Beta Testing

Prior to public release, the research team of midwives and AppHatchery experts encountered several issues related to the mapping of symptoms to conditions. For example, the algorithm for symptoms that link to pre-eclampsia also includes those that overlap with the stroke algorithm. During the evaluation, it was noted that the end output was only identifying stroke as a potential condition. The team identified that the language used by the lead midwife researcher on the visual algorithm platform was being read differently by the design team. Once this difference was identified, the issue was corrected, thus resulting in the desired end conditions appearing in the output. Each section of the tool was carefully evaluated and tested in this manner.

Discussion

Overview

There is limited research on the development, testing, and use of maternal mHealth apps that specifically address serious maternal morbidity and mortality for birthing people of color. Of those evaluated in a recent meta-analysis of 15 randomized controlled trials of mobile technology addressing peripartum physical and mental health behaviors, none specifically focused on the identification of symptoms and risk factors for morbidity

and mortality in the general population nor among populations of color [30].

MAMA LOVE is designed to address the leading physical, mental health, and social risk factors that increase the risk for maternal morbidity and mortality. The leading pregnancy-related causes of death among Black women include cardiovascular conditions, hypertensive disorders, hemorrhage, and infection, conditions in which the timeliness of patient reporting and subsequent medical intervention are critical, as many of these deaths are deemed preventable [7]. The additional focus on mental health and social determinants of health adds a layer of screening that contextualizes risk and highlights the importance of evaluating the individual lived experience within the context of "risk." The final algorithms used in the creation of the MAMA LOVE platform incorporate these concepts in a fashion that is designed to be usable and effective for the end user. As such, this tool would be generalizable and useful, particularly among at-risk populations.

Resources are included in the tool that direct users to well-known, community-led, and state- and national-level academic, governmental, and nonprofit resources. However, there is a need for more robust culturally tailored educational and social support resources. There was an effort to include resources from community groups caring for people of color; however, those resources were not plentiful. The need for culturally designed resources is particularly important for those most at risk for severe maternal morbidity and mortality. Using this cultural perspective, we worked with the development group during the design process to ensure that the imagery, language, and functionalities of the tool were designed with the end user in mind.

Comparison With Prior Work

There is limited research available regarding the use of mHealth apps and their effectiveness in mitigating maternal mortality risk. As previously discussed, there are apps available that provide quality content around health behaviors in pregnancy. However, they do not adequately represent people of color. It has been shown that Black women are willing to use their smartphones to access health promotion content and to participate in mHealth research [18]. Although more than 300 mHealth apps are available, most offerings do not provide adequate evidence-based maternal health information and are not reflective of women of color [20]. We expect that a platform providing immediately accessible, accurate, timely, and culturally appropriate information will be uniquely advantageous when used for the preventive care of Black women [5], as has been shown in Black women experiencing other medical conditions [19,46,47]. As such, the addition of MAMA LOVE fills a unique gap in that it is a community-designed platform specifically focused on the mitigation of maternal mortality risk.

While other studies detailed the development and testing of mHealth apps for pregnant people of color, they focused on topics other than serious maternal morbidity and mortality, such as postpartum fitness and weight loss (BeFAB) [24], physical activity and weight control during pregnancy [23], gestational diabetes (SweetMama) [21], and breastfeeding (KULEA-NET) [22]. The developers of these mHealth apps used a similar approach for the development of their app by reviewing current mHealth app technology and evidence-based best practices for their topic areas to create an initial prototype, conducting formative research with women in the potential user demographic or health care providers, and incorporating their feedback into the final tool. These studies provide support for the mHealth app development pathway used by MAMA LOVE, with an initial design based on current evidence and subsequent iterative feedback sessions with pregnant people of color and health care providers as an effective way to tailor an mHealth app for communities of color.

Limitations

The tool is limited in its scope as it identifies symptoms or social conditions after they have already occurred. In the quest to prevent maternal morbidity and mortality, this may be too late. There is a need for a tool or resource that captures data and information in real time so that interventions can be instituted earlier in the pregnancy or postpartum period. Additionally, the resources that are included in the tool will have to be continually revised to ensure accuracy and relevance to the population. Additionally, the tool has been developed by researchers and app developers in the southeastern United States; as such, the types of resources included were naturally influenced by this geographic lens.

The development group responsible for building the tool consisted of individuals with diverse backgrounds, including in product management, design, and development. The team had prior experience working on other technology projects aimed at African American minorities, which provided a strong foundation for their work on this tool. The group was composed of individuals from African Black, Hispanic, and White backgrounds, which helped ensure a broad perspective and inclusivity during the design and development process.

In addition, the group leveraged specific design methodologies to navigate cultural values and paternalism during the development of the tool. These methodologies included incorporating common visual styles and themes from other tools aimed at Black birthing parents, such as using visuals of birthing parents throughout the tool. The team also sought to avoid paternalistic and critical language in the tool, which could be perceived as condescending or dismissive. By taking these measures, the development group aimed to create a tool that was culturally sensitive and inclusive while also providing accurate and useful information to users.

Despite the outcomes of the heuristic evaluation and design changes implemented, it is important to acknowledge the limitations. Although the conceptualization of the project and creative design of the tool was led by a Black researcher, the evaluation of the tool was conducted by a team of designers who were not specialized in website design for Black birthing parents. While the team had experience in evaluating and designing digital tools, they may not have been fully attuned to the specific cultural and experiential needs of this population. As such, it is possible that certain design issues or cultural considerations were not fully captured by the evaluation, and

additional research by specialized user experience–specific experts may be warranted to further refine the tool.

Conclusions

Maternal morbidity and mortality is a public health crisis needing immediate effective interventions. Comprehensive models and strategies that improve the ability of at-risk groups to better identify their risk are needed. MAMA LOVE seeks to empower pregnant populations with knowledge and resources to encourage self-advocacy, particularly among Black populations who have the greatest risk of dying during the perinatal period. Given that many pregnant populations have identified that they often do not feel heard or are not taken seriously when presenting with concerning symptoms, MAMA LOVE is a tool that has the potential to address that need by increasing knowledge and providing information that can be shared with health care professionals.

Acknowledgments

We would like to acknowledge Wonshik Chee, PhD, for his contributions in assisting with the design of the initial prototype of Morbidity and Mortality Assessment: Lifting Outcomes Via Education (MAMA LOVE). This study was funded by a grant to ADA from the Board of Trustees at Emory University. Additionally, the design of this tool occurred while ADA was funded by the Georgia Clinical Translational Science Alliance 3UL1TR002378. The content of this paper is solely the responsibility of the authors and does not necessarily represent the official views of Emory University.

Conflicts of Interest

None declared.

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Abbreviations

CDC: Centers for Disease Control and Prevention
***ICD-10*:** *International Statistical Classification of Diseases, Tenth Revision*
MAMA LOVE: Morbidity and Mortality Assessment: Lifting Outcomes Via Education
mHealth: mobile health

Edited by S Badawy; submitted 20.12.22; peer-reviewed by J Watterson, K Butten, S Kristoffer; revised version received 27.03.23; accepted 22.05.23; published 18.08.23.

Please cite as:
Amore AD, Britt A, Arconada Alvarez SJ, Greenleaf MN
A Web-Based Intervention to Address Risk Factors for Maternal Morbidity and Mortality (MAMA LOVE): Development and Evaluation Study
JMIR Pediatr Parent 2023;6:e44615
URL: https://pediatrics.jmir.org/2023/1/e44615
doi:10.2196/44615

Using a Design Thinking Approach to Develop a Social Media–Based Parenting Program for Parents of Children With Attention-Deficit/Hyperactivity Disorder: Mixed Methods Study

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Abstract

Background: Parenting programs have proven effective in improving the behavior of children with attention-deficit/hyperactivity disorder (ADHD). However, barriers such as job and transportation constraints hinder parents from attending face-to-face therapy appointments. The COVID-19 pandemic has further exacerbated these challenges.

Objective: This study aimed to develop and test the feasibility of a social media–based parenting program for parents of children with ADHD, considering both the pre-existing challenges faced by parents and the additional barriers imposed by the COVID-19 pandemic.

Methods: This study used a 5-stage design thinking process, encompassing empathizing with parents, defining their needs, ideating innovative solutions, prototyping the program, and testing the program with parents. Qualitative interviews were conducted with 18 parents of children with ADHD to understand their unique needs and values. Brainstorming techniques were used to generate creative ideas, leading to the creation of a prototype that was tested with 32 parents. Participants' engagement with the program was measured, and posttraining feedback was collected to assess the program's effectiveness.

Results: Parents of children with ADHD encounter specific challenges, including managing impulsive behavior and difficulties in emotion regulation. The social media–based parenting program was delivered through the LINE app (Line Corporation) and consisted of 7 modules addressing topics related to ADHD management and effective parenting strategies. The program exhibited a high completion rate, with 84% (27/32) of participants successfully finishing it. Program provider–participant interaction peaked during the first week and gradually decreased over time. Qualitative feedback indicated that the program was feasible, accessible, and well received by participants. The LINE app was found to be convenient and helpful, and participants preferred content delivery once or twice per week, expressing acceptance for various content formats.

Conclusions: This study emphasizes the significance of adopting a human-centered design thinking approach to develop parenting programs that cater to the unique needs and values of parents. By leveraging social media platforms, such as LINE, a parenting program can overcome the challenges posed by the COVID-19 pandemic and other constraints faced by parents. LINE offers a viable and feasible option for supporting parents of children with ADHD, with the potential for customization and widespread dissemination beyond the pandemic context.

(JMIR Pediatr Parent 2023;6(1):e48201) doi:10.2196/48201

KEYWORDS

attention-deficit/hyperactivity disorder; ADHD; parenting programs; human-centered design thinking; online interventions; COVID-19 pandemic; children; development; online parenting program; parenting; behavior; support; feasibility; social media; prototype; testing; design

Introduction

Attention-deficit/hyperactivity disorder (ADHD) is a prevalent psychological condition among school-aged children, affecting approximately 7.2% of children and adolescents aged ≤18 years [1]. ADHD is associated with a range of negative consequences, including academic difficulties, impaired social relationships, and compromised quality of life, for both children and their families [2,3].

In the management of ADHD, parenting programs and medication are recognized as crucial components. Although medication can help manage symptoms, it is often insufficient to address the complex challenges associated with ADHD, without the support and guidance provided by parenting programs [4,5]. Parenting programs have shown effectiveness in reducing children's disruptive behaviors and improving their adaptive functioning, making them a recommended primary intervention for managing ADHD symptoms [6,7]. These

programs typically involve systematic interventions designed to educate and empower parents in effectively managing their child's ADHD-related behaviors and challenges, with the ultimate goal of enhancing the child's overall well-being [8,9].

Traditionally, parenting programs have been delivered through face-to-face group sessions, wherein parents from different families come together at a designated clinic or primary care unit [10]. Although some programs may offer in-home training, group-based face-to-face sessions have been the preferred format for managing ADHD symptoms. However, these programs encounter numerous structural barriers that limit their accessibility and impact. These barriers include financial constraints, limited resources, logistical challenges, time constraints, the lack of available childcare, and scheduling conflicts [11]. In addition to these structural barriers, there may be negative attitudes toward seeking mental health services for children, which can deter parents from engaging in group-based parenting programs [12,13].

The generalizability and effectiveness of traditional parenting programs may also be limited in low- and middle-income countries (LMICs), where socioeconomic conditions and health care systems differ significantly from those of high-income countries. Factors such as inadequate family income and limited access to mental health services can significantly moderate treatment outcomes [14]. Furthermore, the scarcity of trained mental health professionals in LMICs raises concerns about the feasibility and sustainability of therapist-delivered interventions [15]. Research on parenting programs in LMICs is relatively limited, and the delivery of such programs faces additional barriers, including the lack of a skilled and trained workforce and limited resources for supporting the implementation and dissemination of evidence-based interventions [16,17]. These challenges are further exacerbated by the ongoing COVID-19 pandemic, which has introduced additional barriers and limitations to the delivery of parenting programs.

The COVID-19 pandemic has disrupted many aspects of daily life, including access to health care services and support programs. Parents of children with ADHD have faced significant challenges in accessing and completing parenting programs during this time [18]. Lockdown measures and restrictions have resulted in increased behavioral problems among children with ADHD due to reduced opportunities for social interaction and disrupted routines [19]. Moreover, the pandemic has exacerbated parenting-related fatigue and psychological distress, further straining the well-being of parents [20]. Research has shown that parent support programs implemented during the COVID-19 pandemic have been associated with lower levels of parental stress and improved well-being [21].

To address the challenges faced by parents both during the COVID-19 pandemic and beyond, it is essential to prioritize the accessibility and effectiveness of parenting programs [22]. Social media–based programs have emerged as a promising solution, offering convenient and cost-effective interventions for various health issues, including obesity, diabetes mellitus, and certain mental health problems [23]. Social media–based programs provide higher accessibility rates than those of traditional face-to-face methods, allowing for timely intervention and support as soon as prodromal symptoms appear [24]. However, it is important to acknowledge that existing social media–based parenting programs have primarily been commercially driven [25], lacking effective bidirectional communication between parents and program providers [26-29], and have not undergone sufficient research to establish their efficacy in managing ADHD symptoms. Therefore, there is a need for evidence- and social media–based parenting programs specifically designed to address the unique challenges of managing ADHD.

Methods

Setting

This study, which is part of a social media–based parenting program project, took place at a large university hospital in Songkhla, Thailand, during June 2020 (the first wave of the COVID-19 pandemic in Thailand). A multidisciplinary team of health care professionals, including 1 general pediatrician, 2 developmental-behavioral pediatricians, 1 developmental-behavioral nurse, and 2 child psychologists, developed and coordinated the program.

Ethics Approval

The study protocol was approved by the Human Research Ethics Committee of the Faculty of Medicine, Prince of Songkla University (research ethics committee number: 62-381-1-1).

Study Design

We used a mixed methods approach, which involved participatory action research [30] and a design thinking process [31,32], to develop a social media–based parenting program for parents and caregivers of children with ADHD. The 5-step design thinking model from Stanford University's Hasso-Plattner Institute of Design (d. school) was used, including empathy, define, ideate, prototype, and test [33,34].

Phase 1: Empathy

Semistructured in-depth interviews with parents and caregivers of children with ADHD were conducted to understand their challenges, problem-solving abilities, and preferences for a social media–based parenting program [35]. Demographic information was also collected.

Phase 2: Define

The research team synthesized the information from the interviews into a point-of-view statement [36], ensuring that it met the needs of the end users [35,37]. A group discussion refined the definition of parental requirements.

Phase 3: Ideate

Ideas for addressing the challenges and meeting the needs of parents were brainstormed, focusing on the creation of innovative solutions for the program content and features. Visual representations and structured brainstorming sessions facilitated the process [35,37].

Phase 4: Prototype

One or more prototypes were developed based on the previous phases' data. Rapid feedback was collected during testing to

determine end users' needs, and this feedback was used to further develop the prototype toward its full potential [35,37].

Phase 5: Test

Feedback from users was collected after the prototype's launch [35,38]. Data on parental engagement and feedback on both benefits and potential negative interactions were used to refine the parent training program.

This study evaluated the five phases of the design thinking process, assigning distinct study populations to each stage based on the phase-related objectives. Data were collected from parents and caregivers of children with ADHD during the empathizing phase [39]. Afterward, during the ideation phase, these data were integrated into the initial program design and discussed with multidisciplinary health care professionals, including general pediatricians, developmental-behavioral pediatricians, developmental-behavioral nurses, and child psychologists. A prototype [38] was subsequently created and tested with parents and caregivers of children with ADHD. The participants in the test phase included those who were engaged in the empathizing phase, as well as new participants who were recruited specifically to increase the saturation of the findings of the testing phase. Posttraining feedback was collected, and participant engagement with the program was evaluated in the testing phase (Table 1).

Table . The five phases of the design thinking process and the methods used.

Phase	Concepts	Methods	Participants
Empathy	To discover users' needs and values for a familial technology-based solution	In-depth interviews	18 parents
Define	To refine and narrow the definition in the revised solution to meed the end users' needs	Brainstorming technique	The research team
Ideate	To concentrate on idea generation and obtain innovative solutions for users	Brainstorming technique	The research team
Prototype	To generate the demonstrative solution for users	Design a web-based prototype for trial use	The research team
Test	To obtain pilot results and feedback on the prototype	Collect feedback via a quantitative and qualitative approach	32 parents

Data Collection

To assess participant engagement, a manual text mining script was used to extract full transcripts of messages from moderators, researchers, and participants. These messages were categorized as text, images, videos, stickers, and audio messages. In addition to engagement, qualitative research was conducted during the empathy and test phases to gather data on parents' needs, their perceptions, and lessons learned from the groups. Participants answered an open-ended questionnaire at the empathy phase and participated in in-depth interviews during the test phase.

Data Analysis

The engagement analysis involved calculating the total number of messages per topic and the frequency of messages sent per week by mothers and moderators. The frequency of messages, according to the day of the week and time of the day, was also evaluated to estimate mothers' most active moments in social media groups. In terms of the qualitative analysis, a grounded theory approach was adopted. The research team read all in-depth interview transcripts, identified emergent patterns, and used inductive coding to pinpoint key themes and concepts. Text was extracted from transcriptions to generate analysis content, themes, and findings, which were subsequently translated to English.

Results

Phase 1: Empathy

Participant Characteristics

A total of 18 participants (primarily mothers), with a mean age of 42 years, were enrolled in this phase. The demographic data can be found in Table 2. Over half of the participants (10/18, 56%) had a bachelor's degree or higher. The qualitative research involved a thematic analysis and identified 8 themes, which are discussed below.

Table . Summary data of participants (N=18) in the empathy phase.

Characteristic		Value
Age (years), mean (range)		42 (25-55)
Relationship, n (%)		
	Father	4 (22)
	Mother	11 (61)
	Grandmother	2 (11)
	Aunt	1 (6)
Education, n (%)		
	Primary school	1 (6)
	High school	3 (17)
	Diploma	4 (22)
	Bachelor's degree	7 (39)
	Master's degree	3 (17)
Occupation, n (%)		
	Government official	4 (22)
	Businessman	2 (11)
	Freelance	6 (33)
	Gardener	2 (11)
	Merchant	3 (17)
	Housewife	1 (6)

Theme 1: Parenting Problems

Participants expressed concerns about their children's behavior and its impact on their own mental health (eg, "Not only is unfinished homework the most common childrearing issue, but parents' mental health is also important in childrearing management").

Theme 2: Parental Needs

Parents expressed a desire to learn techniques to help their children academically and emotionally (eg, "I'd like to learn the technique so that I can help him improve his academic performance").

Theme 3: Target Problems to Resolve

Participants identified their children's primary issues, such as a lack of focus, disobedience, and a lack of self-control (eg, "I wish he was focused on my words, obedient, and capable of self-control").

Theme 4: Internet Use Behavior

Parents shared information about their preferred electronic devices and social media–based platforms (eg, "I have a smartphone and a PC. In my daily existence, I frequently utilize LINE, Facebook, and Google").

Theme 5: Frequency, Duration, and Time Periods

Participants discussed their daily internet usage habits and preferred times for intervention (eg, "I use my cellphone for 1–2 hours a day, between the hours of 8 and 10p.m.").

Theme 6: Media Types

Parents indicated their preferred media formats for the parenting program, such as infographics and videos (eg, "I recommend infographics and brief video clips").

Theme 7: Individual Versus Group Counseling

Participants debated the merits of individual versus group counseling for addressing parenting issues (eg, "If the program is set up in a group setting, we may share experiences and track the development of the children").

Theme 8: Target Recipients

Parents highlighted the importance of involving all family members in the parenting intervention (eg, "Information should be sent to the parents, grandparents, and grandfather due to possible inconsistencies in childrearing within the family").

Phase 2: Define

In this phase, the research team, consisting of developmental-behavioral pediatricians, general pediatricians, a developmental-behavioral pediatrics nurse, and a psychologist, aimed to incorporate user requirements from the previous phase into the problem statement. They identified the users as "parents and caregivers of children with ADHD" and determined their critical need to be "learning parenting techniques" to help ameliorate their children's behavioral problems.

Through the analysis of the empathize phase, the team gained real insights into the parents' and caregivers' perspectives. Parents expressed feelings of being overwhelmed and sometimes felt helpless in the face of their children's ADHD-related

challenges. They also emphasized the importance of practical and easily applicable solutions that could seamlessly be integrated into their daily routines. The point-of-view statement, which was formulated based on these insights, was as follows:

> *Parents and caregivers of children with ADHD need effective parenting techniques and support to improve their children's behavior and overall well-being, while addressing their own emotional needs and fostering a sense of empowerment.*

The insight synthesized from the data denoted the desire "to improve the behavioral issues of children with ADHD." This understanding led to the formulation of a "How Might We" (HMW) statement, which serves as a driving question to inspire innovative solutions. The HMW statement developed was as follows:

> *How might we create a supportive and accessible program that equips parents and caregivers of children with ADHD with the necessary parenting techniques to effectively manage their children's behavioral challenges and improve their overall well-being, while also addressing their emotional needs and fostering a sense of empowerment?*

Phase 3: Ideate

The ideation phase began with the development team discussing potential solutions, using the HMW statement as a guide. The facilitator led a roundtable discussion centered around the HMW question.

To ensure a diverse range of ideas during the brainstorming session, the team used the "Work Alone Together" technique. This method allowed individual team members to generate ideas independently before sharing them with the group. This approach fostered creativity and encouraged the team to explore multiple channels, formats, and platforms for the parenting program, such as using social media, videoconferencing, booklets, podcasts, and group meetings to deliver the program content.

After the brainstorming session, the team used an affinity map (Textbox 1) to categorize and organize the generated ideas. This process allowed them to identify similarities, relationships, and patterns among the concepts. The affinity map included categories like LINE (Line Corporation), Facebook (Meta Platforms Inc), YouTube (YouTube LLC) or videos, videoconferences, booklets, lists, group meetings, telephone counseling, e-counseling, podcasts, behavioral tutorials, and television advertising.

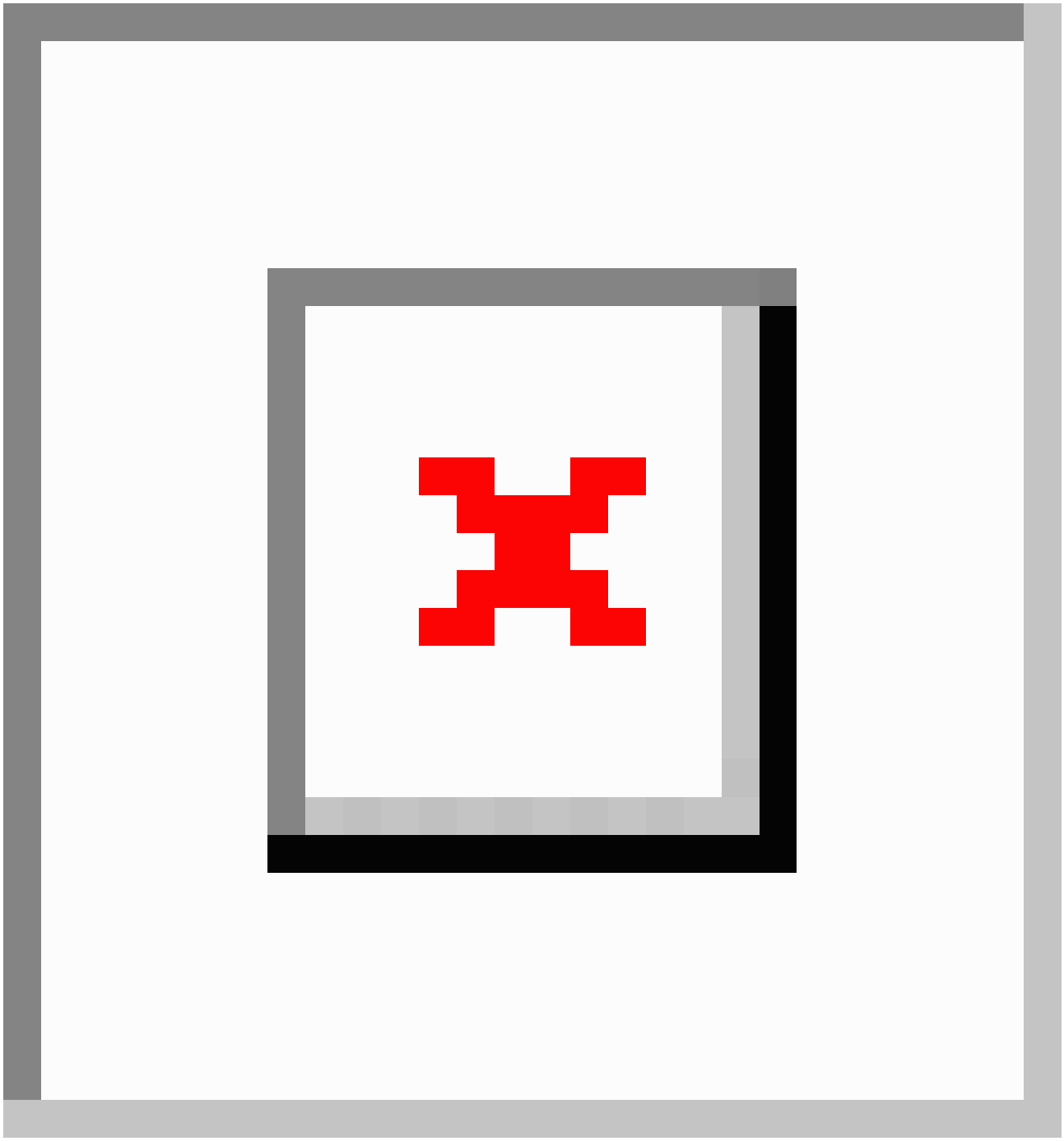
Textbox 1. Affinity mapping.

1. LINE (Line Corporation)
   - LINE group
   - Parent LINE group
   - LINE group: parents and teacher
   - Individual LINE
2. Facebook (Meta Platforms Inc)
   - Facebook: changing behavior
   - Facebook page for children with attention-deficit/hyperactivity disorder (ADHD)
   - Facebook pages
   - Facebook group of ADHD caregivers
3. YouTube (YouTube LLC) or videos
   - Suggested list of videos in YouTube
   - Develop video scenarios for behavioral management (published via a YouTube channel)
   - Videos describing common behavioral problems
4. Videoconferences
   - Use Zoom (Zoom Video Communications Inc) program for tracking behavioral problems
5. Booklets
   - Booklet for behavioral management
   - Brochure
   - Question-and-answer brochure about common behavioral problems
6. Lists
   - List of interesting Facebook pages
   - Lists of websites about parenting
   - Suggest websites about ADHD
7. Group meetings
   - Group meeting for ADHD caregivers
   - Parent group meeting
8. Telephone counseling
9. e-Counseling
   - Advise behavioral management
   - Target behavior according to age
10. Podcast: parenting management
11. Behavioral tutorial via teacher
12. Television advertising at schools and hospitals

The team used a prioritization map (Figure 1) to rank the ideas. Before using the member voting technique, they arranged the ideas in the four quadrants of the prioritization map. This approach helped them evaluate the importance and feasibility of each idea. After organizing the ideas in the quadrants, the team voted to determine the most effective and straightforward platform for developing the parent training program. The results indicated that LINE was the preferred choice. Consequently, LINE was chosen as the social media platform for content delivery in this study. The ideation phase also resulted in the creation of prototypes for the proposed parent training programs, which included text messages, infographics, videos, and

assignments. Weekly learning goals were set, and samples of content for end users were designed.

Figure 1. Prioritization map.



Phase 4: Prototype

The prototype phase involved the development of a comprehensive social media–based parent training program, based on the insights and ideas gathered in the previous three phases of the design thinking process. The prototype consisted of a LINE-based parenting program, which included various components, such as content creation, user experience (UX) development of infographics, and video clip production, to provide parenting models for parents and caregivers.

Content Prototype

The content prototype was designed to address the needs and preferences of the target users. The team developed a curriculum of 7 parent training modules, which were to be completed over a 7-week intervention period. Each module covered a specific topic related to parenting children with ADHD and offered practical strategies, advice, and tips. The content was delivered through a combination of text messages, infographics, videos, and assignments, ensuring that the program was engaging, informative, and easy to follow (Table 3).

Table . Prototype LINE-based parenting contents.

Weeks and days		Contents
Weeks 1-2		Introduction
	Day 1	Program introduction
	Days 1-2	Understanding ADHD[a]
	Day 3	Treatment of ADHD
	Day 4	Case scenario video (homework)
	Day 5	Parental concern and setting goal
	Day 6	Rationale, rule, and cycle of problem
	Days 6-7	Basic principles in child behavioral management
	Day 8	Advantage of parent training
	Days 9-10	ABC[b] model (homework)
	Days 11-12	Problem solutions
	Days 13-14	Summary and discussion
Week 3		Basic communication skills
	Day 1	Inappropriate conversations (homework)
	Days 1-2	Negative conversations
	Days 3-4	Using “I” messages and “you/he/she” messages
	Day 5	Effective communication
	Day 6	Constructive instruction
	Day 7	Case scenario video (homework)
Week 4		Praise
	Day 1	Praise
	Day 2	Case scenario video (homework)
	Day 3	Principles, components, and examples
	Days 3-6	Diary notes
	Days 5-7	Reminders about basic communication skills
	Day 7	Reflection
Week 5		Rewards
	Day 1	Types of rewards
	Day 2	Principles of rewards
	Day 3	Define target behaviors
	Days 4-6	Reflection and technique suggestion
	Days 4-6	Diary notes
	Day 7	Summary and discussion
	Day 7	Reminders about previous skills
Week 6		How to deal with behavioral problems
	Day 1	Objectives and principles of behavioral management
	Day 2	Effective behavioral management
	Day 3	Time-out
	Day 4	Verbal command
	Day 4	Ignorance
	Days 5-6	Case scenario video (homework)

Weeks and days		Contents
	Days 2-6	Sharing the experiences
	Days 2-6	Diary notes
	Day 7	Summary and discussion
Week 7		How to deal with homework
	Day 1	Principles of doing homework
	Day 2	How to deal with homework
	Day 3	Behavioral management
	Day 4	Self-reporting card
	Days 2-7	Sharing the experiences
	Days 2-7	Diary notes
	Day 7	Summary and discussion

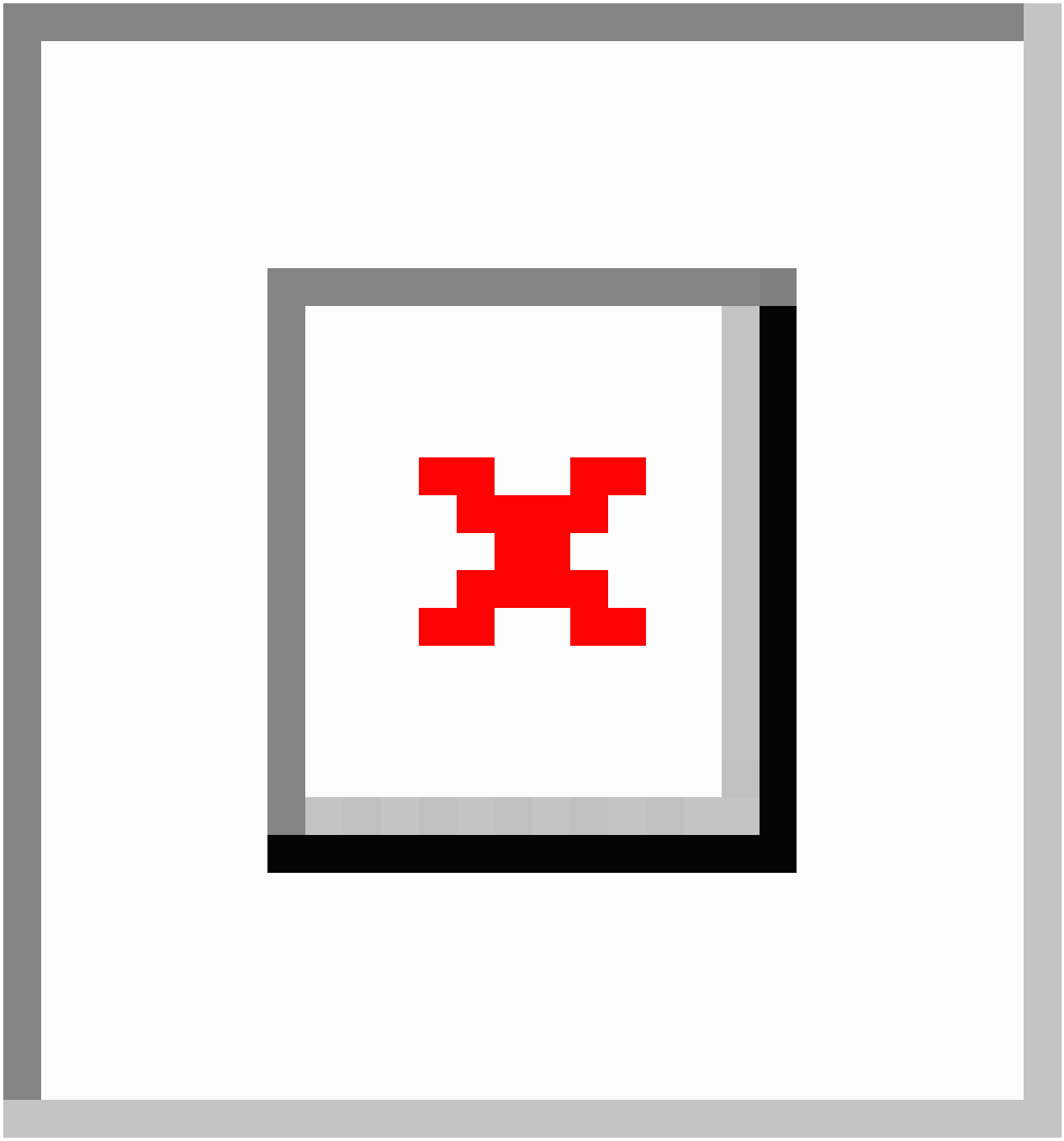
[a]ADHD: attention-deficit/hyperactivity disorder.

[b]ABC: Antecedent, Behavior, and Consequences.

UX Development and Parent Interaction

In order to create a visually appealing, user-friendly experience that also facilitated meaningful interaction among parents, the team focused on the design of infographics and on fostering engagement among users. The infographics were designed to be clear, concise, and informative, presenting complex information in an easily digestible format. They included visuals, charts, and graphs to illustrate key points and concepts, making it easier for parents to understand and apply the strategies discussed in the program. To promote interaction and engagement, the team incorporated features that encouraged parents to share their experiences, ask questions, and provide support to one another. This was achieved through the creation of a dedicated LINE group, wherein users could engage in discussions, share their progress, and seek advice from both experts and fellow parents. The group also served as a platform for sharing additional resources, hosting live question-and-answer sessions, and conducting polls to gather feedback and gauge user satisfaction. By fostering a sense of community and providing opportunities for interaction, the UX development aimed to enhance the overall effectiveness and appeal of the program (Figure 2).

Figure 2. Example of a conversation through a moderated LINE group.



Video Clip Production

To further enhance the program's effectiveness and user engagement, the team produced a series of video clips that demonstrated various parenting models and techniques. These videos featured expert advice, real-life examples, and step-by-step instructions to help parents and caregivers better understand and apply the strategies discussed in the program. The videos were designed to be short, focused, and easy to access, allowing users to watch them at their convenience.

Prototype Evaluation

Once the initial prototype was complete, it was evaluated by a group of parents and caregivers who participated in a pilot testing phase. Participants completed a web-based eligibility screening and informed consent process as part of the baseline survey. Those who met the eligibility criteria and provided their consent were directed to complete comprehensive baseline surveys. Participants received a general schedule for the completion of the seven parent training modules and were provided with approximately one or two inputs daily, between 6 PM and 9 PM. They were also given 2 assignments per week, with a 1-week deadline for completing the assigned tasks.

The feedback gathered from the pilot testing phase was used to refine and improve the prototype, ensuring that it effectively addressed the needs and preferences of the target users. The final prototype of the LINE-based parenting program was then prepared for implementation and further evaluation.

Phase 5: Test

Participants

A total of 32 participants from 24 families, who were parents or caregivers of children (aged 4 to 10 years) diagnosed with ADHD, were enrolled in this phase. Participants included mothers (20/32, 63%) and primary caregivers (29/32, 91%) with a bachelor's degree. Most children were boys aged 8 to 10 years who were receiving medication as primary treatment (24/32, 75%).

Participant Engagement in the Program

Engagement was assessed by tracking the content marked as "read" in the LINE app every week over the 7-week intervention period. The responses to interventions were categorized on a 4-point scale (0=unread; 1=only read; 2=interaction with the intervention [posting a sticker, responding with "OK," or writing "thank you"]; 3=initiating a discussion or asking a question). A score of 46 represented that the participant had read all the content, while scores above 46 indicated that they read and interacted with the program providers. Table 4 illustrates the distribution of participants' levels of engagement with the program, showing that the majority of them (16/32, 50%) completed the intervention, while 34% (11/32) demonstrated higher engagement by actively interacting with the content. On the other hand, 16% (5/32) of the participants were classified as nonadherent, indicating a lower level of engagement with the program.

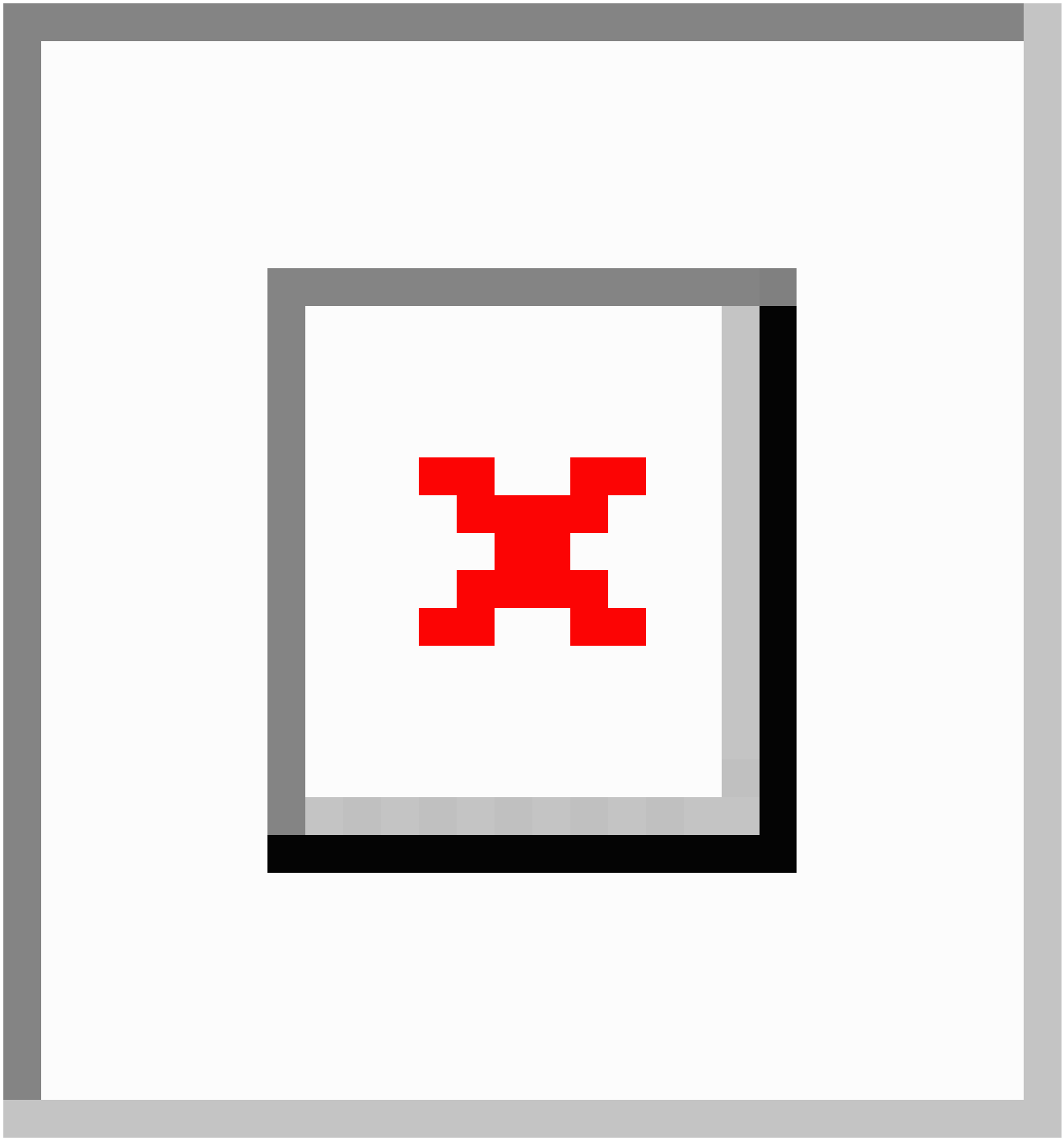
Table . Classification of patient engagement scores.

Classification	Score	Participants (N=32), n (%)
Nonadherence	<46	5 (16)
Completion	46	16 (50)
Adherence	>46	11 (34)

Participants' engagement levels were charted by using a linear graph, which depicted their levels of interaction with the content over the 7-week period (Figure 3). The first week showed the highest engagement levels, which gradually decreased over time, reaching the lowest point in the last week.

These data highlight the overall participant engagement in the program and how it evolved throughout the intervention.

Figure 3. Response from intervention.



Posttraining Feedback

Qualitative data were collected from 32 participants via in-depth interviews after they completed the LINE parenting program. The following four themes emerged from the thematic analysis: (1) social media platform, (2) internet use behavior, (3) content formats, and (4) intervention adherence.

Theme 1: Social Media Platform

Participants found the LINE app to be convenient and accessible, accessing it daily. They appreciated being able to save and review images and videos. One participant said:

> *LINE is convenient, but an OPD visit is still necessary because when the doctor speaks to my son, he listens and follows your advice.*

Theme 2: Internet Use Behavior

Participants often read the content at night or on weekends, and the daily delivery of content was considered appropriate. Primary caregivers preferred daily content delivery, while others favored weekly delivery. A participant stated:

> *I read the content on weekdays, after 21:00. Frequency of content delivery is acceptable at about 2–3 times per day.*

Theme 3: Content Formats

All content formats were deemed acceptable, and participants found Google Forms (Google LLC) to be user-friendly for assignments and questionnaires. They suggested the addition of more video clips that demonstrate communication techniques. One participant made the following suggestion:

> *Google forms make it simple to complete assignments and questionnaires. Some content should be adjusted to reflect the child's age and developmental stage.*

Theme 4: Intervention Adherence

Participants applied the praising and communication skills from the modules in their daily lives. Many believed that a parenting program is suitable for primary caregivers, though some recommended adaptations for specific situations. For example, a participant said:

> *A parenting program is appropriate for primary caregivers. If the recipient is not the primary caregiver, the content should be delivered at a slower rate.*

Discussion

Principal Findings

The innovative social media–based parenting program, which was developed through a design thinking process, demonstrates the potential of leveraging familiar and accessible platforms to address the needs of parents and caregivers of children with ADHD. By using the LINE app, the program delivered content in varied formats, offering valuable ADHD information, parenting guidance, assignments, and screen-to-screen consultations. This approach made the program accessible, feasible, and acceptable for Thai parents, who found it convenient to save and review information as needed. The success of the program can be attributed to the incorporation of the participants' needs and values, its feasibility, and its acceptability, as evidenced by the high retention rate and qualitative feedback.

The internet use behaviors observed in this study, such as preferred communication times and the use of familiar social media apps, align with previous research [40-45]. This highlights the importance of considering user preferences and behaviors in the development of social media–based interventions, as doing so can increase engagement, effectiveness, and acceptability. The use of the LINE app facilitated user engagement, as it was familiar, simple, and accessible. This supports the notion that promoting credible social media sites and educating users on proper social media use can help reduce misinformation regarding parenting issues [46-50]. Additionally, using a platform that users are familiar with can minimize barriers to access and improve UX.

The content, structure, and delivery of the program were crucial factors that contributed to its feasibility and acceptability. Participants appreciated the convenience of receiving the program through the LINE app, which they used daily. The praise-focused content was particularly interesting to the participants, in line with a previous meta-analysis that found a large effect size for praise, reward, and logical sequence techniques [8]. The program's flexible structure allowed parents to engage with the content at their preferred times and facilitated the sharing of content with other individuals facing similar challenges.

Participants were highly engaged with the program, with 84% (27/32) of participants expressing interest in the intervention. Parents were familiar with the LINE app and discussed their children's behavioral difficulties. Although participants did not always respond immediately to the inputs, they reported reading the material later, saving photographs and video clips on their devices, and sharing the materials with others who faced similar problems with their children's behavior. These engagement rates compare favorably with previous studies; Franke et al [51] found that 55% of participants completed all 8 modules of their intervention, while Baker et al [52] reported a retention rate of approximately 92.5% at postintervention assessment, with 81% of participants completing the 9-month follow-up evaluation.

Participants believed that the program should also include other caregivers, but the content should be brief and summarized for nonprimary caregivers. Previous research has also shown that interactive programs are more effective in improving child behavior than noninteractive programs [47]. This highlights the importance of customization in social media–based parenting programs. Participants also provided valuable suggestions for improving the program, such as including more behavioral management video simulations and tailoring content to different family circumstances. These recommendations highlight the importance of continuously refining and adapting interventions to better address the specific needs and contexts of target populations. Customization and personalization have been shown to be significant factors in the success of social media–based parenting programs [8,9,53,54].

Future Research and Implementation

With regard to future research and implementation, human-centered solutions are necessary to reduce the gap between parents' needs and the content and structure of parenting programs, particularly for parents of children with ADHD. Future studies should focus on personalization, engagement, and positive parental experiences to improve social media–based parenting programs. Additionally, more research is needed to understand how to optimize the integration of technology into parenting interventions, especially in LMICs, where resources and access to quality information may be limited. Collaboration among health care providers, researchers, and technology developers is essential for the creation of effective and accessible social media–based interventions. By working together, these stakeholders can ensure that evidence-based information and guidance are disseminated to parents and caregivers in an engaging, user-friendly format. Furthermore, public health organizations and educational institutions can play a critical role in promoting and supporting the adoption of such interventions within communities.

Limitations

This study has several limitations that should be acknowledged. First, the sample size was small, which may impact the statistical

power of the quantitative findings. However, it is important to note that this study used a mixed methods approach, which allows for data saturation and ensures comprehensive exploration of the research questions beyond mere statistical power. Second, this study was conducted within a single institution; as such, there is a possibility of selection bias, and the findings many not be generalizable to a broader population. To address this limitation, future research should consider multicenter collaborations to include more diverse settings and participants, thereby enhancing the external validity of the findings. Additionally, volunteer bias may have influenced the results, as participants who volunteered for this study may have had characteristics or motivations that were distinct from those of nonparticipants. To mitigate this bias, future studies could explore recruitment strategies that reach a wider range of participants, aiming for a more representative sample.

Conclusion

This study provides evidence for the feasibility and acceptability of a social media–based parenting program for Thai parents of children with ADHD. The program was developed by using a design thinking approach and delivered through the LINE app, a social media platform that was familiar and accessible to the participants. The program provided valuable technical skills related to nurturing children with ADHD and was well received by parents and caregivers. Future research on social media–based parenting programs should focus on personalization and on meeting the specific needs of parents and caregivers to improve long-term outcomes for children with ADHD and their families.

Conflicts of Interest

None declared.

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder

HMW: How Might We
LMIC: low- and middle-income country
UX: user experience

Edited by S Badawy; submitted 15.04.23; peer-reviewed by M Gasmi, S Gupta; revised version received 06.06.23; accepted 13.06.23; published 28.07.23.

Please cite as:
Yam-Ubon U, Thongseiratch T
Using a Design Thinking Approach to Develop a Social Media–Based Parenting Program for Parents of Children With Attention-Deficit/Hyperactivity Disorder: Mixed Methods Study
JMIR Pediatr Parent 2023;6(1):e48201
URL: https://pediatrics.jmir.org/2023/1/e48201
doi:10.2196/48201

Pediatric Delirium Educational Tool Development With Intensive Care Unit Clinicians and Caregivers in Canada: Focus Group Study

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Abstract

Background: Pediatric intensive care unit (PICU)–associated delirium contributes to a decline in postdischarge quality of life, with worse outcomes for individuals with delayed identification. As delirium screening rates remain low within PICUs, caregivers may be able to assist with early detection, for which they need more education, as awareness of pediatric delirium among caregivers remains limited.

Objective: This study aimed to develop an educational tool for caregivers to identify potential delirium symptoms during their child's PICU stay, educate them on how to best support their child if they experience delirium, and guide them to relevant family resources.

Methods: Web-based focus groups were conducted at a tertiary pediatric hospital with expected end users of the tool (ie, PICU health care professionals and caregivers of children with an expected PICU length of stay of over 48 h) to identify potential educational information for inclusion in a family resource guide and to identify strategies for effective implementation. Data were analyzed thematically to generate requirements to inform prototype development. Participants then provided critical feedback on the initial prototype, which guided the final design.

Results: In all, 24 participants (18 health care professionals and 6 caregivers) attended 7 focus groups. Participants identified five informational sections for inclusion: (1) delirium definition, (2) key features of delirium (signs and symptoms), (3) postdischarge outcomes associated with delirium, (4) tips to inform family-centered care, and (5) education or supportive resources. Participants identified seven design requirements: information should (1) be presented in an order that resembles the structure of the clinical discussion around delirium; (2) increase accessibility, recall, and preparedness by providing multiple formats; (3) aim to reduce stress by implementing positive framing; (4) minimize cognitive load to ensure adequate information processing; (5) provide supplemental electronic resources via QR codes; (6) emphasize collaboration between caregivers and the health care team; and (7) use prompting questions to act as a call to action for caregivers.

Conclusions: Key design requirements derived from end-user feedback were established and guided the development of a novel pediatric delirium education tool. Implementing this tool into regular practice has the potential to reduce distress and assist in the early recognition and treatment of delirium in the PICU domain. Future evaluation of its clinical utility is necessary.

(JMIR Pediatr Parent 2023;6:e53120) doi:10.2196/53120

KEYWORDS

pediatric delirium education; pediatric ICU; focus groups, prototyping; end users; users; education; educational; educational tool; tool; development; caregiver; Canada; PICU; pediatric intensive care unit; quality of life; child; children; family resource; cognition; clinical utility; intensive care unit

Introduction

Background

Delirium is a neurological dysfunction characterized by an acute onset of inattention, consciousness fluctuations, or disorganized thinking [1,2]. Approximately 25% of pediatric intensive care unit (PICU) patients experience delirium throughout their stay [3], with greater prevalence among children who require mechanical ventilation (54%-74%) [4]. PICU patients with delirium tend to have an increased length of stay, and pediatric delirium has been independently associated with mortality [5]. PICU survivors frequently experience substantial physical and psychosocial morbidities, such as sleep disturbances, anxiety, depression, and memory impairments, which may increase in severity with increased delirium duration [6,7]. Following discharge, PICU patients with delirium also experience decreased quality of life (eg, physical functioning, bodily pain, and social behaviors) [8], as do their caregivers (eg, physical and emotional well-being [8] and financial difficulties [6]). Collectively, pediatric delirium results in long-term complications affecting both patients and their caregivers.

An educational tool can help caregivers recognize delirium symptoms, aid in delirium detection, and help diminish caregiver anxiety and distress when delirium occurs [4,9-18]. Early intervention has been associated with a substantial decrease in delirium duration and subsequent complications [19], further indicating the need to use the caregiver's unique and vital role in recognizing deviations from their child's premorbid baseline functioning [9,14]. Family-based identification can be comparable to clinical identification [14] and is essential in pediatrics, given that only 2% to 7% of PICU patients are routinely screened for delirium [4]. Thus, empowering caregivers to increase their understanding and involvement in preventing, detecting, and managing delirium has been suggested [9,12-14,20,21]. Despite these recommendations and the clinical relevancy of delirium, family caregiver education remains rare [10], representing an opportunity to implement practical educational tools in the PICU.

Objectives

We aimed to develop an educational tool for caregivers whose child may develop PICU-associated delirium, which would enable them to identify signs of delirium and bring that information to the health care providers' attention during the PICU stay, provide education on how they can best support their child if their child experiences delirium, and provide relevant resources to support families.

Methods

Study Design

We applied patient-oriented research principles [22]. We conducted a qualitative study using focus groups with caregivers (ie, parents of children currently receiving, or who recently received, pediatric intensive care with an expected length of stay for over 48 h) and clinicians or allied health professionals (eg, pediatricians, psychiatrists, clinical fellows, resident physicians, psychologists, nurse practitioners, nurses, and pharmacists), all of whom have experience in PICU-associated delirium and who work at BC Children's Hospital (BCCH) in Vancouver, British Columbia, Canada.

Ethical Considerations

Ethical approval was obtained from the University of British Columbia and Children's & Women's Health Centre of British Columbia Research Ethics Board (H22-03478; date of approval: February 28, 2023; principal investigator: SES). Our findings are reported following the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist [23].

Participant Recruitment and Eligibility

Clinicians and allied health professionals were approached by trained research staff at BCCH and contacted via departmental email distribution lists. In contrast, caregivers were recruited in person in the PICU during their child's hospital stay. After a trained research team member described the study and answered any questions, informed consent was obtained in person or electronically using Research Electronic Data Capture (REDCap; Vanderbilt University) [24,25]. As the focus groups were conducted over the web, participants were required to have an internet connection and access to an electronic device (eg, tablet, smartphone, or computer). To encourage participation, participants were provided CAD $25 (US $18.35) per hour as an honorarium for their time and expertise. Each focus group session aimed to have mixed participant types and included approximately 3 to 5 clinicians and allied health professionals and 3 to 5 caregivers.

Data Collection

Following informed consent, a brief demographics questionnaire (eg, age range, education level, etc) was administered using REDCap [25]. Two trained research team members (MW and KG) conducted the focus group meetings between February and August 2023 using Zoom (Zoom Video Communications). One researcher facilitated the sessions (MW) while another research team member took notes (KG); only the 2 research team members and the recruited participants attended each session. At the start of each focus group, the team members introduced themselves and their role and then asked the participants to provide a brief introduction. A team member gave an overview of the research program, including the rationale for educating caregivers about pediatric delirium.

The focus groups were iterative, consisting of 2 stages, and participants were invited to both. First, sessions used guided questions to prompt participants to discuss three themes: (1) how delirium education has been given to caregivers previously, or how clinicians or allied health professionals have previously provided delirium education; (2) what educational tools or instruments participants have used; and (3) what type of information is pertinent to educate caregivers about pediatric delirium (see Multimedia Appendix 1). We then shared adult delirium educational tool examples (created or adapted from Vanderbilt University) to elicit design requirements and visualization preferences to inform prototype development. In follow-up sessions, we reviewed the findings from the previous focus groups and screen-shared our educational tool prototype to obtain end-user feedback to guide the final design. While

viewing examples and the prototype, participants were prompted to indicate their general thoughts on the designs, such as what they liked or disliked about the design and suggestions for improvement.

Sessions lasted approximately 1 hour, were audio recorded, and were digitally transcribed using the live transcription function in Zoom. Transcripts were verified by a research team member (MW or KG), and participant names were replaced by sequential identifiers. For methodological rigor, our data saturation criterion [26] aimed to discontinue data collection when we reached informational redundancy. Specifically, 2 research team members (MW and KG) determined that similar comments and concerns were repeatedly discussed across sessions and that data saturation had occurred.

Data Analysis

Participant characteristic questionnaire data were summarized using R software (version 4.3.1; R Foundation for Statistical Computing). Qualitative data (ie, focus group transcripts) were analyzed using NVivo (QSR International) and summarized using thematic analysis [27]. Two research team members (MW and KG) independently reviewed 2 transcripts and used inductive coding [28] to develop a preliminary list of thematic codes organized by theme, subtheme, and participant labels to describe these data and generated a preliminary codebook [29]. To ensure consistency, these researchers then compared interpretations, resolved any discrepancies, and applied these codes to the remaining transcripts using deductive coding [28]. To ensure key concepts were not missed and that additional coding remained consistent, these researchers iteratively discussed additional themes that emerged after coding the remaining transcripts and adjusted the coding framework accordingly.

Coded quotes were organized by a theme, subtheme, and participant type (ie, a clinician or allied health professional [denoted by "HCP"] or a caregiver [denoted by "CG"]). Prominent themes that emerged from focus groups (see the *Results* section) were used to generate requirements to develop the delirium education tool. Participant responses to the open-ended questions defined how delirium education is conducted in practice and what sections should be included in the tool to resemble this discussion; their responses also suggested potential design requirements to ensure effective use in hospitals, which were further explored based on participant feedback on the adult delirium education tools.

Results

Focus Group Participant Demographics

In all, 24 participants, including 18 PICU clinicians and allied health care professionals (6 registered nurses, 3 psychologists, 3 clinical fellows, 4 psychiatrists, 1 physiotherapist, and 1 intensivist) and 6 family members, attended 7 focus group sessions consisting of 4 to 6 participants (1 session was comprised of only 2 participants due to cancellations), and 57% (4/7) of the sessions consisted of mixed groups (combining clinicians, allied health care professionals, and caregivers). When approached in the PICU, 2 family members declined because they did not have the time and energy to participate, 11 family members could not be contacted following informed consent, and no participants were excluded. However, 67% (4/6) of the caregivers and 40% (6/15) of the health care professionals dropped out of the study from stage 1 to stage 2; thus, 3 additional health care professionals were recruited during stage 2 accordingly. These high attrition rates were predominately attributed to a child being readmitted (worsening or additional illness) or limited availability. Of the enrolled participants, 79% (19/24) identified as female, and 88% (21/24) were aged <50 years. Of the family member participants, 67% (4/6) had a high school diploma (or equivalent) and 33% (2/6) had either a certificate (university or nonuniversity) or university degree.

PICU Delirium Education in Practice: Key Themes

Data from focus group discussions were grouped into 3 thematic domains, described in detail below, with a summary of design requirements and tool informational sections shown in Tables 1 and 2, respectively.

Table . Summary of themes and design requirements identified from the initial focus groups with health care professionals and caregivers of critically ill children.

Identified themes	Design requirements
Present tool information in a logical order	• R1.1: Present educational information in an order that resembles the structure of the discussion between health care professionals and caregivers around delirium
Ensure that the tool is user-friendly	• R2.1: Provide multiple formats to increase information accessibility and recall, and to ensure that all families feel prepared • R2.2: Minimize potential distress by implementing positive framing • R2.3: Reduce cognitive load of caregivers to ensure effective information processing • R2.4: Make detailed supplemental electronic resources readily available via web links and QR codes
Delirium education should provide a sense of agency	• R3.1: Emphasize the importance of collaboration between the caregiver(s) and the health care team • R3.2: Ask prompting questions to act as a call to action for the caregiver(s)

Table . Summary of informational sections that should be included in the tool to ensure effective delirium education.

Section	Description
S1	Provide a succinct delirium definition to indicate that it is a common and transient condition among critically ill children
S2	Describe common signs and symptoms to ensure that families can identify key features of pediatric delirium
S3	Highlight clinically relevant long-term outcomes associated with delirium to contextualize the importance of early detection and management
S4	Indicate suggestions on how caregivers can assist with the care of their child who is currently experiencing delirium
S5	Incorporate education and supportive resources for families that require additional information or assistance
Additional sections for consideration	Delirium risk factors, potential causes, and mental health and supportive resource for caregivers

Overview of Delirium Education in Practice

When considering how clinicians typically provide delirium education to caregivers, PICU health care professionals indicated that they do not typically discuss delirium until "staff start to observe symptom onset" (HCP09). As many health care professionals outside of psychiatry and psychology do not feel that they have delirium expertise, clinicians will typically "provide a short summary" (HCP08) and discuss delirium broadly (eg, signs and symptoms, potential causes, and long-term outcomes) following onset. During this discussion, clinicians may also describe delirium management techniques (eg, prompt extubation, sedation vacation, and early mobilization) if prompted by caregivers. As "parents are typically distressed" (HCP08) during their child's PICU stay and feel that they "lack control for caring for their child" (HCP01), health care professionals consistently provide details on how the family can assist their child (eg, bringing the child's favorite toy or blanket, family photos, and art). Subsequently, the discussion concludes by ensuring that the family has an accurate understanding of delirium and answering any remaining questions. Caregivers who had a child experience delirium indicated a similar process, whereas caregivers of children without delirium believed that the process and format would be informative (requirement R1.1 in Table 1).

Previous Experience With Educational Tools or Instruments

Most participants indicated that delirium education is a conversation at the bedside and that tools or instruments should be regularly implemented. Some clinicians indicated they might refer caregivers to the American Academy of Child & Adolescent Psychiatry web-based resources, such as "Delirium in Children and Adolescents" or "When Your Child has Pediatric Delirium." Notably, most health care professionals were unaware that delirium education tools existed and indicated that their clinic or unit "doesn't currently have a delirium pamphlet or tool" (HCP03) that they can refer families to. A caregiver indicated that they had used surgical education tools (eg, websites and brochures) previously, which were "extremely helpful" (CG02), acted as a resource that could be reviewed as required, and ensured that they were prepared for the surgical journey (requirement R2.1). Another caregiver echoed this sentiment and indicated that that during a stressful event, such as having a child in the PICU, "you don't necessarily remember what was said [by health care professionals]" and having "this information to refer back to is paramount" (CG06) to ensuring effective delirium education.

Information Required to Provide Effective Delirium Education in the PICU

First, participants agreed that delirium should be clearly defined. Due to potential delirium-associated distress, participants suggested that the tool should then provide contextual information to emphasize that delirium is a commonly occurring condition among critically ill children (eg, 1 in 4 children experience delirium) and is a "temporary condition" (HCP12) that typically "resolves as the child's health improves" (HCP10; section S1 in Table 2).

As parents may be able to assist with the early detection of "subtle changes in their child's behavior [from baseline]" (HCP11), participants indicated that a "signs and symptoms" (HCP12) section should identify common features of delirium (eg, fluctuating course, confusion, altered sleep-wake cycle, rapid mood changes, hypoactive to hyperactive features, etc; section S2). Most participants further indicated that a section on outcomes associated with delirium (eg, increased length of hospital stay and decreased postdischarge quality of life) would contextualize the importance of prompt delirium detection and management (section S3). Some clinicians believed that the tool should indicate potential risk factors associated with delirium, as well as indicate how children are diagnosed and treated; however, most participants believed that indicating risk factors may "increase family anxiety" (HCP14). Participants further suggested that due to the complexity of the PICU and the stress associated with their child's acute illness, the educational tool should apply positive framing throughout (requirement R2.2).

To ensure caregivers are effectively used in early recognition of delirium and helpful treatment strategies, participants indicated that the tool should emphasize "the collaborative relationship between families and the medical team" (HCP10; requirement R3.1) and indicate how caregivers can "have an active role in their child's care" (HCP06; section S4). For

example, parents could bring "comfort items" (CG02) to the hospital, as well as implement daily routine reminders, such as opening the blinds, turning on room lights during the day, or brushing their child's teeth and showering them when it is safe to do so.

Most participants indicated that the education tool should conclude with a section for additional resources, such as pediatric delirium websites and options for local supportive services (section S5). As having a child admitted to the PICU greatly "impacts parents and their own mental health" (CG06), some participants further indicated that mental health and supportive resources should be available to ensure that caregivers feel supported during their child's hospital stay.

Additional Requirements and Suggestions Identified From Reviewing Adult Delirium Education Tools

Minimize Cognitive Load of Users

Participants identified that education tools may be cognitively demanding for caregivers who are already experiencing the distress associated with having a critically ill child (requirement R2.3); therefore, the tool should serve as a "quick reference" that is "a summary of the clinical discussion" (HCP11). Specifically, the tool should (1) implement "lay language [throughout]" (CG05); (2) avoid redundancy; (3) have "clear separation between each section" (HCP14); (4) use "bullet points to ensure information is easier to process" (CG06); and (5) use informative and representative icons. Participants further indicated that the 1-page format was less cognitively demanding overall and more accessible to review as an electronic resource than a trifold brochure, but a more detailed document may be beneficial for some families.

The Delirium Education Tool Should Use Prompting Questions

Although the tool can only provide generic pediatric delirium education, most participants felt that the tool should provide a sense of personalization. The tool should "center on the child" (HCP11) by using "prompting questions" (HCP04) to act as a call to action for parents (eg, Is your child experiencing any of the following? and How can you help your child while they experience delirium?), which would engage families and potentially provide a sense of agency over their child's care (requirement R3.2).

Include Multiple Formats to Increase Use

Most participants believed the tool should have a 1-page version and a more detailed version readily available. Participants requested that the 1-page tool should remain a physical copy that provides only "necessary information" to ensure "its education information is not overwhelming" (CG02) and that families can read it "when they have time to process the information" (HCP09). Families (and potentially staff) that request additional educational information should have the option to access a more detailed document and other delirium-related resources via web links or QR codes (requirement R2.4).

Additional Suggestions to Finalize the Delirium Education Tool Design

Participants indicated that our delirium education tool design (Figures 1-3) effectively included all sections and requirements identified from the previous sessions and that the tool would be highly beneficial to future families whose child is experiencing delirium in the PICU. While viewing the prototype, end users provided minor suggestions for improvement and indicated that the tool should (1) implement bold or italic text to emphasize key concepts; (2) provide section headings for each piece of text (acting as a question and answer format); (3) reduce medical terminology, vague constructs (eg, irregular moods), and redundant text; (4) include informative and representative icons; (5) ensure lists have a logical flow; and (6) contextualize if symptoms are in hospital versus after discharge. These suggestions were directly incorporated into our prototype, resulting in the finalized design of a multiformat delirium education tool in pediatrics.

Figure 1. One-page pediatric intensive care unit (PICU) delirium educational tool for caregivers.

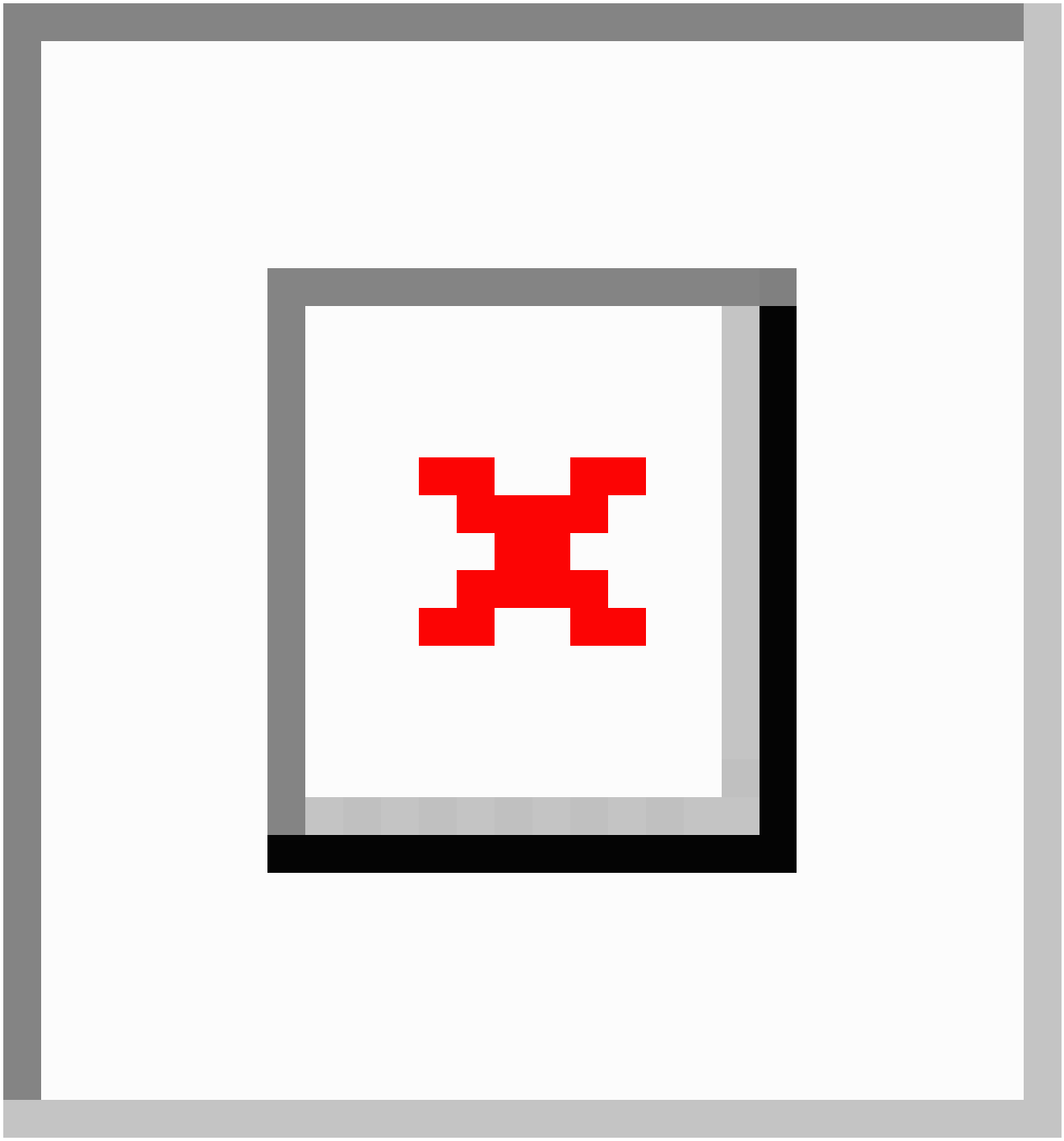


Figure 2. Two-page (front) pediatric intensive care unit (PICU) delirium educational tool for caregivers.

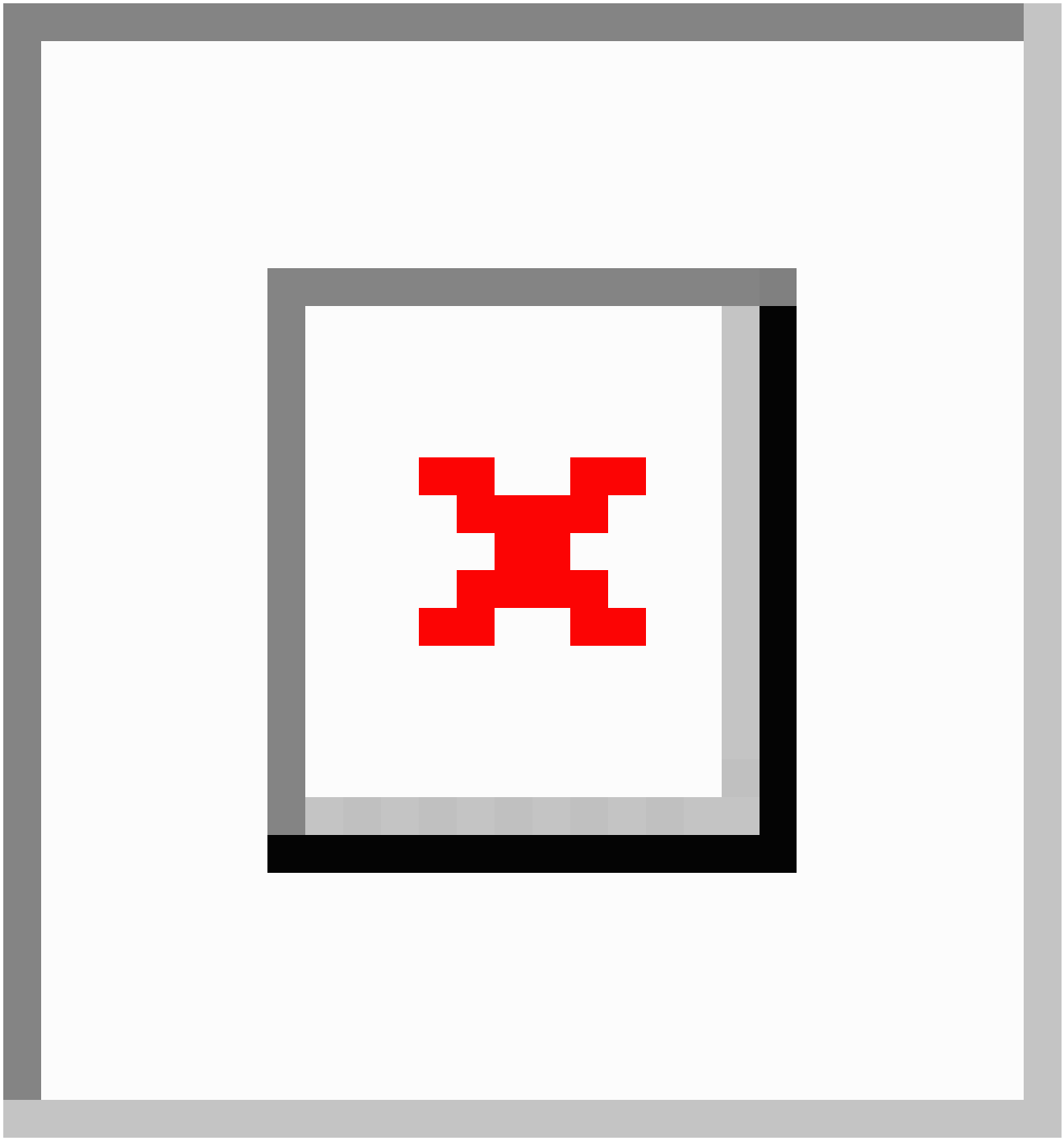
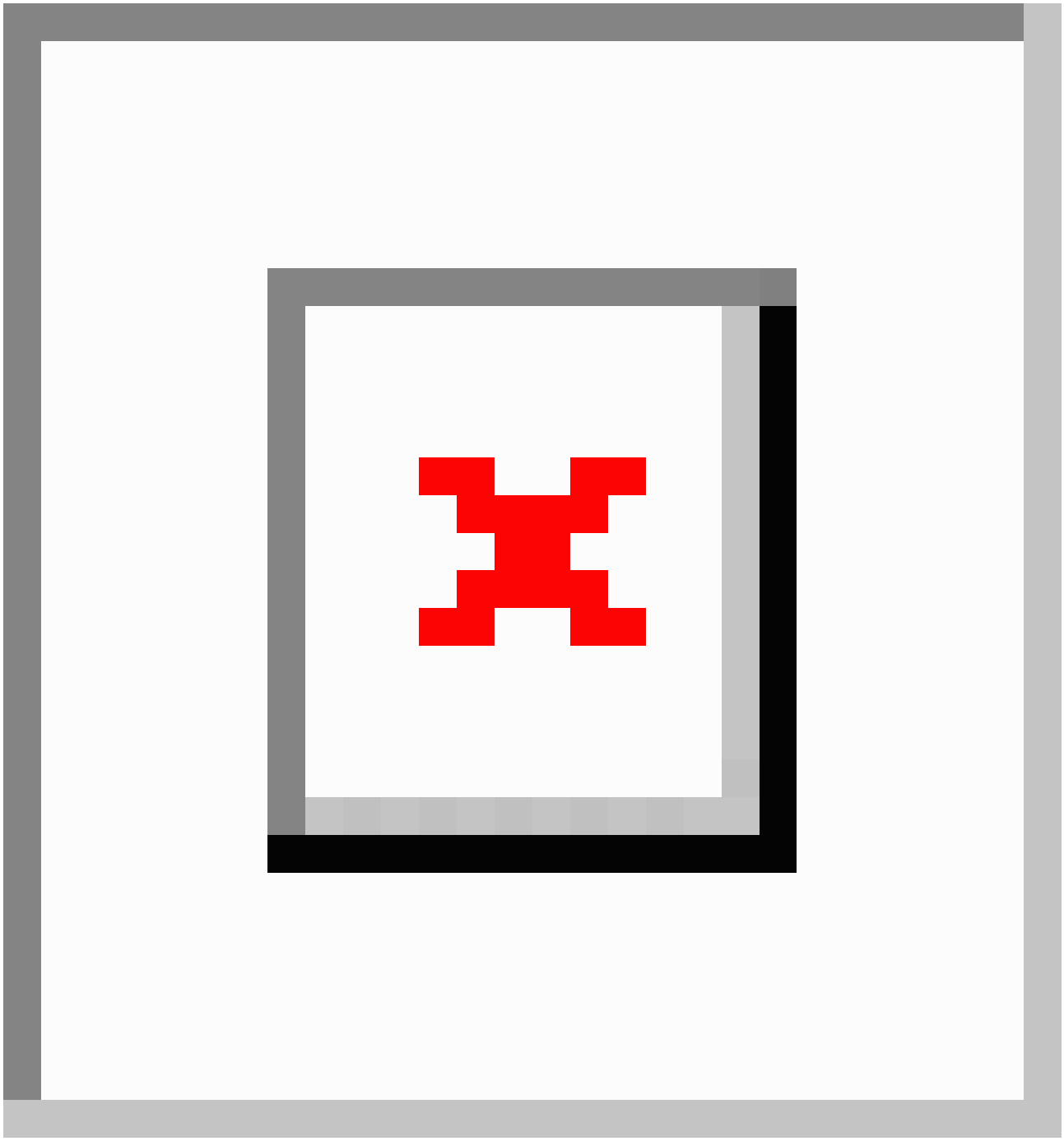


Figure 3. Two-page (back) pediatric intensive care unit (PICU) delirium educational tool for caregivers.



Discussion

Primary Findings

During the focus group sessions, our expected end users (health care professionals and caregivers) indicated five informational sections to develop a pediatric delirium education tool: (1) delirium definition, (2) key features (signs and symptoms), (3) postdischarge outcomes associated with PICU delirium onset, (4) tips and suggestions to inform family-centered care, and (5) education or supportive resources. To use educational information in practice, participants further indicated seven design requirements: information should (1) be presented in an order that resembles the structure of the clinical discussion around delirium; (2) increase accessibility, recall, and preparedness by providing multiple formats; (3) reduce stress by implementing positive framing; (4) minimize the cognitive load of users to ensure adequate information processing; (5) provide supplemental electronic resources via QR codes; (6) emphasize collaboration between caregivers and the health care team; and (7) ask prompting questions to act as a call to action for caregivers. These findings culminated in the development of a delirium education tool for the PICU.

Comparison With Prior Work

Previous research in adult palliative care has resulted in educational tools with similar informational sections and requirements: for example, including a delirium definition, causes, signs and symptoms, as well as the treatment of delirium

[11,15,17,18]; implementing easily understood language throughout [18]; using direct, specific, and action-oriented lists [18]; applying simple layouts to ease processing; reducing text [11,15,17,18], and applying intuitive designs (eg, bold contrasting colors and large headings) [18]. Additional suggestions included implementing rest periods to mitigate caregiver exhaustion and daily communications with the patients' health care professionals about delirium [15]. We tried to address these suggestions by including additional sections on how caregivers can be supported and emphasizing collaboration between caregivers and the health care team. These previous studies were conducted in adult populations, and these findings broadly agree with those from our study. However, previous delirium education tool developments have rarely implemented patient-oriented research principles [22], such as directly involving expected end users [11,18], which may limit their implementation and clinical utility.

Adult delirium education tools have increased caregiver understanding of the causes of delirium [17], and health care professionals indicated that they were an efficient way to support caregivers and facilitate their involvement in providing care [11]. Such educational tools have led caregivers to report increased comfortability in delirium discussions with other family members, increased confidence in caretaking abilities, and decreased emotional distress (eg, feeling responsible, guilty, and powerless) during delirium episodes [15]. Furthermore, caregivers who received a delirium educational tool reported lower levels of anxiety and depression compared to caregivers who did not [30]. Usability surveys further indicated that health care professionals and caregivers found adult delirium education tools to be comprehensive and easily understandable [11] and that health care professionals intended to use them with future families [18]. Taken together, delirium education tools have the potential to increase caregivers' knowledge and confidence while decreasing their delirium-related distress, which suggests that future research is warranted to demonstrate both tool validity and usability in pediatrics.

Limitations

Our participants comprised a representative cohort of PICU health care professionals but only a small number of caregivers from a single center, which may limit the transferability of our findings. We also had a large amount of attrition, which may have further limited transferability but also reflects the challenges of conducting qualitative research with repeated observations among complex patient populations. Future studies will need to implement multiple strategies (eg, providing incentives, conducting rapport-building exercises, enacting frequent communication, and indicating study benefits) to improve retention [31]. However, we included a wide range of health care professions (eg, psychiatrists, pharmacists, nurses, etc) and achieved data saturation; thus, robust findings were likely identified. To reduce additional distress and facilitate effective instruction, including children in future focus groups may be imperative; however, due to the large number of patients aged <7 years at our site, parents and caregivers were deemed as an appropriate proxy. Despite language interpretation services and closed captioning being offered during recruitment, our focus groups comprised only English-speaking participants, which may have further limited transferability. Although participants provided feedback on our current prototype, these findings lay the foundation to investigate the clinical impact of delirium education and inform the development of a study to investigate the family's role in detecting delirium in pediatrics. Assessing the clinical utility and usability of our pediatric delirium education tool prototype was beyond the scope of this study due to limited resources, and further research is warranted.

Conclusions

Our study identified several requirements for developing a PICU-associated delirium education tool, such as presenting the information in a way that resembles the consult, providing multiple formats, implementing positive framing, minimizing the cognitive load of users, using QR codes for additional resources, emphasizing collaboration, and asking prompting questions to act as a call to action. Although clinical evaluation is still required, implementing an educational tool guided by clinicians, allied health professionals, and caregivers into clinical practice can potentially reduce caregiver distress and assist in promptly recognizing and treating delirium in the PICU.

Acknowledgments

The authors thank the participating families, health care professionals, and the Health Promotion & Health Literacy team at BC Children's Hospital (BCCH) for their invaluable time, insights, and support. MW holds a Child and Adolescent Postdoctoral Fellowship at BCCH. MG holds a Michael Smith Health Research BC scholar award. This work was internally funded by a BCCH Research Institute Brain Behavior and Development Research Theme Trainee Boost Award.

Authors' Contributions

MW and KG participated in study design, data collection, qualitative analysis, as well as the drafting and editing of the manuscript. AC, PS, GK, MG, and SES participated in study design, drafting, and critical revision of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Focus group guide for health care professionals and parents.
[DOCX File, 38 KB - pediatrics_v6i1e53120_app1.docx]

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Abbreviations

BCCH: BC Children's Hospital
COREQ: Consolidated Criteria for Reporting Qualitative Research
PICU: pediatric intensive care unit
REDCap: Research Electronic Data Capture

Edited by S Badawy; submitted 26.09.23; peer-reviewed by S Kaur, S Etches; revised version received 13.11.23; accepted 14.11.23; published 11.12.23.

Please cite as:
Wood M, Gandhi K, Chapman A, Skippen P, Krahn G, Görges M, Stewart SE
Pediatric Delirium Educational Tool Development With Intensive Care Unit Clinicians and Caregivers in Canada: Focus Group Study
JMIR Pediatr Parent 2023;6:e53120
URL: https://pediatrics.jmir.org/2023/1/e53120
doi:10.2196/53120

Original Paper

Canadian Pediatric Intensive Care Adaptations for Critically Ill Adults During the COVID-19 Pandemic: Survey Study

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Abstract

Background: The COVID-19 pandemic overwhelmed Canadian hospitals with adult admissions. A large number of adult patients required critical care therapies, placing significant strain on hospital resources. In order to decompress adult intensive care units, pediatric intensive care units (PICUs) introduced adapted models of traditional care to lessen these burdens.

Objective: We aimed to evaluate how PICUs across Canada adapted care for the high volumes of critically ill adults.

Methods: A survey containing 40 questions was sent to the medical directors of 14 Canadian PICUs where English was the primary clinical language. The survey was designed to gain perspective on the various adaptations that PICUs instituted during the COVID-19 pandemic.

Results: Of the 13 PICUs that returned survey responses (response rate: 13/14, 93%), 10 (77%) participated in at least one adaptation to support the influx of admitted adults with COVID-19. The key challenges included disorganization, loss of autonomy, and compromised patient care. The significant advantages of these adaptations included a sense of learning and comradery.

Conclusions: Our study highlighted an unpreparedness in critical care surge capacity. During the COVID-19 pandemic, adaptations rapidly emerged in Canada that involved PICUs with adult care. In the future, preplanned adaptations for optimizing robust critical care services should be developed based on what has been learned from the COVID-19 pandemic.

(JMIR Pediatr Parent 2023;6:e43602) doi:10.2196/43602

KEYWORDS

Canada; COVID-19 pandemic; delivery of health care; pediatrics; population health; health care; intensive care; patient care

Introduction

The COVID-19 pandemic dramatically impacted hospital utilization. Many admitted adult patients had prolonged hospital stays, with a large number requiring support in intensive care units (ICUs) [1]. Unfortunately, the number of adult patients who needed critical care soon outpaced the availability of conventional critical care resources [2-4], while the number of children generally did not [5]. As such, 3 variations to traditional pediatric ICU (PICU) models of care became prevalent to treat this influx.

One adaptation was to have pediatric intensivists mange adult patients in the PICU [6]. As pediatric critical care capacity was protected [7], care was standardized, collaboration with adult physicians occurred, licensing was addressed, and team preparedness was ensured [8], mortality outcomes were very favorable [9-12]. A second adaptation was to redeploy PICU staff to adult ICUs. At least two centers [13,14] documented PICU physician, nurse, and physician assistant redeployment after rapid training sessions. Strain between PICU and ICU staff was noted [14], but this diminished as familiarity with the style of practice was established [14]. The final adaption was to have the PICU to act as a unit for ICU overflow that was staffed by

adult physicians. As a single pool of critical care resources was distributed to both adult and pediatric patients, equitable considerations became necessary [15-19].

The purpose of this study was to evaluate how PICUs across Canada adapted care for the high volumes of critically ill adults during the COVID-19 pandemic.

Methods

Survey Development

PubMed and Google Scholar were searched for articles containing the keywords *COVID-19*, *critical care*, *adults*, and *pediatric intensive care units*. Literature was limited to articles published in the last 2 years, due to the novelty of the COVID-19 pandemic. The literature was retrieved, and the references were reviewed. Following this, 2 pediatric intensive care specialists reviewed the literature and began to create the survey. The survey addressed the following three main adaptations to traditional models of care: opening PICU beds for adult ICU staff and patients, deploying PICU staff to adult ICUs, and managing adult patients with PICU staff in the PICU. Pertinent questions related to these adaptations were reviewed by an independent intensivist to ensure the validity and relevancy of questions. The survey was created and then converted to a REDCap (Research Electronic Data Capture; Vanderbilt University) survey. REDCap was designed to support data capture for research studies, ensure secure web authentication and secure layer encryption, and allow for anonymous participant responses [20]. REDCap was maintained by the University of Saskatchewan.

Ethics Approval

The survey was approved by the human research ethics board of the University of Saskatchewan (#3248).

Survey Format

The survey (Multimedia Appendix 1) consisted of 40 possible questions that were divided into 3 domains that corresponded to an adaptation. The three adaptations were titled *opening PICU beds for adult staff and patients*, *deploying PICU staff to adult ICUs*, and *managing adult patients with PICU staff in the PICU*. Each domain had required responses, and subsequent questions would only be displayed, via an embedded branching logic algorithm, for certain responses. If participants did not participate in any of the three adaptations mentioned in the survey, they were immediately directed to the conclusion of the survey.

Survey Administration

The contact information of 14 Canada medical-surgical PICUs or mixed medical-surgical–cardiac PICUs, where English was the primary clinical language, was gathered from university directories and local sources. In April 2022, a cover letter that introduced the survey and briefly described the content was distributed to the medical directors of each of these PICUs. The link to the REDCap survey was attached to a cover letter that stated “completion and return of the survey implies consent to participate.” Survey answers could be changed prior to submission. Further, 3 reminder emails were sent to the participants every 2 weeks. Coded usernames were stored with responses and later deleted to prevent duplicate entries. No incentive was given for the completion of the survey.

Data Management and Statistics

Data were collected and managed by using REDCap software. Participant data were anonymous and were analyzed by using IBM SPSS Statistics 28 (IBM Corp). Responses were reviewed for completeness. Proportions were calculated for questions, when applicable. Further, 2 authors (GH and TH) inductively coded all comments as a whole and deductively coded comments from each section into a framework of lessons learned and positive or negative aspects. Representative quotations were agreed upon by all authors.

Results

Overview of Survey Responses

A total of 13 survey responses (response rate: 13/14, 93%) were returned by PICU medical directors. All returned surveys were fully completed. Of the 13 PICUs, 3 (23%) had pre-existing pandemic plans that involved adult ICU and PICU collaborations. During the COVID-19 pandemic, 10 (77%) PICUs participated in adult intensive care by opening PICU beds for adult ICU staff and patients (3/13, 23%), deploying PICU staff to adult ICUs (5/13, 38%), and managing adult patients with PICU staff in the PICU (8/13, 62%).

Opening PICU Beds for Adult Staff and Patients (n=3)

This adaptation was coordinated at the institutional (n=1), regional health authority (n=1), and provincial health authority (n=1) levels. The trigger for the initiation of this model of care was adult ICU capacity being overwhelmed (n=3). The PICUs accepted COVID-19–positive patients (n=1), COVID-19–negative patients (n=1), or both COVID-19–positive patients and COVID-19–negative patients (n=1). A range of 4 to >100 adults were admitted, through this adaptation, over a period of <2 weeks to 10 months. Center responses are summarized in Textbox 1.

Textbox 1. Pediatric intensive care unit (PICU) medical directors' perspectives on opening PICU beds for adult patients and staff.

Negative effects on PICU patient care (n=2)

1. "Communication and practice style between adult intensivists, registered nurses (RN) and respiratory therapists (RRT) were very different, and so there were difficulties felt on the part of our staff (PICU, RNs) not wanting to pick up shifts because they did not what not deal with adults and adult style of medicine."
2. "Short staffing in the PICU was amplified, and staff felt they had to sedate their patients more in order to take care of all of the patients."

Positive observations for this adaptation (n=3)

1. "Sense of help during crisis…adult side incredibly grateful."
2. "Saw more early patient mobilization."
3. "Good learning experience during periods of surges."

Lessons learned (n=3)

1. "The great work that we do at end-of-life with children becomes evident when you see how that type of care is provided to dying adults."
2. "A ton of work and planning sent into this – probably easier to replicate in the future."

Deploying PICU Staff to Adult ICUs (n=5)

A total of 5 centers deployed registered nurses, 4 deployed registered respiratory therapists, and 1 deployed physicians. No centers deployed social workers, pharmacists, or dieticians. Further, 2 centers coordinated this adaptation at the institutional level, while the others involved all levels, including the regional health authority, provincial health authority, and provincial Ministry of Health levels. The duration of this adaptation ranged from 6 weeks to 8 months, and this adaptation was specifically triggered by projections of ICU admissions, actual ICU admissions, and ICU staff shortages. Center responses are summarized in Textbox 2.

Textbox 2. Pediatric intensive care unit (PICU) medical directors' perspectives on deploying PICU staff to adult intensive care units.

Concerns of ensuring clinical preparedness (n=3)

1. "Nurses were supposed to be given some training…some got more than others."
2. "There was minimal preparation provided to the RNs and RRTs. They were initially in more supervised roles on the adult units before taking on patients independently."
3. "Buddy days for some people, but the majority were RNs with previous adult experience who just went straight to patient care."

Negative effects in PICUs with this adaptation (n=2)

1. "We had to cancel elective surgeries due to lack of RNs in PICU during high volume days."
2. "The impact was felt more on the RRT side. We often just worked short. The facility did float ward nurses to us more frequently to backfill PICU nursing shortages, but this couldn't be done with RRTs."

Positive observations for this adaptation (n=4)

1. "Team members returned with some added perspectives they were able to share with all of us on the practice of critical care, during the pandemic, and in general."

Lessons learned (n=3)

1. "There is more in common between PICU and adult ICU than there is different."
2. "Be transparent with your team. Consider seeking for volunteers before assuming mandatory deployment."

Managing Adult Patients With PICU Staff in the PICU (n=8)

The coordination of this adaptation was largely done (n=6) via collaborations among the regional health authority, provincial health authority, and provincial Ministry of Health levels. The volume of adult admissions to Canadian PICUs ranged from 6 to 100 patients during an admission period ranging from 2 weeks to 8 months. Further, 4 centers restricted their admissions to COVID-19–positive patients, 1 restricted its admissions to COVID-19–negative patients, and 3 admitted both COVID-19–positive patients and COVID-19–negative patients. Additionally, 3 centers also limited the adults they cared for to those aged a maximum of 50 years. A total of 4 centers had a pre-existing specialized pediatric transport team, but only 1 center became involved with the interfacility transport of adult patients. To ensure that pediatric capacity for critically ill patients was not compromised, most centers (7/8, 87.5%) used a refined daily approach to managing bed availability in the adult ICUs. This adaptation was triggered by projected and

actual surges in hospitalizations, with adult capacity ranging between 100% and 125%.

Center responses are summarized in Textbox 3.

Textbox 3. Pediatric intensive care unit (PICU) medical directors' perspectives on managing adult patients with PICU staff in the PICU.

Measures to ensure that adult care was not compromised (n=8)

1. "Supervised by adult intensivists."
2. "Rapid development of policies and procedures, education sessions, shared folders with resource documents"
3. "We arranged for adult subspecialists to consult with us rather than their pediatric versions."
4. "Adult code simulations"

Negative effects on PICU patient care (n=3)

1. "We worked more hours in the month compromising our lifestyle."
2. "Emotional strain of managing COVID-19 and death of adult patients was different"

Positive observations for this adaptation (n=7)

1. "Some exposure to new ways of doing things."
2. "Adult intensivists understood that were intensivists also."
3. "Multiple opportunities for collaboration and engagement occurred with our adult ICU colleagues."

Lessons learned (n=7)

1. "Different staffing models explored."
2. "Surge capacity can be organized and resiliency in moments of national emergency were very developed"
3. "With good back up, adults can be cared for well in a PICU (some patients' families did not want to go back when the time came!)."

Lack of Engagement and Autonomy (n=8)

The primary theme that arose from PICU directors' responses was their perceived lack of engagement and autonomy (n=8). They commented that adaptation decisions were "imposed," they had "no choice," there was not a venue "for [pushback]," and adaptation decisions were conducted with "excessive zeal." In one instance, directors "had other models proposed…not accepted." Moreover, similar reflections were noted after the crisis had subsided, as follows:

> *Not enough engagement, and not enough push back and not enough power to bring the staff back when the situation improved.*
>
> *Even with very low (adult ICU admission) numbers, the PICU was not given back to us.*
>
> *We did not have enough power (to return to regular model of care) when the situation improved.*

Discussion

Our Canadian survey demonstrated a lack of pre-existing COVID-19 pandemic plans among adult ICUs and PICUs. Grappling to find solutions for adult ICU surges, many PICU directors felt uninvolved with the new care modeling and felt that they had compromised care in the process. However, each center described positive learning experiences, which may be useful for future pandemic planning.

The lack of PICU preparedness for adapting to adult ICU surges resulted in concerns from directors. Many were unhappy with their lack of engagement and autonomy in decision-making, leading to adaptations that were not desirable and precipitously instituted. Although the survey did not specifically ask for details of engagement, acute adult surges may have resulted in efficiency and speed being prioritized. Furthermore, several adaptations were initiated by novel committees from provincial pandemic organizations, which may have lacked adequate pediatric representation.

Regardless of the adaptation, many PICU directors suggested that pediatric care was compromised. The adaptations resulted in strategically placed PICU resources being moved, staff shortages, the cancellation of pediatric surgeries, and increased patient sedation due to busier patient assignments. Although the survey was not designed to quantitatively assess these compromises, the sentiments conveyed an environment of suboptimal care in which both pediatric and adult patient morbidities could have occurred.

Despite the adaptations' negative consequences, some unexpected positive lessons emerged. A sense of esprit de corps and pride emerged, as pediatric intensivists understood the necessity of the adaptions and exhibited a willingness to assist with the adult ICU surge. Positive relationships between adult and pediatric intensivists were fostered, as there was a recognition of the commonalties between adult and pediatric care. Clinically, exposure to adult care and protocols provided unique perspectives and learning opportunities. Most importantly, some centers felt empowered when reflecting on what was accomplished.

Going forward, the concerns that arose from Canadian PICU directors during the COVID-19 pandemic suggest a necessary

preparedness for future pandemics. Provincial commitments are required to ensure dedicated funding for existing adult and pediatric critical care beds, the continuation of opening additional beds, and the recruitment and training of critical care physicians. New models of critical care could be considered that view critical care as a service line and have adaptable transition points between PICUs and adult ICUs. Intraprovincial collaborations that involve institutions, medical leadership, and health authorities at the local, regional, and provincial levels are needed to address pediatric and adult surge planning with potential adaptations that involve cross coverage. Lastly, interprovincial collaborations could be initiated, as many provinces had to rely on cross-border patient transports. However, PICU directors were very clear that any potential shifts must be guided by transparency and multidisciplinary team engagement.

The survey had several potential limitations. Although our total response rate was 93% (13/14), there is a risk of sampling bias with only surveying medical directors from English-speaking PICUs. Furthermore, despite our best efforts to create a survey that avoided leading questions, our data may reflect response biases due to the nature of the pandemic and its progression. As this study addressed large challenges for critical resources, voluntary response bias may have resulted in the overrepresentation of PICU medical directors with strong opinions. Finally, whether the findings here can be generalized to PICUs outside Canada cannot be determined.

Across Canada, the abrupt need for critical care surge capacity resulted in adaptations of PICU care. Although several negative aspects of these adaptations were revealed, many lessons were learned, and some positive feedback emerged. These considerations may be important for ensuring that robust critical care services can be rapidly and efficiently mobilized during future pandemics.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey questionnaire.
[DOCX File , 16 KB - pediatrics_v6i1e43602_app1.docx]

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Abbreviations

ICU: intensive care unit
PICU: pediatric intensive care unit
REDCap: Research Electronic Data Capture

Edited by S Badawy; submitted 17.10.22; peer-reviewed by J Foster, M Bernier, M Kapsetaki; comments to author 02.11.22; revised version received 16.11.22; accepted 16.01.23; published 10.02.23.

Please cite as:
Parchomchuk E, Holt T, Hansen G
Canadian Pediatric Intensive Care Adaptations for Critically Ill Adults During the COVID-19 Pandemic: Survey Study
JMIR Pediatr Parent 2023;6:e43602
URL: https://pediatrics.jmir.org/2023/1/e43602
doi:10.2196/43602
PMID:36724349

Publisher:
JMIR Publications
130 Queens Quay East.
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Email: support@jmir.org