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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.

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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...
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 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.](image)

**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.

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

$\text{a}$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].

$\text{b}$N/A: not applicable.

$\text{c}$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 Naitre et Grandir (N&G) web page rated by the participants.

<table>
<thead>
<tr>
<th>Participant</th>
<th>Last N&amp;G page rated</th>
<th>Context</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alisson (family)</td>
<td>Development: Around 5 years old</td>
<td>“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.”</td>
</tr>
<tr>
<td>Sarah (family)</td>
<td>Learning to walk</td>
<td>(Could not recall the specific N&amp;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.”</td>
</tr>
<tr>
<td>Mark (family)</td>
<td>Verbal dyspraxia</td>
<td>“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.”</td>
</tr>
<tr>
<td>David (friend)</td>
<td>Tantrums: Understanding them to better intervene</td>
<td>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.”</td>
</tr>
<tr>
<td>Mary (grandmother)</td>
<td>The benefits of music</td>
<td>“My interest in the education of this grandson.”</td>
</tr>
<tr>
<td>Nadia (grandmother)</td>
<td>The benefits of reading with your child</td>
<td>“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.”</td>
</tr>
<tr>
<td>Sophie (grandmother)</td>
<td>2 to 2.5 years: intellectual development</td>
<td>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.”</td>
</tr>
<tr>
<td>Nathalie (grandmother)</td>
<td>The child who doesn’t like kisses</td>
<td>“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. Mateo 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.”</td>
</tr>
<tr>
<td>Joelle (grandmother or professional)</td>
<td>Grief in children</td>
<td>“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...”</td>
</tr>
<tr>
<td>Florence (mother or professional)</td>
<td>The child who doesn’t talk yet</td>
<td>“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, Naitre et Grandir is a great, great source.”</td>
</tr>
<tr>
<td>Norma (professional)</td>
<td>The basics of breastfeeding</td>
<td>“I’m a nurse. I work in early childhood. I’ve always worked in the childcare setting.”</td>
</tr>
<tr>
<td>Alice (professional)</td>
<td>Sleep: effects on development and behavior</td>
<td>“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.”</td>
</tr>
<tr>
<td>Emilia (professional or friend)</td>
<td>Yogurt: Which one to choose? &amp; Food rewards</td>
<td>“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.”</td>
</tr>
<tr>
<td>Mathilde (sister)</td>
<td>Lessons and homework: accompanying your child</td>
<td>“Sometimes, also, on health, it’s more my little brother. But for kids in general, it’s mostly for my babysitting.”</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Theme</th>
<th>Excerpt</th>
<th>Frequency, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>For reassurance</td>
<td>“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]</td>
<td>4 (29)</td>
</tr>
<tr>
<td>Out of personal curiosity</td>
<td>“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]</td>
<td>3 (21)</td>
</tr>
<tr>
<td>For work as a caregiver</td>
<td>“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]</td>
<td>4 (29)</td>
</tr>
<tr>
<td>Following an explicit request</td>
<td>“Actually, it was to reassure a pregnant friend about COVID vaccine” [Norma, a professional]</td>
<td>1 (7)</td>
</tr>
</tbody>
</table>
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]
One grandmother described:

- Feeling reassured and proceeded to keep her vaccination appointment.
- Approached by her pregnant friend who was concerned about the COVID-19 vaccine. After Norma shared the N&G web page, they both felt reassured as a result. Norma, a professional, was discussing the information she had found with her partner, and this led to better intellectual development, allowing her to better understand her granddaughter’s 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 common 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:

- “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]

Outcomes of Using Web-Based Parenting Information

Themes related to the outcomes of using N&G information 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.

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To provide emotional support

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

<table>
<thead>
<tr>
<th>Theme</th>
<th>Excerpt</th>
<th>Frequency, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved relationships</td>
<td>“Yes. In the relationship, it’s clearer when we talk. They already know what we’re talking about, how, and they know.” [Alice]</td>
<td>4 (29)</td>
</tr>
<tr>
<td>Less worried</td>
<td>“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]</td>
<td>3 (21)</td>
</tr>
<tr>
<td>More confident in decision-making</td>
<td>“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]</td>
<td>3 (21)</td>
</tr>
<tr>
<td>Tension</td>
<td>“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]</td>
<td>2 (14)</td>
</tr>
</tbody>
</table>

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

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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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1. Table 22-10-0137-01 Selected online activities by gender, age group and highest certificate, diploma or degree completed. Statistics Canada. 2021 Jun 22. URL: https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=2210013701 [accessed 2022-06-01]


https://pediatrics.jmir.org/2023/1/e40043 JMIR Pediatr Parent 2023 | vol. 6 | e40043 | p.15 (page number not for citation purposes)


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

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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.

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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 co-led 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.

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(page number not for citation purposes)
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).

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

<sup>a</sup> Including family members and/or significant others.
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.

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

\(^a\)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).
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 to 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 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 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 to the hospital or physician to access reliable health information:

- 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]

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 lingo, 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]

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.
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 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: I 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.

Table 4. Perceived impact (n=32).

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

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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
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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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
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]. Pâsăreanu 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 preschool 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 Kazdín [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.

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

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.

![Flow diagram](Image)

**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).**

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

\(^{a}\)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).**

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

**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).

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

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.

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

<table>
<thead>
<tr>
<th>Domains</th>
<th>Apps, n (%)</th>
<th>Level of adherence, mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relationship and communication</td>
<td>27 (90)</td>
<td>1.06 (0.49)</td>
</tr>
<tr>
<td>Praise</td>
<td>24 (80)</td>
<td>0.51 (0.42)</td>
</tr>
<tr>
<td>Parent mental health</td>
<td>23 (77)</td>
<td>1.0 (0.70)</td>
</tr>
<tr>
<td>Consequences</td>
<td>22 (73)</td>
<td>0.37 (0.30)</td>
</tr>
<tr>
<td>Psychoeducation</td>
<td>19 (63)</td>
<td>0.98 (0.73)</td>
</tr>
<tr>
<td>Behavioral targets or goals</td>
<td>19 (63)</td>
<td>0.41 (0.38)</td>
</tr>
<tr>
<td>Positive reinforcement</td>
<td>19 (63)</td>
<td>0.26 (0.27)</td>
</tr>
<tr>
<td>Clear rules</td>
<td>19 (63)</td>
<td>0.35 (0.35)</td>
</tr>
<tr>
<td>Maintenance or resources</td>
<td>19 (63)</td>
<td>0.42 (0.36)</td>
</tr>
<tr>
<td>Making requests</td>
<td>18 (60)</td>
<td>0.36 (0.30)</td>
</tr>
<tr>
<td>Tracking</td>
<td>10 (33)</td>
<td>0.16 (0.33)</td>
</tr>
<tr>
<td>Supervision</td>
<td>4 (13)</td>
<td>0.05 (0.15)</td>
</tr>
</tbody>
</table>

**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 ($t_{28}=-0.25; P=.80$). 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 say, ‘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 interactivity, 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
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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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57. IBM SPSS statistics. IBM Corp. URL: https://www.ibm.com/products/spss-statistics [accessed 2021-01-10]


Abbreviations

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

<table>
<thead>
<tr>
<th>Live 5-2-1-0 behaviors</th>
<th>Values, median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Servings of fruits and vegetables per day</td>
<td>3.5 (2-6)</td>
</tr>
<tr>
<td>Hours of screen time per day (excluding time for schoolwork)</td>
<td>1 (1-2)</td>
</tr>
<tr>
<td>Days per week physically active for at least 1 hour (n=13)</td>
<td>5 (3-6)</td>
</tr>
<tr>
<td>Cups of sugary drinks per day</td>
<td>0.5 (0-1)</td>
</tr>
</tbody>
</table>

*a1 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.
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>
<thead>
<tr>
<th>Task</th>
<th>Values, median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete baseline assessment</td>
<td>7 (6-7)</td>
</tr>
<tr>
<td>Select a behavior to work on, a reward, and a tiny step</td>
<td>6 (6-7)</td>
</tr>
<tr>
<td>Respond to a daily notification for your current tiny step</td>
<td>6 (5-7)</td>
</tr>
<tr>
<td>Complete a tiny step and receive a reward for completing your goal</td>
<td>7 (6-7)</td>
</tr>
<tr>
<td>Review goal progress and change your behavior goal</td>
<td>6 (6-7)</td>
</tr>
</tbody>
</table>

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.
**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.

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**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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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 they receive about HIV prevention methods, and PrEP in particular, 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.

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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).


<table>
<thead>
<tr>
<th>Pre-exposure prophylaxis (PrEP) basics</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PrEP access</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The questions in this category aim to find information about ways users can access PrEP in addition to information about privacy concerns.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PrEP use</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The questions in this category aim to find information regarding the proper use of PrEP so that potential users can receive the maximum benefits.</td>
</tr>
</tbody>
</table>
Table 1. PrEP internet search questions.

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


This question was asked using both “sexually transmitted infections” and “sexually transmitted diseases” due to the recent change in terminology.

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.

<table>
<thead>
<tr>
<th>Rating number</th>
<th>Meaning</th>
<th>Example content (question: what is PrEP?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>The resulting answer did not include any information about PrEP.</td>
<td>“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]</td>
</tr>
<tr>
<td>1</td>
<td>The resulting answer included information about PrEP that was completely inaccurate.</td>
<td>“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]</td>
</tr>
<tr>
<td>2</td>
<td>The resulting information about PrEP was partially correct but contained some errors/misleading information. The source providing information was unreliable.</td>
<td>“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]</td>
</tr>
<tr>
<td>3</td>
<td>The resulting information was accurate but lacked many important details.</td>
<td>“Pre-exposure Prophylaxis, also known as PrEP, is when people take medicine to lower their risk of getting HIV” [14]</td>
</tr>
<tr>
<td>4</td>
<td>The resulting information was detailed, accurate, and from a reliable source. However, the information included was outdated.</td>
<td>“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]</td>
</tr>
<tr>
<td>5</td>
<td>The resulting information was detailed, accurate, and from a reliable source. Additionally, the result included the latest information available.</td>
<td>“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]</td>
</tr>
</tbody>
</table>

aPrEP: 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.\(^a\)

<table>
<thead>
<tr>
<th>Resource</th>
<th>PrEP(^b) basics</th>
<th>PrEP access</th>
<th>PrEP use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Search engines</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ask.com</td>
<td>1.8</td>
<td>0.8</td>
<td>0.5</td>
</tr>
<tr>
<td>Bing</td>
<td>3.7</td>
<td>2.7</td>
<td>3.1</td>
</tr>
<tr>
<td>Google</td>
<td>3.4</td>
<td>3.7</td>
<td>3.5</td>
</tr>
<tr>
<td>Yahoo</td>
<td>3.4</td>
<td>2.8</td>
<td>2.9</td>
</tr>
<tr>
<td><strong>Virtual assistants</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amazon Alexa</td>
<td>1.1</td>
<td>0.9</td>
<td>1.4</td>
</tr>
<tr>
<td>Apple Siri</td>
<td>2.4</td>
<td>1.8</td>
<td>3.3</td>
</tr>
<tr>
<td>Google Assistant</td>
<td>3.2</td>
<td>3.3</td>
<td>2.8</td>
</tr>
<tr>
<td>Microsoft Cortana</td>
<td>2.3</td>
<td>2.5</td>
<td>2.0</td>
</tr>
</tbody>
</table>

\(^a\)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\textsuperscript{a}.

<table>
<thead>
<tr>
<th>Resource</th>
<th>PrEP\textsuperscript{b} basics</th>
<th>PrEP access</th>
<th>PrEP use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Search engines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ask.com</td>
<td>8.3</td>
<td>9.2</td>
<td>8.3</td>
</tr>
<tr>
<td>Bing</td>
<td>10.2</td>
<td>8.1</td>
<td>9.1</td>
</tr>
<tr>
<td>Google</td>
<td>9.3</td>
<td>9.6</td>
<td>8.6</td>
</tr>
<tr>
<td>Yahoo</td>
<td>9.7</td>
<td>8.1</td>
<td>9.2</td>
</tr>
<tr>
<td>Virtual assistants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amazon Alexa</td>
<td>7.0</td>
<td>2.7</td>
<td>5.4</td>
</tr>
<tr>
<td>Apple Siri</td>
<td>8.4</td>
<td>4.8</td>
<td>7.1</td>
</tr>
<tr>
<td>Google Assistant</td>
<td>7.4</td>
<td>8.3</td>
<td>6.9</td>
</tr>
<tr>
<td>Microsoft Cortana</td>
<td>7.0</td>
<td>6.4</td>
<td>7.7</td>
</tr>
</tbody>
</table>

\textsuperscript{a}PrEP information readability score formula: grade level = 0.37 (words/sentence) + 5.84 (syllables/word) – 15.59.
\textsuperscript{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 \cite{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 \cite{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

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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; \(P=0.01\)), but no significant difference in vegetable consumption scores was observed before (1.44, SD 0.97) and after intervention (1.55, SD 0.90; \(P=0.54\)). 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; \(P=0.31\)) or vegetables (1.50, SD 0.97 and 1.43, SD 1.03, respectively; \(P=0.30\)) 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

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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 2 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.

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\( p \text{ number not for citation purposes} \)
**Ethics Approval**
The study procedures were approved by the Unit of Biomedical Ethics Research Committee at King Abdullah 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. 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/m²) compared with fathers in the intervention group (26.54, SD 3.76 kg/m²; 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.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control group (n=49)</th>
<th>Intervention group (n=55)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>15.57 (2)</td>
<td>14.74 (1)</td>
<td>.11</td>
</tr>
<tr>
<td><strong>Sex, n (%)</strong></td>
<td></td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Adolescent boys</td>
<td>20 (41)</td>
<td>4 (7)</td>
<td></td>
</tr>
<tr>
<td>Adolescent girls</td>
<td>29 (59)</td>
<td>51 (93)</td>
<td></td>
</tr>
<tr>
<td><strong>Type of school, n (%)</strong></td>
<td></td>
<td></td>
<td>.77</td>
</tr>
<tr>
<td>Government</td>
<td>36 (73)</td>
<td>42 (76)</td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>13 (27)</td>
<td>13 (24)</td>
<td></td>
</tr>
<tr>
<td><strong>BMI (kg/m^2), n (%)</strong></td>
<td></td>
<td></td>
<td>.84</td>
</tr>
<tr>
<td>Normal</td>
<td>40 (82)</td>
<td>45 (83)</td>
<td></td>
</tr>
<tr>
<td>Overweight</td>
<td>7 (14)</td>
<td>6 (11)</td>
<td></td>
</tr>
<tr>
<td>Obese</td>
<td>2 (4)</td>
<td>4 (6)</td>
<td></td>
</tr>
<tr>
<td><strong>Paternal education, n (%)</strong></td>
<td></td>
<td></td>
<td>.31</td>
</tr>
<tr>
<td>High school or lower</td>
<td>18 (36)</td>
<td>17 (32)</td>
<td></td>
</tr>
<tr>
<td>Bachelor</td>
<td>27 (55)</td>
<td>28 (51)</td>
<td></td>
</tr>
<tr>
<td>Postgraduate</td>
<td>4 (8)</td>
<td>10 (19)</td>
<td></td>
</tr>
<tr>
<td><strong>Paternal occupation, n (%)</strong></td>
<td></td>
<td></td>
<td>.08</td>
</tr>
<tr>
<td>Unemployed</td>
<td>1 (2)</td>
<td>3 (6)</td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>42 (86)</td>
<td>37 (67)</td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td>6 (12)</td>
<td>15 (28)</td>
<td></td>
</tr>
<tr>
<td><strong>Maternal education, n (%)</strong></td>
<td></td>
<td></td>
<td>.46</td>
</tr>
<tr>
<td>High school or lower</td>
<td>16 (33)</td>
<td>18 (33)</td>
<td></td>
</tr>
<tr>
<td>Bachelor</td>
<td>22 (45)</td>
<td>31 (56)</td>
<td></td>
</tr>
<tr>
<td>Postgraduate</td>
<td>11 (22)</td>
<td>6 (11)</td>
<td></td>
</tr>
<tr>
<td><strong>Maternal occupation, n (%)</strong></td>
<td></td>
<td></td>
<td>.37</td>
</tr>
<tr>
<td>Unemployed</td>
<td>28 (57)</td>
<td>35 (65)</td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>18 (37)</td>
<td>19 (34)</td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td>2 (4)</td>
<td>1 (2)</td>
<td></td>
</tr>
<tr>
<td>Student</td>
<td>1 (2)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Maternal education, n (%)</strong></td>
<td></td>
<td></td>
<td>.90</td>
</tr>
<tr>
<td>High school or lower</td>
<td>16 (33)</td>
<td>18 (33)</td>
<td></td>
</tr>
<tr>
<td>Bachelor</td>
<td>22 (45)</td>
<td>31 (56)</td>
<td></td>
</tr>
<tr>
<td>Postgraduate</td>
<td>11 (22)</td>
<td>6 (11)</td>
<td></td>
</tr>
<tr>
<td><strong>Maternal BMI (kg/m^2), mean (SD)</strong></td>
<td></td>
<td></td>
<td>.50</td>
</tr>
<tr>
<td>26.55 (6)</td>
<td>26.41 (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number of siblings, mean (SD)</strong></td>
<td></td>
<td></td>
<td>.20</td>
</tr>
<tr>
<td>4.93 (2)</td>
<td>4.61 (2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Family monthly income (SR^a), n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 5000</td>
<td>4 (8)</td>
<td>5 (9)</td>
<td></td>
</tr>
<tr>
<td>5000 to &lt;10,000</td>
<td>4 (8)</td>
<td>13 (24)</td>
<td></td>
</tr>
<tr>
<td>10,000 to &lt;20,000</td>
<td>21 (43)</td>
<td>22 (41)</td>
<td></td>
</tr>
<tr>
<td>&gt;20,000</td>
<td>20 (41)</td>
<td>15 (28)</td>
<td></td>
</tr>
</tbody>
</table>

^aA 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;
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 a significant increase in consumption of some fruit items (ie, potatoes, lettuce, and Jew’s mallow) decreased in the intervention group after 6 weeks of using the app, 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.

<table>
<thead>
<tr>
<th>Fruit score, mean (SD)</th>
<th>Preintervention</th>
<th>Postintervention</th>
<th>Adjusted P value within group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>1.15 (0.68)</td>
<td>1.64 (0.98)</td>
<td>.01</td>
</tr>
<tr>
<td>Intervention</td>
<td>1.48 (0.99)</td>
<td>1.70 (1.11)</td>
<td>.31</td>
</tr>
<tr>
<td>Adjusted P value between groups</td>
<td>.11</td>
<td>.52*</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vegetable score, mean (SD)</th>
<th>Preintervention</th>
<th>Postintervention</th>
<th>Adjusted P value within group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>1.44 (0.97)</td>
<td>1.55 (0.90)</td>
<td>.54</td>
</tr>
<tr>
<td>Intervention</td>
<td>1.50 (0.97)</td>
<td>1.43 (1.03)</td>
<td>.30</td>
</tr>
<tr>
<td>Adjusted P value between groups</td>
<td>.35</td>
<td>.35*</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*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.

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 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, 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 COVID-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

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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]

**References**


https://pediatrics.jmir.org/2023/1/e43160

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Abbreviations

FFQ: food frequency questionnaire
FV: fruit and vegetable

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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
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, quasi-experimental study.

Setting

This study was conducted at the Hiralal Santdevi 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, a reminder text would be sent 3 more times to ensure successful delivery. A phone call

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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).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Routine standard care, n (%)</th>
<th>Counseling, n (%)</th>
<th>SMS and phone call, n (%)</th>
<th>Total, n (%)</th>
<th>Chi-square (df)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>56 (63.64)</td>
<td>53 (60.23)</td>
<td>55 (62.50)</td>
<td>164 (62.12)</td>
<td>0.2254 (2)</td>
<td>.89</td>
</tr>
<tr>
<td>Female</td>
<td>32 (36.36)</td>
<td>35 (39.77)</td>
<td>33 (37.50)</td>
<td>100 (37.88)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤8 years</td>
<td>58 (65.91)</td>
<td>69 (78.41)</td>
<td>68 (72.27)</td>
<td>195 (73.86)</td>
<td>4.36 (2)</td>
<td>.11</td>
</tr>
<tr>
<td>&gt;8 years</td>
<td>30 (34.09)</td>
<td>19 (21.59)</td>
<td>20 (22.73)</td>
<td>69 (26.14)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Parents or guardian</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother</td>
<td>58 (21.96)</td>
<td>58 (21.96)</td>
<td>67 (25.37)</td>
<td>183 (69.31)</td>
<td>1.9003 (4)</td>
<td>.75</td>
</tr>
<tr>
<td>Father</td>
<td>17 (6.43)</td>
<td>19 (7.19)</td>
<td>14 (5.30)</td>
<td>50 (18.93)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>13 (4.92)</td>
<td>10 (3.78)</td>
<td>7 (2.65)</td>
<td>30 (11.36)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aryan</td>
<td>54 (61.36)</td>
<td>54 (61.36)</td>
<td>49 (55.68)</td>
<td>157 (59.47)</td>
<td>0.7858 (2)</td>
<td>.68</td>
</tr>
<tr>
<td>Mongol and others</td>
<td>34 (38.64)</td>
<td>34 (38.64)</td>
<td>39 (44.34)</td>
<td>107 (40.53)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Educational status of parent or guardian</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Illiterate</td>
<td>10 (11.36)</td>
<td>6 (6.82)</td>
<td>10 (11.36)</td>
<td>26 (9.85)</td>
<td>8.87 (6)</td>
<td>.18</td>
</tr>
<tr>
<td>Primary</td>
<td>5 (5.68)</td>
<td>11 (12.50)</td>
<td>7 (7.95)</td>
<td>23 (8.71)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary and higher secondary</td>
<td>62 (70.45)</td>
<td>54 (61.36)</td>
<td>49 (55.68)</td>
<td>165 (62.50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bachelor and above</td>
<td>11 (12.50)</td>
<td>17 (19.32)</td>
<td>22 (25)</td>
<td>50 (18.94)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.9126 (2)</td>
<td>.63</td>
</tr>
<tr>
<td>Non–income-generating occupation</td>
<td>53 (6023)</td>
<td>59 (67.05)</td>
<td>55 (62.50)</td>
<td>167 (63.26)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income-generating occupation</td>
<td>35 (39.77)</td>
<td>29 (32.95)</td>
<td>33 (37.50)</td>
<td>97 (36.74)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Distance (km)</strong></td>
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<td></td>
<td></td>
<td></td>
<td>2.39 (4)</td>
<td>.66</td>
</tr>
<tr>
<td>0-50</td>
<td>76 (86.36)</td>
<td>76 (86.36)</td>
<td>71 (80.68)</td>
<td>223 (84.47)</td>
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</tr>
<tr>
<td>51-100</td>
<td>6 (6.82)</td>
<td>6 (6.82)</td>
<td>6 (6.82)</td>
<td>18 (6.82)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;100</td>
<td>6 (6.82)</td>
<td>6 (6.82)</td>
<td>11 (12.86)</td>
<td>23 (8.71)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Time taken (min)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5.2414 (4)</td>
<td>.26</td>
</tr>
<tr>
<td>0-30</td>
<td>59 (67.05)</td>
<td>60 (68.18)</td>
<td>56 (63.64)</td>
<td>175 (66.29)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31-60</td>
<td>17 (19.32)</td>
<td>19 (21.59)</td>
<td>13 (14.77)</td>
<td>49 (18.56)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;60</td>
<td>12 (13.64)</td>
<td>9 (10.23)</td>
<td>19 (21.59)</td>
<td>40 (15.15)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cost of 2-way travel (NR)a</strong></td>
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<td></td>
<td></td>
<td></td>
<td>4.002 (4)</td>
<td>.41</td>
</tr>
<tr>
<td>0-100</td>
<td>40 (45.45)</td>
<td>49 (55.68)</td>
<td>43 (48.86)</td>
<td>132 (50.00)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>101-500</td>
<td>40 (45.45)</td>
<td>30 (34.09)</td>
<td>32 (36.36)</td>
<td>102 (38.64)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;500</td>
<td>8 (9.09)</td>
<td>9 (10.23)</td>
<td>13 (14.77)</td>
<td>30 (11.36)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*aNR: 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: $\chi^2=3.19, P=.20$; second follow-up chi-square: $\chi^2=0.92, P=.62$; and third follow-up chi-square: $\chi^2=0.25, P=.86$). 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.
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.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Routine standard care (n=88), n (%)</th>
<th>Counselling (n=88), n (%)</th>
<th>SMS and phone call (n=88), n (%)</th>
<th>Total (N=264)</th>
<th>Chi-square (df)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>F/u category</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advised for f/u</td>
<td>88 (100)</td>
<td>88 (100)</td>
<td>88 (100)</td>
<td>N/A b</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>First f/u attended</td>
<td>24 (28.92)</td>
<td>25 (28.41)</td>
<td>34 (38.64)</td>
<td>83 (31.44)</td>
<td>3.19 (2)</td>
<td>.20</td>
</tr>
<tr>
<td>Second f/u attended</td>
<td>9 (10.23)</td>
<td>10 (11.36)</td>
<td>13 (14.77)</td>
<td>32 (12.12)</td>
<td>0.92 (2)</td>
<td>.62</td>
</tr>
<tr>
<td>Third f/u attended</td>
<td>3 (3.41)</td>
<td>3 (3.41)</td>
<td>2 (2.27)</td>
<td>8 (100)</td>
<td>0.25 (2)</td>
<td>.86</td>
</tr>
<tr>
<td>Total f/u visits</td>
<td>36 (29.27)</td>
<td>38 (30.89)</td>
<td>49 (39.84)</td>
<td>123 (100)</td>
<td>2.83 (2)</td>
<td>.24</td>
</tr>
<tr>
<td>Actual attended date at first f/u (n=83)</td>
<td>5.57 (4)</td>
<td>.23</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior to schedule</td>
<td>6 (25.00)</td>
<td>5 (20.00)</td>
<td>3 (8.82)</td>
<td>14 (16.87)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>On schedule</td>
<td>10 (41.67)</td>
<td>9 (36.00)</td>
<td>21 (61.76)</td>
<td>40 (48.19)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After schedule</td>
<td>8 (33.33)</td>
<td>11 (44.00)</td>
<td>10 (29.41)</td>
<td>29 (34.94)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual attended date at second f/u (n=32)</td>
<td>3.25 (4)</td>
<td>.51</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior to schedule</td>
<td>2 (22.22)</td>
<td>0</td>
<td>2 (15.38)</td>
<td>4 (12.50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>On schedule</td>
<td>1 (11.11)</td>
<td>3 (30.00)</td>
<td>4 (30.77)</td>
<td>8 (25.00)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After schedule</td>
<td>6 (66.67)</td>
<td>7 (70.00)</td>
<td>7 (53.85)</td>
<td>20 (62.50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual attended date at third f/u (n=8)</td>
<td>4.00 (4)</td>
<td>.40</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior to schedule</td>
<td>0</td>
<td>1 (33.33)</td>
<td>1 (50.00)</td>
<td>2 (25.00)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>On schedule</td>
<td>1 (33.33)</td>
<td>0</td>
<td>1 (50.00)</td>
<td>2 (25.00)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After schedule</td>
<td>2 (66.67)</td>
<td>2 (67.67)</td>
<td>0</td>
<td>4 (50.00)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

aF/u: follow-up.

bN/A: not applicable.

Table 3. Travel cost with follow-up attendance (N=264).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Presenting, n (%)</th>
<th>First f/u a, n (%)</th>
<th>Chi-square (df)</th>
<th>P value</th>
<th>Second f/u, n (%)</th>
<th>Chi-square (df)</th>
<th>P value</th>
<th>Third f/u, n (%)</th>
<th>Chi-square (df)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost category (NP b)</td>
<td>5.73 (2)</td>
<td>.09</td>
<td>5.15 (2)</td>
<td>.08</td>
<td>1 (12.50)</td>
<td>1 (3.13)</td>
<td></td>
<td>1 (3.03)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up to 100</td>
<td>132 (50.00)</td>
<td>36 (43.37)</td>
<td>13 (40.63)</td>
<td></td>
<td>1 (12.50)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>101-500</td>
<td>102 (38.64)</td>
<td>40 (48.19)</td>
<td>18 (56.25)</td>
<td></td>
<td>6 (75.00)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;500</td>
<td>30 (11.36)</td>
<td>7 (8.43)</td>
<td>1 (3.13)</td>
<td></td>
<td>1 (3.03)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

aF/u: follow-up.

bNP: 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.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>First f/u&lt;sup&gt;a&lt;/sup&gt; attended (n=83), n (%)</th>
<th>P value</th>
<th>Second f/u attended (n=32), n (%)</th>
<th>P value</th>
<th>Third f/u attended (n=8), n (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>55 (66.27)</td>
<td>.34</td>
<td>17 (53.13)</td>
<td>.26</td>
<td>6 (75)</td>
<td>.45</td>
</tr>
<tr>
<td>Female</td>
<td>28 (33.73)</td>
<td></td>
<td>15 (46.88)</td>
<td></td>
<td>2 (25)</td>
<td></td>
</tr>
<tr>
<td><strong>Age group</strong></td>
<td></td>
<td>.16</td>
<td></td>
<td>.79</td>
<td></td>
<td>.94</td>
</tr>
<tr>
<td>≤8 years</td>
<td>66 (79.52)</td>
<td></td>
<td>23 (71.88)</td>
<td></td>
<td>6 (75)</td>
<td></td>
</tr>
<tr>
<td>&gt;8 years</td>
<td>17 (20.48)</td>
<td></td>
<td>9 (28.13)</td>
<td></td>
<td>2 (25)</td>
<td></td>
</tr>
<tr>
<td><strong>Parents or guardian</strong></td>
<td></td>
<td>.14</td>
<td></td>
<td>.90</td>
<td></td>
<td>.16</td>
</tr>
<tr>
<td>Mother or both parents</td>
<td>62 (79.49)</td>
<td></td>
<td>23 (79.31)</td>
<td></td>
<td>8 (100)</td>
<td></td>
</tr>
<tr>
<td>Father</td>
<td>16 (20.51)</td>
<td></td>
<td>6 (20.69)</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>5 (1.89)</td>
<td></td>
<td>3 (1.13)</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td>.15</td>
<td></td>
<td>.69</td>
<td></td>
<td>.58</td>
</tr>
<tr>
<td>Aryan</td>
<td>44 (53.01)</td>
<td></td>
<td>18 (56.25)</td>
<td></td>
<td>4 (50)</td>
<td></td>
</tr>
<tr>
<td>Mongol and others</td>
<td>39 (46.99)</td>
<td></td>
<td>14 (43.75)</td>
<td></td>
<td>4 (50)</td>
<td></td>
</tr>
<tr>
<td><strong>Educational status of parent or guardian</strong></td>
<td></td>
<td>.31</td>
<td></td>
<td>.21</td>
<td></td>
<td>.90</td>
</tr>
<tr>
<td>Illiterate</td>
<td>10 (12.05)</td>
<td></td>
<td>3 (9.38)</td>
<td></td>
<td>1 (12.50)</td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>9 (10.85)</td>
<td></td>
<td>1 (3.13)</td>
<td></td>
<td>1 (12.50)</td>
<td></td>
</tr>
<tr>
<td>Secondary and higher secondary</td>
<td>45 (54.22)</td>
<td></td>
<td>18 (56.25)</td>
<td></td>
<td>4 (50)</td>
<td></td>
</tr>
<tr>
<td>Bachelor and above</td>
<td>19 (22.89)</td>
<td></td>
<td>10 (31.25)</td>
<td></td>
<td>2 (25)</td>
<td></td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td>.68</td>
<td></td>
<td>.21</td>
<td></td>
<td>.48</td>
</tr>
<tr>
<td>Non–income-generating group</td>
<td>51 (61.45)</td>
<td></td>
<td>17 (53.13)</td>
<td></td>
<td>6 (75)</td>
<td></td>
</tr>
<tr>
<td>Income-generating group</td>
<td>32 (38.55)</td>
<td></td>
<td>15 (46.88)</td>
<td></td>
<td>2 (25)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>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 professionals.
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.

The Operational Research Capacity Building Study Group consisted of the following members: Indian Institute of Public Health, Hyderabad (Public Health Foundation of India): Prof Gudlavalleti Venkata Satyanarayana Murthy, Dr Suresh Kumar Rathi, Dr Sureshkumar Kamalakannan, Dr Rajan Shukla, Dr Samiksha Singh, Dr Shailaja Tetali, Dr Hemant Mahajan, Dr Tripura Batchu, Dr Anirudh G Gudlavalleti, Dr Melissa G Lewis, Dr Varun Agiwal and Mr Hira Pant. SEVA: Dr Suzanne Gilbert, Dr Ken Bassett, Ms Priya Adhisesha Reddy, Ms Parami Dhakhwa, Mr Ram Prasad Kandel, Mr Kuldeep Singh and Mr Prasanna Sharma.

Conflicts of Interest
None declared.

References


Abbreviations

BEH: Bharatpur Eye Hospital
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/3rvr6r8e

(JMIR Pediatr Parent 2023;6:e40561) doi:10.2196/40561
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
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).

<table>
<thead>
<tr>
<th>Values</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years), mean (SD)</strong></td>
<td>35 (18)</td>
</tr>
<tr>
<td><strong>Marital status, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Divorced</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Married</td>
<td>9 (26)</td>
</tr>
<tr>
<td>Single, living alone</td>
<td>5 (15)</td>
</tr>
<tr>
<td>Single, living with family</td>
<td>8 (24)</td>
</tr>
<tr>
<td>Single, living with a partner</td>
<td>6 (18)</td>
</tr>
<tr>
<td>Single, living with nonfamily</td>
<td>5 (15)</td>
</tr>
<tr>
<td>Widow</td>
<td>1 (3)</td>
</tr>
<tr>
<td><strong>Educational level, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Below grade 7</td>
<td>15 (44)</td>
</tr>
<tr>
<td>Between grade 7 and grade 12</td>
<td>16 (47)</td>
</tr>
<tr>
<td>Passed high school</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Post–high school education</td>
<td>1 (3)</td>
</tr>
<tr>
<td><strong>Employment status, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>22 (65)</td>
</tr>
<tr>
<td>Pensioner</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>7 (21)</td>
</tr>
<tr>
<td>Not looking for employment</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Never worked</td>
<td>3 (9)</td>
</tr>
<tr>
<td><strong>Monthly income, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>7 (21)</td>
</tr>
<tr>
<td>Pension or social grant</td>
<td>8 (24)</td>
</tr>
<tr>
<td>&lt;ZAR 4000 (US $222.59)</td>
<td>14 (41)</td>
</tr>
<tr>
<td>Between ZAR 4000 and ZAR 10,000 (US $222.59-$556.48)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>&gt;ZAR 10,000 (US $556.48)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>No answer</td>
<td>3 (9)</td>
</tr>
<tr>
<td><strong>Preferred language for reading and writing, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>26 (76)</td>
</tr>
<tr>
<td>Afrikaans</td>
<td>5 (15)</td>
</tr>
<tr>
<td>isiXhosa</td>
<td>3 (9)</td>
</tr>
<tr>
<td><strong>Gravidity, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>0 pregnancies</td>
<td>2 (6)</td>
</tr>
<tr>
<td>1 pregnancy</td>
<td>8 (24)</td>
</tr>
<tr>
<td>2 pregnancies</td>
<td>11 (32)</td>
</tr>
<tr>
<td>3 pregnancies</td>
<td>9 (26)</td>
</tr>
<tr>
<td>4 pregnancies</td>
<td>2 (6)</td>
</tr>
<tr>
<td>5 pregnancies</td>
<td>2 (6)</td>
</tr>
</tbody>
</table>
Table 2. Knowledge scores for questions with binary answers presented as the number of people with adequate knowledge at baseline and exit (N=34).

<table>
<thead>
<tr>
<th>Question</th>
<th>Baseline, n (%)</th>
<th>Exit, n (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is it important for pregnant women to attend pregnancy clinics?</td>
<td>30 (88)</td>
<td>33 (97)</td>
<td>.25</td>
</tr>
<tr>
<td>Should a pregnant woman ask for the results of her pap smear (a test that checks for cancer of the mouth of the womb)?</td>
<td>21 (62)</td>
<td>23 (68)</td>
<td>.80</td>
</tr>
<tr>
<td>Why do the nurses test the urine and blood pressure when pregnant women attend a clinic for pregnancy?</td>
<td>13 (38)</td>
<td>14 (41)</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Why should a pregnant woman take folic acid tablets (which she gets at the clinic) during pregnancy?</td>
<td>5 (15)</td>
<td>12 (35)</td>
<td>.12</td>
</tr>
</tbody>
</table>

Table 3. Knowledge scores for questions with multiple correct answers (N=34).

<table>
<thead>
<tr>
<th>Question (number of correct answers/number of options) and number of correct answers selected</th>
<th>Baseline, n (%)</th>
<th>Exit, n (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why do the nurses test the blood of pregnant women? (3/7)</td>
<td></td>
<td></td>
<td>.96</td>
</tr>
<tr>
<td>0</td>
<td>19 (56)</td>
<td>22 (65)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>13 (38)</td>
<td>6 (18)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2 (6)</td>
<td>6 (18)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>How can a pregnant woman stay healthy during pregnancy? (4/9)</td>
<td></td>
<td></td>
<td>.03</td>
</tr>
<tr>
<td>0</td>
<td>8 (24)</td>
<td>5 (15)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>6 (18)</td>
<td>3 (9)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>9 (26)</td>
<td>3 (9)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>6 (18)</td>
<td>11 (32)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>5 (15)</td>
<td>12 (35)</td>
<td></td>
</tr>
<tr>
<td>How do drugs and alcohol affect the baby growing in the womb? (2/3)</td>
<td></td>
<td></td>
<td>.048</td>
</tr>
<tr>
<td>0</td>
<td>22 (65)</td>
<td>10 (29)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>9 (26)</td>
<td>24 (71)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>3 (9)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Should a pregnant woman seek medical help outside her appointments at the pregnancy clinic? (2/4)</td>
<td></td>
<td></td>
<td>.001</td>
</tr>
<tr>
<td>0</td>
<td>22 (65)</td>
<td>8 (24)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>10 (29)</td>
<td>15 (44)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2 (6)</td>
<td>11 (32)</td>
<td></td>
</tr>
<tr>
<td>What are the signs of labor? (3/6)</td>
<td></td>
<td></td>
<td>.16</td>
</tr>
<tr>
<td>0</td>
<td>16 (47)</td>
<td>14 (41)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>12 (35)</td>
<td>9 (26)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>5 (15)</td>
<td>7 (21)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1 (3)</td>
<td>4 (12)</td>
<td></td>
</tr>
</tbody>
</table>

Table 4. Knowledge scores for questions with a statistically significant improvement.

<table>
<thead>
<tr>
<th>Question</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>How can a woman stay healthy during pregnancy?</td>
<td>.03</td>
</tr>
<tr>
<td>How do drugs and alcohol affect the baby growing in the womb?</td>
<td>.048</td>
</tr>
<tr>
<td>Should a pregnant woman seek medical help outside her appointments at a pregnancy clinic?</td>
<td>.001</td>
</tr>
<tr>
<td>Overall score</td>
<td>.002</td>
</tr>
</tbody>
</table>
Table 5. Acceptability of SMS text messages (N=34).

<table>
<thead>
<tr>
<th>Question</th>
<th>Participants, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Read all or most of the SMS text messages</td>
<td>34 (100)</td>
</tr>
<tr>
<td>Felt that the SMS text messages improved their pregnancy knowledge</td>
<td>28 (82)</td>
</tr>
<tr>
<td>Thought that the SMS text messages were easy to understand</td>
<td>31 (91)</td>
</tr>
<tr>
<td>Found the SMS text messages useful</td>
<td>31 (91)</td>
</tr>
<tr>
<td>Found the SMS text messages trustworthy</td>
<td>28 (82)</td>
</tr>
<tr>
<td>Felt that somebody cared about them</td>
<td>25 (74)</td>
</tr>
<tr>
<td>Found the SMS text messages entertaining</td>
<td>20 (59)</td>
</tr>
<tr>
<td>Found the information in the SMS text messages not helpful</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Found the SMS text messages to be irritating</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Did not like the SMS text messages</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Felt that the SMS text messages were the best way of giving information to Deaf people</td>
<td>5 (15)</td>
</tr>
</tbody>
</table>

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.

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**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 ]
References


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

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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 ($P<.001; \eta^2=0.043$). Perceived patient safety improved more for pregnant women participating in the live seminar than for those participating in the web-based application group ($P=.03, \eta^2=0.015$). 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

(JMR 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 is 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 [8,9]. For a positive labor and birth experience, safe communication between the HCW and pregnant women and their families is 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].

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.
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 Keefe [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.

<table>
<thead>
<tr>
<th>Items</th>
<th>IG1a (n=142), n (%)</th>
<th>CGb (n=144), n (%)</th>
<th>IG2c (n=81), n (%)</th>
<th>Missing valuesd, n</th>
</tr>
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<tbody>
<tr>
<td><strong>Age group (years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;20</td>
<td>N/Af</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>20-29</td>
<td>14 (9.9)</td>
<td>19 (13.2)</td>
<td>9 (11.1)</td>
<td>0</td>
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<tr>
<td>30-39</td>
<td>119 (83.8)</td>
<td>107 (74.3)</td>
<td>57 (70.4)</td>
<td>4</td>
</tr>
<tr>
<td>40-49</td>
<td>9 (6.3)</td>
<td>14 (9.7)</td>
<td>10 (12.3)</td>
<td>5</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Single</td>
<td>2 (1.4)</td>
<td>3 (2.1)</td>
<td>3 (3.7)</td>
<td>0</td>
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<tr>
<td>In a committed relationship</td>
<td>34 (23.9)</td>
<td>27 (18.8)</td>
<td>13 (16)</td>
<td>4</td>
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<tr>
<td>Married or registered partnership</td>
<td>106 (74.6)</td>
<td>109 (75.7)</td>
<td>60 (74.1)</td>
<td>5</td>
</tr>
<tr>
<td>Divorced or separated</td>
<td>N/A</td>
<td>1 (0.7)</td>
<td>N/A</td>
<td></td>
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<tr>
<td><strong>Highest educational level</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No school-leaving qualification</td>
<td>1 (0.7)</td>
<td>N/A</td>
<td>N/A</td>
<td>4</td>
</tr>
<tr>
<td>Secondary or elementary school leaving</td>
<td>N/A</td>
<td>N/A</td>
<td>1 (1.2)</td>
<td>5</td>
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<tr>
<td>Secondary school diploma</td>
<td>2 (1.4)</td>
<td>3 (2.1)</td>
<td>2 (2.5)</td>
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<td>A levels</td>
<td>7 (4.9)</td>
<td>6 (4.2)</td>
<td>4 (4.9)</td>
<td></td>
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<tr>
<td>Completed vocational training</td>
<td>19 (13.4)</td>
<td>27 (18.8)</td>
<td>11 (13.6)</td>
<td></td>
</tr>
<tr>
<td>University degree</td>
<td>27 (19)</td>
<td>26 (18.1)</td>
<td>17 (21)</td>
<td></td>
</tr>
<tr>
<td>University degree</td>
<td>86 (60.6)</td>
<td>78 (54.2)</td>
<td>41 (50.6)</td>
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<tr>
<td><strong>Nationality</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>German</td>
<td>122 (85.9)</td>
<td>122 (84.7)</td>
<td>72 (88.9)</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>20 (14.1)</td>
<td>18 (12.5)</td>
<td>4 (4.9)</td>
<td>4</td>
</tr>
</tbody>
</table>

aIG1: live seminar group.
bCG: control group.
cIG2: web-based application group.
dMissing values for each group.
eIG: intervention group.
fN/A: not applicable.
gSpecial 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 ($\chi^2=4.2; P=.38$, education level ($\chi^2=8.3; P=.76$), marital status ($\chi^2=4.5; P=.61$), or nationality ($\chi^2=5.5; P=.24$). 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 \( \chi^2 = 49.7; P \leq 0.001 \) and nationality with \( \chi^2 = 5.9; P = 0.02 \). No significant differences were found in marital status (\( \chi^2 = 2.3; P = 0.32 \)) and education level (\( \chi^2 = 3.2; P = 0.66 \)). The same picture emerged for IG1 for age (\( \chi^2 = 2.9; P = 0.39 \)), nationality (\( \chi^2 = 0.2; P = 0.67 \)), marital status (\( \chi^2 = 1.4; P = 0.49 \)), and education level (\( \chi^2 = 5.4; P = 0.50 \)). Finally, no significant differences were found in the CG for age (\( \chi^2 = 3.5; P = 0.17 \)), nationality (\( \chi^2 = 2.2; P = 0.34 \)), marital status (\( \chi^2 = 1.5; P = 0.68 \)), and education level (\( \chi^2 = 7.9; P = 0.16 \)). 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 (\( F_{1,336} = 3.322; P = 0.07; \eta^2_p = 0.010 \)). 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.](image)

There was a significant time x group interaction effect, meaning that the change in communication behavior across time differed between IG1 and IG2 (\( F_{1,336} = 15.046; P < 0.001; \eta^2_p = 0.043 \)). Between the CG and IG2, no significant time x group interaction effect emerged (\( F_{1,336} = 2.732; P = 0.10; \eta^2_p = 0.008 \)).

### Perceived Patient Safety

The main effect of time on perceived patient safety scores was not statistically significant (\( F_{1,304} = 0.013; P = 0.91 \)). 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 x group interaction effect, meaning that the change in perceived patient safety across time did significantly differ between IG1 and IG2 (\( F_{1,304} = 4.709; P = 0.03; \eta^2_p = 0.015 \)). There was no significant time x group interaction effect between CG and IG2 (\( F_{1,304} = 0.108; P = 0.74; \eta^2_p \leq 0.001 \)).

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.

<table>
<thead>
<tr>
<th>Parameters (web-based application group)</th>
<th>B(^a) (95% CI; SE)</th>
<th>(\hat{\beta})(^b)</th>
<th>(P) value</th>
<th>Tolerance</th>
<th>VIF(^c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intention T1(^e)</td>
<td>0.300 (0.124 to 0.476; 0.088)</td>
<td>.351</td>
<td>.001(^f)</td>
<td>.794</td>
<td>1.260</td>
</tr>
<tr>
<td>Δ Coping self-efficacy</td>
<td>0.143 (0.015 to 0.272; 0.064)</td>
<td>.259</td>
<td>.03(^e)</td>
<td>.627</td>
<td>1.594</td>
</tr>
<tr>
<td>Δ Coping planning</td>
<td>0.135 (0.015 to 0.262; 0.064)</td>
<td>.270</td>
<td>.04(^e)</td>
<td>.522</td>
<td>1.915</td>
</tr>
<tr>
<td>Communication at T1</td>
<td>0.369 (0.007 to 0.598; 0.115)</td>
<td>.350</td>
<td>.002(^h)</td>
<td>.714</td>
<td>1.401</td>
</tr>
<tr>
<td>Perceived patient safety</td>
<td>−0.111 (0.140 to 0.025; 0.068)</td>
<td>−.153</td>
<td>.1</td>
<td>.965</td>
<td>1.036</td>
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</table>

<table>
<thead>
<tr>
<th>Parameters (live seminar group)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Intention at T1</td>
<td>0.018 (0.070 to 0.440; 0.088)</td>
<td>.018</td>
<td>.84</td>
<td>.924</td>
<td>1.082</td>
</tr>
<tr>
<td>Δ Coping self-efficacy</td>
<td>0.150 (0.004 to 0.207; 0.044)</td>
<td>.290</td>
<td>.001(^f)</td>
<td>.672</td>
<td>1.488</td>
</tr>
<tr>
<td>Δ Coping planning</td>
<td>0.062 (−0.013 to 0.157; 0.038)</td>
<td>.142</td>
<td>.16</td>
<td>.687</td>
<td>1.457</td>
</tr>
<tr>
<td>Communication at T1</td>
<td>0.385 (0.236 to 0.715; 0.088)</td>
<td>.369</td>
<td>.001(^f)</td>
<td>.916</td>
<td>1.092</td>
</tr>
<tr>
<td>Perceived patient safety</td>
<td>&lt;0.001 (−0.250 to −0.002; 0.063)</td>
<td>&lt;.001</td>
<td>&gt;.99</td>
<td>.881</td>
<td>1.135</td>
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</table>

<table>
<thead>
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<th>Parameters (control group)</th>
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<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Intention at T1</td>
<td>0.255 (0.070 to 0.440; 0.093)</td>
<td>.221</td>
<td>.007(^h)</td>
<td>.924</td>
<td>1.082</td>
</tr>
<tr>
<td>Δ Coping self-efficacy</td>
<td>0.106 (0.004 to 0.207; 0.051)</td>
<td>.196</td>
<td>.04(^e)</td>
<td>.672</td>
<td>1.488</td>
</tr>
<tr>
<td>Δ Coping planning</td>
<td>0.072 (−0.013 to 0.157; 0.043)</td>
<td>.157</td>
<td>.10</td>
<td>.687</td>
<td>1.457</td>
</tr>
<tr>
<td>Communication at T1</td>
<td>0.426 (0.236 to 0.615; 0.096)</td>
<td>.362</td>
<td>.001(^f)</td>
<td>.916</td>
<td>1.092</td>
</tr>
<tr>
<td>Perceived patient safety</td>
<td>−0.126 (−0.250 to 0.002; 0.063)</td>
<td>−.166</td>
<td>.047(^e)</td>
<td>.881</td>
<td>1.135</td>
</tr>
</tbody>
</table>

\(a\)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 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

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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.
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

<table>
<thead>
<tr>
<th>Category</th>
<th>Values, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parent sex (n=160)</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>101 (63.1)</td>
</tr>
<tr>
<td>Male</td>
<td>57 (35.6)</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td><strong>Household income, Aus $b (n=161)</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;18,200</td>
<td>3 (1.9)</td>
</tr>
<tr>
<td>18,201–45,000</td>
<td>19 (11.8)</td>
</tr>
<tr>
<td>45,001–120,000</td>
<td>52 (32.3)</td>
</tr>
<tr>
<td>120,001–180,000</td>
<td>48 (29.8)</td>
</tr>
<tr>
<td>&gt;180,001</td>
<td>33 (20.5)</td>
</tr>
<tr>
<td>Prefer not to say</td>
<td>6 (3.7)</td>
</tr>
<tr>
<td><strong>Education (n=161)</strong></td>
<td></td>
</tr>
<tr>
<td>Postgraduate degree</td>
<td>49 (30.4)</td>
</tr>
<tr>
<td>Graduate diploma or graduate certificate</td>
<td>20 (12.4)</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
<td>57 (35.4)</td>
</tr>
<tr>
<td>Advanced diploma or diploma</td>
<td>17 (10.6)</td>
</tr>
<tr>
<td>Certificate I, II, III, or IV</td>
<td>12 (7.4)</td>
</tr>
<tr>
<td>High school</td>
<td>6 (3.7)</td>
</tr>
<tr>
<td><strong>Employment (n=160)</strong></td>
<td></td>
</tr>
<tr>
<td>Employed full-time</td>
<td>115 (71.9)</td>
</tr>
<tr>
<td>Employed part-time or casual</td>
<td>31 (19.3)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>Retired</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Home duties</td>
<td>8 (5)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (1.9)</td>
</tr>
<tr>
<td><strong>Main language spoken (n=179)</strong></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>146 (96.7)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (2.8)</td>
</tr>
<tr>
<td><strong>Postcode (n=121)</strong></td>
<td></td>
</tr>
<tr>
<td>Living in NSWc</td>
<td>71 (58.7)</td>
</tr>
<tr>
<td><strong>Marital status (n=160)</strong></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>125 (78.1)</td>
</tr>
<tr>
<td>Divorced</td>
<td>12 (7.5)</td>
</tr>
<tr>
<td>De facto</td>
<td>12 (7.5)</td>
</tr>
<tr>
<td>Other</td>
<td>11 (6.9)</td>
</tr>
<tr>
<td><strong>Age of adolescent (index child), years (n=132)</strong></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>5 (3.8)</td>
</tr>
<tr>
<td>12</td>
<td>12 (9.1)</td>
</tr>
<tr>
<td>13</td>
<td>23 (17.4)</td>
</tr>
<tr>
<td>14</td>
<td>22 (16.7)</td>
</tr>
<tr>
<td>15</td>
<td>26 (19.7)</td>
</tr>
<tr>
<td>Values, n (%)</td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>21 (16)</td>
</tr>
<tr>
<td>17</td>
<td>16 (12.1)</td>
</tr>
<tr>
<td>18</td>
<td>7 (5.3)</td>
</tr>
</tbody>
</table>

*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.

<table>
<thead>
<tr>
<th></th>
<th>Parent’s health behaviors</th>
<th>Adolescent health behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruit intake (serves/day), mean (SD)</td>
<td>1.66 (0.98)</td>
<td>1.84 (1.09)</td>
</tr>
<tr>
<td>Vegetable intake (serves/day), mean (SD)</td>
<td>2.37 (1.33)</td>
<td>2.14 (1.18)</td>
</tr>
<tr>
<td><strong>Physical activity (days per week), mean (SD)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 minutes moderate</td>
<td>4.13 (1.84)</td>
<td>N/A&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>20 minutes vigorous</td>
<td>3.07 (1.92)</td>
<td>N/A</td>
</tr>
<tr>
<td>60 minutes MVPA&lt;sup&gt;b&lt;/sup&gt;</td>
<td>N/A</td>
<td>3.93 (1.6)</td>
</tr>
<tr>
<td><strong>Sleep duration (hours/day), mean (SD)</strong></td>
<td>8.31 (1.00)</td>
<td>9.18 (0.94)</td>
</tr>
<tr>
<td><strong>Sitting time (hours/day), mean (SD)</strong></td>
<td>N/A</td>
<td>7.15 (3.33)</td>
</tr>
<tr>
<td><strong>Recreational screen time (hours/day), mean (SD)</strong></td>
<td>2.77 (1.51)</td>
<td>N/A</td>
</tr>
<tr>
<td>Weekday</td>
<td>N/A</td>
<td>2.42 (1.55)</td>
</tr>
<tr>
<td>Weekend</td>
<td>N/A</td>
<td>4.48 (2.47)</td>
</tr>
<tr>
<td><strong>Alcohol use, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ever used&lt;sup&gt;c&lt;/sup&gt;</td>
<td>N/A</td>
<td>9 (5.8)</td>
</tr>
<tr>
<td>Yes</td>
<td>N/A</td>
<td>99 (63.5)</td>
</tr>
<tr>
<td>No</td>
<td>N/A</td>
<td>40 (25.6)</td>
</tr>
<tr>
<td>Sip or 2</td>
<td>N/A</td>
<td>8 (5.1)</td>
</tr>
<tr>
<td>Unsure</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Frequency&lt;sup&gt;d&lt;/sup&gt;</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily or almost daily</td>
<td>21 (13)</td>
<td>N/A</td>
</tr>
<tr>
<td>Weekly</td>
<td>40 (24.7)</td>
<td>1 (11.1)</td>
</tr>
<tr>
<td>2-3 times monthly</td>
<td>27 (16.7)</td>
<td>7 (77.8)</td>
</tr>
<tr>
<td>Once a month</td>
<td>21 (13)</td>
<td>1 (11.1)</td>
</tr>
<tr>
<td>Less than a month</td>
<td>32 (19.8)</td>
<td>N/A</td>
</tr>
<tr>
<td>Never</td>
<td>21 (13)</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Tobacco use&lt;sup&gt;e&lt;/sup&gt;, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never smoked</td>
<td>67 (42.7)</td>
<td>N/A</td>
</tr>
<tr>
<td>Tried smoking</td>
<td>26 (16.6)</td>
<td>N/A</td>
</tr>
<tr>
<td>Former smoker</td>
<td>33 (21)</td>
<td>N/A</td>
</tr>
<tr>
<td>Current smoker</td>
<td>31 (19.7)</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Ever used&lt;sup&gt;f&lt;/sup&gt;</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>N/A</td>
<td>12 (7.8)</td>
</tr>
<tr>
<td>No</td>
<td>N/A</td>
<td>125 (81.7)</td>
</tr>
<tr>
<td>Unsure</td>
<td>N/A</td>
<td>16 (10.5)</td>
</tr>
<tr>
<td><strong>Frequency&lt;sup&gt;g&lt;/sup&gt;</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;Monthly</td>
<td>N/A</td>
<td>6 (50)</td>
</tr>
<tr>
<td>Once a month</td>
<td>N/A</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td>2-3 times a month</td>
<td>N/A</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td>Weekly</td>
<td>N/A</td>
<td>3 (25)</td>
</tr>
<tr>
<td>Daily or almost daily</td>
<td>N/A</td>
<td>1 (8.3)</td>
</tr>
<tr>
<td><strong>e-Cigarette use, n (%)</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Data not available for parents.

<sup>b</sup> MVPA: moderate to vigorous physical activity.

<sup>c</sup> Ever used includes those who have ever had an alcoholic drink.

<sup>d</sup> Frequency is reported as the percentage of those who have had alcohol.

<sup>e</sup> Tobacco use includes those who have ever tried smoking.

<sup>f</sup> Ever used includes those who have ever used tobacco products.

<sup>g</sup> Frequency is reported as the percentage of those who have used tobacco products.
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).

<table>
<thead>
<tr>
<th>Parent’s health behaviors</th>
<th>Adolescent health behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ever used(^b)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Unsure</td>
<td>N/A</td>
</tr>
<tr>
<td>Frequency(^i)</td>
<td></td>
</tr>
<tr>
<td>&lt;Monthly</td>
<td>9 (24.3)</td>
</tr>
<tr>
<td>Once a month</td>
<td>4 (10.8)</td>
</tr>
<tr>
<td>2-3 times monthly</td>
<td>5 (13.5)</td>
</tr>
<tr>
<td>Weekly</td>
<td>9 (24.3)</td>
</tr>
<tr>
<td>Daily or almost daily</td>
<td>10 (27)</td>
</tr>
</tbody>
</table>

\(a\) 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.
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.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology</td>
<td></td>
</tr>
<tr>
<td>Excessive screen time</td>
<td>“Addicted to electronic devices” (Female parent of a child aged 17 years)</td>
</tr>
<tr>
<td>Social media</td>
<td>“The content (not quantity) that they are exposed to online” (Female parent of a child aged 12 years)</td>
</tr>
<tr>
<td>Video games</td>
<td>“Staying up late playing games” (Female parent of a child aged 16 years)</td>
</tr>
<tr>
<td>Mental health</td>
<td></td>
</tr>
<tr>
<td>Mental health</td>
<td>“Vaping” (Female parent of a child aged 13 years)</td>
</tr>
<tr>
<td>Stress</td>
<td>“Stress from school” (Female parent of a child aged 17 years)</td>
</tr>
<tr>
<td>Substance use</td>
<td>“Social isolation and mental health” (Female parent of a child aged 12 years)</td>
</tr>
<tr>
<td>Peer relationships</td>
<td></td>
</tr>
<tr>
<td>Peer pressure</td>
<td>“Social pressures to conform” (Female parent of a child aged 16 years)</td>
</tr>
<tr>
<td>Peer acceptance</td>
<td>“Being accepted by their peers” (Female parent of a child aged 14 years)</td>
</tr>
<tr>
<td>Physical health</td>
<td></td>
</tr>
<tr>
<td>Insufficiently active</td>
<td>“Low activity levels” (Male parent of a child aged 15 years)</td>
</tr>
</tbody>
</table>

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).

<table>
<thead>
<tr>
<th></th>
<th>Parents, n (%)</th>
<th>Adolescents, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Barriers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of motivation</td>
<td>76 (42.4)</td>
<td>91 (50.8)</td>
</tr>
<tr>
<td>Limited facilities or resources</td>
<td>43 (24)</td>
<td>N/Aa</td>
</tr>
<tr>
<td>Financial constraints</td>
<td>41 (23)</td>
<td>N/A</td>
</tr>
<tr>
<td>Lack of access to healthy options in the home</td>
<td>N/A</td>
<td>39 (21.8)</td>
</tr>
<tr>
<td>Lack of time</td>
<td>N/A</td>
<td>34 (19)</td>
</tr>
<tr>
<td><strong>Enablers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Integration of healthy behaviors into lifestyle</td>
<td>111 (62)</td>
<td>93 (52)</td>
</tr>
<tr>
<td>Access to healthy options</td>
<td>82 (45.8)</td>
<td>81 (45.2)</td>
</tr>
<tr>
<td>Social support and encouragement</td>
<td>59 (33)</td>
<td>95 (53.1)</td>
</tr>
<tr>
<td><strong>Motivators</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Setting a good example</td>
<td>108 (60.3)</td>
<td>N/A</td>
</tr>
<tr>
<td>Desire to be healthy</td>
<td>103 (57.5)</td>
<td>69 (38.5)</td>
</tr>
<tr>
<td>Mental health benefits</td>
<td>100 (55.9)</td>
<td>71 (49.7)</td>
</tr>
<tr>
<td>Enjoyment of a healthy lifestyle</td>
<td>N/A</td>
<td>87 (48.6)</td>
</tr>
</tbody>
</table>

aN/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

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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]

References


Abbreviations

BCT: behavior change technique
MVPA: moderate to vigorous physical activity

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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 resilience 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).

(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 announced 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>
<thead>
<tr>
<th>Table 1. Query operators.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
</tr>
<tr>
<td>Basic</td>
</tr>
<tr>
<td>Basic</td>
</tr>
<tr>
<td>Complex</td>
</tr>
<tr>
<td>Complex</td>
</tr>
</tbody>
</table>

*The full query is provided in Multimedia Appendix 1.*

<table>
<thead>
<tr>
<th>Table 2. Summary of user posts according to location.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source location</td>
</tr>
<tr>
<td>North America</td>
</tr>
<tr>
<td>Europe</td>
</tr>
<tr>
<td>Africa</td>
</tr>
<tr>
<td>Asia</td>
</tr>
<tr>
<td>Australia and Oceania</td>
</tr>
<tr>
<td>South America</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>ID</th>
<th>Topic</th>
<th>Description</th>
<th>Example</th>
<th>Number of posts (n=15,408), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre1</td>
<td>Fatherhood readiness</td>
<td>Users share whether they are ready to be a father</td>
<td>“People ask me if I’m ready to be a father, and I say I’m as ready as I will be.”</td>
<td>2475 (16.06)</td>
</tr>
<tr>
<td>Pre2</td>
<td>Interpersonal troubles</td>
<td>Users share interpersonal troubles between them and their expectant partner or parent of their child, hoping for advice</td>
<td>“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</td>
<td>2329 (15.12)</td>
</tr>
<tr>
<td>Pre3</td>
<td>Father’s day</td>
<td>Users celebrate Father’s Day on the web</td>
<td>“I am proud to be a father today, and every day. Happy #FathersDay!”</td>
<td>2232 (14.49)</td>
</tr>
<tr>
<td>Pre4</td>
<td>Best dad proclamations</td>
<td>Users claim that they will be the best father</td>
<td>“And I promise for my child I will be the best father a kid could ask for.”</td>
<td>1235 (8.02)</td>
</tr>
<tr>
<td>Pre5</td>
<td>Pregnancy announcements</td>
<td>Users share their pregnancy news on the web</td>
<td>“I’m gonna be a dad!!!”</td>
<td>1654 (10.73)</td>
</tr>
<tr>
<td>Pre6</td>
<td>New father celebration</td>
<td>Users celebrate becoming a father</td>
<td>“I’m gonna be a father. This is not a drill. I’m gonna be a father.”</td>
<td>1261 (8.18)</td>
</tr>
<tr>
<td>Pre7</td>
<td>Expecting parent content</td>
<td>Content originating from or targeting expecting parents</td>
<td>“Pregnancy Definitions: Here are 122 of the top pregnancy terms pregnant parents need to know!”</td>
<td>1543 (10.01)</td>
</tr>
<tr>
<td>Pre8</td>
<td>Becoming a father again</td>
<td>Fathers announce that they are going to be a father again</td>
<td>“I’m going to be a father in a few months. Am I ready? YES!”</td>
<td>664 (4.31)</td>
</tr>
<tr>
<td>Pre9</td>
<td>Newborn-related articles</td>
<td>Links to external articles about various topics about newborns</td>
<td>“About newborn sleep [link removed for privacy].”</td>
<td>2015 (13.08)</td>
</tr>
</tbody>
</table>

^aFor brevity, this example includes only the first 3 sentences of the post.
Table 4. During-pandemic topics, descriptions, and examples.

<table>
<thead>
<tr>
<th>ID</th>
<th>Topic</th>
<th>Description</th>
<th>Example</th>
<th>Number of posts (n=18,745), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dur1</td>
<td>Fatherhood readiness</td>
<td>Users state whether they are ready to be a father</td>
<td>“I am ready to be a husband but not ready to be a father.”</td>
<td>2253 (12.02)</td>
</tr>
<tr>
<td>Dur2</td>
<td>Interpersonal troubles</td>
<td>Users share interpersonal troubles between them and their expectant partner or parent of their child or issues regarding pregnancy, hoping for advice</td>
<td>“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.”</td>
<td>2903 (15.49)</td>
</tr>
<tr>
<td>Dur3</td>
<td>Father’s day</td>
<td>Users celebrate a happy Father’s Day</td>
<td>“I am blessed to be a father. Happy Father’s Day to all the father figures out there.”</td>
<td>2846 (15.18)</td>
</tr>
<tr>
<td>Dur4</td>
<td>Best dad proclamations</td>
<td>Users state that they will be the best father</td>
<td>“I will be the best dad I can be.”</td>
<td>1612 (8.59)</td>
</tr>
<tr>
<td>Dur5</td>
<td>Pregnancy announcements</td>
<td>Users share that they are going to be a father</td>
<td>“Hey everybody! I’m gonna be a dad!”</td>
<td>1934 (10.32)</td>
</tr>
<tr>
<td>Dur6</td>
<td>Pregnancy congratulations</td>
<td>Users congratulate other users for their pregnancy announcements</td>
<td>“Awwwwww congratulations.”</td>
<td>953 (5.08)</td>
</tr>
<tr>
<td>Dur7</td>
<td>New dad life</td>
<td>Posts from new fathers experiencing life with their new baby</td>
<td>“Is it the weekend yet? Oh wait, I have kids!”</td>
<td>2794 (14.91)</td>
</tr>
<tr>
<td>Dur8</td>
<td>Account replies</td>
<td>An account called Family Core is replying to users’ posts</td>
<td>“If YOU are EXPECTING...We are here to HELP Join The Family Core today.”</td>
<td>436 (2.33)</td>
</tr>
<tr>
<td>Dur9</td>
<td>Comedic replies</td>
<td>Comedic replies to other users’ posts</td>
<td>“I am available to be your new dad, if you would like.”</td>
<td>2493 (13.29)</td>
</tr>
<tr>
<td>Dur10</td>
<td>Financial help requests</td>
<td>Replies to other posts, asking for financial help for a small-scale business loan</td>
<td>“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.”</td>
<td>521 (2.78)</td>
</tr>
</tbody>
</table>

*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...
Discussion

Principal Findings
This study examined web-based conversations 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 (i.e., 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 (e.g., joy) have decreased over time, whereas levels of negative emotions (e.g., 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
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. Relatively, 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

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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
References


4. Pretorius KA, Mackert M, Wilcox GB. Sudden infant death syndrome and safe sleep on Twitter: analysis of influences and themes to guide health promotion efforts. JMRI Pediatri Parent 2018 Sep 07;1(2):e10435 [FREE Full text] [doi: 10.2196/10435] [Medline: 31518314]


Abbreviations

RQ: research question
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.

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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>
<thead>
<tr>
<th>Infants</th>
<th>Level II NICU</th>
<th>NICU Level</th>
<th>NICU Level</th>
<th>NICU Level</th>
<th>NICU Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>NICU</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Level</td>
<td>II</td>
<td>III</td>
<td>IV</td>
<td>V</td>
<td>VI</td>
</tr>
<tr>
<td>NICU Level</td>
<td>II</td>
<td>III</td>
<td>IV</td>
<td>V</td>
<td>VI</td>
</tr>
<tr>
<td>NICU Level</td>
<td>II</td>
<td>III</td>
<td>IV</td>
<td>V</td>
<td>VI</td>
</tr>
<tr>
<td>NICU Level</td>
<td>II</td>
<td>III</td>
<td>IV</td>
<td>V</td>
<td>VI</td>
</tr>
<tr>
<td>NICU Level</td>
<td>II</td>
<td>III</td>
<td>IV</td>
<td>V</td>
<td>VI</td>
</tr>
<tr>
<td>NICU Level</td>
<td>II</td>
<td>III</td>
<td>IV</td>
<td>V</td>
<td>VI</td>
</tr>
<tr>
<td>NICU Level</td>
<td>II</td>
<td>III</td>
<td>IV</td>
<td>V</td>
<td>VI</td>
</tr>
</tbody>
</table>

Table 1: Characteristics of the sample.
Table 1. Demographic and obstetric characteristics of the sample.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parent details (n=35)</strong></td>
<td></td>
</tr>
<tr>
<td>Nationality, n (%)</td>
<td></td>
</tr>
<tr>
<td>Dutch</td>
<td>33 (94.2)</td>
</tr>
<tr>
<td>Moroccan</td>
<td>1 (2.9)</td>
</tr>
<tr>
<td>Turkish</td>
<td>1 (2.9)</td>
</tr>
<tr>
<td>Education level, n (%)</td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>9 (25.7)</td>
</tr>
<tr>
<td>Intermediate vocational education</td>
<td>14 (40)</td>
</tr>
<tr>
<td>Higher vocational education</td>
<td>12 (34.3)</td>
</tr>
<tr>
<td>University</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Birth details (n=22)</strong></td>
<td></td>
</tr>
<tr>
<td>Gestational age (weeks), n (%)</td>
<td></td>
</tr>
<tr>
<td>27-28</td>
<td>4 (18.2)</td>
</tr>
<tr>
<td>29-30</td>
<td>3 (9.1)</td>
</tr>
<tr>
<td>31-32</td>
<td>7 (31.8)</td>
</tr>
<tr>
<td>33-34</td>
<td>6 (27.3)</td>
</tr>
<tr>
<td>35</td>
<td>2 (9.1)</td>
</tr>
<tr>
<td>NICU(^{a}) admission (age in days)</td>
<td></td>
</tr>
<tr>
<td>Level III or IV NICU transfers</td>
<td></td>
</tr>
<tr>
<td>Value, n (%)</td>
<td>12 (54.5)</td>
</tr>
<tr>
<td>Value, mean (SD)</td>
<td>23.8 (18.3)</td>
</tr>
<tr>
<td>Level II NICU</td>
<td></td>
</tr>
<tr>
<td>Value, n (%)</td>
<td>10 (45.5)</td>
</tr>
<tr>
<td>Value, mean (SD)</td>
<td>11 (6)</td>
</tr>
</tbody>
</table>

\(^{a}\)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.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Content</th>
<th>Values (n=19), n (%)</th>
<th>Introduced by pediatrician, n (%)</th>
<th>Introduced by parents, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feeding and breastfeeding</td>
<td>Progression of breastfeeding, milk expression, positive effects</td>
<td>17 (90)</td>
<td>9 (53)</td>
<td>8 (47)</td>
</tr>
<tr>
<td>Introduction</td>
<td>Pediatrician introduces oneself; their tasks; the department; daily program</td>
<td>14 (74)</td>
<td>14 (100)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Personal</td>
<td>Personal information about the parents and their lives like work status and psychosocial situation</td>
<td>14 (74)</td>
<td>7 (50)</td>
<td>7 (50)</td>
</tr>
<tr>
<td>Criteria</td>
<td>Criteria for discharge</td>
<td>13 (68)</td>
<td>11 (85)</td>
<td>2 (15)</td>
</tr>
<tr>
<td>Postdischarge follow-up</td>
<td>Explanation how postnatal follow-up will be scheduled</td>
<td>13 (68)</td>
<td>9 (69)</td>
<td>4 (31)</td>
</tr>
<tr>
<td>Respiratory support and caffeine</td>
<td>Supplemental oxygen and pressure, and how these are decreased; medication like caffeine</td>
<td>12 (63)</td>
<td>10 (83)</td>
<td>2 (17)</td>
</tr>
<tr>
<td>Not care related</td>
<td>Small talk</td>
<td>11 (59)</td>
<td>4 (36)</td>
<td>7 (64)</td>
</tr>
<tr>
<td>Monitor or alarms</td>
<td>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</td>
<td>10 (53)</td>
<td>6 (60)</td>
<td>4 (40)</td>
</tr>
<tr>
<td>Department</td>
<td>Opinion and experiences of parents regarding the department; the employees; the nurses; the care; other parents</td>
<td>10 (53)</td>
<td>4 (40)</td>
<td>6 (60)</td>
</tr>
<tr>
<td>Talking about the future</td>
<td>The preterm’s future; how will they grow up, which problems may they face, school</td>
<td>8 (42)</td>
<td>6 (75)</td>
<td>2 (25)</td>
</tr>
<tr>
<td>Weight</td>
<td>The weight or growth of the preterm infant.</td>
<td>8 (42)</td>
<td>5 (62)</td>
<td>3 (38)</td>
</tr>
<tr>
<td>Tube feeding</td>
<td>Whether the preterm is or will be given tube feeding; how much; how long</td>
<td>8 (42)</td>
<td>5 (62)</td>
<td>3 (38)</td>
</tr>
<tr>
<td>Temperature of the child</td>
<td>Can the preterm keep themselves warm; external source for heating; incubator; phototherapy for icterus</td>
<td>8 (42)</td>
<td>6 (75)</td>
<td>2 (25)</td>
</tr>
<tr>
<td>Ultrasound or MRI(b) of the brain</td>
<td>Ultrasound or MRI of the brain; and results of them</td>
<td>8 (42)</td>
<td>6 (75)</td>
<td>2 (25)</td>
</tr>
<tr>
<td>Vaccinations</td>
<td>Parent’s consent for vaccinations and scheduling</td>
<td>8 (42)</td>
<td>6 (75)</td>
<td>2 (25)</td>
</tr>
<tr>
<td>Birth</td>
<td>The process, experience, and possible complications of labor</td>
<td>7 (37)</td>
<td>1 (14)</td>
<td>6 (86)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>If and why the preterm is vomiting (explanations)</td>
<td>7 (37)</td>
<td>1 (14)</td>
<td>6 (86)</td>
</tr>
<tr>
<td>Height and growth</td>
<td>The length, weight, and growth charts</td>
<td>7 (37)</td>
<td>1 (14)</td>
<td>6 (86)</td>
</tr>
<tr>
<td>Laboratory values</td>
<td>blood draw; blood transfusions</td>
<td>7 (37)</td>
<td>7 (100)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>How to care at home</td>
<td>After discharge; what should be paid attention to; differences and similarities from raising a term baby and extra concerns</td>
<td>7 (37)</td>
<td>2 (29)</td>
<td>5 (71)</td>
</tr>
<tr>
<td>Recap</td>
<td>A recap is given of everything that has happened at the NICU(c) so far</td>
<td>6 (32)</td>
<td>6 (100)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Emotional</td>
<td>The emotional state of the parents regarding the situation; their preterm; the hospital</td>
<td>6 (32)</td>
<td>5 (83)</td>
<td>1 (17)</td>
</tr>
<tr>
<td>Bowel movements</td>
<td>Bowel movements of the preterm; use of enemas</td>
<td>6 (32)</td>
<td>3 (50)</td>
<td>3 (50)</td>
</tr>
<tr>
<td>Vitamins</td>
<td>The needed vitamins; iron supplementation</td>
<td>6 (32)</td>
<td>4 (67)</td>
<td>2 (33)</td>
</tr>
<tr>
<td>Child specific</td>
<td>Issues specific for the preterm</td>
<td>6 (32)</td>
<td>4 (67)</td>
<td>2 (33)</td>
</tr>
<tr>
<td>Data or counting</td>
<td>How the birth date and age of the preterm should be corrected regarding growth, and scheduling of vaccinations</td>
<td>5 (26)</td>
<td>3 (60)</td>
<td>2 (40)</td>
</tr>
<tr>
<td>Theme</td>
<td>Content</td>
<td>Values (n=19), n (%)</td>
<td>Introduced by pediatrician(^a), n (%)</td>
<td>Introduced by parents(^a), n (%)</td>
</tr>
<tr>
<td>------------------------------</td>
<td>----------------------------------------------</td>
<td>----------------------</td>
<td>----------------------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Infections</td>
<td>Recent infections; chance of infections; antibiotics</td>
<td>5 (26)</td>
<td>5 (100)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Eyes (retinopathy)</td>
<td>Explaining why the eyes are checked; ophthalmologist appointments</td>
<td>4 (21)</td>
<td>1 (25)</td>
<td>3 (75)</td>
</tr>
<tr>
<td>NICU level III experience</td>
<td>How parents experienced their stay at the level III NICU; what happened there before transfer</td>
<td>4 (21)</td>
<td>1 (25)</td>
<td>3 (75)</td>
</tr>
<tr>
<td>After the NICU</td>
<td>Aftercare by the NICU department; what, when, and how</td>
<td>3 (16)</td>
<td>1 (33)</td>
<td>2 (67)</td>
</tr>
<tr>
<td>(Possible) operations</td>
<td>Possible operations of the heart, lungs, brain, body are discussed and explained</td>
<td>2 (11)</td>
<td>1 (50)</td>
<td>1 (50)</td>
</tr>
<tr>
<td>Lungs</td>
<td>Explaining pulmonary edema; lung capacity</td>
<td>2 (11)</td>
<td>1 (50)</td>
<td>1 (50)</td>
</tr>
</tbody>
</table>

\(^a\)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.

<table>
<thead>
<tr>
<th>Features</th>
<th>Content</th>
<th>Frequency of interviews in which the feature was mentioned (n=19), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graphs</td>
<td>Graphs including their infants’ growth or weight and what is normal for infants to grow or weigh (comparisons)</td>
<td>8 (42)</td>
</tr>
<tr>
<td>Diary or achievements</td>
<td>Diary in which parents could write their own experiences and condition of their infant</td>
<td>6 (32)</td>
</tr>
<tr>
<td>Information</td>
<td>Practical basic information, glossary of terms, what to expect with a preterm infant</td>
<td>6 (32)</td>
</tr>
<tr>
<td>Medical rounds reports</td>
<td>Report of what is discussed during medical rounds provided by all medical caregivers, including the current values</td>
<td>5 (26)</td>
</tr>
<tr>
<td>Baby cam</td>
<td>Camera feature that shows their infant in their bed at the hospital</td>
<td>5 (26)</td>
</tr>
<tr>
<td>Agenda</td>
<td>Schedule including planning or appointments</td>
<td>4 (21)</td>
</tr>
<tr>
<td>Frequently asked questions</td>
<td>Frequently asked questions with answers</td>
<td>3 (16)</td>
</tr>
<tr>
<td>Question suggestions</td>
<td>Suggestions on what the parents could ask their caregivers</td>
<td>2 (11)</td>
</tr>
<tr>
<td>Pictures</td>
<td>Saving and sending pictures</td>
<td>2 (11)</td>
</tr>
<tr>
<td>Information medical exams</td>
<td>Explanation of different medical exams</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Results medical exams</td>
<td>Results of the exams (eg, blood testing, MRI)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Parental presence</td>
<td>Giving parents the option to state when they are at the hospital and when they are gone</td>
<td>1 (5)</td>
</tr>
</tbody>
</table>

aMRI: 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
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Conflicts of Interest
None declared.

References
17. Doron MW, Tenfelde et alJMIR PEDIATRICS AND PARENTING


Abbreviations

mHealth: mobile health
NICU: neonatal intensive care unit
PC: parent-couple
RQ: research question
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.

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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).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender (n=94), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>71 (76)</td>
</tr>
<tr>
<td>Male</td>
<td>23 (24)</td>
</tr>
<tr>
<td><strong>Area of residence (n=94), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>42 (44)</td>
</tr>
<tr>
<td>Suburban</td>
<td>40 (43)</td>
</tr>
<tr>
<td>Rural</td>
<td>12 (13)</td>
</tr>
<tr>
<td><strong>Household income (CAD $; n=85), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Less than 45,000</td>
<td>6 (7)</td>
</tr>
<tr>
<td>45,000 to less than 75,000</td>
<td>9 (11)</td>
</tr>
<tr>
<td>75,000 to less than 100,000</td>
<td>7 (8)</td>
</tr>
<tr>
<td>100,000 to 150,000</td>
<td>33 (39)</td>
</tr>
<tr>
<td>150,000 to 300,000</td>
<td>21 (24)</td>
</tr>
<tr>
<td>Greater than 300,000</td>
<td>9 (11)</td>
</tr>
<tr>
<td><strong>Education (n=91), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>High school graduation or less</td>
<td>5 (6)</td>
</tr>
<tr>
<td>Graduated from trade school</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Some college or university degree</td>
<td>24 (26)</td>
</tr>
<tr>
<td>College or university undergraduate degree</td>
<td>33 (36)</td>
</tr>
<tr>
<td>College or university graduate degree</td>
<td>26 (29)</td>
</tr>
</tbody>
</table>

*CAD $1=US $0.76.
Table 2. Participant characteristics of health care providers (HCPs).

<table>
<thead>
<tr>
<th>HCPs</th>
<th>Participants (n=49), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes nurse educators</td>
<td>18 (37)</td>
</tr>
<tr>
<td>Nursing support services&lt;sup&gt;a&lt;/sup&gt;</td>
<td>12 (25)</td>
</tr>
<tr>
<td>Pediatricians</td>
<td>9 (18)</td>
</tr>
<tr>
<td>Dieticians</td>
<td>6 (12)</td>
</tr>
<tr>
<td>Pediatric endocrinologists</td>
<td>4 (8)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCP health authority of practice</th>
<th>Participants (n=49), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vancouver Island Health Authority</td>
<td>11 (22)</td>
</tr>
<tr>
<td>Provincial Health Services Authority</td>
<td>8 (16)</td>
</tr>
<tr>
<td>Northern Health Authority</td>
<td>8 (16)</td>
</tr>
<tr>
<td>Fraser Health Authority</td>
<td>8 (16)</td>
</tr>
<tr>
<td>Interior Health Authority</td>
<td>8 (16)</td>
</tr>
<tr>
<td>Vancouver Coastal Health Authority</td>
<td>6 (12)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Children and youths &lt;18 years old with T1D&lt;sup&gt;b&lt;/sup&gt; in their practice</th>
<th>Participants (n=49), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 25</td>
<td>20 (42)</td>
</tr>
<tr>
<td>25-49</td>
<td>7 (14)</td>
</tr>
<tr>
<td>50-99</td>
<td>6 (12)</td>
</tr>
<tr>
<td>100-149</td>
<td>5 (10)</td>
</tr>
<tr>
<td>150-200</td>
<td>3 (6)</td>
</tr>
<tr>
<td>More than 200</td>
<td>8 (16)</td>
</tr>
</tbody>
</table>

<sup>a</sup>These health care providers support care of children living with type 1 diabetes in schools.

<sup>b</sup>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.”)

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Participants (n=84), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to diabetes management technologies (ie. insulin pumps and glucose sensors)</td>
<td>45 (54)</td>
</tr>
<tr>
<td>Support for your child's diabetes care in school</td>
<td>45 (54)</td>
</tr>
<tr>
<td>Access to mental health support (social worker or psychologist)</td>
<td>41 (49)</td>
</tr>
<tr>
<td>Accessing your child's medical information (ie, glucose sensor data, pump data, and lab test results)</td>
<td>33 (39)</td>
</tr>
<tr>
<td>Connecting with your diabetes team between visits</td>
<td>32 (38)</td>
</tr>
<tr>
<td>Access to a pediatric diabetes doctor</td>
<td>17 (20)</td>
</tr>
<tr>
<td>Access to a registered dietician with experience in pediatric diabetes</td>
<td>9 (11)</td>
</tr>
<tr>
<td>Access to a diabetes nurse educator</td>
<td>5 (6)</td>
</tr>
<tr>
<td>Other</td>
<td>25 (30)</td>
</tr>
</tbody>
</table>
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.”)

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Participants (n=49), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to a pediatric diabetes doctor</td>
<td>6 (12)</td>
</tr>
<tr>
<td>Access to a diabetes nurse educator</td>
<td>5 (10)</td>
</tr>
<tr>
<td>Access to a registered dietitian with experience in pediatric diabetes</td>
<td>6 (12)</td>
</tr>
<tr>
<td>Access to mental health support (social worker or psychologist)</td>
<td>41 (84)</td>
</tr>
<tr>
<td>Access to diabetes management technologies (ie, insulin pumps and glucose sensors)</td>
<td>26 (53)</td>
</tr>
<tr>
<td>Support for their child’s diabetes care in school</td>
<td>17 (35)</td>
</tr>
<tr>
<td>Accessing their child’s clinical information (ie, glucose sensor data, pump data, and lab investigations)</td>
<td>19 (39)</td>
</tr>
<tr>
<td>Connecting with their diabetes team between visits</td>
<td>17 (35)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (10)</td>
</tr>
</tbody>
</table>

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%).

https://pediatrics.jmir.org/2023/1/e46432

JMR Pediatr Parent 2023 | vol. 6 | e46432 | p.168
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. TvrR 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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27. Diabetes (Type 1 and Type 2) in Children and Young People: Diagnosis and Management. National Institute for Health and Care Excellence (NICE) Guidelines. 2022. URL: https://www.nice.org.uk/guidance/ng18/chapter/Recommendations#type-1-diabetes [accessed 2023-05-05]


29. Digital Supercluster. URL: https://www.digitalsupercluster.ca/ [accessed 2023-06-10]
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

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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 [3].

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 Böhme 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. Mönnighoff 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 technology” OR “mobile technology” 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.
Meanwhile, all 3 studies by Schiel et al [36-38] took 1-4 days to measure PA, which was conducted as a cross-sectional study [41]. Table 1 shows that the shortest period of PA measurement was allowed for comparisons between the methods. And accelerometers or pedometers [40,41,43], which in turn have added self-report questionnaires for PA recall [36,38,41,43]. In addition to using smartphone technology, several studies downloaded smartphone apps from the Android Play Store and in children and adolescents. They either used a built-in and in smartphones or mobile phones as a surveillance tool for PA 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, 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%), and generalizability (3/8, 38%).

### 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, 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 Viciani 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).

<table>
<thead>
<tr>
<th>Study</th>
<th>App name</th>
<th>App purpose</th>
<th>Primary outcome</th>
<th>Pros and cons</th>
</tr>
</thead>
</table>
| 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).

<table>
<thead>
<tr>
<th>Study</th>
<th>App name</th>
<th>App purpose</th>
<th>Primary outcome</th>
<th>Pros and cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dahlgren et al</td>
<td>SSCRIIN activity tracker (for PA), Apple Health</td>
<td>Measure PA(^a)</td>
<td>Active minutes and step count                                                    • Pros: SSCRIIN activity tracker can be purchased; SSCRIIN app can be downloaded via Apple App Store and Google Play Store</td>
<td></td>
</tr>
<tr>
<td>[42], 2021</td>
<td></td>
<td></td>
<td></td>
<td>• Cons: missing and incompleteness of data from SSCRIIN app owing to children’s and adolescents’ need to have access to a smartphone</td>
</tr>
<tr>
<td>Viciana et al</td>
<td>Pedometer, Pacer Step Counter, Google Fit, Apple Health</td>
<td>Measure PA aspects and step count</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>[39], 2022</td>
<td></td>
<td></td>
<td></td>
<td>• Cons: apps are all not empirically validated</td>
</tr>
<tr>
<td>Seah and Koh</td>
<td>MapMyFitness (for PA), Apple Health, Samsung Health, Pacer Step Counter, Pedometer, Weight Loss Coach</td>
<td>Track PA aspects and step count</td>
<td>Duration, distance, pace, speed, elevation, calories burned, and route traveled  • Pros: quick feedback and easy for self-monitoring</td>
<td></td>
</tr>
<tr>
<td>[43], 2020</td>
<td></td>
<td></td>
<td></td>
<td>• Cons: apps are all not empirically validated</td>
</tr>
</tbody>
</table>

\(^a\)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 SSCRIIN 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 SSCRIIN 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 SSCRIIN app used in the study by Dahlgren et al [42] showed a high correlation ($r=0.72; P<.001$) between the SSCRIIN 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 convenient and freely available tool for measuring PA with novel ways to promote healthier lifestyles, including measuring and monitoring PA [52].

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 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).
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 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 have 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
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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

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(page number not for citation purposes)
**STROBE:** Strengthening of the Reporting of Observational Studies in Epidemiology

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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 reassessment 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 assessment 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>
<thead>
<tr>
<th>Assessment number</th>
<th>Elevated depressive symptom group (n=61), n (%)</th>
<th>Elevated anxiety symptom group (n=98), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Complete assessment</td>
<td>Screener or complete assessment</td>
</tr>
<tr>
<td>1 (baseline)</td>
<td>61 (100)</td>
<td>61 (100)</td>
</tr>
<tr>
<td>2</td>
<td>12 (20)</td>
<td>25 (41)</td>
</tr>
<tr>
<td>3</td>
<td>3 (5)</td>
<td>13 (21)</td>
</tr>
<tr>
<td>4</td>
<td>1 (2)</td>
<td>5 (8)</td>
</tr>
<tr>
<td>5</td>
<td>1 (2)</td>
<td>3 (5)</td>
</tr>
<tr>
<td>6</td>
<td>0 (0)</td>
<td>2 (3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Elevated depressive symptom group (n=61)</th>
<th>Elevated anxiety symptom group (n=98)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>13.2 (2.7)</td>
<td>11.9 (3.3)</td>
</tr>
<tr>
<td>Child (6-12 years), n (%)</td>
<td>16 (26)</td>
<td>47 (48)</td>
</tr>
<tr>
<td>Adolescent (13+ years), n (%)</td>
<td>45 (74)</td>
<td>51 (52)</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td>43 (71)</td>
<td>66 (67)</td>
</tr>
<tr>
<td>Female</td>
<td>18 (30)</td>
<td>31 (32)</td>
</tr>
<tr>
<td>Male</td>
<td>33 (54)</td>
<td>57 (58)</td>
</tr>
<tr>
<td>Race/ethnicity, n (%)</td>
<td>22 (36)</td>
<td>31 (32)</td>
</tr>
<tr>
<td>White</td>
<td>5 (8)</td>
<td>8 (8)</td>
</tr>
<tr>
<td>Asian</td>
<td>0 (0)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>1 (2)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Black/African American</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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 the complete 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 ($t_{44}=1.88; P=.07$).
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 (\(\chi^2_{1} = 1.6; P = .20\)). 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.

<table>
<thead>
<tr>
<th>Anxiety symptom severity</th>
<th>Assessment 1 (n=98), n (%)</th>
<th>Assessment 2 (n=44), n (%)</th>
<th>Assessment 3 (n=22), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screened out (no complete assessment)</td>
<td>0 (0)</td>
<td>10 (23)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>None</td>
<td>0 (0)</td>
<td>7 (16)</td>
<td>7 (32)</td>
</tr>
<tr>
<td>Mild</td>
<td>26 (27)</td>
<td>3 (7)</td>
<td>4 (18)</td>
</tr>
<tr>
<td>Moderate</td>
<td>55 (56)</td>
<td>18 (41)</td>
<td>9 (41)</td>
</tr>
<tr>
<td>Severe</td>
<td>17 (17)</td>
<td>6 (14)</td>
<td>1 (5)</td>
</tr>
</tbody>
</table>

**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.\(^a\)

<table>
<thead>
<tr>
<th>Predictors</th>
<th>Anxiety T-score estimates</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Intercept) (95% CI)</td>
<td>64.74 (63.24 to 66.25)</td>
<td>&lt;.001(^b)</td>
</tr>
<tr>
<td>Days from baseline, estimate (95% CI)</td>
<td>–0.06 (–0.09 to –0.03)</td>
<td>&lt;.001(^b)</td>
</tr>
</tbody>
</table>

Random effects

| \(\sigma^2\)                  | 37.64                     |
| \(\tau_{0}\)\(^d\)          | 22.49                     |

\(^a\)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.

<table>
<thead>
<tr>
<th>Depressive symptom severity</th>
<th>Assessment 1 (n=61), n (%)</th>
<th>Assessment 2 (n=25), n (%)</th>
<th>Assessment 3 (n=13), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screened out (no complete assessment)</td>
<td>0 (0)</td>
<td>13 (52)</td>
<td>10 (77)</td>
</tr>
<tr>
<td>None</td>
<td>0 (0)</td>
<td>1 (4)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Mild</td>
<td>6 (10)</td>
<td>2 (8)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Moderate</td>
<td>36 (59)</td>
<td>5 (20)</td>
<td>2 (15)</td>
</tr>
<tr>
<td>Severe</td>
<td>19 (31)</td>
<td>4 (16)</td>
<td>1 (8)</td>
</tr>
</tbody>
</table>

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 ($\chi^2=2.6; P=.11$). 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.\(^a\)

<table>
<thead>
<tr>
<th>Predictors</th>
<th>Depression T-score estimates</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Intercept) (95% CI)</td>
<td>68.10 (66.15 to 70.06)</td>
<td>&lt;.001(^b)</td>
</tr>
<tr>
<td>Days from baseline, estimate (95% CI)</td>
<td>0.00 (-0.06 to 0.06)</td>
<td>.99</td>
</tr>
</tbody>
</table>

Random effects

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>$\sigma^2$</td>
<td>32.59</td>
</tr>
<tr>
<td>$\tau_{00}$</td>
<td>26.92</td>
</tr>
</tbody>
</table>

\(^a\)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 assessment 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.

Methods 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.

References


https://pediatrics.jmir.org/2023/1/e46154


https://pediatrics.jmir.org/2023/1/e46154


Abbreviations

DMHI: digital mental health intervention
MBC: measurement-based care
PCP: primary care provider
PROMIS: Patient-Reported Outcomes Measurement Information System
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.

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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 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 (e.g., delivered via a web platform through computers or laptops, or via smartphone apps) [20]. Digital programs were either supported by school staff (e.g., classroom teachers) or by external facilitators in the classroom (e.g., 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 (i.e., 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” (i.e., 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...
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.
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.](https://pediatrics.jmir.org/2023/1/e42349)
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), \(^a\)

<table>
<thead>
<tr>
<th>Sample characteristics</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>40.09 (11.82)</td>
</tr>
<tr>
<td>Gender, ( n ) (%)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>16 (73)</td>
</tr>
<tr>
<td>Male</td>
<td>6 (27)</td>
</tr>
<tr>
<td>Aboriginal or Torres Strait Islander, ( n ) (%)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>21 (96)</td>
</tr>
<tr>
<td>Born in Australia, ( n ) (%)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>19 (86)</td>
</tr>
<tr>
<td>No</td>
<td>3 (14)</td>
</tr>
<tr>
<td>Highest level of education, ( n ) (%)</td>
<td></td>
</tr>
<tr>
<td>Undergraduate degree</td>
<td>10 (46)</td>
</tr>
<tr>
<td>Postgraduate degree</td>
<td>12 (55)</td>
</tr>
<tr>
<td>Role in future proofing, ( n ) (%)</td>
<td></td>
</tr>
<tr>
<td>Key leader who helped to drive and deliver the FPP(^b)</td>
<td>9 (39)</td>
</tr>
<tr>
<td>Assisted with delivery</td>
<td>14 (61)</td>
</tr>
<tr>
<td>Employment role, ( n ) (%)</td>
<td></td>
</tr>
<tr>
<td>Teacher or year adviser, head teacher</td>
<td>7 (31.8)</td>
</tr>
<tr>
<td>Psychologist, counselor, well-being officer, or guidance counselor</td>
<td>14 (64)</td>
</tr>
<tr>
<td>Principal or deputy</td>
<td>1 (5)</td>
</tr>
<tr>
<td>If counselor, only counselor in school, ( n ) (%)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2 (18)</td>
</tr>
<tr>
<td>No</td>
<td>9 (82)</td>
</tr>
<tr>
<td>Total number of schools worked in, mean (SD)</td>
<td>8.36 (10)</td>
</tr>
<tr>
<td>Number of schools currently working in, mean (SD)</td>
<td>2.23 (3)</td>
</tr>
<tr>
<td>Number of years worked at current school, mean (SD)</td>
<td>6.64 (7)</td>
</tr>
<tr>
<td>Number of years worked in current role, mean (SD)</td>
<td>3.80 (3)</td>
</tr>
<tr>
<td>Employment status, ( n ) (%)</td>
<td></td>
</tr>
<tr>
<td>Full-time</td>
<td>16 (73)</td>
</tr>
<tr>
<td>Part-time</td>
<td>6 (27)</td>
</tr>
</tbody>
</table>

\(^a\)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).

<table>
<thead>
<tr>
<th>Facilitators</th>
<th>FPP status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning and engaging</td>
<td></td>
</tr>
<tr>
<td>Reputable implementing institution and provision of high-quality resources</td>
<td>Provided</td>
</tr>
<tr>
<td>Active leadership support (including recognition of staff input) and school ownership</td>
<td>Encouraged</td>
</tr>
<tr>
<td>Counselors involved in decisions about FPP adoption and planning</td>
<td>Encouraged</td>
</tr>
<tr>
<td>In-school champion that engages staff and students</td>
<td>Encouraged</td>
</tr>
<tr>
<td>Engagement strategy for students and parents to encourage buy-in</td>
<td>Provided</td>
</tr>
<tr>
<td>Supportive school implementation team with clear responsibilities to share load</td>
<td>Encouraged</td>
</tr>
<tr>
<td>Dedicated staff time for planning and reviewing</td>
<td>Encouraged</td>
</tr>
<tr>
<td>Established community support for referrals of high-risk students that are outside the remit or resources of schools</td>
<td>Ideal</td>
</tr>
<tr>
<td>Executing</td>
<td></td>
</tr>
<tr>
<td>Flexible delivery of FPP</td>
<td>Provided</td>
</tr>
<tr>
<td>Integration into school curriculum as an adjunct program</td>
<td>Ideal</td>
</tr>
<tr>
<td>Technology support from implementing institution</td>
<td>Provided</td>
</tr>
<tr>
<td>Adequate school-level resources (eg, rooms, Wi-Fi, and laptops)</td>
<td>Encouraged</td>
</tr>
<tr>
<td>Standardized risk follow-up and referral processes for counselors</td>
<td>Encouraged</td>
</tr>
<tr>
<td>Availability of counselors and provision of adequate time to respond to risk follow-ups</td>
<td>Encouraged</td>
</tr>
<tr>
<td>In-school reminders about SPARX completion for students</td>
<td>Encouraged</td>
</tr>
</tbody>
</table>

*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 intended 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 digital mental health programs:

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

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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.

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**Abbreviations**

CFIR: Consolidated Framework for Implementation Research
FPP: Future Proofing Program
SPARX: Smart, Positive, Active, Realistic, X-factor thoughts

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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 ($t_{256.49}=3.56$, $P<.001$, $d=0.45$; 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 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. 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].

<table>
<thead>
<tr>
<th>Studies and groups in paper</th>
<th>Objective compliance (%)&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Age group (years)</th>
</tr>
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<tr>
<td>Stewart et al [20]</td>
<td>48</td>
<td>3-8</td>
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<tr>
<td><strong>Awan et al [22]</strong></td>
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<tr>
<td>3-h regimen</td>
<td>57.5</td>
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<td>6-h regimen</td>
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<td><strong>Loudon et al [21]</strong></td>
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<tr>
<td>Education intervention group</td>
<td>78</td>
<td>&lt;4</td>
</tr>
<tr>
<td>4-6</td>
<td>77</td>
<td></td>
</tr>
<tr>
<td>&gt;6</td>
<td>74</td>
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<tr>
<td>Control group</td>
<td>57</td>
<td>&lt;4</td>
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<td><strong>Tjiam et al [24]</strong></td>
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<td>Preimplementation cartoon</td>
<td>52</td>
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<tr>
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<td>89</td>
<td>3-6</td>
</tr>
<tr>
<td>Reward sticker group</td>
<td>67</td>
<td></td>
</tr>
<tr>
<td>Parent leaflet group</td>
<td>73</td>
<td></td>
</tr>
<tr>
<td>Control group</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td><strong>Wallace et al [25]</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Educational/motivational intervention group</td>
<td>81</td>
<td>3.5-8.9</td>
</tr>
<tr>
<td>Control group</td>
<td>45</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>Mean 62.33% compliance (SD 13.31%).
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 ambylopia (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.

<table>
<thead>
<tr>
<th>FAVAS-version</th>
<th>2015</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client</td>
<td>Web-based software solution supported by Plugin: Adobe Flash version 10</td>
<td>Web-based software solution</td>
</tr>
<tr>
<td>Browser</td>
<td>Usable, for example, with Microsoft Edge, Microsoft Internet Explorer 7, Mozilla Firefox ab 3.5, Google Chrome 3</td>
<td>Usable, for example, with Microsoft Edge, Mozilla Firefox and Google Chrome</td>
</tr>
<tr>
<td>Operating system</td>
<td>Windows from XP, or OS X from v10.4 or higher required</td>
<td>Plays a minor role</td>
</tr>
<tr>
<td>Stimulus</td>
<td>The stimulus is based on an Adobe Flash implementation</td>
<td>The stimulus is based on an HTML-5 implementation</td>
</tr>
</tbody>
</table>

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.

**Table 3.** Baseline characteristics of the two groups.

<table>
<thead>
<tr>
<th></th>
<th>Group 2015 (n=138)</th>
<th>Group 2020 (n=129)</th>
<th>Chi-square or t test (df)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>70 (50.7)</td>
<td>67 (51.9)</td>
<td></td>
<td>.93</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>68 (49.3)</td>
<td>62 (48.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years), mean (SD; range)</td>
<td>7.8 (2.1; 4.2-15.6)</td>
<td>7.2 (2.3; 4.3-14.7)</td>
<td>2.22 (265)²</td>
<td>.03</td>
</tr>
<tr>
<td>Amblyopia types</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strabismic, n (%)</td>
<td>65 (47.1)</td>
<td>61 (47.3)</td>
<td></td>
<td>.10</td>
</tr>
<tr>
<td>Anisometropic, n (%)</td>
<td>73 (52.9)</td>
<td>68 (52.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BCVAc</td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>&lt;0.39</td>
<td>38</td>
<td>29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.4-0.69</td>
<td>69</td>
<td>68</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;0.7</td>
<td>31</td>
<td>32</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹Chi-square test.
²t test.
³BCVA: best-corrected visual acuity
⁴N/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 ($t_{254.38}=3.48, P=0.001, d=0.44; 95\% CI 0.68-0.19)$.

**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
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.

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**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.

**References**


https://pEDIATRICS.jmir.org/2023/1/e32282

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**XSL•FO RenderX**


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Abbreviations

BCVA: best-corrected visual acuity
CAM: Cambridge Stimulator
FAVAS: focal ambient visual acuity stimulation

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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
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).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic characteristics</td>
<td></td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>15.5 (1.5)</td>
</tr>
<tr>
<td>Sex (female), n (%)</td>
<td>65 (77)</td>
</tr>
<tr>
<td><strong>Ethnicity, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>13 (15)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>5 (6)</td>
</tr>
<tr>
<td>Asian</td>
<td>7 (8)</td>
</tr>
<tr>
<td>Black</td>
<td>4 (4.6)</td>
</tr>
<tr>
<td>Latin American</td>
<td>7 (8)</td>
</tr>
<tr>
<td>White</td>
<td>77 (91)</td>
</tr>
<tr>
<td>More than one race</td>
<td>16 (18)</td>
</tr>
<tr>
<td>Annual household income (US $), n (%)</td>
<td></td>
</tr>
<tr>
<td>&lt;49,999</td>
<td>24 (28)</td>
</tr>
<tr>
<td>50,000-99,999</td>
<td>25 (29)</td>
</tr>
<tr>
<td>&gt;100,000</td>
<td>35 (41)</td>
</tr>
<tr>
<td>Not reported</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Parents’ education, n (%)</td>
<td></td>
</tr>
<tr>
<td>High school or less</td>
<td>4 (5)</td>
</tr>
<tr>
<td>College or vocational school</td>
<td>60 (70)</td>
</tr>
<tr>
<td>Graduate or professional school</td>
<td>20 (24)</td>
</tr>
<tr>
<td>Not reported</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Clinical characteristics</td>
<td></td>
</tr>
<tr>
<td>Usual pain severity (0-10 NRS(^a)), mean (SD)</td>
<td>5.7 (1.7)</td>
</tr>
<tr>
<td>Pain frequency (past 3 months), mean (SD)</td>
<td></td>
</tr>
<tr>
<td>Daily</td>
<td>57 (67)</td>
</tr>
<tr>
<td>Weekly</td>
<td>22 (26)</td>
</tr>
<tr>
<td>Monthly</td>
<td>4 (5)</td>
</tr>
<tr>
<td>Not reported</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Pain locations (0-9), mean (SD)</td>
<td>4 (2.3)</td>
</tr>
</tbody>
</table>

\(^a\)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.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean (SD)</th>
<th>Expectancies</th>
<th>Precontemplation</th>
<th>Difficulty of treatment</th>
<th>Helpfulness of treatment</th>
<th>Online engagement</th>
<th>Offline engagement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expectancies</td>
<td>30.4 (7.1)</td>
<td>—</td>
<td></td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Precontemplation</td>
<td>3.2 (0.9)</td>
<td>−0.30 lame b</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Difficulty of treatment</td>
<td>6.9 (2.3)</td>
<td>0.02</td>
<td>0.02</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Helpfulness of treatment</td>
<td>1.8 (0.9)</td>
<td>0.32 lame b</td>
<td>−0.28 lame c</td>
<td>−0.02</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Online engagement</td>
<td>12.9 (12.2)</td>
<td>0.02</td>
<td>0.08</td>
<td>0.26 lame c</td>
<td>0.22</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Offline engagement</td>
<td>3.1 (0.9)</td>
<td>0.24 lame c</td>
<td>−0.11</td>
<td>0.19</td>
<td>0.27 lame c</td>
<td>0.08</td>
<td>—</td>
</tr>
</tbody>
</table>

aNot available.

bPearson correlations significant at P<.01.

cPearson 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: direct effects.

<table>
<thead>
<tr>
<th>Direct effects</th>
<th>Path</th>
<th>B</th>
<th>SE</th>
<th>P value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expectancies to difficulty</td>
<td>a1</td>
<td>0.004</td>
<td>0.038</td>
<td>.923</td>
<td>−0.073 to 0.080</td>
</tr>
<tr>
<td>Expectancies to helpfulness</td>
<td>a2</td>
<td>0.039</td>
<td>0.014</td>
<td>.007</td>
<td>0.011 to 0.066</td>
</tr>
<tr>
<td>Difficulty to online engagement</td>
<td>b1</td>
<td>1.468</td>
<td>0.615</td>
<td>.019</td>
<td>0.240 to 2.696</td>
</tr>
<tr>
<td>Helpfulness to online engagement</td>
<td>b2</td>
<td>3.948</td>
<td>1.718</td>
<td>.025</td>
<td>0.516 to 7.380</td>
</tr>
<tr>
<td>Expectancies to online engagement</td>
<td>c'</td>
<td>−0.059</td>
<td>0.205</td>
<td>.773</td>
<td>−0.468 to 0.349</td>
</tr>
</tbody>
</table>

\(^a\)R=0.374; \(R^2=0.140\); \(F_{3,65}=3.521\); \(P=.02\).

Table 4. Summary of model 1: indirect effects.

<table>
<thead>
<tr>
<th>Indirect effects</th>
<th>Boot(^a) effect</th>
<th>Boot SE</th>
<th>Boot LL(^b) CI</th>
<th>Boot UL(^c) CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expectancies to difficulty to online engagement</td>
<td>0.006</td>
<td>0.069</td>
<td>−0.134</td>
<td>0.147</td>
</tr>
<tr>
<td>Expectancies to helpfulness to online engagement</td>
<td>0.152</td>
<td>0.098</td>
<td>0.013</td>
<td>0.389</td>
</tr>
</tbody>
</table>

\(^a\)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 a2: 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: direct effects.

<table>
<thead>
<tr>
<th>Direct effects</th>
<th>Path</th>
<th>B</th>
<th>SE</th>
<th>P value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expectancies to difficulty</td>
<td>a1</td>
<td>0.013</td>
<td>0.039</td>
<td>.743</td>
<td>−0.066 to 0.092</td>
</tr>
<tr>
<td>Expectancies to helpfulness</td>
<td>a2</td>
<td>0.032</td>
<td>0.014</td>
<td>.025</td>
<td>0.004 to 0.060</td>
</tr>
<tr>
<td>Difficulty to offline engagement</td>
<td>b1</td>
<td>0.002</td>
<td>0.052</td>
<td>.976</td>
<td>−0.103 to 0.106</td>
</tr>
<tr>
<td>Helpfulness to offline engagement</td>
<td>b2</td>
<td>0.212</td>
<td>0.147</td>
<td>.153</td>
<td>−0.081 to 0.505</td>
</tr>
<tr>
<td>Expectancies to offline engagement</td>
<td>c</td>
<td>0.016</td>
<td>0.164</td>
<td>.325</td>
<td>−0.017 to 0.049</td>
</tr>
</tbody>
</table>

\(^a R^2=0.219; \ R^2=0.048; \ F_{3,61}=1.025; \ P=.39.\

### Table 6. Summary of model 2: indirect effects.

<table>
<thead>
<tr>
<th>Indirect effects</th>
<th>Boot (^a) effect</th>
<th>Boot SE</th>
<th>Boot LLCI(^b)</th>
<th>Boot ULCI(^c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expectancies to difficulty to offline engagement</td>
<td>0.000</td>
<td>0.003</td>
<td>−0.011</td>
<td>0.004</td>
</tr>
<tr>
<td>Expectancies to helpfulness to offline engagement</td>
<td>0.007</td>
<td>0.007</td>
<td>−0.003</td>
<td>0.026</td>
</tr>
</tbody>
</table>

\(^a\) 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 \(a2\): 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 \(b2\): 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 \(b1\): 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).
Table 7. Summary of model 3: direct effects.

<table>
<thead>
<tr>
<th>Direct effects</th>
<th>Path</th>
<th>B</th>
<th>SE</th>
<th>P value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precontemplation to difficulty</td>
<td>a1</td>
<td>0.012</td>
<td>0.296</td>
<td>.968</td>
<td>−0.579 to 0.603</td>
</tr>
<tr>
<td>Precontemplation to helpfulness</td>
<td>a2</td>
<td>−0.254</td>
<td>0.108</td>
<td>.021</td>
<td>−0.468 to −0.039</td>
</tr>
<tr>
<td>Difficulty to online engagement</td>
<td>b1</td>
<td>1.457</td>
<td>0.610</td>
<td>.020</td>
<td>0.240 to 2.675</td>
</tr>
<tr>
<td>Helpfulness to online engagement</td>
<td>b2</td>
<td>4.047</td>
<td>1.678</td>
<td>.019</td>
<td>0.696 to 7.397</td>
</tr>
<tr>
<td>Precontemplation to online engagement</td>
<td>c'</td>
<td>1.276</td>
<td>1.572</td>
<td>.420</td>
<td>−1.862 to 4.415</td>
</tr>
</tbody>
</table>

*R²=0.392; *R²*=0.154; *F*=3.934; *P*=.01.

Table 8. Summary of model 3: indirect effects.

<table>
<thead>
<tr>
<th>Indirect effects</th>
<th>Boot^a Effect</th>
<th>Boot SE</th>
<th>Boot LLCI^b</th>
<th>Boot ULCI^c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precontemplation to difficulty to online engagement</td>
<td>0.017</td>
<td>0.437</td>
<td>−0.793</td>
<td>0.964</td>
</tr>
<tr>
<td>Precontemplation to helpfulness to online engagement</td>
<td>−1.027</td>
<td>0.650</td>
<td>−2.518</td>
<td>−0.054</td>
</tr>
</tbody>
</table>

^aBoot: statistics for the indirect effects are the result of the bootstrapping method.  
^bLLCI: lower limit 5% CI.  
^cULCI: 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*=2.719; *R²=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 a2: 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 b2: B=0.213; SE 0.104; *P*<.05; 95% CI 0.006-0.420). Finally, indirect effects (Table 10) were not significant.

---

Figure 3. Model 3: mediation model with precontemplation predicting online engagement.
Figure 4. Model 4: mediation model with precontemplation predicting offline engagement.

### Table 9. Summary of model 4a: direct effects.

<table>
<thead>
<tr>
<th>Direct effects</th>
<th>Path</th>
<th>B</th>
<th>SE</th>
<th>P value</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precontemplation to difficulty</td>
<td>$a_1$</td>
<td>-0.073</td>
<td>.277</td>
<td>.793</td>
<td>-0.625 to 0.479</td>
</tr>
<tr>
<td>Precontemplation to helpfulness</td>
<td>$a_2$</td>
<td>-0.239</td>
<td>.106</td>
<td>.027</td>
<td>-0.449 to -0.028</td>
</tr>
<tr>
<td>Difficulty to offline engagement</td>
<td>$b_1$</td>
<td>0.063</td>
<td>.040</td>
<td>.118</td>
<td>-0.016 to 0.142</td>
</tr>
<tr>
<td>Helpfulness to offline engagement</td>
<td>$b_2$</td>
<td>0.213</td>
<td>.104</td>
<td>.044</td>
<td>0.006 to 0.420</td>
</tr>
<tr>
<td>Precontemplation to offline engagement</td>
<td>$c'$</td>
<td>-0.100</td>
<td>.093</td>
<td>.287</td>
<td>-0.285 to 0.086</td>
</tr>
</tbody>
</table>

$a = 0.333; R^2 = 0.111; F_{3,65} = 2.710; P = .05.$

### Table 10. Summary of model 4: indirect effects.

<table>
<thead>
<tr>
<th>Indirect effects</th>
<th>Boot Effect</th>
<th>Boot SE</th>
<th>Boot LLCI</th>
<th>Boot ULCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precontemplation to difficulty to offline engagement</td>
<td>-0.005</td>
<td>0.024</td>
<td>-0.066</td>
<td>0.035</td>
</tr>
<tr>
<td>Precontemplation to helpfulness to offline engagement</td>
<td>-0.051</td>
<td>0.035</td>
<td>-0.131</td>
<td>0.002</td>
</tr>
</tbody>
</table>

$^a$ 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.

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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.

References


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.
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).
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.

<table>
<thead>
<tr>
<th>Condition and age group</th>
<th>Day 1, n</th>
<th>Day 2, n</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Typical development</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-9 years</td>
<td>97 (female: 4, male: 3, not available: 89)</td>
<td>56 (female: 4, male: 2, not available: 50)</td>
</tr>
<tr>
<td>10-14 years</td>
<td>31 (female: 3, male: 3, not available: 25)</td>
<td>17 (female: 0, male: 2, not available: 15)</td>
</tr>
<tr>
<td><strong>Neurodevelopmental disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-9 years</td>
<td>30 (female: 7, male: 6, not available: 17)</td>
<td>16 (female: 5, male: 4, not available: 7)</td>
</tr>
<tr>
<td>10-14 years</td>
<td>27 (female: 3, male: 6, not available: 18)</td>
<td>19 (female: 3, male: 6, not available: 10)</td>
</tr>
</tbody>
</table>

### The Memory Game Interface

All participation in the Memory Game was done web-based using a touch screen tablet device (e.g., 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 Schultz, 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 (\( P < .05, \* \* <.01, \*\*\* <.001; \) Cronbach \( \alpha=.05 \)). Effect sizes between groups were reported as Cohen d (GraphPad). All statistical analyses were run using Prism software.

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, \( P=0.01, d=0.90 \)) (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 Pye 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.

**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.

**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 TD of the 10-14 years old group. (D) RT for PA for individuals with TD of the 10-14 years old group. (E) RT for PA for individuals with NDD of the 5-9 years old group. (F) RT for PA for individuals with TD of the 10-14 years old group. (G) 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.

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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
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

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 β2-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.

Conclusions: Few studies have assessed the 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.
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. Coordinates 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.

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 study 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 and adolescent, respectively. The NVS was then administered separately 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.

Measurement

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 measurement 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).

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**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.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (n=79)</th>
<th>Conventional consent process (n=25)</th>
<th>Interactive multimedia consent video and website (n=54)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adolescent sex, male (vs female), n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interactive multimedia consent video and website</td>
<td>45 (57)</td>
<td>13 (52)</td>
<td>32 (59)</td>
</tr>
<tr>
<td>Conventional consent process</td>
<td>9 (11)</td>
<td>4 (16)</td>
<td>5 (9)</td>
</tr>
<tr>
<td><strong>Adolescent age, median (IQR)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interactive multimedia consent video and website</td>
<td>14 (13-15)</td>
<td>15 (13-16)</td>
<td>14 (13-15)</td>
</tr>
<tr>
<td>Conventional consent process</td>
<td>26 (33)</td>
<td>10 (40)</td>
<td>16 (30)</td>
</tr>
<tr>
<td><strong>Adolescent race, Black (vs non-Black), n (%)</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Interactive multimedia consent video and website</td>
<td>34 (74)</td>
<td>14 (70)</td>
<td>34 (74)</td>
</tr>
<tr>
<td>Conventional consent process</td>
<td>8 (15)</td>
<td>5 (20)</td>
<td>8 (15)</td>
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<tr>
<td><strong>Income (US $), n (%)</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>≤$60,000</td>
<td>48 (73)</td>
<td>14 (70)</td>
<td>34 (74)</td>
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<tr>
<td>&gt;$60,000</td>
<td>18 (27)</td>
<td>6 (30)</td>
<td>12 (26)</td>
</tr>
<tr>
<td>Income missing</td>
<td>13 (16)</td>
<td>5 (20)</td>
<td>8 (15)</td>
</tr>
<tr>
<td><strong>Asthma characteristics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unscheduled health care visit for asthma in prior year (vs none), n (%)</td>
<td>32 (41)</td>
<td>9 (36)</td>
<td>23 (43)</td>
</tr>
<tr>
<td>Age of asthma onset, median (IQR)</td>
<td>2 (1-6)</td>
<td>4 (1-7)</td>
<td>2 (1-5)</td>
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<tr>
<td>Secondary smoke exposure, n (%)</td>
<td>15 (19)</td>
<td>6 (24)</td>
<td>9 (17)</td>
</tr>
<tr>
<td><strong>Questionnaires, median (IQR)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Newest Vital Sign</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adolescent score (range 0-6)a</td>
<td>5 (4-6)</td>
<td>5 (3-6)</td>
<td>5 (4-6)</td>
</tr>
<tr>
<td>Caregiver score (range 0-6)</td>
<td>5 (3-6)</td>
<td>4 (3-6)</td>
<td>5 (3-6)</td>
</tr>
<tr>
<td>Asthma Control Test (range 5-25)b</td>
<td>22 (21-24)</td>
<td>22 (21-23)</td>
<td>22 (22-24)</td>
</tr>
<tr>
<td><strong>Spirometry, median (IQR)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-BD percent predicted forced expiratory volume in 1 second</td>
<td>94 (85-102)</td>
<td>90 (80-97)</td>
<td>95 (85-107)</td>
</tr>
<tr>
<td>Pre-BD percent predicted forced vital capacity</td>
<td>102 (94-108)</td>
<td>102 (96-106)</td>
<td>102 (93-109)</td>
</tr>
<tr>
<td>Peak flow (L)</td>
<td>390 (323-451)</td>
<td>350 (290-425)</td>
<td>398 (343-455)</td>
</tr>
</tbody>
</table>

aNewest 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.

bAsthma Control Test: high scores indicate better health.

cPre-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).

<table>
<thead>
<tr>
<th></th>
<th>Conventional, mean (95% CI)</th>
<th>Web-based, mean (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Caregiver score</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enrollment</td>
<td>42.90 (41.06 to 44.74)</td>
<td>43.20 (41.96 to 44.45)</td>
</tr>
<tr>
<td>End of the study (week 20)</td>
<td>41.08 (39.67 to 42.49)</td>
<td>43.28 (42.33 to 44.23)</td>
</tr>
<tr>
<td>Change from enrollment</td>
<td>−1.65 (−3.10 to −0.19)</td>
<td>0.14 (−0.84 to 1.12)</td>
</tr>
<tr>
<td><strong>Adolescent score</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enrollment</td>
<td>42.26 (39.90 to 44.62)</td>
<td>41.08 (39.48 to 42.69)</td>
</tr>
<tr>
<td>End of the study (week 20)</td>
<td>41.27 (39.29 to 43.25)</td>
<td>41.22 (39.88 to 42.55)</td>
</tr>
<tr>
<td>Change from enrollment</td>
<td>−0.75 (−2.27 to 0.77)</td>
<td>0.16 (−0.86 to 1.18)</td>
</tr>
</tbody>
</table>
Consent comprehension score

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).

After adjustment for variables identified in the exploratory analysis (participant race, unscheduled health care visit, and caregiver NVS score), comprehension with the multimedia 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).

<table>
<thead>
<tr>
<th>Participant characteristics</th>
<th>Outcome: score at enrollment</th>
<th>Caregivers</th>
<th>Adolescents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Estimate (95% CI)</td>
<td>P value</td>
<td>Estimate (95% CI)</td>
</tr>
<tr>
<td>Sex, male (vs female)</td>
<td>−1.10 (−3.17 to 0.97)</td>
<td>.30</td>
<td>−3.51 (−6.09 to −0.94)</td>
</tr>
<tr>
<td>Age (years), anchored at 14 years</td>
<td>0.51 (−0.09 to 1.11)</td>
<td>.09</td>
<td>1.29 (0.56 to 2.03)</td>
</tr>
<tr>
<td>Race, Black (vs non-Black)</td>
<td>−2.83 (−4.93 to −0.72)</td>
<td>.009</td>
<td>−5.87 (−8.39 to −3.35)</td>
</tr>
<tr>
<td>Unscheduled health care visits for asthma in the previous 12 months before enrollment (vs none)</td>
<td>−2.41 (−4.45 to −0.38)</td>
<td>.02</td>
<td>−1.50 (−4.19 to 1.19)</td>
</tr>
<tr>
<td>Secondary smoke exposure</td>
<td>−2.52 (−5.09 to 0.05)</td>
<td>.06</td>
<td>−1.26 (−4.65 to 2.12)</td>
</tr>
<tr>
<td>Age of asthma onset (years)</td>
<td>−0.01 (−0.27 to 0.26)</td>
<td>.97</td>
<td>0.28 (−0.05 to 0.62)</td>
</tr>
<tr>
<td>Per point of caregiver NVS from 0</td>
<td>1.06 (0.49 to 1.64)</td>
<td>&lt;.001</td>
<td>1.14 (0.37 to 1.90)</td>
</tr>
<tr>
<td>Per point of participant NVS from 0</td>
<td>0.70 (0.09 to 1.30)</td>
<td>.03</td>
<td>1.74 (1.03 to 2.45)</td>
</tr>
<tr>
<td>Per point in Asthma Control Test from 0</td>
<td>0.01 (−0.69 to 0.72)</td>
<td>.97</td>
<td>0.20 (−0.71 to 1.10)</td>
</tr>
<tr>
<td>Pre-BDb percent predicted forced expiratory volume in 1 second (per 10% unit difference)</td>
<td>0.01 (−0.74 to 0.76)</td>
<td>.99</td>
<td>0.13 (−0.84 to 1.10)</td>
</tr>
<tr>
<td>Pre-BD percent predicted forced vital capacity (per 10% unit difference)</td>
<td>−0.71 (−1.57 to 0.14)</td>
<td>.10</td>
<td>−0.16 (−1.29 to 0.96)</td>
</tr>
<tr>
<td>Peak flow (per 100 L)</td>
<td>0.49 (−0.55 to 1.53)</td>
<td>.36</td>
<td>0.91 (−0.42 to 2.24)</td>
</tr>
</tbody>
</table>

aNVS: Newest Vital Sign.
bPre-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’Lonergeran 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 consent 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

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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.

References


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

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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.

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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
Parental caregivers were given feedback and coaching sessions for the first month and in subsequent monthly sessions thereafter. 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).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Children with medical complexity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>14 (38)</td>
</tr>
<tr>
<td>Male</td>
<td>23 (62)</td>
</tr>
<tr>
<td><strong>Length of time in complex care program, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;1 year</td>
<td>3 (8)</td>
</tr>
<tr>
<td>1-3 years</td>
<td>9 (24)</td>
</tr>
<tr>
<td>&gt;3 years</td>
<td>25 (68)</td>
</tr>
<tr>
<td><strong>Number of diagnoses, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>1-5</td>
<td>2 (5)</td>
</tr>
<tr>
<td>6-10</td>
<td>19 (51)</td>
</tr>
<tr>
<td>11-15</td>
<td>15 (40)</td>
</tr>
<tr>
<td>&gt;15</td>
<td>1 (3)</td>
</tr>
<tr>
<td><strong>Number of medications, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>1-10</td>
<td>15 (41)</td>
</tr>
<tr>
<td>11-20</td>
<td>19 (51)</td>
</tr>
<tr>
<td>21-30</td>
<td>3 (8)</td>
</tr>
<tr>
<td><strong>Number of technologies, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;5</td>
<td>11 (30)</td>
</tr>
<tr>
<td>5-10</td>
<td>19 (51)</td>
</tr>
<tr>
<td>11-15</td>
<td>7 (19)</td>
</tr>
<tr>
<td><strong>Technology devices a, n</strong></td>
<td></td>
</tr>
<tr>
<td>Feeding technology b</td>
<td>45</td>
</tr>
<tr>
<td>Respiratory technology c</td>
<td>67</td>
</tr>
<tr>
<td>Vascular access device d</td>
<td>4</td>
</tr>
<tr>
<td>Mobility device e</td>
<td>111</td>
</tr>
<tr>
<td>Communication device f</td>
<td>4</td>
</tr>
<tr>
<td>Other invasive technology g</td>
<td>1</td>
</tr>
<tr>
<td><strong>Number of subspecialists h, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;5</td>
<td>1 (3)</td>
</tr>
<tr>
<td>5-10</td>
<td>18 (49)</td>
</tr>
<tr>
<td>11-15</td>
<td>18 (49)</td>
</tr>
</tbody>
</table>

aEach CMC used multiple technologies.
bFeeding technology: devices to obtain nutrition (ie, G-J tube, feeding pump).
cRespiratory technology: devices to assist with and monitor respiratory function (ie, tracheostomy, nebulizer, oxygen, heated high flow, bilevel positive airway pressure cough assist, oximeter).
dVascular access device: devices for venous access (ie, central venous line and peripherally inserted central catheter).
eMobility 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).
fCommunication device: devices used for communication purposes (ie, communication systems, cochlear implants, GO Talk board, iPad, and writing aids).
gOther invasive technology includes vagal nerve stimulator.
hMost used specialist included: neurology, respirology, cardiology, genetics, and hematology.
Table 2. Demographic characteristics of parental caregivers (n=37).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Parental caregivers, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Role</strong></td>
<td></td>
</tr>
<tr>
<td>Mother</td>
<td>30 (81)</td>
</tr>
<tr>
<td>Father</td>
<td>7 (19)</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>20-40</td>
<td>19 (51)</td>
</tr>
<tr>
<td>&gt;40</td>
<td>16 (43)</td>
</tr>
<tr>
<td>Did not answer</td>
<td>2 (6)</td>
</tr>
<tr>
<td><strong>Primary language</strong></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>34 (92)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (8)</td>
</tr>
<tr>
<td><strong>Ethnic background</strong></td>
<td></td>
</tr>
<tr>
<td>Caribbean</td>
<td>3 (8)</td>
</tr>
<tr>
<td>East and South Asian</td>
<td>3 (8)</td>
</tr>
<tr>
<td>European ancestry</td>
<td>25 (67)</td>
</tr>
<tr>
<td>Latin, Central and South American</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>3 (8)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
</tr>
<tr>
<td>Single or divorced</td>
<td>4 (12)</td>
</tr>
<tr>
<td>Married or common law</td>
<td>30 (80)</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>3 (8)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Postsecondary school</td>
<td>21 (57)</td>
</tr>
<tr>
<td>Professional or graduate degree</td>
<td>13 (35)</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>1 (3)</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
</tr>
<tr>
<td>Employed full-time or part-time</td>
<td>19 (51)</td>
</tr>
<tr>
<td>Primary caregiver</td>
<td>12 (32)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>3 (8)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>1 (3)</td>
</tr>
<tr>
<td>**Annual household income (CAD $^a$$)</td>
<td></td>
</tr>
<tr>
<td>0-59,999</td>
<td>9 (24)</td>
</tr>
<tr>
<td>60,000-89,999</td>
<td>6 (16)</td>
</tr>
<tr>
<td>&gt;90,000</td>
<td>18 (49)</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>4 (11)</td>
</tr>
</tbody>
</table>

^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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Items of feedback (n=513), n (%)</th>
<th>Parental caregivers who commented (n=33), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care plan</td>
<td>103 (20.1)</td>
<td>31 (93.9)</td>
</tr>
<tr>
<td>Secure messaging</td>
<td>82 (16)</td>
<td>32 (97)</td>
</tr>
<tr>
<td>Health trackers</td>
<td>67 (13)</td>
<td>31 (93.9)</td>
</tr>
<tr>
<td>Nonparticipation</td>
<td>63 (12.3)</td>
<td>31 (93.9)</td>
</tr>
<tr>
<td>Health library and workbooks</td>
<td>41 (8)</td>
<td>26 (78.8)</td>
</tr>
<tr>
<td>Other feedbackc</td>
<td>38 (7.4)</td>
<td>21 (63.6)</td>
</tr>
<tr>
<td>Care map</td>
<td>34 (6.6)</td>
<td>25 (75.8)</td>
</tr>
<tr>
<td>Live platform coach</td>
<td>32 (6.2)</td>
<td>32 (97)</td>
</tr>
<tr>
<td>Platform invitations</td>
<td>24 (4.7)</td>
<td>24 (72.7)</td>
</tr>
<tr>
<td>Technical issues</td>
<td>12 (2.3)</td>
<td>12 (36.4)</td>
</tr>
<tr>
<td>Schedule</td>
<td>8 (1.6)</td>
<td>8 (24.2)</td>
</tr>
<tr>
<td>Questions about research study</td>
<td>7 (1.4)</td>
<td>7 (21.2)</td>
</tr>
<tr>
<td>Functionality</td>
<td>2 (0.4)</td>
<td>2 (6.1)</td>
</tr>
</tbody>
</table>

aA piece of feedback is defined as a comment from a parental caregiver related to a specific aspect of the platform.  
bParental caregivers who provided comments falling under multiple subcodes were counted for each subcode.  
cOther 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.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Parental feedback</th>
</tr>
</thead>
</table>
| 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 do 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 was 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 customization.

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 ]

References


Abbreviations

C2: Connecting2gether
CCP: Complex Care Program
CMC: children with medical complexity
EMR: electronic medical record
FCC: family-centered care
NCW: NexJ Connected Wellness

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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.

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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.
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, we conducted a diagnostic test for each antigens. 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.

```
Assessed for eligibility (n=7045)

Eligible visits (n=6398)

Visits recorded (n=6241)

Ineligible visits (n=647)

- >2 years of age (n=13)
- Not visiting for routine immunization, and do not have a vaccination card (n=634)

Consent refusal (n=157)
```
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Participants in Pakistan (n=3197)</th>
<th>Participants in Bangladesh (n=1416)</th>
<th>Total (N=4613)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Female, n (%)</strong></td>
<td>1477 (46.2)</td>
<td>701 (49.5)</td>
<td>2178 (47.2)</td>
</tr>
<tr>
<td><strong>Enrollment age (months), n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤6</td>
<td>2423 (75.8)</td>
<td>925 (65.3)</td>
<td>3348 (72.6)</td>
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<td>6 to ≤12</td>
<td>462 (14.5)</td>
<td>235 (16.6)</td>
<td>697 (15.1)</td>
</tr>
<tr>
<td>12 to ≤18</td>
<td>284 (8.9)</td>
<td>242 (17.1)</td>
<td>526 (11.4)</td>
</tr>
<tr>
<td>18 to ≤24</td>
<td>28 (0.9)</td>
<td>14 (1)</td>
<td>42 (0.9)</td>
</tr>
<tr>
<td><strong>Father’s age (years), mean (SD)</strong></td>
<td>32.7 (6.6)</td>
<td>33.3 (5.6)</td>
<td>32.9 (6.3)</td>
</tr>
<tr>
<td><strong>Father's education (years), n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>571 (17.9)</td>
<td>19 (1.3)</td>
<td>590 (12.8)</td>
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<td>1-5</td>
<td>180 (5.6)</td>
<td>169 (11.9)</td>
<td>349 (7.6)</td>
</tr>
<tr>
<td>6-10</td>
<td>1018 (31.8)</td>
<td>289 (20.4)</td>
<td>1307 (28.3)</td>
</tr>
<tr>
<td>11-12</td>
<td>486 (15.2)</td>
<td>249 (17.6)</td>
<td>735 (15.9)</td>
</tr>
<tr>
<td>&gt;13</td>
<td>942 (29.5)</td>
<td>690 (48.7)</td>
<td>1632 (35.4)</td>
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<td><strong>Father’s occupation, n (%)</strong></td>
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<td></td>
<td></td>
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<tr>
<td>Government employee</td>
<td>1048 (32.8)</td>
<td>162 (11.4)</td>
<td>1210 (26.2)</td>
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<td>Self-employed</td>
<td>821 (25.7)</td>
<td>518 (36.6)</td>
<td>1339 (29)</td>
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<td>Daily wage earner</td>
<td>678 (21.2)</td>
<td>40 (2.8)</td>
<td>718 (15.6)</td>
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<td>Private employee</td>
<td>337 (10.5)</td>
<td>689 (48.7)</td>
<td>1026 (22.2)</td>
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<td>Others</td>
<td>313 (9.8)</td>
<td>7 (0.5)</td>
<td>320 (6.9)</td>
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<td><strong>Mother’s age (years), mean (SD)</strong></td>
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<td>6-10</td>
<td>177 (5.5)</td>
<td>176 (12.4)</td>
<td>353 (7.7)</td>
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<td>11-12</td>
<td>1024 (32)</td>
<td>373 (26.3)</td>
<td>1397 (30.3)</td>
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<td>&gt;13</td>
<td>473 (14.8)</td>
<td>395 (27.9)</td>
<td>868 (18.8)</td>
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<tr>
<td><strong>Mother’s occupation, n (%)</strong></td>
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<td></td>
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<tr>
<td>Home maker</td>
<td>2806 (87.8)</td>
<td>1151 (81.3)</td>
<td>3957 (85.8)</td>
</tr>
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<td>Private employee</td>
<td>118 (3.7)</td>
<td>128 (9)</td>
<td>246 (5.3)</td>
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<td>Government employee</td>
<td>115 (3.6)</td>
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<td>Other</td>
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<td>198 (4.3)</td>
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<td><strong>Ethnicity, n (%)</strong></td>
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<td>Gilgiti</td>
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<td>Bangal</td>
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<td>Other</td>
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<td>3 (0.2)</td>
<td>233 (5.1)</td>
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<td><strong>Household income (US $ per month), mean (SD)</strong></td>
<td>267.3 (620.3)</td>
<td>442.8 (453.9)</td>
<td>321.1 (580)</td>
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<td><strong>Enrollment vaccine, n (%)</strong></td>
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<td></td>
<td></td>
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<tr>
<td>BCG</td>
<td>1125 (35.2)</td>
<td>367 (25.9)</td>
<td>1492 (32.3)</td>
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<td>OPV-0</td>
<td>4 (0.1)</td>
<td>N/A</td>
<td>4 (0.1)</td>
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<td>Characteristics</td>
<td>Participants in Pakistan (n=3197)</td>
<td>Participants in Bangladesh (n=1416)</td>
<td>Total (N=4613)</td>
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<tr>
<td>-----------------</td>
<td>----------------------------------</td>
<td>-----------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Penta-1&lt;sup&gt;f,g&lt;/sup&gt;</td>
<td>484 (15.1)</td>
<td>107 (7.6)</td>
<td>591 (12.8)</td>
</tr>
<tr>
<td>Penta-2&lt;sup&gt;b&lt;/sup&gt;</td>
<td>480 (15)</td>
<td>228 (16.1)</td>
<td>708 (15.3)</td>
</tr>
<tr>
<td>Penta-3&lt;sup&gt;i&lt;/sup&gt;</td>
<td>381 (11.9)</td>
<td>247 (17.4)</td>
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<tr>
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<td>294 (9.2)</td>
<td>241 (17)</td>
<td>535 (11.6)</td>
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</table>

**Age at enrollment vaccine (weeks), mean (SD)**

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<th>Participants in Bangladesh</th>
<th>Total</th>
</tr>
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</tr>
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<td>0.2 (0.2)</td>
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<td>0.2 (0.2)</td>
</tr>
<tr>
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<td>9.0 (4.4)</td>
<td>8.2 (7.6)</td>
<td>8.8 (5.2)</td>
</tr>
<tr>
<td>Penta-2&lt;sup&gt;b&lt;/sup&gt;</td>
<td>15.2 (5.8)</td>
<td>12.6 (4.1)</td>
<td>14.4 (5.5)</td>
</tr>
<tr>
<td>Penta-3&lt;sup&gt;i&lt;/sup&gt;</td>
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<td>18.8 (8.5)</td>
<td>20.4 (7.7)</td>
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<td>68.1 (6.6)</td>
<td>67.6 (5.2)</td>
<td>67.9 (6.0)</td>
</tr>
</tbody>
</table>

<sup>a</sup>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.

<sup>b</sup>N/A: not applicable.

<sup>c</sup>BCG: bacille Calmette-Guérin.

<sup>d</sup>OPV: oral polio vaccine.

<sup>e</sup>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.

<sup>f</sup>Penta: pentavalent vaccine.

<sup>g</sup>Administered with PCV-1 and OPV-1 and Rota-1 and IPV-1 vaccines.

<sup>h</sup>Administered with PCV-2 and OPV-2 and Rota-2 vaccine.

<sup>i</sup>Administered with PCV-3 and OPV-3 and IPV-2 vaccine.

<sup>j</sup>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.

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<th>Vaccines</th>
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<th>Bangladesh (n=4920)</th>
<th>Total (n=17,956)(^b)</th>
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<tbody>
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<td></td>
<td>Due as per gold standard, n</td>
<td>Due as per iDSS, n (%)</td>
<td>Vaccinated by vaccinator, n (%)</td>
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<td>Yes</td>
<td>No</td>
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<td>BCG(^c)</td>
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</tr>
<tr>
<td>OPV-0(^d)</td>
<td>1212 (100)</td>
<td>1210 (99.8)</td>
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<tr>
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<td>924 (99.8)</td>
<td>898 (97.2)</td>
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</tr>
<tr>
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<td>896 (97)</td>
<td>28 (3)</td>
</tr>
<tr>
<td>PCV-1(^e)</td>
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<tr>
<td>Rota-1(^h)</td>
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<td>898 (97.2)</td>
<td>26 (2.8)</td>
</tr>
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<td>N/A</td>
<td>N/A</td>
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<td>362 (94.5)</td>
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</tr>
<tr>
<td>M-2(^k)</td>
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<td>208 (99.5)</td>
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</tr>
<tr>
<td>Total</td>
<td>13039 (99.8)</td>
<td>12545 (96.2)</td>
<td>494 (3.8)</td>
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</table>

\(^a\)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.

https://pediatrics.jmir.org/2023/1/e40269
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.
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.

---

### Pakistan (n=4557)

<table>
<thead>
<tr>
<th>Vaccines</th>
<th>TP</th>
<th>FN</th>
<th>FP</th>
<th>TN</th>
<th>ROC (%)</th>
<th>LCL (%)</th>
<th>UCL (%)</th>
<th>Accuracy (%)</th>
<th>Sensitivity</th>
<th>Specificity</th>
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<td>96.67</td>
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<td>3495</td>
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</table>

### Bangladesh (n=1684)

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<th>FP</th>
<th>TN</th>
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<th>LCL (%)</th>
<th>UCL (%)</th>
<th>Accuracy (%)</th>
<th>Sensitivity</th>
<th>Specificity</th>
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</table>

### Cumulative (N=6241)

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<th>FP</th>
<th>TN</th>
<th>ROC (%)</th>
<th>LCL (%)</th>
<th>UCL (%)</th>
<th>Accuracy (%)</th>
<th>Sensitivity</th>
<th>Specificity</th>
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</tr>
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</table>

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.
Table 3. Characteristics of vaccinators interviewed in Pakistan and Bangladesh.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Participants</th>
<th>Bangladesh (n=5)</th>
<th>Pakistan (n=11)</th>
<th>Total (N=16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (9.1)</td>
<td>4 (80)</td>
<td>5 (31.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years of education, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤12 5 (45.5)</td>
<td>N/A^a</td>
<td>5 (31.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;12 6 (54.5)</td>
<td>5 (100)</td>
<td>11 (68.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
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<td>32.2 (11.1)</td>
<td>32.0 (9.3)</td>
<td></td>
</tr>
<tr>
<td>Years of experience, mean (SD)</td>
<td>8.1 (9.8)</td>
<td>6.6 (4.7)</td>
<td>7.6 (8.4)</td>
<td></td>
</tr>
</tbody>
</table>

^aN/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,
saying 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
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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 full 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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22. Success factors for women’s and children’s health: Bangladesh. World Health Organization. 2015. URL: https://apps.who.int/iris/handle/10665/210679


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

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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.

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**KEYWORDS**

asthma; asthma education; pediatric asthma; augmented reality; mobile phone

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**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 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
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
doctor education, the use of smartphone and tablet apps for health, and
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
who approached potential participants for screening. Participants
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
interInterview 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).

Table 1. Participant characteristics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Health care professionals (n=6)</th>
<th>Children with asthma (n=5)</th>
<th>Caregivers of children with asthma (n=5)</th>
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<tr>
<td>Age (years), mean (SD)</td>
<td>34.33 (4.32)</td>
<td>9.8 (1.10)</td>
<td>41.8 (2.79)</td>
</tr>
<tr>
<td>Female sex, n</td>
<td>4</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Mean duration of asthma diagnosis (years)</td>
<td>N/Aa</td>
<td>4.77b</td>
<td>N/A</td>
</tr>
<tr>
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<td>4</td>
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</tr>
<tr>
<td>Highest level of education of caregiver (tertiary:high school)</td>
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<td>N/A</td>
<td>1:1c</td>
</tr>
<tr>
<td>Mean duration of treating asthma for health care professionals (years)</td>
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<tr>
<td>Occupation (medical professionals:nursing:other)</td>
<td>1:1:0</td>
<td>N/A</td>
<td>N/A</td>
</tr>
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</table>

aN/A: not applicable.
bOne unknown.
cOne 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.

<table>
<thead>
<tr>
<th>TFA construct</th>
<th>Illustrative quotes</th>
</tr>
</thead>
</table>
| 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’sunsupervised 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.

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**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

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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 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.

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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 for children.

<table>
<thead>
<tr>
<th>Item</th>
<th>SUS statement</th>
<th>Modified statement for children</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I think that I would like to use this system frequently.</td>
<td>I think that I would like to use this resource often.</td>
</tr>
<tr>
<td>2</td>
<td>I found the system unnecessarily complex.</td>
<td>I found the resource unnecessarily complicated.</td>
</tr>
<tr>
<td>3</td>
<td>I thought the system was easy to use.</td>
<td>I thought the resource was easy to use.</td>
</tr>
<tr>
<td>4</td>
<td>I think that I would need the support of a technical person to use this system.</td>
<td>I think that I would need the support of a technical person to use this resource.</td>
</tr>
<tr>
<td>5</td>
<td>I found the various functions in this system were well integrated.</td>
<td>I found the various functions in this resource were put together well.</td>
</tr>
<tr>
<td>6</td>
<td>I thought there was too much inconsistency in this system.</td>
<td>I thought there were too many differences in this resource.</td>
</tr>
<tr>
<td>7</td>
<td>I would imagine that most people would learn to use this system very quickly.</td>
<td>I imagine that most people would learn to use this resource very quickly.</td>
</tr>
<tr>
<td>8</td>
<td>I found the system very cumbersome to use.</td>
<td>I found the resource very difficult to use.</td>
</tr>
<tr>
<td>9</td>
<td>I felt very confident using the system.</td>
<td>I feel very confident using the resource.</td>
</tr>
<tr>
<td>10</td>
<td>I needed to learn a lot of things before I could get going with this system.</td>
<td>I needed to learn a lot of things before I could get going with this resource.</td>
</tr>
</tbody>
</table>

*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).

### Table 2. Number of participants per round of interviews.

<table>
<thead>
<tr>
<th>Category</th>
<th>First iteration (N=4)</th>
<th>Second iteration (N=6)</th>
<th>Third iteration (N=6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health care professionals, n</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Children with asthma, n</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Caregivers of children with asthma, n</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Sex (males:females)</td>
<td>0:4</td>
<td>1:5</td>
<td>4:2</td>
</tr>
</tbody>
</table>

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.
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:
somewhat 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 really 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]
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.
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 >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”).

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>
<thead>
<tr>
<th>Participant group</th>
<th>SUS, mean (SD)</th>
<th>SUS, median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children with asthma</td>
<td>87.5 (16.96)</td>
<td>95 (60-100)</td>
</tr>
<tr>
<td>Caregivers of children with asthma</td>
<td>85.5 (12.17)</td>
<td>92.5 (70-97.5)</td>
</tr>
<tr>
<td>Health professionals</td>
<td>89.58 (5.34)</td>
<td>87.5 (85-100)</td>
</tr>
</tbody>
</table>

*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 advocacy 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

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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
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.
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.

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

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).
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 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.

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].

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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.

How To Perform Measurements
To use the app easily, please watch the following guide.
For more information, particularly on which newborns this app can and cannot be safely used on, and other important information, please read the Instructions For Use.

Preparations
Take a Pictoral Calibration Card and remove the protection from the sticker on the back.

Place the Card
Place the Pictoral Calibration Card on the chest above the sternum of the newborn. Make sure the sticker holds the card in place. You can place the card sideways on the child if you want.

Move the Camera in Position
Hold the camera straight above the calibration card, approximately 20-30 cm above the child.

Find the Card in the Camera
Match the circle displayed on the phone with the outer circle of the calibration card.

Take Pictures
When the camera is correctly placed, the app will automatically start capturing images.
The app needs six images of good quality - three without flash and three with flash.
If an image is not of good enough quality, the app will automatically recapture that image.

Assess the Results
Based on the bilirubin estimate, perform actions according to national guidelines for follow-up and treatment of neonatal jaundice.
For more information, particularly on which newborns this app can and cannot be safely used on, and other important safety information, please read the Instructions For Use.
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

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**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 values were observed.
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).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Values, mean (SD; range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth weight (g)</td>
<td>3642 (460; 2510-4830)</td>
</tr>
<tr>
<td>Gestational age (weeks)</td>
<td>39.7 (1.4; 37-42)</td>
</tr>
</tbody>
</table>

**Bilirubin levels**

<table>
<thead>
<tr>
<th>µmol/L</th>
<th>Picterus Jaundice Pro</th>
<th>TSB</th>
<th>TcB</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>186.6 (66.5; 1-322)</td>
<td>178.2 (76.5; 13-367)</td>
<td>156.7 (70.4; 0-304)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>mg/dL</th>
<th>Picterus Jaundice Pro</th>
<th>TSB</th>
<th>TcB</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10.9 (3.9; .1-18.8)</td>
<td>10.4 (4.5; 0.8-21.5)</td>
<td>9.2 (4.1; 0-17.8)</td>
</tr>
</tbody>
</table>

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
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%
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 learning opportunities that shape the developing brain [16].

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\textsuperscript{a}.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Full package (n=375), n (%)</th>
<th>Limited package (n=416), n (%)</th>
<th>Control (n=220), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age range (years)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-15</td>
<td>64 (20)</td>
<td>63 (15.1)</td>
<td>11 (5)</td>
</tr>
<tr>
<td>16-19</td>
<td>311 (82.9)</td>
<td>353 (84.9)</td>
<td>209 (95)</td>
</tr>
<tr>
<td><strong>Education level</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary, incomplete</td>
<td>134 (38.7)</td>
<td>163 (39.2)</td>
<td>83 (37.5)</td>
</tr>
<tr>
<td>Primary, completed</td>
<td>38 (10.1)</td>
<td>59 (14.2)</td>
<td>27 (12.3)</td>
</tr>
<tr>
<td>Secondary, incomplete</td>
<td>156 (41.6)</td>
<td>162 (38.9)</td>
<td>88 (40.2)</td>
</tr>
<tr>
<td>Secondary, completed and above</td>
<td>47 (12.5)</td>
<td>32 (7.7)</td>
<td>22 (10.1)</td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Business</td>
<td>8 (2.1)</td>
<td>32 (7.7)</td>
<td>11 (5)</td>
</tr>
<tr>
<td>Casual laborer</td>
<td>6 (1.6)</td>
<td>7 (1.7)</td>
<td>4 (1.6)</td>
</tr>
<tr>
<td>Farming</td>
<td>24 (6.4)</td>
<td>50 (12)</td>
<td>20 (9.3)</td>
</tr>
<tr>
<td>Formal employment</td>
<td>0 (0)</td>
<td>2 (0.5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Housewife</td>
<td>68 (18.1)</td>
<td>72 (17.3)</td>
<td>39 (17.9)</td>
</tr>
<tr>
<td>Student</td>
<td>260 (69.3)</td>
<td>227 (54.6)</td>
<td>136 (61.7)</td>
</tr>
<tr>
<td>Other\textsuperscript{b}</td>
<td>9 (2.4)</td>
<td>26 (6.3)</td>
<td>10 (4.5)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>84 (22.4)</td>
<td>123 (29.6)</td>
<td>58 (26.4)</td>
</tr>
<tr>
<td>Single</td>
<td>291 (77.6)</td>
<td>292 (70.2)</td>
<td>162 (73.6)</td>
</tr>
<tr>
<td>Other\textsuperscript{b}</td>
<td>0 (0)</td>
<td>1 (0.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Source of family income</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agriculture</td>
<td>128 (34.1)</td>
<td>286 (68.8)</td>
<td>115 (52.3)</td>
</tr>
<tr>
<td>Business</td>
<td>195 (52)</td>
<td>75 (18)</td>
<td>75 (34.1)</td>
</tr>
<tr>
<td>Employment</td>
<td>30 (8)</td>
<td>14 (3.4)</td>
<td>12 (5.6)</td>
</tr>
<tr>
<td>Others</td>
<td>22 (5.9)</td>
<td>41 (9.9)</td>
<td>18 (8)</td>
</tr>
<tr>
<td><strong>Religion</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Christian</td>
<td>375 (100)</td>
<td>409 (98.3)</td>
<td>218 (99.1)</td>
</tr>
<tr>
<td>Muslim</td>
<td>0 (0)</td>
<td>7 (1.7)</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td><strong>ANC\textsuperscript{c} attendance at least 1 visit</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>370 (98.7)</td>
<td>396 (95.2)</td>
<td>215 (97.7)</td>
</tr>
<tr>
<td>No</td>
<td>5 (1.3)</td>
<td>20 (4.8)</td>
<td>5 (2.3)</td>
</tr>
</tbody>
</table>

\textsuperscript{a}This includes the number of participants as at recruitment—the intervention groups at baseline and the control group at end line.

\textsuperscript{b}Other includes those who are separated, divorced, or widowed; these were combined since the numbers were very small.

\textsuperscript{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\(^a\).

<table>
<thead>
<tr>
<th>Package</th>
<th>Intervention</th>
<th>Control</th>
<th>Knowledge score, mean (SD)</th>
<th>Participant, n</th>
<th>Knowledge score, mean difference</th>
<th>P value (t test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full package</td>
<td>307</td>
<td>199</td>
<td>9.02 (2.19)</td>
<td></td>
<td>8.01 (2.07)</td>
<td>.01</td>
</tr>
<tr>
<td>Limited package</td>
<td>297</td>
<td>199</td>
<td>8.73 (2.22)</td>
<td></td>
<td>8.01 (2.07)</td>
<td>&lt;.001(^b)</td>
</tr>
</tbody>
</table>

\(^a\)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=.01; full package vs limited package: 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.

<table>
<thead>
<tr>
<th>Score</th>
<th>Full package (n=307), mean (SD)</th>
<th>Control (n=199), mean (SD)</th>
<th>P value</th>
<th>Limited package (n=297), mean (SD)</th>
<th>Control (n=199), mean (SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fine motor</td>
<td>12.97 (4.80)</td>
<td>11.41 (5.09)</td>
<td>&lt;.001(^a)</td>
<td>12.59 (4.02)</td>
<td>11.41 (5.03)</td>
<td>&lt;.001(^a)</td>
</tr>
<tr>
<td>Gross motor</td>
<td>26.55 (9.52)</td>
<td>23.50 (10.60)</td>
<td>.56</td>
<td>27.95 (9.33)</td>
<td>23.50 (10.60)</td>
<td>&lt;.001(^a)</td>
</tr>
<tr>
<td>Language</td>
<td>13.57 (8.20)</td>
<td>13.68 (9.18)</td>
<td>.01(^a)</td>
<td>17.75 (7.91)</td>
<td>13.68 (9.18)</td>
<td>&lt;.001(^a)</td>
</tr>
<tr>
<td>Total DMC III score</td>
<td>53.09 (20.02)</td>
<td>48.59 (23.32)</td>
<td>&lt;.001(^a)</td>
<td>58.29 (19.28)</td>
<td>48.59 (23.32)</td>
<td>.002(^a)</td>
</tr>
</tbody>
</table>

\(^a\)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).
what they would have acquired through home visits or support information and sense of support from the platform, similar to platform, the adolescent mothers were able to access both explanation is since we were using an interactive text messaging infant growth and development outcomes. A possible approach therefore could have higher impact \[44\]. Most of the socioeconomic hardships; any intervention in a convenient depression due to the lack of familial social support and Adolescent mothers are at a very high risk of maternal infant development parameters. One possible reason for this study found improvements in both maternal knowledge and impact on the cognitive development of the infants \[43\]. Our delivered until 6 months post partum in South Africa found no improvement in socio-emotional and language development nutritional parameters \[41\]. A randomized trial in Ethiopia found 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.

### 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

##### 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**

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**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

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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.

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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, 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.

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.](image-url)
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.

<table>
<thead>
<tr>
<th>Participants</th>
<th>Parents (n=25)</th>
<th>Children (n=19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD; range)</td>
<td>32 (2.1; 27-48)</td>
<td>10 (1.7; 7-14)</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>16 (64)</td>
<td>11 (58)</td>
</tr>
<tr>
<td>Male</td>
<td>9 (36)</td>
<td>8 (42)</td>
</tr>
<tr>
<td>Residence, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>14 (56)</td>
<td>13 (68)</td>
</tr>
<tr>
<td>Rural</td>
<td>11 (44)</td>
<td>6 (32)</td>
</tr>
<tr>
<td>Education level, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary school</td>
<td>1 (4)</td>
<td>9 (47)</td>
</tr>
<tr>
<td>College diploma</td>
<td>13 (52)</td>
<td>N/A(^{a})</td>
</tr>
<tr>
<td>Junior college</td>
<td>3 (12)</td>
<td>N/A</td>
</tr>
<tr>
<td>Bachelor’s degree and above</td>
<td>8 (32)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

\(^{a}\)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).

<table>
<thead>
<tr>
<th>Measures</th>
<th>Children (n=19)</th>
<th>Parents/caregivers (n=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scales</td>
<td>Mean (SD)</td>
<td>95% CI</td>
</tr>
<tr>
<td>Attractiveness</td>
<td>1.956 (0.547)</td>
<td>1.710-2.202</td>
</tr>
<tr>
<td>Perspicuity</td>
<td>1.895 (0.668)</td>
<td>1.594-2.195</td>
</tr>
<tr>
<td>Efficiency</td>
<td>1.934 (0.668)</td>
<td>1.710-2.159</td>
</tr>
<tr>
<td>Dependability</td>
<td>1.803 (0.668)</td>
<td>1.567-2.038</td>
</tr>
<tr>
<td>Stimulation</td>
<td>1.776 (0.399)</td>
<td>1.597-1.956</td>
</tr>
<tr>
<td>Novelty</td>
<td>1.711 (0.481)</td>
<td>1.494-1.927</td>
</tr>
</tbody>
</table>

Table 3. The CanSelfMan app's pragmatic and hedonic quality scores.

<table>
<thead>
<tr>
<th>Study groups</th>
<th>Children</th>
<th>Parents/caregivers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attractiveness</td>
<td>1.96</td>
<td>1.85</td>
</tr>
<tr>
<td>Pragmatic quality</td>
<td>1.88</td>
<td>1.84</td>
</tr>
<tr>
<td>Hedonic quality</td>
<td>1.74</td>
<td>1.68</td>
</tr>
</tbody>
</table>

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, Safari 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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24. pCloudy. URL: https://www.pcloudy.com/ [accessed 2023-03-13]

25. User Experience Questionnaire. URL: https://www.ueq-online.org/ [accessed 2022-10-20]


Abbreviations

UEQ: User Experience Questionnaire

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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.

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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 possible 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.

KEYWORDS

children with disabilities; social inclusion; participation; accessibility; leisure; web-based activities; pandemic
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].

<table>
<thead>
<tr>
<th>TDF</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beliefs about capabilities</td>
<td>Question to both service providers and parents:</td>
</tr>
<tr>
<td></td>
<td>• In your opinion, how accessible is the program to individuals with different activity limitations?</td>
</tr>
<tr>
<td></td>
<td>• Parents: what were the main challenges that your child faced in the web-based activities in which your child participated?</td>
</tr>
<tr>
<td>Beliefs about consequences</td>
<td>• Service providers: in an ideal world, what would make this web-based activity more accessible or fully accessible or more inclusive?</td>
</tr>
<tr>
<td>Environmental context and resources</td>
<td>Question to both service providers and parents:</td>
</tr>
<tr>
<td></td>
<td>• Is it free or is there a fee?</td>
</tr>
<tr>
<td></td>
<td>• Requires registration or anyone can join?</td>
</tr>
<tr>
<td></td>
<td>• Is it open to “new” members or only for people who participated before COVID?</td>
</tr>
</tbody>
</table>
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 |
| 1 | 30 | University—postgraduate degree | Recreation therapist |
| 2 | 45 | University degree | Executive director |
| 3 | 52 | ___ | Executive director |
| 4 | 31 | University—postgraduate degree | Teacher; therapist |
| 5 | 43 | University degree | Regional manager |
| 6 | 28 | Some high school education | Program’s coordinator |
| 7 | 57 | University—postgraduate degree | Executive director |
| 8 | 66 | University—postgraduate degree | Executive director |
| 9 | 22 | University degree | Community engagement coordinator |
| 10 | 31 | University—postgraduate degree | Founder; Executive Director |
| 11 | 44 | University degree | Director of Operations |
| 12 | 42 | University degree | Founder; Executive Director |

*Missing data as the participant preferred not to answer the question.

| Table 3. Sociodemographic characteristics of parents and their childrena. |
|---|---|---|---|
| ID | Parent’s age | Education | Annual family income |
| 13 | 45 | University degree | Between CAD $40,000 and CAD $60,000 |
| 14 | 54 | High-school diploma | Between CAD $20,000 and CAD $40,000 |
| 15 | 47 | University degree | ___b |
| 16 | 51 | University degree | Between CAD $60,000 and CAD $80,000 |
| 17 | 43 | Postsecondary or professional degree | Between CAD $40,000 and CAD $60,000 |

*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).

<table>
<thead>
<tr>
<th>Characteristics of programs</th>
<th>Values, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Activity type</strong></td>
<td></td>
</tr>
<tr>
<td>Art</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Music</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Sport</td>
<td>7 (21)</td>
</tr>
<tr>
<td>Camp</td>
<td>3 (9)</td>
</tr>
<tr>
<td>Others</td>
<td>19 (56)</td>
</tr>
<tr>
<td><strong>Age range</strong>a</td>
<td></td>
</tr>
<tr>
<td>Preschool (0-5 years old)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>School age (5-18 years old)</td>
<td>25 (71)</td>
</tr>
<tr>
<td>Young adult (&gt;18 years old)</td>
<td>8 (23)</td>
</tr>
<tr>
<td><strong>Types of disabilities accommodated</strong>a</td>
<td></td>
</tr>
<tr>
<td>Intellectual</td>
<td>3 (7)</td>
</tr>
<tr>
<td>Physical or motor</td>
<td>7 (16)</td>
</tr>
<tr>
<td>Autism spectrum disorder</td>
<td>7 (16)</td>
</tr>
<tr>
<td>Visual</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Hearing</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Behavioral or mental health</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Communication</td>
<td>3 (7)</td>
</tr>
<tr>
<td>Chronic illnesses</td>
<td>4 (9)</td>
</tr>
<tr>
<td>Others</td>
<td></td>
</tr>
<tr>
<td>Attention-deficit hyperactivity disorder</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Cerebral palsy</td>
<td>8 (19)</td>
</tr>
<tr>
<td>Developmental coordination disorder</td>
<td>6 (14)</td>
</tr>
<tr>
<td>Fetal alcohol spectrum disorder</td>
<td>3 (7)</td>
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aSome 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.
Environmental context and resources (TDF\(^a\) domain)

**Accommodations**
- 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**
- Close captioning and sign language for live and prerecorded videos
- 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**
- Family involvement in planning
- Collaboration with community organizations

**Material resources**
- 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)**
- 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

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**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.
References


Abbreviations

TDF: Theoretical Domains Framework
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/m²), 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.

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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 ($\beta=.23$, $P<.001$) and anxiety ($\beta=.07$, $P<.01$) [5]. In particular, video game playing ($\beta=.13$, $P<.001$) and computer use ($\beta=.17$, $P<.001$) were associated with more severe depressive symptoms, and video game playing ($\beta=.11$, $P<.001$) 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

Keys

- video games; obesity; pediatrics; computer games; portable device; teenager; adolescents; health data; BMI; diabetes; high blood pressure; high cholesterol; metabolic disorder

https://pediatrics.jmir.org/2023/1/e44920
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.

<table>
<thead>
<tr>
<th>Duration of video games played (hours/week), median (95% CI)</th>
<th>Quartile of the duration of video games played per week</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of video games played (hours/week), median (95% CI)</td>
<td>1 (n=1986)</td>
<td>2 (n=762)</td>
</tr>
<tr>
<td>Age (years), median (95% CI)</td>
<td>0 (0-0)</td>
<td>1 (1-1)</td>
</tr>
<tr>
<td>Race, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>68.7$^a$</td>
<td>75.0$^b$</td>
</tr>
<tr>
<td>Black or African American</td>
<td>20.4$^a$</td>
<td>15.5$^b$</td>
</tr>
<tr>
<td>American Indian or Native American</td>
<td>1.1$^a$</td>
<td>1.9$^a$</td>
</tr>
<tr>
<td>Asian or Pacific Islander</td>
<td>3.2$^a$</td>
<td>4.0$^a$</td>
</tr>
<tr>
<td>Other</td>
<td>6.5$^a$</td>
<td>3.6$^b$</td>
</tr>
<tr>
<td>Completely urban residence, %</td>
<td>52.1$^a$</td>
<td>44.9$^b$</td>
</tr>
<tr>
<td>Receiving public assistance, %</td>
<td>8.5$^a$</td>
<td>4.2$^b$</td>
</tr>
<tr>
<td>Having enough money for bills, %</td>
<td>81.0$^a$</td>
<td>84.8$^{a,b}$</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Quartile of the duration of video game played per week</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Ate dairy products yesterday</td>
<td></td>
</tr>
<tr>
<td>Did not eat</td>
<td>19.3$^a$</td>
</tr>
<tr>
<td>Ate once</td>
<td>35.0$^a$</td>
</tr>
<tr>
<td>Ate twice or more</td>
<td>45.6$^a$</td>
</tr>
<tr>
<td>Ate fruit or fruit juice yesterday</td>
<td></td>
</tr>
<tr>
<td>Did not eat</td>
<td>23.6$^a$</td>
</tr>
<tr>
<td>Ate once</td>
<td>30.3$^a$</td>
</tr>
<tr>
<td>Ate twice or more</td>
<td>46.2$^a$</td>
</tr>
<tr>
<td>Ate vegetables yesterday</td>
<td></td>
</tr>
<tr>
<td>Did not eat</td>
<td>32.5$^a$</td>
</tr>
<tr>
<td>Ate once</td>
<td>39.1$^a$</td>
</tr>
<tr>
<td>Ate twice or more</td>
<td>28.4$^a$</td>
</tr>
<tr>
<td>Ate bread, pasta, or rice yesterday</td>
<td></td>
</tr>
<tr>
<td>Did not eat</td>
<td>8.9$^a$</td>
</tr>
<tr>
<td>Ate once</td>
<td>31.2$^a$</td>
</tr>
<tr>
<td>Ate twice or more</td>
<td>59.9$^a$</td>
</tr>
<tr>
<td>Ate pastry products yesterday</td>
<td></td>
</tr>
<tr>
<td>Did not eat</td>
<td>50.7$^a$</td>
</tr>
<tr>
<td>Ate once</td>
<td>30.6$^a$</td>
</tr>
<tr>
<td>Ate twice or more</td>
<td>18.7$^a$</td>
</tr>
<tr>
<td>Regular cigarette smoking</td>
<td>22.0$^a$</td>
</tr>
<tr>
<td>Drink alcohol &gt;2-3 times</td>
<td>59.4$^a$</td>
</tr>
<tr>
<td>Drug use</td>
<td>29.0$^a$</td>
</tr>
<tr>
<td>Participation in any sports-related clubs at school</td>
<td>100.0</td>
</tr>
<tr>
<td>Days or week of physical education classes</td>
<td></td>
</tr>
<tr>
<td>0 days</td>
<td>43.7$^a$</td>
</tr>
<tr>
<td>1 day</td>
<td>1.5$^a$</td>
</tr>
<tr>
<td>2 days</td>
<td>5.4$^a$</td>
</tr>
<tr>
<td>3 days</td>
<td>9.6$^a$</td>
</tr>
<tr>
<td>4 days</td>
<td>1.7$^a$</td>
</tr>
<tr>
<td>5 days</td>
<td>38.0$^a$</td>
</tr>
</tbody>
</table>

$^c$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/m²), 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.

<table>
<thead>
<tr>
<th>Quartile of the duration of video game played per week</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (n=1986)</td>
<td>2 (n=672)</td>
</tr>
<tr>
<td>BMI (kg/m²), median (95% CI)</td>
<td>28.4 (28.2-29.1)^a</td>
</tr>
<tr>
<td>BMI &gt;30 kg/m², %</td>
<td>42.8^a</td>
</tr>
<tr>
<td>Any one metabolic disorder, %</td>
<td>54.2^a</td>
</tr>
<tr>
<td>Ever diagnosed with diabetes, %</td>
<td>5.5^a</td>
</tr>
<tr>
<td>Ever diagnosed with high BP, %</td>
<td>16.8^a</td>
</tr>
<tr>
<td>Ever diagnosed with hyperlipidemia, %</td>
<td>16.6^a</td>
</tr>
<tr>
<td>Ever diagnosed with depression, %</td>
<td>26.8^a</td>
</tr>
<tr>
<td>Ever diagnosed with eating disorder, %</td>
<td>2.2^a</td>
</tr>
</tbody>
</table>

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).

<table>
<thead>
<tr>
<th>Diagnosis and duration of video game use (hours/week)</th>
<th>Model 1</th>
<th>Model 2</th>
<th>Model 3</th>
<th>Model 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Any one of the metabolic disorders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quartile 1</td>
<td>1.000</td>
<td>1.000</td>
<td>1.000</td>
<td>1.000</td>
</tr>
<tr>
<td>Quartile 2, OR (95% CI)</td>
<td>0.871  (0.731-1.038)</td>
<td>0.897  (0.745-1.080)</td>
<td>0.845  (0.692-1.031)</td>
<td>1.348  (1.087-1.671)</td>
</tr>
<tr>
<td>Quartile 3, OR (95% CI)</td>
<td>0.945  (0.797-1.121)</td>
<td>0.963  (0.802-1.155)</td>
<td>1.015  (0.833-1.237)</td>
<td>1.111  (0.879-1.404)</td>
</tr>
<tr>
<td>Quartile 4, OR (95% CI)</td>
<td>1.287  (1.090-1.519)</td>
<td>1.315  (1.094-1.580)</td>
<td>1.240  (1.018-1.510)</td>
<td>0.941  (0.735-1.205)</td>
</tr>
<tr>
<td>P value</td>
<td>.001</td>
<td>.002</td>
<td>.03</td>
<td>.70</td>
</tr>
<tr>
<td>R²</td>
<td>0.005</td>
<td>0.017</td>
<td>0.013</td>
<td>0.063</td>
</tr>
<tr>
<td>Continuous, OR (95% CI)</td>
<td>1.014  (1.004-1.025)</td>
<td>1.016  (1.005-1.028)</td>
<td>1.015  (1.003-1.028)</td>
<td>1.012  (0.998-1.026)</td>
</tr>
<tr>
<td>P value</td>
<td>.006</td>
<td>.005</td>
<td>.01</td>
<td>.09</td>
</tr>
<tr>
<td>R²</td>
<td>0.003</td>
<td>0.015</td>
<td>0.024</td>
<td>0.060</td>
</tr>
<tr>
<td><strong>Obesity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quartile 1</td>
<td>1.000</td>
<td>1.000</td>
<td>1.000</td>
<td>1.000</td>
</tr>
<tr>
<td>Quartile 2, OR (95% CI)</td>
<td>0.792  (0.660-0.950)</td>
<td>0.856  (0.706-1.037)</td>
<td>0.818  (0.664-1.007)</td>
<td>0.736  (0.594-0.911)</td>
</tr>
<tr>
<td>Quartile 3, OR (95% CI)</td>
<td>0.831  (0.697-0.990)</td>
<td>0.871  (0.722-1.050)</td>
<td>0.892  (0.729-1.092)</td>
<td>0.857  (0.679-1.083)</td>
</tr>
<tr>
<td>Quartile 4, OR (95% CI)</td>
<td>1.189  (1.008-1.403)</td>
<td>1.319  (1.098-1.585)</td>
<td>1.263  (1.037-1.539)</td>
<td>1.144  (0.897-1.460)</td>
</tr>
<tr>
<td>P value</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>.002</td>
<td>.88</td>
</tr>
<tr>
<td>R²</td>
<td>0.006</td>
<td>0.014</td>
<td>0.021</td>
<td>0.076</td>
</tr>
<tr>
<td>Continuous, OR (95% CI)</td>
<td>1.013  (1.003-1.023)</td>
<td>1.019  (1.008-1.030)</td>
<td>1.017  (1.005-1.029)</td>
<td>1.016  (1.003-1.029)</td>
</tr>
<tr>
<td>P value</td>
<td>.009</td>
<td>.001</td>
<td>.004</td>
<td>.02</td>
</tr>
<tr>
<td>R²</td>
<td>0.002</td>
<td>0.011</td>
<td>0.019</td>
<td>0.073</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quartile 1</td>
<td>1.000</td>
<td>1.000</td>
<td>1.000</td>
<td>1.000</td>
</tr>
<tr>
<td>Quartile 2, OR (95% CI)</td>
<td>0.792  (0.660-0.950)</td>
<td>0.856  (0.706-1.037)</td>
<td>0.818  (0.664-1.007)</td>
<td>1.155  (0.620-2.152)</td>
</tr>
<tr>
<td>Quartile 3, OR (95% CI)</td>
<td>0.831  (0.697-0.990)</td>
<td>0.871  (0.722-1.050)</td>
<td>0.892  (0.729-1.092)</td>
<td>1.278  (0.806-2.026)</td>
</tr>
<tr>
<td>Quartile 4, OR (95% CI)</td>
<td>1.189  (1.008-1.403)</td>
<td>1.319  (1.098-1.585)</td>
<td>1.263  (1.037-1.539)</td>
<td>1.356  (0.823-2.235)</td>
</tr>
<tr>
<td>P value</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
<td>.002</td>
<td>.46</td>
</tr>
<tr>
<td>R²</td>
<td>0.006</td>
<td>0.014</td>
<td>0.021</td>
<td>0.023</td>
</tr>
<tr>
<td>Continuous, OR (95% CI)</td>
<td>1.015  (0.999-1.031)</td>
<td>1.020  (1.004-1.037)</td>
<td>1.019  (1.002-1.037)</td>
<td>1.011  (0.991-1.031)</td>
</tr>
<tr>
<td>P value</td>
<td>.06</td>
<td>.02</td>
<td>.03</td>
<td>.29</td>
</tr>
<tr>
<td>R²</td>
<td>0.002</td>
<td>0.007</td>
<td>0.008</td>
<td>0.022</td>
</tr>
<tr>
<td><strong>High BP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quartile 1</td>
<td>1.000</td>
<td>1.000</td>
<td>1.000</td>
<td>1.000</td>
</tr>
<tr>
<td>Quartile 2, OR (95% CI)</td>
<td>1.229  (0.983-1.537)</td>
<td>1.178  (0.926-1.499)</td>
<td>1.158  (0.892-1.504)</td>
<td>1.114  (0.827-1.502)</td>
</tr>
<tr>
<td>Quartile 3, OR (95% CI)</td>
<td>1.372  (1.109-1.698)</td>
<td>1.319  (1.048-1.661)</td>
<td>1.419  (1.108-1.817)</td>
<td>1.291  (0.924-1.806)</td>
</tr>
<tr>
<td>Quartile 4, OR (95% CI)</td>
<td>1.432  (1.169-1.755)</td>
<td>1.217  (0.967-1.531)</td>
<td>1.145  (0.891-1.471)</td>
<td>0.969  (0.723-1.289)</td>
</tr>
<tr>
<td>P value</td>
<td>.001</td>
<td>.09</td>
<td>.05</td>
<td>.92</td>
</tr>
<tr>
<td>R²</td>
<td>0.006</td>
<td>0.023</td>
<td>0.027</td>
<td>0.047</td>
</tr>
<tr>
<td>Continuous, OR (95% CI)</td>
<td>1.013  (1.002-1.024)</td>
<td>1.007  (0.995-1.019)</td>
<td>1.006  (0.993-1.019)</td>
<td>1.002  (0.982-1.023)</td>
</tr>
<tr>
<td>P value</td>
<td>.01</td>
<td>.27</td>
<td>.38</td>
<td>.84</td>
</tr>
<tr>
<td>R²</td>
<td>0.002</td>
<td>0.021</td>
<td>0.024</td>
<td>0.044</td>
</tr>
</tbody>
</table>
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/m²; 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/m². It is estimated that the odds of developing type 2 diabetes per unit increase in BMI (kg/m²) 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 their categorization of video game use, quartile 1 included all
respondents who reported that they did not play video games at
enrollment. This approximately represents 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
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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 ]
References


Abbreviations

Add Health: Adolescent to Adult Health
BP: blood pressure
CVD: cardiovascular disease
OR: odds ratio
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.

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(page number not for citation purposes)
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, Tumbir, 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 as asked participant to identify their 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 Latin
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).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>49 (48.5)</td>
</tr>
<tr>
<td>Female</td>
<td>49 (48.5)</td>
</tr>
<tr>
<td>Nonbinary</td>
<td>3 (3.0)</td>
</tr>
<tr>
<td><strong>Age, mean (SD)</strong></td>
<td>16.4 (1.3)</td>
</tr>
<tr>
<td><strong>Race and ethnicity</strong>&lt;sup&gt;a&lt;/sup&gt;, n (%)</td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latin</td>
<td>79 (79.0)</td>
</tr>
<tr>
<td>Non-Hispanic Black or African American</td>
<td>12 (12.0)</td>
</tr>
<tr>
<td>Non-Hispanic Asian</td>
<td>3 (3.0)</td>
</tr>
<tr>
<td>Non-Hispanic other or multiple races</td>
<td>6 (6.0)</td>
</tr>
<tr>
<td><strong>State of residence</strong>&lt;sup&gt;b&lt;/sup&gt;, n (%)</td>
<td></td>
</tr>
<tr>
<td>California</td>
<td>63 (63.4)</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>28 (28.3)</td>
</tr>
<tr>
<td>Other states</td>
<td>8 (8.1)</td>
</tr>
<tr>
<td><strong>Social media usage frequency, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Once per day or more</td>
<td>89 (88.1)</td>
</tr>
<tr>
<td>Less than once per day</td>
<td>8 (7.9)</td>
</tr>
<tr>
<td><strong>BMI</strong>&lt;sup&gt;c&lt;/sup&gt;, mean (SD)</td>
<td>24.6 (5.2)</td>
</tr>
<tr>
<td>Underweight or healthy</td>
<td>55 (56.7)</td>
</tr>
<tr>
<td>Overweight</td>
<td>25 (25.8)</td>
</tr>
<tr>
<td>Obese</td>
<td>17 (17.5)</td>
</tr>
<tr>
<td><strong>Health behaviors</strong></td>
<td></td>
</tr>
<tr>
<td>Number of days engaged in moderate to vigorous physical activity at least 60 minutes per day over the past 7 days, mean (SD)</td>
<td>4.1 (2.2)</td>
</tr>
<tr>
<td>Engaged in daily moderate to vigorous physical activity at least 60 minutes per day, n (%)</td>
<td>27 (26.7)</td>
</tr>
<tr>
<td>Number of fruit and vegetable servings consumed per day, mean (SD)</td>
<td>4.3 (2.5)</td>
</tr>
<tr>
<td>Consumed at least 5 servings of fruits and vegetables on a typical day over the past 7 days, n (%)</td>
<td>44 (43.6)</td>
</tr>
<tr>
<td>Number of sugar-sweetened beverage servings consumed per day over past 7 days, n (%)</td>
<td>1.8 (1.4)</td>
</tr>
<tr>
<td>Consumed 0 or 1 servings of sugar-sweetened beverages per day on a typical day over the past 7 days, n (%)</td>
<td>54 (53.5)</td>
</tr>
<tr>
<td>Screen time (hours per day) over the past 7 days, mean (SD)</td>
<td>4.4 (2.8)</td>
</tr>
<tr>
<td>Hours slept per night on a typical school night over the past 7 days, mean (SD)</td>
<td>7.2 (1.3)</td>
</tr>
<tr>
<td>Slept at least 8 hours per night on a typical school night over the past 7 days, n (%)</td>
<td>39 (38.6)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Race or ethnicity information was missing for 1 respondent.

<sup>b</sup>State of residence was missing for 2 respondents.

<sup>c</sup>BMIs were 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).

<table>
<thead>
<tr>
<th>Platform</th>
<th>Ever used platform (N=101), n (%)</th>
<th>Most used platform (N=93), n (%)</th>
<th>Preferred platform for advice on health behaviors (N=101), n (%)</th>
<th>Preferred platform to connect with others (N=100), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TikTok</td>
<td>80 (80.2)</td>
<td>38 (40.9)</td>
<td>56 (55.4)</td>
<td>44 (44.0)</td>
</tr>
<tr>
<td>Instagram</td>
<td>72 (71.3)</td>
<td>16 (17.2)</td>
<td>17 (16.8)</td>
<td>22 (22.0)</td>
</tr>
<tr>
<td>YouTube</td>
<td>70 (69.3)</td>
<td>7 (7.5)</td>
<td>2 (2.0)</td>
<td>4 (4.0)</td>
</tr>
<tr>
<td>Snapchat</td>
<td>65 (64.4)</td>
<td>11 (11.8)</td>
<td>4 (4.0)</td>
<td>7 (7.0)</td>
</tr>
<tr>
<td>Twitter</td>
<td>41 (40.6)</td>
<td>8 (8.6)</td>
<td>10 (9.9)</td>
<td>8 (8.0)</td>
</tr>
<tr>
<td>Pinterest</td>
<td>35 (34.7)</td>
<td>3 (3.2)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Facebook</td>
<td>32 (31.7)</td>
<td>6 (6.5)</td>
<td>6 (5.9)</td>
<td>10 (10.0)</td>
</tr>
<tr>
<td>Reddit</td>
<td>17 (16.8)</td>
<td>2 (2.2)</td>
<td>1 (1.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Tumblr</td>
<td>3 (2.97)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (1.0)</td>
</tr>
<tr>
<td>Other or none</td>
<td>N/A</td>
<td>2 (2.2)</td>
<td>5 (5.0)</td>
<td>4 (4.0)</td>
</tr>
</tbody>
</table>

* 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 overweight 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).

<table>
<thead>
<tr>
<th>Themes</th>
<th>Illustrative quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred social medial platform (overall)</strong></td>
<td></td>
</tr>
</tbody>
</table>
| 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;      | • “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.” |
<p>| Instagram for live engagement               |                                                                                                                                                                                                                                        |</p>
<table>
<thead>
<tr>
<th>Themes</th>
<th>Illustrative quotes</th>
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| 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'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] TikTok…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 encouraging.”  
  • “…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…”  
  • “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'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.”                                                                 |
| 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). |
| 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 recent 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_v61e43961_app1.docx ]

**References**


https://pediatrics.jmir.org/2023/1/e43961


Abbreviations

BGC: Massachusetts Alliance of Boys & Girls Clubs
SSB: sugar-sweetened beverage
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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.

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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 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, 68%), while 3 (12%) 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; adjunt 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 ]

References


Abbreviations

**PRISMA:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses

**SES:** socioeconomic status
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.

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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 (e.g., child and parent) at their home location.

**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 at 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.

<table>
<thead>
<tr>
<th>Participant characteristics</th>
<th>Participants (N=12), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parent age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>30-49</td>
<td>9 (75)</td>
</tr>
<tr>
<td>50-64</td>
<td>3 (25)</td>
</tr>
<tr>
<td><strong>Parent gender</strong></td>
<td></td>
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<tr>
<td>Male</td>
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</tr>
<tr>
<td>Female</td>
<td>12 (100)</td>
</tr>
<tr>
<td><strong>Audiology care setting</strong></td>
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</tr>
<tr>
<td>Private practice</td>
<td>2 (17)</td>
</tr>
<tr>
<td>Hospital</td>
<td>4 (33)</td>
</tr>
<tr>
<td>College or University</td>
<td>8 (67)</td>
</tr>
<tr>
<td>Mobile clinic</td>
<td>1 (8)</td>
</tr>
<tr>
<td><strong>Technology owned</strong></td>
<td></td>
</tr>
<tr>
<td>Smartphone</td>
<td>12 (100)</td>
</tr>
<tr>
<td>Tablet</td>
<td>10 (83)</td>
</tr>
<tr>
<td>Desktop</td>
<td>5 (36)</td>
</tr>
<tr>
<td>Laptop</td>
<td>12 (100)</td>
</tr>
<tr>
<td><strong>Computer knowledge level</strong></td>
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</tr>
<tr>
<td>Beginner</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Average</td>
<td>8 (67)</td>
</tr>
<tr>
<td>Advanced</td>
<td>3 (25)</td>
</tr>
<tr>
<td>Expert</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Ability to use smartphones or tablets</strong></td>
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</tr>
<tr>
<td>Beginner</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Average</td>
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<tr>
<td>Advanced</td>
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<tr>
<td><strong>Ability to download “apps” on a smartphone or tablet</strong></td>
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<td>10 (83)</td>
</tr>
<tr>
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</tr>
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<td>Female</td>
<td>4 (33)</td>
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Participant characteristics

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<th>Participants (N=12), n (%)</th>
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<tr>
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</table>

<table>
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<tr>
<th>Child-led technologies</th>
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<tbody>
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<td>8 (57)</td>
</tr>
<tr>
<td>Tablet</td>
<td>11 (92)</td>
</tr>
<tr>
<td>Desktop</td>
<td>4 (33)</td>
</tr>
<tr>
<td>Laptop</td>
<td>10 (83)</td>
</tr>
</tbody>
</table>

**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].

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...”

<table>
<thead>
<tr>
<th>Cluster</th>
<th>Overall subthemes</th>
<th>Example statements</th>
</tr>
</thead>
</table>
| 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.

<table>
<thead>
<tr>
<th>Cluster</th>
<th>Statements, n</th>
<th>Importance values, mean (SD; range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to timely, consistent care</td>
<td>22</td>
<td>4 (0.51; 3.1-4.9)</td>
</tr>
<tr>
<td>Technology considerations</td>
<td>24</td>
<td>3.93 (0.57; 2.2-4.7)</td>
</tr>
<tr>
<td>Convenience</td>
<td>13</td>
<td>3.71 (0.68; 2.3-4.6)</td>
</tr>
<tr>
<td>Child engagement</td>
<td>23</td>
<td>3.65 (0.69; 2.6-4.8)</td>
</tr>
<tr>
<td>Cost (financial and otherwise)</td>
<td>11</td>
<td>3.55 (0.67; 1.8-4.2)</td>
</tr>
<tr>
<td>Partnership considerations</td>
<td>14</td>
<td>3.41 (0.96; 1.3-4.7)</td>
</tr>
</tbody>
</table>

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...
audiolist, 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 parents 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.

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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.

References


37. Allen L, O'Connell A, Kiermer V. How can we ensure visibility and diversity in research contributions? How the Contributor Role Taxonomy (CRediT) is helping the shift from authorship to contributorship. Learn Publ 2019;32(1):71-74 [FREE Full text]

**Abbreviations**

CM: concept mapping
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 attended during the survey period was evaluated and compared with 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.

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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 with only familiar people.
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 chronic 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 Universitäts Essen
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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
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.

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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] 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?”

https://pediatrics.jmir.org/2023/1/e42378

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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.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Screened (n=45)</th>
<th>Interviewed (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>16.2 (1.2)</td>
<td>15.7 (1.1)</td>
</tr>
<tr>
<td><strong>Gender identity</strong>, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transmale or male</td>
<td>30 (62.5)</td>
<td>11 (73.3)</td>
</tr>
<tr>
<td>Transfemale or female</td>
<td>11 (22.9)</td>
<td>3 (20.0)</td>
</tr>
<tr>
<td>Nonbinary</td>
<td>14 (29.2)</td>
<td>6 (40.0)</td>
</tr>
<tr>
<td>Genderqueer</td>
<td>5 (10.4)</td>
<td>3 (20.0)</td>
</tr>
<tr>
<td>Genderfluid</td>
<td>2 (4.2)</td>
<td>2 (13.3)</td>
</tr>
<tr>
<td>Gender questioning</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Gender nonconforming</td>
<td>3 (6.3)</td>
<td>3 (20.0)</td>
</tr>
<tr>
<td>Agender</td>
<td>4 (8.3)</td>
<td>1 (6.7)</td>
</tr>
<tr>
<td>Demigender</td>
<td>4 (8.3)</td>
<td>2 (13.3)</td>
</tr>
<tr>
<td>Gender variant</td>
<td>1 (2.1)</td>
<td>1 (6.7)</td>
</tr>
<tr>
<td>Androgyne</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Two spirit (or other identity of indigenous origin)</td>
<td>1 (2.1)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Cismale</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Cisfemale</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Bigender</td>
<td>2 (4.2)</td>
<td>1 (6.7)</td>
</tr>
<tr>
<td>&gt;1 gender identity (range: 1-8)</td>
<td>15 (33.3)</td>
<td>5 (33.3)</td>
</tr>
<tr>
<td><strong>Ethnicity or race</strong>, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>9 (18.8)</td>
<td>2 (13.3)</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>2 (4.2)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Asian</td>
<td>5 (10.4)</td>
<td>2 (13.3)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>3 (6.3)</td>
<td>1 (6.7)</td>
</tr>
<tr>
<td>Native Hawaiian or Pacific Islander</td>
<td>2 (4.2)</td>
<td>1 (6.7)</td>
</tr>
<tr>
<td>White</td>
<td>37 (77.1)</td>
<td>13 (86.7)</td>
</tr>
<tr>
<td><strong>Distance to clinic</strong>, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤30 minutes</td>
<td>10 (20.8)</td>
<td>5 (33.3)</td>
</tr>
<tr>
<td>31 minutes to 1 hour</td>
<td>25 (52.1)</td>
<td>9 (60.0)</td>
</tr>
<tr>
<td>1 to 2 hours</td>
<td>4 (8.3)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>2 to 3 hours</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>3 to 4 hours</td>
<td>2 (4.2)</td>
<td>1 (6.7)</td>
</tr>
<tr>
<td>&gt;4 hours</td>
<td>2 (4.2)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>First visit</strong>, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In person</td>
<td>29 (60.4)</td>
<td>12 (80.0)</td>
</tr>
<tr>
<td>Telemedicine</td>
<td>14 (29.2)</td>
<td>3 (20.0)</td>
</tr>
<tr>
<td>Parental support for transition (mean; 1-10)</td>
<td>8.2 (2.1)</td>
<td>8.5 (1.9)</td>
</tr>
<tr>
<td>Parent at telemedicine visit, n (%)</td>
<td>38 (79.2)</td>
<td>12 (80.0)</td>
</tr>
</tbody>
</table>

*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>
<thead>
<tr>
<th>Themes and subthemes</th>
<th>Quotations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advantages</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Convenience (n=13, 87%) | "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."
| Travel time | "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."
| User-friendly | "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."
| Comfort (n=10, 67%) | "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."
| Own environment | "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."
| Avoiding COVID-19 | "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."
| Disadvantages |            |
| Technical issues (n=9, 60%) | "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."
| Bad connection | "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."
| 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."
| Impersonal | "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."
Participants preferred telemedicine visits, with 3 (60%) indicating wanting their first visit to the gender clinic to be in person. Regarding the first visit, participants preferred in-person visits, as seen in a quote from a study participant illustrating this preference: "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 your end it's private but also like, on your end, you can be anywhere." Interestingly, of the 5 youth who preferred in-person visits, 3 (60%) indicated wanting their visits, they preferred telemedicine. In fact, of the 5 youth who preferred in-person visits, 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 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.

<table>
<thead>
<tr>
<th>Themes</th>
<th>Visit description and quotations</th>
<th>In-person</th>
<th>Telemedicine</th>
</tr>
</thead>
</table>
| 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

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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.

References


15. Zoom Video Communications. URL: https://zoom.us/ [accessed 2023-02-07]


Abbreviations

REDCap: Research Electronic Data Capture
TGD: transgender and gender diverse
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.
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 non-telehealth 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 non-telehealth 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 non-telehealth 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 non-telehealth services, such as in-person visits, were included. Studies comparing telehealth services and non-telehealth 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 non-telehealth 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 for the outcomes were “patient satisfaction,” “satisfaction,” “perception,” and “attitude.” Synonyms for the type of care and population included “pediatric,” “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*,” “adolescent*,” “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.
Table 1. Location, number, age, and condition among participants in the 14 included studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Number of participants or number of visits</th>
<th>Mean or median age of participants or other information provided on age</th>
<th>Pediatric health condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corona et al [14], 2021</td>
<td>United States</td>
<td>• Total: 95 patients • Video visit patients: 46 • In-person visit patients: 49</td>
<td>Video visits patient mean age: 28.17 months • In-person visits patient mean age: 27.96 months</td>
<td>Autism spectrum disorder</td>
</tr>
<tr>
<td>Hoi et al [15], 2022</td>
<td>United States</td>
<td>• Total: 21,592 visits • Telemedicine visits: 2051 • In-person visits: 19,541</td>
<td>Telemedicine visits patient mean age: 7.2 years • In-person visits patient mean age: 7.3 years</td>
<td>Otolaryngology</td>
</tr>
<tr>
<td>Holzman et al [16], 2021</td>
<td>United States</td>
<td>• Total: 153 patients • Telemedicine visit patients: 51 • In-person visit patients: 102</td>
<td>Telemedicine visits patient median age: 8.0 years • In-person visits patient median age: 7.5 years</td>
<td>Urology</td>
</tr>
<tr>
<td>Johnson et al [17], 2020</td>
<td>United States</td>
<td>• Total: 15,562 visits • Telemedicine visits: 11,192 • In-person visits: 4370</td>
<td>Not stated</td>
<td>A variety of pediatric specialties, such as attention-deficit hyperactivity disorder, adolescent health, developmental and behavioral, cystic fibrosis</td>
</tr>
<tr>
<td>Katz et al [18], 2021</td>
<td>United States</td>
<td>• Total: 150 patients • Telemedicine visit patients: 23 • In-person patients: 127</td>
<td>Telemedicine visits patient age distribution: • &lt;1: 0% • 1-4: 17.39% • 5-10: 39.13% • 11-14: 30.43% • ≥15: 13.04% • In-person visit patient age distribution: • &lt;1: 29.13% • 1-4: 33.07% • 5-10: 25.2% • 11-14: 8.67% • ≥15: 3.94%</td>
<td>Primary care</td>
</tr>
<tr>
<td>Kennelly et al [19], 2021</td>
<td>United States</td>
<td>• Total: 1514 visits • Telemedicine visits: 688 • In-person visits: 826</td>
<td>Not stated</td>
<td>Development pediatrics and autism</td>
</tr>
<tr>
<td>Love et al [20], 2022</td>
<td>United States</td>
<td>• Total: 232 • Telemedicine visit patients: 156 • In-person visit patients: 76</td>
<td>Telemedicine visits patient age distribution: • &lt;1: 6% • 1-10: 44% • ≥10: 50% • In-person visit patient age distribution: • &lt;1: 1% • 1-10: 51% • ≥10: 47%</td>
<td>Pediatric gastroenterology</td>
</tr>
<tr>
<td>Mahmoud et al [21], 2022</td>
<td>Egypt</td>
<td>• Total: 1928 patients • Telemedicine visit patients: 1056 • In-person visit patients: 874</td>
<td>Telemedicine visits patient mean age: 1.2 • In-person visits patient mean age: 1.6</td>
<td>Ambulatory surgery</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Number of participants or number of visits</td>
<td>Mean or median age of participants or other information provided on age</td>
<td>Pediatric health condition</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-----------------</td>
<td>----------------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>Marques et al [22], 2020</td>
<td>United States</td>
<td>Total: 9392 visits • Telemedicine visits: 2960 • In-person visits: 6362</td>
<td>• Not stated</td>
<td>Ambulatory care</td>
</tr>
<tr>
<td>McCoy et al [23], 2022</td>
<td>United States</td>
<td>Total: 172 patients • Telemedicine visit patients: 59 • In-person visit patients: 113</td>
<td>• Telemedicine visits patient mean age: 4.99 • In-person visits patient mean age: 6.15</td>
<td>Otolaryngology</td>
</tr>
<tr>
<td>Mustafa et al [24], 2021</td>
<td>United States</td>
<td>Total: 401 patients • Video visit patients: 98 • In-person visit patients: 303</td>
<td>• Video visits patient mean age: 29 (range 11-52.5) years • In-person visits patient mean age: 20 (range 6-52.5) years</td>
<td>Allergy or immunology</td>
</tr>
<tr>
<td>Summers et al [26], 2022</td>
<td>United States</td>
<td>Total: 817 patients • Video visit patients: 674 • In-person visit patients: 143</td>
<td>• Not stated</td>
<td>Ophthalmology</td>
</tr>
<tr>
<td>Troncone et al [27], 2022</td>
<td>Italy</td>
<td>Total: 610 patients • Video visit patients: 305 • In-person visit patients: 305 • Video visit caregivers: 305 • In-person visit caregivers: 305</td>
<td>• Video visits patient mean age: 12.17 years • In-person visits patient mean age: 12.12 years</td>
<td>Type 1 diabetes</td>
</tr>
</tbody>
</table>

Satisfaction assessed separately for adolescents and caregivers: adolescents answered at least some satisfaction surveys items separately; results were presented separately for adolescents and caregivers.

https://pediatrics.jmir.org/2023/1/e41554
Table 2. Telehealth approach, assessment of satisfaction, and findings among the 14 included studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Telehealth approach and comparison groups</th>
<th>Satisfaction data collection tool examples</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corona et al [14], 2021</td>
<td>Video sessions between March 2020 and August 2020 compared with in-person visits between July 2019 and March 2020</td>
<td>• 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.”</td>
<td>• 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.</td>
</tr>
<tr>
<td>Hoi et al [15], 2022</td>
<td>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</td>
<td>• 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.</td>
<td>• 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 10h drive.”</td>
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<td>Holzman et al [16], 2021</td>
<td>Video visits between April 2020 till 2020 compared with in-person visits between January 2019 and March 2020</td>
<td>• 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?”</td>
<td>• 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).</td>
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<tr>
<td>Johnson et al [17], 2020</td>
<td>Video visits compared with in-person visits between April 2020 and May 2020</td>
<td>• 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?”</td>
<td>• 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).</td>
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<td>Katz et al [18], 2021</td>
<td>Video visits compared with in-person visits between March 10 and June 29, 2020</td>
<td>• Survey with closed-ended questions on satisfaction, such as “Provider explained problem or condition” and “Provider made efforts to include us in decisions”</td>
<td>• 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.</td>
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<td>Kennelly et al [19], 2021</td>
<td>Telemedicine visits for caregivers between June 2020 till July 2021 compared with in-person visits for caregivers/patients between June 2019 and May 2020</td>
<td>• 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.</td>
<td>• 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&lt;.99).</td>
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### Findings

<table>
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<th>Study</th>
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</table>
| 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. 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. | • Open-ended items, such as, “What is the most important reason you would prefer an in-person encounter?” | |
Findings

Satisfaction data collection tool examples

Telehealth approach and comparison groups

- 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.”

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.

- 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.

- Patients themselves completed the JSPPPEa.
- Caregivers completed the CASCb.

Examples of CASC items included “I would like to see improvement in the comfort and support the provider gave to the child: yes/no.”

Satisfaction assessed separately for adolescents and caregivers: adolescents answered at least some satisfaction surveys items separately; results were presented separately for adolescents and caregivers.

- 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).

Patients themselves completed the JSPPPEa.

Caregivers completed the CASCb.

Examples of CASC items included “I would like to see improvement in the comfort and support the provider gave to the child: yes/no.”

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.

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aJSPPPE: Jefferson Scale of Patient Perceptions of Physician Empathy.
bCASC: comprehensive assessment of satisfaction with care.
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 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.

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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.

Multimedia Appendix 2
Search strings by database.

Multimedia Appendix 3
Quality of evidence based on design, sociodemographic participant characteristics, and tool reliability and validity.

Multimedia Appendix 4
Quality of evidence scores based on Joanna Briggs Institute critical assessment tool common questions.

References


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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.

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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 postpartum 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 postpartum), (4) inclusion of women who were experiencing or had experienced a gestational week or postpartum period, and inclusion and exclusion criteria, if present; and type of comparator, if present), (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, PsycoINFO, 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 teledicine) 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].

https://pediatrics.jmir.org/2023/1/e40937

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Table 1. Aims and characteristics of the studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Study type</th>
<th>Study aim</th>
</tr>
</thead>
</table>
| 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.
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 [42,44] 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.

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample, N</th>
<th>Perinatal period</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obikane et al [43], 2021</td>
<td>Over 75 per group</td>
<td>Post partum</td>
<td>• Aged ≥20 years (adult age in Japan)</td>
<td>• Suicidal intent</td>
</tr>
<tr>
<td></td>
<td>(4 groups: estimate)</td>
<td></td>
<td>• Having given birth within the past 10 weeks</td>
<td>• Receiving public livelihood assistance</td>
</tr>
<tr>
<td></td>
<td>EG: 164; CG: 134</td>
<td></td>
<td>• Available internet-access</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Living with the newborn baby</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Fluent in Japanese</td>
<td></td>
</tr>
<tr>
<td>O’Mahen et al [41], 2013</td>
<td>EG*: 164; CG*: 134</td>
<td>Post partum</td>
<td>• Aged ≥18 years</td>
<td>• Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• EPDS &gt; 12</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Having given birth within the past 12 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Being a member of Netmums</td>
<td></td>
</tr>
<tr>
<td>O’Mahen et al [42], 2014; Bagnall [46], 2014</td>
<td>EG: 41; CG: 42</td>
<td>Post partum</td>
<td>• Aged ≥18 years</td>
<td>• Substance abuse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Having given birth within the past 12 months</td>
<td>• Psychosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• EPDS &gt; 12</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• MDD (International Classification of Diseases, Tenth Revision criteria)</td>
<td></td>
</tr>
<tr>
<td>O’Mahen et al [45], 2017</td>
<td>32 (subsample of</td>
<td>Post partum</td>
<td>• As per the study by O’Mahen et al [42]</td>
<td>• As per the study by O’Mahen et al [42]</td>
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<td></td>
<td>the study by O’Mahen et al [42])</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Singla et al [44], 2021</td>
<td>342 per group (4</td>
<td>Perinatal</td>
<td>• Aged ≥18 years</td>
<td>• Suicidal intent</td>
</tr>
<tr>
<td></td>
<td>groups; estimated</td>
<td></td>
<td>• EPDS ≥10</td>
<td>• Active symptoms of psychosis or mania</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Pregnant up to 36 weeks or 4-30 weeks post partum</td>
<td>• Taking psychotropic medication</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Speaks English or (US sites) Spanish</td>
<td>• Change of medication 2 weeks before enrollment</td>
</tr>
<tr>
<td>Singla et al [47], 2022</td>
<td>23</td>
<td>Perinatal</td>
<td>• As per the study by Singla et al [44]</td>
<td>• Ongoing psychotherapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Substance abuse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Severe fetal anomalies, stillbirth, or infant death for pregnant participants</td>
</tr>
</tbody>
</table>

*aEG: experimental group.  
bCG: control group.  
cEPDS: Edinburgh Postnatal Depression Scale.  
dMDD: 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.

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention name</th>
<th>Length (weeks), total number of sessions</th>
<th>Guided versus un-guided</th>
<th>Guided—description</th>
<th>Digital means</th>
<th>Intervention delivery format</th>
</tr>
</thead>
</table>
| 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<sup>a</sup>   | 15, 11                                  | Unguided                | N/A<sup>b</sup>                                                                  | Web based (Netmums site)                      |                               |
| 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 parent supporters |
| Singla et al [44], 2021       | Behavioral activation      | 6-8, 6-8                                | Guided (non-specialists and specialists) | • Delivers the intervention
• Addresses treatment barriers and facilitators | Teledicine | 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 | Teledicine | Zoom or WebEx video calls |

<sup>a</sup>IBA: internet-based Behavioral Activation.

<sup>b</sup>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>
<thead>
<tr>
<th>Study</th>
<th>Assessment time points</th>
<th>Clinical outputs</th>
<th>Intervention-related outputs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bagnall [46], 2014</td>
<td>• T0(^a): baseline • T1(^b): intervention end point</td>
<td>• No significant reduction in depression and anxiety symptoms or improvements in work and social functioning as well as the level of BA(^c) emerged, at any time point, among participants from the intervention group compared with participants in the usual care condition</td>
<td>• 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</td>
</tr>
<tr>
<td>Obikane et al [43], 2021</td>
<td>• T0: baseline • T1: intervention end point • T2: follow-up, 12 weeks from intervention end point</td>
<td>• N/A(^d)</td>
<td>• N/A</td>
</tr>
<tr>
<td>O’Mahen et al [41], 2013</td>
<td>• T0: baseline • T1: intervention end point</td>
<td>• Significant reduction in depression symptoms among participants from the intervention group compared with participants in the usual care condition</td>
<td>• 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</td>
</tr>
<tr>
<td>O’Mahen et al [42], 2014</td>
<td>• T0: baseline • T1: intervention end point • T2: follow-up, 6 months from intervention end point</td>
<td>• 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</td>
<td>• 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)</td>
</tr>
<tr>
<td>O’Mahen et al [45], 2017</td>
<td>As per the study by O’Mahen et al [42]</td>
<td>• 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</td>
<td>• N/A</td>
</tr>
<tr>
<td>Singla et al [44], 2021</td>
<td>• T0: baseline • T1: 3 months from randomization • T3: 6 months from randomization • T4(^e): 12 months from randomization</td>
<td>• N/A</td>
<td>• N/A</td>
</tr>
</tbody>
</table>
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.

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 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 is warranted.
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? 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.

In this regard, O’Mahen et al [41,42] 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 ]

References


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
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.

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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 the 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 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.

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 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 to 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.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mothers (N=24)</th>
<th>Family members (N=24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>32.79 (3.08)</td>
<td>34.13 (4.84)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>2 (8)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>More than one race</td>
<td>1 (4)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>White</td>
<td>21 (88)</td>
<td>23 (96)</td>
</tr>
<tr>
<td>Highest level of education, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school diploma or General Educational Diploma</td>
<td>1 (4)</td>
<td>2 (8)</td>
</tr>
<tr>
<td>College degree</td>
<td>8 (33)</td>
<td>11 (46)</td>
</tr>
<tr>
<td>Graduate school degree</td>
<td>15 (63)</td>
<td>11 (46)</td>
</tr>
<tr>
<td>Employed, n (%)</td>
<td>18 (75)</td>
<td>22 (92)</td>
</tr>
<tr>
<td>Family conflict score(^a), mean</td>
<td>55.8</td>
<td>54.4</td>
</tr>
<tr>
<td>Maternal depression score(^b), mean (SD)</td>
<td>20 (7.62)</td>
<td>N/A(^c)</td>
</tr>
<tr>
<td>Maternal anxiety score(^d), mean (SD)</td>
<td>43.63 (7.37)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

\(^a\) 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.

<table>
<thead>
<tr>
<th>Infant care providers (N=9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
</tr>
<tr>
<td>Female, n (%)</td>
</tr>
<tr>
<td>Race, n (%)</td>
</tr>
<tr>
<td>More than one race</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Clinic implements postpartum depression screens, n (%)</td>
</tr>
<tr>
<td>Job responsibilities for maternal depression, n (%)</td>
</tr>
<tr>
<td>Recognition of postpartum depression</td>
</tr>
<tr>
<td>Strongly agree</td>
</tr>
<tr>
<td>Agree</td>
</tr>
<tr>
<td>Addressing parenting issues that pertain to maternal depression</td>
</tr>
<tr>
<td>Strongly agree</td>
</tr>
<tr>
<td>Agree</td>
</tr>
<tr>
<td>Clinic implements postpartum anxiety screens, n (%)</td>
</tr>
<tr>
<td>Job responsibilities for maternal anxiety, n (%)</td>
</tr>
<tr>
<td>Recognition of postpartum anxiety</td>
</tr>
<tr>
<td>Strongly agree</td>
</tr>
<tr>
<td>Agree</td>
</tr>
<tr>
<td>Addressing parenting issues that pertain to maternal anxiety</td>
</tr>
<tr>
<td>Strongly agree</td>
</tr>
<tr>
<td>Agree</td>
</tr>
</tbody>
</table>

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.
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.

<table>
<thead>
<tr>
<th></th>
<th>Baseline (N=24)</th>
<th>Postintervention (N=24)</th>
<th>$P$ value</th>
<th>3-month follow-up (N=22)</th>
<th>$P$ value</th>
<th>6-month follow-up (N=22)</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BDI-II$^a$, mean (SD)</td>
<td>20 (7.62)</td>
<td>6.96 (2.77)</td>
<td>&lt;.001</td>
<td>8.46 (4.19)</td>
<td>&lt;.001</td>
<td>8.27 (5.11)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>STAI-S$^b$, mean (SD)</td>
<td>43.63 (7.37)</td>
<td>33.17 (6.94)</td>
<td>&lt;.001</td>
<td>33.73 (7.97)</td>
<td>&lt;.001</td>
<td>33.77 (7.56)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

$^a$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 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 ($\chi^2_{3,22}=17.65$, $P<.001$). 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.

<table>
<thead>
<tr>
<th></th>
<th>Baseline (N=48)</th>
<th>Postintervention (N=47)</th>
<th>3-month follow-up (N=44)</th>
<th>6-month follow-up (N=44)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal PHS, mean</td>
<td>55.8</td>
<td>48.1</td>
<td>.001</td>
<td>.003</td>
</tr>
<tr>
<td>Family member PHS, mean</td>
<td>54.4</td>
<td>51.4</td>
<td>48.1</td>
<td>.001</td>
</tr>
</tbody>
</table>

*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.

**References**


56. NIH and Northwestern University. Scoring and interpretation guide for the i-Pad v1.7.5.25.21. NIH Toolbox. URL: https://tinyurl.com/y4mf5pzp [accessed 2023-02-08]


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

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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 breastfeeding 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 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].

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⁺.

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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 close 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 ]
References


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 (t115=7.57; P=.004) and engaged in more moderate- and vigorous-intensity physical activity minutes per week (t115=4.28; P=.04) and steps per day (t115=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.

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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.

<table>
<thead>
<tr>
<th>Study week</th>
<th>School 1 activities</th>
<th>School 2 activities</th>
<th>School 3 activities</th>
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<tbody>
<tr>
<td>1</td>
<td>Basketball</td>
<td>Basketball</td>
<td>Basketball</td>
</tr>
<tr>
<td>2</td>
<td>Basketball</td>
<td>Basketball and flag football</td>
<td>Basketball</td>
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<tr>
<td>3</td>
<td>Flag football</td>
<td>Basketball and flag football</td>
<td>Flag football</td>
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<td>4</td>
<td>Flag football</td>
<td>Basketball</td>
<td>Flag football</td>
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<tr>
<td>5</td>
<td>Soccer</td>
<td>Dodgeball and basketball</td>
<td>Softball and baseball</td>
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<tr>
<td>6</td>
<td>Soccer</td>
<td>Basketball</td>
<td>Basketball</td>
</tr>
<tr>
<td>7</td>
<td>Capture the flag</td>
<td>Kickball</td>
<td>Yoga and aerobics</td>
</tr>
<tr>
<td>8</td>
<td>Games (red light, green light; shark and minnows; and tag)</td>
<td>Basketball</td>
<td>Yoga and aerobics</td>
</tr>
<tr>
<td>9</td>
<td>Games (red light, green light; shark and minnows; and tag)</td>
<td>Basketball</td>
<td>Frisbee, jump rope, and dance</td>
</tr>
<tr>
<td>10</td>
<td>Dodgeball and soccer</td>
<td>Flag football and kickball</td>
<td>Frisbee, jump rope, and dance</td>
</tr>
<tr>
<td>11</td>
<td>Games (red light, green light; shark and minnows; and tag)</td>
<td>Lacrosse and kickball</td>
<td>Soccer, frisbee, and dance</td>
</tr>
<tr>
<td>12</td>
<td>Mini-competition of basketball, soccer, football, and frisbee</td>
<td>Lacrosse and kickball</td>
<td>Soccer, frisbee, and dance</td>
</tr>
<tr>
<td>13</td>
<td>Mini-competition of basketball, soccer, football, and frisbee</td>
<td>Yoga, jump rope, and dodgeball</td>
<td>Free play</td>
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<td>Canceled by school</td>
<td>Canceled by school</td>
<td>Canceled by school</td>
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<tr>
<td>15</td>
<td>Jump rope</td>
<td>Indoor games and trashball</td>
<td>Canceled by school</td>
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<td>Jump rope and jump rope games</td>
<td>Indoor games and trashball</td>
<td>Aerobics, dance, and yoga</td>
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<tr>
<td>17</td>
<td>Basketball</td>
<td>Soccer</td>
<td>Aerobics, dance, and yoga</td>
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<td>18</td>
<td>Basketball</td>
<td>Soccer</td>
<td>Jump rope and jump rope games</td>
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<td>19</td>
<td>Flag football and basketball</td>
<td>Basketball</td>
<td>Kickball and basketball</td>
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<td>Basketball</td>
<td>Flag football</td>
<td>Basketball</td>
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<tr>
<td>22</td>
<td>Basketball and kickball</td>
<td>Flag football</td>
<td>Basketball</td>
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<td>23</td>
<td>Circuit training and basketball</td>
<td>Badminton</td>
<td>Soccer and handball</td>
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<td>Volleyball</td>
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<td>Volleyball</td>
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<tr>
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<td>Kickball</td>
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<td>Olympics week</td>
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<td>Kickball</td>
<td>Football</td>
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<td>Ultimate frisbee</td>
<td>Ultimate frisbee</td>
<td>Football</td>
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<td>29</td>
<td>Ultimate frisbee or dodgeball</td>
<td>Ultimate frisbee</td>
<td>Dodgeball and volleyball</td>
</tr>
<tr>
<td>30</td>
<td>Free play or review of sports</td>
<td>Free play or review of sports</td>
<td>Dodgeball and volleyball</td>
</tr>
<tr>
<td>31</td>
<td>Free play or review of sports</td>
<td>Free play or review of sports</td>
<td>Free play or review of sports</td>
</tr>
</tbody>
</table>

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:

\[
\text{BMI} = \frac{\text{weight (kg)}}{\text{height (m)}^2}
\]

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 categorical 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/m² for intervention participants and 25.19 (SD 7.10) kg/m² for control participants. The small difference in BMIs between groups was not statistically significant (t115=1.41; P=.90).

Physical literacy was statistically different between the intervention and control groups (t115=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 (t115=4.28; P=.04) and steps per day (t115=4.29; P=.03) were statistically different between groups. On average, participants in the intervention group engaged in 107.01 (SD 34.97) 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.

```
Included in the study (n=229)

Intervention group (n=179)
- Completed posttest (n=123)
- Discontinued study (n=56)
- Excluded from analysis (insufficient wear time) (n=42)
  - Included in analysis (n=81)

Control group (n=50)
- Completed posttest (n=35)
- Discontinued study (n=15)
  - Excluded from analysis (insufficient wear time) (n=0)
  - Included in analysis (n=35)
```

Table 2. End point univariate statistics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention group (n=81)</th>
<th>Control group (n=35)</th>
<th>Chi-square (df)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>13.4 (1.0)</td>
<td>13.8 (0.97)</td>
<td>7.61 (115)</td>
<td>.11</td>
</tr>
<tr>
<td>Grade in school, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sixth grade</td>
<td>31 (38)</td>
<td>4 (11)</td>
<td>3.06 (115)</td>
<td>.22</td>
</tr>
<tr>
<td>Seventh grade</td>
<td>26 (32)</td>
<td>11 (31)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eighth grade</td>
<td>24 (30)</td>
<td>20 (57)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td>1.95 (115)</td>
<td>.38</td>
</tr>
<tr>
<td>Male</td>
<td>52 (64)</td>
<td>17 (49)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>28 (35)</td>
<td>18 (51)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prefer not to say</td>
<td>1 (1.2)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race&lt;sup&gt;a&lt;/sup&gt;, n (%)</td>
<td></td>
<td></td>
<td>15.63 (115)</td>
<td>.11</td>
</tr>
<tr>
<td>African American or Black</td>
<td>62 (77)</td>
<td>18 (51)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latinx</td>
<td>12 (15)</td>
<td>3 (9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White, Non-Hispanic</td>
<td>15 (19)</td>
<td>4 (11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>5 (6)</td>
<td>1 (3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>3 (4)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>3 (4)</td>
<td>4 (11)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>Participants were able to choose multiple racial categories.
Table 3. Differences between the intervention and control groups.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention group, mean (SD)</th>
<th>Control group, mean (SD)</th>
<th>Mean difference (95% CI)</th>
<th>t test (df)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m$^2$)</td>
<td>23.37 (5.91)</td>
<td>25.19 (7.10)</td>
<td>1.82 (−4.60 to 0.96)</td>
<td>1.41 (115)</td>
<td>.90</td>
</tr>
<tr>
<td>Physical literacy score</td>
<td>75.62 (14.13)</td>
<td>50.71 (19.73)</td>
<td>24.91 (18.39 to 31.43)</td>
<td>7.57 (115)</td>
<td>.004</td>
</tr>
<tr>
<td>Moderate to vigorous physical activity (minutes per week)</td>
<td>107.01 (34.94)</td>
<td>53.01 (11.17)</td>
<td>53.99 (28.45 to 79.54)</td>
<td>4.28 (115)</td>
<td>.04</td>
</tr>
<tr>
<td>Steps per day</td>
<td>10,847.11 (3758.33)</td>
<td>5030.09 (1128.24)</td>
<td>5817.01 (3073.15 to 8560.88)</td>
<td>4.29 (115)</td>
<td>.03</td>
</tr>
</tbody>
</table>

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.

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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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24. IBM Corp. IBM SPSS Statistics. IBM Corp. URL: https://www.ibm.com/products/spss-statistics [accessed 2023-01-17]

Abbreviations

**KCPS:** Kansas City Public School District

**MVPA:** moderate to vigorous physical activity

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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; t57=-2.06, 95% CI -1.36 to -0.02) and peer problems decreased (mean difference=-0.69; P=.01; t57=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.
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 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 and CP3 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).

<table>
<thead>
<tr>
<th>Role</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP3 coordinator</td>
<td>This is the overarching coordinator of the CP3, who supports sites implementing the CP3 through resourcing, training, activity planning, delivery, and evaluation.</td>
</tr>
<tr>
<td>CP3 site champion</td>
<td>This is the nominated educator who is responsible at a site level for supporting CP3 delivery.</td>
</tr>
<tr>
<td>CP3 skilled mentors</td>
<td>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.</td>
</tr>
<tr>
<td>CP3 principle mentors</td>
<td>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.</td>
</tr>
<tr>
<td>CP3 peer champions</td>
<td>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.</td>
</tr>
</tbody>
</table>

**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.

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(page number not for citation purposes)
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.
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.

<table>
<thead>
<tr>
<th>CP3 principle</th>
<th>Items</th>
<th>Baseline (before CP3 engagement; n=5), item endorsement rate, n/N (%)</th>
<th>Time point 2 (after CP3 taste-tester activity; n=9), item endorsement rate, n/N (%)</th>
<th>Time point 3 (end of CP3; n=18), item endorsement rate, n/N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Build Well-being and Resilience</td>
<td>Social well-being • Emotional well-being • Cognitive well-being • Physical well-being • Resilience</td>
<td>20/50 (40)</td>
<td>38/42 (90)</td>
<td>87/90 (97)</td>
</tr>
<tr>
<td>Broaden Horizons</td>
<td>Broaden children’s skills • Diverse range of experiences</td>
<td>4/10 (40)</td>
<td>18/18 (100)</td>
<td>35/36 (97)</td>
</tr>
<tr>
<td>Inspire and Engage</td>
<td>Interesting • Motivating • Believing that their skills and talents can grow • Part of the decision-making • Leadership skills</td>
<td>13/25 (52)</td>
<td>39/44 (89)</td>
<td>83/90 (92)</td>
</tr>
<tr>
<td>Connect Communities</td>
<td>Strong links with local resources • Strong links with local community • Connectedness and belonging of children and their families • Communication with children and their families</td>
<td>8/20 (40)</td>
<td>29/35 (85)</td>
<td>65/71 (92)</td>
</tr>
</tbody>
</table>

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; t89=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; t57=−2.06, 95% CI −1.36 to −0.02) and peer problems significantly decreased (MD=−0.69; P=.01; t57=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).

<table>
<thead>
<tr>
<th></th>
<th>Mean difference (SD; 95% CI)</th>
<th>t test (df)</th>
<th>P value (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional symptoms</td>
<td>−0.10 (1.71; −0.55 to 0.35)</td>
<td>−0.46 (57)</td>
<td>.65</td>
</tr>
<tr>
<td>Conduct problems</td>
<td>0.22 (1.95; −0.29 to 0.74)</td>
<td>0.87 (57)</td>
<td>.39</td>
</tr>
<tr>
<td>Hyperactivity</td>
<td>0.38 (2.43; −0.26 to 1.02)</td>
<td>1.19 (57)</td>
<td>.24</td>
</tr>
<tr>
<td>Peer problems</td>
<td>0.64 (1.89; 0.14 to 1.13)</td>
<td>2.57 (57)</td>
<td>.01</td>
</tr>
<tr>
<td>Prosocial behaviors</td>
<td>−0.69 (2.55; −1.36 to −0.02)</td>
<td>−2.06 (57)</td>
<td>.04</td>
</tr>
</tbody>
</table>

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 “feeling 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.

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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 ]

References


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

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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.

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**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.
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.
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.

![Diagram showing domains and neurobiological systems/circuits](attachment:Diagram.png)

<table>
<thead>
<tr>
<th>Domains for Collective Action</th>
<th>Neurobiological systems/circuits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cognitive Brain (“Play”)</strong></td>
<td><strong>Stress response</strong></td>
</tr>
<tr>
<td>• Neurocognitive function (eg, attention)</td>
<td>• Major role: Regulate optimal behavioral and physiological responses to stressors</td>
</tr>
<tr>
<td>• Fine and gross motor skills</td>
<td>• App targets: Self-soothing, safety behaviors</td>
</tr>
<tr>
<td>• Imagination (eg, perspective-taking)</td>
<td><strong>Oxytocin</strong></td>
</tr>
<tr>
<td><strong>Social Brain (“Connect”)</strong></td>
<td>• Major role: Reinforce optimal social relations and bonding/attachment to key caregivers</td>
</tr>
<tr>
<td>• Social cues (eg, eye gaze, facial expression)</td>
<td>• App targets: Breastfeeding, physical touch, socializing</td>
</tr>
<tr>
<td>• Social problem-solving</td>
<td><strong>Learning</strong></td>
</tr>
<tr>
<td>• Interpersonal relationships (eg, kindness)</td>
<td>• Major role: Make certain behaviors more or less likely to be repeated over time</td>
</tr>
<tr>
<td><strong>Language &amp; Communication (“Talk”)</strong></td>
<td>• App targets: Positive reinforcement, repetition</td>
</tr>
<tr>
<td>• Verbal communication (eg, language)</td>
<td><strong>Fear-arousal-memory</strong></td>
</tr>
<tr>
<td>• Nonverbal communication (eg, gesturing)</td>
<td>• Major role: Encode threatening events in memory to alter behavior and prevent re-exposure</td>
</tr>
<tr>
<td>• Identifying and communicating emotions</td>
<td>• App targets: Self-soothing, protective environments</td>
</tr>
<tr>
<td><strong>Identity &amp; Culture (“Community”)</strong></td>
<td><strong>Circadian</strong></td>
</tr>
<tr>
<td>• Sense of self (eg, uniqueness, roles)</td>
<td>• Major role: Regulate daily timing of biobehavioral rhythms (eg, sleep-wake cycle, cognition, hormones)</td>
</tr>
<tr>
<td>• Connection to place (eg, nature, locale)</td>
<td>• App targets: Routines, light exposure, activity</td>
</tr>
<tr>
<td>• Connection to family (eg, kinship, trust)</td>
<td></td>
</tr>
</tbody>
</table>

**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.
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 (e.g., 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.
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.

References


Abbreviations

ECD: early childhood development
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.

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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, Mahmeed, 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 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].

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 process, 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.

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.
Table. Heuristic evaluation results and changes.

<table>
<thead>
<tr>
<th>Heuristic principle</th>
<th>Sample quote</th>
<th>Design alterations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visibility of system status</td>
<td>“After selecting symptoms on the cards themselves, the user doesn’t see what those selections were.”</td>
<td>Text with a time estimate for completion of the survey was included. The section the user is on was highlighted on a navigation menu.</td>
</tr>
<tr>
<td>Match between system and the real world</td>
<td>“It might be better to put some illustration of the body parts.”</td>
<td>Images were not included as part of the new design due to time constraints on the construction of the second version of the tool.</td>
</tr>
<tr>
<td>User control and freedom</td>
<td>“Users are not allowed to go back to change their answer.”</td>
<td>A back button on all pages and a navigation bar were incorporated to allow user mobility through the different sections of the tool.</td>
</tr>
<tr>
<td>Consistency and standards</td>
<td>“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.”</td>
<td>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.</td>
</tr>
<tr>
<td>Help users recognize, diagnose, and recover from errors</td>
<td>“Clicking save &amp; continue button without clicking the checkbox doesn’t prompt the user with any messages nor visual feedback of what is missing.”</td>
<td>An error message pops up indicating to the user that they must select an answer to proceed.</td>
</tr>
<tr>
<td>Error prevention</td>
<td>“On mobile, the selection boxes are really close together.”</td>
<td>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.</td>
</tr>
<tr>
<td>Recognition rather than recall</td>
<td>“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.”</td>
<td>User selections are saved from page to page so that going back does not require them to remember what they selected.</td>
</tr>
<tr>
<td>Flexibility and efficiency of use</td>
<td>“It asks what type of delivery the user had, although I selected ‘No’ in the question about giving birth in the last year.”</td>
<td>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.</td>
</tr>
<tr>
<td>Flexibility and efficiency of use</td>
<td>“Symptoms related to a cesarean infection showed up although I did not select cesarean birth.”</td>
<td></td>
</tr>
<tr>
<td>Aesthetic and minimalist design</td>
<td>“Pages are not responsive for mobile, text doesn’t scale, and information is very hard to read.”</td>
<td>Mobile responsiveness was incorporated to allow text and content to scale properly. Redundant text and information was removed to reduce visual cognitive load.</td>
</tr>
<tr>
<td>Help and documentation</td>
<td>“It is unclear what the user should do on the category selection page. The ‘Save &amp; Continue’ button appears only when you select items in each category. This is not obvious to the user.”</td>
<td>Instructions were included throughout the tool to support the users in areas where confusion may arise, such as symptom selection.</td>
</tr>
</tbody>
</table>
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.
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 (i.e., 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.
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
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.

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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 manage 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 adaptation 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.
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 inTextbox 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.

<table>
<thead>
<tr>
<th>Measures to ensure that adult care was not compromised (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. “Supervised by adult intensivists.”</td>
</tr>
<tr>
<td>2. “Rapid development of policies and procedures, education sessions, shared folders with resource documents”</td>
</tr>
<tr>
<td>3. “We arranged for adult subspecialists to consult with us rather than their pediatric versions.”</td>
</tr>
<tr>
<td>4. “Adult code simulations”</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Negative effects on PICU patient care (n=3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. “We worked more hours in the month compromising our lifestyle.”</td>
</tr>
<tr>
<td>2. “Emotional strain of managing COVID-19 and death of adult patients was different”</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Positive observations for this adaptation (n=7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. “Some exposure to new ways of doing things.”</td>
</tr>
<tr>
<td>2. “Adult intensivists understood that were intensivists also.”</td>
</tr>
<tr>
<td>3. “Multiple opportunities for collaboration and engagement occurred with our adult ICU colleagues.”</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lessons learned (n=7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. “Different staffing models explored.”</td>
</tr>
<tr>
<td>2. “Surge capacity can be organized and resiliency in moments of national emergency were very developed”</td>
</tr>
<tr>
<td>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!).”</td>
</tr>
</tbody>
</table>

**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 adoptions 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 commonalities 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 ]

**References**


Abbreviations

ICU: intensive care unit
PICU: pediatric intensive care unit
REDCap: Research Electronic Data Capture
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.

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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>
<thead>
<tr>
<th>Phase</th>
<th>Concepts</th>
<th>Methods</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Empathy</td>
<td>To discover users’ needs and values for a familial technology-based solution</td>
<td>In-depth interviews</td>
<td>18 parents</td>
</tr>
<tr>
<td>Define</td>
<td>To refine and narrow the definition in the revised solution to meet the end users’ needs</td>
<td>Brainstorming technique</td>
<td>The research team</td>
</tr>
<tr>
<td>Ideate</td>
<td>To concentrate on idea generation and obtain innovative solutions for users</td>
<td>Brainstorming technique</td>
<td>The research team</td>
</tr>
<tr>
<td>Prototype</td>
<td>To generate the demonstrative solution for users</td>
<td>Design a web-based prototype for trial use</td>
<td>The research team</td>
</tr>
<tr>
<td>Test</td>
<td>To obtain pilot results and feedback on the prototype</td>
<td>Collect feedback via a quantitative and qualitative approach</td>
<td>32 parents</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (range)</td>
<td>42 (25-55)</td>
</tr>
<tr>
<td><strong>Relationship, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Father</td>
<td>4 (22)</td>
</tr>
<tr>
<td>Mother</td>
<td>11 (61)</td>
</tr>
<tr>
<td>Grandmother</td>
<td>2 (11)</td>
</tr>
<tr>
<td>Aunt</td>
<td>1 (6)</td>
</tr>
<tr>
<td><strong>Education, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Primary school</td>
<td>1 (6)</td>
</tr>
<tr>
<td>High school</td>
<td>3 (17)</td>
</tr>
<tr>
<td>Diploma</td>
<td>4 (22)</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
<td>7 (39)</td>
</tr>
<tr>
<td>Master’s degree</td>
<td>3 (17)</td>
</tr>
<tr>
<td><strong>Occupation, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Government official</td>
<td>4 (22)</td>
</tr>
<tr>
<td>Businessman</td>
<td>2 (11)</td>
</tr>
<tr>
<td>Freelance</td>
<td>6 (33)</td>
</tr>
<tr>
<td>Gardener</td>
<td>2 (11)</td>
</tr>
<tr>
<td>Merchant</td>
<td>3 (17)</td>
</tr>
<tr>
<td>Housewife</td>
<td>1 (6)</td>
</tr>
</tbody>
</table>

**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,
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.

<table>
<thead>
<tr>
<th>Weeks and days</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weeks 1-2</strong></td>
<td>Introduction</td>
</tr>
<tr>
<td>Day 1</td>
<td>Program introduction</td>
</tr>
<tr>
<td>Days 1-2</td>
<td>Understanding ADHD&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Day 3</td>
<td>Treatment of ADHD</td>
</tr>
<tr>
<td>Day 4</td>
<td>Case scenario video (homework)</td>
</tr>
<tr>
<td>Day 5</td>
<td>Parental concern and setting goal</td>
</tr>
<tr>
<td>Day 6</td>
<td>Rationale, rule, and cycle of problem</td>
</tr>
<tr>
<td>Days 6-7</td>
<td>Basic principles in child behavioral management</td>
</tr>
<tr>
<td>Day 8</td>
<td>Advantage of parent training</td>
</tr>
<tr>
<td>Days 9-10</td>
<td>ABC&lt;sup&gt;b&lt;/sup&gt; model (homework)</td>
</tr>
<tr>
<td>Days 11-12</td>
<td>Problem solutions</td>
</tr>
<tr>
<td>Days 13-14</td>
<td>Summary and discussion</td>
</tr>
<tr>
<td><strong>Week 3</strong></td>
<td>Basic communication skills</td>
</tr>
<tr>
<td>Day 1</td>
<td>Inappropriate conversations (homework)</td>
</tr>
<tr>
<td>Days 1-2</td>
<td>Negative conversations</td>
</tr>
<tr>
<td>Days 3-4</td>
<td>Using “I” messages and “you/he/she” messages</td>
</tr>
<tr>
<td>Day 5</td>
<td>Effective communication</td>
</tr>
<tr>
<td>Day 6</td>
<td>Constructive instruction</td>
</tr>
<tr>
<td>Day 7</td>
<td>Case scenario video (homework)</td>
</tr>
<tr>
<td><strong>Week 4</strong></td>
<td>Praise</td>
</tr>
<tr>
<td>Day 1</td>
<td>Praise</td>
</tr>
<tr>
<td>Day 2</td>
<td>Case scenario video (homework)</td>
</tr>
<tr>
<td>Day 3</td>
<td>Principles, components, and examples</td>
</tr>
<tr>
<td>Days 3-6</td>
<td>Diary notes</td>
</tr>
<tr>
<td>Days 5-7</td>
<td>Reminders about basic communication skills</td>
</tr>
<tr>
<td>Day 7</td>
<td>Reflection</td>
</tr>
<tr>
<td><strong>Week 5</strong></td>
<td>Rewards</td>
</tr>
<tr>
<td>Day 1</td>
<td>Types of rewards</td>
</tr>
<tr>
<td>Day 2</td>
<td>Principles of rewards</td>
</tr>
<tr>
<td>Day 3</td>
<td>Define target behaviors</td>
</tr>
<tr>
<td>Days 4-6</td>
<td>Reflection and technique suggestion</td>
</tr>
<tr>
<td>Days 4-6</td>
<td>Diary notes</td>
</tr>
<tr>
<td>Day 7</td>
<td>Summary and discussion</td>
</tr>
<tr>
<td>Day 7</td>
<td>Reminders about previous skills</td>
</tr>
<tr>
<td><strong>Week 6</strong></td>
<td>How to deal with behavioral problems</td>
</tr>
<tr>
<td>Day 1</td>
<td>Objectives and principles of behavioral management</td>
</tr>
<tr>
<td>Day 2</td>
<td>Effective behavioral management</td>
</tr>
<tr>
<td>Day 3</td>
<td>Time-out</td>
</tr>
<tr>
<td>Day 4</td>
<td>Verbal command</td>
</tr>
<tr>
<td>Day 4</td>
<td>Ignorance</td>
</tr>
<tr>
<td>Days 5-6</td>
<td>Case scenario video (homework)</td>
</tr>
</tbody>
</table>
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).
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.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Score</th>
<th>Participants (N=32), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonadherence</td>
<td>&lt;46</td>
<td>5 (16)</td>
</tr>
<tr>
<td>Completion</td>
<td>46</td>
<td>16 (50)</td>
</tr>
<tr>
<td>Adherence</td>
<td>&gt;46</td>
<td>11 (34)</td>
</tr>
</tbody>
</table>

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.
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 may 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.

**References**


Abbreviations

ADHD: attention-deficit/hyperactivity disorder
HMW: How Might We
LMIC: low- and middle-income country
UX: user experience

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