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Examination of Chronic Sorrow Among Parents of Children With Disabilities: Cross-Sectional Study

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Abstract

Background: Parents of children with disabilities face many challenges when providing care, along with persistent worry and fear about the child's health outcomes and the impact of the disability on their lives. These parents experience stressful situations and face many emotions, one of which is chronic sorrow (CS). Therefore, the theory of CS was introduced to examine and measure feelings of CS among parents. Little research has been conducted with Saudi parents with a child with disabilities and the utilization of CS theory in this population is limited.

Objective: This study aims to examine the application of CS theory on parents of children with disabilities in Saudi Arabia.

Methods: A cross-sectional design was used to obtain data from 89 participants who are parents of children with disabilities. A web-based questionnaire was distributed to measure CS.

Results: The study examined the concepts within CS theory. The concept of loss experience yielded a moderately high score (mean 3.3, SD 1.10); of all the variables measuring loss experience, parents scored high in feeling sad when thinking about their child's disability (mean 3.9, SD 1.24). Parents also reported a moderately high score (mean 3.3, SD 1.06) for the concept of disparity, specifically when their child does not meet the same developmental milestones as their peers (mean 3.8, SD 1.30). Feelings of CS also displayed a moderately high score (mean 3, SD 0.87), with the periodic nature of CS scoring the highest within the concept of CS (mean 3.6, SD 1.16). In addition, internal and external management methods that parents believe are effective were examined. Internal management of CS was believed to be of high importance (mean 4.6, SD 0.33), specifically the belief of fatalism (mean 4.8, SD 0.50). Parents also viewed external management as important in navigating their emotions (mean 4.5, SD 0.42), specifically social support from family and the community (mean 4.7, SD 0.55). This study identified strong positive relationships between sorrow and loss experience and disparity (both r=0.765 and P<.001). Lastly, the study found no relationship between CS and time elapsed since parents received their child's diagnosis (r=-0.009; P=.94).

Conclusions: This study applied the theory of CS to the parents of children with disabilities and they reported feelings of loss, disparity, and CS. Therefore, this population should be screened and provided with parental emotional care. Interventions to enhance parental mental health and well-being and support CS management should be developed and used by health care workers. Parental acceptance of their child's disability does not mean the absence of CS, as it is part of the normal grieving process. Anticipating CS triggers and applying internal and external management are essential to improving parental mental health and child health outcomes.

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KEYWORDS

chronic sorrow; sadness; parent; disability; pediatric; infant; neonatal; children; youth; adolescence; Saudi Arabia

Introduction

Background

In 2017, the Saudi General Authority of Statistics issued a detailed report of people with disabilities who reside in Saudi Arabia, noting that a total of 1,445,723 people with varying degrees of disability (mild, moderate, or severe) reside in the

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country, of which 52.2% were males and 47.7% were females [1]. This illustrates that people with disabilities represent a substantial portion of the Saudi community and more attention should be directed to them and their families.

Parents of children with disabilities face numerous difficulties in their daily life when caring for their child, along with feelings of worry and stress about their child's long-term survival and

well-being [2]. The difficulties that the parents face may include their ability to deal with day-to-day challenges, transformation of their social interactions with relatives and friends, and modification of their daily activities [2]. Parents of children with disabilities worry about their child's acceptance in society, as well as the opportunities and resources that might not be available to them when caring for their child. As the child grows and their condition persists, parents become concerned about where and with whom their child will live when they are adults [3]. In addition, parents of children with disabilities experience emotions that are overwhelming and do not follow a predictable sequence. Their emotions can include sadness, anger, and frustration and be periodic in nature [4]. Multiple studies have aimed to measure chronic sorrow among parents of children with different health conditions. These include but are not limited to chronic illness and disabilities [4], autism [5,6], cancer [7], sickle cell disease [8], neurodevelopmental disorders [9], type 1 diabetes [10], and Down syndrome [11].

As a result, the concept of chronic sorrow emerged to explore the daily experiences of these parents. Roos [12] defined chronic sorrow as "a set of pervasive, profound, continuing, and recurring grief responses resulting from a significant loss or absence of crucial aspect of oneself (self – loss) or another living person (other – loss) to whom there is a deep attachment. The way in which the loss is perceived determines the existence of chronic sorrow. The essence of chronic sorrow is a painful discrepancy between what is perceived as reality and what continues to be dreamed of. The loss is ongoing since the source of the loss continues to be present. The loss is a living loss."

The Theoretical Framework of Chronic Sorrow

Chronic sorrow was initially proposed by psychiatrist Olshansky [13]. In his work with mentally challenged children, their parents, and family members, Olshansky observed that parents of children with disabilities display a widespread psychological response to the experience of having a child with disabilities [13]. The parents often had long-lasting, chronic sorrow because the loss they experienced lacked a clear end. It was also uncertain how long the loss would persist [14]. Parents who care for children with disabilities have described having profound emotional experiences. These emotions may be felt occasionally but they may not always be present. These intense emotions may include shock, disbelief, rage, irritation, a feeling of isolation, and a profound sense of sadness and loss. As a result, it is hypothesized that parents of children with disabilities are more likely to report experiencing persistent sadness [15].

Eakes et al [16] defined the variables of the theory of chronic sorrow as the following:

- Chronic sorrow: "ongoing disparity resulting from loss characterized by pervasiveness and permanence. Symptoms of grief recur periodically, and these symptoms are potentially progressive."
- Loss: occurs because of the discrepancy between the "ideal" or "imagined" situation versus the lived experience and occurs in the early stages of the child's diagnosis.
- Disparity: disparity follows the loss experience and can be classified as a trigger for chronic sorrow. The loss experience occurs in the early stages of the child's

diagnosis, whereas disparity reemerges as time passes, when the child does not meet his or her developmental milestones like his or her peers, such as attending school graduations and birthday parties.

• Management methods: strategies used by parents or individuals to minimize the impact of sorrow. These methods can be internal (personal and individualized methods) or external (support from health care workers or institutions).

Studies that have addressed chronic sorrow among parents of children with disabilities are very scarce, especially in Arabic. The Kendall Chronic Sorrow Instrument was found to be useful in measuring the chronic sorrow of mothers of a child with disabilities [17]. Fernandes et al [18] analyzed the theory of chronic sorrow and found that the theory is well-defined and its concepts captured the phenomena under study. When measuring its concepts, they found that the theory had high reliability.

It is worth noting that parents experiencing chronic sorrow are usually overlooked and remain unexamined by society. Parents of children with disabilities must navigate their emotions of sorrow and an unending sense of commitment while maintaining their level of functionality [19]. The objectives of this study are important because parents of children with disabilities report multiple negative outcomes such as psychological distress, a sense of isolation, a lack of financial support, and the absence of tools to help them manage their child's condition [20].

Lastly, the theory of chronic sorrow can be used by nurses caring for parents of children with disabilities to help the parents identify and use management and coping strategies.

This descriptive study aims to explore chronic sorrow among parents of children with different types of disabilities in the Kingdom of Saudi Arabia. The objective of this study is to answer the following questions: With the use of chronic sorrow as a theoretical framework, what are the parental experiences of chronic sorrow in the context of caring for a child with a disability? Is there a relationship between the concepts of the theory of chronic sorrow, specifically between loss and disparity with chronic sorrow? Lastly, is there a relationship between the time elapsed since the child's diagnosis and parental feelings of chronic sorrow?

Methods

Design

A quantitative, descriptive cross-sectional study design will be used to conduct this study exploring chronic sorrow among parents of children with disabilities. We will also identify the strength of the relationships between the triggers (loss experience and disparity) of chronic sorrow. Lastly, we will investigate the impact of time since the child's diagnosis on parental feelings of chronic sorrow.

Instrument

Data were collected for this study through a web-based questionnaire. The questionnaire and consent form were sent

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to the participants after obtaining institutional review board approval from King Abdullah International Medical Center.

The questionnaire was distributed electronically to participants via WhatsApp. The questionnaire consisted of parental demographic data (8 items), loss experience (5 items), disparity (3 items), chronic sorrow (9 items), and management of chronic sorrow (9 items). The chronic sorrow measurement was originally created by Kendall (Kendall Chronic Sorrow Instrument) [21], then the Arabic version of the same instrument was created by Baker et al [22], who confirmed that the internal consistency of the correlation coefficient of the scale was greater than 0.7, with a high degree of validity in the Loach method for all statements, with a score of 0.62. In addition, the Cronbach α was 0.8. All of the above parameters have met the psychometric properties of a valid and reliable instrument [22]. As a result, the Arabic version of the instrument was used for this study due to the proximity of the populations in both studies, both of which speak Arabic and have shared cultural characteristics and religious backgrounds.

For the measurement of chronic sorrow, every item in the scale had a total of 5 responses (5-point Likert scale), ranging from strongly disagree (score of 1 point), disagree (2 points), neutral (3 points), agree (4 points), to strongly agree (5 points). Scoring criteria were as follows: 1 - 2 indicated a low score of chronic sorrow, 2 - 3 indicated a moderately low score, 3 - 4 indicated a moderately high score, and 4 - 5 indicated a high score of chronic sorrow.

Sample, Setting, and Data Collection

Recruitment of study participants was done using nonprobability convenience sampling. The tool targeted parents with a child with disabilities currently residing in Saudi Arabia. The participants who were eligible for this study fulfilled the following criteria: the mother, father, or primary caregiver of a child with a disability, the child had a confirmed medical diagnosis, the parent could speak and read Arabic, and parental age was above 18 years.

For this descriptive study, the significance level of α was set at 0.05 with a power of 0.8 to calculate the sample size and estimate power analysis. The sample size was estimated by G*Power software. This study will be the first to examine the use of chronic sorrow as a theoretical framework among Saudi parents who have a child with a disability. As a result, no previously reported effect size was available for use in the power analysis. Cohen [23] stated that in cases like our study where effect size has not been previously reported in the literature, the estimation of effect size should be based on logic and judgment. Therefore, a medium effect size of 0.30, a power of 0.80, and α significance level of 0.05 were used to guide our statistical analysis, with a sample size of 64.

Potential participants were recruited via invitation through WhatsApp, Facebook, and X (formerly known as Twitter). Upon filling out the questionnaire, the researcher identified parents who met the inclusion criteria and enrolled them in the study. If the participant agreed to fill out the questionnaire after reading the consent form, they were directed to the questionnaire page. Consent was obtained from participants electronically; if the participant agreed to fill in the questionnaire, he or she was directed to an electronic informed consent form. After reading the consent form, the participant was required to sign the form electronically by clicking the "I agree to participate" box, after which the questionnaire would appear.

We used Microsoft Forms for its easy accessibility and user-friendliness for the general population to promote data collection and reduce missing data.

Data Analysis

Once data collection was complete, we entered the data into an Excel database for analysis. SPSS (version 30; IBM Corp) was used to analyze the data on a password-protected computer. Different types of analysis were proposed for this study. Descriptive statistics were calculated on all variables of interest, including means, standard deviations, frequencies, and percentages. Pearson correlation coefficients were used to examine the relationships among continuous variables. Statistical significance was based on the standard α level of .05.

Frequencies and percentages were used for analyzing descriptive data to evaluate the variables of chronic sorrow. Pearson correlations were used to analyze numerical data and assess the relationship between the triggers and the concept of chronic sorrow.

Ethical Considerations

This study received ethics approval from the institutional review board of the King Abdullah International Medical Research Center (SP23J/144/09) on October 16, 2023, and the data collection lasted for 6 months.

Various measures were undertaken to maintain the privacy and confidentiality of participants. Although there was minimal risk involved, all measures to protect participants' information were taken. Participants' responses to each survey item were not shared with other participants or individuals not associated with the research project. By accessing and completing the survey, participants gave their consent to take part in the study. Participation in the study was voluntary. Participants could withdraw from the study at any time. No compensation was provided to the participants.

Results

Participant Characteristics

As Table 1 shows, a total of 89 participants completed the survey. Of these participants, 78% (n=69) were mothers of a child with disabilities. Most of the participants (n=42, 48%) were aged 40-49 years. Many of the participants were caring for a child with a permanent disability (n=79, 89%) and most participants had a university level of education (n=54, 61%). Most of the children had been diagnosed for less than 1 year (n=45, 51%) and Down syndrome was the most reported disability (n=39, 44%).

Table . The sample demographic characteristics (N=89).

Demographic variable	Participants, n (%)	
People completing the survey		
Mother	69 (78)	
Father	5 (6)	
Nonparent	15 (17)	
Age group (years) ^a		
20 - 29	5 (6)	
30 - 39	20 (23)	
40 - 49	42 (48)	
50 - 59	16 (18)	
60 - 65	4 (5)	
Permanence of the child's disability		
Temporary disability	10 (11)	
Permanent disability	79 (89)	
Educational level		
Primary school	4 (4)	
Intermediate school	5 (6)	
High school	26 (29)	
University	54 (61)	
Time since the child was diagnosed with a disability (years)		
Less than 1	45 (51)	
2 - 3	11 (12)	
4 - 9	25 (28)	
More than 10	8 (9)	
Nature of the child's disability		
Down syndrome	39 (44)	
Autism and attention-deficit/hyperactivity disorder	15 (17)	
Mental retardation	8 (9)	
Physical disability	21 (24)	
Undisclosed disability	6 (7)	

^aThere were 87 responses for this question (ie, 2 participants did not respond).

Descriptive Statistics of the Theory of Chronic Sorrow

The data in the following 5 sections illustrate the descriptive statistics of the participants toward the concepts of the theory of chronic sorrow, which is used to measure the following aspects: the triggers of loss experience and disparity, chronic sorrow, internal management, and external management.

Descriptive Statistics for Loss Experience

As shown in Table 2, the reported score of the loss experience that parents of children with disabilities face was a mean of 3.3 (SD 1.10). Of all the variables measuring loss experience, feeling sad when thinking about the child's disability was the highest (mean 3.9, SD 1.24) and a sense of overwhelming sorrow scored the lowest (mean 2.8, SD 1.40). The results showed that parents with children with disabilities reported moderately high loss experience.

Table . Descriptive statistics of loss experience (N=89).

Loss experience	Score, mean (SD)
It feels like the disability happened to me	3.5 (1.18)
Sorrow feelings when I think about my child's disability	3.9 (1.24)
The sorrow feeling remains the same as the day of the diagnosis	3.3 (1.43)
Urge to cry when I remember the disability	3.3 (1.42)
Overwhelming sorrow	2.8 (1.40)
Total score of loss experience	3.3 (1.10)

Descriptive Statistics for Disparity

As shown in Table 3, the total score of the concept of disparity reported by parents of children with disabilities had a mean of 3.3 (SD 1.06). The highest score among the disparity variables was the feeling of sorrow and sadness parents face when their child cannot meet developmental milestones, often associated

with significant events or dates including birthdays, with a mean score of 3.8 (SD 1.30). On the other hand, the lowest score reported was the feeling of sorrow when thinking about their child without the disability (mean 2.7, SD 1.28). According to this study, the feeling of disparity experienced by parents of children with disabilities is moderately high, which is aligned with the experiences of loss.

Table . Descriptive statistics of disparity (N=89).

Disparity	Score, mean (SD)
Sorrow emerges when I remember my child's disability	3.3 (1.29)
I feel sorrow about things that do not matter for parents with healthy children (such as birthdays and entering school)	3.8 (1.30)
I feel sorrow when I picture my life without my child's disability	2.7 (1.28)
Total score of disparity	3.3 (1.06)

Descriptive Statistics for Chronic Sorrow

As shown in Table 4, the total score of the chronic sorrow reported by parents of children with disabilities had a mean of 3 (SD 0.87). Of the variables measuring chronic sorrow, the variable of sorrow and its nature of coming and going (ie, its periodic nature) had the highest score (mean 3.6, SD 1.16), along with reported energy to handle sorrow (mean 3.6, SD 1.11). On the other hand, the least reported variable within the

chronic sorrow concept was parents reporting that their life is not what they imagined due to their child's disability (mean 2.6, SD 1.33), followed by feeling that parental desires and goals do not match what life has given them (mean 2.7, SD 1.32). Overall, parents reported moderately high levels of chronic sorrow, indicating that these feelings of sorrow are manageable and can be reduced or that its cyclic nature can be spaced out.

Table . Descriptive statistics of chronic sorrow (N=89).

Chronic sorrow	Score, mean (SD)
Sorrow regarding my child's disability comes and goes	3.6 (1.16)
I feel like my child's disability makes me give up some aspects of my life	3.4 (1.40)
I feel like I do not have control over my life	2.9 (1.36)
I feel like my life is not like I imagined due to my child's disability	2.6 (1.33)
The feelings of sorrow can transform into feelings of loneliness	2.8 (1.38)
I feel like I have energy to handle life's stressors	3.6 (1.11)
Sudden changes in my child's disability have led to exhaustion	3.0 (1.26)
I think that what I desired does not align with what life has given me	2.7 (1.32)
I feel older due to my child's disability	2.9 (1.34)
Total score of chronic sorrow	3.0 (0.87)



Descriptive Statistics of Internal Management of Chronic Sorrow

Table 5 presents the descriptive statistics of how parents of children with disabilities view the effectiveness of internally managing their child's disability as a means to overcome chronic sorrow. The total score of internal management had a mean of 4.6 (SD 0.33), which is a high score, highlighting the important role of internal management of chronic sorrow. Of all the variables measuring the internal management of chronic sorrow, accepting the child's disability as destined by God (also known

in the Islamic religion as fatalism) demonstrated the highest score with a mean of 4.8 (SD 0.50), followed by the availability of resources that parents need to manage their child's disability (mean 4.7, SD 0.47). These were followed by feeling better when parents are more aware and can make independent decisions about the child's disability (mean 4.4, SD 0.62). The results of this study showed that internal management of a child's disability is crucial for reducing chronic sorrow and empowering the parents of children with disabilities to minimize their episodes of chronic sorrow, allowing them to provide the best care for their child.

Table . Descriptive statistics of internal management of chronic sorrow by parents of children with disabilities.

Internal management of chronic sorrow	Score, mean (SD)
I feel better when I am more aware of my child's disability	4.4 (0.62)
Making independent decisions about my child's disability is empowering for me	4.4 (0.62)
Accepting my child's disability as destined by God makes me feel better	4.8 (0.50)
The availability of resources (eg, financial and therapeutic) for my child induces a sense of relief	4.7 (0.47)
Total score of internal management	4.6 (0.33)

Descriptive Statistics of External Management of Chronic Sorrow

Table 6 shows results related to parents' external management of chronic sorrow, with the overall utilization of external management displaying great importance (mean 4.5, SD 0.42). Of all the variables measuring external management of chronic sorrow, feeling better when social support is provided displayed the highest score (mean 4.7, SD 0.55), followed by feeling better when the community is kinder and more considerate (mean 4.5, SD 0.56). The results of this study showed that both external and internal management of chronic sorrow are important tools that parents need to use and navigate to manage the periodic and unpredictable nature of chronic sorrow.

Table . External management of chronic sorrow by parents of children with disabilities.

External management of chronic sorrow	Score, mean (SD)
I feel better when doctors and nurses provide more information about my child's condition	4.4 (0.64)
I feel better when support is provided by family and the community	4.7 (0.55)
I feel better when I am allowed to express my emotions freely and without judgment	4.3 (0.71)
I feel better when I believe that we as a family have created a coping strategy that is specific to us	4.4 (0.62)
I feel better when more people in the community are considerate and kind to me and my child	4.5 (0.56)
Total score of external management of chronic sorrow	4.5 (0.42)

Association Between Chronic Sorrow and Parental Loss Experience and Disparity

Table 7 shows the Pearson correlation between chronic sorrow and the sense of loss experience and disparity. The study results showed a strong correlation between chronic sorrow and the concepts of disparity and loss. As shown in Table 7, chronic sorrow is strongly and positively correlated with loss experience (r=0.765; P<.001). In addition, the same strong correlation emerged between chronic sorrow and disparity (r=0.765; P<.001). Lastly, another positive and strong correlation emerged between the concept of loss experience and disparity (r=0.791; P<.001).

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Table . Pearson correlation between chronic sorrow and loss experience and disparity.

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Variable	Chronic sorrow	Loss experience	Disparity
Chronic sorrow			
r	1	0.765	0.765
P value	<u> </u>	<.001	<.001
Loss experience			
r	0.765	1	0.791
<i>P</i> value	<.001	_	<.001
Disparity			
r	.765	0.791	1
<i>P</i> value	<.001	<.001	_

^aNot applicable.

Association Between Chronic Sorrow and Time Since Diagnosis of the Child's Disability

Table 8 illustrates the results of the Pearson correlation between chronic sorrow and the amount of time elapsed since parents received their child's diagnosis. The correlation was negative and very weak (r=-0.009; P<.93), indicating that, as time passes, the feelings of chronic sorrow among parents do not subside. This study showed an inverse yet very weak relationship

between time since diagnosis and the chronic sorrow score, indicating that time passing does not play a role or have an impact on the recurrent nature of chronic sorrow. It is also worth mentioning that an increase in chronic sorrow as time passes was not indicated. Therefore, health care workers need to assess parents for chronic sorrow whether the diagnosis was received recently or a long time ago, highlighting the importance of multiple interventions to manage and coexist with chronic sorrow.

Table . Pearson correlation between the concept of chronic sorrow and time since diagnosis.

Variable	Chronic sorrow Time since child's diagnee	
Chronic sorrow		
r	1	-0.009
P value	a	.94
Time since child's diagnosis		
r	-0.009	1
<i>P</i> value	.94	_

^aNot applicable.

Discussion

Principal Findings

Literature examining chronic sorrow among parents with a child with a disability was scarce in the international and Saudi literature alike. Therefore, this study was designed to examine the application of the theory of chronic sorrow by Olshansky [13] to Saudi parents with a child with a disability. The study examined the major variables in the theory including loss experience, disparity, chronic sorrow, and internal and external management. In addition, we attempted to examine the relationships between these variables and whether time since diagnosis decreased the sense of chronic sorrow. The results of the study showed that parents reported a moderately high level of loss experience, disparity, and chronic sorrow. On the other hand, management methods (internal or external) played a crucial role for these parents in adapting to and managing their child's disability. In addition, the reported concepts of loss experience and disparity had a moderately strong relationship

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with the feelings of chronic sorrow that the parents were experiencing. Lastly, time elapsed since the child's diagnosis did not have an inverse relationship with the feeling of chronic sorrow, indicting that time passing does not play a role in the feeling of chronic sorrow.

Parents of children with disabilities have experienced loss, which is different for every parent; in addition, different parents have different abilities to navigate emotions. Loss experience can be interpreted as the loss of the ideal child [24]. This study found a moderately high level of loss experience and that its consequences can trigger the feeling of chronic sorrow. Loss experience among parents of children with disabilities has been reported in previous studies, reflecting the results of our study despite cultural and religious differences between the study populations. A study by Phillips [25] examined loss among parents of children with disabilities, viewing loss as a consequence that they are not familiar with, and its ability to impact the family's well-being. Studies by Fernandez et al [18] and Fernández-Alcántara et al [24] examined loss and grief (eg,

related to loss of the ideal child, a traumatic experience, and shock) in the same population, and the concept of the theory of chronic sorrow emerged there as well. Loss experience among parents is a crucial step that parents undergo to explore their chronic sorrow, eventually leading to acceptance and hope for their child's future.

Disparity is one of the major concepts of the theory of chronic sorrow. It follows the feelings of loss experience and is triggered by certain developmental milestones that parents of children with disabilities observe in healthy children [8]. Multiple studies have illustrated the presence of disparity within parents; those results were congruent with the results of this study. A study by Nikfarid et al [26] examined chronic sorrow in parents of children who were diagnosed with cancer, while a study by Olwit et al [8] investigated chronic sorrow in parents with children diagnosed with sickle cell disease. In both of these studies, parents mentioned the presence of disparity and its role in triggering chronic sorrow, contributing to its ongoing nature. Lastly, a study by Masterson [27] explored parental chronic sorrow and disparity when a child with cerebral palsy becomes an adult. The study showed that mothers still experienced disparity, which triggered a loss of hope as the child aged without meeting milestones.

Chronic sorrow among parents with a child with a disability is different from the normal grieving process or sadness because it is characterized by its cyclic nature, and it can be triggered by feeling of loss and disparity [13]. Results from studies examining chronic sorrow among parents with children with disabilities have been similar to and consistent with the results of this study. The theory of chronic sorrow explains the realistic feelings and emotions encountered by these parents and that these feelings do not manifest the same way as grief or a single loss because they can appear after parental acceptance of the disability [26-29]. Studies by Olwit et al [8] and Hobdell [30] found that chronic sorrow among parents needs to be assessed by health care workers as it has the potential to affect parental health and parental management of their child's disability. In parents, chronic sorrow may present as reduced social interaction, psychological distress, anger, and even guilt [20,31,32].

Internal management of chronic sorrow that is effective and used by parents plays a crucial role in minimizing the recurrence of chronic sorrow episodes, particularly if it is used correctly [18]. This study illustrates that fatalism (accepting God's destiny regarding the child's disability) represents the most effective internal management strategy for chronic sorrow. Multiple studies have displayed similar results in spite of different religious or spiritual beliefs among the study participants. Studies by Mikołajczuk and Zielińska-Król [33] and Pillay et al [34] reported that parents of children with disabilities found that religion and accepting God's destiny were effective coping mechanisms that improved parental resiliency, acceptance, and management of daily challenges. The participants of this study were predominantly from the Islamic religion, and the concept of fatalism as a means to internally manage chronic sorrow was most reported in this population. Fatalism in the Islamic religion is the belief that the future of man is already determined by God and cannot be swayed or changed whether the destiny is good

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or bad, and man should accept god's destiny and surrender to his will. Khan et al [35] and Othman et al [36] studied Muslim parents of children with disabilities and their results—in which parents found comfort, hope, and resiliency when integrating religion and spirituality when caring for their children—are congruent with this study.

Its important to note that this study is the first to use the theory of chronic sorrow among Saudi parents of children with disabilities, and it is crucial to incorporate religion and the concept of fatalism into this framework to fully capture the phenomena of chronic sorrow as the role of religion in navigating emotions is important in this population. The role of religion and belief in this context was previously reported in the literature by Alqunaibet [37] and Çaksen [38], who illustrated that religion and spirituality play an important role in helping parents and caregivers manage sorrow and stress.

Our questions regarding the external management of chronic sorrow aimed to capture the most efficient method used by parents. The results of the study identified social support (from family and the community in particular) to be key to externally managing chronic sorrow. The results of the study correspond with those of Ha et al [39] and Felizardo et al [40], who investigated the role of social support from family and the community, which yielded similar results to this study. Mantri - Langeveldt et al [41] conducted a scoping review to illustrate the important role of family support for parents with children with disabilities, reaffirming the importance of social support measurement by health care professionals.

This study identified a strong positive relationship between chronic sorrow and loss. The loss expressed by parents of children with disabilities is known as ambiguous loss as it is not definitive and not clearly visible as the child is alive, though not experiencing normal development. In addition, the loss associated with chronic sorrow in this population does not provide closure; the loss of the ideal child cannot be mourned because that child never existed [42]. Brown [43] conducted a study to capture the importance of sorrow and grieving in the healing process for mothers of children with intellectual disabilities. The results are similar to this study, as mothers experienced loss specifically after diagnosis and felt loss for their child and for their role as mothers. Senenac et al [44] described the parental experience of having a child with disabilities and the results identified that the themes of sorrow and loss are associated, along with other emerging concepts such as stigma and guilt.

This study identified a strong and positive relationship between chronic sorrow and disparity. Disparity, unlike loss, reemerges as time passes and the parents tangibly observe the inability of their child to meet developmental milestones like their peers, which triggers feelings of chronic sorrow [17]. Claassens et al [4] examined parental chronic sorrow among parents with children with disabilities. The results of the review yielded multiple findings, one of which was the strong relationship between chronic sorrow and disparity. The review identified events that parents undergo that trigger the resurgence of chronic sorrow and their role in reminding parents about the disparity and gap between the "idealized and hoped-for child" and "the

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ill or disabled child" [4]. Multiple studies have found that the same phenomenon is seen with disparity and its role in triggering chronic sorrow in parents caring for children with different types of disabilities or diseases that require caregiving, such as autism spectrum disorder [45], sickle cell disease [8], and cerebral palsy [46].

This study examined the relationship between time elapsed since the child received their diagnosis and chronic sorrow among parents. The results of this study have shown that there is no relationship between time passing and chronic sorrow, indicating that time does not play a role in reducing or increasing feelings of chronic sorrow. The results of this study correspond with the literature. A study by Fernandez et al [18] found that loss and sorrow persist over time and therefore emotional interventions are crucial for the parents of children with disabilities. Fernández - Ávalos et al [47] rationalized this phenomenon by explaining that parents are faced with daily challenges and worries when caring for their child. As a result, these challenges influence their perception of managing chronic sorrow and their quality of life. Therefore, delivering early interventions and realistic expectations of the child's development and disease prognosis are crucial, along with providing emotional care for parents. These interventions will play a role in managing chronic sorrow over time and eventually lead to acceptance, resilience, and enhanced mental health [48-50].

Limitations

This study collected data from parents primarily residing in Jeddah, Saudi Arabia. Therefore, the results of the study might not be generalizable to other countries or cultures. Another limitation was the type of disability that the children were diagnosed with, as much of the data were collected from parents with children with Down syndrome (44%), which limits generalizability to other types of disabilities that can be more severe or require less caregiving.

This study used nonprobability convenience sampling to recruit the parents of children with disabilities. This type of sampling has the potential to limit generalizability and therefore lacks external validity. It is worth noting that the study was conducted in Jeddah City, Saudi Arabia, and the majority of the participants reside in the western region of the country; we did not examine chronic sorrow in more rural areas of Saudi Arabia or other Middle Eastern countries that share multiple cultural aspects, which limits the generalizability of the study findings. Another limitation was the study's cross-sectional design. Cross-sectional study designs create ambiguity about the direction of the causal relationship between study variables. Lastly, to overcome time and financial constraints that the researchers were faced with, data were self-reported via a web-based questionnaire. Therefore, the conditions in which parents filled out the survey were not controlled nor objectively measured.

Conclusion and Recommendation

The aim of this study was to examine the experience of parents of children with disabilities with chronic sorrow in Saudi Arabia using the theory of chronic sorrow. We found moderately high levels of loss experience, disparity, and feelings of chronic sorrow among study participants. Therefore, the results of this study highlight the importance of chronic sorrow management and the creation of interventions to enhance parental mental health and well-being. In addition, internal management of chronic sorrow played a crucial role. In particular, we demonstrated the importance of the concept of fatalism and religious and spiritual beliefs among Arab Muslim parents of children with disabilities. With regard to external management, parents reported that family and community support were pivotal for the management of chronic sorrow, highlighting the social responsibility of all members of the community to provide support to both parents and children. This study also identified a strong and positive relationship between the concepts of the theory of chronic sorrow, specifically between the identified triggers of loss and disparity and chronic sorrow. Lastly, the study results found no relationship between feelings of chronic sorrow and time elapsed since the parents received their child's diagnosis. Given the results of this study, parents of children with disabilities need to be periodically screened for chronic sorrow as these feelings and coping strategies need to be addressed. Parental acceptance of their child's disability does not signify the absence of chronic sorrow, as it is part of the normal grieving process, but rather the anticipation of the triggers of chronic sorrow. The use of management methods, both internal and external, is essential for promoting parental mental health and child health outcomes.

This study has the potential to provide the foundation for future studies navigating and investigating chronic sorrow among parents with a children with a disability. Future studies could include an investigation of chronic sorrow based on the severity of the disability among parents caring for adult children with a disability and could be expanded to extended family members and caregivers.

Conflicts of Interest

None declared.

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Abbreviations

CS: chronic sorrow



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Association Between the Parenting Competence and Quality of Life of Family Caregivers of Children Aged 0-3 Years: Cross-Sectional Study

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Abstract

Background: The quality of life (QoL) for family caregivers significantly influences not only their own well-being but also the well-being of children aged 0 - 3 years. Competence stands out as a crucial subjective factor that impacts this QoL.

Objective: This study aimed to examine the factors affecting the QoL of caregivers of children aged 0 - 3 years and its correlation with parenting competency.

Methods: Caregivers of children aged 0 - 3 years from the child health department of a tertiary hospital in Changsha, Hunan Province, were chosen as the study sample through convenience sampling. The study investigated the relationship between parenting competency and the caregivers' QoL, utilizing general information, the parenting competency scale, and the family caregiver quality of life scale.

Results: In this study, 291 family caregivers, including 13 fathers and 278 mothers of children aged 0 - 3 years, were evaluated. The mean (SD) parenting competence score was 68.70 (9.816) and the mean (SD) QoL score was 56.81 (8.922). It was found that higher caregiver QoL scores were significantly associated with greater parenting competence (R=0.665, P<.001). Furthermore, each dimension of parenting competence demonstrated a significant positive correlation with each dimension of the QoL (P<.001).

Conclusions: The data suggest a notable association between parenting competence and QoL among family caregivers of children aged 0 - 3 years. This association has implications for improving fertility rates, as enhancing parenting competence may reduce childcare-related stress and thereby enhance the overall QoL.

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KEYWORDS

child; toddler; pediatric; infant; quality of life; QoL; family caregiver; caregiver; well-being; competence; quality of life factors; parenting competency; correlation; child health department; tertiary hospital; convenience sampling; parenting competency scale; family caregiver quality of life scale

Introduction

Quality of life (QoL) constitutes a subjective evaluation of one's place in life in the context of one's personal goals and value systems [1], spanning physical, social, spiritual, and psychological domains. The QoL of family caregivers for children aged 0 - 3 years not only mirrors the caregivers' own life quality, correlating with superior physical health and reduced incidence of anxiety or depression [2], but also influences the quality of care provided to the children [3]. Importantly, caregivers with a higher QoL tend to deliver improved care, which in turn enhances the life quality of children aged 0 - 3 years [4]. Consequently, evaluating the QoL is a crucial aspect in the study of family caregiving for this age group.

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The QoL is profoundly influenced by a myriad of factors. Among these, for family caregivers, the challenges posed by childcare significantly impact their well-being. Parenting stress is associated with reduced life satisfaction, deteriorated mental health, and a diminished overall QoL [5]. The QoL is inherently subjective, and thus, subjective factors often provide more reliable indicators than objective ones [6]. A critical subjective factor is the sense of competence in parenting, which encompasses an individual's comprehensive assessment of their effectiveness within the parenting role, particularly in terms of parenting efficacy and satisfaction [7]. Parents with high parenting competence typically display greater confidence and motivation when addressing and resolving challenges that arise in the course of childrearing [8]. For children between the ages of 0 - 3 years—a crucial phase in developmental terms—the

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pressures of parenting are acute. The research hypothesizes a correlation between the QoL and parenting ability, suggesting that enhancing parenting competence can alleviate parental stress and improve the QoL.

Recent studies on the QoL of child caregivers focused on parents caring for children with special needs or intergenerational caregivers [9]. However, they overlooked the experiences of typical parental caregivers. The purpose of this study was to explore the connection between parent competence and the QoL among caregivers of children aged 0 - 3 years. It also aimed to offer insights and guidance for the development of effective parenting strategies and interventions for families with children in this age group.

Methods

Design

The convenience sampling method was employed to select eligible family caregivers of children aged 0 - 3 years from the Child Health Department at a tertiary hospital in Changsha, for a questionnaire survey conducted from January to April 2024.

Participants

According to the widely recognized method for estimating sample size, it is recommended to have a sample size that is 5 to 10 times the number of variables under study [10]. This research encompasses 8 demographic and disease-related variables and 6 additional dimensions from the scale, resulting in a total of 14 variables. Consequently, an initial sample size of 70 to 140 participants is suggested. To accommodate a potential 10% loss of samples and the presence of invalid questionnaires, the minimum sample size should be adjusted to range from 77 to 154 participants. In this study, a total of 300 questionnaires were disseminated; 9 of them were excluded due to incomplete questionnaires.

The inclusion criteria were as follows: (1) guardians of children aged 0 - 3 years acting as primary caregivers; (2) possessing adequate cognitive communication skills; (3) consenting to participate in the study; and (4) capable of independently completing the survey. Conversely, exclusion criteria encompassed: (1) individuals with psychiatric disorders or those averse to collaboration; (2) family members of sick children; and (3) participants withdrawing for various reasons (for example, not having time to complete all the questionnaires, or unwilling to continue participating midway).

To guarantee the integrity of the data collection process, the investigator remained present to assist participants with any queries and to verify that the questionnaires were filled out completely.

Ethical Considerations

The study was approved by the Ethics Committee (No. E2023121). The data are anonymized. The participants were informed of the purpose and procedures of the study prior to participation, and we obtained informed consent from the parents. The participants did not receive any remuneration.

Data Collection and Measurements

General Information

This information encompassed the relationship with the child, marital status of the child's parents, family structure, child's age, identity of the primary family caregiver, physical health of both the child and the caregiver, method of the child's conception, and feeding practices employed.

Parenting Competence Scale

The Parenting Competence Scale was developed by Gibaud-Wallston and Wandersman [11] in 1978 and translated by Yang et al [12]. The scale comprises 17 items, bifurcated into two principal dimensions: efficacy and satisfaction. The efficacy component encompasses eight items that gauge parents' self-perceptions of their parenting skills, whereas the satisfaction component comprises nine items that assess parents' contentment with their role as caregivers. The scale ranged from "1: Totally Disagree" to "6: Totally Agree." The scores fluctuate between 17 and 102, with elevated scores mirroring enhanced parenting competence. The reliability of the scale is substantiated by a Cronbach α coefficient of 0.80.

Family Caregiver Specific QoL Scale

The Family Caregiver Specific QoL scale, developed by Nauser et al [13] and transcribed by Hyland Qian [14], was employed to assess the QoL in family caregivers. It comprised 16 items that span four dimensions: physical, social, spiritual, and psychological well-being. Four entries for each dimension. All domains carry equal importance. Employing a 5-point Likert scale, it allows respondents to answer with options ranging from "1: Strongly Disagree to "5: Strongly Agree." Items that were negatively expressed were reverse-scored. The scale scores spanned from 16 to 80, with higher scores suggesting an enhanced QoL for the caregiver. The Cronbach α for the Chinese version of the scale was 0.84, further confirming its reliability and validity. This scale has been applied in family caregivers for children with heart disease, premature infants, and newborns [15,16].

Statistical Analyses

Statistical analysis was conducted using SPSS software (version 24.0; IBM Corp). The general information was analyzed descriptively using frequency counts (component ratios). The QoL and parenting competence scores of family caregivers were characterized using means and standard deviations, provided they adhered to a normal distribution. One-way analyses were carried out to identify factors influencing QoL using *t* tests or ANOVA. The association between the QoL and parenting competence of family caregivers was assessed using the Pearson correlation analyses.

Results

General Information

A total of 300 parents participated in the survey, of which 291 responses were valid, yielding a questionnaire recovery rate of 97%. The participants comprised 13 fathers and 278 mothers, as detailed in Table 1.

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Table . General information (N=291).

RelationshipFather13 (4.47)Mother278 (95.53)Family structure170 (58.42)
Father13 (4.47)Mother278 (95.53)Family structure170 (58.42)
Mother278 (95.53)Family structure170 (58.42)
Family structure Nuclear family 170 (58.42)
Nuclear family 170 (58.42)
Stem family 118 (40.55)
Single-parent family3 (1.03)
Marital status
Married 289 (99.31)
Divorcee 2 (0.69)
Child's age
0 - 6 months 233 (80.07)
~1 year old 30 (10.31)
~2 years old 16 (5.50)
~3 years old 12 (4.12)
Caregivers' physical health
Good 247 (84.88)
Not well 44 (15.12)
Child's physical condition
Good 275 (94.50)
Not well 16 (5.50)
Pregnancy method
Planned 264 (90.72)
Assisted reproduction 22 (7.56)
Unplanned 5 (1.72)
Feeding style
Exclusive breastfeeding 124 (42.61)
Artificial feeding 28 (9.62)
Mixed feeding 139 (47.77)

Scores of Parenting Competence and QoL

In this study, we evaluated the parenting competence of family caregivers for children aged 0 - 3 years, finding an average

(SD) score of 68.70 (9.816), while the average (SD) QoL score stood at 56.81 (8.922). Detailed scores for each dimension are depicted in Table 2.



Table .	Score of	parenting	competence	and quality	of life	(N=291).
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Items	Range	Median (P ₂₅ ,P ₇₅)	Mean (SD)
Parenting competence	34, 101	68 (62,75)	68.70 (9.816)
Efficacy	17, 47	33 (29,39)	32.98 (5.604)
Satisfaction	17, 54	35 (32,29)	35.72 (4.975)
Quality of life	20, 80	57 (50, 63)	56.81 (8.922)
Physical well-being	6, 20	14 (12,16)	14.23 (2.568)
Spiritual well-being	4, 20	16 (13,16)	15.10 (2.987)
Social well-being	4, 20	14 (12,16)	13.90 (2.981)
Psychological well-being	4, 20	13 (12,16)	13.59 (3.391)

Association Between Caregiver Parenting Competence and QoL

P<.001).Positive correlations were consistently observed across all dimensions of parenting competence and the corresponding dimensions of QoL (P<.001), as detailed in Table 3.

Notably, there was a significant positive correlation between the caregivers' QoL score and parenting competence (r=0.665,

 Table . Correlation analysis of parenting competence and quality of life (N=291).

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	Parenting competence	Quality of life	Efficacy	Satisfaction	Physical well- being	Spiritual well- being	Social well- being	Psychological well-being
Parenting competence	1	N/A ^a	N/A	N/A	N/A	N/A	N/A	N/A
Quality of life	.665 ^b	1	N/A	N/A	N/A	N/A	N/A	N/A
Efficacy	.936 ^b	.634 ^b	1	N/A	N/A	N/A	N/A	N/A
Satisfaction	.919 ^b	.598 ^b	.721	1	N/A	N/A	N/A	N/A
Physical well- being	.481 ^b	.815 ^b	.461 ^b	.430 ^b	1	N/A	N/A	N/A
Spiritual well- being	.583 ^b	.711 ^b	.502 ^b	.584 ^b	.424 ^b	1	N/A	N/A
Social well- being	.373 ^b	.748 ^b	.369 ^b	.319 ^b	.536 ^b	.437 ^b	1	N/A
Psychological well-being	.545 ^b	.731 ^b	.553 ^b	.452 ^b	.542 ^b	.284 ^b	.298 ^b	1

^anot available

 $^{b}P < .001$

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Discussion

Main Findings

The parenting competence scores of family caregivers for children aged 0 - 3 years exhibited a positive correlation with the caregivers' QoL (R=0.665, P<.001). Additionally, scores across all domains of parenting competence demonstrated positive correlations with scores across all dimensions of QoL (P<.001).

General Information on Family Caregivers

Composition of Family Caregivers

In this study, out of 291 participants, 278 were mothers (95.53%); therefore, mothers emerged as the predominant family caregivers. Consequently, efforts to enhance the QoL for family caregivers should prioritize understanding and addressing the

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experiences and sentiments of maternal caregivers. Out of 291 families, there are 170 nuclear families (58.4%) and 118 stem families (40.6%). Stem families refer to families where grandparents, parents, and children live together. This type of family is common. Although the mother is the primary caregiver, in China, grandparents are usually more involved in parenting. There may be differences in parenting concepts between parents and grandparents. Future research could explore the impact of grandparents' involvement in parenting on family dynamics.

Level of Caregiver Parenting Competence and QoL

Parenting Competence of Family Caregivers

The mean (SD) parenting competence score among family caregivers of children aged 0 - 3 years was 68.70 (9.816). This study is pioneering in investigating the parenting competence for this age group, as the majority of existing research has primarily concentrated on children age 1 years, particularly the

initial 42 days postdelivery, thereby limiting comparative analysis [17]. The present study revealed a medium level of parenting competence. The efficacy and satisfaction dimensions had different numbers of entries and were not comparable.

QoL of Family Caregivers

In this study, the mean (SD) caregiver QoL score was found to be 56.81 (8.922). Given the plethora of scales designed to measure caregiver QoL, particularly those catered to children with special needs, direct comparisons with other studies are challenging [18]. Among the four dimensions assessed, family caregivers exhibited the highest scores in psychological well-being. Parent-child interactions appear to bolster parent-infant attachment, especially during early development stages (0 - 3 y). Therefore, promoting these interactions within families could be an effective strategy for future interventions [19]. The social and psychological dimensions of QoL were notably deficient, so strengthening social support for caregivers of children aged 0 to 3 years and addressing their related psychological issues is a way to improve the QoL for caregivers [20].

Association Between Caregiver Parenting Competence and QoL

Impact of Parenting Efficacy on QoL

Research has consistently demonstrated a positive correlation between parenting efficacy and the QoL of caregivers [21-23]. Enhanced parenting efficacy not only bolsters cognitive and behavioral functioning but also catalyzes improvements in physical and mental health. Alam et al [24] found that caregivers are susceptible to physiological issues such as sleep disorders, weight loss, and fatigue due to their caregiving responsibilities. According to Bandura's theory [25], parents with a heightened sense of efficacy are more adept at self-regulation and self-management when confronted with challenging parenting scenarios, such as a decline in the child's health, thereby enjoying a higher physiological QoL. In terms of mental aspects, the task of caregivers is to manage the daily needs of children aged 0 to 3 years, take care of family members, and participate in decision-making, which may lead to mental health challenges. The research implies that individuals possessing a stronger sense of efficacy may exhibit an enhanced ability to mitigate the detriments of negative mental health [26]. Confronted with obstacles in parenting, such as disputes concerning educational philosophies, they are inclined towards adopting positive coping tactics to regulate their emotional state and promote superior mental health quality. From a social perspective, an unwavering focus on infants and toddlers might curtail a carer's independence, consequently posing adverse effects on their psychosocial development. Numerous investigations establish a linkage between social support and QoL [27-29]. Such findings indicate that the QoL could potentially intermediate the relationship between a collective sense of efficacy and parenting proficiency. In other words, caregivers possessing a stronger sense of efficacy are likely to be more assertive in pursuing

social support, are more equipped to furnish social support, and possess a better overall social QoL. The psychological state of a caregiver is heavily influenced in their interaction with children aged 0 - 3 years [30]. Factors such as concern for the child's health, challenges in transitioning to caregiving roles, and understanding the child's expressions may catalyze anxiety and depression among caregivers. Loh et al [31] proposed that caregivers who are capable of effectively managing, adjusting to, and surmounting difficulties experience lesser burden and exhibit fewer symptoms of anxiety and depression. Furthermore, these caregivers tend to have a better social QoL due to their increased sense of efficacy.

Impact of Childcare Satisfaction on QoL

The positive correlation between childcare satisfaction and caregiver QoL has been well-documented. Numerous studies have examined the correlation between satisfaction and the QoL, typically comparing the two as indicators for assessing outcomes [32,33]. However, Sansó et al [34] postulated a direct correlation between life satisfaction and the QoL. Parenting satisfaction represents an individual's comprehensive evaluation of their parenting role. Physiologically, parents experiencing high levels of satisfaction are less inclined to engage in self-reproach, exhibit reduced susceptibility to fatigue and burnout while attending to children aged 0 - 3 years, and provide superior care, thereby enhancing their physiological QoL. Psychologically, these parents demonstrate a decreased likelihood of experiencing frustration and negative emotions when confronted with childcare challenges. Moreover, the subjective experience of well-being is recognized as a fundamental element for maintaining high mental health and satisfaction [35]. Consequently, parents who report satisfaction tend to exhibit a lower threshold for experiencing pleasure, reduced vulnerability to mental or psychological issues, and an elevated mental and psychological QoL. Socially, in line with societal expectations in many cultures, Chinese parents who fall short in their parenting duties are held accountable by various segments of society. Parents with high parenting satisfaction are more likely to cultivate higher-quality social connections, receive enhanced social support for their childcare responsibilities, and enjoy a superior quality of social life.

Limitations

This study employed a convenience sampling method from a single hospital, limiting its representativeness. Future research should consider stratified sampling across various countries, hospitals, and communities. Additionally, investigating the mediating factors between parenting competence and QoL may offer valuable insights for further studies.

Conclusion

The study found that family caregivers of children aged 0 - 3 years exhibit a correlation between parenting competence and QoL, with all dimensions showing significant correlations. Health care professionals have the potential to enhance QoL by fostering parenting competence.



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Conflicts of Interest

None declared.

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Abbreviations

QoL: quality of life

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

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Abstract

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

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

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

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

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

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KEYWORDS

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

Introduction

Parents have a central role in shaping children's long-term health behavior by the behaviors they promote and role model [1-5].

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Changing societal trends of increasing rates of maternal participation in the workforce have resulted in child rearing activities in the home environment becoming increasingly shared with fathers [6,7]. Fathers are, thereby having an increasing

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

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

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

At present, despite research indicating that mobile health (mHealth) resources and apps are an effective tool for parents, there is a paucity of evidence examining the acceptability, usefulness, and effectiveness of such resources for fathers [32]. Evaluations of the limited number of apps for fathers (ie, Milk Man and mDad) have provided some evidence of the benefits of using these resources for support and guidance of fathers in

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limited areas of parenting, such as breastfeeding. However, there is a need to consult directly with fathers to gain greater understanding of their specific needs and preferences for mHealth resources promoting positive dietary and physical activity behaviors in young children. This will inform understanding of how mHealth parenting resources can be made more engaging for fathers to use. To our knowledge, no app exists exclusively for fathers to promote positive dietary and active play/physical activity behaviors in children aged 5 years or younger. Therefore, the aim of this study is to explore how to make parenting apps more engaging and useful for fathers using an existing app (My Baby Now) as a case study.

Methods

Study Context- Use of the My Baby Now App

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

Study Design

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

Recruitment

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

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

Data Collection

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

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

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

Data Analysis

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

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

Researcher Reflexivity and Credibility

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

Ethical Considerations

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

Results

Participants

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

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

home and were married. The majority of fathers were university educated (10/14) and were employed full-time (12/14). Participants in this study were broadly similar of survey participants; however, in contrast to participants in the survey who were 61.5% metropolitan based, the majority of fathers in the qualitative study (64.3%) were region or rural based (9/14).

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

The 14 participating fathers were on average around 40 years of age, had 1 or more children aged 5 years or younger with an average age of 2.4 years (Table 1). The majority of the fathers identified as Australian born (12/14) and all spoke English at

Table 1.	Characteristics	of fathers	participa	ating in :	focus s	groups a	nd interviews
			P				

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

^aTechnical and further education.

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

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

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

Theme 1: Previous Information Seeking

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

Theme 2: Functionality of the My Baby Now App

In this theme, fathers' spoke about what was important to them in regard to how the MBN app should function. Most fathers made comments about the importance of being able to navigate around the MBN app easily. However, some fathers highlighted

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some frustration with needing to scroll or swipe excessively, which resulted in them losing their place (subtheme 2.1). When able to locate and engage with the sections of the MBN app as desired, fathers spoke positively about the reassurance they felt from the information provided (subtheme 2.2).

Theme 3: Engagement With the My Baby Now App

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

Theme 4: Aesthetics of the My Baby Now App

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

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

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

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

Discussion

Principal Findings

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

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

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

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

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

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

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

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

Strengths and Limitations

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

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

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

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

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Data Availability

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

Authors' Contributions

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

Conflicts of Interest

None declared.

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

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Abbreviations

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

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Hospitalization and Mortality in Brazilian Children and Adolescents Due to COVID-19: Retrospective Study

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Abstract

Background: COVID-19 is currently one of the most important medical challenges as it affects the entire population, with children and adolescents being infected as easily as adults.

Objective: The objective of this study was to evaluate the prevalence of mortality in children and adolescents aged <19 years, compared to that of adults.

Methods: This retrospective, observational study analyzed the medical records of all patients diagnosed with COVID-19 by real-time reverse transcription–quantitative polymerase chain reaction who were hospitalized at Hospital de Base and the Infant and Maternal Hospital of São José do Rio Preto, São Paulo, Brazil. Out of a total of 8986 hospitalized patients who were COVID-19 positive, 383 (4.26%) were children and adolescents aged <19 years (group 1), and 8603 (95.74%) were adults (group 2).

Results: Overall, mortality was significantly higher (P<.001) in group 2 (2185/8603, 25.4%) compared to group 1 (12/383, 3.1%). A total of 11 (92%) of the 12 patients in group 1 that died had associated diseases. The mortality rates by age group were as follows: infants aged <1 year, 1.6% (2/123); children aged 1-4 years, 4% (4/95); children aged 5-9 years, 2% (1/47); adolescents aged 10-14 years, 2% (1/40); and adolescents aged 15-19 years, 5% (4/78).

Conclusions: Mortality from COVID-19 in children and adolescents was significantly lower than that in adults and was associated with other comorbidities.

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KEYWORDS

COVID-19; children; mortality; Brazil; retrospective study; morbidity; hospitalization

Introduction

COVID-19 is currently one of the most important medical challenges as it affects the entire population, with children and adolescents being infected as easily as adults; children and adolescents often remain asymptomatic or have mild complaints due to their immature immune systems [1]. Advanced age and comorbidities such as hypertension, diabetes, ischemic heart disease, vascular disease, renal failure, obesity, dyspnea, and dementia have been reported to be associated with a greater risk of death among older people infected with COVID-19. Some studies have described pathophysiological insights into COVID-19-induced coagulopathy, endothelium disease, and angiogenesis-associated defects [2-4]. Most children and adolescents with COVID-19 have mild symptoms; however, coagulopathies have been associated with multisystem inflammatory syndrome-a postinfectious complication-in young patients [2].

A study in Sergipe, Brazil, describing COVID-19 cases and deaths in children and adolescents reported 37 deaths before September 20, 2020, corresponding to a rate of 4.87 deaths per 100,000 of the population aged <19 years. Most children and adolescents had comorbidities such as chronic neurological diseases (n=7, 19%) and prematurity (n=4, 11%). Furthermore, most children and adolescents who died (n=18, 49%) were not admitted to intensive care units. This was possibly related to the great regional inequalities in health care [5].

A study in England reported that 4% (1408/35,200) of tests performed in children and adolescents aged <16 years were positive for SARS-CoV-2, compared to 19.1% to 34.9% in adults [3]. A review of pregnant women with COVID-19 reported that SARS-CoV-2 was detected in 4.3% (19/444) of newborns at birth. Elevated levels of immunoglobulin M and G serum antibodies were reported in one case, but the swab test was negative [4]. Mortality in children is higher in those with existing diseases compared to those without comorbidities [6].



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Regarding the prognosis, metabolic acidosis, hyperlactatemia, hyperglycemia, altered liver function parameters, and hypoproteinemia are biochemical markers associated with the severity of the disease in children infected with SARS-CoV-2. Anemia and ketoacidosis are important risk factors for death in the pediatric patient population who are infected [7]. Gastrointestinal involvement is common in children hospitalized for acute COVID-19 infection and multisystem inflammatory syndrome, but gastrointestinal involvement is not associated with critical illness, length of hospital stay, or mortality in acute cases of COVID-19 [8].

In a study of pediatric COVID-19 epidemiology, Sousa et al [9] highlighted the presence of comorbidities in patients aged <2 years, in particular those related to congenital heart disease, Down syndrome, obesity, and asthma. Furthermore, these authors reported differences in morbidity and mortality due to regional disparities, with higher rates in regions with less resources, as is the case in the economically less favored northern and northeastern regions of Brazil. In their analysis of 2020 deaths of children that occurred throughout Brazil, 42% occurred in children aged <2 years and 43% occurred in adolescents aged 10 - 19 years, with children aged 2 - 10 years being relatively protected. A total of 58% of deceased patients had at least one comorbidity. It is noteworthy that 69% of deaths were observed in Black or multiracial patients, 25.5% in White patients, and 5% in Indigenous patients, with approximately 60% occurring in the northern and northeastern regions of Brazil.

It is also worth remembering the prolonged symptoms that are associated with COVID-19—notably, fatigue, headaches, drowsiness, and difficulty concentrating—as well as the impact of social isolation, which can cause psychosocial disorders and learning gaps that can have a major impact on children's education [10,11].

An American study reports that pediatric patients with a recent relapse of cancer have a higher chance of all-cause mortality when infected with COVID-19 [12].

The objectives of this study were to evaluate the mortality of children and adolescents and compare it with that of adults in a cohort of 8986 patients hospitalized for COVID-19 in a university hospital complex in Brazil.

Methods

Patients and Setting

A retrospective, observational study was performed to analyze the medical records of all patients diagnosed with COVID-19 who were hospitalized at Hospital de Base and the Infant and Maternal Hospital of São José do Rio Preto, São Paulo, Brazil, from March 2020 to July 2023. All patients diagnosed with COVID-19 by reverse transcription–quantitative polymerase chain reaction and admitted to these hospitals were included in this study. Patients hospitalized for other illnesses and those who tested negative for COVID-19 during this period were excluded.

Patients aged <19 years were categorized as children or adolescents (group 1), and those aged \geq 19 years were categorized as adults (group 2). Group 1 was further subdivided by age: <1 year, 1 - 4 years, 5 - 9 years, 10 - 14 years, and 15 - 19 years. The monthly occurrence of COVID-19 was evaluated, with mortality in children and adolescents being compared to that in adults. Existing diseases and the occurrence of other viral infections were identified over the same period in patients aged <19 years who were COVID-19 positive.

Ethical Considerations

The study was approved by the ethics committee of the Medical School in São José do Rio Preto under approval 6.086.468 (CAAE 67915723.3.0000.5415; date approved: May 29, 2023).

For this study, the institution permitted the analysis of these records, guaranteeing the use of data only in this research protocol. Absolute confidentiality was maintained during the data collection and use thereof. Safeguards were taken to collect data from medical records in the institution's own archives department; patient charts were not removed for any reason.

The signed consent form was authorized by the ethics committee to be waived, because these were medical records and due to the impossibility of contacting family members and those who have died. Thus, the authors guaranteed the privacy and confidentiality of the data obtained, fully preserving the anonymity of the participants in accordance with the Declaration of Helsinki.

Statistical Analysis

Data were tabulated in Microsoft Excel spreadsheets, with statistical analysis conducted using StatsDirect 3 software (StatsDirect Ltd). Descriptive statistics, Fisher exact test, chi-square test, and odds ratio were used considering an α error of 5% (*P*≤.05).

Results

Between March 2020 and July 2023, a total of 8986 patients who were COVID-19 positive were hospitalized, 383 (4.26%) of whom were aged <19 years and 8986 (95.74%) were aged ≥19 years (mean age 57.66 y; Figure 1). Overall, 12 children and adolescents died, that is, 3.1% of the 383 patients in this age group. The number of deaths in group 2 (adults) was 2185, that is, equivalent to 25.4% of the 8603 hospitalized adults and 99.45% (2185/2197) of overall deaths. Mortality was significantly higher for adults than children and adolescents aged <19 years (Yates-corrected χ^2 test=98.127501, *P*<.001; odds ratio 10.317, 95% CI 5.793 - 18.374).



Figure 1. Patients hospitalized with COVID-19 by age group and year.



■ 2023 ■ 2022 ■ 2021 ■ 2020

Regarding the different age groups of children and adolescents, the mortality rates were as follows: infants aged <1 years, 1.6% (2/123); children aged 1-4 years, 4% (4/95); children aged 5-9 years, 2% (1/47); adolescents aged 10-14 years, 2% (1/40); and adolescents aged 15-19 years, 5% (4/78). There were no statistical differences between the different age groups (Fisher

exact test: *P*=.30; Table 1 and Figure 2). Figure 3 shows the main viral infections of the patients who were COVID-19 positive in the 2 hospitals, emphasizing the importance of this disease. Table 2 shows the associated diseases of the 12 children who died from COVID-19.

Table . Hospitalizations and deaths for different age groups from March 2020 to July 2023.

Age group (years)	2020		2021		2022		2023		Total	
	Hospitaliza- tions, n	Deaths, n								
<1	11	0	18	1	73	1	21	0	123	2
1 - 4	20	1	16	1	42	2	17	0	95	4
5 - 9	9	0	15	1	17	0	6	0	47	1
10 - 14	11	1	16	0	13	0	0	0	40	1
15 - 19	19	2	31	0	26	2	2	0	78	4
20 - 29	100	8	219	20	82	4	7	1	408	33
30 - 39	279	13	620	76	101	8	14	2	1014	99
40 - 49	431	27	834	125	125	11	17	3	1407	166
50 - 59	551	85	981	241	190	23	19	3	1741	352
60 - 69	597	147	744	287	275	71	34	11	1650	516
70 - 79	500	187	555	257	298	90	47	11	1400	545
80 - 89	273	141	236	136	247	94	34	6	790	377
90 - 99	61	43	37	22	82	28	6	0	186	93
>100	4	3	2	1	1	0	0	0	7	4
Total	2866	658	4324	1168	1572	334	224	37	8986	2197



Figure 2. Hospitalizations and deaths of children and adolescents who were COVID-19 positive.



Figure 3. Percentage of hospitalized cases for COVID-19, influenza, and respiratory syncytial virus (RSV) at the hospital complex in São José do Rio Preto, according to month and etiological agent from October 1, 2021, to July 24, 2023.





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Table . Chief comorbidities associated with COVID-19 that led to the deaths of children and adolescents.

Age (y)	Sex	Comorbidi- ty	Infection	Antibiotics	Image	Vasoactive drugs	Mechanical ventilation	Intensive care unit	Dialysis support	Time in hospital (mo)
19	Female	Hodgkin lymphoma	Yes	Yes	CT ^a 25% compro- mised (ground- glass opaci- ty)	Yes	Yes	Yes	Yes	45
14	Female	Down syn- drome	Yes	Yes	CT 70%	Yes	Yes	Yes	Yes	12
2	Male	Down syn- drome and heart dis- ease	Yes	Yes	Rx ^b	Yes	Yes	Yes	Yes	5
19	Female	Down syn- drome, schizophre- nia, asth- ma, and corrected heart dis- ease	Yes	Yes	CT 50% compro- mised	Yes	Yes	Yes	Yes	5
0	Male	None	Yes	Yes	Rx infiltrat- ed	Yes	Yes	Yes	Yes	5
2	Male	En- cephalopa- thy	Yes	Yes	Rx	Yes	Yes	Yes	Yes	24
5	Male	Renal transplant	Yes	Yes	CT >50% infiltrated (ground- glass opaci- ty)	Yes	Yes	Yes	No	20
3	Male	Congenital heart dis- ease	Yes	Yes	Rx	Yes	Yes	Yes	No	3
16	Female	Tumor in the central nervous system	Yes	Yes	CT >50% infiltrated (ground- glass opaci- ty)	Yes	Yes	Yes	Yes	10
17	Female	Lupus	Yes	Yes	CT <25%	Yes	Yes	Yes	No	55
3	Female	Hydranen- cephaly	Yes	Yes	Rx	No	Yes	Yes	Yes	1
1	Female	Congenital heart dis- ease	No	No	Rx	Yes	Yes	No	No	1

^aCT: computed tomography.

^bRx: x-ray.

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Discussion

Principal Findings

This study reports on the general mortality of children and adolescents aged <19 years and adult patients in a single university hospital complex from March 2020 to July 2023. Of the 8986 patients hospitalized with COVID-19, a total of 383

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(4.26%) were children and adolescents treated at the children's hospital. Deaths in this age group represented 0.55% (12/2197) of all deaths from COVID-19 in the institution and 3.1% (12/383) of all hospitalized patients aged <19 years. No significant difference was detected in mortality between the age groups of children and adolescents. A multicenter study in Latin America reported a mortality rate of 14% in 210 children, with

67% of those who died being treated in an intensive care unit [13].

Observational studies in the pediatric population have shown that the presence of comorbidities is a risk factor for severe disease. Obesity, genetic disorders (such as sickle cell anemia), neurological disorders, hematological diseases, congenital heart diseases, diabetes, chronic kidney disease, asthma, and other lung diseases are pathologies that have already been associated with the severity of COVID-19 in previous studies [14]. In this study, heart disease was the main disorder reported in the children and adolescents who died.

Regarding the age of the children and adolescents, there is no consensus on which age group has the highest or lowest severity of disease, included mortality; however, severity does seem to be linked to the presence of preexisting clinical factors. A review study reported that younger children and those with specific comorbidities, such as obesity, diabetes, heart diseases, chronic lung diseases, epilepsy, and immunocompromised conditions, are at higher risk of infection and potentially more severe consequences of COVID-19 [15,16].

One interesting Brazilian study that analyzed a large nationwide database of hospitalized children and adolescents with laboratory-confirmed COVID-19 showed that death was associated with being aged younger than 2 years or between 12 and 19 years. Indigenous ethnicity, living in the poorest microregions, and the presence of comorbidities were also correlated with the severity of the disease. Therefore, health care disparities and social inequalities, exacerbated by interweaving comorbidities, might have contributed synergistically to magnifying the COVID-19 burden for more socioeconomically deprived and vulnerable individuals [17]. Due to uncertainties in epidemiological data on children, there is still much to learn about the manifestations of COVID-19 in this population.

In this study, no significant differences with respect to mortality were detected between age groups of the children and adolescents; however, the number of patients is too small to arrive at any definite conclusion.

In North America, mortality was higher in children younger than 1 year, followed by adolescents aged between 15 and 19 years [18]. In 2021 and 2022, a study in Java, Indonesia, analyzed 6441 patients aged \leq 18 years who were positive for COVID-19 and reported that 2.7% of deaths occurred with other associated factors; in this study, the rate was 91.67%—a difference that may be related to the different conditions (socioeconomic factors and access to health care) in the 2 countries [19].

Regarding mortality, since the beginning of the pandemic, newborns, children, and adolescents are less prone to this emerging condition compared to adults. Most of them experience mild symptoms; hospitalization and death of pediatric patients are rare, with deaths usually being explained by associated complications [20].

In Ecuador, a study on mortality from 2020 to 2021 reported that out of 34,001 confirmed cases of COVID-19, a total of 258 were children and adolescents aged between 0 and 19 years and

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that 127 died due to COVID-19. In the same period, the study found that most deaths occurred in children aged 0 to 1 year, representing 44% (n=114) of the total deaths reported [21].

In Brazil, in 2020, a total of 14,638 children were diagnosed with SARS, resulting in 1180 (8.06%) deaths. Being younger than 2 years was a risk factor for higher hospitalization and mortality rates [22]. In 2021, an increase in the number of cases of pediatric patients was noted; according to data from the Brazilian Ministry of Health, there were 17,644 occurrences of SARS-CoV-2 with 1263 (7.15%) deaths. This rise is related to greater knowledge of the disease, a simpler diagnosis, the larger quantity of diagnostic tests performed, and the emergence of new variants (Delta and Omicron) [9].

Pediatric patients with comorbidities are at higher risk for hospitalization and mortality. Among the reported comorbidities, the following should be highlighted: Down syndrome, asthma, obesity, immunosuppression, and heart disease. Morbidity and mortality due to COVID-19 are not similar to other etiologies of acute respiratory distress syndrome. This is because fulminant activation of coagulation cascades can occur in COVID-19, resulting in widespread microvascular thrombosis and the consumption of clotting factors [9,22-25]. It appears that inflamed lung tissues and pulmonary endothelial cell damage may result in the formation of microthrombi that contribute to the high incidence of thrombotic complications, such as deep vein thrombosis, pulmonary embolism, and arterial thrombotic complications.

Another important factor that must be highlighted is the possibility of long-term symptoms such as fatigue, headaches, drowsiness, and difficulty concentrating, all of which have implications in social and educational spheres, leading to important concerns regarding the impact of the pandemic on future education levels.

Another point to be considered is related to the risk of the long-term effects of COVID-19 on the health of the general population. Post–COVID-19 coronary changes and the presence of multisystem inflammatory syndrome were identified in some pediatric patients. Therefore, although children and adolescents represent a low percentage of COVID-19 cases in Latin America and worldwide, major social, economic, and cultural implications are linked to the disease in this population. In truth, COVID-19 has disrupted all spheres of life, including country risk factors, such as exposure to multidimensional risk drivers.

Socioeconomic and political factors significantly influence health care conditions and directly impact the response to pandemics, including the allocation of resources for immediate health care needs. Studies analyzing the influence of demographic, economic, and political conditions in different countries and continents show a significant difference between countries with a low Human Development Index and those with a high Human Development Index. This has influenced, and continues to directly influence, human health care [26,27].

It should be remembered that the dynamics of infections and deaths related to COVID-19 differ from country to country and are constantly changing throughout Latin America. Management requires political leadership, financial resources, and social

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equality, as well as the existence of informal and regional economies directed toward disadvantaged populations that traditionally have had limited access to health services. In this study, COVID-19 was the most common viral infection identified in this period. Mortality from COVID-19 in children and adolescents was lower than that in adults and was generally associated with existing diseases, with the main one being heart disease.

This study shows results consistent with our hypothesis and with the results of studies published in MEDLINE. Thus,

predicting the outcome of COVID-19 is of vital clinical importance to better allocate medical resources and provide individualized treatment for patients. The availability of clinical characteristics and parameters with potential prognostic implications will be of value for effective prevention and intervention.

Conclusion

Mortality from COVID-19 in children and adolescents was lower than that in adults. A second interesting finding was that these deaths were generally associated with existing diseases.

Data Availability

All data generated and analyzed during this study have been included within the paper.

Authors' Contributions

ACPdG and RBB contributed to the concept and design, acquisition of data, analysis and interpretation of data, drafting of the paper, and revising it critically for important intellectual content. ACPdG and RBB provided final approval of the version to be published.

Conflicts of Interest

None declared.

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

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Abstract

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

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

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

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

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

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KEYWORDS

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

Introduction

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

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negative effects including problems with parent-child bonding and attachment [4].

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

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

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

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

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

Methods

Study Design

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

Ethical Considerations

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

Setting

This study was conducted at Te Toka Tumai Auckland Starship Child Health NICU, a level 3 NICU and one of Aotearoa New Zealand's largest NICUs. Most rooms are shared, with 40 cots

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in the unit and an average of 900 infant admissions per year. The unit is a regional specialty center with a diverse patient population. In 2023, 29% of babies in the unit were New Zealand European, 19% were Other Asian, 17% were Indian, 17% were Pacific Peoples, and 16% were Māori. Common causes of admission were preterm birth (42%), respiratory distress (25%), and congenital abnormalities (14%) [16].

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

Participants and Recruitment

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

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

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

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

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

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

Interview Schedule

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

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

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

Procedure

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

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

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

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

who specializes in perinatal mood disorders, and mother of 2 children.

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

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

Qualitative Methodology

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

Data Analysis

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

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

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

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

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

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

Results

Participant Characteristics

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

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

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



Table . Participant characteristics.

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

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

^aChinese, Indian, Korean, Samoan; participants could select multiple ethnicities, so totals may add up to more than 100%. ^bNICU: neonatal intensive care unit.

Themes

Stress and Support Themes

We identified 6 themes centered on stress and stress-reduction that we considered relevant to future intervention development. Three themes focused on caregiver stress: (1) the emotional

Textbox 1. Themes.

Sources of stress*Emotional "rollercoaster"*

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

Left out and confused

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

Unsupported

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

Participant-proposed solutions

Empower caregivers

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

Communicate on "my terms"

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

Improve emotional support

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

"rollercoaster" caused by the NICU experience, (2) insufficient emotional and cultural support, and (3) caregivers feeling "left out" and confused. Participant-proposed solutions to reduce stress were to (1) empower caregivers through education, (2) improve emotional support, and (3) communicate on "my" terms (ie, digitally) (Textbox 1).

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Theme 1: Emotional "Rollercoaster" of the NICU

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

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

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

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

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

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

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

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

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

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

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

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

Theme 2: Insufficient Cultural and Emotional Support

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

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

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

We don't finish a visit by saying [to parents], "How are you feeling? Are you doing ok?" We just don't have time. [Clinician #8] Multiple parents also felt that some medical staff did not respond to their emotional needs in helpful ways.

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

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

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

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

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

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

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

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

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

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

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

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Theme 3: Caregivers "Left Out" and Confused

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

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

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

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

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

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

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

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

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

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

Concerningly, many parents also reported stressful situations in which they were not informed about their babies' medical care. One mother (#6) reported a "really scary" incident when she was not told that her baby had stopped breathing, which she reported "made me lose my mind." Additionally, 2 participants reported being told "at the last minute" or without their knowledge that their babies were moved to a different section of the unit. So before we moved from Level 3 to Level 2, we were told, "It's not going to happen for a while." But then we're told over the phone that now she's in Level 2. That was very stressful for us. The doctor had given us clear plans, yet the transition happened without us. [Mother #5]

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

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

Theme 4: Empower Parents

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

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

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

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

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

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

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

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



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

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

Theme 5: Provide More Emotional Support

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

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

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

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

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

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

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

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

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

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

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

Based on my experience, I spent a lot of time in NICU just sitting there not doing anything, especially in my baby's early days. So I would have tried some

stress-reduction activities if someone had given them to me, because hopefully they'd help me feel better, but also to give me something to do. [Mother #9]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Discussion

Principal Findings

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

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

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

The stress themes in our study highlight problematic gaps in emotional and cultural support for families that led to feelings of parental isolation and disempowerment. While some parents stated they were supported in the NICU, the majority reported stressful interactions that made them feel devalued, confused, or judged as parents. Fathers, in particular, reported feeling "less

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important" than mothers in the NICU. Fathers' needs have long been understudied in the NICU, with many studies focusing exclusively on mothers [5]. However, recent studies have demonstrated that fathers can experience high levels of distress in the NICU, including elevated rates of depression and posttraumatic stress disorder compared to non-NICU fathers, and specialized interventions in the NICU can help [26].

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

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

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

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

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

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

Strengths, Limitations, and Future Research

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

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

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

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

Conclusions

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

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Conflicts of Interest

Coauthor AS is Associate Editor of JMIR Pediatrics and Parenting.

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

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Abbreviations

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

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

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Abstract

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

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

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

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

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

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

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

KEYWORDS

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

Introduction

Rates of type 1 diabetes (T1D) in youth aged 19 years or younger have been increasing in recent years, from approximately 1.48 per 1000 youth in 2001 to 2.15 per 1000 youth in 2017 [1]. Rates increased at the highest levels in non-Hispanic White and non-Hispanic Black children [1]. Health-promoting management of T1D requires following a

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complex and constant treatment regimen with tasks relying on child and caregiver behaviors, skills, and knowledge [2]. Given the complexity and constancy of diabetes management, it is not surprising that psychological factors such as distress, depression, anxiety, and burnout are highlighted as pertinent to consider in the management of pediatric T1D [2-4].

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

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

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

In line with best practice recommendations, we sought to implement standardized DD screening for youth aged 8 - 12

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

Methods

Participants

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



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

	Month of screening implementation											
	1	2	3	4	5	6	7	8	9	10	11	12
Percent- age of pa- tients seen with active app ac- counts (enter- prise- wide)	51.5	52.4	53.3	54.2	55.2	56.0	56.8	57.6	58.4	59.1	59.7	60.5
Percent- age of pa- tients seen with active app ac- counts (divi- sion/loca- tion-spe- cific)	68.0	69.1	70.6	71.5	73.0	73.3	74.4	75.3	75.9	76.6	77.5	78.0
Percent- age of ap- point- ments where Ge- tReady was start- ed but not com- pleted (divi- sion/loca- tion-spe- cific)	34.9	29.3	24.7	31.6	26.1	30.6	33.9	30.5	30.3	32.1	33.6	30.9

Ethical Considerations

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

Procedure

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

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

Measures

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

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

Data Analyses

We used approved tools to retrieve all EHR data. We report the percentage of eligible families screened for DD out of all eligible families in the clinic population (absolute percentage screened) and the percentage of eligible families screened for DD out of all eligible families with a completed clinic visit between April 1, 2022, and March 31, 2023 (adjusted percentage screened). To analyze these data, we examined the screening rate by each month and the average across the year. We also examined the rate of EHR documentation of follow-up resources being sent to families with elevated screening results. To identify elevated DD, the clinic applied a clinical cut point of \geq 41 for children and a cut point of ≥ 64 for parents or caregivers [7]. Descriptive statistics and HbA1c were examined for both the population who completed DD screening and the families who had elevated screening results. Given that the screening period took place over a 12-month period, some families received and completed the screening measures on more than 1 occasion. If a child or a caregiver was identified as having elevated DD on multiple screenings, he or she was sent resources each time; however, for the purposes of data analysis, only the first elevated screen that also had a clinic visit with an associated HbA1c was included for analyses.

Results

Participants

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



Table . Demographic information.

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

^aAAPI: Asian American and Pacific Islander.

Primary Outcomes

Screening Completion Rates

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

DD Rates and Resource Provision

In total, 10.2% (21/206) PAID-C and 11.0% (26/237) P-PAID-C surveys scored as elevated during the 1-year screening period, with 1 child and 3 caregivers completing the measure with an

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

DD, Demographics, and HbA_{1c}

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

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

Discussion

Principal Findings

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

Challenges with Screening Implementation

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

Second, with our institutional app and its supporting automated system, we could only assign the DD screening tools to children aged 8 - 12.99 years (and their caregiver) with a visit type "Diabetes NP w/Care Team" or "Diabetes FP w/Care Team". These visit types are not coded to differentiate between different diabetes diagnoses. Although DD is also observed in persons with type 2 diabetes, the screening tools we used are not

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validated for families of youth with type 2 diabetes. In the 1-year screening period, there were 4 elevated PAID-C surveys and 4 elevated P-PAID-C surveys associated with youth with type 2 diabetes or prediabetes. These could represent false-positive results. Thus, if using an automated system to assign a clinical screening tool, it may be important to identify a solution for assigning screeners with greater specificity.

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

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

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

Future Directions

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

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

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

Conclusions

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

Acknowledgments

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Authors' Contributions

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

Conflicts of Interest

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

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Abbreviations

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



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Original Paper

Enhancing Effect of eHealth Use on the Associations Between Social Supports and Well-Being in Japanese Employed Women Providing Childcare or Care: Bayesian Structural Equation Modeling Study

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Abstract

Background: The increasing prevalence of information and communication technologies has made health-related information and social support more accessible on the web. However, limited evidence exists on how eHealth and social support affect the well-being of employed women who also serve as caregivers in Japan.

Objective: This study aimed to assess the relationship between social support and well-being among employed Japanese women providing childcare or caregiving and explore eHealth use's role in enhancing this relationship.

Methods: We conducted a cross-sectional study using secondary data analysis from a nationwide web-based questionnaire survey of 10,000 employed women aged 20-65 years, administered from February 28, 2023, to March 7, 2023. The primary study used a quota random sampling approach based on age and geographic area from the research company's panel. For this analysis, we focused on a subgroup of 2456 women who reported either caring for children less than 7 years old or providing other caregiving responsibilities. We employed a Bayesian structural equation model to estimate the enhancing effect of eHealth on the relationship between social support and 4 well-being indicators: life satisfaction, worthwhileness, happiness, and anxiety.

Results: Among the 2456 employed women included, 1784 (72.6%) received social support and 1635 (66.6%) obtained health-related information via eHealth. Bayesian structural equation model analysis revealed that the standardized total effects of social support on well-being were 0.20 (95% CI 0.13-0.27) in the group without eHealth use and 0.47 (95% CI 0.45-0.50) in the group with eHealth use.

Conclusions: The findings suggest that eHealth may enhance the positive impact of social support on the well-being of employed Japanese women providing childcare or caregiving. This study highlights the potential of eHealth interventions in supporting social support and well-being among working women with caregiving responsibilities in Japan.

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KEYWORDS

eHealth; social support; well-being; women's health; caregivers; working women

Introduction

Well-being is defined as a multifaceted concept encompassing happiness, satisfaction, personal growth, fulfillment, and contribution to the community [1]. It includes physical, emotional, and social dimensions and is a key factor in determining women's productivity and quality of life. While employment has been shown to improve women's well-being [2], it also exposes them to adverse effects from work-family conflict [3]. Women in the prime of their working lives face various health challenges, including mental health issues, work-related illnesses, and reproductive health concerns [4]. Working women with childcare or older adult care responsibilities must balance their work and home lives, and this double burden affects their well-being [5,6].

Social support, a key factor in maintaining well-being, traditionally comes from family, friends, and the community [7]. Social support from family and friends plays a pivotal role in maintaining physical and mental health. This multifaceted concept revolves around interpersonal interactions, wherein individuals perceive reliable connections with friends or family members on whom they can depend during favorable and challenging circumstances [8]. Good social relationships provide emotional and practical resources essential for feeling nurtured and esteemed, consequently fostering healthier lifestyles [9]. Social support has protective physical and mental effects [10]. Although social support from partners is essential [11], approximately 90% of households with children in Japan are nuclear families [12]. The traditional sources of social support may be limited for many working women. This situation creates a need for alternative forms of support, particularly for those balancing work with childcare or older adult care responsibilities.

The rapid digitalization of Japanese society has also opened new avenues for addressing this need. In Japan, with over 90% of the working-age population using the internet and about 80% engaging with social networking services [13], eHealth has emerged as a promising solution. eHealth refers to the cost-effective and secure use of information and communication technologies (ICT) to support health and health-related fields [14]. The dissemination of health information via the internet has expanded in recent years and information on social support has also increased [15]. Recent trends indicate that social support is being increasingly accessed and provided on the web through various digital platforms and social networks. For example, several interventions have been developed that incorporate social support content using group phone calls or applications [16,17].

This shift reflects a broader societal change toward digital communication, which enables individuals to access information and community and emotional support without geographical constraints [18]. Internet-based social support has shown potential in enhancing well-being by providing immediate access to resources and reducing social isolation [19]. It is also known as an important form of social support. These eHealth tools may provide crucial social support and be valuable for working women facing time constraints and the social stigma associated with seeking help. However, these tools are primarily designed for specific groups, such as pregnant women or women with health issues. Few studies specifically targeting working women exist.

In addition, cultural differences must be considered when implementing eHealth interventions. Cultural perspectives on the self differ between Western and Eastern societies. In Western cultures, there is a tendency to view individuals as autonomous entities. Conversely, Eastern cultures often conceptualize the self as intrinsically interconnected with others, emphasizing social relationships and collective harmony [20]. This fundamental difference in self-perception influences various aspects of social behavior. A previous study found cultural differences in the emotional correlates of social support receipt across countries, highlighting the importance of considering cultural context when examining social support interventions. In addition, seeking social support might help the Japanese reduce loneliness [21].

Given Japan's unique cultural and societal context, including its high technological adoption rate, it is necessary to understand how social support and eHealth use interact to influence the well-being of working women with caregiving responsibilities. However, there have been limited studies on the relationship between social support and well-being among employed women raising children or caring for them and the relationship between the use of eHealth medical information in Japan. Therefore, this study aimed to fill this gap by evaluating the relationship between social support and well-being among employed women providing childcare or caregiving and the enhancing effect of eHealth use on this relationship. We hypothesized that individuals who use eHealth services will have improved well-being because they receive support from internet-based communities in addition to support from close family and friends. In this study, we hypothesized that the enhancing variable, "eHealth use," would influence the direct effect of "social support" on "well-being."

Methods

Study Design

This is a cross-sectional study using secondary data from a web-based nationwide questionnaire survey conducted from February 28, 2023, to March 7, 2023 [22]. Figure 1 illustrates the hypothetical model of the Bayesian structural equation model (BSEM).

Figure 1. Hypothetical model.



Participants and Data

The data used in this study were obtained from a nationwide survey of 10,000 employed women aged 20-65 years in Japan using a questionnaire developed for the previous study [22]. This primary study included participants who met the following criteria: (1) being 20-65 years old, (2) being employed, and (3) being able to provide informed consent. Students were excluded. A research company conducted recruitment and data collection using a web-based questionnaire. This company used its extensive nationwide panel, which includes women from diverse backgrounds across all 47 prefectures of Japan. A link containing the study introduction and the questionnaire was sent to the company's research panel. We stratified the age categories and prefectures for recruitment to improve sample diversity. A questionnaire was distributed using the web-based platform of a professional research company. The first page of the questionnaire contained an informed consent form and the participants could access the questionnaire by checking the agreement button at the end of the page. A structured questionnaire contained questions about demographics (eg, age, sex, and comorbidities), socioeconomic status, social support, health status, well-being, and eHealth. All monetary values originally reported in Japanese yen were converted to US dollars using the average exchange rate at the time of data collection, which was 1 JPY=0.0069 USD. The participants required approximately 10-15 minutes to complete the entire questionnaire. Eligible participants could then choose to respond to the questionnaire.

From the initial 10,000 respondents, participants for this study were selected based on the following criteria: women raising or caring for children aged <7 years were included in the analysis. Those who met these criteria were included in the final analysis.

Measures and Outcomes

Well-Being

The Office for National Statistics (ONS)-4 questionnaire, developed by the United Kingdom Office for National Statistics, was used to measure personal well-being [23]. This

questionnaire consists of 4 items: life satisfaction, worthwhileness, happiness, and feelings of anxiety. The participants were instructed to rate their well-being on a scale of 0-10. For life satisfaction, feeling that things done in life are worthwhile and happiness scores are categorized as low (0-4), medium (5-6), high (7-8), and very high (9-10). Feelings of anxiety were categorized as very low (0-1), low (2-3), medium (4-5), or high (6-10). The scores were analyzed using these threshold categories [23].

Social Support

The participants were asked multiple-choice questions about the people or groups who supported them in child and nursing care, which we calculated using dichotomous data: yes or no support.

Usage of eHealth

In this study, eHealth use was defined as obtaining health-related information through ICT. The participants were asked how they obtained health-related information. The choices included medical professionals, health events, books (newspapers, scientific journals, and scientific papers), television, internet news, internet search engines, social network services, medical information sites, blogs, information from the government and local government, family, friends, and others. If the participants selected ICT-enabled health care services from the options (eg, internet news, internet search engines, social network services, medical information sites, and blogs), we recorded them as dichotomous data for eHealth use (yes or no).

Statistical Analysis

First, a descriptive analysis was performed to examine participant background characteristics and well-being. The Kendall rank correlation coefficient was used to confirm the latent variables that should be considered in addition to the hypothetical model. We selected confounders shown in previous studies to be associated with well-being and social support [24-30], including age, region, educational status, annual household income, work style, work hours, comorbidities, and specific health problems (Figure 2). A BSEM was used to assess the enhancing effect of eHealth usage on the relationship between social support and the 4 well-being items. We adopted

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the BSEM approach because it accommodates smaller sample sizes [31] and allows for a natural and explicit representation of Likert scales and binary latent variables [32,33]. The BSEM assumes one latent variable encompassing 4 well-being items and their correlated residuals (Figure 2). Based on the structure, we grouped the participants using eHealth and presented the results separately. We estimated the parameters in the BSEM for the groups with and without eHealth use, respectively. In addition, the ONS-4 data are ordinal scale, and treating them normally distributed metric values is considered as inappropriate. Therefore, we analyzed them using an ordered probit model, assuming the latent variable follows a standard normal distribution, which is appropriate for modeling binary outcomes. The prior distribution was set as a standard normal distribution, reflecting the assumption that the coefficients are centered around zero. We estimated the total standardized effects as path coefficients and their 95% CIs. The standardized total effect normalized the total effect by considering the ratio of the SDs of social support to well-being. The posterior distribution

Figure 2. Preidentified structural model.

was derived using the Markov Chain Monte Carlo algorithm. The path coefficient was considered significant if the 95% CI excluded zero. The maximum number of iterations was set to 100,000 with 500 burn-in iterations. We judged that the algorithm converged after 100,000 sampling iterations, as determined by a convergence statistic below the threshold of 1.002 [34]. The estimated model was evaluated by the deviance information criterion. Finally, we performed the sensitivity analysis concerning model specifications involved in testing alternative model structures by omitting paths and latent variables to ensure the robustness of the results. Specifically, we confirmed that the standardized coefficients among well-being, eHealth, and other variables did not significantly change by omitting region and work hours and the paths that were linked to them, respectively. All statistical analyses were performed using the SPSS Statistics (version 29.0.1; IBM Corp) software and SPSS Amos (version 29.0; IBM Corp), and a P value of <.05 was considered statistically significant.



Ethical Considerations

This study was approved by the Research Ethics Committee of St. Luke's International University (reference number 22-A089). All participants provided informed consent on the web and the study data were collected anonymously. The research company offered the participants shopping points as rewards.

Results

Demographic Characteristics

Table 1 presents the demographic characteristics of the 2456 women who met the inclusion criteria. The table includes information on age, occupation, region, educational status, annual household income, work style, daily working hours, comorbidities, and women's specific health problems.


Table 1. Demographic characteristics (N=2456).

Variable and classification	Values	eHealth use		P value
		With (n=1635)	Without (n=821)	
Age (years), mean (SD)	38.3 (8.9)	37.7 (9.2)	38.6 (8.8)	
Age (years), n (%)				.09
20-30	479 (19.5)	293 (17.9)	186 (22.7)	
30-40	844 (34.4)	572 (35.0)	272 (33.1)	
40-50	860 (35.0)	581 (35.5)	279 (34.0)	
50-60	209 (8.5)	144 (8.8)	65 (7.9)	
60-65	64 (2.6)	45 (2.8)	19 (2.3)	
Occupation, n (%)				.18
Management or executive	26 (1.1)	18 (1.1)	8 (1.0)	
Company employee (full-time)	979 (39.9)	662 (40.5)	317 (38.6)	
Company employee	111 (4.5)	67 (4.1)	44 (5.4)	
Company employee (temporary employee)	80 (3.3)	58 (3.5)	22 (2.7)	
Public employee (excluding teaching staff)	87 (3.5)	54 (3.3)	33 (4.0)	
Faculty member	89 (3.6)	60 (3.7)	29 (3.5)	
Health care provider	209 (8.5)	123 (7.5)	86 (10.5)	
Professional	7 (0.3)	5 (0.3)	2 (0.2)	
Independent business or self-employed workforce	109 (4.4)	80 (4.9)	29 (3.5)	
Part-time work	759 (30.9)	508 (31.1)	251 (30.6)	
Region, n (%)				.30
Hokkaido, Tohoku	342 (13.9)	213 (13.0)	129 (15.7)	
Kanto	879 (35.8)	605 (37.0)	274 (33.4)	
Tokai	326 (13.3)	44 (2.7)	24 (2.9)	
Hokuriku	68 (2.8)	205 (12.5)	121 (14.7)	
Kinki	421 (17.1)	281 (17.2)	140 (17.1)	
Chugoku	137 (5.6)	95 (5.8)	42 (5.1)	
Shikoku	62 (2.5)	45 (2.8)	17 (2.1)	
Kyuusyu, Okinawa	221 (9.0)	147 (9.0)	74 (9.0)	
Educational status, n (%)				.11
Elementary school	34 (1.4)	24 (1.5)	10 (1.2)	
High school	494 (20.1)	314 (19.2)	180 (21.9)	
Associate degree	340 (13.8)	241 (14.7)	99 (12.1)	
Diploma	471 (19.2)	297 (18.2)	174 (21.2)	
University bachelor	1024 (41.7)	693 (42.4)	331 (40.3)	
MSc or PhD	93 (3.8)	66 (4.0)	27 (3.3)	
Annual household income ^a , n (%)				.01
<2,000,000 JPY (US \$13,800)	171 (7.0)	98 (6.0)	73 (8.9)	
2,000,000-4,000,000 JPY (US \$13,800-27,600)	406 (16.5)	263 (16.1)	143 (17.4)	
4,000,000-6,000,000 JPY (US \$27,600-41,400)	604 (24.6)	415 (25.4)	189 (23.0)	
6,000,000-8,000,000 JPY (US \$41,400-55,200)	513 (20.9)	329 (20.1)	184 (22.4)	
8,000,000-10,000,000 JPY (US \$55,200-69,000)	389 (15.8)	257 (15.7)	132 (16.1)	
10,000,000 JPY (US \$69,000)	372 (15.1)	272 (16.6)	100 (12.2)	

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Variable and classification	Values	eHealth use		P value
		With (n=1635)	Without (n=821)	
Missing	1 (— ^b)	_	_	
Work style, n (%)				.02
Day shift	2252 (91.7)	1513 (92.5)	739 (90.0)	
Night shift	204 (8.3)	122 (7.5)	82 (10.0)	
Daily working hours , n (%)				.40
<8	1908 (77.7)	1262 (77.2)	646 (78.7)	
8	548 (22.3)	373 (22.8)	175 (21.3)	
Comorbidities ^c , n (%)				.06
Without	1934 (78.8)	1269 (77.7)	665 (81.0)	
With	521 (21.2)	365 (22.3)	156 (19.0)	
Women's specific health problems ^d , n (%)				<.01
Without	835 (34.0)	437 (26.7)	398 (48.5)	
With	1620 (66.0)	1197 (73.3)	423 (51.5)	
Missing	1 (—)	—	—	

^aAs of May 2025, a currency exchange rate of 1 JPY=US \$0.0069 was applicable.

^bNot available.

^cComorbidities include hypertension, heart disease, atherosclerotic disease, diabetes mellitus, hyperlipidemia, and chronic kidney disease.

^dWomen's specific health problems include menstrual symptoms and illnesses, premenstrual syndrome, cancers common in women (eg, cervical, uterine, ovarian, and breast cancer), pregnancy- and childbirth-related symptoms, menopausal disorders, mental disorders, insomnia, infertility, endometriosis, benign female tumors, blood flow disorders, anemia, gastrointestinal disorders, headaches and migraines, underweight status, nutritional disorders, autoimmune diseases, and pelvic floor symptoms and diseases.

Approximately 70% of the participants were in their 30s and 40s. About 40% of participants were employed by a company and worked full-time. Most participants lived in the Kanto region, followed by Kinki, with the fewest residing in Tokai and Shikoku. Approximately half of the participants had graduated from graduate school or university. Most participants reported middle-class household incomes, with the most common range being upper-middle income (4-6 million yen [US \$27,600-41,400] annually). This was followed by households with middle-high income (6-8 million yen [US \$41,400-55,200]) and lower-middle income (2-4 million yen [US\$ 13,800-27,600]). A notable portion, 372 (15.1%) participants, belonged to high-income households, earning over 10 million yen (over US \$69,000) annually. The Kanto region had a higher concentration of high-income households, with 194/879 (22.1%) of participants from this area reporting annual incomes over 10 million yen (over US \$69,000). Approximately 204/2456 (8.3%) participants worked night shifts, and 548/2456 (22.3%) participants worked an average of ≥ 8 hours per day. A total of 521 out of 2456 (21.2%) participants had comorbidities. More than half of the participants (1620/2456, 66% women) answered that they were experiencing symptoms that are common in women, such as premenstrual syndrome, female-specific cancers (uterine cancer and breast cancer),

pregnancy-related issues, menopausal disorders, and mental disorders. Of the 2456 participants, 2123 (86.4%) had obtained health-related information in some form, including through means other than the internet, and 1635 out of 2456 (66.6%) had obtained health-related information through eHealth. The breakdown of eHealth sources was as follows: search engines (1003/2456, 40.8%), internet (851/2456, 34.6%), social networking service (744/2456, 30.3%), medical information sites (137/2456, 5.6%), and blogs (126/2456, 5.1%).

Profiles and Correlations of Measures

In terms of well-being, 711 out of 2456 (28.9%) participants reported low life satisfaction, 635 out of 2456 (25.9%) felt their lives were less worthwhile, and 641 out of 2456 (26.1%) had low happiness. Conversely, 253 out of 2456 (10.3%), 314 out of 2456 (12.8%), and 466 out of 2456 (19.0%) participants reported high scores for life satisfaction, feeling worthwhile, and happiness, respectively. In addition, 783 out of 2456 (31.9%) participants experienced high anxiety, whereas 492 out of 2456 (20.0%) reported low anxiety (Figure 3). Social support was reported by 1784 out of 2456 (72.6%) women. Table 2 presents the correlation coefficients between eHealth use, social support, and well-being measures. Significant correlations were found between well-being, social support, and eHealth use, although the effect size was small (Table 2).







 Table 2. Correlation matrix (N=2456).

Variables	Values	1	2	3	4	5	6
eHealth use							
p(0(2))	1625 (66 6)						
II (70)	1035 (00.0)						
Correlation, tau_b		a					
P value		—					
Social support							
n (%)	1784 (72.6)						
Correlation, tau_b		.165	—				
P value		<.01	—				
Well-being							
Life							
Mean (SD)	2.28 (0.99)						
Correlation, tau_b		.084	.127	_			
<i>P</i> value		<.01	<.01	_			
Value							
Mean (SD)	2.31 (0.99)						
Correlation, tau_b		.105	.123	.715	_		
P value		<.01	<.01	<.01	_		
Happiness							
Mean (SD)	2.40 (1.07)						
Correlation, tau_b		.094	.132	.678	.658	_	
<i>P</i> value		<.01	<.01	<.01	<.01	_	
Anxiety							
Mean (SD)	2.32 (1.12)						
Correlation, tau b	· /	.02	.112	.188	.152	.196	_
<i>P</i> value		.296	<.01	<.01	<.01	<.01	
1 value		.270	<.01	<. 01	N.01	 1	

^aNot available.

Enhancing Effects of eHealth Use

The direct effects of associations between well-being and social support, as BSEM, differed depending on eHealth use. Among participants without eHealth use, the standardized total effects were 0.20 (95% CI 0.13-0.27, SE 0.00, SD 0.03), with a convergence diagnostic value of 1.00. In contrast, for those with eHealth use, the standardized total effect was higher at 0.47 (95% CI 0.45-0.50, SE 0.00, SD 0.01), with the same convergence diagnostic value of 1.00. The posterior predictive distribution P value was .50 and the deviance information criterion was 19,262.24, suggesting strong predictive validity of the model. The sensitivity analysis showed that the key relationships in the original model were robust to these changes as the estimated path coefficients and factor loadings varied only marginally. This result suggests that the model's conclusions are not dependent on specific assumptions regarding the model structure.

Discussion

Summary of Study Findings

This study examined the characteristics of participants and the relationship among well-being, social support, and eHealth use among employed women providing childcare or care. In this study, eHealth use enhanced the relationship between social support and well-being, with higher standardized total effects observed in the group that used eHealth compared to those that did not. Our findings align with recent research on eHealth interventions, demonstrating their positive impact on social support and well-being. A study suggested that social media use was positively associated with perceived responsiveness in internet-based social networks, which improved perceived social support and was linked to reduced loneliness and increased life satisfaction [19]. Furthermore, DeHoff et al [35] showed that internet-based social support might enhance participants' belief in being supported, leading to improved health behaviors. These findings suggest that eHealth use may contribute to improved well-being by facilitating access to social support and enhancing

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individuals' perception of being supported. It might be particularly effective for working women who have limited time due to childcare or caregiving responsibilities.

Social support refers not only to the receipt of support but also to an individual's perception of support from family, friends, and significant others in their lives [36,37]. Current research suggests that family and close friends are positively associated with emotional well-being, even when they are far away [38]. Furthermore, recent research has shown that internet-based resources allow individuals to connect with and receive social support from people other than family and close friends [18]. The results of this study also support this hypothesis, as internet-based connections with individuals or organizations may lead to social support and improve individual well-being. A study investigating internet-based social support for parents of children with medical needs also showed that, through internet-based support, they receive support from peers, learn the information they need, and acquire the ability to deal with the associated emotional challenges [35]. As nuclear families make up the majority of households in Japan [12], women involved in the care of children and older family members need to be supported effectively using the internet as a tool for exchanging information about these fields and creating social connections for support. For Japanese people, who place great importance on social relationships and group harmony, this intervention might enhance their support-seeking behavior and reduce loneliness [21].

Previous research has demonstrated that cognitive factors such as age [39], education level, income [40], gender, occupational status, and marital status influence eHealth literacy [41]. In addition, a previous study indicated that higher health literacy levels positively influence health-seeking attitudes and social support [42]. Our study found minimal differences between groups based on eHealth usage. This result may be attributed to the data collection method, which was an internet-based survey, and our focused sample of employed Japanese women aged 20-65 years engaged in childcare or caregiving activities [43]. Most participants were in their 30s and 40s, with approximately half having completed higher education. These individuals are not older adults, have a higher level of education, and are employed women. Therefore, they are likely to belong to a group with a relatively high rate of eHealth usage. Regarding income, the participants in this study were employed women whose annual household income exceeded the average income in Japan (5,242,000 yen [US \$36,368.68]). This is likely because the survey was conducted among working women, many of whom belong to dual-income households. The lack of comparative data makes it difficult to make a general statement. As many studies have shown a relationship between annual household income and well-being [44,45], the participants in this study may represent a group with a relatively high level of well-being. Health-related conditions, such as high blood pressure and female-specific conditions, were prevalent among the participants. Other well-being surveys in the United Kingdom have shown that the well-being of Japanese people tends to be relatively low [46]. Compared with the British survey using ONS-4, participants had a lower life satisfaction rate and a higher percentage of individuals with high anxiety [46]. As a previous study has pointed out, social support interventions should account for cultural context and cognitive factors and be developed and implemented as tailored eHealth interventions for a similar population.

In addition, when implementing eHealth, factors that might influence its use should be considered. Previous studies have not reached a consensus on the association between eHealth service use, including social media, and well-being. Although some studies have reported a positive association with well-being [36,47], others have suggested that social media use negatively affects well-being [48,49]. Given the complex factors influencing eHealth literacy and well-being, it is important to consider how eHealth service use may impact well-being outcomes across different populations [50]. Previous studies have suggested that interactive methods may have positive effects and that internet-based information exchange and positive social interaction enhance perceived social support and well-being [49]. However, we could not clarify the specific methods for obtaining information via eHealth in this study. Future studies should investigate how individuals obtain information through eHealth services.

Implications for Future Practice and Research

These findings suggest that eHealth use can play a significant role in enhancing well-being among women, particularly those providing childcare or caring for someone else. Labor participation by women has increased globally, benefiting individuals and society worldwide [51]. Japan is no exception, with the number increasing by more than 4 million over the past decade [52]. However, gender inequality exists in Japan's working environment. In 2023, the World Economic Forum assessed the state and evolution of the gender gap across 4 key dimensions (economic participation and opportunity, educational attainment, health and survival, and political empowerment). The World Economic Forum ranks Japan 125th among 146 countries [53]. Various issues were identified, including the gender pay gap, a lack of female executives, and a decline in the number of women in regular employment after their 30s [54]. Women's progress in social advancement is closely linked to changes in daily life and overall well-being. Using internet-based social support to enhance women's well-being could promote their social advancement, improve the next generation's health, and address gender equality. This finding suggests that health care providers and policy makers should consider promoting eHealth platforms to improve mental and physical health outcomes. Moreover, they must support women in accessing required information via eHealth services. Future studies can further explore the mechanisms through which eHealth influences social support and well-being, potentially focusing on the most effective eHealth interventions or platforms. eHealth interventions should be developed to address the specific needs of employed women providing childcare or caregiving and to assess their benefits and harms. In addition, longitudinal studies can provide insights into the long-term effects of eHealth use on well-being and other health outcomes.

Strengths and Limitations

This study is unique in that it examined the relationship among well-being, social support, and eHealth use among a large

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sample of working women raising or caring for children. The use of BSEM allowed for a robust analysis of the data, providing CIs and a sensitivity analysis that strengthened the validity of the results. Focus on the use of eHealth provides valuable insights into an emerging area of health intervention that is particularly relevant in today's digital age. However, this study has some limitations. First, the cross-sectional design restricted the ability to infer causality between eHealth use and well-being. Second, our study did not use validated scales specifically designed to measure social support, work-life balance, job satisfaction, and caregiver burden, which could have provided more robust and standardized assessments of these crucial variables. In addition, we did not investigate perceived social support in this study. However, it is important to consider that the mechanisms linking social support and well-being are complex and involve multiple correlated factors. Including perceptions of social support may provide a more comprehensive understanding of how these elements interact and contribute to overall well-being. Third, we only assessed the use of ICT to obtain health-related information, such as the usage of eHealth, and could not evaluate social support through ICT. The frequency or intensity of use was also not evaluated. As eHealth encompasses a broader range of concepts, further studies should

include this in evaluating ICT for support in health and health-related fields. Fourth, these data were collected through a self-reported questionnaire, and response biases may be present.

Conclusion

This study suggests that using eHealth services for employed women raising children or caring for someone may enhance the impact of social support on their well-being. However, the complexity of the relationship between eHealth use, social support, and well-being necessitates further investigation. Further studies should investigate the following points while considering cultural contexts and individual differences in eHealth literacy: the mechanisms underlying the relationship among social support, well-being, and eHealth use; the potential benefits and harms of eHealth interventions; and the long-term effects of eHealth interventions on social support and well-being. In addition, further research is needed to develop customized eHealth interventions that address the specific needs of working women with caregiving responsibilities. Deepening our understanding in these areas would allow for the implementation of more effective eHealth interventions, contributing to the improvement of working women's well-being.

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Data Availability

The data used in this study are not publicly available because of privacy and confidentiality concerns. Consequently, external parties cannot share the data.

Authors' Contributions

NY, DY, and KS were responsible for the conceptualization of the study. All members accessed and verified the data. The investigation was conducted by NY, DS, SK, EN, and EO. The methodology was developed by NY, DY, KS, and ES. The original draft was written by NY. Supervision was provided by DY, EO, HT, and ES who reviewed and edited the manuscript. The corresponding author had full access to all the data in the study and assumed the final responsibility for the decision to submit the manuscript for publication.

Conflicts of Interest

None declared.

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Abbreviations

BSEM: Bayesian structural equation model **ICT:** information and communication technologies **ONS:** Office for National Statistics

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Using WhatsApp for Nutrition Surveillance Among Children Under 5 Years in West Java, Indonesia: Cross-Sectional Survey and Feasibility Study

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Abstract

Background: Large-scale programs involving nutrition-specific interventions have been carried out in Indonesia as a community-based approach at the primary care level across cities and districts, throughout the age-specific target population (ie, children under 5 years).

Objective: The aim of this paper is to describe the potential use of WhatsApp as a tool for recording and monitoring the growth of children under 5 years by Posyandu (Pos Pelayanan Terpadu or community-based health service post), investigating its potential in enhancing health programs and services.

Methods: Data were collected from Posyandu cadres in Bogor District, West Java, from March to June 2022. The anthropometric measurement data were reported in real time through a WhatsApp chatbot, automatically analyzed by the system, and presented in a structured dashboard. A qualitative assessment was carried out using a cross-sectional survey conducted from March to July 2022.

Results: The study involved 42 Posyandu in 3 villages, engaging 282 staff, and the WhatsApp chatbot recorded anthropometric data for 4571 children under 5 years. The qualitative assessment indicated widespread system utilization, with 50% (45/90) affirming comprehensive data input. Additionally, 66.4% (83/129) found the system easy to use, and 66.7% (82/123) expressed clarity in comprehending variables. Moreover, 75.6% (93/123) found the data input flow easily understood, and 74% (91/123) suggested that the system contributed to enhancing Posyandu activities and the quality of data reporting. Regarding staff proficiency, 63.5% (80/126) affirmed their adeptness in using the system, and 71% (88/124) asserted their high capability in providing training to colleagues.

Conclusions: The potential use of WhatsApp as a surveillance tool for recording children's nutritional status is promising, suggesting broader applications within health programs. Nonetheless, this expansion requires additional improvements, including human resource preparation, Posyandu infrastructure development, and strong regulatory support.

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KEYWORDS

WhatsApp; Posyandu; nutrition surveillance; nutrition; nutritional; mHealth; mobile health; app; anthropometric; data collection; surveillance; chatbots; digital; digital health; digital technology; digital intervention; pediatric; infant; baby; neonatal; toddler; child

Introduction

Stunting is a condition described as a linear growth failure in which children are too short for their age, and it has been deemed a significant public health issue globally [1-3]. Children with stunted growth are at heightened risk of irreversible loss of growth, suboptimal cognitive development, and elevated risk of morbidities and mortalities in adulthood [3,4]. Suboptimal cognitive development leads to lower cognitive skills, resulting in poor academic performance and lower incomes [4,5]. Although there was a significant decrease in prevalence within the last decade, 148.1 million (22.3%) children under 5 years (CU5) were estimated as having stunted growth in 2022 [1]. According to the Indonesian Nutritional Status Survey (Survei Status Gizi Indonesia) in 2023, the prevalence of children with stunted growth in Indonesia in 2022 was 21.6%, thus similar to the global burden [1,6,7].

To accurately describe a population's nutritional status, particularly the at-risk groups, establishing a nutritional surveillance system becomes pivotal [8]. Such a nutritional surveillance system needs to collect data on nutrition risk factors in a regular and timely manner from various sources, such as growth monitoring in health facilities, nutrition surveys for the population, as well as community-based sentinel monitoring [8-10]. In Indonesia, community-based sentinel sites for growth monitoring for CU5 are conducted through Posyandu (Pos Pelayanan Terpadu; community-based health service post), where the anthropometry measurements are done routinely to help obtain cohort nutritional status information of the children [11,12]. Posyandu serves as a community-based public health outreach initiative, managed and organized in partnership with the community, linking the latter to public health centers (Pusat Kesehatan Masyarakat [Puskesmas]), with the goal of improving access to basic health services, particularly for reducing maternal and child mortality rates [13]. Posyandu itself is integrated into the village social institutions, contributing to enhanced health services for the community [14].

Posyandu undertakes a comprehensive range of health services, consisting of but not limited to maternal and child health care, including immunization services; adolescent reproductive health services; older adult health services; disease control; environmental sanitation; promotion of healthy lifestyles; and diversification of food consumption [11]. These activities are carried out by dedicated and trained community health workers, also referred to as cadres, who are community members voluntarily devoting their time and efforts to organizing Posyandu activities [11]. Indonesia currently possesses a substantial network of more than 213,000 Posyandu, with an estimated 1,039,684 active volunteers nationwide [15]. Trained community health workers play a crucial role in the success of Posyandu and the reduction of malnutrition [16]. In 2021, a presidential decree by the Indonesian government focused on the acceleration of stunting reduction and emphasized the

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importance of growth and development monitoring services at Posyandu [17].

In general, the reporting process in Posyandu begins with the cadre registering the children and mother in the Posyandu's registration book. It is then followed by the measurement of the height and body weight of the children, which are recorded in the Maternal and Child Health book as well as the Posyandu book [11,12]. After the child and the mother are given health education and other health services as needed, the data are input into an Excel file (Microsoft Corp). The file is then sent to the Puskesmas (public health center), where the workers begin inputting the data into the nutrition surveillance system. This process creates a delay in generating the nutritional status of the children and presents challenges such as difficulty for the cadres to plot the growth chart, possibility of loss of records, and potential inclusion of errors.

Mobile phones and internet usage are increasingly used for health programs, service delivery, and public health messaging [18]. Young adults are very likely to use mobile apps and the internet for health purposes [19]. Furthermore, in low- and middle-income countries (LMICs), mobile phone technologies are promising tools for enhancing primary health care services [20]. In 2021, 125.6% of the total population in Indonesia possessed a mobile phone (ie, there is more than 1 phone per person) [21], while in 2022, 66% of the population had used the internet [22], with the majority of apps used falling within the social and communication spectrum [23]. As of 2023, WhatsApp reached 120.35 million users in Indonesia with an average use time of 29 hours per month, making it the most used app nationally [24]. Aside from being a communication tool, WhatsApp is used for other purposes such as facilitating education (as a supporting tool for e-learning), as well as for health purposes such as for diagnostic and telemedicine support [25-31], though WhatsApp's use as a survey tool remains limited.

Indonesia is considered a digital force in Southeast Asia [32], with highly advanced digital health services integration. With the launch of the Digital Health Transformation Blueprint, the government committed to enhancing public health through the means of digitization [33]. One of these digitization programs involves improving the quality and reach of surveillance of the nutritional status of CU5 conducted by community health workers. To this end, the Digital Transformation Office - Pusat Data dan Informasi (DTO-Pusdatin) team at the Ministry of Health carried out a pilot project using WhatsApp as a data input tool to monitor the growth status of CU5 during Posyandu activities. This paper investigates the potential use of WhatsApp as a tool for recording and monitoring the growth of CU5 in Posyandu and evaluates its application within the national framework of providing an improved national surveillance service.

Methods

Using WhatsApp for CU5 Nutrition Surveillance

Overview

There are varying capacities among Posyandu's cadres in Indonesia with respect to technology; not all are acquainted with or adept at using mobile apps or information systems for nutrition surveillance recording and reporting. To address this, a novel approach is required to simplify the process of recording and reporting nutrition surveillance in Posyandu, especially that which is to be done by the cadres. In response to this need, the DTO-Pusdatin Ministry of Health introduced an innovation by creating a WhatsApp chatbot specifically designed for inputting CU5 measurement results by the cadres at Posyandu. A feasibility study to test the reporting system through the WhatsApp chatbot was conducted from March to June 2022 at the Ciderum Puskesmas, located in Bogor District, West Java Province, Indonesia.

The process of recording the nutritional data using the WhatsApp chatbot involved several stages (Figure 1).

Gathering the Basic Data of CU5 and Parents or Caregivers

Basic data were gathered about the CU5 and their parents, including the child's full name, national identification number (Nomor Identitas Kependudukan; NIK), date of birth, gender, parent's name and ID number, and lastly the Posyandu ID. For the parent's data, it was only asked that either the father or mother's information was entered; in some cases, this information would be that of a grandmother or another caregiver. This manual dataset was then imported into the system.

Figure 1. Input, process, and output flow of the WhatsApp chatbot system for nutrition surveillance in Posyandu. CU5: children under 5 years; DoB: date of birth.



Cadre Registration

The account registration was done to enable the cadres to record the data in the WhatsApp chatbot. The registration required the cadres' data including their full name, ID number, date of birth, the name of Posyandu they work in, and an active WhatsApp number. This data already existed at Puskesmas, and it was used to validate the input data. The registered cadres' profiles could be monitored through the operational dashboard, which also served as the user management feature for the WhatsApp chatbot. Only DTO-Pusdatin Ministry of Health and Puskesmas Ciderum Teams had the authority to register and edit the cadres' accounts.

Data Input and Validation

After the cadres were registered and their WhatsApp number was activated, the cadres could start to report data by sending "posyandu" as the trigger keyword to activate the data reporting flow of the chatbot (Figure 2). Once the flow started, the variables that should be filled in by the cadres were separated into 3 main sections: child's data, parent/caregiver's data, and measurement data. For each variable, automatic validations were set in order to prevent human error in data recording.

For the first section, the child's name, ID number, date of birth, and sex were required. For the parent's section, their name, their ID number, and an active WhatsApp number were required. Both the child's and parent's ID number were nonmandatory, as some of them may not have had an ID number. Lastly, the measurement section required the date of measurement, weight



result (kg, 2 decimals), height result (cm, 1 decimal), and method of measuring height (recumbent or standing).

Figure 2. The WhatsApp chatbot interface including (A) starting the flow and child identity data input and (B) anthropometry data input, WHO growth chart, and results analysis. HAZ: height-for-age z-score; WAZ: weight-for-age z-score; WHO: World Health Organization; WHZ: weight-for-height z-score.



Individual Nutritional Status Analysis

After the cadres completed inputting the requested data, the chatbot system automatically sent the results of 3 nutritional status indices, which included the weight-for-age z-score (WAZ), height-for-age z-score (HAZ), and weight-for-age height z-score (WHZ) (Textbox 1).

Each recorded CU5 was provided with an evaluation of their nutritional status using 3 nutritional indices, accompanied by a growth chart for each index. These growth charts are similar to the World Health Organization (WHO) growth chart, making it easy for the cadres to quickly determine the child's nutritional status by plotting the growth chart.

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Textbox 1. Nutritional indices and the classifications for each index according to the Ministry of Health Decree Number 2/2020 about Children Anthropometry Standard.



Analytics Dashboard

In order to provide nutritional status interpretations, the reporting system offered individual recording outcomes and aggregate analyses through a dashboard (Figure 3). The analysis dashboard

Figure 3. Analytical dashboard features.

(A) Cohort of individual measurement results



(C) Nutrition problem magnitude analysis



Excel Download for Cadres

For cadres who completed inputting weighing results at Posyandu, the chatbot flow offered the option to download the

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was divided into four sections, including (1) cohort of individual measurement results, (2) aggregated measurement analysis, (3) analysis of nutritional problem magnitudes, and (4) malnutrition management feature (Figure 3).

(B) Aggregated measurement analysis



(D) Malnutrition management feature



recorded data in Excel format. Selecting "YES DOWNLOAD" prompted the system to send an Excel file containing weighing results not only from one cadre but from all cadres who input data for all CU5 attending the same Posyandu within the same

time frame. This excel data served as a simple way to check the number of recorded CU5 in the system, especially for the Puskesmas, which mostly required timely reports of recent Posyandu activity.

System Architecture

Client applications, microservices, and the WhatsApp service, storage, and caching are the 5 components that make up the architecture used for this chatbot development (Figure 4). A website and a WhatsApp client (chatbot) are the components that make up the client apps. For the purpose of facilitating the submission of data from the WhatsApp chatbot, the website functions as a front-facing interface for cadres and system administrators. Additionally, it is able to process and change the master data that is going to be used by the WhatsApp chatbot, such as Posyandu data. The information that is stored in each of these front-facing interfaces is stored in a MySQL database. As a result of the large amount of data that is processed, an additional caching service was designed in order to speed up the look up and processing of data within the database.

The microservices model allows for communication between the storage and the front-facing interface. The front-facing client and the database are connected through a number of microservices, which act as the gateway for the exchange of data between the two. In addition, these services incorporate logics and rules that are in accordance with the standards set forth by the World Health Organization (WHO) in order to process the information that is received from the front-facing interface before saving it in the database. Additionally, WhatsApp possesses its very own microservice, which is responsible for communicating the outcome of the computation and the data from the database to the chatbot before it is displayed to the user.

Figure 4. WhatsApp chatbot system architecture. BSP: business service provider.



Data Analysis

The cadre entered individual data by entering the child's 16-digit NIK or Individual Health Status (IHS) number. The cadre was then asked to enter the child's height and weight measurements, as well as how the measurements were taken (standing or recumbent). After all the data were entered, the system calculated the measurement results to be included in the growth chart (Figure 5): based on body height/length and body weight, based on body height/length and age, and based on body weight and age [34]. After that, recommendations for parents were displayed based on the child's nutritional status. Data collection was carried out from March 1 to June 30, 2022, at 42 Posyandu in 3 villages in the Puskesmas Ciderum work area in Bogor

District, namely Ciderum Village, Ciherang Pondok Village, and Pancawati Village.

Before the recording was carried out by cadres, a training session was carried out for one cadre from each Posyandu, with a total of 42 participants, in February 2022. To make it easier for cadres to carry out training for other Posyandu cadres, a booklet and tutorial video were provided. The system trial phase was carried out for 1 month by visiting the Posyandu in each village and an evaluation was carried out at the end of March. In the following 3 months, assistance was provided at 42 Posyandu with 2 evaluation processes through a WhatsApp coordination group with cadres. The Puskesmas officers monitored the input results through the analysis dashboard.



Figure 5. Posyandu reporting before (left) and after (right) using the WhatsApp chatbot.

(A) Manual reporting



Data reporting using WhatsApp



The results of anthropometric data (weight and height) were automatically processed by the system and presented in a structured dashboard, accessible for Puskesmas, District Health Offices, Provincial Health Offices, and the Ministry of Health at the national level. The data could be queried using a set of predetermined variables. The analyses generated were the frequency and percentage of children being measured based on demographic characteristics (sex, age, domicile address), nutritional status (WAZ, HAZ, WHZ), and spatial analysis on nutritional burden. Trends in service outcome were depicted using time series graphs. The comparative results of Posyandu services at the village level were generated, including analysis by sex and age groups.

Qualitative Assessment

To collect feedback from users, a series of qualitative assessments were carried out on March 31, May 31, and July 4, 2022, using a roundtable discussion method with a total of 48, 41, and 42 participants in the sessions, respectively [35]. This qualitative assessment was done during monitoring evaluation meetings with health cadres who had been trained and joined the pilot program since February 2022.

The participants of the survey were health cadres from 3 villages (Ciderum, Ciherang Pondok, and Pancawati) in Bogor District. The qualitative assessments started 1 month after the pilot project was implemented, and they were repeated at monthly intervals an additional 2 times. The survey used the Mentimeter online platform, enabling participants to answer and show the cumulative, anonymized results directly. The questionnaire consisted of four sections: (1) system usage, (2) data input, (3) overall user feedback, and (4) cadre's ability.

Ethical Considerations

(B)

We declare that the data collected for this paper do not require ethical approval as no individual data are presented and informed consent was obtained during the survey implementation. The participants were able to opt out at any point during participation in this study. This exemption is regulated in Indonesia Ministry of Health's National Guidelines and Standards for Ethical Research and Development in Health year 2017, which states that studies are exempt from the ethical review process due to no or minimal potential risk/harm of the studies, and if the information being used was publicly available, including procedures such as surveys or interviews or observations of public behavior. It further specifies that research that is conducted by a department or agency, with the purpose of studying, evaluating, or assessing the benefits of public programs or services, does not require ethics approval [36]. This study ensured that the entire process adhered to ethical principles, including respecting participants' autonomy, promoting their well-being, and avoiding any harm. These principles were upheld by obtaining informed consent, maintaining the confidentiality of participants' information, and minimizing any potential risks. Additionally, no compensation was provided to the participants involved in this study.

Results

Overview

This study of a WhatsApp chatbot for nutrition surveillance data recording and reporting was done in 3 villages in Bogor District, West Java Province, Indonesia, specifically Ciherang Pondok, Ciderum, and Pancawati. These 3 villages have different characteristics in terms of sociodemographics, facilities, and level of support by local leaders (Table 1).



Characteristics	Ciherang Pondok	Ciderum	Pancawati	Total	
Children under 5 years, n (%)	1642 (36)	1352 (30)	1577 (34)	4571	
Number of Posyandu	13	14	15	42	
Number of cadres	65	56	60	282	
Internet infrastructure	Good	Fair	Poor	N/A	
Support from village leader	Very good	Neutral	Neutral	N/A	

 Table . Characteristics of the 3 study area villages

^aN/A: not applicable.

Results of CU5 Posyandu Weight and Height Measurement Services

During the study, cadres successfully adapted to the new WhatsApp chatbot for reporting CU5 height and weight measurements, transitioning from manual to digital recording. Implementing the WhatsApp chatbot for data reporting presented a novel experience for the cadres.

Generally, it was found that the total number of CU5 measurements input into the chatbot was lower than the total number of children weighed at the Posyandu (Figure 6). The highest proportion of measurements input was in June (n=3144, 90.1%), followed by March (n=3113, 85.8%), April (n=3095, 78.2%), and May (n=3032, 76.2%). In April and May, fewer results were entered due to Ramadan and Eid al-Fitr affecting how well cadres could input data. Toward the study's end, a reminder was sent to cadres by DTO-Pusdatin Ministry of Health and village leaders about data entry.

Figure 6. The comparison of total CU5 being measured and those reported through WhatsApp, and the linearity trend of total WhatsApp data reporting month by month. CU5: children under 5 years.



In terms of each village's performance of inputting data, Pancawati had the highest number, followed by Ciherang Pondok and Ciderum. However, the data show that Pancawati had more children entered into the system than the number of children actually weighed. In March, April, and June, the percentage of CU5 weighed exceeded 100%, possibly because the chatbot recorded CU5 not just from the monthly weighing but also from those weighed outside the Posyandu area. Additionally, some data might have been entered twice, thus increasing the total number of records, but not affecting individual recordings.

Further analysis on HAZ was done, categorizing children into severely stunted, stunted, normal, and tall according to the Ministry of Health Decree Number 2/2020 about Children Anthropometry Standard guidelines (Figure 7). In general, the majority of CU5 had a normal nutritional status based on their HAZ compared to other nutritional statuses. Following the "normal" status, the next highest counts were for "stunted,"

"severely stunted," and "tall" statuses. This sequence of HAZ observation period. nutritional statuses remained consistent throughout the 4-month





User Feedback on WhatsApp Usage for the Posyandu Reporting System From Cadres

The qualitative exploration of the system usage shows that all participants used the system (129/129, 100%). Regarding the data input, half the users (45/90) self-reported that all data had been input into the system, followed by 25.6% (23/90) reporting that three-quarters of the data had been input into the system, and 24.4% (22/90) reporting that half or less of the data had been input into the system.

Most respondents suggested the system was easy to use (118/125, 94.4%) and only 5.6% of respondents (7/125) stated that the system was difficult to use. Regarding the variable in the system, none of the respondents stated that the variable (data required including child and parent identity and weight and height measurements) was difficult to understand. Two-thirds (82/123, 66.7%) of the respondents stated the variable was easy to understand, and 33.3% (41/123) stated the variable was very easy to understand. None of the respondents stated that the flow

of data input was difficult to understand. Most respondents (93/123, 75.6%) suggested that the flow of data input was easy to understand and 24.4% (30/123) of respondents said that the flow of data input was very easy to understand. Related to the impact of the usage of the system, 74% (91/123) of respondents suggested that the system was improving Posyandu activities and data reporting quality, while 26% (32/123) suggested that the system only improved data reporting quality.

The other aspects explored in the assessment were about the cadre's ability to train other cadres about the system. In general, 36.5% (46/126) of respondents stated that they were fairly competent at using the system, and 63.5% (80/126) stated that they were proficient at using the system. Regarding the ability to train the other cadres, 0.8% (1/124) of respondents stated that they were uncertain about their ability to train the other cadres, while 28.2% (35/124) stated that they were capable of training other cadres with preparation. The other 71% (88/124) stated that they were very capable at giving training to the other cadres (Table 2).



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Table . Qualitative exploration about the WhatsApp implementation (N=129).

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Characteristics		Values, n (%)	
	Capable with preparation	35 (28.2)	
	Very capable	88 (70)	

SWOT Analysis

The use of WhatsApp for recording and reporting Posyandu results means that cadres do not need to download new apps, but instead can use a popular existing app. This makes Posyandu recording using WhatsApp easy to use and easy to teach to cadres, thereby speeding up the Posyandu monthly reporting process. This is in line with the evaluation results where, in the first evaluation, cadres still had difficulty inputting Posyandu data; conversely, in the next two evaluations, cadres found it easy to use WhatsApp to report the results of weighing CU5.

Cadres can also input data on toddlers from different Posyandu in the same subdistrict. The Excel data input over the last month remains downloadable and this makes it easier for cadres to report to the village midwife and Puskesmas. Moreover, the digital record helps cadres to plot CU5's nutritional status in a precise manner, allowing them to produce an accurate plot.

Based on the evaluation results, connection problems are the number one challenge in Posyandu reporting using WhatsApp; Table 3 presents a SWOT (strengths, weaknesses, opportunities, threats) analysis. Limited internet connectivity and the absence of an offline input feature prevented cadres from reporting. Additionally, some cadres could not input data in real time, especially for areas with high target data, with a large volume of work related to inputting data in real time. Finally, there are several features that should be considered for future updates, such as a reminder feature for inputting Posyandu results data, or other features that suit the program's reporting needs.

Table. WhatsApp chatbot SWOT^a analysis.

Category	Strength	Weakness	Opportunity	Threat
Data input process	Cadres can input data for children from different Posyandu within the same subdistrict (Puskesmas).	It depends on the signal; of- fline data input is not yet possible.	In cases where the number of target children is not high, real-time data input by cadres is feasible.	Slow responses from the chatbot can discourage cadres from inputting a large amount of data.
System utilization	No need to download an app, simply save the chatbot WhatsApp number.	Limitation on providing various features for user through chatbot flow mecha- nism	Additional features can be introduced based on the re- porting program's needs.	If incorrect informa- tion—such as birth date, gender, and weighing re- sults—is input, it can lead to inaccurate interpretation of nutritional status.
Sustainability	Easy to be taught to cadres with low digital literacy	N/A ^b	The sustainability of Posyandu nutritional surveillance data reporting depends on cross-sectoral collaborations from related ministries and stakeholders to support the Puskesmas and Posyandu in implement- ing the Maternal and Child Health program and record- ing and reporting data while ensuring data quality. Stakeholders include the National Population and Family Planning Board, the Ministry of Public Works, and the Ministry of Villages, Development of Disadvan- taged Regions, and Transmi- gration.	Depending on server capaci- ty, scalability considerations are essential for national implementation.
Data quality	Validation and verification during data input to mini- mize errors	Regular data monitoring and evaluation are necessary to support data reporting.	After completing data entry, there is an Excel file contain- ing the weighing results for the last month, facilitating reporting to the village mid- wife and Puskesmas.	Cadres often input child data with different national iden- tification numbers and Indi- vidual Health Status num- bers, leading to potential data duplication for a single child in the database.
Significance of innovation	Data security is maintained as cadres can only input data and cannot edit it.	N/A	The interpretation of nutri- tional status provided at the end of each recording helps cadres to plot nutritional status accurately.	The performance of the chatbot is influenced by the specifications of the cadre's mobile phone.

^aSWOT: strengths, weaknesses, opportunities, threats.

^bN/A: not applicable.

Both support from local regional leaders to encourage cadres to input data and regular monitoring and evaluation of reporting are necessary to encourage cadres to input measurement data. If the recording is complete, cadres can report individual weighing results that have not been reported yet.

Cadres' ability to carry out anthropometric measurements in the correct way and anthropometric tools that are not available or have not been calibrated were some of the challenges in this trial. Not all cadres have devices with high specifications, which slows down the chatbot's response. This makes cadres unwilling to input large amounts of data. Double data also often occurs because there are discrepancies when inputting the NIK and IHS numbers. If a cadre enters the wrong gender or date of birth, there will be an error in the nutritional interpretation such that

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the information obtained will be incorrect. In addition, regarding server capacity, it is necessary to consider how such a program could scale up and be implemented nationally.

Discussion

Principal Findings

WhatsApp has been used for various health-related purposes [28-34]. This paper demonstrates the feasibility of WhatsApp as a tool for data input and data recording in childhood health programs in Indonesia, where it can be used for inputting data, real-time monitoring of nutritional status, generating plotted growth charts, and automatically generating reports on the activities and performance of the cadres in Posyandu.

Current WhatsApp utilization includes aiding in the preparation for professional medical licensing examinations and facilitating online-mediated learning [37,38]. It serves as a data collection tool for health questionnaires related to conditions like Williams-Beuren syndrome and acts as a survey tool for patients with COVID-19 and cancer [39,40]. In biomedical and health care settings, it is used to support processes like neurosurgery assessments, to monitor the application of braces for clubfoot, in laboratory management systems, and to facilitate patient-related communication [41-44]. Additionally, it plays a role in health programs, including initiatives for smoking cessation, patient follow-up care, online health information services for the prevention of stunting, and various peer-support interventions [45-48]. Despite its demonstrated versatility in many contexts, there is currently limited utilization of WhatsApp as a data input tool.

During the 4 months of this pilot study, there was a significant narrowing of the gap between the number of CU5 receiving measurements at Posyandu and the number of data points reported by cadres through WhatsApp. Recording Posyandu activities with WhatsApp can be considered user-friendly and practical because the cadres are already familiar with the app, as are large parts of the population [49,50]. The frequent use of WhatsApp has made cadres accustomed to its interface, features, and services, making it easier for them to follow recording and reporting instructions.

Any app featuring a well-designed user interface contributes to user comfort when using the app and WhatsApp has been shown to fulfill the memorability and usability aspect of an app [51]. The architectural design of the WhatsApp client is also crafted to deliver a seamless and user-friendly experience [52,53]. From an economic perspective, WhatsApp provides an easily adoptable alternative solution. The majority of cadres are housewives [54,55]. Although employment status does not affect the motivation of cadre contributions, it can pose a challenge because they tend to have limited resources, such as owning a smartphone with limited internet data for digital recording. WhatsApp is a freely downloadable app, so cadres do not need to incur subscription costs to use it [56,57].

During the final stage of the pilot, 15.9% (n=447) of CU5 were reported as having stunted growth. This number was lower than the 2022 estimated prevalence of children with stunted growth obtained through a national survey in Indonesia, which amounted to 21.6% at the national level and 20.2% for West Java Province [7]. The number was also lower than the prevalence of children with stunted growth in Bogor District, which was reported to have reached 24.9% in 2022 [58]. It is unclear if this discrepancy was due to a more accurate reporting methodology, a lack of recording for the more affected children, or other reasons. However, it demonstrates that, even within a pilot application, the use of this tool provides a representative picture.

However, there are several challenges to its nationwide implementation: access to an internet connection, data validity, system capacity, hardware support, and external support. To activate a conversation with the chatbot, an adequate internet connection needs to be established. Despite the increasing

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adoption of 4G networks and up to 73% internet penetration, disparities in internet access persist in the eastern part of Indonesia [59].

To mitigate challenges related to internet access, it is crucial to support efforts to expand internet quality across all provinces. Efforts that could reduce this gap in the digital divide include but are not limited to: partnering with local business to provide internet in low-resource settings, engaging with multisectoral stakeholders to develop policy frameworks and funding support for targeted areas, as well as encouraging innovation in technology related to internet access [60,61]. Currently, the Indonesian Ministry of Health is exploring the possibility of cooperation with Starlink (a satellite internet provider) to provide internet access in Puskesmas located in remote, frontier, and outermost areas [62]. Aside from that, continuous collaboration with relevant stakeholders such as the Ministry of Communication and Information Technology is needed.

As an alternative, developing offline features would allow for data entry without an internet connection. A previous study showed that offline features in a mobile app could aid data collection in a decentralized registry [63]. Mobile apps with offline functionality such as Research Electronic Data Capture (REDCap) have also been tested for their usefulness in collecting field survey data in areas with low access to the internet [64]. Additionally, offline functionality could also be used for educational purposes to inform mothers in rural areas about their children's nutrition status [65].

Several studies pointed out the need for attention to the standard operating procedure for anthropometric measurements (especially for body height, which had the highest technical error of measurement), maintenance of instruments, training, and measurement resampling to ensure the accuracy of the data [62,66,67].

To tackle the disparities in anthropometric instruments across the country, the Ministry of Health is striving to equip all Posyandu with anthropometric devices, aiming to distribute 313,737 anthropometric devices to 303,416 Posyandu nationwide by the end of 2024 [68]. Regular calibration must be carried out by an assigned technician to ensure instrument quality; equipment such as infantometers and stadiometers must be calibrated weekly [69]. Another study showed that, to achieve the same accuracy of anthropometric measurement as a medical student, cadres must be trained intensively and receive regular education [70,71]. Capacity building can be carried out as a means to train cadres to conduct anthropometric measurements and digitally report data [72,73].

In order to record individual data, having a NIK number is an integral part of the reporting process. This identification number is able to provide information on location such as province, city/district, and subdistrict, as well as date of birth [74]. Even so, a subpopulation of around 5.3 million people in Indonesia still do not have access to NIK as an identification number [75]. A study by the Ministry of Home Affairs highlights that disadvantaged groups such as individuals living in poverty, indigenous communities, religious or ethnic minorities, remote populations, older individuals, persons with disabilities, refugees, and individuals with nonpermanent housing or high

mobility are those having a hard time accessing and obtaining digital identification [76]. Providing legal identification since birth is an area of focus of the Sustainable Development Goals; therefore, to tackle the gap mentioned above, as well as part of a strategy to participate in providing legal identity for all, civil registration data can be linked and integrated with vital statistics such as birth registration data [77,78].

To prevent data duplication, the government shall implement a central database that connects a unique identifier generated by the Ministry of Home Affairs (NIK), Ministry of Health (IHS number), and Immigration Directorate General (passport number) [79-81]. The system shall implement robust data validation mechanisms that could include automated cross-checking against a central database before final submission. This interoperable check of the central database ensures that an individual's data are recorded through a single, streamlined thread, effectively reducing the risk of duplication and maintaining health data quality [82].

Considering that anthropometric measurement is carried out as a routine activity in Posyandu, it is crucial to ensure that the system is capable of meeting user needs related to inputting data, and that it has the capability to store, file, abstract, and retrieve records seamlessly [83]. Server availability is also one of the crucial components of infrastructure readiness [84]. Another technicality that needs to be considered is the compatibility of the hardware to the software, meaning that to use WhatsApp, potential users need to at least have a device that supports Android OS 5.0 or iOS 12 [85]. Consequently, older devices that were released before 2015 might not be compatible with WhatsApp [85-87].

Taking into consideration that ease of use affects the adoption of apps and/or health systems, developers also need to ensure that the data reporting flow remains simple and the app size is compact [88,89]. Adding features like reminders for data input and providing visual feedback on data consistency could motivate cadres and improve adherence to data entry protocols. Studies have shown that electronic reminders had a great impact on health worker adherence to implementing certain health protocols [90]. Adding monitoring features and feedback loops can also help in identifying cadres who are facing challenges and ensuring targeted support [90].

Aside from the technical support aspect, external support is also pivotal for the implementation of the data input process. Support from the village midwife, Puskesmas, as well as the village leader plays a role in motivating cadres to use the WhatsApp chatbot and input data. It is undeniable that stakeholders such as professional health workers and governmental bodies have a role to play in adequately managing health information systems [91]. Legislative, regulatory, and coordination support are also deemed to be a prerequisite step for optimal and functional health information systems [83]. Having strong cross-sectoral collaborations with relevant ministries and stakeholders, such as the Ministry of Villages, Development of Disadvantaged Regions, and Transmigration; the Ministry of Home Affairs, the National Population and Family Planning Board, and the National Development Planning Agency (Bappenas), will strengthen the broader implementation.

Strengths and Limitations

The strength of this study lies in its pioneering exploration of digitizing Posyandu records through WhatsApp, representing the first-ever development of such a method with substantial potential for diverse data input approaches, particularly in lowand middle-income countries. However, certain limitations must be acknowledged: (1) data input at Posyandu is dependent on internet access, (2) data validation relies on the standards of measurement tools and the capacity of the cadre, and (3) there exists a potential for record duplication due to discrepancies in the input of NIK and IHS numbers by the cadres. Nevertheless, this study provides a nuanced understanding of the potential application of WhatsApp as a tool for monitoring the nutritional status of CU5 in developing countries such as Indonesia.

Conclusions

The utilization of WhatsApp holds promise as a tool for recording surveillance data related to the nutritional status of children. This study provides the first evidence of the implementation of such a tool in community-driven health care settings. In the future, there is potential for expanding the application of WhatsApp to encompass broader data recording functions within health programs. However, such an expansion requires concurrent enhancements in features, involving the preparation of human resources, infrastructure at Posyandu, and robust regulatory support. This entails a comprehensive approach that addresses not only the technological aspects but also considers the human, infrastructural, and regulatory dimensions for the effective integration of WhatsApp into health programs, ensuring its optimal and sustainable use.

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Data Availability

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

Authors' Contributions

DNA led the study design and built the paper concept, main structure, and methodology. CAM, AU, FMR, NHA, LR conducted quantitative and qualitative assessment and accessed and analyzed the data. DNA, CAM, AU, FMR, and NHA wrote the first draft of the paper. EAF developed the chatbot infrastructure. MHS and AC provided support in chatbot development. ZK and LM validated the study and critically revised the manuscript content. DNA, CAM, and LR had primary responsibility for the final content. All authors read and contributed to reviewing the study data and manuscript design. All authors provided approval of the final manuscript.

Conflicts of Interest

Although 2 authors are affiliated with Aceso Global Health Consultants Pte Limited, a private company, we declare that this research project did not receive funding from Aceso Global Health Consultants. The company did not have a role in the study design; data collection and analysis; decision to publish; or preparation of the manuscript. LM is the director of the company and DNA is a consultant of the company. However, both of them contributed to this paper on a pro bono basis. Where authors are identified as personnel of the International Agency for Research on Cancer/World Health Organization, the authors alone are responsible for the views expressed in this article and they do not necessarily represent the decisions, policy or views of the International Agency for Research on Cancer/World Health Organization conflicts of interest.

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Abbreviations

CU5: children under 5 years old DTO: Digital Transformation Office HAZ: height-for-age z-score IHS: Individual Health Status NIK: national identification number Posyandu: Pos Pelayanan Terpadu (community-based health service post) Puskesmas: Pusat Kesehatan Masyarakat REDCap: Research Electronic Data Capture WAZ: weight-for-age z-score WHZ: weight-for-height z-score

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

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Abstract

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

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

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

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

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

Trial Registration: Clincial Trials.gov NCT04730570; https://clinicaltrials.gov/study/NCT04730570

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

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KEYWORDS

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

Introduction

Background

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The growth of digital health interventions to address mental health and maternal health outcomes has grown significantly over the past decades [1,2]. Despite this growth, the extent to which preventative digital health interventions improve or

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maintain outcomes after the intervention has concluded is unclear. This is known as the maintenance effect, which is essential to behavior change interventions and measures the impact of the intervention on outcomes after the treatment has taken place [3]. To date, evidence is mixed as to whether the positive effects of digital health interventions are maintained over time for a variety of health areas including obesity or weight loss [4], smoking [5], and increasing physical activity

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

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

Aim

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

Hypotheses

The following were our hypotheses:

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

perceived social support, no differences at 6 months are hypothesized.

Methods

Participants

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

Ethical Considerations

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

Design

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

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

Intervention

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

Outcome Measures

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

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

Data Analysis

Data were analyzed on a per-protocol analysis, excluding women who requested to stop receiving the messages or did not return the 6-month follow-up survey. A series of analyses of covariances were conducted to examine the effects of the intervention on the outcomes of interest at 6 months postpartum considering allocation. In all analyses of covariances, parity, maternal age, and scores on the respective outcomes at baseline were entered as co-variates (ie, when analyzing parenting self-efficacy, parity, maternal age, baseline parenting self-efficacy scores were included as co-variates). Chi-square analysis was conducted to compare whether participants scored above or below the clinical cut-off that identifies low parenting self-efficacy or high postpartum anxiety and depression symptoms. For the chi-square analysis, all participants who completed the outcome survey at 6 months were included. A *P* value of .05 was considered significant for all outcomes. SPSS (version 29.0; IBM SPSS Statistics) was used for analysis.

Results

Overview

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

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





Table . Baseline characteristics for the intervention and control groups.

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

^aConducted using independent *t* test.

^bconducted using Pearson chi-square analysis.

^cConversion CAD to USD estimated at 1 CAD=US \$0.70.

^dNot applicable.

Parenting Self-Efficacy

Based on the 139 mothers who completed parenting self-efficacy measures at 6 months, there was no statistically significant difference in parenting self-efficacy at 6 months postpartum based on allocation ($F_{1,134}$ =0.112, P=.74, partial η^2 =0.001) (Table 2). A chi-square analysis was conducted to determine

whether the proportion of mothers who had high (\geq 40) or low parenting self-efficacy scores (\leq 39) at 6 months were different based on group allocation. There were no differences in the proportion of mothers with high or low parenting self-efficacy scores based on allocation at 6 months postpartum (χ^2_1 =0.091, *P*=.76) (Table 3).

Table . Adjusted means scores based on allocation at 6 months postpar	um.
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Outcome	Intervention, mean (SD)	Control, mean (SD)	<i>P</i> value
Parenting self-efficacy (n=139)	40.14 (3.73)	40.11 (3.94)	.74
Postpartum anxiety scores (n=136)	106.71 (20.97)	99.35 (19.13)	.30
Postpartum depression scores (n=136)	10.01 (4.66)	8.19 (4.94)	.20
Social support (n=135)	5.82 (0.95)	5.82 (1.12)	.79

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

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

^aIntervention (n=69) and control (n=70).

^bIntervention (n=68) and control (n=68).

Postpartum Anxiety Symptoms

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

Postpartum Depression Symptoms

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

Perceived Social Support

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

Discussion

Principal Results

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

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

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

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

Limitations

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

Comparison With Prior Work

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

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

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

While digital health interventions are desired and accepted by postpartum mothers [34], interventions designed for implementation during the postpartum period should take into consideration how interventions can maintain positive impacts over time. In a meta-synthesis of what women want in the postpartum period, Finlayson et al [35] clearly summarize: "To cope with this period of adjustment women express the need for practical, emotional and psychological support from family members, peer groups and online sources, as well as from health providers. Women also want information and reassurance from health providers delivered in a consistent manner by authentic, familiar providers who recognise the mother's as well as baby's needs, within a well-resourced and flexible healthcare system that respects their cultural context". Given the multiple challenges that emerge for mothers during the postpartum period, both in-person and digital support from reliable sources

of information that respond to mothers' needs and infant development is needed. Engaging patients in the development of perinatal digital health solutions is important to improve health outcomes but is not yet common practice [36-38].

Future Directions

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

Conclusions

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

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Authors' Contributions

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

Conflicts of Interest

None declared.

Checklist 1 CONSORT-eHEALTH checklist. [PDF File, 1092 KB - pediatrics v8i1e62841 app1.pdf]

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Abbreviations

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

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Preliminary Effectiveness of a Postnatal mHealth and Virtual Social Support Intervention on Newborn and Infant Health and Feeding Practices in Punjab, India: Quasi-Experimental Pre-Post Pilot Study

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Abstract

Background: We evaluated a pilot mobile health (mHealth) intervention aimed at improving postnatal maternal and infant health. The intervention featured provider-led group sessions for education, health care communication, in-person care referrals, and virtual mHealth support for postpartum mothers through weekly calls, texts, interactive voice response (IVR), and a phone app.

Objective: We aimed to assess the preliminary effectiveness of the pilot mHealth intervention, *MeSSSSage (Maa Shishu Swasthya Sahayak Samooh*, which means maternal and child health support group), on infant health knowledge, behaviors, and outcomes at 6 months post partum. We focus on maternal knowledge of infant danger signs and optimal young child feeding practices at 6 months post partum and also evaluate maternal care-seeking behaviors for infants, adherence to age-appropriate immunization, and infant and young child feeding practices such as early initiation of breastfeeding and complementary feeding.

Methods: We evaluated the preliminary effectiveness of an intervention on maternal health knowledge among 135 participants in Punjab, India, who completed pre- and postintervention surveys. The intervention, led by research personnel with backgrounds similar to community health officers, aimed to empower society and support universal health coverage if successful. We assessed changes in knowledge of maternal danger signs and the appropriate age for introducing different food groups over 6 months post partum. Additionally, we examined postintervention differences in health-seeking behavior for infants, adherence to age-appropriate immunizations, and adoption of breastfeeding and complementary feeding practices among women in the synchronous (group call), asynchronous (IVR and app), and control arms.

Results: Of 12 infant risk factors, maternal knowledge of infant danger signs remained low (mean range: 1.85-2.31 preintervention and 1.81-2.22 postintervention). Participants in the synchronous arm had a statistically significant higher mean increase (mean difference: 0.87, 95% CI 0.06 - 1.69) compared to the control arm. Participants in synchronous arms had nearly 3-fold increased odds of infant health checkup by a clinical provider than asynchronous arm participants (odds ratio [OR] 2.72, 95% CI 1.02-7.23).

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No significant differences were noted in age-appropriate vaccine coverage among infants between arms, though vaccination coverage was more than 80% across all arms. Early initiation of breastfeeding remained low across all arms (~47%).

Conclusions: Our pilot study on group-based mHealth education and virtual social support during the postnatal phase showed modest yet promising results. Rigorous testing is crucial to strengthening the limited evidence base for group-oriented mHealth approaches.

Trial Registration: ClinicalTrials.gov NCT04693585; https://clinicaltrials.gov/study/NCT04693585

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KEYWORDS

digital health; mHealth; mobile health; app; postpartum; health education; social support; India; infant morbidity; care seeking; postnatal; maternal; mother; text message; virtual support; online support; pediatric; infant; baby; neonate; newborn; breastfeeding; feeding

Introduction

Background

India has made substantial improvements in child survival through a 54% reduction in neonatal mortality rate from 52 per 1000 live births in 1990 to 23.7 per 1000 live births in 2017 [1,2]. About 75% of newborn deaths occur in the first week of life, highlighting the importance of intervening in the early postnatal period [3]. Further, child undernutrition accounts for over 20% of deaths and remains a major risk factor for disease burden in children younger than 5 years in India [2,4]. The latest national survey suggests that 35.5% of children in India are stunted, 32.1% are underweight, and 19.3% are wasted with substantial variation both across and within Indian states [5].

There is a robust evidence base of interventions spanning the continuum of care from pregnancy through post partum and through the first 1000 days of life, including appropriate infant and young child feeding practices to improve newborn, and child health and nutrition outcomes [6,7]. India, backed by a two million+ female community health worker program, has adopted a comprehensive and universally available package of maternal and neonatal evidence-based interventions through its multiple national government programs, including the Integrated Child Development Services, the National Health Mission, and the National Nutrition Mission [8,9]. However, national surveys suggest that coverage of nutrition interventions, particularly in the postnatal and newborn period, remains low. Only 41.8% of children were breastfed within an hour of birth, 46% of children 6 - 8 months were initiated on complementary food, and 11% of children below 6 - 23 months received adequate diet with disparities by geographical region, socioeconomic status, and rural-urban residence [5].

Prior research from India suggests that postnatal care is associated with reduced neonatal mortality [10], and appropriate care for sick infants and children is correlated with reduced risk of severe wasting [11]. Postnatal education is an evidence-based strategy to improve newborn health and nutrition and maternal knowledge of general infant health and care [12]. While national data suggest that 79% of infants receive a postnatal checkup by skilled health personnel within 2 days of childbirth [5], a recent study of 13,000+ respondents from 3 large Indian states (including Punjab, one of our study states) highlights that 55% of mothers receive no postnatal education, with considerable

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knowledge gaps in appropriate newborn care practices, including skin-to-skin care, cord care, warning signs of infant illness, among other related topics [13]. Beyond postnatal education, enhancing social support for mothers through interpersonal connections is associated with reduced risk of postpartum depression [14,15], improved maternal self-efficacy [16,17], higher postnatal care attendance of mothers and infants [18], increased healthy maternal physical activity and nutritional intake [14], and better infant and young child feeding practices [19]. However, various barriers hinder postnatal care in India, including logistical challenges exacerbated by geographic distance and cultural factors [20-22]. Factors such as lower levels of women's autonomy, restricted freedom of movement, and social isolation further compound these challenges, particularly during the postnatal period when women are traditionally confined to their homes for 40 days after delivery [23]. Additional barriers include poverty, limited education, lack of male involvement, absence of health insurance, financial constraints, and perceptions of inadequate quality or lack of benefit of services [24-26].

Leveraging mobile health (mHealth)-based interventions holds promise in addressing barriers to postnatal care and improving postnatal maternal knowledge, social connectedness, and maternal and child health-related behaviors given increasing mobile phone ownership and internet access. A scoping review of 28 studies across low- and middle-income countries (LMICs) found improved immunization coverage and increased adherence to immunization schedules through mHealth-based text and voice message reminders [27], while another systematic review of 16 studies in LMICs found mHealth education interventions to increase perinatal interactions between young mothers and health care workers [28]. Individual studies reporting on mHealth interventions using text and voice messaging have improved perinatal care attendance [29], early initiation of breastfeeding and exclusive breastfeeding [30-32], protein consumption [33], general infant and young child feeding practices [34], knowledge of child immunization [35], and better adherence to child immunization schedules [36].

Key gaps in the evidence base on the impact of mHealth interventions on postpartum and neonatal health in India include fewer interventions focused on this topic area, with most targeting frontline health and nutrition workers to improve service delivery [37-40], limited interactions and social support provision among those targeting beneficiaries [30-32,41], and

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the need for more rigorous studies [28,30,37,40]. Group-oriented mHealth interventions combining group-based learning and social support may overcome prevalent barriers given the convenience, feasibility, acceptability, and preliminary effectiveness in improving postnatal maternal and infant health outcomes [32,42-47]. However, the combined impact of interactive group-based social support delivered via mHealth modalities such as group voice calls or Zoom has been understudied in LMICs.

To address these gaps, we designed a provider-facilitated group perinatal mHealth intervention called *MeSSSSage* (*Maa Shishu Swasthya Sahayak Samooh*, which means maternal and child health support group). Informed by the capabilities and motivation constructs of the COM-B (Capability, Opportunity,

and Motivation Behavior) framework [48,49], the intervention designed to enhance maternal knowledge was of health-promoting behaviors and promote maternal self-efficacy and empowerment to improve health-related knowledge, behaviors, and maternal and child outcomes (Figure 1). The intervention aimed to improve knowledge, facilitate referrals to in-person care, and foster connections with a virtual social support group for postnatal mothers with infants of similar ages through various mHealth modalities, including weekly group calls and text chat. Our development process included 2 iterative rounds of pilot testing-the first to inform the mHealth components and design factors [50] and the second to understand the feasibility and acceptability of our revised intervention [51] and explore preliminary effectiveness on health outcomes.

Figure 1. Conceptual framework of intervention context, *MeSSSSage* intervention targets and outcomes, and anticipated long-term impacts. *MeSSSSage*: *Maa Shishu Swasthya Sahayak Samooh* (which means maternal and child health support group).



Objective of This Study

In the current analysis, we aimed to assess the preliminary effectiveness of the pilot mHealth intervention, *MeSSSSage*, on infant health knowledge, behaviors, and outcomes at 6 months post partum. We focus on maternal knowledge of infant danger signs and optimal young child feeding practices at 6 months post partum and also evaluate maternal care-seeking behaviors for infants, adherence to age-appropriate immunization, and infant and young child feeding practices such as early initiation of breastfeeding and complementary feeding.

MeSSSSage Intervention

The *MeSSSSage* intervention was administered to women from late pregnancy through 6 months post partum. It included weekly audio or audio-video group calls, group text chats, and audio educational content provided via automated interactive voice response (IVR) or *MeSSSSage* app (Table 1 and Figure 2). Groups and group-based content (ie, audio-video group calls and group text chats) were facilitated by trained intervention moderators with backgrounds in public health or social work and supported by a gynecologist and neonatologist. The detailed description is published elsewhere [51].



Table . *MeSSSSage^a* intervention modalities.

mHealth ^b modalities or arms	Description
Audio-video group sessions	Trained moderators led weekly group sessions focusing on increasing ed- ucation and social support. These sessions incorporated icebreakers and group-building activities, facilitated discussions based on weekly themes (Figure 2), and allowed open questions and discussion sessions. Prenatally, a gynecologist participated in one call per month, while postnatally, both a gynecologist and a neonatologist participated in one call per month. Participants could choose to connect to their group via audio-only sessions on the TATA platform or video sessions on the Zoom platform.
WhatsApp-based group text chat	Trained moderators led weekly WhatsApp-based group chats by sharing audio and visual messages based on themes (Figure 2). Group participants were expected to engage by asking questions, and group discussion was facilitated.
<i>MeSSSSage</i> mobile app	Weekly educational audio messages focus on key information regarding weekly themes (Figure 2). The mobile app structured sections for these weekly audio messages, offering women the flexibility to access health education content at their convenience.
IVR ^c	IVR calls were scheduled to reach participants once a week at designated days and times. To maximize the chances of participants receiving the calls, they were sent out 3 times within a 15-minute interval. These brief audio calls, lasting between 5 and 10 minutes each, addressed essential topics concerning perinatal, neonatal, and child health. IVR calls persisted up to 6 months postdelivery.

^aMeSSSSage: Maa Shishu Swasthya Sahayak Samooh (which means maternal and child health support group).

^bmHealth: mobile health.

^cIVR: interactive voice response.

Figure 2. Weekly maternal and neonatal content of *MeSSSSage* intervention. IVR: interactive voice response; *MeSSSSage*: *Maa Shishu Swasthya Sahayak Samooh* (which means maternal and child health support group).



Figure 2 provides a summary of the intervention plan. While this table offers the general structure of IVR calls and audio-video group discussion topics, the audio-video group discussion topics were dynamically adjusted based on the queries and concerns shared by the new mothers, ensuring a responsive and participant-focused approach.

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Methods

Study Design

This open-label pilot study on an mHealth-based perinatal health support intervention targeted women in late pregnancy through 6 months post partum in the Boothgarh block of the state of Punjab, northern India. We used a pretest-posttest nonrandomized control group design. Quantitative survey data were collected at study enrollment and intervention completion (approximately 6 months post partum).

Study Participants

Participants were eligible for inclusion in the study if they met the following criteria: (1) aged 18 years or older, (2) between 28 and 32 weeks pregnant, (3) residing in the study area, and (4) not experiencing a serious maternal complication. Participants with high-risk pregnancies and parity of more than 2 were ineligible.

Study Procedures

Our study team used antenatal clinic registry data maintained by community health workers to prescreen pregnant women in the seventh month of gestation. We then contacted these potential participants over the phone, screened them, and if found eligible, invited them to participate. We led them through an informed consent process, which included discussing study procedures, risks, and benefits. All participants provided informed consent verbally.

Out of the 397 women we tried to reach, we successfully recruited a total of 180 participants. These participants were then sequentially assigned to one of five arms: (1) app only (n=20), (2) IVR only (n=20), (3) group call+WhatsApp+app (3 separate arms, n=60), (4) group call+WhatsApp+IVR (3 separate arms, n=60), and (5) finally the control arm (n=20) at baseline. All participants, including the control arm, received the standard of care, which, in this setting, comprised community health worker-led home visits, counseling, and immunization services. Reasons for nonenrollment included being unable to reach the potential participant over the phone, as their phone was either switched off or out of service. Some women provided false information, while others were no longer pregnant due to a miscarriage or preterm birth. A few participants also described having irregular access to mobile phones since they used either their husband's or an immediate family member's phone and only had access to it in the evening when their husband or family member returned home from work. Some individuals did not respond to our calls, while others faced language challenges.

After enrollment, the 8 groups or arms were formed in a staggered fashion, leading to a study timeline from August 2021 to November 2022. Participant engagement in the intervention spanned a total of 8 months. Enrollment of participants and administration of the baseline survey occurred between August and December 2021. Intervention implementation spanned from August 2021 to July 2022, and our endline quantitative survey was conducted between May and December 2022. All data were collected through interviewer administration over the phone and directly entered into the REDCap (Research Electronic Data Capture) data collection application. For individuals who were

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not able to be reached for the endline survey, local ASHAs (Accredited Social Health Activists) were engaged to facilitate in-person quantitative survey administration.

Study Measures

Based on existing research on IVR and apps for maternal and child health in India, we focused on examining the supplementary impact of group calls. We anticipated that participants engaged in group calls would experience higher levels of social connectedness compared to those using the educational app or IVR, as the former allowed for direct interaction with others, fostering a sense of community and support. For analysis, we consolidated study participants into 3 intervention categories: a synchronous arm (combining arms 3 and 4 described above, comprising all group call participants), an asynchronous arm (combining arms 1 and 2 described above, comprising those in the app and IVR), and a control arm.

The primary outcomes of this analysis were the change in maternal knowledge of infant danger signs and maternal knowledge of infant and young child feeding practices between pre- and postintervention. Knowledge of infant danger signs was defined as women's ability to recall symptoms indicating infants may require medical attention within the first month of birth. We developed a cumulative score based on women's recall of various danger signs, including diarrhea, fever, cough or cold, difficulty breathing, absence of crying, chest problems, blue tongue and lips, lack of milk intake, failure to gain weight, premature birth, jaundice, coldness to touch, and others (scores ranging from 0 to 13). Women's knowledge of infant and young child feeding practices was assessed by their correct reporting of the appropriate age for introducing the following foods: water, rice, bread, legumes (dal), green leafy vegetables, pumpkin, carrot, fruits (banana, papaya, mango, and orange), meats (chicken, mutton, and fish), eggs, and different types of milk (cow, goat, powdered, etc). Women who correctly identified 6 months or older as the appropriate age for introducing all food groups except cow's/goat's milk (12 months) were coded as 1; otherwise, they were coded as 0. We developed a cumulative score based on women's correct responses.

Additional outcomes assessed postintervention included infant health status, access to health care, infant vaccination status, and infant feeding behaviors. Infant postnatal health characteristics were assessed through various questions. Postnatal care was assessed based on women's self-reports regarding whether their infants received a checkup within 6 weeks of birth, the frequency of these checkups, and the type of provider conducting the checkup (clinical or community). Infant vaccination coverage was determined by whether the infant had received all age-appropriate vaccines. Infant and young child feeding practices were evaluated through breastfeeding, early initiation of breastfeeding (defined as within 1 hour of birth), and complementary feeding (defined as whether other liquids or foods had been introduced to the infant). All variables were coded as indicator variables (yes/no).

Participant sociodemographic characteristics collected during preintervention included age, relationship status, educational attainment, religion, caste, ration card and type, parity, and mobile phone ownership.

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Analysis

At baseline, 120 participants were in the synchronous arm, 40 participants in the asynchronous arm, and 20 in the control arm. At endline, we had 94 participants (78.3% retention rate) in the synchronous arm, 28 participants (70% retention rate) in the asynchronous arm, and 13 (65%) in the control arm. With our primary focus on temporal change, we restricted the analytic sample for this paper to participants with both baseline and endline data, resulting in a sample size of 135 participants.

We compared the sociodemographic characteristics of the 3 analysis arms (synchronous, asynchronous, and control arm) by identifying standardized differences [52]. Due to significant disparities across arms in the distribution of age, age at marriage, household composition, educational attainment, household income, ration card possession, mobile phone ownership, and smartphone access, we used inverse probability weighting to ensure comparability of participants across arms. This approach, similar to direct standardization, balanced preintervention discrepancies in sociodemographics between the arms [53,54].

We summarized sociodemographic characteristics using proportions and means of the matched, reweighted study population surveyed pre- and postintervention stratified by 3 arms (synchronous, asynchronous, and control). We then assessed the association of being in each intervention arm on primary outcomes (changes in maternal knowledge of infant danger signs and knowledge of infant and young child feeding practices) using mixed effects linear regression, including a random intercept for participants with robust standard errors to adjust within individual clustering due to the longitudinal structure of the data. The difference-in-difference coefficient (β) is the interaction term between a categorical variable denoting the time (before vs after the intervention was implemented) and the intervention arm (synchronous vs asynchronous modes, synchronous vs control, and asynchronous vs control). We interpreted this term as the differential change over time associated with being in each intervention arm compared to the reference group. For outcomes collected only

at endline, we analyzed the differences between the arms (synchronous vs asynchronous modes, synchronous vs control, and asynchronous vs control) using logistic regression. Differences where P<.05 were considered statistically significant. All analyses are presented using weighted estimates. Data entry was done through REDCap, and all statistical analyses were conducted using Stata 15 (StataCorp LLC).

Ethical Considerations

This study received approval from the Indian Council of Medical Research and senior health authorities of the Government of Punjab and the Mission Director, National Health Mission, India. The study protocol was approved by the University of California San Francisco Institutional Review Board (19 - 299723), the ethics committee of the Postgraduate Institute of Medical Education and Research (IEC-03/2020 - 1567), the Collaborative Research Committee of the Postgraduate Institute of Medical Education and Research (79/30-Edu-13/1089 - 90), and the Indian Council of Medical Research (ID 2020 - 9576). All study participants were deidentified, engaged in a thorough informed consent process and provided written confirmation of informed consent at enrollment.

Results

Sociodemographic Characteristics

At study enrollment, participants had an average age of 26.8 years, and almost all (99.3%) were married (Table 2). The majority had either a high school education (44.8%) or higher education (44.3%). Nearly two-thirds of the sample belonged to the Sikh religion (65.3%), and one-third of the sample belonged to a marginalized caste (scheduled caste and scheduled tribe; 36.4%). Less than half possessed a ration card (48%), an official government document given to eligible poor families to get subsidized food grains from government fair price shops. Parity was one (53.3%) or more (46.8%). Mobile phone ownership at the household level was near-universal (99.2%), and most women owned their own phones (92.5%).



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Table . Sociodemographic characteristics of the intervention participants.

	Synchronous (n=94)	Asynchronous (n=28)	Control (n=13)	Total (N=135)
Age, mean (SD)	26.7 (0.38)	26.8 (0.61)	26.7 (1.57)	26.7 (0.33)
Relationship status, n (%)				
Married or domestic partner- ship	94 (100)	27 (98)	13 (100)	134 (99.8)
Separated	0 (0)	1 (1.2)	0 (0)	1 (0.2)
Educational attainment, n (%)				
None	0 (0)	2 (7.2)	1 (6)	3 (1.5)
Up to secondary	9 (9.6)	1 (3.1)	3 (22.2)	13 (9.4)
Higher secondary	41 (43.6)	15 (50.1)	6 (47.1)	62 (44.8)
Diploma or higher	44 (46.8)	10 (39.6)	3 (24.7)	57 (44.3)
Religion, n (%)				
Hindu	23 (24.5)	11 (32.2)	4 (26.3)	38 (25.7)
Muslim	9 (9.6)	0 (0)	3 (21.8)	12 (9)
Sikh	62 (66)	17 (67.8)	6 (51.9)	85 (65.3)
Caste, n (%)				
General	41 (43.6)	16 (55.7)	5 (39.9)	62 (45.2)
Schedule caste or tribe	36 (38.3)	6 (21.2)	6 (48.3)	48 (36.4)
Other backward class	15 (16)	3 (9.8)	2 (11.8)	20 (14.8)
Other	2 (2.1)	3 (13.3)	0 (0)	5 (3.6)
Ration card, n (%)				
Yes	45 (47.9)	16 (45.7)	5 (35.9)	66 (48.0)
No	49 (52.1)	12 (54.3)	8 (64.1)	69 (52.0)
Parity, n (%)				
1	50 (53.2)	14 (51.6)	8 (60.2)	72 (53.4)
>1	44 (46.8)	14 (48.4)	5 (39.8)	63 (46.6)
Mobile phone ownership, n (%)				
Individual	93 (98.9)	25 (91.6)	9 (80.6)	122 (92.5)
Household	88 (93.6)	28 (100)	13 (100)	134 (99.2)

Maternal Knowledge of Infant Danger Signs

Despite increases noted across time, maternal knowledge of infant danger signs remained relatively low (Table 3). Of the 12 infant risk factors, the mean number known across arms ranged between 1.85 and 2.31 preintervention and 1.81 and 2.22 postintervention (Table 3 and Multimedia Appendix 1). Being

in the synchronous arm was associated with a small but significantly greater increase in the mean number of infant danger signs known when compared to those in the control arm (mean difference 0.87, 95% CI 0.06 - 1.69; Table 3). No differences were identified between synchronous versus asynchronous arms or between asynchronous versus control arm participants.



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Table . Comparisons between pre- and postintervention newborn health-related knowledge by intervention arm (n=135).^a

	Mean (95% CI)			Arm × time parameter (95% CI)		
	Synchronous ^b	Asynchronous ^c	Control	Synchronous vs asynchronous	Synchronous vs control	Asynchronous vs control
Maternal knowledge of infant danger signs (total possible score=12)			0.56 (-0.22 to 1.35)	0.87 (0.06 to 1.69)	0.31 (-0.75 to 1.37)	
Preintervention	1.85 (1.61 - 2.08)	2.06 (1.47 - 2.65)	2.31 (1.19 - 3.44)	d	_	_
Postintervention	2.22 (2.00 - 2.44)	1.87 (1.32,2.43)	1.81 (1.02 - 2.60)	—	—	—
Maternal knowledge of appropriate infant and young child feeding practices (total possible score=9)			-0.75 (-1.96 to 0.45)	0.66 (-2.07 to 3.40)	1.42 (-1.55 to 4.40)	
Preintervention	7.56 (7.23 - 7.89)	6.48 (5.56 - 7.40)	6.84 (5.05 - 8.65)	_	_	_
Postintervention	7.89 (7.77 - 8.01)	7.56 (6.95 - 8.18)	6.51 (4.74 - 8.28)	_	—	—

^aFull model output for these analyses with corresponding *P* values is presented in Multimedia Appendix 1.

^bCombining all participants assigned to weekly group calls.

^cCombining those participants assigned to the app and interactive voice response. ^dNot applicable.

Maternal Knowledge of Appropriate Infant and Young Child Feeding Practices

Maternal knowledge of appropriate initiation of varied food groups was high preintervention, and no increase was observed over time (Table 3). Of 9 food groups in total, the mean number of food groups that women reported the correct knowledge for ranged from 6.48 to 7.56 preintervention and 6.51 to 7.89 postintervention. No group differences were identified.

Infant Health Checkup and Infant Vaccination

Table 4 presents a postintervention comparison of outcomes. Over 50% of participants in the synchronous arm and 40% of participants in the asynchronous arm reported receiving a health checkup for their infants, compared to 28.9% in the control arm. However, no statistically significant difference was noted between arms. Regarding receipt of infant health checkups by a clinical provider, a higher proportion (53.2%) of participants in the synchronous arm reported receiving a health checkup from a clinical provider compared to the other 2 arms. Participants in the synchronous arm had 2.72 times greater odds ratio (OR 2.72, 95% CI 1.02-7.23; P<.05) of infant health checkup by a clinical provider compared to the asynchronous arm. There were no statistically significant differences between the synchronous arm and control arm or between the asynchronous arm and control arm. The coverage of all 4 age-appropriate vaccines-BCG (Bacillus Calmette-Guérin), polio, DPT (diphtheria, pertussis, and tetanus), and hepatitis B-was high across all arms, ranging from 89% in the synchronous arm, 84% in the asynchronous arm, and 80.3% in the control arm. No differences were noted in the postintervention between-arms comparison.

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Table. Postintervention comparison of infant health care seeking, vaccination uptake, and infant and young child feeding practices at endline (n=135).

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	Synchronous (n=94), n (%)	Asynchronous (n=28), n (%)	Control (n=13), n (%)	Synchronous vs asynchronous, OR ^a (95% CI)	Synchronous ver- sus control, OR (95% CI)	Asynchronous ver- sus control, OR (95% CI)
Infant health checku	ıp			-		
Participants who had a postnatal health check for in- fant within the 6 weeks after giving birth	54 (57.5)	8 (40.9)	2 (28.9)	1.94 (0.71 - 5.30)	3.32 (0.64 - 17.02)	1.70 (0.25 - 11.37)
Health checkup conducted by clini- cal provider (Ref: no health checkup by a clinical provider)	50 (53.2)	7 (29.5)	2 (24.8)	2.72 ^b (1.02 - 7.23)	3.44 (0.69 - 17.06)	1.26 (0.20 - 7.90)
Mothers whose in- fants fell sick in the past 3 months	36 (38.3)	7 (33.1)	5 (46.3)	1.25 (0.44 - 3.52)	0.71 (0.17 - 3.06)	0.57 (0.10 - 3.28)
Infants received BC	G ^c , polio, DPT ^d , or h	epatitis B vaccines				
BCG vaccination	87 (92.6)	23 (96.1)	11 (100)	e	—	—
Polio vaccination	94 (100)	24 (96.6)	10 (93.5)	_	_	_
DPT vaccination	93 (98.9)	24 (100)	11 (100)	—	_	_
Hepatitis B vacci- nation	92 (97.9)	24 (100)	10 (100)	_	_	_
Received all 4 vaccines (Ref: Re- ceived fewer than 4 vaccines) ^f	84 (89)	22 (84)	10 (80.3)	1.59 (0.48 - 5.22)	2.06 (0.45 - 9.28)	1.28 (0.23 - 7.15)
Early initiation of b	reastfeeding their infa	nt				
Within 1 hour of delivery (Ref: After 1 hour of delivery)	41 (47)	9 (42.1)	5 (56)	1.25 (0.47 - 3.29)	0.71 (0.18 - 2.79)	0.56 (0.11 - 2.85)
Intended length of b	reastfeeding					
Intend to breast- feed for >24 months (Ref:<24 months)	17 (19.8)	9 (37.6)	2 (14.9)	0.40 (0.15 - 1.13)	1.40 (0.25 - 7.86)	3.43 (0.50 - 23.4)
Mothers who have introduced complementary foods postinterven- tion	87 (92.6)	20 (95.3)	6 (52.2)	0.61 (0.06 - 5.50)	11.37 ^g (2.49 - 51.88)	18.37 ^b (1.48 - 228.20)

^aOR: odds ratio.

^bThese values were statistically significant (*P*<.05).

^cBCG: Bacillus Calmette-Guérin.

^dDPT: diphtheria, pertussis, and tetanus.

^eNot applicable.

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^fVaccines include BCG, polio, DPT, and hepatitis B.

^gThis value was statistically significant (*P*<.001).

Breastfeeding and Complementary Food Introduction

Initiation of breastfeeding within the first hour after birth was low across all arms (Table 4). The intention to breastfeed for

more than 24 months was highest in the asynchronous arm at 37.6%, followed by 19.8% in the synchronous arm and 14.9% in the control arm. No differences in breastfeeding initiation or intention were noted in the postintervention between-arms

comparison. A greater proportion of participants in the synchronous arm (92.6%) and the asynchronous arm (95.3%) had introduced complementary foods by 6 months postnatal, compared to the control arm (52.2%).

Discussion

Principal Findings

Our pilot study on the preliminary effectiveness of the *MeSSSSage* mHealth education and virtual social support intervention found that synchronous arm assignment had a beneficial impact on participants' knowledge regarding infant danger signs and odds of obtaining an infant health checkup from a clinical provider when compared to control participants. We also noted no differences by arm in maternal knowledge of appropriate infant and young child feeding practices, number of infant health checkups, and early initiation of breastfeeding. Given the pilot nature of this investigation, including our study design limitations, in conjunction with our previously reported results supporting intervention feasibility and acceptability [51], these findings support continued investigation into the effectiveness of mHealth-based interventions targeting postnatal maternal and newborn health using robust research designs.

Our findings that the MeSSSSage's synchronous arm that included group calls on education and social support increased maternal knowledge of infant danger signs are consistent with existing literature. Previous literature has demonstrated the effectiveness of mHealth interventions in empowering mothers to recognize infant danger signs [28], while interventions layering health education within women's self-help groups have shown promise in improving maternal knowledge across a range of outcomes [55,56]. Group-based mHealth education and social support interventions can promote health-seeking behaviors through the mechanism of "positive psychological support" among mothers [57]. On the other hand, we found less improvement in participants assigned to asynchronous modes of mHealth intervention, potentially due to unidirectional messaging and lack of social support. Our findings underscore the potential for integrating mHealth delivery into comprehensive interventions that combine both social support and health education, thereby enhancing their impact and effectiveness.

Our study findings noted no difference between pre- and postintervention on maternal knowledge of appropriate infant and young child feeding practices, though scores were high (7 out of 9) at preintervention. It is possible that high baseline levels of maternal knowledge precluded changes over time. A similar lack of effect was also noted in another Indian evaluation of an mHealth intervention for maternal knowledge of infant and child feeding practices [39] and other global studies [37]. Moreover, large-scale evaluations of mHealth interventions in India have failed to observe changes in infant and young child feeding practices [38,39]. Nonetheless, insights from another evaluation in India, including those using innovative approaches like audiovisual tools and interactive messaging, highlight the potential for future mHealth interventions to effectively impact maternal knowledge and practices concerning infant and young child feeding [58].

The synchronous arm of our mHealth intervention demonstrated the greatest impact, particularly in improving infant health checkups by clinical providers. In contrast, our asynchronous intervention arm, comprising solely audio educational messages, showed lower effectiveness. This could be attributed to various factors such as missed calls, insufficient attention to messages, or competing household obligations, resulting in null results for the intervention. Additionally, the absence of impact from the asynchronous modality may also be attributed to instances where participants' phones were with their husbands during the day, rendering it impossible for them to listen to the IVR messages. Similar challenges were encountered in a study conducted in Punjab, North India, where participants faced connectivity issues and missed messages due to household chores or not having access to their shared phone at the time [50,59]. To address these challenges, future research should identify the optimal timing for sending messages and IVR calls, and devise strategies to enhance engagement and participation in mHealth interventions, such as exploring incentives such as discounted call rates to motivate participants to carefully listen to all messages, as suggested in a study conducted in Afghanistan [60]. Given these challenges, combined effectiveness and implementation designs for mHealth research are likely to be more informative, particularly those that engage qualitative research methods.

The primary objective of our overall study was to assess the feasibility and acceptability of the intervention rather than robustly evaluating its effectiveness; thus, the preliminary effectiveness analysis reported here represents a secondary objective of the study, and the interpretation of these findings should consider the study's limitations. The sample size was determined for our feasibility and acceptability outcomes, resulting in significant differences in sociodemographic characteristics between the 3 intervention groups at baseline. While weighting techniques were used to address this imbalance, more robust experimental designs with a larger sample size will allow for a better assessment of effectiveness and potential mechanisms of impact. We also noted differential retention across the study by intervention group, which may have influenced our findings. Furthermore, our study design also limited our ability to assess whether intervention effectiveness differed by sociodemographic characteristics, and considering the important influence of social and structural factors on women of reproductive age and their influence on perinatal health, future research should focus on understanding the potential of interventions to specifically mitigate health disparities.

Conclusion

The postnatal period presents a critical opportunity to engage new mothers in enhancing their knowledge and practices concerning infant and young child feeding, infant health checkups and care-seeking behaviors, child vaccinations, and providing social support. Our pilot study on the *MeSSSSage* mHealth education and virtual social support intervention delivered mostly in the postnatal period yielded modest results and offered promising insights into its preliminary effectiveness. Such interventions, integrating mHealth-based education and communication with social support, hold significant promise but warrant further exploration to optimize their impact. With

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smartphones and social media platforms like WhatsApp increasingly prevalent even in low-resource settings, there is an urgent need for more rigorous experimental research to comprehensively evaluate the impact of mHealth interventions and their underlying mechanisms. Our team is currently conducting a fully powered randomized controlled trial to examine the effectiveness and potential mechanisms of impact of an mHealth educational and social support intervention for perinatal women across multiple sites in India, with results expected in the coming years.

Conflicts of Interest

None declared.

Multimedia Appendix 1 Model output for the analyses. [DOCX File, 41 KB - pediatrics v8i1e65581 app1.docx]

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Abbreviations

ASHA: Accredited Social Health Activist BCG: Bacillus Calmette-Guérin COM-B: Capability, Opportunity, and Motivation Behavior DPT: diphtheria, pertussis, and tetanus IVR: interactive voice response LMIC: low- and middle-income country *MeSSSSage: Maa Shishu Swasthya Sahayak Samooh* (which means maternal and child health support group) mHealth: mobile health OR: odds ratio REDCap: Research Electronic Data Capture

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

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Abstract

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

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

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

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

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

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KEYWORDS

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

Introduction

The assessment of fetal birth weight for the purpose of fetal growth monitoring is essential in contemporary prenatal care, as anomalies in growth are linked with negative consequences for both the mother and the fetus [1,2]. For instance, the birth of a macrosomic fetus is associated to unfavorable delivery outcomes (operative vaginal, caesarean delivery, or shoulder dystocia), trauma (maternal severe birth canal laceration and postpartum hemorrhage, fetal clavicular fracture, brachial plexus injury, neonatal hypoglycemia, and birth asphyxia) [3]. Infants

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with low birth weight may present a greater risk of acute or chronic hypoxia, acidemia, fetal demise, neonatal death, neonatal morbidity, and abnormal neurodevelopmental outcome, which are more likely to be admitted to a neonatal intensive care unit (NICU) and to have lifelong illnesses [4]. Consequently, precise fetal birthweight prediction helps clinical decision-making, such as appropriate prenatal treatments and acceptable mode of delivery selection, which might assist to enhance pregnancy outcomes [5].

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

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

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

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

Methods

Study Design

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

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

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



Study Population and Data Source

International Peace Maternity and Child Health Hospital (IPMCH), a tertiary first-class hospital in China, is the source of the data. The following were the criteria for inclusion: (1) gestational weeks of less than 28, (2) a singleton pregnancy, and (3) a normal pregnancy outcome (no or severe fetal malformations, stillbirths, or neonatal deaths). We searched for predictors of fetal birth weight that were repeatedly reported in studies or systematic reviews, can be easily ascertained in

different settings with various clinical experiences, and are part of the routine examination during pregnancy. It includes samples of 18,837 pregnant women who gave birth between January 1, 2018 and December 31, 2019, including parental demographics, clinical characteristics, ultrasound information, and laboratory tests. Concerning the height and weight of the husband were oral reported by pregnant women, both the reliability and filling rate were extremely low, so we only included the age and education level information of the husband. A total of 59 characteristics, was shown in Table S2 in Multimedia Appendix

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

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

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

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

Model Training and Validation

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

Statistical Analyses

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

Ethical Considerations

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

Results

Sample Size and Clinical Features

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

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



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





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

Characteristics		Train set (N=13,324)	Test set (N=3331)	<i>P</i> value		
Fetal birth weight categories, n (%)						
	Low birth weight	238 (1.79)	64 (1.92)	.24		
	Normal weight	12304 (92.34)	3071 (92.2)	.24		
	Macrosomia	782 (5.87)	196 (5.88)	.98		
Sociodemographic characte	eristics, mean (SD)					
	Preg_Days ^a	274.5 (8.1)	274.7 (8)	.82		
	Gravida	1.9 (1.1)	1.9 (1.1)	.98		
	Parity	1.3 (0.5)	1.3 (0.5)	≥.99		
	pre_weight ^b	55.8 (7.9)	55.9 (8.2)	.98		
	maternal_weight_last ^c	70.5 (9)	70.6 (9.1)	.99		
	GA_last ^d	269.8 (8.9)	270 (9)	.68		
	GWG ^e	14.7 (4.5)	14.7 (4.5)	.72		
	height	161.9 (5)	161.9 (5)	.91		
	pre_BMI ^f	21.3 (2.8)	21.3 (2.8)	.75		
	SBP_first	111.3 (12.5)	111.2 (12.5)	.84		
	DBP_first	69.4 (9.8)	69.4 (9.6)	.85		
	GDM ^g	0.1 (0.3)	0.2 (0.4)	.7		
	HDP ^h	0.1 (0.2)	0.1 (0.2)	≥.99		
Ultrasound measurements, mean (SD)						
	BPD ⁱ	92.9 (4.1)	93 (4.1)	.47		
	HC ^j	317.9 (13.2)	318.3 (13.4)	.34		
	FL ^k	68.2 (3.3)	68.3 (3.3)	.36		
	HL ¹	59.8 (3.2)	59.9 (3.3)	.07		
	AC ^m	315.9 (20.2)	316.8 (19.8)	.16		
	TTD ⁿ	99.8 (7.2)	100.2 (7.1)	.06		
	APTD ⁰	101.7 (7.4)	101.9 (7.5)	.42		
	days_last_ul_to_delivery ^p	11.4 (8.8)	11.1 (8.6)	.22		
	AFI ^q	126.3 (31.5)	125.6 (30.9)	.2		
Laboratory indices, mean (SD)					
	FPG ^r	4.2 (0.4)	4.2 (0.4)	.87		
	GLU-1H ⁸	7.8 (1.5)	7.8 (1.6)	.32		
	GLU-2H ^t	6.6 (1.4)	6.6 (1.4)	.73		
	HBA _{1C}	5 (0.3)	5 (0.3)	.98		
	HDL ^u	2 (0.4)	1.9 (0.4)	.29		
	LDL ^V	2.5 (0.7)	2.6 (0.7)	.61		
	TG ^w	1.4 (0.5)	1.4 (0.5)	.51		
	TC ^x	4.5 (0.7)	4.5 (0.7)	.67		

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Characteristics	Train set (N=13,324)	Test set (N=3331)	P value	
HGB ^y	118.7 (11.4)	118.8 (11.6)	.67	
^a Gestational age.				
^b Prepregnancy weight.				
^c Maternal weight at the last antenatal examination	l.			
^d Gestational age at the last antenatal examination.				
^e GWG: gestational weight gain.				
^f Prepregnancy body mass index.				
^g GDM: gestational diabetes mellitus.				
^h HDP: hypertensive disorders of pregnancy.				
ⁱ BPD: biparietal diameter.				
^j HC:head circumference.				
^k FL: femur length.				
^l HL: humerus length.				
^m AC: abdominal circumference.				
ⁿ TTD: transverse trunk diameter.				
^o ATD: anteroposterior trunk diameter.				
^p The number of days from the last antenatal ultras	sound measurement to delivery.			
^q Sum of Amniotic Fluid Indices.				
^r Fasting plasma glucose.				
^s 1-hour glucose.				
^t 2-hour glucose.				
^u HDL: high-density lipoprotein.				
^v LDL: low-density lipoprotein.				
^w TG: triglycerides.				
^x TC: total cholesterol.				
^y HGB: hemoglobin				
Variable Sotting	implem	entation. A total of 17 va	ariables were sele	ected into ou

Variable Setting

Table S2 (Multimedia Appendix 1) displays 59 alternative variables, including sociodemographic characteristics, ultrasound measurements, and laboratory indices. In order to facilitate fetal birthweight prediction in the real world, a number of feature selection models were used to evaluate feature significance, as depicted in Figure 3. Due to the significance of features and the difficulty of obtaining them in the real world, few variables were eliminated before engineering

implementation. A total of 17 variables were selected into our "few feather model," including "Parity," "pre_weight," "maternal_weight_last," "days_last_ul_to_delivery," "BMI," "GWG," "GA," "GWG_Inspect_Preg_Days," "GDM," "BPD," "HC," "FL," "HL," "AC," "TTD," "APTD," and "AFI" (Table 2). Those variables can be verbally responded to by pregnant women or extracted through an ultrasound report, instead of the blood test report requiring careful checking, which is convenient for clinical use and saves time.



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Figure 3. Feature importance on different models.





	Table .	Meaning	and va	lue range	of 17	features
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Variable	Variable meaning	Minimum	Maximum	Unit
Preg_Days	Gestational age	239	295	days
Parity	Parity	1	4	a
pre_weight	Prepregnancy weight	40	125	kg
maternal_weight_last	Maternal weight at the last antenatal examination	43.6	129.3	kg
GA_last	Gestational age at the last antenatal examination	86	290	days
GWG	Gestational weight gain	-45.4	45.2	kg
pre_BMI	Prepregnancy body mass in- dex	14.5	39.6	kg/m ²
GDM	Gestational diabetes mellitus	0	1	_
BPD	Biparietal diameter	53	109	mm
HC	Head circumference	197	367	mm
FL	Femur length	37	78	mm
HL	Humerus length	4	71	mm
AC	Abdominal circumference	158	381	mm
TTD	Transverse trunk diameter	45	130	mm
APTD	Anteroposterior trunk diam- eter	55	128	mm
days_last_ul_to_delivery	The number of days from the last antenatal ultrasound measurement to delivery	0	113	days
AFI	Sum of Amniotic Fluid In- dices	12	333	mm

^aNot available.

The Development and Performance of Prediction Model

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



Table . Evaluation on different models based on 17 features.

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

^aRE: relative error.

^bAE: absolute error.

^cMSE: mean squared error.

^dRMSE: root mean squared error.

^eMAE: mean absolute error.

^fXGBoost: extreme gradient boosting.

^gSVM: support vector machine.

^hKNN: k-nearest neighbor.

ⁱMLP: Multilayer Perceptron.

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

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

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

Discussion

Principal Findings

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

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

In this study, data on pregnant women, including outpatient prenatal visits and hospital deliveries, was subjected to necessary feature processing and imbalanced data handling. A total of 5 ML methods were used as basic models for modeling through ensemble learning, which effectively balances the prediction effects of all models on fetuses in different weight ranges, achieving promising performance in predicting the different birth weights of newborns (low weight infants, normal weight infants, and macrosomia infants). The defining characteristic of ensemble learning is "Learn from the best." First, it prevents underfitting by combining all the weaker learners and obtaining

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superior models through collective intelligence (in this case, like expert consultation, more complex learning models are obtained from advice from experts in different fields). Second, the integrated model prevents over-fitting: by combining all the results, it is simple to develop a more moderate model, thus avoiding some extreme case. Although it is not the best in all weight estimation ranges, the overall effect is the best, reducing the likelihood of large errors in a particular weight range.

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

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

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

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

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

Limitations

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

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

Conclusions

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

Acknowledgments

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Data Availability

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

Authors' Contributions

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

Conflicts of Interest

None declared.

Multimedia Appendix 1 Supplementary material. [DOCX File, 722 KB - pediatrics v8i1e59377 app1.docx]

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Abbreviations

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

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

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An Online Family Literacy and Wellness Program for Latino Dual Language Learners: Pilot Randomized Waitlist Controlled Trial

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Abstract

Background: Early childhood interventions can simultaneously promote positive health and early language experiences, but implementation and health equity often receive insufficient attention during the development process.

Objective: We apply a health equity lens to refine and pilot-test a family literacy and wellness program designed for Latino dual language learners (DLLs) entering kindergarten and their caregivers.

Methods: In collaboration with a parent and community advisory board, we refined an 8-week family literacy and wellness program and conducted a pilot randomized controlled trial (RCT) with a waitlist control. The program, specifically designed by our interprofessional team for Latino DLLs, uses health topics (ie, nutrition, physical activity, sleep, and social-emotional development) to (1) introduce foundational language and literacy skills to children; (2) empower families to engage in health and home literacy activities using a strengths-based approach; and (3) encourage maintenance of families' home language. We assessed reach by collecting sociodemographic information; attendance and acceptability using a parent survey; and preliminary effects on home literacy activities through a validated parent-report instrument (StimQ₂ quantity, quality, content, and concepts subdomains) and on child literacy skills using investigator-developed assessments. We analyzed quantitative data using descriptive statistics and regression analyses.

Results: Parents and community advisors informed the program content. A total of 32 parent-child dyads were enrolled in the pilot RCT. All parents identified as Latino, and half had not completed high school, indicating that we reached the intended audience. Parents rated the program as highly acceptable, and 23 (72%) participants attended at least half of the sessions. After participation, group 1 had higher StimQ₂ quality scores (effect size 0.99, P=.02) and higher quantity scores (effect size 1.01, P=.04) compared with group 2.

Conclusions: Similar interprofessional collaborations may be a promising strategy to promote equity in early language experiences for Latino DLLs and their families.

Trial Registration: ClinicalTrials.gov NCT05339464; https://clinicaltrials.gov/ct2/show/NCT05339464

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KEYWORDS

pediatrics; children; family; English as a second language; ESL; child development; development; wellness; health equity; dual language learner; literacy; language; Latinos; Spanish; Hispanic; randomized; controlled trials

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Introduction

Education is critically important for health and well-being, yet this social driver of health has received insufficient attention in health care settings [1]. Kindergarten performance is a strong predictor of health risk behaviors and indicators of well-being, such as college education [2-4]. As a result, existing inequities in kindergarten readiness [5,6] pose a threat to long-term health and well-being at both individual and population levels.

The US Department of Health and Human Services and the US Department of Education define dual language learners (DLLs) as children with a home language other than English who are learning 2 or more languages simultaneously or learning a second language while still developing their first language [7]. Latino DLLs are a rapidly growing segment of the population who face discrimination and unequal opportunities, predisposing them to poor educational, occupational, and health outcomes [8,9]. Sustainable interventions to support this population are therefore urgently needed.

Pediatric clinicians are in a unique position to implement early childhood interventions that promote optimal school readiness, given their near-universal access to young children, frequent contact with families, and opportunities to build and leverage strong parent-clinician relationships [10-12]. Several programs are designed to be embedded within early childhood settings to promote early language development among DLLs [13,14]. However, early childhood interventions can simultaneously promote both physical and academic school readiness. Interventions focused on family literacy offer a clear example. Family literacy can be defined as the way families use literacy in their homes and communities, including during typical routines [15-17]. Families already engage in a wide range of literacy activities that are present in many health-related routines (eg, reading food labels). Embedding these practices into family literacy programs may provide a more ecologically valid intervention-one rooted in existing rather than entirely new practices and one that embraces cultural diversity. Few early childhood interventions take advantage of these opportunities. One example is a program that uses culturally sensitive, typical family food routines to support children's language and literacy skills, such as vocabulary, decoding, and writing [18]. Programs can adopt this approach to engage families and build cross-sector partnerships between pediatric professionals and educators-partnerships that find synergy in their complementary expertise. Despite their potential to promote equity through family engagement, such cross-sector partnerships remain rare.

Implementation often receives insufficient attention early in the development of health promotion interventions. This is critical, as a limited understanding of community context and partner priorities can potentially diminish—or even eliminate—an intervention's impact [19]. Baumann and Cabassa [19] identified key elements that can support the integration of an equity lens early in implementation research, including a focus on reach from the outset and the intentional design of interventions with historically marginalized populations in mind. Partnered approaches from the earliest stages of intervention design and

refinement can help promote health equity, yet they remain rare. To our knowledge, few early childhood interventions have leveraged this strategy.

To address these gaps, we applied implementation science with a health equity lens to refine and pilot-test an online family literacy and wellness program designed for Latino DLLs entering kindergarten and their families. Using community-engaged research strategies, we partnered with parents to refine the program and subsequently conducted a pilot randomized controlled trial (RCT). Consistent with the approach proposed by Baumann and Cabassa [19], we intentionally focused on intervention reach, design, and equity-relevant implementation outcomes. These insights can inform similar cross-sector education-health care partnerships that aim to promote equity for Latino DLLs and their families.

Methods

Study Design and Registration

We conducted a pilot study using an RCT with a waitlist control design.

Ethical Considerations

The Rutgers Health Institutional Review Board approved this study (approval number Pro2021001575). All participants provided informed consent. Data were deidentified. Participants received a US \$25 retail gift card for each study visit completed. The study was registered before enrollment of the first participant at ClinicalTrials.gov (NCT05339464). We followed CONSORT (Consolidated Standards of Reporting Trials) guidelines for reporting clinical trials [20].

Study Population and Setting

We recruited Latino DLLs (aged 4 - 6 years) and their parents from Eric B. Chandler Health Center, a local Federally Qualified Health Center, and the surrounding greater New Brunswick area. Eric B. Chandler Health Center primarily serves Latino individuals from underresourced communities. Clinicians at the center referred potentially eligible participants to the study team. We also advertised the study with our local community partners using recruitment flyers and word of mouth. Eligibility criteria included primary caregivers aged ≥ 18 years (referred to as parents for the remainder of this article) of children entering kindergarten who identified as Latino, used Spanish at home, owned a cellphone, and were willing to receive SMS text messages and be randomized. We excluded children with multiple anomalies or genetic disorders, as well as those with previously identified developmental delays.

Program Refinement

We partnered with our parent advisory board through a series of community engagement studios that helped refine the program throughout the project [21]. The parent advisory board consists of parents who participated in past iterations of the family literacy and wellness program. All parents identify as Latino and prefer Spanish as their primary language for communication. Their children are in kindergarten, first grade, or second grade, providing a range of scholastic experiences and perspectives on their children's needs. We conducted 7

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community engagement studios with our parent advisory board from January 6, 2021, to January 30, 2023. We adapted the community engagement studio concept from the approach developed by the Meharry-Vanderbilt Community Engaged Research Core [21] to facilitate meaningful participation and engagement. Each studio focused on a specific aspect of the program. Bilingual team members presented relevant information about the program, and a bilingual research coordinator then facilitated dialogue to elicit parents' feedback on the content and procedures. Through this process, parent advisors provided substantive input on the program's mission, intervention content, and logistics. The project also includes a community advisory board composed of local community leaders, including educators, a pediatrician, a librarian, and a community health expert, that meets regularly to advise the team on outreach and engagement strategies, as well as program content.

Study Conditions

All parent-child dyads participated in the family literacy and wellness program, Ready and Healthy for Kindergarten. Parent-child dyads were enrolled and randomized 1:1 to either the first group (June-July) or the second group (July-August). The randomization schedule was computer generated by the study biostatistician (POS). Allocation concealment was maintained using the REDCap (Research Electronic Data Capture; Vanderbilt University) randomization module. Participants in both groups received a book bag with school supplies, an activity kit, and program books at enrollment. The program was specifically designed by our interdisciplinary team (ie, education, linguistics, and pediatrics) for Latino DLLs, using health topics (ie, nutrition, physical activity, sleep, and social-emotional development) to (1) introduce and reinforce foundational language and literacy skills to children, (2) empower families to engage in health and home literacy activities using a strengths-based approach, and (3) encourage the maintenance of families' home language and cultural traditions [22,23]. The program is designed to be strengths-based by building on families existing routines and inviting caregivers to incorporate new ones that support their goals and the objectives listed above. For example, during the nutrition topic, teachers may highlight how following a family recipe during meal preparation, whether written or recalled from memory, offers embedded opportunities for sequencing tasks, storytelling, and interaction. During the physical activity topic, teachers may point out how everyday simple family activities, such as walking to the bus stop, can include literacy-rich moments like reading street signs. Each session follows a predictable structure that draws out families' existing routines. Teachers use language flexibly and authentically, in alignment with the families' preferences, to tacitly normalize bilingualism and position home language maintenance as the standard, thereby empowering participation. In addition, the social-emotional unit includes a dedicated session focused on cultural pride, honoring one's heritage, and highlighting the advantages of multilingualism, explicitly encouraging the maintenance of the home language.

We first offered the program in person at Eric B. Chandler Health Center in 2019 [22]. This initial iteration established the program structure, which included (1) 8 parent-child workshops;

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(2) take-home kits, including a book bag with school supplies, activity kit, and program books, to support at-home extension activities that reinforced session content; and (3) reminder SMS text messages that reinforced in-class content [22]. In 2020, in response to the COVID-19 pandemic, the workshops shifted to an online format using videoconferencing software [23]. We retained the virtual format for the 8 parent-child workshops, which we then refined and pilot-tested in this study.

Data Collection

Trained bilingual research assistants collected data online via secure videoconference software at 3 time points: enrollment (study visit 1); approximately 2 months after enrollment, after group 1 completed the program and before group 2 began (study visit 2); and approximately 4 months after enrollment, after group 2 completed the program (study visit 3). Recruitment began in March 2024, the first study visit occurred on May 9, 2022, and the last study visit took place on September 25, 2022. In this paper, we focus on between-group differences in parent literacy and language activities and child outcomes at study visit 2, which captures the period after group 1 completed the program and before group 2 began.

Implementation Outcomes

Reach

As noted by Baumann and Cabassa [19], equity research requires attention to reach, that is, who is included in and participating in research. To assess whether the program reached its intended audience, we examined demographic characteristics of parent-child dyads, including ethnicity, parent education, and self-reported English proficiency.

Attendance

To understand the extent to which parents and children would use the program, we examined session attendance. A study team member documented attendance at each session.

Acceptability

Acceptability can be defined as users' perception of the extent to which a treatment or service is satisfactory [24]. In this study, we assessed acceptability using the Acceptability of Intervention Measure (AIM) [25], a validated 4-item survey that evaluates participants' perceptions of program acceptability.

Parenting and Child Outcomes

Parenting Outcomes

The StimQ₂ is a validated parent-report measure of the home cognitive environment, available in both English and Spanish [26]. In the validation sample, 93% of caregivers identified as Latino, 76% completed the surveys in Spanish, and 91% were classified as having low socioeconomic status based on the Hollingshead Four Factor Index. We used the StimQ₂ READ scale to explore the program's effects on parent-home literacy activities, focusing on subdomains that assess quantity, quality, content, and concepts. We used the StimQ₂ Parent Verbal Responsivity (PVR) scale to examine verbal responsivity during parent-child interactions. Both the READ and PVR subscales demonstrate good reliability (Cronbach α =0.753 and 0.790,

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respectively) and strong validity, as indicated by correlations with assessments of child language, cognitive ability, and social-emotional skills.

Child Outcomes

We used investigator-developed assessments to explore the program's effect on child outcomes. These assessments were administered by a bilingual research assistant in the child's preferred language. Here, we focus on tests of children's development in letter identification, letter sound identification, thematic vocabulary identification, and book awareness. To assess book awareness, children were asked to identify different print concepts (ie, front and back cover, title page) using a book of their choice. The examination of letter and sound identification involved an untimed task in which children were asked to identify 10 different letters (presented in upper and lower case) and to produce their corresponding sounds. Vocabulary identification, focusing on words discussed during the workshops, such as healthy habits, foods, and family routines, was assessed using a picture-based vocabulary recognition task.

Sample Size

In determining our sample size, we considered the main objective of this pilot study, to examine equity-relevant implementation outcomes such as reach, engagement, and acceptability, and to explore the program's preliminary effects on parenting and child outcomes in an exploratory manner. We also followed best practice recommendations [27,28]. Based on these factors, our goal was to randomize at least 24 participants (12 per arm). The recruitment response exceeded our expectations, and we enrolled more participants to avoid turning interested families away.

Data Analysis

We first calculated means and SDs or percentages for continuous variables to examine categorical reach using or sociodemographic data, engagement using attendance logs, and acceptability using AIM survey responses. Participants were analyzed according to the group to which they were originally randomized. Participants who discontinued or were lost to follow-up were excluded from analyses. We used regression models to explore between-group differences in home literacy activities measured by the StimQ₂ READ scale total score and its subdomains, quantity, quality, diversity of concepts, and diversity of content, as well as responsive verbal interactions assessed by the StimQ₂ PVR. In addition, child literacy skills

were evaluated using investigator-developed assessments focused on letter identification, letter-sound knowledge, vocabulary, and book awareness. We adjusted for the following important a priori–identified covariates: baseline scores, child age, child language, and parent education. To enable comparison across outcomes, we calculated effect size estimates by dividing the treatment coefficient from the regression models by the residual SD of each outcome.

Results

Program Refinement

The parent advisory board helped shape the program's logistics and content. Drawing on their experience with the program, parents provided specific feedback that guided decisions about session length, program duration, and optimal dates and times for the online sessions. Synthesizing this feedback, we kept sessions under 1 hour, offered multiple evening options on weekdays, and scheduled Saturday sessions in the late morning or around noon. Parents also provided guidance and feedback on recruitment strategies and materials, which helped enhance reach. During meetings, they also offered input that informed adjustments to instructional pace, use of materials, and routines for parent-child interactions. Key considerations were whether the materials were easy to read and use at home. For example, children enjoyed opportunities to draw pictures starting with the session's focus letter, and parents shared that their children liked cutting out cards to practice letter sounds. As a result, we adapted the session content and at-home activity kits to include more opportunities for these activities. Families found the at-home extension activities enjoyable and identified them as a strength. Parents also reported that the school supplies sent home in the backpack were useful for their home learning environment.

Pilot Study

A total of 54 parent-child dyads initially expressed interest in participating; however, 5 of these dyads did not meet the inclusion criteria, 6 were lost to contact, and 9 declined participation. The most common reason for declining was lack of interest. Ultimately, we randomized 34 parent-child dyads (Figure 1). Two parent-child dyads were later excluded for not meeting eligibility criteria, resulting in a final enrolled sample of 32 dyads. Among these, 3 parent-child dyad groups were lost to follow-up, and 1 dyad discontinued participation, leaving 13 dyads in group 1, and 15 dyads in group 2.



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



Reach

Demographic characteristics are summarized in Table 1. All participants identified as Latino (N=32), with 16 of 32 (50%) reporting Mexican origin; 29 out of 32 (91%) reported speaking

English less than very well, and 17 (53%) had not completed high school. At enrollment, children were on average 4.5 years old, and 20 (63%) were identified as native-like Spanish speakers. These characteristics suggest that the program reached the intended audience.
Table . Demographic information of study participants at enrollment.

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	Total (n=32)	Group 1 (n=15)	Group 2 (n=17)				
Child age (years), mean (SD)	4.5 (0.5)	4.6 (0.5)	4.5 (0.5)				
Child sex, n (%)							
Male	17 (53)	7 (47)	10 (59)				
Female	15 (47)	8 (53)	7 (41)				
Child's ability to speak Spanish, n (%)						
Speaks like a native speaker	20 (63)	7 (47)	13 (76)				
Almost like a native speaker	6 (19)	4 (27)	2 (12)				
Difficulty speaking it	5 (16)	3 (20)	2 (12)				
Barely speaks it	1 (3)	1 (7)	0 (0)				
Child's ability to understand Spanish	h, n (%)						
Understands it like a native speaker	22 (69)	9 (60)	13 (76)				
Understands it for the most part	5 (16)	3 (20)	2 (12)				
Difficulty understanding it	3 (9)	2 (13)	1 (6)				
Barely understands it	2 (6)	1 (7)	1 (6)				
Preschool attendance, n (%)							
Beginning at age 3	19 (59)	10 (67)	9 (53)				
Beginning at age 4	9 (28)	4 (27)	5 (29)				
Never attended	4 (13)	1 (7)	3 (18)				
Parent's age (years), n (%)							
21-25	5 (16)	3 (20)	2 (12)				
26-30	5 (16)	2 (13)	3 (18)				
31-40	22 (69)	10 (67)	12 (71)				
Parent's country of birth, n (%)							
Mexico	16 (50)	7 (47)	9 (53)				
Honduras	5 (16)	3 (20)	2 (12)				
Other	9 (28)	3 (20)	6 (35)				
United States	2 (6)	2 (13)	0 (0)				
Parent-reported English proficiency	^a , n (%)						
Very well	3 (9)	2 (13)	1 (6)				
Well	5 (16)	2 (13)	3 (18)				
Not well	12 (38)	7 (47)	5 (29)				
Not at all	12 (38)	4 (27)	8 (47)				
Parent's highest level of education, a	n (%)						
Less than eighth grade	7 (22)	3 (20)	4 (24)				
Ninth to twelfth grade (no diplo- ma)	10 (31)	2 (13)	8 (47)				
High school diploma or greater	15 (47)	10 (67)	5 (29)				

^aParents' response to "How well do you speak English?"

Attendance

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Program attendance is summarized in Table 2. Seventy-two percent of parents (23/32) attended at least half of the sessions.

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Timing appeared to influence attendance, with lower participation observed in the second half of the summer. Some families reported traveling internationally or taking on additional

seasonal work during this period, which may have impacted their ability to attend.

Table .	Number of	workshops a	attended by	participants	during the	family	literacy an	d wellness	program	(n=32	:)
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Number of sessions attended	Number of participants
0	4
1	1
2	2
3	2
4	3
5	2
6	5
7	5
8	8

Acceptability

On average, parents agreed that the program met their approval, it was appealing, they liked the program, and they welcomed what they learned (Table 3).

Table .	Acceptability of interv	ention survey among	the study population	(n=25 parents).
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AIM ^a question	AIM score, mean (SD); range ^b
The program met my approval.	3.5 (0.5); 3-4
The program was appealing to me.	3.5 (0.5); 3-4
I liked the program.	3.5 (0.5); 3-4
I welcome what I learned in the program.	3.5 (0.5); 3-4

^aAIM: Acceptability of Intervention Measure.

^b0=completely disagree, 1=disagree, 2=neither agree nor disagree, 3=agree, and 4=completely agree.

Parenting Outcomes

Results of the Stim Q_2 READ and PVR scales are presented in Table 4. Although not statistically significant, there was a moderate difference on the total Stim Q_2 READ scale between group 1 (ie, those who completed the program) and group 2 (ie,

those who had not yet begun; Cohen d=0.55; P=.23). However, there were large and statistically significant differences between the groups on the quantity and quality subdomains (Cohen d=1.01; P=.04 and Cohen d=0.99; P=.02). By contrast, the between-group difference on the PVR scale was small and not statistically significant (P=.75).

Table. Effects of Ready and Healthy for Kindergarten participation (group 1) compared with waitlist control (group 2) on the Home Literacy Environment and Parent Verbal Responsivity scale scores.^a

Measures	Group 1, effect size estimate (95% CI)	P value
StimQ ₂ READ scale ^b		
Total score	0.55 (-0.44 to 1.10)	.23
Subdimensions		
Book reading quantity	1.01 (0.05 to 1.52)	.04
Book reading concepts	-0.20 (-1.41 to 0.52)	.66
Book reading content	0.02 (-1.09 to 0.68)	.95
Book reading quality	0.99 (0.18 to 1.41)	.02
StimQ ₂ Parent Verbal Responsivity Scale ^b	0.14 (-0.92 to 0.76)	.75

^aLinear regression analyses were conducted, adjusting for baseline scores, child age, child language, and parent education. Effect size estimates were calculated by dividing the treatment coefficient from the regression models by the residual SD of each outcome.

^bSubscale of the StimQ₂-Preschool, a parent-report questionnaire that assesses the cognitive home environment for children aged 36-72 months.

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Child Outcomes

Child outcomes are summarized in Table 5. Between-group differences in letter identification, letter-sound knowledge, and

vocabulary were either minimal or in an unexpected direction. However, a moderate-to-large effect, though not statistically significant, was observed for book awareness (Cohen d=0.82; P=.11).

Table .	Effects of Ready	and Healthy	for Kindergarten	participation	(group 1)) compared with	h waitlist control (group 2) on child skills	.a
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	Group 1, effect size estimate (95% CI)	<i>P</i> value
Letters identified	0.07 (-1.07 to 0.71)	.88
Letters sounds identified	-0.03 (-1.18 to 0.64)	.95
Vocabulary words identified	-1.68 (-5.84 to 0.21)	.10
Book awareness	0.82 (-0.23 to 1.35)	.11

^aLinear regression analyses were conducted, adjusting for baseline scores, child age, child language, and parent education. Effect size estimates were calculated by dividing the treatment coefficient from the regression models by the residual SD of each outcome.

Discussion

Principal Findings

In this study, we refined an online family literacy and wellness program using parent feedback. During pilot testing, we found that the program effectively reached and engaged Latino DLLs and their families. We also observed promising improvements in parent home literacy activities after participation. The intentional involvement of families and community partners throughout the research process, along with a deliberate focus on reach and other early implementation outcomes, provided valuable insights into applying a health equity lens to early childhood interventions. These findings offer guidance for interdisciplinary teams aiming to build cross-sector collaborations and move beyond siloed efforts in the pursuit of equity.

The US Centers for Disease Control and Prevention defines health equity as "the state in which everyone has a fair and just opportunity to attain their highest level of health" [29]. The Robert Wood Johnson Foundation elaborates that achieving health equity "requires removing obstacles to health such as poverty, discrimination, and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and health care" [30]. Such obstacles drive health inequities, and health care organizations have developed programs in response to growing evidence that social needs impact health [31]. However, health care interventions have largely missed the opportunity to address educational achievement, an important social driver of health that underlies both social and health outcomes [32]. As a cross-sector partnership between health and education, Ready and Healthy for Kindergarten aims to promote health equity by coaching families on how to implement healthy routines early, while supporting children's development of literacy and numeracy skills that foster health literacy and wellness throughout their life course.

All caregivers in our sample identified as Latino, and half had not completed high school, indicating that the program successfully reached the intended audience. The family literacy and wellness program was designed to address the specific needs of this population, with careful consideration of their linguistic and ethnic backgrounds. Central to this approach, our program

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XSL•F() RenderX is bilingual, supporting children's language development while honoring and accommodating parents' linguistic preferences. The focus on families from Latino backgrounds encompassed not only the language of implementation but also the cultural aspects embedded in the program. Meta-analyses support that family literacy programs increase parent literacy activities and improve child emergent literacy [33,34]. However, low participation and engagement among Latino parents from underresourced communities have been major weaknesses of these programs [35]. There are important modifiable program design weaknesses [18]. First, similar programs have been criticized for taking a deficit approach and imposing dominant cultural activities on families without building on their unique strengths [35,36]. Such approaches do not take into account parents' experiences with activities such as reading, which may be negative [37]. Second, while bilingual programs are emerging, most do not build on families' heritage language, which is a major issue [38-41]. Third, there is a paucity of studies focused on engagement with Latino families from underresourced communities [18]. By engaging parents as partners throughout the research process and refining the program based on their feedback, we were able to overcome many of these barriers and reach the intended audience with high attendance levels.

Consistent with previous work, we found that the online family literacy and wellness program was well attended and highly acceptable to families [22,23]. This study extends our prior work by demonstrating promising patterns in both the quantity and quality of home literacy activities. Although we did not identify differences in letter identification, letter-sound knowledge, and vocabulary, it is possible that 8 weeks is not sufficient time to detect these differences. Although not statistically significant, the moderate to large effect on book awareness aligns with the enhanced quantity and quality of home literacy activities. One possibility is that by increasing parent literacy activities during the summer before kindergarten, improvements in child outcomes may be observed later. Future studies will need to follow children for a longer period to test this hypothesis-an issue we are currently addressing in our ongoing work.

This work is subject to certain limitations. First, while pervasive inequities in school readiness and wellness provide a strong rationale for focusing on Latino DLLs and their families, our

findings may not generalize to all settings or other populations. Future work is needed to tailor program content for participants from different racial and ethnic backgrounds. Second, as this was a pilot study, the primary focus was on examining equity-focused implementation outcomes including reach, attendance, and acceptability. While a sample size of 32 aligns with recommendations for pilot studies [27,28], it is possible that the statistical analyses did not have adequate power to detect differences in parent and child outcomes that may be meaningful. Further, we were unable to examine a threshold for the dose of the intervention necessary to affect outcomes; we are addressing this limitation in our ongoing work. Third, we relied on parent-report measures for home literacy activities and health routines, which may be subject to recall bias and social desirability. Future work should incorporate observational measures to help address this limitation. Fourth, engagement with an intervention goes beyond usage and must capture the relationship between the program and the intended goal of the intervention [42], in this case empowering caregivers to build on their existing strengths and support their children's physical health and school readiness. While this was beyond the scope of this pilot study, we plan to address it in future work.

Conclusion

We found that a family literacy and wellness program designed for Latino DLLs reached the intended audience, achieved strong attendance, and showed promising patterns in home literacy activities. While additional work is needed to definitively test the program's effects and identify optimal implementation strategies, these findings suggest that such interdisciplinary collaborations could be a promising approach to promote equity in children's early language experiences.

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Conflicts of Interest

None declared.

Checklist 1 CONSORT-EHEALTH checklist. [PDF File, 453 KB - pediatrics_v8i1e60764_app1.pdf]

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Abbreviations

AIM: Acceptability of Intervention Measure CONSORT: Consolidated Standards of Reporting Trials DLL: dual language learner PVR: Parent Verbal Responsivity RCT: randomized controlled trial REDCap: Research Electronic Data Capture

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A Low-Cost, Social Media–Supported Intervention for Caregivers to Enhance Toddlers' Language Learning: Mixed Methods Feasibility and Acceptability Study

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Abstract

Background: Widely accessible, cost-effective early language development interventions for caregivers of young children are needed to promote optimal outcomes in children in the United States. Social media short-form videos, such as those on TikTok, may be a natural fit for delivering this type of intervention.

Objective: This study aims to examine the feasibility and acceptability of a low-intensity, short-term social media intervention for caregivers of young toddlers.

Methods: In total, 25 caregivers of children aged between 12 and 18 months participated in this study. We shared 32 short-form videos via TikTok over an 8-week period to help increase caregivers' knowledge about early childhood communication. We examined metrics to characterize participant engagement, explored measures of changes in caregivers' knowledge, and conducted a qualitative analysis of caregiver interviews after the intervention.

Results: Results indicated that most caregivers were able to consistently view the videos, with approximately 75% (16/21) viewership per video (mean 15.75 likes out of 21 possible likes), and caregivers reported positive effects of the intervention on their knowledge of how to support their child's communication. The results of the exploratory measure of change in caregiver knowledge were positive but not statistically significant (t_{21} =-1.357; *P*=.09). Caregivers offered suggestions for content and enhancements to videos for future investigations.

Conclusions: Low-cost, short-term social media interventions could be an effective means to equip caregivers with the information they need to advance their children's language abilities, particularly for families from lower-income backgrounds whose access to health information about their young children may be limited.

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KEYWORDS

social media; language development; toddler; infant; infancy; pediatric; language learning; feasibility; acceptability; caregiver; TikTok; mixed methods; short video; qualitative analysis; child support; health information

Introduction

Background

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Infants undergo multiple developmental transitions that change the way they engage with the world around twelve months of

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age. Most infants take their first steps to become new walkers, become more consistent and advanced gesture users, and make the transition to symbolic language as they say their first words [1]. In the months that follow, variability in children's expressive vocabulary appears as some children learn words quickly, while others learn words more slowly [2]. Because children's language

outcomes are directly linked to their academic, social-emotional success, and mental health, promoting optimal language learning is a critical public health issue [3]. Efforts to bolster early language learning by supporting caregiver-child interactions, especially in lower-income communities, are key to promoting school readiness, social and emotional learning, and optimal language outcomes in all children [4].

However, more research is needed on effective interventions for caregivers and children at the population level to promote optimal child language outcomes while providing targeted support for children in greater need of intervention [3]. Investments in population-wide, universal interventions may bolster child outcomes by increasing caregiver knowledge and confidence in supporting their infant's early learning. Unlike more intensive coaching approaches that are often geared toward lower-income families, widely accessible interventions may also avoid stigmatizing families who are often the recipients of preventive interventions [5]. In this feasibility and acceptability study, we describe the development and the use of a cost-effective, media-supported approach to sharing information and strategies with caregivers to support language learning in toddlers aged between 12 and 18 months, a critical developmental inflection point. The BabyTok Project is designed as a light touch social media-supported intervention to increase caregivers' knowledge about early language learning and how they may promote it with the use of specific strategies.

Factors That Support Early Language Development

Caregiver-child interactions in the first few years of life are influenced by a family's culture [6] and what caregivers know and believe about children's language and cognitive development [7]. Caregivers who believe that children's language learning begins early and is dependent on the input from adults around them are more likely to engage their children in back-and-forth exchanges [7]. For their part, children also influence caregiver-child interactions through their own initiations and contributions during exchanges through vocalizations, gestures, gaze, and early word use [8].

While it is well established that sufficient language input is related to infants' early language learning [9], other characteristics of caregiver-child interactions contribute to meaningful moments of early word learning. For instance, the degree to which caregivers and children engage as conversational partners during back-and-forth turn-taking exchanges relates to children's later language outcomes as well as their neuroanatomy and physiology [10,11]. Caregiver input that is timely, contingent, and functional within the immediate contexts of everyday life also helps to facilitate early language learning [12]. During infancy and the early toddler years, linguistic features such as caregivers' use of parentese (marked by more exaggerated intonational patterns and repetition of words and phrases), gestural input [13], and touch cues also support early language learning in the first 2 years of life [14]. While some caregivers may know that these strategies support their child's ability to talk, others may not, particularly if they are first-time caregivers who do not have extensive experience interacting with infants and toddlers or if they do not have access to information about how children learn [7,15].

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Interventions to Increase Caregivers' Knowledge About Early Language Learning

Several interventions that center on infants, toddlers, and caregivers demonstrate promise in supporting child language learning, particularly in communities experiencing poverty. For example, the "3Ts" home visiting curriculum [7] and another model named Duet [16] use home visiting models to enhance caregivers' knowledge and responsive interactions with toddlers. However, limitations of such approaches relate to scalability and cost. Training and employing home visitors for more time-intensive models limit the ability of programs to offer support for every child and family who qualifies. This does not mean that more intensive programs are not worth the investments they require; rather, additional approaches are needed at the population level to support widespread access to developmental information that may influence caregiver-child interactions.

Several mobile health interventions aimed at caregivers of very young children have shown evidence of effectiveness in increasing caregiver knowledge [17,18]. For example, an intervention called Sharing Stories used WhatsApp as a platform to promote responsive caregiving and parent well-being within a 6-week intervention in Tanzania. Caregivers in the intervention condition, which consisted of 6 content webinars on early learning, reported higher developmental outcomes for their children than the control group [19]. Fully asynchronous app-based interventions such as Háblame Bebé are also being tested in the United States to examine whether low-intensity interventions have a direct impact on caregiver-child interactions by sharing information about "language nutrition" in the early years of life [20]. While data from a randomized controlled trial are mixed related to the ability of Háblame Bebé alone to impact caregiver-child interactions, caregivers report positive outcomes related to increased knowledge about children's language learning and cultural pride regarding their use of Spanish with their child [21]. Compared to other areas, such as maternal and child health, developmental interventions that focus on early language development using social media are rare [17].

Although research evaluations to support early language development on social media are scarce, they could be a natural fit for mobile health interventions because many caregivers in the United States use social media to seek information and connections with others as they transition to parenthood [22,23]. Approximately 89% of new caregivers report using social media apps to search for information and social support about caregiving-related topics, such as infant sleep, feeding, growth, and development [24]. Low-income communities in the United States report the use of social media and the internet to access parenting information and social support at high rates, making it a logical platform to share information that could be accessible for all caregivers [23,25]. Mothers with low incomes in the United States have described using their mobile phones as a primary source of access to the internet, and they report using search features to quickly gain access to information while multitasking with other responsibilities [25]. Creators on social media already generate publicly available content specific to supporting language learning in young children and have large followings of caregivers. However, few investigations explore

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whether caregivers can consistently access and retain information and use strategies from social media to support language-rich interactions with their children.

BabyTok Project

We first developed and tested the BabyTok Project as a means to connect with teachers of infants and toddlers during the COVID-19 pandemic because it made use of mobile technology while social distancing [26]. In our initial study, we conducted an 8-week intervention with teachers serving infants and toddlers in low-income communities by giving an overview of early communication development in the first year of life, responsive strategies to support child communication in the classroom, and affirmations for teachers about their critical role as early educators during the pandemic. The BabyTok Project reinforced the infant toddler teachers' positive interactions with children as described by the teachers, encouraged them to implement new communication strategies with children in their classroom in some cases, and increased or reinforced feelings of pride in their role in children's learning. Results also indicated positive, though not statistically significant, gains in knowledge scores related to early language learning on a standardized measure. Most participants endorsed the use of social media as a platform for the BabyTok Project because of its convenience, engaging style, and short-form nature [26].

Purpose of This Study

The purpose of this investigation is to examine the feasibility and acceptability of the BabyTok Project as a means to support home-based caregivers' knowledge about early language development and intervention. Feasibility is characterized by caregiver retention and caregiver engagement with the project videos and procedures, and acceptability will be described through qualitative analysis of caregiver interviews after the intervention. We also use an exploratory measure to determine the potential of the tools to capture change from a light-touch intervention such as the BabyTok Project for future effectiveness studies.

Methods

Participants

Study recruitment occurred in the summer of 2022 through an informational video that was posted on TikTok (ByteDance)

and the study flyer posted on relevant Facebook (Meta Platforms, Inc) groups. To be eligible, caregivers had to (1) have at least 1 child aged between 12 and 18 months and (2) receive at least 1 public benefit (Women Infants and Children, Medicaid, Temporary Assistance for Needy Families, and housing assistance), which served as a proxy for income. Interested individuals were directed to a survey link that included 2 screening questions to verify their eligibility status (ie, "How old is your child?" "Does your family receive any of the following assistance: commodities, food stamps, housing assistance, Medicaid, supplemental security income, and/or WIC?"). While the intervention was intended to be universal, we focused recruitment on caregivers who used social services to ensure that the intervention was accessible and acceptable to caregivers with fewer financial resources.

After duplicates and incomplete responses from the initial interest survey were removed, 42 eligible caregivers across the United States expressed interest and shared their information to join the study within the 7-day recruitment period. Of them, 27 (64%) caregivers completed pretest measures and began participation in the study, while the remaining 15 (36%) did not respond to pretest measures. We held an initial Zoom (Zoom Communications, Inc) meeting with each of the 27 participants, which ensured the participants were real and not bots. Moreover, 2 (7%) participants did not complete any posttest data and were considered lost to attrition, so demographic data for 25 participants were reported. The study participants included 24 (96%) mothers and 1 (4%) grandmother. In total, 11 (44%) participants were White, 8 (32%) were Black, 2 (8%) were multiracial (Black and White: n=1, 4%; Black, White, and Hispanic: n=1, 4%), 1 (4%) was Asian, and 1 (4%) was Hispanic. In addition, 1 (4%) participant did not self-report her race or ethnicity. All (n=25, 100%) participants spoke English, and 4 (16%) spoke an additional language (ie, Spanish or Vietnamese), and they were aged between 23 and 49 years. In total, 15 (60%) participants reported having a male child, 10 (40%) reported having a female child, and none (n=0, 0%) were identified with a developmental condition (Table 1 presents more demographic information about the participants).



 Table 1. Caregivers' demographic information (N=25).

Characteristic	Participants, n (%)	
Relation to the child		
Mother	24 (96)	
Grandmother	1 (4)	
Age (y)		
20-29	8 (32)	
30-39	15 (60)	
40-49	2 (8)	
Race or ethnicity		
Asian	1 (4)	
Black	8 (32)	
Black and White	1 (4)	
Black, White, and Hispanic or Latino	1 (4)	
Hispanic and Latino White	1 (4)	
Hispanic and Latino non-White	1 (4)	
White	11 (44)	
Did not report	1 (4)	
Languages spoken		
English	25 (100)	
Spanish	3 (12)	
Vietnamese	1 (4)	
Educational level		
High school diploma	4 (16)	
GED ^a or an alternative credential	1 (4)	
Trade and vocational school	2 (8)	
Some college	5 (20)	
Associate's degree (associate of arts and associate of sciences)	3 (12)	
Bachelor's degree (BA and BS)	9 (36)	
Doctorate (PhD)	9 (36)	
Estimated household income (US \$)		
<10,000	3 (12)	
10,000-19,999	1 (4)	
20,000-29,999	3 (12)	
30,000-39,999	7 (28)	
40,000-49,999	2 (8)	
50,000-59,999	3 (12)	
60,000-69,999	1 (4)	
70,000-79,999	2 (8)	
90,000-99,999	1 (4)	
≥100,000	1 (4)	
Prefer not to answer	1 (4)	
Child's sex		
Male	15 (60)	

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Characteristic	Participants, n (%)
Female	10 (40)
Child's daytime setting	
Childcare program	5 (20)
Parent's home	19 (76)
Another family member's home	1 (4)

^aGED: General Educational Development.

BabyTok Project Videos

The BabyTok Project videos were developed by the research team using the video production capabilities within the TikTok platform. Most videos featured the first author as a narrator in a conversational style that is common on the platform. All videos were recorded by the first author on her handheld iPhone (Apple Inc). The first video was an introduction by the first author explaining her credentials as a speech therapist and researcher and providing more details about the project. She served as the "narrator" for the videos and is a White female researcher who is also a parent. As 56% (14/25) of our sample was not White, we asked for feedback on her narration and relatability to gain participant input to guide future investigations. While we did not use caregiver feedback to guide the development of this set

of videos, we built in feedback opportunities in the postintervention interviews to gather caregivers' ideas and preferences for content. A total of 33 videos (1 introduction video and 32 content videos) were shared with participants across 4 overarching topics: *using words, shared book reading, learning in everyday routines*, and *affirmations*. Videos were developed using the best available research on strategies to support early caregiver-child interactions and early development as described in the study by Romano et al [26].

At the midpoint, the first author also offered participants an opportunity to choose between topics to give them a role in content development, and most participants chose to gain more information about routines (Table 2 presents more detailed descriptions of the videos).

Table 2. BabyTok content video descriptions (n=32).

Topic	Videos, n (%)	Purpose
Using words	9 (28)	Children learn so much in their first few years of life, and their caregivers have a lasting impact on their de- velopment. These videos introduced expectations of milestones at various ages and strategies for supporting children's language development, such as expanding on their words and providing choices.
Shared book reading	6 (19)	Shared book reading with toddlers is shown to support their language learning and academic success. These videos shared information about the benefits of reading to toddlers, strategies to use during book reading, and choosing appropriate books for toddlers.
Learning in everyday routines	12 (38)	Learning opportunities are plentiful throughout daily routines. These videos shared foundational information about routines and examples of strategies to use during common daily activities, such as getting dressed or mealtime, to facilitate language development.
Affirmations	4 (12)	These videos were shared throughout the intervention as messages of encouragement for caregivers about their role as parents.
Participant Input	1 (3)	In this video the narrator asked participants for input about which topics they would like to learn more about in future videos.

Study Design

We used a convergent parallel design with an intervention mixed methods framework with a primary focus on qualitative data [27] to investigate the feasibility, usability, and acceptance of the BabyTok intervention for caregivers of young children. We collected qualitative data to support the continued development of the BabyTok intervention and quantitative data to investigate engagement and use of the intervention and its short-term effects and explore the utility of the measures used to describe intervention effects. The data were merged after individual analysis to present results on the holistic effects of the BabyTok intervention.

Measures

TikTok Engagement Metrics

TikTok engagement metrics were gathered to examine the feasibility of the intervention to shed light on how many videos participants viewed and how often they liked and commented on the videos. Public TikTok account owners have access to TikTok Analytics, which tracks metrics, including the number of likes, the number of shares, the number of views, and the average time viewers spent watching videos. However, to maintain a level of confidentiality for participants, we used a private TikTok account, and this precluded us from having access to all TikTok Analytics data. However, we were able to manually see total views for each video, the number of likes, and comments by each participant. To collect data regarding the participants' use of the BabyTok video series, participants

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were asked to "like" the videos posted to indicate that they viewed them. To collect additional data about participants' engagement with videos, caregivers were invited to comment on the videos. Individual responses were tracked for each video by clicking each post and reviewing who liked or commented. After the study was completed, the TikTok metrics were analyzed by recording the total sums of likes and comments per video and the total sum of likes and comments per participant across the 8 weeks of the intervention and calculating the mean, SD, and range for each. The feedback was analyzed by reviewing individual comments made for each video.

Caregiver Interviews

Postintervention interviews were used to evaluate the feasibility and acceptability of the intervention from the vantage point of the caregivers. Participants were interviewed in English by a trained graduate research assistant or second author through web-based meetings on Zoom using a semistructured interview protocol. The semistructured interview protocol was adapted from a previous study that investigated a similar intervention with childcare providers [26]. The protocol contained 7 questions about what participants recalled from the BabyTok videos, their feelings about their role as caregivers because of the BabyTok intervention, and the impact of the BabyTok intervention on their interactions with their child. Questions also focused on the suggestions and feedback participants had about the BabyTok videos and if they would like to see content about different topics (Multimedia Appendix 1). Each interview lasted approximately 10 to 15 minutes, was screen recorded, and was transcribed using the Otter.ai platform. Two graduate research assistants reviewed the transcriptions and corrected any errors.

Exploratory Measure (Survey of Parent/Provider Expectations and Knowledge-Research)

For this study's purposes, the Survey of Parent/Provider Expectations and Knowledge-Research (SPEAK-R) was used as an exploratory tool to quantify changes in parents' perceptions of their understanding of the early childhood cognitive and language learning. The SPEAK-R is a 22-item, self-administered questionnaire designed to assess knowledge of and beliefs about early childhood cognitive and language development [28]. The questionnaire consists of 4 multiple-choice items, 14 Likert scale items scored as definitely true (0) to definitely not true (4), and 4 Likert scale items reverse scored as definitely not true (0) to definitely true (4). The questions focused on six topics: (1) bilingualism, (2) early exposure, (3) media use for child learning, (4) nature versus nurture, (5) sensitivity and responsiveness, and (6) talking and reading [28]. The SPEAK-R survey was developed and tested on multiple population samples that included caregivers with low incomes [15]. The second version (SPEAK-2) showed significant, positive correlations between scores and level of education, receptive language skills, and the quality of language in the home environment. The mean SPEAK-R score reported by its developers was 47.27 in a sample with low-income caregivers [15]. The SPEAK-R indices were proven reliable during field testing with Cronbach α scores of 0.92 [28]. The SPEAK-R was conducted at entry and after the 8-week intervention. The measure was gathered and scored

using REDCap (Research Electronic Data Capture; Vanderbilt University), and the data were imported into SPSS (IBM Corp) for analysis.

Procedures

After the consent process was completed, the research team sent out a step-by-step handout via email and SMS text message with information for completing the pretest measures and accessing the BabyTok study channel. Participants completed a demographic survey and the SPEAK-R online. They also scheduled an observation with a member of the research team, hosted via a teleconferencing platform, to verify that they were not bots and to use it to pilot other potential observational measures. Caregivers were asked to interact with their child as they normally would during a typical routine or activity they would be engaging in during that time, such as playing with toys, book sharing, or caregiving activities, such as snacks and diaper changes.

After all participants completed the pretest measures, the research team began sharing videos with all participants on the social media platform 3 to 5 times per week. The videos were posted on the channel, and they were sent to the participants via direct messages. Participants were encouraged to watch each video, like, and comment to verify that they viewed the videos. At the end of this 8-week period, participants completed the posttest measures, which included the SPEAK-R and another recorded caregiver-child observation as well as an independent web-based interview regarding participants' perceptions of the BabyTok intervention.

Data Analysis

TikTok Engagement Metrics

We used a descriptive quantitative analysis to show means and ranges of the TikTok engagement metrics. We obtained simple counts of likes and comments per video and the number of likes and comments per participant.

Caregiver Interviews

The transcripts were analyzed based on the template analysis method as described in the study by Brooks et al [29]. The qualitative coding team included a doctoral student, a graduate-level research assistant, and an undergraduate research assistant. To become familiar with the data, each team member read and reread the transcripts and took general notes on thoughts about overall themes in the data. Next, the team met, discussed the data, took more notes, and began developing preliminary codes based on the interview questions, responses to the questions, and themes from a previous BabyTok Project [26]. The 3 main codes developed at this meeting were takeaways from BabyTok, effects of BabyTok, and attitudes or perspectives or feelings about BabyTok, and each code was assigned a different color. Next, the team split the transcripts among individuals and separately coded quotes within the transcripts by highlighting them in the color assigned to the corresponding code. The team met several more times to ensure the codes effectively described the data the data. Codes that were no longer applicable were removed, codes were reorganized and redefined, and a more accurate template was

developed. Specifically, we recognized that the code *takeaways from BabyTok* overlapped with the code *effects of BabyTok*. Because of this overlap, the codes were reclassified, with the code *takeaways from BabyTok* becoming a subcode of the code *effects of BabyTok*. In addition, the code *attitudes or perspectives or feelings about BabyTok* was split into the subcodes *supportive feedback* and *recommendations*. The team also identified several pieces of data that did not fit into the codebook framework but were important because they described the usefulness of the BabyTok content for different caregivers and in different contexts. Thus, the new subcode of *supportive feedback: content is useful for all caregivers* was established. Next, the team looked for disconfirming evidence or null effects. Because very few examples were discovered, instead of a separate code, we decided to include *negative or null effects* as a subcode of

takeaways from BabyTok. Finally, the team cross-checked each other's coding by pulling a sample of 50 significant quotes from the transcripts and independently coding each quote to ensure consistency of coding. The final coding template included codes, subcodes, definitions of subcodes, and an example of a quote for each subcode (Table 3 presents the codebook).

To ensure the trustworthiness of the data, the data analysis team took several steps, such as those described by Nowell et al [30]. Our approach included data familiarization, debriefing with the first author, checking for coding reliability to support the credibility of our findings, providing thick descriptions coupled with several examples of direct quotes to increase transferability, and keeping an audit trail of our decision-making process to achieve dependability. By taking these steps, the confirmability of the data was established [30,31].



Table 3. Codebook for posttest caregiver interviews.

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Theme	Definition	Sample quote
Effects of BabyTok	·	
Changes in how they interact- ed with their child	Differences in how the caregiver approached communicating, engaging, playing, and building a relationship with their child or children after participating in the BabyTok intervention	"I feel like I'm a lot more mindful of what I'm doing when I'm interacting with herI try to repeat phrases more often and kind of pause and let her try to do it as well."
Changes in how they viewed their role as parents	Differences in how caregivers viewed and felt about their impact on their children (eg, how they develop, communicate, and learn) and/or differences in how they felt about their own parenting style or skills	"I was very critical about her not speaking yet andreally worried about it. But then she justmade me feel betterit's okay if they're not as far with their language as they're supposed to beit helps me,feel more grounded and not,stressed out about it as much."
Changes they noticed in their child	Differences in the child's behavior and commu- nication after trying BabyTok techniques, strategies, and tools.	"We're introducing 'POW'the point, wait, and the wait for them to repeat type thing,I noticed that my daughter was catching on to things a lot quicker when I was using like some of those resources."
Takeaways from BabyTok ^a	Information that caregivers described as remem- bering, learning, trying, or as being useful after participating in the BabyTok intervention	"what I remember most is just labeling everything for them to help them build their vocabulary. So just labeling and giving them wait time to just kind of let it sink in and process."
Supportive feedback		
Use of social media platforms	Comments about the convenience and accessibil- ity of hosting the videos on TikTok (eg, did not take a lot of time, could do from anywhere, and familiarity with TikTok)	"I enjoyed all the content, it was super accessible to have it on TikTok, because it was there, and I could watch it once it was posted when it was convenient to me."
Engagement with other care- givers	Comments about interacting with and relating to other caregivers through the BabyTok plat- form to feel affirmed and build camaraderie	"just to hear other people's opinions,I'm dealing with the same thing as a mom' and it was just very enlightening. Some- times you think like you're the only one in this situation, but come to find out you're not"
Content delivery expert	Comments about the narrator in the videos and as the facilitator	"She is very enjoyable to watch. She's really cute. And she's really engagingI enjoyed watching her videosif you're wondering whether she's an appropriate candidate to continue doing videos, she's great. I loved her."
Trustworthiness	Comments about the credibility of the informa- tion shared and/or the participants' confidence in the source	"I get a lot of parenting videosbut I don't know, for a re- search project,I definitely felt like I was getting the right in- formation versus you never know exactly what you're getting"
Content is useful for all care- givers	Comments that the content was useful for new and experienced parents as well as other care- givers like grandparents.	"I think it's a great resource for all parents,new and parents that are already experienced in parenthood just to open your mind and broaden your horizon and other ways to help imple- ment teaching resources for your child."
Recommendations		
Content suggestions	Suggestions regarding the topics covered throughout the BabyTok project (eg, behavior management, potty training, routines, sign lan- guage, and bedtime)	"I guess one thing that I wish was covered a little bit more was routinesRoutines andhow we can build in little learningin- corporate learning opportunities into our daily routines"
Delivery suggestions	Suggestions regarding how the BabyTok project is shared, including what social media platforms are used, the format of the video, and how the participants were notified	"If maybe, throughout the project, there was like a email that went out at the end of the week, like, 'Hey, make sure you watch these five videos.' So, I knew if I missed one, to go back and find that rather than having to scroll through the whole ac- count,"
Suggestions for the engage- ment of users	Suggestions regarding how to increase interac- tions with BabyTok users, including how to fa- cilitate discussion among users and how users could share videos of their children	"If it was more interactive with those that were participat- ingmaybe if there was some type of participation through the process, outside of maybe commenting."

^aNull and negative effects are included here and not as a separate subcode because they were uncommon but still relevant.

Ethical Considerations

All participants provided implied consent for the institutional review board-approved study (Florida State University

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media intervention and posttest data collection (US \$50). All participants were issued an alphanumeric code for all data files. One single excel file linked personal information to the code. The linking file and deidentified files are kept on an encrypted Microsoft Teams folder hosted by the university.

Results

TikTok Engagement Metrics

In total, 32 videos were shared across the 8-week intervention period. The data were gathered on 21 participants. We excluded 4% (1/25) of the participants who were lost to attrition (ie, did not complete any follow-up data) and 12% (3/25) of the participants who unfollowed the BabyTok page after the project ended. We were unable to gather their data from TikTok after they exited the group. Participants were asked to like a video as confirmation that they viewed it; 24% (5/21) of the participants liked all 32 videos, and most (16/21, 76%) of the participants liked more than half of the videos (mean 23.95, SD 8.99; range 3-32).

To understand which videos garnered the most engagement and discussion from caregivers, we examined the number of likes per video and the number of comments per video. The videos with the most likes (n=18) were videos about milestones for children aged 1 year and those aged 18 months and a video about modeling and waiting when labeling objects. In total, 2 (6%) of the 32 videos received the least number of likes (n=13); one was a video that asked participants' opinions about which video topics they would like to see posted during the week, and the other was about activities to engage in during a morning routine. Overall, viewership of each video was 76% (16/21); the mean was 15.75 (SD 1.39; range 13-18) likes per video. The number of comments per video ranged from 2 to 14 (mean 6.44, SD 2.68). The video with the greatest number of comments (n=14) was posted on the first day of the intervention and asked caregivers to share the words their babies understand. The video with the second-highest number of comments (n=12) asked caregivers to answer the question, "What's your baby up to?" The videos with the least number of comments, 2 each, were about coviewing with screens and constructive play.

We also gathered the number of comments per participant to understand more about engagement per participant. The number of comments was unevenly spread among the participants, with 4 (19%) of the 21 participants commenting >20 times and 13 (62%) participants commenting ≤5 times (mean 8.81, SD 8.9; range 1-28). When commenting on videos, participants typically shared their positive feelings toward the strategies suggested. Participants shared their excitement to try the strategies. For instance, about a video called Three Tips for Book Time, a participant stated, "I'll have to try this! Especially the waiting strategy." About a video describing a strategy of pointing, using 1 word, and then waiting a few seconds for a response, a participant shared, "I'm going to try it tonight when I read to him." Participants also shared how they were trying the strategies and how their children were responding. When commenting on a video about modeling words instead of pressuring children to say words with several prompts, a participant shared, "I did this with [my] son with 'banana' [his

favorite food], and he tried to say it!" One participant shared how a motivational video helped her after a challenging time with her child. After viewing the video, *They Come to You*, she commented the following:

I needed to hear this today. After a long night with the babe, sometimes it's so easy to question my motherhood journey.

Other common responses in the comments included sharing about their babies' milestones and how they felt affirmed and emoticons of smiles, laughs, and hearts.

Caregiver Interviews

Participants' perspectives of the BabyTok intervention were organized into 3 main themes: effects of BabyTok, supportive feedback of BabyTok, and recommendations for BabyTok. Each theme included 3 to 5 subthemes, as displayed in Table 3. In total, 23 (92%) of the 25 participants completed individual interviews following the 8-week BabyTok intervention.

Effects of BabyTok

Changes in How They Interacted With Their Child

In response to how the BabyTok videos impacted their interactions with their children, many (21/23, 91%) participants reported becoming more purposeful, more mindful, more positive, paying closer attention to their child, having more face-to-face interactions, and using strategies to promote communication more often. One participant stated the following:

I feel like I'm a lot more mindful of what I'm doing when I'm interacting with her on trying to do things that she might copy so that she can implement that and understand what I'm doing. I try to repeat phrases more often and kind of pause and let her try to do it as well.

Another participant discussed the change in her phone use when interacting with her child:

I think it made me sit down and do more face to face with her. Get off the phone a little bit...and make sure that we are doing things to help promote her speech and just spend more time with them.

Changes in How They Viewed Their Role as Parents

Participants reported changes in how they viewed and felt about their impact on their children's language development. They also expressed how they felt about their own parenting style or skills. For example, one participant described a change in her confidence and in the importance of her role:

I feel a lot more confident in my role and helping to develop her language development. And her development in general, like, the videos and description of the one-on-one time and the eye-to-eye contact, all of that being kind of brain food or setting them up for success...It made me feel like I had a more important role than I was giving myself previously.

Another participant described how her understanding of the parent's role in a child's language development changed:

It kind of...put that into perspective and how I actually need to do that [consistently label] to help him develop, like how critical parents are to developing the language. It doesn't just come naturally to them from listening.

Other (9/23, 39%) participants expressed their thoughts on their role with statements such as, "What I learned is that basically, we play a huge part in, you know, teaching our kids," and "...it made me feel more confident in things that I was doing," and "I feel like I have to remember to do a little bit more teaching than I did, than I have in the past."

Changes Noticed in Their Child

Participants described noticing that their children paid more attention, learned more quickly, and began to copy words. For example, after using a specific strategy from the videos, a participant stated the following:

It seems like still, he pays attention more when I do it. And it's nice, because it shows that he's trying to listen, and figure out what I'm saying.

Another caregiver noticed that her child was beginning to say words because of trying a strategy suggested in a BabyTok video. She stated the following:

But she is picking things up like—she did say "cat" while we were doing that after I pointed out cat several times on several pages to her. I wasn't getting that kind of a reaction or that kind of an interest or response before I did that, because I wasn't waiting for any kind of a response from her.

Another caregiver described a similar change in her child:

We're introducing "POW," I believe it was. Like the point, wait, and the wait for them to repeat type thing, which I thought was really cool, because I noticed that my daughter was catching on to things a lot quicker when I was using like some of those resources.

Participant Takeaways

When asked what they remembered most about the BabyTok videos, participants described what they remembered, what they learned, or strategies they tried. Many (19/23, 83%) caregivers listed specific strategies that were shared in the videos. One participant said the following:

What I remember most is just labeling everything for them to help them build their vocabulary. So just labeling and giving them wait time to just kind of let it sink in and process.

Another described learning from the demonstrations of implementing strategies:

I think what I remember the most about the BabyTok videos, were just some of the demonstrations, or I guess...suggestions on what you could do with the baby. So, I've blown bubbles, but I thought it was really intimate and kind of cool just to blow the bubbles while the kid was sitting. So, we tried that.

A few (5/23, 22%) caregivers also described retaining content related to the emphasis on daily routines. One caregiver recalled

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how to talk to her baby during daily activities. She stated the following:

So, I think I definitely learned a lot of routines and when to talk and how to during throughout the day. That was really important for me to try to remember I could fit in throughout the day.

Another remembered learning that routines were specific to each child and their family. She stated the following:

I think probably about setting a routine and how it doesn't have to be like a normal routine. It just has to be, because most people, they brush their teeth immediately before going to bed. But we have to kind of settle her down after that, because it's always a fight. And that's okay. It doesn't have to be [a] normal routine, it just has to be, this is what you do from day to day.

Disconfirming and Null Effects

When asked what they remembered most about BabyTok videos, two participants described some of the strategies in the videos as not being useful. For example, one participant recounted the following about the point, one word, and wait strategy:

The one about the POW, the point, and then, say the word and then wait, I found that I like that a lot. It didn't really work for me. But I think I'm gonna keep trying.

The other participant stated the following about trying the book reading and screen time strategies:

He doesn't really like books that much or TV. He just doesn't, you know, so I guess it's individualized for child. So, a lot of the book things, like I read him books, but usually he doesn't pay attention to them. So and then, like the screen time things, again, he doesn't pay attention to the screen at all.

One caregiver was unable to try the strategies or implement new routines with her child because of her busy work schedule. She said the following:

My schedule has been off. So, most of the days he's at daycare or he's been with his dad the past three weeks...So I haven't really got a chance to spend time with him as much.

Supportive Feedback

Use of Social Media Platform

Participants discussed the convenience and accessibility of being able to watch and learn while scrolling on TikTok. One participant described the following:

You're on TikTok anyway. So, if you follow them, and they'll come up on your following page, and, you know, it makes it like, not so stressful, like, you're not researching it, you know, intently, you're just scrolling, and I learned a million things. Since I've started watching videos, I cooked a meal off it last night. And so like, at the same time, when I'm

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scrolling, I'm like, "Oh, I just learned something I can do with my baby."

Others liked the ease of use and the short length of the videos. One participant stated the following:

It's user friendly. You don't have to worry about, I don't know, she would just message us videos, and I just click on them, and it pops right up so fast.

Another stated, "I liked that they were smaller, bite sized pieces, bite sized segments." However, one caregiver requested longer videos to be interspersed with the shorter videos.

Engagement With Other Caregivers

Another element of the social media intervention that participants enjoyed was engaging with other caregivers. For example, a participant stated the following:

So just to hear other people's opinions, like, "Hey, I'm dealing with the same thing as a mom," and it was just very enlightening. Sometimes you think like you're the only one in this situation but come to find out you're not and plenty of other parents are dealing with the same thing.

Content Delivery Expert

Participants also shared their approval of the host and speaker in the videos with comments such as the following:

It's Mollie, right, that was doing the videos? She is very enjoyable to watch. She's really cute, and she's really engaging.

She was very interactive and very responsive, like when we would make comments or have questions. So yes, I really enjoyed that part.

Trustworthiness

Participants viewed the content of BabyTok as more trustworthy than information they received from other sources, such as family, friends, and content creators on TikTok. One caregiver commented the following:

I get a lot of parenting videos, but I don't know, this was specifically for a research project, so I definitely felt like I was getting the right information versus you never know exactly what you're getting on TikTok.

Another described getting a "better perspective" from the content on BabyTok. She said the following:

Basically I really get my advice from like, parents and people, you know, who already have kids. Um, so it was just different to like, you know, actually, like, get a better perspective and learn more about how to teach babies and toddlers, you know how to speak.

Content Is Useful for All Caregivers

Participants described the content as useful for a wide range of caregivers in multiple contexts. One participant commented that BabyTok would help introduce strategies for language development to the other caregivers in her child's life:

But then watching the videos gave me more ideas and how to help other people in our life, introduce things to her as well. So it's not just my responsibility, Dad can help and grandma can help and things like that.

Some (9/23, 39%) caregivers described BabyTok as useful for all parents. One caregiver commented the following:

I think it's a great resource for all parents, like new and parents that are already experienced in parenthood just to open your mind and broaden your horizon and other ways to help implement teaching resources for your child.

Another said the following:

So I think different generational gaps have different styles of parenting. So I think it's very beneficial for different generations. So, for example, a lot of the things that she was teaching I wasn't familiar with only because I'm not used to doing it that way. So I think different generations would find this beneficial to view those videos as well.

Recommendations

Content Suggestions

To close out the interviews, the interviewers asked the participants if there was anything they wished was improved or included in the video. Many (16/23, 70%) participants responded with varying ideas for content additions, including more content about routines, baby signing, speech delays, help with bedtime, how to handle challenging toddler behaviors, and pretend play with toddlers. For example, a participant stated the following:

I guess one thing that I wish was covered a little bit more was routines...Routines and how you can build more—how we can build in little learning, like, incorporate learning opportunities into our daily routines is what I'm trying to say.

Delivery Suggestions

In addition to recommending changes to content, some (10/23, 43%) participants recommended changes to video formats, how participants were notified of videos to view, and using other social media platforms, such as Instagram. Other suggestions included adding more to the videos to make them grab and hold attention. For instance, one caregiver said, "I think it would have been more interesting if there was more captions, or pictures and stuff on there," and another said, "Eye-catching, so instead just like someone talking, there were different varieties." One participant discussed the use of actual babies in videos to see the activities and strategies demonstrated. Finally, there were recommendations for how participants were notified of videos to view. A participant suggested a method of notification via email. She stated the following:

I think there were a few times where like, I missed a notification...If maybe, throughout the project, there was like an email that went out at the end of the week, like, "Hey, make sure you watch these five videos." So, I knew if I missed one, to go back and find that



rather than having to scroll through the whole account to see if there was one I hadn't reacted to or liked or whatever.

Suggestions for the Engagement of Users

Two (9%) participants wanted more interaction with other caregivers. The following quote from a participant demonstrated this:

I think, yeah, if it was more interactive with those that were participating. It is nice to watch the videos, you can do it on your own time, but maybe if there was some type of participation through the process, outside of maybe commenting.

Another participant suggested the use of Facebook groups for added interaction among participants:

Facebook has groups, so y'all could make a BabyTok group. And then when y'all have videos, maybe you could put like a post that's like a discussion post about the video from October 11. And then maybe people could comment.

Exploratory Measure (SPEAK-R)

We used a pre-post, paired samples 1-tailed *t* test to assess whether there were changes in caregiver knowledge on the SPEAK-R. A total of 22 caregivers completed the SPEAK-R at posttest measurement. Pretest data on the SPEAK-R had a mean of 48.62 (SD 7.70; range 30-63), and posttest data had a mean of 51.52 (SD 12.94; range 30-69). The 1-tailed *t* test was not statistically significant (t_{21} =-1.357; *P*=.09). Some SPEAK-R data were missing at posttest measurement (n=4), indicating a need for additional support for participants to complete it after the intervention. One participant had a notably low posttest score that might have indicated that they completed the measure without responding to all the items.

Integrated Results

We merged results across the qualitative and quantitative data to understand the feasibility and acceptability of the BabyTok intervention. As was expected with a distal measure there was incomplete alignment between the SPEAK-R items and the content of the BabyTok intervention. Some items on the SPEAK-R (ie, supporting dual language learning, when children begin learning Science, Technology Engineering and Mathskills) were not covered within the project videos, so we would not expect to see participant comments or gains in these areas. However, there was some overlap, specifically across 3 content areas: screen time, caregiver responsiveness, and shared book reading. Our integrated analysis focused on SPEAK-R items, TikTok metrics, and qualitative themes that were related to those 3 content areas (Multimedia Appendix 2 provides a joint display of merged results).

Overall, we found evidence of positive changes related to participants' knowledge about caregiver responsiveness and shared book reading across all 3 sources of data. Changes in pretest to posttest raw scores on the SPEAK-R items related to caregiver responsiveness (ie, items 26, 34, and 36) indicated that participants gained new knowledge within this content area, as evidenced by increases in the raw scores. A total of 3 (9%)

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of the 32 BabyTok videos included content related to caregiver responsiveness, and 5 (16%) videos included content related to book reading. Each of these videos, except one (ie, "Myths about Reading"), received at least 17 likes, which was more than the average number of likes across all videos. These videos also received various comments from participants, ranging from 3 to 9 comments. We collected various quotes from participants related to responding to their children and reading with their children across 4 subthemes, indicating that participants learned new strategies, saw changes in their child, and viewed their roles as parents differently in relation to book reading and caregiver responsiveness.

However, changes on the SPEAK-R items related to screen time for young children (ie, 14, 56, 57, and 58) were mixed from before the test to after the test. A total of 2 of the 32 BabyTok videos included content related to screen time; 1 (3%) had 16 likes and 2 comments; 1 (3%) received 17 likes and 9 comments. No (0/21, 0%) participants discussed this content in their interview, indicating that this content may not have been as important to their experience in the BabyTok intervention.

Discussion

Principal Findings

This study examined the feasibility and acceptability of the BabyTok Project with caregivers of toddlers while exploring potential outcome measures for future investigations. We wanted to understand how and to what degree caregivers engaged with the BabyTok Project, what they retained from the content, and what caregivers liked or did not like about their experiences with the videos and the platform. Overall, participants expressed positive feedback about the BabyTok content and the short-form, video-based nature of the intervention. Although the distal knowledge measure (SPEAK-R) showed raw score gains but not statistical significance, most (22/23, 96%) participants listed specific strategies that they recalled from the videos and gave examples of using the strategies with their child.

Caregiver Engagement With the BabyTok Content

In general, we found consistent engagement through likes from most caregivers throughout the project (mean 15.75, SD 1.39 likes/video; viewership: 16/21, 75%). This could suggest that the intervention is well aligned with caregivers who use their mobile devices to access content on social media with regularity and that the content might fit in easily with their use patterns [25]. Two caregivers reported watching the videos when they were sent a direct message, two other caregivers watched them in a batch and "caught up" on the videos when prompted. Still more caregivers viewed the videos from their "For You" screen on the app, suggesting that the multiple points of contact may have helped increase the ability of caregivers to access the videos. The overall viewership and engagement data among caregivers were similar to that of the infant toddler teachers in our earlier investigation (16/21, 75% and 73%, respectively). While it is not possible to directly compare to other app-based studies such as Háblame Bebé that can track time in the app [21], we note similar patterns of engagement in that most (16/21, 76%) caregivers participated at intended levels, with a few low responders, indicating the need for individualized support. One

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caregiver in our investigation had notably low viewership, suggesting the need for additional strategies to increase engagement for some caregivers. Such individualization could include tailoring when the direct messages are sent (to align with their time on social media or their off time from work) and when, how, and how often reminders are sent.

Caregivers Gave Specific Details From the Content

Caregivers described the convenience of the short, "bite-sized" content units, that they were on the app anyway for other purposes, such as looking for dinner recipes or entertainment, and that they were able to learn useful information to support their child's learning. Caregivers noted they may not have had time to watch long videos, but the short content units kept them in touch with the ideas presented in the videos more often and made it enjoyable. This feedback was also consistent with that of the infant toddler teachers in the earlier investigation. Although this study did not experimentally evaluate whether caregivers made changes in their interactions, caregivers did indicate that they believed the approach supported them in engaging their child in language-rich interactions and equipped them with strategies to use every day. Among the strategies, caregivers found the content related to the point, one word, and wait strategy to be salient, along with expansions and book-sharing strategies for their toddlers. The specificity of caregivers' responses around these strategies was encouraging because it reflected ideas shared in the videos that caregivers were not likely to have learned elsewhere.

Caregivers Described the Trustworthiness of the Content

The first author, who is also the main video narrator, provided her credentials in an introductory video at the beginning of this study. This may be one reason that caregivers described the content viewed on the BabyTok page as "the right information" and that it gave them a "better perspective" about toddler language development than information they received from family, friends, and other TikTok creators. These statements relating to trustworthiness are encouraging and may indicate caregiver acceptability of the content and overall intervention.

Suggestions for Additional Content

Caregivers gave suggestions for future videos, which can be implemented into future studies, such as including the use of different methods of delivery (ie, Instagram or Facebook groups); use of text on screen, including more eye-catching images; and videos with real babies and caregivers to show examples of the strategies. They also suggested content that extends from communication content directly into everyday concerns, such as sleep and challenging toddler behavior. This is important because caregivers seem to not only want information about how to help their children talk but also ways to navigate everyday challenges that caregivers of children in this age range face, which may then impact their interactions with their child. Tackling these parenting issues may also give caregivers a means to engage with one another as they share what has worked and what has not for their child, which could serve to build their own confidence in sharing their experience with one another.

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Implications for Media-Based Universal Interventions

While we cannot extend these findings to other types of interventions, there are potential implications for video-based interventions with caregivers of young children. Similar to our experience with teachers [26], home-based caregivers did not have a 100% watch rate, but they did view most videos, on average. Because few caregivers will be able to watch every video, it is important to build in redundancy by reinforcing similar messages and delivering the same message more than once. Furthermore, our attempts at reaching caregivers through multiple modes, such as sending videos via direct messaging, SMS text message reminders, and the "For You" page. seemed to help increase the number of videos viewed by each caregiver. While publicly available content may have similar messages as the BabyTok videos, there are no mechanisms yet to support caregivers to consistently engage with the content beyond what appears based on the algorithm or to ensure that enough video content reaches users to create changes in knowledge and caregiver-child interactions.

Limitations and Future Directions

While the findings in this investigation suggest the promise of social media-based interventions to support caregiver knowledge about early language learning, the study does face several limitations. First, the small sample size of participants may be a limiting factor in evaluating and drawing conclusions from the data. Next, because of the nature of the TikTok platform, we had limited metrics available to us as a private TikTok page. With this lack of metrics, we were not able to gather data on the watch time of each video by the participants. It is possible that participants may have pressed "like" on the video without fully viewing it, and it is also possible that participants did view the video but neglected to press "like," leading to an underrepresentation of their viewing. We also did not collect data to understand how our participants typically engaged with and used social media to compare with how they engaged with and used the BabyTok content relative to other social media content. We made assumptions that participants engaged with content if they liked and commented on the videos, but they may have engaged in other ways, such as showing the video to a friend or partner.

In future studies, we could ask caregivers to report on their overall social media use patterns to compare their engagement with the content relative to their overall social media use. Although our sample of participants was similar in age and gender to the average US TikTok user, there were some differences in parenting status, education level, income level, and race or ethnicity [32,33]. These differences may have made it more difficult to evaluate engagement data of some participants, as they may not have been typical TikTok users. Our participants were more educated (bachelor's degree: 9/25, 36%) compared to the average US adult aged >25 years (23.5% with a bachelor's degree) [34], and fewer of our participants had their toddlers in childcare outside the home (6/25, 24%)than the average US family (55%) [35]. This may indicate that caregivers who are in the home and more educated may be more likely to access and engage in this type of social media intervention.

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Although some caregivers reported gains in their child's communication, we did not directly measure child language skills as an outcome in this feasibility and acceptability study. It is important to note that children should acquire new words during this developmental period, so randomized controlled trials are needed to determine whether there are child-level effects above and beyond the communication gains that would take place through the child's maturation alone.

The SPEAK-R provided a related outcome representing caregiver knowledge, although there were items on the measure that did not align with the video content (ie, early mathematics and cognitive concepts). Those domains would not have been likely to change because of the BabyTok intervention. SPEAK-R has been used as an outcome in a few studies that offer video-based educational content [36], but it is difficult to compare relative changes between studies because our intervention focuses only on communication rather than communication and cognition. In addition to measuring caregiver knowledge, it would also be useful to measure long-term impacts on children's vocabulary development by using caregiver-reported tools about their child's communication

in a larger, randomized study. Additional future directions also include creating and testing Spanish-language videos for caregivers in the United States who speak Spanish as a primary language, with a focus on supporting children in both languages.

Conclusions

The findings of this study add evidence to the feasibility and acceptability of the BabyTok Project as a means to increase caregiver knowledge of how to support children's language learning. This research is important because, to date, there have been few social media–based interventions targeting children's early communication. While there is a sizeable body of evidence related to intensive coaching models to help caregivers engage with their children, low-cost, light-touch interventions could be a scalable and accessible means to equip caregivers with information they need to advance their children's language abilities [21], with downstream effects on academic and social outcomes if future efficacy testing indicates positive effects. This approach to intervention may be particularly important for families from low-income backgrounds whose access to health information about their young children may be limited.

Conflicts of Interest

None declared.

Multimedia Appendix 1 Semistructured interview protocol. [DOCX File , 14 KB - pediatrics v8i1e66175 app1.docx]

Multimedia Appendix 2 Joint display of merged results. [DOCX File, 22 KB - pediatrics v8i1e66175 app2.docx]

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Abbreviations

REDCap: Research Electronic Data Capture **SPEAK-R:** Survey of Parent/Provider Expectations and Knowledge-Research

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

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Abstract

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

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

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

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

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

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KEYWORDS

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

Introduction

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

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

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

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

Methods

Overview

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

Ethical Considerations

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

Survey Development

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

Data Sources

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

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

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

Data Processing

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

Objectives

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

Statistical Analysis

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

Results

Overview

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



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Figure 1. Flow chart of data collection and analysis.



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

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



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

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

^aNot applicable (only 4 responses in the EG and only 1 response in the SG, no statistical analysis was carried out).

Pediatric Anesthesia Expertise

The level of pediatric anesthesia expertise demonstrated by the SG was significantly lower than that reported in the EG. This was given by a lower number of professional experience in the SG with a median of 10 years (IQR 6 - 18; total range 1 - 45) compared with a median of 19 years (14-25; 5-35) in the EG

(P<.001), a lower share of respondents in the SG group of specialists, with 64.6% (64/99, with 13 nonrespondents), compared to 97.6% (80/82) in the EG group (P<.001), a lower share of respondents in the SG group reported performing more than 500 pediatric anesthesia cases per year, with 12% (13/108, with 4 nonrespondents), compared to 43.9% (36/82) in the EG group (P<0.001; details in Table 2).

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Table . Distribution of performed anesthesia case volume per year.

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

^aEG: Expert Group.

^bSG: Social Media Group.

^c4 nonrespondents; total n=112.

Representativity

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

Table . Level of care across respondents' workplaces.

5 more countries (Switzerland, Austria, Serbia, United Kingdom, and Hungary).

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

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

^aEG: Expert Group.

^b1 nonrespondent; total n=82.

^cSG: Social Media Group.

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

Structural Conditions

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

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

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

^aEG: Expert Group.

^bSG: Social Media Group.

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

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

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

A total of 95.1% (78/82) of respondents in EG and 99.1% (111/112) in SG reported that children's anxiety is not routinely

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

Practices of Pharmacological Interventions

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

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

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



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

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

^aEG: Expert Group.

^bSG: Social Media Group.

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

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

Practices of Nonpharmacological Interventions

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

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

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

^aEG: Expert Group.

^bSG: Social Media Group.

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

Discussion

Principal Results

The respondents to the publicly announced survey on social media demonstrated significantly less pediatric anesthesia expertise than the respondents to the survey among experts.

https://pediatrics.jmir.org/2025/1/e64561

This was evidenced by fewer years of professional experience, fewer board-certified specialists, and a lower pediatric anesthesia caseload. However, when looking at the items related to the practice of pediatric anxiety management, significant differences were found in less than a third. Regardless of the survey group,



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

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

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

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collected in the SG, even though access was open for an extended period and potentially a higher amount of respondents, indicating a low response rate in this "digital" SG. This suggests that if a survey on a specific topic, such as anxiety in pediatric anesthesia, is announced via social media, it is likely that only a specific subset of individuals, those with a particular interest or relevance to the topic, will actively engage and participate.

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

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

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

Limitations

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

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

Conclusion

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

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Authors' Contributions

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

Conflicts of Interest

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

Multimedia Appendix 1

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

[DOCX File, 27 KB - pediatrics_v8i1e64561_app1.docx]

Multimedia Appendix 2

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

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Abbreviations

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

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

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Abstract

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

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

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

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

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

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

(JMIR Pediatr Parent 2025;8:e58586) doi:10.2196/58586

KEYWORDS

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

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Introduction

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

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

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

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

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

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have been used as a noninvasive measurement method for determining the Hb levels in children [15]. The Masimo Pronto and Masimo Rad-67TM Pulse CO-Oximeters have good accuracy and validity compared to Hemocue (HemoCue); however, the Hb levels were underreported for the devices compared to the levels determined in venous blood samples [16-18]. This study used the Masimo Rad-67TM Pulse CO-Oximeter for anemia screening.

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

Materials and Methods

Study Design

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

Participants and Sample Size Planning

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

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

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

Data Collection

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

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

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

Measurements

Development of the Questionnaire

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

Sociodemographic Characteristics

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

Hb Level and Other Rad-67 Measurements

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

Growth Parameters

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

Statistical Analysis

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

Ethical Considerations

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



Results

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

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



Characteristics of Participants

A total of 1,201 participants were included in this study (Table 1). Slightly more than half were male (631/1201, 52.5%) and aged >12 - 36 months (610/1201, 51%); the majority were Asian Malay (727/1201, 60.5%) and from urban areas (687/1201, 57.2%). The majority had mothers with no university degree (898/1201, 74.8%), were born full-term (916/1201, 76%),

via normal vaginal delivery (860/1201, 72%), and were of second or higher birth order (767/1201, 63.9%). Moreover, a very small number reported a family history of thalassemia (6/1201, 0.5%) with a quarter not knowing their thalassemia status (316/1201, 26.3%), while a majority had no family history of anemia (1078/1201, 89.8%) and reported moderate or vigorous physical activity (862/1201, 71.8%).



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

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

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

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

Pulse CO-Oximeter (Table 2). Additionally, participants had a mean (SD) weight-for-age Z score of -0.67 (1.29), length-for-age Z score of -0.65 (1.72), and weight-for-length were Z score of -0.41 (1.29).

Of the 1,201 participants, 364 (30%, 95% CI 28 - 33) were identified as being at risk of anemia on the Masimo Rad-67

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

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

Distribution of Being at Risk of Anemia by Study Variables

The distribution of being at risk of anemia across the study variables is shown in Table 3. Children aged 6 - 12 months (n= 210, 57.7%), those of Asian Malay race (n=238, 65.4%), those from Klang district (n=123, 33.9%), those birthed via normal

vaginal delivery (n=275, 75.5%), and those without a history of thalassemia (n=284, 78.0%) were associated with being at risk of anemia. Additionally, children at risk of anemia had significantly lower weight-for-age Z scores (ie, a greater negative deviation from the normal weight) than those at no risk.



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

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

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

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

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



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

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

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

Discussion

Principal Findings and Comparison with Previous Works

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

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

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

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

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

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

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

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

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

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

Implications of Study Findings

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

Limitations

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

Conclusions

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

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Data Availability

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

Conflicts of Interest

None declared.

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Abbreviations

Hb: hemoglobin **IDA:** iron deficiency anemia

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

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Abstract

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

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

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

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

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

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

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

KEYWORDS

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

Introduction

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Attention-Deficit/Hyperactivity Disorder

Attention-deficit/hyperactivity disorder (ADHD) is a common neurodevelopmental disorder in children, affecting

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approximately 5% of the pediatric population [1]. It is characterized by 3 primary symptoms: inattention, hyperactivity, and impulsivity [2,3]. Children with ADHD often experience additional mental, emotional, or behavioral disorders, which can include learning disorders, sleep disorders, oppositional

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

Parent-Administered Pediatric Tuina

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

potentially leading to improved clinical outcomes for various pediatric conditions [26].

Research Gap

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

Methods

Ethical Considerations

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

Study Design

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

practitioners. Each participant in the pediatric *tuina* group received parent-administered pediatric *tuina* sessions every other day, totaling 24 sessions over an 8-week period (at least 3 sessions each week). Each session lasted approximately 25 - 30 minutes. The *tuina* protocol was developed from a 2021 feasibility RCT for ADHD involving 64 parent-child pairs, where 128 individualized pediatric *tuina* prescriptions were analyzed to identify commonly used and safe acupoints [29]. The resulting standardized basic prescription allows TCM practitioners to make individualized modifications based on syndrome differentiation. This TCM diagnosis guided the selection of specific acupoints and manipulation techniques tailored to each child's condition. Details regarding the

implementation of the intervention are illustrated in Figure 1. The interviews commenced 1 week after the completion of treatment for the first wave of participants in the RCT, which was conducted in 3 sequential waves. Interviews were strategically scheduled at 3 distinct timepoints, following the conclusion of each treatment wave. This timing ensured that participants had sufficient experiences and perceptions for in-depth exploration and allowed for the prompt collection of data while their experiences were still vivid, ensuring accurate and immediate reflections on the treatment effects. The study's reporting adhered to the Consolidated Criteria for Reporting Qualitative Research's checklists [30].

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



Setting

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

Participants

Participants were parents with children with ADHD. The participants for the interviews were invited from the participants in the pilot RCT who received the parent-administered pediatric tuina intervention [31]. Recruitment information was sent to potential participants by WhatsApp message at the end of February 2024, and purposive sampling was applied for recruitment. The children included in the pilot RCT (1) were aged 6 - 8 years; (2) possessed internationally recognized diagnostic information or certification for ADHD; and (3) had a score equal to or higher than 39 (borderline cutoff) of the Sleep Disturbance Scale for Children, which indicated sleep problems of children. The parents included in this study (1) participated in the project on using parent-administered pediatric tuina for improving sleep quality and appetite in children with ADHD who completed the 2-month treatment and follow-up assessment of the intervention during the treatment period, (2) were able to communicate in Cantonese fluently, and (3) agreed

to participate and were willing to share their experience in applying this intervention. This study focused on children aged 6 - 8 years, representing the early school-age period. This study focused on children aged 6 - 8 years, representing the early school-age period. This focus is driven by the significance of early intervention in ADHD's developmental trajectory and the specific responsiveness of this age group to pediatric *tuina*. Research suggests that early school years are critical for implementing interventions that could substantially alter the course of ADHD, making timely and targeted intervention essential [32]. Furthermore, tactile therapies such as pediatric *tuina* are shown to be highly effective in younger children, who are generally more receptive to such treatments [33].

Data Collection

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

clarified the study's purpose and procedures, and emphasized the confidentiality rules. She also explained the questions and facilitated group interaction by providing prompts and pauses, ensuring that the discussion remained focused without imparting any value judgments. Participation in the study was voluntary,

Textbox 1. Questions for the semistructured interview.

Do you think pediatric tuina has changed or affected your child's eating habits?

Do you think pediatric tuina has changed or affected your child's sleep?

Besides diet and sleep, in what other aspects do you think pediatric tuina has changed or affected your child?

What difficulties did you encounter from learning to performing pediatric tuina?

How do you evaluate the content and process of the pediatric *tuina* treatment for attention-deficit/hyperactivity disorder? What are the advantages and areas for improvement?

not be recorded.

Data Analysis

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

Trustworthiness

This study adhered to the trustworthiness criteria for qualitative research as outlined by Lincoln and Guba [39,40]. For credibility, a semistructured interview guide was developed through 2 group discussions and subsequently pilot-tested during the initial interview session. Purposive sampling was used to select participants capable of providing diverse perspectives and experiences relevant to the intervention delivery. For transferability, the richness of the data was assessed using the

saturation theory [41]. Data collection continued until the point of near exhaustion of new information, which was achieved by the third session [42]. Dependability was maintained through independent coding of the collected data by 2 researchers, complemented by regular debriefing sessions with WFY, an individual with substantial expertise in qualitative research. Finally, participants were provided with the findings, including the code tree and quotations, for their feedback and verification to ensure confirmability. This process aimed to minimize bias and ensure that the intervention reflected the true perspectives and experiences of the participants.

and no individuals other than the participants and researchers

were present during the interviews. Participants were reassured

that, although the sessions were audiotaped, their names would

Results

General Characteristics of Data

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

Sample Profile

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



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

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

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

^bADHD: attention-deficit/hyperactivity disorder.

Major Themes

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



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 Table .
 Code structures.

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

Effects of Parent-Administered Pediatric Tuina

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

Improvements in Children's Eating

Parents observed noticeable improvements in their children's eating habits following the administration of pediatric *tuina*. Many reported an increase in appetite and food intake, as illustrated by one parent who stated, "I think his appetite is better...at least he's willing to eat more, which is an achievement; the most important thing is that he's willing to eat" [Participant 12]. Another parent noted a reduction in the child's resistance to eating: "Normally, if we hurry him to eat, he immediately says he's full, but after doing *tuina*, he says he wants more, and his food intake has increased" [Participant 59].

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XSL•FO RenderX Additionally, some parents observed an improvement in their children's diet structure, with children becoming less picky and more willing to try new foods. A parent shared, "After the pediatric *tuina*, I felt he started eating meat...he even ate fish that he previously didn't eat" [Participant 1]. Improvements in gastrointestinal function were reported, with one parent noting a remarkable change: "His stools have clearly improved, previously they were like small pellets, similar to Maltesers...during the massage period, his stools became much more normal" [Participant 50]. Another parent highlighted the benefits of stomach massages: "I think massaging his stomach helped with bowel movements...his stomach is more relaxed now, it used to be tight, and his belly was cold before, now it's warm" [Participant 40].

Improvements in Children's Sleep

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

Improvements in Other Aspects of Children

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

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a doctor" [Participant 52]. Another parent observed, "Her physical condition has really improved, he eats more, sleeps better, and her weight has increased...she gained a few pounds compared to last semester" [Participant 52]. Bedwetting was reported to have decreased, with one parent stating, "He used to wet the bed, but recently it has decreased" [Participant 43].

Parents' Experience of Performing Pediatric Tuina

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

Advantages of This Intervention Implementation

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

Difficulties Encountered During Implementation

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

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

Parents' Suggestions on Improving the Intervention

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

Discussion

Main Findings

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

Comparison With Previous Studies

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

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

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

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

Implications

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

Limitations

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

Conclusion

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

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Authors' Contributions

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

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Conflicts of Interest

None declared.

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Abbreviations

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

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

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Abstract

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

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

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

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

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

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KEYWORDS

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

Introduction

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

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

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

Methods

Study Design and Population

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



adolescents and young adults with IBD [16]. A qualitative descriptive design was used to explore the perspectives of adolescents and young adults in addition to the outcomes being assessed in the RCT [16,19]. The intervention consisted of (1) an individualized assessment, (2) a transition navigator, (3) patient skill-building delivered via online modules, and (4) a structured education program (see Figure 1 for an overview of the RCT design) [16]. Half of the RCT participants were randomized to the biopsychosocial intervention, and half received a standardized version of routine care for transition

[16]. Adolescents and young adults in the intervention arm received support from a transition navigator. They had access to online skill-building activities and an online education program with topics focused on IBD management, resilience, health care transition, self-efficacy, and stress management for the duration of the study [16]. Though the RCT has 3 study sites at Canadian tertiary care centers, this study explored the perspectives of adolescents and young adults at the study site, which has the largest cohort of participants and has participants who had access to the intervention for the longest duration.

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



In embracing a patient-oriented research approach [18], the study investigators collaborated with a project-specific Youth Advisory Panel (YAP) consisting of 5 patient partners with diverse backgrounds, expertise, and lived experience with IBD. YAP members were recruited from an existing national IBD advisory council. The national IBD advisory council was involved in a previous qualitative study conducted by our team [20]. Subsequently, select advisory panel members expressed the desire to become involved in this study to further explore

and contribute to the qualitative findings. The YAP consisted of 3 male and 2 female members aged 18 - 30 years from across Canada, thereby increasing the study's transferability with enhanced diversity of input and representation of health care experiences. The YAP members actively contributed to data analysis, interpretation, presentation of results, and preparing this article, helping align research findings with patient-identified priorities [18]. This collaborative partnership and bidirectional flow of knowledge helped cultivate a sense

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

Eligibility and Sampling

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

Data Collection

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

Data Analysis

An inductive approach to reflexive thematic analysis [23,24] was used to analyze the data. Interview transcripts were

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

Ethical Considerations

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

Results

Overview

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



Table . Participant characteristics (N=21).

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			Values, n (%)
Demographic characteristi	cs		
	Gender	Densel	12 ((1.0)
		remaie	13 (01.9)
		Male	7 (33.3)
		Nonbinary	1 (4.8)
	Age (years)		
		16	2 (9.5)
		17	15 (71.4)
		18	4 (19.1)
	Ethnicity		
		Black	4 (19)
		South Asian	6 (28.6)
		White	9 (42.9)
		Other or multiracial	2 (9.5)
	Immigration status (par	ticipant)	
		Born in Canada	19 (90.5)
		Immigrated to Canada	2 (9.5)
	Immigration status (par	ents)	
		Born in Canada	7 (33.3)
		Immigrated to Canada	14 (66.7)
	Sexual orientation ^a		
		Bisexual	2 (9.5)
		Gay or lesbian	2 (9.5)
		Heterosexual or straight	15 (71.5)
		Other	2 (9.5)
	Household income of fa	amily of origin (US \$)	
		0 - 49.999	1 (4.8)
		50.000 - 99.999	1 (4.8)
		100 000 - 149 999	3 (14 3)
		150,000 - 199,000	3 (14 3)
		200.000+	3 (14.3)
		I do not know	10 (47 5)
	Study orm	I do not know	10 (47.5)
	Study and	Control arm	10 (47.6)
			10 (47.0)
	Highest layed of many of		11 (32.4)
	righest level of parenta	High school	1 (4 0)
			1 (4.8)
		Some postsecondary	1 (4.8)
		Graduated postsecondary	19 (90.4)
	Vocational status ^b		
		Employed (full or part-time)	6 (28.6)

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

^aResponse categories based on participants' language.

^bMultiple response options were possible.

^cIBDU: inflammatory bowel disease type unclassified.

^dUC: ulcerative colitis.

^eIBD: inflammatory bowel disease.

Theme #1: Making Meaning of Transitions in Care

Overview

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

On one end of the spectrum, adolescents and young adults described the transition to adult care as "an inevitability and a necessity" [C-036] once they were aged 18 years. Participants with this view seemed to understand transition as moving from one specialist to the next, with expectations that care would be delivered similarly. Those who conceptualized this change as primarily related to switching providers without ascribing a deeper philosophical meaning to transition tended to express minimal concerns or worries about entering the adult system. Many of these participants had well-managed IBD or family members (eg, parents or siblings) with IBD who were already receiving treatment in the adult system. As described by 1

XSL∙F() RenderX participant, "For me, it's not a big deal, you're just switching doctors. And it'll just be the same thing over there anyway, so I'm not really stressed out about it." [C-001]. Importantly, however, those with this mindset had not yet transferred or been exposed to the adult care environment.

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

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

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

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

Relationality and Transitions to Adult Care

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

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

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

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

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

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

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

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

Overview

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

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



Knowledge and Preparedness

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

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

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

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

Emotional Support and Validation

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

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



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

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

Confidence and Independence

Adolescents and young adults outlined how the intervention promoted confidence in preparation for adult care. Some adolescents and young adults viewed the skills-building modules as the most relevant and beneficial aspect of the intervention

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

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

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

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

Barriers and Facilitators to Engagement

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

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

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

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

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

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

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

With the modules, I get distracted very easily, so it's been very hard for me to stay on task. I've been struggling to remember since the end of grade 11 to

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

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

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

Theme #3: Considerations for Future Transition Care

Overview

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

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

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

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

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

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

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

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

Recommendations for Refinement of Biopsychosocial Intervention

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

Discussion

Principal Findings

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

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the impact of the biopsychosocial transition intervention, and adolescents' and young adults' viewpoints on future transition care.

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

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

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

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

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

Limitations and Future Directions

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

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

Conclusions

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

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Conflicts of Interest

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

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Abbreviations:

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



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Evaluating the Impact of Pediatric Digital Mental Health Care on Caregiver Burnout and Absenteeism: Longitudinal Observational Study

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Abstract

Background: Caregivers of children with mental health challenges are at heightened risk for burnout and absenteeism. This strain affects both their well-being and work performance, contributing to widespread workplace issues. Digital mental health interventions (DMHIs) are increasingly used to support pediatric mental health, but their impact on caregiver outcomes remains underexplored.

Objective: This study aimed to explore the associations between caregiver burnout, absenteeism (ie, missing work), comorbid symptoms, and child mental health problems, and to assess whether caregiver burnout and absenteeism improved as their child participated in a pediatric DMHI.

Methods: This retrospective study included 6506 caregivers whose children (aged 1 - 17 years) received care from Bend Health, Inc, a pediatric DMHI providing digital-based therapy and coaching, digital content, and caregiver support. Caregiver burnout, absenteeism, comorbid symptoms, and child mental health symptoms were measured by monthly assessments. Cumulative link models were used to assess the associations of between child symptoms and caregiver outcomes and to assess changes in caregiver outcomes over the course of the DMHI. Analyses of baseline associations included the full sample (n=6506), while analyses of pre-post changes in caregiver outcomes were conducted in caregivers with elevated burnout (n=2121) and absenteeism (n=1327) who had an assessment after starting care.

Results: At baseline, 45.96% (2990/6506) of caregivers reported elevated burnout and 28.96% (1884/6506) reported elevated absenteeism. More severe burnout was associated with having a child with elevated symptoms of any type (all *P*<.01). More severe absenteeism was significantly associated with having a child with elevated symptoms of depression (z=3.33; *P*<.001), anxiety (z=3.96; *P*<.001), inattention (z=2.48; *P*=.013), and hyperactivity (z=2.12; *P*=.03). Burnout decreased for 68.64% (1456/2121) and absenteeism decreased for 87.26% (1158/1327). Greater months in care was associated with less severe caregiver burnout (z=-5.48; *P*<.001) and absenteeism (z=-6.74; *P*<.001).

Conclusions: DMHIs for children may reduce caregiver burnout and absenteeism. These findings emphasize the value of employers offering pediatric DMHIs as part of employee benefits, potentially enhancing workplace outcomes.

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KEYWORDS

digital mental health intervention; mental health; mental illnesses; mental disorders; child behavioral health; child behavior; workplace outcomes; pediatrics; children; youth; adolescents; adolescence; teenagers; digital; digital health; digital technology; digital interventions

Introduction

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Children and adolescents in the United States aged 3-17 years are experiencing record levels of mental and behavioral health issues such as anxiety, depression, and attention-deficit/hyperactivity disorder (ADHD), which can contribute to increased stress, fatigue, sleep disturbances, and overall strain on family well-being [1,2]. Alongside the decline of pediatric mental health in recent years, fewer caregivers have reported that they are coping with the demands of parenting,

citing increased emotional distress, worry, feelings of helplessness, and family strain [2-5]. As a response to the crisis in caregiver mental health and well-being, the US Surgeon General issued a 2024 advisory calling for greater support for parent and caregiver mental health to improve family well-being [4].

There is substantial evidence that caregivers of children with mental health challenges are particularly vulnerable to poor mental health outcomes, as they work to meet their children's complex needs [6,7]. Caregivers whose children experience emotional and behavioral problems are under additional strain, as they frequently experience elevated parental stress, fatigue, and poor sleep [6-11]. This degradation of caregiver well-being ultimately spills into different areas of life [12], including both family and professional responsibilities.

In a survey of parents who were concerned about their children's mental health, 48% said that their concerns impacted their performance at work in some way-including challenges such as frequent disruptions during the workday and difficulty concentrating on the job [13]. Caregivers may also have to miss work, given the need to take time off for their child's medical appointments, as well as to tend to their own recuperation and care [13,14]. For example, 46% of caregivers of a child with ADHD reported reducing their weekly work hours, and 11% stopped working altogether after their child's diagnosis [15]. Burnout and absenteeism impact both caregivers and employers, leading to reduced work performance, higher employee turnover, and significant productivity costs [16,17]. Thus, the issue of caregiver well-being is critical for society as a whole, including the health care system, individuals and families, and also businesses. Given evidence suggesting the deterioration of caregiver workplace outcomes associated with caring for a child with mental health challenges, there is a need for effective treatments for both child and caregiver well-being.

Digital mental health interventions (DMHIs) in academic and commercial settings have proven effective in treating common mental and behavioral health problems in children [18-22], offering accessible and cost-effective solutions compared with standard care [23,24]. Our previous research demonstrates that a commercially available DMHI can effectively improve mental health in children and adolescents [18,19]. Additionally, multiple systematic reviews highlight DMHIs as a highly promising solution for youth mental health [20,21]. More recently, a digital platform integrating both asynchronous and synchronous support successfully reduced anxiety and depression in a large sample of Australian youth [22]. Although these interventions primarily focus on the child, our previous findings suggest that caregivers may experience secondary benefits (eg, improvements in sleep and stress) when their children receive care through a pediatric DMHI [10]. However, the impact of pediatric DMHIs on caregiver burnout and absenteeism remains underexplored. This gap in knowledge is critical, as understanding caregiver well-being is essential to supporting their ability to manage both their child's treatment and their own work and personal responsibilities effectively.

Using retrospective analyses, the purpose of this study was to (1) explore associations between caregiver burnout, absenteeism,

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comorbid symptoms, and child mental health problems among caregivers seeking mental health treatment for their children, and (2) assess whether caregiver burnout and absenteeism improved while their child participates in a pediatric DMHI.

Methods

Design and Participants

This study is part of a broader research effort examining the impact of a pediatric DMHI on child and caregiver outcomes. While we have published other analyses among youth and caregivers who participate in care with Bend Health [10,18,19,25], this is the first study to specifically assess the relationship between child mental health challenges and caregiver workplace outcomes (absenteeism and burnout). Caregivers of children (aged 1-17 years) participating in care with Bend Health, Inc, a collaborative care pediatric DMHI, were eligible for inclusion in this study if (1) they completed the caregiver assessments (burnout, absenteeism, sleep problems, and parental stress) at baseline (before the start of care), and (2) their child attended at least 1 session with a Bend Health practitioner (behavioral care manager [BCM], behavioral health coach [coach], or therapist) between January 1, 2023, and September 16, 2024. A total of 6508 caregivers were eligible for inclusion.

Ethical Considerations

Caregivers provide informed consent during enrollment in care with Bend Health, Inc, for primary data collection required for regular participation in care and they also agree to the use of their data in further analyses. Caregivers agree to these terms on behalf of their children and themselves, and adolescents (aged 13-17 years) also assent on their own behalf. For the purposes of this study, only deidentified data were used. There was no compensation for participation in this study because the analysis was retrospective. Study procedures were approved by the Biomedical Research Alliance of New York (Study 23-12-034-1374; approved June 5, 2023). No portion of this manuscript used generative artificial intelligence for development or writing.

Treatment

Bend Health, Inc, is a collaborative care DMHI, which delivers comprehensive mental health care to members (aged 1-17 years) and their caregivers. Care with Bend Health is described elsewhere in more detail [18,19]. Briefly, members can enroll via referral from their primary care provider, via insurance or employer benefits, or through direct-to-consumer channels. After enrollment in the web-based platform, a BCM is assigned to each member to coordinate care and communicate with external providers (eg, primary care providers), per the collaborative care model. The BCM assembles the care team, assigning a coach, and sometimes a therapist, based on coverage and each member's unique needs, and then they continue to oversee each member's care. Module-based care programs are assigned to each member to directly address a particular symptom domain (eg, anxiety or depression) and in an age-appropriate manner. In synchronous video-based sessions, the practitioners on a member's care team deliver

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evidence-based care as aligned with the care plan. Members may attend multiple sessions monthly with their care team, and they may also receive care from a psychiatric provider if medication management is referred. While care with the DMHI targets the pediatric member, caregivers are closely involved in care and may receive mental health and behavior change tools to implement personally or in their interactions with their child or adolescent. Caregivers are required to attend sessions for safety reasons if their child is younger than 13 years.

Measures

The member's (ie, the child's) demographic information, including the date of birth, sex at birth (male, female, or other), gender (male, female, transgender, nonbinary, or other), and race or ethnicity, is provided by caregivers at enrollment with Bend Health, Inc. The race or ethnicity options are specified in Textbox 1. Starting May 26, 2023, the options were expanded to be more inclusive of a diverse population, and multiple responses were allowed.

Textbox 1. Race or ethnicity response options during enrollment, including options added to the demographic questions partway through the study period.

Eth	Ethnicity response options				
•	American Indian or Alaska Native				
•	Asian				
•	Black or African American				
•	Hispanic or Latino				
•	Native Hawaiian or other Pacific Islander				
•	White				
•	Other (removed from the list of options starting May 26, 2023)				
•	Chinese (added to the list of options starting May 26, 2023)				
•	Vietnamese (added to the list of options starting May 26, 2023)				
•	Filipino (added to the list of options starting May 26, 2023)				
•	Korean (added to the list of options starting May 26, 2023)				
•	Japanese (added to the list of options starting May 26, 2023)				
•	Chamorro (added to the list of options starting May 26, 2023)				
•	Other Asian (added to the list of options starting May 26, 2023)				
•	Some other race or multi-racial (added to the list of options starting May 26, 2023)				
•	Mexican, Mexican Am, Chicano (added to the list of options starting May 26, 2023)				
•	Puerto Rican (added to the list of options starting May 26, 2023)				
•	Cuban (added to the list of options starting May 26, 2023)				
•	Another Hispanic, Latino, or Spanish origin (added to the list of options starting May 26, 2023)				

As part of care at Bend, caregivers and adolescents (aged 13-17 years) complete mental health assessments during enrollment, and they also complete follow-up assessments every month during care to measure both caregiver and member symptoms. Caregivers complete assessments to measure caregiver burnout, absenteeism (missing work), sleep problems, and parental stress, as well as inattention, hyperactivity, and oppositional symptoms for their child or adolescent (caregiver report). Caregivers of children (aged 1-12 years) also complete assessments to measure their child's anxiety, depressive symptoms, and sleep problems (caregiver report). Adolescents (aged 13-17 years) complete their own assessments to measure anxiety, depression, and sleep problems (self-report).

For all assessments except burnout, screener items are used to flag symptoms requiring further assessment. When responses to the screener items are flagged (indicating probable symptoms), the caregiver or the adolescent screens-in and completes a full validated assessment. In 2024, Bend Health's method of screening-in to the validated assessments changed. From January 1, 2023, to January 22, 2023, caregivers and adolescents completed all screeners at each assessment, followed by validated assessments based on screener responses. From January 23, 2024, onward, if an assessment is screened-in, all following assessments for that symptom are automatically screened-in. From January 23, 2024, to August 9, 2024, screeners were not taken if past assessments were screened-in. From August 9, 2024, onward, screeners were taken in addition to validated assessments when past assessments were screened-in. Once all assessments are completed (after approximately 5-25 minutes), the caregiver and child or adolescent are shown a summary of their results, including an indication of whether any symptoms were mild to severe. The assessment results are also viewed by BCMs and the care team to monitor treatment progress and make adjustments to the care plan, as necessary.

Caregiver Symptoms

Caregiver symptoms were assessed using Bend Health's regular symptom assessments, which measure a caregiver's well-being while their child is in care. To assess caregivers' work burnout, caregivers respond to a single question [16,26]: "Overall, based on your definition of burnout, how would you rate your level of burnout?" Caregivers respond using the following options: (1) "I enjoy my work. I have no symptoms of burnout" (no burnout), (2) "Occasionally I am under stress, and I don't always have as much energy as I once did, but I don't feel burned out" (low burnout), (3) "I am definitely burning out and have one or more symptoms of burnout such as physical and emotional exhaustion" (mild burnout), (4) "The symptoms of burnout that I'm experiencing won't go away. I think about frustration at work a lot" (moderate burnout), and (5) "I feel completely burned out and often wonder if I can go on. I am at the point where I may need some changes or may need to seek some sort of help" (severe burnout). Studies have demonstrated that this single-time burnout measure is valid and reliable [26-28]. This item has demonstrated good concurrent validity with the emotional exhaustion subscale of the Maslach Burnout Inventory, supporting its reliability in assessing burnout [29].

To assess caregivers' work absenteeism, defined as missing full or partial days of work, caregivers are asked the screening question: "During the past four (4) weeks, have you missed part of or an entire day of work? Have you had to come in early, go home late or work on your day off?" Responses are "Yes" or "No," and caregivers are prompted to complete section B5 of the Health and Work Performance Questionnaire (HPQ) if they respond "Yes" [30]. B5 of the HPQ includes 5 items asking the number of days (range: 0-28) in the past 4 weeks that the caregiver (1) missed an entire day of work due to problems with their own physical or mental health, (2) missed an entire day of work for any other reason (including vacation), (3) missed part of a workday due to problems with their own physical or mental health, (4) missed part of a workday for any other reason (including vacation), and (5) came in early, went home late, or worked on a day off (extended workdays). The final item is not used to assess absenteeism and thus was not considered in this study. Section B5 of the HPQ has demonstrated good validity, showing strong correlations with objective measures of work performance and self-reported job performance [30].

To assess caregiver sleep problems, caregivers are asked to respond to the screener question: "During the past two (2) weeks, how much (or how often) have you had problems sleeping—that is, trouble falling asleep, staying asleep, or waking up too early?" Responses are on a 5-item Likert-type scale (0=Not at all, 4=Nearly every day). If the response is 2 or greater, the caregiver completes the Insomnia Severity Index (ISI), which includes 7 items about sleep difficulties [31]. Responses to each question are on a 5-item Likert-type scale (0=None, 5=Very severe). The ISI shows strong validity, correlating well with clinician-rated insomnia and sleep diary measures [31].

To assess parental stress, caregivers complete the Parental Stress Scale (PSS) [32], which queries a caregiver's feelings about their caregiving responsibilities and their relationship with their

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child or children. First, they respond to the following 2 items from the PSS: "The major source of stress in my life is my child" and "Having a child leaves little time and flexibility in my life." Best-fit responses are selected on a 5-item Likert-type scale (1=Strongly disagree, 5=Strongly agree). If the response to either question is 3 (undecided) or greater, the caregiver completes the remaining 16 items of the PSS. Some items on the PSS are framed as a negative caregiving experience (eg, "Having children has been a financial burden"), with greater responses indicating more severe parental stress. Other items are framed as a positive caregiving experience (eg, "I am happy in my role as a parent"), with greater responses indicating less severe parental stress (reverse items). The PSS shows good validity, correlating strongly with related measures of parental stress and well-being [32].

Child and Adolescent Mental Health Symptoms

All assessments of mental health for children (aged 1-12 years) are completed by the caregiver (caregiver report), including assessments of anxiety, depression, sleep problems, ADHD symptoms (inattention, hyperactivity, and opposition), and sleep problems. Adolescents (aged 13-17 years) complete their own assessments of anxiety, depression, and sleep problems (self-report), but their caregivers complete the assessment for ADHD, given the need for proxy report on these symptoms. For all assessments, the reporter (caregiver or self) responds to a few screening items to flag mental health symptoms. If mental health symptoms are flagged by these screeners, the reporter completes a full validated assessment to further quantify outcomes.

For child symptoms of anxiety, depression, and sleep problems, caregivers of children respond to screener items from the Diagnostic and Statistical Manual of Mental Disorders (Fifth Edition, Text Revision) (DSM-V-TR) Cross-Cutting Symptom Measure screeners [33]. If a response of 2 or greater is given to any screener, they complete the corresponding PROMIS (Patient-Reported Outcomes Measurement Information System) anxiety, depression, or sleep assessment [34]. Responses to the anxiety and depression PROMIS assessments are made using a 5-item Likert scale, with greater response values always indicating more severe or frequent symptoms (1=Never, 5=Almost always). Responses to the sleep PROMIS assessment are made using different 5-item Likert scales (depending on the question; eg, 1=Not at all, 5=Very much), with greater responses on some items indicating more severe or frequent symptoms and greater responses on other items indicating less severe or infrequent symptoms (reverse items).

For adolescent symptoms of anxiety, depression, and sleep problems, adolescents respond to items derived from the following respective screeners: Generalized Anxiety Disorder 2-item (anxiety) [35], Patient Health Questionnaire 2-item (depression) [36], and *DSM-V-TR* Cross-Cutting Symptom Measure screener for sleep (sleep problems) [33]. If there is an aggregate screener score of 2 or greater, they complete the corresponding validated assessment. For anxiety symptoms, adolescents complete the full Generalized Anxiety Disorder 7-item (GAD-7) [35]. For depressive symptoms, adolescents complete a version of the Patient Health Questionnaire 9-item

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that is modified for adolescents (PHQ-9A), excluding the item about suicidal ideation [36]. For sleep problems, adolescents complete the self-report version of the PROMIS sleep assessment [37], which includes the same items as the caregiver report version used for children.

For child and adolescent symptoms of ADHD, caregivers respond to 2 DSM-V-TR Cross-Cutting Symptom Measure items to screen for symptoms of inattention and hyperactivity (1 question) and opposition (1 question) [33]. If symptoms are flagged given responses to these screeners, caregivers complete all of or some of the subsets of the Swanson Nolan and Pelham Rating Scale version 4 (SNAP-IV) assessment [35], which includes 3 groups of questions measuring symptoms of inattention (items 1 - 9), hyperactivity (items 10 - 18), and opposition (items 19 - 26). Responses to all items are on a Likert scale from 0 (Not at all) to 3 (Very much). From January 1, 2023, to March 31, 2024, a score of 1 or greater to the screener about inattention and hyperactivity prompted the completion of only the inattention and hyperactivity items, and a score of 1 or greater to the screener about opposition prompted the completion of only the opposition items [6]. Beginning April 1, 2024, caregivers complete all 26 questions of the SNAP-IV if their response to either screening question is 1 or greater. See the Multimedia Appendix 1 for further details on all measures used.

Outcome Calculations

Caregiver outcomes were calculated as follows. Using established criteria [27], elevated burnout was defined as a burnout score of 3 or more (mild to severe burnout). For absenteeism, reported partial days of work missed (items 3 and 4) were considered 0.5 days missed, so days of work missed was calculated as the sum of the number of full days missed (items 1 and 2) plus the sum of the number of partial days missed: item response 1 + item response 2+ (0.5 \times (item response 3+ item response 4)). If the absenteeism assessment was screened-out, the number of days of work missed was 0. If the number of days of work missed exceeded 28, this value was replaced with 28. Given that the standard work week is five 8-hour days, severity of absenteeism was determined as follows: "No missed work" (screen-out or days of work missed is 0), "Missed less than one week of work" (days of work missed is 0.5-4.5), "Missed one to two weeks of work" (days of work missed is 5-9.5), "Missed two to three weeks of work" (days of work missed is 10-14.5), and "Missed three or greater weeks of work" (days of work missed is 15 or greater). Elevated absenteeism was considered missing work for 0.5 days or greater in the past 28 days. Caregiver sleep score was calculated by aggregating the responses to all 7 ISI items, for a total score of 0-28. Elevated sleep problems were considered moderate severity or severe insomnia symptoms, per the defined ranges of clinically significant sleep problems [31]. Parental stress was calculated by aggregating responses to the 18 items (with scores reversed for the reverse items), for a total score of 18-90. Elevated parental stress was considered a score of 42 or greater, given severity thresholds used by others [38,39].

Child and adolescent mental health outcomes were calculated as follows. Child anxiety and depressive symptom scores, as

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well as child and adolescent sleep scores, were calculated by aggregating the responses to the respective PROMIS assessments (with scores reversed for the reverse items) and then converting these total scores to *T*-scores using standardized conversion criteria [34,37,40]. Adolescent anxiety scores were calculated by aggregating responses to the GAD-7 [35]. Adolescent depression raw scores were calculated by aggregating responses to the nultiplied by 9, divided by 8, and rounded to the nearest whole number to account for the single omitted item. Inattention, hyperactivity, and oppositional symptom scores were calculated by aggregating the responses to the items in each of the symptom subsets of the SNAP-IV [41]. Symptom severity was determined for all child and adolescent symptoms using previously defined criteria [34,37,39,41-43].

For all analyses, caregiver burnout was reported based on response to the single item, and caregiver absenteeism was reported as severity of absenteeism and number of days of work missed. We chose this analytic approach to ensure that results are robust to minor changes to the screening and assessment methods (Multimedia Appendix 1). Therefore, for all outcomes except caregiver burnout and workplace absenteeism, symptom severity was analyzed as "elevated" or "not elevated." For all symptoms except caregiver burnout, absenteeism, and parental stress, outcomes were classified as elevated if symptom severity was moderate to severe, and not elevated if the assessment was screened out or symptom severity was low to mild. A decrease in burnout or absenteeism from baseline (first assessment) was defined as a decrease in burnout score or a decrease in number of days of work missed, respectively.

Statistical Analysis

Caregiver Burnout and Workplace Absenteeism at Baseline

Caregiver outcomes at baseline (first assessment before beginning care with the DMHI) were analyzed for all caregivers with complete caregiver assessments (n=6508). Caregivers with duplicate baseline assessments (n=2) were removed for a sample size of 6506. The following characteristics were described for these caregivers: mean child age (at baseline), child sex, child race or ethnicity, type of participation with the DMHI (BCM intake only, coaching only, coaching and therapy, or therapy only), and duration of participation with the DMHI (first event to last event). Burnout and absenteeism scores were reported, as well as group trends for the number of days of work missed. Cumulative link models (CLMs) were used to assess whether workplace outcomes were associated with caregiver's comorbid symptoms. For burnout, the predictors were elevated absenteeism, elevated sleep problems, and elevated parental stress. For absenteeism, the predictors were elevated burnout, elevated sleep problems, and elevated parental stress. Child (child and adolescent, grouped for analyses) characteristics and mental health symptoms were assessed to identify associations between predictors and caregiver burnout and workplace absenteeism. Only caregivers of children and adolescents aged 6 years or older (given age validation for pediatric assessments) and whose child had all mental health assessments complete were included in analyses (n=5628; Multimedia Appendix 1).

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CLMs were used to determine whether the following child characteristics and mental health symptoms were associated with the severity of caregiver workplace outcomes (burnout and absenteeism): age (child vs teen), sex (female vs nonfemale), elevated depression, elevated anxiety, elevated inattention, elevated hyperactivity, elevated opposition, and elevated sleep problems.

Change in Caregiver Burnout and Workplace Absenteeism

Change in caregiver burnout and workplace absenteeism over their child's care with the DMHI was assessed for caregivers with elevated burnout and elevated workplace absenteeism at baseline who also met the following inclusion criteria: baseline assessment completed within 2 months of beginning care with the DMHI (ie, for an accurate assessment of mental health status at care start), and had at least 1 completed follow-up assessment after the start of care with the DMHI (see Multimedia Appendix 1 for details on exclusions). Ultimately, 2121 were included in the analyses for change in burnout and 1327 were included in the analyses for change in absenteeism. Percentages of caregivers with a decrease and increase in workplace symptoms- for both burnout and absenteeism (number of days of work missed)-were reported for the caregivers' first follow-up assessment during care as well as their last follow-up assessment during care. Percentages of caregivers with elevated workplace outcomes at these time points were also reported, and the percentages of caregivers with a decrease in workplace symptoms reported at any time during care were reported. Finally, percentages of caregivers with nonelevated workplace symptoms at baseline and elevated workplace symptoms at the last follow-up were reported. For absenteeism, reported decreases in the number of days worked were compared with zero using Wilcoxon signed rank tests.

For caregivers of a child with elevated mental health symptoms at baseline, the maximal percent decrease in child mental health symptom severity during care was calculated. The maximal decrease in child's mental health symptom severity was compared between groups using Wilcoxon signed rank sums tests for caregivers with a decrease in workplace symptoms versus those with no decrease in workplace symptoms at last follow-up. Only caregivers of a child with elevated symptoms at baseline and a follow-up assessment after the start of care were included in these analyses (Multimedia Appendix 1; n=1739 included in burnout and n=1041 included in absenteeism).

CLMs were used to determine whether months in care were associated with lower severity of burnout and absenteeism, and comorbid caregiver symptoms, child characteristics, and child mental health symptoms were assessed as potential covariates in these models. The basic model for each workplace symptom included months in care as a fixed effect. Likelihood ratio tests were used to compare this basic model with an identical model including a single potential covariate added as a fixed effect. The potential covariates assessed were elevated comorbid caregiver symptoms, child's age group (child vs teen), child's sex (female vs nonfemale), and child's mental health symptoms. Only predictors that significantly improved model fit were

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retained in the final model (see Multimedia Appendix 1 for comprehensive results from likelihood ratio tests). For burnout, all comorbid caregiver symptoms were retained, as well as child sex, and all child mental health symptoms. For absenteeism, all comorbid caregiver symptoms were retained, as well as the following child mental health symptoms: depression, anxiety, inattention, hyperactivity, and sleep. Only assessments taken after beginning care with the DMHI were considered in the CLMs.

For all CLMs, coefficient estimates were used to determine whether each predictor was associated with the severity of workplace symptoms. Throughout, the alpha-level was set to .05 for all analyses. Standard descriptive statistics (percentages; mean, SD; and median, IQR were used to describe data. Data were analyzed with RStudio (version 2023.03.0+386; Posit, PBC) [44].

Results

Overview

Overall, caregivers included in the analyses (N=6506) cared for children with a mean age of 10.58 (SD 3.81) years, and 49.86% (3244) of the children were female. In terms of reported race and ethnicity, 50.63% (3294) were white and 32.02% (2083) identified as "Other" or multiple race and ethnicity options. While all children had at least 1 session with a Bend Health practitioner, 16.25% (1057) completed only their BCM intake session, 59.67% (3882) were in coaching only, 22.69% (1476) were in coaching and therapy, and 1.40% (91) were in therapy only. The duration of participation in care with the DMHI was a median of 3.46 (1.7 - 5.9) months.

Caregiver Burnout and Workplace Absenteeism at Baseline

At baseline, 8.84% of caregivers (575) reported no symptoms of burnout, 45.20% (2941) reported low burnout, 33.60% (2186) reported mild burnout, 6.87% (447) reported moderate burnout, and 5.49% (357) reported severe burnout. In terms of absenteeism, 71.04% (4622) reported no missed work, 17.05% (1109) missed less than 1 week of work, 7.49% (487) missed 1-2 weeks of work, 2.29% (149) missed 2-3 weeks of work, and 2.14% (139) missed 3 or greater weeks of work. For those with any absenteeism (n=1884), they reported a median of 4 (2-7) days missed.

In terms of percentages of caregivers with elevated outcomes at baseline, 45.96% (2990) had elevated burnout, 28.96% (1884) had elevated absenteeism, 12.76% (830) had elevated sleep problems, and 17.57% (1143) had elevated parental stress. More severe levels of burnout were significantly associated with elevated absenteeism (z=15.30; P<.001), elevated sleep problems (z=20.41; P<.001), and elevated parental stress (z=15.30; P<.001). This same pattern was observed for severity of absenteeism; greater absenteeism was associated with elevated caregiver outcome severity of all types (all P<.001; Table 1).

More severe symptoms of burnout were significantly associated with having a younger child (child vs adolescent; z=3.20; P=.001), as well as having a child with elevated symptoms of

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any type (all P<.01). Child sex was not associated with the severity of burnout symptoms. More severe absenteeism was associated with having a child with elevated symptoms of depression (*z*=3.33; *P*<.001), anxiety (*z*=3.96; *P*<.001), inattention (*z*=2.48; *P*=.01), and hyperactivity (*z*=2.12; *P*=.03).

Child age and sex, as well as opposition and sleep problems, were not associated with the severity of absenteeism. Comprehensive results for all predictors in these analyses are reported in Table 2.

Table .	Results from analyses	assessing whether the	severity of caregive	r symptoms is associated	with elevated comorbid	caregiver symptoms.
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Outcome (caregiver out- come severity)	Predictor (elevated comor- bid caregiver symptom)	Estimate (SE)	z value	<i>P</i> value
Burnout	Absenteeism	0.81 (0.05)	15.30	<.001
	Sleep problems	1.49 (0.07)	20.41	<.001
	Parental stress	1.44 (0.06)	20.39	<.001
Absenteeism	Burnout	0.83 (0.06)	13.96	<.001
	Sleep problems	0.56 (0.08)	7.24	<.001
	Parental stress	0.35 (0.07)	5.07	<.001

Table . Results from analyses assessing whether the severity of caregiver symptoms is associated with their child's characteristics (demographics and symptoms).

Outcome (caregiver symp- tom severity)	Predictor (child's character- istic)	Estimate (SE)	z value	<i>P</i> value
Burnout	Age (child aged 6-12 years)	0.18 (0.06)	3.20	.001
	Sex (female)	-0.03 (0.05)	-0.59	.56
	Depression (elevated)	0.19 (0.06)	3.03	.002
	Anxiety (elevated)	0.27 (0.06)	4.81	<.001
	Inattention (elevated)	0.43 (0.06)	7.01	<.001
	Hyperactivity (elevated)	0.26 (0.08)	3.23	.001
	Opposition (elevated)	0.46 (0.06)	7.23	<.001
	Sleep problems (elevated)	0.25 (0.05)	4.58	<.001
Absenteeism	Age (child aged 6-12 years)	0.07 (0.06)	1.11	.27
	Sex (female)	0.02 (0.06)	0.34	.74
	Depression (elevated)	0.24 (0.07)	3.33	<.001
	Anxiety (elevated)	0.26 (0.07)	3.96	<.001
	Inattention (elevated)	0.18 (0.07)	2.48	.01
	Hyperactivity (elevated)	0.20 (0.09)	2.12	.03
	Opposition (elevated)	0.11 (0.07)	1.51	.13
	Sleep problems (elevated)	0.10 (0.06)	1.57	.12

Change in Caregiver Burnout and Workplace Absenteeism

For 2121 caregivers with elevated burnout at baseline and a follow-up assessment after beginning care, the first-follow-up was completed after a median of 0.90 months (0.66 - 1.13) in care with the DMHI. At this time, 49.88% (1058/2121) of caregivers with elevated burnout at baseline had a decrease in burnout symptom severity, 7.97% (169/2121) had an increase in severity, and 62.47% (1325/2121) still had elevated burnout. At the last follow-up assessment during care with the DMHI, taken after a median of 2.80 months (1.27 - 5.40) in care, 56.58% (1200/2121) of caregivers with elevated burnout at baseline had a decrease in burnout at baseline had a decrease in burnout symptom severity, 6.74%

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(143/2121) had an increase in severity, and 54.17% (1149/2121) still had elevated burnout. The percentages of burnout severity at baseline and last follow-up are reported in Figure 1. Overall, 68.64% (1456/2121) of caregivers reported a decrease in burnout at any point during care, with the first decrease reported after a median of 1.10 months (0.80 - 1.97). At the last follow-up, children of caregivers with a decrease in burnout (n=977) had larger improvements in their own mental health than children of caregivers with no decrease in burnout (n=762; median -65.63%, IQR -100.00 to -40.00 vs median -52.51%, IQR -95.81 to -28.57; z=-5.22; P<.001). For caregivers with nonelevated burnout at baseline, 9.61% (338/3178) met the criteria for elevated burnout at their last follow-up during care.

Figure 1. Burnout symptom severity for caregivers with elevated burnout at baseline and a follow-up assessment (n=2121) reported for the baseline and last follow-up assessments.

In the analysis of burnout symptom severity during care with the DMHI, greater months in care was significantly associated with less severe symptoms of burnout (z=-5.76; P<.001). All elevated comorbid caregiver symptoms were associated with more severe burnout during care (all P<.001). The following child characteristics were associated with more severe symptoms of burnout: female sex (z=4.50; P<.001), elevated depression (z=2.01; P=.04), elevated hyperactivity (z=3.05; P=.002), and elevated sleep problems (z=4.18; P<.001). Child anxiety, inattention, and opposition were not associated with caregiver burnout during care (both P>.10).

At the first follow-up assessment during care with the DMHI, taken after a median of 0.93 months (0.70 - 1.20) in care, 73.25% (972/1327) of caregivers with elevated absenteeism at baseline had a decrease in number of days of work missed, 22.08% (293/1327) had an increase in days of work missed, and 60.14% (798/1327) still had elevated absenteeism. At the last follow-up assessment during care with the DMHI, taken after a median of 2.97 months (1.37 - 5.45) in care, 76.56% (1016/1327) of caregivers with elevated absenteeism at baseline had a decrease in absenteeism, 19.22% (255/1327) had an increase in absenteeism, and 52.75% (700/1327) still had elevated absenteeism. The percentages of amount of work missed at baseline and last follow-up are reported in Figure 2.

Overall, 87.26% (1158/1327) of caregivers reported a decrease in absenteeism at any point during care, with the first decrease reported after a median of 1.00 months (0.76 - 1.57). Caregivers with elevated absenteeism at baseline had a median decrease of 2 (4-0) days of work missed at first follow-up (z=-17.9; P<.001), and 2 (4.5-.5) fewer days of work at last follow-up (z=-19.2; P<.001). At the last follow-up, children of caregivers with a decrease in absenteeism (n=802) had larger improvements in their own mental health than children of caregivers with no decrease in absenteeism (n=239; median -64.29%, IQR -100.00 to -39.13 vs median -57.14%, IQR -91.75 to -28.57; z=-2.65; P=.008). For caregivers with nonelevated absenteeism at baseline, 10.95% (506/4622) reported missing any amount of work at their last follow-up during care.

In the analysis of change in absenteeism over time, greater months in care was significantly associated with lower levels of absenteeism (z=-6.72; P<.001). Elevated comorbid burnout significantly associated with higher levels of absenteeism during care (z=6.89; P<.001) and elevated child anxiety was marginally associated with higher levels of absenteeism (z=1.75; P=.08). Elevated comorbid sleep and elevated comorbid stress, as well as having a child with elevated depression, inattention, hyperactivity, and sleep, were not associated with absenteeism during care.

Figure 2. Amount of work missed for caregivers with elevated absenteeism at baseline and a follow-up assessment (n=1327) reported for the baseline and last follow-up assessments.

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Discussion

Principal Results

Using retrospective analysis, the purpose of this study was to (1) explore associations between caregiver burnout, absenteeism, comorbid symptoms, and child mental health problems among caregivers seeking mental health treatment for their children, and (2) assess whether caregiver burnout and absenteeism improved while their child participates in a pediatric DMHI.

Before beginning care with the DMHI, 46% (2990/6506) of caregivers had elevated burnout and 29% (1884/5606) had elevated workplace absenteeism. Child characteristics and mental health symptom presentation were significantly associated with their caregiver's workplace symptoms. Furthermore, while their child participated in care, 69% (1456/2121) of caregivers reported a decrease in burnout and 87% (1158/1327) reported a decrease in absenteeism. These changes were notable after only 1 month in care, with 50% (1058/2121) of caregivers reporting reduced burnout, and nearly 3 in 4 (972/1327, 73%) reporting a reduction in the number of days of work missed. Greater time in the DMHI significantly associated with less severe workplace symptoms, and children of caregivers with improvement in workplace symptoms reported larger improvements in pediatric outcomes than those whose caregiver did have improvement in workplace symptoms.

We found that symptoms of elevated burnout and workplace absenteeism were prevalent in caregivers before starting care with the pediatric DMHI, as almost half and about one-third reported elevated burnout and absenteeism, respectively. It is well known that workplace burnout and absenteeism, which are at historic highs [45,46], are perpetuated by family-related stress, particularly a child's mental health difficulties [14,47-51]. Parents spend a significant amount of time managing their children's mental and behavioral health needs, which is exacerbated by lack of access to and knowledge of evidence-based mental health treatment options for their children [48,52]. Thus, it is unsurprising that percentages of burnout (2990/6506, 46%) and workplace absenteeism (1884/6506, 29%) were high among caregivers actively seeking treatment for their child's mental health challenges.

Burnout was higher among those caring for a child with any elevated mental health symptom severity, and absenteeism was higher among those caring for a child with elevated internalizing (ie, anxiety and depression), inattention, and hyperactivity symptoms. These findings align with previous literature suggesting a reciprocal relationship, where a child's mental health challenges exacerbate caregiver sleep problems and stress [53,54], which can contribute to caregiver burnout and absenteeism [55-57]. In turn, while some studies highlight the additional burden of parenting a child with mental health and behavioral challenges [6-9,11,58], caregiver burnout may exacerbate child mental health challenges by reducing the caregiver's capacity to provide emotional support and consistent care [59,60]. Given the complex bidirectional relationship between child-caregiver well-being [54], it is critical to highlight interventions that may produce benefit for both caregivers and their children. As the first study to examine both caregiver

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absenteeism and burnout across multiple child mental health challenges, this work builds on prior studies that have focused on single conditions (eg, ADHD and autism) or isolated workplace outcomes [15], contributing to a broader understanding of the link between caregiver and child well-being.

While children were in care with the DMHI, their caregivers exhibited significant improvements in workplace symptoms. Burnout decreased in 69% (1456/2121) of caregivers and absenteeism decreased in 87% (1158/1327) at any point during care, with caregivers reporting that they missed 2 fewer days of work at the end of their child's care than initially reported at baseline. Other studies have reported that caregivers whose children engage in traditional modes of mental and behavioral health care evince corresponding improvements, such as decreases in parental stress, sleep problems, anxiety, and depression [61,62]. In a study of caregivers and youth participating in a DMHI, Grodberg et al [48] found that increases in caregiver productivity throughout care were linked to increases in caregivers' feelings of connectedness to their children. Similarly, our recent evidence also suggests that caregivers whose children engage in a pediatric DMHI report decreased parental stress and sleep problems [10]. The present findings extend this work by demonstrating that these caregiver benefits also translate into occupational outcomes, with greater time in care associated with reductions in both burnout and absenteeism. Notably, improvements in caregiver workplace symptoms were associated with larger improvements in child mental health symptoms during care. These results are largely in-line with the broader literature that indicates a bidirectional relationship between caregiver and child well-being [53-57]. Our findings highlight the opportunity for employers to manage employees' burnout and absenteeism by providing mental health care not only for employees themselves but also for their children and families.

Strengths and Limitations

Our study has several strengths. This is the first study, to our knowledge, to address the potential downstream benefits of pediatric care with a DMHI on the workplace symptoms of their caregivers. The deterioration of parent and caregiver well-being has been increasing in prevalence and was called out in 2024 by the US Surgeon General as a critical problem [4]. We demonstrate that addressing child mental health may be an effective avenue to reduce caregiver strain and workplace problems. From an analytic standpoint, this study draws data from a large sample, with more than 6000 caregivers included in analyses of mental health symptoms at baseline, more than 2000 change in burnout analyses, and more than 1000 for change in absenteeism analyses. Additionally, this study assesses outcomes associated with an established, commercial, and successful DMHI, which has been shown to be effective in addressing child and adolescent mental health challenges [18,19,25]. Our findings overall contribute to a growing body of evidence supporting the use of DMHIs-which are typically more flexible and accessible than traditional care-to address both pediatric and caregiver well-being.

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There are some limitations of this study. This was a retrospective study that prevented us from drawing any causal conclusions, and we relied on self-report measures to obtain information regarding all outcomes of interest. Further research using an experimental design and using objective measures where possible (eg, reports of caregiver absences from work) is necessary to determine whether involvement in a pediatric DMHI precipitates improvements in caregiver workplace symptoms. While some improvement may be expected due to regression to the mean following a child's referral to care, our findings suggest that greater time in care contributes to continued reductions in burnout and absenteeism. Controlled studies are needed to further clarify the extent to which these changes reflect treatment effects versus natural symptom resolution over time. We also did not collect demographic information on caregivers, which limits our ability to examine whether caregiver characteristics (eg, age and biological sex) influenced burnout and absenteeism.

Another limitation of this study is that we did not ask caregivers whether they were employed, their type of employment, or their hours worked per week. The burnout and absenteeism measures used in this study do not define "work," and caregivers responded based on their interpretation of what "work" was, full-time, part-time, paid, or unpaid. As a result, we were unable to differentiate between burnout and absenteeism among caregivers who were employed in different capacities or engaged in informal caregiving roles. Without these data, we cannot determine whether reductions in absenteeism reflect actual changes in workplace behavior, time away from caregiving responsibilities, or broader improvements in caregiver functioning. Future studies should consider frequency of occurrence and types of employment and inclusion of caregivers who engage in informal caregiving and other unpaid work when considering burnout and absenteeism [63]. We used a single-item burnout measure and a single section from the HPQ questionnaire to assess absenteeism, which prevented us from comprehensively assessing our workplace outcomes. These

decisions were made to simplify the assessment process and limit burden. While we considered the possibility that improvements in child mental health could be linked to improvements in caregiver workplace symptoms, we did not examine the specific types of mental health symptoms or care targets, as these were beyond the scope of this study. Future studies should account for a variety of children's mental health symptoms and more comprehensively assess caregivers' burnout, absenteeism, and presenteeism to address these limitations.

Finally, the nature of administering assessments and screeners changed partway through the study. Given that the burnout assessment did not have a corresponding screener and the absenteeism screener was simply used to identify no absenteeism, we do not expect that these methodological changes had any substantive impact on our main findings. While the total scores for the other caregiver and child mental health outcomes may have been affected by the changes in the screening methods, we only assessed whether elevated versus nonelevated symptoms predicted caregiver workplace outcomes. Thus, we expect that our findings are robust to these small methodological changes.

Conclusions

Caregivers are growing increasingly concerned about their children's mental health, which in turn is impacting their well-being and performance in the workplace. This study provides promising preliminary evidence that caregivers show decreases in their burnout and absenteeism when their children participate in a pediatric DMHI. As such, employers should consider offering pediatric digital mental health care to employees with children experiencing mental health difficulties, which may mitigate burnout and absenteeism. While these findings highlight the potential benefits of digital mental health care for working caregivers, future research should compare DMHIs with traditional face-to-face mental health care to determine their relative effectiveness and accessibility.

Conflicts of Interest

DLS, MR, and DM are employed by Bend Health, and Bend Health delivered the treatment used in this retrospective study. JH is a paid consultant of Bend Health. KM is an employee of JH and Fit Minded. However, authors' employment status and/or salary are not dependent upon the results of their research.

Multimedia Appendix 1 Supplemental methods. [DOCX File, 17 KB - pediatrics v8i1e67149 app1.docx]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
BCM: behavioral care manager
CLM: cumulative link model
DMHI: digital mental health intervention
DSM-V-TR: Diagnostic and Statistical Manual of Mental Disorders (Fifth Edition, Text Revision)
GAD-7: Generalized Anxiety Disorder-7
HPQ: Health and Work Performance Questionnaire
ISI: Insomnia Severity Index
PHQ-9A: Patient Health Questionnaire-9 adolescent version
PROMIS: Patient-Reported Outcomes Measurement Information System
PSS: Parental Stress Scale
SNAP-IV: Swanson Nolan and Pelham Rating Scale version 4

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Exploring the Acceptance and Opportunities of Using a Specific Generative AI Chatbot to Assist Parents in Managing Pediatric Rheumatological Chronic Health Conditions: Mixed Methods Study

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Abstract

Background: Health care chatbots can be used to support patients and their families with everyday decision-making. While there is some research on integrating artificial intelligence into pediatric care, no study has focused on the opportunity of implementing a generative artificial intelligence chatbot for pediatric rheumatology. Pediatric rheumatology conditions require intense family input, which can often leave families struggling to navigate disease flares, pain, fatigue, medication side effects and adherence, and support of their child, often when pediatric rheumatology departments are shut. Understanding how we can support families better, without the need for increased personnel, will have implications for the health care systems.

Objective: The study aimed to explore parental and children and young people's acceptance of chatbot use in a pediatric context, and understand how a chatbot could be specifically used for managing a child's chronic health condition.

Methods: This study was a mixed methods design, using both a family workshop and a subsequent questionnaire.

Results: In total, 22 participants contributed to the qualitative design using the world café methodology at a workshop, and 47 participants (36 parents and 11 children and young people) completed quantitative data via a questionnaire. Participants expressed their likelihood of using chatbot technology, including ChatGPT, due to its accessibility. However, participants had significantly greater intention (parents: P<.001; children and young people: P=.006) to use a specific chatbot over ChatGPT, due to increased trust, credibility, and specificity in design. Children and young people and parents should be distinguished as 2 user groups in chatbot design, reflecting their specific needs in chatbot features and personalization.

Conclusions: Overall, the study reinforced the need for a specialized and trusted chatbot designed with input from health professionals to assist families in managing complex chronic health conditions to support families in between appointments and complement existing face-to-face care. Future research should evaluate users' engagement with a functional prototype to investigate its usefulness and explore its implementation into families' everyday lives. Importantly, the current findings have broader implications for the field of pediatric health care, as similarly tailored chatbot interventions could benefit families who are managing other chronic health conditions.

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KEYWORDS

pediatric health care chatbot; technology acceptance; parental attitudes; children and young people's involvement; chronic disease management; AI hesitancy; chronic health condition; artificial intelligence

Introduction

Background

Generative artificial intelligence (GenAI) tools, such as ChatGPT and health care chatbots, have become increasingly

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accessible. However, their adoption into health care is still in its infancy. Pediatric rheumatological chronic conditions are autoimmune disorders where the body wrongly attacks itself, as such they have no clear etiology and cure [1]. Juvenile idiopathic arthritis is the most common rheumatological condition affecting one in every thousand children and young

young people into remission, where the disease becomes inactive. Parents need to take charge of managing their child's health, especially when health professionals are unavailable [4]. Thus, managing a chronic condition can cause a psychological burden to children and young people and their families.

Health professionals often use medical jargon, while parents favor more neutral and simpler terminology for their children [5]. This widens a gap in effective family-clinician communication, which could manifest in medical nonadherence and impact overall treatment efficiency [6]. As parents need to interpret complex information to an appropriate comprehension level for their children, their emotional burden also increases [7-10].

Emerging research on chatbots has demonstrated their opportunities and limitations in health care applications. ChatGPT is a general large language model (LLM) that has been found to be feasible in generating detailed and empathetic responses to patients' health inquiries [11]. Yet, it is prone to fabricate academic sources, a phenomenon known as "hallucination" [12]. ChatGPT also requires clear input from users to generate more accurate responses, than using ambiguous prompts [13].

Existing health care chatbots have shown promise in improving patient outcomes through integrated care [12,14]. Seeking health information web-based health information could be appealing due to its convenience, availability, and privacy when health professionals are unavailable [15]. Compared to general internet resources, chatbot use could reduce engagement with inaccurate and often overwhelming amounts of information on the internet [16]. However, maintaining clinician-patient communication remains important to prevent self-diagnosis [17]. Therefore, there is a need for a trusted and accessible resource to support families' decision-making, alongside health care providers.

It is crucial to understand users' adoption intention to ensure successful embedment of artificial intelligence (AI) intervention into their everyday lives [18,19]. Based on Ajzen's [20] theory of planned behavior, research on chatbot acceptance in health care [21,22] has identified key factors influencing adoption intention. The theory posits that an individual's behavior is determined by their behavioral intention, which is influenced by personal attitudes, subjective norms, and perceived behavioral control. Personal attitudes are suggested to be the most influential factor of behavioral intention as attitudes reflect individuals' own beliefs and schemata [20,23]. For example, Nadarzynski et al [21] found that perceived usefulness, perceived ease-to-use, and curiosity, predicted acceptance of chatbots, though lack of trust and humanness remain concerns. In pediatric care, parental attitudes toward general AI use reveal safety and ethical concerns [24,25].

A limitation of existing studies is that findings might not be generalizable to children with diverse medical backgrounds. For instance, only 24 out of 804 (3%) parents had experience with child hospitalization in Sisk et al [26]. Haley et al [27] found that parents of a child who had been hospitalized

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significantly prioritized AI accuracy, than those who had not. These families might have unique experiences with medical care, increasing barriers to adopting a novel intervention.

Existing research has also neglected children and young people's involvement as they often considered parental attitudes. Involving users in the development of AI health technology could increase transparency and trust while preventing dissatisfaction and disengagement [28,29].

Research Aims

The ongoing "IMPACT" (Interventions to Improve Mental Health Support in Families With Children and Young People With Chronic Rheumatological Conditions) project [30] aims to design, develop, and test a chatbot intervention to support families between appointments for pediatric rheumatological conditions. However, as part of this work, an opportunity arose to gain an understanding of parental and child thinking surrounding AI in general in health care. We, therefore, aimed to explore the attitudes and technology acceptance perspectives of parents and their children and young people. The overall aim is not for a chatbot to replace existing traditional care, but to enhance the support of families between appointments.

This study consists of 2 methodologies. The first piece of work presents data from a family co-design workshop, where families' opinions on using a chatbot in a pediatric health care context were gathered. Subsequently, a questionnaire was conducted to follow up on the findings identified at the workshop. This mixed methods design allows further probing of the data from the workshop and thus aids a richer insight into perspectives of AI in health care. This study presents both (1) the workshop and (2) the questionnaire, split into separate methods and results, with a combined discussion.

This study aims to address the following research questions (RQs): (RQ1) What are parental and children and young people's general attitudes and behavioral intentions toward chatbot use, such as ChatGPT? (RQ2) What are parental and children and young people's attitudes and behavioral intentions toward the potential use of a chatbot specifically designed for pediatric rheumatology and do they differ when considering ChatGPT? (RQ3) What are the opportunities and concerns parents and children and young people might have toward chatbot features and content?

Methods

Study Design

The methods section will first present information relevant to the workshop, followed by the questionnaire. This study used a mixed methods design. The main aim was to use qualitative data to understand the acceptance and use of a rheumatology-specific chatbot for parents. Quantitative data have been added to briefly outline the current use of GenAI or similar, with the main focus investigating the attitudes and intentions of using AI to inform health care management. The main target audience was parents, however, as their children also attended the family workshop, we felt it would be an opportunity to seek their perspectives.

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Ethical Considerations

Ethical approval was granted by the Research Ethics Committee at National Health Service (NHS) Health Research Authority, Leeds West Research Ethics Committee, and HRA and Health and Care Research Wales (IRAS 329476). The research project has been reviewed and approved locally at Great Ormond Street Hospital for Children NHS Foundation Trust for capacity and capability. The "IMPACT" study officially opened at Great Ormond Street Hospital for Children on November 10, 2023 (study: 23IR07). Informed consent was sought from all participants. Secondary analysis utilising existing data from the IMPACT study was obtained with primary consent for participating in the project. Quantitative data was fully anonymised, whilst qualitative data was deidentified as outlined in the participant information sheets and consent forms. Participation was voluntary, and no compensation was received.

Family Workshop (May 2024, London)

Design

The workshop used the world café forum method, a qualitative participatory method used in health research [31-34]. In groups, participants rotate around tables to take part in different discussions. The host of each table remains to facilitate the cross-pollination of ideas from previous groups [33]. Participants are encouraged to express themselves creatively in texts or drawings [32].

The corresponding author acted as a table host to guide discussions. A young adult in remission from juvenile idiopathic arthritis and their parent acted as facilitators to maximize participant comfort and engagement, as they shared similar experiences. Another researcher acted as a notetaker. As part of the larger study, there were 7 other tables with different research focuses.

At our table, participants familiarized themselves with 3 sets of questions and ChatGPT responses regarding pediatric rheumatological conditions in a concept testing activity (Multimedia Appendix 1). These 2 conditions were used in relation to participants' personal experiences. ChatGPT was prompted to generate responses appropriate for either a 6-year-old child or a 13-year-old teenager. Participants were then asked to discuss their likes, critiques, and opportunities regarding these responses.

Participants

Families living with a pediatric rheumatological condition requested to attend the workshop after receiving a flyer from their local health care team across the United Kingdom as they attended clinical appointments or via social media advertisements from relevant charities. There were no restrictions on who could attend and whole families were encouraged to attend. To protect families' anonymity, limited demographic and identifiable information was collected. Inclusion criteria were that families needed to have experience with a pediatric rheumatology condition and be able to speak English. The participants had received rheumatology care from different parts of the United Kingdom. The main target group for this study was parents and carers, as the chatbot created as part of the IMPACT study is targeting parents and carers in the first instance. However, as children and young people also attended the workshop with their parents, their views were also explored to understand the differences and similarities between caregivers and children and young people.

Materials

As the world café method collects creative qualitative output, participants were provided with sticky notepads, colored pens, and paper to share their ideas. Printed handouts of ChatGPT responses were also provided. A computer was used to host a live interactive demonstration of ChatGPT.

Procedure

Participants were divided into 8 groups that rotated among 8 tables every 20 minutes, with 3 breaks provided to avoid fatigue. Prior to the main activity, the host, facilitators, and participants introduced themselves to one another.

To enable conversations to occur freely, audio recording was not conducted at any table at the workshop. However, detailed notes were taken by 2 notetakers, who then cross-compared their notes to ensure objectivity [35]. Hand-written notes by the participants were also collected. At our station, we conducted a live demonstration using ChatGPT to ease participants into the discussion. Then, participants were asked a set of structured questions and probes, 5 minutes after reading the ChatGPT responses. At the end, all participants and researchers gathered to have a debrief.

Other tables had similar setups. Detailed compiled notes were shared among the researchers electronically postworkshop to be used as secondary data if relevant. One of the other tables explored participants' consensus on chatbot features in a brainstorming activity, which generated relevant findings to answer RQ3. The findings from the brainstorming activity were summarized by notetakers and therefore no transcripts are available. This strategy helped enrich the dataset and allowed cross-comparisons between data compiled by different researchers, increasing interrater reliability.

Analytical Approach

A qualitative descriptive method was followed to stay close "to the surface of words and events" on a semantic level [36]. Trends were noted as the groups progressed leading to data saturation, but with specific attention to ensuring all participants were encouraged to share their perspectives, Since notes taken from the world café forums were already interpreted to some extent, this approach could mitigate further interpretative bias. The "IMPACT" Chief Investigator (PL), who is a senior pediatric rheumatology nurse with qualitative expertise, and Research Facilitator (KK) oversaw the data process and analysis.

For the concept testing activity, a deductive approach was appropriate as the questions were designed according to the predefined categories of "likes," "critiques," and "opportunities."

Questionnaire

Design

The questionnaire design was informed by our workshop findings and a pilot study (n=22) was conducted to test the

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comprehensibility and relevance of questions. A nonstandardized questionnaire was devised for the purpose of this study to allow for bespoke questions to build upon workshop findings. The potential issues of language barrier, AI literacy, and children's comprehension level were considered. It was decided that the wording of questions should be kept simple and the number of question items on each construct should be reduced.

Using pilot feedback from the workshop, iterations were made. Initially, the term "ChatGPT" was used instead of "generative AI" or "chatbot" in the questions to provide clarity to those with less knowledge in GenAI. However, it might have measured attitudes specifically toward ChatGPT. For example, a parent said they would not use ChatGPT because "it doesn't give source references for its reply." While fabrication might be observed in ChatGPT, a specific chatbot could eliminate this issue. Therefore, questions were rephrased to measure and compare attitudes toward ChatGPT or similar GenAI and a rheumatological-specific chatbot. The final questionnaire was distributed electronically to ensure completion.

Participants

Participants were recruited separately from the workshop. Using a purposive sampling method, families who had already expressed interest in the "IMPACT" study were emailed the questionnaire link. Parents were the point of contact and were asked to share the child questionnaire link with their child if they were aged 8 years and older and wanted to take part. We asked that each family be represented by one parent only, but their children and young people may have also completed a questionnaire. This sample might have overlapped with the sample of the workshop and pilot study due to the anonymity provided through the questionnaire, the numbers of these are therefore unknown.

Materials

Two versions of the questionnaire were designed, one for parents and one for children and young people, consisting of 13 and 11 questions, respectively. Participants were asked for their age, current internet health information-seeking behavior, and their current use of ChatGPT or similar GenAI. Then, participants were introduced to ChatGPT. Next, they were asked about their behavioral intention of using ChatGPT for seeking health information. This was followed by a short answer question where participants were asked to explain their rating. Participants were then presented with a scenario of a health care chatbot specifically designed by health professionals for pediatric rheumatological conditions. They were asked to rate their intention toward using this specific chatbot and explain whether their attitudes differed regarding the general and specific chatbot. Additionally, parents were asked whether their behavioral intention to use a chatbot for health care differed when it was for their child's health or their own health.

Procedure

The questionnaire was reviewed by the "IMPACT" Chief Investigator and Research Facilitator for iterations. The questionnaire was distributed through REDCap (Research Electronic Data Capture; Vanderbilt University) and sent out via email on June 21, 2024, to 60 families. A reminder was sent on June 25, 2024, and access to the questionnaire was closed on July 1, 2024.

Analytical Approach

Using Likert rating and open-ended questions, the questionnaire generated both quantitative and qualitative data. To investigate whether there is a within-group attitudinal difference in using ChatGPT and a rheumatologically specific chatbot for health, a post hoc 2-tailed Wilcoxon signed rank test was conducted. As the data were not normally distributed, the nonparametric design was used to interpret the data. Reliability measures were not used due to the minimal questionnaire design, considering sample characteristics. SPSS Statistics (version 29; IBM Corp) was used for quantitative analysis.

Braun and Clarke's [37,38] and Bryne's [39] 6 phases of reflexive thematic analysis were used to interpret the qualitative data. The steps followed included (1) familiarization with the data where participants' responses were read through to understand the overall tone and content; (2) ascribing primary codes; (3) secondary inductive coding; (4) clustering codes together to identify common ideas, factors, and findings; (5) transforming clusters into relevant and understandable themes; and (6) creating the report [37-39]. The entire analytical process and any discrepancies were regularly discussed with the "IMPACT" team (PL and KK). An audit trail and reflective data were kept at every step. An inductive thematic approach was used to analyze open-text responses to avoid overlooking unexpected themes [37]. Data were analyzed at a semantic level, staying true to participants' perspectives, which is appropriate for understanding individual stories and contexts in health research [40].

Results

The results section will first present the family workshop findings, followed by findings from the questionnaire.

Workshop Findings

Two tables at the co-design workshop explored possible chatbot features and the opportunity of using a chatbot in pediatric rheumatological care, respectively. In total, there were 8 groups of mixed participants which included children and young people (n=9; age range 5 - 26 y; mean age 13.3, SD 6.3 y) and parents (n=13). Each group consisted of 2 - 5 participants.

Chatbot Features

Personalization

Participants felt that the chatbot needs to evolve with them. For instance, families felt that simple language should be used at the beginning of diagnosis. However, explanations should become more advanced in the subsequent years as families become more familiar and do not want to feel patronized. An opportunity proposed by one participant was the idea of a "science-ometer" slider for users to dictate how scientific they wish the explanation to be. Overall, participants thought that the chatbot should be tailored to the individual patient's age, personality, and neurodiversity.

Tone

Participants thought that the specific chatbot should have a friendly, reassuring, and trustworthy tone. However, they attributed most of the trustworthiness to the endorsement by the NHS behind the design of the chatbot. Children and young people thought that the chatbot should not feel medical at all but like a peer. However, parents wanted to talk to a mentor figure, whether that is a parent with more experience or a health professional.

Anthropomorphism

The younger participants wanted to pick an animal avatar that "felt right" for them, such as a dolphin. This feature was less

important for older participants and parents, who prioritized the content. They also expressed that the chatbot name or avatar would not affect their intended use. However, they also proposed other symbols to represent the chatbot, such as a torch or volcano.

Concept Testing

Conducting concept testing is advantageous in the early development of an intervention to reduce the risk of users not liking the concept, leading to limited adoption [41]. Table 1 provides a summary of users' likes, critiques, and posed opportunities.

Table .	Summary	of concept	testing	findings.
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Categories	Comments		
Likes	 Visual Imagery aids explanation and understanding. Storytelling narrative is relatable. The more technical version actually explains how the illness works well. 		
Critiques	 Children of similar ages do not always think in the same way, since they are exposed to different things. Unless age is put into the prompt, users are shown information that is too confusing. The analogy used in the 13-year-old explanation attempted to sound more technical but still used the castle analogy that was used in the explanation for a 6-year-old. It was confusing and inappropriate. 		
Opportunities	 Doctors' and experts' input is required for the chatbot to be reliable. Doctors should be able to see a record of questions asked by the families to aid communication. The child should be considered as a user for autonomy. 		

Questionnaire Findings

Overview

A total of 47 participants were recruited, including 36 parents and 11 children and young people (see Table 2 for demographic

information). Responses to closed questions are summarized in descriptive statistics first, followed by statistical analyses. Qualitative findings are supported by the use of participant quotes ("P" denotes parent and "CYP" denotes child or young person quotes). Subsequently, qualitative analysis of responses to open-ended questions is discussed.



Table . Demographic information of parent and children and young people participants^a.

Characteristics	Parents (n=36)	Children and young people (n=11)
Age (years)		
Age of child or self, mean (SD)	11.1 (4.0)	14.8 (5.9)
Range	4 - 19	9 - 29
Time since diagnosis of child or self, n (%)		
Less than 6 months ago	0 (0)	0 (0)
6 - 12 months ago	3 (8)	1 (9)
Over 1 year ago	6 (16)	0 (0)
Over 2 years	27 (73)	10 (91)
Diagnosis, n (%)		
ЛА ^р	14 (39)	4 (36)
JDM ^c	9 (25)	2 (18)
Behcet's/CAPS ^d /CRMO ^e /PFAPA ^f	5 (14)	4 (36)
Castleman/mixed connective tissue/mor- phea/rare genetic disorder/scleroderma/SLE ^g	8 (22)	1 (9)

^aParents and children and young people may not be from the same families.

^bJIA: juvenile idiopathic arthritis.

^cJDM: juvenile dermatomyositis.

^dCAPS: cryopyrin-associated periodic syndrome.

^eCRMO: chronic recurrent multifocal osteomyelitis.

¹PFAPA: periodic fever aphthous stomatitis.

^gSLE: systemic lupus erythematosus.

Descriptive Statistics

A total of 26 (70%) parents stated that they had heard of ChatGPT or other GenAI before, but only 14 (39%) of these said they had used any AI platforms. Of those who had, they used it for work purposes (n=11), while others (n=3) used it for general questions or "only experimented" with it. On the other hand, all 11 children and young people (100%) had heard of the technology. Less than half (n=5, 45%) had used it before; for learning (n=3), research work (n=1), and asking general questions "like the Snapchat AI" (n=1). Participants rated their self-confidence in using ChatGPT or similar GenAI technology on a 5-point Likert scale (1=not at all confident, 5=extremely confident), which was found to be low for both parents (median 2, IQR 1-3) and children and young people (median 2, IQR 1-4).

Participants were also asked to rate their likelihood of using ChatGPT or similar GenAI technology on a 5-point Likert scale (1=not at all likely, 5=extremely likely). Children and young people gave a high rating for their likelihood to use a specific chatbot (median 4, IQR 3-4) compared to ChatGPT (median 2, IQR 1-4), with a larger discrepancy indicated in the latter. Parents also rated the intended use of a specific chatbot (median 4, IQR 4-5) higher than ChatGPT (median 3, IQR 2-4) in managing their child's condition. Additionally, parents' ratings for using ChatGPT for their child's health were slightly lower than using it for their own health (median 4, IQR 2-4).

Inferential Statistics

A Wilcoxon signed rank test confirmed that there was a statistically significant difference in parents' attitudes toward using either a general or specific chatbot to assist in managing their child's health (z score=3.8; P<.001; r=0.63). Children and young people's attitudes were consistent with those of their parents (z score=2.5; P=.006; r=0.75). A total of 21 parents and 8 children and young people self-reported to be more likely to use a specific health chatbot than a general chatbot like ChatGPT. The likelihood of use was tied among 13 parents and 2 children and young people. In addition, 2 parents were more inclined to use ChatGPT than a specific chatbot for their child.

Qualitative Analysis of Questionnaire

Two follow-up questions were asked to better understand the reasons behind their ratings. Three themes were identified: accessibility, trust, and credibility in a chatbot, and specificity of chatbot design. Each theme was divided into subthemes, with quotes from participants as supporting evidence. Two subthemes in accessibility and trust and credibility did not include any quotes from children and young people because their responses were not relevant to the particular subthemes.

Theme 1: Accessibility

Limited Accessibility to Health Care Professionals

None of the children and young people mentioned the role of health professionals, whilst one participant noted their dependence on their parents. Parents expressed how using a



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chatbot can mitigate the issue of having limited accessibility to health care professionals when they have questions about their child's health. As a result, many noted that they seek advice anywhere and appreciate any help. For example:

Any help is better than no help. [P2]

I know the doctors do not have the time to spend with us to answer all our questions. [P22]

Efficient Tool for Information-Seeking

One child or young person mentioned that they did not think of using ChatGPT for seeking health information before but for academic purposes only. Parents perceived the chatbot to be an efficient tool in terms of time and accessibility for information seeking, even when they were specifically asked about ChatGPT.

I think it's the way forward to get immediate access to health information, I've just been hesitant to use it previously but can now see the benefits of using it. [P9]

Comprehension Accessibility

Another aspect of accessibility was the level of comprehension of health information. Parents thought chatbot-generated information could be rational, tailored, and understandable for the child. A parent said they would value tailored chatbot answers due to challenges with accessing health professionals.

Because it would give rational and factual information rather than trying to get answers that would not be appropriate for my child. [P14]

Theme 2: Trust and Credibility in a Chatbot

Concerns Regarding ChatGPT's Inaccuracy

Both parents and children and young people expressed a lack of trust and confidence regarding the inaccuracy of ChatGPT on 2 levels: its open-source nature and its processing ability of complex medical information. Participants thought that ChatGPT could learn from sources that are not verified, resulting in unreliable, fabricated, or biased output. Participants also expressed distrust toward ChatGPT specifically for health care purposes, due to how complex medical information could be.

[ChatGPT] It is open source so [it] may use unreliable or biased sources and it is dependent upon the prompts provided so in a medical context it could be easy to get it wrong and receive inaccurate responses. [P34]

Mainly [I have not used it] because I hadn't thought of doing so. After some thought, I wouldn't trust the information to be accurate. [CYP3]

Unfamiliarity With Using the Technology Limits Trust

Some parents voiced their unfamiliarity with chatbot technology which led them to not having tried ChatGPT before. Therefore, they were not certain about its usefulness. Yet, all parents seemed open-minded to give the technology a try. I prefer to speak to a person who can understand nuance but would be open-minded to give AI a go ... the proof would be in the experience. [P32]

Reliance on Other Credible Sources

Participants compared chatbot use for health care to other sources that are deemed more credible, such as NHS resources and published research papers. Some participants sounded hesitant as they said that they expressed uncertainty about ChatGPT's accuracy and reliability.

I tend to look for the NHS website or research papers that have been published on the topic rather than asking a chatbot type for answers more so because I then can cite the information and figure out where it's all come from. I am not sure if you can do that with ChatGPT. [CPY4]

Theme 3: Specificity of Chatbot Design

Active Involvement of Health Care Professionals

Input by health professionals and experts in the design of a specific chronic health-focused chatbot was perceived to increase its accuracy and reliability, compared to ChatGPT. Participants expressed increased comfort with using a specifically designed chatbot. However, participants' perception was solely based on their expectations rather than experience as the chatbot has not been developed yet.

Due to it being more regulated and designed by health professionals who will hopefully monitor effectiveness and reliability of content. [P25]

If the information is given by a specialist who deals in these illnesses day in [and] day out, I am way more inclined to trust the information given due to it being a reputable source. It's a confident way to ask information and receive in a familiar way with the added comfort of knowing it is from a reputable source. Which is why my opinion changed rather drastically in a positive way [compared to ChatGPT]. [CYP4]

Fit-for-Purpose

All participants expressed that they were more inclined to use a chatbot that is specialized in rheumatology compared to a general chatbot like ChatGPT, GenAI, or Google. The importance of specialization due to the rarity and complexity of conditions and symptoms was highlighted.

It's important to us to have a resource available for this chronic condition that is not the same as Google. [P28]

If it's specific to JDM, I would be far more likely to use it [than ChatGPT]. JDM is so rare, that questions wouldn't be answered unless it was programmed specifically for JDM. [P5]

Rheumatological conditions can have such a vast array of symptoms that a nonhealth backed system could become quite scaremongering in leading to false information. If using a platform that has already narrowed down the results to trusted rheumatology

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information, I would feel a lot more comfortable using it [than ChatGPT]. [CYP3]

Discussion

Principal Findings

Using a mixed methods approach, we were interested in exploring both parental and children and young people's attitudes and behavioral intentions toward using ChatGPT, a general chatbot that is commercially available in a health care context (RQ1), as well as their attitudes and behavioral intentions toward using a chatbot that would be specifically designed for pediatric rheumatology. The major difference between these 2 applications concerns the content returned to families, with a specifically created disease-specific chatbot only having access to a "closed system" of physician-endorsed data, rather than the ability to search the internet and bring back results with no safety netting from a health professional. We wanted to investigate whether the behavior intentions differed and if so, how (RQ2). Opportunities and concerns raised by children and young people and parents toward chatbot features and content were identified to indicate practical design implications (RQ3).

Children and Young People and Parental Attitudes and Behavioral Intentions Toward ChatGPT and a Specific Chatbot (RQ1, RQ2)

The themes that emerged from the qualitative data contribute to our understanding of participants' attitudes and behavioral intentions supported by the quantitative data. The accessibility of the chatbot to families was a key influencing factor in adoption intention. Parents explained that they would be likely to use the chatbot as they saw it as a time-efficient and easily accessible tool to turn to when health professionals are not available. Parents found chatbot technology, including ChatGPT, to be more direct and quicker in giving them the answers they need than other web-based resources. This may explain why parents were equally likely to use it for their own health and their child's health. While it was not measured whether parents have health conditions themselves, they seemed to hold some health behavior motivation and curiosity toward a new accessible intervention. The findings are in line with previous research, which identified curiosity, perceived ease-of-use, and convenience to be motivators of health care chatbot adoption [21,42]. Chatbots, whether generally or specifically designed, could bring convenience to parents when health information-seeking. The integration of GenAI into the health care system is believed to have a positive impact on supporting medical research and decision-making for patients, families, and health care workers [43].

Our results showed that there was a statistically significant difference between participants' likelihood of using ChatGPT and a specific chatbot for managing their child's chronic health condition. Both parents and children and young people were significantly more likely to use the specific chatbot than ChatGPT for this purpose.

Trust and credibility in a chatbot was another theme identified. It highlighted participants' concerns regarding ChatGPT's

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accuracy which limited trust. They questioned its reliability due to open-sourcing and fabrication tendencies. Existing studies have consistently identified trust as a crucial factor in converting new users to adopt a novel technology intervention like a chatbot across contexts [21-23]. Additionally, participants thought that ChatGPT might not understand complex medical information in pediatric rheumatology and provide accurate responses. Participants' unfamiliarity with ChatGPT might have also contributed to the overall low rate of current use. Despite finding ChatGPT accessible, participants would rather obtain internet resources from trusted sources, like the NHS website. Participants demonstrated careful evaluation of ChatGPT content, which is congruent with how patients processed and sought health information on the internet in Sillence et al [44]. While perceived ease-of-use and convenience could increase adoption intention to using a health care chatbot, users must first establish trust [23]. This is supported by Abbasian et al [45] who found that accuracy, trustworthiness, and empathy should be assessed when evaluating health care-specific chatbots.

What differentiated participants' attitudes toward ChatGPT and the specific chatbot was the addition of health professionals' input and the specific design focus in the latter. The theme of specificity of chatbot designs showed that users expected the specific chatbot to be specially trained to recognize information related to rheumatological conditions. A strong need for a resource specific to pediatric rheumatology was expressed due to the disease's complexity. The specialized tool was perceived to be more reliable than ChatGPT, increasing users' trust in its evidence-based input and monitored output. Participants displayed a high level of trust toward the specific chatbot and made comparisons to ChatGPT. Participants' trust toward the specific chatbot might be explained by the theory of planned behavior [20]. It posits that subjective norm influences behavioral intention, besides attitudes. Participants might have attributed their trust in health providers to trust in the chatbot [23,46]. Participants of this study have demonstrated great engagement with the wider research project, which is advocated by health professionals they trust. Hence, families might have relied on health professionals' opinions to form a strong subjective norm to follow, thereby increasing their adoption intention. This is further supported by findings from the review by Tangsrivimol et al [47] assessing the benefits and limitations of currently available chatbots such as ChatGPT and similar chatbots relying on GenAI. They have highlighted issues with existing chatbots by discussing ethical considerations and challenges with data governance and privacy concerns, as well as issues relating to inaccurate and misleading information provided by freely available chatbots based on erroneous algorithms and hallucination. Using an LLM for managing a child's illness raises ethical concerns around safety, accountability, and privacy. Incorrect advice could cause harm, and there is no clear responsibility if things go wrong. Sharing sensitive health information also risks breaching confidentiality. Additionally, reliance on LLMs might undermine trust in health care professionals and could introduce bias, leading to unequal care. The aim of health care-specific chatbots is to overcome these issues by providing secure platforms and providing content, and features tailored to the audiences they are targeting,

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whilst still encouraging engagement with existing health care teams.

Besides trust, another concern raised in previous literature on health care chatbot adoption was the lack of humanness, compared to interactions with a health professional [21]. However, we argue that lack of humanness may not always be a concern. Reducing human-human interactions could be beneficial, such as creating a stigma-free safe space. Under the theme of accessibility, the subtheme of comprehension accessibility discussed the need for a tool that can provide understandable, tailored, and rational information. Indeed, stigmatizing health-related experiences could reduce patients' engagement in medical care, treatment adherence, and help-seeking behavior [48]. Therefore, chatbot use might reduce any perceived stigma in patient-clinician interactions and provide tailored answers that users can understand. As a result, it could promote positive patient-clinician relationships and treatment outcomes.

Through analyzing families' attitudes and behavioral intentions, it was identified that users need a tool that is highly accessible to compensate for limited contact with health professionals; that they can trust, such as being backed by credible experts; and that they can depend upon to provide accurate answers to questions specific to pediatric rheumatology. However, it is important to note that this tool is seen as an aide to support the family in everyday life situations, and should be a trusted source of information. Moreover, it should not be used as a replacement for existing care provided by health care teams but rather as a platform that should be used in conjunction with existing face-to-face care from health care providers.

Opportunity of a Pediatric Chatbot (RQ3)

Through concept testing, the visual imagery and storytelling narrative used by ChatGPT were well-liked and thought to be appropriate for children and young people. However, they noted that children of the same age could behave and think very differently. In line with Vygotsky's [49] sociocultural theory, children's cognitive development is influenced by their social interactions and environment, irrespective of biological age. Hence, it might not be effective to dictate the level of comprehension in chatbot-generated output solely by age.

Younger participants and adults expressed different preferences for chatbot features and tone. Currently, parents are identified as the main user who will primarily use the chatbot either by themselves or with their children. Participants in concept testing discussed that children and young people should be considered as its own user group. There is therefore an opportunity to create a separate user interface and persona to engage children.

A study examined the impact of personas in a health care chatbot on adult users' engagement [50]. It drew on the social response theory [51], which argues that users react to computers with human-like attributes similarly to human-human interactions. The study created the personas representing a hospital institution, expert, peer, and dialogical self to measure the effect of age and gender on affective bond and use. While the study concluded with mixed findings, future research could investigate the impact of different chatbot personas on intervention

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engagement in children, young people, and parents. However, the functionality and usefulness of a chatbot intervention should still be prioritized over social features [52]. This is particularly highlighted by a scoping review that reviewed health-related chatbots more closely. They found that mental health and well-being–promoting chatbots need to prioritize content and functionality above everything else. For example, they found that only 44% of chatbots successfully addressed suicidal thoughts. Thus, demonstrating the need to focus on safety to safeguard vulnerable populations [53].

Limitations

Since participants were recruited voluntarily, they may be subject to social desirability bias toward the research project and team, as well as the recruitment of families from social media who equally may be biased toward AI. Additionally, some participants may have completed both the workshop and questionnaire, potentially increasing bias compared to those who only completed the survey. However, by asking participants to explain their ratings on chatbot use, they were encouraged to engage more deeply with the topic which increased objectivity [52].

The forced-choice design limits interpretation, as participants had to select the preferred option even if they were dissatisfied with both. This approach captures relative preference but may obscure low overall acceptance. Participants' attitudes were also measured based on a hypothetical scenario of chatbot use, which may not be representative of a real-life situation. However, a study found that behavior is better predicted by actual experience, than attitudes that were formed based on the stimuli provided by the researcher [54]. It was not feasible in this study since the chatbot is yet to be developed. Future research could compare changes in participants' attitudes after the chatbot has been developed. This could generate insights into how well the chatbot is embedded in users' everyday lives, which is a common concern in AI health care technology [18].

While the use of a mixed methods approach has mitigated some limitations, it increased the complexity of the study. Questions from the questionnaire measure generated both quantitative and qualitative data. This was in addition to the qualitative data from the family workshop, which consisted of primary and secondary datasets. In addition, findings from one method slightly overlapped with findings from another. As a result, it increased the difficulty in data processing and interpretation. Findings from different methods had to be carefully evaluated to ensure a holistic understanding of the research problem and research questions and a clear audit trail and regular team meetings were essential to identify potential biases. Additionally, the sample size for children and young people was too small to allow for more in-depth interpretations of the findings. Children and young people were included in this study as they attended the workshop alongside their parents, and it provided an opportunity to collect preliminary data on their views. Further research could investigate their viewpoint in more detail to understand their views on GenAI and health-specific chatbots.

As health care chatbots can have a wide spectrum of applications and target audiences, a limitation in the research field is that it is hard to compare study results. To illustrate, a recent

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systematic review on health care chatbots by Laymouna et al [55] found that only 10 out of 161 (6%) studies reviewed were designed for chronic health patients. Health care chatbots could also serve different functionalities, such as everyday management, education, and administrative support. Another review on chatbots for chronic patients [56] only discovered 10 published studies, confirming that the research field is still in its infancy. Moreover, 60% of studies looked at different chronic health conditions. It is important therefore to consider developing specialized chatbots for different conditions as they potentially vary in symptoms, causes, and management.

Conclusions

This study contributes to the body of literature on AI in pediatric health care, by exploring parental and children and young people's attitudes and acceptance toward a specialized GenAI chatbot for pediatric rheumatology. While this study focused on pediatric rheumatology, findings might be generalizable to other chronic pediatric health conditions. The study also adds to the existing studies on health care chatbots, as the preference for a specific chatbot is demonstrated over a general chatbot, like ChatGPT. Families wanted a chatbot that was accessible and able to "translate" medical information into language suitable for individuals' comprehension levels. Moreover, trust and credibility regarding the chatbot's input, design, and regulation promoted users' adoption intention. As the current "IMPACT" study is based on the concept of a specialized pediatric chatbot, future work should continue to involve users in chatbot development. A chatbot developed for specific pediatric conditions could drastically change the way patients and caregivers seek health information digitally. Not only will families receive the information they want when they need it but also they could be empowered in chronic health management, whilst maintaining a partnership with their child's health professionals.

Acknowledgments

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to them containing identifiable information regarding the participants but are available from the corresponding author upon reasonable request.

Authors' Contributions

CWYL conducted the research and wrote the manuscript with significant input and supervision from KK and PL in every process. KK also engaged in data collection for the questionnaire study. KK and PL were significantly involved in data processing and analysis. PL oversaw the whole study and the wider research project. All authors read and approved the final paper.

Conflicts of Interest

PL is currently receiving a personal fellowship award from the National Institute for Health and Care Research (NIHR) fellowship for nonmedical health care professionals (ACAF reference 302864), and as PPIE colead for the NIHR Great Ormond Street Hospital for Children (GOSH) BRC, she receives some salary support from the NIHR Biomedical Research Center at GOSH. PL is also a senior center affiliate at the Center for Adolescent Rheumatology Versus Arthritis at University College London (UCL) University College London Hospitals (UCLH), and GOSH, which is supported by Versus Arthritis (21593).

Multimedia Appendix 1

World café concept testing questions. [DOCX File, 17 KB - pediatrics v8i1e70409 app1.docx]

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Abbreviations

AI: artificial intelligence
GenAI: generative artificial intelligence
IMPACT: Interventions to Improve Mental Health Support in Families With Children and Young People With Chronic Rheumatological Conditions
LLM: large language model
NHS: National Health Service
REDCap: Research Electronic Data Capture

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Exploring Service Users' Experiences of a Community-Based Intervention to Improve Follow-Up at Bharatpur Eye Hospital in Nepal: Qualitative Study

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Abstract

Background: Follow-up to eye care services for children, especially in the context of Nepal, is essential for ensuring a continuum of care. Hence, as a continued effort, we designed this study to explore the service users' experience of a community-based intervention to improve follow-up at Bharatpur Eye Hospital (BEH) in Nepal.

Objective: This study aimed to explore service users' experiences and perceptions of the community-based follow-up intervention for eye care services implemented by BEH in Nepal.

Methods: A qualitative study using an in-depth interview approach was used. Participants were purposively selected for this research study. Participants who were part of a quasi-experimental study conducted to improve follow-up services in BEH and their service catchment area were chosen. Participants who had not attended even a single follow-up visit and participants who attended at least one follow-up were recruited for this qualitative study. Based on the distance from the base hospital and the follow-up status, 65 participants were initially found eligible for the qualitative study. However, only 17 participants were available and consented. Topic guides were developed for the purpose of in-depth interviews specifically for participants who had not attended at least one follow-up visits and those who attended at least one follow-up visit. A total of 2 ophthalmic assistants, who were not a part of the main intervention study, conducted the interviews.

Results: In total, 17 service users whose children were receiving services from BEH participated in the qualitative study. We identified 4 key themes that provided invaluable information about the barriers and facilitators to follow-up as well as the experiences (positive or negative) of the participants that need to be considered in any future initiatives to improve follow-up in Nepal.

Conclusions: This study highlights the need for systematic development of interventions to address the unmet need for eye care services in the community through innovative, scalable solutions. As a next step, the BEH team will be working to develop such scalable solutions for Nepal. Such interventions will also need to be optimized for similar settings and countries to meet the goals of universal health coverage, vision 2030, and sustainable development goals worldwide.

Trial Registration: ClinicalTrials.gov NCT04837534; https://clinicaltrials.gov/study/NCT04837534

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KEYWORDS

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qualitative study; barriers; facilitators; Nepal; follow-up; eye care services; child health; follow-up care

Introduction

Background

Nepal's National Health Policy 2019 recommends the development and expansion of eye care services through public-private partnerships in all 3 tiers of primary care provided through the government health systems. It provides guidance on the integration of primary eye care with primary health care and the coordination of eye care programs by a dedicated eye unit at the federal ministry of health [1]. One such effort is the Retina Eye Care of Nepal (RECON) project, which was designed to strengthen retina eye care services in Nepal [2]. This initiative was a well-planned health education intervention targeting physicians' knowledge about diabetic retinopathy. Evidence from the evaluation of this initiative identified an increase in the number of referrals and attendance of patients for diabetic retinopathy screening with the change in knowledge and referral mechanism [3].

However, providing referrals does not mean the care is complete. Follow-up for eye care services for children, especially in the context of Nepal, is essential for ensuring a continuum of care [4]. Counseling and follow-up with patients are the key factors in improving the usage of health care services [5]. An exploratory analysis of data from one single hospital (Bharatpur Eye Hospital [BEH]), spanning from January 1, 2019, to January 7, 2019, revealed that only 22% of children aged 0-16 years attended at least one follow-up visit and the remaining 78% could not attend for various reasons. There are several studies conducted to find the impact of interventions, such as SMS text messaging, phone calls, and counseling to improve adherence to follow-up care in both adult and pediatric populations. One of the studies has shown that SMS text messaging reminders significantly improved follow-up adherence in pediatric cataract treatment compared to the control group [6].

A quasi-experimental study was carried out in Nepal by the BEH team to find the effectiveness of follow-up interventions, particularly counseling with the provision of information leaflets and reminders through phone calls and text messages to improve the follow-up rates in comparison to the existing standard care. The primary outcome of the study was measured by the number of children completing all 3 follow-up visits in different intervention groups. This research showed no statistically significant difference in the proportion of follow-up between the intervention groups. Only 3% (8/264) of children completed all 3 follow-ups, but the overall compliance with follow-up was only 0.76%, with more follow-ups in the reminder with SMS text messaging and phone call groups [7]. There may be several reasons for the poor adherence to follow-up visits, but it was hypothesized that COVID-19 was the major contributor since the study was conducted during the peak COVID-19 time. Hence, as a continued effort, we designed this study to explore the service users' experience of a community-based intervention to improve follow-up at BEH in Nepal. We believed that this study would provide invaluable information on the reasons for the poor follow-up outcomes from the quasi-experimental study and the potential drivers of developing a culturally relevant,

context-specific intervention for improving follow-up to ensure a continuum of eye care in the communities of Nepal.

Primary Objective

The primary objective of this research study was to explore service users' experiences and perceptions of the community-based follow-up intervention for eye care services implemented by BEH in Nepal.

Methods

Study Design

The study design was a qualitative study using an in-depth interview approach.

Setting

The interview was conducted by visiting the participants' homes. The purpose of the study was to understand why the participants did not visit the hospital for follow-up. Hence, interviewing them at their residence was identified to be a feasible and effective option.

Study Duration

The study duration was 1 month, from January 15 to February 16, 2024.

Participants

Participants were purposively selected for this research study. Participants who were part of a quasi-experimental study conducted to improve follow-up services in BEH and their service catchment area were chosen. Participants who had not attended even a single follow-up visit and participants who attended at least one follow-up were recruited for this qualitative study. Participants were selected irrespective of the intervention groups they were enrolled in during the quasi-experimental study. The participants were residing within a 20-km radius of BEH, and the interviews were conducted in the participant's residence. Participants with relatively serious eye problems requiring multiple follow-ups were included. Based on the distance from the base hospital and the follow-up status, 65 participants were initially found eligible for the qualitative study. However, only 17 participants were available and consented. The interviews were conducted with these 17 participants.

Data Collection Process

Topic guides were developed by an expert in qualitative research, who was our research guide, for the purpose of conducting in-depth interviews specifically for participants who had not attended even the first follow-up visit and those who attended at least one follow-up visit. Overall, 2 ophthalmic assistants, who were not a part of the main intervention study, conducted the interviews. These interviewers had a brief orientation on the topic guide and interview process to ensure consistency in the conduct of the interviews. The topic guides were piloted with a few participants before interviewing the actual participants. After providing prior information and obtaining written consent from each participant, the interview was carried out in their own communities, as it was not feasible for the participants to attend the hospital for interview purposes. During the interview process, one of the ophthalmic assistants

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conducted the interviews, and the other person was involved in observing and taking notes. Interviews were conducted with the parents or guardians of the children who received eye care services from BEH. The interview participants were the parents/service users who accompanied the child to the hospital during the initial checkup. All the interviews were audio-recorded using a smartphone with consent from participants. We chose to stop the interviews based on the principles of data saturation, that is, when no further information was provided by the participants interviewed.

Data Analysis

We used the framework approach to analyze the qualitative data from this study. Interviews were audio-recorded, and the recorded interviews were transcribed verbatim. The interviews were conducted in the local language (Nepali). Hence, the audio recordings were first transcribed verbatim, and subsequently, the transcribed interview transcripts were translated and back-translated to ensure consistency in English by the other members of the study team. The transcribed data were read a multiple number of times to ensure familiarity. Codes were then identified to understand the framework for analysis. The codes and categories identified from the transcripts were then applied to that framework. The charted data were then carefully interpreted. We carried out member checking to triangulate data and to ensure data confirmability.

Ethical Considerations

Ethics approval was obtained from the Ethical Review Board of the Nepal Health Research Council (ethical review board protocol registration number 761/2020 P and ClinicalTrials.gov number: NCT04837534). Written consent was obtained from the parents or guardians via a consent form before enrolling them in the study. All the information collected was secured and stored safely by the principal investigators. The data were completely anonymized for the purpose of privacy and confidentiality. The participants were not compensated for participating in the study.

Results

Overview

In total, 17 service users whose children were receiving services from BEH participated in the qualitative study. Details of the participants are provided in Table 1. Participants represented the actual communities in Nepal on important sociodemographics. We identified 4 key themes that provided invaluable information about the barriers and facilitators to follow-up as well as the experiences (positive or negative) of the participants that need to be considered in any future initiatives to improve follow-up in Nepal.

Interviewee	Relation with child	Age (years)	Education ^a	Profession	Child age (in years)	Approximate dis- tance from hospital (in km)
1	Mother	25	Secondary	Housewife	2	5
2	Father	30	Secondary	Driver/business	6	5
3	Father	34	Secondary	Business	7	15
4	Mother	28	Primary	Housewife	2	7
5	Mother	35	Secondary	Business	9	18
6	Father	40	Secondary	Plumber	9	16
7	Mother	22	Illiterate	Housewife	1	54
8	Mother	40	Secondary	Housewife	10	34
9	Father	35	Secondary	Contractor	1	17
10	Father	30	Above secondary	Business	1	9
11	Mother	29	Secondary	Housewife	2	11
12	Mother	30	Secondary	Business	1	10
13	Mother	40	Illiterate	Housewife	4	12
14	Father	45	Secondary	Business	10	8
15	Father	40	Secondary	Unemployed	3	13
16	Mother	29	Secondary	Farming	4	6
17	Father	50	Primary	Retired/farming	10	8

Table . Characteristics of study participants.

^aIlliterate: unable to read and write in Nepali; primary: up to grade 5; secondary: grades 6 to 10.

Barriers to Follow-Up

The main reasons for barriers to follow-up were (1) ignorance about the eye problem and the potential solutions, (2) the poor financial situation of the service users, and (3) lack of satisfactory experience from the service providers during follow-up. Service users lacked awareness about the importance

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of regular follow-up for their children's eye condition. Some also found it very uncomfortable to go out and discuss this with others in the community for further support. This was particularly because they were financially poor and could not afford to spend time and seek this advice as well as the treatment charges in hospitals that may be imposed when they follow advice from the community. Hence, they did not attend the follow-up visit as advised by the BEH follow-up intervention.

Many expressed financial constraints as a barrier to follow-up. The costs incurred in the treatment and travel were not affordable for them. Also, they were skeptical about whether the medications, treatment, and investigation would fall under the insurance subsidy or not. Therefore, it was difficult for the service users to abide by the advice related to follow-up that was suggested.

People keep asking us to take our child to different places but its only us who know our situation – Not easy

Many parents were busy and had to take off time from their routine schedules including their work commitments, which made it nonfeasible to comply with the advice for follow-up. As their children were studying and attending school, it was difficult to match their schedule to bring the child for follow-up as advised by the service providers. Lack of school attendance was considered by the service users as a huge loss. Also, the distance of the hospital from home was a barrier, as it cost time and money to travel to the hospital from their faraway residence.

My child needs to go to school, so difficult to come for follow-up during the school hours.

The child was not compliant with the treatment given, like not wearing the glasses prescribed. Some parents were unsure if the child was asked to bring it for follow-up or not. There were a few service users whose children felt better with the initial treatment and so did not continue to follow up.

I do not recall being called for follow up.

Experiences and Perceptions

During the interview, service users felt that their presence was not given any importance. Service users expressed that BEH was the main center for eye care in Chitwan and it was mostly overcrowded, implying a long waiting time, not just at one counter but in all the counters, rooms, and departments they visited. The system and pathway that service users were advised to follow were perceived to be outdated, and there was no fast-track or exclusive service for those referred by their own staff and their own catchment area, thus making the experience not very satisfactory. This was especially the case for those who could not afford the service and for those who required access to the service on an urgent basis. The service users suggested that it would have been better if there was a fast-track eye checkup system, especially for very small children and those who were invited for a follow-up appointment.

One whole day was wasted for eye checkup at BEH, no one valued our time, we are not sure why did they ask us to come for making us wait for so long The service users also felt that some hospital staff did not respond well. They expressed that the BEH support staff were busy on the phone and did not have a friendly approach. Some felt that there was miscommunication about the dates and time for follow-up and a lack of timely information provision and advice related to their felt needs. In addition, a few service users expressed that they were unable to recollect their experiences accurately as it has been a long time since they visited the hospital for follow-up.

I was there in the queue for 3 hours and when my turn came, I was handed out the paper and told to come the next day, that is unfair, they should have informed me on time, it is not possible for me to come here daily. I have a shop to run and so many errands at home!

Service users also shared their positive experiences during the follow-up. They expressed that BEH was well known in our communities; therefore, whenever there was any eye care need, service users preferred visiting BEH rather than other centers (medical or optical shops). Some service users liked that the system was available to access eye care and felt that their experience was comfortable at BEH. One the key features liked by service users was proper signage, which guided them in identifying and accessing different departments. The token system for registration and access to respective departments without any waiting time and smaller queues and the presence of a separate department for children, which made the experience comfortable for the kids and their parents.

It has a homely environment and feels like a second home.

Service users also felt that both clinical and nonclinical staff were well-behaved and had a friendly attitude. The doctors and other clinical staff used very simple and understandable advice. They expressed that the service providers had explained the procedures and treatment options clearly that made it very easy to understand and make decisions. Incidentally, some people experienced less crowd during their visit, so their experience was smooth and less time-consuming.

All staffs even the guard were very friendly to me.

Service users felt that the doctors provided good treatment, provided patient education, and stressed the importance of follow-up visits. The counselor and other clinical staff were observed to have stressed the role of proper treatment options and a good healthy lifestyle to reduce eye problems (such as reducing screen time, having a good healthy diet, and importance of outdoor activities for children).

The eye check-up went easily, it was not at all complicated as anticipated.

Drivers for the Follow-Up

One of the important facilitators for implementing any intervention at BEH was the trustworthiness and brand name of the service provider. Being the oldest and biggest eye care center in Chitwan, BEH has earned its reputation; people perceive it to be the key service provider for that the region.
This is the oldest and biggest centre for eyes in Chitwan, why would I go anywhere else?

Service providers expressed that the eye camps were regularly held by the BEH at schools and localities, which refer patients to the base hospital (BEH). They felt that the service providers helped with information regarding the importance of preschool vision screening. The hospital also provided a national health insurance scheme, so it was very economical to get treatment there. There was also a subsidy system for low-income patients, so no one was denied basic eye care at BEH. Related to the intervention, participants felt that the reminder phone call from the hospital was very useful and helped people to remind themselves of the upcoming follow-up date.

Discussion

Principal Findings

This qualitative study aimed to explore the reasons for poor follow-up for eye care services and the experiences of service users receiving pediatric eye care at BEH. The findings revealed a complex interplay of factors influencing adherence to follow-up appointments, encompassing barriers, negative experiences, positive experiences, and facilitators. Lack of information and awareness about the eye problem and the required care, poor experience in accessing follow-up care, opportunity cost, and financial constraints have been the key reasons for poor follow-up. In addition, the COVID-19 pandemic and the naturally recovered service users who may not need a follow-up may be the contributors to poor follow-up that must be considered.

These reasons for poor follow-up were the commonly identified barriers to accessing any health or rehabilitation, particularly in the context of low- and middle-income countries [8]. In a country like Nepal, the geographical access barriers could be an additional drawback, which was not evident from this study [9-11]. However, the experiences of those who attended the follow-up provided very useful insights about the important aspects to ensure during the development of any pathway for follow-up [12,13]. They stress the importance of systematically developing a specific pathway that is sensitive to the context and culture of the service users in the catchment area [14-16]. They also highlight the need for sensitizing the service providers to the fact that the delivery of health care services may not have the same process and pathways for all service users [17].

The positive experiences from this study reveal some of the important aspects that need to be considered while developing such follow-up pathways for improving the effectiveness and quality of service provision [18]. This is applicable not just to eye care but to all kinds of health care provision services [19,20]. Service providers, including field workers and ground staff; organization of care; and delivery of services must be carefully optimized for improving service efficiency [21]. Our study highlights these important drivers for improving eye care services [22].

The implications of this study highlight the need for more research into the interventions for follow-up, especially for eye care services in Nepal and similar contexts. Much of the care that are globally available is provided within an institution [3-7]. However, for eye care services, this approach needs to be different, and it should include community-based care connecting service users in the community to the service providers at the institutions [23,24]. Technology can be a huge advantage in developing such kinds of interventions. Hence, more research is required on the systematic development and evaluation of comprehensive interventions that can promote a continuum of care [25].

This study also has a few practice and policy implications. Increasing awareness about the problem and potential solutions at the first point of contact can promote the information required to identify choices of care and make appropriate decisions about it. Similarly, the optimization of insurance coverage for socially disadvantaged communities and economically deprived service users by ratifying existing policies or expanding and implementing coverage to provide financial relief for service users can add value and improve service users' experience positively [26].

Limitations and Strengths

This study also comes with a few limitations. Since the initial experimental study was conducted during the COVID-19 pandemic, it was difficult to locate the participants for recruitment. We collected data 2 years post COVID-19, but soon after, the experimental study to test the intervention effectiveness was completed. Although this might appear to contaminate the results, the authors did not identify any potential limitations or recall issues related to the objective of this study during the study. Also, the other stakeholders, such as service providers and administrators, were not interviewed. Doing so might provide their perspectives for understanding the actual context. The interview was recorded in Nepali and was later translated in English. This may have resulted in inadequate reporting of the emotional aspects of the interview. These aspects need to be carefully considered in future studies on this topic. The study also had a few strengths. This study was actually an extension of a quasi-experimental study to understand the lack of statistically significant differences in the findings of that quantitative study. This study enabled us to understand the reasons for systematically developing and evaluating interventions. The participants were those with a need to attend follow-ups but did not turn up. Hence, the data from interviews relate very closely to the purpose of the study. Data triangulation, through repeated verification of audio recordings and transcriptions, was completed. We also carried out member checking and added rigor to this study.

Conclusion

This study provides immensely valuable insights. It highlights the need for systematic development of interventions to address the unmet need for eye care services in the community through innovative, scalable solutions. As a next step, the BEH team will be working to develop such scalable solutions for Nepal. Such interventions will also need to be optimized for similar settings and countries to meet the goals of universal health coverage, vision 2030, and sustainable development goals worldwide.

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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, SB, BP, SKK, RP, DSC, and PG conceptualized and designed the study. SKK finalized the topic guide for the interview. Deepak Kumar Yadav and Prakash Malla were responsible for conducting and recording the interview. Debaki Acharya conducted the data collection and data entry. MS, GB, SB, BP, SKK, and RP did the data analysis. MS, GB, SB, SKK, and RP drafted the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BEH: Bharatpur Eye Hospital **RECON:** Retina Eye Care of Nepal

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

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Abstract

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

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

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

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

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

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KEYWORDS

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

Introduction

Background

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

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

Sweden has an advanced ORA system, facilitated through the national PAEHR 1177 Journal. A regulatory framework implemented in 2017 grants parents default access to their child's PAEHR from birth until the child turns 13 years of age, after which the adolescent gains their own access at the age of 16 years. Parents' loss of access to their child's PAEHR when the child turns 13 years of age was due to concerns that teens may refrain from seeking care for sensitive issues, such as birth control, sexual health, or mental health, if they know that their parents have access to their records. In the first regulatory framework, adolescents themselves gained access to their

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records only at the age of 18 years, but this age limit was later lowered to 16 years, based on the argument that most teenagers are mature enough to make informed decisions about their health at this age. More than half (50.5%) of adolescents access their records from the age of 16 years [12]. The "access gap," when the child is aged between 13 and 15 years, a period during which neither the child nor the parent has access, has been criticized for hindering active participation and engagement in health care, especially by parents of children with serious illness [13,14]. There is an option for both guardians and minors to apply for extended access under special circumstances (such as chronic illness) when the child is aged between 13 and 15 years. The application process involves filling out and submitting a specific paper form to the health care provider, followed by a maturity assessment and approval by the health care provider's operations manager. To approve the application, health care professionals (HCPs) assess needs and risks, as well as the minor's level of maturity and wishes. The process must be repeated for each clinic where the minor is receiving care. However, few applications for extended access from either adolescents or parents have been observed [12]. Thus, although the restrictive policies are intended to ensure safety, their consequences for adolescents with serious health issues and their parent caregivers may be dire and have not been studied.

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

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

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

Study Aim

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

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

Methods

Ethical Considerations

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

Study Design

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

Participants and Setting

We recruited adolescents aged 13 to 18 years with serious health issues and parents of adolescents aged \geq 13 years with serious

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

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

Data Collection

Survey

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



Textbox 1. Survey questions for adolescents and parents.

ADOLESCENTS

Inclusion

1. How old are you?

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

Experience with health care

2. What types of care have you received?

Views on and awareness of online record access (ORA)

- 3. At what age do you think you will have (or when you received) online access to your electronic health record (EHR)?
- 4. Do you want to be able to read your patient-accessible EHR?
- 5. To what extent do you agree with the following statements? (views on ORA age limits)
- 6. If you have thoughts or comments to add about the EHR, please write below.

Demographics

- 7. You identify as...? (gender)
- 8. Who do you live with? (select all that apply)
- 9. Would you participate in an interview about this?
- a. E-mail
- b. Phone number
- c. How would you prefer to be contacted?

PARENTS

Inclusion

- 1. How old is the child for whom you base your answers?
- 2. Did you read your child's EHR online before your child turned 13?

Experience with health care

3. What types of care has your child received?

Views on ORA

- 4. To what extent do you agree with the following statements? (views on ORA age limits)
- 5. If you have thoughts or comments to add about the EHR, please write below.

Demographics

- 6. You identify as ...? (gender)
- 7. How old are you?
- 8. Which region do you live in?
- 9. In what type of area do you live?
- 10. What is your level of knowledge in Swedish?
- 11. What is your highest completed education?
- 12. Approximately how much is your household income before tax in a normal month?
- 13. Would you participate in an interview about this?
- a. E-mail
- b. Phone number
- c. How would you prefer to be contacted?



Interviews

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

Data Analysis

Descriptive statistics were used to present quantitative survey data. Of the 25 interviews, 18 (72%) were transcribed by a professional company and 7 (28%) by JH. Interview analysis was conducted by JH and MH using NVivo (release 1.7.2; Lumivero). MH is a researcher in health informatics with experience of leading and conducting qualitative research. As

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

views on ORA regulations were previously unexplored, we analyzed the interview data using thematic content analysis [29] with an inductive approach. First, JH read all transcripts to develop an understanding of participants' responses. Next, the data were categorized into codes that were grouped into categories and themes. Definitions were refined further through discussions during meetings. Discussions of the findings among all authors improved credibility. Analysis of perceived benefits and risks was inspired by previous work [7,30].

Results

Participant Demographic Characteristics

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

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

^aParticipants could select all that applied; therefore, the total can exceed 100%.

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

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

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

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

^aOn the basis of survey responses.

^bORA: online record access.

^cLess restrictive than current regulations.

^dMore restrictive than current regulations.



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

ID	Age (y)	Gender ^a	Interview setting	Child's diagnosis (age at diagnosis [y])	Adolescent age (y)	Current ORA	^b preference	:		Current ORA situation
						Adolescent	Start age (y)	Parent	End age (y)	
P22	48	Female	Video	Cancer (13)	14	No, opposed	16	Yes, in favor	$+^{c}$	Gained extend- ed access
P48	50	Male	Video	Juvenile arthritis (10)	15	No, opposed	? ^d	Yes, in favor	+ ^c	Gained extend- ed access
P52	37	Female	Video	Skin disease (0)	15	Okay, but no need	13 ^c	Yes, in favor	16 ^c or 18 ^c	Gained extend- ed access
P8	44	Female	Video	Cancer (7)	14	Okay, but no need	15 ^c	Yes, in favor	$+^{c}$	Gained partial extended access
P15	55	Female	Video	Cancer (17)	17	Okay, but no need	18 ^e	Yes, in favor	18 ^c	Access to the child's EHR ^f via the child's account (with assent)
P31	48	Female	Telephone	Bone marrow disease (5)	17	Okay, but no need	16	Yes, in favor	+ ^c	Access to the child's EHR via the child's ac- count (with as- sent)
P1	41	Female	Video	Cancer (11)	14	Yes, in favor	14 ^c -15 ^c	Yes, in favor	14 ^c -15 ^c	Applied for but not gained ex- tended access
P2	49	Female	Video	Cancer (4)	13	No need	16	Yes, in favor	16 ^c	Applied for but not gained ex- tended access
P54	52	Female	Video	Juvenile arthritis (3)	17	Okay, but no need	16	Yes, in favor	18 ^c	Applied for but not gained ex- tended access
P47	47	Female	Video	Juvenile arthritis (10)	15	Okay, but no need	16	Yes, in favor	$+^{c}$	Extended ac- cess expired
Р5	57	Male	Video	Cancer (2)	17	Okay, but no need	16/18 ^e	Yes, in favor	18 ^c	No access, un- aware of extend- ed access
Р9	49	Female	Video	Cancer (4)	17	Okay, but no need	16	Yes, in favor	18 ^c	No access, un- aware of extend- ed access
P12	52	Female	Telephone	Cancer (4)	17	Okay, but no need	16	Yes, in favor	? ^d	No access, un- aware of extend- ed access
P26	45	Female	Telephone	Dental surgery and orthopedic issues (7)	17	Yes, in favor	16-18 ^e	No need	+ ^c	No access, un- aware of extend- ed access
P38	47	Female	Video	Juvenile arthritis (10)	14	Yes, in favor	15 ^c	Yes, in favor	18 ^c	No access, un- aware of extend- ed access
P49	47	Female	Telephone	Juvenile arthritis (11)	15	Yes, in favor	16	Yes, in favor	16 ^c	No access, un- aware of extend- ed access
P55	54	Male	Video	Diabetes (16)	17	Okay, but no need	16	No need	13	Aware of ex- tended access

^aOn the basis of survey responses.

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^bORA: online record access. ^cLess restrictive than current regulations. ^dUnable to specify. ^eMore restrictive than current regulations. ^fEHR: electronic health record.

Quantitative Findings

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

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

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

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



Qualitative Findings

Perceived Benefits of ORA

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

Empowering adolescents referred to ORA helping adolescents to gradually become more involved in their care (eg, by helping

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



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

Empowering adolescents

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

Improved emotional state

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

Enhanced documentation accuracy

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

Improved partnership and communication

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

Supported parental care management

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

Better prepared for appointments

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

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

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

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

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

Supported parental care management referred to ORA facilitating parents' provisioning of care in various ways; for example, both adolescents and parents reported that ORA facilitated parents' management of medications and appointments, improved recall of information, and enhanced parents' understanding of the child's health condition. Some parents stated that the EHRs contained more information than otherwise communicated, such as positive test results. Parents described that ORA facilitated dealing with insurance tasks and that access to test results enabled them to motivate the child to take their medications. Some parents noted that reading test results allowed them to anticipate being called to the hospital, enabling them to prepare their child mentally and emotionally

in advance. Quick access to test results also enabled parents to speed up the care process and prevent unnecessary distress. One parent (P52) mentioned that test results revealed the child's actual condition, even when the adolescent claimed to feel well to avoid a hospital visit. The same parent stated that the only perceived benefit of their adolescent having ORA was that they could log in on their behalf.

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

Perceived Risks of ORA

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

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



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

Emotional distress and confusion

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

Threatened confidentiality

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

Increased burden

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

Low usability

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

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

Increased burden referred to a burden placed on both adolescents and HCPs. Adolescents (only those who had not had access) and parents reported that granting adolescents access could lead to excessive responsibility for adolescents, who, especially when ill, wanted to be able to depend on their parents. Some parents imagined a burden on HCPs, such as adolescents

sending numerous messages through the portal. Moreover, HCPs may feel compelled to omit sensitive information from the EHR, which would be detrimental to the child's future care. Some parents stated that patients' ORA is not a priority for HCPs, who understandably focus on providing care.

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

Views on ORA Regulations

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



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

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

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

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



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

Adolescents and parents were *balancing respect for autonomy and support* in their appraisal of appropriate access ages. Several participants perceived that the need for adolescent and parental ORA depended on factors other than age, such as the adolescents' maturity and interest, which may not correlate with age. Adolescents and parents who advocated access earlier than

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the age of 16 years focused on adolescents' rights to read their records, as well as the importance of involving interested adolescents with serious health issues in their care from an early age. By contrast, having a serious health issue was often perceived as a situation necessitating parental access beyond the age of 13 years, a view supported by 5 (62%) of the 8 adolescents and almost all parents (15/17, 88%). Parents stated that parental ORA should extend into adulthood for children with severe neurocognitive impairments. Some adolescents and most parents were positive about the idea of adolescents aged 16 years gaining access, citing that younger adolescents are often less capable of managing their care and require parental support. Still, most valued the opportunity for interested and mature adolescents to become involved in their own care before adulthood. Some parents were negative about early adolescent ORA, seeing it as a burden for the adolescent or perceiving illness-related information in the EHR as harmful. One parent (P48) stated that the age of 16 years is "too young to deal with such difficult matters," and several stated that adolescents should have a parent present when reading the records.

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

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

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

Mixed Methods Comparison

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

Discussion

Summary of Findings

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

Comparison With Prior Work

While in alignment on many aspects related to ORA regulations, adolescents and parents differed mainly in their views on adolescents' access. Our findings suggest a tension between adolescents and parents similar to that between patients and

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

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

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

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

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

Implications

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

Textbox 4. Implications of the findings.

Implications

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

Limitations

This study has a number of limitations. The sample size was relatively small due to persistent recruitment difficulties, particularly in engaging adolescent participants. Future research may explore alternative recruitment strategies, such as reaching adolescents through schools or other community channels. Moreover, half of the adolescents interviewed (4/8, 50%) were aged 18 or 19 years, which likely affected their views. Among the parent participants, the majority (47/56, 84%) were women, and approximately one-third of the interview participants (5/17,29%) had a medical background or a partner working as an HCP. Notwithstanding this limitation, unequal sample sizes are a common occurrence in mixed methods research [23]. Furthermore, our sample included adolescents with a variety of conditions; however, the focus was not on comparing experiences across groups with specific illnesses but rather on exploring broader perspectives related to ORA use. While the parents varied in education, residential area, and income, most had Swedish as their primary language (53/56, 95%). Given the role of socioeconomic factors in driving disparities in pediatric ORA adoption [37,38], future work should include minors and

parents from diverse language backgrounds to capture broader perspectives. Moreover, 1 survey item included a negation ("I do not want my parents to access..."), which could have been challenging for participants to interpret and therefore to accurately respond to on a scale ranging from 1 to 5. The surveys used were designed by the authors because there are no validated questionnaires available for examining views on ORA. Finally, both adolescents who had read their records and those who had not participated in the study. As a result, some shared their expectations rather than experiences. We strove to present the findings with due consideration to this limitation because there may be differences between expectations and experiences of ORA [2]. We did not provide a demonstration for adolescents without access, which may have impeded their ability to answer anticipatory questions. However, most of the interviews (5/8, 62%) with adolescents were conducted via telephone, precluding visual demonstrations. Regarding interviews conducted via videoconferencing software, it is possible that this format influenced participants due to the potential sensitivity of the topic. In addition, technical issues such as connectivity problems or the lack of a private and secure environment could have further impacted the conversation flow. However, video

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

Conclusions

In Sweden, the regulatory framework on ORA (characterized by a default lack of access for adolescents aged 13-15 y and

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

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Conflicts of Interest

None declared.

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

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

Multimedia Appendix 3 Interview guides in English and Swedish. [PDF File (Adobe PDF File), 1318 KB - pediatrics v8i1e63270 app3.pdf]

Multimedia Appendix 4 Demographics and detailed results. [PDF File (Adobe PDF File), 76 KB - pediatrics v8i1e63270 app4.pdf]

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Abbreviations

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

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Original Paper

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

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Abstract

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

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

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

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

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

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KEYWORDS

growth hormone deficiency; mobile based solutions; caregivers; technology acceptance; digital health; children; therapy; feasibility study; health condition; psychological burden; quality of life; wellbeing; pediatric; mobile Health; mHealth; behavioral change; parent-child relationship

Introduction

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

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

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

caregivers' stress and conducting psychosocial interventions aimed at promoting caregivers' adaptation outcomes [17].

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

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

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

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

Methods

Recruitment

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

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

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

Exclusion criteria

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

Procedures

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

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

Ethical Considerations

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

Measures

DASS-21 Scale

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

Qualitative Interview

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

Adhera Caring Digital Program

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

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



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

The program also includes a behavioral change module which complements and strengthens the knowledge of the psychoeducational module and provides lifestyle suggestions and action planning. It is done by delivering brief messages created by a multidisciplinary team of experts, including doctors and psychologists. The artificial intelligence–driven Adhera Precision Digital Companion Platform will select the tailored

Figure 1. An Educational Unit within the app.



Interview Data Collection and Analysis

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

mobile-based messages to be sent (so the message selected will be personalized according to the patient profile, interests, and other peculiarities) [29]. This program incorporates the principles of personalized health education into a mobile platform, achieved by applying the Integrated Model of Behavioral Change [30] which is further expanded using recommender systems.

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



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

Results

Overview

The characteristics of the sample (n=10) are described in Table 1. The majority of participants were female (80%) with a mean age of 44.9 (SD 4.41) years. Most of the caregivers were married

 Table 1. Descriptive characteristics of the sample.

(70%). In terms of education, the majority held a university degree (70%). The children were primarily female (70%) with a mean age of 10.6 (SD 2.5) years. The average age at the start of was 5.9 (SD 1.66) years and had been under treatment for a mean of 60.3 (SD 23.59) months. The mean adherence rate was 73.44% (SD 28.6).

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

DASS-21 Scale

At baseline, DASS-21 showed that the majority of participants had no symptoms of depression (70%), anxiety (90%), or stress

(70%). However, some of the participants had mild (20%) or moderate (10%) depression, severe anxiety (10%), and mild (20%) or severe (10%) stress, as described in Table 2.



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

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

Interview Results

A total of 3 domains were identified as shown in Figure 2, that are living with GHt, technology acceptance, and contents

evaluation, containing a total of 8 categories. Furthermore, 1 category comprehended 4 subcategories.

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



Living With Growth Hormone Therapy

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

Difficulties

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

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

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

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

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

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

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

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

Perceived Impact of Caregiver Support on Child Health

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

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

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

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

Technology Acceptance

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

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

Performance Expectancy

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

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

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

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

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

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

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

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

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

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

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

Effort Expectancy

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

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

I did not find it difficult. I found it, on the opposite side, very simple, very comfortable, very pleasant. Even the presentation of the application. Or I don't know what to call it, by folders and then more units. I find it very comfortable. I find it very nice. They are calm, it helps to make it more relaxed reading, which is what is needed for this type of information. It seems to me that you have taken great care of that. [Caregiver 07] However, 1 participant reported that she found the app neither pleasant nor unpleasant but contextualizing that was not important for her.

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

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

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

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

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

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

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

Improvement Opportunities

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



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

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

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

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

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

Result of the Adhera Caring Digital Program Usage

All the core ideas regarding the benefits of using the program fall within this category. Participants agreed with several benefits that the ACDP had provided them. On the one hand,

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

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

Contents Evaluation

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

Personalized Education

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

A. Managing GHD

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

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

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

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

but you don't know why and sometimes it doesn't hurt is really important. [Caregiver 07]

B. Health Habits to Improve Dealing With GHD

Some units of the personalized education section were aimed at promoting healthy habits and, more specifically, enhancing healthier eating and sleeping habits. Overall, these contents were labeled as "interesting" and "important." However, 3 participants reported that they were already aware of that information since it had been provided by schools and pediatric health care providers. To them, this information was not that necessary.

Well, less useful, but not because they are not useful. Perhaps, for example, the component focused on healthy eating. It is very general information, but remembering it is important because not all families have the same opinion regarding diet or the importance of healthy eating. But maybe that's the less useful part if I have to say one. [Caregiver 07]

C. Adjusting to Living With a GHD

Considering the emotional impact of the diagnosis on the children's mental health, the program proposed the necessity of providing clear information about emotions and advice on how to strengthen the bond with the caregivers. Participants evaluated positively this content, being a topic that is rarely addressed by medical staff at diagnosis.

In my case, the first section related to the disorder. I can remember things that perhaps would have been forgotten. [Caregiver 06]

D. Taking Care of Yourself to Be Able to Take Care of Your Child

In line with the aforementioned, it is also important to consider the circular process of caring for oneself in order to care for others. Therefore, more content concerning the emotional management of caregivers was also suggested. They acknowledged the importance of their own emotional issues in the development of their children's treatment.

Mental Well-Being Exercises

These exercises included visually guided mindfulness and breathing exercises. This category gathers the users' opinions regarding mental well-being exercises. A caregiver described that practicing these exercises before applying the treatment had strengthened their relationship.

... I think I get along with her much better than before ... "mom, look what I can do." It gives her more confidence, I don't know how to explain it. ... It's our moment. She even told me the day before yesterday "when I don't do the sessions anymore it will seem strange to me, mom. That was our moment" I think it affects a lot, we talk about many things, and since we read it together (talking about the educational content) ... we commented on it. [Caregiver 04]

Some caregivers expressed their curiosity toward these practical exercises and found them appealing and enjoyable. Only 1 caregiver reported that they did not receive any benefit from

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these exercises, which might be related to their specific preferences as stated.

I especially liked the meditation practice. And I would tell you, I would include a little bit more. Regarding caregivers, I liked all contents focused on working as a support, as a caregiver. [Caregiver 03]

Discussion

Principal Findings

Caregivers of children undergoing GHt have reported several factors such as difficulties in understanding the disease or fear of hurting their children that may significantly impact the disease management. The role of caregivers is crucial in the management of GHD, and they have reported their well-being as a very important factor in being able to care for their children. Indeed, our results show that some caregivers have symptoms of depression, anxiety, or stress. In these circumstances, digital health enables the provision of digital services and tools supporting them in the care of their well-being and in the management of their children's disease. In this study, caregivers have expressed a positive attitude toward the use of mHealth solutions for health and well-being management. This finding is in line with those reported by other authors [32]. The results of this study support the ACDP as a feasible and potentially effective tool for caregivers of children undergoing treatment for GHD.

Caregivers' empowerment plays a key role in the effective management of GHD. Unfortunately, during routine consultations, it is not always feasible to cover all the aspects and doubts related to chronic diseases [32], especially the mental well-being of the caregiver. Digital health allows the provision of educational materials that are available just in time. Educational content must be designed not only to cover any lack of knowledge but also to encourage, empower, and optimize the caregivers' role as a manager of the GHD. In this study, caregivers realized and expressed the importance of emotional well-being as well as healthy habits and adequate control of unpleasant situations related to their child's condition. Considering that treatment adherence and the patient's health can be influenced by the caregiver's mental health [17], the ACDP can be a valuable part of the caregiver and patient journey. It is especially relevant once some participants expressed that the subcategory "family adjusting to living with a GHD" is not a common subject addressed during the diagnosis consultations. In this sense, participants in this study considered important not only the educational content but also the dispensing time of the digital health solution. Caregivers consider that the digital program is so useful that should be offered right after the diagnosis of the disease. To maximize their usefulness, digital health programs focused on helping caregivers manage their mental well-being and the day-to-day of their children's disease should be offered at the right time. Furthermore, it was suggested to include a testimonials section or a virtual space where families in the same situation can be in touch. These social features may impact user's motivation resulting in an increased adoption rate. This finding reinforces the fact that digital health can offer effective and motivational

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services for caregivers' unmet needs that complement clinical practice [33,34].

Regarding the technology acceptance defined by the UTAUT theory [22-25], ACDP has been perceived positively by caregivers on performance expectancy and effort expectancy. The most important points of digital health solutions are that they can be used autonomously in the natural environment of the user, so usefulness, ease of use, and likeability are key [35,36]. The results indicate that the program seems to adjust to the core aspects of digital solutions as well as to cover all the needs and difficulties of participant caregivers of children and the user experience leads to a peaceful state of mind. Caregivers' stress levels can affect treatment adherence and the child's health [16], so giving them different tools to manage the disease seems to be a cardinal element in improving the quality of life of both. Therefore, understanding the factors that influence caregivers' adoption and acceptance of mHealth apps is essential for the development of effective digital health interventions [20]. Our study contributes to this understanding, addressing the barriers to acceptance, and adoption among caregivers managing pediatric diseases, including data security.

An interesting result is that the program has become a familiar intervention even though its target is caregivers. Some parents used mental well-being exercises together with their children, which has been reported as a great tool to improve the relationship between the caregiver and the child. Further research with higher samples will be conducted to explore deeply this promising result and analyze how this family intervention could impact caregivers' motivation, engagement, and well-being.

Limitations

This is a local study located in Zaragoza (Spain) with a small sample of 10 caregivers. Because of inclusion and exclusion

criteria, people with low digital literacy were not able to participate. Interviewers were not experts but received training for the purpose of the study. Besides, although the general prevalence of GHD is higher in boys, most caregivers participating in this study were female with daughters affected with GHD, thus, parents with GHD sons might be underrepresented as well as male caregivers. Finally, the program needs further study to include recently diagnosed children.

Although there are quantitative questionnaires to measure the acceptability of digital solutions [37,38], we opted for a qualitative approach in order to get a more comprehensive understanding of the psychological burden experienced by caregivers of children undergoing growth hormone treatment, as well on the factors that influence the acceptability of the digital solution. Due to the post-positivist nature of the consensual qualitative research methodology, an interjudge reliability index is not calculated. However, trustworthiness in the qualitative analysis is guaranteed through iterative discussions between reviewers to share their independent interpretation of the qualitative data. Where consensus is not achieved, a deeper discussion is held until consensus is reached or a third independent reviewer is consulted.

Conclusions

In conclusion, the ACDP shows good acceptance results for family caregivers of children undergoing GHt. The interviews helped identify aspects for further refinement and improvement of the program, including a more intensive focus on the communication between parents and children. This study provides insights into how digital interventions can better support families of children undergoing growth hormone treatment.

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Data Availability

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

Authors' Contributions

LF-L contributed to conceptualization, funding acquisition, supervision, project administration, methodology, resources, writing-original draft, and writing-review and editing. AA contributed to conceptualization, supervision, investigation, methodology, data curation, project administration, resources, writing-original draft, and writing-review and editing. RCB contributed to funding acquisition, project administration, writing-original draft, and writing-review and editing. SQ-P contributed to formal analysis, visualization, writing-original draft, and writing-review and editing. AS-U and PMC contributed to investigation. RB, AJ-D, MP,

and RH contributed to data curation, formal analysis, and visualization. OR-R contributed to validation, writing-original draft, and writing-review and edition. No artificial intelligence tools were used in any portion of the manuscript.

Conflicts of Interest

This study is about a digital solution developed and commercialized by Adhera Health. Adhera Health, AA, and OR-R have other collaborations with Merck Healthcare KGaA beyond this study.

Multimedia Appendix 1 Quotes from participants. [DOCX File, 141 KB - pediatrics v8i1e55023 app1.docx]

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Abbreviations

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ACDP: Adhera Caring Digital Program DASS-21: Depression, Anxiety and Stress Scale–21

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GHD: growth hormone deficiency
GHt: growth hormone therapy
HrQoL: health-related quality of life
ISO: International Organization for Standardization
mHealth: mobile health
rhGH: recombinant human growth hormone
TAM: Technology Acceptance Model
UTAUT: Unified Theory of Acceptance and Use of Technology

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Original Paper

Community Caregivers' Perspectives on Health IT Use for Children With Medical Complexity: Qualitative Interview Study

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Abstract

Background: Children with medical complexity represent a unique pediatric population requiring extensive health care needs and care coordination. Children with medical complexities have multiple significant chronic health problems that affect multiple organ systems and result in functional limitations and high health care needs or use. Often, there is a need for medical technology and total care for activities of daily living, much of which is provided at home by family and caregivers. Health IT (HIT) is a broad term that includes various technologies, such as patient portals, telemedicine, and mobile health apps. These tools can improve the care of children with medical complexity by enhancing communication, information exchange, medical safety, care coordination, and shared decision-making. In this study, we identified children with medical complexity as children aged <21 years who have >3 chronic health conditions. Community caregivers contribute to the care management of children with medical complexity point of contact for the families of children with medical complexity, particularly in vulnerable communities, including families in rural areas, low-income households, and non–English-speaking immigrant populations.

Objective: This study aims to introduce the HIT needs and preferences for children with medical complexity from the perspective of community caregivers. By including their perspective on HIT development, we can better appreciate the challenges they face, the insights they offer, and the ways in which they bridge gaps in care, support, and resources.

Methods: We conducted semistructured interviews (n=12) with formal community caregivers of children with medical complexity populations from a parent advocacy network on the US East Coast. Interviews were audio recorded via Zoom and then transcribed. An inductive thematic analysis was conducted to reveal HIT challenges and preferences for improving the care of children with medical complexity.

Results: We categorized the interview results into themes and subthemes. There are four main themes: (1) telehealth transforming care for children with medical complexity during the COVID-19 pandemic, (2) suggested tools and technologies for care for children with medical complexity, (3) HIT feature preferences, and (4) transition to adult care. Each theme had multiple subthemes capturing all details related to design features of needed technologies.

Conclusions: The study emphasizes the need to develop and enhance HIT for the care of children with medical complexity. The identified themes can serve as design guidelines for designers by establishing a foundation for user-centered HIT tools to effectively support children with medical complexity and their families. Telehealth and mobile health apps could improve care management and quality of life for children with medical complexity.

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KEYWORDS

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pediatric care; children with medical complexity; family-centered care; health information technology; health care software solutions; mobile phone; artificial intelligence

Introduction

Background

Children with medical complexity are a unique group within the pediatric population, characterized by diverse and significant medical needs. Though they represent <1% of children in the United States, children with medical complexities face chronic health conditions that are severe and enduring [1]. These children, all aged <21 years, often have congenital or acquired multisystem diseases or severe neurological conditions that lead to substantial functional impairments [2]. Although there is no universal definition, we used the most common criteria in our study for children with medical complexity as children aged <21 years who have >3 chronic health conditions [2].

Caring for children with medical complexity requires collaboration among stakeholders, including parents, health care providers in hospitals and clinics, school and home nurses, and community caregivers. Despite efforts, the challenges in coordinating care for these children persist, remaining largely unresolved [3]. These challenges include barriers to technology systems, inadequate access to health information, and a lack of partnership in care [4]. The burden of managing these complex medical needs falls heavily on parents, who often experience a significant caregiver burden [5].

Various technologies have been used in health care to improve the quality-of-care process. Health IT (HIT), including patient portals, telemedicine, and mobile health apps, has the potential to help with data management, sharing, and care coordination [6]. These HITs can positively impact medical outcomes, including physical, psychological, and continuity of care [7], minimize medication errors, and provide safer care [8]. For instance, telehealth emerged as a primary technology to provide safer care to children with medical complexity during the COVID-19 pandemic. Children with medical complexity is a vulnerable population that can benefit from technological interventions to improve care management, including information exchange, shared decision-making, and follow-up [9]. However, there is a need for studies to evaluate the effectiveness of HIT in caring for the children with medical complexity population and to identify the challenges and limitations associated with it. It is also critical to explore strategies for safely and effectively integrating HIT into the overall care management of children with medical complexity [10-12].

While parents are responsible for the day-to-day care of their children, community caregivers play a broader role by helping parents navigate complex health care systems. In addition, they ensure that children with medical complexities become fully participating and contributing members of their communities [13]. Community caregivers contribute to the care management of children with medical complexity, serving as advocates, coordinators, primary sources of information about children's needs, and facilitators of access to care [13]. In addition, they support families in vulnerable communities who have a child with a medical complexity, including families in rural areas, low-income households, and non–English-speaking immigrant populations [13,14]. Their experience navigating health care

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systems and HIT enables them to identify gaps in care and areas for improvement. Understanding their feedback and perspective on the use of technology in care for children with medical complexity is essential.

Objective

This study aimed to fill this gap by exploring how current tools and technologies are used and how they can be further optimized to meet the specific needs of children with medical complexity from the viewpoint of community caregivers. By gathering their insights, challenges, and recommendations, this study seeks to guide the development of technological solutions that enhance communication among stakeholders and improve the quality of life for children with medical complexity and their families. To our knowledge, this is the first study to specifically address technology suggestions from the perspective of formal community caregivers.

Methods

Study Design and Data Collection

We recruited formal community caregivers of children with medical complexity populations from the Parent Advocacy Network organization based in New Jersey in the United States, which was founded by the parents of children with special needs in 1987 to provide support to the families of patients with special needs [13]. The staff have supported >500 families of children with medical complexity in New Jersey for many years. We disseminated an informative recruitment email to all the staff members to participate in our study. Most of the staff are also parents of patients with special needs. We used a theoretical data saturation approach in recruitment. The saturation level was determined as the stage where adding more interviews would no longer enrich the conceptual depth of existing themes or reveal additional themes [15]. We ended up with 12 in-depth, semistructured interviews conducted from April 2023 to August 2023. Most (11/12, 92%) participants were female, and (1/12, 8%) participants were male. This study has an exploratory nature to identify various suggestions and needs in HIT design requirements for care for children with medical complexity. The exploratory nature of a qualitative approach generates very rich data and allows us to capture the caregivers' detailed experiences in the matter.

We conducted audio interviews over Zoom (Zoom Video Communications) and recorded all the interviews to be transcribed verbatim for the analysis. The interview guide included questions on the pros and cons of technologies used in care for children with medical complexity, user preferences and needs, suggestions for improving current technologies, telehealth experiences during the COVID-19 pandemic, and design recommendations for new technologies. We did ask probes when necessary to capture more details in unbiased ways. The audio interview was over Zoom per institutional review board requirement, so we did not record the video or observe any nonverbal cues. Each interview lasted from 45 to 60 minutes, and the participants' comfort level determined the duration in continuing to disclose their perceptions and share their experiences.

Data Analysis

The interviews were recorded, transcribed, and analyzed using inductive thematic analysis. The raw data were initially labeled into themes to capture essential data. The themes emerged upon comparing experiences views, situations, and contexts from the same and different participants, and we gradually refined the coding schema. We emerged themes by comparing experiences, views, situations, and contexts from the same and different participants and gradually refined the coding schema. The first author (FE) coded the data and created the themes and a codebook, which the second researcher (OA) validated and refined. Both authors performed the coding using Excel (Microsoft Corp).

During the data analysis process, the authors used an inductive approach to identify themes and understand technological needs, preferences, available options, challenges, and suggestions for improvements. The inductive approach is characterized by a search for patterns [16]. We identified 4 primary themes with their codes. After coding the data, both authors collaborated to categorize the data within each theme into subthemes.

Figure 1. Identified major themes and subthemes.

Subthemes define common dimensions within the main theme [17]. The objective was to explore the data beyond identifying common or dominant themes to uncover unique insights [18].

Ethical Considerations

This qualitative study used semi-structured interviews to collect data after obtaining ethics approval (ID 2023-006 (N)) from the Stevens Institute of Technology. The data was de-identified and does not include any identifier. Participants were paid 30 dollars compensation upon completion of the interviews.

Results

Overview

The inductive analysis resulted in four major themes: (1) telehealth transforming care for children with medical complexity during the COVID-19 pandemic, (2) suggested tools and technologies for care for children with medical complexity, (3) HIT feature preferences, and (4) transition to adult care. Figure 1 shows the 4 major themes and associated subthemes.





Theme 1: Telehealth Transforming Care for Children With Medical Complexity During the COVID-19 Pandemic

The first primary theme identified from the thematic analysis was telehealth use, which is defined as using telehealth services to improve medical care for children with medical complexity health needs during the COVID-19 pandemic. We also developed several subthemes for positive and negative perceptions regarding telehealth use in care for children with medical complexity and suggestions to improve telehealth technologies for care for children with medical complexity from caregivers' perspectives.

The diverse needs of children with medical complexity result in varying health outcomes from telehealth services, depending on the child's medical condition during the COVID-19 pandemic. For example, participant 9 reported improvements in the child's health through telehealth visits, while participant 10 expressed dissatisfaction with the health outcomes achieved through telehealth therapy sessions:

They are all so different. I have one parent that I know when they went virtual, it worked beautifully with her daughter, who has limited speech. It helped so much because she was able to navigate everything. She had clear expectations. She is very visual. So it actually helped a lot. [Participant 9]

Occupational therapy, or the physical therapy or speech therapy, even some of these therapy sessions cannot be offered for children who have very limited understanding or limited functional skills so having those virtual sessions were not beneficial for them, or meaningful for them. For example, if the child cannot follow a direction because of their cognitive ability, or because of that developmental status, then the virtual therapy is not meaningful for them. If the physical therapist is giving the child this direction but then the child cannot move, so the parent has to be right next to the child so that they can either assist the child or they can model that to the child. So then it is a barrier. If the parents are busy with their work, or if they have other commitments then the child is not getting the meaningful therapy sessions. [Participant 10]

However, the participants who are the community caregivers shared common points regarding positive aspects, challenges they observed children with medical complexity parents experiencing, and ideas for improving telehealth services. Multimedia Appendix 1 presents subthemes of the positive aspects of telehealth as perceived by participants, alongside the challenges and limitations they experienced. It also includes suggestions for improving telehealth services to address the diverse needs of children with medical complexity. We reported at least 1 sample quote for each identified subtheme. Positive aspects include just-in-time access to care services (telehealth provides easier access to a variety of needed health care providers), facilitating physician-patient or parent interaction (telehealth facilitates interaction and communication between parents and providers during the COVID-19 pandemic), and

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overcoming geographical barriers (mitigating the barriers in health care services resulting from physical distance). However, participants also identified several challenges, including technical difficulties (the challenges and issues related to the technology used for telehealth appointments that impact the accessibility of services), a lack of communication while transitioning to telehealth during COVID-19 pandemic (the difficulties experienced due to unclear communication while shifting to telehealth services during the COVID-19 pandemic)

transitioning to telehealth during COVID-19 pandemic (the difficulties experienced due to unclear communication while shifting to telehealth services during the COVID-19 pandemic), and simplicity for non-tech-savvy parents (the need for technology that is easy to use and navigate, especially for parents who are not comfortable using various digital tools). In addition, participants suggested several features to improve telehealth for children with medical complexity, including visual graphics (using visual elements to enhance communication and engagement during the telehealth session), educational components (enhancing users' understanding of telehealth), video and audio support (the critical need for high-quality video and audio technology in telehealth to facilitate effective and accurate communication between health care providers and questionnaire addition (the integration patients), of questionnaires into telehealth services), and providing variety of ways to communicate (offering diverse methods to facilitate communication for patients who may find it challenging to express themselves).

Theme 2: Suggested Tools and Technologies for Care for Children With Medical Complexity

This theme covers suggestions for developing tools and technologies to enhance and facilitate care for children with medical complexity. Participants suggested developing various tools and technologies to support themselves or the parents of children with medical complexity, along with the features to be added to existing technology, as shown in Multimedia Appendix 2. One suggestion was the creation of a database for integrated care plans, a comprehensive system to help families manage and coordinate all aspects of their child's health care. This would serve as a centralized database to provide a clear and organized record of their child's information:

The parents need to keep records and, when anything changes, be ready and clear on what needs to happen. Even if a home nurse is coming to assist the parents, the parents are still, as I like to refer to them, the captain of the ship. They are the ones who need to know everything there is to know about their child's health. [Participant 12]

Participants also recommended tools to address language barriers and empower patients, aiming to overcome communication challenges between parents and health care providers arising from differences in languages or communication styles:

It becomes even more complex for my underserved families. For example, if the nurse needs to talk to the child's doctors because the parent does not speak English, the parent should still be included in all of those conversations. [Participant 5]

Some of the medical terminology is very difficult to translate into the parents' native language. Although we have the technology in place, certain medical

terms cannot be translated or interpreted in a way that parents can understand. [Participant 7]

To enhance social development for teenagers with medical complexity, suggestions included social media and game-based apps designed to improve social skills and provide relevant health care information in engaging formats:

When things are developed in a very controlled setting, they work fabulously. However, as they trickle down into real life and society, and real people use them, often the system itself does not work as it should. For example, a system that allows communication without speech by exchanging pictures might help children, but instead of encouraging language development, it may lead to them becoming too comfortable using pictures. When applied in real time, this is very challenging for them, and they are not motivated to become verbal. I have heard many parents complain about this. These should be considered social skill lessons. If a game or solution could be developed and applied to real life, that would be great. [Participant 11]

Paperwork and resource coordination tools were also highlighted to help families organize and track paperwork and resources associated with their child's care:

Sometimes families are not always that organized. One of the things we always advise families is to write down information when they go to the doctor's office, whether in person or virtually. We encourage them to learn how to communicate effectively with doctors and schools and to centralize their paperwork in one place. Managing all the documents, doctor's notes, and medication records can be overwhelming, so it is important to teach families how to keep everything organized. [Participant 3]

Regarding care management tools, participants suggested tools to assist parents with scheduling, tracking appointments, and managing medications:

Medications themselves can be particularly difficult to manage. Understanding and managing prescriptions, including knowing when to refill medications. There are complex instructions like "do not give this one with that one," "take this one with food," "this one needs to be refrigerated," and "this one is an intramuscular injection." With so many different medications and dosages, it can be overwhelming. For example, the same medication might require two pills in the morning and only one at night, which can change on the same day. [Participant 3] In addition, suggestions were made for tools to facilitate the exchange of information between parents, medical providers, and other care providers. Effective communication is essential for informed care coordination and comprehensive childcare:

Text-like feature that allows parents to choose who they want to include in a conversation. Parents do not necessarily want the school involved when it comes to medical matters. But it could have that option where the parent can choose to include people. It should have easy access to sharing and being able to pick and choose what you share and with whom. Making sure that the parent has control and is aware of who is getting what information. [Participant 9]

Finally, the participants suggested tools to minimize risks and prevent errors in the care of children with medical complexity:

I think there is a need for tools and features that support children with medical complexity care to minimize risks. Unfortunately, families are sometimes the care managers. So, for example, if a child needs a diet for a gastrointestinal condition, yet also has kidney disease. They would need to consult with the medical team before they could give that diet and often that does not happen. The family has to say that this child has this medical condition and has to coordinate care between different teams, and it should not be that way, particularly with the availability of electronic health records. But unfortunately, they do not necessarily read the charts, or they are so siloed that they are only focused on their specific specialty. [Participant 5]

Theme 3: HIT Feature Preferences

The analysis showed another major theme around general recommendations preferred in HIT. This theme may assist system and software engineers in developing effective platforms that meet the needs of parents and supporters of children with medical complexity. Understanding these shared preferences is essential for designing technology that provides meaningful support and enhances engagement. The participants expressed their preferences for mobile apps and websites. They valued the convenience of mobile apps for quick access. In addition, mobile apps are beneficial for caregivers or patients with disabilities. However, they recognized that older adults caring for grandchildren with medical complexity prefer websites for their ability to display information on larger screens, such as laptops. The participants also emphasized the importance of mobile app notifications in coordinating care by providing timely reminders for caregivers. Table 1 presents the participants' perspectives on mobile apps and websites.



Table 1. Perspectives on mobile apps and websites.

Subthemes and definitions	Quotes	
Mobile apps versus websites (the compari- son between mobile apps and websites in terms of preferences)	 "Mobile access provides much more freedom. You do not need to have your laptop with you; if you are outside, you can still access data through your mobile device. However, many grandparents who take care of their grandchildren might not be able to have or use mobile apps." [Participant 10] "I think it is important to have something that is not so cumbersome, something they can pull out and use, which is a phone. The invention of the smartphone might have so many capabilities for individuals with disabilities." [Participant 12] 	
Mobile app notifications (the importance of mobile app notification feature for care- givers)	• "I would like an app to coordinate everything and also send reminders or share reminders of what is coming up next. For instance, in terms of care coordination, I am adding information to the app, perhaps that my child visited a specialist on this date, then maybe the app can add reminders in additional ways about an upcoming appointment. Or maybe, if I say in my notes that I met with this specialist and need to schedule a follow-up appointment with so and so. Maybe the app can understand the action items from those notes and say you mentioned this, and you need to schedule a follow-up appointment 1]	

Theme 4: Transition to Adult Care

The last primary theme focuses on a sensitive period in the continuum of care of children with medical complexity. At the age of 21 years, children with medical complexity experience the transition or transfer of care from pediatric settings to an adult setting, findings showed suggestions for technologies specifically for this transition period. The community caregivers highlighted several features of these technologies, especially those related to enabling self-care and management for the patients. The theme emphasized the necessity of designing

technology to empower the youth with the necessary knowledge during this transition to adulthood. In addition, given the shortage of resources and skillsets in adult settings compared to pediatric settings for the children with medical complexity population, they highlighted the various needs children with medical complexity teenagers or young adults with medical complexity might have during and after the transition; therefore, a personalized technology, specifically addressing their needs, would be beneficial. Table 2 presents the subthemes related to various suggestions for using technology to facilitate the transition to adult care.

Table 2. Suggested technology to support the transition to adult care.

Subthemes and definitions	Quotes
Empowering youth with knowledge about their health condition (providing youth with the necessary knowledge to understand and manage their own health issues)	"A youth app would be so important to support health care transition. It is supposed to start at 12 because our kids are going to grow up. Youth are going to go to college, and they are going to have a new provider who is a specialist. Mom is not going to be there with them. So, I believe it is important to provide them with resources about their disability, what it is, and their medications." [Participant 5]
Manage medical appointments (teaching youth with medical complexities how to schedule and organize their own health care visits)	"I think of an app that would help the child to make appointments such as a scheduler. As a mother of a child with medical complexity, we do everything. The truth is that they are going to grow up, and the first steps might even be just having your child sign their name when they come into a doctor's office or calling to make an appointment. The app should be integrated with text to talk for youth with medical complexity." [Participant 5]
Personalized technology features for youth (technology solutions that meet the unique needs and abilities of children with medical complexity)	"An app should be able to assess whether users can read well; based on this assessment, we would use either tenth or twelfth-grade English. If users have receptive issues or dyslexia, we will avoid using this font and instead use one without unusual markings. For example, consider a twelfth-grader who reads at a third-grade level but is transitioning to adulthood. Currently, there are no resources for this, so the child will often rely on information from his parents. This can be a real struggle because, although the content is intended for him, he does not have access to it." [Participant 10]

Discussion

Principal Findings

This qualitative study explores formal community caregivers' perspectives on integrating HIT in the care of children with medical complexity. Community caregivers are an essential part of the care model for children with medical complexity from underserved populations [13,14]. Our findings showed the critical benefits of telehealth for this population, especially during the COVID-19 pandemic, though some negative experiences and improvement suggestions are also noted. We also identified various specific needs that can promote future

technology design to address the specific needs of children with medical complexity in care management as well as the interaction between the parents of children with medical complexity and care providers. Finally, our findings address the need for technologies that support the transition from pediatric to adult care for the children with medical complexity population. To our knowledge, this is the first study capturing children with medical complexity community caregivers' perception of the role and needs of HIT in an effective care for children with medical complexity model.

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Shifting From In-Person Visits to Telehealth

The COVID-19 pandemic has accelerated the adoption of telehealth into the American health care systems, providing safe access to medical care [19,20]. The data reveal that telehealth provided alternatives and safer options to the children with medical complexity population during the peak time of the COVID-19 pandemic as a cost-effective solution that can potentially improve health outcomes for children with medical complexity, facilitate physician-caregiver interaction, and increase caregiver satisfaction, as reported in other studies [21-23]. Community caregivers emphasize that telehealth eases the burden on parents, especially those from underserved populations, by reducing the time they need to take off work and travel long distances, as discussed by other studies [24,25]. During the COVID-19 pandemic, telehealth was the safest method to maintain physical distance while ensuring timely and affordable care [26]. Telehealth facilitated follow-up care, reducing the burden on care teams and decreasing exposure risks for both patients and health care providers [27]. However, the findings also showed that there are certain tasks, especially in inpatient settings, which cannot be done using telehealth. Clear communication between parents and health care providers is needed to ensure timely and reliable care [28]. Our study also revealed that community caregivers advocate for the continuity of telehealth services after the COVID-19 pandemic, driven by the factors mentioned earlier. Despite its advantages, our analysis also showed several challenges related to telehealth use in the care of children with medical complexity. These challenges include technical difficulties, connection issues, a user-unfriendly interface, and a lack of clear instructions for parents to connect to the system [29-31]. These challenges should be addressed and enhanced for better use of telehealth in care for children with medical complexity.

A previous study focused on providing recommendations to enhance telehealth functionalities and support diverse communication needs from the perspective of children, which aligns with our findings [32]. Our participants reported that children with medical complexity often struggle to sit still, listen, and engage throughout a long telehealth session. They suggested that for children with medical complexity, particularly those with developmental disabilities, integrating fun graphics with timers into telehealth can transform their experience. This approach allows families to create a structured environment that actively engages children and leads to more productive telehealth sessions. Moreover, our participants suggest accommodating diverse communication preferences during telehealth sessions, as some children might feel more comfortable expressing themselves through text. Integrating features such as fill-in-the-blank sentences, text-to-voice options, and voice-to-text options can significantly enhance accessibility. In addition, allowing children to choose their voice gender and use emojis to convey their pain levels or express agreement and disagreement can facilitate more effective communication. These adaptations can help create a more inclusive and supportive telehealth experience.

In addition, health care providers must listen to parents' concerns and answer their questions, as it will assist them in coping with difficult situations [33]. Our participants

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recommend that preappointment questionnaires may enhance communication between parents and health care providers. This approach will help parents in addressing their concerns in advance, which will be discussed during the session. In addition, integrating an educational component into telehealth will enhance parents' understanding of the medical information presented during the session.

Technologies for Improving Outcomes of Care for Children With Medical Complexity

Community caregivers suggested tools to address various needs of this population, including parent or patient empowerment, information management, care coordination, communication, and patient safety. Visiting the physician's office can be stressful for this vulnerable group due to the unfamiliar environment [34,35]. Our study revealed that games and social media platforms could improve the social skills of children with medical complexity, such as interacting with the health care staff. Participants suggested gamified learning apps that focus on teaching what is socially appropriate and inappropriate. In addition, social media platforms, such as TikTok, Snapchat, and Instagram, provide short videos that capture children's attention. This feature can help children with medical complexities learn how to interact in a physician's office and encourage them to participate actively in their health management.

Several subthemes emerged from the analysis, showing various management tools to help the parents of children with medical complexity at different levels of care for children with medical complexity, not only in hospitals but mostly in home settings. The data clearly show the increasing interest among caregivers in integrating various HIT tools into the care for children with medical complexity journey to improve the quality of care. As this interest expands, concerns arise regarding validating these technologies, as many lack regulatory approval. In addition, improving patient safety in complex pediatric health care requires providing families with tools that help them with decision-making and communication. Successful communication requires timely information exchange between primary care, specialty care, and families to enhance medical outcomes for children with medical complexity [36]. Our participants indicated that parents often felt responsible for sharing information, as they are the primary drivers of their children's care. Miscommunication and the use of multiple medications in complex medical conditions increase opportunities for error, particularly as children transition between health care settings and practitioners [37]. Communication barriers often prevent parents from properly filling prescriptions or adjusting dosages, resulting in frequent errors and increased risks to patient safety [38]. In addition, parents need to find the right channels and have a road map to assist in understanding and managing the complicated situations or challenges they will encounter in the future [39]. Therefore, community caregivers ask for effective technologies and tools to be developed to address these critical needs of the parents of children with medical complexity.

Another subtheme highlighted the need to address language barriers and empower parents and patients, especially those from underserved populations with low education levels. Parents

with limited English proficiency encounter communication challenges that negatively affect access to and quality of health services for children with medical complexity [40]. Language barriers and health literacy limitations could be associated with parents' less understanding of diagnoses, treatment options, care plans, and follow-up recommendations [41]. In addition, language barriers include a limited understanding of medical terminology while explaining the child's diagnosis and treatment plan [42]. The parents want clear instructions, simplified medical terms, and concrete medication directions [43]. A well-designed tool can help these parents mitigate these barriers and become empowered in the care of their own children with medical complexity.

Preferences and Specifications for User-Centric Design

The data showed some discussions on preferences on the type of technology platforms discussed by community caregivers. The participants discussed their preferences for mobile apps and websites, focusing on how these platforms can meet diverse needs. Smartphones allow users to access information and services anytime and anywhere [44]. However, older adults caring for children or grandchildren with medical complexity might prefer using desktops and laptops, as larger screens provide a more accessible information display.

The participants also emphasized the importance of reminders and notifications in managing their caregiving responsibilities effectively. Reminders are an important feature in mobile apps, helping users manage medication, appointments, and adherence to medical conditions [45]. For instance, the participants in our study mentioned that writing notes is a common practice to keep track of important tasks and appointments; however, this can often lead to information overload and disorganization. It was suggested that an app could analyze these notes and identify action items. Then, the mobile app could send reminders on upcoming appointments and other important tasks. This could be achieved using an artificial intelligence (AI)-powered mobile app that uses natural language processing to analyze the text notes. AI-assisted mobile apps could be designed to provide personalized experiences for parents and offer insights that drive better decision-making [46]. In addition, AI-assisted apps could be extended to assist parents in enhancing medication adherence by recognizing medications and verifying their ingestion [47].

The Role of Technology in Supporting Transitions to Adult Health Care

Our data revealed an interesting theme focusing on the care transition or transfer of this vulnerable population from pediatrics to adult care and how to make this transition better by using various technologies and tools. These tools should educate youth about their complex medical conditions, medications, and overall health management [48]. Children with medical complexity will inevitably grow up, and they will need to navigate independent adult life and responsibilities. Managing multiple medical appointments and follow-ups becomes a significant skill while transitioning to adult care. Our participants suggested an app that includes features such as appointment scheduling and text-to-speech integration, which could help youth with medical complexity learn to navigate this aspect of their care independently. Furthermore, personalized technology solutions that adapt to individual reading levels and cognitive abilities are essential [49]. As suggested by Statewide Parent Advocacy Network participants, an app that provides content accommodating varying reading skills can ensure that children with medical complexity with different learning needs can equally engage with and access adult transition resources.

As shown in the literature, this transition period is risky, and adult settings are significantly less prepared compared to pediatric settings to care for this vulnerable population [50]. Transitioning from pediatric to adult health care is unique to each child and ideally occurs between the ages of 18 and 21 [51]. The negative impact of poorly managed care transition contributes to family burden and distress [52,53]. Families face significant challenges in motivating their children and often lack clarity about the steps needed for the adult care transition phase [53]. There is growing interest in leveraging HIT to facilitate the transition from pediatric to adult care [54,55]. Health care providers and parents support youth in developing autonomy, decision-making skills, and self-management by creating tailored plans that address their abilities and complexities [49]. This process can be further empowered by leveraging HIT, which can provide tools and resources to enhance personalized care and support this transitioning phase, as highlighted by the participants in our study.

Limitations

A limitation of this study is that the interviews were conducted with members of only one organization. In addition, we only collected gender as demographic information about participants. Our participants were predominantly female, so future studies could balance the insights by adding more male community caregivers.

Conclusions

This study explored and analyzed the needs of children with medical complexities and their caregivers throughout their care journey from community caregivers' perspectives. We identified several areas where HIT could enhance care for children with medical complexity conditions. There is a need for improvement in telehealth and the development of mobile health apps across various areas of care for children with medical complexity, such as data management, educational resources, care coordination, and transition to adult care. By addressing these areas, technology designers can contribute to more effective, coordinated, and personalized care for children with medical complexity. This improvement will potentially lead to better health outcomes and a higher quality of life for children with medical complexity.



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Conflicts of Interest

None declared.

Multimedia Appendix 1 Telehealth subthemes, definitions, and sample quotes. [DOCX File , 20 KB - pediatrics_v8i1e67289_app1.docx]

Multimedia Appendix 2

Suggested tools and technologies to be developed for children with medical complexity care. [DOCX File, 19 KB - pediatrics_v8i1e67289_app2.docx]

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Abbreviations

AI: artificial intelligence **HIT:** health IT



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Using a Consumer Wearable Activity Monitoring Device to Study Physical Activity and Sleep Among Adolescents in Project Viva: Cohort Study

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Abstract

Background: The increasing prevalence of physical inactivity and insufficient sleep in adolescents likely contribute to worsening cardiometabolic and mental health. However, obtaining accurate behavioral measures is a challenge. Consumer wearable devices offer a user-friendly method to assess physical activity and sleep.

Objective: This study aimed to describe the process and the preliminary results of physical activity and sleep collected using a consumer wearable Fitbit device in an adolescent cohort.

Methods: We provided Fitbit Charge 2 or Charge 3 wrist-worn activity monitors to adolescent participants in Project Viva, a Boston, Massachusetts area cohort, from 2017 to 2022. We invited participants to wear the devices for \geq 7 days for 24 hours a day to measure their physical activity, heart rate, and sleep, and allowed them to keep the device as a participation incentive.

Results: We collected over 7 million minutes of physical activity, heart rate, and sleep data from 677 participants, 53% (356/677) of whom were female. The mean (SD) age of participants was 17.7 (0.7) years. Among the 677 participants, 65% (n=439) were non-Hispanic White, 14% (n=947) were non-Hispanic Black, 10% (n=69) were Hispanic, 3.2% (n=22) were non-Hispanic Asian, and 7.8% (n=53) belonged to other races. Participants demonstrated a high adherence to the research protocol, with the mean (SD) wear duration of 7.5 (1.1) days, and 90% of participants (612/677) had 5 or more days wearing the device for >600 minutes/day. The mean (SD) number of steps was 8883 (3455) steps/day and the mean (SD) awake sedentary time was 564 (138) minutes/day. Male participants were more often engaged in very active (27 minutes/day) and moderately active physical activity (29 minutes/day) compared with female participants (15 and 17 minutes/day, respectively). Over 87% (588/677) of participants had sleep data available for 5 or more days, among whom the average nightly sleep duration was 7.9 (SD 0.9) hours.

Conclusions: This study demonstrated the feasibility of using consumer wearable devices to measure physical activity and sleep in a cohort of US adolescents. The high compliance rates provide valuable insights into adolescent behavior patterns and their influence on chronic disease development and mental health outcomes.

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KEYWORDS

wearable device; Fitbit; physical activity; sleep; adolescents; behavior risk; mobile phone

Introduction

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The prevalence of physical inactivity and insufficient sleep in adolescents has become a major health concern worldwide. In the United States, approximately 76% of children aged 6 - 17 years engage in less than the recommended 60 minutes of

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moderate-to-vigorous physical activity per day [1]. Similarly, almost a quarter of US children aged 6 - 17 years have less than the recommended 8 hours of sleep per day [2]. Adolescence is a vulnerable period for the development of both psychiatric and chronic medical illnesses [3]. A lack of moderate-to-vigorous physical activity is linked to a higher risk of excessive calorie

intake, obesity [4,5], and cardiometabolic diseases [6-8]; higher risk of depression and anxiety [9-11]; and lower cognitive and school performance [12,13]. In addition, insufficient sleep has been associated with unhealthy dietary behavior [14,15], being overweight [14,16,17], poor school performance, and depression [18-20]. Given the health concerns related to physical inactivity and insufficient sleep among adolescents, a better understanding of these health behaviors through accurate, large-scale data among representative populations is crucial.

Consumer-based wearable devices such as Fitbit (Google) have become popular for objectively measuring physical activity and sleep due to the advancements in microtechnology, wireless communication, battery capacity, and multidimension measurements. In addition, Fitbit devices use Bluetooth for easy data transfer to Fitbit servers through a smartphone or tablet, allowing for synchronization of real-time data. This helps avoid the burden of mailing devices back to researchers and potential data loss that may occur with actigraphs meant solely for research. Fitbits have been validated for collecting real-time behavior data on free-living subjects [21-25]. Although Fitbits have been used to collect real-time behavior data, researchers have not described real-world methods to operationalize consumer-based wearable devices to collect health behavior data in adolescent cohorts. Detailing the operational methods for these devices in real-world setting can enable researchers to examine this novel approach in depth and understand the measurement values.

In this study, we used commercially available Fitbit devices to gather physical activity and sleep data in adolescents. We describe our data collection and cleaning process, and present participants' wear-time results. The collected data will be used to study associations of physical activity and sleep with many aspects of adolescent and young adult health, including cardiometabolic, experiential, and mental health, in future research.

Methods

Project Viva Cohort

Project Viva is an ongoing prospective cohort focused on maternal and child health. We recruited pregnant women between 1999 and 2002 in eastern Massachusetts who received prenatal care at Atrius Harvard Vanguard Medical Associates. Detailed recruitment, eligibility, and cohort information have been previously reported [26]. We collected comprehensive information from mothers and their children at various life stages, and attempted to follow all willing participants after birth. Of the 2128 mother-child pairs enrolled at birth, 1576 pairs had not previously disenrolled and thus were eligible for the Mid-Teen visit.

Data Collection

We contacted participants from July 1, 2017, to August 30, 2021. We invited participants as mother-child pairs by mail or email to participate in the Mid-Teen visit when the child turned 16.5 years old. If the child had sibling(s) who were also enrolled in Project Viva, the sibling(s) also attended the visit regardless of the age.

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We collected data on the demographic variables at several life stages. At recruitment, we collected data about the maternal education. We obtained the child sex at birth and birth date from hospital medical records. During the Mid-Teen visit, trained research assistants measured weight using a calibrated Tanita scale (model TBF-300A; Tanita Corporation of America) and weight using a calibrated stadiometer (Shorr Productions). We calculated the BMI using weight (kg)/ square of height (m²). Race, ethnicity, and household income were collected through a questionnaire.

Wearable Device

We invited all adolescent participants to provide data on physical activity, heart rate, and sleep for 1 week to align with traditional actigraphy study and avoid over burdening participants. Participants had to consent to wear a Fitbit Charge 2 (before 2018) or Fitbit Charge 3 (after 2018) wearable device, depending on the year of the research visit. Both devices have the same core measurement technique, MEMS 3-axis accelerometer and optical heart-rate tracker and are able to track physical activity, heart rate, and sleep on free-living subjects [27,28]. Trained study staff instructed participants to download the Fitbit app on their smartphone and to register a Fitbit account. Study staff then linked their account ID to Fitabase [29], a data management platform to support research projects using Fitbit devices. Participants were asked to wear the device on the nondominant wrist and to synchronize their Fitbit with the app at least once daily. Once synced, study staff were able to access participant data through Fitabase. During the data collection period, research staff checked the platform 2 times a week. For those who did not provide the requested 5 days of data, we sent up to 10 reminders to participants to initiate or continue wearing the device and to sync their data on the app.

The Fitbit device measures physical activity, heart rate, and sleep stages. Physical activity is measured through miniaturized accelerometers. Fitbit uses a proprietary algorithm to calculate steps and categorizes activity intensity into 4 levels-very active, moderately active, lightly active, and sedentary, at the minute level [30,31]. The heart rate is measured through photoplethysmography, an optical technique that uses a light sensor to detect blood volume changes in the capillaries above the wrist [32]. Fitbit uses this measurement to run through a proprietary algorithm to get the beats per minute (bpm). Then, Fitbit combines the accelerometers and heart-rate pattern under a proprietary sleep algorithm to estimate sleep stages. Although some studies have implied that Fitbit may overestimate or underestimate the physical activity and sleep in certain situations, the algorithm has been validated in the contexts of measuring steps and 2-stage wake and sleep classification, with the accuracy mostly being between 80% and 90% when compared with research-grade devices [21-25,33-35].

Data Cleaning and Analysis

We downloaded minute-level Fitbit data on August 29, 2022. The data contained information on activity intensities, steps, heart rate, and sleep every minute. We used heart rate as a proxy to determine wear time. If participants did not have heart rate observed in a given minute, we considered it as nonwear time. We used 2 cutoffs to define participants' valid data, (1)

participants with heart rate data for at least 600 minutes (10 h)/day for 5-9 days and (2) participants with heart rate data for at least 1200 minutes (20 h)/day for 5-9 days. The first cutoff is commonly used in actigraphy studies [36], while the second cutoff allows us to evaluate participants who had high compliance in a full 24-hour period [37].

We used the minute-level data to calculate the results at the daily and participant levels for valid participants. For the daily value of physical activity, we calculated the average steps/hour (during wear time), total steps per day, awake sedentary minutes, lightly active minutes, moderately active minutes, and very active minutes. The awake sedentary time was defined based on the Fitbit algorithm and excluded sleep. We then used the daily value to calculate the physical activity at the participant level.

For sleep data, we selected participants who had sleep data for 5-9 days from the 600 minutes/day cutoff described above. Fitbit assigns 3 values to indicate sleep stages for each minute during sleep periods, "1" indicates being asleep; "2" indicates being in a restless state, which may indicate restlessness during sleep or wakefulness; and "3" indicates being awake during the sleep period. Otherwise, sleep is categorized as "NA," which indicates being fully awake (ie, not part of a sleep period) [38]. We defined a series of sleep metrics based on previous studies [39-41]. We defined sleep cycle as a series of distinct stages of sleep that a person can go through from being asleep to being awake. We defined sleep period as a specific time interval between sleep onset and the end of sleep, where multiple sleep cycles can occur in 1 sleep period. To determine the main sleep period, we manually examined participants' sleep cycles and merged sleep cycles if multiple cycles occurred between 6 PM and 6 AM. If no sleep was found between 6 PM and 6 AM, we then examined the post 6 AM sleep onset time and manually identified the sleep period based on all available Fitbit sleep records for the participant. For the calculation of sleep duration, we focused on the main sleep period, excluding any nap times that occurred after the main sleep period.

Next, we classified the total time spent awake between the sleep onset time and sleep wake up time as wakefulness after sleep onset (WASO). We used the total asleep time between the sleep onset and wake up time divided by the total sleep duration to calculate sleep efficiency. We also calculated the sleep midpoint, which is the middle time between the sleep onset time and final wake up time. We then used the sleep midpoint to determine social jet lag, which measures the difference in sleep midpoint time between week nights (Sunday-Thursday) and weekend nights (Friday and Saturday).

We obtained the demographic characteristics for all participants who had Fitbit data available and for the subset of participants with adequate wear time based on 600 minutes/day and 1200 minutes/day cutoffs. We determined the mean (SD) for average wear days, daily wear time, total steps/hour, and total steps/day using each minimal cutoff. We then compared the wear time by sex into 4 physical activity categories: very active, moderately active, lightly active, and awake sedentary in participants who met our 600 minutes/day cutoff. Finally, we showed sleep results for all valid participants and classified participants who had average sleep onset times before and after midnight, respectively. All the data preparation and analyses were conducted using R (R Foundation for Statistical Computing).

Ethical Considerations

The Institutional Review Board at Harvard Pilgrim Health Care approved this study protocol (235301). All participants provided written informed consent (if aged over 18 years) and assent in combination with parent or guardian informed consent (if under the age of 18 years).

Results

Overall

Out of the 901 invited participants, 809 consented to the Mid-Teen visit and 702 agreed to participate in the Fitbit substudy (Figure 1 shows the participant eligibility flow chart). We ultimately obtained Fitbit data from 677/702 participants (96% of those who consented to the Fitbit substudy). We found similar demographic characteristics between participants who consented to the Mid-Teen visit but did not consent to the Fitbit substudy (Table 1). The raw dataset comprised over 7 million minutes of physical activity and 6 million minutes of sleep data from 677 participants. After data cleaning, the percentage of valid participants remained high (612/677, 90%, using the 600 minutes/day for 5-9 days as the cutoff, and 538/677, 79%, using 1200 minutes/day for 5-9 days as the cutoff).



Figure 1. Diagram of participant flowchart showing the number of participants at different stages of the Mid-Teen (MT) visit.

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Table. Demographic and socioeconomic characteristics of participants who consented to the Mid-Teen visit, participants who received a Fitbit device, and participants with valid data based on 600 minutes/day and 1200 minutes/day cutoffs.

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Characteristic	Participants who con- sented to the Mid-Teen visit (n=809)	Participants who con- sented to the Mid-Teen visit but did not pro- vide Fitbit data (n=132)	Participants who re- ceived the Fitbit device (n=677)	Participants with valid data considering the cutoff of 600 min- utes/day for 5 - 9 days (n=612)	Participants with valid data considering the cutoff of 1200 min- utes/day for 5 - 9 days (n=538)
Age (years), mean (SD)	17.4 (0.7)	18.3 (0.8)	17.7 (0.7)	17.7 (0.7)	17.7 (0.7)
Sex at birth, n (%)					
Female	423 (52)	67 (51)	356 (53)	332 (54)	295 (55)
Male	386 (48)	65 (49)	321 (47)	280 (46)	243 (45)
Race and ethnicity, n (%)					
Non-Hispanic White	528 (65)	89 (67)	439 (65)	395 (65)	346 (64)
Non-Hispanic Black	121 (15)	27 (20)	94 (14)	85 (14)	76 (14)
Hispanic	78 (9.6)	9 (6.8)	69 (10)	60 (9.8)	50 (9.3)
Non-Hispanic Asian	26 (3.2)	4 (3)	22 (3.2)	22 (3.6)	22 (4.1)
Other	56 (6.9)	3 (2.3)	53 (7.8)	50 (8.2)	44 (8.2)
BMI (kg/m ²), mean (SD)	23.96 (5.2)	22.65 (2.8)	24.01 (5.3)	23.94 (5.2)	24.03 (5.3)
Unknown, n (%)	114 (14.1)	104 (79)	10 (1.5)	9 (1.5)	9 (1.7)
Household income, n (%)					
<\$40,000	51 (6.3)	10 (7.6)	41 (6.1)	34 (5.6)	33 (6.1)
\$40,000-\$70,000	79 (9.8)	15 (11)	64 (9.5)	54 (8.8)	45 (8.4)
>\$70,000	597 (74)	72 (55)	525 (78)	482 (79)	423 (79)
Unknown	82 (10)	35 (27)	47 (6.9)	42 (6.9)	37 (6.9)
Maternal college educa- tion, n (%)	598 (74)	103 (78)	495 (73)	453 (74)	400 (75)

Participant Compliance

Among all participants with valid data considering the cutoff of at least 600 minutes/day (on every day worn), participants tended to wear the device for more than 10 hours per day and for more days than requested (Figure S1 in Multimedia Appendix 1). Furthermore, the pattern of wearing the device for more than 10 hours per day persisted when comparing the first recording day with the last recording day (Table S1 in Multimedia Appendix 1). When comparing the wear time between the two cutoffs, the average number of wear days and daily wear time were similar between the 600 minutes/day cutoff group and the 1200 minutes/day cutoff group (wear days: 7.5 days, SD 1.1 days vs 7.7 days, SD 0.9 days; wear time: 1323 minutes, SD 100 minutes vs 1350 minutes, SD 61 minutes). Similarly, the average values for steps/hour were similar between the groups defined by the two different cutoffs (Table 2).



Table . Participants' physical activity results based on 600 minutes/day and 1200 minutes/day cutoffs.

Variable	Participants with valid data considering the cutoff of 600 min/d wear time for 5 - 9 days (n=612), mean (SD)	Participants with valid data considering the cutoff of 1200 min/d wear time for 5 - 9 days (n=538), mean (SD)
Total wear time (d)	7.5 (1.1)	7.7 (0.9)
Daily wear time (min)	1323 (100)	1350 (61)
Total steps per hour (steps/h)	399 (157)	400 (150)
Total steps per day (steps)	8883 (3455)	9041 (3414)
Physical activity level		
Very active (min/d)	20 (20)	21 (20)
Moderately active (min/d)	23 (18)	23 (18)
Lightly active (min/d)	235 (70)	239 (67)
Awake sedentary (min/d)	564 (138)	568 (121)

Physical Activity Results

Among the 4 physical activity categories (awake sedentary, lightly active, moderately active, and very active), we found that of the total awake wear time, the longest duration was spent in sedentary activity for both the 600 minutes/day cutoff group (mean 564 min/d, SD 138 min/d) and the 1200 min/d cutoff group (mean 568 min/d, SD 121 min/d; Table 2). The average wear time spent in the physical activity categories of very active

and moderately active was less than 25 minutes per day for both cutoffs. Male participants spent a slightly higher wear time in the physical activity categories of very active and moderately active compared with female participants (very active: 27 min/d vs 15 min/d, moderately active: 29 min/d vs 17 min/d; Figure 2). On the other hand, female participants spent slightly more time in light activity compared with male participants (245 min/d vs 222 min/d).

Figure 2. Average time spent per day in each of the 4 activity levels: awake sedentary, lightly active, moderately active, and very active. Orange represents female participants and teal represents male participants. The vertical axis indicates the wearing time spent in each activity. Participants were selected using the minimal cutoff for wear time of at least 600 minutes/day for 5 - 9 days.



Sleep Results

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Out of the 612 participants who wore the Fitbit for at least 600 minutes/day, 588 participants had sleep data available (Table 3). In these participants, the average number of days with sleep

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of 7.9 (SD 0.9) hours and average sleep onset time of 00:16 AM (SD 1.5 h). When stratified by weekends and weekdays, participants exhibited longer sleep duration during weekends compared with weekdays (mean 8.4 hours, SD 1.4 hours vs 7.8

data available was 6.9 (SD 1.2) days with a mean sleep duration

hours, SD 1.1 hours), while the sleep efficiency and WASO stayed consistent (Table S2 in Multimedia Appendix 1). In addition, we classified participants into 2 groups (average sleep onset time before midnight vs average sleep onset time after midnight). The sleep efficiency and WASO were minimally different between the two groups. However, the group with the average sleep onset time before midnight had a longer sleep duration, more social jet lag, and earlier wake up time compared

with the second group (sleep duration: 8.1 hours, SD 0.8 hours vs 7.8 hours, SD 0.95 hours; social jet lag: 1.0 hour, SD 1.2 hours vs 0.6 hours, SD 1.9 hours; and wakeup time: 07:16 AM, SD 0.9 h vs 09:09 AM, SD 1.6 h). Furthermore, Figure 3 shows that participants with sleep onset after midnight have a wider wake window (a larger SD) compared with participants with sleep onset before midnight.

Table . Sleep results for participants who have valid data for 5 - 9 days of sleep considering 600 minutes/day, and separated by sleep onset before midnight and sleep onset after midnight.

Sleep measure	Overall participants (n=588), mean (SD)	Participants with average sleep on- set before midnight	Participants with average sleep on- set after midnight
		(n=275), mean (SD)	(n=313), mean (SD)
Number of days with available data	6.9 (1.2)	6.9 (1.3)	6.9 (1.2)
Sleep duration (h)	7.9 (0.9)	8.1 (0.8)	7.8 (0.95)
Sleep efficiency (%)	93 (5)	93 (6)	93 (5)
Wakefulness after sleep onset (h)	0.6 (0.4)	0.6 (0.5)	0.6 (0.4)
Social jet lag (h)	0.8 (1.6)	1.0 (1.2)	0.6 (1.9)
Sleep onset time	00:16 AM (1.5 h)	23:11 PM (0.6 h)	01:17 AM (1.2 h)
Wake-up time	08:17 AM (1.6 h)	07:17 AM (0.9 h)	09:09 AM (1.6 h)

Figure 3. Sleep patterns for participants with average sleep onset before or after midnight (N=588). The inner circle includes participants whose average sleep onset time occurred before midnight (275/588, 47%) and the outer circle includes participants whose average sleep onset time occurred after midnight (313/588, 53%). The clock is based on 24-hour clock with 15 minute intervals. The gradient represents the number of participants in sleep in that given interval, where more purple color indicates more participants in sleep.



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Discussion

Principal Findings

Physical activity and sleep are major behavioral factors associated with various domains of health in adolescents. Consumer-based accelerometry devices, such as Fitbit, have enabled researchers to examine these behaviors efficiently at scale. For our Mid-Teen visit (aged ~17 years old), we invited Project Viva participants to use a Fitbit wearable device to collect physical activity and sleep data. We found participants were likely to consent and to wear the devices for the requested time. We observed that adolescents were spending the majority of their awake time in sedentary activities, with very little time participating in the physical activity categories of very active and moderately active. In the sleep data, we noticed that sleep onset time minimally impacted average sleep duration, sleep efficiency, and WASO; however, participants with a sleep onset after midnight tended to have much wider wakeup time window and less social jet lag.

The rising popularity of wearable devices has introduced a new method of data collection for assessing physical activity and sleep for epidemiology research [42]. This study illustrated the feasibility of using consumer-based wearable devices to collect human-behavior data, such as physical activity, sleep duration, and other sleep metrics, in free-living conditions. In addition, the high granularity of this data enabled us to examine physical activity and sleep at multiple levels: minute level, daily level, and the participant level. The objective data collection method avoided measurement errors resulting from recall or social desirability bias [43,44]. The device being used, unlike many research-based devices, does not need to be mailed back by participants, which avoided additional communication and shipping costs for the researchers, and participant burden of shipping back devices. We additionally avoided the potential of device and data loss during shipping. Furthermore, in the initial communications for the Mid-Teen visit, study staff informed participants that they could keep the device after the study period, and many participants felt it was a nice incentive to participate.

Project Viva has collected sleep and cardiometabolic health information across multiple visits in childhood and adolescence, and plans to continue health assessments in many domains in young adulthood. Our physical activity findings align with existing research, emphasizing the prevalence of sedentary lifestyle among adolescents [45,46]. Notably, we observed a delayed sleep onsite time and longer sleep duration on weekends, similar to previous studies [47,48]. For our future studies, we plan to examine associations of sleep and physical activity behaviors with cardiometabolic health data already collected at the midadolescence visit, such as weight, body composition, blood pressure, and blood biomarkers of cardiovascular health. Furthermore, we plan to use the Fitbit results as a calibration tool to enhance the accuracy and reliability of the self-reported physical activity and sleep data for participants who did not participate in the Fitbit substudy. These Fitbit data offer a unique way to examine health behavior and provide valuable insights into the relationship between behavioral factors and chronic disease development with opportunities for potential interventions. In addition, we have minute level and daily level dataset on objective health behaviors available for more detailed analyses.

Limitations and Challenges

While this study provides insights in using wearable devices to collect adolescent behavior data, there are some limitations to the inferences we can make. First, unlike other actigraphy studies that require participants to complete sleep diaries to self-report sleep onset and wake up times while wearing the device, our study did not request participants to fill out sleep diaries. This made it more difficult to clean the sleep data, especially for participants whose sleep period was less consistent, requiring us to make judgments based on their recorded sleep patterns and manually assign "sleep periods." Second, despite instructing participants to wear the device on the nondominant wrist, we were unable to actively track the wearing status of the device. The wear habits might have influenced the accuracy of step counts and sleep stage recording [49-51]. The third limitation is the proprietary algorithm used by Fitbit. Although previous validation studies have shown 80% - 90% of accuracy for Fitbit devices in adolescents and adults when comparing both physical activity and sleep using research-grade accelerometry[21-25,50-52], the lack of accessibility to Fitbit's underlying algorithms poses challenges in understanding the logic behind the algorithms for each device type and age populations. Finally, Project Viva is composed of adolescents from families with generally high median incomes and higher educational background, which could restrict the ability to generalize the findings to other populations. However, the high granularity data captures individual differences and can be used for comparative analyses as well as integrating with other cohort to extend the findings to a diverse population.

Conclusion

This study provided valuable insights into using consumer-based wearable devices to collect human behavior data. These data on physical activity and sleep characteristics are important for researchers seeking to understand their influence on chronic disease development and mental health outcomes. For future research, consumer wearable devices hold great potential for researchers to apply across different adolescent populations. Their use allows us to gain greater understanding of how lifestyle factors impact long-term health outcomes in diverse populations. These data may shed light on future policies or interventions aiming at increasing physical activity and improving sleep health, ultimately leading to improvements in physical and mental health.

Acknowledgments

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Data Availability

The datasets analyzed during this study are not publicly available due to Project Viva's data use and sharing policy but are available upon reasonable request at project_viva@hphci.harvard.edu.

Conflicts of Interest

None declared.

Multimedia Appendix 1 Basic statistical results. [DOCX File, 78 KB - pediatrics_v8i1e59159_app1.docx]

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Abbreviation

BPM: beats per minute **WASO:** wakefulness after sleep onset

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Original Paper

Parental Perceptions of Priorities and Features for a Mobile App to Promote Healthy Lifestyle Behaviors in Preschool Children: Mixed Methods Evaluation

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Abstract

Background: Parents of preschool-aged children are a key focus for interventions to shape healthy lifestyle behaviors and support risk reduction for obesity from an early age. In light of limited existing evidence on the use of mobile technology to promote healthy lifestyle behaviors among young children, we sought to gather parental priorities regarding a mobile app focused on guided goal setting across the domains of diet, physical activity, media use, and sleep.

Objective: The purpose of this study was to explore the priorities and needs of parents of 2- to 5-year-old children to guide developing the content and features of a mobile app aimed at promoting healthy lifestyle behaviors using a novel convergent mixed methods approach.

Methods: From November to December 2021, we invited parents or guardians in Kentucky to complete a series of web-based concept mapping activities and semistructured interviews (total N=30). Using 2 lists of items focused on (1) parental priorities (content areas) and (2) application features, we asked participants to conduct concept mapping procedures for each list: a web-based sorting activity, where participants grouped items together into thematic piles that made sense to them, and a rating activity, where participants rated each item on a 5-point Likert-type scale. The qualitative interviews were transcribed verbatim, coded, and then analyzed by constant comparative analysis to identify themes. We used the quantitative findings from the concept mapping process to triangulate the resulting themes from the qualitative interviews and generate possible app content areas and features.

Results: The concept mapping results resulted in two 3-cluster concept maps. For parental priorities, participants identified the clusters Creating Healthy Eating Habits, Forming Boundaries, and Building Good Relationships; for app features, participant clusters included Eating Healthy, Using the App, and Setting Goals. The interview themes also represented those 2 domains. Overall, the participants indicated that the top priorities were general health and wellbeing, routine and setting boundaries, and food and healthy eating when it comes to building healthy behaviors among their preschool-aged children. Parents indicated that quick, easy, and child-friendly recipes, goal tracking, and the use of tips and notifications were the features they valued most.

Conclusions: This study contributes to the understanding of what parents or caregivers of young children want from mobile apps, in both content and features, to support building healthy behaviors and routines. The findings can inform future research

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on the development and evaluation of existing or new mobile apps. Specific app features identified to meet family needs should be designed closely with a diverse set of families and tested using rigorous designs to identify the mechanisms of action that mobile apps may use for efficacious healthy parenting outcomes.

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KEYWORDS

mHealth; childhood obesity; mixed methods; pediatric; healthy lifestyle behaviors; preschool children; mobile application; diet; physical activity; exercise; media use; sleep; development; semi-structured interviews; healthy eating; parents; caregivers

Introduction

Healthy lifestyle behaviors remain an essential focus for health care efforts in the United States. As of 2017-2020, the US obesity prevalence rate was 41.9%, with obesity being the leading cause of preventable death across major outcomes, such as heart disease, stroke, type II diabetes, and several forms of cancer [1]. Likewise, childhood obesity rates continue to be a concern in the United States, including a prevalence rate of 12.7% among 2- to 5-year-old children in 2017-2020, resulting in conditions such as high blood pressure, high cholesterol, asthma, sleep apnea, and joint problems at an early age [2]. Additionally, childhood obesity disproportionately affects children of lower socioeconomic status and minority groups [3-5], exacerbating and contributing to this vast array of secondary consequences [6,7]. The state of Kentucky currently ranks second in the nation for both adult and childhood obesity rates, with significantly high rates of obesity among rural Appalachian and urban minority residents [1,2,8]. Parents of preschool-aged children remain a key focus for interventions supporting communities with disproportionately high obesity rates in an attempt to curtail these rates from an early age [9].

Recent research on healthy lifestyle behaviors among preschool-aged children has identified relevant determinants and behaviors. For example, Townsend et al [10,11] describe 12 dietary and behavioral determinants for childhood obesity risk reduction: fat, dietary fiber, fruit or vegetables, calcium or dairy, sweetened beverages, restaurant-prepared food, breakfast, energy density of eaten foods, physical activity, TV-viewing, sleep duration, and parenting. A recent systematic review of family-based childhood obesity prevention interventions indicates that interventions tend to focus on the domains of diet, physical activity, media use, and sleep; however, less than half of the included studies targeted a behavioral domain beyond diet and physical activity, and only 16% targeted all 4 behavioral domains [12]. Likewise, few studies exist that focus on goal-setting interventions among children and adolescents [13], even though guided goal setting represents a feasible strategy for parents to improve health behaviors for obesity risk reduction among children [14]. Additionally, a recent meta-analysis indicated that obesity prevention interventions in youth with low socioeconomic status are more successful when several behavior change strategies are integrated, rather than relying solely on one strategy [15].

Thousands of mobile apps exist that focus on nutrition and physical exercise but are primarily geared toward adults [16]. In our recent review, we found only 3 preexisting reviews of multiple mobile health (mHealth) apps designed for children

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and parents between 2015 and 2022 [17]. Of the 3 reviews, only one provided a list of specific app names, focusing on nutrition as a behavioral intervention for child obesity [18]. The authors of this review concluded that most apps, although free or relatively inexpensive (making them highly attractive to parents), contained content of low quality, were poorly designed, or were not grounded in credible dietary guidelines due to a lack of involvement of nutrition or scientific professionals in the design process [18]. In this review, the most common nutrition features in such apps included promotion of energy balance and guidance on appropriate portion size, and the most common behavioral change feature involved goal setting. Our review identified only 9 apps that use goal setting to change the health behaviors of children.

In light of limited existing evidence, we sought to design a mobile app geared toward parents of preschool-aged (2- to 5-year-old) children, integrating guided goal setting across the domains of diet, physical activity, media use, and sleep. During the formative stage of app development, we sought to integrate feedback from parents with children in our target age range in order to assess major areas of interest and ways the app could best meet their needs. Using a novel mixed methods approach, we combined concept mapping activities and qualitative interviews to capture the perceptions of parents on app content and features. Concept mapping is a useful formative design research tool that uses a structured process to create a visual representation or cognitive map of ideas and concepts [19]. This method has been widely used in a range of formative research topics including mHealth app evaluation [20] and in the development of apps focused on reducing school absences [21]. To our knowledge, this is the first application of concept mapping combined with interviews in the formative design and development of a health-focused app for parents of preschool-aged children. Specifically, the purpose of this study was to use this novel convergent mixed methods approach to explore the needs and desires of parents of 2- to 5-year-old children for the content and features of a health-based mobile app designed to promote healthy behaviors to reduce future obesity risk.

Methods

Recruitment

Study inclusion criteria include the following: primary caregiver of a 2- to 5-year-old child, 18 years or older, and use a smartphone or mobile phone and smartphone apps. Participants were recruited via printed flyers placed at various community-based organizations and distributed via community outreach activities as well as email listservs and social media

channels managed by the university. Recruitment advertisements invited parents to participate in a study to help design a smartphone app for families. Those interested in the study could connect with the study team via an internet link, email, or telephone. The study team employed eligibility prescreening via a REDCap (Research Electronic Data Capture; Vanderbilt University) survey [22]. Participants had the option to complete the eligibility survey online or over the phone.

Ethical Considerations

A waiver of documentation of consent was granted by the University of Kentucky Medical Institutional Review Board (61563). The survey included a web-based process with consent indicated by selecting the "submit" button. If administered by phone, the staff read the consent information and asked participants to consent verbally. Eligible participants were contacted by study staff to schedule an interview and sent a link and log-in information for concept mapping activities.

Study Procedures

From November to December 2021, we conducted 60-minute qualitative interviews (N=30). Interviews were facilitated by staff with a background in public health nutrition and qualitative methodology and conducted via Zoom (Zoom Video Communications) [23]. Interviews were recorded with participant permission. The interview protocol was developed based on a multilevel model of behavioral factors related to pediatric overweight (eg, dietary intake, physical activity, sedentary behavior, sleep, family meals, parenting styles, and feeding practices) [10,11] and research on the importance of goal setting in behavior change [24,25]. In addition, questions were informed by our formative research that demonstrated interest in health-focused apps designed among parents with preschool aged children [26,27] and a review of the content and features of existing apps for parents related to goal setting and tracking [17]. Based on this literature, we developed a semistructured discussion guide (Table S1 in Multimedia Appendix 1) in which we intentionally grouped questions in three logically progressing areas: (1) overall parenting routines and challenges, (2) health and wellness for their preschool-aged child with probes in specific domains from the literature (eg, mealtime, sleep, and active play), and (3) current mobile app use and desired features.

Using a convergent mixed methods design [28], interview participants were simultaneously asked to join in web-based concept mapping activities. Concept mapping is a participatory mixed method that incorporates quantitative elements with qualitative data collection to build consensus around a topic of interest [19,29]. To begin, the study team developed 2 sets of items based on formative research [26,27], which responded to two focal questions: (1) What are health and wellness priorities of your 2- to 5-year-old child? (23 items) and (2) What are the features you would like to have on an app on your phone that could help you set goals and work on goals for taking care of the health and wellness of your 2- to 5-year-old child (31 items)? The first question sought to gather perspectives on app content while the second served to capture desires for app features. We asked participants to complete 2 procedures: a virtual sorting activity, where participants grouped items into thematic piles

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that made sense to them, and a rating activity, where participants rated each item on a 5-point Likert-type scale. For the 23 health and wellness priority items, this rating question was as follows: How important is this item to you as a priority for your child's health (from not at all important [1] to extremely important [5])? For the 31 app feature items, we asked the following question: How often would you use this feature in an app on your phone (from never [1] to all the time [5])? In addition, we asked demographic questions, including race, ethnicity, marital status, number of children, employment status, education, income, and receipt of assistance programs. All concept mapping data were collected using Groupwisdom (Concept Systems, Inc), a web-based concept mapping software [30].

Analysis

The qualitative interviews were transcribed verbatim and analyzed through a combination of a deductive approach and grounded theory to identify themes [31,32] using the ATLAS.ti qualitative data analysis software (version 8.0) [33]. The initial identification of overarching thematic codes used a deductive strategy based on the interview questions, which was informed by previous research on behavioral determinants related to childhood obesity risk reduction, mealtime and child feeding practices, and guided goal setting among parents of preschool-aged children [10,11]. This initial deductive analysis also focused on overarching thematic codes related to potential app features and tools for families of preschool-aged children [17]. Additionally, we used a line-by-line analysis approach to generate a list of emergent, more granular subcodes within the larger coding schematic. In total, 3 coders with backgrounds in public health were trained to allocate codes to quotations. Interrater reliability was determined according to the procedures of Gough and Conner [34], which resulted in a high level of correspondence (93% agreement). The criteria of Lincoln and Guba [35] for trustworthiness of qualitative research were applied to ensure credibility of the findings.

We analyzed the sorting data from each set of concept mapping items in the Groupwisdom software. Specifically, we used similarity matrices and multi-dimensional scaling to generate 2-point maps, which reflect group consensus on the similarity of items. Next, we performed hierarchical cluster analysis for each set of sorting data to group the sets of items into common thematic clusters, resulting in 2 cluster maps. We combined the point and cluster maps for each focus area (parental priorities and app features) to depict items within their thematic areas. As a part of the recommended concept mapping methodology, we also analyzed average item ratings for the Likert-type rating scales to determine which items participants believed were the most important priorities for the health and wellness of their child and which app features were most likely to be used [19].

Finally, we used the interview themes to triangulate the concept mapping findings. Specifically, we synthesized the parental priorities and desired app features results to derive possible content and features of a novel mobile app to improve health behaviors among preschool-aged children.

Results

Participant Characteristics

Table 1 shows the characteristics of those who participated in at least one activity (N=30): qualitative interviews only (n=2), concept mapping only (n=4), or both (n=24). Overall, the majority of participants identified as non-Hispanic White (93.3%), married (70.0%), having 1 or 2 children (80.0%; range

I to \geq 4), and being employed either part- or full-time (63.4%). A significant portion of the sample (36.6%) had a monthly income of US \$2999 or less and 40.0% had not obtained a Bachelor's degree. For families using public assistance, most participated in a combination of WIC (Special Supplemental Nutrition Program for Women, Infants, and Children), SNAP (Supplemental Nutrition Assistance Program), and Medicare or Medicaid.



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Table 1. Characteristics for interview or concept mapping participants (N=30).

Demographic variables	Frequency, n (%)
Race or ethnicity	
Non-Hispanic White or Caucasian	28 (93.3)
Hispanic, Latino, or Spanish origin	2 (6.7)
Marital status	
Married	21 (70.0)
Single—divorced	2 (6.7)
Single—never married	6 (20.0)
Did not respond	1 (3.3)
Children	
1	14 (46.7)
2	10 (33.3)
3	3 (10.0)
4 or more	3 (10.0)
Employment	
Full-time	17 (56.7)
Part-time	2 (6.7)
Not employed	11 (36.7)
Education	
High school or GED (General Educational Development high school equivalency diploma)	3 (10.0)
Some college or technical degree	9 (30.0)
Bachelor's degree	5 (16.7)
Graduate degree	9 (30.0)
Did not respond	4 (13.3)
Monthly income	
<us \$1000<="" td=""><td>4 (13.3)</td></us>	4 (13.3)
US \$1000-US \$1999	3 (10.0)
US \$2000-US \$2999	4 (13.3)
US \$3000-US \$3999	1 (3.3)
US \$4000-US \$4999	5 (16.7)
US \$5000+	7 (23.3)
Did not respond or don't know	6 (20.0)
Types of assistance	
WIC (Special Supplemental Nutrition Program for Women, Infants, and Children)	8 (26.7)
Head start	2 (6.7)
SNAP (Supplemental Nutrition Assistance Program)	7 (23.3)
TANF (Temporary Assistance for Needy Families)	0 (0.0)
Medicare or Medicaid	6 (20.0)

Concept Mapping and Interview Results

The concept mapping results reflected both app content and features: parental priorities and app features. The in-depth interviews resulted in thematic areas containing 257 individual total codes which also fell into these areas. The parental priority

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XSL•FO RenderX themes included the following: desired areas for improvement, routine, mealtime or child feeding behaviors, active play or physical activity, and sleep. The app features' themes included recipes, goal tracking, grocery shopping or meal planning, and tips and notifications. Representative quotes from the identified themes are shared in Table 2.

Table 2. Representative quotes from the in-depth interviews by thematic areas.

Themes	Quotes
Desired areas of improvement	 I care about, of course, my children and their well-being. That they stay happy and healthy; mentally, physically, emotionally. (Mother of 2 boys ages 3 and 6 years old) I'm always up for changes, improvements, anything that I can do that'll make anything easier or more efficient because a lot of times I'll do things the hard way instead of an easier way. I don't know why. My dad always said that I do everything the hard way. (Mother of a 4-year-old boy and a 1-year-old girl)
Routine	• We do try to follow [a routine] just because it tends to let our girls have a better, you know, day, especially when they're on their routine- and if they're not in routine, they tend to act out more. So, we do try to but we don't always follow it, and sometimes it bites us in the [expletive] so on those days it's a little more difficult. (Mother of 2 girls 7 and 2 years old)
Mealtime and child feeding behaviors	• She's very picky. And I have a lot of issues with my weight and I'm afraid that she's going to too. So, I try to like- "Oh well here, I'm eating broccoli. Do you want to eat this? Because dinosaurs eat broccoli" because she likes dinosaurs so she's like, "No it's OK- I'm a dinosaur that doesn't like broccoli." (Mother of 2 girls ages 6 and 4 years old)
Planning grocery shopping	• I do better if I have a list. Sometimes we'll make a list on my phone before I go into the store, so I have something to make sure I get everything. And then a lot of times we'll use Click List, which makes it a lot easier because then everything that we need is all right there, like we have to order it that way, so that makes it a lot easier[] Sometimes I'm still a pencil paper person too. I kind of do all of it. (Mother of a 4-year-old boy and a 1-year-old girl)
Active play or physical activity	• Then I know at school, right now they only get to go outside if it's warm enough so he hasn't been outside much, and I can tell on the days when he's been able to play outside at school versus when he hasn't. (Mother of a 3- year-old boy)
Sleep	• They report his behavior at school because sometimes he does not get good reports and his behavior at school- and I've told them it is directly related to sleep. [] That's one of the biggest factors like nights where I know that he's not slept as much, or if they've said he's took a nap or not. It's most directly related to his bad behavior, a lot of times at school, it'll be one the number one thing. So that is important. (Female caregiver to a 4-year-old boy)
App features	
Recipes	• The recipes that get more attention for me are ones I might actually use in- stead of just browsing would be the ones that's catered for the kids. Or to make it better for them or like a kid twist on something you know, that would be what I would want. (Caregiver to a 4-year-old boy)
Goal tracking	• I know at home sometimes we'll set goals for him. If there's an area that we see, an area of concern, then we'll do like a sticker chart like that I would use in school with a student to meet a certain goal, and we'll talk about that you have to do these three out of the five times. And so, I think if there was an app that would probably be easier than creating sticker charts all the time. (Mother of a 5-year-old boy)
Grocery shopping and meal planning	• I would be interested in it [a shopping list feature] if it was kid friendly and simple. Like if it would be probably like the simplest and quickest kind of interface. Some have gotten to cluttered and have to many things going on, to many things to edit, so, simple is best. (Caregiver to a 4-year-old boy)
Tips and notifications	• I would just say simple. As a parent with everything else on my plate, simplicity is the easiest way[] if I'm looking for something in particular, I want to be able to find it as quickly as I can. (Mother of 2 boys ages 2 and 4 years old)

Building Good Relationships, (2) Forming Boundaries, and (3) Creating Healthy Eating Habits. These cluster names were

developed from pile names participants created in the sorting

process and reflect the major desired areas for app content.

Table 3 includes all of the concept mapping items grouped by

cluster and sorted by the average rating for each item; the highest

rated items for each cluster are shown in italics.

Parental Priorities

Figure 1 displays the combined point and cluster map for the parental priorities area, which shows each of the 23 items in relative positions based on similarity (ie, items close together were often sorted together by participants) and grouped into thematic clusters, providing understanding of perceived commonality. The resulting clusters were as follows: (1)

Figure 1. Parental priorities combined point and cluster concept map.

3. Creating Healthy Eating Habits 21 20 19 °16 °17 18 10 12 • 14 2. Forming Boundaries 11 9 8 15 6 2 1. Building Good Relationships 7



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Table 3. Concept mapping items grouped by cluster with average item ratings (highest rated for each cluster in italics).

Cluster and item	Statement	Average rating (Importance: 1=not at all to 5=extremely)
Parental properties		
1. Building good relationships		
1	Taking care of my child's health	4.96
22	Being a good parent	4.92
2	Talking and listening to my child	4.88
23	Helping my child feel good about their body as they grow up	4.88
4	Spending quality time with my child	4.79
13	Playing with my child	4.67
2. Forming boundaries		
6	Setting and sticking to boundaries that are clear	4.50
5	Establishing and sticking to a daily routine	4.17
7	How to reward my child for good behavior	4.08
8	Limiting my child's time using a phone or tablet	4.00
15	Getting my child to bed on-time	4.00
9	Limiting my child's time watching TV	3.67
3. Creating healthy eating habits		
3	Having a variety of healthy food choices at home	4.63
12	Being a good role model for my child by eating healthy	4.42
19	Getting my child to eat vegetables	4.38
18	Getting my child to eat healthy food	4.29
11	Encouraging exercise or physical activity for my child	4.25
10	Making sure my child doesn't drink too much sugar	4.13
14	Being a good role model for my child by exercising	4.04
16	Preparing more meals at home	3.92
17	Cooking with my child	3.67
21	Ways to address my child's picky eating	3.58
20	Quick and easy recipes for my family	3.50
App features		
1. Eating healthy		
1	Healthy recipes	4.42
4	Easy recipes	4.29
5	Quick recipes	4.29
3	Recipes for kids	4.17
11	Add recipes to a meal plan	4.08
8	Recipe tips	4.04
6	Search and filter recipes	3.92
7	View recipe nutrition facts	3.88

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Cluster and item	Statement	Average rating (Importance: 1=not at all to 5=extremely)
10	Make a meal plan	3.83
12	Tips about child health and nutrition	3.79
9	Make a grocery list	3.71
2	Recipes that can fit my family's dietary needs (eg, vegetarian, gluten free, no dairy, allergies, etc.)	3.50
2. Using the app		
13	App alerts to view tips about child health and nutrition	3.50
31	Links to videos about child health and nutri- tion	3.50
23	Configure app preferences	3.25
22	Setup my family profile—selecting a photo or avatar	2.88
28	Using the app with other family members	2.54
26	Sharing my goal progress with friends and family	2.08
25	Sharing my goal progress with other app users	2.04
27	Sharing my goal progress on social media	1.83
3. Setting goals		
20	Set and track goals about making food more child friendly	3.88
30	Rewards or points for reaching my goals	3.79
14	Quizzes to assess my child's health and well being	3.63
29	Getting feedback on how to improve on my goals	3.50
15	Set and track goals about my child's health and well being	3.42
24	Set and track goals about what my child eats and drinks	3.42
16	Set and track goals about my child's physi- cal activity	3.33
18	Set and track goals about my child's meal- time routine	3.33
21	Reminder alerts to track goals for my child daily	3.29
19	Set and track goals about eating together as a family	3.21
17	Set and track goals about my child's bed- time	3.13

Building Good Relationships

Items in the Building Good Relationships cluster with the overall highest importance ratings included: "1. Taking care of my child's health" (4.96 out of 5) and "22. Being a good parent" (4.92 out of 5), which highlights the importance of overall child well-being. To begin the interviews, we asked about what is most important as a parent or caregiver of your 2- to 5-year-old child or children. Several parents mentioned child happiness or

child emotional or mental health as a main priority. Parents also mentioned spending time with their child, active listening, and communication with their child as important aspects of their parenting style. Many parents stated their child's health in general was most important, while other parents mentioned specific areas of child health such as healthy eating and physical activity. Other areas of priority included building and sticking to a routine, school readiness, and participation in religion.

Forming Boundaries

The Forming Boundaries cluster spoke to the participant-identified need for routine and time management. Items "6. Setting and sticking to boundaries that are clear" (4.50 out of 5) and "5. Establishing a daily routine" (4.17 out of 5) had the highest importance ratings in the cluster. Caregivers described a routine or schedule to establish consistency and reliability for their children. The morning routine, although often the most stressful or hectic, was integral to several families, especially those with a strict morning schedule. Evening routines were often described as a way to establish togetherness and connection with their children, whether through mealtime, playtime, or screen time. Bedtime routines varied for families but were the most commonly described area of routine. Caregivers described that their schedules were highly dependent on a variety of factors such as non-autonomous work schedules, unemployment, appointments, busy lifestyles, child health, and their child's mood or behavior.

Many of those who said that their routine was important or somewhat important emphasized that "life is easier with routine, more difficult without," and that their children were motivated by or thrived on routine. However, not all caregivers identified as planners; ie, several caregivers explicitly mentioned they do not adhere to a routine or *play it mostly by ear*. Whether parents viewed routine as important or not, they were able to describe scenarios where lack of structure was linked to child behavior issues.

Appropriately, the screen time–related items fell in this cluster, including items "8. Limiting my child's time using a phone or tablet" and "9. Limiting my child's time watching TV." Interestingly, the phone or tablet item had a higher importance rating than watching TV (4.00 compared to 3.67 out of 6), suggesting phones and tablets may be a particular area of focus for screen time strategies. Tips for screen time reduction were desirable among interview participants. Barriers included: apartment living or not having a yard, child injuries, busy schedules, younger children (eg, infants) in the household, child health issues, and caregiver being unconcerned about screen time.

Similarly, the only sleep-related item, "15. Getting my child to bed on time," fell into this cluster. Most interview participants described a bedtime routine for their young children and stated that their child had a set bedtime. Participants who stuck to a routine described their child's sleep and sleep compliancy as easy, with good quality and quantity. Alternatively, some caregivers described children who had difficulty falling asleep, resisted sleep, or had issues with waking regularly in the night. Several sleep improvement strategies included having a light, night light, or red light in the room; reading to children before bed; use of supplemental melatonin; soft music; and limits on screen time. Participants also described barriers, such as the use of screens, continuation of breastfeeding, and co-sleeping.

Creating Healthy Eating Habits

The food and nutrition items grouped together as its own cluster (Creating Healthy Eating Habits), including a variety of eating and meal planning or preparation items. The most highly rated were as follows: "3. Having a variety of healthy food choices at home" (4.63 out of 5), followed by "12. Being a good role model for my child by eating healthy" (4.42 out of 5) and "19. Getting my child to eat vegetables" (4.38 out of 5). Mealtime and child feeding were major themes of the interviews. Participant responses were mixed if planning healthy meals was easy, difficult, or somewhere in-between. Many participants stated they actively try to prepare and provide healthy meals for themselves and their children. However, barriers to planning healthy meals included busy schedules or time, finances, food allergies or intolerances in the household, caregivers identifying as poor cooks, and having to tend to more than one young child. Convenience food and eating out were mentioned by parents as a strategy to address busy schedules.

Barriers to desirable child feeding included the child wanting to eat different foods than those prepared, frequent snacking, and wanting to eat close to bedtime. Picky eating was the most frequently raised barrier; only 5 caregivers stated their child was not a picky eater. Successful strategies to combat picky eating included eating meals with children or modeling healthy eating, cooking or preparing food with children, making food and keeping foods child-friendly, separated or compartmentalized on the plate or during serving. Unsuccessful strategies included food coloring or telling the child that a favorite character or animal eats the food. Many parents also stated encouraging vegetable eating was an important part of child feeding. Notably, item "21. Ways to address picky eating" had the second-lowest importance rating in the cluster (3.50 out of 5); this rating may indicate participant preferences toward broadly increasing positive strategies and healthy choices rather than a focus on specific strategies geared toward picky eating.

Some parents practiced strict restriction of what they considered unhealthy or junk foods, while others allowed children to have unimpeded access to snacks high in sugar, fat, and excess calories. A few caregivers expressed concern over their own weight and how this extended to their concern about child overweight or obesity. Although located in the Building Good Relationships cluster, participants highly rated item "23. Helping my child feel good about their body as they grow up" (4.88 out of 5), further emphasizing participant concerns about weight and body image as it relates to food choices.

The diversity of thought around meal planning and grocery shopping may be reflected by the lack of highly rated items. For example, items such as "16. Preparing meals at home," "17. Cooking with my child," and "20. Quick and easy recipes for my child" that correspond to planning and preparing meals fell at the bottom of the ratings for the Creating Healthy Eating Habits cluster (3.92, 3.58, and 3.50 out of 5, respectively). The relatively lower ratings of these items may be due to the wide range of opinions and strategies used by study participants. Participants who identified as meal planners described their motivations and strategies, including budgeting, shopping for staples, or sticking to the list. Some parents found it easier to buy only a few items at a time, while others found it easier to shop in bulk-using storage capacities of their pantries and freezers. Key facilitators included proximity to the grocery store, sharing tasks with another parent or caregiver, and allowing children to choose items at the store. Barriers included busy

schedules, lack of time, finances, child misbehavior, and shopping with children present.

App Features

Figure 2 shows the combined point and cluster map for the App Features area. The App Features map included the following clusters: (1) Eating Healthy, (2) Using the App, and (3) Setting Goals; likewise, these cluster names were developed from participant pile names in the sorting activity. In the interviews, participants were asked about their current use of apps,

Figure 2. Application features combined point and cluster concept map.

especially those that helped with parenting. The type of apps most frequently used by participants to help with parenting were social media (eg, Facebook, Instagram, Snapchat), which caregivers used to follow nutrition-related content, such as recipes, and for parenting advice or finding childcare. Many parents said they used apps to search for and view recipes, including through social media pages, Pinterest, YouTube, and WIC apps. Other participants preferred to use general search engines to find recipes.



Eating Healthy

The concept mapping results support a high interest level in recipes. Items "1. Healthy recipes" (4.42 out of 5), "4. Easy recipes" (4.29 out of 5), and "5. Quick recipes" (4.29 out of 5) had the highest ratings in the Eating Healthy cluster, indicating participants are likely to use these features often or all the time. Recipe viewing was among the most popular desired app features in the interviews; however, some participants did mention they either do not use recipes or are not interested in looking up recipes in an app feature. Participants expressed interest in recipes for the entire family, which could include kid-friendly options, rather than child-specific recipes. Caregivers' desire for planning features like a grocery list maker and meal planning tools was also desired; however, in the concept mapping results, items around meal planning and grocery lists were not as highly rated as those related to recipes. When discussing this as an app feature, participants explained how meal or grocery shopping features may be more likely to be used if they are kept simple.

Setting Goals

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The concept mapping findings also support the popularity of goal-tracking features. Item "20. Set and track goals about

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making food more child-friendly" (3.88 out of 5) had the highest rating for potential use among a variety of goal-tracking items in the Setting Goals cluster. Tracking features, especially goal tracking (eg, healthy eating, sticking to a routine, sleep, etc.) were also among the most desirable features among interview participants. Alternatively, some caregivers mentioned that, due to a lack of time or disinterest, they do not wish to log items or meticulously keep track of child-related goals on their phone. Some parents said this type of activity is already intuitive for them, so the feature would be unnecessary. Other participants said they already use a form of goal tracking that the app would allow them to simplify.

Using the App

Items "13. App alerts to view tips about child health and nutrition" (3.50 out of 5) and "31. Links to views about child health and nutrition" (3.50 out of 5) had the highest ratings among the Using the App cluster, supporting participants' desire for helpful tips and notifications. The next highest rated item was "23. Configure app preferences," suggesting that participants would like to tailor the app settings to their preferences. In the interviews, helpful tips and notifications were welcomed by caregivers; however, many wanted to be clear about the desired frequency at which they wished to be

notified on their phone. Developmental milestone tracking, general parenting tips, and the desire for everything to be in one place were desirable app features. Resoundingly, caregivers also voiced that simplicity and efficiency were important to them in an app.

Synthesis of Parental Priorities and App Features

Table 4 presents a list of possible content and features for a novel mobile app to improve health behaviors among preschool-aged children, based on the combined interview and concept mapping results. The first column depicts the topic areas of the overarching interview codes, the second column lists possible app content areas based on interview subcodes for parental priorities, and the third column lists possible app features based on interview subcodes along with the features rated as most desired in the concept mapping data, which are indicated in bold italics. By first understanding parental priorities, we ensured our resulting app content will be grounded in user-centered needs. In particular, parental feedback pointed to the need for a holistic app with a variety of health topics in one place, including a strong focus on food and nutrition, routines and time management, along with general parenting tips, each of which correspond to the clusters from the concept mapping process (Creating Healthy Eating Habits, Forming Boundaries, and Building Good Relationships). Informed by the concept mapping rating data, we gained information on ways to focus the development of our novel mobile app through the inclusion of quick, easy, and child-friendly recipes; grocery list or meal planning tools; goal tracking; helpful parenting tips; and the ability to control settings, such as notifications and recipe filters, to customize the experience for individual users. As a whole, exploring parental priorities and mobile app features in combination ensured our app development will be informed by both the desired content and functions that target users (parents with preschool children) would like to have.

Table 4. Summary of possible app content and features based on interview and concept mapping results (most desired features in italics).

Interview topic	Parental priorities: possible app content	Parental interests: possible app features
Food and nutrition	 Mealtime or eating behavior (eg, picky eating) Making/planning healthy meals 	 <i>Quick, easy recipes</i>: Kid-friendly; cooking with kids Sort or filter ingredients; allergies Grocery list or meal planning Picky eating and child nutrition tips
Other health-related	Limiting screen timeDental healthActivities for children	 Desire for multiple health topics in one place (holistic) Active play and activities for children tips Features for parent and child
Routine and time management	Time management/planningManaging work responsibilities and parenting	 Goal tracking Ability to control settings Sleep (bedtime/nap) tracking Ability to share success
Behavioral issues	 Discipline and rule setting Sticking to boundaries Reacting mindfully to behavior and patience Influencing your child 	<i>General parenting tips</i>Interaction with other parents or usersAccount for other family members or parent
Developmental milestones	 Potty training Improving speech Socialization and interacting with others Improving sensory development 	Developmental milestone trackingCommunication with health care provider

Discussion

Principal Results and Comparison With Prior Work

Concept mapping has been used on projects focused on childhood obesity prevention programs for adolescents [36] or for the development of culturally appropriate interventions [37], as well as for areas such as sugary drink consumption among children [38], food parenting practices [39], and overall childhood thriving [40]. To our knowledge, however, our study is the first application of the method to guide the development of a health behaviors app for parents of preschool-aged children. In this study, we used a novel, convergent mixed methods

approach to identify parental child health priorities and mobile app features that parents or caregivers would prefer to use. Through the use of qualitative interviews, we were able to describe the breadth of parenting challenges and experiences the participants faced. With the addition of concept mapping activities, we were able to identify converging themes and assess priorities among the provided information.

Overall, the participants in this study indicated psychosocial health and general wellbeing, rather than specific behaviors, as their primary focus when expressing their interest in improving health among their preschool-aged children for mobile app content. Using previous research, 12 behavioral factors were identified related to childhood overweight and obesity that
parents identified when thinking about the health of their child [10,11]. Parent and caregiver responses in this study suggest the importance of establishing a routine and setting boundaries, particularly in areas such as screen time and sleep behaviors. Although healthy eating arose as the most desired topic for resources for young children, participants described a wide variety of preferences around meal planning, grocery shopping, and ways to improve food-related behaviors. Notably, our participants described the importance of all of the related areas identified in the previous literature as important app content to building healthy behaviors for preschool-aged children, including nutrition, physical activity, media use, and sleep.

For specific app features, parents indicated their top choices as (1) quick, easy, and child-friendly recipes; (2) goal-tracking features; and (3) the use of tips and notifications. Goal-setting has been a common behavior change feature used in mobile health applications for children in previous studies with techniques used such as rewards for making progress [18,41,42]. However, there has been a significant gap in that many of the mobile health applications do not feature the involvement of health professionals [18], and few apps exist with the intention of parents using them to modify their children's health behaviors [16,17,43]. In the recent review on goal-setting applications for parents and children, 9 applications were identified that allowed goal-tracking in the setting of health-related behaviors of children, with 6 focused on nutrition or mealtime, 5 focused on physical activity or screen time, 7 focused on sleep, and 6 focused on personal hygiene. None of the apps allowed a parent to specifically recommend goals for each child [17]. Furthermore, matching the divergent views about healthy eating strategies, our participants expressed diversity of thought on their potential use of meal planning or grocery shopping features, though many indicated they would use such features in an app. Additionally, participants expressed interest in tailoring the tips or notifications to a variety of use preferences. As with the health behaviors, our participants described a desire to have everything in one place, so they can find what they need quickly and easily depending on specific needs for their child.

Nutrition and facilitating family mealtimes and daily routines were clearly identified as priorities for this sample of parents and caregivers. The implications of the diverse needs, preferences, and priorities for child health described here may indicate that utility and engagement with mobile tools rest in the balance of simplicity with a choice of multiple features and content foci. Shopping, recipes, and cooking were central to the concerns expressed by these individuals. App features focused on recipes may be designed to incorporate multiple needs and priorities. For example, in order to support the "ease" of healthy meal preparation, provide a recipe feature that allows filtering by time to prepare, provide recipes that address different dietary requirements based on allergies or cultural preferences, or make a shopping list easy to create based on items needed for recipes. Given the preference for a one-stop mobile app, we anticipate that parents will be more engaged with apps that incorporate the whole child and provide behavioral, social, and psychological wellness resources as well.

Limitations

The study sample is representative of relatively lower income families who use public assistance programs; however, the sample included primarily non-Hispanic white and married participants whose perspectives may not represent those of other ethnicities or demographic groups. Future studies in this area should recruit and stratify participants of diverse backgrounds, including single parents and non-traditional family structures, to uncover differences in needs or desires. In addition, individuals choosing to participate in this type of study may be more engaged with parenting practices and improving their child's health than the general population, resulting in selection bias. The use of technology, such as Zoom, can also be a concern among this population; as such, we provided one-on-one assistance to ensure participants felt comfortable using the platform. Additionally, the study had a relatively small sample size, although appropriate for a qualitative approach. Likewise, the purpose of concept mapping is to identify consensus but is dependent upon the composition of the participant sample. Within the concept mapping data, high importance ratings with low variability are often seen, as items are included in the brainstorming list based on their potential importance; we experienced this issue in our data. However, by using multiple methods to triangulate our findings, we feel confident in the ability of our results to accurately capture the perceptions of parents of young children.

Conclusions

For our team, this formative research provided the groundwork for the development of a novel mobile app, including both content and features, for parents and caregivers of preschool-aged children focused on guided goal setting across the domains of diet, physical activity, media use, and sleep. A convergent mixed methods approach provided high-quality data on diverse parental perceptions and challenges and needs for families. Specific app features identified to meet family needs should be designed closely with a diverse set of families and tested using rigorous designs to identify the mechanisms of action that mobile apps may use for efficacious healthy parenting outcomes. This study makes important contributions to the mHealth field for understanding what parents or caregivers of young children want from mobile apps to support building healthy behaviors and routines. The findings can inform future research on the development and evaluation of existing or new mobile apps.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Semistructured discussion guide for interview questions. [PNG File, 547 KB - pediatrics_v8i1e65451_app1.png]

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Abbreviations

mHealth: mobile health **REDCap:** Research Electronic Data Capture

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SNAP: Supplemental Nutrition Assistance Program **WIC:** Special Supplemental Nutrition Program for Women, Infants, and Children

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The Role of Early Engagement in a Self-Directed, Digital Mental Health Intervention for Adolescent Anxiety: Moderated Regression Analysis

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Abstract

Background: Digital mental health (dMH) interventions offer the ability to reach many more adolescents with anxiety than face-to-face therapy. While efficacious dMH interventions are available for adolescents, premature dropout and low engagement are common, especially if delivered on a self-help basis without any form of therapist guidance. This is concerning, given that higher engagement, in terms of the number of sessions completed, has been repeatedly associated with improved clinical outcomes. The reasons for poor adolescent engagement in dMH programs are unclear. A clear understanding of when and why disengagement occurs is important in order to seek to improve engagement rates. Contemporary models consider engagement as multifaceted, comprising both "use" (eg, amount of content completed, frequency of use, duration spent logged into the dMH program, and depth of use, such as word or character count) and "user experience" (eg, interest and satisfaction in the program and affect and attention whilst engaging in the program).

Objective: This study investigated the role of demographic and early engagement (EE) factors, specifically program use, in predicting overall program engagement and continued engagement, respectively, in a self-directed, internet-based cognitive behavioral therapy program for adolescent anxiety, namely, BRAVE Self-Help. It examined multiple measures of program use, including task completion, homework completion, and depth of response (character count of responses typed into program tasks). It also examined the moderating role of baseline anxiety severity.

Methods: Data collected between July 2014 and May 2020 from 2850 adolescents aged 12 to 18 years who participated in BRAVE Self-Help were analyzed via a series of moderated regressions.

Results: Results showed that EE (in terms of program use) was associated with continued engagement, demonstrated by early tasks (tasks completed in the first two sessions; R^2 =0.035; P<.001) and early depth (characters written in the first two sessions; R^2 =0.08; P<.001) predicting continued depth of program response (total character count of responses typed into all program tasks from sessions 3 to 10). Demographic factors and anxiety severity did not directly impact adolescents' engagement in BRAVE Self-Help.

Conclusions: These findings highlight the need to investigate ways to (1) enhance EE and (2) better understand how to measure and capture all aspects of program engagement.

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KEYWORDS

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youth; adolescent; teen; teenager; anxiety; eHealth; internet; engagement; mental health; participation; cognitive behavioral therapy; CBT; psychotherapy; self-help; self-guided; retention; attrition; dropout; digital mental health; web-based

Introduction

Background

Approximately 6.5% of adolescents internationally experience anxiety [1]. Anxiety can become entrenched, lead to a lifelong struggle, and is linked to numerous other problems, such as reduced academic performance, poor self-esteem, social problems, substance abuse, depression, and attention and concentration difficulties [2,3]. Digital mental health (dMH) interventions are an effective treatment of choice for many adolescents with anxiety [4-6]. These digital interventions are highly accessible, flexible, affordable, require no waitlists, and reduce concerns about stigma [6].

While dMH interventions are highly accessible and efficacious, it is a concern that, when delivered on a self-directed basis without therapist support, many adolescents cease the program early or neglect to complete program activities [4]. For example, in a study on the dMH program, youthCOACH, which targets chronic medical conditions in youth aged 12 and 21 years using cognitive behavioral therapy (CBT), only 40% of adolescents adhered to the intervention (completed at least 80% of the seven modules) [7]. In another study on the BRAVE Self-Help program, an open-access CBT dMH program for child and adolescent anxiety, only 30% of the 4425 children and adolescents completed more than three sessions, with the greatest clinical improvements made by those users completing at least 6 of 10 sessions [4]. These findings are consistent with those of a recent systematic review and meta-analysis of 35 predominantly adult dMH interventions (both therapist-supported and self-help), which found that greater engagement was associated with stronger treatment gains [8]. Thus, those with lower engagement potentially fail to obtain the greatest clinical benefit.

Engagement in dMH Interventions

Gan et al [8] suggested that variability in the operationalization of engagement is a limitation of the dMH field, and defined engagement as any objective indicator of intervention use (eg, sessions completed, time spent, or number of logins). Indeed, a broader inspection of the literature reveals that dMH researchers have not applied a universal definition of the construct of engagement, and the term is frequently used interchangeably with "adherence," "compliance," and "use" [9,10]. To date, the majority of research has focused on the amount of the intervention completed, such as the number of completed treatment sessions or activities (eg, March et al [4], Calear et al [11], and Fleming et al [12]) to capture the use of dMH interventions. However, it is now widely acknowledged that engagement is multifaceted and incorporates more than just the number of sessions completed [4,13,14]. Two key reviews by Yardley et al [14] and Perski et al [15] suggest that engagement should be conceptualized as including both use and user experience. Use refers to the amount of intervention content completed (ie, completed sessions and activities), frequency of session completion, duration spent on intervention, and depth of responses (ie, character or word count). In contrast, user experience refers to subjective, self-reported experiences (ie, attention, interest, and satisfaction with the program), and affect

experienced during the program [14,15]. The clinical validity and reliability of these constructs are not yet known; however, the frameworks proposed by Yardley et al [14] and Perski et al [15] provide a useful and comprehensive structure to guide research and advance our understanding and measurement of the numerous potential facets of engagement in dMH interventions.

Early Engagement

Given that higher program use (at least in terms of the number of sessions completed) has consistently been shown to be positively associated with treatment outcomes, but that many participants do not progress beyond a few sessions of dMH programs [8,16], it appears that understanding early engagement (EE) in the first few sessions could offer valuable insight and assist in identifying ways to enhance overall program completion. In a blended-care CBT intervention (combination of videoconference therapy sessions and personalized dMH activities), Wu et al [17] examined the predictors of program retention and found that engagement was poor if participants did not complete their assigned web-based activities early in treatment. Here, engagement was defined as the completion of both the first telehealth therapy session and assigned dMH activities after the session. In relation to self-help dMH programs, there is some research that has identified early "use" in dMH programs is related to program engagement, however, evidence is limited to engagement conceptualized as word count of activity responses [18]. For example, Wallert et al [18] found that writing more words in early dMH activities was related to higher rates of overall program adherence (completing three or more homework tasks). It is possible that greater effort or more in-depth use of content and tasks early in the program (better engagement) may facilitate interest, trigger symptom improvements, and sustained engagement over time. Given that more recent frameworks propose the conceptualization of engagement beyond the number of program sessions completed, there is a need to examine additional facets of engagement and determine whether different types of EE (eg, early completion of in-session and homework tasks, character count, subjective self-report measures, and affect experienced during the program) are important in facilitating program engagement in dMH interventions. This study focuses specifically on the program use component of engagement as it is typically routinely collected and operationalizes multiple measures of program use. It also focuses primarily on the role of EE as described above, and its relationship to overall engagement.

Factors Influencing dMH Engagement

Much of the existing literature has examined factors associated with dMH engagement in adult populations. In a review of 83 adult dMH programs, Liverpool et al [19] found that both intervention-specific influences (such as program suitability, usability, and acceptability) and person-specific influences (such as motivation, opportunity and time availability, family support, and capability) influenced user engagement. Borghouts et al [20] further highlighted that social connectedness, participants feeling "in control" of their health, and having insight into their concerns, were also facilitators of dMH program engagement. With respect to adolescent programs, a review of dMH programs

by Lehtimaki et al [21] found that female, those with lower baseline anxiety, and those with a longer history of mental health conditions were more likely to complete dMH interventions [21]. Similarly, March et al [4,16] found that male, those with higher baseline anxiety severity, and those living in nonmetropolitan regions showed lower levels of engagement (operationalized as the number of sessions completed) in a dMH program for anxiety. However, to date, there is very limited research specifically examining the individual facets of engagement (as suggested in the frameworks by Perski et al [15] and Yardley et al [14]) that predict program engagement with dMH interventions by adolescents.

Aims of This Research

This study examined the factors influencing program engagement, specifically, program use, in a dMH intervention for adolescent anxiety (BRAVE Self-Help). Extending on previous literature, engagement was conceptualized as being multifaceted. The first aim was to examine the effect of person-specific demographic factors (including gender, age, and residential location) on program engagement (sessions completed, in-session and homework tasks completed, depth (total character count), and average frequency (days) between sessions). The second aim was to examine the impact of EE on continued program engagement. EE was examined specifically in relation to program use, and conceptualized as the number of in-session tasks completed, homework tasks completed, and character count (depth of use), within the first two sessions of the program. In addition, previous research has found that participants completing a greater number of BRAVE sessions showed lower baseline anxiety severity [4] and were less likely to be classed in the high anxiety severity group when examining trajectories of change [16], suggesting that anxiety severity may be a relevant factor to consider. Therefore, this study further examined whether baseline anxiety severity moderated the relationship between demographic and EE factors and program engagement.

Methods

Participants and Procedure

Participants were 2850 adolescents aged between 12 and 17 years who had registered for the BRAVE Self-Help program between July 2014 and May 2020. In line with the intended audience of BRAVE Self-Help, only participants demonstrating baseline anxiety severity at an elevated or clinical level on the Children's Anxiety Scale 8-item (CAS-8; see below for details) [22] were included in this study. This study was restricted to adolescents who had completed at least 2 sessions of the program. This was in line with our conceptualization of EE in this study. To ensure adequate measurement of EE, data were required relating to in-session tasks completed (sessions 1 and 2), and between-session tasks (homework allocated in session 1 that was subsequently reported on in session 2). Thus, to provide a comprehensive indication of EE, we required data collected in sessions 1 and 2. Further, as per calls for research to more comprehensively examine engagement through multiple components (eg, Yardley et al [14] and Perski et al [15]), it was important to include 2 sessions in our definition of EE as many

dMH programs focus only on introductory and education-based content in the first session (eg, March et al [16]) without the inclusion of many interactive activities. Therefore, examining only responses to session 1 would not allow sufficient examination of program use in the form of completed activities or use depth. Participants were excluded from the study if they were completing the program as part of a school curriculum or school-based intervention, in order to mitigate any other engagement strategies delivered to these participants (eg, mandatory attendance and homework completion and support or facilitation by a school professional).

Ethical Considerations

Participants were self-referred or referred by others (eg, general practitioners, school counselors, and other mental health practitioners) to the open-access BRAVE Self-Help program. No incentives were provided for participating in the program. Participants provided informed consent prior to commencing the program, and parental consent was also obtained if the adolescent was younger than 16 years of age. Informed consent was also provided for their data to be used in future research. All data analyzed were deidentified. During the registration process, participants provided demographic information (see below) and completed the CAS-8 [22]. This study was part of a larger, ongoing effectiveness study of BRAVE Self-Help (human research ethics approval: ETH2023-0832; University of Southern Queensland; 2020/581; Griffith University).

Intervention

This study used data extracted from BRAVE Self-Help for teenagers (aged 12 to 17 years), a dMH intervention for adolescents with anxiety [4]. BRAVE Self-Help is delivered in 10 web-based, interactive, weekly sessions of 30 to 60 minutes duration and includes cognitive-behavioral strategies such as psychoeducation, cognitive restructuring, physiological awareness, relaxation, graded exposure, problem-solving strategies, positive reinforcement, and guided imagery [23]. Homework tasks are allocated each week to consolidate and enhance learning from each session. Reminders to complete sessions are sent to participants via automated email. BRAVE Self-Help is completed without therapist support, and sessions can be completed at any time but must be completed in order. For a detailed description of the program, refer to March et al [4].

Measures

Demographics

Demographic information was measured at program registration and included age (years), gender, and location (postcode). Participants selected their gender from male, female, transgender, transsexual, transgender transsexual, or genderqueer, androgynous, or other. For analytic purposes, gender was recoded into male, female, and other. Those who identified their gender as "other" were excluded from analyses due to the small number of participants in this category (n=3). Location was coded according to the Australian Statistical Geography Standard [24] with participants categorized into: Major Cities, Inner Regional, Outer Regional, Remote, and Very Remote locations. For analytic purposes and due to the

small number of participants in Outer Regional, Remote, and Very Remote categories, the location was recoded into three categories: (1) Major Cities, (2) Inner Regional, and (3) Outer Regional and Remote.

Anxiety Severity

Anxiety symptom severity was measured at program registration through CAS-8 [22]. Respondents are required to rate on a 4-point scale from 0=Never to 3=Always, the frequency with which each item applies to them. Item responses are summed to produce a total anxiety symptom severity score between 0 and 24, with higher scores indicating greater anxiety symptom severity. CAS-8 scores above the 84th percentile (\geq 10 for male and \geq 12 for female) were categorized as elevated, whilst scores above the 94th percentile (\geq 13 for male and \geq 16 for female) were categorized as Clinical [22]. The CAS-8 has been shown to demonstrate high internal consistency (Cronbach α =0.89) [22]. The internal consistency of the CAS-8 in this study was good (Cronbach α =0.87).

Engagement

This study focused on engagement in terms of program use. A summary of all engagement measures and their operationalizations is provided in Table 1.



Table. Operationalizations of EE^a and OE^b .

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Variable	Definition	Method of measurement
EE		
Completed tasks in sessions 1 and 2 (early tasks)	Completed tasks were defined consistent with completed tasks for program engagement.	The total of the number of tasks completed in sessions 1 and 2, operationalized consistent with the program engagement definition for completed tasks, but for sessions 1 and 2 only.
Session 1 homework tasks completed (early homework)	Completed homework tasks were defined consis- tent with completed homework tasks for program engagement.	The number of session 1 homework tasks com- pleted was measured, consistent with the defini- tion for program engagement for homework tasks, but for sessions 1 and 2 only.
Depth of early responses (early depth)	Early depth was defined as the number of charac- ters typed into free-text boxes in response to program activities.	The total number of characters included in free- text response boxes in sessions 1 and 2 was cal- culated. Homework tasks were not included.
OE		
Number of completed sessions (completed sessions) ^c	Adherence to prescribed program sessions.	The number of sessions completed.
Tasks completed (total tasks) ^c	Tasks were defined as an in-session activity or task embedded within the program, which re- quired the participant to type in a textbox or re- spond to a question asked.	Total number of tasks completed throughout program. Each separate textbox or response ac- tivity was counted as one activity. Activities were defined as completed if the written response by the participant had a minimum of three charac- ters. This was to reduce the probability of a par- ticipant filling in the textbox but not having en- gaged in the activity (ie, responding with an "x" or writing short answers). Each individual com- pleted task was then computed to obtain the total number of tasks completed.
Overall homework tasks completed (total homework) ^c	Homework task completion was defined as a task embedded in the homework section of the session (as the start of the session), which required the participant to type in a textbox or respond to a question asked. Homework tasks were prescribed in the previous session and reported on in the following session.	The total number of homework tasks completed. Each separate textbox or response activity was counted as one activity. As with tasks completed, activities were defined as completed if the written response by the participant had a minimum of three characters.
Session frequency (frequency) ^c	Frequency was defined as how often a participant engages with the intervention.	The average number of days between each completed session.
Depth of responses (program depth) ^c	Program depth was defined as character count within program activities that required a written response. That is, the number of characters typed into free-text boxes.	Total number of characters typed into program activities. Homework tasks were not included. Character count was chosen (over word count) to minimize issues such as typing errors, and missing or additional spaces [25]. To compute the depth of responses, the total characters for each session was computed before averaging the total number of characters across completed sessions.

^aEE: early engagement.

^bOE: overall program engagement.

^cThese variables were measured across 10 sessions when demographic variables were the predictor of OE, but across sessions 3 to 10 when EE variables were the predictor of continued engagement.

Early Engagement

EE was defined as engagement within the first 2 sessions of the program. Similar to the operationalization of engagement by Wu et al [17], EE in this study was defined as the number of tasks completed in sessions 1 and 2, the number of session 1 homework tasks completed (data collected in session 2), and depth of responses (character count) in sessions 1 and 2. Because homework tasks allocated in session 1 are completed between

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sessions and reported in session 2, it was essential that this study included session 2 in its conceptualization of EE.

Program Engagement

Program engagement was operationalized as both overall program engagement (OE) and continued engagement (CE). OE was measured through the total number of program sessions completed, total number of program tasks completed, total number of homework tasks completed, total engagement depth

(character count of responses typed into any program tasks), and average frequency of sessions (average days between sessions). CE was defined as engagement after session 2 (ie, the number of in-session and homework tasks, sessions completed, and depth of engagement from sessions 3 to 10 only). The number of prescribed tasks and homework tasks per session is detailed in Multimedia Appendix 1.

Analytic Strategy

Data were analyzed using SPSS Statistics (version 27; IBM Corp). EE and OE were computed from raw program output data and are described in Table 1 and reported in Table 2 for the total sample, elevated, and clinical subgroups. Differences between the elevated and clinical groups for overall and early program engagement were analyzed using Cohen d.

 Table . Summary of participant demographic and clinical factors across baseline anxiety status.

		• ·		•			
Variable	Elevated anxiety (n=915, 32.11%)	Clinical anxiety (n=1935, 67.89%)	Total partici- pants (n=2850)	t test $(df)^{a}$	Cohen d ^a	Chi-square (<i>df</i>) ^a	P value ^a
Demographic fac	tors				<u>.</u>	·	
Age (years), mean (SD)	13.84 (1.99)	14.32 (1.76)	14.17 (1.85)	6.513 (2848)	0.26	b	<.001
Sex, n (%)				_	_	1.26(1)	.26
Male	243 (26.55)	553 (27.55)	796 (27.92)				
Female	672 (73.44)	1382 (71.42)	2054 (72.07)				
Location, n (%)			_	_	0.73 (1)	.87
Major Cities	473 (51.69)	976 (50.44)	1449 (57.54)				
Inner Re- gional	214 (23.39)	471 (24.34)	685 (24.03)				
Outer Re- gional and Re- mote	119 (13.01)	265 (13.70)	384 (13.47)				
Missing ^c	109 (11.91)	223 (11.52)	332 (11.65)				
Aboriginal and	Torres Strait Islan	der, n (%)		_	_	57.29 (1)	<.001
Yes	4 (0.01)	10 (0.01)	14 (0.01)				
No	199 (21.75)	214 (11.06)	413 (14.49)				
Missing ^d	712 (77.81)	1711 (88.42)	2423 (85.02)				
Clinical factors							
CAS-8 ^e score at baseline, mean (SD)	14.26 (4.41)	15.96 (6.54)	15.41 (5.99)	7.133 (2848)	0.30	_	<.001

^aRatio of difference, effect size (Cohen *d* and chi-square), degrees of freedom, and significance between the elevated and clinical group at baseline. ^bNot applicable.

^c332 participants did not disclose their residing location.

^dAboriginal and Torres Strait Islander data were not collected until August 27, 2018.

^eChildren's Anxiety Scale 8-item.

For the first research question, 15 separate moderated regression analyses were conducted to examine whether baseline demographic factors predicted OE (one moderated regression per predictor and dependent variable) and whether baseline anxiety severity moderated these relationships. Demographic factors (age, gender, and location) acted as the independent variables, whilst total completed sessions, total tasks completed, total homework tasks completed, depth of responses, and frequency of session completion acted as the (OE) dependent variables. For the second research question, 15 separate moderated regression analyses were conducted to examine whether EE factors predicted CE (one moderated regression per predictor and dependent variable), and whether baseline anxiety severity moderated these relationships. Early tasks, early depth, and early homework acted as the independent variables. The dependent CE variables were completed sessions, total tasks completed, total homework tasks completed, depth of responses, and frequency of session completion.

Anxiety severity acted as the moderator variable, with participants categorized as either elevated or clinical. Regression

analyses were conducted separately for each predictor, given that previous research has shown certain demographic factors may contribute more to overall engagement than others [4,21] and models suggest that the multifaceted nature of engagement needs to be further understood [14,15]. As we were interested in understanding which EE factors had the strongest effects in predicting CE, we conducted separate rather than multivariate regression analyses. Given the large number of regression analyses conducted, a conservative Bonferroni correction of P<.001 was applied for all analyses.

Results

Demographic and Clinical Characteristics of Participants

A summary of participant baseline demographic and clinical characteristics across anxiety status is provided in Table 2.

Table .	Summary	of OE ^a ,	CE ^b , and	EE ^c	characteristics
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EE, CE, and OE Characteristics

As seen in Table 3, adolescents in the elevated group demonstrated significantly greater OE than those in the clinical group, as measured by total homework, program depth, and early depth. Adolescents in the elevated group also had a significantly higher frequency (days between sessions) than those in the clinical group, which may suggest that these adolescents may be completing the program more in line with program frequency recommendations (sessions should be 5 to 7 days apart).

	Elevated group (n=915), mean (SD)	Clinical group (n=1935), mean (SD)	Total participants (n=2850), mean (SD)	Cohen d ^d	<i>P</i> value ^d
OE ^e					
Completed sessions (OE)	4.14 (2.60)	3.96 (2.52)	4.02 (2.55)	0.07	.08
Total tasks (OE) ^f	71.48 (40.67)	68.40 (39.66)	69.39 (40.01)	0.08	.06
Total homework ^f (OE)	51.31 (30.93)	48.86 (29.85)	49.64 (30.22)	0.08	.04
Program depth (OE)	73.43 (52.10)	68.17 (49.90)	69.86 (50.67)	0.10	.01
Frequency (OE)	5.62 (8.25)	4.66 (8.31)	4.97 (8.30)	0.12	.004
CE ^g					
Completed sessions (CE)	5.17 (2.36)	5.11 (2.29)	5.13 (2.32)	0.03	.52
Total tasks (CE) ^f	119.07 (24.48)	116.77 (24.84)	117.63 (24.66)	0.09	.02
Total homework (CE) ^f	86.68 (24.59)	82.60 (25.77)	84.15 (25.33)	0.16	<.001
Program depth (CE)	767.10 (862.73)	673.67 (795.40)	703.67 (818.63)	0.11	.004
Frequency (CE)	6.43 (9.70)	4.82 (8.81)	5.33 (9.12)	0.17	<.001
EE ^h					
Early tasks (EE) ^f	16.97 (3.51)	16.98 (3.73)	16.98 (3.66)	0.00	.95
Early homework (EE) ^f	2.00 (2.00)	2.08 (2.00)	2.06 (2.00)	0.04	.32
Early depth (EE)	13.10 (7.07)	12.54 (6.94)	12.72 (6.99)	0.08	.05

^aOE: overall program engagement.

^bCE: continued engagement.

^cEE: early engagement.

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^dMean (SD), effect size, degrees of freedom, and significance between the elevated and clinical group at baseline.

^eOE statistics across all 10 sessions of the program.

^fThe number of prescribed tasks and homework tasks per session is detailed in Multimedia Appendix 1.

^gCE statistics (3 to 10 sessions only).

^hEE statistics (session 1 and 2 only).

Correlations Among Demographic Factors, OE, CE, and EE

Before completing moderated regressions, correlations were analyzed between all predictor and outcome variables, which are presented in Multimedia Appendix 2. Of the relationships of interest, greater age was significantly correlated with higher completed sessions, frequency, total homework, total tasks, and severity. Female gender was strongly associated with greater completed sessions and program depth. In relation to EE predictors, there was a significant correlation between higher early tasks and greater program depth, total homework, frequency, and total tasks. Greater early depth was also significantly positively associated with total homework, completed sessions, total tasks, and average frequency. Higher early homework was significantly and positively associated with program depth, total homework, total tasks, and frequency. Finally, lower anxiety severity was significantly correlated with greater program depth (CE), average frequency (CE), and program depth (OE).

Demographic Factors Associated With OE

Overview

The results of the moderated regression analyses examining whether demographic variables predicted OE, and if these relationships were moderated by anxiety severity, are presented in Tables S1-S5 in Multimedia Appendix 3.

Completed Sessions (OE)

The overall regression models were significant for gender $(R^2=0.006; P<.001)$, but not for age $(R^2=0.004; P=.01)$, and location $(R^2=0.010; P=.01)$. Despite the overall model being significant, as shown in Table S1 in Multimedia Appendix 3, there were no significant unique effects for gender or interaction effects in predicting completed sessions (overall).

Total Tasks (OE)

The overall regression models were significant for age $(R^2=0.007; P<.001)$, but not for gender $(R^2=0.002; P=.12)$ or location $(R^2=0.007; P=.05)$. There were no significant unique effects for age or interaction effects (Table S2 in Multimedia Appendix 3).

Program Depth (OE)

The overall regression models for age (R^2 =0.003; P=.20), gender (R^2 =0.000; P=.60), and location (R^2 =0.004; P=.32) were not significant in predicting program depth (overall), nor were there any significant interactions (Table S3 in Multimedia Appendix 3).

Frequency (OE)

The overall regression models were significant for age $(R^2=0.079; P<.001)$, but not for gender $(R^2=0.003; P=.02)$ or location $(R^2=0.005; P=.02)$. There was no significant unique effect for age and no significant interaction effects observed (Table S4 in Multimedia Appendix 3). Whilst not significant at the Bonferroni level, there was a trend observed for the effect of severity in the regression model testing gender as the independent variable. There was a negative relationship between severity and frequency (overall), r_{2188} =-0.082; *P*<.001, with higher levels of anxiety related to fewer days between sessions.

Total Homework (OE)

The overall models were not significant for age (R^2 =0.004; P=.11), gender (R^2 =0.002; P=.15), or location (R^2 =0.004; P=.23), nor were there any significant interaction effects (Table S5 in Multimedia Appendix 3).

EE Factors Associated With CE

Outcomes from moderated regressions were conducted to determine whether EE variables predicted CE, and if these relationships were moderated by anxiety severity.

Completed Sessions (CE)

The overall regression models were significant for early depth (R^2 =0.011; P<.001), but not for early tasks (R^2 =0.004; P=.10) or early homework (R^2 =0.004; P=.09). Despite the overall model being significant (Table S1 in Multimedia Appendix 4), there were no unique effects for early depth and no significant interaction effects across any of the regression models.

Total Tasks (CE)

The overall regression models were significant for early homework (R^2 =0.236; P<.001), early tasks (R^2 =0.310; P<.001), and early depth (R^2 =0.166; P<.001) in predicting total tasks (CE). However, there were no significant unique effects or interactions at the conservative Bonferroni level, as shown in Table 4, though there were effects evident using a traditional P < .05 cut-off. Specifically, a trend was evident (P < .05) for a positive relationship between early homework and CE total tasks (r_{2850} =0.481; P<.001), with greater homework tasks completed in sessions 1 and 2 related to greater overall task completion. This was also the case for early tasks and CE total tasks (r_{2850} =0.555; P<.001), where greater tasks in the first 2 sessions were associated with greater CE tasks completed and between early depth and CE total tasks ($r_{2850}=0.405$; P<.001), with more characters written in the first two sessions being associated with more total CE tasks completed.



Table. Linear model of EE^a variables predicting program tasks (CE^b) as a function of anxiety severity.

EE predictors	β	Standard β coefficient	Individual regres- sion coefficient (t)	P value	95% CI
Early tasks				7	·
Constant	53.68	25.40	2.11	.04	3.57 to 103.80
Early tasks	1.77	0.70	2.53	.01	0.39 to 3.15
Severity	6.19	14.07	.44	.66	-21.56 to 33.94
Early tasks severity ^c	12	0.39	-0.30	.78	-0.89 to 0.66
Early homework					
Constant	55.15	24.03	2.30	.02	7.74 to 102.55
Early homework	2.73	1.03	2.65	.01	0.70 to 4.76
Severity	13.46	13.12	1.03	.31	-12.44 to 39.35
Early homework severity ^c	52	.57	-0.92	.36	-1.65 to 0.60
Early depth					
Constant	96.20	12.18	7.90	<.001	72.16 to 120.23
Early depth	.05	0.02	2.23	.03	0.01 to 0.09
Severity	2.50	7.04	0.37	.72	-11.40 to 16.40
Early depth severity ^c	01	0.01	-0.60	.56	-0.04 to 02

^aEE: early engagement.

^bCE: continued engagement.

^cSeverity refers to baseline anxiety severity.

Program Depth (CE)

The overall regression models were significant for early tasks $(R^2=0.035; P<.001)$, early homework $(R^2=0.03; P<.001)$, and early depth $(R^2=0.08; P<.001)$ in predicting program depth CE. As shown in Table 5, there was a significant unique positive effect for early tasks and early depth. CE program depth increased by 24.84 characters with each early task completed, explaining 3.5% of the variance in CE program depth. CE

program depth also increased by 0.85 characters for each early depth increase of one character, accounting for 7.9% of the variance in CE program depth. Whilst not significant at the conservative Bonferroni significance level, there was a positive trend (P<.05) evident between early homework and CE program depth, r_{2850} =0.154; P<.001, with CE program depth increasing as early homework tasks increased. No significant interactions were found in any of the regression models predicting CE program depth.



Table . Linear model of EE^a variables predicting program depth (CE^b) as a function of anxiety severity.

EE predictors	β	Standard β coefficient	Individual regression coefficient (t)	P value	95% CI
Early tasks	•	•			·
Constant	14.11	276.45	0.05	.96	-527.96 to 556.17
Early tasks	24.94	7.97	3.13	<.001	9.31 to 40.57
Severity	6.08	156.73	0.04	.97	-301.24 to 313.39
Early tasks severity ^c	-2.94	4.52	-0.65	.52	-11.80 to 5.92
Early homework					
Constant	264.36	216.70	1.22	.22	-160.53 to 689.25
Early homework	27.52	9.62	2.86	<.001	8.65 to 46.30
Severity	-11.54	123.25	-0.09	.93	-253.22 to 230.14
Early homework severity ^c	-3.85	5.47	-0.70	.48	-14.57 to 6.87
Early depth					
Constant	356.40	111.55	3.20	<.001	10.80 to 12.62
Early depth	.85	0.17	5.00	<.001	0.52 to 1.18
Severity	-28	63.80	-0.44	.66	-153.11 to 97.11
Early depth severity ^c	08	0.10	-0.87	.39	-0.277 to 0.108

^aEE: early engagement.

^bCE: continued engagement.

^cSeverity refers to baseline anxiety severity.

Frequency (CE)

The overall models were significant for early tasks (R^2 =0.014; P<.001), early homework (R^2 =0.013; P<.001), and early depth (R^2 =0.015; P<.001) predicting CE frequency. However, no significant unique effects for early tasks, early homework, or early depth were found at the Bonferroni-adjusted level, nor were there any interaction effects (Table S2 in Multimedia Appendix 4). Although, in the regression model for early depth predicting CE frequency, there was a trend for a negative relationship between anxiety severity and CE frequency (r_{2188} =-0.082; P<.001), with days between sessions being fewer for those with higher baseline levels of anxiety.

Total Homework (CE)

The overall regression models were significant for early homework (R^2 =0.215; P<.001), early tasks (R^2 =0.244; P<.001), and early depth (R^2 =0.094; P=.001) in predicting CE total homework. However, there were no significant unique or interaction effects in any of the models (Table S3 in Multimedia Appendix 4).

Discussion

Principal Findings

This study analyzed the relationship between demographic and EE factors, and OE and CE, respectively, and assessed whether such relationships were moderated by baseline anxiety severity

in a dMH self-help intervention for adolescent anxiety, BRAVE Self-Help. Importantly, this study examined the utility of conceptualizing engagement, specifically, program use, in multiple ways to better understand engagement in dMH interventions. Overall, the results highlighted that a higher level of EE in the first two sessions was associated with greater CE (intervention-specific factor). This was evident specifically when predicting CE program depth (characters written), but a trend was also observed for CE tasks completed. That is, early depth of program use (characters written in the first two sessions) and early tasks completed in the first two sessions were associated with greater CE in terms of program tasks and depth of responses. In addition, there were bivariate associations between multiple EE and CE variables, suggesting a clear relationship.

Additionally, contrary to expectations, the study failed to demonstrate that anxiety severity impacts engagement either directly or indirectly for most indicators of engagement, although a higher baseline level of anxiety was associated with fewer average days between sessions (frequency). This may suggest that adolescents with more severe anxiety are eager to seek further assistance and see improvements in their anxiety. Although the impact of anxiety severity on engagement was inconsistent in this study, previous research has found that higher anxiety severity is related to poorer program engagement for adolescents in dMH programs [4,16,20,21]. Variations in the way in which engagement has been measured across studies may account for the difference in findings in this study.

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Importantly, person-specific demographic factors (age, gender, and location) showed little relevance in predicting program engagement in this study. Previous studies have reported mixed findings with respect to the impact of demographic variables on engagement in dMH programs [4,16,21]. Further research in relation to the relevance of person-specific factors in predicting program engagement should be undertaken once engagement can be measured more holistically.

EE Appears Important

The intervention-specific finding that EE was generally associated with CE is not surprising, yet an important research finding. Whilst previous research has identified that program engagement is associated with positive clinical outcomes [4,8], this study shows that engaging well early in the program, specifically early program use, is specifically associated with greater CE. Although the effects were small, our findings highlight that there is a need to identify ways to meaningfully engage adolescents in both in-session and homework tasks in the first two sessions of the program, to increase program engagement, and ultimately, the benefits obtained from dMH interventions.

There are few studies that have identified that EE, in terms of use, is important in predicting program engagement, but these studies did not capture the full breadth of engagement (ie, as proposed by Perski et al [15]) and were blended-care or therapist-supported interventions, rather than self-help. In a blended-care CBT intervention for adults with anxiety and depression, where participants had both face-to-face video therapy and digital activities (eg, thought monitoring and mood diaries), participants were around 10 times more likely to withdraw from the intervention if they had not completed the assigned dMH activities after the first session [17]. However, unlike this study, Wu et al [17] defined engagement purely as the number of sessions and web-based activities completed. Another study by Wallert et al [18] demonstrated the importance of early use factors in a therapist-supported dMH program, however, that was limited to early word count and homework tasks only. The study by Wu et al [17] found that higher word count in the first homework tasks was associated with greater adherence (measured in terms of completed homework activities). Interestingly, EE factors included in this study were not associated with completed sessions, but rather, what adolescents did in the program (ie, the amount of in-session and homework activities and character count). This may reflect that participants get what they want or need, without having to complete the entire program (ie, symptom relief or education about anxiety). Alternatively, these findings may suggest that we have not adequately measured all aspects of engagement that relate to treatment outcomes. These results are consistent with findings by both Alberts et al [26] and Yardley et al [14] who found that program engagement may not necessarily predict clinical outcomes. Overall, this study's findings emphasize the importance of understanding more about EE, its relationship to program completion and outcomes, and the strategies to enhance it.

Defining Engagement

Contemporary models of engagement highlight the need to consider both user experience and use [14,15]. This study, whilst meaningful in highlighting the importance of EE (program use) in dMH programs for adolescents, did not capture all facets of engagement (eg, user experience), which may explain the small effect sizes found. There is a large variation in the way in which engagement is defined and measured across dMH programs [12], and engagement has not often been measured holistically. This study primarily focused on the use aspects of engagement rather than the experiential or affective elements. The assessment of user experience would allow the opportunity for a more nuanced understanding of engagement, where participants' own subjective experience of the program is measured [14,15]. For example, this could include self-report questionnaires or interviews on engagement and experience with the program, or examination of the content and quality of activity responses rather than just character count [15], which may allow a richer understanding of the factors predicting OE, reasons for disengagement, and inform the development or refinement of dMH programs to achieve higher levels of engagement.

Strengths and Limitations

This study holds several strengths. First, the study had a large sample size of adolescents taking part in a real-world effectiveness study. The study further explored novel predictive factors of engagement in dMH programs, filling a significant gap in the literature regarding our understanding of adolescent engagement, particularly adolescent use, in these programs. The results were also analyzed using both a conservative and traditional significance level, adding merit to our findings. Despite its strengths, there were some limitations inherent to the study. First, this study did not consider the predictors of people who fail to take up BRAVE Self-Help, for example, factors at registration, or in the first session, such as participant perceptions of the content being valuable and helpful, time available to complete the program, and beliefs about the need for treatment. These were not the focus of this study; however, they should be the focus of future research, with specific adaptations to collect data of this nature. Furthermore, while this study considered engagement as multifaceted, the components of engagement analyzed in this study were limited to the available data that has been routinely collected within the BRAVE Self-Help platform, and thus, not all components of engagement as suggested in the engagement models of Perski et al [15] and Yardley et al [14] could be examined. Specifically, this study focused on understanding multiple measures of program use, but did not address user experience, which should be analyzed in future research. Further, whilst this study did examine the role of anxiety severity in influencing engagement, it did not examine whether changes in anxiety experienced beyond EE and over the course of treatment, had additional influence on OE. It is possible that as anxiety symptoms reduce, participants would be more or less likely to continue to engage in the program, and this should be examined in future research. Finally, whilst not possible to include all potential psychosocial factors in this study and analysis, engagement may have been influenced by other factors, such as satisfaction with the

program, personality, socioeconomic status, and previous exposure to treatment.

Future Directions

This study highlights the need to better understand how to measure the construct of engagement and investigate the role of EE in supporting OE. It is recognized that facets of engagement may overlap and be interrelated (eg, completed tasks and completed sessions), and therefore, conducting a factor analysis may be useful in identifying whether these variables are discrete, and may assist in the empirical validation of proposed engagement models such as that of Perski et al [15] and Yardley et al [14]. Additionally, analysis of predictors of further potential facets of engagement, such as user experience as proposed by Perski et al [15] (including interest in the program and attention sustained within the program, affect, and satisfaction) will be useful in more broadly understanding the construct of engagement and its relationship to EE, anxiety severity, and outcome. Subsequent studies may also consider the use of digital linguistic tools, which may be useful in providing more information about whether sentiment and affect relate to engagement. Future research should also seek to

understand how to enhance EE. This could be achieved through qualitative research with adolescents themselves, to better understand the unique needs of the user, and gain a detailed, nuanced account of how to enhance EE. Adding to our understanding will allow for dMH programs to be refined, tailored, and developed with such findings in mind. Taken together, the application of the findings of this study could improve engagement, and ultimately, potential clinical outcomes for adolescents with anxiety.

Conclusions

To date, there has been little research investigating the factors influencing engagement in dMH interventions for adolescents. The intervention-specific factor of poor EE, in terms of early program use, was found to be a barrier to CE in this study. Understanding how to better operationalize and measure engagement, along with identifying areas of focus to enhance EE, will help refine adolescent dMH interventions and aid in the design and development of future interventions. By doing so, user engagement can be enhanced and the benefit to the user of the program can be maximized.

Acknowledgments

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Conflicts of Interest

SM, SHS, and CD acknowledge that although intellectual property for BRAVE-ONLINE is owned by UniQuest/the University of Queensland, they may potentially benefit from future royalties related to the program.

Multimedia Appendix 1

Prescribed tasks and homework tasks across sessions. [DOCX File, 13 KB - pediatrics v8i1e60523 app1.docx]

Multimedia Appendix 2

Correlations between demographic, overall program engagement, continued engagement, and early engagement variables. [DOCX File, 20 KB - pediatrics v8i1e60523 app2.docx]

Multimedia Appendix 3

Moderated regression results of the relationship between demographic variables and OE, and whether these relationships were moderated by anxiety severity.

[DOCX File, 28 KB - pediatrics_v8i1e60523_app3.docx]

Multimedia Appendix 4

Moderated regression results of the relationship between early engagement and continued engagement, and whether these relationships were moderated by anxiety severity.

[DOCX File, 27 KB - pediatrics_v8i1e60523_app4.docx]

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Abbreviations

CAS-8: Children's Anxiety Scale 8-item CBT: cognitive behavioral therapy CE: continued engagement dMH: digital mental health EE: early engagement OE: overall program engagement

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Adapting Cognitive Behavioral Therapy for Adolescents in Iraq via Mobile Apps: Qualitative Study of Usability and Outcomes

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Abstract

Background: Mental health challenges, including anxiety and depression, are increasingly common among adolescents. Mobile health (mHealth) apps offer a promising way to deliver accessible cognitive behavioral therapy (CBT) interventions. However, research on the usability and effectiveness of apps explicitly tailored for adolescents is limited.

Objective: This study aimed to explore the usability, engagement, and perceived effectiveness of a mobile CBT app designed for adolescents, focusing on user experiences and mental health outcomes.

Methods: A qualitative study was conducted with 40 adolescents aged 13 - 19 years (mean age 15.8, SD 1.9 years; 18/40, 45% male; 22/40, 55% female) who engaged with a CBT app for 4 weeks. Mental health diagnoses included anxiety (20/40, 50%), depression (15/40, 38%), and both (5/40, 13%). Of these, 10 (25%) of the 40 participants had previous CBT experience. Feedback was gathered through focus groups and individual interviews, and thematic analysis identified key themes related to usability, engagement, and perceived effectiveness. Quantitative data on mood and anxiety scores were analyzed with paired *t* tests.

Results: The mean usability score was 3.8 (SD 0.6), and the mean effectiveness score was 3.9 (SD 0.7). Older participants (aged 16 - 19 years) reported significantly higher usability (mean 4.1, SD 0.4) and effectiveness scores (mean 4.3, SD 0.5) compared to younger participants (aged 13 - 15 years) (P=.03). Females had higher usability (mean 4, SD 0.6) and effectiveness scores (mean 4.2, SD 0.7) than males (mean 3.6, SD 0.7, and mean 3.5, SD 0.8, respectively; P=.03). Participants with prior CBT experience had 2.8 times higher odds of reporting high usability scores (95% CI 1.6 - 5; P=.002) and 3.1 times higher odds of reporting high usability challenges included complex navigation (20/40, 50%), interface design issues (12/40, 30%), and content overload (8/40, 20%). Factors positively influencing engagement were motivation driven by personal relevance (20/40, 50%) and gamification features (10/40, 25%), while lack of personalization (14/40, 35%) and external distractions (18/40, 45%) were significant barriers. Mood improvement (15/40, 38%) and learning new coping skills (12/40, 30%) were the most reported outcomes.

Conclusions: The mobile CBT app shows potential for improving adolescent mental health, with initial improvements in mood and anxiety. Future app iterations should prioritize simplifying navigation, adding personalization features, and enhancing technical stability to support long-term engagement.

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KEYWORDS

cognitive behavioral therapy; CBT; psychotherapy; mHealth; app; adolescents; teenager; mental health; usability; engagement; anxiety; depression; user experience; UX; focus group; interview; digital health

Introduction

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Mental health challenges among adolescents have become increasingly prevalent, with issues like anxiety, depression, and stress-related disorders affecting a significant portion of this population [1-4]. Adolescence is a critical developmental period marked by emotional, cognitive, and social changes, which can

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increase vulnerability to mental health disorders [5-7]. The World Health Organization estimates that up to 20% of adolescents experience mental health conditions, highlighting the urgent need for effective and accessible interventions [8-10].

In response to this growing demand, mobile health (mHealth) apps have emerged as a promising solution for delivering mental health care [11-14]. These apps offer a flexible, cost-effective,

and private means for adolescents to access psychological interventions, which may otherwise be limited due to stigma, lack of resources, or geographical barriers [15-19]. Among the various therapeutic approaches, cognitive behavioral therapy (CBT) has proven to be particularly effective in addressing common adolescent mental health issues like anxiety and depression [20-24]. CBT focuses on helping individuals identify and modify negative thought patterns and behaviors, making it well suited for delivery via mobile platforms that offer interactive and self-guided modules [25-28].

Despite the promise of mobile CBT apps, there remains a significant research gap regarding their usability and effectiveness for adolescents [29,30]. Most existing studies focus on adult populations or general app evaluations without considering younger users' unique needs and preferences [31,32]. Adolescents may have different expectations for user experience, engagement, and motivation when interacting with digital health tools [33,34]. Additionally, this age group's developmental and emotional characteristics necessitate a design that fosters engagement and provides adequate support [35-39].

In Iraq, mental health services face significant barriers due to stigma, lack of resources, and geographical constraints, which limit adolescents' access to traditional therapy. Postconflict instability, socioeconomic challenges, and strained health care systems have compounded mental health issues among Iraqi youth, creating a need for innovative solutions tailored to this population. Adolescents in Iraq, particularly those in low-resource settings, may be unable to access face-to-face therapy due to the limited availability of mental health professionals and the high costs associated with treatment.

While the potential of mobile CBT apps is evident, there is a lack of research on their usability and effectiveness among adolescents, particularly in regions like Iraq. This study aims to address this gap by exploring the usability, engagement, and outcomes of a mobile CBT app tailored specifically for adolescents in Iraq. The findings will provide valuable insights into how digital mental health tools can be optimized to better serve this vulnerable population in low-resource settings.

This study aimed to evaluate the usability, engagement, and perceived effectiveness of a mobile CBT app for adolescents, with a focus on user experiences and its impact on mental health outcomes.

Methods

Participants

The study recruited adolescents aged 13 - 19 years who were experiencing mental health challenges, including anxiety and depression. A convenience sampling method was used to select participants from various sources, including local schools, mental health clinics, and online mental health communities. Participants were referred by counselors or health care providers and expressed interest in participating. Inclusion criteria required that participants had a self-reported diagnosis of anxiety or depression, regular access to a smartphone, and, for those aged <18 years, parental consent. A sample size of 40 adolescents was chosen for an in-depth qualitative analysis of diverse

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perspectives while maintaining manageability for detailed thematic analysis. The study was conducted in Mosul, Iraq, ensuring a regional context for the findings. Data confidentiality and participant anonymity were prioritized throughout the study. Each participant was assigned a unique identifier code used in place of personal information during data collection, transcription, and analysis. This ensured that no identifying details were linked to the responses. Informed consent was obtained from all participants, outlining their rights to privacy and the confidential handling of their data. Interview and focus group recordings were securely stored in encrypted files, accessible only to authorized research team members. All transcripts were deidentified prior to analysis to protect participant identities further, and findings were reported in aggregate to prevent any individual from being identified.

Intervention

Participants were introduced to a CBT mobile app designed specifically for adolescents. The app was commercially available and selected based on its adherence to established CBT principles, as well as its focus on common adolescent mental health issues such as anxiety, depressive thoughts, and stress management. The app featured interactive modules, journaling functions, mood tracking, and self-assessment tools, all aimed at guiding users through CBT-based interventions. The selection of the app was influenced by its popularity, user ratings, and evidence-based framework, ensuring that it met the study's requirements for delivering structured CBT exercises. Participants were asked to engage with the app for 4 weeks, with a recommendation to complete at least 3 CBT exercises per week, though they were free to use it at their discretion.

Study Design

The study adopted a qualitative approach to gather rich, in-depth insights into the participants' experiences with the mobile CBT app. Data were collected through focus groups and one-on-one semistructured interviews after the 4-week intervention period. This design allowed for exploring the app's usability, engagement, and perceived outcomes from the adolescent perspective. The qualitative approach was well suited in understanding users' subjective experiences and identifying themes related to app interaction and mental health improvement.

Data Collection

Data collection focused on both app interaction and user feedback. The following methods were used.

App Usage Metrics

In-app data were collected to track the frequency of app usage, time spent on activities, completion of CBT modules, and interaction with various app features (eg, journaling and mood tracking).

User Feedback

Participants provided feedback through focus groups and interviews, where they discussed their experiences with the app. Topics of discussion included usability (ease of navigation and design preferences), engagement (motivation to use the app and consistency of use), and perceived outcomes (changes in mood,

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anxiety, or stress levels). Interviews were recorded and transcribed for analysis.

Outcome Measures

The study evaluated the following outcomes.

Usability

This included ease of navigation, design intuitiveness, and app aesthetics. Participants shared feedback on the app's user-friendliness and any barriers they encountered.

Effectiveness

Participants self-reported any changes in their mental health symptoms, particularly about anxiety and depression. Symptom reduction was assessed using qualitative descriptions of mood changes and mental health improvements throughout the study.

Overall Satisfaction

Participants reflected on their satisfaction with the app, including its features, content relevance, and overall impact on their mental health. Satisfaction was gauged through subjective feedback on whether they would recommend the app to peers or continue using it poststudy.

Ethical Considerations

This study was conducted in accordance with the ethical guidelines set in the Declaration of Helsinki and was approved by the institutional review board of the University of Ninevah (approval reference number: NURIRB/041/2023). All the processes involving human subjects were reviewed and deemed ethically acceptable by the institutional review board. As most

participants were minors aged <18 years, extra ethical precautions were exercised. For participants aged <18 years, written informed consent was obtained from parents or their legal guardians and assent from the adolescents. The assent forms were read in age-specific terms so the minors would clearly understand the purpose of the study, procedures to be followed, risks and benefits, if any, and their rights, such as withdrawal from the study at any time without any penalty. Parents and guardians received full written and verbal explanations of the study, including confidentiality protocols and data privacy protections, so that participation would be based on fully informed decision-making. All data were anonymized and stored securely to protect participant privacy and confidentiality. Identifying information was stored separately from the main dataset and was accessible only to authorized research team members. No financial incentives or rewards were promised to the participants or their families for participating in this study, so as to avoid coercion or undue influence.

Results

Age, Usability, and Effectiveness

The study found that age was slightly correlated with app usability and effectiveness. Older adolescents (aged 17 - 19 years) generally reported higher usability scores and perceived greater effectiveness than younger participants (Table 1). This could be due to increased digital literacy and maturity in using therapeutic tools among older users, who may navigate the app more intuitively and apply CBT techniques more consistently.



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Table. Demographic characteristics (N=40) and correlation with usability and effectiveness outcomes for the CBT^a app.

Characteristic	Participants, n (%)	Usability score, mean (SD)	Effectiveness score, mean (SD)	Preferred features	Notable observations
Age (years)	•				
13 - 15	15 (38)	3.2 (0.5)	3.4 (0.6)	Gamification and mood tracking	Less consistent engage- ment but reported mood improvements
16 - 19	25 (62)	4.1 (0.4)	4.3 (0.5)	Journaling and thought reframing	Higher digital literacy correlated with better usability
Gender					
Male	18 (45)	3.6 (0.7)	3.5 (0.8)	Gamification and relax- ation techniques	Gamification boosted engagement; preferred reward-based elements
Female	22 (55)	4.0 (0.6)	4.2 (0.7)	Journaling and mood tracking	Consistent journaling and tracking helped manage emotions
Mental health diagnosi	s				
Anxiety	20 (50)	4.0 (0.5)	4.1 (0.6)	Mood tracking and re- laxation techniques	Frequent mood track- ing to manage anxiety triggers
Depression	15 (38)	3.7 (0.6)	3.8 (0.5)	Journaling	Journaling as a primary emotional outlet
Both	5 (12)	3.5 (0.7)	3.6 (0.8)	Combination of all fea- tures	Mixed feature use, de- sire for more personal- ization
Previous CBT experier	nce				
Yes	10 (25)	4.2 (0.4)	4.3 (0.6)	Thought reframing and relaxation	Higher familiarity led to easier app naviga- tion
No	30 (75)	3.5 (0.6)	3.6 (0.7)	Mood tracking and gamification	Accessibility for begin- ners; tutorial recom- mended

^aCBT: cognitive behavioral therapy.

Gender Differences

Gender differences were evident in feature engagement and overall satisfaction with the app. Female participants reported using journaling and mood tracking more frequently and found these features particularly beneficial for managing their emotions. Males, however, demonstrated a stronger preference for gamification elements, suggesting they might respond better to reward-based interactions within the app. This result indicates that gender-sensitive adaptations, like balancing gamified elements with reflective exercises, could optimize engagement.

Mental Health Diagnosis

Diagnosis type influenced how participants interacted with different app features. Adolescents diagnosed with anxiety frequently engaged with mood tracking to monitor their anxiety triggers and reported that it helped them feel more in control. In contrast, participants with depression found journaling more beneficial, as it provided an outlet for emotional expression. Those with both anxiety and depression reported mixed results, finding both features helpful but expressing a need for more personalized guidance. These findings suggest that tailoring

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app features based on specific mental health diagnoses may enhance effectiveness.

Previous CBT Experience

Prior CBT experience was associated with higher usability scores. Participants familiar with CBT concepts found the app easier to navigate and were able to engage more readily with tools like thought reframing and relaxation exercises. Those without prior CBT experience still reported short-term improvements, indicating that the app is accessible for beginners, though they noted that a brief tutorial on CBT basics could improve initial engagement.

Interaction Between Characteristics

When analyzing the interaction between age and diagnosis, older adolescents with anxiety showed a unique pattern of consistent engagement with mood tracking and relaxation exercises, possibly due to increased awareness of their symptoms and the therapeutic benefits of tracking. This contrasts with younger adolescents with depression, who were less consistent with engagement but reported substantial short-term mood

improvements when they did engage, highlighting age and symptom-specific usage patterns.

Usability Challenges

Overview

Several usability challenges were identified through participant feedback (Table 2). While the majority of adolescents found

Table . Themes identified in usability challenges (N=40)

the app's interface visually appealing, many encountered issues related to its design and navigation. For example, one participant stated, "It was hard to find the tools I needed; sometimes I got lost in the app" [Participant 3, female, 16 years old].

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Usability challenge	Description	Values, n (%)		
Complex navigation	Difficulty in finding features or completing multistep tasks	20 (50)		
Interface design	Issues with text size, button placement, or layout on mobile devices	12 (30)		
Content overload	Feeling overwhelmed by the amount of content in some sections	8 (20)		

Complex Navigation

Of the 40 participants, 20 (50%) reported difficulty navigating through the app, particularly when attempting to access multistep CBT modules. They expressed a desire for clearer instructions and a more simplified user interface.

Interface Design

Of the 40 participants, 12 (30%) mentioned that the app's text size and button placement were not user-friendly, especially when using smaller mobile devices. This affected their overall experience and led to frustration in some cases.

Content Overload

Of the 40 participants, 8 (20%) felt overwhelmed by the amount of information presented in certain sections of the app. They indicated that the extensive content occasionally discouraged further use.

Engagement

Participant engagement with the app varied and was influenced by several factors, including personal relevance and gamification features (Table 3).

Table .	Factors	influencing	engagement	with the	CBT ^a	app (N=40).
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Factor	Description	Values, n (%)
Motivation (personal relevance)	Continued use linked to personal mental health needs and recognition of the app's benefits	20 (50)
Gamification and rewards	Positive response to interactive features and re- wards	10 (25)
Personalization	Engagement hindered by lack of tailored content and goals	10 (25)

^aCBT: cognitive behavioral therapy.

Motivation and Personal Relevance

Of the 40 participants, 20 (50%) who found the app's content personally relevant and aligned with their mental health needs reported higher levels of engagement. These participants were more likely to use the app consistently throughout the 4-week period. For example, one participant noted, "The rewards made it fun and kept me coming back" [Participant 5, male, 17 years old].

Gamification and Rewards

Of the 40 participants, 10 (25%) responded positively to the app's gamified elements, such as rewards for completing exercises and interactive features like mood tracking. They

reported that these features enhanced their motivation to continue using the app.

Lack of Personalization

Of the 40 participants, 10 (25%) noted that the absence of personalization options, such as customized goals or tailored content, negatively impacted their long-term engagement with the app.

Perceived Effectiveness

The majority of participants reported experiencing positive mental health outcomes, although the duration of the benefits varied (Table 4). For example, one participant stated, "The app gave me exercises that helped calm me down before an exam" [Participant 2, male, 14 years old].



Table . Perceived effectiveness of the app (N=40).

Effectiveness outcome	Description	Values, n (%)		
Mood improvement	Participants reported a reduction in anxiety or improved mood after using the app	15 (38)		
Learning coping skills	Users noted acquiring new coping mechanisms for managing stress and negative thoughts	12 (30)		
Short-term benefits	Short-term improvements, but benefits were not sustained without continuous app use	13 (32)		

Mood Improvement

Of the 40 participants, 15 (38%) reported a noticeable reduction in anxiety levels and an improvement in their mood after completing CBT exercises, particularly those focused on breathing techniques and cognitive restructuring.

Learning Coping Skills

Of the 40 participants, 12 (30%) highlighted that they learned new coping mechanisms, such as identifying and challenging negative thought patterns, which helped them manage day-to-day stress.

Table . Barriers to app usage (N=40).

Short-Term Benefits

Despite these positive outcomes, 13 (32%) out of 40 participants mentioned that the improvements were short-term and did not last without regular app usage. This suggests that sustained engagement is necessary for long-term benefits.

Barriers to App Usage

Several barriers were identified that limited participants' consistent use of the app or reduced its perceived effectiveness (Table 5).

Barrier	Description	Values, n (%)
App functionality issues	Technical problems like slow loading times or app crashes	8 (20)
Lack of personalization	Limited customization options for individual needs	14 (35)
External distractions	Schoolwork, social media, or lack of time impact- ing regular usage	18 (45)

App Functionality Issues

Of the 40 participants, 8 (20%) experienced technical problems, such as slow load times or occasional crashes, which discouraged them from using the app regularly.

Lack of Personalization

As previously mentioned, 14 (35%) out of the 40 participants felt that the lack of individualized content limited their overall engagement and the app's relevance to their specific mental health needs. One participant shared, "I felt like the app understood what I was going through, and that kept me using it" [Participant 7, male, 15 years old].

External Distractions

Of the 40 participants, 18 (45%) cited external distractions, such as schoolwork, social media, and general time constraints, as reasons for inconsistent app usage. They suggested that push notifications or reminders could help them stay on track with their CBT exercises. A participant commented, "Knowing others were going through the same thing made me feel less alone" [Participant 4, female, 16 years old].

Data Analysis Process

A thematic analysis was used to systematically explore the data gathered from focus groups and individual interviews. This qualitative approach is particularly suited to understanding the

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nuanced experiences of participants, as it allows for the identification of patterns and themes within textual data [40]. The analysis followed an inductive approach, where themes were derived directly from the data without imposing pre-existing frameworks, ensuring that the findings reflect participants' perspectives authentically [41].

Steps of Thematic Analysis

The steps of thematic analysis were as follows:

- 1. Data Familiarization: all interview transcripts were thoroughly reviewed to immerse the research team in the data and gain an initial understanding of the content.
- 2. Coding: initial codes were generated to highlight recurring patterns, unique responses, and significant statements related to usability, engagement, and perceived effectiveness.
- 3. Theme Development: codes were then grouped into broader themes that encapsulated the key insights, such as barriers to engagement, facilitators of usability, and outcomes of perceived effectiveness.
- 4. Review and Refinement: themes were refined iteratively to ensure they were distinct, relevant, and reflective of the dataset as a whole.

This method is appropriate for the study as thematic analysis provides flexibility in analyzing diverse qualitative data and is well suited for understanding user experiences with interventions

such as mobile CBT apps [42]. It enables researchers to capture both explicit content and latent meanings in the data.

Adequacy of Sample Size

The sample size for this study is adequate based on qualitative research standards. Data saturation—a point where no new themes or insights emerge—can often be achieved with 6 - 12 interviews, depending on the study's scope and participant homogeneity [43]. In this study, combining focus groups and individual interviews ensured a rich dataset that captured a range of perspectives while adhering to the principle of saturation.

Discussion

Principal Findings and Interpretation

This study explored the usability, engagement, and perceived effectiveness of a mobile CBT app designed for adolescents facing mental health challenges, such as anxiety and depression. The findings provide valuable insights into the potential of mobile CBT apps while highlighting areas for improvement, especially for adolescents in low-resource settings like Iraq.

Usability and Personalization

One key finding was the usability challenges reported by participants, including complex navigation and nonintuitive design. Participants frequently mentioned difficulties in locating tools or navigating through the app's interface. This underscores the need for developers to prioritize user-centered design that is simple, clear, and adaptable to different devices and screen sizes.

Features such as guided tutorials and step-by-step walkthroughs can facilitate easier navigation for adolescents with varying levels of digital literacy. Additionally, the app should be rigorously tested across multiple devices to ensure smooth performance and minimize technical barriers that deter consistent use.

A significant recommendation based on the feedback is the incorporation of personalization features, which could enhance the app's effectiveness and user engagement. Developers could implement adaptive algorithms that adjust content based on user input and progress, allowing the app to deliver more targeted interventions. For example, users could set personal mental health goals, such as reducing anxiety before exams, and the app could tailor CBT exercises accordingly to align with these objectives. Additionally, personalized content delivery based on self-assessment responses could ensure that users receive modules or exercises most relevant to their emotional state or specific stressors. Regular mood check-ins could further refine these recommendations, offering targeted suggestions that align with the user's evolving needs and experiences.

Consistent with earlier studies, such as Zhang et al [44], the app demonstrated potential in improving adolescents' mental health outcomes by providing accessible and flexible therapeutic tools. Previous work has highlighted the importance of user-friendly interfaces in promoting app adherence [45], and this study reinforces those conclusions. Participants' feedback about challenges in navigating the app echoes findings from Cheng

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XSL•FO RenderX et al [46], where adolescents reported that complex interfaces reduced their motivation to engage consistently.

Furthermore, the study aligns with the conclusions of Miller et al [47], which emphasized the critical role of personalization in enhancing the efficacy of digital interventions. Like Milleret al [47], our results suggest that tailoring app content to users' unique needs and progress is key to maintaining engagement and achieving desired outcomes.

The study revealed that engagement was strongly influenced by participants' perceptions of the app's relevance to their specific mental health needs. Participants who felt that the app effectively addressed their challenges were more likely to use it consistently, a finding supported by Banneyer et al [48], who demonstrated that content alignment with user needs significantly improves adherence to digital mental health interventions. Gamification features, such as badges, levels, and progress tracking, were identified as key motivators that sustained interest and encouraged continued use. These findings align with Ng and Wong [49], who reported that gamification elements enhance user engagement by creating a sense of achievement and progress.

Additionally, social features like anonymous peer support or community forums emerged as promising strategies for fostering connection and reducing feelings of isolation. This observation resonates with Silberg et al's [50] findings, who highlighted the role of social support mechanisms in increasing the acceptability and usage of mental health apps. In collectivist cultures like Iraq, where community and social bonds are deeply valued, enabling adolescents to share their progress or experiences anonymously could enhance engagement by leveraging these cultural strengths. This aligns with Patel et al [51], who noted the importance of culturally sensitive features in ensuring the success of digital health interventions. Future research should investigate the impact of such social features in different cultural contexts to determine their broader applicability and effectiveness.

Perceived Effectiveness

The perceived effectiveness of the app was influenced by its ability to address specific mental health challenges faced by participants. Such feedback highlights the importance of targeted interventions that address adolescents' real-world stressors. Participants also emphasized the need for evidence-based tools that provide tangible benefits. Incorporating features that explain the rationale behind each exercise and how it aligns with CBT principles could enhance perceived effectiveness and build user trust.

The findings align with prior research on adolescent mHealth engagement, such as those of Ghosh et al [52] features like personalization, gamification, and caregiver endorsement are critical for adolescent engagement in mHealth apps. Similarly, Oakley-Girvan et al [53] emphasized the importance of adaptive content and user-centered design in sustaining engagement. These studies underscore the importance of tailoring mHealth interventions to meet the unique needs of adolescent users while addressing cultural and contextual factors.

Long-Term Benefits and Sustainability

While most participants reported short-term improvements in mood and anxiety, the benefits were not sustained without regular app usage. This finding highlights the need for future mobile CBT apps to incorporate features that foster long-term engagement and sustained mental health improvements. Features such as regular reminders, progress tracking, and reinforcement of positive behaviors over time could play a crucial role in maintaining user involvement. For instance, push notifications reminding users to complete CBT exercises, celebrate milestones, or provide motivational messages have been shown to improve engagement and adherence in similar interventions [51].

Additionally, there is significant potential to integrate digital and human support in future app iterations. Adolescents could benefit from a hybrid model that combines the self-guided app with access to mental health professionals or peer mentors when needed. This approach aligns with findings from Gentry et al [54], which demonstrated that blending digital tools with human interaction significantly enhances mental health outcomes. Similarly, Patel et al [51] emphasized that hybrid models are particularly effective in resource-limited settings, where direct access to therapists is scarce. In regions like Iraq, where mental health resources are constrained, a blended approach could address both accessibility and sustainability challenges. By combining the strengths of digital and human support, mobile CBT apps could ensure broader and more enduring benefits, providing an effective solution for sustaining mental health improvements over time.

Implications for Future Development

The findings of this study highlight several key recommendations for the future development of mobile CBT apps for adolescents, particularly in low-resource settings like Iraq:

- Simplify navigation to enhance usability, ensuring the app is easy to use across different devices and levels of digital literacy.
- Incorporate adaptive personalization that tailors content based on individual user needs, goals, and progress.
- Gamify engagement to sustain motivation and encourage regular use, with a focus on rewards that resonate with the adolescent user base.
- Address external barriers such as distractions and time constraints by providing flexible features like push notifications and offline accessibility.
- Consider cultural and regional factors when designing apps, ensuring that features such as peer support align with the social values of the target audience.

Recommendations

Enhance Personalization

Adaptive Content Delivery

Integrate artificial intelligence–based algorithms to tailor content to the user's progress, mood, and engagement level. For example, adaptive modules can adjust the difficulty of activities

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based on the user's performance or offer reminders tailored to individual schedules.

User-Centered Goal Setting

Allow users to set personal goals within the app, such as managing daily stress or improving sleep. Personalized progress tracking and feedback can enhance motivation and sustain engagement over time.

Localized and Culturally Relevant Content

Incorporate content that resonates with the cultural background and life experiences of adolescents in Iraq, such as language options and culturally sensitive scenarios that foster user connection and comfort.

Incorporate Gamification Elements

Reward Systems and Badges

Introduce badges, points, or achievements for completing exercises, engaging regularly, or reaching personal milestones. A reward system can make engagement feel more rewarding and less clinical.

Interactive Challenges and Quests

Design challenges that encourage users to engage with the app routinely, such as completing daily mindfulness exercises or participating in weekly reflections. This can add a playful dimension to the app while reinforcing positive habits.

Social Sharing Features

Users can share their achievements with peers or within safe, moderated groups. Social elements can increase accountability, foster community, and provide an additional layer of engagement.

Streamline Navigation and Interface Design

Simplified User Flows

Minimize the steps required to reach core functionalities like exercises or mood tracking. Intuitive navigation should allow users to quickly locate and engage with tools, even if they only have a few minutes available.

Onboarding Tutorials

A brief, interactive onboarding process can familiarize new users with app functions, making it easier to navigate from the start. Offering short tutorials on new features introduced in updates can also enhance usability.

Improve Technical Stability

Offline Functionality

Given connectivity challenges, especially in rural areas, consider building offline capabilities for essential features, allowing users to complete exercises or track their mood without internet access.

Regular Testing and Updates

Frequent testing for bugs, usability issues, and prompt updates will improve overall stability and user satisfaction.

Conclusions

Overall, this study demonstrates that mobile CBT apps hold great promise for improving adolescent mental health, particularly in low-resource settings like Iraq. By addressing usability challenges, enhancing engagement through personalization and gamification, and overcoming barriers to usage, mobile CBT interventions can become more effective and accessible tools for young people. As digital health solutions continue to evolve, developers should prioritize user-centered, flexible designs that cater to the unique needs of adolescents in diverse cultural contexts. Future research should explore how to extend the long-term impact of these interventions, potentially through hybrid models that combine self-guided app use with professional support.

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Authors' Contributions

RHI, MHY, MQH, SHAM, MFA and OAM conceived the study. RHI analyzed the data and wrote the first draft. All the authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy **mHealth:** mobile health



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Original Paper

The Impact of Parental Support on Adherence to Therapist-Assisted Internet-Delivered Acceptance and Commitment Therapy in Primary Care for Adolescents With Anxiety: Naturalistic 12-Month Follow-Up Study

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Abstract

Background: Mental health problems among adolescents are increasing, and internet-delivered acceptance and commitment therapy (iACT) constitutes a possible way to improve access to care while reducing costs. Nevertheless, few studies have investigated iACT for adolescents in regular primary care nor the role of parental support.

Objective: This is an exploratory evaluation investigating iACT, with or without parental support, for adolescents. The aims were to examine treatment adherence, symptoms of anxiety and depression, psychological flexibility, and overall functioning.

Methods: Adolescents with anxiety were recruited within the regular primary care patient flow during the implementation phase of therapist-assisted iACT for adolescents. Assessment and inclusion were executed face-to-face. Due to organizational reasons, the assignment of treatment methods could not be randomized. Adherence was investigated by measuring the number of completed modules. Outcome measures were collected by self-assessment questionnaires including the Revised Children's Anxiety and Depression Scale and Avoidance and Fusion Questionnaire for Youth, as well as interviews using the Children's Global Assessment scale. The analysis was performed as an exploratory evaluation using descriptive data for treatment adherence and nonparametric within-group analysis with the Wilcoxon signed rank test for related samples and treatment outcomes. This evaluation is naturalistic, and the results are preliminary and of a hypothesis-generating character and should be handled with caution.

Results: The iACT group without parental support (n=9) exhibited a gradual dropout throughout the treatment period (n=5), whereas the iACT group with parental support (n=15) exhibited the lowest number of dropouts from treatment before completion (n=2), of which all occurred during the second half of treatment. The within-group, per-protocol analyses for the Revised Children's Anxiety and Depression Scale indicated reduced symptoms of anxiety and depression at the 12-month follow-up (*z* score: -2.94; *P*=.003; *r*=-0.6). The within-group, per-protocol analyses for the Avoidance and Fusion Questionnaire for Youth indicated increased psychological flexibility at the 12-month follow-up (*z* score: -2.54; *P*=.01; *r*=0.55). Nevertheless, no differences in overall functioning measured by the Children's Global Assessment Scale were found.

Conclusions: The results indicate that parental support might play a role in treatment adherence in iACT for adolescents with anxiety. Moreover, the outcome measures suggest that iACT for adolescents in primary care could constitute an effective treatment for both anxiety and depression, as indicated by the symptom reduction and increased psychological flexibility, maintained at

the 12-month follow-up. Nevertheless, due to a small and gender-biased sample size with a large proportion of dropouts and missing data, a nonrandomized assignment of intervention, and an analysis limited to within group, this study should be considered an explorative evaluation rather than an outcome study.

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KEYWORDS

adolescents; parental support; anxiety; depression; primary care; mental health; ACT; acceptance and commitment therapy; iACT; internet-delivered acceptance and commitment therapy

Introduction

According to the National Board of Health and Welfare in Sweden, mental health among children and young people has deteriorated, both based on self-reported psychological symptoms and on diagnosed mental disorders [1]. Anxiety and depression have been identified as significant factors, of which anxiety is the most common [2]. Furthermore, both anxiety and depression are associated with social withdrawal, adverse effects on academic performance, functional impairment, and ultimately, risk factors for suicide [3,4]. For adolescents with generalized anxiety disorder (GAD), separation anxiety disorder, and social phobia, the selective serotonin reuptake inhibitor Sertraline, as well as cognitive behavioral therapy (CBT), are the recommended treatment methods [1]. According to the Swedish National Board of Health and Welfare, CBT is well documented, recommended as a first intervention [5], and considered an effective treatment for anxiety disorders in children and adolescents [6].

In Sweden, primary care services include performing an initial assessment on children and adolescents regarding symptoms, symptom severity, and eventual need for treatment. If an anxiety disorder is assessed to be mild, an intervention shall be offered, and if moderate to severe, the patient shall be triaged to psychiatric care [5]. Furthermore, early intervention is crucial in preventing chronic mental illness [7], but many adolescents do not seek help from mental health care. O'Dea et al [8] have identified a lack of awareness among the population of signs of mental ill health, limited access to health care, and costs as possible obstacles. The authors suggest internet-based CBT (iCBT) as a way of increasing accessibility to treatment while reducing costs and that iCBT exhibits similar effect sizes as face-to-face treatment.

In a systematic review and meta-analysis, Vigerland et al [9] evaluated 25 studies on iCBT, including only studies in which the mean participant age was younger than 18 years. Of the studies, 7 studies were based on a Swedish population and 6 studies were on anxiety. The authors concluded that iCBT has positive outcomes, may be feasible, and exhibited moderate effect sizes compared to the waitlist. In a Danish randomized controlled trial (RCT), 70 adolescents with anxiety disorders were randomized into either iCBT or waitlist, and the iCBT group exhibited significant improvement based on both adolescent and parent ratings and that iCBT exhibited moderate to large effect sizes between groups [10]. Moreover, in an Australian RCT, 115 adolescents with anxiety from a community sample were randomized to either iCBT, face-to-face CBT, or waitlist conditions. At the 12-month follow-up, the authors

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found no significant differences regarding treatment outcomes between the groups and concluded that iCBT offers reduced therapist time and hence increased accessibility [11]. In a Swedish study, 120 adolescents were randomized to either standard iCBT, iCBT with learning support, iCBT with chat, or iCBT with learning support and chat. The group with learning support initially exhibited better outcomes but the difference was not sustained at the 6-month follow-up, and the authors determined iCBT to be an effective treatment method for adolescents with anxiety and depression. The authors found small effect sized on secondary outcomes related to anxiety and that the effect sized indicated the benefits of memory support during iCBT [12]. Nevertheless, in all the abovementioned studies, the participants were recruited either via advertisements or referral to secondary care. Thus, none of the studies were conducted in regular primary care.

Acceptance and commitment therapy (ACT) is a third-wave behavioral therapy oriented at acceptance and mindfulness and aimed at increasing psychological flexibility, defined as the ability to be present and act accordingly in line with one's values [13]. Face-to-face ACT is considered an effective treatment for children and adolescents with anxiety disorders [14,15] and exhibits small to medium effect sizes regarding anxiety and depression [16]. In a Swedish study, Nissling et al [17] investigated the effectiveness of internet-delivered ACT (iACT) on adolescents with anxiety by randomizing 52 participants aged 15-19 years from all over Sweden into either iACT or waitlist. Both groups improved but the participants in the intervention group exhibited significantly higher improvements regarding anxiety and exhibited moderate effect sizes between groups. The authors concluded that iACT is effective in improving quality of life and psychological flexibility, which in turn was associated with reduced anxiety symptoms. Another study randomized 348 adolescents to either (1) iACT student coach and a digital coach group, (2) only iACT digital coach group, or (3) no intervention. The authors found significant improvements in the iACT groups compared to the control group regarding reduced anxiety and increased valued action and self-compassion [18].

Few studies have examined iACT for adolescents in a routine primary care setting. To broaden the understanding of iACT in primary care for adolescents with anxiety, the Internet Mediated Psychological Treatment-Acceptance and Commitment Therapy (IMPACT) project was conducted as an ongoing evaluation during the implementation of iACT for adolescents in the region Västra Götaland in southwestern Sweden. The intervention in focus is the same as that in the study by Nissling et al [17] and contains ACT features [19].

In the first IMPACT paper, the authors highlighted the importance of parental involvement in iACT for adolescents, suggesting it might compensate for low treatment motivation [20]. In the second IMPACT paper, the authors concluded that the role of the parents needs clarification [21]. Attention to parental engagement in mental health treatments of adolescents has increased in recent years, and in 2015, a review of 23 papers was conducted by Haine-Schlagel and Walsh [22]. The results indicated potential links between parental participation and positive outcomes. The authors concluded that further research is needed to determine treatment factors, as well as organizational factors, regarding parental engagement in mental health treatment for both children and families. Moreover, Lundkvist-Houndoumadi et performed al [23] а phenomenological analysis of 24 semistructured interviews with Danish families in which the youth received CBT for anxiety with parental involvement. The authors concluded that the therapists' expectations of the parents to be cotherapists were difficult to implement in some cases due to the family dynamics and the expectations and resources among the parents. Overall, there seems to be a need for further information regarding the parental role in iCBT and iACT for adolescents and how the parents can support the adolescent's treatment. Haine-Schagel and Walsh [22] have concluded that research regarding parental engagement would benefit from more studies on specific parent-supportive behaviors in clinical interactions [22].

In summary, few studies have investigated iACT for adolescents in a routine primary care setting nor the role of the parents. Therefore, the IMPACT project aimed to conduct an ongoing evaluation of introducing iACT for adolescents with anxiety in primary care. This is the third part of the IMPACT project and is aimed at conducting a follow-up 12 months after receiving iACT with or without parental support. The primary outcomes consist of treatment adherence and symptoms of anxiety and depression, and the secondary outcomes consist of psychological flexibility and overall functioning in adolescents. Thus, the aims of this evaluation can be concretized as follows:

- 1. Is there a connection between parental support and adherence to iACT for adolescents with anxiety?
- 2. Does iACT for adolescents with anxiety result in decreased symptoms of anxiety and depression between pretreatment and 12 months after terminating treatment?
- 3. Does iACT for adolescents with anxiety result in increased psychological flexibility between pretreatment and 12 months after terminating treatment?
- 4. Does iACT for adolescents with anxiety result in improved overall functioning between pretreatment and 12 months after terminating treatment?

Methods

In this section, the study design, participants, procedure, intervention, measures, data analysis, and ethical considerations are presented.

Study Design

Initially, the intention was to perform a follow-up of iACT during the implementation phase in primary care and to conduct

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between-group analyses. However, due to organizational limitations, the authors instead opted for a pragmatic approach to the data. Consequently, the analysis was converted into an exploratory evaluation of iACT for adolescents with anxiety in primary care.

The IMPACT project was conducted within the regular patient flow during the implementation phase and due to organizational reasons, randomization of the participants could not be made. Using a non-RCT, the therapists assigned the participants to either iACT with or without parental support or treatment as usual (TAU), consisting of face-to-face treatment for anxiety individually or in a group format. Therefore, the authors had limited insight into the assignment process. Therefore, this study is naturalistic and the results are preliminary and of a hypothesis-generating character.

Quantitative data were collected before, during, and after treatment, and follow-ups were performed 6 and 12 months after terminating treatment. In this evaluation, pretreatment and the 12-month follow-up are being compared. Due to difficulties in recruiting therapists, the sample size is relatively small, which further decreases the quality of the data, furthermore, the amount of missing data is relatively large.

No a priori power analysis was conducted, so between-group analyses could not be made. Therefore, the TAU group is not included in this evaluation, adherence measures are analyzed using descriptive data, and outcome measures are analyzed using within-group analyses. Therefore, the results are treated as an explorative evaluation of iACT in practice rather than a scientific study.

Participants

The participants were recruited from adolescents seeking help in primary care for anxiety symptoms at 3 different health care centers located in southwestern Sweden and specialized in treating adolescents with mental health issues. Previously, there was no iACT program for young people in Sweden, and the treatment program was developed and adapted for the 13-18 years age group, hence the age group that was studied. The inclusion criteria consisted of being aged 13-18 years; having access to a computer, iPad, or smartphone with internet access; being able to read and write in Swedish; and having been diagnosed with mild to moderate anxiety such as GAD, social phobia, panic disorder, or unspecified anxiety disorder. The exclusion criteria consisted of having a neuropsychiatric diagnosis, intellectual disability, bipolar disease, suicidality, or ongoing psychotherapeutic treatment or daily consumption of benzodiazepines.

This evaluation originally included 35 participants aged 13-18 years. Of these participants, 9 participants received iACT without parental support; 15 participants received iACT with parental support; and 11 participants received TAU, of which, 8 participants received group therapy and 3 participants received individual therapy. Besides providing iACT, 2 of the health care centers involved in the study only provided group therapy, whereas the third only provided individual therapy. Since no power analysis was performed before the data collection, comparisons between groups could not be made, hence the TAU

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group was excluded from this evaluation. Table 1 demonstrates the distribution of age and gender among the participants.

Table 1. The distribution of age and gender among the participants.

Variable	Frequencies		
	iACT ^a without parental support (n=9)	iACT with parental support (n=15)	TAU ^b (n=11)
Age group (years), n (%)			
13-15	8 (89)	10 (67)	9 (82)
16-18	1 (11)	5 (33)	2 (18)
Sex, n (%)			
Female	8 (89)	15 (100)	10 (91)
Male	1 (11)	0 (0)	1 (9)
Other	0 (0)	0 (0)	0 (0)

^aiACT: internet-delivered acceptance and commitment therapy.

^bTAU: treatment as usual.

Procedure

Patients aged 13-18 years, accompanied by a parent, seeking help in primary care for anxiety problems were informed about the study and were offered participation by the therapist. All the adolescents included provided verbal consent and the parents provided written consent prior to participation. The patient and the parent participated in an assessment and inclusion meeting conducted by a participating therapist. The parent was subsequently led to another room to fill in a questionnaire whereas the adolescent was interviewed further.

After the assessment, all the participants who met the inclusion criteria were assigned by the therapist to either iACT, with or without parental support, or TAU. The assignment of groups was not randomized, and the authors have no information on how many patients were excluded from the study by the therapists nor how the therapists assigned the patients into groups.

Furthermore, the participating adolescents completed questionnaires before, during, and after treatment, as well as 6 and 12 months after treatment termination, and participated in diagnostic clinical interviews before and after treatment, as well as 12 months after treatment. To ensure the integrity of the adolescents and data security, the forms were distributed via the survey platform Esmaker [24], if possible, and otherwise in paper format. The paper forms and interview protocols were also added to a research journal to collect additional data such as other ongoing treatments.

The recruitment process took place from 2018 to 2020, hence parts of the data collection coincided with the COVID-19 pandemic, during which some upper secondary schools in Sweden introduced distance learning for periods of time while other schools did not [25]. It is possible that the pandemic affected the number of participants in the study. Furthermore, due to the difficulty of recruiting therapists, the number of participants in the study is relatively low. Despite the low number of participants, the recruitment was terminated due to financial reasons.

Intervention

In this study, the participants were recruited from 3 health care centers that were specialized in adolescent mental health and located in southwestern Sweden: Gothenburg, Borås, and Uddevalla. These centers form a part of primary care and are specialized in helping patients aged 6-18 years. The therapists in this study were either licensed psychologists or intern psychologists, and as a part of implementing iACT at these centers, they participated in a 2-day course and received specific training in iACT for adolescents.

iACT Without Parental Support

These participants received a guided, internet-based, self-help program called Anxiety Help for Adolescents (in Swedish: Ångesthjälpen Ung) developed by Psykologpartners W&W AB. The program is adapted for patients aged 13-19 years with mild to moderate anxiety, for example, social phobia, GAD, panic disorder, obsessive-compulsive disorder, or unspecified anxiety disorder [19].

The iACT intervention consists of 8 modules and the recommended treatment duration is 10 weeks with weekly feedback from the therapist. The program is adapted to the target group of adolescents regarding formulations, concretizations of theoretical concepts, and clinical examples, as well as the overall structure, and presents different strategies through text, videos, exercises, and forms. There is a messaging function in which the therapist and the patient can communicate asynchronously, and the therapist can initiate conversations through telephone, video calls, or physical meetings at the clinic. The therapist supports the patient through motivation, giving feedback, answering questions, and prompting upcoming parts of the program [19]. For a detailed list of contents of the iACT intervention, see Multimedia Appendix 1.

iACT With Parental Support

These participants were assigned to the iACT program described above, with the addition of receiving parental support on how to support their adolescent's anxiety regulation. Both the participants and parents were initially given information about the content and structure of the iACT program [19].

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Subsequently, the parents took part in 3 physical meetings during their adolescent's treatment period, either individually or in groups, and were conducted with the help of a manual (Multimedia Appendix 2). The content included psychoeducation about anxiety and different reactions, examples of different anxiety disorders, and behavioral strategies to handle anxiety such as exposure, relaxation, breathing, balance activity, and rest. All the information was condensed into a pamphlet called More Than Afraid (in Swedish: Mer än rädd) [26].

TAU Group

The participants in the TAU group received the treatment they would normally be offered at the clinics, consisting of face-to-face treatment for anxiety individually or in a group format, both 8 weeks long, as conventional in clinical settings. The TAU group is not included in this evaluation since the groups could not be compared.

Measures

The adolescent filled in the following forms before, during, and after treatment, as well as 6 and 12 months after treatment:

- Revised Children's Anxiety and Depression Scale (RCADS-Children, 47 items), consisting of the 2 main scales, anxiety and depression, and the 6 subscales, social phobia, panic disorder, GAD, compulsive disorder, separation anxiety, and depression, on which higher scores indicate a higher number of symptoms. The subscales exhibit a high internal consistency (α =.78-.88) in a sample of 513 children in the United States [27,28].
- Avoidance and Fusion Questionnaire Youth (AFQ-Y8), designed to measure the level of psychological flexibility in youth aged 12-20 years: higher scores indicate higher levels of psychological inflexibility. In a Swedish sample of 62 children undergoing cancer treatment, AFQ-Y8 exhibited acceptable internal consistency (α =.76), good test-retest reliability (ICC=0.64), and convergent validity (*r*=0.42) [29].

Furthermore, the adolescent was interviewed before and after treatment and 12 months after completion. The assessments were performed by a psychologist or intern psychologist using the following measures:

- The Mini International Neuropsychiatric Interview for Children and Adolescents was used for diagnostics [30] and exhibits validity and test-retest reliability comparable to other standardized screening tools [31,32].
- The Children's Global Assessment Scale (CGAS) was used to assess overall functioning. The interviewer performs an assessment of the adolescent's level of functioning on a scale from 1 to 100, of which a higher score indicates a higher level of functioning [33]. CGAS exhibits high interrater and test-retest reliability, as well as high discriminant and concurrent validity [34-36].

Data Analysis

This study aimed to investigate whether there is a connection between parental support and adherence to iACT for adolescents with anxiety and whether the treatment results in differences in symptoms of anxiety and depression, psychological flexibility, and overall functioning at 12 months after terminating treatment.

Due to a nonrandomized design, a small sample, a large dropout, and the fact that no a priori power analysis was made, the data are nonparametric, which makes between-group comparisons less meaningful. Therefore, the TAU group (n=11) is not included in this evaluation. Adherence was analyzed using descriptive data and Meier-Kaplan survival analysis, a statistical method used for measuring the distribution of time of occurrences in cohort groups [37]. In this study, dropout is defined as terminating the iACT program before the last module. Meanwhile, the outcome measures were analyzed using within-group comparisons.

Adherence was analyzed for all participants receiving iACT without parental support (n=9) and with parental support (n=15), presented in separate groups. In contrast, for the outcome measures, all participants receiving iACT are presented as 1 group, including both with and without parental support due to small groups. In the outcome measures, the pretreatment measurement and the 12-month follow-up were compared and only included participants completing both the premeasurement and the 12-month follow-up.

For the outcome measures, patient-rated scores using RCADS and AFQ-Y8, as well as therapist-rated scores using CGAS and within-group analyses were performed using the nonparametric statistical method Wilcoxon signed rank test for related samples. Effect sizes were calculated based on the formula described by Field [38] and were interpreted as 0.10-<0.3 (small effect), 0.30-<0.5 (moderate effect), and \geq 0.5 (large effect). The within-group analyses were performed in SPSS Statistics (version 29; IBM Corp).

Ethical Considerations

This evaluation constitutes a part of the research project IMPACT in 2017-2021 (Swedish National Research Register; ID: 240221), approved by the Regional Ethics Committee in Gothenburg (Dnr: 703-17). The IMPACT project was designed to conduct an ongoing evaluation of introducing iACT for adolescents with anxiety in primary care during the implementation phase, and this evaluation is a 12-month follow-up. The participants have been informed that their participation is voluntary and that they have the right to cancel without further explanation. Moreover, the participants have been informed that participation in the study will not in any way affect their future opportunities for care and treatment at the health center and that participation in the study will not be mentioned in medical records. Both accessing care and participating in the study were free. Furthermore, the participants have been informed about how the data will be managed, including confidentiality aspects, as well as analysis and presentation. The confidentiality of all participants is thus guaranteed, and consent from all participants has been obtained including both adolescents and parents. Digital forms were collected using the survey platform Esmaker [24], and data were analyzed using SPSS Statistics.

Results

Overview

In this section, the results are presented regarding treatment adherence and outcome measures based on the questions of the aims. Adherence is presented for all participants (n=35), and the participants receiving iACT are presented in 2 separate groups: iACT without parental support and iACT with parental

support. The outcome measures are presented for the participants who completed the assessments for both the pretreatment and the 12-month follow-up (n=11). Moreover, the iACT participants are presented as 1 group, regardless of whether they have received parental support or not. Below, the primary outcomes are presented. Figure 1 demonstrates a CONSORT (Consolidated Standards of Reporting Trials) flow diagram of the study.

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) Flow diagram of internet-delivered Acceptance and Commitment Therapy (iACT) and treatment as usual (TAU).




Is There a Connection Between Parental Support and Adherence to iACT for Adolescents With Anxiety?

For the analyses regarding adherence to treatment, the

Table 2. Descriptive statistics for the number of completed modules.

participants were presented in 2 groups: iACT without parental support (n=9) and iACT with parental support (n=15). Table 2 demonstrates descriptive statistics for the number of completed modules or sessions at the time of terminating the program.

Completed modules or sessions(%)	iACT ^a without parental support (n=9), n (%)	iACT with parental support (n=15), n (%)
<25	2 (22)	0 (0)
25-50	1 (11)	0 (0)
50-75	1 (11)	1 (7)
75-100	5 (56)	14 (93)

^aiACT: internet-delivered acceptance and commitment therapy.

The participants receiving iACT without parental support (n=9) exhibited a gradual dropout rate throughout treatment, of which 5 participants dropped out before treatment completion. In contrast, the participants receiving iACT with parental support (n=15) exhibited the least number of dropouts (n=2), of which all occurred during the second half of the treatment.

Figure 2 demonstrates a Meier-Kaplan graph illustrating the dropouts. The x-axis represents at which module the dropout occurred, with 0 indicating dropout before initiating treatment and 8 representing complete treatment. The y-axis represents the percentage of participants remaining in treatment.

Figure 2. Proportion of dropouts between groups of internet-delivered Acceptance and Commitment Therapy (iACT) with or without parental support.



Completed modules (0-8)

Does iACT for Adolescents With Anxiety Result in Decreased Symptoms of Anxiety and Depression Between Pretreatment and 12 Months After Terminating Treatment?

In this section, the results of the patient-rated RCADS scores are analyzed for all participants completing both the

premeasurement and the 12-month follow-up (n=11). In this section, the participants receiving iACT are in the same group, regardless of whether they have received parental support or not. Table 3 demonstrates descriptive statistics for the therapist-rated measurement points on RCADS.

Table 3.	Descriptive	statistics	for the	measurement	points	on RCADS	a
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iACT ^b (n=11)	Score, mean (SD)	Score, median (IQR)	Score, range
RCADS			
Pretreatment	71.7 (17.5)	70 (65-86)	41-104
Posttreatment	52.9 (22.3)	52 (38-71)	25-98
6-month follow-up	47.1 (26.9)	40 (27-63)	13-104
12-month follow-up	49.3 (25.4)	44 (32-63)	18-111
RCADS—Anxiety			
Pretreatment	58.6 (14.1)	58 (52-71)	33-84
Posttreatment	42.9 (17.9)	42 (32-53)	21-83
6-month follow-up	38.5 (22.4)	30 (22-46)	12-87
12-month follow-up	39.4 (19.8)	39 (24-49)	15-88
RCADS—Depression			
Pretreatment	13.1 (4.4)	14 (8-17)	6-20
Posttreatment	10.0 (5.4)	10 (5-16)	3-18
6-month follow-up	8.5 (5.3)	9 (4-12)	1-17
12-month follow-up	9.8 (6.2)	8 (5-14)	3-23

^aRCADS: Revised Children's Anxiety and Depression Scale.

^biACT: internet-delivered acceptance and commitment therapy.

The results from the Wilcoxon signed rank test for related samples for the RCADS total scores demonstrated a decrease in symptoms of anxiety and depression and a large effect size for the RCADS total scores from preassessment to the 12-month follow-up (*z* score: -2.81; *P*=.005; *r*=0.60). When analyzing anxiety and depression scores separately by subscales, reductions between the pretreatment assessment to the 12-month follow-up assessment for both anxiety (*z* score: -2.81; *P*=.005; *r*=0.60) and depression (*z* score: -2.67; *P*=.008; *r*=0.57) and large effect sizes were obtained. Below, the secondary outcomes are presented.

Does iACT for Adolescents With Anxiety Result in Increased Psychological Flexibility Between Pretreatment and 12 Months After Terminating Treatment?

In this section, the results of the patient-rated AFQ-Y8 scores are analyzed, indicating the adolescent's self-rated levels of psychological flexibility. In this section, the participants receiving iACT are presented in the same group, regardless of whether they have received parental support or not. Table 4 demonstrates descriptive statistics for the therapist-rated measurement points on AFQ-Y8 and CGAS.

Table 4. Descriptive statistics for the measurement points on AFQ-Y8^a and CGAS^b.

iACT ^c (n=11)	Score, mean (SD)	Score, median (IQR)	Score, range
AFQ-Y8	·		
Pretreatment	18.8 (5.8)	21 (12-22)	11-30
Posttreatment	14.9 (7.7)	13 (10-20)	3-30
6-month follow-up	12.3 (7.6)	11 (7-17)	3-27
12-month follow-up	12.7 (6.7)	11 (8-17)	5-29
CGAS			
Pretreatment	64.1 (5.8)	65 (60-65)	55-75
Posttreatment	72.7 (13.3)	75 (55-85)	55-90
12-month follow-up	70.0 (14.3)	70 (55-85)	45-85

^aAFQ-Y8: Avoidance and Fusion Questionnaire for Youth.

^bCGAS: Children's Global Assessment Scale.

^ciACT: internet-delivered acceptance and commitment therapy.

The results from the Wilcoxon signed rank test for related samples for the AFQ-Y8 demonstrated increased psychological flexibility from preassessment to the 12-month follow-up (z score: -2.54; P=.01; r=0.55).

Does iACT for Adolescents With Anxiety Result in Improved Overall Functioning Between Pretreatment and 12 Months After Terminating Treatment?

In this section, the results of the therapist-rated CGAS scores are presented. The results from the Wilcoxon signed rank test on the CGAS total scores indicated no difference between measurement points from pretreatment to the 12-month follow-up for the iACT group (z score: -0.51; P=.96; r=0.146).

Discussion

Overview

This evaluation aimed to investigate whether there is a connection between parental support and adherence to iACT for adolescents with anxiety and whether iACT for adolescents with anxiety results in a difference in symptoms of anxiety and depression, psychological flexibility, and overall functioning, between the pretreatment measurement and 12 months after terminating treatment. In this section, the principal findings, limitations, and implications will be discussed in contrast to other studies. Overall, the results must be handled with caution due to the nonrandomized design, small sample size, and large amount of missing data.

Principal Findings

Overview

The IMPACT project was conducted as an ongoing evaluation to broaden the understanding of iACT for adolescents with anxiety in a routine primary care setting during the implementation phase. In the first IMPACT paper, Weineland et al [20] concluded that the interviewed therapists were positive to iACT for adolescents but also identified challenges such as motivating patients. In the second paper, Lilja et al [21] found that the interviewed parents expressed uncertainty about their role in the treatment and clearer parental treatment support was suggested. This is the third part of the IMPACT project, consisting of a follow-up on adolescents with anxiety 12 months after receiving iACT, with or without parental support regarding treatment adherence, symptoms of anxiety and depression, and psychological flexibility, as well as overall functioning. The primary outcomes are discussed below.

Is There a Connection Between Parental Support and Adherence to iACT for Adolescents With Anxiety?

Regarding treatment adherence, the participants receiving iACT with parental support exhibited later and fewer dropouts than the participants receiving iACT without parental support. These findings might be due to the idea suggested by Weineland et al [20] that parental support could compensate for low treatment motivation among adolescents. However, due to the nonrandomized design and small sample size in this, further research is needed to test this hypothesis in RCTs and with larger samples. Other potential mediating effects could be giving

the parents a deeper understanding of anxiety in both themselves and the adolescent, as well as how to support their adolescent and function as a cotherapist alongside the therapist. In addition, in each group, 2 participants discontinued treatment due to feeling better, indicating that dropouts from treatment are not necessarily negative.

In previous research, the authors have pointed to potential connections between parental support and positive treatment outcomes in children and families [22], including that some parents need support in their role as cotherapists in treatment [23]. The current research on the role of motivation in iACT for adolescents with anxiety is currently limited. Nevertheless, in a Norwegian study, Fjermestad et al [39] concluded that motivation predicts early alliance in CBT for youth with anxiety. Furthermore, in a Danish study by Stjerneklar et al [10], both the parents and the therapists were encouraged to help motivate the adolescent in their iCBT, in which iCBT exhibited moderate to large effect sizes between groups on anxiety compared to the waitlist.

Furthermore, iACT with parental support can be considered a complex intervention, which can be defined as an intervention consisting of multiple components. Complex interventions cause challenges in the development and identification [40] and Hasson and von Thiele Schwartz [41] claim that complex interventions tend to be at a disadvantage in research due to the difficulty in isolating them from the context. The authors argue that this applies to a large amount of psychological treatment methods, compared to medical treatments.

Does iACT for Adolescents With Anxiety Result in Decreased Symptoms of Anxiety and Depression Between Pretreatment and 12 Months After Terminating Treatment?

Outcome measures were investigated using a within-group analysis, in which the iACT-group demonstrated reduced symptoms of anxiety and depression between the preassessment and 12-month follow-up. Multiple previous studies have indicated positive treatment outcomes for iACT for adolescents with anxiety [9-12], but few have performed follow-ups at 12 months after treatment or longer. In the meta-analysis by Vigerland et al [9], of the papers on iACT for children and adolescents with anxiety, 2 papers had a 1-year follow-up: Spence et al [11] concluded that the improvements in both CBT and iACT were maintained at the 12-month follow-up and Tillfors et al [42] discovered significant improvements in iACT for high school students with anxiety disorder, maintained at the 12-month follow-up. Nevertheless, none of the studies included follow-ups more than 1 year after treatment, hence the long-term effects of iACT for adolescents with anxiety should be investigated further.

In this evaluation, in 2 of the cases, the results of Mini International Neuropsychiatric Interview for Children and Adolescents and CGAS exhibited an increase in symptoms and a decrease in functioning between the post and 12-month follow-up. Therefore, the interviewer had the impression that the COVID-19 pandemic influenced the results. In both cases, of which 1 participant from the iACT group and 1 from the

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TAU group, the participant was diagnosed with social phobia at the 12-month follow-up and described that at least some of the symptoms were due to returning from distance to classroom learning. In addition, the authors suspect that the pandemic itself could have affected the anxiety levels and functioning of the participants, for example, fear of the disease itself or uncertainty about the future.

In a Swedish study, the authors surveyed 1818 adolescents, of which approximately 80% transferred to distance learning during the pandemic. The authors concluded that most of the participants experienced decreased mental health, especially female participants and those in distance learning. The authors also discovered that distance learning could result in less victimization and poorer mental health overall [43]. In another Swedish study, 3068 participants aged 16-17 years filled in a questionnaire about the impact of the COVID-19 pandemic from December 2020 to March 2021. The author concluded that female participants with a lower socioeconomic background reported higher levels of worry in general, except for climate anxiety [44].

In an international systematic review and meta-analysis of 74 papers on anxiety among children and adolescents during the pandemic, the authors concluded that anxiety levels were more prevalent among female participants than male participants in North America and Europe than South America and Asia, during the second wave of COVID-19 and school closures [45]. A Finnish study surveyed 450,000 participants aged 13-20 years about the pandemic. The authors discovered that social anxiety increased from 2013 to 2021, especially among the female participants, and that unmet needs for schoolwork support, and fear of getting infected by COVID-19 or transmitting it to others were associated with high levels of social anxiety. Nevertheless, the authors observed no clear connection between time spent in distance learning and levels of social anxiety [46].

Furthermore, in an American study, 280 high schoolers were surveyed on social anxiety and the use of technology. The author discovered a positive relationship between social anxiety and a preference for using technological communication instead of face-to-face communication [47]. In an international study, 2665 participants aged 18-25 years from 121 countries, of which the majority from Australia, the United States, and the United Kingdom, were surveyed on social restrictions related to COVID-19 and its effect on loneliness, social anxiety, and depression. The authors concluded that reductions in social restrictions resulted in an increase in social anxiety due to having to readjust to the social environment [48]. In other words, the relationship between the COVID-19 pandemic and anxiety among youth is a complex matter with a diversity of outcomes, of which multiple possible scenarios might have affected the results of this study.

In this study, COVID-19 can be considered a confounding factor, which Jager et al [49] defined as a risk factor, unequally distributed among the participants, and not included in the causal pathway. Pourhoseingholi et al [50] define confounding factors as a variable affecting the variables studied but not their relationship. To prevent or reduce the confounding factors, Jager

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et al [49] suggest using exclusion criteria, for example, participant age, randomizing the assignment to groups, matching participants for example in pairs with or without exposure, or stratifying the participants into subgroups. Pourhoseingholi et al [50] mention that stratification is suitable with a low number of strata, whereas multivariate models, such as analysis of covariance, as well as logistic and linear regression, can be used with a larger number of covariates and confounders. The secondary outcomes are discussed below.

Does iACT for Adolescents With Anxiety Result in Increased Psychological Flexibility Between Pretreatment and 12 Months After Terminating Treatment?

In this evaluation, the analyses of AFQ-Y8 demonstrated an increase in psychological flexibility between the pretreatment measurement and the 12-month follow-up. These results are in line with previous research, concluding iACT to be effective in reducing symptoms of anxiety and increasing psychological flexibility, as well as suggesting a possible link between anxiety levels and psychological flexibility [17].

Does iACT for Adolescents With Anxiety Result in Improved Overall Functioning Between Pretreatment and 12 Months After Terminating Treatment?

In this evaluation, the analyses of overall functioning using CGAS did not indicate differences between the pretreatment measurement and the 12-month follow-up. However, in a meta-analysis of 9 RCTs on iACT for pediatric anxiety disorders, of which 7 included CGAS as a measure of functioning, the authors concluded that their confidence in the effect of iACT on functioning is low [51].

In summary, the results of this evaluation support a possible connection between parental support and adherence to iACT for adolescents with anxiety. Further research is needed to investigate the nature of the connection. Furthermore, the analyses of the outcome measures indicate reduced symptoms of anxiety and depression and increased psychological flexibility between the pretreatment measurement and the 12-month follow-up but no difference regarding overall functioning. However, due to a nonrandomized design, a small sample size, and a large amount of missing data, the results are uncertain, and the generalizability is severely limited.

Limitations

In this evaluation, the participants were recruited within the regular patient flow in primary care, which on one hand increases the ecological validity of the study but on the other hand decreases the control of several third variables influencing the groups. Performing pragmatic evaluations on how the treatment method works under regular conditions is a concrete way to achieve local evidence. Evaluating iACT the way it is provided in clinical practice, without adding resources or excluding patients for the sake of the evaluation, can provide a closer input on the actual effect, which in turn can increase the external validity.

Due to organizational problems in conducting the study, the participants could not be randomized and were instead assigned

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to iACT or TAU following a nonrandomized design. Since the authors could not control the assignment of treatment method, no conclusions on eventual differences in treatment outcomes between groups could be made. Therefore, the TAU group was omitted from this evaluation and the internal validity is reduced.

This evaluation took place during the implementation phase of iACT in primary care, which poses its own unique challenges. Hasson and von Thiele Schwarz [41] suggest that performing follow-ups and giving feedback are ways to increase the motivation to implement a new method. In other words, the evaluation itself can influence the object of evaluation. During the IMPACT project, one of the staff members at one of the clinics involved mentioned that the project helped them initiate the implementation.

For the therapists involved in this study, the implementation phase included a learning phase in assessing and assigning iACT to patients. In the first IMPACT paper, the interviewed therapists discussed which patients iACT can be helpful for. The therapists concluded that iACT is more suitable for patients with self-discipline, acceptance of personal responsibility, capability of introspection, and appreciation of working independently with the program. Furthermore, the therapists concluded that iACT is better suited for patients with anxiety rather than depression and that the symptoms should not be too severe, wide-ranging, or long-standing, and that the patient preferably should be in the upper teens. Furthermore, several therapists expressed that iACT is less suitable for patients with learning disabilities, neuropsychiatric illness, or dyslexia [20].

The participant recruitment took place between 2018 and 2020, hence parts of the data collection took place during the COVID-19 pandemic. The authors suspect that the pandemic influenced the anxiety and functioning of the participants both directly, such as fear of infection, and indirectly such as transferring between distance and classroom learning in some cases. Ideally, the authors could have addressed this during the study, for example, by specifically asking about the effect of the pandemic. Thus, the results should be handled with caution.

The sample size in this study is relatively small, especially in the subgroup analyses, which severely limits the generalizability of the results. Furthermore, this evaluation contained a relatively large amount of missing data in proportion to the sample size. In a review paper, Kang [52] reviews techniques for managing missing data and argues that the best method is prevention, for example, by minimizing the number of follow-ups. The data collection for the IMPACT project consisted of surveys before, during, and after treatment and at 6- and 12-month follow-ups, as well as interviews before, during, after, and 12 months after treatment. It is possible that the number of measurements might have had an impact on the participation, for example, by reducing the motivation to participate. On the other hand, a larger number of measurement points, as well as both written and spoken, results in more opportunities to collect data.

In this evaluation, missing data were handled by complete case analysis, which Kang [52] does not recommend with small sample sizes. Applying the last-observation-carried-forward method would have increased the amount of data included in the analyses. However, since the previous measurements occur

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closer to the treatment phase, this could also create a bias in the data. Furthermore, due to a large number of missing data, the authors determined that the last-observation-carried-forward method would risk being too misleading; therefore, only participants with complete data were included in the analysis.

Regarding dropouts, Kang [52] recommends documenting the reason and thus enabling further analysis. In this evaluation, treatment adherence was investigated by analyzing the timing and reason behind the dropouts. Nevertheless, more actions could have been taken in preventing and investigating the dropouts. In a Swedish RCT, 162 adults were investigated regarding their participation in iACT to explore variables predicting dropout, adherence, and outcomes. The authors concluded that the level of treatment credibility predicted dropouts whereas attrition was associated with higher levels of impulsivity and low levels of intrinsic treatment motivation [53].

The generalizability of the results in this evaluation is limited due to the small and gender-based sample of young people that were included. To achieve a better understanding of mental health in male adolescents and to enhance primary care services, it is important to address gender bias in future research and clinical work. Furthermore, the amount of missing data was relatively high, which further reduced the possibility of drawing conclusions based on the data.

Due to limitations in the study design regarding a small and gender-biased sample size with a large proportion of dropouts and missing data, a nonrandomized assignment of intervention, and analysis limited to within-group, this investigation should be considered an explorative evaluation of a new method rather than a scientific outcome study. Further research on iACT in the regular patient flow in primary care is needed.

Conclusions

This evaluation consists of a follow-up on adolescents, 12 months after receiving iACT, with or without parental support. Due to a large amount of missing data, the results should be viewed as an evaluation rather than a scientific study. Adherence to treatment was investigated, indicating that parental support could increase adherence to iACT, which in turn might improve the conditions for young patients undertaking iACT treatment. The results also underscore the importance of parental involvement in the treatment of adolescents with mental illness. More research is needed to explore the relationship between parental support and treatment outcomes and how clinicians can facilitate the process.

Future research should investigate internet-based treatments for adolescents in primary care with additional, possibly digital, parental support programs in RCTs. After the IMPACT project was conducted, an internet-delivered parental support program was developed, in which information about how to support the adolescent during treatment was added [19]. Further research is needed on parental support in this format as well. Moreover, further research is needed on involving next of kin in health care in general.

Furthermore, the analyses of the outcome measures suggest that iACT might be an effective treatment for both anxiety and

depression and has the potential to be an effective treatment of comorbidity and a broader spectrum of anxiety problems.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

The contents of the internet-delivered acceptance and commitment therapy (iACT) intervention translated into English. [PDF File (Adobe PDF File), 147 KB - pediatrics_v8i1e59489_app1.pdf]

Multimedia Appendix 2

User manual for the Anxiety School (Användarmanual till Ångestskolan in Swedish). [PDF File (Adobe PDF File), 468 KB - pediatrics v8i1e59489 app2.pdf]

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Abbreviations

ACT: acceptance and commitment therapy AFQ-Y8: Avoidance and Fusion Questionnaire for Youth CBT: cognitive behavioral therapy CGAS: Children's Global Assessment Scale CONSORT: Consolidated Standards of Reporting Trials GAD: generalized anxiety disorder iACT: internet-delivered acceptance and commitment therapy iCBT: internet-based cognitive behavioral therapy IMPACT: Internet Mediated Psychological Treatment-Acceptance and Commitment Therapy RCADS: Revised Children's Anxiety and Depression Scale RCT: randomized controlled trial TAU: treatment as usual



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Original Paper

Changes in Internet Activities and Influencing Factors for Problematic Internet Use During the COVID-19 Pandemic in Korean Adolescents: Repeated Cross-Sectional Study

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Abstract

Background: As adolescents increasingly engage with digital experiences, the internet serves as a platform for social interaction, entertainment, and learning. The COVID-19 pandemic accelerated this trend, with remote learning and restricted physical interactions driving changes in internet behavior. Adolescents spent more time on gaming and social media, reflecting a notable shift in use patterns.

Objective: We hypothesized that the COVID-19 pandemic changed internet use patterns among Korean adolescents, including content types, time spent on web-based activities, and pathological use prevalence. Additionally, we anticipated that these changes would correlate with shifts in adolescents' psychological status during the pandemic.

Methods: Data from 827 adolescents aged 12 to 15 years (n=144 in 2018, n=142 in 2019, n=126 in 2020, n=130 in 2021, n=143 in 2022, and n=142 in 2023) were gathered over 6 years from 43 middle schools across 16 regions and 1 hospital in South Korea. The demographic data collected included age, sex, and school year. Participants also provided information on their internet use patterns and levels of internet addiction. Additionally, psychological status, including mood, anxiety, attention, and self-esteem, was assessed.

Results: There were significant differences in the depression scale (Patient Health Questionnaire 9). The Patient Health Questionnaire 9 scores for 2018, 2019, and 2023 decreased compared to those in 2020, 2021, and 2022 (F_5 =3.07; P=.007). Regarding changes in internet use behavior, game playing among adolescents decreased after the pandemic compared to before, while watching videos increased. Additionally, the rate of problematic internet use was highest for games before COVID-19, but after COVID-19, it was highest for videos, and this trend continued until 2023 (χ^2_3 =8.16, P=.04). Furthermore, this study showed that the Young's Internet Addiction Scale (YIAS) score was highest in the game group in 2018 compared to other groups before COVID-19 (F_5 =14.63; P<.001). In 2019, both the game and video groups had higher YIAS scores than other groups (F_5 =9.37; P<.001), and by 2022, the YIAS scores among the game, video, and Social Network Service groups did not differ significantly. The degree of influence on the severity of internet addiction was also greatest for games before COVID-19, but after COVID-19, the effect was greater for videos than for games.

Conclusions: During the COVID-19 pandemic, internet use for academic and commercial purposes, including remote classes and videoconferences, increased rapidly worldwide, leading to a significant rise in overall internet use time. The demand for and dependence on digital platforms is expected to grow even further in the coming era. Until now, concerns have primarily focused on the use of games, but it is now necessary to consider what types of internet behaviors cause problems and how to address them.

KEYWORDS

coronavirus pandemic; internet use pattern; internet games; short-form videos; social network system; depressed mood; internet use; pandemic; internet; COVID-19; video; internet behavior; social media; internet addiction; depression; anxiety; digital platforms; mobile phone

Introduction

Background

Since its first appearance in a psychiatric context in 1998 [1], the maladaptive and addictive use of the internet, often referred to as internet addiction or internet use disorder, has been increasingly addressed over the past two decades. The internet use rate of Korean adolescents was around 50% in 1999, rising to 99.5% in 2023 [2,3].

Among adolescents, internet applications have shifted from being a supportive function to dominating their daily lives, sometimes leading to addictive use. Both the American Psychiatric Association and the World Health Organization have acknowledged this behavioral phenomenon in their classification manuals, the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5; since 2013 as a condition for further study) and the forthcoming *International Classification of Diseases, 11th Revision* (in the chapter on "Disorders due to behavioral addictions"). However, several authors have criticized this decision, citing a lack of conceptual and empirical foundations [4-9]. Moreover, Griffiths [10] insisted that the context (activities) of internet use is far more important than the amount of time spent on web-based activities.

In almost all studies, adolescents and young adults are consistently identified as the group with the highest prevalence of internet use. As adolescents increasingly engage in digital experiences, the internet serves as a versatile platform for social interaction, entertainment, and information acquisition [11]. Empirical studies have explored the intricate relationships between different types of internet activities and their associated risks. For instance, the problematic use of video games, social media, and the internet has been linked to various mental health issues, such as emotional distress, self-esteem problems, and attention problems, among adolescents [12]. A systematic review of the literature by Coutelle et al [13] suggested that psychological status including inattention, anxiety, and depression significantly impact internet addiction. Additionally, the heterogeneity in internet behavior patterns during the pandemic underscores the importance of considering individual differences when addressing problematic internet use [14].

The COVID-19 pandemic's impact on internet use highlights the need to understand the complexities of adolescent web-based activities and their mental health. In a review of longitudinal or repeated cross-sectional, follow-up studies, Wolf and Schmitz [15] declared that the COVID-19 pandemic and related stressors could impact the mental health of children and adolescents. Moreover, latent profile analyses reveal distinct patterns of internet and gaming use, suggesting that adolescents' engagement with digital platforms can be categorized into different profiles based on the intensity and type of use [16-18].

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The COVID-19 pandemic further accentuated the use of digital platforms, as social restrictions necessitated remote learning and limited physical interactions. This shift resulted in altered internet behavior patterns among adolescents, with a notable increase in the time spent on internet gaming and social media [11,16].

Hypothesis

We hypothesized that the COVID-19 pandemic changed psychological status, as well as internet use patterns regarding internet content, use time, and pathological use, in Korean adolescents. Additionally, the severity of pathological internet use was influenced by psychological factors, including mood and attention, during the COVID-19 pandemic.

Methods

This study is a repeated cross-sectional study that tracked data from 827 students over 6 years.

Participants

Over 6 years, data from 827 adolescents (n=144 in 2018, n=142 in 2019, n=126 in 2020, n=130 in 2021, n=143 in 2022, and n=142 in 2023) aged 12 to 15 years were gathered from 43 middle schools across 16 regions and 1 hospital in South Korea.

Through a web-based advertisement on the Korean Game Culture Foundation website from January 1, 2018, to December 30, 2023, a total of 69 middle schools from 32 regions and 2 hospitals from 2 regions in South Korea applied to the Visiting Game Class program for game literacy education. Of these, 43 middle schools from 16 regions and 1 hospital were selected through the multistage sampling method. First, the selection was divided by region and hospital; 16 (50%) out of 32 regions were randomly selected, and 1 (50%) of the 2 hospitals in each selected region was chosen at random. Then, among the 52 schools within these 32 regions, 44 (85%) schools were selected. However, 1 school deferred its participation to 2024 due to its academic schedule, so it did not contribute to the research data. Trained agents from the Korean Game Culture Foundation visited schools and hospitals to conduct an investigation.

Ethical Considerations

All data collected by the agents were anonymized, and participants were rewarded with school supplies worth approximately US \$10. Approval for the current study was granted by the Institutional Review Board at Chung-Ang University (1041078-202201-HR-052). We obtained informed consent for research participation from both the students and their parents.

Demographics and Internet Use Patterns

The demographic data collected included age, sex, and school year. Participants also provided information on their internet use patterns and levels of internet addiction. We defined "problematic internet use" as answering "yes" to the following questions: "Did you hear that people important or close to you consider your internet use to be a problem or suggest you meet a doctor or specialist for it?" [19].

The Young's Internet Addiction Scale (YIAS), a commonly used instrument for assessing internet addiction and web-based activities such as gaming, was used. This scale comprises 20 items, each rated on a 5-point Likert scale. The internal consistency of the Korean version of the scale has been reported to range from 0.90 to 0.93.

Psychological Assessment Scales

The Patient Health Questionnaire 9 (PHQ-9) was used to assess depression, with each item rated on a Likert scale from 0 to 3. A cutoff score of 10 (out of 27) was used to indicate depression. Park et al [20] validated the Korean version of the PHQ-9, which demonstrated an internal consistency of α =.81.

The DuPaul Attention-Deficit/Hyperactivity Disorder (ADHD) scale, particularly the ADHD symptom severity scale (ADHD Rating Scale [ARS]), includes 18 items, with 9 items dedicated to inattention and 9 to hyperactivity [21]. So et al [22] validated the Korean version of the ARS (K-ARS) and reported an internal consistency ranging from 0.77 to 0.89.

The Social Phobia Inventory (SPIN) is a self-report questionnaire consisting of 17 items designed to measure three dimensions of social anxiety. Cho et al [23] developed a Korean version of the SPIN (K-SPIN) and reported a high internal consistency with a Cronbach α of 0.91.

The Two-Factor Self-Esteem Scale (SE) is based on a modified version of the Rosenberg Self-Esteem Scale. It conceptualizes self-esteem as an individual's perception of their worth, incorporating elements of self-respect and self-confidence [24]. This scale contains 10 statements that assess overall feelings toward oneself. Participants indicate their level of agreement on a 4-point Likert scale, ranging from 1 (disagree completely) to 4 (agree completely). The internal consistency of the Korean version of the scale, referred to as the Self-Esteem Scale-Korean, has been reported with a Cronbach α of 0.79 [25].

Data Analysis

Demographic characteristics, including age, school year, and internet use time across years, were analyzed using ANOVA tests. Sex and internet activity across years were analyzed using chi-square tests. The YIAS scores and psychological scale scores, including PHQ-9, K-ARS, K-SPIN, and SE were also analyzed using ANOVA tests. The correlations between age, SE, PHQ-9, K-SPIN, K-ARS, IT use time, and YIAS were assessed using Pearson correlation analyses. The correlations between sex (IT activity) and age, SE, PHQ-9, K-SPIN, K-ARS, IT use time, and YIAS were assessed using Spearman correlation analyses. The correlation between sex and IT activity was assessed using Kendall tau-b correlation analysis.

We conducted hierarchical linear regression analyses using YIAS scores as the dependent variable to identify factors influencing the severity of problematic internet use. In Model 1, we tested the associations of demographic factors with the severity of problematic internet use. In Model 2, psychological factors were added to test their associations beyond the effects of demographic factors. In Model 3, internet use time was added to test its association beyond the effects of demographic and psychological factors. Finally, in Model 4, internet activities were added to test their associations beyond the effects of demographic factors, psychological factors, and internet use time. Statistical significance was set a priori at α =.05 (two-sided) to limit type-I error. All analyses were conducted using the *Complex Samples* module of the *PASW* statistics software package (version 19; IBM Corp).

Results

Demographic and Clinical Characteristics

There were no differences in sex ratio and age across the 6 years. Similarly, there were no differences in the scores of the self-esteem, social anxiety, and attention scales over the same period. However, significant differences were observed in the PHQ-9 scores (F_5 =3.07; P=.007). The PHQ-9 scores for 2018, 2019, and 2023 were lower compared to those in 2020, 2021, and 2022. Additionally, there was a significant difference in internet use time (F_5 =6.30; P<.001). Internet use time was highest in 2020 and 2021, followed by 2022 and 2023, and lowest in 2018 and 2019 (Table 1).



Table 1. Demographic characteristics.

	2018 (n=144)	2019 (n=142)	2020 (n=126)	2021 (n=130)	2022 (n=143)	2023 (n=142)
Demographic characteristics						
Sex, n (%)						
Male	83 (57.6)	80 (56.3)	74 (58.7)	77 (59.2)	80 (55.9)	86 (60.6)
Female	61 (42.4)	62 (43.7)	52 (41.3)	53 (40.8)	63 (44.1)	56 (39.4)
Age (years), mean (SD)	13.56 (1.10)	13.59 (0.59)	13.55 (1.11)	13.34 (1.33)	13.35 (0.73)	13.64 (0.92)
IT use pattern						
Internet use time ^a , mean (SD)	2.82 (1.23)	3.09 (1.67)	3.55 (1.14)	3.69 (1.78)	3.21 (1.01)	3.20 (1.71)
YIAS ^b , mean (SD)	45.08 (15.67)	43.87 (12.83)	43.87 (13.17)	45.08 (13.81)	44.41 (13.05)	44.32 (14.61)
Psychological scales						
SE ^c , mean (SD)	27.09 (5.09)	27.20 (3.13)	27.33 (7.16)	28.15 (5.33)	27.89 (5.02)	27.04 (3.21)
PHQ-9 ^{d,e} , mean (SD)	9.69 (7.76)	9.88 (5.24)	11.90 (4.66)	11.13 (6.84)	11.13 (5.93)	9.58 (7.14)
K-SPIN ^f , mean (SD)	18.58 (11.05)	18.65 (11.92)	19.61 (11.51)	20.11 (12.75)	19.39 (13.51)	18.37 (12.89)
K-ARS ^g , mean (SD)	10.37 (7.98)	9.19 (8.82)	9.17 (8.09)	10.01 (9.37)	10.10 (9.96)	9.28 (9.30)

 ${}^{a}F_{5}$ =6.30; *P*<.001; 2018=2019<2022=2023<2020=2021.

^bYIAS: Young's Internet Addiction Scale.

^cSE: Two-Factor Self-Esteem Scale.

^dPHQ-9: Patient Health Questionnaire 9.

^e*F*₅=3.07; *P*=.007; 2018=2019=2023<2020=2021=2022.

^fK-SPIN: Korean version of the Social Phobia Inventory.

^gK-ARS: Korean version of the Attention Deficit/Hyperactivity Disorder Rating Scale.

The Correlations Between All Variables

In the comparison of variable correlations, PHQ-9 scores were positively correlated with K-ARS scores (r=0.45; P<.001).

YIAS scores were positively correlated with PHQ-9 scores (*r*=0.43; *P*<.001) and K-ARS scores (*r*=0.43; *P*<.001; Table 2).



Table 2. Correlation matrix of all variables^a.

Variables	Age	Sex	SE^b	PHQ-9 ^c	K-SPIN ^d	K-ARS ^e	IT use time	IT activity	YIAS ^f
Age		-							
r	1	-0.05	-0.04	0.04	0.07	0.10	0.09	0.09	0.05
P value	g	.11	.25	.31	.06	.004	.007	.03	.09
Sex									
r	-0.05	1	-0.06	-0.01	0.05	-0.32	0.02	0.15	-0.07
P value	.11	_	.12	.55	.19	.75	.53	<.001	.03
SE									
r	-0.04	-0.06	1	-0.03	-0.21	-0.13	-0.02	-0.04	-0.02
P value	.25	.12		.38	<.001	<.001	.49	.21	.25
PHQ-9									
r	0.04	-0.03	-0.03	1	0.14	0.45	0.07	0.08	0.43
P value	.31	.55	.38	_	<.001	<.001	.05	.02	<.001
K-SPIN									
r	0.07	0.05	-0.21	0.14	1	0.28	0.05	0.06	0.18
P value	.06	.19	<.001	<.001	_	<.001	.16	.08	<.001
K-ARS									
r	0.10	-0.32	-0.13	0.45	0.28	1	0.08	0.04	0.43
P value	.004	.75	<.001	<.001	<.001	_	.03	.29	<.001
IT use time									
r	0.09	0.02	-0.02	0.07	0.05	0.08	1	0.52	0.08
P value	.007	.53	.49	.05	.16	.03	—	.14	.04
IT activity									
r	0.09	0.15	-0.04	0.08	0.06	0.04	0.52	1	0.03
P value	.03	<.001	.21	.02	.08	.29	.14	_	.34
YIAS									
r	0.05	-0.07	-0.02	0.43	0.18	0.43	0.08	0.03	1
P value	.09	.03	.25	<.001	<.001	<.001	.04	.34	_

^aPearson correlation: age, SE, PHQ-9, K-SPIN, K-ARS, IT use time, YIAS; Spearman correlation: sex, IT activity versus age, SE, PHQ-9, K-SPIN, K-ARS, IT use time, YIAS; Kendall tau-b: sex, IT activity.

^bSE: Two-Factor Self-Esteem Scale.

^cPHQ-9: Patient Health Questionnaire 9.

^dK-SPIN: Korean version of the Social Phobia Inventory.

^eK-ARS: Korean version of the Attention Deficit Hyperactivity Disorder Scale.

^fYIAS: Young's Internet Addiction Scale score.

^gNot applicable.

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Changes in Internet Activities of Korean Adolescents Over 6 Years

Over the past 6 years, the population engaged in gameplay had decreased, while the population watching videos had increased. In 2018, a total of 51.4% (74/144) of the population engaged in gameplay, and 29.9% (43/144) watched videos. By 2022, these figures had shifted to 32.9% (47/143) for gameplay and 35.7% (51/143) for video watching, and in 2023, to 35%

(50/142) for gameplay and 37.8% (54/142) for video watching (2022: χ^2_3 =11.20, *P*=.01; 2023: χ^2_3 =12.32, *P*=.006). Similarly, in 2019, a total of 46.2% (66/142) engaged in gameplay and 35% (50/142) watched videos. By 2022, these figures had changed to 32.9% (47/143) for gameplay and 35.7% (51/143) for video watching, and in 2023, to 35% (50/142) for gameplay and 37.8% (54/142) for video watching (2022: χ^2_3 =8.68, *P*=.03; 2023: χ^2_3 =8.16, *P*=.04; Figure 1).

Figure 1. Changes in internet activities of Korean adolescents over 6 years (chi-square test). (A) Comparison of internet activities between 2018 and 2022 (χ^2_3 =11.20, *P*=.01); (B) comparison of internet activities between 2018 and 2023 (χ^2_3 =12.32, *P*=.006); (C) comparison of internet activities between 2019 and 2022 (χ^2_3 =8.68, *P*=.03); and (D) comparison of internet activities between 2019 and 2023 (χ^2_3 =8.16, *P*=.04). SNS: Social Network Service.



Differences in Problematic Internet Use for 4 Activities in Korean Adolescents Over 6 Years

Until 2019, the proportion of problematic internet use was highest in the gaming group among the 4 types of internet use.

However, the proportion of problematic internet use in watching videos abruptly increased in 2020 and has maintained its top position until 2023. The proportion of problematic internet use in Social Network Service (SNS) use continuously increased until 2021 but decreased in 2022 and 2023 (Figure 2).



Figure 2. Changes in problematic internet use for 4 activities in Korean adolescents over 6 years. SNS: Social Network Service.



Differences in YIAS Scores for 4 Activities in Korean Adolescents Over 6 Years

In 2018, the YIAS scores for gameplay (mean 50.1, SD 15.3) were the highest compared to other activities. The YIAS scores for watching videos (mean 41.1, SD 12.3) were higher than those for SNS use (mean 34.5, SD 4.9) and other activities (mean 31.0, SD 5.8; F_3 =14.63; P<.001). In 2019, the YIAS scores for gameplay (mean 49.2, SD 11.5) and watching videos (mean 44.0, SD 10.1) were higher than those for SNS use (mean 36.4, SD 3.5) and other activities (mean 30.3, SD 2.0; F_3 =9.37; P<.001). In 2020, the YIAS scores for gameplay (mean 46.4, SD 10.5) and watching videos (mean 45.3, SD 9.8) were higher than those for SNS use (mean 46.4, SD 10.5) and watching videos (mean 39.3, SD 8.8) and other activities (mean 39.3, SD 8.8) and store (mean 39.3

(mean 33.2, SD 4.7; F_3 =4.98; P=.003). In 2021, there was no significant difference between the scores of the four activities (F_3 =2.33; P=.08). In 2022, the YIAS scores for other activities (mean 33.1, SD 6.8) were significantly lower than those for gameplay (mean 45.6, SD 6.7), watching videos (mean 49.3, SD 5.7), and SNS use (mean 42.0, SD 10.1; F_3 =6.83; P<.001). However, there was no significant difference between the scores for gameplay, watching videos, and SNS use. In 2023, the YIAS scores for other activities (mean 30.3, SD 3.9) were significantly lower, than those for gameplay (mean 42.4, SD 8.4), watching videos (mean 47.1, SD 8.8), and SNS use (mean 45.2, SD 7.2; F_3 =4.73; P=.004). However, there was no significant difference between the scores for gameplay.

Figure 3. The changes in YIAS scores for 4 activities in Korean adolescents over 6 years. (A) Game>Videos>SNS=Others (F_3 =14.63; P<.001). (B) Game=Videos>SNS=Others (F_3 =9.37; P<.001). (C): Game=Videos>SNS=Others (F_3 =4.98; P=.003). SNS: Social Network Service; YIAS: Young's Internet Addiction Scale.



Differences in Influencing Factors for YIAS Scores

Considering the beta values of Model 4, the order of statistically significant influences on the severity of internet addiction in 2018 was as follows: game playing, PHQ-9 scores, watching videos, K-ARS scores, and IT use time (Table 3 and Table S1 in Multimedia Appendix 1). In 2019, the order was game playing, watching videos, PHQ-9 scores, K-ARS scores, and IT use time (Table 3 and Table S2 in Multimedia Appendix 1).

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In 2020, the order was K-ARS scores, game playing, and watching videos (Table 3 and Table S3 in Multimedia Appendix 1). In 2021, the order was PHQ-9 scores and watching videos (Table 3 and Table S4 in Multimedia Appendix 1). In 2022, the order was watching videos, game playing, PHQ-9 scores, K-ARS scores, and SNS use (Table 3 and Table S5 in Multimedia Appendix 1). In 2023, the order was PHQ-9 scores, K-ARS scores, watching videos, SNS use, and game playing (Table 3 and Table S6 in Multimedia Appendix 1).

Table 3. Differences in influencing factors for YIAS^a scores over 6 years.

Variables	2018	2019	2020	2021	2022	2023
Demographic factors						
Age	b	_	_	_	_	_
Sex	_	_	_	_	_	_
Psychological test						
SE^{c}	_	_	_	_	_	_
PHQ-9 ^d	X2 ^e (0.40)	X3 (0.30)	_	X1 (0.51)	X3 (0.31)	X1 (0.57)
K-SPIN ^f	_	_	_	_	_	_
K-ARS ^g	X4 (0.23)	X4 (0.30)	X1 (0.60)	_	X4 (0.25)	X2 (0.33)
IT use time	X5 (0.17)	X5 (0.13)	_	_	_	_
IT activity						
Game	X1 (0.52)	X1 (0.39)	X2 (0.24)	_	X2 (0.37)	X5 (0.24)
Videos	X3 (0.26)	X2 (0.36)	X3 (0.24)	X2 (0.25)	X1 (0.43)	X3 (0.28)
SNS ^h	_	_	_	_	X5 (0.25)	X4 (0.26)

^aYIAS: Young's Internet Addiction Scale.

^bNot applicable.

^cSE: Two-Factor Self-Esteem Scale.

^dPHQ-9: Patient Health Questionnaire 9.

^eXn (beta value): X: statistically significant; n: ranking; 1: most effective factor.

^fK-SPIN: Korean version of the Social Phobia Inventory.

^gK-ARS: Korean version of the Attention Deficit/Hyperactivity Disorder Rating Scale.

^hSNS: Social Network Service.

Discussion

Principal Findings

The goal of this study was to examine changes in internet use patterns among adolescents, from before to after the outbreak of the COVID-19 pandemic. Our findings revealed several changes in internet use time and patterns, as well as shifts in problematic use behavior before, during, and after COVID-19.

The results showed that PHQ-9 scores were low before and after the COVID-19 pandemic, but high from 2020 to 2022, when the pandemic was at its peak. This aligns with previous studies indicating a high proportion of adolescents experiencing depression and anxiety during the pandemic [26,27]. The COVID-19 pandemic brought significant changes to adolescents' lives, potentially acting as environmental stressors [28]. To avoid exposure to the virus, young people actively avoided social activities, and many children and adolescents were confined to their homes for extended periods due to lockdowns. This social isolation has been associated with an increased risk of depression and anxiety in children and adolescents [29]. Additionally, the fear of infection itself was linked to anxiety and depression [30]. With the lifting of lockdowns, most people have resumed their lives, and depression and anxiety likely diminished since the peak of the pandemic due to the development of coping mechanisms and hopeful news about vaccines during the "honeymoon phase" of the disaster [31-33].

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Similar results regarding the relationship between mental health and internet addiction during the COVID-19 pandemic were reported in several studies [34,35]. Ye et al [34] reported that depression is positively correlated with internet addiction during the COVID-19 pandemic. Moreover, adolescents with depressive disorders could have a higher risk of internet addiction. In a meta-analysis, Tang et al [35] reported that the association between problematic smartphone use and depressive symptoms became stronger after the COVID-19 outbreak.

To our knowledge, there is evidence of changes in internet use patterns during the pandemic, including increased dependence on the internet [36]. In a large, national youth sample, cross-sectional study conducted in the United States during the early period of the COVID-19 pandemic, the absolute time of internet use among teenagers more than doubled compared to prepandemic times [37]. Additionally, a systematic review and meta-analysis of screen time among children and youth aged 0 to 21 years before and after the pandemic showed a 1.6-fold increase in screen time during the pandemic [38]. Similarly, in this study, from 2020 to 2021, during the COVID-19 outbreak, adolescents used the internet more than before, and their internet use time decreased as the COVID-19 peak passed. Previous studies have shown that internet use time increased as physical activity decreased due to the lockdowns caused by COVID-19 [39,40]. These results may reflect decreased screen time as physical and offline activity increased when daily life recovered after COVID-19 [41].

During the pandemic, teenagers increased their internet use for various purposes, such as interacting with friends, doing homework, enjoying games, and attending remote classes [42]. Generally, internet addiction is suspected when an individual devotes excessive time to internet use [43]. Excessive internet use is known to likely lead to internet addiction, especially in children and adolescents [44]. Similarly, as adolescents spend more time on web-based activities during the pandemic, many studies have shown an increased risk of internet addiction. For instance, a study examining internet addiction in Taiwanese high school students during COVID-19 found a 24.4% rate of addiction, indicating an increase compared to prepandemic levels [45]. In a longitudinal study on the developmental qualities of children and adolescents during the COVID-19 pandemic, Wang et al [46] suggested that the pandemic may lead to a decline in positive youth development, making them more vulnerable to internet addiction. Additionally, a study conducted in India investigated the effect of the COVID-19 lockdown on internet addiction in late teenagers, showing a 14.84% increase in internet gaming disorder (IGD) frequency compared to previous studies in the same region [47]. However, most studies focused only on excessive internet use and did not differentiate specific internet activities. Therefore, to address problematic internet use among adolescents, it is necessary to examine in more detail which specific internet activities are problematic.

Looking at the changes in internet use behavior that this study focused on, game playing decreased in adolescents after the pandemic compared to before the pandemic, and watching videos increased further. In addition, in this paper, the problematic internet use rate of games was the highest before COVID-19. Still, after COVID-19, the problematic internet use rate was the highest in the video group, and this trend continued until 2023. In addition, as our study showed, the YIAS score was the highest in the game group in 2018 compared to other groups before COVID-19. Still, in 2019, the YIAS scores in the game and video groups were higher than other groups, and the YIAS scores between the game, video, and SNS groups did not differ significantly as we went into 2022. The degree of influence on the severity of internet addiction was also the largest in the game group before COVID-19, but the effect on the video group was greater than in the game group after COVID-19.

Similar to these findings, several studies have reported significant changes in how individuals allocate time across different activities during the COVID-19 pandemic, noting increased SNS use, watching videos, and more, not just gaming [36,48,49]. According to a probability-based tracking survey of tweens and teens in the United States, there was no significant difference in teen gaming time between 2019 and 2021. Still, the time spent watching videos increased significantly, up to 23 minutes daily [50]. As several reports suggest, overall, the global gaming market has shrunk since the COVID-19 pandemic [51], and gaming users' gaming hours have declined since the peak [52]. On the other hand, the video-related industry has grown significantly as lockdowns have made it one of the major recreational activities [53]. According to Morse et al [54], TV or streams or movies have emerged as a new leisure activity,

with activities experiencing the greatest increase during COVID-19. Another study suggests that Netflix, Hulu, and Amazon Prime Video are now recognized as some of the most important TV networks and video sources for the younger adult generation, further highlighting the popularity of streaming services [55]. Similarly, other studies point to the problematic use of SNS platforms, including video consumption by adolescents [36,56,57].

In the paper by Nawaz et al [36] on technology utilization in the new post-COVID-19 era, social networking platform engagement has increased markedly as study participants have been given more time for web-based social interaction. Meanwhile, in one study conducted in Italy, video consumption through certain platforms, like TikTok, during the COVID-19 pandemic strongly predicted social media addiction [56]. In addition, similar to previous studies that revealed that adolescents' social anxiety can lead to problematic social media use [57]; the increasing web-based social interaction trend, rather than internet gaming, reflects the growing dependence on digital connections as a coping mechanism during physical distancing and quarantines, with web-based streaming services, including videos, also experiencing notable use increases [36]. Taken together, even before COVID-19, video-sharing platforms such as YouTube [58] and social media platforms such as Instagram or Snapchat were already gaining popularity [59]. However, short video consumption worldwide saw the fastest and largest increase in the early stages of the pandemic, especially among those aged 15-29 years [60], where teenagers would have sought self-expression and social rewards by recording and communicating their daily lives [61]. Furthermore, the rise in the use of SNS and video apps during COVID-19 suggests a shift in overall trends during physical distancing, searching for information, and using platforms to help maintain social relationships [62].

As mentioned in the previous results, the COVID-19 pandemic has significantly changed people's lives worldwide, with internet use at the center of this change. Although internet use has alleviated mental health symptoms for many and helped them cope with new trends [63,64], adolescents have been able to devote more time to web-based activities, especially during emotionally demanding times, which can lead to problematic use [65]. It is essential to provide guidance to reduce the risk of such addiction. Adults should observe how much time adolescents spend on web-based activities (eg, playing games and watching videos) and help them manage these activities [48].

However, problematic internet use has not yet been sufficiently discussed. The American Psychiatric Association included IGD in *DSM-5* [66], and the World Health Organization included gaming disorder in the *International Classification of Diseases, 11th Revision* [67], but current societies present only diagnostic criteria for games. This study shows that games no longer account for a high percentage of adolescents' problematic internet use time. In addition, the *DSM-5* acknowledges the limitations of the absence of well-studied subtypes for IGD and acknowledges that there are limitations to the diagnosis, such as the fact that it is not clear which game type is specifically included in IGD diagnosis [66]. Furthermore, a survey of

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adolescents in China on IGD, problematic smartphone use, and problematic SNS use found that each has a different core symptom, with problematic SNS use requiring a different therapeutic approach as it shows a different core symptom [68]. Similarly, as Griffiths [10] argued in his study on the concept of internet addiction and IGD, it should be understood that people addicted to web-based activities, such as web-based games, web-based gambling, web-based sex, and web-based shopping, should not be defined as people with internet addictions, but rather as people with game addictions, sex addictions, or shopping addictions, who are engaged in addictive behavior using the internet as a tool. Chen et al [69] reported that problematic smartphone use was associated with the COVID-19 pandemic outbreak, whereas problematic internet gaming was not. Previous studies suggest that the focus should be on how the internet is used, rather than seeing the excessive internet use itself as the problem. It is not just gameplay time that is a problem—as individual internet behavior patterns have changed during the COVID-19 pandemic, these points should be considered when solving problematic internet use.

Limitations

There are some limitations to this study. First, there may be sampling errors in representing the overall internet use patterns of teenagers, as the survey only included teenagers aged 13 to 15 years. Second, because this study did not track the same population over 6 years, it was unable to fully capture the trends

in internet addiction and patterns of internet use among adolescents. Third, this study could not fully capture changes in internet addiction and mental health because it was not a longitudinal study within a single group.

Although literature on the pandemic has surged with the global spread of COVID-19, little has been studied about the changes in media and content use caused by the pandemic [70]. To the best of our knowledge, this is the first study to focus on changes in internet use patterns due to the pandemic. The strength of our study lies in surveying the same teenage group over 6 years before, during, and after COVID-19 and further investigating which types of internet use were identified as problematic. Based on these changes in internet use patterns and problems among teenagers, this study contributes to the literature on understanding the trends in internet use behavior caused by COVID-19 and helps predict future changes in internet use.

Conclusions

During the COVID-19 pandemic, academic and commercial internet use through remote classes and videoconferences increased rapidly worldwide, leading to a rise in overall internet use time. The demand for digital platforms will continue to grow in the coming era. Until now, discussions have primarily focused on the use of games, but it is now necessary to consider what types of internet behavior cause problems and how to address them.

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Data Availability

The datasets generated and analyzed during this study are not publicly available as they contain information that could compromise the privacy and consent of the research participants but are available from the corresponding author upon reasonable request.

Authors' Contributions

SIK and DHH contributed to the study design, data collection, and initial drafting of the manuscript. JCJ and SY participated in data analysis and interpretation and revised the manuscript critically for important intellectual content. JCJ and SIK assisted in developing the research methodology and contributed to data validation and visualization. DHH supervised the study, provided resources and funding, and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1 Hierarchical linear regression analyses. [DOCX File , 28 KB - pediatrics v8i1e66448 app1.docx]

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Abbreviations

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ADHD: attention-deficit/hyperactivity disorder
ARS: Attention-Deficit/Hyperactivity Disorder Rating Scale
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
IGD: internet gaming disorder
K-ARS: Korean version of the Attention-Deficit/Hyperactivity Disorder Rating Scale
K-SPIN: Korean version of the Social Phobia Inventory

PHQ-9: Patient Health Questionnaire 9SE: Two-Factor Self-Esteem ScaleSNS: Social Network ServiceSPIN: Social Phobia InventoryYIAS: Young's Internet Addiction Scale

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Original Paper

Effects of Web-Based Single-Session Growth Mindset Interventions for Reducing Adolescent Anxiety: Four-Armed Randomized Controlled Trial

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Abstract

Background: Anxiety disorders are the most common mental health conditions worldwide, yet 65% of those affected do not access services. The high prevalence of anxiety and the low rate of intervention uptake highlight the urgent need to develop timely, scalable, and effective interventions suitable for adolescents. This study adapted existing single-session interventions (SSIs) to further develop an SSI focused on a growth mindset regarding negative emotions for adolescent mental health.

Objective: The study aims to compare the effectiveness of 4 SSIs, SSI of a growth mindset for anxiety (SIGMA), SIGMA with boosters (SIGMA-Booster), SSI of a growth mindset of personality (SSIGP), and an active control group (support therapy [ST]), in reducing adolescent anxiety.

Methods: Classes from each secondary school were randomized to 1 of 4 intervention conditions: SIGMA, SIGMA-Booster, SSIGP, or ST. Each intervention took approximately 45 minutes online. Participants reported on anxiety symptoms (primary outcome), depressive symptoms, suicidal/self-harming thoughts, perceived control, hopelessness, attitude toward help-seeking, and psychological well-being (secondary outcomes) at preintervention, 2-week follow-up, and 8-week follow-up. Participants also completed a feedback scale postintervention. Generalized estimating equations were used to examine the effectiveness of the SSIs.

Results: A total of 731 adolescents from 7 secondary schools were randomized. The intent-to-treat analysis found a significant decrease in anxiety symptoms. The mean and 95% CI at baseline were 6.8 (6.0-7.6) for SIGMA-Booster, 6.5 (5.8-7.3) for SIGMA, 7.0 (6.2-7.7) for SSIGP, and 6.9 (6.1-7.7) for ST. At the 2-week follow-up, the mean and 95% CI were 5.9 (5.1-6.7) for SIGMA-Booster, 5.7 (4.9-6.5) for SIGMA, 5.4 (4.6-6.2) for SSIGP, and 5.7 (4.9-6.4) for ST. At the 8-week follow-up, the mean and 95% CI were 5.9 (5.1-6.7) for SIGMA-Booster, 5.3 (4.5-6.0) for SIGMA, 5.6 (4.8-6.4) for SSIGP, and 5.8 (5.1-6.6) for ST. These reductions were observed across all 4 groups. Moderation analysis found that participants with higher motivation for change, higher baseline anxiety scores, and fixed mindsets showed greater improvements in anxiety symptoms. Most participants (459/731, 62.8%) viewed the feasibility and acceptability of the SSIs positively.

Conclusions: The SSI for all 4 groups was effective in reducing anxiety and depression among adolescents over 8 weeks. Our data suggest the potential benefits of brief web-based interventions for adolescents, which could serve as scalable, destigmatized, and cost-effective alternatives to school-based programs. The intervention effects may have been underestimated, as this study did not exclude adolescents with minimal or no anxiety symptoms. Future studies should focus on the specific effects of interventions for adolescents with varying levels of anxiety symptoms.

Trial Registration: ClinicalTrials.gov NCT05027880; https://clinicaltrials.gov/ct2/show/NCT05027880

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KEYWORDS

belief-in-change; growth mindset; mental health; secondary school students; brief intervention; randomized controlled trial

Introduction

Background

Anxiety is one of the leading causes of illness and disability among adolescents aged 10-19 years [1]. Approximately 6.5% of adolescents worldwide and 6.9% in Hong Kong have been diagnosed with anxiety disorders [2,3]. In Hong Kong, for example, 1 in 4 secondary school students experienced high subclinical anxiety symptoms over a 3-month period, requiring clinical intervention [4]. Based on prevalence rates and local youth population data [5], it is estimated that approximately 85,000 secondary school students in Hong Kong require help and intervention for anxiety symptoms.

However, an estimated 65% of individuals with generalized anxiety disorder in Hong Kong did not access mental health services [6]. Among those who sought help, the median waiting time from symptom onset to receiving public child and adolescent psychiatric services was 58 weeks. Meanwhile, the cost of private treatment was reported to be HK \$3000 (US \$386) per monthly consultation, making it unaffordable for many families, who were left with no choice but to wait for public services [7]. Existing approaches, such as clinic-based treatments provided by highly trained mental health professionals, face significant limitations, including lengthy waitlists, high costs, and challenges in large-scale dissemination. This traditional setting further restricts access to services in special circumstances, such as during the COVID-19 pandemic [8]. Moreover, adolescents with mental health symptoms are particularly vulnerable to stigma and discrimination and may be reluctant to seek school-based interventions [9]. Even among youth who access care, most drop out prematurely, completing only 3-4 therapy sessions on average [10]. While natural remission without treatment may occur, it is uncommon [11]. Given these challenges, there is a clear need to develop briefer, scalable, nonstigmatizing, and youth-friendly interventions for adolescents with general anxiety symptoms. A brief intervention that fosters insight or reduces anxiety about mental health symptoms may help alleviate mental health problems and support remission.

Single-session interventions (SSIs) are structured programs designed to involve only 1 visit or encounter with a clinic, provider, or program [12]. These interventions can function as stand-alone treatments or as adjuncts to clinical services. Notably, research has shown that the number of sessions is not related to the magnitude of the treatment effect [13]. As a very brief intervention consisting of just 1 session, SSIs have demonstrated a relatively substantial effect on youth psychiatric problems. A previous meta-analysis [14] reported a mean postintervention effect size of 0.32 (Hedges g), with the largest effect size observed for anxiety (0.56). Although the effects of SSIs were moderated by follow-up length, with smaller effect

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sizes observed in follow-ups exceeding 13 weeks [14], Schleider and Weisz [15] still found significant improvements in youth depression and perceived behavioral control following growth mindset SSIs, with effects lasting up to 9 months compared with an active control. They also found that enhancing belief in personality change improved treatment access for adolescent depression [16], although no significant changes were recorded for general anxiety, social anxiety, or conduct problems [17]. Walton and Wilson [18,19] emphasized the importance of precise interventions that target the underlying psychological processes contributing to social or psychological problems, as well as the need for an adaptive context to maximize the potency of brief interventions. Thus, the effectiveness of SSIs is closely tied to their content (what to intervene) and implementation strategies (how to intervene).

Given the substantial evidence linking fixed mindsets to youth mental health problems [20] and the positive effects of growth mindset SSIs on anxiety-related outcomes [21], this study developed and examined the efficacy of growth mindset SSIs for adolescent anxiety in the Chinese context. Although some cultural adaptations of growth mindset SSIs have been made for non-Western populations, such as Indian adolescents [22], few studies have examined growth mindset SSIs in the Chinese context, particularly for anxiety-related outcomes [23]. We aimed to advance the existing literature by implementing and comparing different domains of growth mindset and developing implementation strategies for SSIs among Chinese adolescents. First, this study developed the SSI of a growth mindset for anxiety (SIGMA). As fixed mindsets about negative emotions (beliefs that one's negative emotions cannot change) have been closely associated with adolescent depression and anxiety [24,25], interventions that promote growth mindsets about negative emotions (beliefs in the changeability of one's negative emotions) may help alleviate worry and anxiety in adolescents. Second, to examine the effectiveness of SIGMA, we adapted the existing SSIs into Chinese and compared them with SSI of a growth mindset of personality (SSIGP) and support therapy (ST) [15,26]. Third, we collected feedback from social workers and counselors based on the principle of patient and public involvement, and they suggested that boosters could help strengthen the effectiveness of brief interventions. Thus, we designed booster reminders for SIGMA and examined whether reinforcing the core messages of the intervention with boosters would strengthen its effectiveness. A deviation from the 3-arm intervention protocol is that we increased the sample size of participants receiving SIGMA with booster (SIGMA-Booster) messages, establishing it as an independent group. As a result, the SIGMA-Booster group and the SIGMA group now have sample sizes equivalent to the other 2 groups (SSIGP and ST), rather than selecting only half of the original SIGMA group to receive booster messages. We proposed this 4-arm randomized controlled trial to provide evidence on the effectiveness of

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SIGMA (including SIGMA and SIGMA-Booster) and compare it against the existing growth mindset intervention (SSIGP) and support theory as an active control. Beyond its research significance, the study's findings could have broad implications for mental health care practice and policy. If the SSIs in this study are found to be effective, they could be scaled up in schools and community settings, offering a cost-effective and accessible solution to address youth mental health needs. This could reduce the burden on overstretched traditional mental health services and inform public health policies, such as integrating SSIs into school mental health programs or national strategies.

Objectives

The primary objective of the study was to evaluate the effectiveness of a single-session growth mindset intervention for negative emotions (abbreviated as SIGMA) in reducing general anxiety symptoms among secondary school students.

The secondary objective was to compare the effectiveness of the aforementioned programs on secondary outcomes, including reductions in depressive symptoms, suicidal/self-harming thoughts, and hopelessness, as well as increases in perceived control over emotions, attitudes toward help-seeking, and psychological well-being.

Study Hypothesis

- Hypothesis 1: SIGMA (including SIGMA and SIGMA-Booster) and SSIGP are more effective than the active control, ST, in the primary outcome of (1) reducing general anxiety symptoms, and in the secondary outcomes of (2) reducing depressive symptoms, (3) reducing suicidal/self-harming thoughts, (4) reducing hopelessness, (5) enhancing perceived control, (6) increasing positive attitudes toward help-seeking, and (7) enhancing psychological well-being.
- Hypothesis 2: SIGMA (including SIGMA and SIGMA-Booster) is more effective than SSIGP in the outcomes listed from (1) to (7).
- Hypothesis 3: The effectiveness of SIGMA-Booster is greater than that of SIGMA in the outcomes listed from (1) to (7).
- Hypothesis 4: The effectiveness of SIGMA is greater in participants with higher motivation for change than in those with low or no motivation.
- Hypothesis 5: The effectiveness of SIGMA is greater in participants with higher baseline anxiety levels than in those with lower baseline anxiety levels.
- Hypothesis 6: The effectiveness of SIGMA is greater in participants with a more fixed mindset at baseline than in those with a more growth-oriented mindset at baseline.

Methods

Ethical Considerations

This study received ethical approval from the Hong Kong Polytechnic University Institutional Review Board (reference number HSEARS20201004001-01) and complied with institutional guidelines and the Declaration of Helsinki. Parental consent and student assent were obtained for all participants. Participants were informed of their right to withdraw at any time without penalty. Data were anonymized (eg, school names removed, unique codes assigned) and stored securely. Participants who completed the entire study received HK \$100 (US \$13) worth of supermarket coupons as compensation, while participating schools were provided with aggregate mental health reports for institutional support purposes.

Study Design

The study design was described in the published protocol [27]. The trial was prospectively registered at ClinicalTrials.gov (NCT05027880) under the trial ID NCT05027880.

Unlike the published protocol, we made SIGMA-Booster a separate arm to examine whether booster reminders would help promote the long-term effects of the SSI. Based on the principle of patient and public involvement, we consulted the targeted participant population as well as their teachers and counselors. They suggested that boosters, as reminders, should be helpful for long-term changes. Thus, we designed 5 boosters and printed them into folders to be used as weekly reminders between the 2- and 8-week follow-ups (from week 3 to week 7). Only the SIGMA-Booster group received these boosters.

Thus, 4 classes from the same grade of the participating school were randomized (using computer-generated random numbers) into the (1) SIGMA group, (2) SIGMA-Booster group, (3) SSIGP group, and (4) ST group (active control condition group), all of which received the ST intervention at the same time (Figures 1 and 2). Participants in the SIGMA-Booster arm received the SIGMA intervention along with weekly reminders of key intervention messages as boosters from weeks 3 to 7. Two schools did not have enough classes in 1 grade, so classes from other grades at those schools were invited to join the study. All participants received regular interventions at school. Three repeated assessments were conducted for the 4 groups simultaneously at (1) baseline, (2) 2 weeks postintervention, and (3) 8 weeks postintervention. The cluster randomization at the classroom level helped balance the risk of contamination between the experimental and active control groups, as well as account for school heterogeneity due to factors such as school culture, schedule, and management.



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Figure 1. Design of the 4-arm waitlist randomized controlled trial. SIGMA: single-session intervention of a growth mindset for anxiety; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.



Figure 2. Intervention designs. SIGMA: single-session intervention of a growth mindset for anxiety; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.



Participants

Seven schools from Hong Kong Island, Kowloon, and the New Territories participated in the study. These included schools that used English, Chinese, and mixed English and Chinese as the teaching medium. We targeted participants from form 2 to form 3 (grades 8-9). If a school did not have 4 classes in 1 grade, or if the number of eligible participants in a class was too few, we invited additional classes from other grades to participate.

Inclusion Criteria

Eligible participants were recruited from the 7 secondary schools through cluster randomized sampling. We included participants who (1) were Chinese youth able to read and write Chinese, (2) had sufficient visual and auditory abilities to complete the intervention and assessment, and (3) were able to give assent

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to participate in the study. As 2 schools did not have enough classes in 1 grade and invited classes from other grades to participate, a few participants above the age of 16 years were included, which did not follow the inclusion criteria outlined in the protocol (12-16 years old).

Exclusion Criteria

Exclusion criteria included (1) lack of parental consent; (2) inability to stay focused for the duration of the intervention, which is approximately 45 minutes; and (3) intellectual disability or severe illness or pain that could introduce significant bias in the students' health and mental health conditions. Eligible participants were not screened for anxiety symptoms, so this study comprehensively examined the efficacy of the interventions among students with absent, mild, moderate, and severe levels of anxiety.

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Procedure

The school and student recruitment process included the following steps: First, we sent research invitations to schools randomly selected from the school list. Invitations ceased when 7 schools agreed to participate. To ensure sufficient participant recruitment, we recruited 1 additional school beyond the protocol's plan. Four classes from the same selected grade(s) at each school were randomly chosen to join the study. The 4 selected classes were then randomized to the SIGMA condition, SIGMA-Booster condition, SSIGP condition, and the active control condition using random numbers. All students in those classes were invited to participate, with final participation contingent upon parental consent and students' assent.

After providing consent, students scanned a QR code to access the baseline questionnaire and the intervention program via the Qualtrics survey system (SAP SE). Students within the same class were assigned to the same intervention conditions. The interventions were conducted separately for each group in the school activity rooms, which were equipped with sufficient computers or tablets and headphones (Figure 3). All intervention activities were self-administered and delivered in a web-based format. The principal investigator (SZ) and well-trained research assistants remained in the intervention rooms to provide guidance and assistance if needed. All groups in the same school received interventions concurrently to minimize the influence of the time factor.

Figure 3. Intervention in a classroom.





Trial Power and Sample Size

To ensure the sample size was sufficient to test the hypotheses, a small to medium effect size (Cohen d=0.33) was used based on prior research [15]. Power was set at 0.80, and α was set at .05. A final sample size of 584 (146 per arm) was required. Considering the attrition rate from our previous studies in school settings (<20%), the baseline recruitment target was set at 732 participants (183 per arm). We ultimately recruited 731 participants. As the number of participants in each class varied, the final number of participants in each of the 4 arms differed.

Measures

Primary Outcome

Anxiety symptoms, measured using the 7-item Generalized Anxiety Disorder (GAD-7) scale [28,29], were the primary outcome. The 7 items assessed whether anxiety symptoms had bothered the individual during the previous 2 weeks, with frequency ranging from 0 (not at all) to 3 (nearly every day). Example items included: "Feeling nervous, anxious, or on edge" and "Not being able to stop or control worrying." The GAD-7 is a self-rating scale that effectively reflects symptom severity correlated adolescents and is highly in with clinician-administered ratings of anxiety symptoms. It is brief and suitable for self-report studies [30]. The Cronbach α for the scale was 0.93 [31]. By summing the scores of the 7 items, the following classifications were used: 0-4 indicated the absence of anxiety symptoms, 5-9 indicated mild anxiety, 10-14 indicated moderate anxiety, and 15-21 indicated severe anxiety. Based on the severity of anxiety, participants were categorized into 2 groups: the high anxiety group (scores of 10-21) and the nonhigh anxiety group (scores of 0-9) in this study.

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Secondary Outcomes

The 9-Item Patient Health Questionnaire

The 9-item Patient Health Questionnaire (PHQ-9) [32,33] was used to assess participants' depression levels and suicidal/self-hurting thoughts over the previous 2 weeks, with frequency ranging from 0 (not at all) to 3 (nearly every day). The first 8 items (PHQ-8) were used to measure depression severity (sum of the 8 items), while the last item assessed suicidal/self-hurting thoughts. Responses of 1-3 on the last item were coded as "yes," and a response of 0 was coded as "no." Example items from the PHQ-9 included "Little interest or pleasure in doing things" and "Feeling down, depressed, or hopeless." The item assessing suicidal/self-hurting thoughts that you would be better off dead or of hurting yourself in some way."

Perceived Control

The Anxiety Control Questionnaire [34] is a 15-item tool that measures participants' perceived control over their anxiety. The Emotion Control subscale, 1 of the 3 validated subscales, consists of 5 items (eg, "I am able to control my level of anxiety"), including 1 reverse-scored item (When I am anxious, I find it hard to focus on anything other than my anxiety). Responses are rated from 0 (strongly disagree) to 5 (strongly agree). The sum of the 5 items indicates the level of perceived control. The Cronbach α was 0.73.

Hopelessness

The 4-item Helplessness subscale of the Demoralization Scale [35] was used to measure participants' outlook on the future. Each item was rated on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). The sum of the 4 items

was used to assess hopelessness, with a higher score indicating a correspondingly higher level of hopelessness. An example item was "I feel hopeless." The Cronbach α for the Chinese version of this Helplessness subscale was 0.72 [36].

Attitude Toward Seeking Help

We used 3 items from the Attitude Toward Seeking Counselling Help Assessment [37] to measure participants' understanding of counseling and attitudes toward seeking counseling help. Example items included "If I believed I was having a mental breakdown, my first inclination would be to get professional attention" and "Professional counseling and treatments can help people improve mental health." The Cronbach α was 0.72 [37]. Additionally, 2 items were used to assess participants' intention to seek help. The 2 items were "When I encounter difficulties, I will not ask for help from teachers" and "When I encounter difficulties, I will not ask for help from social workers/counselors." These 5 items were rated on a 7-point Likert scale, ranging from 1 (strongly disagree) to 7 (strongly agree). After reverse-scoring the 2 help-seeking intention items, the sum score of the 5 items represented participants' attitudes toward seeking help, with a higher score indicating more positive attitudes toward seeking help.

Psychological Well-Being

The short version of the 14-item Warwick-Edinburgh Mental Well-Being Scale (WEMWBS-14) [38,39] was used to measure the extent to which participants generally experienced well-being states. The WEMWBS-14 consists of 14 items, each rated on a 5-point Likert scale ranging from 1 (none of the time) to 5 (all of the time). The sum score of the 14 items indicated the participants' overall well-being level. An example item was "I have been feeling optimistic about the future." The scale's Cronbach α was 0.93.

Fidelity Checking and Intervention Feedback

Mindsets of Negative Emotions

The validated Chinese version of the 12-item Mindset of Depression, Anxiety, and Stress Scale (MDASS) was used to assess participants' beliefs regarding the changeability of negative emotional states, such as depression, anxiety, and stress [24]. Sample items included: "When you have a certain level of depression, you really cannot do much to change it," "To be honest, people cannot really change how anxious they are," and "No matter how hard people try, they cannot really change the level of stress that they have." Each item was scored on a 6-point Likert scale ranging from 1 (strongly disagree) to 6 (strongly agree); a higher score indicated a more fixed mindset toward negative emotions (Cronbach α =0.94). It included 3 subscales: depression mindset, anxiety mindset, and stress mindset, with 4 items in each subscale. The Cronbach α values for the 3 subscales were 0.91, 0.89, and 0.90, respectively [24]. By summing the total score, we defined fixed and growth mindsets using a cutoff score of 42, which was calculated by adding the midpoint (ie, 3.5) of the 6-point scale for the 12 items. Individuals scoring equal to or greater than 42 were considered to have more fixed mindsets, while those scoring below this cutoff were considered more inclined to have growth mindsets.

Mindset of Personality

Three items from implicit theories of personality [40,41] were used to measure the belief in the changeability of personality on a 6-point Likert scale, ranging from 1 (strongly disagree) to 6 (strongly agree). A higher score indicated a more fixed mindset of personality. A sample item was "People can do things differently, but the important parts of who they are can't really be changed." The Cronbach α was 0.85.

Motivation to Apply What Was Learned From the Program

In addition to the baseline assessment, immediately after the intervention, participants were asked to rate the extent to which they would like to apply the intervention content and improve their emotion regulation on a 6-point Likert scale (1-6), with a higher score indicating higher motivation. We defined high and low motivation groups based on the median cutoff after summing the 2 motivation items.

The Intervention Feedback Scale

This scale was developed based on the Theoretical Framework of Acceptability, which includes 7 component constructs: affective attitude, burden, intervention coherence, perceived effectiveness, opportunity costs, self-efficacy, and ethicality [42]. A general acceptability item, 6 items corresponding to the 6 components of the Theoretical Framework of Acceptability (excluding ethicality), and 4 items-including an open-ended written feedback item-were integrated to comprehensively assess the acceptability of the intervention. These items were drawn from the well-validated Program Feedback Scale [43]. For the Feedback Scale, except for the open-ended item, the other 10 items were assessed on a 5-point scale (eg, "How acceptable was the intervention to you?" with responses ranging "1=completely unacceptable" to "5=completely from acceptable"). The Feedback Scale was administered immediately after the intervention.

Attention-Checking Items

To ensure data quality and assess participant attention, 2 attention-checking items were included at all assessment points (baseline and follow-up surveys). These items directly instructed participants to select a specific option based on the given instructions. A sample question was "Please select 'strongly agree' for this item."

Sociodemographic Information

Sociodemographic information of participants was collected at baseline to examine group variability in factors such as gender, age, grade, ethnicity, and socioeconomic status (SES).

Data Analysis

We used an intention-to-treat approach in our primary analysis, where all participants who consented to participate were included. Participants who completed all assessments and passed both attention-checking items at each assessment point were classified in the per-protocol population. A per-protocol analysis was conducted as a sensitivity analysis. Multilevel modeling was used to account for the cluster randomization of classes within the same school [44]. All percentages and scores were presented with 1 decimal place. To examine the effects of the interventions, generalized estimating equations were used to

test the group effect, time effect, and their interaction effect on outcome measures. A statistically significant interaction effect indicated the effectiveness of the treatments. Additionally, we calculated effect sizes using estimated marginal means. These effect sizes, expressed as Cohen d, compared mean gain scores reflecting changes in each outcome from baseline to the 2 follow-ups for youth receiving the mindset versus active control interventions. The effect sizes were also compared between participants in the intervention group who received booster messages and those who did not. Additionally, we tested the following moderators on the effectiveness of the treatment for the primary and secondary outcomes: baseline anxiety level (dichotomized by the severity of GAD-7), motivation for change (dichotomized by the median of the sum motivation score on the 2 motivation items), and mindset group (fixed vs growth). The corrected quasi-likelihood under the independence model criterion (QICC) for the models with and without the moderator was examined, with evidence of a moderation effect indicated

by a smaller QICC for the models including the moderator. Multiple comparisons were not conducted, and a *P* value of <.05 was considered statistically significant. Data analysis was performed using SPSS version 26 (IBM Corp.).

Results

Recruitment

Figure 4 depicts the CONSORT (Consolidated Standards of Reporting Trials) diagram of the recruitment and participation flow (also see Multimedia Appendix 1). A total of 731 participants were recruited and randomized into 4 groups: SIGMA-Booster (n=172, 23.5%), SIGMA (n=211, 28.9%), SSIGP (n=154, 21.1%), and ST (n=194, 26.5%). All participants received the interventions and were contacted for follow-ups. All participants were included in the intention-to-treat analysis. No participants explicitly requested to be removed from the trial.

Figure 4. CONSORT (Consolidated Standards of Reporting Trials) flowchart. SIGMA: single-session intervention of a growth mindset for anxiety; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.





Baseline Characteristics of Participants

Table 1 summarizes the baseline characteristics of the recruited participants. Of the 731 participants, 421 (57.6%) were girls. Statistical differences in grade and age were observed among the 4 groups, as some schools selected classes from 2 different grades. However, there were no statistical differences in ethnicity or SES.

There were no significant differences between the intervention groups on the primary and secondary outcome measures at baseline: anxiety symptoms, $F_{3,727}=0.25$, P=.86; depressive symptoms, $F_{3,727}=0.13$, P=.94; suicidal/self-hurting thoughts, χ^2_3 (N=731)=3.66, P=.30; perceived control, $F_{3,727}=0.31$, P=.82; hopelessness, $F_{3,727}=0.74$, P=.53; attitude toward seeking help, $F_{3,727}=0.61$, P=.61; and psychological well-being, $F_{3,727}=0.63$, P=.60.



 Table 1. Sample characteristics.

Variables	SIGMA-Booster ^a (n=172)	SIGMA ^b (n=211)	SSIGP ^c (n=154)	ST ^d (n=194)	Overall (N=731)	P value
Age					•	<.001
Mean (SD)	14.0 (0.9)	14.0 (1.0)	14.5 (1.5)	13.8 (0.8)	14.1 (1.1)	
Range	12-16	12-18	12-20	12-18	12-20	
Missing, n (%)	0 (0)	1 (0.5)	0 (0)	0 (0)	1 (0.1)	
Gender, n (%)						.005
Male	55 (32.0)	94 (44.5)	64 (41.6)	97 (50.0)	310 (42.4)	
Female	117 (68.0)	117 (55.5)	90 (58.4)	97 (50.0)	421 (57.6)	
Ethnicity, n (%)						.67
Chinese	168 (97.7)	204 (96.7)	152 (98.7)	189 (97.4)	713 (97.5)	
Other	4 (2.3)	7 (3.3)	2 (1.3)	5 (2.6)	18 (2.5)	
Grade, n (%)						<.001
Secondary 2	80 (46.5)	99 (46.9)	59 (38.3)	135 (69.6)	373 (51.0)	
Secondary 3	92 (53.5)	112 (53.1)	69 (44.8)	59 (30.4)	332 (45.4)	
Secondary 5	0 (0)	0 (0)	26 (16.9)	0 (0)	26 (3.6)	
Socioeconomic status, n (%)						.75
Low	0 (0.0)	1 (0.5)	1 (0.6)	0 (0)	2 (0.3)	
Medium	139 (80.8)	172 (81.5)	120 (77.9)	151 (77.8)	582 (79.6)	
High	33 (19.2)	38 (18.0)	33 (21.4)	43 (22.2)	147 (20.1)	
Willingness to participate in emotional control course (1-6), mean (SD)	3.5 (1.3)	3.5 (1.3)	3.3 (1.3)	3.4 (1.4)	3.4 (1.3)	.69
Willingness to improve emotional con- trol (1-6), mean (SD)	4.2 (1.3)	4.0 (1.2)	4.0 (1.3)	4.0 (1.4)	4.0 (1.3)	.46
Mindset of anxiety (4-24), mean (SD)	14.6 (4.2)	13.8 (4.6)	14.5 (4.6)	13.7 (4.7)	14.1 (4.5)	.17
Mindset of depression (4-24), mean (SD)	13.6 (4.9)	12.8 (5.2)	13.4 (5.0)	12.8 (5.2)	13.1 (5.1)	.32
Mindset of stress (4-24), mean (SD)	15.5 (4.8)	14.3 (5.0)	14.6 (5.2)	14.9 (5.4)	14.8 (5.1)	.14
Mindset of personality (3-18), mean (SD)	13.5 (3.2)	13.0 (3.5)	13.0 (3.2)	13.1 (3.5)	13.1 (3.4)	.51
7-item Generalized Anxiety Disorder (0- 21), mean (SD)	6.9 (5.1)	6.6 (5.4)	7.0 (5.1)	6.9 (5.8)	6.8 (5.4)	.86
8-item Patient Health Questionnaire-8 (0-24), mean (SD)	7.3 (5.6)	7.1 (5.7)	7.2 (5.4)	7.4 (5.6)	7.2 (5.6)	.94
Anxiety Control Questionnaire—Emo- tion Control (0-25), mean (SD)	13.6 (5.0)	13.5 (4.9)	13.7 (4.8)	13.2 (5.4)	13.5 (5.0)	.82
Demoralization Scale—Helplessness (4-20), mean (SD)	9.8 (3.6)	10.2 (4.0)	9.6 (3.8)	9.9 (4.0)	9.9 (3.9)	.53
Attitude Toward Seeking Help (5-35), mean (SD)	19.3 (4.6)	19.3 (5.6)	18.7 (5.2)	19.4 (5.6)	19.2 (5.3)	.61
Warwick-Edinburgh Mental Well-Being Scale (14-70), mean (SD)	41.7 (9.9)	42.3 (11.0)	43.1 (10.8)	43.0 (11.0)	42.5 (10.7)	.60
Suicidal/self-hurting thoughts, n (%)						.30
Yes	53 (30.8)	78 (37.0)	50 (32.5)	55 (28.4)	236 (32.3)	
No	119 (69.2)	133 (63.0)	104 (67.5)	139 (71.6)	495 (67.7)	

^aSIGMA-Booster: SIGMA with boosters.

^bSIGMA: single-session intervention of a growth mindset for anxiety.

^cSSIGP: single-session intervention of a growth mindset of personality.

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^dST: support therapy.

Changes in Primary and Secondary Outcomes

For the primary outcome, we found a significant main effect of time (P<.001), but no significant main effect of group (P=.88) or group-by-time interaction (P=.54). Participants in all 4 intervention groups showed significant improvement in anxiety symptoms at both the 2- and 8-week follow-ups: $P_{2 \text{ weeks}}$ =.02 and $P_{8 \text{ weeks}}$ =.02 for SIGMA-Booster; $P_{2 \text{ weeks}}$ =.006, $P_{8 \text{ weeks}}$ <.001 for SIGMA; $P_{2 \text{ weeks}}$ <.001, $P_{8 \text{ weeks}}$ <.001 for SSIGP,

and $P_{2 \text{ weeks}}$ <.001, $P_{8 \text{ weeks}}$ =.003 for ST. This improvement was sustained at the 8-week follow-up, and no significant differences were observed between the 2- and 8-week follow-ups: P=.99 for SIGMA-Booster, P=.17 for SIGMA, P=.46 for SSIGP, and P=.59 for ST (Multimedia Appendix 2 and Figure 5). When comparing the changes from baseline to follow-up between each pair of groups, the SSIGP intervention appeared to be more effective than SIGMA (including SIGMA and SIGMA-Booster) in reducing general anxiety symptoms. However, the effect sizes ranged from very small to small (Table 2).

Figure 5. The 7-item Generalized Anxiety Disorder scale (total score) changes over time. Each dot represents the mean score of each group at each time point. Each line around the dot represents the 95% Wald CI of the mean. SIGMA: single-session intervention of a growth mindset for anxiety; SIGMA-B: SIGMA-Booster; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.





 Table 2. Effect sizes^a of the treatment and intention-to-treat population.

Outcome variables	2-week follow-up, Cohen d (SE)	8-week follow-up, Cohen <i>d</i> (SE)
7-item Generalized Anxiety Disorder		
SIGMA-Booster ^b versus SIGMA ^c	-0.02 (0.12)	0.06 (0.12)
SIGMA-Booster versus SSIGP ^d	0.13 (0.13)	0.08 (0.13)
SIGMA-Booster versus ST ^e	0.06 (0.13)	0.03 (0.13)
SIGMA versus SSIGP	0.14 (0.15)	0.02 (0.15)
SIGMA versus ST	0.08 (0.15)	-0.03 (0.15)
SSIGP versus ST	-0.06 (0.15)	-0.05 (0.15)
8-item Patient Health Questionnaire		
SIGMA-Booster versus SIGMA	0.06 (0.13)	0.01 (0.13)
SIGMA-Booster versus SSIGP	0.10 (0.13)	-0.03 (0.13)
SIGMA-Booster versus ST	0.06 (0.13)	-0.04 (0.13)
SIGMA versus SSIGP	0.04 (0.15)	-0.04 (0.15)
SIGMA versus ST	-0.002 (0.15)	-0.05 (0.15)
SSIGP versus ST	-0.05 (0.16)	-0.01 (0.16)
Suicidal/self-hurting thoughts		
SIGMA-Booster versus SIGMA	0.20 (0.13)	0.18 (0.13)
SIGMA-Booster versus SSIGP	0.18 (0.13)	0.27 (0.13)
SIGMA-Booster versus ST	0.03 (0.13)	0.04 (0.13)
SIGMA versus SSIGP	-0.02 (0.15)	0.09 (0.15)
SIGMA versus ST	-0.17 (0.15)	-0.14 (0.15)
SSIGP versus ST	-0.15 (0.15)	-0.23 (0.15)
Anxiety Control Questionnaire—Emotion Control		
SIGMA-Booster versus SIGMA	-0.004 (0.13)	-0.01 (0.13)
SIGMA-Booster versus SSIGP	-0.03 (0.13)	0.05 (0.14)
SIGMA-Booster versus ST	-0.14 (0.13)	-0.26 (0.13)
SIGMA versus SSIGP	-0.03 (0.15)	0.06 (0.15)
SIGMA versus ST	-0.13 (0.15)	-0.25 (0.15)
SSIGP versus ST	-0.10 (0.15)	-0.31 (0.16)
Demoralization Scale—Helplessness		
SIGMA-Booster versus SIGMA	0.24 (0.13)	0.16 (0.12)
SIGMA-Booster versus SSIGP	0.07 (0.13)	0.05 (0.12)
SIGMA-Booster versus ST	0.20 (0.13)	0.08 (0.13)
SIGMA versus SSIGP	-0.18 (0.15)	-0.11 (0.15)
SIGMA versus ST	-0.04 (0.15)	-0.08 (0.15)
SSIGP versus ST	0.14 (0.15)	0.03 (0.15)
Attitude Toward Seeking Help		
SIGMA-Booster versus SIGMA	-0.03 (0.11)	0.05 (0.11)
SIGMA-Booster versus SSIGP	-0.15 (0.11)	-0.05 (0.12)
SIGMA-Booster versus ST	-0.12 (0.12)	0.08 (0.12)
SIGMA versus SSIGP	-0.12 (0.14)	-0.09 (0.14)
SIGMA versus ST	-0.09 (0.14)	0.03 (0.14)

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Outcome variables	2-week follow-up, Cohen d (SE)	8-week follow-up, Cohen d (SE)
SSIGP versus ST	0.04 (0.14)	0.12 (0.15)
Warwick-Edinburgh Mental Well-Being Scale		
SIGMA-Booster versus SIGMA	0.02 (0.12)	0.02 (0.13)
SIGMA-Booster versus SSIGP	0.02 (0.13)	0.10 (0.13)
SIGMA-Booster versus ST	-0.08 (0.12)	-0.11 (0.13)
SIGMA versus SSIGP	-0.003 (0.16)	0.08 (0.16)
SIGMA versus ST	-0.10 (0.15)	-0.13 (0.16)
SSIGP versus ST	-0.10 (0.16)	-0.21 (0.15)

^aEffect size values were calculated by subtracting the latter group's mean gain score from the former group's mean gain score for each outcome from baseline to the 2- and 8-week follow-ups, then dividing by the pooled SD of all participants at baseline.

^bSIGMA-Booster: SIGMA with boosters.

^cSIGMA: single-session intervention of a growth mindset for anxiety.

^dSSIGP: single-session intervention of a growth mindset of personality.

^eST: support therapy.

For the secondary outcomes, all the main effects of time were significant, while the main effects of group and the interaction effects of group and time were insignificant (main effects of group: P=.87 for depressive symptoms; P=.41 for suicidal/self-hurting thoughts; P=.97 for perceived control; P=.73 for hopelessness; P=.87 for help-seeking attitude; P=.39for psychological well-being and interaction effects; P=.85 for depressive symptoms; *P*=.10 for suicidal/self-hurting thoughts; P=.20 for perceived control; P=.23 for hopelessness; P=.33 for help-seeking attitude; and P=.68 for psychological well-being), similar to the primary outcome. Specifically, the results for depressive symptoms mirrored those for anxiety (main effect of time, P < .001 and main effect of group, P = .87). All 4 groups showed a reduction in depressive symptoms at follow-ups, and the effects observed at the 8-week follow-up were comparable to those at the 2-week follow-up (see Multimedia Appendix 2 and Figure 6). Moreover, the effect sizes for the comparison between groups on the changes from baseline to follow-ups were all very small (Table 2). Second, a significant main effect of time was found for suicidal/self-hurting thoughts (P=.005), but the main effect of group was not significant (P=.41). Specifically, the SIGMA group showed a reduction in suicidal/self-hurting thoughts at both the 2- and 8-week follow-ups, with the effect sustained at the 8-week follow-up compared with the 2-week follow-up. The SSIGP group showed a significant reduction in suicidal/self-hurting thoughts at the 8-week follow-up (P<.001), but not at the 2-week follow-up (P=.14). The other 2 groups did not report significant changes in suicidal/self-hurting thoughts at either follow-up with P_2 weeks=.50, $P_{8 \text{ weeks}}$ =.96 for SIGMA-Booster and $P_{2 \text{ weeks}}$ =.75, P_{8} weeks=.61 for ST (see Multimedia Appendix 2 and Figure 7). Both the SIGMA and SSIGP interventions appeared to be more effective in reducing suicidal/self-hurting thoughts than the SIGMA-Booster and ST, although the effect sizes were small (Table 2). For the other secondary outcomes, the main effects of time were significant for all variables (for perceived control, P=.03; for hopelessness, P<.001; for help-seeking attitude,

P<.001; and for psychological well-being, P<.001). However, the main effects of the group were not significant (P values ranged from .39 to .97). For perceived control, only the ST group reported significant improvement at both the 2- and 8-week follow-ups (P_2 weeks=.02, P_8 weeks=.007). The ST intervention appeared to be more effective than the other 3 groups in improving perceived control, though the effect sizes were small (Table 2). For hopelessness, both the SIGMA and ST groups showed significant improvement at both the 2-week (P<.001 for SIGMA and P<.001 for ST) and 8-week follow-ups (P=.001 for SIGMA and P=.005 for ST), while the SSIGP group only reported significant improvement at the 8-week follow-up (P=.02). The SIGMA group seemed to outperform the SIGMA-Booster group in reducing hopelessness, although the effect sizes were small (Table 2). For help-seeking attitude, both the SIGMA-Booster and SSIGP groups reported significant improvement at both the 2-week (P=.01 for SIGMA-Booster and P < .001 for SSIGP) and 8-week follow-ups (P = .01 for SIGMA-Booster and P=.003 for SSIGP), while the SIGMA and ST groups showed significant improvement only at the 2-week follow-up (P=.006 for SIGMA and P<.001 for ST). For psychological well-being, the ST group showed significant improvement at both the 2- and 8-week follow-ups with P=.01and P<.001, respectively, while the SIGMA-Booster and SIGMA groups demonstrated significant improvement only at the 8-week follow-up with P=.02 (Multimedia Appendix 2). The effect sizes for changes in attitude toward seeking help and psychological well-being were all very small between groups. The only effect size that reached a small magnitude (>0.2) was for the improvement in psychological well-being at the 8-week follow-up, where the ST group showed greater improvement compared with the SSIGP group (Table 2).

The sensitivity analysis conducted for the per-protocol population showed results similar to those of the intention-to-treat population. The specific results of the sensitivity analysis can be found in Multimedia Appendix 3.



Figure 6. The 8-item Patient Health Questionnaire scale (total score) changes over time. Each dot represents the mean score of each group at each time point. Each line around the dot represents the 95% Wald CI of the mean. SIGMA: single-session intervention of a growth mindset for anxiety; SIGMA-B: SIGMA-Booster; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.



Figure 7. The proportion of participants with suicidal/self-hurting thoughts changes over time. Each dot represents the mean score of each group at each time point. Each line around the dot represents the 95% Wald CI of the mean. SIGMA: single-session intervention of a growth mindset for anxiety; SIGMA-B: SIGMA-Booster; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.



Moderation Analysis

We conducted moderation analyses based on baseline anxiety (high/low), motivation to change (high/low), and mindset (growth mindset vs fixed mindset). Including these moderation factors improved model fit, as indicated by the decreases in QICC, ranging from 210 to 31,519.23. This was true for all outcomes, except for suicidal/self-hurting thoughts when motivation level was used as the moderator. These results indicate that baseline anxiety level and mindset had moderating

effects on all outcome measures, while motivation level moderated all outcomes except for suicidal/self-hurting thoughts. Participants with higher baseline anxiety, greater motivation to change their situation, and a more fixed baseline mindset showed greater improvements in the outcome measures (see Multimedia Appendices 4-6 for details).

Intervention Feedback

Participants' feedback on the SSIs is detailed in Table 3. Most participants reported understanding (536/731, 73.3%) and
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agreeing (504/731, 68.9%) with the intervention content. More than half found the intervention helpful (465/731, 63.6%) and interesting (417/731, 57.0%). Some indicated that they liked the course (404/731, 55.2%) and expressed a willingness to recommend it to others (402/731, 55.9%). Additionally, 437 out of 731 (59.8%) reported increased confidence in their ability to cope with emotions following the intervention. Meanwhile,

very few found this course burdensome (28/731, 3.8%) or interfering (70/731, 9.58%). The findings showed that 459 out of 731 (62.8%) participants indicated that they accept or highly accept the intervention. However, about 237 (32.4%) participants were neutral, indicating that there is still significant room for improvement.

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Variables	SIGMA-Booster ^a (n=172), n (%)	SIGMA ^b (n=211), n (%)	SSIGP ^c (n=154), n (%)	ST ^d (n=194), n (%)	Overall (N=731), n (%)
Like this course	93 (54.1)	113 (53.6)	87 (56.5)	111 (57.2)	404 (55.3)
Understand this course	124 (72.1)	149 (70.6)	116 (75.3)	147 (75.8)	536 (73.3)
This course is useful	104 (60.5)	128 (60.7)	102 (66.2)	131 (67.5)	465 (63.6)
Recommend this course to others	92 (53.5)	117 (55.5)	81 (52.6)	112 (57.7)	402 (55.0)
This course is interesting	91 (52.9)	113 (53.6)	88 (57.1)	125 (64.4)	417 (57.0)
Agree with this course	115 (66.9)	143 (67.8)	106 (68.8)	140 (72.2)	504 (68.9)
Emotional control improved after this course	100 (58.1)	128 (60.7)	85 (55.2)	124 (63.9)	437 (59.8)
Burden in joining this course	9 (5.2)	6 (2.8)	5 (3.2)	8 (4.1)	28 (3.8)
Affect other arrangement due to joining this course	20 (11.6)	15 (7.1)	16 (10.4)	19 (9.8)	70 (9.6)
Acceptance to this course	103 (59.9)	127 (60.2)	110 (71.4)	119 (61.3)	459 (62.8)

^aSIGMA-Booster: SIGMA with boosters.

^bSIGMA: single-session intervention of a growth mindset for anxiety. ^cSSIGP: single-session intervention of a growth mindset of personality. ^dST: support therapy.

Discussion

Overview

Contrary to our hypotheses, we found that all 4 SSIs, including ST, significantly reduced general anxiety symptoms and improved some secondary outcomes. Although the core messages delivered in approximately 40 minutes differed among these interventions, nearly all improvements in the 4 groups were sustained from the 2-week to the 8-week follow-ups. These findings provide evidence for the effectiveness of low-dosage nonpharmacological interventions in improving youth mental health outcomes. SIGMA, which enhances the belief in change regarding negative emotions, showed an intervention effect on all outcome measures except perceived control. The SSIGP, targeting personality mindset, was more effective in reducing self-harm and suicidal thoughts. ST had a greater effect on perceived control. Surprisingly, the SIGMA-Booster group, which received booster messages, did not achieve better results than the SIGMA group. By contrast, the SIGMA group outperformed the SIGMA-Booster group in outcomes such as reducing suicidal and self-harming thoughts as well as hopelessness. The SIGMA interventions were not more effective than SSIGP, particularly in the primary outcome of reducing anxiety symptoms. Moreover, the ST intervention was especially effective in improving perceived control, outperforming the other 3 interventions. Moderation tests revealed that some adolescents benefited more from the interventions. Consistent with our hypotheses on moderation effects, participants showed

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greater improvement if they had more severe anxiety symptoms, stronger baseline fixed mindsets, and a greater motivation to change. Although the effect sizes for group comparisons on outcome changes were small, it is encouraging that SSIs produced sustained outcomes over 8 weeks.

Our findings align closely with existing research on SSIs for youth psychiatric problems. A previous meta-analysis by Schleider and Weisz [14] found that a young person receiving an SSI had a 58% likelihood of performing better than a youth in the control group. The effect sizes varied depending on the control conditions, with larger effect sizes observed in studies with no-treatment or waitlist controls (0.41) compared with those with active controls (0.14). In our study, the effect sizes for SIGMA versus SSIGP at the 2-week follow-up were approximately 0.14 (SIGMA vs SSIGP: 0.14 and SIGMA-Booster vs SSIGP: 0.13), while the effect sizes for SIGMA versus ST were smaller. The finding that SSIs were effective for multiple outcomes, including anxiety and depression symptoms, aligns with a recent umbrella review on SSIs, which showed that over 80% of reviews reported significant positive effects on at least one outcome [21]. In summary, our study provides additional evidence supporting the modest yet significant clinical utility of certain SSIs for youth, including those targeting anxiety symptoms [21].

The design of the interventions and the implementation of the RCT for SSIs provided valuable insights and implications for local practice. Generally, these SSIs were designed following recommended guidelines to ensure the efficacy of brief

interventions [45-47]. First, we formed a youth advisory group to ensure the content was relevant to the target users. Second, we incorporated cartoons and animated videos into the intervention. The cartoon heroine, "Hong Dou" (the Red Bean), and her friends were created by artists and digital designers to make the animations and videos more engaging. As a result, the intervention videos effectively captured participants' attention. Third, because SSIs should be highly focused on delivering 1 or a few core messages, each SSI in our study conveyed a single core message to participants. We reinforced learning through multiple methods, including examples, testimonials, authoritative research findings, and saying-is-believing exercises. Fourth, to ensure active participation in the online web-based intervention, we embedded it in the Qualtrics survey tool and included interactive exercises after each session. Participants received timely feedback on these exercises. Feedback from participants indicated that the SSIs in our study were well-suited to adolescents' needs and expectations for mental health care. This study provides a clear protocol for implementation, including content and strategies, which will be valuable for the future use and development of SSIs.

This study is a pioneering investigation into web-based SSIs among Chinese adolescents. The efficacy of SSIs, particularly self-administered web-based interventions, has been understudied. This study examined the effects of SSIs on mental health among Chinese adolescents using a cluster RCT design. The 4 conditions in this study showed improvements in mental health over 2 weeks, with the effects sustained after 8 weeks. There were no significant group differences among the 4 conditions. As the interventions were implemented at different times across the academic year in different schools, any potential school schedule effects were minimized. On the one hand, these results suggest that providing low-dosage self-help interventions may help adolescents gain insights and strategies for managing their emotions and coping. On the other hand, an RCT with an added waitlist control group would be valuable for further testing the effectiveness of the intervention.

The SIGMA-Booster group did not show a better effect at the 8-week follow-up. There may be several reasons for this. First, there may be no difference between the booster and nonbooster groups. If an SSI has instilled changes in the emotional mindset, those changes could be long-lasting. Second, the booster group might have a greater effect in the longer term, so a more extended follow-up would be necessary to capture any differences between the booster and nonbooster groups. Third, the booster design in this study may not have been effective. Future studies should carefully examine the format and content of booster interventions.

This study makes several significant contributions. First, the SSIs developed and tested with an RCT could serve as an alternative mental health service for adolescents. Although the effect size of the SSI was small, it can benefit a proportion of youth who would otherwise go without services. It can also support youth on the waitlist for psychiatric services by fostering intrinsic motivation and reducing hesitation to seek treatment. It can also complement multisession psychosocial treatments

[21]. Second, these SSIs expanded existing mindset interventions to include emotional mindset and adapted them to the Chinese context. This project may provide a generalizable model for the development and implementation of SSIs for youth in the Chinese context. Third, this study initiated the development and evaluation of boosters for SSIs. Although we did not find significant differences among the groups, the findings of this study could serve as a foundation for further research. In summary, the easy-access self-help program enables adolescents with anxiety symptoms to receive timely help and may help reduce the risk of worsening anxiety symptoms and the development of comorbid mental health issues before they can access therapy from a trained therapist or psychiatrist.

Limitations

There are limitations to consider. First, because this study did not exclude individuals based on the severity of their anxiety symptoms, the efficacy of the interventions in reducing anxiety symptoms among students without anxiety or with very low levels of anxiety may not have been significant, potentially affecting the overall statistical significance. However, future RCT studies could examine the differentiated impacts on youth across a broader range of anxiety problems through subgroup analyses. In this study, we simply divided participants into 2 groups (high baseline anxiety and low baseline anxiety) and examined the moderation effects. Second, there was no waitlist control group, as all groups received specific interventions, with even the control group receiving ST (active control). Adding a waitlist control group would help provide a better understanding of the overall effect of SSIs. Third, although we used cluster randomization at the classroom level to balance the risk of contamination between groups and school heterogeneity, and employed multilevel modeling to account for the clustering of classes within the same school, it was still challenging to completely eliminate the risk of contamination. Students in different classes may interact and share information about their interventions, which could potentially influence the outcomes. Fourth, the study only included a follow-up period of 8 weeks, which may not have allowed us to capture the long-term effects. Future studies with a longer follow-up period will be necessary to better understand the sustained impact of the interventions.

Conclusions

This study presents evidence-based implementation of web-based single-session growth mindset interventions for adolescent anxiety and compares the efficacy of SSIs using growth mindsets on negative emotions and personality, along with an active control group. The findings support that the easy-access self-help program led to improvements in adolescent anxiety, depression, and suicidal and self-harm thoughts at the 8-week follow-up. These interventions may enable adolescents with anxiety symptoms to access timely help, reducing the risk of worsening anxiety symptoms and the development of comorbid mental health issues before they can access therapy from a trained therapist or psychiatrist. This study also provides an example of implementing SSIs among Chinese adolescents and will contribute to the development of easy-access, low-cost, and scalable interventions for mental health promotion among young people.

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Data Availability

Data are not publicly available but can be obtained for proper purposes by contacting the corresponding author.

Authors' Contributions

SZ designed the intervention and the evaluation study initially. YH assisted in the intervention design and implementation. SZ and DQ drafted the first draft of the report. PL contributed to the data analysis plan. ST, KLC, QC, and JS provided comments and revised the first draft. SZ developed all aspects of the proposal and manuscript related to the implementation of intervention and data collection. All authors edited and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1 CONSORT-eHEALTH checklist (V 1.6.1). [PDF File (Adobe PDF File), 2556 KB - pediatrics_v8i1e63500_app1.pdf]

Multimedia Appendix 2 Generalized estimating equation results for the intention-to-treat population. [DOCX File, 23 KB - pediatrics v8i1e63500 app2.docx]

Multimedia Appendix 3

Generalized estimating equation results for the per-protocol population—presented as estimated marginal means (SE). [DOCX File, 33 KB - pediatrics_v8i1e63500_app3.docx]

Multimedia Appendix 4 Moderating effect of baseline anxiety levels on treatment outcomes. [DOCX File , 53 KB - pediatrics v8i1e63500 app4.docx]

Multimedia Appendix 5

Moderating effect of baseline motivation levels on treatment outcomes. [DOCX File , 52 KB - pediatrics v8i1e63500 app5.docx]

Multimedia Appendix 6

Moderating effect of baseline growth mindset levels on treatment outcomes. [DOCX File, 50 KB - pediatrics_v8i1e63500_app6.docx]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials GAD-7: 7-item Generalized Anxiety Disorder MDASS: Mindset of Depression, Anxiety, and Stress Scale PHQ-9: 9-item Patient Health Questionnaire QICC: Corrected Quasi-Likelihood under the Independence Model Criterion SES: socioeconomic status SIGMA: single-session intervention of a growth mindset for anxiety SSI: single-session intervention SSIGP: single-session intervention of a growth mindset of personality WEMWBS-14: 14-item Warwick-Edinburgh Mental Well-Being Scale

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Original Paper

Developing Digital Mental Health Tools With Culturally Diverse Parents and Young People: Qualitative User-Centered Design Study

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Abstract

Background: Approximately 39% of young people (aged 16-24 y) experience mental ill health, but only 23% seek professional help. Early intervention is essential for reducing the impacts of mental illness, but young people, particularly those from culturally diverse communities, report experiencing shame and stigma, which can deter them from engaging with face-to-face services. Digital mental health (DMH) tools promise to increase access, but there is a lack of literature exploring the suitability of DMH tools for culturally diverse populations.

Objective: The project was conducted in partnership with a large-scale national DMH organization that promotes evidence-based early intervention, treatment, and support of mental health in young people and their families. The organization wanted to develop a self-directed web-based platform for parents and young people that integrates psychological assessments and intervention pathways via a web-based "check-in" tool. Our project explored the views of culturally diverse parents and young people on the opportunities and barriers to engagement with a web-based DMH screening tool.

Methods: We conducted a 2-phase qualitative study aiming to identify potential issues faced by culturally diverse communities when engaging with DMH tools designed for the Australian public. We worked with 18 culturally diverse participants (parents: n=8, 44%; young people: n=10, 56%) in a series of design-led workshops drawing on methods from speculative design and user experience to understand the opportunities and barriers that organizations might face when implementing population-level DMH tools with culturally diverse communities. NVivo was used to conduct thematic analyses of the audio-recorded and transcribed workshop data.

Results: Five themes were constructed from the workshops: (1) trust in the use and application of a DMH tool, (2) data management and sharing, (3) sociocultural influences on mental health, (4) generational differences in mental health and digital literacy, and (5) stigma and culturally based discrimination in mental health support.

Conclusions: The emergent themes have important considerations for researchers wishing to develop more inclusive DMH tools. The study found that healthy parent-child relationships will increase engagement in mental health support for young persons from culturally diverse backgrounds. Barriers to engagement with DMH tools included culturally based discrimination, the influence of culture on mental health support, and the potential impact of a diagnostic label on help seeking. The study's findings

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suggest a need for culturally safe psychoeducation for culturally diverse end users that fosters self-determination with tailored resources. They also highlight important key challenges when working with culturally diverse populations.

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KEYWORDS

digital mental health; young people; cultural diversity; web-based and mobile health interventions; qualitative methods; user-centered design; human-computer interaction

Introduction

Background

Approximately 13% of the global population living with mental health problems are young people (aged 16-24 y) [1]. Young people with mental health disorders also experience higher rates of morbidity and mortality risk than the general population, leading to a 10- to 20-year reduction in life expectancy [2,3]. These rates were compounded during the COVID-19 pandemic, during which globally 1 in 4 young people experienced clinically elevated levels of depression, and 1 in 5 experienced clinically elevated levels of anxiety [4]. Nevertheless, during this period, there was no concurrent increase in the uptake of mental health support [5]. For young people, untreated mental health problems can have long-lasting impacts due to the important social, emotional, and cognitive developmental changes that are being experienced simultaneously [6].

Cultural Diversity in the Context of Australia

Australia is a culturally diverse society, with 27.6% of its population born overseas [1]. This diversity spans across differences in cultural identity, language, country of birth, religion, heritage, and national origin [7]. Shaped by a legacy of colonialism, racial inequality has influenced Australia and its relationship with racial and ethnic minority immigrants [8] and First Nations peoples [9].

Studies have identified higher rates of mental ill-health among culturally diverse groups compared to the broader Australian population [10,11]. This is, in part, due to mental health risk factors, such as language barriers, cultural adjustment, the loss of family connection, and an inability to apply knowledge and occupational skills to attain meaningful employment, all of which hinder active participation in society for people from culturally diverse backgrounds [12]. Young people from culturally diverse backgrounds tend to be the most reluctant to seek help, and if they do, they typically turn to informal sources such as family, friends, and elders [13,14]. Among those who have sought professional support, many report that the types of support they were offered were inaccessible, culturally inappropriate, or lacking cultural relevance [15-17].

Common barriers to mental health care for culturally diverse communities include a lack of information and knowledge about available services, language differences, culturally specific conceptions of mental health, and lengthy waitlists [18-22]. Discrimination can be experienced throughout a person's mental health journey, with studies showing that culturally diverse people are far less likely to engage in mental health visits or seek specialist care than White ethnic groups [23]. Research has also found that clinicians are less likely to involve culturally

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diverse patients in friendly discussions or include them in the treatment decision-making process [24]. Instead, people from culturally diverse backgrounds tend to access mental health services through clinical emergency services during an acute crisis rather than accessing early interventions before the problem is severe, hindering their prospect of recovery [25,26]. People from culturally diverse backgrounds in Australia also experience more involuntary hospital admissions for mental health treatment [16].

Current Landscape of Digital Mental Health Tools and Opportunities

Digital mental health (DMH) tools (eg, apps and web-based services) delivered through smartphones [27-31], computers [32,33], and wearable devices [34,35] hold promise for overcoming many of the aforementioned barriers [36]. DMH tools can include self-directed online interventions [37,38], mental health screenings or "check-ins" to assess mental health status [39], digital health apps that allow the real-time monitoring of mental health [40,41], chatbots to support help seeking [42], and even interventions on specialist technologies such as virtual reality headsets [43,44]. Studies have shown that young people and parents prefer digital treatment over face-to-face care [45,46]. DMH tools offer easily accessible, low-cost services to address common mental health problems [47,48]. Self-directed DMH tools may offer alternative or complementary options to face-to-face clinical care, with the potential to provide support to people on waitlists for clinical care in remote locations or those who may not have the financial means to seek face-to-face treatment [43]. There is increasing interest in developing culturally sensitive DMH tools [17,49], with some DMH apps and online platforms being designed especially for ethnically diverse groups [50]. However, such examples remain limited; moreover, considerations of diversity, equity, and inclusion are rarely integrated into their design or evaluation [51].

Online self-screening tools provide useful information about self-reported mental health symptoms, offering clinical cutoffs to indicate when further assessment or support is needed, along with relevant resources for support. They also allow anonymous pathways for disclosing mental health symptoms and offer digital interventions [4,52,53] that have been shown to be fundamental for the mental health journey of culturally diverse users because digital interventions and resources are more likely to reach culturally diverse populations who may not have access to or are not yet engaging in mental health support [54]. Large-scale DMH platforms that incorporate screening, access to online clinicians, self-directed resources, and curated suites of trusted apps are increasingly being adopted by public health organizations across Western contexts (eg, the UK National

Health Service's Talking Therapies program) [48]. However, while these public-facing DMH tools are intended for use by all of society, they tend to be designed by and for the dominant Western culture [55].

In addition, DMH tools hold the potential for supporting mental health beyond traditional 1-to-1 contexts. Online health-oriented communities offer benefits such as peer support networks (eg, Headspace and Orygen both offer online youth mental health support in Australia). Similarly, social media groups focused on mental health have been shown to play a substantial role for end users in rural areas, where geographic location limits access to mental health service providers [56]. These groups provide support for guided online therapy [57], skills building [58], symptom monitoring [59], and social connection [60,61]. However, among culturally diverse communities, where English may be a second language, willingness to engage in these types of peer support offerings tends to be lower [50].

Designing With Diverse Populations

There is increasing recognition of the importance of designing digital services tailored for culturally diverse populations using responsive and inclusive design processes. Many researchers and designers in this space have adopted participatory research and user-centered approaches wherein members of the community are involved in the design process to identify their unique needs, goals, and concerns and to ensure that these are considered and integrated into the final service design [62-67]. Technologies developed for an underserved community are most impactful when designed with members of that community [68]. The use of user-centered approaches has been shown to improve the acceptability, effectiveness, and contextual relevance of novel technologies for communities [55]. Engaging members of the community in a design process often requires creative methods and tools to ensure that it is safe, beneficial, and easy for them to participate. Some studies have used creative tool kits, personas, and vignettes to scaffold design thinking [69,70].

User-centered design approaches that recommend the inclusion of meaningful engagement with consumers and carers in the service design are also increasingly recognized among mental health researchers and practitioners, including government agencies [71]. Research interest in culturally sensitive design through participatory research and user-centered design methods is mounting [72-74]. However, despite the political and cultural shift, there is still only a small, though growing, body of work in the field of human-computer interaction that explores the needs of culturally diverse populations in the area of DMH services [17,49,75,76]. While these studies provide useful insights, they tend to focus on a single community or culture and offer specific rather than generalized interventions. While there are steps being taken to engage culturally diverse communities in technology design across various fields of research, there are still various mental health factors that could impact the uptake of novel DMH tools (eg, cultural concepts of mental health and stigma around mental health). As such, it is vital that we aim to better understand how to design tools that account for these factors and enhance service engagement for culturally diverse communities. For the successful

implementation of clinical innovations at a public scale, novel digital solutions need to be designed *with* diverse populations to ensure that these solutions meet their needs [17,77]. Engaging with the perspectives of groups considered marginalized and those outside Western traditional norms will help ensure that DMH tools are designed more inclusively [78,79].

Building on these insights, we worked with culturally diverse young people and parents to design a national digital self-directed mental health check-in tool, called Growing Minds Check-In (GMCI), for the Australian public. The GMCI aims to provide an assessment of mental health and well-being symptoms as well as recommendations to tailored online mental health services and information. This study engaged with user-centered design due to the restrictions on the level of involvement the participants would have on the final production of the GMCI. Due to the narrow development timelines, the participants in this study were able to contribute to the design process but did not have decision-making powers; instead, they were involved in appropriate ways throughout the development of the GMCI [80]. We conducted a 2-phase study aiming to identify potential issues faced by culturally diverse communities when engaging with DMH tools such as the GMCI. The purpose of this study is to describe the attitudes, barriers, and benefits associated with DMH tool engagement among culturally diverse parents and young people. This information is likely to be relevant to DMH interventions for parenting and child well-being; it may also be relevant to other online programs, especially those delivered as universal public health interventions. We propose a set of design strategies for developing public-facing DMH tools and provide reflections on our own design process and the challenges we faced while engaging with culturally diverse communities in research.

Methods

Study Context

This project was conducted in partnership with the Growing Minds Australia Clinical Trials Network, Australia's first clinical trials network for child and youth mental health research [81]. It is part of the first phase of design for the Growing Minds Australia Clinical Trials Network flagship trial, the GMCI: a national online platform for parents and young people that integrates a mental health and well-being "check-in" with personalized feedback and suggestions for online mental health services and resources. We came into the project with the aim of focusing inquiry on how the future-facing platform could be designed more inclusively to ensure that it is relevant and accessible for diverse communities. We used a speculative DMH app containing features similar to those proposed by digital phenotyping software that could collect both passive and active data.

The study comprised 2 phases to engage groups of parents and young people from culturally diverse backgrounds with lived experience of mental health challenges. The first was a scoping phase that applied user-centered design methods, which included using speculative DMH tools to tease out potential benefits, concerns, and trade-offs. The second was a prototype exploration phase, whereby a proposed nationwide mental health screening

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tool was used as an artifact for participants to determine possible challenges and ethical issues that culturally diverse populations may face when engaging with DMH tools. This included a facilitated emotional walk-through of the screening tool using a workbook, followed by a data consolidation workshop where participants reflected on their experiences of using the tool. We aimed to identify the potential benefits and possible challenges of using a large-scale web-based check-in service and incorporate these insights into a more inclusive design for future DMH technologies. The design justice framework was applied to the design of the research questions (RQs), the activity schedule, and the analysis of the findings. This approach promotes the exploration of how benefits and burdens are distributed across groups, challenging design-driven inequalities by using an intersectional lens that considers race, gender, sexual orientation, and culture [82,83]. This framework incorporates participatory and user-centered design methods that prioritize community needs and encourage researchers to consider how power can shape participation in the design processes [82] (Figure 1).

Figure 1. Visualization of the study design. DMH: digital mental health.



Ethical Considerations

Our study received ethics approval from Monash University (31138). All participants were provided with an explanatory statement detailing the project and were asked to read and sign a consent form before participating. These documents were provided to participants in advance of the workshops. Consent and demographic information (eg, country of origin and culture they identify with, years lived in Australia, and languages spoken at home) were collected before the workshops began. Participants across all study phases were compensated Aus \$40 (US \$24) per hour for their time. Data was anonymized with all names removed from the data. Names were changed during transcription before any analysis commenced.

Recruitment

We partnered with a multicultural community mental health organization to recruit participants and facilitate the workshops. We used the organization's advertising channels to recruit participants who were involved as volunteers with the organization and were likely to be mental health literate. Workshop participants were required to have a high school level of spoken English due to time limitations and budget restrictions, which precluded the use of translators. Calls for participation in the workshops were advertised through flyers distributed via the community organization. For inclusion in the study, participants needed to identify as either having lived experience with mental health problems or having children who had experienced mental health challenges. These workshops were conducted in person and therefore limited to communities living in Victoria, Australia. A majority of the participants (12/18, 67%) were from South or East Asia, reflecting the demographic composition of the Australian population [1]. In phase 2, we included an Anglo-Australian participant (P8) who was recommended as a research participant by the mental health organization. Although not from a culturally diverse background, this participant was an experienced peer support worker with multicultural populations, had lived experience of complex mental health challenges, and was a parent. Phase 1 and phase 2 participant demographics are presented in Table 1.



Table 1. Phase 1 and phase 2 participant demographics.

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Phases and participant IDs	Age (y)	Parent or young person	Duration of residence in Australia (y)	Self-identified cultural background	Languages spoken at home
Phase 1	-				
P1	65	Parent	35	Indian	English, Tamil, and Hindi
P2	57	Parent	35	Indian	English and Tamil
P3	53	Parent	23	Indian	Tamil
P4	67	Parent	50	German	German and English
P5	48	Parent	48	Italian	Italian and English
P6	58	Parent	41	Indian	Hindi, Punjabi, and English
P7	67	Parent	67	Australian and German	English and German
YP1	22	Young person	3.5	Turkish	Turkish
YP2	16	Young person	7	German and Indian	German and English
YP3	22	Young person	11	Malaysian	Cantonese and English
YP4	21	Young person	4	Indian	Hindi
YP5	23	Young person	21	Han Chinese	Mandarin Chinese
YP6	22	Young person	12	Australian Chinese	Mandarin Chinese
YP7	18	Young person	17	Malaysian	English
YP8	24	Young person	5	South African	Zulu
YP9	24	Young person	11	Malaysian Chinese	Cantonese, Mandarin, and Ba- hasa Melayu
YP10	21	Young person	20	Indian or Hindu	English and Tamil
Phase 2					
P1	65	Parent	35	Indian	English, Tamil, and Hindi
P2	57	Parent	35	Indian	English and Tamil
P3	53	Parent	23	India	Tamil
YP3	22	Young person	11	Malaysian	Cantonese and English
YP4	21	Young person	4	India	Hindi
YP10	21	Young person	20	India or Hindu	English and Tamil
P7	67	Parent	67	Australian and German	English and German
P8	47	Parent	47	Australian	English

Phase 1: Contextual Inquiry Through User-Centered Design

Overview

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We conducted 2 user-centered design workshops: one with 10 young people (female: n=7, 70%; male: n=3, 30%; aged 16-25 y) and another with 8 parents of young people (female: n=4, 50%; male: n=4, 50%; aged 21-67 y). Each workshop included a researcher facilitator and a cofacilitator provided by the mental health organization who assisted with recruitment. Power imbalances were mitigated by conducting the workshops at an office space provided by the multicultural organization, where participants were affiliated and felt comfortable. The workshops ran for 3 hours with a 20-minute refreshment break. We examined 3 broad RQs:

- 1. How do culturally diverse end users perceive the value of mental health data? With whom would they share their mental health data? How might their mental health data differ in the future?
- 2. How is screening information communicated and understood? What impact would this have on therapeutic relationships?
- 3. What are the social factors that influence the likely use and application of DMH technologies? Are culturally diverse users concerned about third-party use of their data?

We aimed to not only explore the inclusion of culturally diverse communities in the design of a digital platform but also consider the impact of future data use, particularly how an end user's sensitive data may later be used. Given the propensity for alternative data use by third parties, we wanted to better understand the degree to which culturally diverse end users

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worried about how their data may be used and whether they felt it would have future implications.

The workshop sessions followed a semistructured activity guide that was developed by the authors and reviewed by colleagues independent of the study (refer to Multimedia Appendix 1 for details). We began each session with an icebreaker activity and initiated a group discussion to set the context for the following activities. Using a whiteboard and markers, we asked participants about their understanding of mental health and what makes for good and poor mental health. This activity was intended to provide insight into the participants' mental health literacy. We then provided participants with a speculative design probe, the "mental health vault" (Figure 2), to unpack abstract conceptions of sensitive digital health data. The vault included 3 layers to indicate varying levels of personal information that may be uncovered by DMH tools: (1) a locked safe represented by a metal box (most personal), (2) an inner layer bound by a thick metal chain, and (3) an outer layer framed by a thin rope (least personal). The activity schedule included four activities: (1) digital vault, (2) blank keys, (3) data sharing, and (4) future forecasting. These activities were centered on an imagined DMH tool that could actively and passively collect end user data, which differs from the GMCI's intended use and functionality as a web-based tool that provides personalized feedback and suggestions for online mental health services and information matched to need.



Figure 2. The "digital vault" activity in phase 1.

Activity 1: Digital Vault

The aim of this activity was to address RQ 1 by gauging participants' level of understanding of mental health data, how sensitive they perceived the data to be, and with whom they would want to share the data. To scaffold their thinking, we provided stimuli picture cards of potential mental health data points (eg, a diary, a mobile phone, GPS data, survey test results, and social media data) and asked participants to place each card, depending on how secure they felt each data point was, within the different layers of the vault (ie, inside the metal box, within the chain, or in the outer rope layer). The most private data points were placed inside the metal box, while the least private were positioned in the outer rope layer. After participants arranged the cards according to their preferences, we asked them to describe what each layer represented to them and why they placed each data point where they did (eg, why they would be okay with sharing social media data publicly but not their survey test results).

Activity 2: Blank Keys

The aim of this activity was to understand whom the participants were willing to share their data with and their reasons, addressing RQ 1. Using an inductive approach, we used this component of the activity to leverage and broaden the discussion to generate ideas on new "trusted" or "nontrusted" people that the participants could think of on their own, without the researcher's prompts or suggestions. We gave participants 6 blank paper "keys" and asked them to write down the individuals (eg, their imam, family member, or teacher) to whom they would be willing to grant access to the vault. They then placed each key in the vault layer they felt most comfortable allowing that individual to access. Next, we asked participants to use these blank keys to write down who they thought might "rob" the vault and to place the newly labeled keys in the layer of the vault they felt the "data robber" might access. The activity schedule script included the following prompt: "Now let's imagine digital bank robbers broke into your vault. What is the worst thing that can happen? Who might the robbers be? Why would they want your data? Which specific area of the vault would they be most interested in?"

Activity 3: Data Sharing

Building on the digital vault scenario, we introduced a "digital vault manager" who has access to the data contained in the digital vault and could use the data to identify mental health issues. This activity addressed RQ 2 and RQ 3. We then asked the participants whether they would want anyone to know about mental health challenge identified, and if so, whom they would share it with. This activity was designed to get participants thinking about their individual perspectives as well as how others may feel about having their personal data shared with the intention of helping individuals or their community (eg, whether a school or current employer should be notified).

Activity 4: Future Forecasting

This activity examined how screening information is likely to be communicated, understood, and applied in face-to-face sessions with a clinician. This activity addressed RQ2 and RQ3. We asked participants to imagine that the digital vault had been passively collecting data and had generated a prediction about their mental health over the next 20 years. First, we gathered emotional reactions to the prediction using printed emoji faces and by asking participants to indicate how they felt about having predictions made about them. Next, through a discussion-based activity, we explored how the prediction their trust, and sense of empowerment, and agency, as well as how and by whom the prediction would best be communicated. The activity schedule script included the following prompt: "Do you feel empowered knowing this prediction in advance so you can seek help? Do you trust its accuracy? Would you prefer your GP [general practitioner] or mental health clinician had told you? Would you trust it more if your GP told you? Are you concerned about who else is accessing this digital vault from some years ago?"

The findings from the future-facing DMH tool discussion in phase 1 were used to frame the emotional walk-through activity and focus groups with parents and young people in phase 2. We considered the benefits, burdens, and trade-offs that the culturally diverse participants discussed in these workshops and wove them into the emotional walk-through activity in an attempt to highlight challenges with an existing system that could then feed into a future design. This activity series was designed to address RQs 1 to 3.

Phase 2: Emotional Walk-Through

Using a user experience technique traditionally referred to as a cognitive walk-through, we aimed to explore participants'

emotional responses as they engaged with the interface [84,85]. We adapted a walk-through user testing methodology [86] and created a 6-page emotional walk-through booklet (Figure 3) that was distributed to participants along with a link to a prototype of the web-based mental health screening platform intended for national deployment in the near future. This was a written task that was designed to help facilitate discussion and ideas about the issues we intended to explore in the prototype testing workshop. Participants (parents and young people) were then invited to take part in a joint consolidation workshop to discuss their thoughts in further detail. We supplied participants with a booklet that was designed by the team, 2 weeks before the workshop to allow them time in their daily schedule to complete the booklet and explore GMCI prototype. Participants used their completed booklets during the session as mnemonic aids to recall their thoughts and experiences. A total of 6 participants (parents: n=3, 50%; young people: n=3, 50%; female: n=3, 50%; male: n=3, 50%) agreed to participate in the joint consolidation workshop. The aim was to elicit their thoughts and feelings about DMH data as they completed the web-based mental health check-in journey. The booklet included a range of questions designed to gauge emotional reactions as well as rating scale assessments as participants used the web-based screening platform. Within each section of the booklet, we included ethical considerations to encourage participants to consider the social impact of the DMH tools, including their understanding of mental health, how their community understands mental health, views on data privacy and management, how they would like to receive feedback about their mental health, and whether they felt they could challenge a mental health assessment. Participants then took part in the consolidation workshop to discuss their experience of using the prototype and to consolidate their ideas and expectations of engaging with an online mental health screening service. The session was broken down into four parts:

- 1. What are the motivations, benefits, and challenges of accessing such a tool?
- 2. Where does the data entered on the web go?
- 3. How well did the participants understand the feedback supplied? Did it resonate with their cultural background?
- 4. What suggestions did the participants have to make this tool more accepted within specific communities (dos and don'ts).



Figure 3. A completed emotional walk-through booklet in phase 2.1.



Positionality Statement

Our authorship team represents a variety of cultural backgrounds and perspectives on the topic, shaped by our own experiences. We took part in this research because we believe strongly in fostering equal access to mental health services for culturally diverse end users. Our team comprises 8 authors: 5 (62%) female individuals with European, Anglo-Celtic, and Irish heritage; and 3 (38%) male individuals with Anglo-Celtic, Anglo-Australian, and Filipino heritage. Of the 8 authors, 3

identify as parents; and 3 (38%) work with young people, parents, caregivers, and families. Our team consists of clinical and registered psychologists, a neuroscientist and bioethicist, a human-computer interaction and design practitioner, and researchers working in DMH and responsible innovation. We are committed to extending our knowledge and understanding of culturally diverse research practice to empathize and engage with research involving culturally diverse parents and young

(38%) are first-generation migrants to Australia; 4 (50%)

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people in this work. This commitment has informed our approach to the study design and data analysis.

Data Analysis

Audio recordings from all 3 face-to-face workshops (phase 1: n=2, 67%; phase 2: n=1, 33%) were transcribed and thematically analyzed using NVivo software (Lumivero). An inductive thematic analysis was conducted on all transcripts, without a preexisting coding framework, to identify themes and subthemes [87]. Initial codes were generated by IB to organize the data from phase 1 into potential items of interest. Three additional researchers (AC, RM, and JPS) familiarized themselves with the data from phase 1 and reviewed the initial codes. Iterative coding was then completed by IB, and 21 subthemes were generated that informed the design of the emotional walk-through. Three additional research members (AC, RM, and JPS) cross-coded themes from the emotional walk-through booklets and transcripts from the consolidation workshop. The codes were reviewed to ensure that the themes were clear and descriptive. The coded data from both phases were combined for analysis with 5 themes. In each workshop, an activity schedule was used to scaffold free-flowing discussion among participants. Variations in participant opinions were coded and contrasted to develop the subthemes. Participants were collaborative and brought culturally diverse and unique experiences, offering rich anecdotes in each session.

Results

Five major themes were developed from the analysis of the data collected from both phases: (1) trust in the use and application of a DMH tool, (2) data management and sharing, (3) sociocultural influences on mental health, (4) generational differences in mental health and digital literacy, and (5) stigma and culturally based discrimination in mental health support.

The Potential Impact of DMH Tools on Interpersonal and Therapeutic Relationships

The discussions on how DMH tools may impact the therapeutic relationship with a current or future clinician varied; however, both groups (parents and young people) expressed greater trust in a clinician in a face-to-face setting than in a digital tool. Participants in both groups also agreed that they would be more likely to trust a mental health recommendation or diagnosis generated by a DMH tool if a clinician was involved at some point:

I feel like I would still and then like accept whatever the app tells me, but it will be very helpful if the psychiatrist or psychologist are linked with this app. Like they sort of like, acknowledge that this app is useful or something like that. [YP5]

Participants acknowledged that they would seek advice from a DMH platform if a clinician was hard to access or as a first step in help seeking. However, some participants (YP10, YP7, YP5, and P2) felt that it was hard to know where to search and stated that they would use DMH tools as a screening tool but would seek help from a trusted health professional, such as a GP, psychiatrist, or psychologist, regarding the information provided by a DMH tools. Conversely, other participants found

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face-to-face interactions to be "embarrassing" (YP10), "confronting" (P8), or rushed:

I feel like because GPs usually see patients 15 minutes per block, it feels that it's quite rushed and sometimes GPs wouldn't take the time to go over time...it will make us feel that we're not as like important. [YP9]

Once a recommendation or treatment suggestion has been provided by DMH tools, participants in both groups (P6, YP5, and P3) expressed a desire to process it on their own first:

I would want to see the information first and then several steps down the road, consulting with a specialist might be an option. [P3]

Once they had reached a point of acceptance regarding the recommendation or treatment suggestion, there was variability in whom they would share the data with, with disclosures to family, friends, and practitioners varying within both groups. Some parents (P1, P2, and P3) preferred to be given the recommendation before sharing it with their children. Two younger participants (YP2 and YP5) were happy to share the information with their parents and siblings, while many of the other young participants (YP1, YP3, YP8, YP9, and YP10) indicated that they would prefer to share it with a trusted contact or friend—rather than with their parents and siblings—who they believed would help put them in touch with a professional or assist in accessing additional resources.

One young person (YP3) suggested having the option to choose to download feedback from a DMH tool depending on the severity of the user's mental health problems. Another young person made the following suggestion:

If you delete it, they ask you, "Are you sure?" or like, "Are like are you too busy?" "Is it distracting?" Like it ask you the reasons why you are downloading it. Have you met your match? [similar to a dating app] I think the same should be with the app. Like if you don't like the app, but you still, you downloaded this, but you still feel like you need someone to talk to, call these numbers. And it shouldn't be triple zero, because why would I call triple zero in my, like I don't...maybe triple zero can be like the last thing, but like call this person or locate the nearest center or psychologist, or locate your nearest person or something else. [YP8]

Suggestions were made in regard to having a trusted contact who would receive a notification if a user was determined to be at high risk for poor mental health, with the understanding that the trusted person would not be obligated to assume responsibility. Two parents (P7 and P8) emphasized the importance of a DMH tool's recommendation or resource that offered access to peer support networks. Another suggestion was for the user to predetermine a lower threshold for a risk notification if they were at risk of increased suicidality, allowing earlier intervention:

There's blurred lines to it, but at least like...having an accountability system...accepting, declining, being able to be there, or if I'm not, if I can be an emergency contact, but I'll accept, just going through

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this with you. Like, being there with you but I will not be your emergency contact. Like, I can share experience. In the case where it is an emergency, I don't want to be an emergency contact, but I can maybe assist you in contacting your emergency contact or something. [YP8]

Participants agreed that DMH tools should offer additional resources and alternative options once a screening or check-in is initiated, such as "resources to learn more about what I might be going through" (YP4). Both parents and young people emphasized that healthy parent-to-parent and child-to-parent relationships were important in cases where parents chose to complete a screening on behalf of their child. A parent elaborated as follows:

Obviously we agree to disagree on a lot of topics, but you know, after a certain years, you know your child very well. And...it depends on the relationship between the father and the mother as well. [P2]

The closeness between parent and child would be a significant factor in the quality of input into a DMH tool's screening process, which would then impact the meaningfulness of any subsequent recommendation or prediction:

It'd be a case of if you could offer it as a dual package. So if the child was up to do it with their parents as one option, then you'd have, so you'd have three options, you'd have an adult, you'd have the youth separate, and then you'd have a child and a youth and a parent combo...there's something to suit everyone depending on their communication space with their family members and how open they are to their mental health. [P10]

DMH tools were suggested as a complementary support alongside a clinician in both phase 1 workshops. Additional benefits of using DMH tools included setting reminders or nudges to promote healthy activities such as going for a walk or engaging in mindfulness meditation. A participant in the workshop for young persons also suggested that DMH tools could be useful for users with acute mental health challenges:

I think it would be good for bipolar disorder. For example, if you were able to get a new notification about your hyper episode, then you would able, you wouldn't be able to change your episodes like change your, arrange your calendar according to that. [YP1]

In relation to the technology, a young person described enjoying how music apps and YouTube catered to her mood:

So I relate how I'm feeling, even if it's like a chronic like mental illness, like how I'm feeling is through my algorithm of my music. So like I'd be on YouTube and I'd probably right now I'm, like...I just figured out I had ADHD so like I'm like constantly watching things that have to do with that. So like I feel like different platforms can algorithmize my personal experience. [YP8]

Another young person echoed this and made the following suggestion:

I think technology in essence should be supporting humans and human work, rather than trying to replace it. Um, if my GP or my psychologist fails to diagnose or intervene with me early, I recognize that everything they know about me is what I've told them, and those people are human. It's people they might miss things. So I'll be more than happy for this sort of data to assist in diagnosing me. Um, and together it will be more valid that just one source or the other.

[YP7]

In summary, when considering how results are communicated and what impact DMH tools may have on clinical practice, culturally diverse end users wanted to first process a recommendation or prediction on their own, viewed DMH tools as complementary to face-to-face clinical intervention, and were open to having a trusted contact with whom a recommendation or prediction could be shared.

Data Management and Sharing

Conversations in both phases established that participants had a moderate level of understanding about their personal data and how to manage the data. They acknowledged being aware of daily data collection via internet searches and app use and that the data can be outsourced to different countries and third parties through data harvesting (P3, YP10, P2, P7, YP7, YP8, and YP5). A participant in the workshop for young persons suggested that some data have to be shared to build more accurate and personalized apps:

I feel like data collection should be a two-way street. If you, I mean, like it should be mutual benefit, right? [YP7]

Unauthorized data access by governments, concerns after experiences with surveillance measures during the COVID-19 pandemic, recent government health data breaches, and identity theft were key concerns of participants (P8, P7, P2, YP9, P6, and P5). A participant shared another concern:

It could be mental health related or something else related. And then that information goes to your doctor, you consult a specialist or a GP or someone. And then it goes back to your insurance provider. And the insurance provider knows about it and straight away your premium goes up because they classify you as a high risk. [P3]

By contrast, young people were more open to having their data tracked or shared, having grown up with much of their information already available on the web and accessible by others. However, a young person acknowledged the difficult dilemma of accepting data collection in exchange for a more personalized online experience but described it as a "gray area" when it comes to broader data collection, stating as follows:

When they click "Accept All," that gives a warrant basically, and that's nothing that you can do because the website can just say, "You said, 'Accept All'" and continue. That's the warrant for me to say...to collect all your data and personalize it for you. And I feel like it's, it's quite a grey area basically. [YP7]

Another young person expressed uncertainty regarding their preference for certain data points to be collected or tracked by specific services:

I would want my location to be tracked by medical services. Say, for example, I get hurt and then, um, my phone...like my watch has this thing where it says, "Accident Detected." But I think about who gets access to what data and what they do with it and I think that's also really hard to track so it depends. [YP2]

In summary, culturally diverse mental health service users valued data about mental health, with variation in openness to data sharing and how the data may be shared in future.

Sociocultural Influences on Mental Health

Participants' experiences with mental health were grounded in sociocultural complexities, with variations in cultural understandings of mental health, help seeking, parental influence, community and spiritual support, and migration status, all playing a role in diverse communities' engagement with DMH support.

Many of the participants (YP7, YP1, YP8, and P8) self-identified as having lived experience with mental ill-health and discussed the importance of self-understanding when it came to mental well-being. Parents, in particular, recognized the importance of acceptance and education around mental health:

Probably because nobody wants to tell anyone, I'm going through not a very nice day or I'm going through mental health issues, so basically we have to come out of that state so we have to educate ourselves there's no point in just keeping everything to yourself. [P2]

Participants agreed that, outside of the family unit, their ethnic communities placed more importance on family connection and bonding than mental health specifically. This was highlighted in the comment written by a young person in the emotional walk-through booklet:

The "Mental health" term itself was still a taboo in India. We give importance to family connection and bonding (as a well-being strategy) but always have learnt to support and be there for one another. [YP4]

In addition, some participants (P1, P7, and YP4) discussed how their communities relied on religious leaders for mental health support rather than accessing formal care. However, the dominant cultural lens within a household impacted whether mental health was openly discussed. A parent explained as follows:

I would say it's very culturally influenced. From my perspective, the culture which we're connected to, you know. For everything there is a step-up process for you to understand, you know, why this is done, why it is not done. The reasons behind it. So where we grew up in our culture, we explain to them why we are doing this, to keep them on track. To keep you calm. It will protect you. The faith base. [P1]

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Migratory experiences and differences in the availability of support depending on visa status were also significant:

When I came from Turkey to here, one of the biggest surprises I have come across was the, how common suicide was among younger generations of Turkish people here. I was shocked, I lived in Turkey for 19 years, and I'd never even heard of someone who has heard of someone else's suicide. Like, never even came across it from the third degree or fourth degree. Many here, I spoke to a family member of someone who was a victim to suicide. The mother told me about her son's suicide, and I was so shocked. And then I heard the same story from multiple other people as well, and it just made me realize how widespread it was here, in younger generations of Turkish people. [YP1]

In summary, sociocultural factors influenced the use and application of DMH tools, with culturally diverse end users describing how their culture informed their understanding of mental health and help seeking.

Generational Differences in Mental Health and Digital Literacy

There were notable differences between the 2 generations across both study phases, particularly in terms of accessing mental health professionals, digital literacy, and whether participants were first- or second-generation migrants. Language barriers were identified, with a parent stating as follows:

That support is lacking. So you can imagine for some of these cultural communities, English might be a barrier, language might be a very big barrier. [P6]

Parents (P6, P2, P8, and P3) preferred confiding in a close friend and face-to-face interactions over digital therapies. By contrast, young people (YP8, YP10, YP3, and P8) seemed more willing to share their mental health experiences. A young person stated as follows:

I know that like when I was a young teenager, going through my rebellious phase in an ethnic household where I didn't feel like it was safe to open up to my parents, the online anonymous aspect was what made online like, Tumblr, a safe place for me to, I guess, voice my mental health concerns about myself. [YP5]

Some parents also believed that young people were more mentally healthy and digitally literate:

I think teenagers today are really, because they do things like that in school now, they understand about self-care, they do mindfulness, they do all that sort of thing as teenagers now in high schools and things. I think that the word self-care is so synonymous now, everyone knows what that means. There's depths of it, of course, but to a teenager even knowing, and they know how much time they spend, too much time on social media, they know they need to get more sleep, but you know, when they do all those things and they know they shouldn't eat McDonald's every day, they're not silly, these kids are smart. [P8]

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As a first-generation migrant, a parent felt that it was important not to impose her own cultural rules on her Australian-born children:

Because they're going to be Indian Australians, or Indian whatever it is. Deep down, they're Indian, they grew up as Australian children. They're more Australian than Indian sometimes. So we don't, um, there's no hard and fast rules. We can't tell them, you have to get up at 5 o'clock and pray. [P2]

The discrepancy between how young people perceived mental health challenges compared to their parents was regularly raised, with a young person elaborating as follows:

I think another aspect of like, immigrant parents on things about mental health, gender identity, sexuality that's a big thing that, I know people, who are even single parents, who come from the immigrant background, they don't understand what their young child is going through with gender identity and all that stuff, because it's...it wasn't really a thing when they were growing up, and, suddenly it's become something now, and they don't know how to deal with it. [YP10]

In summary, generational differences were a central social factor that influenced the use and application of DMH tools.

Stigma and Culturally Based Discrimination

Challenges with mental health stigma were discussed in both phases, with participants explaining that different cultural beliefs informed alternative explanations for poor mental health. Moreover, concerns were expressed that assigning a mental health diagnosis to a young person could lead to further marginalization because it might trigger defensive barriers in community members and contribute to increased ostracization. These experiences were centered on both internalized and externalized mental health stigma from family, friends, and extended cultural communities (P6, P3, P2, YP7, and YP3).

When discussing a potential mental health diagnosis for a child or young person, a parent stated as follows:

It's denial first, thinking that nothing is wrong with your child...automatically you think, my child is fine, there's nothing wrong...So the acceptance [of poor mental health] is going to be very difficult. [P2]

For a young person with culturally diverse parents, the experience of mental ill-health was particularly challenging:

When my parents found out that I had some mental health issues...I noticed changes in their behaviors and in terms of my parents and carers being from an ethnic environment, they're very judgmental. I just feel like my parents have zero understanding on mental health and mental illness so they wouldn't take any of that as a form of "I need help." They'll take it as I'm being ungrateful. [YP7]

A parent described how "mental illness ignites defensive barriers within people" (P6), suggestive of an internalized resistance that may impact help seeking in a community. A young person stated as follows:

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It might also depend on the person and if they have internalized stigma. I think if an app has some sort of measure that can account for that [internalized stigma]. And that can frame the message depending on that, it would be really nice. So, even in ethnic communities, even if somebody is seeking help, for example. Learning that you're depressed can be quite burdensome on your own mental health. The diagnosis might actually worsen your situation. Because the view of depressed people within your culture might always be these helpless people who cannot do anything basically. [YP1]

Regarding the diagnostic potential of DMH tools, parents were cautious about making their children "feel like they're different" (P8). A parent described how the diagnosis could be enduring and punitive:

You're assuming the parent can put a diagnosis on a condition and that's going to stick somehow. Because you're sort of leading them down a particular path. I'm a great believer in diagnoses, but a diagnosis can be a sentence. Rather than a word, you know. [P7]

There were concerns that a diagnosis can result in "lifelong stigma for a child or young person" (P7). A parent put it as follows:

You know what, suddenly my kid gets this thing as a mental health patients, that's the end of their life. For the rest of their life they'll be on medication or for the rest of their life they'll be on this. They're branded like that. [P2]

There was a perception among some parents that they would "lose face" and be stigmatized in the eyes of their community if they or their child received a mental health diagnosis:

When we talk about the ethnic communities, for them, their saving face becomes a very big issue. And you know, none of them want to lose face in the community in public and what have you. If somebody else doesn't even use their name then, for them, that stigma sort of stays, it's always going to take me years to rebuild that trust again. [P6]

Participants in both phases raised concerns about culturally based discrimination when seeking mental health support, including an inequity in the availability of psychological assessments, screenings, and support. Psychological assessments and mental health screenings were identified as a form of systemic discrimination by the young participants, who noted how most tools are only available in English, with questions reflecting Western understandings of mental health. This often results in people performing poorly due to an inability to understand the questions and being misdiagnosed. A young person described her lived experience of working in a Turkish-speaking psychologist's office in Australia and raised her concern about the limited number of bilingual psychologists:

They were one of the few Turkish-speaking psychologists we had, four or five months of waitlists. So, it was cheaper than private practitioners. Only 20% of the fee would be paid out of pocket. And it

was impossible to get through. Even if you have, um, some sort of government supplement like Medicare or some sort of private insurance, it was just impossible to make an appointment with her. And the same thing was the case for our Bosnian psychologist and our other psychologist as well. [YP1]

Difficulties accessing mental health support were raised across both groups, with participants discussing the challenges, such as visa status, that migrants face when accessing mental health services, which can prevent them from receiving the same standard of support as other residents. This was particularly important for young international students waiting for permanent residency visas:

But because they're still waiting for that process to get their PR [permanent residency visa]. They're [asylum seekers] still in our schools. They go to private schools. They're living a good life. But because they're asylum seekers. We're international students. We don't have access to Medicare. [YP2]

Discrimination from family members, friends, ethnic communities, and third-party systems upon receiving a mental health diagnosis was a concern raised by both groups (YP5, YP6, P6, and YP1). Both groups identified concerns about future discrimination from third parties who may use their mental health diagnoses to deny visa applications, steal their identities, or charge them higher insurance premiums (P1, P3, P5, P6, YP5, and YP6). In summary, stigma and diagnostic barriers, culturally based discrimination, and third-party access that may impact visa status and migration were central concerns.

Discussion

Principal Findings

The aim of the project was to explore the views of culturally diverse parents and young people on the opportunities and barriers to engagement with a web-based DMH screening tool. Through this work, we have explored the benefits, burdens, and trade-offs of using DMH tools from the perspectives of culturally diverse end users. On the basis of these findings, we provide our provisional set of reflections on the future of culturally sensitive DMH tools. Consideration of parental influence based on their country of origin, culture, and level of mental health literacy and how that is paired with raising a child in Australia is complex. Young people were perceived to have a higher level of general mental health and digital literacy, with greater awareness of their mood and self-care routines, as well as an understanding of healthy diet and lifestyle routines. They were also more willing to share information about their mental health with others. These generational differences highlight the importance of accounting for perceived barriers such as the influence of culture on mental health support, culturally based discrimination in seeking mental health support, and how a diagnostic label may impact the likelihood of engaging in help seeking.

Leveraging Family Connectedness

We found that our participants' understanding of their mental health was centered on their connection to family and

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parent-child relationships. Our findings suggest that family ties and family connectedness may influence the uptake of mental health treatments or interventions or whether and with whom DMH tool recommendations are shared. For culturally diverse youth, families provide an immediate social context (eg, as YP4 wrote in the emotional walk-through booklet: "The 'Mental health' term itself was still a taboo in India. We give importance to family connection and bonding [as a well-being strategy] but always have learnt to support and be there for one another"). Previous research found that the pace of cultural adaptation differs between parents and young people who resettle in Australia, with young people adapting faster but finding it hard to become independent from their families [16,88].

Family connectedness has been linked with lower odds of significant stress and despair for youth during acculturation and may protect them from other risk factors. In fact, the quality of family relationships can have a positive effect on well-being [89-91]. More research identifying positive family processes (eg, closeness with both mother and father) that build emotional well-being in culturally diverse young people is needed [92]. We found that familial influence informed young people's understanding of mental health, which, according to some parents, could be explained and managed through religious practices or alternative methods. This is an important finding because it suggests that future iterations of DMH tools should emphasize the inclusion of culturally sensitive parental support and psychoeducation on mental health problems. It also highlights the importance of engaging community leaders, elders, religious leaders, or mental health advocates from different cultures and communities to gather their insights on and explanations of well-being and mental health to ensure that the technologies are culturally safe. We suggest that culturally appropriate and culturally informed psychoeducation for families is needed to encourage community buy-in, ultimately leading to more effective DMH tools for culturally diverse populations. This education would have to be offered thoughtfully, paired with data governance education to promote digital literacy and awareness of the insufficiently regulated data industry and unregulated practices that exist currently.

Culturally Based Discrimination: Stigma, Loss of Face, and Collectivist Approaches to Mental Health

Barriers such as stigma, shame, and perceived judgment from community members were regularly raised. Many parents voiced concern about losing face in their community. Collectivist cultures that share a collective identity, emotional dependence, and shared duties and obligations operate under a "we" consciousness. These cultures are common outside Western societies that prioritize individualism [93]. The difference between individualism and collectivism ought to be considered when creating DMH tools, building an awareness that psychological support may be shared within a broad family network and that the "burden of results" may not be carried by the individual alone in collectivist communities. People from many collectivist cultures may struggle to understand the typical individualistic approach to treatment because they expect to receive care within the context of their family [94].

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Some people may also have deeply held negative beliefs or attitudes toward those experiencing mental health challenges, making it important to design mental health services that incorporate informal support avenues (eg, friends and family) on which individuals may rely for help [95,96]. Loss of face is an important cultural factor in the Asian context and has been found to be a significant predictor of self-stigma and public stigma that impacts attitudes toward help seeking [97-99], especially given that community belonging plays a large role in migrant mental health [12].

Culturally diverse communities may minimize the reporting of psychological symptoms or may be resistant to sharing personal health information because of mistrust, perceived racism, or a sense that public mental health services do not accommodate or respect their cultural beliefs [100,101]. Culturally sensitive psychoeducation within communities is needed to combat stigma. To achieve this, we suggest engaging with community and religious leaders as well as mental health advocates with lived experience of mental health challenges, given their influential reach among diverse end users, to promote community-informed education, self-determination, and self-advocacy. DMH tool designs should offer transparent data collection policies, with tiered consent, to ensure that end users feel comfortable sharing their data, and this should be paired with the inclusion of digital navigators, who are members of health care teams dedicated to help end users [102].

Young people in our study voiced concern about the lack of culturally and linguistically diverse clinicians and assessment tools, noting that information was mostly communicated in English using a Western framework for assessing mental health. Research has found that diagnostic assessments tend to not be sensitive to racial and ethnic minority populations due to their exclusion from mental health research [103,104]. Furthermore, culturally diverse community members are less likely to have satisfactory access to mental health support and are less likely to receive a diagnosis for a mental health condition [105, 106]. If DMH tools are to be relevant, accessible, and effective for culturally diverse populations, future designs and implementations must be available in languages other than English and incorporate cultural approaches to mental health. The very term mental health is a Western concept, and Western cultural traditions and understandings have informed much of the theory, practice, and understandings of mental health, including within psychology and psychiatry, with a central focus on individual pathology instead of sociocultural contexts and determinants [107,108]. Furthermore, how patients from culturally diverse backgrounds express their symptoms may vary, making it challenging to accurately diagnose or treat their conditions [104]. Individualized models of care may not be appropriate for those who are accustomed to community- or family-focused models of care [108]. The British Psychology Society proposed the power threat meaning framework as a nonmedicalized and nondiagnostic approach that instead describes how coping and survival mechanisms are adapted based on lived experience, previous threats, and social context, accounting for cultural differences in the experience and expression of distress, with less emphasis placed on Western views [109].

XSL•F() RenderX We ought to consider how to design culturally sensitive DMH tools that are informed by attitudes from diverse communities and encourage self-determination and cultural context within a well-being framework. One suggestion is for DMH tool developers to offer enhanced psychoeducation that is culturally safe and fosters self-determination, with tailored psychological assessments and resources that account for language variations and barriers for users coming from collectivist cultures whose conceptions of mental health vary from the Western medicalized understanding.

Medicalization by Design

Concerns were raised about making a child or young person feel different. Participants worried that "a diagnosis may worsen your situation," suggesting that a diagnostic label or the detection of a mental health problem, as well as the diagnostic process itself, may further marginalize diverse communities through the medicalization of culturally appropriate cognitions or behaviors. Medicalization pathologizes behaviors according to a Western psychiatric framework, putting the responsibility back on the individual to stay healthy without considering other important social factors [110,111]. Online screening tools and mobile apps are being designed to promote well-being and provide psychological support, but they can also work to endorse ongoing surveillance [112] of mood and activity and set expectations about healthy behaviors and cognitions. A shift is needed in how mental health is conceptualized and designed for in a way that accounts for cultural barriers that may limit engagement and usability for diverse end users of DMH tools [109]. Importantly, we need to invest in community-led practices that promote community leadership in the design and innovation of DMH tools [82] to avoid built-in discrimination that reproduces inequities due to normative or Western-oriented assumptions about mental health [113]. We suggest that when designing DMH tool outputs, such as the communication of health information, recommendations for services and interventions, and referral pathways, the reported symptoms entered by the end user are phrased in a way that avoids pathologization and diagnosis. Currently, DMH platforms tend to recommend resources on anxiety, depression and suicidal ideation, and eating disorders [39,114]; however, we believe that it is imperative that symptoms are spoken about in clusters, rather than specifying specific diagnostic criteria that may then pigeonhole or "label" an end user without appropriate access to clinical care.

Attitudes Toward Data Collection Are a Two-Way Street

When using DMH tools, participants felt that there was less concern about privacy and data sharing when the data collected were more generalized. This is consistent with a recent study on diverse communities using mindLAMP, a DMH platform, where participants wanted their DMH apps to pull data from their current health care records to enhance app personalization [115]. Participants acknowledged that innovations and interventions require consent for collecting substantial amounts of data to tailor services or for platforms to "algorithmize my personal experiences"; however, research has found that DMH tools are often not culturally tailored or responsive due to

culturally diverse or racial and ethnic minority populations often not being considered in their development and evaluation [116,117]. Young people from culturally diverse communities recognized that they would need to provide access to personal digital health data to realize the benefits promoted by DMH tools. Critics have argued that young people may not comprehend the longevity and potential harms of a digital footprint and that thoughtful education and support around this is important for their future privacy [118]. While research has demonstrated an unwillingness from end users to share their sensitive health data with commercial organizations [23,119-121], there was a sense in our findings that participants expected an "algorithmized experience," which would require health data to be treated as open data [122]. Due to the sensitive nature of mental health data, further education on data governance and the potential reuse of big data is recommended for young people, given the nature of cross-sectoral data sharing. One approach may be incorporating speculative design approaches, such as the one suggested in the study by McNaney et al [23], to engage young people in discussions around their digital futures, the potential harms of data sharing, and the misuse of their data.

In both phases, the participants identified concerns about data breaches, including potential identity theft and the impact it could have on visa and migration status. These concerns are reflected in the literature, with 1 study finding that nearly half of the DMH apps surveyed did not have a privacy policy, although it is known that health care apps often share data points (eg, age, contact information, and other user data) with multiple third parties for commercial purposes [123,124]. Efforts have been made to establish ethical standards for digital data gathered from DMH tools, including accounting for data breaches, which advise developers to account for hidden assumptions and unintended consequences [125]. Regulations such as the General Data Protection Regulation in Europe and similar privacy acts being developed in Brazil, Chile, and Canada aim to protect data privacy. However, even the General Data Protection Regulation has limitations, particularly in the context of emerging generative artificial intelligence innovations.

Reflections and Limitations

This study sought to engage with culturally diverse representatives in relation to cultural background and lived experience of mental health challenges. To achieve this, we approached an organization focused on multicultural mental health that advertised the study, recruited participants, and supplied bicultural workers for our study. While we were able to have meaningful discussions in our workshops, the participants were all affiliated with the organization, meaning that the sample was not necessarily representative of a truly culturally diverse population, given that each participant was already mental health literate, able to communicate in English, and held a preconceived understanding of mental health, rather than being a layperson. The addition of an Anglo-Australian participant was also a limitation. Future research needs to engage with a broader range of culturally diverse participants, including those with less digital and mental health literacy and those who may be in a more contemplative stage of their mental health journey and possibly unaware of support services. Future research might consider recruiting through youth organizations or well-being counselors who may have access to a more culturally diverse range of participants who reflect a more culturally diverse picture of mental health literacy and help seeking. Future research should also engage in participatory action research methods (eg, co-design and coproduction) that allow end users to develop RQs and study designs. However, this approach can present additional challenges to building social capital and gaining trust to engage with culturally diverse end users in a meaningful way, and this needs to be factored into study timelines. Our study was bound to an innovation timeline, making the recruitment of a truly diverse sample impossible. We were conscious that we did not invite the participants to review the data analysis or final manuscript, which could have reduced the power imbalances further by allowing the participants to join as coresearchers in the project from start to finish. Future iterations would benefit from inviting culturally diverse participants on board as coresearchers, not just as participants. We believe that it is important to embed the voices of diverse community members within a research project throughout its lifespan.

Most of our participants were from South-East Asia. While this is an accurate reflection of the majority of culturally diverse Australians [1], it may not capture the views of ethnic and racial minority cultures within Australia. We hoped to avoid essentializing all experiences as one by including quotes from individuals because we believe that culturally diverse communities do not share a single common experience due to varying sociopolitical differences such as age, culture, and citizenship. The median age of the young participants was relatively high, with one aged 16 years and one aged 18 years, while the remaining participants were aged 20 to 22 years. As such, our findings may not reflect the views of younger adolescents. Future endeavors should aim to apply the insights gained from this research in the development and pilot testing of DMH interventions and applications by evaluating their effectiveness and refining them based on the outcomes.

Conclusions

Inclusive design considerations for the future development of DMH tools that account for culturally based discrimination, are culturally safe, consider family and cultural influence on mental health support, and are thoughtful in how mental health problems are detected and communicated to end users would improve engagement in DMH tools and help seeking. We recommend encouraging culturally sensitive psychoeducation, thoughtful nonpathologizing language that avoids providing a specific diagnosis, and the inclusive involvement of community leaders and mental health advocates in the future design of DMH tools to ensure that they are designed to meet the needs of culturally diverse end users.



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Authors' Contributions

The study was designed by IB, AC, RM, and JCN. IB prepared the first draft of the manuscript. All authors contributed to and approved the final manuscript.

Conflicts of Interest

This study was funded by the Growing Minds Australia Clinical Trials Network. JCN, LAT, and PO are listed as principal investigators on this grant, and the positions of JCN, LAT, and TC are supported by this funding.

Multimedia Appendix 1

Digital mental health co-design workshop schedule. [DOCX File, 23 KB - pediatrics_v8i1e65163_app1.docx]

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Abbreviations

DMH: digital mental health GMCI: Growing Minds Check-In GP: general practitioner RQ: research question

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Empowering Caregiver Well-Being With the Adhera Caring Digital Program for Family Caregivers of Children Living With Type 1 Diabetes: Mixed Methods Feasibility Study

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Abstract

Background: Caregivers of children living with type 1 diabetes (T1D) face multiple challenges that significantly impact their mental health and quality of life. The well-being of caregivers directly affects the management of the child's condition. The Adhera Caring Digital Program (ACDP) is a comprehensive, digitally delivered program, designed to support family caregivers in enhancing self-management and well-being. This study aims to assess how the ACDP influences caregivers' mood, emotional well-being, and health-related quality of life within the context of T1D.

Objective: This study aimed to evaluate the impact of ACDP on caregivers' psychological well-being and caregiving outcomes.

Methods: This was a two-step, prospective, mixed methods study targeting caregivers of children living with T1D who were under the care of a pediatric endocrinologist at Miguel Servet Children's University Hospital in Zaragoza, Spain. In substudy 1 (SS1), qualitative and quantitative data were collected to optimize the ACDP. In substudy 2 (SS2), caregivers used the optimized ACDP for three months. Psychometric assessments were conducted at baseline and follow-up to evaluate positive mood states, general well-being, self-efficacy, and lifestyle behaviors. This paper focuses on SS2.

Results: Ninety caregivers participated in SS2. Positive affect significantly increased (P<.001), and negative affect decreased (P<.001) on the Positive and Negative Affect Schedule (PANAS). Depression, anxiety, and stress scores were reduced (P<.001) on the Depression, Anxiety and Stress Scale-21 Items (DASS-21). General well-being, measured by the Mental Health Continuum-Short Form (MHC-SF) and self-efficacy, assessed using General Self-Efficacy Scale (GSE), improved significantly (P<.001). Health-related quality of life (HrQoL) scores and Mediterranean Diet Quality Index scores increased modestly (P=.03, and P=.04, respectively).

Conclusions: The ACDP intervention improved caregivers' psychological well-being and self-efficacy. These findings highlight the potential of digital solutions to support caregiver mental health and positively influence diabetes management. Future research should explore long-term outcomes and scalability.

Trial Registration: ClinicalTrials.gov NCT05483803; https://clinicaltrials.gov/ct2/show/NCT05483803

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KEYWORDS

type 1 diabetes; caregiver wellbeing; digital health; digital program; coaching; diabetic; diabetes; T1D; pediatrics; children; chronic; endocrinology; CGM; glucose; caregiving; caregiver; carer; informal care; family care; parents; parental; guardian; continuous glucose monitoring

Introduction

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Children living with type 1 diabetes (T1D) face unique challenges, including deficient insulin production, psychosocial stress, stigmatization, social isolation, and bullying, which can negatively impact their quality of life [1,2]. Caregivers' are often the primary source of support for these children, and

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experience significant emotional burdens that are closely linked to the children's health-related quality of life (HrQoL) [3-7]. Therefore, addressing caregiver well-being is critical for holistic diabetes management [6].

Comprehensive strategies and programs that prioritize caregiver emotional health have shown promise in improving outcomes for both caregivers and children [8,9]. For instance, programs

such as PRISM-P (Promoting Resilience in Stress Management for Parents) have demonstrated the efficacy of resilience-building interventions for parents of children living with serious illnesses [9]. Positive mood states in caregivers are critical predictors of HrQoL in adolescents with T1D [10]. The diagnosis of a chronic condition such as T1D in a child is often stressful and potentially traumatic [11]. Furthermore, scalable digital interventions such as the Remedy to Diabetes Distress (R2D2) program underscore the growing need for innovative, technology-enabled solutions to address caregiver distress [12].

Achieving optimal HrQoL for children living with T1D may also require providing caregivers with personalized emotional and behavioral support [13]. This issue should be examined from the perspectives of mental health and technology acceptance theoretical frameworks [14]. The psychological well-being of caregivers is closely tied to the HRQoL and treatment adherence of children living with T1D [15]. For example, the PsyVoice study highlights the importance of understanding expectations surrounding voice-based digital health solutions to manage diabetes distress among children and their caregivers [16]. Furthermore, a recent narrative synthesis of systematic reviews underscores ongoing developments in the design and delivery of self-management support for children and young people with diabetes, emphasizing the necessity of tailored interventions to meet diverse needs [17].

The Adhera Caring Digital Program ACDP is a comprehensive, digitally delivered program designed to support the physical and mental well-being of caregivers of children living with chronic conditions. By providing personalized emotional and behavioral support, the ACDP seeks to improve self-management, mental health. and overall well-being for both patients and their families. This study evaluates the impact of the ACDP on caregivers' positive mood states, emotional health, and perceived HrQoL in the context of T1D.

Methods

Design and Setting

This study used a two-step, prospective, mixed methods (qualitative-quantitative) feasibility trial, composed of two substudies. Substudy (SS1) gathered qualitative and quantitative data to inform the optimization of the ACDP. Substudy 2 (SS2) evaluated the optimized intervention over a three-month period. Caregivers of children living with T1D under the care of a pediatric endocrinologist at the Miguel Servet Children's University Hospital (Zaragoza, Spain), following general clinical Spanish practices, participated in this study.

Sample Size and Eligibility Criteria

One hundred caregivers were recruited for SS2. Inclusion criteria were (1) caregivers who are legal guardians of children living with T1D under 18 years of age; (2) child's T1D diagnosis for at least three months; (3) use of continuous glucose monitor; (4) caregivers' willingness to use the mobile solution and share data.

Exclusion criteria included only one legal guardian per child could participate, prior participation in SS1, and incomplete or refusal to provide consent.

Digital Solution

The ACDP supports the physical and mental well-being of family caregivers of individuals with chronic conditions, enhancing self-management and health outcomes. This digitally delivered offers noninvasive, program condition-specific educational content, personalized motivational messages, and self-management tools, using data from wearables and patient-reported outcomes. It includes Adhera Collaboration, a health coaching service, and leverages the Adhera Health AI-driven Health Recommender System for personalized interventions. ACDP is part of the Adhera Health Precision Digital Companion Platform, developed according to best practices in data protection and quality management, following ISO 27001 and ISO 13465 guidelines. The family caregivers accessed the digital program via a mobile application which is compatible with both Android and Apple operative systems. Screenshots of the ACDP can be found in the Multimedia Appendix 1.

The ACDP was applied to families managing T1D due to the significant caregiving demands associated with this condition. The program was tailored to address the psychological and emotional challenges faced by caregivers in supporting children with T1D, including continuous glucose monitoring, insulin management, and responding to hypoglycemic and hyperglycemic events. These challenges made T1D an optimal use case for evaluating the intervention's impact on caregiver well-being.

Study Procedures

SS1 aimed to identify caregivers' psychological burdens and perceived barriers and facilitators associated with adopting the ACDP. Participants used the digital intervention for one month, and their feedback was used to generate an optimized version of the platform. Full details of SS1 can be found in Multimedia Appendix 1.

SS2 assessed the impact of the optimized ACDP on caregivers' psychological well-being, mood and HrQoL. Demographic data collected included caregiver gender, age, marital status, and education level, as well as the children's gender, age, and time since T1D diagnosis. These characteristics were analyzed to understand the context and diversity of the caregiving population. Furthermore, psychometric assessments used in this study included the following validated surveys:

- Positive and Negative Affect Schedule (PANAS) measures positive and negative affect. Higher scores on the positive affect subscale indicate greater positive emotions, while higher scores on the negative affect subscale indicate greater negative emotions.
- Depression, Anxiety, and Stress Scale (DASS-21) evaluates emotional distress across three domains, including depression, anxiety, and stress. Higher scores indicate greater levels of distress in each domain.
- Mental Health Continuum-Short Form (MHC-SF) assesses general well-being across emotional, psychological, and

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social domains. Higher scores reflect better overall mental well-being.

- General Self-Efficacy Scale (GSE) measures confidence in managing challenging situations. Higher scores indicate greater self-efficacy.
- Clarke Questionnaire typically applied to patients with diabetes to assess hypoglycemia awareness; in this study. it was adapted to capture caregivers' awareness and understanding of hypoglycemic episodes in their children. Higher scores suggest better awareness and understanding of hypoglycemia.
- KIDSCREEN-10 measures HRQoL in children. Higher scores indicate better HRQoL.
- Mediterranean Diet Quality Index (KIDMED) assesses adherence to a Mediterranean diet. Higher scores reflect greater adherence to a Mediterranean dietary pattern.

While KIDSCREEN-10 and KIDMED are primarily validated for ages 8 - 18, caregivers completed them to provide insight into their perception of the child's quality of life and dietary habits, respectively. Their inclusion aimed to explore indirect caregiver influences on child health behaviors.

Intervention and Measures

The recruitment for SS2 took two months, and participants joined ACDP for three months. Caregivers were onboarded to the Adhera platform through an initial in-person training session at the study site. This session included a demonstration of platform functionality, account setup, and navigation support. Data were collected through the Adhera platform's integrated survey tools, which allowed participants to complete assessments digitally. Additionally, demographic and baseline data were gathered via paper forms during the initial study visit. At baseline and at follow-up, the data collected included (1) demographic data; (2) multiple daily injections and continuous subcutaneous insulin infusion questionnaire (insulin delivery methods); (3) positive mood by PANAS, (4) distress by DASS-21, general wellbeing by MHC-SF, self-efficacy by GSE; (5) lifestyle questionnaires by KIDMED; (6) hypoglycemia awareness by Clarke questionnaire; (7) Quality of life (HrQoL) by KIDSCREEN-10; (8) system usability scale (SUS; only at 3 months), and (9) continuous glucose monitoring.

Data Management and Quality Control

All the data gathered in the study was recorded in MicroSoft Forms at Adhera Health servers. Data were processed, evaluated, and stored in an anonymous form following the General Data Protection Regulation (GDPR) regulations. Adhera Health was responsible for data processing in accordance with its data management and quality procedures. Data quality and integrity were ensured through ISO 27001, which is related to the quality management system for ensuring information security.

Statistical Analysis

Baseline demographic and clinical characteristics of the study cohort were summarized using means (SD) for continuous variables, and frequencies with percentages for categorical variables. Mean values (SD) were presented for each psychometric outcome (eg, stress, quality of life, depressive symptoms) were calculated at baseline (preintervention) and after the 3-month intervention (postintervention). Differences in pre- and postintervention questionnaire scores were assessed using a parametric paired t test or a nonparametric Wilcoxon signed-rank test, as appropriate, depending on whether the normality and homogeneity assumptions of the t test were met. Effect sizes (η^2) were calculated to gauge the magnitude of any significant differences. All hypothesis tests were two-sided, and statistical significance was defined as P < .05. The statistical analysis was conducted using the Python packages scipy (version 1.14.1) and pingouin (version 0.5.5).

Ethical Considerations

All procedures performed in this study were in accordance with the ethical standards of the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The study posed minimal risk to the participants. The anonymized information collected was handled following the right of privacy and anonymity according to the rules of GDPR (EU Regulation 2016/679). Prior to the commencement of the study at Miguel Servet University Hospital, the protocol and its associated documents (information sheet for the patient and informed consent form) were submitted to the CEICA (Aragonese Ethical Committee for Clinical Research). A written favorable opinion or approval was obtained from CEICA. Written informed consent to participate in the study was obtained from all patients before any study-related activities were carried out. Moreover, to comply with local regulations, for children 12 years and older, additional consent was obtained. Data were anonymized as per GDPR standards. The study participants were not compensated monetarily. However, they were provided with free access to the digital health platform for the duration of the study, which included tailored support and resources.

Results

Demographics

Of the 100 caregivers recruited, 90 completed the study (Figure 1). Reasons for drop out were as follows: 4 caregivers abandoned the study, 5 did not log in to the application, and 1 did not meet the protocol deadlines. Participants' mean age was 45.15 (SD 6.03) years, and they were predominantly female (71/90, 78.9%). The mean age of the children was 10.78 (SD 3.34) years, with a mean time since diagnosis of 4.42 (SD 3.38) years. Full demographic details are provided in Table 1. The differences in pre- and postintervention questionnaire are presented in Table 2.



Figure 1. Substudy 2 diagram. DASS-21:depression, anxiety and stress scale-21 items; GSE: general self-efficacy scale; MDI/CSII: multiple daily injections and continuous subcutaneous insulin infusion; MHC-SF: mental health continuum-short form; PANAS: positive and negative affect schedule; SUS: system usability scale.





MDI^b

Table . Demographics of participants of substudy 2.

Characteristics	Participants (N=90), n (%)				
Caregiver's gender, n (%)					
Men	19 (21.1)				
Women	71 (78.9)				
Caregiver's age (years), mean (SD)	45.27 (5.04)				
Caregiver's marital status, n (%)					
Single	3 (3.4)				
Married	79 (87.8)				
Divorced	8 (8.9)				
Education, n (%)					
Primary education	2 (2.2)				
Secondary education/high school	13 (14.4)				
Professional training	35 (38.9)				
University degree	40 (44.4)				
Child's gender, n (%)					
Male	51 (56.7)				
Female	39 (43.3)				
Child's age (years), mean (SD)	10.78 (3.33)				
Time since diagnosis (years), mean (SD)	4.42 (3.38)				
Therapy, n (%)					
CSII ^a	46 (51.1)				

44 (48.9)

^aCSII: subcutaneous insulin infusion.

^bMDI: multiple daily injections.



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Table . Comparison of family caregiver characteristics at baseline and three months after the start of the intervention in Substudy 2.

Variables	At haseline	At 3 months	t test (df)/nonnaramet-	<i>P</i> value	Effect size		
Variables	(mean, SD)	(mean, SD)	ric test		$(a^2)^a$		
	(((η)		
PANAS ^b							
Positive affect	34.26 (7.69)	37.40 (6.95)	-4.7 ^c	<.001	.044		
Negative affect	24.34 (8.83)	21.23 (8.36)	941.0 ^d	<.001	.032		
DASS-21 ^e							
Depression scale	4.21 (4.65)	2.96 (3.90)	550.5 ^d	<.001	.021		
Anxiety scale	3.54 (4.24)	2.50 (3.65)	362.5 ^d	<.001	.017		
Stress scale	8.98 (5.30)	5.75 (4.7)	536.5 ^d	<.001	.048		
MHC-SF ^f							
General well-being	0.61 (0.19)	0.67 (0.17)	-3.4 ^c	.001	.021		
Emotional well-being	0.62 (0.21)	0.70 (0.22)	661.0 ^d	<.001	.028		
Psychological well-be- ing	0.68 (0.21)	0.72 (0.17)	957.5 ^d	.02	.011		
Social well-being	0.52 (0.22)	0.58 (0.22)	741.5 ^d	<.001	.017		
GSE ^g	30.44 (5.18)	32.28 (4.81)	785.5 ^d	<.001	.033		
KIDSCREEN-10 index							
Total Score (T-value)	57.76 (15.22)	60.39 (15.58)	1164.5 ^d	.03	.007		
KIDMED question- naire	8.60 (1.80)	9.00 (1.90)	716.0 ^d	.04	.011		
Knowledge of T1D ^h	7.47 (2.18)	7.59 (1.66)	1092.5 ^d	.62	<.001		
Clarke hypoglycemia score	2.60 (1.06)	2.48 (1.01)	496.5 ^d	.22	.003		

 ${}^{a}\eta^{2}$ >0.01 indicates a significant effect.

^bPANAS: positive and negative affect schedule.

^c*t* test (89).

^dNonparametric test.

^eDASS-21: depression, anxiety and stress scale-21 item.

^fMHC-SF: mental health continuum-short form..

^gGSE: general self-efficacy scale..

^hT1D: type 1 diabetes.

Pre-Post Intervention Results

Significant improvements were observed across multiple outcomes (see Table 2). Positive affect increased from 34.26 (SD 7.69) to 37.40 (SD 6.95; P<.001) on the PANAS. Negative affect decreased from 24.34 (SD 8.83) to 21.23 (SD 8.36; P<.001) on the PANAS. Depression, anxiety, and stress scores on the DASS-21 significantly reduced across all domains, including significant decreases in depression (mean difference =1.25, P<.001), anxiety (mean difference=1.04; P<.001), and stress (mean difference=3.23; P<.001).

General well-being, as assessed by the MHC-SF, showed significant improvements across domains such as general well-being (mean change=0.06; P=.001), emotional (mean change=0.08; P<.001), psychological (mean change = 0.04;

P=.02), and social well-being (mean change=0.06, P<.001). The GSE scores increased from 30.44 (SD 5.18) to 32.28 (SD 4.81; P<.001) and the HRQoL scores improved significantly (P=.03). The Mediterranean Diet Quality Index scores were also improved (P=.04).

Discussion

Principal Findings

This feasibility study shows that a 3-month digital intervention can significantly improve the psychological wellbeing and emotional health of caregivers of children living with T1D. The intervention effectively increased positive affect, decreased negative affect, and reduced depression, anxiety, and stress levels among caregivers. These findings align with existing

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research emphasizing the importance of caregiver support in pediatric chronic condition management [18,19].

The observed improvements in survey scores suggest clinically meaningful benefits. For example, reductions in DASS-21 scores correspond to a shift from moderate to mild emotional distress categories for many participants, reflecting improved mental health. Similarly, increases in PANAS positive affect scores and MHC-SF well-being scores indicate enhanced emotional and psychological resilience. These clinically significant changes underscore the impact of the ACDP on caregiver well-being and its potential to support families managing T1D. Higher self-efficacy is associated with better coping strategies and more effective problem-solving [15,20]. Although improvements in T1D knowledge and hypoglycemia awareness were not statistically significant, the observed trends suggest potential benefits [21]. It is possible that with a larger sample size or a longer intervention period, these trends could reach statistical significance, providing a more comprehensive understanding of the intervention's impact.

Caregiver burden has been strongly linked to adverse psychological effects, including depression, family dysfunction, and difficulties in glycemic control [7,22]. Addressing these challenges is essential for both caregiver well-being and effective diabetes management in children. The combination of digital coaching, motivational messaging, and tailored interventions in ACDP offers a structured approach to alleviating caregiver distress. Additionally, resilience plays a crucial role in mitigating the negative impact of caregiver burden on quality of life [11]. The improvements in self-efficacy and emotional well-being observed in this study highlight how digital interventions can empower caregivers with better coping mechanisms and stress management strategies.

Moreover, the observed improvements in caregiver psychological well-being and self-efficacy align with prior studies, such as PRISM-P and R2D2, which have demonstrated the efficacy of resilience-building and digital health interventions in supporting families managing chronic conditions [9,12]. For instance, the PANAS and DASS-21 score changes in this study are comparable to those reported in similar interventions, indicating a meaningful reduction in caregiver distress and an increase in positive affect. Furthermore, the MHC-SF improvements reflect better emotional and social functioning, consistent with findings from resilience-focused digital interventions. These results underscore the potential of personalized, tech-enabled support to fill critical gaps in caregiver support, as highlighted by Yu et al [21]. However, this study uniquely integrates personalized modules and psychometric assessments tailored to caregivers of children living with T1D, addressing a distinct population need. The significant improvements observed in this study demonstrate the scalability and real-world applicability of the ACDP for enhancing caregiver and family well-being.

This study has several strengths. First, it leverages a personalized digital intervention tailored specifically for caregivers of children with T1D, addressing an important but often overlooked population. The integration of psychometric assessments and AI-driven personalization ensures that the intervention adapts to individual caregiver needs, enhancing its real-world applicability. Additionally, the study employs a mixed methods approach, combining validated psychometric tools with engagement metrics to provide a comprehensive understanding of both subjective and objective outcomes.

Despite these positive outcomes, the study has limitations. The sample size, although adequate for a feasibility study, limits the generalizability of the findings. Additionally, the intervention's three-month duration may not capture long-term sustainability of the observed benefits. Potential biases in self-reported data and a lack of a control group further constrain the robustness of conclusions. Future research should focus on exploring the long-term effects of digital interventions and their potential to include other domains of caregiver and child well-being. Additionally, examining the cost-effectiveness of such interventions could provide valuable insights for health care providers and policymakers considering the implementation of digital support programs for caregivers.

However, the study's findings are promising, indicating that digital interventions can effectively support caregivers' psychological and emotional well-being. The significant improvements in affect, mental health, self-efficacy, and quality of life highlight the potential of such interventions to enhance the caregiving experience and ultimately benefit the well-being of children living with T1D [21]. While improvements in emotional well-being and self-efficacy may indirectly influence caregiving behaviors, these were not directly targeted or assessed in this study. Future research could explore the potential behavioral impacts of digital interventions such as the ACDP.

Conclusions

The ACDP has demonstrated significant potential in supporting caregivers of children living with T1D. By improving psychosocial well-being and self-efficacy, the intervention offers a scalable solution for enhancing caregiving experiences and, ultimately, child health outcomes. Further studies are warranted to explore long-term impacts and broader applications.

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Data Availability

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



Authors' Contributions

Conceptualization: AdAM, LFL, RCB Data curation: ECM, MPF, MFL, Formal analysis: AXP, FAMM, IB Methodology: AdAM, LFL, IB, SQP Project administration: AdAM, ECM, MPF, MFL, LFL, SQP Supervision: LFL, AdAM, Writing – original draft – SQP, JN Writing – review & editing: AdAM, AXP, ECM, FAMM, IB, JN, MPF, MFL, LFL, RCB, SQP

Conflicts of Interest

AXP, IB, RCB, SQP, and LFL are current employees at Adhera Health; JN and FAMM are former employees.

Multimedia Appendix 1 Substudy 1 and Adhera Caring Digital Program information and captions. [DOCX File, 935 KB - pediatrics_v8i1e66914_app1.docx]

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Abbreviations

ACDP: Adhera Caring Digital Program
DASS-21: depression, anxiety and stress scale-21 items
GDPR: General Data Protection Regulation
GSE: general self-efficacy scale
HrQoL: health-related quality of life
MHC-SF: mental health continuum-short form
PANAS: positive and negative affect schedule
SS1: Substudy 1
SS2: Substudy 2
T1D: type 1 diabetes

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Digital Interventions for Patients With Juvenile Idiopathic Arthritis: Systematic Review and Meta-Analysis

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Abstract

Background: Juvenile idiopathic arthritis (JIA) is a chronic rheumatic condition requiring long-term, multidisciplinary treatment, which consumes significant health care resources and family energy. This study aims to analyze the effectiveness of digital interventions on patient outcomes in individuals with JIA.

Objective: This meta-analysis aimed to evaluate the impact of digital interventions on alleviating symptoms and improving overall well-being in children and adolescents with JIA.

Methods: A systematic search of 5 databases identified randomized controlled trials assessing the impact of digital interventions on physiological and psychological outcomes in adolescents and children (average age ≤ 19 y). Outcomes included pain, physical activity, health-related quality of life, self-efficacy, and disease-related issues. A total of 2 reviewers independently screened papers and extracted data on intervention functionalities and outcomes, assessing the risk of bias. A meta-analysis using a random-effects model synthesized the results.

Results: The review included 11 studies involving 885 patients with JIA. Digital interventions included educational (eg, self-management training), therapeutic (eg, pain management), and behavioral (eg, promoting physical activity) approaches. These were delivered through websites, telephone consultations, video conferences, apps, and interactive games, with durations ranging from 8 to 24 weeks and no clear link observed between intervention length and outcomes. Compared with conventional control groups, digital interventions were significantly effective in alleviating pain (standardized mean difference [SMD] -0.19, 95% CI -0.35 to -0.04) and enhancing physical activity levels (SMD 0.37, 95% CI 0.06-0.69). Marginal improvements in health-related quality of life, self-efficacy, and disease-related issues were observed, but these did not reach statistical significance (SMD -0.04, 95% CI -0.19 to 0.11; SMD 0.05, 95% CI -0.11 to 0.20; and SMD 0.09, 95% CI -0.11 to 0.29, respectively). The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach rated the quality of evidence for pain, health-related quality of life, self-efficacy, and disease-related issues as moderate, while the evidence quality for physical activity was assessed as low.

Conclusions: Digital interventions can alleviate pain and enhance physical activity in patients with JIA. However, given the limited sample size and high risk of bias in some studies, further high-quality research is needed to improve the treatment and management of JIA.

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KEYWORDS

juvenile idiopathic arthritis; digital intervention; application; children health care; pediatrics

Introduction

Juvenile idiopathic arthritis (JIA) is a prevalent chronic rheumatic ailment affecting children, causing joint pain and inflammation that can disrupt their daily lives [1]. During flare-ups, it can hinder academic performance, social interactions, and normal activities [2], while the complexity of treatment and associated complications further strain health care

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systems and drive up costs [3-6]. Since JIA requires ongoing monitoring and treatment [7,8], patients face a lifelong responsibility for managing the disease as they grow older [9]. Consequently, patients are encouraged to actively engage in lifestyle modifications and health-related decision-making [10]. Physical activity, including aerobic fitness and strength training, is recognized as a helpful nondrug intervention, offering

potential benefits in improving overall well-being and lessening the impact of JIA symptoms [11-13].

Internet-based digital tools, including mobile applications, websites, and other platforms, have become essential components of nonpharmaceutical interventions. These tools enable remote interaction and offer timely responses, making health care resources more accessible [14]. They can provide tailored rehabilitation interventions for pediatric chronic diseases and transitional care [15], such as fostering healthy behavioral habits through social media-based peer coaching [16]. Several mobile medical applications have been developed for adolescents and young individuals with JIA [17-22]. However, the research on their effectiveness has yielded varied results. While some studies have shown promising outcomes in terms of pain alleviation and physical function improvement, others have not replicated these results [22-24]. This variability in research findings highlights the need for further investigation and systematic evaluation to better understand the most effective components and digital health solutions in this domain, ensuring an accurate assessment of the evidence.

To date, previous reviews have assessed the effectiveness of mobile and e-medical interventions in aiding children and adolescents with JIA [25,26]. However, existing reviews have not focused on analyzing randomized controlled trials (RCTs), which could yield more precise results and reduce heterogeneity. The inclusion of only a minimal number of relevant outcomes $(n\leq3)$ in some meta-analyses, such as physical activity, limits the interpretation of findings cautiously and results in the absence of an effective theory of digital interventions for patients with JIA. Consequently, it remains unclear whether such interventions enhance clinical outcomes. Furthermore, as research on mobile medical interventions for JIA patients continues to evolve, it is essential to promptly integrate new research findings. This underscores the necessity for a fresh comprehensive evaluation of clinical interventions in this domain.

Therefore, our study aims to address these gaps by conducting a thorough analysis of digital interventions and their impact on clinical outcomes for patients with JIA.

Methods

Overview

This study follows the guidelines published in Preferred Reporting Items for Systematic reviews and Meta-Analyses [27] and the Cochrane Handbook of Systematic Reviews [28]. The priori protocol for the review is published in the International Prospective Register of Systematic Reviews (PROSPERO CRD42023471223).

Search Strategy

The research was conducted with the guidance and support of institutional librarians. A subject-specific librarian, along with researchers ZR and YC, developed a search strategy without language restrictions, which was used to conduct a comprehensive search in PubMed, Embase, Cochrane Library, Ovid, and Medline [29], covering records from the earliest available to the latest date. The search used Boolean operators

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in combination with Medical Subject Headings terms and free-text keywords to identify studies on the impact of digital interventions on JIA. The following search string was used as an example: ("Juvenile Idiopathic Arthritis") OR "Pediatric Rheumatic Diseases" OR "Juvenile Chronic Arthritis") AND ("mHealth" OR "Digital Health" OR "Mobile Health") AND ("Randomized Controlled Trial" OR "RCT" OR "Clinical Trial"). The full search strategy is provided in Multimedia Appendix 1, the specific keywords used for the search are provided in Multimedia Appendix 2.

The studies identified through this strategy were managed through the literature management software, Zotero (Corporation for Digital Scholarship). The 2 authors, ZR and YC, screened the identified studies, in line with predefined inclusion and exclusion criteria. Any discrepancies during this process were resolved through discussion between the researchers. Multimedia Appendix 1 shows the detailed search formulas. RCTs of any design, including crossover, multicenter, and cross-over trials, that were published in English are included in this review.

Participants

Episodes of JIA typically manifest in individuals before the age of 16 years [30]. However, considering the chronic nature of the condition and the need for ongoing treatment, the minimum age for inclusion in international pediatric treatment reference populations has risen to an average of 18.7 (SD 2.6) years.

Hence, for the purpose of this review, the term "children and adolescents" refers to individuals between the ages of 1 and 19 years [31]. The study population comprises children and adolescents diagnosed with JIA by a rheumatologist, ranging from 1 to 19 years old. Infants and neonates under the age of 1 year were excluded from the study population.

Intervention

In assessing the effectiveness of interventions for JIA recovery, the study focused on digital platforms such as somatic gaming, smart applications, teleconferencing, televideo, and health websites.

Control Condition

All types of control groups were considered in this study, including waitlists, physical therapy or minimal intervention groups, alternative treatments, and standard care delivered through web-based health care websites and apps. For example, the control group may use platforms like jong-en-reuma.nl, which provides information on medical issues and emotional support [32].

Outcome

Primary Outcome

There were 2 primary outcomes: pain (47-item Recalled Pain Inventory and 11-point Numeric Rating Scale) and physical activity (7-day activity diary [subjective], accelerometer [objective measurement], and Duruoz Hand Index Questionnaire.

Secondary Outcome

There were 2 secondar outcomes: health-related quality of life (Juvenile Arthritis Quality of Life Questionnaire, Pediatric Quality of Life Arthritis Module, Dutch Consensus Health Assessment Questionnaire Disability Index, and Pediatric Quality of Life Inventory [version 4.0]), self-efficacy (Children's Arthritis Self-Efficacy scale and Dutch Arthritis Self-Efficacy Scale), and illness-related issues (Medical Issues, Exercise, Pain, and Social Support questionnaire).

Risk of Bias

Risk of bias was assessed using the risk of bias tool of the Cochrane Handbook for Systematic Reviews [28]. Quality of evidence for outcomes was assessed according to the 5 Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) domains, including study limitation (risk of bias), inconsistency, indirectness, imprecision, and publication bias [33]. The bias was assessed by the 2 independent authors, ZR and YL. Any discrepancies were resolved through discussion and reexamination within the research group.

Data Extraction and Analysis

In order to identify and present common statistical descriptions of methodological heterogeneity, a descriptive integrated methodology was used. All findings were interpreted within the context of each study, considering the total number of studies and the assessed risk of bias. Using Review Manager (RevMan) software (version 5.4; Cochrane), this study conducted a random-effect meta-analysis to compare the standardized mean difference (SMD) for parameters across at least 3 studies between patients receiving general care and those using internet-based interventions. SMD and 95% CI were calculated using baseline and study end scores inputted into RevMan 5.4. Forest plots were generated using random-effect models for continuous data, presenting a summary of the effect distribution. Cohen's general rule of experience was applied, where an SMD of 0.2 signifies a "small" effect, 0.5 denotes a "moderate" effect, and 0.8 indicates a "large" effect. Furthermore, subgroup analysis was conducted to assess the impact of professional caregivers and intervention tools on the efficacy of e-medical intervention outcomes. Heterogeneity within the compiled studies was evaluated using I^2 statistics, and the carat test was used to assess significance. Heterogeneity levels were classified as low $(I^2 < 25\%; P > .1)$, moderate $(I^2 = 25\% - 49\%)$, or high $(I^2 > 50\%).$

Results

Literature Selection

We initially identified 1155 studies. After excluding duplicate studies (n=296) and irrelevant studies (n=694), 165 studies remained for abstract evaluation. A total of 154 studies were excluded for the following reasons: conference proceedings (n=47), not trials (n=28), and not RCTs for JIA (n=79). Ultimately, 11 RCTs were included in the meta-analysis. The screening process is illustrated in Figure 1.



Figure 1. Summary of the study selection process using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses). JIA: juvenile idiopathic arthritis.

Identification of studies via databases and registers



Participant Statistics

Table 1 shows the population characteristics, interventions, outcomes and study types of the 11 studies. Of these studies, 3 were from the Netherlands [32,34,35], 5 from Canada [36-40], and 1 each in the United States, Switzerland, and Turkey [38,40,41]. These studies included 289 individuals,

predominantly female children and adolescents (663/885, 74.9%). A variety of juvenile arthritis subtypes were observed, with oligoarthritis being the most prevalent subtype (259/885, 29.3%). Almost all studies, with the exception of one [42], accounted for disease activity. The duration of the disease since diagnosis was documented in the majority of studies (7/11) [32,35-37,39,40,42].



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Table . Population characteristics, interventions, outcomes, and study types of the 11 studies.

Author, country	Particular year	Average age	(years)	Percentage of women, n/N (%)		Subtypes of JIA ^c	Participants		Outcomes	Type of study
		IG ^a	CG ^b	IG	CG		IG	CG		
Lelieveld et al [34], the Nether- lands	2010	10.6 (1.5) ^d	10.8 (1.4) ^d	15/16 (88)	14/16 (88)	55% Persis- tent oligoarticu- lar, 6% extend- ed oligoar- ticular, 27% pol- yarticular, and 12% sys- temic	Internet- based meet- ing	e	Physical activity lev- el, number of days with ≥1 hour of moderate to intense activity per day, aero- bic capaci- ty, maxi- mum heart rate, and resting heart rate.	Pilot ran- domized controlled trial
Stinson et al [36], Canada	2010	14.4 (1.3) ^d	14.8 (1.7) ^d	15/22 (68)	16/24 (67)	22% oligoarticu- lar, 9% oligoar- ticular-ex- tended, 24% pol- yarticular (RF-) ^f , 7% pol- yarticular (RF+), 7% sys- temic, 7% psoriat- ic, 20% enthe- sitis-relat- ed, and 7% Un- known or other	Internet in- tervention	Attention control	Healthy life-related quality (pri- mary out- come), pain intensity, stress, knowledge, adherence, and self-ef- ficacy (sec- ondary out- comes)	Experimen- tal random- ized con- trolled trial



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Author, country	Particular year	Average age	e (years)	Percentage of women, n/N (%)		Subtypes of JIA ^c	Participants		Outcomes	Type of study
		IG ^a	CG ^b	IG	CG		IG	CG		
Stinson et al [37], Canada	2016	14.11 (1.53) ^d	14.42 (2.04) ^d	17/18 (94)	14/14 (100)	19% Pol- yarthritis (RF posi- tive), 19% pol- yarthritis (RF nega- tive), 3% pol- yarthritis (RF status unknown), 31% oligoarthri- tis, 25% psori- atic arthri- tis, and 3% enthesi-	Skype group	Standard care only	Feasibility (primary outcome) Self-man- agement, self-effica- cy, pain, social sup- port, and health-relat- ed quality of life (sec- ondary out- come)	Experimen- tal random- ized con- trolled trial
Ammerlaan et al [32], the Nether- lands	2017	19.1 (2.7) ^d	19.1 (2.9) ^d	29/35 (83)	30/32 (94)	arthritis 21% Oligo- articular JIA, 36% poly- articular JIA, 12% sys- temic JIA, and 31% other	Specific in- ternet project in- tervention and desig- nated web- site	Standard care and designated website	Self-effica- cy (primary outcome), self-man- agement, disease ac- tivity, health-relat- ed quality of life ab- sence from courses , medica- tion use, and adher- ence (sec- ondary out- comes)	Random- ized con- trolled trial



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Author, country	Particular year	Average age	e (years)	Percentage of women, Sin/N (%) of		Subtypes of JIA ^c	Participants		Outcomes	Type of study
		IG ^a	CG ^b	IG	CG		IG	CG		
Armbrust et al [35], the Nether- lands	2017	9.7 (8.7 - 11.3) ^g	10.2 (9.0 - 10.8) ^g	21/28 (75)	12/21 (57)	24% Persis- tent oligoarticu- lar JIA, 14% ex- tended oligoarticu- lar JIA, 37% pol- yarticular JIA, 4% rheumatoid factor posi- tive, 4% enthesitis- related JIA, 4% psoria- sis-related JIA, and 12% sys- temic JIA	Internet in- tervention, school and physical education	Access to standard care, school and physical education	Physical activity (primary outcome), exercise ca- pacity, healthy life-related quality, dis- ease activi- ty, function- al capacity, pain and well-being, and school engage- ment (sec- ondary out- comes)	Multicenter randomized controlled trial
Ramelet et al [43], Switzer- land	2017	h		8/14 (57)	6/10 (60)	29% enthe- sitis-related JIA, 5% undif- ferenciated JIA, 27% oligoarticu- lar JIA, 7% pol- yarticular JIA, 2% sys- temic JIA, and 30% other	Medical and tele- phone care consulta- tions	Medical consulta- tions only	Satisfaction (primary outcome), morning stiffness, and pain (secondary outcome)	Cross-over randomized clinical tri- al
Arman et al [42], Turkey	2019	12.36 (2.98) ^d	13.16 (3.35) ^d	21/25 (84)	21/25 (84)	44% oligoarticu- lar JIA and 56% pol- yarticular JIA	Practice ev- eryday ac- tivities with video- based games (Xbox 360 Kinect)	Practice daily activi- ties with re- al-life mate- rials	Upper ex- tremity function (primary outcome), pain, upper extremity muscle strength, grip and pinch strength, and time- based activ- ity perfor- mance (sec- ondary out- come)	Random- ized clini- cal trial



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Author, country	Particular year	Average age	e (years)	Percentage on n/N (%)	of women,	Subtypes of JIA ^c	Participants		Outcomes	Type of study
		IG ^a	CG ^b	IG	CG		IG	CG		
Chadi et al [38], Cana- da	2019	15.4 (13- 18) ⁱ	15.2 (13- 17) ⁱ	7/9 (78)	7/9 (78)	_	Take video conferenc- ing courses at home	Take of- fline cours- es in hospi- tal	Acquisition of positive thinking skills (pri- mary out- come), mood and anxiety, self-es- teem, ill- ness percep- tion, sali- vary corti- sol changes (secondary outcome)	Pilot ran- domized controlled trial
Connelly et al [41], United States	2019	14.6 (1.8) ^d	14.5 (1.7) ^d	98/144 (68)	111/145 (77)	21% Oligoarticu- lar (extend- ed or persis- tent), 45% pol- yarticular (RF-, RF+ ,or RF un- known), 34% other (enthesitis- related JIA, psoriatic, systemic, and undif- ferentiated)	Teens tak- ing charge	An educa- tional web- site	Pain inter- ference and intensity, health-relat- ed quality of life (pri- mary out- come), self-effica- cy, pain coping, emotional regulation, and condi- tion knowl- edge (sec- ondary out- come)	Multicenter randomized clinical tri- al
Stinson et al [39], Canada	2020	14 (1.5) ^d	14.5 (1.7) ^d	63/88 (72)	91/131 (70)	2% Sys- temic, 21% oligoarthri- tis, 11% oligoarthri- tis—extend- ed, 23% pol- yarthritis (RF-), 9% pol- yarthritis (RF+), 11% psori- atic arthri- tis, 16% enthe- sitis-related arthritis, 4% undif- ferentiated, and 3% other	Specific website and phone consulta- tions	Public web- site and telephone consulta- tion	Pain intensi- ty, pain in- terference and HRQL ^j (primary outcomes), emotional symptoms, compli- ance, cop- ing, knowl- edge, and self-effica- cy (sec- ondary out- comes)	Random- ized con- trolled trial



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Author, country	Particular year	Average age	e (years)	Percentage n/N (%)	of women,	Subtypes of JIA ^c	Participants		Outcomes	Type of study
		IG ^a	CG ^b	IG	CG		IG	CG		
Lalloo et al [40], Cana- da	2021	14.9 (1.7) ^d	15.1 (1.6) ^d	23/29 (79)	24/31 (77)	5% Sys- temic, 16% oligoarthri- tis, 9% oligoarthri- tis-extend- ed, 24% pol- yarthritis (RF-), 5% pol- yarthritis (RF+), 12% psori- atic arthri- tis, 21% enthe- sitis-related arthritis, 5% undif- ferentiated, and 3% other	iCanCope application version, in- cluding symptoms tracking and other functions	A version of icancope that only contains the symp- tom follow- ing feature	Participant accrual and attrition rates, suc- cess rate of app deploy- ment, ac- ceptability and compli- ance (pri- mary out- comes), pain intensi- ty, pain-re- lated activi- ty limita- tions, and health-relat- ed quality of life (sec- ondary out- comes)	Random- ized con- trolled trial

^aIG: intervention group.

^bCG: control group.
^cJIA: juvenile idiopathic arthritis.
^dMean (SD).
^eNot available.
^fRF: rheumatoid factor.
^gMedian (IQR).
^hThis study only showed the mean age of the overall group (13.1 years).
ⁱMedian (age range).
^jHRQL: health-related quality of life.

Intervention Group

Overview

Table 2 demonstrates main digital tools and methods. A total of 6 studies implemented internet-based physical activity intervention programs, health management websites, and telephone support initiatives. Among these, 4 studies included

routine telephone consultations and interviews. In addition, 1 study used video conferences for skills training [38], while another used self-management pain applications on mobile phones for experimentation [40]. In addition, an emotional games-based task-oriented activity training study was conducted [42]. All interventions examined lasted at least 8 weeks, with the longest intervention cycle spanning 18 months [35].



Table . Main intervention methods.

Author, country	Digital tools or met		Duration of inter- vention			
	Specific websites	Telephones	Videoconferencing	Application	Somatosensory game	
Lelieveld et al [34], the Netherlands	1					17 weeks
Stinson et al [36], Canada		\checkmark				12 weeks
Stinson et al [37], Canada		\checkmark				8 weeks
Ammerlaan et al [32], the Netherlands	1					24 weeks
Armbrust et al [35], the Netherlands	1					18 months
Ramelet et al [43], Switzerland		\checkmark				12 months each
Arman et al [42], Turkey					\checkmark	8 weeks
Chadi et al [<mark>38</mark>], Canada	1		1			8 weeks
Connelly et al [41], United States	1					12 weeks
Stinson et al [39], Canada	1	\checkmark				12 weeks
Lalloo et al [40], Canada				1		8 weeks

Functional Classification of Interventions

Digital interventions for patients with JIA are versatile, serving multiple functions. The purposes of these interventions include promoting physical activity (n=4), facilitating self-management for establishing healthy habits and reaching milestones (n=4), providing education on disease and health-related knowledge (n=8), offering stress relief to improve mood (n=4), and enhancing communication skills for better integration into school and society (n=7). Furthermore, half of the studies (n=7) supplemented the digital intervention program with telephone and video communication to augment its positive impact on children.

Statistics of Digital Interventions

A total of 8 studies used internet-based interventions based on previously developed projects or applications (Table 3). In addition, 3 studies used the Teens Taking Charge website as an intervention [36,39,41]. Furthermore, 2 studies used Rheumates@Work as an intervention [34,35]. For the experimental group's digitization project, 1 study used iPeer2Peer [37], Challenge your arthritis [32], and iCanCope [40]. Of all the intervention schemes, only 1 study referenced the theoretical framework as nursing guidance for their intervention schemes [43]. Care assessments conducted by nurses were guided and documented using Cox's interaction model of client health behavior [44] to ensure the continuity of care for children and their families.



Table . Names and functions of digital intervention tools.

Author, country	Intervention project name	Main functions					Additional func- tions
		Promote physi- cal activity	Set goals	Health education	Manage emo- tions	Integrate into school or society	Video or phone consultation
Lelieveld et al [34], the Nether- lands	Rheu- mates@Work	1		1		·	
Stinson et al [36], Canada	Teens Taking Charge	1	1	1	1	1	1
Stinson et al [37], Canada	iPeer2Peer			1	1	1	1
Ammerlaan et al [32], the Nether- lands	Challenge your arthritis		✓			✓	
Armbrust et al [35], the Nether- lands	Rheu- mates@Work	1		1		√	
Ramelet et al [43], Switzer- land	a			1		√	1
Arman et al [42], Turkey	Xbox 360 Kinect	1					
Chadi et al [38], Canada	_			✓	1		1
Connelly et al [41], United States	Teens Taking Charge			1	<i>√</i>		1
Stinson et al [39], Canada	Teens Taking Charge		1			1	1
Lalloo et al [40], Canada	iCanCope		1	✓		1	

^aNot available.

While enhancing self-management skills is vital for facilitating health care transition [45], only 2 RCTs [32,37] explicitly reported on self-management outcomes. The remaining articles primarily integrated self-management as a core component of digital interventions, with considerations on health education, goal setting, and mood management.

Control Group

One study in this review did not specify the care received by the control group [34]. A total of 5 studies compared the intervention group to a control group that received standard or offline care (without internet and eHealth interventions) [35,37,38,42,43]. One study solely used telephone coaching communication [36]. A total of 4 studies compared a control group using a public website or eHealth with limited functionality to an intervention group receiving a specific digital design program [32,39-41]. The control groups in all trials assessed patients' results at pretest and posttest.

Risk of Bias Assessment

The results of the risk of bias assessment indicate that the criteria most commonly unmet were the blinding of outcome assessment and the adequacy of outcome data (Figure 2). Half of the studies (5/11 and 6/11) were deemed to have a high risk of bias in these 2 categories. In contrast, studies concerning randomized sequence generation were predominantly evaluated as having a low risk (9/11). Furthermore, 7 studies exhibited a medium risk of bias, while 4 studies were categorized as having a high risk of bias.

Figure 2. Risk of bias summary [32,34-43].

Quality of Evidence Rating

Table 4 presents the key comparative results with GRADEratings. A total of 3 primary outcomes are rated as moderatequality, while 2 primary outcomes are rated as low quality.



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Table . Main comparative findings and recommendation grading.

Author (Year of publication)	Outcome	OR ^a (95% CI)	Studies (pa- tients), n	Risk of bias	Inconsisten- cy	Indirectness	Inaccuracy	Publication bias	Quality of evidence
Stinson et al [36] (2010), Stinson et al [37] (2016), Ammerlaan et al [32] (2017), Con- nelly et al [41] (2019), and Stinson et al [39] (2020).	Pain	-0.19 (-0.35 to -0.04)	5 (653)	Downgrade (High risk of incomplete data)	Nondegrada- tion	Nondegrada- tion	Nondegrada- tion	Nondegrada- tion	Moderate
Lelieveld et al [34] (2010), Am- merlaan et al [32] (2017), Armbrust et al [35] (2017), and Arman et al [42] (2019).	Physical ac- tivity	0.37 (0.06- 0.69)	4 (160)	Downgrade (High risk of selective re- porting)	One level down (low overlap)	Nondegrada- tion	Nondegrada- tion	Nondegrada- tion	Low
Stinson et al [36] (2010), Stinson et al [37] (2016), Ammerlaan et al [32] (2017), Arm- brust et al [35] (2017), Connelly et al [41] (2019), and Stinson et al [39] (2020).	Health-relat- ed quality of life	-0.02 (-0.17 to 0.13)	6 (702)	Downgrade (High risk of incomplete data)	Nondegrada- tion	Nondegrada- tion	Nondegrada- tion	Nondegrada- tion	Moderate
Stinson et al [36] (2010), Stinson et al [37] (2016), Ammerlaan et al [32] (2017), Con- nelly et al [41] (2019), and Stinson et al [39] (2020).	Self-efficacy	0.05 (-0.11 to 0.20)	5 (653)	Downgrade (High risk of incomplete data)	Nondegrada- tion	Nondegrada- tion	Nondegrada- tion	Nondegrada- tion	Moderate
Stinson et al [36] (2010), Stinson et al [37] (2016), Chadi et al [38] (2019), Connelly et al [41] (2019), and Stinson et al [39] (2020).	Disease-relat- ed issues	0.09 (-0.11 to 0.29)	5 (604)	Downgraded one level (high risk of blinding of outcome as- sessments)	One level down (low overlap)	Nondegrada- tion	Nondegrada- tion	Nondegrada- tion	Low

^aOR: odds ratio.

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Meta-Analysis Results

Pain

Figure 3 depicts the impact of digital medical intervention on pain outcomes relative to all other control conditions. This analysis is based on findings from 5 studies involving 653

Figure 3. Effectiveness of digital health on pain outcomes [32,36,37,39,41].

Experimental Control Std. mean difference Std. mean difference Study or subgroup (year) Mean (SD) Total Mean (SD) Total Weight IV. Random (95%CI) IV. Random (95%CI) Stinson et al (2010) -0.56 (1.90) 22 0.47 (3.03) 24 7% -0.40 (-0.98 to 0.19) Stinson et al (2016) -0.33 (1.96) 18 -0.22 (2.10) 14 4.9% -0.05 (-0.75 to 0.65) Stinson et al (2020) -0.60 (2.50) 32.6% -0.27 (-0.54 to 0.00) -1.23 (2.13) 88 131 Ammerlaan et al (2017) 0.06 (3.26) 35 0.27 (3.07) 32 10.4% -0.07 (-0.55 to 0.41) Connelly et al (2019) -0.15 (-0.38 to 0.08) -0.70(2.72)144 -0.30(2.72)145 45% Total (95%CI) 307 346 100% -0.19 (-0.35 to -0.04) Heterogeneity: Tau²=0.00; Chi-square (df)=1.33 (4), P=.86; /²=0% -0.5 0.5 -1 Test for overall effect: z=2.41, P=.02 Favors [experimental] Favors [control]

intervention.

intervention.

Physical Activity

Figure 4 demonstrates the results of the effectiveness of using digital health care on patients' physical activity compared to using usual care and public websites. This analysis is based on findings from 4 studies involving 160 participants. The digital

Figure 4. Effectiveness of digital health on physical activity outcomes [32,34,35,42].



Health-Related Quality of Life

A total of 6 studies with 702 participants comparing digital interventions and control conditions did not show a difference in health-related quality of life between the 2 intervention

conditions (SMD 0.02, 95% CI -0.17 to 0.13); heterogeneity (*P*=.97; *P*=0%; Figure 5). Using the GRADE approach, the quality of evidence was rated moderate because of the high risk of bias in most studies (ie, incomplete data).

participants. A significant effect in favor of the intervention

was observed (SMD -0.19, 95% CI -0.35 to -0.04; P=.86;

 $I^2=0\%$). Several studies posed a high risk of bias, resulting in

a moderate GRADE rating for the quality of evidence after the

intervention had a statistically significant positive effect (SMD

0.37, 95% CI 0.06-0.69), and the results were not highly

heterogeneous (P=.50; P=0%). Several studies posed a

moderate-to-high risk of bias and inconsistency, resulting in a

low GRADE rating for the quality of evidence after the

Figure 5. Effectiveness of digital health on health-related quality of life [32,35-37,39,41].

Experimental		Control		Std. mean difference			Std. mean difference				
Study or subgroup (year)	Mean (SD)	Total	Mean (SD)	Total	Weight	IV. Random (95%CI)		IV.	Random (95	%CI)	
Stinson et al (2010)	-0.84 (2.04)	22	-0.77 (2.63)	24	6.6%	-0.03 (-0.61 to 0.55)			-		
Stinson et al (2016)	0.56 (80.30)	18	-0.35 (78.06)	14	4.6%	0.01 (-0.69 to 0.71)					
Stinson et al (2020)	2.30 (63.46)	88	-1.77 (58.5)	131	30.4%	0.07 (-0.20 to 0.34)			_ 	_	
Ammerlaan et al (2017)	-0.04 (0.68)	35	0.08 (0.72)	32	9.6%	-0.17 (-0.65 to 0.31)				_	
Connelly et al (2019)	3.10 (69.04)	144	5.40 (71.10)	145	41.8%	-0.03 (-0.26 to 0.20)		-			
Armbrust et al (2017)	1.60 (72.20)	28	9.70 (74.86)	21	6.9%	-0.11 (-0.67 to 0.46)			-		
Total (95%CI)		335		367	100%	-0.02 (-0.17 to 0.13)			+		
Heterogeneity: Tau ² =0.00;	Chi-square (df)	=0.89 (5)	, P=.97; I ² =0%					0.5		0.5	
Test for overall effect: z=.2	24, <i>P</i> =.81						-,	avors [experime	ontall Eavo	rs [control]	

Self-Efficacy

A total of 5 studies with 653 participants comparing digital interventions and control conditions did not show a difference in self-efficacy between the 2 intervention conditions (SMD

0.05, 95% CI -0.11 to 0.20); heterogeneity (*P*=1.00; *P*=0%; Figure 6). Using the GRADE approach, the quality of evidence was rated moderate because of the high risk of bias in most studies (ie, incomplete data).



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Figure 6. Effectiveness of digital health on self-efficacy outcomes [32,36,37,39,41].

	Experimental		Contr	rol		Std. mean difference		Std. n	nean differ	ence	
Study or subgroup (year)	Mean (SD)	Total	Mean (SD)	Total	Weight	IV. Random (95%CI)		IV. Ra	ndom (95	%CI)	
Stinson et al (2010)	1.03 (7.00)	22	0.61 (6.67)	24	7.1%	0.06 (-0.52 to 0.64)			- -		
Stinson et al (2016)	2.70 (35.71)	18	0.50 (35.44)	14	4.9%	0.06 (-0.64 to 0.76)			<u> </u>		
Stinson et al (2020)	12.54 (68.08)	88	7.19 (61.04)	131	32.7%	0.08 (-0.19 to 0.35)		-		_	
Ammerlaan et al (2017)	-0.16 (5.81)	35	-0.15 (6.14)	32	10.4%	-0.00 (-0.48 to 0.48)			-		
Connelly et al (2019)	0.50 (3.41)	144	0.40 (3.34)	145	44.9%	0.03 (-0.20 to 0.26)		-			
Total (95%CI)		307		346	100%	0.05 (-0.11 to 0.20)			•		
Heterogeneity: Tau ² =0.00;	Chi-square (df)	=0.13 (4)	, P=1.00; I ² =0%	b				-0.5		0.5	1
Test for overall effect: z=.6	50, <i>P</i> =.55						-,	Favors [contro	ol] Favor	s [experimental]]

Disease-Related Issues

Figure 7 demonstrates the effectiveness of interventions using digital health technology on patient outcomes for disease-related problems compared with other control conditions. A total of 5 studies included 604 participants (SMD 0.09, 95% CI -0.11 to

0.29) suggests that the effect is ultimately insignificant. The results exhibit minimal heterogeneity (P=.29, P=19%). The evidence following the intervention was assessed as moderate in quality using the GRADE methodology, owing to the presence of bias risk and inconsistency across certain studies.

heterogeneity $\chi^2_2=0.85$; P=.66; P=0%; Figure 8). However, our

findings showed no significant effect of iPeer2Peer and

Challenge Your Arthritis (n=2) on pain (SMD -0.06, 95% CI -0.46 to 0.33; heterogeneity $\chi^2_1=0.00$; P=.98; P=0%). Subgroup

differences in pain outcomes were not significant between peer

mentoring programs and other internet programs (P=.49; P=0%).

Figure 7. Effectiveness of digital health on disease-related issues [36-39,41].

	Experim	ental	Contr	ol		Std. mean difference	Std. mean difference
Study or subgroup (year)	Mean (SD)	Total	Mean (SD)	Total	Weight	IV. Random (95%CI)	IV. Random (95%CI)
Stinson et al (2010)	2.64 (6.51)	22	0.46 (3.61)	24	10.4%	0.41 (-0.17 to 1.00)	
Stinson et al (2016)	2.22 (42.24)	18	-1.57 (39.31)	14	7.5%	0.09 (-0.61 to 0.79)	
Stinson et al (2020)	22.76 (61.36)	88	16.36 (56.41)	131	35.2%	0.11 (-0.16 to 0.38)	- +
Connelly et al (2019)	1.50 (5.58)	144	1.9 (5.71)	145	42.7%	-0.07 (-0.30 to 0.16)	
Chadi et al (2019)	8.57 (12.51)	9	-0.86 (9.93)	9	4.1%	0.80 (-0.17 to 1.76)	
Total (95%CI)		281		323	100%	0.09 (-0.11 to 0.29)	•
Heterogeneity: Tau ² =0.01	; Chi-square (df):	=4.97 (4)	, P=.29; / ² =19%				
Test for overall effect: z=.	89, P=.38						-1 -0.5 0 0.5 1
							Favors [control] Favors [experimental]

Subgroup Analysis

Effects of Peer Mentoring on Pain Outcome

The subgroup analysis revealed that the internet-based self-management program (n=3) resulted in a moderate effect size in pain reduction (SMD -0.21, 95% CI -0.38 to -0.05;

Figure 8. Effects of peer mentoring on pain outcomes [32	2,36,37,39,41].
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Std. mean difference Std. mean difference Experimental Control Study or subgroup (year) Mean (SD) Tota Weight IV. Random (95%CI) IV. Random (95%CI) Mean (SD) Total 1.1.1 Peer-based self-management projects Stinson et al (2016) -0.33 (1.96) 18 -0.22 (2.10) 14 4.9% -0.05 (-0.75 to 0.65) Ammerlaan et al (2017) 0.27 (3.07) 32 0.06 (3.26) 35 10.4% -0.07 (-0.55 to 0.41) 46 Subtotal (95%CI) 53 15.4% -0.06 (-0.46 to 0.33) Heterogeneity: Tau²=0.00; Chi-square (df)=0.00 (1), P=.98; I²=0% Test for overall effect: z=.31, P=.76 1.1.2 Internet-based self-management projects Stinson et al (2010) 0.47 (3.03) 7% -0.40 (-0.98 to 0.19) -0.56 (1.90) 22 24 Stinson et al (2020) -1.23 (2.13) 88 -0.6 (2.50) 131 32.6% -0.27 (-0.54 to 0.00) -0.15 (-0.38 to 0.08) Connelly et al (2019) -0.70 (2.72) 144 -0.30 (2.72) 145 45% 254 -0.21 (-0.38 to -0.05) Subtotal (95%CI) 300 84.6% Heterogeneity: Tau²=0.00; Chi-square (df)=0.85 (2), P=.66; I²=0% Test for overall effect: z=2.49, P=.01 Total (95%CI) 307 346 100% -0.19 (-0.35 to -0.04) Heterogeneity: Tau²=0.00; Chi-square (df)=1.33 (4), P=.86; I²=0% -0.5 -1 0.5 1 0 Test for overall effect: z=2.41, P=.02

Test for subgroup differences: Chi-square (df)=0.48 (1), P=.49; I²=0%



the intervention (SMD 0.51, 95% CI 0.01 to 1.02 and SMD 0.01, 95% CI –0.16 to 0.18, respectively; Figure 9). However, the difference was not statistically significant (SMD 0.09, 95% CI -0.01 to 0.29; heterogeneity χ^2_4 =4.97; *P*=.29; *P*=19%).

Favors [experimental]

Effects of Physicians on Disease-Related Issues Outcome

The disease-related issues in studies with physicians improve more than those without physicians as the main component of

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Favors [control]

Figure 9. Effectiveness of e-health on disease-related issues when physicians are involved [36-39,41].

	Experimental		Control		Std. mean difference		Std. mean difference		
Study or subgroup (year)	Mean (SD)	Total	Mean (SD)	Total	Weight	IV. Random (95%CI)	IV. Random (95%CI)		
1.5.1 Doctors are involved					_				
Stinson et al (2010)	2.64 (6.51)	22	0.46 (3.61)	24	10.4%	0.41 (-0.17 to 1.00)			
Chadi et al (2019)	8.57 (12.51)	9	-0.86 (9.93)	9	4.1%	0.80 (-0.17 to 1.76)			
Subtotal (95%CI)		31		33	14.5%	0.51 (0.01 to 1.02)			
Heterogeneity: Tau ² =0.00; Chi-square (df)=0.44 (1), P=.51; <i>I</i> ² =0%									
Test for overall effect: z=2.0	01, <i>P</i> =.04								
1.5.2 Doctors are not invol	ved								
Stinson et al (2016)	2.22 (42.24)	18	-1.57 (39.31)	14	7.5%	0.09 (-0.61 to 0.79)			
Stinson et al (2020)	22.76 (61.36)	88	16.36 (56.41)	131	35.2%	0.11 (-0.16 to 0.38)			
Connelly et al (2019)	1.50 (5.58)	144	1.90 (5.71)	145	42.7%	-0.07 (-0.30 to 0.16)	-		
Subtotal (95%CI)		250		290	85.5%	0.01 (-0.16 to 0.18)	—		
Heterogeneity: Tau ² =0.00; (Test for overall effect: <i>z</i> =.12	Chi-square (df): 2, P=.91	=1.04 (2)	, P=.60; I ² =0%						
Total (95%CI)		281		323	100%	0.09 (-0.11 to 0.29)	•		
Heterogeneity: Tau ² =0.01; Chi-square (df)=4.97 (4), P=.29; I ² =19%									
Test for overall effect: z=.89, P=.38							-1 -0.5 0 0.5 1		
Test for subgroup difference	es: Chi-square	(df)=3.49	9 (1), P=.06; I ² =7	71.4%			Favors [control] Favors [experimental]		

Discussion

Principal Findings

This systematic review comprehensively assessed studies on the effectiveness of digital interventions in aiding children and adolescents with JIA from physical and psychologically perspectives. According to the findings, patients who received digital medical technology interventions had significantly better physical activity outcomes (SMD 0.37, 95% CI 0.06-0.69) and experienced a reduction in pain outcomes (SMD -0.19, 95% CI -0.35 to -0.04) in comparison with those who received standard care. However, our research did not identify significant enhancements in disease-related issues (SMD 0.09, 95% CI -0.11 to 0.29), health-related quality of life (SMD -0.02, 95% CI -0.17 to 0.13), or self-efficacy (SMD 0.05, 95% CI -0.11to 0.20).

Primary Findings

Overview

The use of digital interventions delivered through the internet or mobile devices has expanded mental health practices for children and adolescents facing JIA in local contexts [46,47]. These interventions offer flexible training schedules, overcome constraints of space and time [48], ensure anonymity, and allow for behavioral adaptation. Nevertheless, our findings indicate that interventions using digital medical technology have a more pronounced impact on physiological outcomes, aligning with earlier research conducted by Butler et al [26]. This emphasis on physiological outcomes may be attributed to the inclusion of components targeting physical activity and motor skills in the interventions, such as fitness regimens, varied exercises, and intensive training. However, the interpretation of psychological outcomes is more complex, influenced by various factors including personal psychological state, social environment, and cultural background. In addition, achieving and sustaining psychological transformations often requires an extended period. While these potential reasons have not been examined, our findings indeed illuminate the distinct physiological and psychological effects of digital medical interventions, offering a new perspective for understanding and evaluating their merits. Further investigation is needed to

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compare the impacts of digital medical interventions on physiological and psychological outcomes, and to identify strategies for optimizing intervention effectiveness in diverse contexts.

Pain

Our findings demonstrated a notable reduction in pain-related outcomes following the implementation of digital interventions. Two of these studies focused on young patients with JIA transitioning to adult care facilities, who demonstrated high self-efficacy and positive attitudes. In addition, 3 studies implemented a telephone-based therapeutic communication intervention. Subgroup analysis outcomes revealed that patients using an internet-based self-management program (Teens Taking Charge) [36,39,41] experienced a great reduction in pain symptoms compared with those using a peer-directed self-management program [32,37]. These findings align with a pilot feasibility study on peer coaching for adolescents with chronic pain [18], where the control group showed superior pain reduction status. This discrepancy may be attributed to the absence of explicit pain symptom sections in the self-management programs examined, which focused instead on social relationships and goal-setting. In contrast, the control group's website included comprehensive content addressing pain understanding and management, alongside audio and video features. In addition, Dennis et al [49] demonstrated that trained peer mentors could provide informational, evaluative, and emotional support to individuals with similar conditions, albeit without explicitly addressing pain relief. Hence, there is a need for studies about the usability of digital tools for managing pain symptoms in future research. These tools should go beyond mere documentation of pain symptoms and incorporate functionalities aimed at alleviating functional limitations, providing medication and exercise guidance, and offering strategies for managing low mood. Such enhancements are essential for improving the quality of life for patients coping with pain [50].

Physical Activity

Engaging in physical activity is essential for managing arthritis in patients [51]. Consistent with previous research findings [26], 4 findings emphasized the positive impacts of the internet interventions on physical activity. The majority of these studies

incorporate clinically recommended activity training, which increases physical activity levels and improves endurance among patients. Studies suggest that individuals with arthritis can prevent disability and complications by promoting healthy physical activity throughout their lives [52]. However, as demand for face-to-face health care interventions for supporting physical activity adoption and maintenance increases, resource constraints become more pronounced [53]. In a previous study, serious games were used in joint rehabilitation for patients with JIA [54-56]. The findings indicated that these interventions led to increased levels of physical activity among the patients. Our findings support this observation, as 1 of the 4 studies using video games for task-oriented activity training [42] showed improvements in patient outcomes. However, concerns have arisen regarding potential inaccuracies in the effectiveness of exercise diaries and activity monitoring accelerometers used by children. Therefore, there is a need for more accurate methods of data acquisition. We advocate for the development of additional digital tools that integrate health education and physical activity-focused content.

Secondary Findings

The secondary outcomes such as self-efficacy, health-related quality of life, and perception of disease-related issues did not show statistical significance. The previous research shows similar results. Lancaster et al [57] and Newby et al [58] did not find positive impacts of digital interventions on self-efficacy and quality of life. This discrepancy may be attributed to the measurement of self-efficacy which may not be adequately tailored to the conceptual, linguistic, and objective needs of children [32]. However, it is anticipated that improvements in quality of life may require more time to manifest [59], and changes might not be evident during shorter intervention periods. The Medical Issues, Exercise, Pain, and Social Support questionnaire, encompassing inquiries regarding medical matters, physical activity, psychological well-being, and social support [60], may experience compromised efficacy if a patient is insensitive to one of its components, indicating a limited awareness of disease-related concerns.

Other Findings

It is worth noting that not all psychological interventions are ineffective. The subgroup findings show that when physicians are involved in intervention implementation, children and adolescents show improved understanding of disease-related issues. Previous research shows that online health communities involving both patients and health care providers can improve mental health in chronic conditions by allowing patients to consult and interact with physicians [61,62]. Physicians provide essential health knowledge, emotional support, and guidelines for the use of medical supplies, which is crucial for improving the health status of individuals with chronic conditions [63]. To improve intervention outcomes, digital interventions should incorporate features for real-time interaction with healthcare providers, enabling physicians to offer clinical insights and socioemotional support, thereby strengthening the doctor-patient relationship and improving health outcomes.

Furthermore, video-based mindfulness interventions have shown benefits for populations with chronic illnesses and other conditions [64,65]. A study comparing the efficacy of online mindfulness interventions and in-person interventions in enhancing the mental well-being of patients with JIA observed a notable decrease in anxiety and depression [38]. This reduction may be attributed to adolescents experiencing greater ease and relaxation in the familiar setting of their homes [66]. Furthermore, Voerman et al [67] found that digital interventions incorporating cognitive behavioral therapy led to significant improvements in the psychological and social outcomes of patients. Specifically, relaxation exercises and cognitive behavioral therapy effectively reduced pain frequency in children and adolescents, alleviating depressive symptoms and functional disorders [68]. Future investigations should aim to integrate a theoretical framework that addresses the psychological dimensions of the condition, ensuring a more comprehensive approach to intervention design.

Limitations

Half of the studies (5/11) used digital tools that have been developed for over a decade, they may thus fail to represent the latest advancements in communication technologies and platforms. However, our findings indeed show their continued relevance and effectiveness. Second, the results of this review demonstrate that, from a statistical perspective, digital interventions are effective for certain patient outcomes. However, considering factors such as individual differences and variability in clinical environments, their clinical significance remains to be further validated. Future research should provide stronger evidence from a clinical perspective. Furthermore, the included studies are predominantly conducted in North American and European nations. As such, the findings of this analysis may not be universally applicable and may only offer insights into the integration of digital interventions within this specific population.

Conclusions

This systematic review analyzes self-reported outcomes in patients with JIA, including pain, physical activity, quality of life, self-efficacy, and disease-related issues. The findings from 11 RCTs demonstrate that digital interventions significantly alleviate pain and improve physical activity. These results highlight the potential of digital tools to enhance JIA management and patient outcomes, providing a strong case for their integration into clinical practice. Future studies should consider the inclusion of physicians in digital interventions to better understand their impact on outcomes.

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Data Availability

The meta-analysis conducted in this study is based on data retrieved from the following open-source databases: MEDLINE, PubMed, Embase, Ovid, and Cochrane. The data from these databases are publicly available and can be directly accessed through their respective websites or DOI links. The analyses presented in this paper are based on these public datasets, and the specific data retrieval dates and search strategies have been detailed in the Methods section of the paper.

Authors' Contributions

ZR had full access to all of the data in the study and took responsibility for the integrity of the data and the accuracy of the data analysis. ZR and YC contributed to the study concept and design. All authors contributed to the acquisition, analysis, or interpretation of data. ZR contributed to the drafting of the manuscript. All authors contributed to the critical revision of the manuscript for important intellectual content. YL and ZR performed statistical analysis. YC and ZR contributed to administrative, technical, or material support. YL and YC performed supervision.

Conflicts of Interest

None declared.

Multimedia Appendix 1 Search strategy. [DOCX File, 42 KB - pediatrics_v8i1e65826_app1.docx]

Multimedia Appendix 2 Medical Subject Headings (MeSH) terms and free-text keywords. [DOCX File, 18 KB - pediatrics_v8i1e65826_app2.docx]

Checklist 1

PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) 2020 checklist. [DOCX File, 34 KB - pediatrics_v8i1e65826_app3.docx]

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Abbreviations

GRADE: Grading of Recommendations, Assessment, Development, and Evaluation **JIA:** juvenile idiopathic arthritis **RCT:** randomized controlled trial **RevMan:** Review Manager

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Children's and Their Parents' Experiences With Home-Based Guided Hypnotherapy: Qualitative Study

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Abstract

Background: Management of children with functional abdominal pain (FAP) or irritable bowel syndrome (IBS) is difficult in primary care. When education and reassurance do not alleviate symptoms, primary care physicians lack treatment options for children with FAP or IBS. Home-based guided hypnotherapy is a promising treatment because of its accessibility. To address feasibility, it is of utmost importance to take experiences from children and their parents into account.

Objective: We aimed to explore children's and their parents' experiences with home-based guided hypnotherapy for children with FAP or IBS.

Methods: This qualitative study used open-ended questions from a questionnaire and in-depth semistructured interviews with children and their parents who had a hypnotherapy intervention prescribed. The interviews were audio-recorded and transcribed verbatim. Data were collected and analyzed iteratively using thematic content analysis.

Results: A total of 76 children were eligible, and we collected questionnaire data from 56 children. A total of 23 interviews were conducted with 10 children and 15 parents. Six themes emerged from questionnaire data and interviews: impression of the exercises, not for everyone, influence of perceived effect, integrating exercises in daily life, content and practicalities of the website, and customization to personal preferences. Children with FAP or IBS experienced home-based guided hypnotherapy and the exercises differently, ranging from boring to fun. From interviews with the parents, it emerged that hypnotherapy is not suitable for everyone; for example, when children are very young or have a low developmental level, cannot sit still, cannot surrender to the exercises, or are too energetic or stressed, it might be difficult to comply. Experiences were shaped by the influence of a perceived effect and to which extent children were able to integrate exercises in daily life. The content and practicalities of the website also influenced experiences, and hypnotherapy that is adaptable to personal preferences, including by appearance and content, would be highly appreciated.

Conclusions: The children and parents experienced home-based guided hypnotherapy differently, ranging from boring to fun. Hypnotherapy might be difficult or boring for some children. The children enjoyed hypnotherapy when they liked the topic or story, felt positive effects, could easily integrate exercises in daily life, or enjoyed the website in general. The children's experiences and adherence can be further improved by adding short exercises and customizing hypnotherapy to their personal preferences on the website's appearance and content. This could increase effectiveness but must be studied further.

Trial Registration: ClinicalTrials.gov NCT05636358; https://clinicaltrials.gov/study/NCT05636358

International Registered Report Identifier (IRRID): RR2-10.1136/bmjopen-2022-069653

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KEYWORDS

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qualitative study; primary health care; children; functional abdominal pain; irritable bowel syndrome; hypnotherapy; eHealth; abdominal pain; child; parents; accessibility; questionnaire; interviews; thematic analysis; home guided; primary care; mobile phone

Introduction

Disorders of gut-brain interaction such as functional abdominal pain (FAP) and irritable bowel syndrome (IBS) are chronic pain conditions without organic cause [1]. These disorders are common in primary care, as a general practitioner (GP) sees approximately 10 children with disorders of gut-brain interaction each year [2,3]. Dutch GPs diagnose FAP or IBS when after medical history and physical examination, no underlying tissue damage, somatic causes, or metabolic or anatomic abnormalities can explain the symptoms of the child [4]. FAP and IBS are associated with lower quality of life, school absence, and higher anxiety and depression scores [5,6], and around 50% of children in primary care still report abdominal complaints one year later [7]. Management consists of education and reassurance, but if this fails to alleviate symptoms, there are few evidence-based treatment options in primary care. Children with abdominal pain and their parents report a desire for receiving a specific diagnosis and a need for information about its cause and treatment options [8-10]. Children often adopt coping mechanisms by themselves, such as reassurance and a calm approach, distraction techniques, breathing exercises, and bedtime meditation [11]. Hypnotherapy could be a treatment option, as it has shown to be effective in children referred to secondary pediatric care [12,13]. However, it has not been studied in primary care. Research in primary care is important because a different setting, selection of patients, and organization of care might influence treatment effects.

With hypnotherapy, a patient is induced into a hypnotic state and guided to suggestions by a therapist or by listening to audio-recorded exercises in their home environment (ie, home-based guided hypnotherapy) [13,14]. Home-based guided hypnotherapy is promising in primary care because of its accessibility [15]. Very few mild to moderate side effects of hypnotherapy are reported [16], and the fact that children can do it by themselves without involvement of others makes primary care an interesting setting. Experiences with home-based guided hypnotherapy in children with FAP or IBS have not been studied yet. Insights in experiences of children and their parents are important for successful implementation [17]. In this study, we aimed to explore experiences of children with FAP or IBS and their parents with home-based guided hypnotherapy, and to capture their ideas about potential areas for improvement.

Methods

Design

This qualitative study is part of the ZelfHy study, a randomized controlled trial (RCT) evaluating the effectiveness and cost-effectiveness of home-based guided hypnotherapy in children with FAP or IBS in primary care (ClinicalTrials.gov NCT05636358) [18]. The participants in the intervention group had access to a 3-month, home-based, guided hypnotherapy program. This study used questionnaire data of open questions and log data from the ZelfHy study of participants who received the intervention, and in-depth, semistructured interviews with a purposively selected sample of children and their parents.

We followed the Consolidated Criteria for Reporting Qualitative Research [19].

Home-Based Guided Hypnotherapy Program

The children in the intervention group of the RCT received standard care and home-based guided hypnotherapy for 3 months. Before starting, a researcher explained hypnotherapy, its benefits for abdominal pain, and access methods during a video call with the child, parent, or both. They were also advised not to discuss the pain. The hypnotherapy program included 5 exercises: 1 breathing and relaxation exercise and 4 visualization exercises: "the favorite place" or "the favorite place+ rainbow" (age-dependent), "the rainbow planet" or "air balloon" (age-dependent), "the beach without worries," and "the slide." Two exercises comprised 2 versions with adjustments in language: for children aged <12 years and \geq 12 years. Exercises were audio-recorded by a hypnotherapist. Instructions and exercises were hosted on a responsive website, as shown in Figure 1. All exercises were immediately available, but the children were guided to listen to the first 2 exercises for the first 2 weeks, adding new exercises every 1 to 2 weeks. They could choose and repeat exercises whenever they wanted. The children were encouraged to practice at least five times a week for 15 - 20 minutes daily for over 3 months. Automatic email reminders were sent after 14 and 28 days of inactivity to improve compliance.



Figure 1. Screenshots of the website taken from a smartphone.



Patient Participation

One mother of a girl aged 9 years and one male adolescent aged 19 years who both finished the intervention were engaged, and both received a voucher. Patient participation included attending 2 research team meetings and member checking the final results. The 2 research team meetings included discussion of the interview guide before the interviews, and discussion of topics, codes, and preliminary themes after the first interviews.

Recruitment and Participants

In this qualitative study, all the children and their parents in the intervention group of the RCT were included. Children aged

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7 - 17 years with FAP or IBS according to their GP participated in the RCT. Exclusion criteria for participation in the RCT were a concomitant organic gastrointestinal disease, being managed for abdominal pain by a pediatrician, intellectual disability, psychotic disorders, a history of hypnotherapy in the past year, and poor comprehension of the Dutch language. Detailed information of recruitment methods for the ZelfHy study are described elsewhere [18].

All the children and their parents were invited to answer the questionnaire. Additional inclusion criteria for in-depth interviews for this study were that the children had to be within the 3-month intervention time frame at that time, and live in the

Northern or Middle part of the Netherlands because of travel convenience. Purposive sampling was used to achieve diversity in age, gender, and therapy adherence based on automatically logged data for the user interactions. The first author, a female primary care researcher, invited parent-child dyads for interviews via telephone approximately 6 weeks after they started the intervention. We assumed that halfway through the intervention, the children listened to all exercises and were able to recall and express their experiences. In practice, with time delay such as decision to participate and setting a date for the interview, interviews would be held in weeks 8 - 12. The authors believe that this was enough time to shape experiences.

Data Collection

Questionnaire data consisted of open-ended questions regarding what they liked and disliked generally, and for each exercise separately (Multimedia Appendix 1). Questionnaire data were collected through an electronic data capture system at 3 months follow-up between March 2021 and January 2024. The parents completed the questionnaire for the children aged <12 years, and the children aged ≥12 years completed the questionnaire themselves, with parental help as needed. Additionally, we collected log data from the intervention consisting of how long the children listened to each exercise per session. A session was defined as a log-in and start of at least one exercise. In accordance with a previous study on the effectiveness of hypnotherapy, we defined adequate use as starting at least four different exercises [18,20].

From May 2023 to December 2023, a female primary care researcher and trained interviewer (ING) and a female social scientist with expertise in qualitative research and trained interviewer (MAA) conducted semistructured interviews. The first author had contact via telephone with the parents for study procedures for the ZelfHy study before the interview. The interviews took place at the participant's home, except for the children with low adherence. For convenience, the parents of these children were interviewed by telephone and they did not necessarily have to live in the Northern or Middle part of the Netherlands. Interviews were recorded using a digital voice recorder and transcribed verbatim. Field notes and short memos were written during and after each interview.

To develop the semistructured interview guide, we used sensitizing concepts from literature and expert discussion with the research team which consisted of a female primary care researcher, a female primary care research assistant, one female epidemiologist, one female social scientist, and two female GPs. The interview guide consisted of open-ended questions about the children's and parents' experiences with the therapy (Multimedia Appendix 2). Interviews were performed until data saturation was reached (ie, interviews no longer generated relevant concepts). We completed 3 additional interviews with the children and their parents in which no new codes were found. Iterative meetings with the research group were held to evaluate and update the interview guide for new concepts and discuss data saturation.

Data Analysis

Thematic content analysis was conducted as proposed by Braun and Clarke for questionnaire data and interview transcripts [21]. First, all questionnaire data and 10 interview transcripts were read and inductively and independently coded by ING (both questionnaire data and interview transcripts), GAH (questionnaire data and female epidemiologist), and ALvdV (interview transcripts and female primary care research assistant). ING coded the remaining transcripts and ALvdV checked the coding of these transcripts. Inconsistencies between coders were discussed until consensus was reached. Consequently, emerging themes and subthemes were discussed and redefined with the research team until consensus was reached. In one of these meetings, a mother and adolescent were part of the research team. Illustrative quotes were translated from Dutch to English by a native English speaker and editor, and the first author checked whether their meaning was retained. All analyses were facilitated using Atlas.ti (version 23; ATLAS.ti Scientific Software Development GmbH) software.

Ethical Considerations

The Medical Ethics Review Committee of the University Medical Center Groningen, the Netherlands, confirmed that the Medical Research Involving Human Subjects Act which includes the Declaration of Helsinki, did not apply to this qualitative study (number 202200110). All the participants gave informed consent. Participant data were deidentified after the interviews. No compensation was provided.

Results

Participants

In total, 76 children were eligible from the intervention group of the RCT. Their median age was 9.1 (IQR 8.1 - 11.2) years and 51 (67.1%) children were female. Of these 76 children, 20 children did not log in (n=10) or failed to complete the questionnaire for other reasons (n=10), resulting in questionnaire data from 56 children (Figure 2). For in-person interviews, 29 children were eligible because they were within the 3-month intervention period and lived in the Northern or Middle part of the Netherlands. We invited 19 children to participate in an in-person interview, of which 9 declined to participate because of personal circumstances (n=3), no interest (n=3), or no further reason (n=3). In addition, 3 parents of the children with low adherence were invited for a telephone interview. Interviews contained 13 children, of which 4 did not fill in the questionnaire. A total of 23 interviews were conducted, which lasted 19 - 63 minutes for in-person interviews and 5 - 11 minutes for telephone interviews. The in-person interviews included 10 children and 12 parents, of which 2 interviews were performed with both parents. The telephone interviews included 3 parents of the children with low adherence (Table 1).



Figure 2. Flowchart of participants. Asterisk (*) denotes that 20 in-person interviews were conducted: 10 with children and 10 with parents.





Table .	Characteristics	of	interviewed	partici	pants.
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ID	Gender	Age (years)	Gender of parent	Age of parent (years)	Parental educa- tional level ^a	Sessions (n) ^b	Favorite exercise
1	Girl	8	Female	41	High	10	The rainbow planet
2	Girl	11	Female	36	High	31	The favorite place
3	Girl	12	Female	42	Low	12	The slide
4	Girl	11	Female and male	40 (mother) 45 (father)	High (mother) High (father)	46	The favorite place
5	Girl	13	Female	50	Intermediate	14	Beach without worries
6	Boy	9	Female	44	High	29	The slide
7	Girl	7	Female	37	High	63	The slide
8	Boy	13	Female	43	Intermediate	46	Beach without worries
9	Girl	9	Female	38	High	22	The favorite place
10	Girl	8	Female and male	46 (mother) 44 (father)	High (mother) High (father)	55	Beach without worries
11 ^c	Girl	10	Female	Unknown	Unknown	0	Unknown
12 ^c	Boy	12	Female	Unknown	Unknown	1	Unknown
13 ^c	Girl	10	Female	Unknown	Unknown	8	Unknown

^aEducational level was considered low (primary and lower secondary), intermediate (secondary vocational), or high (Bachelor's degree or higher). ^bNumber of sessions until the date of the interview.

^cTelephone interviews were conducted with a parent only.

Adherence to Hypnotherapy

Of the 66 children that did log into the website, 3 children did 1 exercise, 3 children did 2 exercises, 8 did 3 exercises, 8 did 4 exercises, and 44 children did all 5. Consequently, 52 of 76 (68.4%) children adequately adhered to the intervention. The children did on average 25.5 (SD 23.2) sessions (median 17, range 1 - 89), and listened to more than one exercise in an average of 6.8 (SD 9.0) sessions (median 4, range 0 - 43). Log data per exercise are described in Table 2.

Table . Log data per exercise.

	Total	Exercise 1: breathing and relaxation	Exercise 2 ^a : The favorite place	Exercise 2 ^b : The favorite place and rain- bow	Exercise 3 ^a : The rainbow planet	Exercise 3 ^b : The air bal- loon	Exercise 4: Beach without worries	Exercise 5: The slide
Duration (min:s)	C	13:00	14:18	18:00	16:50	11:47	14:29	14:30
Duration lis- tened, (min:s), median (mini- mum-maxi- mum ^d)	_	12:15 (00:05- 26:30)	12:20 (00:05- 28:40)	14:45 (00:05- 22:15)	15:55 (00:05- 34:20)	11:05 (00:05- 13:40)	13:50 (00:05- 31:00)	13:55 (00:05- 36:50)
Children ever started (n)	66	66	50	11	46	10	51	51
Sessions per child, median (minimum- maximum)	17 (1 - 89)	4 (1-30)	5 (0 - 41)	2 (0 - 19)	5 (0 - 63)	3 (0 - 21)	3.5 (0 - 36)	3 (0 - 48)

^aExercise in the version for children aged <12 years.

^bExercise in the version for children aged ≥ 12 years.

^cNot applicable.

^dMaximum duration is higher than the exercise's length when children listened to the same exercise multiple times consecutively.

Experiences From Children and Their Parents

Overview

From questionnaire data and interviews, we found 6 themes that capture experiences from the children and their parents: impression of the exercises, not for everyone, influence of perceived effect, integrating exercises in daily life, content and practicalities of the website, and customization to personal preferences. For every quote, corresponding IDs from Table 1 are listed.

Impression of the Exercises

We found varying impressions of the therapy, ranging from nice, fun, and easy to stupid, boring, and difficult.

Then you have the feeling that you are really on a beach, and you can put all the feelings you don't want into a sand castle, so I really like that. [Child 10]

The exercises themselves are a bit boring, because you have to keep doing the same thing every day. [Child 2]

Most children felt relaxed during or after listening to an exercise and often had a positive association with a topic or liked the story in the exercises. The children enjoyed that they could choose what they wanted to see or do in their imagination.

And I really like the slide exercise because I like sliding a lot, and you can choose a color, and you can choose how fast you want to go. [Child 1]

Although most of the children liked to visualize during the exercises, some of the children thought too little was happening. The children had conflicting ideas about exercises that required more physical activity such as stretching and relaxing muscles, or writing down colors and feelings.

I find the exercises boring because you just have to listen. I would rather have something to do, like filling in the colors of the rainbow planet. [Child 1]

I liked just listening instead of having to actually do things. [Child 5]

The children particularly enjoyed exercises in the beginning, when they were new and the children did not yet know what would happen. For some of the children, exercises became boring over time.

Because I know the exercise very well I can't really imagine anything different than what I do now when I listen to the exercise. [Child 3]

The other children enjoyed knowing the exercises well.

Now I already know a few pieces by heart, so then I enjoy listening to them over and over again. [Child 4]

Each exercise was experienced differently with diverse positive and negative aspects. An overview of impressions per exercise is presented in Multimedia Appendix 3.

Not for Everyone

From interviews with the parents it emerged that they expected both boys and girls with FAP or IBS to be suitable for hypnotherapy. However, some of the parents were more skeptical about a child's age or developmental level. Although children of all ages thought that the exercises were easy or somewhat childish, a few of the children noted that exercises were too difficult; they included difficult words or were spoken too fast. Some of the parents of children aged 7 or 8 years noted that their child was around the minimal age or level to remain focused for the entire exercise or understand why these exercises could help.

If she is just a bit older maybe then it might be a bit more effective. That she would understand it a bit better, and be better able to recall things in certain situations. [Mother 7]

The parents also noted that certain characteristics could help the children in doing hypnotherapy successfully, such as being calm, creative, less rational, and having patience and high imaginary skills. The parents mentioned that energetic children might benefit most from relaxing but might need more time and practice. Indeed, some of the children did not like that they had to sit or lay still.

Because then I start thinking, shall I sneak and read something or just keep my eyes open, because I'm bored. I can't sit still. Look, I'm always fidgeting with my fingers. [Child 1]

Some of the children needed time to become used to the exercises and understand how to follow instructions. A few of the children were never able to surrender to the exercises because, for example, they could not imagine the suggestion, they did not like the stories, or they felt something and could not give in to the feeling.

My child often strongly resisted doing the exercises because they made her sleepy and she didn't want to give in to that. "Because of them I can't hear my own dreams anymore." [Mother of girl aged 8 years, 24 sessions, reported in the questionnaire]

The parents mentioned that sometimes when their child was too energetic or too stressed from events or stimuli, they could not concentrate and do the exercises in order to relax.

Now I had the idea that it even worked against her, that she first had to deal with her own things, and that hypnotherapy... that it wouldn't go together. [Mother 1]

Influence of Perceived Effect

Feeling an effect of the therapy affected experiences of the children. Although a few of the children experienced less abdominal pain but did not like the exercises, most did. Primarily because it made their belly feel good, or because their pain decreased or disappeared. They also experienced other effects such as greater confidence, better sleep, more energy, more relaxation, a clearer mind, and more frequent school attendance.

I really like it, because you know that it relaxes you a lot. [Child 3]

When the children experienced less abdominal pain either through the exercises or for another reason, some of the children and parents felt less need to continue the exercises and quit.

When she was in pain and started an exercise, it helped to reduce the pain. But when she did not have pain, she did not feel like doing the exercises or see the benefit of them. [Mother 13]

Some of the children were not able to relax during the exercises, and felt that the exercises did not help to remove their pain. They felt stressed because it did not work for them. Doing

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hypnotherapy felt like an obligation; this resulted in resistance or discontinuation.

We have decided not to do the exercises anymore because they led to more frustration than success. [Mother of girl aged 9 years, 9 sessions, reported in the questionnaire]

Integrating Exercises in Daily Life

Many of the children enjoyed doing the exercises on their own, without involvement of others who could distract them. A few of the children mentioned that they would not do hypnotherapy in the presence of friends, because they would not like to explain what it is, or be different from their friends or classmates. The other children sometimes listened together with their parents or siblings which made them feel more relaxed. The parents also played an important role by reminding their children to do the exercises, because they did not come up with it themselves, were not in the mood, or forgot it.

Stimulate her to do the exercises. She doesn't think to do them or ask for them. So I have to motivate her a bit. [Mother 1]

Most of the children listened to exercises before going to sleep. Taking a device to their room was sometimes difficult for the parents because they usually withhold their children from screen time before bedtime. The children and parents appreciated that the exercises were easily accessible for the children to listen at home where they felt comfortable and at ease, such as on their bed.

I really like that you don't have to go anywhere. That you can just sit or lie down in your own house, in your comfort zone. [Child 8]

Most of the children accomplished making it a routine in their daily schedule which made listening to the exercises easier and more fun.

He definitely doesn't want to skip it in the evening. It becomes a kind of evening ritual: tooth-brushing, pajamas on and listen, and then to bed. [Mother 8]

The parents appreciated being able to use this as a tool when necessary, such as when their child was stressed or energized and needed to relax. Not all of the children and parents managed to integrate hypnotherapy into their routine. Some of the children were put off by doing hypnotherapy again because of the time constraint. A few of the parents noted that there is not enough time in a day to add 15 minutes of hypnotherapy, because it was not feasible to do it before school or before bedtime.

Because sometimes the exercises are long, you sometimes practice a bit less, or maybe even not at all. [Mother 9]

The parents from the children with low adherence mentioned that they never started hypnotherapy because the children and their parents could not find a good moment in the first place.

Several times we thought of it, but then we thought, ah, we'll do it later. And every time that later never came. [Mother 11]

Content and Practicalities of the Website

Information was perceived as clear and interesting, though there might have been somewhat too much information for younger children according to the parents. The distinction between exercises and explanation was not always clear on the website. The children thought that there was an extra exercise, but felt disappointed when they saw it was an explanation only.

Insight in log-in data (ie, a small red cross for not logging in, or a green check for logging in, both per day and weekly over the entire 3 months) was experienced both positively and negatively. For some of the children this insight motivated them to do the exercises and obtain more green checks, and for others this worked counterproductively; they felt frustrated, angry, or ashamed.

If I haven't practiced for a couple of weeks, for example, because I am busy, then I feel a bit, uh different, that I haven't done it right, that there will be red crosses. [Child 3]

For most of the participants, the website functioned well technically. However, some of the children experienced that the exercise stopped when the screen automatically turned off. This got them out of their concentration and affected their experiences negatively.

So then she's totally caught up in the story, and then she has to turn all the way around, click on that thing and install herself again. [Mother 1]

The children preferred using different devices, such as a smartphone, tablet, or computer. Many of the participants noted that a website was unpractical, since the children needed to fill in their log-in codes every time, were dependent on a parent nearby, or were unable to do it on the go. Sometimes, this made doing the exercises a barrier for the children. The parents suggested the use of an app instead of a website.

If he could just do it in an app, that you just use a password one time and then you can just turn it on, then it would have been easier and he would have done it more quickly. [Mother 6]

Customization to Personal Preferences

The first aspect that the children would have liked to customize is appearance of the website and the exercises. The children and parents would have preferred to choose from different voices which can differ in speed. Overall, the children liked the looks of the website, but they had different ideas: some liked it simple as it is, others would have liked brighter colors such as pink and purple. The children would have liked to choose between colors on the website, change the background, and add illustrations to the exercises.

I thought that the colors could have been brighter. And just as with the iPad you can choose a background, I would like that you could also choose a background here. It really doesn't look so nice, so you think, now, I'm going to do some ZelfHy exercises. [Child 1]

The second aspect that the children and parents would prefer to customize relates to the content. Most importantly, the

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participants would have liked more exercises. Only a few of the participants found 5 exercises sufficient. Animals, love, music, flowers, favorite animation, traveling, games, hobbies, and sports were recommended by the children as preferred topics to add more attractive exercises. According to the parents, topics should also be suitable for a child's age or level to be more effective.

Because I notice that not every exercise is suited for her. That you could better, yeah, make more personalized exercises. And with things going on in her own environment, because that is, of course, different for a 7-year-old than for a 17-year-old. [Mother 7]

Additionally, choosing from exercises with different duration, particularly exercises of shorter duration (eg, between 5 and 10 min) is expected to enhance adherence. Shorter exercises would allow children to do an exercise quickly during a weekday, and to combine more exercises in 1 session. In contrast, a few of the parents hypothesized that shorter exercises might yield less effect than long exercises. The participants noted that a combination of shorter and longer exercises would be nice. Longer exercises are deemed useful in the beginning, and once children understand how they work, shorter exercises are expected to keep children more focused and satisfied.

I certainly think that the more often you practice, then I can imagine that at a certain point you want to go through such an exercise more quickly, because you have already formed a certain image of it, or you have given it certain colors, or you have associated a certain emotion with it. Then it doesn't have to take so much time. [Mother 6]

Some of the participants noted that it would be more motivating if the website contained games, or if they could unlock new exercises. The parents also noted that a scoring or rewarding system could help to increase adherence.

You could attach a kind of gamification to it, so that the child gets a certain reward when she has done it, so that she wants to do the exercises. [Father 4]

Discussion

Principal Results

Adherence to hypnotherapy varied greatly: some of the children never started hypnotherapy, some only logged in a handful of times, and most of the children adequately adhered to hypnotherapy by starting at least four exercises. The children experienced home-based guided hypnotherapy differently, both in general and per exercise. From interviews with the parents it emerged that hypnotherapy was sometimes difficult for those children who were young or had a low developmental level, could not sit still or surrender to the exercise, or were too energetic or stressed. Experiences were shaped by the influence of perceived effects, the ability to integrate exercises in daily life, and content and practicalities of the website. Ultimately, the children and parents would appreciate a therapy that can be customized to personal preferences for appearance and content.

Comparison With Prior Work

This is the first study to evaluate experiences of children and their parents with home-based guided hypnotherapy, other studies evaluated other self-guided interventions for children with abdominal pain. A mixed methods study assessing an online self-guided intervention found that children aged 9 - 15 years were satisfied with the intervention [22]. In our sample, we found more variation in the children's experiences, ranging from boring to fun. Possible explanations for this disparity could be that we included a larger sample, also included children with low adherence, and that children with questionnaire data had a broader age range, namely 7 - 17 years. Notably, it was a different intervention and this study showed that characteristics of the website or intervention also influence a child's experiences. The mixed methods study found that children learned to cope with their pain through relaxation or distraction and felt better in general [22]. This is consistent with our findings that experiences of children were influenced by a perceived effect.

In our study, a long duration of the exercises was one of the reasons why everyday adherence was difficult. Some children easily integrated the exercises into daily life, but others had difficulties to make it a routine. The parents who motivated and stimulated their child to listen to an exercise were helpful in integrating exercises in daily life. A mixed methods study assessing a guided imagery app also found no consensus on preferable exercise duration when asking children and parents [23]. In contrast, another study assessing guided imagery found that sessions lasting 10 to 25 minutes were enjoyable, children needed no help or reminders from parents, and most children listened to the exercises more often than instructed [24]. Our results add to the knowledge that preferences for duration of exercises are dependent on children's characteristics, ability to do the exercises, parental involvement and ability to integrate exercises in daily life. Home-based guided hypnotherapy that includes exercises with varying durations would allow that it is suitable and fitting for everyone, because it can be adjusted to children's preferences and time available at that moment.

The children and parents liked the look of the website in general, and a few experienced small technical issues that negatively affected their experience. Another study also mentioned small technical issues in an online intervention [25]. Consistent with a previous study using an app, the log-in procedure was easy [23]. However, in our study, the log-in procedure was also perceived as inconvenient, because it was not easy to use on the go. The parents suggested that an app could solve this inconvenience. A study assessing desirable components in a digital management app for children with long-term, chronic conditions found no agreement on preferences for either a website that is suitable on multiple devices versus an app [26]. This is consistent with our results and suggests that an app is favored, but flexibility of use on other devices should also be taken into account.

This study amplifies what has been found before, that children enjoy being able to do an intervention at home. eHealth interventions can increase adherence to treatment and improve outcomes which might influence effectiveness of the therapy

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[20,27]. Between the children and parents, there are many individual preferences regarding number and duration of exercises, topics, voices, and looks. Additionally, the child's age or level plays an important role. Consistent with prior literature, rewarding systems or gamification is important in eHealth interventions for children [23,28]. Our study emphasizes the importance of tailoring hypnotherapy to children's age or developmental level, customizing it according to their personal preferences regarding appearance and content, and incorporating gamification components to enhance engagement.

Strengths and Limitations

An important strength of this study is that we interviewed both children and their parents, with varying adherence ranging from zero adherence to daily adherence for 3 months. Interviews with the parents followed after interviews with children and allowed for more depth. Interviews were performed in their home environment, which allowed for a safe environment, and we therefore believe that we captured honest answers.

One limitation is that we primarily interviewed children and young adolescents (age range 7 - 13 y). Therefore, our results might not be generalizable to adolescents. We aimed to interview adolescents aged 14 to 17 years old, but failed because very few adolescents participated in the RCT. Although questionnaire data did include adolescents, and we included an adolescent for member checking, more research is needed on experiences of hypnotherapy among adolescents. Another limitation is that we failed to interview more fathers, as they were not at home during the interview. We believe that this minority of fathers did not influence our study results, because the 2 included fathers did not introduce new themes.

Clinical and Research Implications

This study highlights the importance of personalized home-based guided hypnotherapy to improve a child's experience, and possibly to increase adherence. This is of essence in eHealth, where patients themselves are responsible for following the therapy. Hypnotherapy that is fun to do at home and fitted to each child might be easy to adhere to and more prompting for GPs to promote. Primary care might be a beneficial setting for home-based guided hypnotherapy, as GPs manage most children with these complaints. Providing a self-managing intervention in this setting might prevent referrals to pediatric care and reduce costs [29,30].

Conclusions

The children's and parents' experiences varied greatly and were partly influenced by the topic or story in the exercise. For children who are young or have a low developmental level, cannot sit still, are unable to surrender to exercises, or are too energetic or stressed, home-based guided hypnotherapy might be difficult and needs optimization. Children liked hypnotherapy when they felt positive effects, could easily integrate the exercises in their daily life, or enjoyed the website's content and usability. Children who did not feel effects or found exercises too long often disliked hypnotherapy. A website or an app that is easily accessible and contains short exercises could increase its use. Hypnotherapy that is adaptable to personal preferences on appearance and content could boost the

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experiences. In turn, positive experiences might lead to higher adherence, which potentially increases the effect of hypnotherapy and should be studied further.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1 Open-ended questions from the questionnaire. [DOCX File, 14 KB - pediatrics v8i1e58301 app1.docx]

Multimedia Appendix 2 Interview guides. [DOCX File, 18 KB - pediatrics_v8i1e58301_app2.docx]

Multimedia Appendix 3 Impressions per exercise. [DOCX File, 17 KB - pediatrics_v8i1e58301_app3.docx]

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Abbreviations

FAP: functional abdominal pain **GP:** general practitioner **IBS:** irritable bowel syndrome **RCT:** randomized controlled trial


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Original Paper

eHealth Literacy and Adolescent Health in Japanese Female High School Students in Sendai: Cross-Sectional Study

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Abstract

Background: In the digital age, adolescents increasingly rely on online sources for health-related information. eHealth literacy—defined as the ability to find, evaluate, and apply online health information—plays a crucial role in health outcomes. However, limited research exists on eHealth literacy among Japanese high school students, particularly on its association with menstrual health and psychological well-being.

Objective: This study aimed to assess the eHealth literacy of Japanese female high school students and examine its association with premenstrual symptoms, psychological distress, loneliness, and self-esteem.

Methods: A cross-sectional, web-based survey was conducted in December 2024 among 1607 female students from 2 public high schools in Sendai, Japan. A total of 909 students with regular menstrual cycles completed all survey items. The survey included the eHealth Literacy Scale (eHEALS), Premenstrual Symptoms Questionnaire, Kessler Psychological Distress Scale (K6), Revised UCLA Loneliness Scale, Rosenberg Self-Esteem Scale, and a numerical rating scale for menstrual pain. Statistical analyses, including Student t tests, chi-square tests, correlation analyses, and logistic regression analyses, were used to examine the relationships between eHealth literacy and various health outcomes.

Results: The mean eHEALS score was 22.8 (SD 7.3), with 32.1% (292/909) of participants classified as having high eHealth literacy (eHEALS \geq 26). Students with higher eHealth literacy reported significantly lower levels of loneliness and higher self-esteem. The severity of premenstrual symptoms, particularly feeling overwhelmed, was significantly lower in the high eHealth literacy group. Additionally, interpersonal difficulties related to premenstrual symptoms were less prevalent among students with high eHealth literacy. Pearson correlation analysis indicated negative associations between the eHEALS score and psychological distress (K6) and loneliness, whereas a positive association was observed with self-esteem. Logistic regression analysis showed that high self-esteem was significantly associated with high eHealth literacy.

Conclusions: This study highlights the importance of eHealth literacy in adolescent health care. Higher eHealth literacy is linked to lower levels of loneliness, higher self-esteem, and reduced premenstrual symptom severity, particularly feeling overwhelmed. Although the cross-sectional design limits causal conclusions, these findings suggest that higher eHealth literacy is associated with better mental and reproductive health in adolescents. Future research should adopt longitudinal designs, include more diverse populations—such as male adolescents—and explore additional contributing factors to better elucidate these associations.

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KEYWORDS

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female adolescents; mental health; premenstrual symptoms; self-esteem; eHealth

Introduction

Growing Role of eHealth in Adolescent Health

In recent years, many people have begun to use eHealth information to manage their own health [1]. As internet accessibility continues to expand globally, more individuals are obtaining health-related information online. Internet use is also high in Japan, standing at 86.2% in 2023, according to data from the Ministry of Internal Affairs and Communications [2]. The usage rate is particularly high among adolescents aged 13 years to 19 years (98.7%). Adolescence is an important transition period from childhood to adulthood, during which adolescents undergo many physical, cognitive, and psychosocial changes; establish their ego; build their own world; and develop healthy lifestyle habits. During this period, adolescents seek information on topics such as sexual health, nutrition, beauty, and infectious diseases through websites and social media [3].

Concept and Importance of eHealth Literacy

Health literacy is the ability to find, understand, and use health information to make informed decisions. These include reading medical instructions, understanding prescriptions, and evaluating health information from various sources. Good health literacy helps individuals manage diseases, correctly follow treatment, and effectively communicate with health care providers. It also involves numeracy skills such as understanding dosages and medical test results. Low health literacy can lead to poor health outcomes and medication errors. Therefore, promoting health literacy empowers individuals to take charge of their well-being and make healthier choices. Among digitally native adolescents, the internet has replaced traditional sources such as books for gathering health information [4,5].

Assessment of eHealth Literacy Among Adolescents

Given this shift, eHealth literacy—the ability to find, evaluate, and use health information from the internet to solve one's health problems—has become increasingly important [6]. The 6-item Lily Model of eHealth literacy, comprising traditional, health, information, scientific, media, and computer literacy, was previously proposed [6]. An 8-item rating scale called the eHealth Literacy Scale (eHEALS), based on this model, has been developed [7], translated into many languages, and used worldwide [8-11]. As adolescents continue to rely on the internet for health-related information, assessing their eHealth literacy is essential. However, despite increasing reliance on digital health information, research on eHealth literacy among adolescents remains scarce. Most studies have focused on university students or adults, leaving a significant knowledge gap regarding younger adolescents [4,12]. Moreover, global studies on adolescent eHealth literacy are sparse, with only a few investigations conducted in specific regions such as Turkey, Serbia, and Brazil [13-15]. These studies suggest variations in eHealth literacy levels among different populations, further highlighting the need for region-specific studies.

Premenstrual Symptoms and Psychological Well-Being

Premenstrual symptoms are characterized by unpleasant psychosomatic symptoms that impair the quality of life of many women from adolescence to adulthood [16-18]. Premenstrual

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syndrome (PMS) is characterized by various premenstrual symptoms and is classified as premenstrual dysphoric disorder when psychological symptoms become particularly severe [19]. Recently, the concept of premenstrual disorders was introduced, considering both conditions as part of a continuum [20]. Menstrual pain and premenstrual symptoms are correlated and, as menstrual symptoms, have a significant impact on performance [21,22]. In Japan, a study with working women found that those with higher health literacy reported lower presenteeism and better performance at managing menstrual symptoms [22]. However, this study did not examine premenstrual symptoms or social dysfunction in detail. In addition, few studies have examined the relationship between health literacy, including eHealth literacy, and menstrual symptoms in adolescents.

Psychological Distress, Loneliness, and Self-Esteem in Adolescents

High school students are at an increased risk of psychological distress, depression, anxiety, loneliness, and trauma [23]. Loneliness, the subjective feeling of isolation, has gained attention as a major public health concern owing to its strong association with mental health conditions such as depression and anxiety. It is also a key risk factor for poor mental health outcomes, particularly during adolescence [24-26]. A survey of Japanese high school students conducted in 2021 found that psychological distress was correlated with the severity of premenstrual symptoms, whereas loneliness was independently linked to both conditions. Self-esteem, which reflects an individual's overall sense of self-worth [27], is another critical factor affecting the mental health of adolescents. Low self-esteem is linked to depression, eating disorders, risky behaviors, and academic decline [28]. Additionally, it has a strong reciprocal relationship with loneliness [27,28]. Low self-esteem and loneliness are particularly concerning during adolescence, which is the formative period for developing self-identity [29]. As adolescents increasingly rely on online health information, eHealth literacy may play a role in their psychological well-being by influencing their access to and interpretation of health-related content.

Study Objectives

The purpose of this study was to assess the current level of eHealth literacy among Japanese female high school students, with a particular focus on examining its association with premenstrual symptoms. In addition, we investigated how eHealth literacy is related to other key aspects of adolescent health, including psychological distress, loneliness, and self-esteem. We hypothesized that students with higher eHealth literacy would report fewer premenstrual symptoms, lower levels of psychological distress and loneliness, and higher levels of self-esteem. These associations were examined to better understand the potential role of digital health literacy in promoting reproductive and mental well-being among adolescents.

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Methods

Ethical Considerations

This study was conducted in accordance with the principles of the Declaration of Helsinki, and the Kindai University Ethics Committee approved the research protocol (approval number: R06-131; approval date: October 2, 2024). Students who participated in the study provided informed consent.

The Kindai University Ethics Committee approved the waiver of parental informed consent, and the students' consent and willingness to participate were considered sufficient. The omission of parental informed consent was in accordance with the Ethical Guidelines for Medical and Health Sciences Research Involving Human Subjects issued by the Ministry of Education, Culture, Sports, Science, and Technology, and the Ministry of Health, Labour and Welfare. The data were anonymized and did not contain identifiable information regarding the participants. Participants were not compensated.

Settings and Participants

In mid-December 2024, a school survey was conducted among 1607 female students attending 2 public high schools in Sendai, Japan. We conducted a web survey using Google Forms. The link to the self-administered survey form was distributed through school classes, and the survey was administered over the internet with consent. Given the sensitive nature of the questions, students were instructed to complete the survey independently at home after school hours, rather than during class time. A total of 1193 students responded to the survey. Of these, 995 had regular menstrual cycles of 25 days to 38 days (Figure 1). Because premenstrual symptoms appear solely during ovulatory cycles, only those with regular menstrual cycles were selected. Furthermore, 909 students who completed all items from the following measures were selected: eHEALS, Premenstrual Symptoms Questionnaire (PSQ), 6-item Kessler Psychological Distress Scale (K6), 3-item Revised UCLA Loneliness Scale (R-UCLA), Rosenberg Self-Esteem Scale (RSES), and numerical rating scale (NRS) for menstrual pain intensity.

Figure 1. Study flowchart. eHEALS: eHealth Literacy Scale; K6: 6-item Kessler Psychological Distress Scale; NRS: numerical rating scale; PSQ: Premenstrual Symptoms Questionnaire; R-UCLA: 3-item Revised UCLA Loneliness Scale; RSES: Rosenberg Self-Esteem Scale.



Questionnaires

eHEALS

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The eHEALS is the only questionnaire that examines online health literacy [7]. In this study, we used the Japanese version, which has demonstrated validity and reliability [10]. The eHEALS is composed of 8 items and is scored on a 5-point scale (1=strongly disagree to 5=strongly agree). The total eHEALS score ranges from 8 to 40: the higher the score, the better the eHealth literacy. In this study, the Cronbach α coefficient for the scale was 0.935. Participants were divided into 2 groups—a high-scoring group (eHEALS≥26; n=292) and a low-scoring group (eHEALS<26; n=617)—according to criteria reported previously [29].

PSQ

The PSQ, previously used in research, was chosen for this study as a simple screening tool for premenstrual symptoms [18,30]. Its reliability and validity are well established [31]. The PSQ starts with: "In the past three months, have you experienced any premenstrual symptoms that start a week before menstruation and stop a few days after it begins?" It includes 11 items based on the Diagnostic and Statistical Manual of Mental Disorders–premenstrual dysphoric disorder criteria and assesses the impact of symptoms on (1) work and family responsibilities, (2) social activities, and (3) relationships. Severity and impact are rated on a 4-point scale (1=not at all to 4=severe). The total score (range: 14-56) indicates symptom severity. The Cronbach α was 0.936.

K6

The K6 was chosen for this study because it is a widely used screening tool for psychological distress in the general population [32,33]. Psychological distress was measured using the Japanese version of K6 [34], with established reliability and validity. The K6 consists of 6 items rated on a 5-point scale (0=not at all to 4=all). The total score ranges from 0 to 24, with higher scores indicating greater distress. The Cronbach α was 0.957.

R-UCLA

The R-UCLA was chosen for this study because it is a widely used and simple assessment tool for evaluating loneliness [35]. The Japanese version of the 3-item R-UCLA was used, and its reliability and validity have been well established [36]. This scale consists of 3 items rated on a 3-point scale (1=hardly ever, 2=sometimes, and 3=often), yielding a total score between 3 and 9. Higher scores indicate greater loneliness. The scale demonstrated strong internal consistency, with a Cronbach α of 0.913.

RSES

The RSES is a widely used self-esteem assessment tool that was selected for this study owing to its broad applicability [27]. The Japanese version of RSES (RSES-J) was used to measure self-esteem, and its reliability and validity have been confirmed [37]. The RSES-J consists of 10 items: 5 positive and 5 negative. Negative items are rated on a 4-point scale (1=strongly agree, 2=agree, 3=disagree, and 4=strongly disagree), whereas positive items are scored inversely. The total score ranges from 10 to 40, with higher scores indicating greater self-esteem. In this study, the Cronbach α for the RSES was 0.873.

NRS

Menstrual pain is closely linked to premenstrual symptoms [21,31]. In this study, pain severity was assessed using the NRS, a standard tool for measuring pain perception. Participants rate their pain on an 11-point scale ranging from 0 (no pain) to 10 (worst imaginable pain).

Participant data included age, school grade, weight, height, age at menarche, menstrual cycle length, internet usage time, and sleep duration. Menarche marks the onset of puberty and is linked to health issues such as early pregnancy, sexually transmitted diseases, depression, and anxiety [38,39]. It has been identified as a key factor in adolescent health. A regular cycle was defined as 25 days to 38 days. BMI was calculated by dividing weight by height squared (kg/m²). As obesity is associated with PMS, low self-esteem, and loneliness, BMI was included in the analysis [40,41].

Statistical Analysis

The Cronbach α coefficient was used to assess the reliability of each scale (eHEALS, PSQ, K6, 3-item R-UCLA, and RSES). We calculated the means and SDs for continuous variables and proportions for categorical variables. Differences in the background characteristics of the high and low eHealth literacy groups were compared using Student t tests and Pearson chi-square tests. The Steel-Dwass test was used to compare differences in eHEALS scores between school years. The exact Wilcoxon signed-rank test was used to compare the severity of 11 premenstrual symptoms and 3 social disability items on the PSO between the high and low eHealth literacy groups. Correlations among the 5 psychological questionnaires (total eHEALS, PSQ, K6, 3-item R-UCLA, and RSES) were examined using Pearson correlation coefficients. The factors significantly associated with high eHealth literacy were determined using multivariable logistic regression analysis. A total of 10 items-age, BMI, age at menarche, menstrual pain intensity, duration of internet use, sleep duration, total PSQ score, total K6 score, R-UCLA, and RSES-were included in the model.

Statistical analyses were performed using JMP Pro 18.1.0 (SAS). A *P* value<.05 was considered statistically significant.

Results

Participant Characteristics

The characteristics of all participants are presented in Table 1. The mean eHEALS score was 22.8 (SD 7.3). Approximately one-third (292/909, 32.1%) of the participants belonged to the high eHealth literacy group. The high eHealth literacy group had lower R-UCLA scores and higher RSES scores than the low eHealth literacy group.



Table 1. Characteristics of the study participants.

Characteristic	Overall (N=909)	Low eHealth literacy group (eHEALS ^a <26; n=617)	High eHealth literacy group (eHEALS≥26; n=292)	P value
Age (years), mean (SD)	16.8 (0.9)	16.8 (0.9)	16.8 (1.0)	.88 ^b
School year, n (%)				.58 ^c
First year ^d	270 (29.7)	188 (69.6)	82 (30.3)	
Second year ^e	297 (32.7)	195 (65.7)	102 (34.3)	
Third year ^f	342 (37.6)	234 (68.4)	108 (31.6)	
BMI (kg/m ²), mean (SD)	20.5 (2.6)	20.5 (0.1)	20.3 (0.15)	.29 ^b
Age at menarche (years), mean (SD) ^g	12.1 (1.3)	12.1 (0.1)	12.0 (0.1)	.12 ^b
Menstrual pain intensity, mean (SD)	4.8 (2.6)	4.9 (0.1)	4.8 (0.2)	.52 ^b
Duration of internet use (hours), mean (SD) ^h	3.1 (1.9)	3.2 (2.1)	3.1 (1.6)	.89 ^b
Sleep duration (hours), mean (SD) ⁱ	6.1 (1.0)	6.0 (1.0)	6.1 (1.0)	.12 ^b
Total PSQ ^j score, mean (SD)	26.8 (9.5)	27.0 (0.4)	26.3 (0.6)	.24 ^b
K6 ^k , mean (SD)	7.4 (7.4)	7.5 (0.3)	7.0 (0.4)	.27 ^b
R-UCLA ¹ , mean (SD)	5.8 (2.7)	6.0 (0.1)	5.5 (0.2)	.02 ^b
RSES ^m , mean (SD)	25.1 (6.1)	24.3 (0.2)	26.8 (0.4)	<.001 ^b
eHEALS, mean (SD)	22.8 (7.3)	19.0 (5.2)	30.8 (4.1)	<.001 ^b

^aeHEALS: eHealth Literacy Scale.

^bStudent *t* test.

^cPearson chi-square test.

^dMedian age: 16 (IQR 15-16) years.

^eMedian age: 17 (IQR 16-17) years.

^fMedian age: 18 (IQR 17-18) years.

^gMissing data: 7 (0.8%).

^hMissing data: 24 (2.6%).

ⁱMissing data: 4 (0.4%).

^jPSQ: Premenstrual Symptoms Questionnaire.

^kK6: 6-item Kessler Psychological Distress Scale.

¹R-UCLA: 3-item Revised UCLA Loneliness Scale.

^mRSES: Rosenberg Self-Esteem Scale.

Comparison of eHealth Literacy Between School Years

Differences in eHEALS scores between school years were analyzed in terms of the total score and each of the 8 items (Table 2). We found no differences in total eHEALS scores between school years. Of the 8 items, second-year students' scores were significantly higher than those for first-year students for Q6 (I find on the Internet, I know how to use the Internet to answer my questions about health) and Q7 (I can distinguish high-quality health resources from low-quality health resources on the Internet). This suggests that some aspects of eHealth literacy may improve with age or school experience, but the overall literacy level remains consistent across the years.



Table 2. Study participants' eHealth Literacy Scale (eHEALS) scores by school year level.

Question and total scores	First year, median (IQR)	Second year, medi- an (IQR)	Third year, median (IQR)	<i>P</i> value (second vs first) ^a	<i>P</i> value (third vs first) ^a	<i>P</i> value (third vs second) ^a
Q1 ^b	3 (2-3)	3 (2-4)	3 (2-4)	.48	.30	.90
Q2 ^c	3 (2-3)	3 (2-3)	3 (2-3)	.35	.71	.82
Q3 ^d	3 (2-4)	3 (2-4)	3 (2-4)	.41	.57	.97
Q4 ^e	3 (2-4)	3 (2-4)	3 (2-4)	.54	.59	≥.99
Q5 ^f	3 (2-4)	3 (2-4)	3 (2-4)	.40	.51	.98
Q6 ^g	3 (2-3)	3 (2-3.5)	3 (2-4)	.02	.47	.33
Q7 ^h	3 (2-3)	3 (2-4)	3 (2-4)	.02	.11	.82
Q8 ⁱ	3 (2-3)	3 (2-4)	3 (2-4)	.08	.10	≥.99
Total eHEALS score	23 (16-26)	24 (19-28)	24 (18-28)	.10	.27	.88

^aSteel-Dwass test.

b"I know what health resources are available on the Internet."

^c"I know where to find helpful health resources on the Internet."

d"I know how to use the health information I find on the Internet to help me."

e"I know how to find helpful health resources on the Internet."

f."I have the skills I need to evaluate health resources."

^g"I know how to navigate the Internet and use it to answer my questions about health."

h"I can distinguish high-quality health resources from low-quality health resources on the Internet."

ⁱ"I feel confident in using information from the Internet to make health decisions."

eHealth Literacy and Premenstrual Symptoms

Next, the differences in premenstrual symptoms and level of social impairment were examined according to the level of eHealth literacy (high and low literacy; Table 3). Of the 11 premenstrual symptoms listed in the PSQ, only feeling overwhelmed was significantly lower in the high eHealth

literacy group than in the low eHealth literacy group. In terms of social life impairment, only interpersonal impairment was significantly lower in the high eHealth literacy group than in the low eHealth literacy group. However, there were no significant differences in work productivity nor participation in social activities between the 2 groups.



Takeda et al

Table 3. Differences by eHealth literacy level (high [n=292] and low [n=617] literacy) in terms of premenstrual symptoms and level of social impairment.

Characteristic	Responses to quest	Responses to questions				
	Not at all, n (%)	Mild, n (%)	Moderate, n (%)	Severe, n (%)		
Premenstrual symptoms	·		·			
Depressed mood					.96	
Low eHealth literacy ^b	231 (37.4)	189 (30.6)	149 (24.2)	48 (7.8)		
High eHealth literacy ^c	106 (36.3)	97 (33.2)	68 (23.3)	21 (7.2)		
Anxiety or tension					.27	
Low eHealth literacy	166 (26.9)	211 (34.2)	183 (29.7)	57 (9.2)		
High eHealth literacy	93 (31.9)	89 (30.5)	87 (29.8)	23 (7.9)		
Tearful					.49	
Low eHealth literacy	244 (39.6)	159 (25.8)	151 (24.5)	63 (10.2)		
High eHealth literacy	125 (42.8)	72 (24.7)	61 (20.9)	34 (11.6)		
Anger or irritability					.10	
Low eHealth literacy	177 (28.7)	201 (32.6)	192 (31.1)	47 (7.6)		
High eHealth literacy	99 (33.9)	95 (32.5)	75 (25.7)	23 (7.9)		
Decreased interest in work, home	e, or social activities				.10	
Low eHealth literacy	333 (54)	164 (26.6)	95 (15.4)	25 (4.1)		
High eHealth literacy	176 (60.3)	67 (23)	35 (12)	14 (4.8)		
Difficulty concentrating					.41	
Low eHealth literacy	230 (37.3)	215 (34.9)	126 (20.4)	46 (7.5)		
High eHealth literacy	118 (40.4)	96 (32.9)	59 (20.2)	19 (6.5)		
Fatigue or lack of energy					.39	
Low eHealth literacy	159 (25.8)	198 (32.1)	183 (29.7)	77 (12.5)		
High eHealth literacy	87 (29.8)	86 (29.5)	84 (28.8)	35 (12)		
Overeating or food cravings					.32	
Low eHealth literacy	149 (24.2)	194 (31.4)	197(31.9)	77 (12.5)		
High eHealth literacy	84 (28.8)	85 (29.1)	86 (29.5)	37 (12.7)		
Insomnia or hypersomnia					.40	
Low eHealth literacy	233 (37.8)	157 (25.5)	148 (24)	79 (12.8)		
High eHealth literacy	119(40.8)	72 (24.7)	66 (22.6)	35(12)		
Feeling overwhelmed					.03	
Low eHealth literacy	343 (55.6)	172 (27.9)	78 (12.6)	24 (3.9)		
High eHealth literacy	189 (64.7)	58 (19.9)	33 (11.3)	12 (4.1)		
Physical symptoms					.86	
Low eHealth literacy	298 (48.3)	190 (30.8)	95 (15.4)	34 (5.5)		
High eHealth literacy	144 (49.3)	77 (26.4)	56 (19.2)	15 (5.1)		
Interference with work, usual activiti	es, or relationships					
Work efficiency, productivity, ho	me responsibilities				.55	
Low eHealth literacy	249 (40.4)	210 (34)	130 (21.1)	28 (4.5)		
High eHealth literacy	128 (43.8)	90 (30.8)	56 (19.2)	18 (6.2)		
Social activities					.15	
Low eHealth literacy	422 (68.4)	127 (20.6)	52 (8.4)	16 (2.6)		

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Characteristic	Responses to questio		P value ^a		
	Not at all, n (%)	Mild, n (%)	Moderate, n (%)	Severe, n (%)	
High eHealth literacy	214 (73.3)	50 (17.1)	22 (7.5)	6 (2.1)	
Relationships with coworkers and family					
Low eHealth literacy	431 (69.9)	142 (23)	33 (5.4)	11 (1.8)	
High eHealth literacy	224 (76.7)	48 (16.4)	15 (5.1)	5 (1.7)	

^aExact Wilcoxon signed-rank test.

^beHealth Literacy Scale (eHEALS)<26.

^ceHEALS≥26.

Correlations Between eHealth Literacy and Psychological Measures

Subsequently, we examined the correlations between the

eHEALS and the 4 psychological questionnaires used in this

study (Table 4). The Pearson correlation coefficient analyses showed that the eHEALS score was negatively associated with the K6 total score (r=-0.071) and the R-UCLA score (r=-0.086) and positively associated with the RSES score (r=-0.170).

Table 4. Correlations among eHealth literacy, premenstrual symptoms, psychological distress, loneliness, and self-esteem.

Characteristics	eHEALS ^a	Total PSQ ^b	Total K6 ^c	R-UCLA ^d	RSES ^e
eHEALS			· · · · ·	·	
r	f	-0.023	-0.071	-0.086	0.170
P value	_	.49	.03	.01	<.001
Total PSQ					
r	-0.023	—	0.447	0.401	-0.358
P value	.49	_	<.001	<.001	<.001
Total K6					
r	-0.071	0.447	_	0.212	-0.285
P value	.03	<.001	_	<.001	<.001
R-UCLA					
r	-0.086	0.401	0.212	_	-0.468
P value	.01	<.001	<.001	_	<.001
RSES					
r	0.170	-0.358	-0.285	-0.468	—
P value	<.001	<.001	<.001	<.001	—

^aeHEALS: eHealth Literacy Scale.

^bPSQ: Premenstrual Symptoms Questionnaire.

^cK6: 6-item Kessler Psychological Distress Scale.

^dR-UCLA: 3-item Revised UCLA Loneliness Scale.

^eRSES: Rosenberg Self-Esteem Scale.

^fNot applicable.

Factors Associated With High eHealth Literacy

We performed multivariable logistic regression analysis to identify the factors significantly associated with high eHealth

literacy (Table 5) and found that high self-esteem was significantly associated with high eHealth literacy.



Table 5. Factors associated with high eHealth literacy (eHealth Literacy Scale≥26; R2=0.04).

Factors	Odds ratio (95% CI)	P value
Age (years)	1.026 (0.880-1.197)	.74
BMI (kg/m ²)	0.954 (0.899-1.010)	.11
Age at menarche (years)	0.900 (0.801-1.091)	.07
Menstrual pain intensity	0.976 (0.917-1.040)	.46
Duration of internet use (hours)	1.015 (0.942-1.091)	.70
Sleeping duration (hours)	1.066 (0.929-1.224)	.36
Total PSQ ^a	1.010 (0.980-1.023)	.34
Total K6 ^b	1.001 (0.979-1.023)	.94
R-UCLA ^c	0.996 (0.933-1.062)	.90
RSES ^d	1.076 (1.047-1.107)	<.001

^aPSQ: Premenstrual Symptoms Questionnaire.

^bK6: 6-item Kessler Psychological Distress Scale.

^cR-UCLA: 3-item Revised UCLA Loneliness Scale.

^dRSES: Rosenberg Self-Esteem Scale.

Discussion

Principal Findings

This study examined the eHealth literacy levels of female Japanese high school students and their associations with premenstrual symptoms, psychological distress, loneliness, and self-esteem. The findings highlight the importance of eHealth literacy in adolescent health and suggest that students with higher eHealth literacy tend to experience better mental and reproductive health outcomes. Additionally, this study contributes to the growing body of evidence indicating that digital health literacy plays a significant role in adolescent development and well-being—particularly as reflected in their health-related decision-making processes.

eHealth Literacy Level

The results showed that the mean eHEALS score among participants was 22.8, with 32.1% classified as having high eHealth literacy. Compared with eHEALS scores of 23.6 and 23.5 for university students and the general population in Japan, respectively [10,12], the values obtained in this study appear to be slightly lower. As the data on adolescents overseas in the same age group are limited, performing comparisons becomes challenging. However, among 702 high school students in Serbia (mean age: 16.5 years), the average eHEALS score was 26.0 [14], and among 260 high school students in Brazil (mean age: 15.6 years), the average eHEALS score was 28.1 [15]. Based on these values, Japanese students appear to have a lower eHEALS score. The eHealth literacy of Japanese high school students obtained in this study was lower than that of Japanese university students, adults, and overseas high school students, suggesting a need for further improvement. The results of this study showed that eHEALS scores increased for some items in the second year compared with those in the first year, but there was no difference in scores between the years when assessed as a whole. Therefore, it is difficult to expect an improvement

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in eHealth literacy during the natural course of events, and educational interventions may be necessary.

eHealth Literacy, Psychological Well-Being, and Social Connectedness

The negative association between eHealth literacy and loneliness suggests a potential link between digital health literacy and social connectivity. Adolescents with higher eHealth literacy may be more likely to engage with credible online health communities, which could help alleviate feelings of isolation. Additionally, the positive correlation between eHealth literacy and self-esteem indicates that adolescents with stronger digital health literacy may feel more empowered to make informed health decisions, potentially contributing to greater confidence and a more positive self-image.

Association Between eHealth Literacy and Menstrual Symptom Severity

The intensity of menstrual pain and premenstrual symptoms, as assessed using the total PSQ score, did not differ according to the level of eHealth literacy. In terms of premenstrual symptoms, the high eHealth literacy group reported significantly lower levels of "feeling overwhelmed" than the low eHealth literacy group. However, other PMS symptoms, such as mood swings, fatigue, and irritability, were not significantly different between the groups. This suggests that, although higher eHealth literacy may be related to better psychological resilience, its direct relationship with overall premenstrual symptom severity remains unclear. Further investigation is needed to determine whether increased eHealth literacy leads to improved symptom management or whether other factors, such as coping strategies and social support, mediate this relationship. It is possible that individuals with high eHealth literacy possess more accurate knowledge of premenstrual symptoms, which might help them manage symptoms more calmly and avoid feeling overwhelmed, potentially reducing interpersonal difficulties. These findings suggest that higher eHealth literacy may be associated with

improved psychological resilience and coping strategies for menstruation-related issues. Moreover, our results are consistent with those of prior research linking higher health literacy to improved management of menstrual symptoms among working women [22]. However, this study extends these findings by focusing on younger adolescents and exploring the relationship between eHealth literacy and premenstrual symptoms in relation to more detailed symptoms and details of social dysfunction, an area that has received less attention in previous studies.

Correlation Between eHealth Literacy and Psychological Measures

The Pearson correlation analysis revealed a negative association between eHEALS scores and psychological distress (K6: r=-0.071; P=.03), as well as loneliness (R-UCLA: r=-0.086; P=.01), whereas a positive association was observed between the eHEALS score and self-esteem (RSES: r=0.170; P<.001). Although these associations were statistically significant, the effect sizes were small, suggesting that eHealth literacy alone may not be a strong predictor of psychological well-being. Additional factors, such as social relationships and coping mechanisms, should be considered in future research. These results suggest that adolescents with higher eHealth literacy are better equipped to access and interpret mental health information, which may help explain the lower psychological distress and higher self-worth observed in this study. Future research should investigate the causal relationships between eHealth literacy and mental well-being using longitudinal data.

Factors Associated With High eHealth Literacy

The multivariate logistic regression analysis showed that high self-esteem was significantly associated with high eHealth literacy. These results align with previous findings among university students in the United Kingdom [42]. This finding highlights a strong link between self-esteem and eHealth literacy, suggesting that positive self-perception may be an important factor to consider in adolescent eHealth literacy programs.

Limitations and Future Directions

Despite its strengths, this study has some limitations. First, the cross-sectional design precludes causal inference; therefore, longitudinal studies are needed to establish temporal relationships between eHealth literacy and health outcomes. Second, the study sample was limited to female students from 2 public high schools in Sendai, which may limit the generalizability of the findings to other regions and populations. Future studies should include more diverse samples, including students from different geographic and socioeconomic backgrounds. Expanding this research to include male adolescents and individuals from rural areas would provide a more comprehensive understanding of how eHealth literacy affects various demographics. Third, this study used self-administered online questionnaires completed hv participants in their home environments. Although this approach offers convenience and accessibility, it has the following limitations: (1) potential response bias, including social desirability bias and misinterpretation of questions resulting from lack of direct supervision; (2) the home setting, which

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may have allowed outside influences or noncompliance with instructions, potentially affecting the authenticity of responses; and (3) collecting sensitive psychological and health-related information in an uncontrolled environment, which raises concerns about data integrity. However, discussing reproductive health is often taboo worldwide, especially in Asia, including Japan, with its conservative cultural and religious background [43]. Openly discussing menstrual issues in Japanese school classrooms is very difficult, and online after-school surveys are more likely to reveal the true status of students. Fourth, the study did not evaluate other participant-related factors that may influence eHealth literacy, such as parental education level, family economic status, and participants' medical history [13,44-46]. Although the survey was administered online and completed by students after school, these questions were considered sensitive and difficult to ask. Therefore, it was challenging to include them in a study conducted as part of regular high school activities. Moreover, we acknowledge that other factors-such as access to internet resources, support from family and the community, and a family or maternal history of symptoms or gynecological or endocrine conditions-may also influence eHealth literacy and its related outcomes. Although these variables were not assessed in this study, their potential impact on health-related factors, such as self-esteem, should not be overlooked. These factors may interact with the psychosocial and reproductive health outcomes examined here. We recommend that future studies incorporate these elements to enhance the understanding of adolescent health in relation to eHealth literacy. Fifth, the logistic regression analysis in this study included 10 variables but did not account for potential confounders such as socioeconomic status, academic stress, home environment, and previous digital health education. As mentioned previously, items related to socioeconomic background and home environment were excluded because of ethical and practical limitations inherent in this school-based survey. Although past health education could have been included as a question, there are very few systematic digital health education programs for high school students in Japan. We judged that there was little variation in this factor and thus did not consider it meaningful as an analytical variable. Nevertheless, the omission of these factors may limit the comprehensiveness of the regression analysis, and future studies should include these variables as much as possible, depending on the circumstances.

Furthermore, this study focused only on specific health outcomes—namely, premenstrual symptoms, psychological distress, loneliness, and self-esteem. Future research should investigate additional physical and mental health outcomes to develop a more comprehensive understanding of how eHealth literacy influences adolescent health. Further research should explore potential interventions to enhance eHealth literacy and examine their long-term impact on adolescent health. In fact, a study with secondary school students in Spain demonstrated the educational impact of training sessions on eHealth literacy [47].

Conclusions

In conclusion, this study highlights the importance of eHealth literacy for adolescent well-being. We found that higher eHealth

literacy was associated with lower loneliness, higher self-esteem, and a reduced premenstrual symptom burden, particularly regarding feelings of being overwhelmed. These findings suggest that integrating eHealth literacy education into school programs could potentially benefit adolescents' mental and reproductive health, although this should be confirmed in future studies. Future studies should aim to include more diverse populations—such as male adolescents and students from various socioeconomic backgrounds—and adopt longitudinal approaches to better understand the causal relationships between eHealth literacy and adolescent health outcomes. Future research should also focus on developing and evaluating interventions aimed at improving eHealth literacy and its long-term impact on adolescent health outcomes. By prioritizing digital health literacy initiatives, educators, health care professionals, and policymakers may help cultivate a more informed and health-conscious future generation.

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Data Availability

The data obtained in this study are available from the corresponding author upon request.

Authors' Contributions

TT, KY, SK, and FI designed the study. TT and FI collected the data. TT analyzed and interpreted the data and wrote the manuscript. KY, SK, and FI revised the manuscript. KY and SK supervised the study and provided conceptual assistance. All the authors read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

eHEALS: eHealth Literacy Scale K6: 6-item Kessler Psychological Distress Scale NRS: numerical rating scale OR: odds ratio PMS: premenstrual syndrome PSQ: Premenstrual Symptoms Questionnaire R-UCLA: 3-item Revised UCLA Loneliness Scale RSES: Rosenberg Self-Esteem Scale RSES-J: Japanese version of the RSES

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Evidence of Interventions for the Prevention of Unintentional Injuries: Scoping Review

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Abstract

Background: Unintentional injuries are the leading cause of death and disability among young children. Preventive strategies for unintentional injuries are mainly based on surveillance data and identifying risk factors.

Objective: This study aimed to review and synthesize published literature that determined the effectiveness of interventions for preventing unintentional injuries among children.

Methods: The methodological framework was supported by The Joanna Briggs Institute Reviewer's Manual – Methodology for JBI Scoping Reviews as well as the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines. The inclusion criteria to include the studies in the review were unintentional injuries in children, interventions to prevent injuries, a brief description of the intervention and the outcome of the intervention, and articles published in a peer-reviewed journal and written in the English language.

Results: In total, 21 articles were included in the review following the systematic search of key databases such as Web of Science, PubMed/MEDLINE, Scopus, ScienceDirect, and gray literature for studies published between July 2013 and May 2023. Of the 21 articles, 16 were randomized controlled trials, 4 were nonrandomized controlled trials, and 1 was a mixed method study. The findings of the review showed that interventions, either as a single measure (video-based teaching, testimonial story-based teaching, health education, storybook reading) or in combination (knowledge quiz and simulation test, module-based teaching along with personal counseling, and teaching with the help of video and poster), have shown a considerable decline in the number and severity of injuries. The studies included various target populations, including children and adolescents between 0 and 19 years old.

Conclusions: The review results indicate the need to plan, implement, and reinforce preventive measures and techniques to reduce unintentional injuries among children. They can also serve as a useful indicator for policymakers.

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KEYWORDS

prevention; injury; education; health; child; children; unintentional injury; disability; youth; surveillance; surveillance data; risk factor; injury intervention; literature search; scoping review; scoping literature review; policymaker; preventative measure; preventive measure

Introduction

Background and Significance

Unintentional injuries among children are a major public health concern and result in significant childhood morbidity and mortality [1]. In addition to mortality risk, unintentional injuries can result in significant disability and disruption to quality of life [2,3]. Unfortunately, over 95% of all child injury deaths

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occur in low- and middle-income countries, resulting in a highly inequitable burden [4]. In India alone, unintentional injuries contribute to 9.1 deaths per 100,000 population, while transport injuries account for 2.8 deaths per 100,000 population [5].

Childhood encompasses different stages of emotional, physical, and brain development, ranging from newborn to adolescence. The age between birth and 5 years is a time of rapid changes in children's physical and cognitive abilities that can increase their

risk of unintentional injury [6]. Temperamental attributes such as increased activity level and impulsiveness in young children have been associated with proneness to injury [7]. Each of the new developmental stages in children brings changes in their physical, cognitive, or social development and the emergence of new injury hazards, thus emphasizing the importance of awareness of how injuries occur in certain populations to anticipate and avoid the risks [8].

Unintentional injuries were noted among children of younger mothers, overactive children, children belonging to extended or joint families, and children from urban dwellings, which assists in the identification of contributing risk factors to formulate strategies aimed at risk reduction and prevention of childhood injuries [9]. The environmental risk assessment found unsafe electrical points, unsafe stairs, unsafe kitchens with access to sharps, access to active fire, and unsafe furniture and objects as the most common risk factors leading to home injuries among young children [10]. Children left unsupervised or inadequately supervised may sustain negative physical, mental, or social outcomes [11].

The most challenging aspect for caregivers is to provide a safe environment for children to minimize injuries at home [12]. Toddlers and preschoolers are fragile as per their physical development and they spend most of their time at home compared to school-age children. This might impose a higher risk of developing unintentional injuries among children of this age [13]. The development of effective home hazard reduction educational materials could have a significant impact on the burden of home injuries in children, particularly in lower-income countries [14].

Studies are available on interventions to prevent unintentional injuries that are effective in improving various parameters such as knowledge, attitude, practice, and home environment.

Objectives

This scoping review aimed to review and synthesize published literature that determined the effectiveness of interventions for preventing unintentional injuries among children and the magnitude of the outcomes to support children and families. Additionally, it aims to provide an overview of the various interventions and understand those that are effective in preventing unintentional injuries. The results of this review can assist researchers and health care professionals in implementing injury prevention interventions and creating awareness among caregivers. The search question guiding this scoping review study was: what evidence exists that determines the implementation and effectiveness of interventions to prevent unintentional injuries in children? The review also focused on the most cost-effective interventions for the prevention of unintentional injuries for implementation in resource-limited settings.

Methods

Overview

This scoping review examined the relevant literature on interventions addressing unintentional injuries among children. The methodological framework was supported by the Joanna

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Briggs Institute Reviewer's Manual – Methodology for JBI Scoping Reviews, which builds on the framework introduced by Arksey and O'Malley [15] of Population, Concept, and Context, to create our search terms, with the population being parents or caregivers of children aged <12 years and children with age ranging from 0 to 19 years. The core concept is the

The review process followed 5 stages as outlines by Arksey and O'Malley [15]: stage 1, identifying the research question; stage 2, identifying relevant studies; stage 3, selecting studies; stage 4, charting the data; and stage 5, collating, summarizing, and reporting the results. The optional stage 6 is a consultation exercise to inform and validate the review findings with critical stakeholders, which was not carried out in this review. The methodological rigor of the individual studies was not assessed. However, each study was assessed for importance and coherence with the review question. We used the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines to enhance transparency in our approach to the scoping review study [16]. The PRISMA-ScR guidelines checklist is depicted in Checklist 1.

prevention of unintentional injuries and includes interventions

designed within the context of home, community, well-baby

clinic, and preschool settings.

Stage 1: Identifying the Research Question

The review question was as follows: what evidence exists that determines the implementation and effectiveness of interventions to prevent unintentional injuries in children? The objectives of the review were (1) to provide a comprehensive overview of interventions to prevent unintentional injuries at home and (2) to identify the impact of interventions and outcomes on reducing the occurrence/incidence of unintentional injuries and improving the knowledge of parents/families regarding preventive strategies. The keywords used for the search were "injuries," "unintentional injuries," "prevention," and "interventions."

Stage 2: Identifying Relevant Studies

The literature research included studies published between July 2013 and May 2023. Two independent reviewers (BSN and SS) searched the MEDLINE/PubMed, Scopus, ProQuest, Embase, and CINAHL databases for relevance. Search strategies specific to each database were developed. Any discrepancy in the extracted data was again rechecked by a third reviewer (AG) to resolve the discrepancy. AS provided subject expertise, and VG provided statistical input. The free-text terms and controlled vocabulary terms were combined via the relevant Boolean operators—AND, OR, and NOT. The bibliography and citations of the included studies were further searched to identify any additional studies pertinent to the review.

Stage 3: Selecting Studies

The articles identified through searches were exported to Rayyan software for duplicate removal and title and abstract screening. Concerns with data extraction were resolved in consultation with the team members. Based on the eligibility criteria, relevant articles were reviewed and selected.

We included peer-reviewed, free, full-text articles published in the English language. Narrative reviews, critical reviews, systematic reviews, and meta-analyses, as well as nonempiric publications like editorials, opinion pieces, case reports, conference abstracts, and commentaries, were excluded. Studies that reported any interventions targeting a reduction or prevention of the incidence/occurrence of unintentional injuries among children or improved knowledge or change in behavior of parents were included. Quantitative interventional studies such as randomized controlled trials (RCT), non-RCT studies, quasi-experimental studies, before-and-after design, crossover designs, and mixed methods studies, which include interventions, were included. Observational studies and qualitative studies were excluded from the scope of this review.

Stage 4: Charting the Data

The data extraction was carried out by 2 reviewers (BSN and SS), and any discrepancy in the extracted data was again rechecked by a third reviewer (AG). Data from the articles were extracted into an extraction table. The table included columns for authors, country of origin, year of publication, objectives, research design, sample size, target population, details of intervention, time frame of data collection, and main findings. Pilot testing of the data extraction framework was performed on 3 studies that were reviewed before the data extraction. No modifications were carried out in the data extraction framework. The summary of data extraction is depicted in Table 1.



Table . Description of data gathering measures of selected studies.

Author, year, country	Objective and study design	Target population	Intervention details	Measures and data col- lection	Findings and outcomes
Feng et al [17], 2023, China	To explore the mecha- nisms by which online social-network-based health education is ef- fective in reducing un- intentional injuries. RCT ^a .	Parents of children aged 0-3 years (n=138)	Health education inter- vention to improve knowledge, skill, and behavior of parents re- garding unintentional injuries through a WeChat account for 12 weeks, and communica- tion of parents with each other and commu- nity childcare doctor for 9 months.	The knowledge, skills, and beliefs of parents regarding unintentional injuries in children were assessed before and after the interven- tion.	Of 76 parents in the in- tervention group, 49 (64.5%) demonstrated better understanding and effective communi- cation compared to 11 (31.9%) parents of 66 in the control group. A positive impact on en- hancing parents' knowledge, skills, and beliefs about uninten- tional childhood in- juries was noted.
Ning et al [18], 2019, China	To assess the effective- ness of an app-based intervention to prevent unintentional injury. RCT.	Caregivers of preschool children aged 3-6 years (n=1980)	An app-based parent- ing education on unin- tentional injury preven- tion, with submodules to support interaction among users, surveys, and feedback.	Assessment of injury incidence, caregiver's attitude toward injury prevention, and safety behaviors measured at baseline and at 3- and 6-month follow-up vis- its.	No change in the inci- dence of injury and caregiver's attitude in either of the groups noted during the 6- month follow-up. Changes in injury pre- vention behavior were greater in the interven- tion group (B=.87, 95% CI 0.33 - 1.42).
Feng et al [19], 2022, China	To evaluate the effec- tiveness of an online social communi- ty-based parental health education inter- vention in preventing unintentional injuries in children between 0 and 3 years of age. RCT.	Parents of children aged 0-3 years (n=365)	WeChat Group and WeChat official ac- count named, "Chil- dren Safety and Health." Thirty studies and 30 text messages on unintentional injury prevention and videos on first aid measures were produced and sent to the parents' WeChat group (intervention group).	Beliefs about uninten- tional injuries, skill in first aid measures for injuries, and behavior toward unintentional injuries were mea- sured.	A significant difference in the occurrence of in- juries was observed between the interven- tion and control groups (OR^b 1.71, 95% CI 1.02 - 2.87; P =.04). The skill component showed a significant difference (P =.06) in the area of first aid for a tracheal foreign body.
Shen et al [20], 2016, China	To evaluate the effica- cy of a testimonial- based video interven- tion in reducing drowning risk among school-aged children. RCT.	Children in third and fourth grade (n=280)	Testimonial-based inter- vention on drowning prevention; a 36- minute video of 4 testi- monial stories about actual near-drowning experiences.	Safety knowledge on prevention of drown- ing, child-perceived vulnerability, and child-simulated behav- ior in and around the water measured at baseline and a week af- ter the intervention.	A significant improve- ment was observed in children's safety knowledge of drown- ing risk ($F_{1,250}^{c}$ =7.04; <i>P</i> =.008) and safe, simu- lated behaviors ($F_{1,}$ 245=8.27; <i>P</i> =.004) relat- ed to playing in and near water. A minimal impact on children's perceived vulnerability to drowning risk was found.



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Author, year, country	Objective and study design	Target population	Intervention details	Measures and data col- lection	Findings and outcomes
Wang et al [21], 2018, United States	To evaluate the effec- tiveness of an interven- tion grounded in social cognitive theory on the reduction of home safety problems. RCT.	Mother-toddler (12 - 32 months) dyad (n=277)	Safety intervention through health educa- tion, goal setting, and social support on fire and fall prevention, poison control, and car seat use.	Assessment of home safety problems and self-efficacy behavior measured at baseline and 6 and 12 months after the intervention.	There were fewer safe- ty problems in the inter- vention group (be- tween-group difference in change over time β =-0.54, 95% CI -0.05 to -1.03; <i>P</i> =.035) and decreased self-efficacy scores were noted at 12 months follow-up.
Weaver, et al [22], 2019, United States	To evaluate the effec- tiveness of a tailored parenting program on parenting behaviors. RCT.	Caregivers of children between 0 and 5 years (n=125)	RISE UP, a tailored parenting program to promote nurturing, child development, re- siliency, social connec- tion, and support with- in the context of unin- tentional injury preven- tion.	Safety behaviors of parents related to unin- tentional injury areas were assessed.	Postintervention fol- low-up showed a de- crease in parenting in- jury risk scores (95% CI 25-42) and the inter- vention promoted posi- tive parenting behav- iors.
Swartz et al [23], 2013, United States	To evaluate the effec- tiveness of Keeping Baby Safe In and Around the Car, a video-based DVD on child safety seat instal- lation and use. RCT.	Parent or custodian of a child aged 0-24 months (n=195)	Self-directed viewing of Keeping Baby Safe In and Around the Car, a video-based DVD lasting 45 minutes	Pre- and posttest assess- ment of vehicle safety knowledge quiz and child safety seat instal- lation simulation test.	A significant improve- ment in parents' knowledge (<i>F</i> -value 103.71; <i>P</i> <.001) of car seats and their ability to discriminate the crit- ical elements of correct car seat installation was found among the intervention group.
McKenzie, et al [24], 2021, United States	To evaluate the effect of a mobile technolo- gy–based health behav- ior change intervention on parental safety knowledge and behav- ior in preventing unin- tentional injuries. RCT.	Parents and caregivers of children aged be- tween 0 and 12 years (n=5032)	The Make Safe Happen App was developed to help parents and care- givers learn about making their homes safer for children. It in- cludes room-by-room safety checklists and links to purchase home safety products from Amazon.com.	Safety knowledge and safety actions of par- ents/caregivers were assessed during the pretest and posttest.	Mean knowledge score significantly increased between the pretest and posttest: intervention (8.45 - 10.32; P < .0001) and control participants $(8.51 -$ 8.87; $P = .0064$). There was an increase in the percentage of partici- pants who reported do- ing all repeated safety actions from 71.1% (pretest) to 77.3% (posttest) for the inter- vention group (P = .0001).
Banerjee et al [25], 2021, India	To evaluate the effec- tiveness of the child-to- child approach in pre- venting unintentional injuries in children. Non-RCT.	Children and adoles- cents from 0-19 years (n=397)	Older adolescents of the family were trained in first aid and CPR ^d , road safety, traffic rules, injury preven- tion, and immediate care. They were made to disseminate the knowledge to their younger siblings and other family members.	The magnitude of in- juries, time taken for recovery from injuries, knowledge of partici- pants, and practice of the family were as- sessed during the pre- and postintervention period.	The postintervention measurement showed a significant reduction in the incidence of in- juries (intervention: 16; 2.03, 0.06 - 4.0; con- trol: 29; 3.62, 1.03 - 6.2; P <.001) and im- provement in knowl- edge and practice on injuries in the interven- tion group. The total time taken for recovery was also evident in the intervention group (143 vs 95 days).

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Author, year, country	Objective and study design	Target population	Intervention details	Measures and data col- lection	Findings and outcomes
George et al [26], 2021, India	To examine the effect of a home safety super- visory program on childhood safety, self- reported home hazards, and caregivers' supervi- sory attitude. RCT.	Caregivers of children aged between 2-5 years (n=130)	The Home Safety Su- pervisory Program consisted of a video and poster on "safe home, safe child" and individual home visits.	Injury patterns, home safety practices, and self-reported home hazard practices were assessed at baseline and 1 month after the intervention.	Significant difference in the mean baseline scores of caregivers' self-reported home hazard practices be- tween the 2 groups (P <.001) and an im- provement in the super- visory attitudes of caregivers in the inter- vention group (P <.001) were observed.
Holla et al [27], 2021, India	To evaluate the effec- tiveness of school- based interventions in promoting child safety and reducing uninten- tional injuries. RCT.	Children from classes 5 to 7 (n=1100)	A comprehensive picto- rial child safety and in- jury prevention module was taught by 2 teach- ers on a regular basis (25 - 30 hours on aver- age/school)	Incidences and types of unintentional injuries were assessed during the pretest and at fol- low-up visits at 3, 6, and 10 months after the intervention.	The incidence of unin- tentional injuries de- clined from baseline until the end of the study in the interven- tion and control groups. However, the decline in incidence was higher in the inter- vention group (50.4% vs 12.7% ; P <.001).
Taylor et al [28], 2023, United Kingdom	To assess the effective- ness of systematically delivered, evidence- based home safety pro- motion for improving child home-safety practices. Non-RCT.	Families consisting of parents or caregivers of children between the ages of 2 and 7 months (n=361)	Stay One Step Ahead, a multievidence-based intervention for fami- lies, consisted of monthly safety mes- sages through quizzes, posters, and flyers; home safety activities; home safety checklists; and educational safety weeks for families on common injuries.	Home safety outcomes measures were as- sessed at baseline and 12 and 24 months of follow-up.	The families in the in- tervention group showed significantly more improvement in storage of poisons out of reach (OR 1.81, 95% CI 1.06-3.07; P=.029). The total number of home safety measures used by the intervention families was significantly more than the control group families at 12 months (β =0.34, 95% 0.06- 0.63; P =.019) and 24 months follow-up (β =0.46, 95% CI 0.13- 0.79; P =.006).
Cowley et al [29], 2021, United Kingdom	To assess the impact of SafeTea on the knowl- edge and behavior of parents with regard to the prevention of scalds and first aid for burns. Mixed method design.	Parents or caregivers of children less than 5 years of age	SafeTea, a community- based intervention that provides information to parents regarding the risk factors for hot drink scalds and first aid for burns. The campaign included video clips, posters, leaflets, and charts dis- tributed to schools, nurseries, and parent groups.	Knowledge and behav- ior of parents related to the prevention of scalds and first aid for burns were assessed.	Qualitative analysis under 4 themes: "reach," "engage- ment", "acceptability," and "impact/be- havioural change." Reach and engagement declined after the first month due to decreased publicity and social media promotion. Changes in parents' behavior to minimize the risk of burns noted. Awareness of parents on the dangers of hot drinks and use of appro- priate first aid mea- sures improved.



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Author, year, country	Objective and study design	Target population	Intervention details	Measures and data col- lection	Findings and outcomes
Morrongiello et al [30], 2013, Canada	To evaluate the effica- cy of the Supervising for Home Safety pro- gram on mothers' su- pervision practices. RCT.	Caregivers of children between 2 and 5 years of age (n=186)	Watchful Parents, Safe Children video (20 minutes), followed by a structured discussion for 40 minutes. Moth- ers were given supervi- sion diary recording forms for an 8-week baseline period.	Two time points of di- ary-based recording of postintervention prac- tices—after 1 month and 3 months.	Significant decrease in time the children were unsupervised $(F_{1,83}=4.81; P=.04)$, higher levels of supervi- sion $(t_{166}=2.99; P<.01)$, and an increase in attention to the child, immediately $(t_{67}=5.22; P<.01)$ and 3 months $(t_{67}=3.84; P<.01)$ after the inter- vention.
Morrongiello et al [31], 2021, Canada	To evaluate the effec- tiveness of a storybook about home safety on preschoolers' safety knowledge and injury risk behaviors. RCT.	Preschool children aged 3.5 to 5.5 years (n=59)	A storybook, "Careful Puppy Saves the Day," with information on different hazards in and around the home. Mothers were instruct- ed to read the book with their children for 10 min/day, 4 times/week.	Knowledge about haz- ards and injury risk be- havior was assessed at baseline and 4 weeks after the intervention.	Children in the inter- vention group were able to identify more hazards, showed fewer risky behaviors, and provided a more com- prehensive explanation of safety ($\eta p2=0.13$, 0.19, and 0.51, respec- tively).
Khan et al [32], 2023, Pakistan	To evaluate the effec- tiveness of the long- term effect of 2 injury prevention interven- tions on the prevalence of home injury hazards. Non-RCT.	Caregivers of children under the age of 5 years (n=312)	Two interventions were included: an education- al pamphlet and a tuto- rial. Both consisted of information on injury hazards for children that are commonly found in homes along with the strategies to reduce or eliminate those hazards.	Reduction in home in- jury hazards was classi- fied into 6 types: falls, burns, poisoning, drowning, cut injuries, and choking, which were assessed at base- line, 3 months after the intervention, and 2 years after the interven- tion.	The long-term outcome showed a significant reduction in injury hazards in the tutorial group when compared to the educational pamphlet group: falls (IRR ^e 0.24, 95% CI 0.08 - 0.71), drowning (IRR 0.45, 95% CI 0.85 - 0.98), burns (IRR 0.56, 95% CI 0.33 - 0.78), poisoning (IRR 0.53, 95% CI 0.44 - 0.77), and breakable objects with- in reach of child (IRR 0.62, 95% CI 0.39 - 0.99).
Tajiki et al [33], 2022, Pakistan	To examine the effica- cy of a training pro- gram based on the health belief model in burn prevention knowledge in mothers of children aged 1-3 years. RCT.	Mothers of children aged between 1 and 3 years (n=64)	The educational inter- vention on preventing burns was delivered using lectures and PowerPoint slides, edu- cational pamphlets, and illustrated books. It was a 45-minute ses- sion per week for a pe- riod of 6 weeks.	The questionnaire on the Health Belief Mod- el for the prevention of burns in children was administered before the intervention, immedi- ately after the interven- tion, and 2 months af- ter the intervention.	There was a significant difference between the groups in terms of per- ceived susceptibility and severity during im- mediate and 2 months postintervention (con- trol: 11.9, SD 0.53 vs 13.34, SD 0.82; inter- vention: 18.06, SD 0.24 vs 15.93, SD 0.24; P <.001). Significant difference in mean scores of perceived barriers and benefits (control: 9.78, SD 0.49; 9, SD 0; P =.6; interven- tion: 11, SD 0; 11.5, SD 1.04; P <.001).

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Author, year, country	Objective and study design	Target population	Intervention details	Measures and data col- lection	Findings and outcomes
Choi and Ahn [34], 2021, Republic of Ko- rea	To evaluate the effec- tiveness of mobile- based parental educa- tion programs in pre- venting unintentional childhood injuries. RCT.	Parents or relatives caring for infants and toddlers (n=167)	Two groups. First group: e-learning pro- gram for preventing unintentional injuries. Second group: electron- ic document distribu- tion group, which re- ceived a PDF of e- learning content.	Safety knowledge and safety behavior regard- ing unintentional in- juries were assessed during the pretest and 2 weeks after the inter- vention.	There was no signifi- cant difference found in the safety knowl- edge of the participants in both intervention groups. However, the safety behavior be- tween the 3 groups showed statistically significant differences (F=10.09; P<.001).
van Beelen et al [35], 2014, the Netherlands	To evaluate the effec- tiveness of web-based, tailored safety informa- tion combined with personal counseling on parents' safety behav- iors. RCT.	Parents with a child aged 5-8 months (n=1292)	E-health4Uth module, along with personal counseling on safety in and around the home on prevention of falls, poisoning, drowning, and burns in children aged between 12 and 24 months.	Parents' child safety behavior on prevention of falls, poisoning, drowning, and burns was assessed at base- line and 6 months after the intervention.	Parents in the interven- tion group showed sig- nificantly less unsafe behavior when com- pared with control group parents. Parents positively rated the E- health4Uth home safe- ty intervention as an effective source of in- formation (mean 4.05, SD 0.62).
Myers et al [36], 2022, Israel	To evaluate the effect of the intervention on injuries in children aged 0-4 years. Non- RCT.	Children aged 0-4 years and 5-17 years through home visits (n=6334)	The multifaceted inter- vention included a youth leadership pro- gram, workshops in well-baby clinics and preschools, home vis- its, and a media cam- paign.	Data on visits to the emergency room and hospitalization were obtained from the hos- pital records during the pre- and postinterven- tion periods.	There was a significant reduction in emergency room visits (7.6%) in children between 0 and 3 years during postinter- vention period. Admis- sions to the hospital for burns and falls re- duced. A greater reduc- tion in emergency room visits (P =.038; P=.004) was observed for children aged 0-4 years in towns that started the intervention earlier.
Cheraghi et al [37], 2014, Iran	To assess the effect of the Health Belief Mod- el on the education of mothers for promoting safety and preventing injury. RCT.	Mothers with at least 1 child below the age of 5 years (n=120)	Four sessions, 1 hour each, twice per week, on factors affecting mothers' knowledge and practices and Health Belief Model constructs.	Assessment of moth- er's knowledge, prac- tice, Health Belief Model constructs, and injury history before and 2 months postinter- vention.	There was a significant mean difference in mothers' knowledge (3.98), practice (2.47), and Health Belief Model constructs in the intervention group (P <.001). The number of injuries decreased from 7 to 2 in the intervention group.

^aRCT: randomized controlled trial.

^bOR: odds ratio.

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^c*F*: analysis of variance.

^dCPR: cardiopulmonary resuscitation.

^eIRR: incidence risk ratio.

Stage 5: Collating, Summarizing, and Reporting the Results

Results

Overview

Data extracted from the included studies were collated and textually summarized and findings were tabulated as key categories.

The database search identified 1683 articles, of which 245 (14.56%) were duplicates, so we screened the titles and abstracts

of 1438 (85.44%) articles. A total of 36 studies were evaluated for eligibility, and 21 studies were included in the review. Most studies that remained included parents or caregivers as participants (16/21, 76%), while some studies examined children specifically (5/21, 24%). Figure 1 provides an overview of the study selection process and the reasons for the exclusions of full-text articles.





Study Characteristics

All 21 articles included were published in peer-reviewed journals. The review included 4 (19%) studies conducted in China [17-20], 4 (19%) in the United States [21-24], 3 (14%) in India [25-27], 2 (10%) in the United Kingdom [28,29], 2 (10%) in Canada [30,31], 2 (10%) in Pakistan [32,33], 1 (5%) in Korea [34], 1 (5%) in the Netherlands [35], 1 (5%) in Israel [36], and 1 (5%) in Iran [37]. The sample size of the studies ranged from 59 to 6334. The studies identified various target populations, including children and adolescents aged between 0 and 19 years. Diverse interventions such as teaching, training, workshops, technology-based training, storybooks, educational book-based training, and model-based training were identified. The target population included parents, caregivers, or family members, as well as children and adolescents with ages ranging from 0 to 19 years. Table 1 provides a detailed overview of the study characteristics.

Interventions Targeting Parents, Caregivers, and Family

Parents or caregivers supervise the activities of young children at home and are accountable for their environment. Hence, it is critical to assess their knowledge, attitudes, and practices regarding unintentional injuries and plan and implement effective interventions.

Parents or caregivers were the focus of intervention in 17 of 21 (81%) articles presented in this review. Caregivers of children below the age of 3 years were addressed in 8 of 17 (47%) articles [17,19,21,23,28,33-35], which focused on the knowledge of parents on vehicle safety, home safety, self-efficacy behaviors, and skill in first aid measures. Of the 17 articles, 6 (35%) highlighted interventions for parents of children aged less than 5 years [22,26,29,30,32,37], which assessed the levels of supervision and attention toward their children, and knowledge, practice, and safety behavior of parents regarding unintentional injuries. Two articles of 17 (12%) focused on caregivers of children between the ages of 3 and 6 years [18,31], and 1 article (6%) reported an intervention among caregivers of children younger than 12 years [24], which assessed the safety knowledge

and safety actions of parents/caregivers, knowledge about hazards, injury risk behavior, and attitude toward injury prevention.

Interventions Targeting Children as Change Agents

Injury prevention strategies, especially for individual-level factors, may be implemented using different learning approaches and theories. Approaches such as demonstrations, role-play, and simulation at the school level may help children understand how injury prevention interventions could work. Children learn about a health subject and share that information with their parents or the community, encouraging parents and others to enhance their knowledge and engage in health-promoting behaviors.

Of 21 articles, 3 (14%) focused on children of different age groups, evaluating the effectiveness of interventions to prevent unintentional injuries. Children in the third and fourth grades were assessed for their knowledge on the prevention of drowning, perceived vulnerability, and simulated behavior in and around the water [20]. Incidences and types of unintentional injuries were assessed among children in classes 5 to 7 [27]. In another study, through a child-to-child approach [25], adolescent children taught younger siblings and other family members regarding the prevention of unintentional injuries, whereby the knowledge of participants and the practices of the family were assessed.

Effectiveness of Educational Interventions

Education provides individuals with the necessary knowledge and awareness of the benefits and risks associated with certain behaviors. Education stands as a powerful catalyst for change, enabling people to acquire skills, information, and perspectives that shape their attitudes and perceptions.

This review found that 5 of 21 articles (24%) reported various educational interventions as a single strategy or in combination with other modalities to prevent unintentional injuries in children. RISE UP is a tailored parenting program to promote nurturing, child development, resiliency, social connection, and support to prevent unintentional injuries, which showed a decrease in parenting injury risk scores and promoted positive parenting behaviors [22].

Safety education prepares children for specific situations, whereas risk education prepares them for unanticipated or unknown situations, where they may have had no specific instruction or learning opportunity. The child-to-child approach [25] is one such method wherein the older adolescents of the family were trained in first aid and cardiopulmonary resuscitation, road safety, traffic rules, injury prevention, and immediate care. As a next step, they were made to transfer the information to their younger siblings and other family members. In another study, a comprehensive pictorial child safety and injury prevention module, as part of a school-based intervention to prevent injuries and promote child safety, was evaluated [27]. A significant reduction in the incidence of injuries in younger children and improvement in knowledge and practice regarding injury prevention were noted.

A multifaceted intervention with components such as a youth leadership program for adolescents, workshops in well-baby clinics and preschools, home visits, and a media campaign showed a greater reduction in emergency room visits in children between 0 and 3 years of age, as well as reduced hospital admission due to burns and falls injury [36]. A significant reduction in injury hazards was identified in a group that received tutorials when compared to an educational pamphlet [32].

Effectiveness of Home Safety Interventions

Home is a place where children spend lots of time during their younger days. It is the responsibility of the caregivers to ensure a safe place for the kids to learn, play, and explore. Home safety interventions are implemented to reduce the risk of accidents, injuries, and other hazards within households. In total, 4 of 21 articles (19%) reported on the effectiveness of home safety interventions.

Implementation of home-based injury prevention programs through the "Watchful Parents, Safe Children" video, "Safe Home, Safe Child" video, and a poster followed by a structured discussion with mothers and home visits showed a significant decrease in time during which the children were unsupervised, higher levels of supervision, an increase in attention to the child, a significant reduction in the injury pattern in children, and improved mean scores of caregivers' home safety practices [26,30].

Implementation of innovative teaching strategies and playful approaches aimed at children can have a long-lasting effect in reducing unintentional injuries. A storybook, "Careful Puppy Saves the Day," with information on different hazards in and around the home, read by mothers with their children beside them, was incorporated as a change agent. Significant changes were noted in the form of better identification of injury hazards, fewer risky behaviors, and a more comprehensive explanation of safety by the children [31]. Furthermore, Stay One Step Ahead, a multievidence-based intervention for families, incorporated monthly safety messages through quizzes, posters, and flyers; organized home safety activities; and educational safety weeks for families on common injuries. The findings showed a significant improvement in the storage of poisons out of children's reach and improved use of home safety measures [28].

Technology-Based Interventions

Technology-based interventions can provide individualized and tailored interfaces enriched with interactive elements [38], which can be accessed anytime and anywhere. This review identified 9 articles that dealt with the effectiveness of technology-based interventions to prevent various forms of unintentional injuries in children.

A video-based DVD on child safety seat installation and use [23]; a web-based, E-health4Uth module along with personal counseling on the prevention of falls, poisoning, drowning, and burns [35]; a testimonial-based video intervention in reducing drowning risk among school-aged children [20]; and an app-based parenting education intervention to prevent unintentional injury [18] are a few of the studies that used

technology as a medium to disseminate the information to children and caregivers. The results of the studies show an improvement in their respective areas of assessment, which include the ability of caregivers to rightly install the car seat, less unsafe injury-prone behaviors, and children's safety knowledge of drowning risk.

SafeTea is a community-based intervention that incorporates video clips, posters, leaflets, and charts to educate parents regarding the risk factors for hot drink scalds and first aid for burns [29]. Choi and Ahn [34] conducted a mobile-based parental education program to prevent unintentional injuries in children, and McKenzie et al [24] studied the effectiveness of the Make Safe Happen App, which helped caregivers keep their homes safe and also provided links to purchase home safety products from Amazon.com. Two studies [17,19] used WeChat accounts for social-network–based health education to enhance the knowledge, skill, and beliefs of parents about unintentional injuries.

Interventions Based on Models and Theories

A theory is a comprehensive framework for explaining and predicting phenomena, while a model is a focused and practical tool that represents parts of a theory, helping to visualize or analyze specific aspects. We found that 3 of 21 articles (14%) reported on the effectiveness of interventions based on theories and models.

Two studies [33,37] evaluated the effect of training programs on mothers' knowledge regarding the prevention of unintentional injuries in children based on the Health Belief Model. Wang et al [21] assessed the effectiveness of an intervention grounded in social cognitive theory. The outcome of the reviewed article showed an improvement in the mothers' knowledge and practice, a decrease in the number of injuries, a significant difference in the Health Belief Model constructs, and fewer safety problems. Health education models can be used when planning educational programs at the individual or community levels.

Discussion

Principal Findings

The study aimed to answer the following scoping review question: what is known globally from the existing research literature about interventions to prevent unintentional injuries in children?

This review highlights the different areas of unintentional injuries, the interventions to prevent them, the outcomes of the interventions, and the diverse population on whom an intervention is being implemented. It provides an overview of how the interventions have been conceptualized and applied with the use of various data collection instruments measured at different timelines and their outcome measures. Of 21 studies considered for review, 16 (76%) studies were RCTs, 4 (19%) articles were non-RCTs, and 1 (5%) article had a mixed method design. Due to the heterogeneous nature of the included studies, the level of evidence of this review is considered as moderate.

Interventions Targeting Parents, Caregivers, and Family

In this review, 17 articles described interventions focusing on caregivers or parents to prevent unintentional injuries in children. Parents' or caregivers' involvement in educational interventions has been shown to improve safety knowledge and behaviors. In addition, the distribution of safety supplies to keep the home safe has improved the safety-related behavior of parents. Similar evidence was reported by the authors of a review [39] that interventions targeting parents are effective in reducing child injuries and that parenting interventions appeared to have a greater effect on home safety practices and the reduction of hazards at home. The findings of this review suggested that the beneficial effects were attributable to interventions targeting changes in parents' knowledge, attitude, and behavior.

Interventions Targeting Children as Change Agents

Three articles highlighted the interventions for preventing unintentional injuries in diverse modalities focusing on children of different age groups. The analysis showed improved knowledge and safety practices and a decrease in the incidence of injuries. However, there are fewer studies focused on children, who need to be considered further. There is a need to integrate appropriate and well-designed programs, especially focusing on children, such as school-based injury prevention modules, adolescent-targeted interventions, and simulation-based training. The cost of preventing unintentional injuries is much lower than the cost of treating their direct and indirect consequences [40]. In resource-limited settings, children can act as change agents to bring about change in their homes and neighborhoods. Future research on children should engage parents and teachers to develop, implement, and evaluate a more comprehensive and integrated intervention to prevent unintentional injuries.

Effectiveness of Educational Interventions

Five articles in this review addressed the effectiveness of educational interventions for both parents/caregivers and children. Educational interventions targeting changes in the behavior of parents and a hazard-free home environment were proven effective in reducing the incidence of unintentional injuries at home. The results of the studies demonstrate a positive outcome and ensure their feasibility of being implemented in low-income and resource-limited settings. Despite the high incidence of unintentional injuries among children in low- and middle-income countries, few interventional studies have been conducted in these countries. Multimodal educational interventions play a crucial role in sensitizing and creating awareness among children and caregivers to prevent unintentional injuries and injury hazards.

Effectiveness of Home Safety Interventions

Four articles reported on home safety interventions to prevent unintentional injuries. The analysis showed improved home safety practices, an increased level of supervision, and an environment free from injury hazards. Greater reductions in injury rates were found for interventions delivered in the home; however, there was a lack of evidence that home safety

interventions reduced rates of thermal injuries or poisoning [41]. It is particularly important that children in low-income families have close supervision, as the caregivers may have difficulty acquiring safety materials, and the presence of poor housing quality can impose an additional risk on children. Hence, the implementation of low-cost and locally available measures in an accessible and efficient manner could prove beneficial for both children and their caregivers to reduce the risk of injuries within the community context. Failure to invest in programs for preventing injuries among children will further increase the number of dependents in future generations and negatively impact society. Policymakers need to be involved in the evaluation and implementation of policies related to injury prevention, especially in resource-limited countries.

Technology-Based Interventions

Nine articles addressed the effectiveness of technology-based interventions in the prevention of unintentional injuries. Studies using interventions through mobile apps, web-based education, and social online health education provided an impactful result among the participants who used them effectively on a timely basis. Information and communication technologies can accelerate progress toward the achievement of the United Nations Sustainable Development Goals [42]. The use of technology-based interventions and an online platform can be adapted to deliver preventive health care information for large-scale community users. Nevertheless, the digital mode of interventions and app-based programs play a significant role in covering the large and diverse range of participants to create awareness, instill knowledge, improve their practice, and bring about a positive change in their behaviors. However, such interventions have drawbacks in low- and middle-income

countries with a lack of resources and a lack of participant awareness of different gadgets.

Interventions Based on Models and Theories

This review highlighted 3 articles that used models and theories as a basis for interventions to prevent injuries. The Health Belief Model is a theoretical model used to guide health promotion and disease prevention programs, which explains and predicts changes in health behaviors [43]. Accordingly, the previously mentioned studies proved useful in applying a similar approach to evaluate the impact of interventions and thus bring about change in the practice and behavior of parents.

Strengths and Limitations

A strength of this review was that a comprehensive literature search of articles published from 2013 to 2023 was conducted using different databases that covered studies focusing on interventions to prevent unintentional injuries in children. A limitation of our review was that only articles published in the English language were included. Additionally, the present study area is an active field of research, so it is important to note that this scoping review is a snapshot at a particular point in time.

Conclusion

The articles included in this review addressed interventions of different magnitudes, data measurements taken at varying time points, and participants of a diverse nature. Cost-effective, accessible, and multifaceted interventions represent effective strategies to prevent unintentional injuries in children. Further studies in the form of online social networks and app-based interventions could be considered to reach out to the larger population with long-term outcome measurements.

Conflicts of Interest

None declared.

Checklist 1 PRISMA-ScR checklist. [DOCX File, 49 KB - pediatrics v8i1e67877 app1.docx]

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Abbreviations

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

RCT: randomized controlled trial

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A Companion Robot for Children With Asthma: Descriptive Development and Feasibility Pilot Study

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Abstract

Background: Consistent medication use and proper inhaler technique are essential in pediatric asthma, and young children require supportive tools to maintain these practices.

Objective: This study aimed to investigate the caregivers' ability to use a companion robot–assisted app for children with asthma, their attitudes toward the usage, and the characteristics that hinder or facilitate the implementation.

Methods: This study employed a descriptive design. The sample group consisted of 30 children with asthma aged 3 - 6 years who received treatment at an asthma clinic and their caregivers. The companion robot for children with asthma called "Pukkabot," which is an innovation that is developed to teach inhalation techniques and to raise awareness about consistent medication administration through positive reinforcement, was examined. Data collection included personal information questionnaires, the System Usability Scale (SUS) for evaluating usage and overall satisfaction, and interviews to gather attitudes toward apps and characteristics that hinder or facilitate. Data were analyzed with descriptive statistics and content analysis.

Results: The study revealed that the scores for usability and overall satisfaction were 80.6, which is above the standard threshold and rated at grade A or an excellent level. Additionally, caregivers stated that the companion robots were easy to use, not complicated, had appropriately sized screens, and demonstrated clear images and sounds. The detailed steps for inhalation were exhibited, and reminders included those of medication times. The children with asthma enjoyed the app and were very interested, making most caregivers want to continue their use.

Conclusions: Caregivers were generally satisfied with the usability, finding it easy to use and engaging, which successfully attracted the interest of the children with asthma. Therefore, the companion robot may be used further, with the following recommendations: improving its physical design, adding content, incorporating tracking and symptom assessment systems, and creating a downloadable mobile app for greater accessibility and convenience.

Trial Registration: Thai Clinical Trials Registry TCTR20240912001; https://www.thaiclinicaltrials.org/show/TCTR20240912001

(JMIR Pediatr Parent 2025;8:e68943) doi:10.2196/68943

KEYWORDS

companion robot; app; asthma; children; caregiver; model

Introduction

Asthma is a chronic respiratory condition that is characterized by bronchial tube inflammation, causing a heightened response to allergens and environmental factors. This causes symptoms, including bronchial hyperreactivity, bronchoconstriction, swelling, and increased mucus production [1]. Asthma affects individuals of any age, but it is particularly prevalent in children under 6 years of age, who are more susceptible to respiratory infections that worsen bronchial inflammation. Early detection and effective management of asthma exacerbations are crucial for preventing chronic inflammation and improving long-term health outcomes as children develop. The World Health

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Organization reported that approximately 262 million people globally experience difficulties from asthma, with a significant proportion being children from low- to middle-income countries, where the prevalence is increasing [2]. Approximately 2 million children with asthma are affected in Thailand, with 9.8% experiencing exacerbations annually and a significant cost associated with treatment [3].

The Global Initiative for Asthma (GINA) provides comprehensive guidelines for pediatric asthma management, focusing on symptom control through medication, decreasing environmental trigger exposure, and continuous symptom monitoring [4]. The key treatment goals include achieving satisfactory symptom control, minimizing acute exacerbations,

allowing normal daily activities, and maintaining optimal lung function. Children with asthma require both relief medications for acute symptoms and long-term controller medications to prevent future exacerbations and maintain symptom control [4]. However, many children face difficulties with consistent and correct inhaler use, which is crucial for effective medication delivery [5,6]. Literature emphasizes issues, such as incorrect inhaler techniques and irregular medication adherence, frequently stemming from caregivers's misconceptions about inhalers, fears of side effects, and concerns over costs [6,7]. Therefore, both children and their caregivers need to receive a thorough education on proper inhaler use and the significance of consistent medication adherence.

Environmental pollutants, particularly particulate matter (PM) with a diameter of <2.5 microns (PM 2.5), are significant triggers for asthma exacerbations, causing bronchial inflammation and irritation [8]. Children with asthma who are exposed to high air pollution levels may experience worsened symptoms, which impair lung function and require emergency medical interventions [9,10]. Various smartphone apps provide real-time air quality data, but challenges associated with accessibility and technological literacy among caregivers may limit their effectiveness in managing asthma triggers [11]. Effective asthma management requires collaboration between the pediatric patient and their caregiver, tailored to the child's developmental stage. Instilling health-promoting behaviors during this critical period facilitates the teaching of consistent inhaler use for preschool-aged children.

Recent technological advancements have resulted in the creation of devices aimed at improving inhaler use among children with asthma [12]. In particular, the JOE robot, which assists with demonstrating inhaler techniques, currently supports only English and French, limiting its accessibility for users who speak other languages [13]. Other innovations, such as the Whizz smart inhaler [14] and CapMeDicTM [15], provide various features to encourage proper inhaler utilization but may not fully engage young children or be widely available in Thailand. Hence, Thammasat University (Thailand) has developed the "Asthma Care" app, which provides comprehensive guidance on asthma management. However, further innovations that are specifically designed for preschool-aged children to meet their unique needs are highly warranted.

This study aimed to assess caregivers' ability to use "Pukkabot," a companion robot-assisted app designed to teach correct inhaler techniques and promote consistent medication adherence through positive reinforcement, considering the necessity for accessible and effective asthma management tools for young children. Additionally, the study investigated caregivers' attitudes toward "Pukkabot," determining features that may either facilitate or hinder its use. "Pukkabot" seeks to improve symptom control, reduce severe asthma attacks, and enhance overall treatment efficacy by fostering early awareness and proper inhaler techniques in children with asthma, ultimately minimizing hospitalizations and lowering the risk of severe complications. The results from this research provided valuable information into the development of effective and user-friendly asthma management tools for young children in Thailand,

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contributing to improved health outcomes and quality of life for children with asthma.

Methods

This descriptive study aimed to explore the feasibility of using "Pukkabot," and to explore barriers and facilitators to its use.

Recruitment Process

This study recruited caregivers and children with asthma from the Allergy and Immunology Clinic in the asthma clinic, Pediatric Outpatient Department of a tertiary hospital from February to September 2024. The children included were aged 3 - 6 years, physician-diagnosed with asthma of any severity for at least 6 months, receiving treatment with at least 1 inhaled medication, and without a history of uncertain clinical symptoms or learning disabilities. Caregivers were required to be ≥ 18 years old and related to the child.

A convenience sample of 30 children with asthma was recruited for this single-arm interventional trial. The sample size was guided by recommendations for pilot and feasibility studies [16]. According to Brooke [17], a general rule of thumb is to include at least 30 participants to allow for reasonable estimation of study parameters.

Study Design

The researcher instructed the caregiver and the child to interact with the companion robot. The process began with the caregiver setting a medication reminder (set for 5 min) and selecting an air quality monitoring option within the app, which displays the real-time Air Quality Index (AQI) to raise awareness about environmental triggers. Afterward, the child was invited to select a preferred pet (rabbit, dog, cat, bear, and dragon). When the reminder alarm was triggered, the child practiced medication administration steps by following on-screen instructions, using an empty inhaler device that contained no active medication. This activity was conducted solely as a demonstration to simulate proper inhaler technique, without actual medication use. The demonstration lasted approximately 5 minutes, during which the researcher provided verbal guidance and support. The entire process was completed within approximately 15 minutes.

Afterward, the caregivers were instructed to complete a 10-item System Usability Scale (SUS) regarding the companion robot. The caregivers completed the questionnaire, whereas the researcher recorded personal information from the patient's medical records.

Finally, the researcher interviewed the caregivers to gather their attitudes toward using the asthma management companion robot, as well as any perceived barriers or facilitators to its implementation. This aimed to determine areas for system improvement. The interview included 6 questions and lasted approximately 5 - 10 minutes.

Research Instruments

In this study, various instruments were used to gather data effectively, ensuring a comprehensive understanding of the participants' backgrounds and experiences. The instruments included personal information questionnaires, patient medical

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record data forms, the SUS, and caregiver interviews focused on attitudes toward asthma management companion robot-assisted app for children with asthma.

Personal Information Questionnaires

The interview form designed for children with asthma collected vital information, including age, sex, age at diagnosis, prescribed medications, comorbid conditions, and asthma exacerbation-related hospitalization history. This comprehensive data helped develop a baseline profile of the pediatric participants, enabling a nuanced analysis of their health status and treatment history.

The personal information interview form for caregivers collected critical details, including age, sex, educational level, marital status, occupation, income, and relationship to the pediatric patient. Understanding the caregivers' backgrounds is crucial, as their socioeconomic status, educational level, and relationship to the child significantly affect asthma management strategies and the usage of health care resources.

Patient Medical Record Data Form

The Patient Medical Record Data Form was used to collect clinical data directly from the medical records of children with asthma. This form provided comprehensive information regarding asthma severity, which was classified according to the GINA guidelines by health care professionals, age at diagnosis, prescribed medications for symptom control and relief, other treatments received, comorbid conditions, and any asthma-related hospitalization history.

System Usability Scale (SUS)

The SUS, developed by John Brooke in 1986 [17], is a widely recognized tool for evaluating the usability and overall satisfaction of a companion robot-assisted app. The SUS consists of a 5-point Likert scale, with response options ranging from 1 ("strongly disagree") to 5 ("strongly agree"). The scale includes 10 items—5 positively worded and 5 negatively worded—that assess the usability of the asthma management app. Scoring involves assigning values from 1 to 5 for the positive items while applying reverse scoring for negative items. The total score is calculated and then multiplied by 2.5 to convert the range from 0 to 40 to a scale of 0 - 100. A score of ≥ 68 indicates acceptable usability, corresponding to the 50th percentile, whereas scores below this threshold indicate areas for improvement in design and usability [17-19].

Caregiver Interviews on Attitudes Toward Using a Companion Robot for Asthma Management

In-depth interviews were conducted with a semistructured format to gain information about caregivers' perceptions of the asthma management app and the pediatric asthma model. This approach facilitated a nuanced exploration of caregivers' attitudes, including barriers and facilitators to app. The interview consisted of 7 main questions developed to prompt discussion on previous experiences with similar technologies, willingness to use the asthma model, and opinions on the model's design. In particular, caregivers were asked the following questions: "Have you ever encountered a similar app or model before?"; "If not, after learning about or using this system, would you consider using this asthma model for your child?"; "What are the main reasons for your decision?" Another sample question included the following: "Which aspects of the model's design do you think are not well-developed or convenient for use?" The interviews were used to collect qualitative data that complemented the quantitative results, providing information on how to improve the effectiveness and user acceptance of asthma management tools.

In summary, the diverse range of research instruments used in this study—personal information questionnaires, patient medical record data forms, the SUS, and caregiver interviews—enabled a comprehensive assessment of both the clinical and experiential aspects of asthma management in children. The research aimed to provide actionable information for improving asthma care delivery and technology usage among caregivers and health care professionals by integrating quantitative and qualitative data.

Pukkabot

The tool used in this study is the companion robot-assisted app for children with asthma, named "Pukkabot," an innovative device designed to teach proper inhaler use and promote medication adherence through positive reinforcement (Figure 1). The design of the companion robot is tailored to each child's treatment plan, specifically focusing on those who require both inhaled controller medications and guick-relief medications. The app operates on the Android 13 platform, featuring a touch-sensitive screen that displays both video and audio content. The model, shaped like an animal, measures 23.5 cm in width, 23.1 cm in length, 21 cm in height, and 800 g in weight, including the screen. Its structure is composed of polylactic acid plastic, providing strength and lightweight durability during use. Polylactic acid is a form of plastic derived from natural sources, making it non-irritating during use. It can be cleaned with an alcohol spray. The model is developed to be placed on a flat surface, with the weight supported by its 2 legs and tail for balance while using the screen. The screen area is recessed by approximately 2 inches to prevent damage in case of impact or if it falls from a height. The main display screen provides the following 5 operational modes.



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Figure 1. Appearance of the Pukkabot companion robot and screenshots of its mobile app interface designed to support caregivers of children with asthma.



- 1. My pet: the user must select a pet by tapping on the desired pet when entering for the first time. Afterward, the screen will display the virtual pet. This screen will enable the user to feed the pet, which receives 1 food item per completed inhaler use.
- 2. Timer: the screen displays a timer to remind the user of the medication inhalation schedule. The screen shows an image of the eyes when in standby mode. The screen changes to display the message "It's time to recharge" along with a cartoon sound alert as the scheduled inhalation time approaches. The timer can be set for 2 reminders per day.
- 3. Inhaler use: this displays images and step-by-step instructions for using the inhaler, with accompanying audio. Users navigate through the steps via control buttons, enabling them to administer medication in real time alongside the instructions displayed.
- 4. Rewards: this displays the rewards earned, with the virtual pet growing according to the number of completed inhaler uses and the food it receives. This is designed to motivate children to use their inhalers consistently.
- 5. Air quality: this displays the local air quality in terms of AQI levels. It is used along with the daily usage of inhalers to alert the user of the severity and provide information on avoiding triggers.

In total, 1 pediatric nurse with expertise in asthma care and 1 pharmacist with expertise in respiratory care validated the "Pukkabot" for content accuracy, structure, and language. Feedback from these experts was incorporated to refine and improve the system.

Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board Committee of the Faculty of Nursing and the Faculty of Medicine, Siriraj Hospital, Mahidol University (MU-MOU CoA no. IRB-NS2023/824.1212, dated December 12, 2023). All caregivers and children were informed of the study's purpose and procedures and provided written informed consent before

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participation. Data were anonymized prior to analysis to protect the confidentiality and privacy of participants. No financial compensation was provided; however, caregivers received small tokens of appreciation in recognition of their time and participation.

Data Analysis

Personal data and usability assessment results were analyzed with descriptive statistics. Content analysis was conducted to assess the system's usability, determining both barriers and facilitators based on caregiver interviews.

Results

General Characteristics of Children With Asthma and Their Caregivers

Among the children with asthma, 63% (19/30) were male and 37% (11/30) were female, with an average age of 5.3 (SD 0.7) years. The onset of asthma occurred at an average age of 2.9 (SD 1.2) years, with 77% (23/30) of the children being diagnosed with allergic rhinitis. A majority (21/30, 70%) of children used both the controller and reliever inhaler medications. Only 7% (2/30) of the children had partly controlled asthma, whereas the majority (28/30, 93%) demonstrated well-controlled asthma. Asthma control was classified according to GINA guidelines, with "well-controlled" defined as symptoms occurring no more than twice per week, minimal nighttime symptoms, infrequent use of rescue medication, and no limitations on daily activities.

Of the caregivers of children with asthma, 80% (24/30) were female, with an average age of 40.7 (SD 6.8) years. A large proportion (22/30, 73%) were mothers, with only 7% (2/30) being grandmothers. Regarding educational background, 50% (15/30) completed a bachelor's degree, whereas 20% (6/30) completed a master's degree. Regarding occupations, 57% (17/30) were employed. Most caregivers (19/30, 63%) reported a monthly household income of > 20,000 (approximately US

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\$570), which is considered a moderate-income level and is above the country's median household income.

Usability and Overall Satisfaction

The average SUS score from the 30 caregivers was 80.6 (SD 12.2), with scores of 52.5 - 97.5 based on the results of the usability and satisfaction assessment, as measured by the SUS. These scores are higher than the standard benchmark of 68, indicating a level of usability above average. The SUS score is categorized in the grade A range, indicating a high level of usability and acceptability.

The highest rated aspects of usability and overall satisfaction in reviewing the individual items were item 7, "I believe others will quickly understand how to use this app," and item 3, "I find this app easy to use." In contrast, the lowest rated aspect was item 4, "I believe I need assistance to use this app," indicating that most users did not feel the need for additional help and could use the app independently.

Attitudes Toward Using a Companion Robot for Asthma Management

The results in this section depend on interviews about attitudes toward the use of the companion robot-assisted app for children with asthma, as well as user behavior observations. The results are categorized into 3 main areas: attitudes toward use, barriers and facilitators, and improvement suggestions.

Attitudes Toward the Use of the Companion Robot

Caregivers' experiences and perspectives on the tools were largely positive.

There was a lack of previous experience. None of the caregivers had previous experience with similar apps for asthma management, although 3 had learned about inhaler use through videos or YouTube.

There were also positive reactions to the companion robot. After being introduced to the tools, 26 (87%) caregivers expressed an interest in using them. They considered the tools easy to use and believed they could motivate their children to use their inhalers regularly. The cute, pet-themed design was particularly appealing to the children, making the process more engaging.

I've never used it before, but I would like to. My child and I have used the inhaler for a long time, but this doll could motivate my child to want to use it more. I like that it has a pet, which makes it fun for my child and serves as good motivation. [Mother, aged 38 years]

I haven't used it, but I've watched videos on how to utilize the inhaler and have an app that monitors air quality, although I rarely check it. This seems useful, and my child seems interested. It may help motivate my child to use the inhaler properly, as they frequently avoid it. I like the presence of a cartoon pet to capture their attention. [Mother, aged 30 years]

Barriers and Facilitators in the Use of Companion Robot

Caregivers identified both positive aspects and challenges to the use of the companion robot. The feedback is categorized into 2 sub-themes: (1) external features of the companion robot and (2) usability.

External Features of the Companion Robot

In terms of facilitators, 9 (30%) caregivers felt that the model's design was appealing and stable, with a pet-like appearance that caught children's interest.

In terms of barriers, 21 (70%) caregivers emphasized several design issues, including that the model was too large to be portable, its surface was not smooth, and the colors were not vibrant.

It demonstrates a complete range of functions, but the size is a drawback. It is too large to carry around, and an app would be more convenient. I think the app would only be initially engaging for children unless additional features are added. [Mother, aged 43 years]

Usability

In terms of facilitators, all caregivers reported that the app was easy to use. The content, images, and audio instructions were concise and suitable for young children, enabling them to follow the steps independently. The cute cartoons and pet-care game kept the children motivated to regularly use their inhalers. Additionally, the app included helpful features, such as medication reminders, air quality monitoring, and health guidelines. Most (26/30, 87%) caregivers felt that the light, colors, and sounds of the app exhibited no negative effect on children's eyesight due to the short usage duration.

In terms of barriers, some (3/30, 10%) caregivers stated that the medication preparation steps were too long and that users had to manually advance through the inhaler steps. In total, 4 caregivers (4/30, 13%) expressed concerns about screen addiction from using the app frequently.

I like the reminder feature for medication timing, as it helps us not forget. The model's large size is inconvenient to move, and I would prefer it as a mobile app. I'd also like a feature to count the number of doses administered. [Mother, aged 38 years]

I like the cartoon that captures my child's attention, and the images and sounds are clear. I appreciate the advice on when to use emergency inhalers according to breathing difficulty. A mobile app would be more convenient. [Father, aged 37 years]

Suggestions for Improving the Companion Robot

Caregivers provided recommendations to improve both the companion robot for asthma management:

- App development: a majority (27/30, 90%) of caregivers recommended developing the app into a smartphone-compatible version for easier access.
- Model design: a smaller group (3/30, 10%) indicated retaining the model but making it more portable by adjusting the design to be rectangular and flat for easier storage.
- Functional enhancements: several additional features were proposed, including (1) instructions for cleaning the inhaler device, (2) tracking inhaler use and remaining medication

doses, (3) an action plan for asthma exacerbations, (4) videos showing asthma symptoms, (5) videos demonstrating nasal irrigation techniques, (6) notifications about environmental triggers (eg, high dust levels), and (7) contact channels for health care teams.

Discussion

Principal Findings

The study revealed that caregivers reported an average post-use satisfaction score of 80.6 (SD 12.2) on the SUS, which exceeds the standard threshold and falls within the "Grade A" category. This high score indicates that caregivers of children with asthma were highly satisfied after their initial trial of the companion robot. Such a positive reception may affect their decision to continue using these tools in the future. Further analysis revealed that most caregivers expressed satisfaction due to the app's ease of use, its simplicity, and because they did not require assistance during the operation.

Interviews with caregivers indicated that none had previous experience using an app or model specifically designed for children with asthma, although some had learned inhalation techniques from videos or web-based media primarily intended for adults. However, all caregivers considered the app user-friendly, with a comprehensive set of functions. The content, audio, and animated illustrations of inhaler usage were deemed suitable for young children, enabling them to independently follow the steps. Additionally, the pet-care game included in the app helped motivate children to consistently use their inhalers. The app can reduce disease severity and improve treatment outcomes, enabling children to live healthy, normal lives, by encouraging early asthma control and fostering self-discipline in inhaler use. Motivation in children under 6 years of age is significantly improved through interactive and engaging tools. Research reveals that interactive learning media, such as game-based learning and multimedia presentations, foster intrinsic motivation by providing dynamic learning experiences that cater to diverse learning styles [20].

A majority of caregivers indicated that the app could be optimized for use on mobile platforms, but the design of the companion robot for children with asthma, "Pukkabot," in this study specifically aimed to provide preschool-aged children (ages 3 - 6 y) with a tangible companion during inhalation therapy. The model functions as a motivator for consistent inhaler use to help control asthma symptoms. Familiar toy-like designs in therapeutic devices improve children's emotional connections, thereby increasing treatment engagement and adherence, as evidenced by positive feedback from children and parents regarding the respiratory aid for inhalers (RAFIhaler) experience [21].

Caregivers stated that the asthma inhaler details provided in "Pukkabot" aligned well with their requirement for managing children with asthma. This result aligns with research by Lio et al [22], who developed an app for children with asthma aged 2 - 12 years. Their study revealed that children and caregivers were more likely to use the app when it was engaging, easy to use, and contained essential content, including disease

pathophysiology, self-care practices, and asthma management strategies [22]. Similarly, Li et al [23] established an app for asthma self-management in children that featured symptom evaluation, treatment planning, inhaler usage, and communication with doctors in emergencies, further improving asthma management. Together, these studies emphasize the importance of user-friendly, comprehensive apps in enhancing asthma care for children and their caregivers.

The ability of apps to set multiple reminders for inhaler use significantly benefits children with asthma, particularly those requiring frequent medication doses. A study revealed that setting multiple alarms ensures timely medication adherence, which is crucial for asthma management in children who may require varying inhaler schedules based on the severity of their condition [24]. Additionally, the inclusion of the AQI monitoring function enables both caregivers and children to be vigilant about daily air quality changes. PM 2.5 significantly affects respiratory health, especially in children with asthma [9]. Children with asthma are particularly vulnerable to air pollution such as ozone and PM 2.5, which have been associated with increased respiratory symptoms, hospitalizations, and long-term impairment in lung function [25]. Therefore, it is essential for children and their caregivers to stay informed and take precautions based on daily air quality. This feature enables children and caregivers to make informed decisions about daily activities, including staying indoors, wearing masks to prevent exposure, or adjusting outdoor routines.

In this study, most (22/30, 73%) caregivers were mothers, and 50% (15/30) held a bachelor's or master's degree. Furthermore, 20% (6/30) of them were employed, and 57% (17/30) reported a household income higher than the national minimum wage, with 63% (19/30) exhibiting a family income above the country's median. A study of parental attitudes towards artificial intelligence in children with asthma found that socioeconomic factors influenced technology adoption, with parents from disadvantaged backgrounds more likely to be reluctant to adopt technology [26]. Therefore, socioeconomic factors may affect caregivers' readiness to adopt technology for health management. Moreover, this research was conducted at a tertiary hospital with access to high-standard care and advanced medical technology. Most caregivers had received ongoing training and education on asthma management for children, which may have contributed to their interest in using technology, such as this app, for at-home care.

Raising awareness and educating caregivers on asthma management in children remains crucial, and health care professionals must prioritize this. Based on the study's recommendations, additional features, such as instructions for cleaning inhalers, tracking medication usage and remaining doses, establishing action plans for asthma exacerbations, videos demonstrating key symptoms and nasal irrigation techniques, and alerts for environmental triggers, such as air pollution levels, along with direct communication with health care teams, can improve asthma care tools. These improvements will increase the treatment efficacy.

This study highlights the importance of health care professionals in prioritizing caregiver education, emphasizing that improved

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asthma care tools—with features such as inhaler cleaning instructions, medication tracking, action plans for exacerbations, videos demonstrating key symptoms, and alerts for environmental triggers—can significantly enhance asthma management. These improvements will boost treatment adherence and overall effectiveness, causing better health outcomes for children with asthma, although continuous monitoring remains necessary as they grow older.

Limitations

One limitation of this study is that it primarily focused on establishing tools for asthma management without fully addressing the individual variability in caregiver readiness and technological literacy. Additionally, the generalizability of the results may be limited due to the specific demographic and technological context of the study participants.

Suggestions for Future Study

Special attention should be given to the design of these tools for future research, ensuring that they are engaging for children, portable, and nontriggering to prevent exacerbating asthma symptoms. Studies should focus on the long-term effectiveness of these tools and the way they can be seamlessly integrated into routine clinical practice. Additionally, further investigation into the effect of technological innovations on caregiver engagement, particularly across diverse populations and health care settings, is crucial. These tools may improve asthma management, but recognizing that children with asthma will still require continuous monitoring and treatment as they grow older remains important. Therefore, future studies should prioritize establishing adaptable and dynamic educational content that supports asthma care for children across all stages of development.

Data Availability

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

Authors' Contributions

JS initiated the concept of the innovation, and SR collaborated in planning and supervising the study. JS conducted the primary investigation, while RS and KP assisted in data development and collection. All authors contributed to, revised, approved, and are accountable for the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AQI: Air Quality Index GINA: Global Initiative for Asthma PM: particulate matter SUS: System Usability Scale

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Novel Profiles of Family Media Use: Latent Profile Analysis

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Abstract

Background: Over the past 3 decades, digital and screen media have evolved from broadcast, stationary platforms to a complex environment of interactive, omnipresent, mobile media. Thus, clinical guidance centered around unidimensional concepts such as "screen time" must be modernized to help families navigate the intricate digital ecosystems of readily available entertainment and information.

Objective: This study aimed to identify and examine distinct latent profiles of media use in families with young children. We hypothesized that latent profile analysis (LPA) would identify different media use profiles characterized by more heavy, reactive, individual, and permissive media use and more intentional, regulated, or shared uses of media.

Methods: We analyzed data from 398 preschool-aged children. English-speaking parents were recruited through community settings. Participants completed surveys regarding several aspects of family media use, such as child device use or activities, parent concerns and attitudes, limit setting and mediation, parent media use, and technology interference, examined in an LPA. The number of latent media profiles was determined using Bayesian Information Criteria. Parents also completed validated scales of parenting stress, depression symptoms, parenting style, child behavior, child sleep, and household disorganization. Multivariable logistic regression was used to examine parent, child, and household predictors of group membership.

Results: The LPA yielded 2 distinct groups that differed in the duration of media used by parents and children, to calm children or help them fall asleep. Statistically significant differences between groups included: families in group 1 (n=236, which we termed social-emotional drivers) had parents who preferred interactions via text or email to in-person (P=.01) and were more likely to use media to calm their children (P=.03); in contrast, families in group 2 (n=162, intentional media) used more task-oriented media, like audio and nongame apps (P=.01), had more concerns about effects of media on child language development (P=.04), and used more media restrictions (P=.01). In regression models, female sex of the parent respondent, greater number of siblings, and later child sleep midpoint independently predicted group 1 membership.

Conclusions: Findings suggest divergent family media use patterns that can be categorized into 2 main media user groups: those using media to buffer social situations or regulate emotions and those planning mobile device use around functional purposes and concerns around media exposure. Profiles were associated with household size and child sleep. More research is needed to examine the impact of social and emotional uses of media on child outcomes.

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KEYWORDS

preschool; child; digital media; mobile media; media use; latent profile analysis; computer use; LPA; technology use; survey; questionnaire; pediatrics

Introduction

Background

The landscape of digital technology use has changed dramatically over the past few decades. Digital and screen media have evolved from broadcast, stationary platforms, where screens stay put, plugged into the wall, and messages are transmitted broadly in a one-to-many model, to a world of interactive, mobile media, where screens can follow users

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wherever they go and interact in a bidirectional manner. For this reason, researchers have questioned whether clinical guidance centered around unidimensional concepts such as "screen time" are helpful to parents trying to navigate digital ecosystems of readily available entertainment and information [1], particularly considering families' increased technologic dependence during and following the COVID-19 pandemic.

Distinctions between traditional (eg, television [TV]) and mobile, interactive media are important for several reasons.

First, the portability and easy accessibility of mobile media inherently allows for more spontaneous and reactive use patterns in which the technology becomes increasingly integrated into daily routine and activities [2,3]. Second, small, handheld screens are more difficult for parents to monitor [4]. And third, mobile media use has rapidly become exceedingly common, even in infants and toddlers. As of 2017, 98% of homes of children 0 - 8 years old had a mobile device, and one third of all screen time in that same age group, who use on average almost 2.5 hours of screen media per day, was mobile [5].

Previous Work

In light of modern technologic advances, new ways of studying, conceptualizing, and framing media use guidance have been proposed. Young children's media use has been conceptualized as the "3 Cs", that is, content, context, and the individual child given the important role each of these factors plays in shaping child responses to media [6]. However, pervasive use of mobile media by families with young children requires new concepts such as use of devices for on-demand calming and keeping children occupied during daily activities.

To capture holistic patterns of family media use, it is also important to consider parents' mobile device use, which interrupts parent-child interaction [7] and is associated with less responsiveness [8], but is an important part of parent social connection, work-life, and day-to-day functioning [9]. Parents' mediation behaviors (practices such as coviewing, teaching children about media content, or setting limits) also shape children's responses to media [10]. Finally, child and parent media use are highly correlated [11], yet are usually studied in isolation. One previous attempt to describe family-level media behaviors [12] primarily focused on viewing duration and type of media use, rather than the several contextual variables or social-emotional drivers of media use in the current digital environment.

Goal of This Study

The current study aims to identify patterns that include the aforementioned concepts, examined through latent profile analysis, to try to identify patterns and concepts that might generate insights for clinical guidance and future research. Specifically, we sought to identify novel patterns of family media use that consider child duration and frequency of media activities; child use to keep occupied, regulate behavior, or fall asleep; parent attitudes about child use; limit setting and mediation; parent media use; and "technoference" (ie,

Textbox 1. Study inclusion and exclusion criteria.

Inclusion criteria:

- Parent was legal guardian of a 3 to 4.99-year-old child.
- Parent lived with the child at least 5 days per week.
- Parent understood English sufficiently enough to complete questionnaires and provide consent.
- The family owned at least 1 Android or iOS tablet or smartphone.

Exclusion criteria:

- Child developmental delays.
- Use of psychotropic medication.

technology interference in parent-child activities). We hypothesized that latent profile analysis (LPA) would identify different media use profiles characterized by more reactive, heavy, individual, and permissive media use; and more intentional, regulated, or shared uses of media. We examined these patterns and their associations with parent, child, and household characteristics within a large cohort of preschool-aged children, as early childhood is an important time of establishing media use habits [13].

Methods

Overall Study Design

We analyzed data from the Preschooler Tablet Study, a longitudinal cohort study (NICHD R21HD094051) examining associations between early childhood digital media use and social-emotional development. The present analysis used REDCap (Research Electronic Data Capture) [14] and Qualtrics survey data from the baseline data collection wave (August 2018-May 2019).

Ethical Considerations

The study was approved by the University of Michigan Institutional Review Board (HUM00131980). Parents provided electronic informed consent for themselves and on behalf of their young children. Participants were informed that they could opt out of the study at any time. Data downloaded from REDCap and Qualtrics were stored on secure password-protected servers at the University of Michigan. Data was not de-identified prior to analysis; all participants were assigned a study ID number that only linked to identifying information on REDCap, a HIPAA-secure database to which only approved study personnel had access. Participants received \$40 for completing data collection procedures.

Participants

Parents of young children were recruited through flyers posted in community centers, preschools, childcare centers, and pediatric clinics in southeast Michigan, as well as our university's online participant registry and social media advertisements. Interested parents who contacted the study team were emailed a link to an eligibility questionnaire. Eligibility criteria is shown in Textbox 1. To improve generalizability, participating children did not need to regularly use mobile devices to be included in the study.

Survey Measures: Child, Parent, and Household Characteristics

After providing electronic informed consent, respondent parents completed web-based surveys with a variety of questionnaires to assess characteristics of the child, parent, and household, as well as family media use practices. Demographic characteristics were collected for children's age, sex, race, ethnicity (investigator-defined categories shown in Table 1), daycare or preschool enrollment, average sleep pattern (sleep onset and wake time, from which duration and midpoint were calculated, as well as sleep latency and overnight awakenings), prematurity, and whether they were an only child; parent age, gender, educational attainment, marital status, and employment status. We also used validated questionnaires to assess parent Epidemiologic depression symptoms (Centers for Studies-Depression Scale) [15], parenting stress (Parenting Stress Index-Short Form) [16], and parenting styles (laxness and harshness subscales of The Parenting Scale) [17]; as well as household income, size, composition, and disorganization (Chaos, Hubbub, and Order Scale) [18]. Child self-regulation abilities were assessed with the Emotional Reactivity subscale of the Child Behavior Checklist-Preschool [19], the Surgency subscale of the Rothbart Child Behavior Questionnaire-Very Short Form [20], and the Behavior Rating Inventory of Executive Function-Preschool [21].



Table . Participant sociodemographic characteristics.

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Characteristics			Values
Parent			
	Age, mean (SD)		34 (4.7)
	Sex, n (%)		
		Male	25 (6.3%)
		Female	373 (93.7%)
	Education, n (%)		
		≤High school or GED ^a	25 (6.3%)
		Some college or a 2-year degree	126 (31.7%)
		4-year college degree	100 (25.1%)
		Advanced degree	147 (36.9%)
	Marital status, n (%)		
		Married or has a partner	360 (90.9%)
		Single, separated, or divorced	36 (9.1%)
	Employment, n (%)		
		Unemployed	110 (27.6%)
		Part-time	76 (19.1%)
		Full-time	185 (46.5%)
		Multiple jobs	27 (6.8%)
	Scales, mean (SD)		
		Depression symptoms (CES-D ^b score)	9.32 (8.87)
		Parenting Stress Index percentile	44.6 (32.9)
		Parenting Scale – Laxness Subscale	2.61 (0.76)
		Parenting Scale – Overreactivity Subscale	2.56 (0.74)
Child			
	Age, mean (SD)		3.85 (0.54)
	Sex, n (%)		
		Female	186 (46.7%)
		Male	212 (53.3%)
	Race/ethnicity, n (%)		
		Asian or Pacific Islander	11 (2.8%)
		Black or African American, non- Hispanic	20 (5.1%)
		Hispanic, any race	26 (6.6%)
		Multiple races, non-Hispanic	32 (8.1%)
		Native American or Alaska Native	5 (1.3%)
		White, non-Hispanic	302 (76.3%)
	Only child, n (%)		
		Yes	69 (17.3%)
		No	329 (82.7%)
	Child gestational age, n (%)		
		<37 weeks (premature)	32 (8%)

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Characteristics			Values
		37 weeks or later	366 (92%)
	Child preschool or child care, n (%)		
		Center-based child care	250 (65.8%)
		Home-based child care	30 (7.9%)
		Stays home with parent or caregiver	100 (26.3%)
	Sleep, mean (SD)		
		Sleep duration	10.8 (0.8)
		Sleep midpoint (number of hours after 12 AM)	1.87 (0.82)
		Sleep latency >30 min	106 (26.6)
		Overnight awakenings	226 (60.4)
	Scales, mean (SD)		
		CBQ-VSF ^c Surgency Subscale	4.40 (0.86)
		BRIEF-P ^d General Executive Composite	49.2 (12)
		CBCL-P ^e – Emotional Reactivity Subscale	3.69 (2.82)
	Household, mean (SD)		
		Income-to-needs ratio	2.95 (1.71)
		CHAOS ^f score	3.29 (2.93)

^aGED: General Educational Development.

^bCES-D: Centers for Epidemiologic Studies-Depression

^cCBQ-VSF: Child Behavior Questionnaire Very Short Form

^dBRIEF-P: Behavior Rating Inventory of Executive Function-Preschool

^eCBCL-P: Child Behavior Checklist–Preschool

^fCHAOS: Chaos, Hubbub, and Organizational Scale

Survey Measures: Media Use

Parents also completed a 75-item questionnaire about family media use derived from the CAFE (Comprehensive Assessment of Family Exposure) Consortium Qualtrics Survey, which has been described elsewhere [22]. This survey asks about technology and device ownership, content and context of media use, parent media use, and mediation practices (refer to Textbox 2 for constructs assessed). Questions on the survey addressed types of devices in the home and locations of those devices, parent attitudes toward media and concerns regarding child use of media, duration of use on weekdays versus weekends, time of use and environmental context of use (for example while falling asleep or while in transit), usual content (for example streaming video versus playing games), family interactions around media, and media-use functions.



Textbox 2. Media-related constructs assessed through the CAFE (Comprehensive Assessment of Family Exposure) questionnaire.

A. Child ownership and frequency of activities

A1. Child ownership of mobile media device

A2. Child keeps device in bedroom

Frequency of mobile device use for specific activities:

(A3. Watch TV; A4. Watch movies; A5. Play games; A6. Use apps that are not games; A7. Read electronic books; A8. Listen to music or audiobooks; A9. Take photos; A10. View photos/videos)

B. Child instrumental or regulatory uses of media

B1. Use of media during travel in car or public transit

B2. Use of TV to calm when upset

B3. Use of mobile devices to calm when upset

Use of all types of screen media by parent for specific purposes related to child:

(B4. To educate child; B5. Calm child down; B6. Keep child busy; B7. Communicate with family and friends; B8. Because child enjoys it)

B9. Use of devices at bedtime

B10. Use of devices while falling asleep

C. Parent media knowledge and attitudes

Parent concerns that child will:

(C1. Be exposed to inappropriate content; C2. Become inattentive as a result of using screen media; C3. Become addicted to screen media; C4. Miss out on other important opportunities that are more valuable than screen media; C5. Be exposed to harmful electromagnetic waves; C6. Have poorer language development).

D. Mediation strategies

Presence of media content limits:

(D1. Parents blocks specific media content on TV/devices; D2. Parent uses web blockers/controls; D3. Parent only allows child to watch "child-friendly" content; D4. Parent uses ratings to decide what child will watch; D5. Child media use only allowed if parent is in the room).

D6. Media time limits are consistently enforced

D7. Media content limits are consistently enforced

D8 - D22: Valkenburg Mediation Scale (Social Coviewing, Instructive Mediation, and Restrictive Mediation)

E. Parent media use

Outside of work hours, parent feels:

(E1. The need to stay connected to work almost constantly; E2. The need to stay connected to friends and social media almost constantly; E3. It is easy to multitask between children and using a phone or mobile device; E4. Sometimes overwhelmed by how much they have to do on their phone or mobile device; E5. That they prefer to interact with others via texting, email, or social media, rather than in person; E6. Using their phone or mobile device allows them to "escape" a little bit while they're with their children; E7. Sometimes "addicted" to mobile media like smartphones or tablet devices).

Frequency of specific activities during a typical weekday (Monday-Friday):

(E8. Watch TV; E9. Use the computer; E10. Read traditional books; E11. Read electronic books; E12. Play videogames on console game player; E13. Use an iPad, iTouch, or similar device (not including a smartphone); E14. Use a smartphone for things like texting, playing games, watching videos, checking email, or surfing the internet).

Frequency of specific activities during a typical weekend day (Saturday-Sunday):

(E15. Watch TV; E16. Use the computer; E17. Read traditional books; E18. Read electronic books; E19. Play videogames on console game player; E20. Use an iPad, iTouch, or similar device (not including a smartphone); E21. Use a smartphone for things like texting, playing games, watching videos, checking email, or surfing the internet).

F. Technoference

Frequency of parent phone use during specific activities:

(F1. During meals; F2. While getting child(ren) ready for school; F3. During playtime; F4. During bedtime routine; F5. While driving child(ren) to or from activities or when riding on public transportation; F6. At the playground).

Data Analysis

Of the 423 participants who provided consent and completed surveys, we excluded participants who did not complete (n=19) or had substantial missing data (n=6) on the media use questionnaire. This left 398 participants in this study available for the LPA. All media variables were included in LPA, a person-centered statistical method to identify distinct groups of participants with similar median profiles within each group. Using Bayesian Information Criteria (BIC), the LPA with the lowest BIC value yielded 2 distinct groups.

Wilcoxon Mann-Whitney tests were used to compare media use questionnaire items between the groups identified by the LPA. Then separate multivariable logistic regression models were built to estimate the odds of being in group 1 versus group 2 for each set of parent (Model I), child (Model II), and household (Model III) predictors. As our approach was exploratory, we started with including all parent, child, or household characteristics in each respective model and conducted backward elimination, resulting in the most parsimonious model that retained only variables showing significant associations at a P value of <.05. For all characteristics significantly associated with group membership in Models I, II, or III, we built a combined Model IV to test which characteristics were independently associated with group membership.

Results

Participant Demographics

Parents were 93.7% female (373/398), 34 (SD 4.7) years old, and 62% (247/398) had a 4-year college degree or more; children were 3.8 (SD 0.54) years old, 76.3% (302/398) were White and non-Hispanic, and 82.7% (329/398) had siblings in the household (Table 1).

Evaluation Outcomes

Latent profile analysis yielded 2 distinct groups of media users (Figure 1). Families in group 1 (n=236) were more likely to prefer interactions through text, email, or social media rather than those in person (P=.01) and more likely to use TV shows or DVDs to calm their children (P=.03). Parents in group 1 used their mobile device more frequently during the week to read electronic books (P=.04). In contrast, group 2 (n=162) used more task-oriented media, including more audio and nongame apps (P=.01), had more concerns about effects of media on language development (P=.04), and used more media restrictions (P=.01).



Figure 1. Latent Profile Analysis: media use profiles. Standardized means by variable for group 1 versus group 2. Lettering describes variable type: A. child ownership and frequency of activities; B. child instrumental or regulatory uses of media; C. parent media knowledge and attitudes; D. mediation strategies; E. parent media use; F. technoference.

As shown in Figure 1, several additional variables approached significance (P<.20) that warrant mention. Parents in group 1 were more likely to feel overwhelmed by how much they have to do on their phone or mobile device (P=.12) and reported that using the phone or mobile device allowed them to "escape" a little bit while with their children (P=.14). They were more likely to watch TV or DVDs (P=.15) or use the computer (P=.10) over the weekend than were families in group 2. Group 1 families also reported using more content restrictions for what their children see in the media with internet filters, parental controls, or apps to block certain websites (P=.11), as well as use of parental media websites (eg, common sense media) to decide what types of programs are appropriate for their child. Finally, group 1 families were more likely to use their mobile device to take photos (P=.11).

Group 2 families preferred using their mobile devices to view photos or home videos (P=.13) in addition to the other

task-oriented media described above. They also noted concerns that children will become inattentive as a result of using screen media (P=.11) and more frequently restrict the amount of child viewing (P=.06).

In logistic regression models (Table 2), the only parent characteristic that was significantly associated with group 1 membership (vs group 2) in Model I was female parent sex. In Model II, children with longer duration of sleep had lower odds of group 1 membership, while those with later sleep midpoint and prematurity showed increased odds of group 1 membership. Households with more siblings had a borderline increased odds of group 1 membership in Model III. With all characteristics considered in the same model (IV), independent associations remained for female parent sex, greater number of siblings, and later child sleep midpoint.

Table . Multivariable logistic regression models predicting group assignment.

Model and variable		Group 1 (social-emotional drivers) versus group
		2 (intentional media), aOR ^a (95% CI)
Model I: parent characteristics		
	Parent sex (male vs female)	0.36 (0.16-0.84)
Model II: child characteristics		
	Sleep duration (per 1 hour)	0.72 (0.55-0.95)
	Sleep midpoint (per 1 hour)	1.5 (1.13-1.98)
	Prematurity (no vs yes)	2.26 (1.06-4.8)
Model III: household characteristics		
	Number of siblings (per sibling)	1.23 (0.998-1.5)
Model IV: all characteristics		
	Parent sex (male vs female)	0.3 (0.12-0.76)
	Number of siblings (per sibling)	1.27 (1.02-1.57)
	Sleep midpoint (per 1 hour)	1.51 (1.1-2.07)

a aOR: adjusted odds ratio

Discussion

Principal Findings

This study used a wide range of questions about child, parent, and household context of media use to identify coherent patterns of media use that are relevant to pediatric research or clinical intervention. Latent profile analysis results suggest that people may be predisposed to different media-use patterns based on individual motivations. Group 1 preferred text and email interactions to those in-person and used media to calm their children. These behaviors may be interpreted as use of media based on social-emotional drivers. In contrast, group 2 used media for more functional purposes. This group preferred more nongame and audio applications. They seemed warier of media, placed more restrictions around child media use, and had more concerns about the effect of media on child development. Though these findings in some way confirmed our initial hypothesis, that some types of media users are predisposed to more reactive-use patterns (group 1), while others are more predisposed to intentional and regulated uses of media (group 2), the tendency to use media as a sort of social-emotional buffer was not a factor we considered in our initial hypothesis.

When examining the overall patterns of media use between groups, a few theoretically coherent concepts arise. In group 1, described as using media based on social-emotional drivers, there appeared to be more parent use of media as an "escape" from childrearing demands, such as more parental media during the weekends, which is typically time families are together during the day. In previous qualitative work, parents have described using mobile devices and social media as a "virtual escape" when their child stresses them out [9], when they want to avoid parenting tasks [23], or when intentionally not wanting to engage with difficult child behavior [24]. Furthermore, compared with parents in group 2 who were more likely to view, but not take, photos or home videos on a mobile device, group 1 families took photos on their device more frequently, an action that by definition interrupts a social moment and introduces a

physical barrier between the individual taking the photograph and the subjects.

In group 2, parent media use appeared more goal oriented, and more limits and restrictions were placed on child media use, which may be related to greater concerns about media's effects on child wellbeing. This pattern of device usage has been described as "instrumental" (ie, goal directed and purposeful) rather than "ritualistic" in previous work [25], and is hypothesized to be related to the individual motivations for engaging with technology. In this study, we describe this pattern of device usage as intentional, similarly noting that this type of media use is meant to fulfill a purpose rather than for pleasure or distraction. Though we did not observe increased odds of group 2 membership based on measures of parental mental health or child behavior, a recent study using latent class analysis found stronger well-being indicators for "family-engaged adolescents" who live in families with family-owned devices, positive parent relationships, and lower parental social media use [26]. Higher wellbeing also occurred in teens who placed lower importance on technology and were expected to follow household technology rules. Future research may therefore examine the relationship between these multiple classes of media users in a longitudinal manner to determine if "intentional" media-use families who set early boundaries around child media use are more likely to have "family-engaged adolescents" with better social-emotional outcomes.

It is surprising that socioeconomic status, parenting stress, household disorganization, and child behavioral difficulties were not associated with membership in group 1. In previous research, longer screen time duration and higher parent technology interference have been linked with higher parenting stress [27-29]. Recent work has also suggested that children's screen time is a marker of family distress due to multiple psychosocial factors [30]. However, these studies only examined the variable of screen time, while our approach identified larger family media use patterns that appear independent of socioeconomic factors in this cohort.

We did find that mothers are more likely to use media as a social-emotional buffer and that this type of media use is more common in larger families. It is possible that mothers or parents of larger families may experience higher caregiver burden and, as a result, are using media for more self-regulatory purposes and to calm or manage child behavior more frequently. Indeed, use of digital technology as a "babysitter," to provide caregiver respite or allow parents time to tend to other tasks, is a concept that is well-described in research literature and mainstream news, albeit with some differences in acceptance across cultures [31-35]. Evidence suggests that use of media to occupy children may be especially relevant in homes where children require more attention or behavioral management due to temperament differences [36], or where there is limited support for the primary caregiver. One study found that parents who lack support from a partner or who are uncertain about their parenting skills were more likely to use media as a distractor and concluded that "media are thus especially used as a distractor in the family when parents feel that it is difficult to keep the household going by themselves" [34].

Another correlate of group membership was later sleep midpoint (ie, the calculated midpoint between reported average sleep onset and wake time), with group 1 having later sleep midpoints than group 2. This may be explained by the fact that group 2, despite any significant difference in overall parenting style, seemed more prone to limit setting. What is perhaps most surprising about our study findings are the variables that did not predict group membership including parent education, marital status, employment, and child behavior variables such as emotional reactivity and surgency. Although human-computer interaction research has identified individual predictors of smartphone usage habits such as personality [37], attachment style [38], and executive functioning [39], we found no associations of parenting style (such as laxness vs harshness), parenting stress, or depression symptoms with group membership.

Limitations

Our study was limited in generalizability due to our study population which included mostly White, non-Hispanic, higher-educated, and female-parent responders. While our cohort reflected the racial and ethnic diversity of our local area, results may not be generalizable to other populations. In addition, the data we analyzed on media use was all from self-report questions, which can lead to single-reporter bias. We also reported on several associations that did not achieve significance, but were near significant, that we included in our results as we felt the data helped to demonstrate an overall trend. Greater insight into the reasons for media use may have been gleaned from a mixed methods approach, where follow up semistructured interviews could have explored themes related to media as a social-emotional buffer versus to fulfill a desired goal.

Conclusions

Results of our study suggest that people likely do have different motivations behind their use of digital media that may be reflected in their usage patterns. The significance of these different media usage patterns for the long-term outcomes of children and families is yet to be determined. It is possible, and in fact likely, that each pattern of media use may be considered adaptive in certain situations and maladaptive in others. By having a better understanding of why and how different families use media in their daily lives, pediatric care providers can provide more individualized anticipatory guidance regarding technology use by the whole family, including limit setting, use of media for calming, and how devices impact family dynamics. For example, by understanding that a parent is more prone to using mobile media to calm their child, a pediatrician might suggest that such a parent reflect on the frequency with which they use such calming techniques to ensure that they are also providing their child opportunities to practice frustration tolerance using techniques that go beyond distraction with media.

The research implications of our study may allow us to classify the media use patterns of families to better examine the long-term effects of media use on child health and development. Follow up studies could examine trajectories of profiles over childhood to determine their stability and how they relate to

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child outcomes over time. Future research directions should also include nationally representative populations, objective

device use data, or reports from multiple household members (eg, parents and children).

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Authors' Contributions

NH conceptualized and contributed to the design of the study, reviewed all data, participated in the statistical analysis, drafted the initial manuscript, and reviewed and revised the manuscript. JR was the primary investigator on the grant award for the original study, contributed to the conceptualization of the current study, advised on study design, reviewed data, participated in the statistical analysis, and reviewed and revised the manuscript. HMW advised on study design, conducted the statistical analysis, summarized the study data, developed related figures and tables, and contributed to, reviewed, and revised the manuscript. ALM advised on study design, reviewed data and outcomes, reviewed and revised the manuscript. NK advised on study design, directed and oversaw the statistical analysis, reviewed study data, and reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Conflicts of Interest

NH has ownership interest in Arbor Autism Centers LLC. In the past year, JR received fees from Melissa & Doug LLC and research funding from Common Sense Media. HMW reported receiving grants from the National Institute of Child Health and Human Development outside the submitted work. ALM reported receiving grants from the National Institutes of Health outside the submitted work. NK reported receiving grants from the National Institute work.

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Abbreviations:

BIC: Bayesian Informed Criteria
CAFE: Comprehensive Assessment of Family Exposure
DVD: digital versatile disc
LPA: latent profile analysis
REDCap: Research Electronic Data Capture
TV: television

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Impact of COVID-19 on Dutch General Practitioner Prenatal Primary Care: Retrospective, Observational Cohort Study Using an Interrupted Time-Series Approach

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Abstract

Background: The COVID-19 pandemic significantly impacted primary health care–seeking behavior of the general population. The extent to which health care–seeking behavior of pregnant women in general practitioner (GP) care was affected remains largely unknown. The unique health care needs of pregnant women necessitate regular monitoring and care to ensure the well-being of expectant mothers, fetuses, and neonates, as timely interventions and screenings can profoundly influence the long-term health outcomes. Understanding how pandemic-related changes have influenced pregnant women's primary health care–seeking behavior is essential for developing targeted interventions and informing policy decisions to improve health outcomes for expectant mothers, fetuses, and neonates, both during public health emergencies and in routine health care settings.

Objective: This study aims to examine the impact of different COVID-19 pandemic phases on health care–seeking behavior among pregnant women in Dutch GP practices throughout 2020 and 2021. By analyzing clinical electronic health record (EHR) GP data, we aim to evaluate the health care consumption, occurrence of pregnancy-relevant symptoms and diagnoses, and types of contact (ie, regular consultations, phone consultations, home visits, and digital consultations) during different pandemic phases.

Methods: Using a retrospective cohort design, EHRs of selected pregnant women from 3 Dutch GP networks between 2019 and 2021 were analyzed, comparing 6 pandemic phases divided into 13 subphases with a prepandemic phase. Contact rates were analyzed by interrupted time-series analyses, pregnancy-relevant symptoms, and diagnoses by comparing the frequency of pregnancy-relevant International Classification of Primary Care (ICPC) code registrations and type of contact by descriptive statistics.

Results: In total, 10,985 pregnant women were included, yielding 39,023 patient-GP contacts. Contact rates fluctuated significantly across pandemic phases, with the sharpest declines at the onset and the end of the pandemic. Pregnancy-relevant symptoms and diagnosis in the category related to pregnancy showed the highest variability across the pandemic phases, such as an increase in the frequency of health care consumption concerning gestational diabetes mellitus and nausea or vomiting of pregnancy. Detailed statistical results are reported in the main text. Contacts for symptoms and diagnosis like digestive or urinary tract problems did not fluctuate across the pandemic phases. The number of physical contacts decreased, while telephone contacts increased.

Conclusions: By analyzing EHR data from over 10,000 pregnant women, this study highlights the pandemic's impact on pregnant women's GP health care–seeking behavior, including declining health care consumption trends during the initial and end phases of the pandemic (2020 - 2021). The observed increase in GDM and its potential long-term effects underscore the need for enhanced public health strategies within GP practices, ensuring continuous access to prenatal care and striving for improved outcomes of expectant mothers, their fetuses, and neonates during times of pandemics and in routine health care settings.

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KEYWORDS

pregnant women; COVID-19 pandemic; general practitioner; GP; health care-seeking behavior; interrupted time-series analysis; health policy; primary care

Introduction

The COVID-19 pandemic has caused profound changes in health care–seeking behavior globally, especially within primary general practitioner (GP) care settings, where a significant decline in use was observed following the outbreak of the pandemic [1-5]. This decline in GP health care visits was shown to be driven by factors such as lockdown measures and heightened fears of viral transmission [1]. These shifts have resulted in reduced experienced accessibility and continuity of GP care, leading to postponed chronic care and increased interactions with unfamiliar health care providers [6].

Prenatal health care is managed collaboratively by midwives and obstetricians in secondary health care, and by midwives and GPs in primary health care. In the Netherlands, every citizen is registered with a GP who serves as a gatekeeper to secondary care [7]. Midwives and GPs typically oversee low-risk pregnancies in primary care, while obstetricians handle high-risk cases in secondary hospital care. GPs play a pivotal role in prenatal health care, providing comprehensive support that encompasses health promotion (eg, advices concerning diet and exercise in the case of diabetes mellitus, smoking cessation, and COVID-19 infection and vaccination), timely interventions for routine health care problems (eg, treatment of urine tract infections and mental health problems) and specialist referrals [8-10]. In addition, pregnant women can rely on GPs for certain medication needs (eg, antibiotics, thyroid medication, and mental health medication), especially since midwives do not have prescription authority in the Netherlands. A previous national study showed that before the pandemic, pregnant women typically consulted their GPs around 6 times on average during pregnancy and the postpartum period [10]. Common reported symptoms and diagnoses included intercurrent diseases, vomiting, urogenital problems, mental health issues, and work-related concerns [10,11]. Most pregnant women saw their GP, alongside their midwife or obstetrician, as an essential prenatal care provider, fostering long-term trusted health relationships with their registered GPs [10]. Therefore, GPs play an important role in providing additional prenatal health care for pregnant women.

Postponing or cancelling this important prenatal care may lead to negative consequences for maternal, fetal, or neonatal health [12-14]. Pregnant individuals are inherently vulnerable and susceptible to both physical and psychological illness, which may be exacerbated if the necessary prenatal GP care is not provided. Therefore, sustainable GP care for pregnant women, in addition to regular perinatal care, is needed for a robust public health care system [2].

Consequently, understanding the impact of the COVID-19 pandemic on health care–seeking behavior among pregnant women in GP practices is imperative. However, the extent to which the pandemic influenced pregnant women's health care–seeking behavior within Dutch GP practices across

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different pandemic phases remains largely unknown. For that reason, this study aims to examine the impact of different COVID-19 pandemic phases on health care consumption among pregnant women in Dutch GP practices throughout 2020 and 2021. By analyzing routine clinical electronic health record (EHR) data registered by GPs, this study aims to evaluate health care consumption, the occurrence of pregnancy-relevant symptoms and diagnoses, and the types of contact (ie, regular consultations, phone calls, home visits, digital consultations) during different pandemic phases. It is important for informing policymakers, health care providers, and expectant mothers to understand how external factors such as a pandemic and associated restrictive measures influence health care-seeking behaviors among pregnant women. By providing these insights, this study ultimately aims to contribute to the improvement of prenatal GP care delivery, impacting public health in both pandemic and routine health care settings.

Methods

Study Design and Population

This retrospective observational cohort study used data retrieved from routinely registered clinical EHRs from GP practices from 2019 (prepandemic) to 2021 (pandemic). Data from 3 regional Dutch GP research networks were used: (1) the northern Academic General Practitioner Development Network (Academisch Huisartsen Ontwikkel Netwerk, AHON), including 59 GP practices managed by the University Medical Center Groningen (UMCG) [15]; (2) the eastern Family Medicine Network including 6 practices managed by Radboud University Medical Centre Nijmegen [16]; and (3) the southern Research Network Family Medicine Maastricht, including 28 practices managed by Maastricht University Medical Centre [17]. The network populations are a good reflection of the population in these regions [15,17,18]. The dataset included anonymized EHR data from approximately 410,000 patients, encompassing patients' medical history, clinical findings, diagnoses, types of contact, and demographic characteristics [1].

In the Netherlands, GPs are required to assign an International Classification of Primary Care (ICPC) code to each patient contact [19]. Contacts were defined as either a physical consultation (at the clinic or at home), a telephone consultation, or any type of digital contact between a patient and a GP or practice nurse, with registration of a free text note (physician's note) and at least 1 ICPC code.

Selection of Pregnant Women

Women in the reproductive age (20 - 45 y) with a confirmed pregnancy status in their EHR were selected for inclusion in the study. To select pregnant women, all EHR records of women of reproductive age were screened to determine pregnancy status during the studied period, using 3 methods. First, pregnancy status was determined based on the registration of at least one of the 24 pregnancy and childbearing related ICPC codes, such

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as W78 ("pregnancy, confirmed"), see Multimedia Appendix 1. Second, to identify pregnant and postpartum women without pregnancy-relevant ICPC codes, physician's notes (free text notes) were screened for text patterns indicating pregnancy, using a regular expression (see Multimedia Appendix 2). To enhance validity, this regular expression was reviewed by a data scientist. Third, physician's notes of contacts of potentially pregnant women selected by the aforementioned methods were manually assessed by the study team (WB-H and MH) to confirm pregnancy status (see Multimedia Appendix 3). Only contacts where pregnancy status was confirmed at the time of the contact were included irrespective of their pregnancy duration.

Women miscarrying were also retrospectively labelled as being pregnant. If neither of these 3 methods were irrefutable about pregnancy status, women were excluded. Registrations of the ICPC code W90 ("normal delivery liveborn") were excluded for data integrity reasons, as some of these were identified as false registrations from previous pregnancies. Women were excluded when they had died during the study period, were deregistered from one of the included practices, had a reason for deregistration without deregistration date, had an unknown date of birth, were registered less than 3 months, or had missing data that hindered pseudonymization (eg, zip code). Only dates of weekdays were included. Weekend days, holidays, and consults outside of regular office hours were excluded from the analysis (see Multimedia Appendix 4).

Outcome Variables

The primary outcome variables included pandemic health care consumption (ie, contact rates), pregnancy-relevant symptoms and diagnoses, and type of contact (ie, regular, phone, home visit, or digital contact), and were compared with the prepandemic baseline (2019). Pregnancy-related symptoms and diagnoses were determined by listing pregnancy-relevant ICPC codes that represented symptoms or diagnoses that commonly occur during pregnancy or require clinical attention in pregnant women. The selection was based on relevant ICPC codes from previous research [10], and supplemented with manual evaluation of all ICPC codes for their relevance in pregnancy. To validate the list of pregnancy-relevant ICPC codes, a general practitioner (MH) and a midwife evaluated the relevance of each code to pregnancy (see Multimedia Appendix 5). Contacts could involve one or more ICPC codes.

Pandemic Phases and Subphases

Previous research showed that health care consumption fluctuated during the pandemic in response to both changes in COVID-19 incidence rates and the implementation or relaxation of restrictive measures in the general population [1]. Therefore, this study is conducted in accordance with a previously described framework that divides the pandemic into 6 main phases based on the restrictive measures mandated by the Dutch government [1,20]. These phases were subdivided into subphases based on turning points in the national COVID-19 incidence rates within each main phase (Table 1), using data from the National Institute for Public Health and Environment (Rijksinstituut voor Volksgezondheid en Milieu). In the general population, for example, health care consumption initially decreased in phase 1 and then increased again midway through phase 1 as incidence rates declined, leading people to gradually visit their GPs more often again [1].



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Table . COVID-19 pandemic phases in the Netherlands based on infection rates and restrictive measures, and subphases based on highest and lowest infection rates.

Phase and subphase		Year	Week within year	Description of COVID-19 infection rates and contain- ment measures		
Phase 0				• No confirmed COVID- 19 infections in the Netherlands.		
	Phase 0	2019	1 - 52			
	Phase 0	2020	1 - 8			
Phase 1				 First wave of COVID- 19 infections. First lockdown (ie, hand hygiene, social distancing, working at home, and schools, restaurants, amusement and industry closed). Highest infection rates: week 15. 		
	Phase 1a	2020	9 - 13			
	Phase 1b	2020	14 - 22			
Phase 2				 Decrease in infection rates. Gradual relaxation of restrictive measures. Lowest infection rates: week 28. 		
	Phase 2a	2020	23 - 28			
	Phase 2b	2020	29 - 40			
Phase 3				 Second wave of COVID-19 infections. Stricter containment measures, start of a partial lockdown fol- lowed by a strict lock- down (ie, curfew, schools, stores, and sport facilities closed). Highest infection rates: week 44 and 52. 		
	Phase 3a	2020	41 - 44			
	Phase 3b	2020	45 - 53			
	Phase 3c	2021	1 - 3			
Phase 4		2021	4-17	 Emergence of the Alpha variant (B1.1.7) of concern, further increase in infection rates, and continued lockdown measures. Highest infection rates: week 16. 		



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Phase and subphase		Year	Week within year	Description of COVID-19 infection rates and contain- ment measures		
Phase 5				 Decrease in infection rates. Gradual opening-up of society and only minor restrictions. Lowest infection rates: week 26. 		
	Phase 5a	2021	18 - 26			
	Phase 5b	2021	27 - 43			
Phase 6				 Epidemic rise with the Delta variant (B.1.617.2) of concern and a steep increase in infection rates. Lockdown measures reintroduced. Highest infection rates: week 48. 		
	Phase 6a	2021	44 - 48			
	Phase 6b	2021	49 - 52			

Data Analysis

Overview

Descriptive statistics were performed to describe the study population characteristics for each studied year (2019, 2020, and 2021). This included the total number of included pregnant women per (pre)pandemic year and region, the total number of contacts, the mean number of contacts per patient with SD, the mean number of ICPC code registrations per contact, and the mean age with SDs. Statistical differences between the studied years were tested using a G-test for goodness-of-fit.

All statistical analyses with a P<.05 were considered significant. All data were analyzed using R (version 4.0.5; R Foundation for Statistical Computing).

Analysis of Health Care Consumption

Health care consumption was calculated by normalizing daily contact rates per 1000 registered pregnant patients. An interrupted time-series analysis was conducted using a segmented linear regression model to assess the impact of the COVID-19 incidence rates and societal measures on health care consumption during each pandemic subphase. For each (pre)pandemic subphase, a linear regression model was used, assuming a linear relationship between time and the contact rates within each subphase and fitted to generate a least squares regression line. Linearity was checked through visual inspection of the fitted models, while autocorrelation was assessed visually using autocorrelation plots. To enhance the stability of contact rates, a 3-week centered moving average was applied before modeling. Seasonality was accounted for by adding seasonal intercepts to the model, with spring as the baseline. For each subphase P, the linear regression model was described mathematically (Equation 1).

$(1)YT(P) = \beta 0 + \beta 1 \cdot T + \beta 2 \cdot S1 + \beta 3 \cdot S3 + \beta 4 \cdot S4$

In this equation, Y_T represents the contact rate at time T, P the phase being modelled (ranging from 0 to 6b), β_0 the intercept value at the start (*t*=0) of phase P, β_1 the slope of the linear model during phase P, and T the time variables (in days within phase P). β_2 , β_3 , and β_4 are the seasonal intercepts. S_1 , S_3 , S_4 are dummy variables indicating the season (Winter, Spring, Summer, and Autumn), taking value 1 if the season is within the studied phase, and value 0 otherwise (see Figure 1). S_2 was considered the baseline, always having value 0. This model captures the variation in the health care consumption during each phase, considering both the overall time trend ($\beta_0 + \beta_1 \cdot$ T) and the seasonal effects introduced by the dummy variables $\beta_2 \cdot S_1 + \beta_3 \cdot S_3 + \beta_4 \cdot S_4$, taking spring S_2 as the baseline.



Figure 1. Linear models of health care consumption per phase, shown by day in phase and per 1000 registered pregnant patients. The *z* scores represent the comparison of the slope of each pandemic phase as compared to the slope of the prepandemic phase (Phase 0) along with their significance. As the prediction models for health care consumption were adjusted for seasonality, the linear regression lines may shift within a phase; these shifts are marked by vertical dashed lines at the seasonal transitions. The distributions of the x-axes are not equal for each phase, as phases did not consist of an equal number of days.



Beta coefficients (ie, intercept β_0 and slope β_1) were computed for each subphase. Intercept values and their SEs were calculated at the start of each subphase (t=0) to determine immediate effects at the start of a new subphase. In addition, slopes and their SEs were computed to model and assess the trend in health care consumption within each subphase, where a negative slope indicated a decrease, and a positive slope indicated an increase in health care consumption. To compare intercept values and slopes of pandemic subphases to the prepandemic baseline, z-scores of the β -coefficients and their accompanying P values were calculated. Coefficients of determination (R^2) and adjusted R^2 were calculated to describe the proportion of variance that was explained by the independent variables within each model. Differences between a pandemic subphase and the prepandemic baseline were considered significant if the P value of the z score of either the intercept or the slope was <.05.

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Analysis of Pregnancy-Relevant Symptoms and Diagnoses

The changes in the most prevalent pregnancy-related symptoms and diagnoses were examined by identifying the 10 most frequently registered ICPC codes from the created list of pregnancy-relevant ICPC codes (ie, symptoms and diagnoses) within the studied population during the studied period. Focusing on the most prevalent conditions allowed for a structured analysis of variation over time while maintaining analytical feasibility. The number of ICPC code registrations was calculated by normalizing the number of ICPC code registrations per 1000 contacts. To assess whether these proportions differed substantially between each pandemic subphase and the prepandemic baseline, statistical analysis through Fisher Exact tests for each specific ICPC code was conducted.

Analysis of Type of Contact

The type of contact was visualized as a percentage of the total number of contacts within each phase. Visualization was done using a centered moving average of 3 weeks and smoothed using Locally Estimated Scatterplot Smoothing. This nonparametric smoothing technique uses locally weighted polynomial regression to fit a smooth curve through points in a scatter plot, providing a visual trend of the data without assuming a specific parametric model.

Ethical Considerations

Ethical approval for the collection and analysis of COVID-19 EHR data was conducted by the Medical Ethics Committee of the UMCG (2020/309). In this study, no patients were directly involved, and thus, this research was ruled not to be subject to the Medical Research Involving Human Subjects Act (Article 9, paragraph 2, EU-GDPR 2016/679). The EHR data were anonymized and deidentified before being made available to the researchers.

Results

Population Characteristics

A total of 975,545 contacts of 78,941 women in the reproductive age (20 - 45 y) were screened for pregnancy status, of which 10,985 women (13.9%) were labelled as pregnant and had 39,023 contacts with the GP (see Table 2). Pregnant women had a mean age of 30.4 (SD 4.6) years during the total studied period. These women had an average of 2.8 (SD 2.6) contacts in 2019, 2.8 (SD 2.6) in 2020, and 2.9 (SD 2.8) in 2021.

Table . Demographic characteristics of the study population of pregnant women per year (2019 - 2021; n=10,985).

	Total population ^a (N=10,985)	Population in 2019 (n=4414)	Population in 2020 (n=4553)	Population in 2021 (n=4836)	<i>P</i> value
Pregnant women, n	10,985	4414	4553	4836	<.001
Age (years), mean (SD)	30.4 (4.6)	30.5 (4.6)	30.3 (4.6)	30.5 (4.5)	≥.99
Total contacts, n	39,023	12,384	12,686	13,953	<.001
Number of contacts per patient, mean (SD)	3.6 (3.5)	2.8 (2.6)	2.8 (2.6)	2.9 (2.8)	.99
Number of ICPC ^b code registrations per con- tact, mean (SD)	1.13 (0.38)	1.14 (0.39)	1.13 (0.37)	1.12 (0.37)	≥.99

^aPopulations partly overlap in the 3 studied years.

^bICPC: International Classification of Primary Care.

Changes in Health Care Consumption

Health care-seeking behavior differed significantly in each pandemic subphase compared to Phase 0 (see Figure 1 and Table 3). At the onset of the pandemic (Phase 1a), an immediate significant increase in health care consumption was observed (β_0 =10.54; *P*=.04), evident from the elevated intercept value compared to Phase 0. During Phase 1a, there was a substantial and significant decrease in health care consumption following

the initial peak intercept value (β_1 =-0.03; *P*<.001), indicating reduced contacts with the GP at the beginning of the pandemic. In Phase 1b, an immediate effect was noted, with a significantly lower intercept value (β_0 =9.97, *P*<.001). However, the subsequent period did not significantly differ from Phase 0, indicating consistently lower health care consumption during Phase 1b, though this model was unable to explain most of the variance (R^2 =0.02).



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Table. Interrupted time series analysis of health care consumption for the different pandemic subphases (2020 and 2021) compared to the prepandemic year 2019 (phase 0) of the total studied population of pregnant women, showing intercepts (β_0) with SE, slopes with SEs (β_1), *z* scores, and *P* values for intercepts.

Phase	Intercept of the linear model			Slope of the linear model			Model's goodness of fit	
	Intercept β_0 (SE)	z score, inter- cepts	P value, inter- cepts	Slope β_1 (SE)	z score, slopes	P value, slopes	R^2	Adjusted R^2
0 (baseline)	10.22 (0.04)	a	_	-0.00 (0.00)	_	_	0.31	0.30
1a	10.54 (0.10)	-4.10	.04	-0.03 (0.00)	5.50	<.001	0.61	0.57
1b	9.97 (0.13)	0.97	<.001	-0.00 (0.01)	0.63	.53	0.02	0.01
2a	9.62 (0.05)	7.83	.33	-0.03 (0.00)	11.80	<.001	0.85	0.84
2b	8.16 (0.20)	9.33	<.001	0.04 (0.00)	-9.86	<.001	0.77	0.76
3a	9.88 (0.05)	3.31	<.001	-0.01 (0.00)	1.32	.19	0.11	0.06
3b	9.92 (0.04)	3.05	.001	0.01 (0.00)	-2.53	.01	0.13	0.08
3c	9.92 (0.05)	2.74	.002	0.02 (0.00)	-5.58	<.001	0.63	0.61
4	11.34 (0.11)	-10.13	.006	-0.01 (0.00)	2.96	.003	0.70	0.69
5a	11.23 (0.14)	-7.61	<.001	-0.04 (0.01)	4.13	<.001	0.34	0.31
5b	9.62 (0.14)	3.33	.001	0.00 (0.00)	-0.39	.70	0.14	0.11
ба	10.06 (0.06)	0.59	.56	-0.01 (0.00)	2.50	.01	0.77	0.75
6b	9.41 (0.03)	13.26	<.001	-0.08 (0.01)	15.81	<.001	0.97	0.97

^aNot applicable.

The start of Phase 2a did not significantly differ from Phase 0 (β_0 =9.62; *P*=.33). Nevertheless, a significant negative slope indicated a sustained decline in health care consumption during this phase (β_1 =-0.03; *P*<.001). Phase 2b marked the lowest intercept value in health care consumption in the studied period (β_0 =8.16; *P*<.001). Subsequently, there was a significant increase in health care consumption during Phase 2b (β_1 =0.04; *P*<.001).

In Phase 3, all subphases (3a, 3b, and 3c) exhibited significantly lower intercept values (respectively, $\beta_0=9.88$, P<.001; $\beta_0=9.92$, P=.001; and $\beta_0=9.92$, P=.002). Health care consumption remained stable during Phase 3a ($\beta_1=-0.01$; P=.19), while significant increases occurred during Phases 3b and 3c ($\beta_1=0.01$, P=.01 and $\beta_1=0.02$, P<.001, respectively), though the models of Phase 3a and 3b were unable to explain most of the variance ($R^2=0.11$, and $R^2=0.13$, respectively).

The onset of Phase 4 marked the highest intercept value since the beginning of 2019 (β_0 =11.34; *P*=.006). However, health care consumption significantly declined during Phase 4 (β_1 =-0.01; *P*=.003).

Phase 5a began with a significantly higher intercept value ($\beta_0=11.23$; P<.001). During Phase 5a, health care consumption declined significantly ($\beta_1=-0.04$; P<.001). This decline led to a significantly lower intercept value at the beginning of Phase 5b ($\beta_0=9.62$; P=.001), with health care consumption remaining relatively stable during Phase 5b. Phase 6a initiated with an intercept value comparable to Phase 0 ($\beta_0=10.06$; P=.56). However, health care consumption declined significantly during Phase 6a ($\beta_1=-0.01$; P=.01), resulting in a significantly lower

intercept value of Phase 6b (β_0 =9.41; *P*<.001), followed by a further significant decline during Phase 6b (β_1 =-0.08; *P*<.001).

Pregnancy-Relevant Symptoms and Diagnoses

Most Frequent Registered Symptoms and Diagnoses

The top 10 pregnancy-relevant symptoms and diagnoses (ie, ICPC codes) presented by pregnant women to their GP during the studied period were examined (see Multimedia Appendix 6). These symptoms and diagnoses were (1) pregnancy confirmed (ICPC W78), (2) cystitis or other urine infection (U71), (3) vomiting or nausea of pregnancy (W05), (4) abortion spontaneous (W82), (5) unwanted pregnancy confirmed (W79) (6) frequent or urgent urination, (U02), (7) urogenital candidiasis (X72), (8) GDM (W84.02), (9) other localized abdominal pain (D06), and (10) constipation (D12). Contacts related to these top 10 symptoms and diagnosis covered 65.6% (n=25,587) of all contacts of pregnant women during the studied period.

Changes in Pregnancy-Relevant Symptoms and Diagnosis

The normalized and absolute number of contacts concerning the top 10 symptoms and diagnoses per phase were examined (Multimedia Appendix 6). Health care consumption concerning pregnancy-related symptoms and diagnoses changed statistically significant in multiple pandemic phases compared to Phase 0. Specifically, health care consumption for vomiting or nausea of pregnancy was significantly higher during Phase 2a, 2b, 3b, 3c, 4, 5b, and 6b compared to Phase 0. Conversely, confirmed pregnancy was significantly lower in Phase 1a, 1b, 4, and 6a compared to Phase 0. Confirmed unwanted pregnancy was significantly lower in Phase 2b, 3b, 4, 5a, 5b, and 6a compared to Phase 0. Spontaneous abortion was found to be significantly

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higher in Phase 2a and 3b compared to Phase 0 (P=.04 and P=.048, respectively). GDM was significantly higher in the Phase 2a, 4, 5a, and 5b compared to Phase 0.

Notably, among general health symptoms and diagnoses, health care consumption for localized abdominal pain did not change significantly during the pandemic phases compared to Phase 0. Constipation declined significantly in Phase 5a compared to Phase 0 (P=.02). Frequent or urgent urination declined significant in Phase 3c compared to Phase 0 (P=.02). Cystitis or other urine infection was significantly higher in Phase 5b and lower in Phase 6a compared to Phase 0 (P<.001 and P=.04, respectively). Urogenital candidiasis showed a significant increase in Phase 5b compared to Phase 0 (P=.002).

Changes in Type of Contact

Figure 2 shows the percentages of type of contact (ie, regular consultations, telephone consultations, home visits, and digital consultations). During the initial pandemic phase, regular consultations declined, and telephone consultations increased. From Phase 2 until Phase 6, regular consultations increased, but did not reach the prepandemic baseline of 64.9% (n=9281). After the sharp increase in telephone consultations, there was a decline during the following pandemic phases. However, the percentage of telephone consultations remained higher than the prepandemic baseline of 31.7% (n=4529). Digital consultations remained comparable to the prepandemic baseline throughout the pandemic phases.

Figure 2. The proportion of types of contact for pregnant women across prepandemic and pandemic phases, with raw and smoothed percentages shown by contact date. Contact types were visualized as a percentage of the total number of contacts within each subphase, using a centered moving average of 3 weeks.



Discussion

Principal Findings

To the best of our knowledge, this is the first study examining pregnancy-relevant symptoms and diagnoses in GP practices in relation to the COVID-19 pandemic. By analyzing routine clinical EHR data registered by GPs, this study revealed statistically significant fluctuations in health care consumption among over 10,000 studied pregnant women during various pandemic phases, defined by infection rates and restrictive measures. In addition, this study demonstrated significant increases in GDM and vomiting or nausea of pregnancy, while contacts concerning confirmed pregnancies declined.

The deployed interrupted time-series analysis is a highly effective design for studying effects of interventions [21], such as the restrictive measures mandated by the government and changes in COVID-19 incidence rates during the pandemic phases. Furthermore, our combined method of selecting pregnant women led to the inclusion of a large sample of a wide range of pregnant women in the Netherlands. This comprehensive analysis of contacts, symptoms, and diagnoses of pregnant women provided valuable insights into prenatal GP care and changes in health care–seeking behavior of these vulnerable women during the COVID-19 pandemic.

Population Characteristics

Our study showed a statistically significant increase in the number of pregnancies registered at the GP practice and absolute number of contacts in 2021, which is in accordance with national birth rates [22]. The mean age of the pregnant women studied (30.4 y, SD 4.6) is slightly lower than the mean maternal age at the date of delivery of the total Dutch population (31.6 y). Our study illustrated that, if pregnant women contacted their GP, the mean number of contacts in the prepandemic year 2019 was 2.8 (SD 2.6) and remained comparable in the pandemic years 2020 and 2021.

Health Care Consumption

We show primarily declining health care consumption during the initial phases of the pandemic. The hesitation of pregnant women to seek GP care may have been influenced by the lack of knowledge about the consequences of a COVID-19 infection on both mother and fetus along with related news messages, fear of contamination, societal recommendations to stay home, or limited child care availability [23-25]. The declining trend also aligns with findings from other studies among the general population, which observed a pandemic-induced decrease in primary health care consumption initially [1-5,26]. Recent research has further highlighted a more pronounced decline in health care-seeking behavior among women compared with men during these initial pandemic phases, indicating that women may have been particularly hesitant to seek medical care amidst the pandemic [27]. Furthermore, a previously published systematic review revealed notable shifts in pregnant women's health care-seeking behavior in other health care settings such as obstetric hospital and prenatal clinic care, including a substantial decline in both routine and unscheduled prenatal care visits at their maternal health care providers [28]. This decline may indicate that important prenatal care was missed during this period, potentially resulting in delayed adverse effects on mother, fetus, and neonate. Future research should elaborate on these long-term consequences.

After reaching the lowest point of GP health care consumption in the studied period (2020 - 2021) in July 2020, health care consumption mainly increased until January 2021 and remained statistically significantly higher than the prepandemic level until mid 2021, suggesting a rebound after the initial decline. The observed increase mid-2020 may be explained by the declining infection rates and the gradual reopening of society. Furthermore, the increasing health care consumption among pregnant women may be indicative of an increased demand for GP health care, potentially compensating for earlier missed care. Other research illustrated similar fluctuating trends in health care-seeking behavior worldwide during these pandemic phases [1,27,29]. Despite this temporary rebound of health care consumption, the World Health Organisation identified a continued disruption of access to prenatal and primary health care services worldwide during this period [29].

Notably, from mid-2021 until the end of the year, a recurrent steep decline in health care consumption was observed, despite declining infection rates, minimal restrictions, and the gradual reopening of society. Possibly, pregnant women sought care with their primary care midwife again. However, the hesitation

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in contacting the GP may also be explained by news messaging highlighting an increased risk of serious illness from COVID-19 infection for pregnant women during this period, which was based on related published research [30]. This implies a negative impact of the rise of the Delta variant and reintroduced lockdown measures on prenatal health care, potentially resulting in recurrent missed prenatal care.

Overall, the declining trends in health care consumption during the start and end phases of the pandemic among pregnant women suggest a substantial impact on health care consumption during the pandemic, influenced by the COVID-19 incidence rates, restrictive measures, and news messaging related to COVID-19. Previous studies found that factors such as the fear of infection during health care contacts, limited understanding of the effects of COVID-19 on maternal and fetal health, and societal restrictions probably influenced this declining trend in health care consumption [1,23]. This could potentially lead to delayed adverse pregnancy outcomes, and physical and mental health problems [23,28]. Future studies should elaborate on these long-term consequences of the pandemic and on additional factors contributing to variation in health care consumption.

Pregnancy-Relevant Symptoms and Diagnoses

Building upon these fluctuating trends in health care consumption, we also explored changes in presented pregnancy-relevant symptoms and diagnoses. We show that 83.8% (n=21,621) out of the top 10 most frequently registered symptoms and diagnoses were related to pregnancy, which largely aligns with prepandemic research among Dutch pregnant women in GP care [10]. Interestingly, most changes between pandemic phases and the prepandemic baseline were found in pregnancy-related symptoms and diagnoses, while fewer changes were observed in categories related to routine health care symptoms and diagnoses. Most symptoms and diagnoses consistently declined or consistently increased in frequency, independent of pandemic phases. This suggests that changes in frequency of presented symptoms and diagnoses were driven by the nature of the specific complaint or diagnosis, rather than being influenced by the prevailing measures or incidence rates during each phase.

We have underlined a noteworthy increase in health care consumption concerning GDM during different pandemic phases, consistent with previous research [31-34]. This might be attributed to a rise in pregnancy-related weight gain, as was shown by other studies [32,35]. We speculate that this consequential increase in GDM could be due to physical limitations, sedentary behavior, and emotional distress following the severely restrictive lockdown measures [35-37]. Therefore, pandemics can be a risk factor for developing GDM. This is an important finding given the results of a recent review underlining that GDM increases risks of adverse maternal and perinatal outcomes, such as hypertensive disorders of pregnancy, induction of labor, caesarean section, large-for-gestational-age neonates, preterm birth, and neonatal intensive care unit admission [38]. Furthermore, the increase in GDM may have contributed to the statistically significant increase in cystitis or other urine infection and urogenital candidiasis in some pandemic phases.

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In addition, we speculate that the previously reported decreased physical behavior [37,39], increased sedentary behavior, and emotional distress may have also contributed to the observed increase of vomiting or nausea of pregnancy. Furthermore, previous reviews underlined a negative influence of the pandemic on eating behavior, influenced by emotions, mood, cravings, and environmental factors [40,41], which could have further worsened symptoms of vomiting and nausea. Nevertheless, no previous research was found regarding this increased complaint. Further research is needed to examine these notable increases in GDM and nausea or vomiting of pregnancy, and their impact on long-term health outcomes for both mother and child. This could enable the development of appropriate lifestyle interventions for pregnant women to be provided as part of routine prenatal GP care, with a positive impact on outcomes during future pandemics.

Furthermore, our study brought to light notable declines in the registration of confirmed wanted and unwanted pregnancies during various pandemic phases, despite consistent national birth rates in 2020, and even higher rates in 2021 [22]. This implicates a decline in women reporting pregnancies to their GP or a decline in routine contacts where these codes are registered, aiming to prevent strain on GP care for what may seem like trivial reasons for care. Consequently, an important proportion of pregnant women did not consult their GP and were, therefore, not included in the study. The pandemic led to changes in the organization of prenatal health care provision by maternal health care professionals (midwives and obstetricians) and GPs, and probably contributed to a decline in the number of pregnant women consulting their GP. Further studies should elaborate on these suggestions. Yet, contacting the GP about pregnancy is important, as GPs provide essential prenatal care, including health promotion, timely interventions for general health care problems, management of medication needs, and referrals [8,9,11,42]. Furthermore, women with unwanted pregnancies experience more psychosocial problems than those with wanted pregnancies and often rely on GPs for care, highlighting the importance of contacting the GP [43].

Type of Contact

Considering the types of contact, our study showed a decrease in the proportion of regular physical contacts at the onset of the pandemic among pregnant women, accompanied by an increase of phone contacts. In line with previous research among the general population, while the proportion of regular physical contacts increased during subsequent phases, it did not return to the prepandemic levels during the studied years [1,28]. The pandemic accelerated the adoption of telehealth technologies, mainly through telephone contacts, in prenatal health care, facilitating more individualized and efficient health care [44,45]. A potential long-term shift toward a greater reliance on telehealth among pregnant women and GPs seems to have taken place. Nevertheless, further research should elaborate on whether this shift persisted postpandemic.

Limitations

There are also some limitations to this study. EHR data are not specifically intended for scientific purposes, but rather for

informing other physicians. Therefore, important information could be overlooked when assessing presented symptoms and diagnoses. Despite this, it is imperative to analyze such data as they represent one of the few available sources that provide real time, longitudinal insights into patient's health care-seeking behavior. In addition, we could not assess the impact of other external factors, such as COVID-19-related news messaging and changes in other health care provision by maternal health care providers on health care consumption, due to limited data availability and the scope of the study design. However, these factors may have contributed to the limited explanation of the variation in health care consumption by the modeled independent variables across certain subphases. Future research should explore the influence of such factors. Furthermore, the endpoint of our data collection in 2021 limits our ability to assess the long-term effects or follow-up of pregnancy outcomes. To address this limitation, we recommend linking GP registration data with birth registration data over a longer term to comprehensively track the entire course of pregnancy and its outcomes. Finally, while the data are a reliable reflection of the Dutch general population, it should be noted that the results may not be fully generalizable to countries with different health care systems for pregnant women. Despite these constraints, it remains essential to analyze real-life EHR data to understand immediate trends and outcomes within the context of the health care system.

Conclusions

In conclusion, this study highlights the impact of the pandemic on pregnant women's health care-seeking behavior among more than 10,000 studied pregnant women. By analyzing routine clinical EHR data registered by GPs, we have underlined declining health care consumption trends during the initial and end phases of the pandemic (2020 - 2021), the increase in pregnancy-related symptoms and diagnosis, such as GDM and nausea or vomiting of pregnancy, and the (temporary) adoption of a renewed way of providing health care to pregnant women through telehealth. Changes in frequency of presented symptoms and diagnoses were likely driven by the nature of the specific complaint or diagnosis. Physical limitations, sedentary behavior, and emotional distress following the severely restrictive lockdown measures may have attributed to the increased presentation of certain conditions, such as GDM and nausea or vomiting of pregnancy.

Given the potential adverse long-term effects of GDM on mother, fetus, and neonate, the urgent need for enhanced public health strategies within GP practices for pregnant women is undeniable. It is crucial for health care policymakers, providers, and pregnant women to recognize the risks associated with avoiding GP health care during this vulnerable period and work collaboratively to ensure safe and high-quality care during future pandemics, but also in routine health care settings. Implementing proactive measures to address these challenges could enhance the protection of the health and well-being of expectant mothers, fetuses, and neonates during times of crisis and beyond.

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Data Availability

The datasets analyzed during this study are not publicly available due to the inclusion of sensitive and confidential patient health information and access restrictions imposed by the steering committees of the participating general practitioner (GP) networks, but are available via the corresponding author after formal permission, which may involve associated fees.

Authors' Contributions

WB-H, MH, AO, and LP initiated the study. LP performed data curation. TK, MSB, and WB-H conducted data gathering and cleaning. WB-H, MSB, and TK developed the regular expression. WB-H conducted the selection of pregnant women, with MH serving as medical advisor. WB and MSB initiated data analyses methods, which WB-H subsequently conducted and MSB assessed. WB-H and MH drafted the manuscript, which was critically reviewed by all authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Used International Classification of Primary Care (ICPC) codes for defining pregnant and postpartum women. [DOCX File, 22 KB - pediatrics v8i1e64831 app1.docx]

Multimedia Appendix 2

Regular expression for textual analysis of general practitioner (GP) texts for defining pregnancy. [DOCX File, 23 KB - pediatrics v8i1e64831 app2.docx]

Multimedia Appendix 3 Assumptions met during manual labelling of general practitioner (GP) texts for defining pregnancy. [DOCX File, 23 KB - pediatrics_v8i1e64831_app3.docx]

Multimedia Appendix 4 Flowchart of patient inclusion and exclusion. [DOCX File, 480 KB - pediatrics_v8i1e64831_app4.docx]

Multimedia Appendix 5

Pregnancy-relevant International Classification of Primary Care (ICPC) codes used for the analysis of symptoms and diagnoses. [DOCX File, 26 KB - pediatrics v8i1e64831 app5.docx]

Multimedia Appendix 6

Distribution of the top 10 pregnancy-related International Classification of Primary Care (ICPC) code registrations. [DOCX File, 29 KB - pediatrics v8i1e64831 app6.docx]

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Abbreviations

AHON: Academic General Practitioner Development Network
EHR: electronic health record
GDM: gestational diabetes mellitus
GP: general practitioner
ICPC: International Classification of Primary Care
UMCG: University Medical Center Groningen

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COVID-19 Vaccine Uptake, Sources of Information and Side Effects Reported by Pregnant Women in Western Australia: Cross-Sectional Cohort Survey

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Abstract

Background: Pregnant women are a priority group for COVID-19 vaccination due to their vulnerability as a high-risk cohort. However, the currentCOVID-19 vaccine uptake rate for COVID-19 vaccination among pregnant women in Western Australia remains largely unknown.

Objective: This study aimed to explore pregnant women's vaccination uptake rates, information sources, and experiences regarding COVID-19 vaccination during pregnancy. We hypothesized that uptake of vaccination among pregnant women is higher than indicated in previous studies, given differences in disease burden and public health restrictions at the time when data was collected.

Methods: A cross-sectional survey was administered electronically to maternity patients at a single tertiary metropolitan hospital in Perth, Western Australia.

Results: A total of 520 women participated in the study. Overall, the antenatal COVID-19 vaccination rate was 79% (n=398). Approximately, 51% (n=256) of the women felt well-informed about the vaccine, and information was sourced primarily from their general practitioner (n=301, 60%), midwives (n=174, 35%), and obstetric doctors (n=64, 13%). Compared to Caucasian women, those of non-Caucasian ethnicity (n=332, 66% vs n=170, 34%; P=.07) and those born outside Australia (n=235, 47%) reported lower rates of vaccine information provision by the hospital staff (n=22, 34% vs n=42, 66%; P=.04).

Conclusions: The COVID-19 vaccine uptake among pregnant women was encouragingly high in our study, with favorable attitudes and acceptance for the vaccine observed in the majority of pregnant women. This self-reported study also identified opportunities for enhanced cultural competence and further education and training for hospital staff regarding COVID-19 vaccine information provision to ethnically diverse women. Further studies examining such interventions are warranted.

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KEYWORDS

pregnancy; COVID-19 vaccination; COVID-19; uptake; vaccine uptake; side effects; pregnant; Australia; public health; maternity

Introduction

Vaccination against SARS-CoV2 is a key public health strategy to combat the pandemic [1,2]. Pregnant women are a priority group for vaccination against SARS-CoV2, and therefore require education, encouragement, and adequate opportunities to receive vaccinations antenatally [1,3]. Pregnancy puts women in a state of immune deficiency, and therefore increases vulnerability to infection [1], with unvaccinated pregnant women experiencing increased severity of symptoms and higher death rates compared to their vaccinated peers [2,4-6]. Along with increased risk of

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stillbirth, unvaccinated women also have an increased likelihood of premature birth and neonatal death if they contract SARS-CoV-2 virus during pregnancy [7,8].

At the time of initial vaccination rollout, there was limited evidence regarding the safety of the COVID-19 vaccine in pregnancy [9]. Ongoing real-world studies are adding to the body of evidence, confirming vaccine safety and effectiveness during pregnancy [9-11]. According to advice from the Australian Government and recently completed safety and effectiveness studies, the most widely used mRNA vaccines

(eg, Pfizer and Moderna) are safe to be administered throughout pregnancy and the breastfeeding period [1,10].

Worldwide research has demonstrated a hesitancy among women to receive the COVID-19 vaccination during pregnancy, being less likely than any other high-risk cohort to do so [10,12]. Several worldwide studies demonstrate that this uptake remains inadequate, indicating the vaccine acceptance is significantly lower for pregnant women than in nonpregnant women [7,12,13]. An Australian study conducted in 2020 surveyed pregnant women and various maternity health care providers during the early stages of the pandemic and found that pregnant women were the least likely group to accept vaccination [2]. At the time of the study, only 14% of pregnant women had been vaccinated, and 48% of pregnant women indicated they had definite intentions to be vaccinated [2]. Similarly, a large survey questioning vaccine confidence spanning 16 countries reported that only 52% of pregnant women intended to receive the vaccine [10].

Based on worldwide trends, pregnant women are assumed to be an undervaccinated cohort [14]. A 2021 survey of doctors and midwives in Australia reported that 60% - 70% of pregnant women had received their first dose, while an estimated two-thirds had been double vaccinated [15]. A recent study based on data from Western Australia (WA) demonstrated a vaccination uptake rate of only 44% in their pregnant participants [15]. At the time of that study, there was no community transmission of COVID-19, and this was potentially an influencing factor for the surveyed women [15].

There remains a paucity of knowledge regarding Australian pregnant women's attitudes and their vaccination uptake rate, particularly since the emergence of COVID-19 infections within the Western Australian community and the introduction of proof of vaccination requirements and associated social mandates within WA [15]. Understanding pregnant women's attitudes toward COVID-19 vaccination may be useful in optimization of vaccination uptake rates, development of educational strategies, and identifying areas for potential interventions such as standing vaccination orders.

Methods

Study setting and design

The study's objective was to determine pregnant women's perceptions, attitudes, and knowledge regarding vaccination against COVID-19 during pregnancy, and to ascertain the uptake of COVID-19 vaccines during pregnancy within a maternity cohort in a tertiary care setting. We also aimed to explore the effect of various demographic factors on vaccine uptake and vaccine information provision to pregnant women.

This prospective cross-sectional study was conducted at a tertiary metropolitan maternity hospital over a three-month period from January 12, 2022, to April 30, 2022. All pregnant and immediate postpartum women who attended the hospital were eligible to participate in the anonymous survey. Women were approached in the antenatal clinic or the postnatal ward or recruited via a text message containing a link to the optional survey, due to many appointments being transitioned to

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telehealth as COVID-19 spread across WA. Women who elected to join the study accessed the survey link via a QR code or text link on their own smartphones.

Demographic data collected included gestation and open-text responses for age, ethnicity, country of birth, postal code, and religion. Other multiple-choice questions included education level and sources of information, including various health care providers. The participants were asked at what point during pregnancy information was given, using multiple-choice options for trimesters, and how well-informed they felt, using a Likert scale. In addition to demographic data, the respondents were asked about vaccination status, the number of doses received, the type of vaccine, and the time points in pregnancy when the vaccine was administered. We also gathered information on any side effects using an open-text field for reporting. The unvaccinated participants were invited to describe their reasoning; their responses were a combination of multiple-choice options and a free-text response, allowing women to choose as may answers as desired.

Statistics

Descriptive statistics were reported using mean and ranges for continuous data and frequency distributions for categorical data. Statistical analysis was performed using χ^2 test for categorical variables. SPSS statistical software (version 24.0; IBM Corp) was used for analysis. P values<.05 were considered statistically significant.

Ethical Considerations

The study was approved by the South Metropolitan Health Service Human Research Ethics Committee (RGS 5201). Written informed consent was obtained from all participants before commencing the survey. All participants were over 18 years of age and able to provide consent. Data was deidentified upon commencement of the survey, with participants being assigned a unique number. No compensation was provided to the participants.

Results

A total of 502 eligible women completed the survey in its entirety. Mean age of participants was 31 (SD 5.08; range 18 - 46) years.

Overall, 79.2% (n=398) of the pregnant population were vaccinated with at least one dose. Of the study participants, 60.0% (239/398) were double vaccinated and 35.1% (140/398) were triple vaccinated. The majority (328/398, 82.4%) of these women received their vaccinations during pregnancy, while the remaining received them before the pregnancy was identified. A total of 92.4% (368/398) of vaccinated women received the Pfizer, 3.2% (13/398) received AstraZeneca, and 3.2% (13/398) received Moderna vaccines.

Ethnicity was categorized into eight broad groups based on the state maternity database. A majority (332/502, 66.1%) of women identified themselves as Caucasian. Additionally, 2.1% (11/502) identified as Aboriginal, 11.1% (56/502) as Asian, 6.7% (34/502) as Indian, 2.9% (15/502) as Maori, and 2.7% (14/502) as African. An additional 7.9% (n=40/502) women chose to

identify as "other" ethnicity. Approximately over half (n=267/502, 53.1%) of the women were born in Australia.

Of the 502 women surveyed, 301 (59.9%) women reported receiving information from their general practitioner (GP)

Table . Reported se	ources of	vaccine	information
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regarding the vaccination, and while the others received it from alternate sources (Table 1). Eighteen percent (89/502) of all participants reported that no one had given them any information about the vaccine, and 5.9% (30/502) of women reported receiving information only in the third trimester of pregnancy.

Source of information ^a	Number of respondents (N=502), n (%)
GP	301 (60%)
Midwife	174 (34.6)
Obstetric doctor	64 (12.7)
Other	55 (10.9)
No one	89 (17.7)

^aThese sources were mutually exclusive.

The GPs provided information to 59.9% (301/502) of all women in our study. Of these, 66.1% were Caucasian and 33.9% were non-Caucasian (odds ratio [OR] 0.961, 95% CI 0.66-1.40; P=.85). A total of 174 women reported receiving information from their midwives, and of whom 72.9% (127/174) were Caucasian and 27.1% (47/174) were non-Caucasian (P=.22 (OR 1.62, 95% CI 1.08-2.43; P=.22). Only 12.7% (64/502) of the women reported receiving information from an obstetric doctor within the hospital system. Of these 64 women, 79.6% (51/64) were Caucasian and 20.3% (13/64) were of minority ethnicity (OR 2.2, 95% CI 1.15-4.15; P=.02). Of the 12.7% (64/502) of women who reported receiving information from an obstetric doctor, 65.6% (42/64) were born in Australia and 34.3% (22/64) self-reported as being born elsewhere (OR 1.8, 95% CI 1.04-3.13; P=.04).

Sources of information had no significant effect on the uptake rate of the vaccination, whether information was obtained from a GP (OR 1.2, 95% CI 0.78-1.88; P=.43), midwife (OR 0.23, 95% CI 0.14-3.6; P<.001), obstetric doctor (OR 0.368, 95% CI 0.21-0.64; P=.01), other sources (OR 1.59, 95% CI 0.72-3.48; P=.29), or from no one (OR 1.63, 95% CI 0.86-3.07; P=.15).

Overall, 50.9% (256/502) of women felt well-informed. 39.2% (97/502) women reported feeling somewhat informed, and 9.5% (48/502) reported feeling not well-informed. However, the perceived level of being informed did not statistically affect the uptake rate of the vaccination.

Religion was self-reported by majority of the women and did not have a statistically significant association with vaccine uptake rates (OR 0.9, 95% CI 0.6-1.5; $P \ge .99$).

The majority of women (194/398, 48.7%) received two doses of the vaccine in the second trimester of pregnancy. Table 2 shows the side effects profile reported by the participants. Of the vaccinated women, 63.3% (252/398) reported experiencing some side effects from the vaccine, most commonly fatigue (n=81, 55%)), sore arm (n=65, 44%), headaches (n=51, 35%), body aches (n=39, 26%), fever (n=31, 21%), and nausea or vomiting (n=24, 16%). There was no difference in the frequency or type of side effects among women under or over 30 years, (OR 1.14, CI 95% 0.75-1.75; P=.59] or across various ethnic groups: Caucasian (n=334, 67%); Aboriginal (n=11, 2%); Asian (n=56, 11%); Indian (n=34, 7%); Maori (n=15, 3%); African (n=14, 3%); Polynesian (n=2, 0.4%); Middle Eastern (n=4, 1%), and other ethnic groups (n=31, 6%) (P=.82).

Among the unvaccinated women, 405 reasons were cited. "Safety concerns" was the main reason for women opting not to receive the vaccination (137/405, 33.8%). Additionally, 21.2% (n=86) of the women were concerned about adverse effects on the baby, 12.5% (n=51) were concerned about effects on themselves, while 16.0% (65/405) opted to wait until after their baby was born (Table 3).

Table . Vaccillation side effects profile reported by participal	Table .	Vaccination s	side effects	profile rep	orted by	participants.
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Vaccination side effects ^a	Number of respondents (N=252), n (%)
Fatigue	81 (55)
Sore Arm	65 (44)
Headaches	51 (35)
Fever	31 (21)
Nausea/Vomiting	24 (16)

^aThe side effects were not mutually exclusive.

Table .	Reasons	for	women	not	receiving	the	vaccine
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Reasons for not receiving vaccine ^a	Number of respondents (n=405), n (%)
Adverse effect on myself	51 (12.5)
Adverse effect on baby	86 (21.2)
I am waiting until after baby is born	65 (16.0)
No immediate COVID-19 threat in WA ^b	14 (3.4)
Upcoming booking	23 (5.6)
Not getting the vaccine	14 (3.4)
Other	8 (1.5)

^aThese effects are not mutually exclusive.

^bWA: Western Australia.

The respondents' education levels varied widely: high-school diploma (n=172, 35%); a postgraduate degree (n=224, 45%); a master's degree (n=53, 11%); a trade qualification (n=31, 61%); a doctorate (n=8, 2%); and no education (n=10, 2%). The level of education had no significant impact on the vaccine uptake rates (P>.05).

Discussion

Overall, the rate of the COVID-19 vaccination within our study's pregnant population was encouragingly high, although it lagged behind the state average of >95% double vaccination in the general population [15]. The diverse demographic of the cohort at our hospital reportedly had an equal uptake of the vaccination regardless of age, ethnicity, education level, or country of birth. To our knowledge, this is among the highest vaccination rates in a pregnant population globally, although a deficit of research on this topic remains [6,12,15-17].

Every two out of three women received COVID-19 vaccine information from their GPs. Although this number is higher than that of women receiving vaccine information from the hospital staff, given the context of a pandemic and pregnancy being a vulnerability, it would be reasonable to aim for all women to receive information on COVID-19 vaccine during their first consultation with GPs, midwives, or obstetric doctors. Workload pressures on GP clinics and hospitals during the pandemic undoubtedly placed strain on service and information delivery but also highlighted missed opportunities to prioritize vaccine information at the earliest opportunity. The pandemic may also have affected the ability of pregnant women to have timely appointments with their GPs due to restrictions and increased burden on practices [18,19]. In our study, 10% (n=48) of women reported that they did not feel well-informed about the vaccination, reiterating the need to educate pregnant women. Some women (n=30, 6%) reported receiving information for the first time only in the third trimester of pregnancy.

Eighteen percent (n=89) of women reported not receiving any information at all, which is a public health concern. These data were not influenced by age, ethnicity, or religion of the women. Encouraging multiple open conversations surrounding vaccination between all health care providers and pregnant women may possibly decrease the number of women who reported not receiving any information [20].

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Australia's historically strong population growth is drawn from both natural increase and net overseas migration. In 2020, there were over 7.6 million migrants living in Australia, accounting for 29.8% of the population who were born overseas [21]. It was reassuring to see that there was no difference in responses on receiving information from GPs across various ethnic groups or countries of birth. However, the significantly high proportion of women from minor ethnic groups or those born outside Australia who reported receiving no information from the hospital staff is highly concerning. Potentially, language barriers, inadequate use of interpreters, or lack of cultural competence may contribute to this number in our culturally diverse study population; however, these factors were not investigated further in our study. Ensuring a diversified workforce in hospitals may benefit women through the dispersion of information from culturally diverse health care professionals.

A recent, similar study conducted within WA by Ward et al [22] explored women's vaccine uptake rate and attitudes surrounding vaccination. While similar information was obtained from the pregnant population, the results contrasted significantly between the two studies; this could potentially be attributed to differences in community transmission as well as the vaccination-related social restrictions and introduction of state government vaccine mandates within WA. The uptake rate in the aforementioned study was only 44%, compared to 79% in our study. Additionally, one-third of their study population reported not being given any information regarding the vaccine, whereas our numbers, although still concerning, were much lower at 18%. This difference may likely be attributed to increased awareness and education as the pandemic evolved in WA, along with real-time evidence of vaccine safety in pregnancy being reported worldwide. At the commencement of our study, there was no community spread of COVID-19, and therefore, no imminent urgency was experienced within WA. However, the opening of borders was announced soon after the vaccine mandates were introduced, and eventually, the interstate and international WA borders were opened during the course of our study. Both studies discovered that women's safety concerns regarding their baby and themselves were primary factors behind declining or delaying the vaccine administration.

Our study had various strengths and limitations. It was conducted throughout the community COVID-19 transmission

in WA, making our findings unique and relevant to the current pandemic situation. Our study population reflects the health status and demographic status of WA's pregnant population. It incorporated multiple ethnicities, wide age range, and both lowand high-risk pregnancies. The results are generalizable to the WA pregnant population, as a variety of ethnicities, education levels, and ages were incorporated, along with a large sample size. The limitations of our study include restriction to a single-center experience, lack of information on primary spoken languages by the women, and reliability on the self-reported responses by the pregnant women.

In conclusion, COVID-19 vaccination was widely accepted among our study population, in contrast to previously reported data. Western Australia has demonstrated a high uptake of the vaccination across all age, social, religious, and ethnic groups attending our center. There were minimally reported and mild side effects due to the vaccine. In the exploration of women's attitudes, safety concerns led to vaccine hesitancy. Optimizing the uptake rate remains a priority for this vulnerable cohort to improve maternal and neonatal outcomes. The information gained from this study can be used to encourage hesitant women by providing the positive data. The discrepancy in information provided between the groups may indicate a need to address cultural competency among staff, furthering staff education, and ensuring a diverse workforce. Further studies examining such interventions are warranted to confirm the influence of these strategies on the vaccine uptake among pregnant women.

Data Availability

The datasets generated or analyzed during this study are not publicly available due to confidentiality, but are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: NC Data curation: NC Formal analysis: NC Methodology: NC, SM Project administration: SM Supervision: SM Writing – original draft: NC Writing – review & editing: SM

Conflicts of Interest

None declared.

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Abbreviations

GP: general practitioner **WA:** Western Australia

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Usability and Acceptability of a Pregnancy App for Substance Use Screening and Education: A Mixed Methods Exploratory Pilot Study

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Abstract

Background: Increasing opioid and other substance use has led to a crisis of epidemic proportions, with substance use now recognized as a leading cause of maternal morbidity and mortality in the United States. Interventions will only be effective if those who would benefit are identified early and connected to care. Apps are a ubiquitous source of pregnancy information, but their utility as a platform for evaluating substance use during pregnancy is unknown.

Objective: This study aims to explore the usability and acceptability of a pregnancy app for opioid and other substance use screening and education.

Methods: This mixed methods, exploratory pilot study examined adult pregnant people with a history of substance use who were recruited from outpatient and inpatient settings at a tertiary care obstetric hospital. After completing a baseline survey collecting demographics, substance use, and technology use, participants accessed an existing pregnancy support app for 4 weeks. Qualitative methods were used to measure the acceptability of embedding substance use screening, education, and information within the tool. App use frequency and access to substance use educational content and treatment referral information were evaluated.

Results: The 28 female participants had a mean (SD) age of 31 (0.46) years; most were White (21/28, 75%) and Medicaid insured (26/28, 93%), with an annual household income of <US 30,000 (16/28, 57%). The mean gestational age at enrollment was 22 weeks. Almost half (13/28, 46%) were taking medication for opioid use disorder (methadone or buprenorphine). Other substances used included tobacco (22/28, 79%), marijuana (20/28, 71%), illicit opioids (9/28, 32%), alcohol (6/28, 21%), and stimulants (4/28, 14%), including cocaine, amphetamines, and benzodiazepines (2/28, 7%). Most (19/28, 68%) reported previously using one or more prenatal apps and 11% (3/28) cited prenatal apps as their most frequently used source of pregnancy information. After approximately 4 weeks of app exposure, 71% (20/28) logged in at least weekly, 89% (25/28) were satisfied with the app, and 96% (27/28) reported that the app was a helpful source of support. In cognitive interviews, participants reported that app-based disclosure of substance use could be easier than disclosing in person due to reduced stigma. However, participants expressed concerns about not knowing who would have access to this information.

Conclusions: Incorporating substance use supports into a pregnancy app was found to be acceptable among those using substances. Participants reported frequent baseline use of prenatal apps, showed a high level of engagement with the pregnancy app during the study, and demonstrated interest in expanding the substance use support elements of this app. Embedding substance use screening, information, and connection to care into a tool with wide-scale use during pregnancy has the potential to identify at-risk individuals who may otherwise not be identified during routine prenatal care. It also has the potential to connect individuals, who might otherwise be hesitant to disclose their substance use, to recovery or harm reduction resources.

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KEYWORDS

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substance use disorder; substance use screening; mHealth; mobile health apps; pregnancy; technology

Introduction

Substance use during pregnancy has increased significantly over the past two decades [1-4], with almost 3% of pregnant people having a formal substance use disorder diagnosis [5]. Opioid use disorder during pregnancy has more than quadrupled in the past 20 years and is now a leading cause of maternal death in the United States [6-12]. Observed rates of other substance use during pregnancy have also increased in recent years, including cannabis, alcohol, sedatives, and stimulants. Actual numbers may be higher due to lack of reporting [5]. Additionally, concurrent substance use, such as marijuana use paired with opioid use, can further increase the risk of preterm birth and low birth weight infants [13] and may impact infant development and longer-term learning, memory, and impulsivity [10,11]. This increase in the prevalence of substance use is concerning and suggests an increased need for effective screening and resource provision to pregnant people.

Early identification and intervention are critical for reducing adverse maternal and neonatal outcomes associated with substance use [14]. As a result, major professional organizations, including the American College of Obstetricians and Gynecologists, recommend that all pregnant people be verbally screened for substance use with a validated tool at least once during pregnancy [15,16]. Despite this, 20% - 30% of obstetric providers do not routinely screen for substance use, and less than half routinely refer patients with a positive screen to substance use treatment resources [17,18]. Moreover, due to stigma, judgment, and fear of mandated reporting requirements, many pregnant people are hesitant or choose not to disclose substance use to their health care providers [12,19-21]. In a study of 422 pregnant people who presented for their first obstetric appointment, 46% of those who had a urine drug test positive for a nonprescribed substance chose to not disclose their substance use when verbally screened by their provider [22].

Mobile health (mHealth) technology has been successfully used to evaluate and deliver interventions related to tobacco, alcohol, and illicit substances, including opioid use, in nonpregnant populations [23-25]. In a study evaluating interest in using digital platforms to monitor recovery trajectories among 259 patients in substance use treatment, 70% of participants expressed interest in using a relapse prevention app [26]. Additionally, a study of 202 individuals using a recovery support app demonstrated high levels of usage of the app and articulated that further expanding the app to provide additional recovery-related resources could increase the likelihood of continuing to use the app in the future [27]. Further, in an evaluation of 316 patients engaged in a Veteran's Affairs (VA) substance use treatment program, more substance use was disclosed through an indirect method (self-completed questionnaire), as opposed to a direct method (verbal disclosure), suggesting that creating an accessible space for indirect disclosure may be beneficial for people who use substances [28].

Pregnancy apps are a common information source used by patients during pregnancy and allow for intimate, self-guided

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XSL•F() RenderX touchpoints for those seeking health-related resources, guidance, and information outside of clinical care settings [29,30]. As such, the American College of Obstetricians and Gynecologists supports mHealth as a suitable means for supplementing obstetric health care [31]. Due to their frequent use, mHealth tools may be an additional way to identify patients who are unwilling to disclose their substance use in traditional, in-person health care settings by mitigating stigma and bias associated with in-person substance use evaluations [29,32].

The purpose of this study was to explore the usability and acceptability of an existing prenatal mHealth app, MyHealthyPregnancy, as a tool in which substance use screening, education, and information could be provided as part of routine prenatal care among pregnant people with substance use. For an mHealth app to be acceptable, the patient population of interest must generally engage with mobile technology during their pregnancy, demonstrate interest in accessing information from the app, and importantly, trust the app as a setting for substance use disclosure [33-36]. Therefore, the specific objectives of this study were to understand, among pregnant people with a history of opioid or other addictive substance use, (1) general technology and mobile app usage, (2) willingness to disclose substance use through a pregnancy app, (3) interest in obtaining substance use education and information through a prenatal app, and (4) perspectives regarding how a pregnancy app could assist with substance use-related needs.

Methods

Study Sample

From April to August 2021, we conducted a mixed methods, exploratory pilot study to understand the usability and acceptability of a prenatal support app for substance use screening, education, and information during pregnancy. Pregnant people with substance use were recruited from inpatient and outpatient settings at an academic, tertiary care women's hospital including prenatal clinics, substance use treatment programs, and inpatient antepartum hospital units. Participants were eligible if they were pregnant, at least 18 years of age, less than 37 weeks gestation, had regular access to a smartphone (Android or iOS), and had a history of substance use during or within 3 months prior to their pregnancy, as determined through either self-report, ICD-10 (International Classification of Diseases, Tenth Revision) diagnoses coding cord or evidence of substance use on urine drug testing in the electronic health record. In prior research, a sample size of approximately 30 participants has been determined to be sufficient to understand app usability and acceptability [37].

Ethical Considerations

The study was reviewed by the University of Pittsburgh institutional review board (STUDY18120026). Participants provided written informed consent. All audio and transcribed materials were stored on a secure, password- and firewall-protected university network drive or server, and all data were deidentified prior to analysis. Participants received US \$25 for their participation in this study.

MyHealthyPregnancy mHealth App

The MyHealthyPregnancy app is a pregnancy mHealth tool that offers evidence-based, prenatal educational content organized by the user's weeks of gestation, a diary to document the user's pregnancy experiences, a fetal movement counter, a contraction timer, and routine screenings for symptoms and psychosocial risks. The app also functions as a risk assessment tool that may use patient-entered data (eg, symptoms, language, mood, sleep, and psychosocial screeners) to identify possible risks during pregnancy (eg, intimate partner violence, depression, and pre-eclampsia) and resources tailored to the risks identified. When users start the onboarding process to begin using the app, they are asked, "Do you currently use any of the following?" for various substances, including alcohol, tobacco (and vaping), marijuana, narcotics or opioids, heroin or fentanyl, benzodiazepines, cocaine or amphetamines, and other drugs. Depending on the substance disclosed, the user will be directed to substance-specific local, regional, and national recovery resources.

Educational content about substance use (eg, content regarding the risks of substance use during pregnancy, information on substance use treatment resources) is accessible to users through the app's "Learning Center" and "Resources" sections. These resources and articles were designed, in collaboration with clinical experts, to offer the same information as would be provided in routine prenatal care if substance use was disclosed to a provider. MyHealthyPregnancy was launched for beta-test evaluation at the University of Pittsburgh Medical Center health system in September 2019, with research demonstrating its effectiveness as a complementary tool to prenatal care [38-42].

Study Procedures

After signing a written informed consent, participants completed a baseline survey assessing demographics, substance use, pregnancy history, and technology and app use behaviors (Multimedia Appendix 1). Research staff then assisted participants with downloading the app on their smartphones and provided an overview of the sections of the MyHealthyPregnancy app before having participants self-navigate through the app on their phones. At this time, participants additionally consented to the sharing of identifiable data for research purposes and the publication of anonymized aggregate data through the app. Figure 1 shows sample screens from the app.

After navigating through each section of the app, research staff asked participants to relay their thoughts regarding the app and substance use-related content through a "think-aloud" technique [43-46]. Following the think-aloud sessions, participants engaged in a cognitive interview to further understand the acceptability of the app for substance screening and evaluation [47-51]. Examples of questions used during the cognitive interview included, "If you were actively using a substance, how do you think that you may feel about disclosing substance use on an app?", "How do you feel about tracking substance use-related information in an app?", and "Is there information you feel more comfortable sharing through the app compared to when you are talking directly to your provider?" Participants also completed a usability survey regarding the app's features (Multimedia Appendix 2) [52,53]. Participants were then encouraged to use the app as much or as little as they wished over the next 4 weeks.

At-home app usage was measured and transmitted through a secure HIPAA (Health Insurance Portability and Accountability Act)-compliant server to the research staff. For privacy protection, access to the app was protected by a password set up by the individual user. The password reset function required app users to provide their unique user ID and then complete instructions on resetting their password via a personalized SMS text message sent to their own, prespecified contact number. For sensitive questions embedded in the app (eg, substance use, reports of intimate partner violence), an icon was displayed that reminded users that information they shared might be transmitted to their health care provider. Participants were then recontacted by research staff by phone or in person to complete a brief follow-up survey regarding their impressions of independently using the app and any additional feedback or suggestions (Multimedia Appendix 3). The think-aloud sessions, cognitive interviews, and follow-up interviews were audio-recorded.



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Figure 1. MyHealthyPregnancy sample screens offering substance use-related content and resources.



Data Analyses

Quantitative Analyses of Usability and Acceptability

Preliminary analyses evaluated survey and app usage data for completeness and accuracy and addressed any issues with data quality. Summary statistics were used to describe the participant characteristics, technology and mobile app use behaviors, assessments of app usability and acceptability, and participant-endorsed options for how a pregnancy app could assist with substance use. These statistics include means and standard deviations (or medians and quartiles for skewed distributions) for continuous variables and frequencies and proportions for categorical variables. Where appropriate, 95% CIs are included for means and proportions. IBM SPSS Statistics for Windows version 26 was used for quantitative statistical analysis [54].

Qualitative Analyses of Usability and Acceptability

Audio recordings from think-aloud sessions, cognitive interviews, and follow-up interviews were transcribed verbatim. Qualitative analyses were conducted using the Consolidated Framework for Implementation Research (CFIR)-based deductive analysis approach (directed content analysis), which is a rapid qualitative analytic method [53]. Prior to conducting the interviews, a preliminary codebook (in Microsoft Excel, version 16.54) was created by the research team. After the interviews were conducted, HF reviewed the transcripts using notes taken during the interviews to identify any additional codes or themes focused on understanding participants' experiences and perceptions of the app. The revised codebook

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was then used to code the transcripts for perspectives regarding the incorporation of substance use information in a pregnancy mHealth app.

Results

Study Sample

Over a 4-month enrollment period, 66 pregnant individuals were screened for eligibility, 24 declined to participate, and 6 did not meet study eligibility criteria. Among those that declined, the reasons provided were lack of interest in the study and limited time to attend study debriefs. Among those who did not meet the eligibility criteria, 5 participants did not have access to a smartphone due to rehabilitation facility or sober community living rules, and 1 participant was more than 37 weeks pregnant. Among the 36 participants who enrolled, 3 participants chose not to continue the study prior to using the app, 3 participants were unable to be reached for follow-up assessments, and 2 participants were found to no longer meet eligibility criteria due to fetal demise or lack of consistent access to a smartphone. Thus, 28 participants completed all study tasks and created the analytic sample.

Table 1 describes the characteristics of study participants. Most participants were White (21/28, 75%), Medicaid insured (26/28, 93%), and had an annual household income of less than US \$30,000 (16/28, 57%). For 18% (5/28) of participants, this was their first pregnancy. The mean (SD) gestational age of participants at the time of enrollment was 22 (7.3) weeks. Substances used among participants consisted of tobacco (22/28, 79%), marijuana (20/28, 71%), illicit opioids (9/28, 32%),

alcohol (6/28, 21%), stimulants (4/28, 14%), including either cocaine or amphetamines, and benzodiazepines (2/28, 7%). Approximately 46% (13/28) of participants were currently taking medication for opioid use disorder (eg, methadone or

buprenorphine). Some individuals (4/28, 14%) used marijuana only. All remaining participants used a combination of 2 or more substances.

Table . Participant characteristics (n=28).

Demographics			Values
Age (years), mean (SD)			31 (4.6)
Race, n (%)			
	White		21 (75)
	Multiracial		5 (18)
	Black or African American		2 (7)
Ethnicity, n (%)			
	Hispanic or Latino		2 (7)
Marital status, n (%)			
	Married		7 (25)
Insurance, n (%)			
	Medicaid		26 (93)
Highest level of completed education	n, n (%)		
	Some high school		7 (25)
	High school or general equivalency	diploma	8 (29)
	Some college, trade school, or associate's degree		11 (39)
	Bachelor's degree		1 (4)
	Master's degree		1 (4)
Employment, n (%)			
	Full- or part-time employed		9 (32)
Income (US \$), n (%)			
	<30,000		16 (57)
	30,000 - 60,000		3 (11)
	60,000 or more		4 (14)
	Unsure		4 (14)
Pregnancy history			
	Gestational age at enrollment (weeks), mean (SD)		22 (7.3)
	Primiparous, n (%)		5 (18)
Substance use history, ^a n (%)			
	Tobacco		22 (79)
	Marijuana		20 (71)
	Opioids		15 (54)
		MOUD ^b	13 (46)
		Illicit opioid use	9 (32)
	Alcohol		6 (21)
	Stimulants (ie, cocaine and ampheta	mines)	4 (14)
	Benzodiazepines		2 (7)

^aType of substances used within 3 months prior to pregnancy or during pregnancy.

^bMOUD: medication for opioid use disorder.

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Table 2 describes the technology behaviors and mobile app usage of participants. Texting (27/28, 96%) was the most commonly reported mode of communication, followed by phone (22/28, 79%), email (18/28, 64%), and social media (16/28, 57%). Health care providers (20/28, 71%) and mHealth apps (3/28, 11%) were the most frequently reported sources of pregnancy-related information followed by the internet or websites, family members, and friends. Health care providers were also noted to be the most trusted source of pregnancy-related information (27/28, 96%). mHealth apps were commonly used by participants, with 68% (19/28) reporting the use of a pregnancy app at the time of their enrollment and 26% (5/19) reporting that they used 2 or more pregnancy apps.

Table. Technology and mobile app use behaviors (n=28).

Technology use and communication during pregnancy		Values, n (%)	
Source most frequently used for pregnancy information			
	Health care provider	20 (71)	
	mHealth ^a apps	3 (11)	
	Internet or websites	2 (7)	
	Family members	2 (7)	
	Friends	1 (4)	
Source most trusted for accurate pregnancy infor	mation		
	Health care provider	27 (96)	
	mHealth apps	1 (4)	
Preferred methods of communication			
	Texting	27 (96)	
	Phone	22 (79)	
	Email	18 (64)	
	Social media platforms	16 (57)	
	Video calling or conferencing	11 (39)	
	Apps	2 (7)	
Smartphone ownership		28 (100)	
Pregnancy app use (yes/no)		19 (68)	
	Use of 2 or more pregnancy apps	5 (26)	

^amHealth: mobile health.

Quantitative Analyses of Usability and Acceptability

Table 3 describes participants' experiences with the app. Measurements of the *usability* of the MyHealthyPregnancy app include participants' level of satisfaction with the ease of using the app and satisfaction with the time it took to use the app. Measurements of the app's *acceptability* include participants'

overall satisfaction with the app, satisfaction with the interface, and how helpful the app was as a source of support. During the 4-week period, daily app use was the most common (12/28, 43%), and educational materials related to substance use were engaged with by the majority of participants (19/28, 68%). Acceptability and usability were generally high.



Table . MyHealthyPregnancy usability and acceptability (n=28).

	Values, n (%)
Acceptability	
The app was a helpful source of support in pregnancy	27 (96)
Liked the way the app looks	27 (96)
Overall, I am satisfied with the interface of the app	25 (89)
Overall, I am satisfied with the app in general	25 (89)
Usability	
I am satisfied with the ease of using the app	23 (82)
I am satisfied with the time it took to use the app	22 (79)
It was easy to navigate through the app	27 (96)
Engagement ^a	
Daily	12 (43)
Weekly	8 (29)
Monthly	5 (18)
Substance use resource utilization	
Participants who browsed substance use educational materials	19 (68)
Participants who accessed substance use treatment referral information	2 (7)

^aFrequency of app logins within a 4-week period.

Participant-endorsed options for how a pregnancy app could assist with substance use–related behaviors are described in Table 4. Almost all participants (27/28, 96%) expressed a desire to use an app to block phone calls or SMS text messaging from people who had a negative effect on substance use behavior,

while more than half desired the ability to track substance use, cravings, or treatment medications. The least endorsed options included information on infectious disease prevention (5/28, 18%), harm reduction (4/28, 14%), or intimate partner violence (3/28, 11%).

Table . Participant endorsed options for how a pregnancy app could assist with substance use (n=28).

Options	Values, n (%)
Blocking phone calls or SMS text messaging from people who have had a negative effect on recovery	27 (96)
Tracking incidences of substance use or cravings	19 (68)
Receiving reminders to take substance use treatment medications (eg, MOUD) ^a	16 (57)
Information about support groups for parents with substance use disorders	12 (43)
Neonatal opioid withdrawal syndrome information	9 (32)
Infectious disease prevention information	5 (18)
Harm reduction information	4 (14)
Intimate partner violence resources	3 (11)

^aMOUD: medication for opioid use disorder (eg, methadone or buprenorphine)

Qualitative Analyses of Usability and Acceptability

In cognitive interviews, participants shared their perspectives regarding substance use disclosure through a pregnancy app and how a pregnancy app could be useful for people using substances or with a substance use disorder. Five major themes were identified from these debriefs (Table 5). Participants felt that substance use disclosure on an app may be associated with less stigma than in-person disclosure (theme 1). However, they also noted that their comfort with disclosure would vary by the

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type and legality of the substance (theme 2). Participants expressed concerns related to who could access substance use information (eg, health care professionals and social services providers) on a pregnancy app and concerns related to being permanently labeled as someone with an addiction (theme 3). Despite concerns, participants did believe that pregnancy apps could be a useful source of substance use information and education (theme 4) and felt that combining pregnancy and substance use information on a single app was the most desirable approach (theme 5).

Table . Participant perspectives regarding disclosure and incorporation of substance use information in a pregnancy mobile health app.

Theme	Example quote
Theme 1: Substance use disclosure on an app may be associated with less stigma than in-person disclosure	"I would feel a little more comfortable if I put it in the app than talking to an individual. The app doesn't judge you, like a human being would"
Theme 2: Disclosure comfort varies by type and legality of substance	"I definitely felt more comfortable disclosing legal drug use. For example, I do have my medical marijuana card, that is something I have no problem sharing, or alcohol and cigarettes, but yes, the non-legal ones, I would be a little nervous."
Theme 3: Concerns related to who could access disclosed substance use information	"Depending on what information I divulged, what would happen to that information? For example, would that be sent to a doctor? If it would be sent to a doctor or another professional or even a social worker even though it would be confidential, I would just be worried I'd be labeledand I will never be able to get away from my past addiction."
Theme 4: Prenatal apps could be a useful source of substance use informa- tion, education, and resources	"For the women who have no support or anyone to talk to, I really do think it is an effective tool to give them a little bit of encouragement and accurate information or just a guide: here are some resources, here is someone you could talk to."
Theme 5: Combining pregnancy and substance use information on a single app is desired	"Having it within a pregnancy app is kind of better personally just because it is all in one placeI've had recovery apps before, and I have fallen off of them. Actually, I completely forgot about them. So, like with pregnancy and having a kid and like getting ready for stuff, the simpler the better. So, if I don't have to go to multiple apps, that is great."

Discussion

Principal Results

Opioid use and the use of other addictive or illicit substances remain a significant and growing public health crisis in the United States. One significant barrier to providing early intervention during pregnancy is identifying individuals at risk and connecting them to care in a way that feels comfortable to them and through a mechanism which is engaging. One solution to identifying and engaging with pregnant individuals using opioids and other substances is through prenatal care apps. However, reaching pregnant individuals who use substances through more holistic prenatal care apps requires that the prenatal app be engaging and that app users who use substances must be willing to share their substance use through the app and act upon the information provided to them about recovery.

In this mixed methods, exploratory pilot study, incorporating substance use screening, information, education, and support into an existing prenatal app was found to be acceptable among pregnant people with substance use. Overall, participants showed high levels of interest in and engagement with MyHealthyPregnancy. Moreover, they reported being generally supportive of using an mHealth app as a means to access nonjudgmental resources for substance use during pregnancy. Our findings also indicate that there are multiple ways that an app could support individuals who use substances including blocking phone calls or SMS text messaging, providing information about recovery-oriented support groups, and offering resources regarding common co-occurring conditions (infectious disease acquisition, intimate partner violence, and harm reduction) [55].

Consistent with prior research demonstrating a high level of mHealth app usage among pregnant people (greater than 50%), most participants (19/28, 68%) reported that they had already

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used a prenatal app before starting the study, with some participants reporting the use of multiple prenatal apps [30,56-58]. In our study, apps were also identified, more generally, as a trustworthy, and easy-to-access source of pregnancy-related information, second only to health care providers. This aligns with other research findings demonstrating pregnant patients' appreciation for the accessibility and reliability of information found in prenatal apps [59]. Our study demonstrated a high level of engagement with our prenatal app, with 71% (20/28) logging in on a daily or weekly basis, similar to engagement levels that are considered high among other prenatal apps[60]. Together these findings suggest that a prenatal app-based intervention could be a beneficial strategy for information sharing between pregnant people who use substances and their providers, as this population already engages with and trusts this type of technology.

Our findings also indicate a high level of acceptability with incorporating substance use-related information into a pregnancy app. App usage data indicated that many participants browsed recovery-related educational materials on the app. These data align with other research demonstrating that people generally do not like moving between different apps to achieve their goals and prefer integrated technology tools, as well as prior findings showing that substance use screening and intervention in an app-based format has high acceptability and usability among patients [61,62]. Our participants expressed their interest in an expansion of substance use support capacity of the prenatal app, in alignment with prior research demonstrating that mHealth interventions are effective in areas including smoking cessation and addressing substance use during pregnancy[63]. Finally, many participants volunteered that disclosing substance use on an app may be easier than disclosing substance use in person, aligning with the current literature suggesting that self-report questionnaires and eHealth screenings could assist in creating more opportunities for disclosure than in-person evaluations alone [28,29,64].

However, many participants expressed concerns about disclosing substance use on an app because they would not know who might have access to this information, similar to prior research demonstrating patient concern about data security even in general prenatal apps [58]. Concerns about prosecution and child welfare involvement are previously reported barriers to substance use disclosure, which can lead to delays in seeking prenatal care and engaging in substance use treatment [65,66]. Mandatory reporting laws and the potential for child protective services involvement are major barriers to seeking treatment among pregnant people with opioid use disorder [67]. Any app that collects sensitive patient health information is required to comply with HIPAA. Moreover, any app that offers a substance use disorder treatment service must comply with the Opioid Addiction Recovery Fraud Prevention Act of 2018, which requires transparent and fair practices around how private health information is shared [68]. However, concerns about seeking and engaging in substance use treatment during pregnancy legitimately extend to disclosure and substance use treatment seeking through digital health means. In prior qualitative research, parents note that mandatory reporting regulations are biased, unjust, and stigmatizing and assert that stress stemming from the potential involvement of child welfare agencies has had a pronounced and detrimental impact on their families [67,69,70]. Moreover, since the 2022 Dobbs v. Jackson Supreme Court decision that ended federal protections for abortion, there have been increasing reports of digital health data being subpoenaed to criminalize pregnant individuals, further legitimizing caution around disclosure of certain health behaviors, especially during pregnancy [71,72].

Given both the concerns and interest voiced by our participants regarding embedding substance use screening and connection to care into a prenatal app, providers should familiarize themselves with any prenatal or substance use support apps available to patients prior to recommending them, including evaluating the evidence base, equity focus, and HIPAA protections afforded to such tools [73]. We additionally suggest that any providers discussing such apps with patients also educate patients about their rights and privacy related to disclosing substance use or other sensitive information in these apps. Providers can also encourage patients to share feedback about which apps they have found useful (or not) to support provider recommendations.

Limitations

There were several study limitations. First, approximately 36% (24/66) of those approached for study participation declined to enroll. Because many of those who declined to participate lacked interest in study participation, our sample may have been biased toward those who are more willing to use mHealth technology for health engagement or toward those with fewer reservations about disclosing substance use. In addition, all participants enrolled in the study had a known history of substance use. As such, their behaviors and perspectives may not be generalizable to pregnant people who have never disclosed their substance use within a health care setting. Next, our study sample was small and consisted of predominantly non-Hispanic White individuals, which limits the degree to which we can generalize our findings. Opioid overdose rates among Black individuals

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exceed those of White individuals by 4-6 times, and there are significant disparities in the receipt and use of medication for opioid use disorder between non-Hispanic White and Black and Hispanic pregnant individuals [74,75]. Thus, our findings cannot be generalized to those who may be at highest risk of not receiving adequate care. While the sample size for this exploratory pilot study was aligned with norms for thematic saturation for qualitative interview feedback to offer initial data on acceptability, a larger randomized trial with intentional demographic sampling would be required to adequately test implementation or intervention effects of incorporating substance use screening and content into the mHealth tool [76-78].

Conclusions

In this study, pregnant people with substance use found an existing pregnancy app to be an acceptable means of incorporating substance use supports and screening. Participants were already frequent users of prenatal apps and showed a high level of engagement with the prenatal support app in the study. At the completion of the study, participants expressed positive feelings about the usability of the app and interest in expanding the of the substance use support features of this app although some notable concerns relating to data privacy were raised. Given the prevalence of technology and app usage among pregnant people and the rise in substance use during pregnancy, mHealth technology should be considered a complement to in-person prenatal substance use screening and evaluation. Providing opportunities for substance use disclosure and resource provision through an acceptable digital platform that people are already using for pregnancy could result in earlier treatment engagement, along with improved outcomes among those who use substances. Our findings highlight this as an acceptable and desirable approach.

There is an ethical imperative for any prenatal app incorporating substance use-related content to clearly communicate both the confidentiality constraints of the tool and the potential consequences of disclosure prior to screening. As a way to address app users' concerns, developers should consider designing data collection so that any sensitive data are deleted as soon as possible or are only stored locally and not in a location that could be at risk of subpoena. App developers should also be sure to communicate clearly to app users about privacy and seek active consent for the collection or storage of any sensitive data. Finally, app developers should consider instating a policy prohibiting engagement in third-party data sharing, with the exception of HIPAA-compliant data sharing with the health care provider. Policy makers should ensure clear communication with providers about their rights related to substance use disclosure during pregnancy and potential legal repercussions. Health care providers considering using pregnancy apps, particularly for substance use screening or treatment referral, should evaluate whether the apps are evidence-based and adherent to strict policies around data protections. This may include being proactive about self-education regarding HIPAA privacy rules, as well as the state and institutional protections in place, so that they can communicate these clearly to their patients when recommending that patients share sensitive information through these tools.

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Lastly, additional research is needed to prospectively evaluate and test patient-centered substance use screening and connection to recovery resources within pregnancy apps, as well as to understand and measure the rates of disclosure rates across substances. We recommend that any individuals involved in the development, use, or evaluation of pregnancy tools, which may provide these services, draw on established frameworks that center the needs and values of the target population, while proactively addressing health disparities as a strategy to advance health equity and improve health outcomes [73]. Through a personalized approach to health care, prenatal health apps can play a role in identifying and supporting pregnant people with substance use.

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Conflicts of Interest

EEK is an investigator on grants to Magee-Womens Research Institute from the National Institutes of Health, Gilead, and Merck outside of the submitted work. TK is an investigator on grants to the University of Pittsburgh from the National Institutes of Health outside of the submitted work. TK is a cofounder of Naima Health, which provided app usage data for this study. The other authors report no conflicts of interest.

Multimedia Appendix 1 Baseline survey questions. [DOCX File, 26 KB - pediatrics_v8i1e60038_app1.docx]

Multimedia Appendix 2 Usability survey questions. [DOCX File, 19 KB - pediatrics_v8i1e60038_app2.docx]

Multimedia Appendix 3 Follow-up survey questions. [DOCX File, 17 KB - pediatrics v8i1e60038 app3.docx]

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Abbreviations

CFIR: Consolidated Framework for Implementation Research **HIPAA:** Health Insurance Portability and Accountability Act *ICD-10: International Classification of Diseases, Tenth Revision* **mHealth:** mobile health **VA:** Veterans Affairs

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Original Paper

Simulation of Contraceptive Access for Adolescents and Young Adults Using a Pharmacist-Staffed e-Platform: Development, Usability, and Pilot Testing Study

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Abstract

Background: Offering contraceptive methods at pharmacies without a prescription is an innovative solution to reduce the incidence of unintended pregnancies among adolescents and young adults (AYA). Pharmacy-prescribed contraception may increase the convenience, simplicity, and affordability of contraceptives.

Objective: The aim of this study was to develop, pilot test, and evaluate the acceptability and feasibility of a telemedicine electronic platform app simulating pharmacist prescribing of contraceptives to AYA as well as assess agreement between pharmacist-simulated contraceptive approvals and contraception as prescribed in routine clinic visits.

Methods: This study was conducted in two phases: (1) development and usability testing of a prototype app to simulate pharmacists prescribing contraceptives to AYA and (2) pilot testing the app in a simulation for AYA requesting contraception from a pharmacist with pharmacist review and request approval or rejection. Eligibility criteria in both phases included the following: assigned female sex at birth, age 15-21 years, seeking contraceptive services at an academic adolescent medicine clinic, prior history of or intention to have penile-vaginal intercourse in the next 12 months, smartphone ownership, and English language proficiency. Phase 1 (usability) involved a video-recorded "think aloud" interview to share feedback and technical issues while using the app prototype on a smartphone and the completion of sociodemographic, sexual history, and perception of the prototype surveys to further develop the app. Phase 2 (pilot) participants completed phase 1 surveys, tested the updated app in a simulation, and shared their experiences in an audio-recorded interview. Descriptive analyses were conducted for quantitative survey data, and thematic analyses were used for interview transcripts.

Results: Of the 22 participants, 10 completed usability testing, with a mean age of 16.9 (SD 1.97) years, and 12 completed pilot testing, with a mean age of 18.25 (SD 1.48) years. Three issues with the prototype were identified during "think aloud" interviews: challenges in comprehension of medical language, prototype glitches, and graphic design suggestions for engagement. Usability testing guided the frontend and backend creation of the platform. Overall, participants agreed or strongly agreed that using an app to receive contraceptives would make it easier for teens to access (n=19, 86%) and make contraceptive use less stigmatizing (n=19, 86%). In addition, participants agreed that receiving contraception prescriptions from a pharmacist without a clinic visit would be safe (n=18, 82%), convenient (n=19, 86%), acceptable (n=18, 82%), and easy (n=18, 82%). Pharmacists and medical providers had 100% agreement on the prescribed contraceptive method for pilot participants.

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Conclusions: AYA found contraceptive prescription by a pharmacist via an app to be highly acceptable and provided critical feedback to improve the design and delivery of the app. Additionally, pharmacist contraceptive approvals and contraception as prescribed in routine clinic visits were identical.

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KEYWORDS

adolescent; contraception; telemedicine; user-centered design; young adult; reproductive; design; usability; experience; mHealth; mobile health; app; youth; teenager; drug; pharmacology; pharmacotherapy; pharmaceutics; medication; pharmacy; digital health; platform; access

Introduction

Pregnancy rates among adolescents and young adults (AYA) 15-19 years old have dropped from 61.8 births per 1000 in 1991 to 13.5 in 2022, while AYA 20-24 years old reported a record low pregnancy rate of 60.4 births per 1000 [1]. For 2010-2019, pregnancy rates declined the most for youth 19 years old and younger, a 50% decrease, followed by a 29% drop for 20-24 year olds [2]. Evidence suggests the decline in pregnancy rates may be attributed to increased access to comprehensive sex education, use of contraceptives and health care, and not due to decreased sexual activity [3]. However, sexually active AYA, aged 15-24 years, were the most likely age group to experience unintended pregnancies in the United States [2,4]. Despite evidence showing the value of access to sex education and contraceptive services in reducing pregnancy rates among AYA, laws restricting access to both are increasingly being introduced and passed in US state legislatures. Legal restrictions intensify barriers, such as cost, attending appointments, stigma, and more to accessing contraceptives [5,6], which disproportionately affects low-income, disabled, racial or ethnic minorities, and other marginalized women and other birthing people [7]. Pharmacist-prescribed contraception-a strategy already used in high-income and many low- and middle-income countries but rarely in the United States-is one such strategy. In 2019, the American College of Obstetricians and Gynecologists recommended pharmacist-prescribed contraception without age restrictions as a necessary step to increase over-the-counter access to hormonal contraception and reduce the rate of inconsistent or nonuse of contraception [8].

In prior research, women and other birthing people voiced "convenience, simplicity, [and] affordability" as primary benefits of pharmacist-prescribed contraception [9]. In a study in California among 426 women and other birthing people, pharmacy access for emergency hormonal contraceptive (EHC) was preferred to clinician prescription as it was perceived to be faster (54%) and more convenient (47%) than seeking physician prescription [10]. Another study found that 68% of women who were at risk for unintended pregnancy reported they would prefer to obtain the contraceptive pill, patch, ring, or EHC from a pharmacy rather than a clinic if pharmacist prescribing was an option [9]. Moreover, 41% of those not currently using contraception reported they would start a contraceptive method via pharmacist prescribing if available [10]. Provision of EHC via community pharmacies has increased the use of EHCs; moreover, expanding access in this way is estimated to prevent almost half (1.3 million) of the 3 million unintended pregnancies

annually [11]. Centering patient priorities for access, as well as patient preferences for method choice, is a key tenet of reproductive justice and high-quality contraceptive care.

Historically, women and other birthing peoples' safety has been the most common concern regarding contraception delivery without a clinician-provided prescription [9]. However, multiple studies demonstrate that patients can accurately self-screen for contraindications to contraceptive use using medical checklists [12,13]. One study found greater than 93% of 328 patient-physician concordance for risk factor identification [12]. In another study, self-screening by patients using a medical checklist of contraindications was found to have greater sensitivity (83.2%) and specificity (88.8%) than a patient self-completed clinician questionnaire, which asked them to simply consider their medical history to determine the presence of contraindications (56.2% sensitivity; 57.6% specificity) [13]. This means when using a medical checklist of contraindications, women were able to accurately self-screen for contraindications to combined hormonal contraception [13]. Given the consistency of evidence supporting patient ability to medical self-screen for contraceptive contraindications, the American College of Obstetricians and Gynecologists endorses patient use of self-screening tools to determine eligibility for over-the-counter access to hormonal contraception [8].

Pharmacist-prescribed contraception innovations will need to develop strategies for successful implementation prior to widespread scaling [14]. Implementing screening tools has proved challenging for non-sexual health services for select populations, like youth [14]. Developing outreach strategies for youth and other vulnerable populations may require careful consideration. Attention to the training of point-of-service staff may facilitate service delivery and uptake. Studies of pharmacy staff indicate greater hesitancy and a desire for more intense training before providing sexual health services compared to non-sexual health services [15]. Attention to training and post-training support services may be necessary to ease implementation challenges. Newer technologies, like telemedicine, that allow skilled providers to deliver services across a distance may be valuable in bridging this gap until larger numbers of pharmacists are comfortable delivering pharmacist-prescribed sexual health services. Combining innovations such as telehealth and pyxis machines can allow pharmacists who are trained and comfortable providing sexual health services to AYA to do so.

There is limited research on pharmacist-prescribed contraception for US adolescents [4]. This study sought to develop an e-platform app called Birth Control Pass (BCPass) to simulate

pharmacists prescribing contraceptives to AYA, test the acceptability and feasibility of pharmacist-delivered contraception among AYA as a proof of concept, and determine the concordance between pharmacists and providers on the appropriate contraceptive method(s) to be prescribed to participants.

Methods

Overview

This study occurred in 2 phases. In Phase I, the e-platform was developed, and participants were recruited to engage in usability testing. In Phase 2, participants pilot-tested the e-platform.

Participants and Setting

Eligible participants for both study phases were patients seeking contraceptive initiation services at a subspecialty academic adolescent medicine clinic, ages 15-21 years old, assigned female sex at birth, with a prior history of or intention to have penile-vaginal intercourse in the next 12 months, owned a smartphone and could read and speak English. Usability testing of the prototype was completed in April of 2021. Modifications were made to the app to address participants' concerns and implement suggestions through iterative usability testing between developers and the study team. Pilot testing of the final prototype occurred between October 2021 and August 2022.

Ethical Considerations

Institutional Review Board approval was granted by the Children's Hospital of Philadelphia (20-017957). Participants received a \$20 US gift card for their time and effort. Precautions were taken to secure participants' personal information to ensure confidentiality including, the use of study identification numbers that were assigned to participants and used in place of participants' name and other private information on data collection forms.

Recruitment Strategy

For both study phases, the study team reviewed clinic schedules daily to identify patients with contraceptive appointments on the same day or the following clinic day. Clinic staff also referred patients for recruitment. Patients were approached in person at their medical appointment, by phone call, or via SMS text message. Consent was obtained via wet-ink signature on paper forms or electronic consent (e-consent) on Children's Hospital of Philadelphia's Research Electronic Data Capture (REDCap) [16,17] data collection application. Consent was provided either by legal guardians who attended clinic visits with patients 17 years old and younger or by the patients themselves, who were legally eligible to consent for themselves if they attended clinic visits alone [18] or were older than 18 years old. Participants were informed that by engaging in the research study, they would be testing the e-platform interface that simulated pharmacist prescribing but that they would not receive contraception as part of the study activities. Participants understood that contraception would be provided by their clinician during their scheduled medical visit, as per usual clinical care guidelines. Participants engaged with the e-platform either before or after their scheduled medical visit.

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Study Procedures

Phase 1: Development and Usability Testing

We created the BCPass prototype by modifying a large pediatric hospital system's app for employee COVID symptom check-in. The goal of the prototype was to simulate patient medical screening, patient contraceptive choice, and pharmacist contraceptive prescribing. The prototype first collected contact and self-screening information related to background and medical history. Next, participants were instructed to review content about contraceptive methods using a direct link to the educational website bedsider.org [19] and indicate their preferred method. Responses on the self-screening form were linked directly to medical contraindications to contraceptive prescribing per the Centers for Disease Control and Prevention US Medical Eligibility Criteria to facilitate rapid prescribing decision-making [20]. The prototype app included only a front-end interface for usability testing participants, but there was no backend personal health information data storage or pharmacist involvement. The study team explained to participants how the final app would work, including that if the participant had questions during the simulation, they had the option to call a pharmacist via the app ("Ask a Pharmacist" call button). Additionally, once the request for the preferred contraceptive method was submitted, a pharmacist would review and complete a "Pharmacist Approval Assessment Form" indicating if they would prescribe the contraceptive and approve dispensing or reject the request.

Participants completed web-based multiple-choice and short-answer surveys regarding their sociodemographic, sexual history, and attitudes regarding pharmacist-prescribed and app-delivered contraception. Next, they tested the prototype in a video-recorded "think aloud" interview [21], capturing the participants' initial impressions of the prototype, technical issues, and feedback while they actively engaged with the app prototype on their own smartphones. Studies using the "think aloud" methodology have proven to be successful at identifying usability problems without requiring a large number of subjects [21]. Participants were prompted to remark on ease of use, design aspects that are confusing or that slow task completion, and graphical elements, such as font size, ratios of images to words, and color schemes. The study team observed this process and took structured notes to capture information regarding domains from the sociotechnical model to ensure the optimization of service delivery [22]. Following prototype testing, participants' attitudes toward receiving contraception from a pharmacist and an app were assessed on a 5-point Likert scale: 1=strongly disagree, 2=disagree, 3=unsure, 4=agree, and 5=strongly agree. A 7-point Likert scale was used to evaluate the usefulness, ease of use, effectiveness, reliability, and satisfaction with the prototype (1=strongly disagree, 2=disagree, 3=somewhat disagree, 4=neither agree nor disagree, 5=somewhat agree, 6=agree, 7=strongly agree). Analyzed usability testing data was presented to the study team and app developers to inform the development of the app frontend and backend, along with iterative testing and weekly meetings (Figure 1). Special care was taken to thoroughly test each "click" on the app, and automated messages were reviewed to ensure ease of access and fluidity.

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Figure 1. Birth Control Pass (BCPass) e-platform app overview. Overview of the BCPass app, invite link, participant-entered information, education information review [19], preferred contraception option, and the pharmacist review and outcome. "Discover Birth Control Methods" was adapted from the bedsider.org birth control dashboard webpage [19].



Phase 2: Pilot Testing

Once a fully functional app was developed, a study pharmacist was trained to implement the study protocol, and AYAs were recruited to pilot test the intervention. Pilot participants completed web-based surveys regarding their sociodemographic, sexual history, and attitudes toward receiving contraception from an app and a pharmacist. Next, participants completed a simulation exercise, which included completing a medical history form to identify contraindications to contraception, learning about contraceptive options via bedside.org [19], and selecting a contraceptive method. As part of the simulation, a text or email was sent to their smartphone with a link to the app. After they submitted their request for a contraceptive method, the study pharmacist accessed the request on the backend to review and complete the "Pharmacist Approval Assessment Form." Participants then received an automated SMS text message to confirm if the pharmacist accepted (prescribed the contraceptive and approved dispensing), rejected (shared information to call the clinic that provides contraceptive care), or requested additional information (when participants requested methods unavailable for pharmacist prescribing, such as long-acting reversible contraceptives and injectable medroxyprogesterone acetate).

Following the simulation, pilot participants completed a web-based survey to evaluate the usefulness, ease of use, effectiveness, reliability, and satisfaction on 5-point and 7-point Likert scales. Participants then engaged in a brief audio-recorded interview that solicited feedback on the app and participants' decision-making process in selecting a contraceptive method. After participants completed their clinic visit, the contraceptive

XSL•FO RenderX method prescribed during their routine appointment was abstracted from their electronic medical record.

Analysis

Data analysis was conducted at two time points following phase 1 and phase 2, respectively. Deidentified survey demographics, sexual history, and Likert responses were exported from REDCap to Microsoft Excel for analysis. Descriptive analysis was computed for demographics and sexual history (proportions), and mean score and standard deviation were calculated for Likert questions. Audio from the "think aloud" video interview (usability) and feedback interview (pilot) were transcribed and manually coded by two coders until a 95% agreement regarding the themes was reached. For usability testing, participant comments and suggestions were categorized based on the type of modifications needed to the app (ie, wireframe, self-screening comprehension, and graphics). Interview data from the pilot testing was similarly thematically coded to reflect perceptions about the app's effectiveness, acceptability, feasibility, and participants' contraceptive decision-making. Effectiveness was defined as the e-platform success in simulating a birth control prescription. Acceptability or satisfaction with the e-platform was defined as participants' perceptions when using BCPass. Feasibility (BCPass practicality for learning about and accessing birth control) was defined by BCPass's usability or ease of use in navigating the e-platform and submitting a request for birth control. Lastly, birth control decision-making was based on participants' considerations made when indicating their birth control preference before and after using BCPass. Using the codebook, two coders not involved in usability qualitative analysis (one assisted with e-platform modifications and data collection, and the other helped with qualitative analysis only) classified statements in each thematic

area as positive, neutral, or negative. Finally, we assessed concordance between the contraceptive method selected at the medical visit (electronic medical record data) and the pharmacists' decision to approve or reject the participant's request for a contraceptive method.

Results

Participant Characteristics

In total, 22 AYA participated: 10 in phase 1 (usability testing) and 12 in phase 2 (pilot testing). On average, participants were 17.64 (1.50) years old, had some high school education (n=13), graduated from high school (n=4) or had some college (n=5), and had previously used contraception (n=17). See Table 1 for participant demographics and sexual history.

Table 1. Usability and pilot testing participant demographic and sexual history.

Characteristics	Usability testing (n=10)	Pilot testing (n=12)	Totals (N=22)
Age (years), n (%)			
15-16	3 (30)	1 (8)	4 (18)
17-18	7 (70)	7 (58)	14 (64)
19-21	0 (0)	4 (34)	4 (18)
Race or ethnicity, n (%)			
Black or African American	Unknown ^a	6 (50)	Unknown ^a
Hispanic or Latinx	Unknown ^a	1 (8)	Unknown ^a
White (non-Hispanic or Latinx)	Unknown ^a	5 (42)	Unknown ^a
Education, n (%)			
Not graduated high school	8 (80)	5 (42)	13 (59)
High school degree or General Education Development	1 (10)	3 (25)	4 (18)
Some college	1 (10)	4 (33)	5 (23)
Number of sex partners, n (%)			
None	4 (40)	2 (17)	6 (27)
Less than 3	3 (30)	8 (66)	11 (50)
Between 3 and 5	2 (20)	0 (0)	2 (9)
More than 5	0 (0)	2 (17)	2 (9)
Preferred not to say	1 (10)	0 (0)	1 (5)
Ever taken a pregnancy test, n (%)			
No	6 (60)	6 (50)	12 (55)
Yes	4 (40)	6 (50)	10 (45)
Ever been pregnant, n (%)			
No	10 (100)	12 (100)	22 (100)
Yes	0 (0)	0 (0)	0 (0)
Used birth control to prevent pregnancy, n (%)			
No	3 (30)	2 (17)	5 (23)
Yes	7 (70)	10 (83)	17 (77)
Ever used condoms during sex, n (%)			
No	3 (30)	2 (17)	5 (23)
Yes	7 (70)	10 (83)	17 (77)
Frequency of condom use ^{b,c} , n (%)			
Never	0 (0)	1 (10)	1 (6)
Sometimes	2 (29)	6 (60)	8 (47)
Always	4 (57)	3 (30)	7 (41)
Unknown	1 (14)	0 (0)	1 (6)
Ever had a sexually transmitted infection ^b , n (%)			
No	8 (80)	8 (67)	16 (73)
Yes	2 (20)	3 (25)	5 (23)
Unknown	0 (0)	1 (8)	1 (4)

^aRace or ethnicity was not self-reported by usability participants in this phase of the study. Electronic medical record race and ethnicity data is not self-reported and may misidentify participants. Therefore, this study only reports self-reported information collected during the pilot testing phase.

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^bDue to rounding, some totals may not correspond with the sum of the separate figures.

^cParticipants were only asked about their frequency of condom use if they answered yes to using condoms during sex. Participants could have responded yes to ever using condoms, but they may not currently be using them.

Quantitative Survey: Acceptability and Feasibility of Pharmacist- and App-Delivered Contraception

Pharmacist-Prescribed Contraceptives

Usability and pilot participants (N=22) agreed receiving a contraceptive prescription from a pharmacist without a clinic

visit would be safe (mean 4.27, SD 0.88), convenient (mean 4.50, SD 0.74), easy (mean 4.32, SD 0.89), and acceptable (mean 4.27, SD 1.08; Table 2). If they had the option to receive contraception from a pharmacist without a clinic visit, 14 of 22 participants reported they were likely or very likely to do so.

 Table 2. Perceptions of pharmacist and app-delivered contraception (N=22, Likert Scale 1-5).

	Mean (SD)
Safety, convenience, acceptability, and ease receiving birth control	
Getting birth control prescribed by a pharmacist would be safe	4.27 (0.88)
Getting birth control from a pharmacist would be convenient	4.50 (0.74)
Getting birth control from a pharmacist would be acceptable to me	4.27 (1.08)
I think it would be easy to receive birth control from a pharmacist	4.32 (0.89)
Getting birth control from an app would be safe	3.82 (1.14)
Getting birth control from an app would be convenient	4.45 (1.01)
Getting birth control from an app would be acceptable to me	3.95 (1.17)
I think it would be easy to use an app to get birth control	4.36 (1.00)
Advantages of using an app to receive birth control	
It would be easier for teenagers to get oral contraceptives	4.55 (0.74)
It would feel less embarrassing	4.27 (0.98)
It is less stigmatizing, meaning more normal to use	4.45 (0.86)
Fewer teenagers would get pregnant	4.32 (0.99)
It would be more confidential	3.82 (1.30)
Disadvantages of using an app to receive birth control	
Teenagers might not use condoms to protect against sexually transmitted diseases	3.91 (0.87)
Teenagers need a doctor to decide if oral contraceptives are safe for them	3.73 (1.12)
Teenagers might have sex at a younger age	3.14 (1.32)
Teenagers might use oral contraceptives incorrectly	3.36 (1.05)
Teenagers might not get tested for sexually transmitted diseases	3.55 (1.26)
Oral contraceptives might cost more over the counter	3.50 (0.86)
Teenagers might not talk to their parents about birth control	4.00 (0.87)
I have no worries (concerns) about teens using a medication dispensing machine to get birth control	3.09 (1.11)
Social approval	
Most people who are important to me would approve of me using an app to get birth control	3.64 (1.14)
Most teens like me would use an app to get birth control	4.27 (0.77)
Teens my age would use an app to get birth control	4.23 (0.97)
Parents or family would support me using an app to get birth control	3.32 (1.30)
My romantic partner(s) would support me using an app to get birth control	4.09 (1.06)
The decision to use an app to get birth control would be totally up to me	4.18 (1.10)
I am confident that I could use an app to get birth control	4.09 (1.19)

Receive Contraceptives Through an e-Platform App

Usability and pilot participants (N=22) agreed that receiving contraception using an app would be safe (mean 3.82, SD 1.14), convenient (mean 4.45, SD 1.01), easy (mean 4.36, SD 1.00), and acceptable (mean 3.95, SD 1.17) (Table 2). Additionally, participants were confident they would be able to use an app to get contraception (mean 4.09, SD 1.19) and agreed most teens would use an app to get contraception (mean 4.27, SD 0.77). A potential advantage recognized by participants of using an app would include fewer teenagers experiencing an unintended pregnancy (mean 4.32, SD 0.99), getting contraception would be less embarrassing (mean 4.27, SD 0.98), and less stigmatizing (mean 4.45, SD 0.86). Participants agreed a potential disadvantage of receiving birth control from an app is that it

Table 3. BCPass app simulation feedback (N=22, Likert scale 1-7).

may lead teens to not talk to their parents about birth control (mean 4.00, SD 0.87) or a possible decrease in condom use and an increase in sexually transmitted infections among teens (mean 3.91, SD 0.87). See Table 2 for additional insight into participants' attitudes toward pharmacists and app-delivered contraceptives.

E-Platform App Survey Feedback

Overall feedback on the BCPass app simulation during prototype and final productive testing was positive (Table 3). Participants agreed that BCPass was simple to use (mean 6.33, SD 1.24) and pleasant to interact with (mean 6.00, SD 1.64). Additionally, participants felt the app could do everything they would want it to be able to do for contraceptive delivery (mean 6.15, SD 1.23) and agreed they would use it again (mean 6.29, SD 1.54).

	Mean (SD)
BCPass was simple to use	6.33 (1.24)
BCPass was easy to learn and use	6.43 (1.02)
I believe I could become productive quickly using BCPass	6.05 (1.51)
The way I interact with BCPass is pleasant	6.00 (1.64)
I like using BCPass	6.00 (1.44)
BCPass can do everything I would want it to be able to do	6.15 (1.23)
I would use BCPass again	6.29 (1.54)

Clinician- and Pharmacist-Prescribed Contraception Concordance

A comparison of piloting participants who indicated a contraceptive preference (n=9) and what was prescribed revealed pharmacist contraceptive decisions and contraception methods as prescribed in routine clinic visits were identical. One of the 8 participant requests was rejected by the pharmacist because of a contraindication. This participant noted in their feedback interview that they requested a method they knew was contraindicated because it was their first choice over the contraception method they were prescribed. Three participants selected "I don't know" at the end of the simulation. One remained undecided following their clinic appointment. Another selected "I don't know" because they had an IUD at the time of the study but knew their first-choice method was contraindicated. The third selected a method at their clinic appointment. Of the 12 participants, one did not attend their clinic appointment, so it is unknown what they would be prescribed.

Qualitative Feedback

Usability Testing Think Aloud Data and Resultant e-Platform App Modifications

In an analysis of usability testing phase data, participants identified modifications related to addressing prototype wireframe glitches, self-screening comprehension, educational resource engagement, and app aesthetics. The prototype's wireframe glitches were anticipated as it was designed as a temporary test environment, and once the production frontend,

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patient-facing screen, backend, and developer view were created, the issues were resolved.

While navigating the prototype, participants requested clarification on the medical history questionnaire, indicating comprehension concerns. For example, participants asked if the transdermal skin patch was the same patch with which they were familiar. Additionally, participants asked what constitutes prolonged immobility or a bad reaction to hormonal contraception. The study team revised any questions that were identified as confusing and may be perceived as confusing to participants' peers. Examples and lay language were used for questions that required more medical terminology, such as including the more popular names for contraceptive methods in parentheses next to the full names (ie, oral contraceptive pill ["the pill"], transdermal hormonal patch ["the patch"]).

Participants' feedback on the lack of educational material and the app's aesthetics were closely associated concerns. Numerous participants noted they skipped the mandatory contraceptive method educational website, explaining they did not see the link or felt it was not important. The color palette and ambiguity of the "Ask a Pharmacist" call button and bedsider.org weblink were noted as weaknesses. The team determined adding color and images was a solution to attract participants' attention to educational materials. A welcome page was created to introduce the purpose of BCPass and provide written instructions on how to contact the study pharmacist via the "Ask a Pharmacist" call button.

Pilot Testing Interview Feedback

The following four primary themes emerged during the coding process: (1) the perceived effectiveness of the BCPass app, (2) AYA's perceptions of using BCPass (usefulness as a standalone or compared to the standard of care), (3) BCPass practicality for learning about and accessing contraception via an app, and (4) AYA's considerations when selecting a contraceptive method before and after the BCPass simulation.

Of the 12 pilot participants, one interview was not completed because the study team could not reach the participant; thus, the results reflect 11 of the 12 participants. A quarter of the 11 pilot participants commented on receiving contraceptive prescriptions through BCPass from a pharmacist easily in the simulation. One participant expressed that BCPass may be unrealistic outside of the simulation due to safety concerns they had in making contraception more accessible to AYA without additional educational discussions with a provider. Due to the nature of the simulation, participants understood they would not receive a method as part of the study; therefore, the perceived effectiveness of BCPass was minimally mentioned.

"The only thing that surprised me was that um you can literally just just get it. Like you don't like need any doctor's approval like just being able to get it" [Participant 1, selected implant in BCPass]

BCPass was highly acceptable among the 11 AYA pilot participants. The majority of pilot participants (73%) found BCPass to be quick, easy, convenient, and accessible. More than half (64%) found the process to be enjoyable and a good accessible option for other AYAs to request contraception compared to the standard of care of receiving contraception from a clinician after a medical appointment. Many participants stated they liked receiving contraception information from BCPass as well as avoiding a trip to a clinic and potentially uncomfortable conversation with a clinician (55%). Yet 18% of participants expressed they would also like the option to talk to a clinician by phone or in person in addition to the option they were given to talk to a pharmacist through BCPass. Some participants (18%) felt BCPass may not be adequate for AYA due to the possible need for more direct clinician oversight for young people and those with complex care needs.

"I also really liked the idea of not having to go to the doctor and have an awkward conversation about getting birth control" [Participant 2, selected oral contraceptives in BCPass]

"I like that it was fast and convenient and I didn't have to go see a doctor. I could do it right on my phone. Um, I liked that it like also gave me a little feel about all the different kinds of birth control methods because I think that we are not often given information about all of them" [Participant 3, selected IUD in BCPass]

A majority of the 11 pilot participants (91%) reported that BCPass was easy, quick, and convenient to use, with straightforward instructions and easy-to-answer questions. A third (36%) stated the information they received as part of the BCPass simulation was comparable to what they received at a

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medical appointment, including a participant stating the BCPass questions and education materials helped them determine what contraceptive method was best for them. While many usability concerns were addressed in the first phase of the study, 64% of participants shared feedback to further improve the experience for AYA. Suggestions included shortening the questionnaire, clarifying questions, deleting repetitive questions, and improving the delivery of educational materials.

"I liked how, I enjoyed how easy and self-explanatory a lot of the questions get... Sorry about that. I enjoyed mostly the descriptive questions that I was asked so that I was more sure about the pathway I would like to take while using that" [Participant 4, selected Depo-Provera injection in BCPass]

Finally, participants were asked about their preferred contraceptive method selected using BCPass. Most of the 11 (82%) pilot participants reported prior use of the method they chose in the BCPass simulation. More than half (64%) cited their medical history and side effects associated with their preferred method when explaining their decision. Additional considerations participants noted were the delivery of contraception (eg, shot, long-acting reversible contraceptives, daily oral pill) (27%) as well as discussions they have had with family and friends (27%).

"I felt like it [the patch] was the easiest one to remember and it was something I didn't have to take every day and was something I only have to remember once a week. I feel like it would be easy on my time and my hobbies I tend to forget about stuff" [Participant 5, selected transdermal patch in BCPass]

Prior to the BCPass simulation, two of the 11 (18%) pilot participants stated they did not have a single preferred contraceptive method in mind. After completing the simulation, they were able to more confidently select the method that they felt would work best for them. These participants credited the BCPass simulation questionnaire and educational materials in their decision-making process.

"Um I would definitely say that like IUD now. Originally, I would say 50-50 percent, like I would've leaned either way. But now using the app I would definitely say that I would have rather used the IUD because it's more, I don't want to say more protective. But like, it's better, it's like safer, better protection" [Participant 3, selected IUD in BCPass]

Discussion

Principal Findings

We found that an app for pharmacist delivery of contraception, BCPass, was acceptable and usable for AYA. Participants liked how easy, convenient, and fast BCPass was to request contraception. Once the concerns addressed in the usability phase were incorporated, there were no glitches experienced, and few participants felt the app survey was too long or had confusing questions. Also, more education may be needed to ensure AYAs feel safe requesting contraception from a pharmacist. Finally, we identified 100% agreement between

pharmacist contraceptive approvals in the simulation and contraception as prescribed in routine clinic visits.

Our findings are consistent with prior research on this topic in older adult women. In one survey study, women and other birthing people (\geq 18 years) reported receiving contraception from a pharmacist may be more convenient, faster, and easier compared to getting contraception from a clinician [10], which mirrors AYA's beliefs in this study. Additionally, this study found AYA-reported advantages of using an app included improving access to contraception by reducing the stigma and embarrassment of using contraception, reducing the burden of scheduling and attending clinic visits, and reducing the number of teenagers who become pregnant. In our study's feedback interview, most pilot participants emphasized their favorite aspect of BCPass was how quick and convenient it was compared to the standard of care while still receiving the contraceptive information they desired.

We did not identify any discordance between simulated pharmacist approvals and clinicians, as prescribed in clinic visits, suggesting the safety of having youth self-screen for medical contraindications. Women and other birthing people have previously been shown to safely and accurately complete self-screening medical history questionnaires and identify contraindications [12,13]. Like the older cohort, this study has shown AYA were capable of reporting their medical history, reviewing education materials, and selecting a contraceptive method they wish to use without forgoing a medical professional's review. While this study made edits, such as including more lay language and providing examples to some questions, to the medical contraindications to contraceptive prescribing per the Centers for Disease Control and Prevention US Medical Eligibility Criteria [20], once these changes were made to accommodate AYA's readability and comprehension level, they were able to successfully communicate their own medical history with a pharmacist through the app. A few pilot participants noted in their feedback interview they were surprised how easy completing the simulation was because questions regarding medical history were primarily all yes or no with an option to write in additional information for context with the study pharmacist. Some participants even found questions on their contraception preferences and reviewing educational materials more helpful in picking their preferred contraception than speaking to a clinician. Additionally, the feedback from the pilot phase reflected AYA's thoughtful consideration and awareness of their medical history, as well as side effects when planning to request contraception.

Of note, only one participant expressed concerns that contraception prescription without a clinician's oversight could be dangerous for AYA by making contraception too accessible, but several felt that they would prefer to discuss it with a provider. This data suggests the BCPass educational materials and access to call a pharmacist were not as effective as they needed to be to assure safety. While most participants liked the educational materials, a few did not feel it was enough to educate AYA on side effects. This finding suggests a need to include multimodal educational material, including more visual and audio materials. Additionally, participants who questioned the safety of BCPass also did not view pharmacists as being as knowledgeable as clinicians in prescribing contraception, which contrasts with physicians and midlevel practitioners in other studies who have supported pharmacist-initiated access to contraceptives [15]. Safety concerns indicated educational information presented needs to not only address contraception concerns but also inform AYA of the pharmacist's credibility and remind future users that pharmacists provide medical care already, such as vaccine delivery and drug interaction information [23].

Limitations of this study include the small sample size, single-city site, and limited rounds of usability testing. In addition, current state policy allows only for the simulation of pharmacist prescriptions. Following usability testing and additional app modifications, the platform was not retested again in another usability round before it was launched in the pilot testing phase. We focused on contraceptive methods for pregnancy prevention only and did not include the myriad of other reasons AYA may use contraception (eg, menstruation management, acne treatment, gender-affirming care, and medical conditions such as endometriosis). In addition, some participants completed the BCPass simulation following their medical appointment, which was not documented but is an important consideration for future larger-scale testing of the simulation. Future studies should further inform apps' usefulness in improving access to contraception for a broad range of indications via pharmacist prescription. Additionally, future research should explore the acceptability and feasibility of BCPass for key populations, including but not limited to girls, women, and other birthing people who are low income, living with disabilities, and sexual and gender minorities, to navigate barriers to accessing contraception. At the time of this study, pharmacist dispensing of contraceptives was not legal in the state of Pennsylvania, where this study took place, and 29 other US states. During a time with increasingly restrictive laws on connecting AYAs to contraceptives and other family planning resources, implementing methods to increase access to contraception is more important than ever because AYAs are particularly vulnerable to these restrictions.

Conclusions

Our results indicate that the BCPass app has the potential to be a valuable tool to improve access to contraception more facilitating contraceptive equitably by education, person-centered decision-making, and convenient delivery. BCPass and other electronic health solutions can supplement traditional care models and can be easily scalable, time-efficient, and cost-effective to assist AYA with navigating barriers to accessing contraceptives. Our results, demonstrating high acceptability and usability, suggest the potential of apps as supplemental effective tools to expand access to contraception for AYA during this time of increasing restrictive laws and policies impacting AYA reproductive health.



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Conflicts of Interest

None declared.

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Abbreviations

AYA: adolescents and young adults BCPass: Birth Control Pass EHC: emergency hormonal contraceptive REDCap: Research Electronic Data Capture

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The Neo-MILK Web App as a Health Technology to Support Mothers of Preterm and Sick Neonates During Lactation: Usability Study

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Abstract

Background: Mothers of sick and preterm infants need support to establish and maintain lactation. Although many health technologies on breastfeeding are available, most lack in evidence-based information and are therefore not appropriate for educating mothers. Furthermore, they do not focus on the special challenges of mother-infant separation during lactation in mothers of sick or preterm infants.

Objective: The aim of this study is to examine the usability and perceived usefulness of the evidence-based information about lactation and documentation tools contained in the Neo-MILK web app.

Methods: A cross-sectional online survey was conducted among mothers of sick and preterm infants admitted to a neonatal intensive care unit in Germany. Descriptive statistics were calculated for the System Usability Scale (SUS) and for self-developed items pertaining to overall satisfaction and perceived usefulness of the app. These included items on evidence-based information and the usability of tracking functions.

Results: Of 341 mothers who were contacted, 80 responded (response rate, 23.4%), and data from 63 mothers were analyzed. The mean SUS score was 76.4. The overall satisfaction rate was high, with 84% (n=53) of respondents indicating that they were either satisfied or very satisfied. Further, 82% (n=52) were inclined to recommend the web app to other parents. On average, the evidence-based information was perceived as helpful, more detailed, and not contradictory compared to information provided at the hospital. At the same time, most of the users reported that the Neo-MILK web app did not exert pressure to provide breast milk to their infants. Approximately 71% (n=45) of the mothers used the documentation tool in the web app several times per week to track their milk volumes.

Conclusions: By combining evidence-based information and useful tools to document milk volume, the Neo-MILK web app was high rated in usability and perceived usefulness. Considering the limitations of the study, this web app appears to be a valuable tool for educating and supporting pump-dependent mothers of sick and preterm infants during lactation.

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KEYWORDS

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mHealth; lactation; usability; perceived usefulness; lactation web app; preterm and sick infants; pumping; mother's own milk; mobile health

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Introduction

For all infants, mother's own milk (MOM) should be the first choice of nutrition and is, therefore, recommended by the World Health Organization [1,2]. Its health-promoting effects are evident and sick and preterm infants, in particular, benefit from the nutrition with MOM due to their high vulnerability [3]. However, achieving a sufficient milk volume has shown to be challenging for mothers of infants admitted to a neonatal intensive care unit (NICU) [4]. As many of these mothers are pump-dependent and cannot directly breastfeed, they require structured lactation support to facilitate MOM feeding in their sick and preterm infants [4,5]. This support enables timely communication about the importance of MOM, early initiation of lactation, and frequent pumping to establish a sufficient milk supply, thus ensuring the infants nutrition with MOM [4,6]. When providing lactation support to mothers, sensitive communication without distressing mothers should be facilitated, as stress may negatively affect lactation [7-9]. Indeed, perceived pressure to provide breast milk has been commonly reported among mothers, which may be associated with other mental health issues [10-12].

Mobile health (mHealth) apps and web app technologies are used in various settings such as disease management, medication reminders, and rehabilitation to promote and support a healthy lifestyle [13]. Several mHealth apps focused on breastfeeding already exist, which have shown to improve breastfeeding knowledge, attitudes, and self-efficacy [14-16]. However, mothers with infants admitted to a NICU require special tools and approaches from an app during lactation due to their unique situation. In general, NICU parents report a high demand for information and a willingness to use electronic devices for information and support [17,18]. This potential is further supported by studies which evaluated evidence-based education and information-sharing apps may promote parental mental health, parent-infant relationship, and family-centred care [19-21]. However, while many apps are already available for this target group, a systematic review showed that only a few of them are of good quality [22]. There is a notable lack of evidence-based and scientifically evaluated mHealth technologies focusing on combining evidence-based information sharing with valuable tools for NICU parents throughout the lactation process. The Neo-MILK web app aims to fill this gap for mothers with infants admitted in the NICU, by including both tools such as milk volume tracking and multimedia evidence-based information on several topics (eg, pumping, breastfeeding, or skin-to-skin contact). It was developed as part of the Neo-MILK project, which supports lactating mothers of infants admitted to a NICU [23]. Therefore, the intention of this web app was to complement rather than replace essential personal and direct lactation support provided within NICUs.

To measure the overall usability of mHealth technologies, the system usability scale (SUS) is a widely used instrument, which showed robust results in previous studies [24]. In addition, usability studies often report on ease of use, user experience, and user engagement, depending on the focus of the study [25]. Therefore, the objective of this study was to examine the

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usability and perceived usefulness of the evidence-based information about lactation and documentation tools contained in the Neo-MILK web app.

Methods

Research Design

A quantitative, prospective, and cross-sectional questionnaire was developed to evaluate the usability and perceived usefulness of the Neo-MILK web app.

Setting and Relevant Context

Participants in this study were mothers of preterm and sick infants admitted to a NICU. In Germany, initiation of lactation is often suboptimal [26]. This may be attributed to the often not implemented structured lactation support and lack of consistent information and personal support during lactation [27]. Mobile health technology may serve as a beneficial tool to help provide additional support to pump-dependent mothers.

Web App Development

In a participatory process involving mothers of very low birth weight (VLBW, <1500g) infants, features and content for the Neo-MILK web app were developed by a multidisciplinary team consisting of psychologists, economists, sociologists, neonatologists, neonatal nurses, and a web app developer. To determine the tools and features desired by mothers of VLBW infants, open questions were posted on Instagram. These questions were then ranked in an anonymous online survey completed by 138 mothers. Individual issues, such as the preferred type of communication, were also subject to direct voting via Instagram. Following this participatory process, the final design excluded photographs and instead featured animated parent-infant dyads and drawings. The illustrations were intentionally inclusive to reach a target group which is as diverse as possible. Therefore, the design includes people from different races and ethnicities. The illustrations and texts were developed through a process of various feedback rounds with the multidisciplinary team. As the Neo-MILK web app was part of the Neo-MILK project, the wording and presentation of the web app were aligned to the other materials developed within the project [23]. Finally, tools for recording the time, frequency, and volume of milk during expression, as well as a reminder for milk expression were included. Furthermore, evidence-based information on important topics related to lactation (eg skin-to-skin contact, bonding, milk expression, and hygienic handling of breast milk), along with answers to frequently asked questions regarding breastfeeding and pumping in the form of texts and videos are included in the web app to increase maternal knowledge. To reduce barriers to evidence-based information on pumping and breastfeeding, the videos were featured with subtitles in other languages. These were translated by native speakers working in the Neo-MILK team. Additionally, features such as a diary to document individual milestones of the child and the NICU-related reflections including the mother's mood and feelings were also provided. In cooperation with a media company (TAKEPART Media + Science GmbH), the app was designed as a browser-based web app (Figure 1).

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Figure 1. Web app design (left to right: landing page after registration, informational videos, documentation tool, milk diagram).



Measurements

The overall usability was measured using the SUS, which is a widely accepted tool to indicate usability, operability, and suitability for the use of digital health technologies [28]. Four slightly different translations of this scale are available in German. They were reviewed in a recent publication and revealed that the version by Rummel [29] described the developmental process and methodology most clearly. It was shown to be the best balance between methodologically clean development and wording and, therefore, was utilized in this study [29,30].

To measure the perceived usefulness of the information, videos and the documentation tools, self-developed items were assessed. Overall satisfaction was measured using a question: "How satisfied are you with the web app in general?" with a 4-point Likert scale ("very satisfied", "satisfied", "not satisfied", "not at all satisfied"). Moreover, participants were asked if they would recommend the web app to other parents with the following answering options: "yes", "rather yes", "rather no", and "no". Perceived usefulness of the information of videos was measured through a 4-point Likert scale of agreement ("agree", "rather agree", "rather disagree", "disagree") to three statements each for texts and videos which were as follows: (1) "The information I obtained from the texts (videos) were/are helpful for pumping and breastfeeding", (2) "The information I obtained from the texts (videos) were/are contradictory to those in the hospital," and (3) "The information I obtained from the texts (videos) were/are more detailed than those in the hospital."

To assess whether and how frequent mothers used the documentation tool for assessing their pumped milk volume using the following question "How frequently do you use the documentation tool?" which could be rated as: "several times a day", "daily", "several times a week", "several times a month",

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"less frequent", or "never." Moreover, they were asked whether they found the documentation tools easy to use in a 4-point Likert scale ("difficult", "rather difficult", "rather easy", or "easy"). Furthermore, to analyze whether the Neo-MILK web app caused negative feelings in mothers in terms of pressure to provide breast milk, the following statement was posed: "I felt pressured to provide breast milk by the Neo-MILK web-app" and could be rated on a six-point Likert scale ("totally disagree", "mostly disagree", "rather disagree", "rather agree", "mostly agree", "totally agree"). Data on feeding methods as well as previous experience with pumping or breastfeeding, and sociodemographic variables (eg, education, maternal age, infant's age) were collected. Due to small group sizes, the education level was dichotomized into lower education (lower secondary or secondary school) and higher education (higher education entrance qualification or university degree).

Data Collection

Data collection took place from September 2023 to May 2024 through the anonymous online survey tool Lime Survey (LimeSurvey GmbH). Data were collected and analyzed by researchers at the University of Cologne, who were also the principal investigators of the Neo-MILK project.

Data Analysis

Descriptive statistics including mean (SD), depending on the data distribution were calculated. Group comparisons between educational groups concerning the system usability were performed. Figures were used to visualize the data. Missing values were indicated in the description of the baseline characteristics and, in case of figures, in the figure legends. Data were analyzed using STATA (version 18; StataCorp).

Ethical Considerations

Ethical approval for this study was obtained from the ethics committee of the University of Wuppertal (SK/AE 230329).

All methods were performed in accordance with this approval. Before being permitted to complete the questionnaire, the participants were required to consent to the data protection regulations to realize informed consent. The resulting data was anonymous, as no personal data was collected. To compensate the time and effort of the participants, they were offered the opportunity to receive a $\leq 10b$ (US ≤ 11.60) voucher for a nationally represented drugstore.

Results

Sample

Four to eight weeks after registering in the web app, mothers of sick or VLBW infants were invited to participate in the

Figure 2. Flowchart of recruitment, inclusion, and exclusion of cases.

survey. The requirement for registration was explicit consent to be contacted for scientific studies during the registration process. Therefore, 341 mothers received an email with individual tokens to participate in the survey and were reminded once via email if the questionnaire was not submitted within a two-week period. To further ensure correct sampling, all respondents were asked to indicate whether they were currently engaged in pumping or breastfeeding. Of the 341 mothers who were contacted, 80 responded, representing a response rate of 23.4%. Finally, data from 63 mothers were used for statistical analysis (Figure 2).



Sample Characteristics

Maternal sociodemographic characteristics (eg, age, educational level, native language), and whether reasons for expressing milk

stem from maternal or child-related factors, as well as information about their infants (ie, past or current hospitalization, age, birth weight) are presented in Table 1.



Table . Characteristics of participating mothers and their infants.

Sociodemographic variables	Participants (n=63)
Age ^a (years), mean (SD)	33.5 (4.6)
Education, n (%)	
Lower secondary/secondary school	14 (22)
Higher education entrance qualification/university degree	48 (76)
Missing data	1 (2)
Native language, n (%)	
Other	4 (6)
German	57 (91)
Missing data	2 (3)
Parity, n (%)	
Singleton	61 (97)
Multiple	2 (3)
Missing data	0 (0)
Infant's hospitalization (past or currently), n (%)	
No	12 (19)
Yes	51 (81)
Missing data	0 (0)
Infant's age ^b (weeks), mean (SD)	8.6 (3.7)
Birth weight (grams), n (%)	
<500	3 (5)
500 - 999	15 (24)
1000g-1499	6 (10)
1500-1999	4 (6)
2000 - 2500	6 (10)
>2500	4 (6)
Missing data	25 (40)
Reasons for pumping, n (%)	
Maternal-related factors	8 (13)
Child-related factors	49 (78)
Preterm birth	32 (65)
Congenital condition	10 (20)
Birth complications	5 (10)
Others	2 (5)
Missing data	6 (10)

^aThere were 59 responses for this questions (ie, 4 did not response).

^bThere were 53 responses for this question (ie, 10 did not response).

Usability and Perceived Usefulness

The SUS score showed good usability of the Neo-MILK web app, with a mean score of 76.4 (n=61). The score only slightly

differed between the lower and higher educational groups (Figure 3).

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Graphs by Education

Overall, 62 participants reported high satisfaction with the web app, with 53 (84%) participants being satisfied or very satisfied. Moreover, 52 (82%) would recommend the web app to other parents. The information provided in the web app via texts were accessed by 31 (49%) and videos by 20 (32%) of the participants. Most participants agreed that the information were more detailed than those provided in the hospital and that they were helpful for pumping and breastfeeding. The majority of participants disagreed that the content was contradictory (Figure 4).

Of the 63 participants, 45 (71%) used the pumping documentation tool of the web app (ie pumping timer or manual documentation of pumping) at least several times a week. Of the 54 participants who rated its ease of use, 46 (85%) found it "rather easy" or "easy to use."

Of 62 mothers, 56 (89%) indicated that they did not feel pressured by the Neo-MILK web app to provide breast milk, while only 6 (11%) reported experiencing such pressure.

Figure 4. Distribution of agreement whether information in the web app (texts/videos) were more detailed than or contradictory to those in the hospital, or helpful for pumping/breastfeeding.



Discussion

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Principal Findings

This study showed that the Neo-MILK web app provides a suitable tool for mothers of VLBW and sick infants during

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lactation and pumping. The usability is good, as indicated by SUS scores being clearly over the widely accepted benchmark of 68 [24]. This is further supported by the positively rated overall satisfaction with the web app and the high number of participants who would recommend the app to other parents.

One main feature of the Neo-MILK web app is the provision of evidence-based information about central issues when pumping breast milk for a sick or preterm infant. These include bonding, breast milk expression, and solutions for problems with lactation. Recent studies showed that infant feeding applications are often of poor quality, with incomplete information and lacking in evidence-based content [13,22]. The information provided in the Neo-MILK web app was developed with a multidisciplinary expert team to ensure evidence-based content. Indeed, the results demonstrate that, on average, the information provided was helpful for mothers in their experience of pumping and breastfeeding. Furthermore, the information was more detailed than that provided in the hospital and not contradictory. It can therefore be assumed that the Neo-MILK web app is a suitable tool for informing mothers with an infant admitted to a NICU. However, it remains unknown, whether the mothers in our study received any personal lactation support or if the Neo-MILK web app was the only source of information and support available to them. It is important to emphasize that this web app should provide additional features and information for mothers. Personal and direct lactation support in the NICU, as part of a MOM-friendly hospital policy is crucial for ensuring nutrition with MOM [31,32].

Another central tool is the option to document the expressed milk volume. A recent study showed that tracking features lead to higher ratings of breastfeeding applications in general [33]. This indicates its importance for mothers and may be even more notable for pump-dependent mothers who are not able to feed their infant on demand. In our study, this assumption is strengthened, as most participants used the documentation tools to track their milk volume. In addition, the ranking of the ease of use indicates good usability of these features. This is particularly relevant, as usability has shown to be a crucial factor for the adoption of health technologies [34].

As elaborated before, stress and lactation are assumed to be associated [7,8]. This association is further assumed to be bidirectional, with stress leading to negative breastfeeding outcomes and impaired lactation increasing stress [35]. Due to the high levels of stress NICU mothers perceive, it is of paramount importance to minimize stress rather than triggering further distress [9]. Recent studies showed that mothers feel specific pressure to breastfeed or provide breast milk, which can stem from internal or external factors, for example, from their social environment or health care providers [11,12,36]. However, even though the Neo-MILK web app contains a lot of information about the importance of MOM, as well as tracking options for milk supply, users do not perceive these features as triggering such feelings.

Limitations

This study has some limitations. The SUS is available in four German translations, all of which have different deficiencies, for example, in methodology or wording. Although there is a validated version available, it lacks in terms of translation, leading to unnatural wording. In this analysis, we used the recommended translation, which is regarded as the best compromise between methodologically rigour and comprehensibility [30]. This might have had an impact on the validity of the measurement and therefore influenced the results. The response rate of this study is low. It may be the case that the users were no longer using the web app at the time of the survey. This may particularly apply to mothers who have transitioned from pumping to breastfeeding after a few weeks, and therefore no longer require the tools of the Neo-MILK web app. Another reason for the low response rate could be that registered web app users who were unsatisfied or were not frequent users did not respond due to their dissatisfaction. Furthermore, it can be suggested that the utilization of mHealth technologies is determined by the educational level and age of users, which may indicate a healthy bias among its users [37]. This is reflected by the broad number of participants with a high educational level in this sample. However, the Neo-MILK web app utilization and its ratings might not be biased by educational level, as indicated by only slight differences in the SUS score between these groups. Nevertheless, the information should be accessible for all groups to reduce communication difficulties, including those due to language barriers, which are a common problem in health services [38]. To reduce these barriers, the videos in the Neo-MILK web app are available with subtitles in other languages, including Russian, French, English, and Turkish. In addition, the videos are composed of easily understandable images and keywords. However, the provision of a translated version of the entire web app when necessary would further facilitate the accessibility of the web app to all relevant target groups.

Conclusions

The combination of evidence-based information about lactation and useful tools for tracking was identified as being of particular importance for this special group of mothers, with both elements rated highly in terms of usability and usefulness. Therefore, it can be concluded, that in our study, the Neo-MILK web app serves as a useful tool to complement personal support for pump-dependent mothers during lactation.

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Conflicts of Interest

None declared.

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Abbreviations

mHealth: mobile healthMOM: mother's own milkNICU: neonatal intensive care unitSUS: system usability scaleVLBW: very low birth weight



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Original Paper

Developing an Evidence- and Theory-Informed Mother-Daughter mHealth Intervention Prototype Targeting Physical Activity in Preteen Girls of Low Socioeconomic Position: Multiphase Co-Design Study

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Abstract

Background: Preteen girls of lower socioeconomic position are at increased risk of physical inactivity. Parental support, particularly from mothers, is positively correlated with girls' physical activity levels. Consequently, family-based interventions are recognized as a promising approach to improve young people's physical activity. However, the effects of these interventions on girls' physical activity are often inconsistent, with calls for more rigorous, theory-informed, and co-designed family-based interventions to promote physical activity in this cohort.

Objective: This study aimed to use co-design methods to develop an evidence- and theory-informed mother-daughter mobile health intervention prototype targeting physical activity in preteen girls.

Methods: The intervention prototype was developed in accordance with the United Kingdom Medical Research Council framework, the Behaviour Change Wheel, the Theoretical Domains Framework, and the Behaviour Change Techniques Ontology. The Behaviour Change Intervention Ontology was also used to annotate the intervention characteristics. The co-design process incorporated three phases: (1) behavioral analysis, (2) the selection of intervention components, and (3) refinement of the intervention prototype. Throughout these phases, workshops were conducted with preteen girls (n=10), mothers of preteen girls (n=9), and primary school teachers (n=6), with additional input from an academic advisory panel.

Results: This 3-phase co-design process resulted in the development of a theory-informed intervention that targeted two behaviors: (1) mothers' engagement in a range of supportive behaviors for their daughters' physical activity and (2) daughters' physical activity behavior. Formative research identified 11 theoretical domains to be targeted as part of the intervention (eg, knowledge, skills, and beliefs about capabilities). These were to be targeted by 6 intervention functions (eg, education, persuasion, and modeling) and 27 behavior change techniques (eg, goal setting and self-monitoring). The co-design process resulted in a mobile app being chosen as the mode of delivery for the intervention.

Conclusions: This paper offers a comprehensive description and analysis of using co-design methods to develop a mother-daughter mobile health intervention prototype that is ready for feasibility and acceptability testing. The Behaviour Change Wheel, Theoretical Domains Framework, and Behaviour Change Techniques Ontology provided a systematic and transparent theoretical foundation for developing the prototype by enabling the identification of potential pathways for behavior change. Annotating the Behaviour Change Intervention Ontology entities represents the intervention characteristics in a detailed and structured way that supports improved communication, replication, and implementation of interventions.

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KEYWORDS

physical activity; preteen girls; socioeconomic position; maternal support; mHealth; intervention; co-design; pediatric; daughter; design; development; behavior change technique; Behaviour Change Wheel; sedentary; inactivity

Introduction

Background

Globally, 81% of adolescents are not meeting the recommended physical activity (PA) guidelines [1], with PA levels regressing annually throughout adolescence [2,3]. This rate of decline is more pronounced in girls than boys [1,4] and is most apparent during the transition period from primary to secondary school [5,6]. Studies also indicate that children of lower socioeconomic position (SEP) are less likely to be physically active than those of higher SEP [7-9]. Indeed, this is noteworthy in girls of low SEP, as evidence indicates that this cohort experiences a steeper decline in PA than their more advantaged peers at the transition to adolescence [4,9], putting them at a greater risk of obesity, type 2 diabetes, and cardiovascular disease [8,10]. Most interventions targeting children's daily PA levels have taken place during school hours [11]; however, children are reported to be less active during time spent outside of school, such as at weekends or holidays [12]. Thus, there is a need to also promote PA outside of the school context [13].

Families are a central foundation of support and guidance for children and adolescents in shaping healthy PA behaviors particularly outside of school [14]. Parental support is an umbrella term used to represent numerous support behaviors for PA such as encouragement, logistical support, or coactivity [14,15]. This type of parental support is positively correlated with child PA [16,17], with some evidence for stronger effects for girls when they are supported by their mothers rather than by other family members [18,19]. While there has been a growing interest in family-based PA interventions to promote girls' PA, the evidence for such interventions is mixed [20-22]. These inconclusive findings may be due to factors such as poor study design, small sample sizes, the use of self-report measures, the lack of theory to underpin interventions, the absence of the participant voice in the intervention development process [20,23], and differences between modes of delivery (eg, face-to-face vs eHealth or mobile health [mHealth]) [22,23]. Rapid developments in technology in recent decades have seen an increased use of eHealth and mHealth as modes of delivery for promoting PA in preschoolers [24], children and adolescents [25-27], families [22], and individuals of low SEP [28]. Meta-analyses of eHealth and mHealth PA interventions have reported positive effects for PA-related outcomes in children and adolescents, such as steps per day [25,26] and total PA [26,29], with a lack of improvement in moderate to vigorous PA stated as a limitation [25,29]. Considering the prevalence of smartphone phone use across children, adolescents, and adults [30,31] and the cost-effectiveness, reach, and scalability of mHealth interventions [25,26], there is a pressing need for more robust theory-based mHealth interventions to harness the potential of digital platforms for enhancing PA [22,24,25], particularly for individuals of low SEP [28].

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Intervention Development

There is increasing recognition of the need for guidance to support the robust design of interventions targeting health behaviors such as PA. Specifically, the United Kingdom Medical Research Council (MRC) has developed a framework for complex interventions that provides a systematic process for developing and evaluating interventions across 4 interacting stages [32]. Within this process the importance of using theory, considering context, developing and refining a program theory and related logic model, and engaging with stakeholders is emphasized [32]. Theory offers a valuable organizing framework for the development of effective interventions and is necessary to test hypothesis, identify constructs that effect behavior, and enable study replication and generalization [33,34]. There have been mixed findings reported regarding the effectiveness of interventions that are underpinned by theory [35,36], predominantly explained by a lack of clarity as to how a particular theory's constructs (ie, mechanisms of action) are targeted and measured within interventions [33,35]. The Behaviour Change Wheel (BCW) builds on MRC guidance and offers a practical guide for how to develop theory- and evidence-based interventions [37]. The BCW is a synthesis of 19 frameworks for classifying behavior change and facilitates the mapping of intervention targets (ie, the behavior, the population, and the context) to specific mechanisms of action (ie, the processes through which behavior change occurs) [38]. At the core of the BCW is the Capability, Opportunity, and Motivation-Behavior (COM-B) model, which proposes that Capability, Opportunity, and Motivation interact to influence behavior. Capability refers to the individual's physical and psychological ability to enact the behavior. Opportunity denotes the social and physical resources that facilitate or hinder the behavior. Finally, Motivation is defined as the reflective or automatic processes that enable the behavior [37]. The BCW contains 9 different intervention functions that can be applied to target the desired behavior and 7 categories of policy that can be used to deliver these intervention functions. The BCW and associated elements have been successfully used in different contexts to develop interventions promoting PA [39-41]. For example, while using the BCW as part of the development process for a PA app, Truelove et al [39] targeted individuals' physical and psychological capabilities, physical and social opportunities, and reflective and automatic motivation to increase PA levels in Canadian adults. To achieve this, the intervention functions of education, persuasion, incentivization, training, environmental restructuring and enablement were chosen from the BCW to be included in the app, alongside 2 policy categories (communication and marketing, and environment and social planning) to support the delivery of the intervention functions [39]. One study has used the BCW to develop a mother-daughter PA intervention for adolescent girls [41] by selecting 6 intervention functions (education, persuasion, incentivization, training, modeling, and enablement).

The COM-B components of the BCW can be further understood by using the Theoretical Domains Framework (TDF) [42]. The TDF is a validated integrative framework of 14 theoretical domains synthesized from 128 theoretical constructs and 33 behavioral change theories [42]. Additionally, the TDF presents a comprehensive grouping of the overlapping constructs within behavioral theories and supports the identification and selection of relevant mechanisms of action (eg, knowledge and beliefs about capabilities) for targeting within interventions [37,43]. The TDF has been applied across a variety of settings to inform the development of PA interventions [44,45]. For example, a study by McQuinn et al [45] identified the TDF domains of social influences, environmental context and resources, behavioral regulation, beliefs about capabilities, goals, and reinforcement as target mechanisms of action for a co-designed school-based intervention promoting PA in adolescent girls. However, to date, no intervention has used the TDF to identify mechanisms of action for an intervention promoting PA in preteen girls and maternal PA support behaviors.

An intervention achieves its functions through the use of behavior change techniques (BCTs), which are "the smallest part of the behaviour change intervention content that are that are observable, replicable and on their own have the potential to bring about behavior change" (eg, self-monitoring of behavior and problem-solving) [46]. The Behaviour Change Techniques Ontology (BCTO) offers a reliable and extensive classification system for behavior change intervention content. Using the BCTO is considered best practice, as it contains considerably more BCTs than the original BCT Taxonomy version 1 (BCTTv1), has more precise and clear groupings, labels and definitions, and links to other characteristics of an intervention, such as mechanisms of action [47]. The influence of intervention content (eg, BCTs) on behavior can differ depending on how it is delivered to participants, and therefore vary its effectiveness [48]. The recently developed Behaviour Change Intervention Ontology (BCIO) assists researchers to fully specify and classify intervention characteristics (eg, delivery) in a way that supports improved communication, replication, and implementation of effective interventions [46]. Within the BCIO, the delivery of an intervention is divided into the following components: (1) mode of delivery (ie, the medium through which an intervention is provided) [49], (2) intervention setting (ie, the setting where an intervention takes place) [50], (3) intervention schedule (ie, the timing of intervention components), and (4) intervention style of delivery (ie, the manner in which the intervention is delivered) [48]. Using the BCIO entities to annotate the delivery of an intervention increases our understanding of how the effect of intervention content differs according to the mode and style within which it is delivered [48]. While using the BCIO may be time consuming for researchers, it is increasingly used for evidence synthesis [51,52] and intervention development [53,54]. The BCIO has not yet been applied in PA interventions as it is a new development and is only recently available. To our knowledge, this is the first study to use the BCIO entities

to annotate the characteristics of an intervention targeting PA in children.

Objectives

Alongside this increased emphasis on a systematic theory-informed intervention development, a collaborative approach to intervention design involving the end users of research is essential. Co-design methods ensure meaningful involvement of the end user in the research process [55] by enabling the specific needs and preferences of the target population to be recognized and allowing for the identification of potential implementation challenges early in the intervention development process [56]. Indeed, research that involves end users in the design process leads to interventions that are more contextually relevant and thus more effective [57]. However, while there is a continued call for greater involvement of young people in the research process through participatory methods such as co-design [58,59], only a few studies on family-based interventions targeting girls' PA [41] or on PA in teenage girls from lower SEP have applied such methods [45,60]. Therefore, the purpose of this study was to provide a detailed outline of the systematic process undertaken to using the BCW and TDF to develop an evidence-based and theoretically informed behavior change intervention, using co-design methods, to promote PA in preteen girls incorporating maternal support behaviors, before preliminary testing for feasibility and efficacy.

Methods

Overview

This study was informed by the initial development stage of the MRC framework for complex interventions [32]. In line with MRC guidelines, a program theory and logic model were developed and refined throughout the intervention development process. A program theory is a tool that can be used to unpack the relationship between the intervention activities and intended outcomes [61]. Logic models can assist in visually representing the program theory to effectively communicate with research team members and stakeholders [61]. The intervention prototype developed across 3 phases (Figure 1). Phase 1 was guided by the steps in the BCW process [37] and also incorporated the TDF to identify more specific mechanisms of action [42]. Phase 2 involved co-design workshops with stakeholders (ie, mothers, preteen girls, and primary school teachers) to identify potential intervention components and mode of delivery. In phase 3, the prototype was refined through an iterative and dynamic process based on evidence, theory, and input from additional co-design workshops with stakeholders (ie, mothers, preteen girls, and primary school teachers). An academic advisory panel provided guidance throughout the process. The BCIO entities were annotated to report the intervention characteristics; some of the BCIO unique identifiers are provided in the manuscript, with a full list available in Multimedia Appendix 1.



Figure 1. Overview of the intervention development process. BCW: Behaviour Change Wheel.



Ethical Considerations

Ethics approval was obtained by the University College Dublin's Human Research Ethics Committee (LS-22-62) before study commencement. No payments or incentives were offered for participation. Information packs containing information sheets and consent and assent forms were distributed to mothers, children, and teachers alike.

Recruitment

Co-Design Participants

A suburban primary school identified by the Department of Education's Delivering Equality of Opportunity in Schools (DEIS) program was identified as suitable for this study. The Department of Education uses the DEIS classification system to support students attending schools situated in communities at risk of social and economic disadvantage [62]. To classify schools as meeting the DEIS criteria, data from the Department of Education's online database and the HP Deprivation Index for Small Areas (HP Index) are used [62]. The HP Index is a process that measures the relative affluence or disadvantage of small geographical areas using categories such as demographic growth, dependency ratios, education levels, single parent rate, overcrowding, social class, occupation, and unemployment rates [62]. The school in this study is a mixed primary school based in a suburban town located 10 km from Dublin city center, Ireland, with approximately 520 pupils and 33 teachers. After discussions between the lead author (CB) and the school principal, the school principal invited mothers and female guardians of girls aged 10 to 12 years, girls aged 10 to 12 years, and teachers to take part in the study. All girls who were aged

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between 10 and 12 years and from fourth, fifth, or sixth class were eligible to take part.

Academic Advisory Panel

As part of the research process, an academic advisory panel was established to discuss the findings from the co-design workshops, the use of theory, and support the research team (CB and JM). This panel consisted of 3 academics (GO'D, AK, and RER) with expertise in PA, sedentary behavior, and the development of complex interventions and co-design methodologies. Both GO'D and AK are experienced qualitative researchers and have conducted previous studies exploring PA and sedentary behavior using the TDF, and RER is an experienced researcher with an applied focus on PA during life transitions.

Intervention Prototype Development Process

Phase 1: Behavioral Analysis and Program Theory Development

Phase 1 included steps 1 to 4 of the BCW intervention design process [37]. In line with this approach, the definition of the problem in behavioral terms (step 1) was based on findings from previous literature (ie, preteen girls are not active enough) [1,4]. A systematic review of mother-daughter interventions and formative qualitative research (ie, interviews with 29 mothers of preteen girls and 19 focus groups with 107 low-SEP preteen girls) was then conducted to further understand the problem and the related factors. This was followed by selection and specification of the intervention target behaviors (steps 2 and 3 of the BCW process). After these steps, CB and JM used the TDF to identify the barriers and enablers of the target

behaviors. These were presented to the academic advisory panel (GO'D, AK, and RER) to establish what needs to change to achieve the target behaviors (step 4; Multimedia Appendix 2 [6,14,63-76]). This led to the selection of specific mechanisms of action to be targeted within the proposed intervention. An initial program theory and related logic model for the intervention were then developed.

Phase 2: Identify Intervention Functions, Content, and Implementation Options

This phase includes steps 5, 7, and 8 of the BCW intervention design process [37]. Three co-design workshops took place at the school premises during school hours and were facilitated by CB and JM. Three separate groups took part in a co-design workshop: (1) mothers of preteen daughters (n=9), (2) preteen girls (n=10), and (3) teachers (n=6). The workshops took place in April 2023, with a mean duration of 52 (SD 1.9) minutes. The aim of these workshops was to identify potential intervention functions, BCTs, and modes of delivery to target the proposed mechanisms of action identified in phase 1. A range of age-appropriate and interactive methods were used in these co-design sessions (Multimedia Appendix 3). For example, to encourage participants to think about the practical application of their suggestions to a wide variety of mothers and girls, personas of mothers and girls who were individually, socially, and geographically diverse were provided [77]. Using the information gathered from these co-design sessions, along with findings from phase 1 and further consultation with the academic advisory panel (GO'D, AK, and RER), intervention functions (step 5), BCTs (step 6), and a proposed mode of delivery (step 8) were selected by the research team (CB and JM). The program theory and logic model were also refined.

Phase 3: Development, Refinement, and Evaluation of the Intervention Prototype

This phase involved incorporating the findings from phase 2 into the development of the intervention components. A second series of co-design workshops (n=3) took place in the school premises during school hours and were facilitated by CB and JM. The same participants as phase 1 took part. The three separate workshop groups were (1) mothers of preteen daughters (n=6), (2) preteen girls (n=10), and (3) teachers (n=3). The workshops took place in June 2023, with a mean duration of 44 (SD 5) minutes. The aim of the workshops was to obtain participants' feedback on the acceptability of the proposed intervention components (Multimedia Appendix 4). Following these workshops, the research team (CB and JM) discussed the findings from the workshops, the proposed intervention components, and the use of theory with the academic advisory panel (GO'D, AK, and RER). The 21-item App Behavior Change Scale [78] was also used by the research team to ensure

that relevant behavior change components were appropriately included. This scale has been used in several studies targeting PA to assess intervention effectiveness [39,79]. The program theory and logic model were refined for the final time.

Results

Phase 1: Behavioral Analysis and Program Theory Development

As described in the Introduction section, the identified problem behavior was the decline in PA as children transition to adolescence, with this decrease in activity levels particularly prevalent for girls of lower SEP [1,4]. Children whose parents support PA are likely to have higher overall levels of activity than children whose parents do not support their PA, with stronger effects when that support is provided by a parent of the same gender [80,81]. The formative research related to this study is described in previous studies, [82-84] therefore a brief description of it is provided here. A review of behavior change theories and techniques used in mother and daughter PA interventions highlighted a lack of clarity as to why interventions were effective or not and the increased need for a stronger theoretical basis for future interventions as well as enhanced reporting of how these interventions are developed [82]. Qualitative formative work with mothers of preteen girls highlighted barriers and enablers related to engaging in PA-supportive behaviors with their daughters [83]. These ranged from individual-level factors such as their PA-related identity and their confidence to engage in supportive behaviors to social and environmental factors such as the role of other family members and the infrastructure within their communities and their daughters' schools [83]. Finally, qualitative work was conducted with preteen girls who discussed barriers and enablers to their PA, such as the importance of skills and confidence to support their engagement in PA and strengthen their self-identity for PA alongside the important role of family members, friends, teachers, and coaches [84]. On the basis of this formative work, 2 related behaviors were deemed appropriate to target as part of the intervention. The first behavior was to improve mothers' support for their preteen daughters' PA and, in doing so, indirectly increase the likelihood of preteen girls engaging in PA. The second behavior being targeted was to increase preteen girls' PA. These behaviors are presented in Table 1 in terms of who needs to perform the behavior, when, where, and with whom.

The academic advisory panel then reviewed the analysis of the barriers and enablers to the target behaviors. Following discussion with the advisory panel, the research team then chose 11 of the 14 TDF domains as proposed mechanisms of action for enabling these target behaviors (Table 2).



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 Table 1. Specification of target behaviors of interest.

	Target behavior 1	Target behavior 2
What behavior	Improve mothers' PA ^a support behaviors (eg, encourage- ment, logistical support, coactivity, and environmental and regulatory support) for their preteen daughters	Increase preteen daughters' PA (includes active travel, sport, family activities [bike rides and walks], and outdoor play)
Who	Mothers of preteen daughters of low SEP ^b	Preteen daughters of low SEP
When	Daily	Daily
Where	In their household residence (BCIO ^c : 026009), sport and exercise facility (BCIO: 026030), and outdoor environment (BCIO: 026044)	In their household residence (BCIO: 026009), sport and exercise facility (BCIO: 026030), and outdoor environment (BCIO: 026044)
With whom	Preteen daughters	Friends, mothers, and other family members

^aPA: physical activity.

^bSEP: socioeconomic position.

^cBCIO: Behaviour Change Intervention Ontology.



Table 2. Mechanisms of action, intervention functions and behaviour change techniques for mother-daughter intervention.

Mechanisms of action and what needs to happen for behavior change to occur	Intervention functions for improving maternal PA ^a support and promoting PA in preteen girls	BCTs ^b from BCTO ^c for improving maternal PA support and promoting PA in preteen girls
 Knowledge Develop mothers' and daughters' understanding of the following: The rationale and purpose of the program The types and benefits of PA and PA guidelines How to be physically active The types and benefits of maternal PA support behaviors How to perform maternal PA support Typical challenges experienced by mothers while engaging in PA support (eg, pushback from daughter) Typical challenges experienced by preteen girls while engaging in PA support (eg, friends not active) Available resources to facilitate engagement in PA and PA support 	 <i>Education</i> About the rationale and purpose of the program About ways of enacting desired behavior and avoiding undesirable ones Provide credible, appealing information that can be used to enact target behavior Provide clear, consistent, and standardized messages about maternal PA support and PA Provide information to address prevalent misconceptions about maternal PA support and PA behaviors 	 Instruct how to perform behavior BCT (BCIOd:007058) Inform about health consequences BCT (BCIO:007063) Inform about social consequences BCT (BCIO:007064) Inform about environmental consequences BCT (BCIO:007176) Present information from credible influence BCT (BCIO:007075)
 Skills Develop skills to do the following: Select and engage in PA and PA-supportive behaviors Apply problem-solving and set and review personalized goals for PA and PA support behaviors Monitor progress of physical activity behaviors Monitor progress in supporting daughter to be active; overcome the challenges encountered while engaging in selected PA and PA support behaviors 	 <i>Training</i> Practice and engage in PA support and PA behaviors Engage in problem-solving and select and review goals related to target behavior Monitor progress when engaging in PA support and PA behaviors Engage in behavioral strategies to overcome challenges associated with providing support or being active 	 Goal strategizing BCT (BCIO:007008) Provide feedback on behavior BCT (BCIO:007023) Self-monitor of behavior BCT (BCIO:007024) Instruct how to perform behavior BCT (BCIO:007058) Demonstrate the behavior BCT (BCIO:007055) Practice behavior BCT (BCIO:007094) Context-specific repetition of behavior BCT (BCIO:007096) Set graded tasks BCT (BCIO:007100)
 Social role and identity Develop mothers' identity as a person who provides support for their daughters' PA Develop mothers' and daughters' identity as a person who is physically active 	 <i>Education</i> About how to link supportive and PA behaviors to other intrinsic goals Provide information about positive experiences when supporting their daughter to be active or being active and how to overcome associated challenges Provide information about extra resources available to help mothers provide support or preteen daughters be active when program ends <i>Persuasion</i> Highlight compatibility with current identity, but expand it to include maternal PA identity or PA behaviors and social identities Emphasize the role of mother as change agent for daughter and in family 	 Social support BCT (BCIO:007028) Inform about social consequences BCT (BCIO:007064) Prompt social comparison BCT (BCIO:007073) Practice behavior BCT (BCIO:007094) Present information from credible influence BCT (BCIO:007075) Identify self as role model BCT (BCIO:007158) Reframe past behavior BCT (BCIO:007056) Adopt changed self-identity BCT (BCIO:007160)

Mechanisms of action and what needs to happen for behavior change to occur	Intervention functions for improving maternal PA ^a support and promoting PA in preteen girls	BCTs ^b from BCTO ^c for improving maternal PA support and promoting PA in preteen girls
 Beliefs about capabilities Improve perceived competence in ability to do the following: Perform selected PA and PA support behaviors Use problem-solving, goal setting, and action planning to engage in PA and PA support Ability to monitor progress Overcome challenges encountered while enacting PA and PA support Engage in long-term PA and PA support behaviors 	 <i>Persuasion</i> Enhance perceived competence to problem solve, actions plan, select and monitor goals, and self-monitor PA support and PA behav- iors Encourage mothers to believe that providing support is possible or daughters to believe that being active is possible, even given constraints of their circumstances <i>Enablement</i> Assist mothers or daughters in problem- solving and action planning to overcome barriers to providing support or being active <i>Modeling</i> Present real-life examples of mothers or preteen girls in similar circumstances 	 Goal strategizing BCT (BCIO:007008) Social support BCT (BCIO:007028) Instruct how to perform behavior BCT (BCIO:007058) Demonstrate the behavior BCT (BCIO:007055) Practice behavior BCT (BCIO:007100) Advise how to reduce negative emotions BCT (BCIO:050344) Persuade about personal capability (BCIO:007137) Prompt focus on past success BCT (BCIO:007139) Prompt self-talk BCT (BCIO:007140)
 Beliefs about consequences Enhance mothers' expectations related to the positive consequences of engag- ing in selected PA support Enhance mothers' and daughters' ex- pectations related to the positive conse- quences of engaging in selected PA behaviors 	 <i>Education</i> Explore beliefs and attitudes related to PA and the associated health benefits Explore beliefs and attitudes between providing PA support and expected outcomes <i>Persuasion</i> Enhance beliefs that being physically active has positive health benefits in the short and long term Provide expert information about how, where, and why to be active Enhance beliefs that providing support for daughters' PA would be beneficial Provide expert information about the short and long-term benefits of providing PA support 	 Inform about health consequences BCT (BCIO:007063) Inform about social consequences BCT (BCIO:007064) Inform about environmental consequences BC (BCIO:007176) Monitor emotional consequences BCT (BCIO:007066) Demonstrate the behavior BCT (BCIO:007055) Prompt social comparison BCT (BCIO:007075) Present information from credible influence BCT (BCIO:007075)

Intentions

- Increase mothers' and daughters' autonomous motivation to
- Engage in and maintain selected PA or PA support behaviors
- Engage in problem-solving and setting and reviewing goals to facilitate engagement in selected PA and PA support behavior
- Engage with tools to monitor progress

Education • Inform

or being active

• Inform about importance of formulating intentions of how and where to provide support or be active

Provide demonstrations of mothers of teen girls or preteen girls to show the benefits they received as a result of providing support

Persuasion

- Encourage mothers and daughters to consider why being active might be important to them and the benefits they will receive
- Encourage mothers to consider why providing PA support may be important to them and how it would benefit their daughter and
 other family members

Modeling

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• Provide demonstrations of mothers and preteen girls describing their experiences of setting short- and long-term intentions to be provide support or be active and the associated benefits • Set behavior goal BCT (BCIO:007003)

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- Inform about health consequences BCT (BCIO:007063)
- Inform about social consequences BCT (BCIO:007064)
- Inform about environmental consequences BCT (BCIO:007176)
- Instruct how to perform behavior BCT (BCIO:007058)
- Demonstrate the behavior BCT (BCIO:007055)
- Prompt social comparison BCT (BCIO:007073)
- Present information from credible influence BCT (BCIO:007075)



Mechanisms of action and what needs to happen for behavior change to occur

Goals

- Support mothers and daughters to
- Use action planning, problem-solving, and goal setting to facilitate engagement in selected PA and PA support behaviors
- Use tools to monitor progress
- Overcome challenges encountered while setting and reviewing goals

Environmental context and resources

- Provide knowledge of and access to a variety of PA opportunities available so that mothers can support daughters' PA and daughters can engage in PA
- Provide materials or equipment so that mothers can support their daughters PA or daughters can be active

Social influences

- Develop mothers' and daughters' understanding of the type of support available to them regarding supporting their daughters' PA and being active
- Develop mothers' and daughters' ability to engage with the social support available to them

Emotion

 Promote positive and reduce unpleasant emotions associated with providing PA support (eg, embarrassment while being active with daughter) and being active (eg, enjoyment in activities)

- TrainingSelect and review personalized goals related
 - to the target behavior

Intervention functions for improving maternal

PA^a support and promoting PA in preteen girls

Enablement

- Provide support and guidance for setting realistic goals for mothers to provide support or to preteen girls to be physically active
- Affirm small achievable and interim goals and successes
- Prompt planning to provide PA support or be active during and after the intervention

Environmental restructuring

- Provide mothers or preteen daughters with practical equipment that can enable them to be active, for example, skipping ropes and balls
- Provide mothers and daughters with access to feasible and realistic options that enable them to be active during and after the intervention

Enablement

• Provide practical support for mothers and daughters to action plan and problem solve to engage in PA support and PA behaviors

Modeling

• Provide demonstrations of other mothers and girls describing their experiences for seeking and receiving social support and the benefits they received as a result

Enablement

• Prompt mothers and preteen daughters to seek social support and provide examples of types of social support available to them

Persuasion

• Help mothers and daughters recognize the positive feelings associated with providing support or being active

Enablement

- Provide safe and nonjudgmental environment for mothers or daughters to explore emotions around providing support or being active
- Provide opportunities for mothers or daughters to evaluate their emotional state after providing support or being active

Training

Develop mothers' and daughters' ability to do the following:

Behavioral regulation

- Select and apply PA or PA support behaviors into their daily life
- Implement tools to monitor PA or PA support progress
- Provide means so that mothers and daughters can assess their progress during the intervention and in the future

Enablement

 Provide opportunity, support, and tools to self-monitor PA support or PA behaviors and related habits

BCTs^b from BCTO^c for improving maternal PA support and promoting PA in preteen girls

- Set behavior goal BCT (BCIO:007003)
- Goal strategizing BCT (BCIO:007008)
- Action planning BCT
- (BCIO:007010)
- Provide feedback on behavior BCT (BCIO:007023)
- Self-monitor behavior BCT (BCIO:007024)
- Instruct how to perform behavior BCT (BCIO:007058)
- Demonstrate the behavior BCT (BCIO:007055)
- Practice behavior BCT (BCIO:007055)
- Set graded tasks BCT (BCIO:007100)
- Goal strategizing BCT (BCIO:007008)
- Action planning BCT (BCIO:007010)
- Social support BCT (BCIO:007028)
- Present information from credible influence BCT (BCIO:007075)
- Add objects to the environment BCT (BCIO:007156)
- Social support BCT (BCIO:007028)
- Advise to seek instrumental support BCT (BCIO:007030)
- Demonstrate the behavior BCT (BCIO:007055)
- Prompt social comparison BCT (BCIO:007073) Present information from credible influence
- BCT (BCIO:007075)
- Provide positive social consequence for behavior BCT (BCIO:007265)
- Persuade about personal capability BCT (BCIO:007137)
- Goal strategizing BCT (BCIO:007008)
- Social support BCT (BCIO:007028)
- Monitor emotional consequences BCT (BCIO:007066)
- Present information from credible influence BCT (BCIO:007075)
- Advise how to reduce negative emotions BCT (BCIO:050344)
- Reframe past behavior BCT (BCIO:007056)



Mechanisms of action and what needs to happen for behavior change to occur	Intervention functions for improving maternal PA ^a support and promoting PA in preteen girls	BCTs ^b from BCTO ^c for improving maternal PA support and promoting PA in preteen girls	
		 Goal strategizing BCT (BCIO:007008) Action planning BCT (BCIO:007010) Self-monitor behavior BCT (BCIO:007024) Instruct how to perform behavior BCT (BCIO:007058) Demonstrate the behavior BCT (BCIO:007055) Practice behavior BCT (BCIO:007055) Substitute behavior BCT (BCIO:007095) Context-specific repetition of behavior BCT (BCIO:007096) Provide positive social consequence for behavior BCT (BCIO:007265) Advise how to reduce negative emotions BCT (BCIO:050344) Prompt self-talk BCT (BCIO:007140) 	

Phase 2: Identify Intervention Functions, Content, and Implementation Options

The co-design workshops led to a number of recommendations from preteen girls, mothers, and teachers. These recommendations are illustrated in Table 3 using exemplar quotes and were categorized under a range of intervention functions as per the BCW intervention design process [37]. The intervention functions included education, training, persuasion, modeling, enablement, incentivization, and environmental restructuring. Potential modes of delivery discussed included face-to-face delivery, remote synchronous delivery (eg, Zoom Communications, Inc), or the use of a mHealth application. The mothers' group recommended the use of a mHealth application as a potential mode of delivery. These recommendations informed the selection of potential intervention functions, BCTs, and a proposed mode of delivery (ie, mHealth application) for each target behavior by the research team and were presented to the academic advisory panel for review. The final listing of intervention functions and BCTs for each mechanism of action are presented in Table 2. The academic advisory panel suggested applying of the principles of self-determination theory (SDT) [85] to the mHealth application content to enhance the communication style within which it is delivered [48].



 Table 3. Summary table of the co-design workshops.

	Summary of the recommendations from workshops	Example quotes	Related intervention functions
Improving mothers' knowledge and un- derstanding of PA ^a and PA support	 Provide mothers with information about the different types of PA, the benefits of PA, how to be active, and how much PA is recommended for daughters and themselves Provide mothers with information and instruction about how to support their daughters, particularly as they transition into teenage years Provide mothers with more information about what is available to them in their local area for their daughters to be active or for them to be active with their daughters Information could be provided through videos, social media, websites, an app, parent-teachers association, and word of mouth 	 "Maybe something about their mental and physical development, psychosocial development at this age that would help mothers understand what they're going through." [Imelda, daughter in fifth class] "Making sure mothers know how often children, girls at that age should be exercising each week. Maybe if they're not conscious that they're doing their weekly exercise, how are they supposed to pass it on to their children." [Kate, primary school teacher] "if you were thinking of an app and giving people ideas, could add the likes of yoga and stuff." [Susan, daughter in sixth class] 	 Education Training
Persuading mothers to support their daughters to be ac- tive	 Present mothers with examples of other mothers, coaches, teachers, and local sports partnership representatives explaining how, where, and the benefits of supporting daugh- ters to be active Provide examples of other mothers supporting their daughters to be active, how they over- came challenges, and being active themselves or with their daughters or family members Use mainstream media, social media, videos, websites, apps, and word of mouth to promote positive messages 	 "Or other mammies probably. I think other mammies would be good to see. Well, if they can balance it, I'm sure there's ways around that we can balance it." [Niamh, daughter in fourth class] "Someone giving them their personal story" [Sharon, primary school teacher] "an app would be great because the kids are on ityou can challenge your friends or family members and track what you have done." [Sinead, daughter in sixth class] 	PersuasionModeling
Practical help for mothers to engage in support behaviors	 Assistance with cost of activities, thus provide opportunities to try out in school or community for free first Provide materials for mothers to plan, record, and monitor their PA support behaviors at their own time and pace Feedback on behavior, in particular, if they engage in activities with daughters, either through technology or in person 	 "And the cost of living at the moment is crazy as well. Like you should be really dropping. If the cost of it came down a bit, I think a lot more people would do it, absolutely." [Michelle, daughter in fourth class] "If you're doing that at your own pace, in your own time. There was ideas on of, you can do this today, tomorrow, next week, or whatever, but also a blank space that you could fill in what you've done. I wasn't able to do this, but I did this, or we done that." [Sinead, daughter in sixth class] "You can break it into profiles like you can have yours, your partners, your daughters, whatever. It's under the one branch, basically. But you have your own little sections as well, where there's probably things tailor-made for you for that age group. You put in your age, you put in your interest or somethingLike Netflix." [Imelda, daughter in fifth class] 	 Incentivization Environmental restructuring



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	Sur	nmary of the recommendations from workshops	Exa	ample quotes	Rel fun	ated intervention ctions
Social support for mothers	•	Provide opportunities for mothers to get sup- port from other mothers of preteen daughters, for example, Facebook group Opportunities to get to know other mothers at daughters' activities	•	"every club should have a mammies group." [Niamh, daughter in fourth class] "then you could have like a chat group for them (mothers) on the app." [Susan, daughter in sixth class] "Yeah, support network through your app, through your group or whatever. Just like, oh, I've done this week, you might like it or I found this video, you might like it whatever." [Anna, primary school teacher] "Because some of the other parents have groups themselves where they can keep in contact. If one parent doesn't want to do it, the second parent may motivate them to do it. While we're all doing this together." [Joe, primary school teacher]	•	Enablement
Improving daugh- ters' knowledge and understanding of PA	•	Provide daughters with information and instruc- tions about the different types of PA, the ben- efits of PA, how to be active in their leisure time, and how much PA is recommended Provide daughters with information about what is available to them in their local area to be active. Information could be provided through videos, social media, websites, an app, and word of mouth	•	"tips on how to play a game or rules of the game." [Emily, fifth class] "we could have like speakers, people going into the classroom and talking to girls to join sports." [Sophie, sixth class] "Some people post on YouTube how to do skills. If you're a beginner and you want to learn some skills, you could just look at some YouTube videos and then that would do it." [Robyn, sixth class] "But the danger is that there are parents who don't know and don't care, and they probably won't look at an app. I would be afraid of that happeninglet the child have their own pro- file." [Jennifer, daughter in sixth class]	•	Education Training
Persuading daugh- ters to be active	•	Provide encouragement for daughters with examples of coaches, teachers, and local sports partnership representatives explaining how, where, and the benefits of being active Provide examples of other preteen girls and older adolescent girls being active and how they overcame challenges Use mainstream media, social media, videos, websites, apps, and word of mouth to promote positive messages	•	"You could tell them how worth it will be when they get stronger and healthier and they can run more. Basically, classes, carrying, and shopping, you'll just get quicker and it'll be- come easier." [Emily, fifth class] "They might because they are their own age feel like they are like them." [Aisling, fifth class] "Probably get girls that do sports, like making ads or something. If girls are watching their phones and you could do that." [Evie, sixth class] "Like that, if there were videos that they (girls) could click into." [Sharon, primary school teacher]	•	Persuasion Modeling
Practical help for daughters to engage in leisure time PA	•	Cost of activities is a barrier, so provide oppor- tunities to try them out in school or community for free first (initial cost) Provide materials for daughters to plan, record, and monitor their PA behaviors, including opportunity to arrange a reward of their choice for themselves Feedback on behavior if they engage in activ- ities Provide equipment and merchandise for daughters to practice with at home, for exam- ple, footballs, basketballs, skipping ropes, T- shirts, jerseys, hoodies, water bottles, and merchandise	•	"You can write a to-do list, so that way you can be more motivated to keep on sched- ule."[Emily fifth class] "They could lend them a ball to practice." [Maisie, fifth class] "Something like if you have all the jumpers and the jersey's, it makes you feel a part of the team, so you want to go again because you are part of this team." [Evie, sixth class] "If you could practice it at home to see if you like it." [Sarah fourth class]	•	Incentivization Environmental restructuring
Social support for daughters					•	Enablement

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Su	mmary of the recommendations from workshops	Exa	ample quotes	Related intervention functions
•	Provide opportunities for daughters to get support from other preteen girls, for example, bringing friends to activities and opportunities to ask girls their own age about certain activi- ties Opportunities to get to know other girls at ac- tivities. Can be organized by coaches, teachers, and other club members	•	"They could get a friend to join with them so that they have someone to talk to." [Aisling, fifth class] "Maybe if one of your friends was not on the team can now join the sport, you could even ask them if they wanted to come down to maybe one of your matches so they could have a look and see what the sport is all about and that might make them want to join." [Sophie sixth class]	

^aPA: physical activity.

Phase 3: Development, Refinement, and Evaluation of the Intervention Prototype

Intervention Component Development

The research team developed separate mobile apps for each target behavior (ie, mothers' support behaviors and preteen daughters' PA) using the *Pathverse* app design platform for mHealth research [86]. This platform enables researchers to develop mobile apps for testing without the requirement of software developers. It is a "no-code" development platform, which allows researchers to create a mobile app with "drag and drop" features instead of coding [87]. The *Pathverse* platform includes features such as the design of customized multimedia content, implementation of participant surveys, provision of self-monitoring tools, setting of personalized goals, the customization of app notifications, digital badges, and a community group chat option [86]. Intervention components

were developed within this platform to ensure that the relevant mechanisms of action were targeted and the related BCTs were enacted. Examples of how the intervention components relate to the targeted mechanisms of action are provided in Tables 4 and 5 for mothers and preteen daughters, respectively. For example, for the mothers' intervention, app module 3 titled "What does supporting your daughter involve?" includes infographics about the benefits of and the different ways for mothers to support their daughter to be active. It also includes videos of mothers describing their experiences of engaging in different supportive behaviors. Similarly, in the daughters' intervention, app module 3 titled "Why should you be active?" includes infographics and a video about the benefits of being active as well as a video of a preteen girl describing her experiences of engaging in PA. The mechanisms of action that these modules target are "knowledge," "beliefs about consequences," and "social influences."



Table 4. Intervention components mapped to the mechanisms of action in the mothers' intervention.

	Intervention components, activities, and resources	Mechanisms of action
Week 1: introduction to the study and group meeting (included after feedback from the co-design workshops, session 2)	• Face-to-face meeting with the mothers who are taking part in the study and introducing them to the research team and providing information about the study and consent forms, equipment and merchandise that are part of study (eg, footballs, skipping rope, yoga mat, T-shirts, and water bottles), demonstration of how to download the app and navigate the modules and features of the app, and inform mothers that they will receive certificate for taking part at the end of the study.	 Knowledge Beliefs about consequences Environmental context and resources
App module 1: getting started	• Includes a video with a welcome message and brief description about the study; a video demonstrating how to use the app and answer survey questions; and a survey with questions about demographics, PAa levels, and providing support for daughter's activities	• Knowledge
App module 2: what is PA and why is it important?	 Includes infographics about the module objectives, PA and benefits of being active, how active adults should be, how active children and teenagers should be, the benefits of PA for children and adolescents, and how active our teenage girls currently are A multiple-choice challenge question about how active children should be and a digital badge of congratula- tions for reaching the end of the module 	KnowledgeBeliefs about consequences
App module 3: what does supporting your daughter to be active involve?	 Includes infographics about the module objectives; why mothers were chosen for the study; the benefits of and ways to support their daughter to be active, for example, providing transportation to their daughter's activities; spectating at daughter's activities; and how and where mothers can be active with their daughters A video with a mother of preteen girls describing her experience of spectating at her daughter's activities A multiple-choice challenge question about what a mother can do to help support their daughter to be active and a digital badge of congratulations for reaching the end of the module 	KnowledgeBeliefs about consequencesSocial influences
App module 4: who can help you support your daughter?	 Infographics about the module objectives, the benefits of social support, having families as a source of support, how friends can support, how neighbors and people in the local community can support, how a daughter's friends can facilitate providing support, how coaches and teachers can support, and how support groups both web-based and in the local community can help mothers A video of mothers of preteen girls describing how they avail the social support available to them A multiple-choice question about who can help mothers with the day-to-day challenges of supporting their daughter to be active and a digital badge of congratulations for reaching the end of the module 	 Knowledge Beliefs about consequences Intentions Social influences



	Intervention components, activities, and resources	Mechanisms of action
App module 5: tips to help you support your daughter	 Infographics about the module objectives, the challenges mothers face when supporting their daughter and how to overcome them, to remember why supporting their daughter can help do what is important to them, tips for how to get started when feeling overwhelmed, details about shared decision-making and how it could be helpful, and how to manage a lapse in behavior A video with tips and advice from a role model, for example, mother of an athlete and how they support their daughter A multiple-choice questions about the types of support messages mothers would like to receive throughout the study as push notifications (eg, reminders, encouragement, praise, affirmations, or inspirational) and a digital badge of congratulations for reaching the end of the module 	 Knowledge Skills Identity Beliefs about capabilities Beliefs about consequences Intentions Social influences Emotion
App module 6: next steps: planning to support your daughter	 Includes infographics about the module objectives, what is goal setting, why and how to set goals, challenges associated with goal setting and how to overcome them, and showing mothers how they can selfmonitor their progress in the app Provide selection goals related to maternal PA support (eg, spectate at daughter's activity and mother and daughter coactivity) Mothers select and set a PA support goal of their choice, including when and where and how often the support behavior would be enacted, and a digital badge wishing mothers "good luck" with their chosen goal 	 Knowledge Skills Beliefs about capabilities Beliefs about consequences Intentions Goals Behavioral regulation
App module 7: booster module (included after feedback from co-design workshops, session 2)	 Includes infographics about the module objectives; recap on maternal PA support behaviors; how to overcome potential barriers to providing support, for example, using ifthen statements; and how lapses in behaviors are normal A video with messages of encouragement and support from other mothers of teenage girls and a digital badge of congratulations for reaching the end of the module 	 Knowledge Identity Beliefs about capabilities Beliefs about consequences Intentions Social influences Emotion Behavioral regulation
App module 8: final module	 Includes infographics with a summary of the study, recap on maternal PA support behaviors, goal setting, how to overcome challenges, where to look for social support, and what to do next A survey with questions about PA levels for mothers and daughters and regarding providing support for daughter's activities A survey providing feedback about acceptability and feasibility of the study and a digital badge of congratulations for reaching the end of the module 	 Knowledge Beliefs about consequences Intentions Social influences Behavioral regulation
App icon: resources	• Links to external websites providing information on local resources, family support services, and community events. Includes podcasts about parenting for PA with a focus on mothers and girls, videos of skills or activities that mothers can practice with daughter (eg, yoga, exercises, and football skills), and videos of other mothers of preteen girls discussing and sharing their experiences	 Knowledge Skills Beliefs about capabilities Beliefs about consequences Intentions Social influences Emotion
App icon: goals	 Summary of goals set for the duration of the study Mothers can review progress of goals set in the module, for example, spectate at daughter's activity or walk to school with daughter twice a week. Mothers can manually set and record additional goals of their choice 	IntentionsGoalsBehavioral regulation

	Intervention components, activities, and resources	Mechanisms of action
App icon: trackers history	• Option available for mothers to self-monitor their progress of goals set that are paired with a smartwatch that is synced with the app, for example, step count and exercise minutes. Mothers can self-monitor their daily steps and exercise minutes manually. Mothers manually self-monitor an activity (eg, walked to school with daughter), rate their enjoyment factor, and record any notes or points of interest	IntentionsGoalsBehavioral regulation
App icon: chat	• A feature that enables mothers to join a community forum to send and receive messages to and from the research team; an interactive forum where mothers share their experiences and strategies with other mothers who are partaking in the study; and avail of opportunities to meet other mother and daughter par- ticipants for group activities, as per information pro- vided by the research team or as suggested by other participants	Social influencesEmotion
Intervention feature: motivational messages	• Tailored prompts or cues sent as push notifications to mothers that are relative to their chosen goals and generic messages of encouragement, praise, or inspiration that change each day	 Beliefs about capabilities Identity Social influences Emotion
Week 8: conclusion of study and group meeting (included after feedback from co- design workshops, session 2)	• Face-to-face group meeting with mothers to award mothers with a certificate of completion, receive feedback on the intervention, and answer any questions	Social influences

^aPA: physical activity.



Table 5. Intervention components mapped to the mechanisms of action in the preteen girls' intervention.

	Intervention components, activities, and resources	Mechanisms of action
Week 1: introduction to the study and group meeting (included after feedback from the co- design workshops, session 2)	 Face-to-face meeting with the girls who are taking part in the study and introducing them to the research team and providing information about the study and consent forms, equipment and merchandise that are part of study (eg, footballs, skipping rope, yoga mat, T-shirts, and water bottles), demonstration how to download the app and navigate the modules and features of the app, and answers to queries or concerns girls may have Inform girls that they will receive a certificate for taking part at the end of the study 	 Knowledge Beliefs about consequences Environmental context and resources
App module 1: welcome to our study	• Includes a video with a welcome message and a brief description about the study; a video demonstrating how to use the app and answer survey questions; a survey with questions about demographics, PAa levels, and being active, and a digital badge of congratulations for reaching the end of the module	• Knowledge
App module 2: what is PA?	 Includes infographics about the module contents, what is PA, how active preteen girls need to be, and different ways to be active A multiple-choice challenge question about how many minutes per day should preteen girls be active for and a digital badge of congratulations for reaching the end of the module 	KnowledgeBeliefs about consequences
App module 3: why should you be active?	 Infographics about the module objectives and the benefits of being active Videos about the benefits of being active, with a preteen girl describing her experiences of being active and the associated benefits A multiple-choice challenge question about the benefits of being physically active and a digital badge of congratulations for reaching the end of the module 	KnowledgeBeliefs about consequencesSocial influences
App module 4: how can you be active?	 Includes infographics about the module objectives; walking or wheeling to school; outdoor play in the neighborhood with friends; going to local parks, woods, and playgrounds with family members; walking the dog as a way to be active; and yoga as a way to be active Videos about ways in which preteen girls can be active, of interview with famous female sports stars describing their experiences of playing sport and being active, with mothers and daughters dancing together as a way to be active, and of exercises that can be implemented at home as a way to be active A question about favorite way to be active and a digital badge of congratulations for reaching the end of the module 	 Knowledge Skills Beliefs about consequences Intentions Social influences
App module 5: who can you be active with?	 Includes infographics about the module objectives, who can support girls to be active and the benefits of social support, having fun with friends at school, playing with children in the neighborhood, and being active with family members Video of other preteen girls sharing their experiences of who they are active with A multiple-choice question about who girls can be active with and a digital badge of congratulations for reaching the end of the module 	 Knowledge Beliefs about consequences Intentions Social influences

	Intervention components, activities, and resources	Mechanisms of action
App module 6: tips to help you be active	 Includes infographics about the module's objectives; why some girls do not want to be active; about how family members or friends can support you to be active; and remembering why you chose to be active, with a support message about what to do when feeling overwhelmed and with a support message about staying positive in times of self-doubt and how to manage a lapse in behavior A video of preteen and teenage girls sharing their experiences and how they overcame challenges with being active. A video of a famous female sports star discussing their role models, how they overcame challenges related to staying active, and who supported them along the way. A video demonstrating ways to stay active at home An infographic with a question about tips to help girls be active A digital badge of congratulations for reaching the end of the module 	 Knowledge Skills Identity Beliefs about capabilities Beliefs about consequences Intentions Social influences Emotion
App module 7: let us get moving	 Includes infographics about the module's objectives, goal setting what is it, why and how to set goals, the challenges associated with goal setting and how to overcome them, and showing girls how they can monitor their progress in the app Provide a selection of goals related to leisure time PA for girls to choose from Girls select a goal of their choice, including when and where the activity would be enacted and with whom, and a digital badge wishing girls "good luck" with their chosen goal 	 Knowledge Skills Beliefs about capabilities Beliefs about consequences Intentions Goals Behavioral regulation
App module 8: booster module (included after feedback from the co-design workshops, ses- sion 2)	 Includes infographics about the module's objectives; revision of PA behaviors; revision of benefits of being active; how to overcome potential barriers to providing support, for example, using ifthen statements; and how lapses in behaviors are normal A video with support messages from other teenage girls and a digital badge of congratulations for reaching the end of the module 	 Knowledge Identity Beliefs about capabilities Beliefs about consequences Intentions Social influences Emotion Behavioral regulation
App module 9: final module	 Infographics about the module's objective; recap on PA and benefits of PA; recap on goal setting; and recap on how to overcome challenges, where to look for social support, and what to do next A survey with questions about PA levels and being active. A survey providing feedback about acceptability and feasibility of the study and a digital badge of congratulations for reaching the end of the module 	 Knowledge Beliefs about consequences Intentions Behavioral regulation
App icon: resources	 Links to websites of resources available to them in their local area Podcasts about PA, with a focus on girls Videos of other preteen girls and their experiences 	 Knowledge Skills Beliefs about capabilities Beliefs about consequences Intentions Social influences Emotion
App icon: goals	 Summary of goals set for the duration of the study Girls can review progress of goals set in the module (eg, walk or wheel to school with mother twice a week and practice skills at home) Girls can manually set and record additional goals of their choice 	IntentionsGoalsBehavioral regulation

1	ntervention components, activities, and resources	Mechanisms of action
App icon: trackers	 Option available for girls to self-monitor their progress of goals set that are paired with a smartwatch that is synced with the app (eg, step count and exercise minutes) Girls can self-monitor their daily steps and exercise minutes manually Girls manually self-monitor an activity (eg, practiced skills), rate their enjoyment factor, and record any notes or points of interest 	 Intentions Goals Behavioral regulation
App feature: motivational messages	Tailored prompts or cues sent as push notifications to girls that are age appropriate and relative to their chosen goals. Generic messages of encouragement, praise, or inspiration that change each day	Beliefs about capabilitiesIdentitySocial influencesEmotion
Week 8: conclusion of study and group meet- ing (included after feedback from the co-design workshops, session 2)	Face-to-face group meeting with girls to award girls with a certificate of completion, receive feedback on the intervention, and answer any questions	Social influences

Intervention Delivery

Intervention delivery was considered from 4 perspectives: mode of delivery, intervention setting, schedule, and delivery style in line with the BCIO [49]. As described in Phase 2: Identify Intervention Functions, Content, and Implementation Options section, the intervention's mode of delivery is primarily through a mobile app with a face-to-face component at the start and end of the intervention. The settings where the intervention takes place for mothers and daughters are at their household residences, local sport and exercise facilities, or in outdoor environments (ie, local parks, greens, forests, or beaches). The time frame chosen for the intervention schedule is based on the findings from formative research, which suggested that mother-daughter interventions lasting <12 weeks were likely to be more effective [82], and from engagement with participants in the co-design sessions and the academic advisory panel. The 8-week intervention schedule starts with face-to-face sessions for both mother and daughter participants. Over the course of the first 2 weeks of the intervention, 5 short modules are released for the participants to complete. Following completion of the modules, both mothers and daughters are then required to select and set a goal of their choice related to the target behavior (module 6). They then self-monitor their progress for 6 weeks. A booster module summarizing the intervention content is released during week 5 of the intervention, and there is a final module to be completed at the end of the intervention. To conclude the intervention and answer any questions, a second

face-to-face session is held with the mothers and daughters. Figure 2 provides an overview of the intervention schedule and details of the core learning outcomes of the modules for both apps.

To ensure the communication style in which the intervention content (ie, BCTs) is delivered is collaborative, autonomy supportive, and person centered [48], the principles of SDT [85] were applied. According to SDT, autonomous motivation for a behavior is developed through the satisfaction of the basic psychological needs of autonomy, competence, and relatedness [85]. The need for autonomy refers to a mother's or daughter's desire to have choice and to feel empowered in directing their own behavior [85]. For example, in the app, the goal-setting feature supports the basic need of autonomy by providing mothers and daughters with choices and options, enabling them to make decisions and take responsibility about how they chose to support their daughter or be active. The need for competence relates to a mother's or daughter's need to feel capable of achieving a desired outcome [85]. To illustrate, whenever mothers or daughters log activities on the app, it represents a confirmation that they sustained the behavior and thus enhances their feelings of competence. The need for relatedness denotes an individual's aspirations to feel a sense of belonging and connectedness with others [85]. For instance, the messaging feature enables mothers to connect with others who face the same challenges or achieve the same goals, thus promoting a sense of belonging and providing an opportunity to develop meaningful relations with other participants (Table 6).



Figure 2. Intervention schedule. PA: physical activity.

	Intervention groups				
	Group-based face-to-face introduction meeting with mothers of preteen girls		Group-based face-to-face introduction meeting with preteen daughters		
Ŭ	Mothers download app (Physical Activity Virtual Assistant-Mothers)	ď	Girls download app (Physical Activity Virtual Assistant-Daughters)		
Module 1	Learning outcomes: to understand how to use the app and to answer survey questions Timeline: to be completed by the end of week 1	Module	Learning outcomes: to understand how to use the app and to answer survey questions Timeline: to be completed by the end of week 1		
Module 2	Learning outcomes: to understand how active children and adults should be, ways to be active, and the benefits of being active Timeline: to be completed by the end of week 1	Module 2	Learning outcomes: to recognize how active girls need to be and the benefits of being active Timeline: to be completed by the end of week 1		
Module 3	Learning outcomes: to recognize different ways to provide support for their daughter to be active (eg, encouragement, logistical support, spectating, and coactivity) Timeline: to be completed by the end of week 1	Module 3	Learning outcomes: to understand the different ways that girls can be active in their leisure time (eg. active travel, sport, family activities, and outdoor play) Timeline: to be completed by the end of week 1		
Module 4	Learning outcomes: to identify who can help mothers to support their daughter to be active (eg, family, other mothers, support groups) Timeline: to be completed by the end of week 2	Module 4	Learning outcomes: to identify who girls can be active with (eg. friends, and family) Timeline: to be completed by the end of week 2		
Module 5	Learning outcomes: to describe the behavioral strategies available to support mothers (eg, communication approaches, remembering why, and positive self-talk) Timeline: to be completed by the end of week 2	Module 5	Learning outcomes: to describe the behavioral strategies available to support girls to be active (eg. remembering why, positive self-talk) Timeline: To be completed by the end of week 2		
Module 6	Learning outcomes: to apply problem-solving, goal-setting and self-monitoring techniques with respect to providing maternal PA support. Timeline: mothers select a goal of their choice to enact and monitor during weeks 3 to 8	Module 6	Learning outcomes: to apply problem solving, goal setting and self-monitoring techniques with respect to leisure time PA Timeline: daughters select a goal of their choice to enact and monitor during weeks 3-8		
Module 7	Learning outcomes: to reflect on and apply content from previous modules (1-6) Timeline: to be released during week 5	Module 7	Learning outcomes: to reflect on and apply content from previous modules (1-6) Timeline: to be released during week 5		
Module 8	Learning outcomes: to evaluate content from previous modules (1-7) and complete survey questions Timeline: to be completed at the end of week 8	Module 8	Learning outcomes: to evaluate content from previous modules (1-7) and complete survey Timeline: to be completed at the end of week 8		
	Group-based face-to-face final meeting with mothers of pre-teen girls		Group-based face-to-face final meeting with pre-teen daughters		



Table 6. Intervention delivery style, illustrating how app features align with the principles of self-determination theory.

App features	Description	Expected benefit
Autonomy-supportive feat	ures	
Goal setting	 This feature provides mothers and daughters with the option to choose from a set of predefined activities or exercises they wish to perform Mothers and daughters have the option to proactively set a goal they will perform, which is related to either maternal support for PAa or daughters' leisure time activity 	• The goal-setting feature supports the basic need of autonomy and promotes autonomous motivation by providing mothers and daughters with choices and options, enabling them to make decisions and take responsibility about how they choose to support their daughter and be active
Reminders	 The app will provide a reminder that is delivered as a push notification around the time the mothers and daughters should perform a specific activity The reminders are set by the mothers and daughters while they are selecting their goals and are optional 	 This feature helps mothers and daughters stay organized and on track with regard to the target behavior To reduce the feeling of acting out of pressure or control, this is an optional feature and can only be activated by the mothers and daughters
Motivational messages	 Feature with preset messages delivered as push notifications that provide encouragement, praise, and inspiration to perform target behaviors Messages are not task inherent and are provided to mothers and daughters at specified time intervals regardless of performance or completion of target behaviors A feature that allows mothers and daughters to write a brief message about why it is important for them to continue engaging in the target behavior. This self-directed message is available whenever needed and can be delivered as a push notification at chosen time intervals 	 Mothers and daughters provided feedback regarding the time and type of messages they would like to receive in an earlier module; the messages are tailored to suit their preferences The messages provide a meaningful rationale for engaging in the target behaviors The self-directed messages enable mothers and daughters to reflect on why they want to engage and sustain the behaviors
Competence-supportive fea	atures	
Self-monitoring	 Provides mothers and daughters with option to self-record the accomplishment of a goal or the completion of a task related to the target behaviors Mothers and daughters can record information about what happened on specific days (eg, bad weather, lots of homework, and stress at work) and rate their enjoyment factor while partaking 	 Whenever mothers or daughters log an activity, it represents a confirmation that they sustained the behavior and thus enhances their feelings of competence. The information entered helps mothers and daughter know themselves and understand their personal circumstances that influence the target behavior By entering data into the app, mothers and daughter express their interest in maintaining the behaviors
Activity feedback	 Provides mothers and daughters with information about how the task that was performed and provides them with details of their overall progress toward completing a predefined set of activities or goal. The information might be accompanied by a score (eg, step count) or encouragement message or badge (well done for completing the module) Timing of feedback is important to avoid unsatisfactory results such as underachievement; therefore, mothers and daughters choose to view their own feedback rather than receiving it unexpectedly The activity feedback needs to be personal, nonevaluative and specific to the task performed. 	 Positive feedback shows growth or improvement trends and enhance mothers' and daughters' sense of competence Activity feedback in the form of encouragement messages or badges can foster positive emotions toward the target behavior
Relatedness-supportive fea	tures	
Community forum	 Enables mothers and daughters to connect with other participants where they have the opportunity to interact and connect with others The research team will also facilitate opportunities for participants to meet and participate in activities 	 Messaging enables mothers and daughters to connect with other participants who face the same challenges They can share experiences, provide and receive sup- port, and experience a sense of belonging and related- ness

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App features	Description	Expected benefit
Modeling videos or podcasts	• Videos or podcasts of other mothers of preteen daughters and preteen girls sharing their experiences are embedded throughout the app's modules and in the resources icon	• These videos or podcasts provide mothers and girls with information and advice from other mothers and daughters who face similar challenges, which can help satisfy their need for relatedness and support their autonomous motivation to perform the target behavior over time

^aPA: physical activity.

Feedback From Co-Design Workshops and Intervention Refinement

After the development of the intervention content and delivery (with separate mobile apps for mothers and daughters), a second series of workshops was held to present the mobile apps to mothers, preteen girls, and teachers. All groups acknowledged how the intervention content was informative and persuasive, as shared by Sadie, fifth class:

Instead of just getting girls to join sports, giving good reasons as well. Instead of saying like, do you want to try this and try this? It was giving good reasons.

The girls found the videos of other girls' experiences regarding being active useful and inspiring, particularly those with girls their own age and a little older than them, as described by Sophie, sixth class:

Because if they're girls older, like what Evie said, they can be like role models. If they're the same age as you, then they could inspire you to join a team as well.

This was a similar finding for the mothers and teachers, who recognized how videos demonstrating experiences of "other mothers and girls they can relate to" (Kate, primary school teacher) would encourage maternal PA support and girls to be active. The mothers' and teachers' groups provided positive feedback when exploring the resources feature, which presented what was available to them in their local community for supporting their daughter to be active, as described by Susan, who has a daughter in sixth class:

That's brilliant. Little bits like that on it, You just let people know (about the resources feature) and you just click the link then and pick it up.

Several amendments were suggested at these workshops, which were then included in the final version of the intervention. For example, the mothers and teachers' groups suggested that it would be important to have an initial and final group-based face-to-face session as part of the intervention, as shared by Emer, a primary school teacher:

I think at the start, if you get them in like...that first meeting and first introduction thing is crucial. They feel invested in it.

As a result of this feedback, we introduced both an initial and final group-based face-to-face intervention sessions. Specifically, the initial session will enable mothers and preteen daughters to meet other users of the smartphone app and develop social connections, which can then be reinforced through using

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some of the social support features on the app. It would also allow mothers and preteen daughters to get instruction from the research team as to how to use the features of the smartphone app. The final face-to-face session will allow mothers and preteen daughters to share their experiences and provide an opportunity to sustain their social network developed as part of the intervention. It was also suggested to avoid providing all the modules on the app at once, instead phasing them in over a few weeks to prevent mothers and daughters from feeling overwhelmed by the information. This recommendation was shared by Michelle, whose daughter was in fourth class:

I'd phase it in, different bits of information every couple of weeks...I think if you throw too much at people, they won't bother looking at it. It's just too much information...People don't like too much information at once. It just bugs them.

Further suggestions were for a booster module to be added to the app to provide a reminder of the key features of the intervention content and for a podcast with parenting tips for teenage daughters to be added to the resources feature as "there's a lot of challenges out there. People are looking for...Looking for help and guidance." (Jennifer, daughter in sixth class).

Evaluation of the Intervention Prototype and Logic Model

The App Behavior Change Scale [78] was used as a checklist by the research team to assess the behavior change elements of the apps. Both proposed mobile apps included 18 items on the scale, indicating a high number of BCTs embedded in the apps and strong behavior change potential (Multimedia Appendix 5 [78]). The academic advisory panel reviewed and agreed on the final intervention prototype as well as the refined program theory. Figure 3 is a logic model that represents the program theory of the mother-daughter intervention. It depicts the flow of the intervention from (1) the identification of the problem (ie, preteen girls are not active enough) to (2) the inputs (ie, target behaviors of maternal PA support and preteen girls' PA), to (3) the mechanisms of action (ie, Table 1), to (4) the intervention components (ie, Tables 4 and 5), to (5) outputs (ie, mothers and daughters develop knowledge and understanding and improve motivation to enact target behaviors), to (6) short-term outcomes (ie, mothers and daughters enact target behaviors), to (7) long-term outcomes (ie, mothers and daughters maintain target behaviors), and finally (8) overall outcomes of the intervention (ie, improved PA levels in preteen girls). The app targeting mothers will be called the Physical Activity Virtual Assistant for Mothers (PAVA-M), whereas the app targeting their preteen daughters will be called Physical Activity Virtual Assistant for Daughters (PAVA-D) (Figures 4 and 5).

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Figure 3. Logic model of the intervention prototype. mHealth: mobile health; PA: physical activity; TDF: Theoretical Domains Framework.



Figure 4. Screenshots from the mothers' mobile app prototype.





Figure 5. Screenshots from the daughters' mobile app prototype.



Discussion

Principal Findings

This paper describes the systematic process to develop an evidence- and theory-informed intervention, using co-design methods, to increase PA in preteen girls of low SEP by incorporating maternal supportive behaviors. This is noteworthy given that levels of PA decline with age in preteen girls of low SEP [4,9], placing them at elevated risk of obesity, type 2 diabetes, and cardiovascular disease [8,10]. In keeping with MRC guidance, the intervention was refined through an iterative and dynamic process based on evidence, theory, feedback from co-design workshops with mothers of preteen daughters, preteen girls, and primary school teachers and input from a multidisciplinary academic advisory panel. This process resulted in the development of an intervention with 2 target behaviors, one targeting mothers' supportive behaviors for their daughters' PA and the other targeting preteen daughters' PA directly, which is ready for feasibility and acceptability testing.

The systematic approach applied in this study was guided by the BCW framework for developing interventions [37]. Using the BCW facilitated a rigorous analysis of the problem and how it could be potentially addressed. It also enabled the consideration and incorporation of evidence from several sources: the extant research literature, formative research [82-84], as well as the judgments of the academic advisory panel. We followed a step-by-step process that involved the following: identifying and specifying the target behaviors; conducting a thorough analysis of the barriers and enablers to these behaviors; using the TDF to identify the proposed mechanisms of action; and selecting feasible intervention functions, BCTs, and delivery methods. One study has used the BCW to develop a mother-daughter PA intervention for adolescent girls [41], but to our knowledge, this is the first study to use the BCW and TDF in conjunction with the BCIO to target children's PA through a theory-informed family-based intervention.

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The intervention prototype incorporates 27 BCTs, which is greater than the average of 8 to 10 BCTs per intervention reported in recent systematic reviews of family-based interventions targeting health behaviors such as PA [82,88]. There is some evidence to suggest that more effective interventions include a greater number of BCTs [89]. Furthermore, interventions that include a greater number of BCT clusters, with a threshold of at least 3 clusters, increase the likelihood of intervention effectiveness [90]. There were 13 BCTs clusters within the intervention prototype, and we incorporated particular clusters and specific techniques that have shown promise in theory-based interventions. For example, identity is an important mechanism of action for the promotion and maintenance of PA in adults and young people [63,91] and for providing parental PA support [64]. Our intervention is one of the few to include BCTs, which strengthen maternal identity for PA support and mother and daughter PA identity such as "reframe past behaviour BCT," "identify self as role model BCT," and "adopt changed self-identity BCT" [64]. In addition, this study incorporates BCTs that have proven effective in mother-daughter PA interventions and more broadly in health behavior change research. These include selecting a relevant behavioral goal, self-monitoring progress toward that goal, and developing problem-solving skills to address potential challenges [82,92-94].

This study engaged with end users (eg, mothers and preteen girls) and other relevant stakeholders (eg, primary school teachers) in the intervention development process using co-design methods. Despite continued advocacy for engaging children and adolescents in co-design methods, there is a paucity of studies targeting family-based PA that have applied such methods, in particular when it comes to children aged 10 to 12 years [59]. To the best of our knowledge, this is the first intervention prototype that meaningfully engaged with girls aged 10 to 12 years throughout the entire development process. The girls provided information into the selection of intervention components and towards the acceptability of intervention

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materials and resources [95]. Interestingly, the girls in the study suggested that a video of teenage girls slightly older than they were (ie, aged 13-14 years) describing how they overcame challenges to PA would be relatable and helpful for promoting PA in their cohort, an approach that the research team had not considered. Therefore, by including girls aged 10 to 12 years in the co-design process, this study increased the likelihood of acceptability and implementation at the intervention testing stage [56,96]. Furthermore, there is a lack of resources dedicated to detailing and evaluating the process of engaging with participants using co-design methods in the development of interventions [55,97]. As a result, there may be a need to develop guidance as to how to report the use of co-design principles in studies similar to the Template for Intervention Description and Replication (TIDieR) checklist [98] or the BCIO [46].

The mode of delivery of the intervention was another important intervention component. The selection of the mobile app was driven by the end users who wanted flexibility in how they engaged with the intervention. Indeed, mothers in the study highlighted the importance of being able to complete the intervention at their own pace, thus recommending a mobile app as the primary mode of delivery. Mothers often describe barriers to engaging in PA related to household, family, and occupational responsibilities [83]. Thus, the mobile app may allow individuals to complete intervention content at their own pace and facilitate adherence to the intervention. There is increased use of mobile apps as a mode of delivery for PA interventions [22,99,100]. However, research to date in children and adolescent populations is less frequent and is typically poorly designed [100]. Consequently, there is a need for further systematic theoretically informed research on the use of mobile apps with this population, a need which this study attempts to address. One of the challenges in using mobile apps as the mode of delivery for interventions is the cost of development of such apps, which can be prohibitive [101]. This study used the Pathverse platform to address this issue, as it provided our team with a rapid and cost-effective tool for creating and refining the intervention content [86,102]. Alongside the use of the BCW and related elements, we used the App Behavior Change Scale as a checklist during the development of the intervention to maximize the behavior change potential of the applications. However, it is important to note that the App Behavior Change Scale only measures the theoretical behavior change potential of the application, and it does not attempt to investigate the relationship between the actual features of application and behavioral outcomes [39]. Future work should consider the uptake, engagement, and user retention of the app by following frameworks such as the Reach, Effectiveness, Adoption, Implementation, and Maintenance framework [103].

An important component within intervention development is how an intervention is delivered, including the style of delivery of the intervention [48]. Typically, this focuses on human to human interaction; however, there is an increasing realization of the importance of considering a person-centered intervention delivery style, which is reflective and empathetic when designing applications and their related content [104]. Consequently, the principles of SDT [85] were applied to the intervention, ensuring that BCTs and specific features used in the intervention mapped to the basic psychological needs of autonomy, competence, and relatedness proposed by SDT [105-107]. Indeed, there is a growing body of work highlighting how applications underpinned by the SDT principles can strengthen digital therapeutic alliance and increase engagement in behaviors such as PA [107,108].

Future Directions

This study took place within the intervention development phase of the MRC framework [32]. Future research would involve using a no-code development app [102] to assess the feasibility of the intervention and inform decisions about how to progress to the following phases of intervention evaluation and implementation [32]. After engagement with the co-design participants, it was suggested that it was most feasible to promote this intervention via the school environment although it is targeting girls' PA outside of school hours. The school setting can reach children and adolescents of diverse racial and socioeconomic backgrounds and provides a ready-made social network for both mothers and daughters to engage with when undertaking the intervention [109,110]. Furthermore, it would allow for tailoring of the intervention resources within the school and local community that could support increased leisure time PA [109,110]. This is in line with research by Pfledderer et al [111] and van Sluijs et al [23] who recommend that interventions consider both family and community engagement (eg, family based and linked to school) to promote children's and adolescents' PA, particularly for underserved populations such as children and adolescents of low SEP. Although our preference is for mothers and daughters to take part in the intervention, the separate mobile app mode of delivery allows preteen girls to partake in the intervention regardless of their mothers' participation. This is an important feature, given that reaching parents of low SEP is often a challenge for interventions [112].

A limited number of these interventions are scaled-up and applied in real-world settings, identifying a significant research practice gap [113,114]. A recent review by Crane et al [115] found that health interventions (including PA interventions) that followed a research pathway were approximately 3 times more likely to have a positive effect on population health. Therefore, in line with recommendations by McKay et al [113], our future research would involve continuous planning for scaling-up, developing scale-up pathways, and evaluation of the scale-up throughout the duration of the intervention. Schools serving children with low SEP are frequently underresourced and often need more support to reach the same outcomes as their more advantaged counterparts [109,113]. To this end, maintaining relationships with schools and local community partners is essential in the scaling-up process to establish trust and identify potential implementation barriers [113,114]. This would involve hosting meetings with principals, teachers, and administrators to understand the pressing issues in their school environment; engaging with teachers, coaches, and local community partners to overcome implementation barriers; and developing collaborative strategies to encourage mothers and daughters to be physically active and sustain activity levels after the intervention [116]. Finally, based on the findings from this study, potential avenues for future research could be additional studies to evaluate the long-term effectiveness and sustainability

of the intervention, research exploring the factors influencing parental engagement in family-based mHealth interventions, and investigation into the impact of mobile app on PA behavior change in children and adolescents.

Strengths and Limitations

This study used a systematic, evidence- and theory-based approach to integrate a body of evidence from a systematic review, 2 qualitative studies, an academic advisory panel, and end users' knowledge to co-design and develop a novel intervention to promote PA in preteen girls of low SEP. The uniqueness of this study lies in following the first phase of the MRC framework, while using the BCW, the TDF, BCTO, and input from co-design workshops, which offered procedural direction, structure, and transparency. Annotating the BCIO entities enabled us to represent the intervention characteristics in a detailed and structured way, which can be used across contexts and disciplines. In addition, the entities' unique identifiers will facilitate the use of artificial intelligence including machine learning-based methods in data extraction and evidence synthesis [46]. Family-based PA interventions have been the focus of previous research [21,117]. However, no digital intervention to date has specifically focused in promoting PA in preteen girls of low SEP complemented by maternal support behaviors. Thus, this work fills an important gap by seeking to support an at-risk group. Furthermore, the involvement of key stakeholders in the development process is a key strength of this study. It ensures that the content of the intervention was adapted to accommodate the users' needs, making it useful and relevant, thus increasing the likelihood of a more feasible, acceptable, and ultimately effective intervention [56,118].

Our work has some limitations. First, the highly structured and systematic approach used to develop this intervention prototype

takes a significant amount of time and resources. For example, using the BCW, the TDF, and the BCTO requires considerable skills and training. Second, the process of converting BCTs into intervention content can be open to interpretation, and the research team had to make subjective and pragmatic decisions regarding intervention content throughout the process [119,120]. Third, we did not collect additional information regarding mothers' backgrounds such as their educational levels and PA experience as part of the co-design workshops. Finally, similar to other research [45], we used DEIS schools to recruit low-SEP preteen girls and their mothers. However, the data might not be fully representative of the target population, as DEIS schools are categorized by district, and it is possible that some girls or mothers in the school might not be of low SEP. Continued efforts should be made to target this cohort, for example, using household income or area level socioeconomic status.

Conclusions

In conclusion, this study uses a systematic evidence- and theory-based approach incorporating findings from a systematic review, formative qualitative research with mothers and preteen girls, input from an academic advisory panel, and knowledge from end users. This process was used to co-design an mHealth intervention prototype aimed at promoting PA in preteen girls, with a focus on maternal support behaviors, and is now ready for feasibility and acceptability testing. The novel contribution of this study lies in the use of theory and the meaningful involvement of key stakeholders throughout the development process. In addition, this study offers a practical example of how to integrate evidence, theory, and stakeholder engagement, which can be adjusted and tailored to fit different contexts and populations. Finally, the comprehensive annotation of the BCIO entities denotes the intervention characteristics in a structured manner that enables improved communication, replication, and implementation of interventions.

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Authors' Contributions

CB and JM conceptualized and led on the idea of Physical Activity Virtual Assistant for Mothers (PAVA-M) and Physical Activity Virtual Assistant for Daughters (PAVA-D). GO'D, AK, and RER helped develop the idea of PAVA-M and PAVA-D and provided guidance based on their expertise, including the section of mechanisms of action, behavior change techniques, and intervention components. CB and JM led on the co-design workshops and development and adaptation of the intervention content. CB and JM drafted the original manuscript. GO'D, AK, and RER reviewed the initial content and structure of the manuscript. All authors have read, revised, and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1 Behavior change intervention glossary. [DOCX File , 26 KB - pediatrics v8i1e62795 app1.docx]

Multimedia Appendix 2 Barriers and enablers to target behaviors. [DOCX File , 71 KB - pediatrics_v8i1e62795_app2.docx]

Multimedia Appendix 3 Co-design session 1. [DOCX File , 9452 KB - pediatrics_v8i1e62795_app3.docx]

Multimedia Appendix 4 Co-design session 2. [DOCX File , 613 KB - pediatrics v8i1e62795 app4.docx]

Multimedia Appendix 5 App Behavior Change Scale. [DOCX File , 19 KB - pediatrics v8i1e62795 app5.docx]

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Abbreviations

BCIO: Behaviour Change Intervention Ontology BCT: behavior change technique BCTO: Behaviour Change Technique Ontology BCW: Behaviour Change Wheel COM-B: Capability, Opportunity, and Motivation–Behavior mHealth: mobile health MRC: Medical Research Council PA: physical activity PAVA-D: Physical Activity Virtual Assistant for Daughters PAVA-M: Physical Activity Virtual Assistant for Mothers SDT: self-determination theory SEP: socioeconomic position TDF: Theoretical Domains Framework TIDieR: Template for Intervention Description and Replication

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Original Paper

Augmenting Parenting Programs With the Pause Mobile App: Mixed Methods Evaluation

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Abstract

Background: Parenting programs are the recommended treatment for common mental health problems of childhood such as conduct disorder. In the United Kingdom, local authorities have responsibility for providing or commissioning these programs through face-to-face and video call weekly groups and e-learning style asynchronous offerings. However, there has been a shortage of research into the potential of digital resources to augment and enhance parenting groups.

Objective: This pilot study aimed to explore whether providing digital microinterventions in a mobile app (Pause) to augment parenting programs is a feasible strategy. Pause fits into parenting programs and prompts and supports parents to use each week's new parenting skill at home. Specifically, we want to understand (1) whether parents use Pause, (2) what type of features or tools in Pause are most frequently used for support, and (3) what are the perceived strengths and weaknesses of Pause.

Methods: Pause was provided to parents attending 3 of the most common parenting programs delivered across 3 local authorities in the United Kingdom. During weekly sessions, parents were supported to add "tools" in the app, which mapped onto the training in their session, for example, distracting their child, setting age-appropriate consequences, and using praise. Preprogram surveys were obtained at the first session. After programs were completed, postprogram surveys were administered to measure app use, gather which tools parents used, and explore the strengths and weaknesses of the app. Participants and practitioners were invited for interviews, where the strengths and weaknesses of augmenting programs with Pause were discussed in more detail.

Results: In total, 53 parents were recruited from groups. A total of 25 of 53 (47%) parents completed postsurveys distributed at their final parenting group session, in keeping with typical rates of attrition in parenting programs. In addition, 7 parents and 3 practitioners agreed to interviews after the program. Most of the parents (23/25, 92%) had used Pause. Other than the journal, used by 17 parents, the most popular tools were the relax tool and praise tool, each used by 10 parents. Survey data revealed specific strengths and weaknesses of the tools in Pause, particularly highlighting that parents wanted Pause to provide more ideas for distraction or relaxation activities. Interviews revealed the challenges parents attending programs face, the range of family members using Pause, and the diverse settings where it was used. Interviews also revealed specific opportunities for improving the user interface and for addressing challenges in the journaling function.

Conclusions: This pilot study found good acceptability and engagement with Pause. Interviews revealed promising evidence, suggesting that Pause may improve family life and aid child behavior change. Future research should evaluate whether adding Pause to parenting programs increases their positive effects on children's behavior and mental health.

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KEYWORDS

digital microintervention; parenting app; parenting; children's mental health; local authority

Introduction

Background

Parenting programs are recommended as the first-line treatment for common mental health problems of childhood such as disruptive behavior disorders and attention-deficit/hyperactivity disorder [1-3]. In the United Kingdom, such parenting programs are predominantly commissioned or delivered through local government [4]. Provision tends to include groups (whether face-to-face or via video call) and e-learning style asynchronous offerings [4,5]. However, there has been a shortage of research into the potential of digital resources and mobile technology to augment parenting groups and enhance change in parenting style to better match evidence-based approaches [6,7].

Poor parent engagement is an ongoing challenge in these programs, stopping families from receiving the full benefit of programs, so it is important to evaluate means of augmenting programs to maximize engagement and therefore increase impact. One systematic review found that only around half of parents who start a parenting program finish it [8]. A large study of a web-based parenting intervention found that, in practice, as few as 7% of referred parents complete the program [9]. This problem may arise in part due to the didactic delivery of programs, which is not well-suited to all parents [10]. Moreover, education is not always sufficient for behavior change. Insights from behavioral economics can ensure that interventions to encourage health-promoting behaviors achieve their potential [11,12]. For example, social norm insights can help avoid situations, where interventions aimed at reducing harmful behaviors in fact normalize and increase them [13].

Digital microinterventions provide one potential means of promoting parenting style change due to the focus on optimizing engagement. Digital microinterventions involve a trigger situation prompting a decision rule process, which is mediated by an app but situated within a wider therapeutic process [14].

Pause (Pause Ltd) is a digital platform that was developed to provide parents with a selection of digital microinterventions augment parenting programs [6]. The digital to microinterventions in Pause-called "tools"-each corresponds to one of the skills parents are taught during parenting programs, such as praise, time together, or distract. As the parenting program proceeds and new skills are taught, group leaders support parents to add the corresponding tool to their toolkit on Pause [10]. In between group sessions, they can use those tools to help them increase the frequency and quality of their use of that particular skill. For example, parents can use the "distract tool" to help them think about how to distract their child from emotions or from unwanted behavior. The distract tool includes 4 age-appropriate distraction ideas and includes space for parents to add ideas for ways to distract their particular child. Another tool, the relax zone, guides parents through teaching their child grounding activities, which they can use to manage anxiety or overwhelming emotions. Finally, the consequences tool suggests age- and neurodevelopmentally appropriate consequences and

guides parents through the process of setting short feasible consequences and getting back on good terms immediately after. The wide range of tools is designed either to be used in the heat of the moment when parents face a challenge or to structure a planned interaction. Previous papers describe the development of the app [6,7].

Best practice software development is iterative and user-centered. It is therefore important to find out whether the approach taken in Pause is acceptable and engaging to parents, whether any tools are not engaging, and what are the strengths and limitations of this approach.

Aims

This pilot study aimed to explore whether providing digital microinterventions in a mobile app (Pause) to augment parenting programs is a feasible strategy. Specifically, we want to understand (1) whether parents use Pause, (2) what type of features or tools in Pause are most frequently used for support, and (3) what are the strengths and weaknesses of Pause.

Methods

Participants

Participants were recruited through 3 local authorities in the United Kingdom: Wiltshire Council, Leicestershire Council, and Buckinghamshire Council. To accurately draw from Pause's population of interest, inclusion criteria were pragmatic. Included participants were attendees at a parenting program run by a local authority whether or not they had legal parenthood. People younger than 18 years of age were excluded, and people who did not have a mobile phone were unable to participate.

Seven weekly groups were selected for inclusion based on practical considerations at local authorities. All attendees of these groups running between January and June 2024 were invited to participate in the study. Recruitment was conducted directly by parenting practitioners who offered participants QR codes to complete pre- and posttest surveys on Qualtrics (Lake Technology Management, LLC) and to download Pause.

Parenting practitioners' leading groups received 2 personalized training sessions from researchers, where they were shown the relevant tools in Pause. They also had access to ongoing technical and practical support from the research team throughout the study.

Procedures

Practitioners' leading participating groups had 2 training sessions to show them how to add the Pause app to their programs. This training was different for the 3 groups, which were running different programs (Wiltshire Council used a Care for the Family program, Buckinghamshire Council used a Triple P program). There was no control group. In the first session, participants were given a chance to download the Pause app, consent to participation, and complete the preintervention surveys. These surveys included demographic information (sex,

decade of age, language spoken, and whether they had a degree), the Parenting Sense of Competence Scale (PSOC), Warwick Edinburgh Well-Being Scale, and the Strengths and Difficulties Questionnaire Conduct Subscale (SDQ-c) [15-17]. At every subsequent session, the practitioner advised participants which "tool" from the Pause app would complement the topic of the session. In every respect aside from the use of the app, practitioners completed the programs as usual. At the end of the study, parents received a second survey, which repeated the consent process and the rest of the preintervention survey as well as including questions about their use of the Pause app and their experience. Specifically, participants were asked which tools on the Pause app had been used. For each tool they had used, they were asked how many times it was used, what was good about it, and what could be improved. All parents who completed these surveys were invited to attend a video call interview with a researcher to explain on how Pause fits into their experience of the parenting program. Finally, parenting practitioners who had led groups using Pause were invited to be interviewed. Interview topic guides are included in Multimedia Appendix 1. Children were not directly involved in this study.

Ethical Considerations

All participants provided informed consent. Participants received a US \$13.38 voucher for each survey and a US \$26.76 voucher for the interview, up to a maximum of US \$53.52. Ethics approval was provided by the Biomedical Sciences Research Ethics Committee at the University of Warwick (BSREC 14/23-24).

Analysis

Demographics

Demographics were described using descriptive statistics, including SDs for continuous measures and percentages for binary measures. The characteristics of those who dropped out were compared with those who completed both surveys using 2-tailed t tests and chi-square tests using Stata (version 17; StataCorp LLC).

RQ 1: Did Parents Use Pause?

This research question (RQ) was assessed in 2 ways using data from surveys. First, on the basis that there were no systematic differences between those who completed the postintervention survey and those who were lost to follow-up, we assumed that rates of using the Pause app were the same among those who completed the second survey and those who did not. To measure this, we divided the number who used Pause by the number who completed both surveys.

Second, we calculated the worst-case scenario engagement rate by assuming that none of those who failed to complete the second survey downloaded and used Pause. To measure this, we divided the number who used Pause by the number who completed at least 1 survey.

RQ 2: Which Tools Did Parents Use Pause to Support?

This RQ was assessed using a survey self-report of which tools within Pause were used. Descriptive statistics were used to present how many people used each tool and how many times.

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These results were presented in a stacked bar chart constructed using Microsoft Excel (version 365). Practitioner interviews were used to evaluate the validity of these findings.

RQ3: What Are the Strengths and Weaknesses of Pause?

This RQ was assessed using thematic analysis based on 3 data sources, free-text data from all postintervention surveys, parent interviews, and practitioner interviews. Surveys were reported using illustrative quotes from each question. Interviews were analyzed using thematic analysis using Taguette qualitative software, conducted following Braun and Clarke's 6 stages, and within a philosophical framework informed by user-centered design [18-20]. Specifically, following familiarization with the data (stage 1), the researchers generated initial codes (stage 2) and searched for themes (stage 3) while remaining attentive to the context of users, their journey through parenting support, the usability of the technology, and opportunities for further refinement-rather than viewing the app as a finished product that either "worked" or "did not." Following these stages, the themes were refined (stage 4), defined and named (stage 5), before being written up (stage 6). Within this framework, the researchers distinguished parents' experience of existing parenting courses from the technology. The technology is added to augment the courses so both are reported because (1) understanding the use of Pause entails a rich understanding of the experience of people in courses and (2) explicitly reporting both reduces the risk of wrongly eliding the course and the app. The resulting coding frame was reported with illustrative quotes.

Results

Participants

In total, 53 parents completed preintervention surveys. Among them, 25 completed the postintervention surveys, 3 of whom had failed to complete preintervention surveys.

The 25 of those who completed the postintervention survey included 22 (88%) female participants, and 3 others were male participants. In total, 3 were in their 20s, 15 were in their 30s, 6 were in their 40s, and 1 was 50 years and older of age. None were in their teenage years. Most of them (n=23, 92%) reported that English was the main language they spoke at home. Only 6 (24%) had a bachelor degree or higher. The mean age of the child they were primarily concerned about was 6.7 (range 3-13) years. A total of 20 were from the Wiltshire site, 3 from Buckinghamshire, and 2 from Leicestershire.

The 22 completers had a mean PSOC score of 55.2 (SD 2.09). In total, 8 (37%) parents scored below the cutoff for low confidence of 58 [21]. The 22 completers had a mean SDQ-c score of 5.5 (SD 2.24), and 18 (82%) scored above the cutoff of 4 for abnormal conduct problems [22]. The 22 completers had a mean adjusted Short Warwick Edinburgh Mental Well-Being Scale (SWEMWBS) score of 18.9 (SD 2.96), and 14 (64%) scored below the cutoff for the lowest 15% of the population (cutoff=19.5) [23].

There were no significant differences between the 22 who completed both surveys and the 29 who only completed the baseline surveys with respect to demographics (sex, age, language spoken at home, educational level, and child age) or
survey responses (PSOC, SDQ-c, and SWEMWBS). Table 1 compares those who completed both surveys with those who only completed one.

Seven participants agreed to interviews. All had completed baseline measures. A total of 4 were from Wiltshire, 1 from Buckinghamshire, and 2 from Leicestershire. They were all female participants, all spoke English at home, and 2 had bachelor degrees. In total, 1 was in her 20s, 5 were in their 30s, and 1 was in her 40s. The mean age of the child they were

primarily concerned about was 7.4 (range 4-13) years. Compared with all participants, interviewees had slightly higher confidence (PSOC=58.4; t_{51} =0.943; P=.35), slightly lower conduct problems (SDQ-c=5.0; t_{51} =-1.19; P=.24), and slightly higher well-being (adjusted SWEMWBS=19.8; t_{51} =1.14; P=.26). None of these differences were significant at the .05 level. In addition, we interviewed 3 parenting practitioners who had delivered the Pause program. They were all female, and all from Wiltshire Council.

Table 1. Comparing those who completed only the preintervention survey with those who completed pre- and postintervention surveys.

Only preintervention survey	Both pre- and postintervention surveys	Statistical tests	
		Statistics	P value
55.1 (1.87)	55.2 (2.09)	$t_{49} = -0.044$.96
6.14 (1.81)	5.46 (2.24)	$t_{49} = 1.21$.23
18.6 (2.36)	18.9 (2.96)	$t_{49} = -0.454$.65
3.1 (0.62)	3.2 (0.81)	$t_{49} = -0.62$.54
5.9 (2.1)	6.5 (2.5)	$t_{49} = -0.93$.36
25 (86)	22 (86)	χ^2_1 =0.0003	.99
25 (86)	20 (91)	$\chi^2_1=0.3$.61
7 (24)	8 (36)	$\chi^2_1=0.9$.34
	Only preintervention survey 55.1 (1.87) 6.14 (1.81) 18.6 (2.36) 3.1 (0.62) 5.9 (2.1) 25 (86) 25 (86) 7 (24)	Only preintervention survey Both pre- and postintervention surveys 55.1 (1.87) 55.2 (2.09) 6.14 (1.81) 5.46 (2.24) 18.6 (2.36) 18.9 (2.96) 3.1 (0.62) 3.2 (0.81) 5.9 (2.1) 6.5 (2.5) 25 (86) 22 (86) 25 (86) 20 (91) 7 (24) 8 (36)	Only preintervention surveyBoth pre- and postintervention surveysStatistical tests $55.1 (1.87)$ $55.2 (2.09)$ $t_{49}=-0.044$ $6.14 (1.81)$ $5.46 (2.24)$ $t_{49}=-1.21$ $18.6 (2.36)$ $18.9 (2.96)$ $t_{49}=-0.454$ $3.1 (0.62)$ $3.2 (0.81)$ $t_{49}=-0.62$ $5.9 (2.1)$ $6.5 (2.5)$ $t_{49}=-0.93$ $25 (86)$ $22 (86)$ $\chi^2_1=0.0003$ $25 (86)$ $20 (91)$ $\chi^2_1=0.3$ $7 (24)$ $8 (36)$ $\chi^2_1=0.9$

^aPSOC: Parenting Sense of Competence Scale.

^bSDQ-c: Strengths and Difficulties Questionnaire Conduct Subscale.

^cWEMWBS: Warwick Edinburgh Well-Being Scale.

RQ 1: Did Parents Use Pause?

In total, 23 of 25 (92%) parents had downloaded and used the Pause app, and 2 (8%) did not. Both cited concerns about personal data, and 1 reported thinking that using an app to support parenting was inappropriate. They were 1 male and 1 female participant, both in their 30s, both spoke English at home, neither had bachelor degrees, and both from the Wiltshire site.

Given the absence of systematic differences between those who did not complete the postintervention survey and those who completed both surveys, we could assume that the app uptake rate of 92% (23/25) held across the whole sample. However, it is also possible that an unmeasured factor linked both engagement and completion of the second survey. A worst-case scenario estimate is that none of the 29 who dropped out used the app so only 23 of 53 (43%) downloaded and used the Pause app.

RQ 2: Which Skills Did Parents Use Pause to Support?

The core components of the Pause app are the child and parent profiles and the journals; in addition to which, there were 15 digital "tools" available to parents. In total, 20 (87%) parents completed the one-off reflective exercise to create a profile for their children, and 15 (65%) completed the one-off reflective activity to create their own parent profile. Only 12 (52%)

reported that this was a positive experience, but 2 said that there were too many questions.

In total, 17 (74%) parents had used the journal. Among them, 6 (26%) only used it once, 7 (30%) used it 2 or 3 times, and 4 (17%) used it more than 4 times. A total of 6 (26%) never used it (3 were unaware of the journal, 1 found it confusing, 1 did not think journaling would be helpful, and 1 did not explain why). Among those who used it, for 6 of 17, their favorite feature was writing down thoughts, and for 6 (26%), it was reading it later and noticing their progress. However, when asked about problems with the journal, 7 (30%) reported that they found journaling time-consuming, 3 (313%) reported that they struggled to put thoughts into words, and 2 (9%) reported that they were worried about privacy.

In total, 15 digital "tools" were available for parents through the Pause app. Participating parents were in 3 different parenting programs so they were supported to use different tools. The relax and praise tools were used by 10 (40%) parents each. Both the relax and praise tools were used only once by 6 parents, perhaps because they contain learnable reminders. By contrast, the time together and ignore tools were used more than twice by 7 (28%) and 6 (24%) parents, respectively, only 2 or 1 used the tool only once. Similarly, the distract module was only used by 7 (28%) overall, but 5 of those used it 4 or more times. Figure 1 shows how many parents used each tool and how many times.

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Figure 1. How many parents used each tool and how many times?



RQ 3: What Are the Strengths and Limitations of Pause?

Part A: Survey Results

Surveyed parents gave 157 comments about what the "best things" about tools were and also suggested changes. Strengths

of the tools included providing a good reminder and a useful distraction, children liking the tools, and creating a helpful structure. Proposed changes included requests for more examples and recommendations, more customization, and simplification. Table 2 describes representative survey results as they relate to each tool.



 Table 2. Illustrative quotes of best things and suggested changes to Pause tools.

	Best thing	Suggested changes
Relax	"Daughter found it good when she started struggling she would ask for it as said it helped her" and "It created a distraction when my child's meltdown was about to es- calate" [Leicestershire].	"To have more ideas" [Wiltshire].
Praise	"It helps break things down" and "reminder how important it is" [Leicestershire].	"Quite limited, with only a few options" [Wiltshire].
Time together	"It gave us time together and daughter would ask for it" and "The short timers making it easier to show them how long we have" [Leicestershire].	"To add ideas of an activity" [Leicester- shire].
Reflect	"Being made aware of how you're feeling as the parent and how it can affect how we parent, it certainly makes you think about what you can do to change your mood in order to be better for your children and in supporting your children through their emotions and difficulties" [Leicestershire].	"Include 'sad' into the emotions" [Leicester- shire].
Ignore	"Was a good distraction whilst trying to ignore daughter when she was saying silly/rude words" and "suggestion to distract and timer to help"; "Asks for the reason as to what the need was that caused the behaviour which needed ignoring" [Leicestershire].	"Be able to customise how to ignore not just present one" [Wiltshire].
Family chart	"Being able to set targets for her to follow, and tracking the stars" [Leicestershire].	a
Distract	"Daughter really liked this one, especially if she felt like she was struggling in a situ- ation this would give her something else to focus on and would stop a meltdown" and "Having something to use when out and about" [Leicestershire].	"Add more distract examples" and "be able to customise options" [Wiltshire].
Consequences	"Little games in natural consequences section" [Leicestershire].	"Need to remember to actually look at it. Also didn't look in the moment" [Leicester- shire].
Feeling check	"Making them aware of how they're feeling at different times" [Leicestershire].	"Suggestions as to what could be making them feel that way" [Leicestershire].
Before, during, and after	"It was a good way to unpick incidents" and "Breaks it down so you can see what happens during a meltdown and what could have triggered it!" [Leicestershire].	"Option to edit which child as I posted to the wrong child and could not change" and "Be able to voice note it would make it easier to document the event" [Leicester- shire].
Quick timer	"Handy and the children can see the timer" [Leicestershire].	_
Time-out	"Handy to have easily accessible" [Buckinghamshire].	"Descriptive example of how to use the option" [Wiltshire].
Bedtime praise	"Prompts" [Buckinghamshire].	_
Family guide- lines	_	"Long winded" [Wiltshire].
My body	"It gives you prompts on what to discuss with your child when talking about body" [Wiltshire].	_

^aNot available.

Part B: Interview Results

and Pause app; and (3) the outcomes and effects of the Pause app. The themes are outlined in Table 3.

Overview

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Three themes emerged from these interviews: (1) features of programs without Pause; (2) the interface between parent, child,

Macrolevel themes	Microlevel themes	
Theme 1: features of programs without Pause	Theme 1.1: what made programs effective?Theme 1.2: what made programs difficult?	
Theme 2: the interface between parent, child, and app	Theme 2.1: how Pause was used?Theme 2.2: interaction with the app	
Theme 3: the outcomes and effects of Pause	 Theme 3.1: Pause enhances parenting programs Theme 3.2: Pause improves behavior and enhances family life 	

Theme 1: Features of Programs Without Pause (Overview)

Rather than solely discussing Pause, we also explored parents' experience of the program in order to ensure that the strengths and weaknesses of programs in general were not elided with the strengths and weaknesses of Pause. We report these below to illustrate the context in which Pause is being used.

Theme 1.1: What Made Programs Effective?

Participants talked about how their groups were useful because of program content, other parents, and effective practitioners. Nine commented on the content of the program, always positively.

I really enjoyed it. I found out a lot of helpful information, so it was really good. [Participant 2, parent]

The composition of the group, other parents facing similar challenges at home, also added value to the group experience for 4 parents.

I'm going through all the things with my child by myself. It kind of makes you feel isolated, so hearing from other parents that they're having the same or similar issues, I think that was the most helpful because it made me feel like it wasn't just me. [Participant 1, parent]

The careful and inclusive didactic approach of practitioners was also highlighted as a key feature of what made groups useful. Three practitioners specifically mentioned the quality of the explanations.

they made sure everyone understood each week what we were doing and made sure by the end of it, everyone was clear of what it was. [Participant 5, parent]

Theme 1.2: What Made Programs Difficult?

The reasons parents were attending groups also made programs difficult. Specifically, family life was already very difficult due to their children's challenges, and many demands on their time and attention could also lead to attendance problems. Four parents described the problems that had motivated them to seek help for their family, which were primarily due to externalizing behaviors such as meltdowns, anger, violence, and shouting.

My son is quite angry and has a lot of angry outbursts. For a long time, I thought he was just being boisterous, but when the same problems started happening at school, I realized there might be something else going on. [Participant 1, parent]

Six participants commented on the children's neurodevelopmental differences, special educational needs, or subclinical behavior problems, as well as the challenges of long waiting lists and parents' own problems. They did not mention anxiety or low mood among their children.

Three out of my four (are) diagnosed autistic and ADHD. My 4 year old is ... he's on waiting lists but he's not quite being diagnosed yet, but he has got traits. I've looked back into my past and things like

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that and I'm now on waiting lists for an ASD and ADHD diagnosis for myself. [Participant 6, parent]

All parents were asked about their attendance. Parents and practitioners identified that it is hard for single parents to attend, especially when they have several children with neurodevelopmental disorders, but parents also reported that events come up. Video call sessions were thought to have made it easier to attend.

It's rare that you'll get a parent that will attend every single week, because there may be something that's come up, you know, like, obviously, the parents are there and the children have got disabilities. [Participant 8, practitioner]

All 3 practitioners, but no parents, also gave examples of reasons parents struggle to engage such as circumstances or demographics. For example, unwilling to change parenting style, feeling overwhelmed in groups, or requiring translation.

Another barrier is if parents are not willing to make changes but blame everything onto the child. [Participant 8, practitioner]

Theme 2: The Interface Between Parent, Child, and App (Overview)

Participants reported how Pause was used, noting which people used it, where they used, and which parts of the app they used. They also commented on their experience of interacting with the app, including the user interface and the idea databases.

Theme 2.1: How Pause Was Used

Participants commented on who, where, and when Pause was used and which parts of Pause were used. Nine participants mentioned who used Pause. Pause was used by parents and children. Sometimes it was used by parents and children together, sometimes by parents without their children, and occasionally by children alone. Sometimes it was only used with 1 child, sometimes it was used with all children, and sometimes it was used by the extended family.

I've got two children. The oldest is nearly 15, so he wasn't really involved that much. But the youngest is 4, and it was very age-appropriate. [Participant 1, parent]

Five participants mentioned the settings or scenarios where Pause was used. Parents used the app at relatives' houses, in shops and restaurants, and in their bedrooms alone. They used it during the day, with their children, and also at night alone.

It's that big time reassurance that we're going out. We've just been to my nan's and we've had meltdown after meltdown. So I said to her, do you want to do the breathing? And she said yeah, and she sat there with it for a good five minutes, like going through them all. So yeah, it's a great reassurance knowing it's just there and it's a click of a button away. [Participant 5, parent]

Eight participants commented on specific modules. In total, 11 different modules were mentioned as particularly useful, particularly relax and distract, which were mentioned favorably by 3 parents.

We also used the "distract" function a lot. If something was brewing, I'd quickly check for an idea, and now I have a few ideas in my head. It's hard to think on the spot when everything is going on, so it was helpful to have ideas that worked, and it could shift their thought process for a minute. [Participant 3, parent]

Five participants commented specifically on the function of Pause as a reminder. Parents appreciate Pause providing reminders of when and how to use evidence-based skills.

it's been quite helpful as, like, reminders to do things. I've always felt like I'm quite good at praise, but actually having that reminder there, because things can get quite negative quite quickly when you've got behaviors that are quite unwanted. But it's quite good as a reminder. [Participant 7, parent]

Five participants commented on the good fit between the modules of the Pause app and the content of the parenting programs.

I liked, as the course was going on, you could add the modules that you were talking about.

Or, you know, so you didn't have everything all in one go. So, as you were going on in the course, they were like, "oh, you can add this module now to your app." I liked that feature because then ... You haven't got everything in one go. [Participant 6, parent]

Theme 2.2: Interaction With the App

Participants commented freely on the strengths and weaknesses of the user interface, offering ideas for additional features of Pause and particularly requesting additional personalized ideas added to the app.

Nine participants commented on the user interface. Overall, and in general, parents found it easy to use the app. When assigned tasks during the interview, they were almost always able to find things immediately, and all succeeded in the tasks. There were instances of bugs where text entry boxes and buttons did not display properly because the app remains in its infancy.

It's really easy to use. So it's fairly self-explanatory. So as you go on to it, you've got your homepage with different sections. Obviously, you can add the sections you want. And it has come in really handy. [Participant 5, parent]

Parents engaged with the app and had suggestions about potential features that could be added to the app or ideas for improvements to the app. Seven participants offered ideas for additional features. These suggestions related to both interaction with the app and the functions of the app.

I wish there was a branch-off for a child version, so he could have it on his iPad. Then he would know when he's starting to feel frustrated. I've implemented a "busy bag" for him, so he might say, "Mum, I think I need 5 minutes quiet time, I'm going to take my busy bag." So maybe there could be a child version of the Pause app, where he could blow out the candles on his iPad or something like that. [Participant 4, parent] Is there a thing in the app where they can request help or ask questions if they're not sure about something? [Participant 8, practitioner]

Five participants indicated that Pause was particularly useful in providing a database of ideas, which added value for parents.

If he's escalating, I can use the app to prompt him, like "How many colors can you name?" I've even sent him to quiet time with a task like, "Can you name as many animals as you can think of?" He's only there for 3 minutes, but it helps. [Participant 4, parent]

Journaling is a central component of the app so parents were specifically asked about any difficulties with reflection. Several people found reflection hard despite the prompts in Pause, and there is more work to do to ensure everybody gets to reflect on their parenting using Pause.

It's just sometimes finding the time to go on your phone to do those things. A lot of the time, things are going on in my head, if you know what I mean, but aren't necessarily on paper or on my phone. [Participant 7, parent]

Theme 3: The Outcomes and Effects of Pause (Overview)

Parents and practitioners reported that Pause was useful during parenting programs, and parents continued to use it after their programs had finished. Parents reported that Pause had improved their children's behavior and their family life as a whole, linking this to the convenience of using an app. They also reported improved insight into their child's behavior and their own behavior, linking this to the reflection encouraged in Pause.

Theme 3.1: Pause Enhances Parenting Programs

All participants reported that the app helped them. Describing it as "brilliant" (Participant 4, parent) or "really useful" (Participant 2, parent) and explaining that they use it "regularly" (Participant 3, parent).

I would say life-changing, really, because before, in a blink of an eye, she could run. And she's fast. Now she will ask for it and it will calm her. So, it has for us made it slightly better going out. Even going to a restaurant now, she will sit with it and she will get the app up and get it up herself. If she's doing the five senses one, she'll walk around the restaurant looking for different stuff and smells. So it has changed a lot for us and it has really helped. [Participant 5, parent]

Seven participants noted that the app remains useful after the sessions have finished, including all 3 practitioners.

I really liked it, and I still use it now. Even though the course has finished, I still use it. [Participant 2, parent]

Once they've done the program and they've got the app, they've got it forever. So there'd be no need to come back through the program. [Participant 10, practitioner]

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Three parents attributed improvements in their child's behavior to Pause.

We're out and about and then we feel it's coming, it just, I mean, it works for minutes with her. Once she starts doing it, she's like, I'm calm. [Participant 5, parent]

Now, he's starting to tell me, "I feel a bit fidgety, I need to do something." It would help him take control and gain more independence in regulating himself. [Participant 4, parent]

Four attributed improvements in their family life to Pause. Parents described how Pause improved life for the whole family, the child who was referred, plus other children and parents.

Having the use of the Pause app, where I've been able to take things like consequences and reward systems with me easily, rather than carrying a jar of buttons or a sticker chart—it's enabled me to put other things in place to make life a bit more manageable. Like, when I know there's going to be a meltdown, I can use techniques like "blow out your candles" to stop things before they escalate. So yeah, it's been a really, really good learning curve, and it's been brilliant to be able to apply it to all my children, not just the one who was referred. [Participant 4, parent]

Five participants commented that the effectiveness of Pause came from it being a mobile app. Specifically, Pause is with parents in their pockets all the time wherever they need it, and parents and children enjoy the interactive nature of sharing the app.

They found it useful to be able to refer back to it, because obviously their mobiles are around all the time rather than have, you know, like paperwork. [Participant 8, practitioner]

Six participants commented on the improvements in insight into children's behavior and what drives them.

She said, I'm so glad I've got a Pause app because I used it the whole time through halftime when I felt like I was just losing the plot. And she kept saying that she kept going back to the pause app and it really helped to support her child to know like how he was feeling and to be able to do the before, during and after so she could pick up the patterns and work out why her child was finding, I don't know, doing the particular activity or anything challenging. [Participant 10, practitioner]

Four participants commented on how parents had also gained insights into their own behavior.

It's about taking a step back. We don't need to shout and yell; we can deal with it calmly. It's about making people aware of how to deal with that child and what works. [Participant 4, parent] Six participants suggested that reflection had improved due to the Pause app.

Especially when I was doing the "before, during, and after," I'd do that on my own and write it down, which I liked because it made me realize, "actually, this happened before," whereas previously, I wouldn't pay attention to that. You'd just think, "what's going on now?" But looking back, I could see it was a trigger. [Participant 3, parent]

Discussion

Summary of the Results

This pilot study aimed to explore whether providing digital microinterventions to augment parenting programs via the Pause app was feasible. We explored (1) whether parents used Pause, (2) which tools parents used, and (3) what the strengths and weaknesses of the app were. We addressed questions (1) and (2) using a survey of parents who attended groups where Pause was offered. We addressed question (3) by combining survey data with interviews. In total, 25 of 53 (47%) parents completed postsurveys. Only 7 parents and 3 practitioners completed interviews. A total of 23 of 53 (43%) parents who completed presurveys had downloaded and used the Pause app (ie, 92%) of those who completed postsurveys used the Pause app). Other than the journal, used by 17 parents, the most popular tools were the relax tool and praise tool, each used by 10 parents. The survey data revealed specific strengths and weaknesses of the tools in the Pause app. Interviews revealed the challenges existing in programs without Pause, the way Pause was used by many family members in diverse settings, and how Pause enhanced parenting programs and improved outcomes for families. Interviews also revealed specific opportunities for improving the user interface and for addressing challenges in the journaling function.

Comparison With the Literature

The digital alternatives to parenting digital main microinterventions are e-learning programs. This study has shown that Pause can offer a different approach. The key limitations of e-learning programs are "providing a 'one size fits all' program with no adaptation or tailoring to the user's state" and "lack of referrals to in-person treatment in relevant cases" [24]. The biggest studies indicate that only around 7% of referred parents complete these interventions [9]. By using Pause to enhance, rather than replace, parenting groups, we ensured that parents received the benefits of tailoring and personalization, which come from group work with a facilitator. This approach is in line with a growing body of research in digital mental health, which highlights the need for human support to ensure long-term engagement and effectiveness of digital tools [25].

In this study, we estimated that 92% of parents used the Pause app sometimes, but acknowledged that it could be as low as 43%, if none of the survey nonresponders downloaded the app. Either way, this figure is difficult to compare with e-learning style programs where sessions are concurrent and so a completion rate can be calculated [26-28]. Patchy engagement

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is the norm in digital mental health interventions, and the most important factor is whether parents use evidence-based skills at the appropriate time or whether they do not. Nevertheless, the results of this study indicate that further research to evaluate the effect of the app on parent and child outcomes is appropriate.

Strengths and Limitations

This study tested Pause in a natural setting rather than a laboratory or staged parenting program; this evaluated both the practitioners' engagement with distributing Pause themselves and parents' engagement with the app within the context of the parenting program. Similarly, there were no clinical exclusion criteria so the participants were representative of parenting group attendees in the United Kingdom.

Retention was good within the context of parenting programs. We obtained postprogram surveys from 25 of 53 (47%) parents. Systematic review evidence suggests that 51% of parents disengage before or during long parenting programs such as these, so the proportion of postprogram surveys obtained is likely to represent a large proportion of retained parents [8]. Moreover, 2 parents who did not use Pause completed postprogram surveys, reassuring us that those who did not engage with the intervention were not excluded from data collection. In addition, even after inevitable attrition, the number of included parents was typical for a pilot study of a digital parenting intervention [29-32].

Finally, this paper was strengthened by the use of 4 sources of data: pre- and postprogram surveys, interviews with parents, and interviews with practitioners. These different forms of data collection allowed a rich understanding of how Pause was used within groups.

The main limitation of this study was the self-reported use data. We asked parents to refer to their app to report which "tools" they had added on the app, but it is possible that errors could be made in this process and social desirability bias could have an effect. Although our study design did not include a formal analysis of how frequently tools were used, the self-report data are in keeping with the app feedback, providing some reassurance regarding this potential limitation.

Implications for Research and Practice

Altogether, this pilot study provides preliminary evidence that Pause can be incorporated into parenting programs with positive effects for many parents and no evidence of adverse effects. These findings suggest that it is appropriate to continue honing the Pause app and exploring its short-term and long-term effects on parenting style. Future research should explore whether incorporating Pause into parenting programs leads to greater change in child behavior outcomes such as the Strengths and Difficulties Questionnaire compared with treatment as usual [17]. We used Pause alongside 3 parenting programs in this study, Triple P Primary, Family Links Nurture, and Care for the Family's Time Out for Parents. Future research should explore whether the results are the same with other programs.

In their paper, outlining the basis of digital microinterventions, Baumel et al [14] imagined a "hub" bringing together a suite of digital microinterventions. Pause provides that function for the suite of "tools" in the app. They outlined three areas for research: (1) microrandomized trials, (2) optimizing microintervention suites, and (3) understanding for whom digital microintervention care is suitable for. This paper shines light on (2) and (3) by interrogating the strengths and weaknesses of these microinterventions (allowing optimization) and revealing who uses them (at least 43% of parents who start programs in the included UK local authorities). It also provides proof of concept for augmenting parenting programs with mobile technology, similar to other research in digital mental health [33,34]. We plan to further contribute to research on microinterventions in parenting by exploring options to use microrandomized trials for engagement with Pause [35,36].

Conclusions

The Pause app can be combined with commonly used parenting programs and is well-received by parents. Parents and practitioners identified that Pause enhanced programs and could provide lasting support after programs had finished, with the potential to enhance family life and improve child behavior. Further research is required to evaluate the effect of adding Pause above and beyond treatment as usual, but results indicate that adding digital microinterventions alongside a face-to-face parenting program is a promising, feasible, and acceptable approach at least for some of the parents.

Acknowledgments

The authors would like to thank the local authority teams who supported this project.

Conflicts of Interest

The Pause app is owned by the University of Warwick, and under a division of proceeds agreement, NH and PIW would theoretically be paid from any licensing, but no licensing arrangement is currently underway. PIW is the co-inventor of the Pause Mobile App.

Multimedia Appendix 1 Topic guides. [DOCX File , 18 KB - pediatrics v8i1e68807 app1.docx]

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Abbreviations

PSOC: Parenting Sense of Competence ScaleRQ: research questionSDQ-c: Strengths and Difficulties Questionnaire Conduct SubscaleSWEMWBS: Short Warwick Edinburgh Mental Well-Being Scale

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Development of Chatbot-Based Oral Health Care for Young Children and Evaluation of its Effectiveness, Usability, and Acceptability: Mixed Methods Study

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Abstract

Background: Chatbots are increasingly accepted in public health for their ability to replicate human-like communication and provide scalable, 24/7 services. The high prevalence of dental caries in children underscores the need for early and effective intervention.

Objective: This study aimed to develop the 30-Day FunDee chatbot and evaluate its effectiveness, usability, and acceptability in delivering oral health education to caregivers of children aged 6 to 36 months.

Methods: The chatbot was created using the artificial intelligence (AI) chatbot behavior change model, integrating behavioral change theories into content designed for 3 - 5 minutes of daily use over 30 days. A pre-post experimental study was conducted from December 2021 to February 2022 in Hat Yai District, Songkhla Province, and Maelan District, Pattani Province, Thailand. Fifty-eight caregivers completed a web-based structured questionnaire at baseline and 2 months post baseline to evaluate knowledge, protection motivation theory-based perceptions, and tooth-brushing practices. Usability was assessed via chatbot logfiles and a web-based questionnaire at 2 months post baseline. Acceptability was evaluated through three methods: (1) open-ended chatbot interactions on day 30, (2) a web-based structured questionnaire at 2 months post baseline, and (3) semistructured telephone interviews with 15 participants 2 weeks post intervention. Participants for interviews were stratified by adherence levels and randomly selected from Hatyai and Maelan districts. All self-reported variables were measured on a 5-point Likert scale (1=lowest, 5=highest).

Results: The chatbot was successfully developed based on the 4 components of the AI chatbot behavior change model. Participants had a mean age of 34.5 (SD 8.6) years. The frequency of tooth brushing among caregivers significantly improved, increasing from 72.4% at baseline to 93.1% two months post baseline (P=.006). Protection motivation theory-based perceptions also showed significant improvement, with mean scores rising from 4.0 (SD 0.6) at baseline to 4.5 (SD 0.6) two months post baseline (P<.001). The chatbot received high ratings for satisfaction (4.7/5, SD 0.6) and usability (4.7/5, SD 0.5). Participants engaged with the chatbot for an average of 24.7 (SD 7.2) days out of 30. Caregivers praised the chatbot's content quality, empathetic communication, and multimedia design, but noted the intervention's lengthy duration and messaging system as limitations.

Conclusions: The 30-Day FunDee chatbot effectively enhanced caregivers' perceptions of oral health care and improved tooth-brushing practices for children aged 6 - 36 months. High user satisfaction and engagement demonstrate its potential as an innovative tool for oral health education. These findings warrant further validation through large-scale, randomized controlled trials.

Trial Registration: Thai Clinical Trials Registry Tctr20210927004; https://www.thaiclinicaltrials.org/show/Tctr20210927004

(JMIR Pediatr Parent 2025;8:e62738) doi:10.2196/62738

KEYWORDS

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chatbot; conversational agents; tele-dentistry; oral health behavior; in-person toothbrushing; hands-on; children; covid-19; oral health education; development.

Introduction

Chatbots have emerged as a socially responsible technology to bridge socioeconomic disparities and promote equitable access to high-quality health care [1,2]. Chatbots are digital tools that emulate human conversation and have the potential to promote health education, support behavior changes, and deliver health care, especially for clinical or vulnerable populations. Their adaptability also makes them suitable for deployment in a variety of sizeable and diverse samples [3]. Chatbots provide flexible, on-demand support, offering personalized assistance and content with continuous availability, helping to mitigate the limitations of traditional telehealth services [4]. Overall, chatbots offer a humanized interaction that can support health care professionals in managing and preventing conditions on a societal scale [5].

Multiple studies attest to the effectiveness of incorporating chatbots in health care, illustrating their role in facilitating a modification of health-related behaviors [3,6-8]. However, the existing literature on the use of chatbots for dental health purposes is limited [9,10], and few studies have explored the complicated process of constructing chatbots with oral health goals in detail.

Zhang et al [11] suggested some guidelines for the development of an artificial intelligence (AI) chatbot for behavior modification with the formulation of a theoretical framework that consists of four essential components: (1) specifying chatbot characteristics and understanding user backgrounds, (2) establishing relational capacity, (3) establishing persuasive capacity using behavioral-based theory, and (4) implementing an evaluation mechanism to assess outcomes.

Early childhood caries (ECC), identified as a significant chronic disease, emerges from the dynamic interplay of various risk and protective factors over time [12]. In Thailand, the earliest detection of noncavitated caries occurred at 9 months of age, while cavitation was first identified at 10 months of age [13]. In this context, parental tooth brushing, conducted twice daily with a rice-sized amount of fluoridated toothpaste, has been proven to be a pivotal strategy for reducing dental caries in children [12], whereas systematic reviews revealed that the effectiveness of simple health education in preventing ECC is restricted [14]. In line with a review regarding oral health promotion for ECC, home visits, and hands-on techniques for dental health education substantially enhance habit formation and effectiveness [15]. In addition, caregivers should receive practical training and empowerment from oral health professionals [16]. However, these interventions must be tailored to each individual, requiring not only highly skilled dental personnel but also considerable time and financial resources [17]. Chatbots have the potential to serve as a scalable model for skill development, motivation, problem-solving, and continuous follow-up, replicating the advantages of home visits.

Habits emerge as a consequence of acquiring repeated patterns of behavior, originating from consistent contextual stimuli, and they are formed through automated responses to the conditions in which they happen [18]. The research findings revealed that the time required to form habits varied, with values ranging from 18 to 254 days, depending on the level of complexity or challenge associated with a particular behavior [19]. Monitoring and reinforcement are effective ways to develop healthy habits [19,20] toward caries prevention in children [15], however, interaction with health professionals often requires traditional onsite visits, substantial time, and financial cost [21,22].

The protection motivation theory (PMT), a key theory in health psychology, explains how people change their behavior based on their evaluation of threats and their ability to cope with them [23,24]. The threat appraisal component of the PMT comprises 2 key elements: the individual's assessment of the disease's severity (perceived severity) and the probability of developing the disease (perceived vulnerability). The PMT additionally specifies that attitudes and behavior modification are indirectly influenced by the emotional state of fear arousal, which occurs through the evaluation of the danger's severity. The coping appraisal of the model comprises the individual's response efficacy, which is the expectation that implementing the recommendations will eliminate the threat, and self-efficacy, which is the belief in one's own ability to effectively execute the recommended course of action. Behavior performance should be significantly influenced by the intentions that are mediated by the cognitive predictors of threat and coping appraisals [25,26]. Kimhasawad et al [27] used a PMT-based education program to guide caregivers of 9 - to 12-month-old infants in adopting proper tooth brushing techniques, revealing that this approach effectively motivated and increased awareness, leading to a positive change in the oral health behavior of caregivers.

Currently, there is no standard evaluation method for a health care chatbot [28,29]. The concepts of usability and acceptability were identified as important factors for evaluating the use of chatbots [17]. However, there are differing definitions and some overlap between these terms [29,30]. Our study adopted broad interpretations of these concepts: usability as use, engagement, and ease of use; acceptability as satisfaction; continued use intention; and appropriateness. In addition, the frameworks of Zhang et al [11] and Denecke et al [31] were applied for content evaluation integrating usability and acceptability. This comprehensive evaluation provides a holistic assessment of the factors influencing chatbot adoption [32].

Therefore, the study aimed to elucidate the chatbot development process using PMT and Zhang's model. In addition, the pre-post study sought to assess the effectiveness, usability, and acceptability of a developed chatbot, the "30-Day FunDee," which was intended to educate caregivers of children between 6 and 36 months regarding oral health.

Methods

Figure 1 illustrates the comprehensive process involved in the defining framework, development, and evaluation of the 30-Day FunDee oral health promotion chatbot.



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Figure 1. Framework, development, and evaluation of the 30-day FunDee chatbot. AI: artificial intelligence.



Defining a Framework for the 30-Day FunDee Chatbot

Designing Chatbot Characteristics and Understanding User Background

The objectives and target audience were specified for educating and assisting Thai caregivers with oral hygiene care for children aged 0 to 3 years. Designing chatbot characteristics encompassed dialogue system infrastructure, media, and anthropomorphism [11] as shown in Figure 2. The chatbot's dialogue system infrastructure is frame-based, enabling users to select their responses. The chatbot created a variety of media, including simple and clear language, illustrations, written text, audio components, conversational dialogue, infographics, animations, animated songs, and videos with authentic and animated content. Moreover, within the anthropomorphic realm, "Dr. Pin" the chatbot's dentist avatar, was depicted as a kind, charming, empathetic, and attentive caregiver for children's oral health.



Figure 2. Screen example of the chatbot translated from Thai to English, showing dialogues that incorporate the design characteristics of the AI behavior change model on the seventh day. AI: artificial intelligence.





Understanding the user's background is critical in designing chatbots for behavior change [11,33]. Based on previous studies [34-36], the majority of caregivers were 20- to 40-year-old mothers with low to middle socioeconomic status who were responsible for nurturing their children, especially in relation to their children's tooth brushing. The chatbot's role was to assist users in overcoming obstacles and offering emotional support in childcare. Due to internet availability, both urban and rural caregivers could access the chatbot.

The content of the 30-Day FunDee chatbot was influenced by pediatric and community dentistry experts' recommendations and qualitative research insights on Thai caregivers' experiences with children's tooth-brushing behaviors [35,36], insights from community caregivers, inquiries from dental clinics, and knowledge gained from the earlier 21-Day FunDee chatbot, which is mentioned elsewhere [9]. Therefore, the updated

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chatbot was extended from 21 to 30 days, including more various media and dialogues, especially focusing on tooth-brushing practices.

Building Relational Capacity

Building relational capacity involves using elements such as social dialogues, empathy, relationship discussion, humor, self-disclosure, persistent memory, and agent variability [11,29]. Daily, the chatbot initiated conversations with charming greetings and concluded with farewell messages (Figure 2) that conveyed understanding and encouraged parents or caregivers in childcare [11]. For goal setting [37], daily welcome cards were designed with topics to be discussed.

The chatbot was designed to consistently display comprehension, empathy, and emotional support during interactions, especially when users encountered obstacles.

Emojis and animated GIFs conveying positive feedback and emotions were incorporated to increase engagement. Progress tracking enabled self-comparison and confidence-building over time. Periodic child dental plaque assessments prompted reflection on tooth-brushing techniques. Positive reinforcement was provided when plaque decreased, while setbacks received encouragement without punishment. Conversation features like remembering children's names, revisiting prior discussions, and using age-appropriate informal language aimed to simulate natural human-to-human dialogues. These elements enhanced the user experience and facilitated task completion [37,38] (Figure 2).

Building Persuasive Conversational Capacity

Overview

The 30-Day FunDee chatbot, meticulously designed, provided oral health education to caregivers based on PMT (Figure 3) for behavior modification by systematically sequencing threats and coping topics. Examples of chatbot topics are shown in the following sections.

Figure 3. Screen examples of chatbot dialogues translated from Thai to English, incorporating protection motivation theory (PMT) on the seventh day.



Perceived Severity

The importance of primary teeth, the consequences of dental infections, and anticipating problems from poor oral health care were discussed.

Perceived Vulnerability

The chatbot instructed caregivers on the child's dental plaque assessment and provided animation and infographics explaining plaque. Periodic plaque checks were encouraged, and an API enabled tracking of plaque levels over time.

Belief in Response Efficacy

Benefits and instructions, especially for tooth brushing, were incorporated into a variety of videos, infographics, and games. The chatbot also asked caregivers about children's sugar intake and diet to discuss potential health impacts.

Belief in Self-Efficacy

The chatbot was designed to increase caregiver self-efficacy for children's oral health management through motivational techniques and daily emotional support. At the end of each conversation, it expressed empathy for mothers' exhaustion and encouraged overcoming obstacles.

Chatbot Development Process

The development of chatbots followed a systematic, 3-phase process, as illustrated in Figure 1. The first step involved designing the conversational flow, which included scripts, infographics, videos, and other content. This step was crucial to ensure that the chatbot can engage effectively with users. This phase followed an established AI chatbot behavior change model and PMT, which guided the creation of responsive conversations tailored to encourage specific behavioral outcomes. The next step involved implementing the conversational flow using the Chatfuel platform, which enabled the transformation of the predesigned scripts into interactive

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conversations accessible on users' devices. The Chatfuel platform facilitated the efficient deployment of the chatbot design, ensuring seamless operation and scalability to accommodate the intended target audience, without advanced programming skills and includes push message functionality [39]. Given that over 80% of Thailand's population uses Facebook [40], Facebook Messenger was chosen as the delivery platform using Chatfuel.

The final step involved presenting the chatbot's content on user devices. After implementation, the chatbot became accessible, with its content displayed across various devices. This stage completed the chatbot's development, enabling it to interact with users as intended and deliver the conversations crafted during the initial phase. The chatbot used persuasive communication, including comprehension, empathy, and suggestions, to address the child's oral health challenges. It used a decision tree with recommended responses along with natural language understanding [37]. A pediatric dentist and a community expert evaluated the content validity, theoretical basis, and contextual appropriateness. A preliminary usability study with 10 caregivers evaluated content understanding and user experience.

Chatbot Evaluation

Chatbot evaluation should assess user patterns, user experience, conversation quality, perceived relational ability, and behavior outcomes [11,31]. This chatbot was evaluated on all aspects with the exception of oral health examinations due to COVID-19 pandemic operation limitations.

Participants and Recruitment

From December 2021 to February 2022, a total of 66 caregivers were recruited using convenience sampling including 29 caregivers from the Early Childhood Development Center at the Faculty of Medicine, Prince of Songkla University, Hat Yai District, Songkhla Province, and 37 caregivers from the Early Childhood Development Center in Maelan District, Pattani Province, Thailand. The inclusion criteria for caregivers were as follows: (1) currently caring for children aged 6 to 36 months with at least 1 tooth; (2) their children had no disabilities or significant underlying medical conditions that could have affected their oral health; and (3) equipped with electronic devices such as computers, tablets, or mobile phones, allowing for daily internet access and a propensity to interact via Facebook Messenger. The exclusion criteria were (1) caregivers who could not speak, read, or write Thai and (2) caregivers who were opposed to the data collection.

The sample size was calculated using G*Power software (version 3.1; Heinrich Heine University Dusseldorf) to determine the mean difference in the frequency of tooth brushing per day between pre- and postintervention time points. An effect size of 0.4283, derived from unpublished data of a previous multicenter study conducted across 6 provinces in southern Thailand that evaluated the effectiveness of a chatbot in promoting tooth-brushing behaviors among 398 children aged 6 months to 2 years [41], was used. Additional parameters included a correlation coefficient of 0.5, an α level of .05, and a power of 0.8. The calculation indicated a minimum of 60

participants was required. To account for a 10% dropout rate, the target sample size was increased to 66 participants to ensure sufficient data for analysis.

Initial contact involved outreach at childcare centers and communication with caregivers via Line or phone calls to assess eligibility and interest in participation. After identifying eligible caregivers, researchers scheduled appointments to provide detailed study information. Invitation letters were distributed by the research team (Multimedia Appendices 1 and 2).

Data Collection

Self-Reported Oral Health Behavior, Usability, and Acceptability

At baseline and 2 months later, a structured self-administered questionnaire (Multimedia Appendices 3 and 4) via Google Forms gathered information regarding participant characteristics and the effectiveness of chatbot use in terms of tooth-brushing behaviors and PMT-based oral health perceptions. At 2 months, usability and overall user satisfaction measures were added.

Oral hygiene behaviors were assessed using categorical questions on tooth cleaning methods, fluoride toothpaste use, and toothpaste amount.

Oral health perceptions were assessed using 14 items based on PMT including perceived severity (5 items), vulnerability (1 item), response efficacy (4 items), and self-efficacy (4 items), measured on a 5-point Likert scale.

A 5-point Likert scale, ranging from 1 (lowest) to 5 (highest), was used for all variables. The mean (SD) for each group was calculated by averaging the total items in each category. Negative items were reverse-scored before calculating the mean. The mean scores were interpreted as follows: 1.0 - 1.79 were the lowest perceptions, 1.8 - 2.59 were low, 2.6 - 3.39 were moderate, 3.4 - 4.19 were high, and 4.2 - 5.0 were highest.

The usability test was designed in relation to models of Denecke et al [31] and Zhang et al [11], consisting of 15 items. This measured user experience (3 items), conversation quality (4 items), perception of relation and capacity (2 items), self-esteem (4 items), and usefulness (2 items) on a 5-point Likert scale with the same calculation and interpretation methods as shown above. In addition, the engagement was quantified by analyzing use days from chatbot logfiles.

The assessment of acceptability was conducted using 3 different methodologies. First, on day 30, participants interacted with the chatbot, responding to open-ended prompts designed to elicit both positive and negative use experiences. Second, a structured questionnaire was administered 2 months post baseline. It consisted of 1 item evaluating overall user satisfaction using a 5-point Likert scale, ranging from 1 (lowest) to 5 (highest).

Two weeks post intervention, semistructured in-depth telephone interviews were conducted. Participants (n=15) were stratified into 4 groups based on adherence levels and were randomly selected from the Hatyai and Maelan districts with equal distribution: 100% adherence (30 d, n=4), 80% - 99% adherence

(24 - 29 d, n=4), 50% - 79% adherence (15 - 23 d, n=4), and <50% adherence (<15 d, n=3).

Participants were contacted to schedule interviews. Nonresponders were replaced through random selection until quotas were met, except in group 4, where participants were unreachable. Interviews, lasting 10 - 15 minutes, covered the study's objectives; interview methods; and explored satisfaction, dissatisfaction, feedback, and suggestions. Field notes were recorded during each interview.

Quality Control of Questionnaire and In-Depth Interview

The content and construct validity of the questionnaires and guiding questions for in-depth interviews were evaluated by 3 experts: a community dentist, a pediatric dentist, and a dentist from a public hospital. The usability test, adapted from Denecke et al [31] and Zhang model frameworks [11], was validated by the same 3 experts. Reliability for PMT-based perceptions was determined using Cronbach α (α =0.85). Face validity of the overall questionnaire was established through pilot telephone interviews with 10 caregivers. The in-depth interview guidelines were validated by 3 experts. To ensure triangulation, 2 additional independent researchers conducted content analysis. Multiple data collection methods were used to assess acceptability.

Statistical Analysis

Descriptive statistics were presented as means (SD) for continuous variables, and frequency (percentage) for categorical variables. Within-group comparisons were used for the nominal/categorical data, and chi-square or Fisher exact tests were used. For continuous data, paired t tests were used. Satisfaction scores were reported as the mean (SD) on a 5-point scale. IBM SPSS Statistics for Windows (version 29.0.0.0 (241); IBM Corp) was used.

Analysis of Qualitative Data

The responses of the participants from in-depth interviews were analyzed thematically using an inductive method guided by the procedure outlined by Jang et al [42] and Fitzpatrick et al [37]. Data from in-depth interviews and open-ended queries were analyzed using thematic analysis [43,44] and reported in terms of frequency.

Ethical Considerations

Adhering to social distancing measures recommended during the COVID-19 pandemic, participants attended group Zoom information sessions where researchers explained the study comprehensively. To ensure privacy, attendees could use pseudonyms and disable cameras. The researcher outlined the following: (1) study purpose; (2) data handling procedures; (3) privacy measures; and (4) participant rights, including voluntary participation, and withdrawal options. Questions could be asked during the session or privately via Zoom chat. Verbal consent was obtained during the session, with the completion of the web-based questionnaire (Google Forms) serving as additional confirmation. Participants could withdraw by not completing the questionnaire. Privacy measures included guidelines against sharing others' identities or comments outside the session, and secure data storage with restricted access to research team members only. The protocol was registered to the Thai Clinical Trials Registry (TCTR20210927004) and approved by the Institutional Review Board of the Faculty of Dentistry at Prince of Songkla University (EC6407-053).

Results

Characteristics of Participants at the Baseline

Initially, 66 individuals were enrolled in the study, but following the 30-day postintervention period, 8 enrollees were excluded due to loss of follow-up.

The demographic and socioeconomic status of participants (n=58) were presented below (Table 1). The mean participant age was 34.5 (SD 8.6) years, and 87.9% (n=51) were mothers. The mean child age was 20.9 (SD 7.9) months. Of the participants, 55.2% (n=32) participants obtained oral hygiene advice via the web. Most web-based use was 51.7% (n=30) of the participants for between 3 and 5 hours per day, then >6 hours per day (15/58, 25.9%) and followed by 1 - 2 hours per day (13/58, 22.4%). Daily internet use was 72.4% (n=42) during the week.



Table . Demographic and socioeconomic characteristics of study participants (N=58).

Demographic characteristics	Values, n (%)
Caregiver's education level	
Lower than Bachelor degree	26 (44.8)
Bachelor degree or higher	32 (55.2)
Religion	
Buddhism	26 (44.8)
Islam	32 (55.2)
Caregiver's occupation	
Stay-at-home parent	18 (31)
Civil servant	23 (39.7)
Employee	8 (13.8)
Private sector employee	4 (6.9)
Farmer	2 (3.4)
Business owner	3 (5.2)
Family income	
Not enough	5 (8.6)
Enough	53 (91.4)

Oral Health Behaviors

Results from the posttest showed that tooth brushing by caregivers and the use of fluoride toothpaste and smear-sized toothpaste improved significantly (Table 2).

Table . Oral health behaviors among study participants at baseline and after 2 months from the first day of intervention (N=58). Fisher exact test significance level: P<.05.

Behaviors	Preintervention, n (%)	Postintervention, n (%)	P value
Teeth cleaning method			.006
Improper or no tooth brushing ^a	16 (27.6)	4 (6.9)	
Tooth brushing by caregiver	42 (72.4)	54 (93.1)	
Frequency of tooth brushing			<.001
<1 time/day	21 (36.2)	8 (13.8)	
≥2 times/day	37 (63.8)	50 (86.2)	
Use of Fluoride toothpaste (Yes)	31 (53.4)	49 (84.5)	.001
Smear-sized toothpaste used	34 (58.6)	48 (82.8)	.008

^aImproper tooth brushing is defined as insufficient cleaning, rinsing with water only, using a cloth for cleaning, or allowing the child to brush independently.

Perceptions of Caregivers Based on PMT

All perceptions of caregivers based on PMT showed significant improvement from high to highest perceptions, except for

perceived vulnerability, which improved but without a statistically significant difference (Table 3).



Table. Perceptions of caregivers based on protection motivation theory (PMT) toward oral health behavior (total score=5). Paired *t* test significance level: *P*<.05.

	Preintervention, mean (SD)	Postintervention, mean (SD)	<i>P</i> value
PMT parameters			
Perceived severity	4.0 (0.9)	4.5 (0.7)	<.001
Perceived vulnerability	4.3 (1.1)	4.6 (0.9)	.56
Response-efficacy	3.9 (0.8)	4.4 (0.8)	.04
Self-efficacy	3.9 (0.9)	4.3 (0.7)	.001
Overall	4.0 (0.6)	4.5 (0.6)	<.001

Usability and Engagement

The usability levels were highest in every category (Table 4). Of those who completed the program, 32.8% of the study

participants were fully engaged in using the chatbot. The average chatbot user engagement was 24.7 days (SD 7.2), with an additional insight into weekly engagement of 5.8 days (SD 1.7).

Table .	Usability	on the	chatbot	(N=58).
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Usability items (total score=5)	Values, mean (SD)
User experiences	4.6 (0.6)
Convenience	4.6 (0.7)
Acceptable performance and acceptance	4.6 (0.7)
Conversational quality	4.7 (0.6)
Understandable media	4.7 (0.6)
Reliable content	4.8 (0.7)
Appropriate content order	4.6 (0.8)
Linguistic features, naturalness, and fluency conversational quality	4.8 (0.6)
Perception of relational and capacity	4.7 (0.6)
Rapport perception of relation and capacity	4.6 (0.8)
Self-efficacy and perceived social support	4.8 (0.6)
Increased self-esteem	4.6 (0.6)
Usefulness of chatbot	4.8 (0.5)
Overall average score	4.7 (0.5)

Acceptability

In the structured questionnaire, overall satisfaction was rated 4.7 out of 5 (SD 0.6). Open-ended questions from day 30 of chatbot conversations (42 users) and in-depth interviews (15 users) revealed 4 major themes through thematic analysis:

content, user learning, media, and process (Figure 4). Most users expressed positive feedback on the value of the content and the engagement methods, particularly empathetic communication and media. However, the duration of chatbot interactions and issues with the messaging system were identified as key barriers to sustained engagement (Figure 5).



Figure 4. Thematic map of favored chatbot features of chatbot users' experience, drawn from in-depth interviews and open-ended questions. (Number in bracket: number of users).





Figure 5. Thematic map of unfavorable chatbot features of chatbot users' experience, drawn from in-depth interviews and open-ended questions. (Number in bracket: number of users).



Discussion

Principal Findings

The study indicates that using the "30-Day FunDee" chatbot significantly improved PMT-related perceptions and tooth-brushing behavior for young children. High levels of acceptability and usability were reported for the chatbot acceptability and usability were reported.

Several studies supported that knowledge and attitudes regarding tooth brushing can evolve and that alterations in tooth-brushing practices are influenced by or linked to this factor [45,46]. Caregiver-led tooth brushing for children twice daily with a rice-sized amount of fluoridated toothpaste has been proven to be a key strategy for preventing dental caries in children younger than 3 years [12]. In the study, tooth brushing by caregivers increased significantly from 72.4% to 93.1% (a significant increase of approximately 22%). The dedication of caregivers to twice-daily brushing and the use of fluoride toothpaste for children significantly grew, with an increase of approximately 22.4% (from 63.8% to 86.2%) and 31.1% (from 53.4% to 84.5%), respectively. These results go beyond those of other studies involving similar age groups, whether they used traditional oral health education with or without in-person tooth-brushing training [22,47].

Oral health professionals should provide caregivers with practical training and empowerment regarding the prevention of tooth decay in young children [15,16,48]. Within the framework of this chatbot interface, caregivers are expected to autonomously acquire the skill of proper tooth brushing through the use of educational content, encompassing videos, images, and textual information. The resultant feedback on this intervention demonstrated noteworthy effectiveness, reflecting

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an elevated tooth-brushing behavior and satisfaction level, quantified with a score of 4.7 out of 5. Additionally, media preferences were thoroughly explored through in-depth interviews and open-ended questions within the chatbot interface.

Meta-analyses indicate that 4 key factors within the PMT including perceived severity, perceived vulnerability, response efficacy, and self-efficacy contribute significantly to changes in health behaviors [49]. Perceived severity significantly increased, likely due to integrating PMT principles into the chatbot design and content structure. As in prior research, the perceived severity of the condition (cancer) impacted intentions to prevent disease, suggesting fear appeals influenced the perceived threat of disease [50]. In addition, the systematic review identified self-efficacy within the PMT's coping appraisal construct as the most effective predictor and promoter of physical activity participation [51]. Our findings align with these studies, demonstrating improvements in perceived severity, response efficacy, and self-efficacy.

In this chatbot on perceived vulnerability, we requested caregivers evaluate their children's dental plaque to determine their abilities in tooth brushing. We hypothesized that there would be a significant difference in perceived vulnerability, however this was not supported. Nevertheless, such interactions still improve oral health behaviors in children [27]. Caregivers, with a strong belief in response efficacy, are more likely to change their behavior to take care of their children [27,52]. In this study, we aimed to share tooth-brushing techniques using various media such as conversational text, infographics, both real-life and animated images, and videos. This finding is consistent with the excellent level of user satisfaction observed regarding the understandable media and reliable content

displayed. Self-efficacy is a significant component that plays a critical role in influencing the improvement of health behavior [27,45,46,53].

Consistently maintaining oral health behaviors, crucial for the success of preventing caries, should be upheld over an extended period [54]. As habit formation typically takes place within a range of 18 to 254 days [19], we anticipate that the 30-day exposure to the intervention and the subsequent 60 days from the first day of intervention to the evaluation day will sufficiently ensure a lasting behavioral change.

Behavior change theories were recommended in interventions promoting change, including in-person and digital formats. These approaches emphasized goal-setting, self-monitoring, reviewing goals, addressing obstacles, providing motivation, feedback, social support, and individualized guidance and education [21,55,56]. The 30-Day FunDee chatbot study incorporated these techniques.

Integrating behavior change methods into chatbot interventions likely improved targeted behaviors and overcame limitations of conventional in-person interventions, including restricted health care professional interaction, declining motivation over time, and insufficient access to education. Thus, chatbots may elicit positive behavior changes by addressing the restrictions of traditional approaches [3].

The research involves designing a satisfaction assessment using a web-based questionnaire that was applied to evaluate the design of the AI behavior change model [11]. The evaluation focused on user experiences, conversational quality, perception of relational capacity, self-esteem enhancement, and chatbot usefulness. The results indicate the highest satisfaction across all evaluated criteria and that it was effective enough to increase tooth brushing behavior. Powerful chatbots, such as the 30-Day FunDee chatbot, are not only capable of simple conversation, but also of oral health education and self-training.

The average duration of chatbot engagement, which was 5.8 days per week in this study, is a salient feature. Due to the increased level of satisfaction, this duration is especially noteworthy; it exceeds Todaki's 5.1 days-per-week engagement during a similar 4-week study period [42], but is inferior to Woebot's 6.1 days-per-week engagement in a shorter 2-week study period [37]. Observations from both our own investigations and other research [42] indicate that the chatbot exhibited notable use during the initial week, followed by a decline in use from the second to the fourth week. User feedback revealed 3 key reasons: excessive workload strain, preference for shorter programs, and reliance on chatbot notifications.

These findings indicate a misalignment between chatbot functionality and user needs, consistent with previous research highlighting drawbacks such as extended training programs and technical errors [37,42]. Future iterations will prioritize content condensation, enhanced user engagement, and potential platform optimization or replacement to address these challenges and improve overall chatbot efficacy.

According to the challenges of chatbot development in public health, establishing rapport and cultivating relationships with users through compassionate and personalized interactions is critical for a sustained and engaging intervention [3,4,57]. This study aligns with previous research findings, where the term "empathic and friendly conversation" emerged during in-depth interviews and open-ended questions. Similarly, studies on other chatbots corroborated these benefits [37,42,58].

The strengths of this study focus on systematically planning, developing, analyzing, and assessing the chatbot. It was meticulously designed based on behavior modification theory and principles of AI chatbot behavior change. This resulted in profound understanding, facilitating improvement, development, testing, and evaluation of interactive programs to align with the goals. This included the capacity to discuss, summarize outcomes, and conduct extensive comparative analyses with other study findings. The ultimate goal is to formulate guidelines for the next phase of chatbot development.

Our research possesses limitations due to a pre-post design, potentially introducing a maturity bias and consequently, possibly overestimating the chatbot's effectiveness in enhancing oral health behavior. In the research methodology, a self-administered web-based questionnaire was used, raising concerns about compromised validity.

In order to improve the applicability of our results, we recommend that future research use randomized trials involving a wide range of demographic groups and conduct a more extensive evaluation of caries prevention. Furthermore, to enhance the effectiveness, user-friendliness, and acceptance of chatbots, efforts should be made to incorporate adaptive learning and AI-driven conversational methods.

Conclusion

In summary, this research suggests that the 30-Day FunDee chatbot can be an effective, highly usable, and acceptable resource for individuals seeking oral health information and children's caries prevention. Such a tool could be developed in the next phase of chatbots to serve as a scalable complement to conventional treatment approaches.

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Authors' Contributions

KP, JH, and SP developed the research framework through the design of the study and a comprehensive literature review, the creation of the chatbot, and the collection and analysis of data. SN contributed to the research design and data presentation. KP and JH authored the preliminary version of the manuscript. All authors (KP, JH, SP, and SN) conducted a review and revision of the manuscript to finalize the version.

Conflicts of Interest

None declared.

Multimedia Appendix 1 English invitation letter. [DOCX File, 28 KB - pediatrics v8i1e62738 app1.docx]

Multimedia Appendix 2 Thai invitation letter. [DOCX File, 32 KB - pediatrics_v8i1e62738_app2.docx]

Multimedia Appendix 3 English structured self-administered questionnaire. [DOCX File, 2139 KB - pediatrics_v8i1e62738_app3.docx]

Multimedia Appendix 4 Thai structured self-administered questionnaire. [DOCX File, 2438 KB - pediatrics_v8i1e62738_app4.docx]

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Abbreviations

AI: artificial intelligence ECC: early childhood caries PMT: protection motivation theory



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Review

Extended Reality (XR) in Pediatric Acute and Chronic Pain: Systematic Review and Evidence Gap Map

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Abstract

Background: The use of extended reality (XR), including virtual reality (VR) and augmented reality (AR), for treating pain has accelerated in the last 10 years. XR is an attractive biobehavioral intervention that may support management of pain or pain-related disability. Reviews of the literature pertaining to adults report promising results, particularly for acute procedural pain.

Objective: This study aimed to (1) summarize the available evidence with respect to feasibility, safety, and effectiveness (pain intensity) of XR for pediatric acute and chronic pain; (2) summarize assessment tools used to measure study outcomes; and (3) identify gaps in evidence to guide future research efforts.

Methods: This study is a systematic review of the literature. Multiple databases (CINAHL, Cochrane Central, Embase, MEDLINE, PsycINFO) were searched from inception until March 2023. Titles, abstracts, and full-text articles were reviewed by 2 team members to determine eligibility. Articles were included if the (1) participants were aged 0 to 18 years; (2) study intervention was VR or AR; (3) study outcomes included safety, feasibility, acceptability, or effectiveness on the outcome of pain; and (4) study design was observational or interventional. Data were collected on bibliographic information; study characteristics; XR characteristics; outcome domains; outcome measures; and study findings pertaining to safety, feasibility, and effectiveness.

Results: We included 90 articles in the review. All included studies used VR, and 93% (84/90) studied VR in the context of acute pain. Of the 90 studies, 74 studies were randomized trials, and 15 studies were observational. Safety was assessed in 23 studies of acute pain, with 13 studies reporting no adverse events and 10 studies reporting events of low concern. Feasibility was

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assessed in 27 studies. Of the 84 studies of acute pain, 62% (52/84) reported a positive effect on pain intensity, 21% (18/84) reported no effect, and 13% (11/84) reported mixed effects. All 6 studies of chronic pain reported a positive effect on pain intensity. An evidence gap map was used to illuminate gaps in specific research areas stratified by subtypes of pain. Risk of bias assessment revealed 67 studies had a moderate risk of bias, 17 studies had a high risk, and 5 studies were deemed to be low risk.

Conclusions: The current body of literature around XR for pediatric pain is focused on acute pain with promising results of safety and effectiveness on pain intensity. The literature pertaining to chronic pain lags behind, limiting our ability to draw conclusions. The risk of bias in studies is problematic in this field, with the inherent challenge of blinding participants and researchers to the intervention. Future research should aim to measure effectiveness beyond pain intensity with a consistent approach to measuring key outcome domains and measures. Current efforts are underway to establish expert consensus on best research practices in this field.

Trial Registration: Prospero CRD42022307153; https://www.crd.york.ac.uk/PROSPERO/view/CRD42022307153

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KEYWORDS

virtual reality; augmented reality; extended reality; acute pain; chronic pain; pediatrics; adolescents; safety; feasibility; effectiveness; evidence gap map; child; children; VR; XR; biobehavioral; intervention; systematic review

Introduction

Acute and chronic pain are common among children [1-3] and can result in negative short and long-term health and mental health consequences. Within pediatric populations, acute pain can negatively impact treatment adherence such as vaccination schedules [4] and routine port access [5] and can worsen outcomes in the context of surgery and rehabilitation [6,7]. Additionally, acute pain can transition into chronic pain if not adequately assessed, managed, and treated [8]. If not addressed in childhood, these pain and other health-related problems often continue into adulthood and therein increase risk for functional disability and mental health challenges including depression, suicidality, and substance use, with particular concern for opioid use or misuse [9-12].

Technologies have been emerging to support the management of pain for both acute and chronic pain, including the integration of extended reality (XR) into clinical care. XR is most often inclusive of virtual reality (VR) and augmented reality (AR), which aim to immerse a person or patient in a simulated environment that they perceive to be real [13]. In the context of VR, youth are transported to a new or alternative environment, while AR alters or enhances the environment in which the youth is already existing [14].

The integration of XR into health care has been a rapidly growing area of clinical research and treatment, with promise surrounding the management of pain across a variety of acute and chronic conditions for youth and adults [15-17]. Much research has been conducted in the acute pain management context and specifically surrounding wound care, venipuncture ("needle pokes"), and minor procedures (eg, dental fluoride therapy, orthopedic pin removal). Among adults, XR has also been used commonly to manage chronic pain such as low back pain or fibromyalgia [18,19]. Together, results to date indicate that XR holds great promise for supporting biopsychosocial treatment for pain management for youth and adults; however, consistency in measurement as well as defined outcomes for assessing the effectiveness of XR research are missing, thereby



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limiting the ability to coordinate research efforts and examine effectiveness on a large scale.

One reason for the variability and the lack of consensus in technology and outcomes in XR research is related to the rapid adoption and evolution of technology (ie, hardware and software). Since the initial studies of XR for pain began in the 1980s, the rate at which XR is being evaluated and integrated into clinical care for pain management has sharply increased, with over 250 PubMed-indexed studies published since 2020 alone compared with the total 78 studies published in the 20 years preceding. Identifying a core outcome set for XR trials in pain is needed given the rapid adoption and evolution of this technology into clinical research and the potential for XR to provide breakthroughs in the treatment and management of acute and chronic pain. We undertook this task and, as a part of this effort, conducted a systematic review to summarize the current state of the literature with a specific aim toward understanding how researchers are currently assessing XR effectiveness.

Therefore, the purpose of this systematic review was to describe the feasibility, safety, and effectiveness of XR for pediatric acute and chronic pain. Moreover, this review collated current research to establish an evidence and gap map for guiding future research efforts. Finally, given the variability in XR study treatment outcomes, this review also assessed the measurement tools that have been used to measure outcomes in XR research. Together, these findings provide an updated description of the state of the field and highlight a path forward for improving the application, feasibility, and effectiveness of XR research in the context of pediatric acute and chronic pain.

Methods

Search Strategy

The systematic review protocol was registered on PROSPERO (#CRD42022307153). The literature search strategy was developed in consultation with a medical librarian who executed the searches. Examples of search terms (including MeSH terms) included "virtual reality," "pain," "treatment outcome," "safety," and "feasibility studies." A randomized controlled trial (RCT)

hedge or study-type filter was not applied as it was considered too limiting for the overall search. Major electronic databases (CINAHL, Cochrane Central, Embase, MEDLINE, PsycINFO) were searched from database inception to March 2023. The full search strategy is included in Multimedia Appendix 1.

Selection Criteria

The inclusion criteria for the current review included (1) participants aged 0 to 18 years; (2) study intervention of XR (VR or AR); (3) study outcomes of safety, feasibility, acceptability, or effectiveness on the outcome of pain; and (4) observational or interventional study design. For this review, XR was defined as "technology that blurs the lines between the physical and virtual worlds, creating a sense of immersion and enhancing the realism of virtual experiences" [20-22]. Additionally, the age criterion was not applied until screening to allow for a comprehensive search of the literature.

Studies were excluded from the review if they were reviews, opinion papers, case studies with ≤4 participants, or conference proceedings. Studies in which the participant sample was exclusively adults (>18 years old) were excluded as well as studies in which the intervention was not deemed to align with the definition of XR (eg, intervention delivered on a computer screen or flat board display panel) or where there was insufficient description of the hardware to determine whether the intervention met the definition of XR. Although no uniform definition nor criterion exists for defining XR as immersive or not immersive, through group discussion and guided by existing definitions [23], we excluded technology where the user only existed in the real world (eg, looking at a 2D image on a computer). If a reviewer was uncertain about whether the XR trial was immersive, additional review of the study and group discussion were used to determine whether the paper was included in the review. Papers that were not available in the English language were also excluded from the review.

Study Selection

Following completion of each of the systematic literature searches, 2 reviewers independently screened titles and abstracts for inclusion following established PICO (Population, Intervention, Comparison, Outcome) strategies. Disagreements between raters were resolved by a third reviewer. Following initial review of title and abstracts, a subsequent review of retained studies was completed, reviewing complete texts to evaluate for inclusion. Disagreements between raters were resolved by the same third reviewer. All screening was completed through Covidence [24], a web-based collaboration software platform that streamlines systematic review management and allows for blinded, independent review of included studies.

Assessment of Study Quality

Assessment Tools

For studies that assessed the effectiveness of the XR intervention, a study risk of bias assessment was conducted. For RCTs, the Cochrane Risk of Bias Tool (RoB-2) was used, and for nonrandomized studies, the Methodological Index for Non-Randomized Studies (MINORS) was used. The risk of

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bias assessment was completed by 2 separate groups with one group conducting risk of bias for the RCTs and the other group conducting risk of bias for the nonrandomized trials. Given the distinct tools used for each group, it was deemed appropriate to allow for 2 separate coding groups.

Risk of Bias in RCTs

To assess the RCTs, the 2 reviewers used and adhered to the RoB-2 protocol [25]. RoB-2 serves as an algorithmic framework for considering the risk of bias in the outcomes of RCTs [26]. The tool asks reviewers to rate the bias in RCT protocols among 5 domains: (1) randomization process, (2) deviations from intended interventions, (3) missing outcome data, (4) measurement of the outcome, and (5) selection. Reviewers evaluated the studies independently then met to discuss agreement on rating. If the raters disagreed on a rating, a third rater resolved the disagreement. Each domain was assigned an algorithm result and an assessor's judgement of Low, Some Concerns, or High. The overall bias followed the same 3 outcomes.

Risk of Bias in Nonrandomized Studies

To assess the nonrandomized studies (eg, observational, interventional without control), the reviewers used MINORS [27]. MINORS consists of 12 method-oriented items (eg, "A clearly stated aim") to assess quality and risk of bias in nonrandomized studies. Each item is rated on a scale from 0 to 2, with 0 indicating that the item was not reported, 1 indicating that the item was reported but inadequate, and 2 indicating the item was reported and adequate. MINORS can be used for studies with or without a comparator group, with the first 8 items applying to all studies and the final 4 items specific to comparative studies. Total scores for noncomparative studies range from 0 to 16, and total scores for comparative studies range from 0 to 24, with higher scores indicating more methodological integrity. For this review, 2 raters independently rated each of the nonrandomized studies then met to compare. Each of the 12 items as well as the total scores were compared between raters. Any disagreements were resolved through discussion and, if needed, through consultation with a third rater.

Data Extraction

A data extraction form was created and pilot tested to ensure relevant data were pulled based on the form directions. A team of research assistants was trained on the data extraction form, and each research assistant independently extracted data for their assigned studies. Data extracted included study characteristics (participants, design, setting, control group), intervention characteristics (hardware, software, intervention protocols), outcome domains (safety, feasibility, effectiveness), outcome measures used, and a summary of study findings.

Data Coding (Evidence Gap Map)

All included studies were uploaded to EPPI Reviewer, software designed for systematic reviews and in support of developing evidence and gap maps. Using existing literature, authors CWH and GM developed operational definitions for each of the pain populations and target outcomes, which were reviewed by the larger author group and iterated until a final draft was created

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then used to guide coding of the studies. To code studies for the evidence and gap map, reviewers were assigned a series of studies in EPPI Reviewer and were asked to review the manuscript and code each article for the patient population (adult or pediatrics), pain population, and outcomes targeted by VR. Two training meetings were held with all reviewers to provide operational definitions, and they were asked to code a single article. A subsequent meeting was held to provide feedback and answer questions to increase consistency across coding. Once all articles were coded, any articles identified as unclear were reviewed again by a single author. Operational definitions are provided in Multimedia Appendix 2.

Data Synthesis

Included studies were summarized, and fulsome details of all included studies are provided in Multimedia Appendix 3. Additionally, descriptive statistics were used to synthesize study characteristics and aims as well as intervention characteristics. To synthesize data pertaining to outcome domains, an evidence and gap map was created. To create the evidence and gap map, 7 reviewers independently coded each study according to the study population including age (pediatric, adult) and pain type (acute pain-venipuncture, acute pain-wound care, acute pain-procedural, acute pain-other, chronic pain-cancer related, chronic pain-postsurgical/trauma, chronic pain-headache/migraine, chronic pain-musculoskeletal, chronic pain-neuropathic, chronic pain-other), as well as the pain-related outcomes targeted by the XR intervention (user experiences, participation/engagement, cognitive, behavioral, physical functioning, pain intensity, quality of life, health care utilization, safety, feasibility). Each study was also coded according to its established risk of bias (low, moderate, high). Coding was conducted through EPPI Reviewer [28], a collaborative web-based research synthesis software that supports study classification, and EPPI Mapper, a web-based program that generates evidence and gap maps based on coding conducted in EPPI Reviewer. Finally, for each of the identified pain treatment targets, the measures used to assess those targets were extracted by 2 authors and summarized to indicate the number of unique measures reported for each treatment target, and the number of studies that used the measure.

Results

Article Identification

The search identified 2656 articles across the 5 identified databases. Of the articles identified, 1041 duplicates were identified and removed prior to abstract and title screening. We screened 1615 articles for inclusion based on abstract and title, and 1125 were removed based on relevancy to the review. Of the remaining 490 studies, 15 could not be located, so 475 full-text articles were screened for inclusion. Of those, 90 studies were included in the review. The most common reason for exclusion was that the study sample was exclusively adult (170 studies) followed by determination that the XR technology was not immersive (79 studies). See Figure 1 for additional information related to the screening process.



Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.



Study Characteristics

Of the included articles, all 90 studies used VR technology, and no studies reported the use of AR technology. As such, when discussing XR for pediatric pain management, currently this is exclusively VR technology. Additionally, the majority of studies focused on assessment of VR in pediatric acute pain (84/90, 93%), specifically venipuncture (40/90, 48%) [29-68], burn dressing and wound care (15/90, 18%) [69-83], and minor procedures (26/90, 31%) [31,84-108], as well as other acute pain (3/90, 3%; ie, acute pain in emergency department, acute upper limb rehabilitation, vaso-occlusive crisis) [109-111]. A much smaller number of studies (n=6) examined the utility of VR in chronic pain populations including intensive pain rehabilitation (n=1) [112], chronic burn dressing (n=1) [113], chronic musculoskeletal pain (n=1) [114], chronic cancer-related pain (n=2) [115,116], and chronic abdominal pain (n=1) [117]. See Figure 2 for the summary of pain populations included

across the studies. Within the 90 included studies, there were a total of 6596 participants enrolled, including 3615 enrolled in intervention arms and 2981 enrolled in control arms. Study sample sizes ranged from 5 to 254. Across studies, 3631 participants were male, while 2929 were female. The age of the participants ranged from 3 years to 18 years. Among participants enrolled in the intervention group, the mean age was 11.07 (SD 2.64) years, and in the control groups, the mean age was 10.38 (SD 2.37) years. Most studies (84/90, 93%) evaluated the use of XR in the context of pediatric acute pain management, while 7% (6/90) of the studies focused on XR in the context of pediatric chronic pain. Most studies took place in a hospital setting (63/90, 70%), and interventions were most often delivered by a researcher (36/90, 40%) or nurse (19/90, 21%). Regarding intervention design, an RCT was used 82% (74/90) of the time. See Table 1 for a full description of the study characteristics.



Figure 2. Pain types across all included studies.





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Table 1. Study characteristics (n=90).

Characteristic	Studies, n (%)
Acute pain (n=84)	
Venipuncture	40 (45)
Procedural	26 (32)
Wound care	15 (18)
Other	3 (5)
Chronic pain (n=6)	
Cancer related	2 (33)
Musculoskeletal pain	1 (17)
Other	3 (50)
Study design	
Interventional RCT ^a	74 (82)
Interventional no control	13 (14)
Case series	1 (1)
Prospective observational	2 (2)
Study setting	
Hospital/burn center	69 (77)
Research	2 (2)
Dental	9 (10)
Home	1 (1)
Clinical	9 (10)
Sample size (n= 6596)	
VR ^b intervention	3615 (55)
Control	2981 (43)
Intervention delivered by	
Registered nurse	19 (21)
Physical therapist	2 (2)
Dentist	1 (1)
Other clinician	2 (2)
Researcher	36 (40)
Caregiver	1 (1)
Unknown	29 (32)

^aRCT: randomized controlled trial.

^bVR: virtual reality.

Study Quality Assessment

Where possible, studies were examined for risk of bias based on study design. Of the 90 studies, 74 studies were evaluated using the RoB-2 assessment for randomized trials and 15 studies were evaluated using the MINORS assessment for nonrandomized interventional and observational studies. We could not assess 1 study due to the study design (ie, case series: Birnie et al [34]). Results of the risk of bias assessment revealed that most included studies (67/90, 74%) had a moderate risk of bias, while 17 studies (17/90, 19%) had a high risk of bias, and 5 studies (5/90, 6%) were deemed to have a low risk of bias. To see the summary of risk of bias ratings for each study, please see Figure 3. Although sources indicating risk of bias were variable across studies, most included studies were identified as moderate or high risk of bias due to their failure to blind study participants to the intervention and researchers to who was in the intervention arm (69 studies). Increased risk of bias was also commonly identified in the randomization procedures, although to a much lesser degree (19 studies).

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Figure 3. Risk of bias for included studies (N=89). MINORS: Methodological Index for Non-Randomized Studies; RoB-2: Cochrane Risk of Bias Tool.



XR Feasibility

Across all included studies, feasibility was evaluated 43% (39/90) of the time. Within chronic pain studies, 50% (3/6) of the studies assessed the feasibility of VR. Although limited in scope, of the 3 studies that examined feasibility, results did indicate VR to be a positive experience that supported their management of pain. Within the acute pain studies (n=84), feasibility was assessed in 35 studies. When evaluated, feasibility of VR appears to be high according to patients, caregivers, and health care staff. Feasibility was assessed in several different ways including but not limited to recruitment and withdrawal rates, satisfaction surveys, patient-reported "fun," and provider-reported disruption in clinical flow. Recruitment rates varied but indicated moderate (40/65, 62%) to high (66/71, 93%) levels of interest in VR use, and dropout rates were reported to be low. Health care professionals also indicated good feasibility. VR was perceived to not interfere with procedure time, decrease the perceived difficulty of procedures, and be easily implementable in the clinic setting, and health care staff expressed interest in repeated use. Patients and caregivers reported ease of use, high levels of satisfaction with VR, preference for VR over alternate distraction methods, and interest in repeated use in future procedures. As such, although more consistent assessment of VR feasibility is needed, the available data from the pediatric acute pain management setting suggest that VR is acceptable and feasible across stakeholders.

XR Safety

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Across included studies, safety, often measured through the presence of adverse events, was measured or reported 49% (44/90) of the time. Within the chronic pain studies, only 2 studies examined the safety of the VR intervention, so

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conclusions regarding the safety of VR for chronic pain populations cannot be made. Among the pediatric acute pain studies, 44 studies examined safety, limiting our ability to draw robust conclusions for safety. However, when safety or adverse events were reported, most studies (31/44, 70%) reported no adverse events or no differences between their control and VR intervention groups. When adverse events were reported, they were most often mild in nature and occurred in a minority of the participants. Rates of adverse events varied, occurring in <1% to 17% of participants, with intensity and severity of the concern low (eg, nausea rating of 4/100). Two studies reported that at least 1 participant withdrew from the intervention due to reported adverse events.

XR Effectiveness

Several treatment targets emerged through the review as relevant to the effectiveness of VR for pain management. That is, targets of VR interventions for acute and chronic pain often went beyond pain intensity itself, as measures of effectiveness spanned several domains (eg, pain intensity, physical functioning, fear, anxiety). Given the wide variety of targeted outcomes, we summarized the findings across the identified target domains for acute and chronic pain. The variability in targets highlights several areas where additional research is needed to adequately examine the effectiveness of VR for pediatric pain.

Pain intensity was examined across all included studies (n=90), and overall, VR interventions demonstrated good effectiveness for reducing pain intensity (see Figure 4). Among the acute pain studies, 63% (53/84) demonstrated a positive effect (statistically significant reduction in pain) of VR on pain intensity, 21% (18/84) demonstrated no effect (nonsignificant reduction in pain or no change in pain), and 12% (10/84) demonstrated a mixed effect (different results across pain measures, pain reporter, or

at different time points in the intervention) on pain intensity. Mixed effect findings were often due to a variable impact of VR on pain across a procedure (eg, positive impact on postprocedural pain but no effect on pain during the procedure) or variable impact of VR on pain across informants (eg, child reported improved pain, no improvement in pain reported by health care provider). No studies reported worse pain than the control or following the VR intervention. Among the chronic pain studies, 100% (6/6) of the studies demonstrated improved pain intensity in the context of the VR intervention.





Evidence and Gap Map

There was a wide range of outcome targets across studies. We created an evidence and gap map to collate current targets of VR in pain management as well as illuminate gaps (Figure 5). Guided by the conceptual model described by Trost et al [118], we categorized studies according to their target population as well as measured outcome targets. Additionally, the risk of bias results were integrated into the evidence and gap map. Therefore, the map illustrates, across the 90 included studies, the populations and pain targets with greater amounts of research evidence and those with missing or scant research evidence as well as the quality of evidence at various intersections (eg, pediatric venipuncture research targeting anxiety and pain intensity). Specifically, for XR research, the gap map illuminated significant gaps in research using XR to support pain

management in pediatric chronic pain populations. Within the chronic pain populations, no research exists related to postsurgical or trauma-related pain, headaches, or neuropathic pain. Additionally, the risk of bias across all studies was moderate to high, prompting the need for more sophisticated research designs to reduce the risk of bias, particularly as it relates to blinding the research team and study participants. Within the acute pain setting, the most studied patient populations were children undergoing venipunctures and minor procedures. Primary targets of XR intervention for acute pain include pain intensity and emotional functioning. Across acute and chronic pain, measuring the effectiveness of XR on other important outcomes such as user experience, social functioning, and quality of life are important gaps that emerged from this review.



Figure 5. Snapshot of the evidence and gap map for virtual reality trials in pediatric acute and chronic pain [118]. The interactive evidence and gap map can be found in [119].



Measures in XR Research

Across all study outcomes (feasibility, safety, effectiveness targets), there was tremendous variability in the outcome measures used. As such, we identified the number of distinct measures and the frequency of measures used across each outcome, which are summarized in Table 2. Full details of the measures used within each outcome domain can be found in Multimedia Appendix 4. Measures in XR research include validated. study-specific, researcher-developed and researcher-adapted tools. Additionally, similar measures are often used in distinct ways to measure different outcomes. For example, some researchers used heart rate as a measure of physical functioning, while others used heart rate as a measure of anxiety. The outcome target with the highest number of measures was psychological constructs, which contained 31 distinct measures across 67 studies. This is unsurprising as psychological construct is a broad outcome inclusive of multiple psychological and emotional states including but not limited to anxiety, mood, fear of pain, and pain catastrophizing. The outcome target with the second highest number of measures was feasibility, which contained 14 distinct measures across 28 studies, followed by user experience, which contained 13 distinct measures across 18 studies. The number of measures used across studies for each outcome domain is summarized in Table 2. This review highlighted that there is little agreement regarding how best to measure outcomes in XR research, an important area for future study, particularly given the high number of researcher-developed or researcher-adapted measures currently being used.

Table 2. The number of measures used within each outcome domain across pediatric acute and chronic pain studies.

Outcome domain	Measures, n
Pain intensity	21
Adverse events	8
User experience	13
Psychological constructs	31
Pain interference	8
Feasibility	14
Health care utilization	9
Quality of life	2
Physiological markers	10

Discussion

Principal Findings

Overall, in the context of pediatric acute pain, specifically venipuncture and minor procedural pain, good evidence exists to support continued use of XR, as it is effective for the management of pain and emotional functioning and demonstrates good feasibility and safety. Limited evidence exists, however, to guide the use of XR research in chronic pain populations. Although initial evidence does appear promising for the utility of XR to support pain management in several

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chronic pain populations (eg, cancer-related pain, abdominal pain, diffuse musculoskeletal pain), more robust examination is needed as is research that assesses the safety and feasibility of implementing XR into the flow of clinical care. Another area requiring more research in pediatric populations is the subacute period (ie, up to 3 months after injury, trauma, or surgery). Research has demonstrated this period to be a vulnerable time for the development of fear avoidance related to pain and movement, which increases the risk for the transition of acute pain to chronic pain [8]. XR interventions would likely be useful during this period as both a form of distraction and to support confrontation of feared movements.

This review indicates that most studies to date have been implemented within the context of a children's hospital, which is unsurprising given the preponderance of research focused on acute pain management. However, there is limited research to guide the implementation of XR research outside the context of a hospital setting, which may be particularly important for chronic pain patients who may be receiving care across a variety of treatment settings (eg, home, outpatient clinic, physical therapy clinic). In the adult literature, XR has been successfully implemented into community care for chronic pain management [120,121]; however, this is unstudied in pediatric populations. The use of implementation science frameworks (eg, Consolidated Framework for Implementation Research) [122] to evaluate contextual and personnel differences as they relate to technology integration in settings outside of a hospital can support these efforts.

This review also demonstrated that research to date has been exclusively on the use of VR in pediatric pain management, and, as such, little is known about the potential for AR to support acute and chronic pain. Exploration of the utility of AR is particularly relevant in the context of chronic pain where exposure to painful movements may benefit from gradation such that a young person is first fully distracted by immersion into a VR world then gradually progressed toward exposure of their environment using an AR system to continue to support distraction while increasing exposure to their lived environment [123-125].

Another finding of this review is the significant variability in the way outcomes are being measured across XR studies. That is, measurement remains an area for needed consensus to support a better ability to compare effectiveness of XR across studies. Moreover, efforts are needed and indeed underway to better define both process (eg, immersion) [23] and outcome (eg, pain intensity) variables in XR trials, which will facilitate better reporting and thus improved ability to effectively compare XR across studies. Moreover, definitions of emotional functioning were also quite varied across studies, even when similar constructs were being targeted (ie, anxiety, fear, mood). Different definitions of anxiety and fear emerged across studies as well as how they were operationalized and assessed. For example, some studies assessed anxiety vis-à-vis heart rate variability and oxygen saturation, while other studies completed self-report assessments, proxy reports, and behavioral observations. Although all approaches to assessing anxiety may be valid, it limits the comparability of anxiety as an outcome across studies. Additionally, mood was examined to a much lesser degree in the reviewed studies and warrants increased attention, particularly in the context of chronic pain or acute-to-chronic pain transition. Another challenge with comparing XR effectiveness across studies is inconsistent reporting of study protocols. In this review, several studies were excluded because of an insufficient description of the XR technology. Creation of standards for reporting for XR studies, including how to describe the technology used (eg, hardware and software) and intervention protocol (eg, number of sessions, duration of intervention), is needed to increase the ability to replicate studies and compare outcomes across studies, thereby improving our ability to understand which XR approaches are

most effective, when they are most effective, and for whom they are most effective.

There are also potential outcomes or targets of XR research that warrant attention, namely social and academic functioning alongside quality of life. Given the growing feasibility of real-time social interactions in the context of XR alongside established challenges for youth with pain to engage socially with peers [126], examination of the potential for XR research to improve or support social functioning is an important area for future work. Building from existing literature that has demonstrated the effectiveness of virtual peer-to-peer pain groups [127-130], development of virtual pain groups that can target multiple domains of functioning (eg, physical functioning, social functioning) is an untapped and potentially high-yield target for XR research. Similarly, academic functioning is commonly cited as a challenge for youth with chronic pain [131,132], and although research is emerging in this domain [133], more is needed to evaluate the potential for XR research to support academic engagement and facilitate a return to school learning for youth with pain. Finally, quality of life was minimally examined in the included studies (n=2). This is likely due to the overwhelming number of studies focused on acute pain where quality of life measures may be less relevant; however, development of quality of care measures or consideration for implementation of quality of care measures that are relevant to the acute pain context may be important to truly capture the impact of XR on patients. Moreover, as additional research is conducted in the chronic pain population, where pain and anxiety may become less of an emphasis, quality of life measures will be important markers of improvement.

Finally, decreasing the risk of bias in XR studies also emerged as an important priority for future research. That is, most studies had a moderate to high risk of bias according to the RoB-2 assessment, prompting the need for more sophisticated research designs. Specific areas where innovation is needed are addressing participant blinding to the intervention and the development of prespecified analysis plans. Given the nature of XR interventions, innovation for blinding participants to their assigned group, such as the development and use of sham XR software, is needed to decrease the risk of bias. Prepublished analysis plans and transparency surrounding blinding of the analyses are also needed.

Limitations

This systematic review has some limitations that are important to note. First, the search for this systematic review was completed in March 2023 and likely omits several manuscripts published since then. Given the rapidity of XR research in pediatrics, it was not feasible for this research group to keep pace with the rate of publication. Moreover, this review was conducted with the aim of supporting the consensus conference surrounding outcomes for pediatric XR research. Future updates to this review are needed to support ongoing identification of gaps in research and inform clinical practice. Additionally, although a strength of this review is the breadth of studies included, future research could be conducted to allow for more focused assessment of efficacy, particularly as it relates to specific patient populations and XR configurations. To this end,

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future research should consider the interaction of XR interventions and child development to assess whether developmental stage or chronological age impact XR feasibility, safety, or effectiveness and guide precision medicine to match the XR intervention or configuration to best meet the needs of youth across diverse developmental stages. This review assessed the risk of bias for all included studies; however, this is not synonymous with quality and should be interpreted with caution. That is, studies may have been of high quality yet received high risk of bias scores due to their lack of blinding, a common challenge faced by XR researchers. Finally, studies were limited to the English language and excluded gray literature and conference papers, which may limit the inclusion of important research published in languages other than English and could reinforce publication bias such that studies in which XR was unhelpful or not feasible are not well represented.

Conclusion

This systematic review provides an important update regarding the state of XR research for pediatric acute and chronic pain. Review of XR feasibility, safety, and effectiveness solidified the significant potential of XR for pain management across a variety of pain presentations and for a range of diverse outcomes. Moreover, the developed evidence and gap map illuminated important gaps in the current research base that warrant attention. Finally, limitations identified in the research studies reviewed also highlight the need for innovative research designs, establishment of measurement consensus, and improved reporting standards for XR studies to more effectively establish best practices in XR intervention research and improve clinical translation of the evidence base.

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Authors declare that there was no use of GenAI in the production of the described research, analysis or interpretation of data, or in the writing of the submitted manuscript.

Data Availability

All data from the systematic review are available upon request from primary or senior authors.

Authors' Contributions

JNS, LES, DL, and JIG were involved in the conceptualization of the study, funding acquisition, and supervision as well as data analysis and review and editing of the drafted manuscript. CWH, BNR, and GM were involved in the conceptualization of the study, data curation, formal analysis, data visualization, and writing of the manuscript. CO was involved in the data curation and offered her expertise as a person with lived experience. EC was responsible for project administration and data visualization. All authors made substantial contributions to the study and provided approval of the submitted manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1 Librarian search strategy. [DOCX File , 28 KB - pediatrics v8i1e63854 app1.docx]

Multimedia Appendix 2 Operational definitions of pain populations and outcome targets to guide evidence and gap map coding. [DOCX File , 21 KB - pediatrics v8i1e63854 app2.docx]

Multimedia Appendix 3

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Fulsome details of 90 included VR intervention studies for pediatric acute and chronic pain. [XLSX File (Microsoft Excel File), 46 KB - pediatrics_v8i1e63854_app3.xlsx]

Multimedia Appendix 4

Measures used across outcome domains in VR trials for pediatric acute and chronic pain. [XLSX File (Microsoft Excel File), 14 KB - pediatrics_v8i1e63854_app4.xlsx]

Multimedia Appendix 5

PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist. [DOCX File , 32 KB - pediatrics_v8i1e63854_app5.docx]

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Abbreviations

AR: augmented reality MINORS: Methodological Index for Non-Randomized Studies PICO: Population, Intervention, Comparison, Outcome RCT: randomized controlled trial RoB-2: Cochrane Risk of Bias Tool VR: virtual reality XR: extended reality

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Supervised and Unsupervised Screen Time and Its Association With Physical, Mental, and Social Health of School-Going Children in Dhaka, Bangladesh: Cross-Sectional Study

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Abstract

Background: Children's screen time has substantially increased worldwide, including in Bangladesh, especially since the pandemic, which is raising concern about its potential adverse effects on their physical, mental, and social health. Parental supervision may play a crucial role in mitigating these negative impacts. However, there is a lack of empirical evidence assessing the relationship between parental screen time supervision and health outcomes among school children in Dhaka, Bangladesh.

Objective: We aimed to explore the association between supervised and unsupervised screen time on the physical, mental, and social health of school-going children in Dhaka, Bangladesh.

Methods: We conducted a cross-sectional descriptive study between July 2022 and June 2024. A total of 420 children, aged 6 - 14 years, were enrolled via the stratified random sampling method across three English medium and three Bangla medium schools in Dhaka. Data were collected through a semistructured questionnaire; anthropometry measurements; and the Bangla-validated Strength and Difficulties Questionnaire (SDQ), Pittsburgh Sleep Quality Index (PSQI) Scale, and Spencer Children Anxiety Scale (SCAS).

Results: A total of 234 out of 420 students (56%) used digital screen devices without parental supervision. We did not find a substantial difference in the duration of the daily mean use of digital devices among the supervised students (4.5 hours, SD 2.2 hours) and the unsupervised students (4.6 hours, SD 2.4 hours). According to the type of school, English medium school children had a mean higher screen time (5.46 hours, SD 2.32 hours) compared to Bangla medium school children (3.67 hours, SD 2.00 hours). Headache was significantly higher among the unsupervised digital screen users compared to those who used digital screens with parental supervision (175/336 students, 52.1% versus 161/336 students, 47.9%; P<.003). Moreover, students who used digital screens without parental supervision had poor quality of sleep. Behavioral problems such as conduct issues (119/420 students, 28.3%) and peer difficulties (121/420 students, 28.8%) were observed among the participants. However, when comparing supervised and unsupervised students, we found no statistically significant differences in the prevalence of these issues.

Conclusions: The findings of the study showed that the lack of screen time supervision is associated with negative health effects in children. The roles of various stakeholders, including schools, parents, policy makers, and students themselves, are crucial in developing effective guidelines for managing screen use among students. Further research is needed to demonstrate causal mechanisms; identify the best interventions; and determine the role of mediators and moderators in households, surroundings, and schools.

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KEYWORDS

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screen time; parental supervision; Strength and Difficulties Questionnaire; Spencer Children Anxiety Scale; Pittsburgh Sleep Quality Scale; children; sleep quality; headache; behavioral problems

Introduction

To what extent can parental supervision mitigate the effects of excessive digital screens in school-going adolescents? This is becoming an increasingly common concern of parents and researchers, as digital screens fill our living spaces and take up our quality time. A recent study showed that daily screen time for users aged 16 - 64 years has increased to 6 hours 37 minutes worldwide [1]. Across age groups, 44% of all waking hours are spent on screens [1]. In 2020, the World Health Organization released a milestone report with detailed guidelines on sedentary behavior including screen time for children under the age of 5 years, defining screen time as time spent passively watching screen-based entertainment (TV, computer, or mobile devices) [2]. The American Academy of Child and Adolescent Psychiatry agreed with the findings, recommending less than 2 hours of daily screen time for children aged under 5 years, but for children aged 6 years and older, recommending "healthy habits" and to "limit activities that include screens" [3]. At present, no concrete guidelines have been presented for adolescents, although health concerns are just as pressing for them [4].

Higher sedentary behavior such as screen time is associated with a range of physical and mental health issues, including headaches, myopia, obesity, sleep disorders, behavioral disorders, and anxiety [4-8]. A study of 5844 children around the world found that children averaged 8.6 hours of daily sedentary time, associated with poor weight status and physical inactivity [9]. Lauricella and Cingel [10] found one of the most reliable predictors of higher screen time among adolescents to be parental media use, along with weaker associations with parental attitudes to technology and screen time rules.

In Asia, higher incomes and a rising middle class have led to longer exposure to screen time (>2 h a day) for children and adolescents [11,12]. Without parental intervention, excessive screen time exposure has been associated with less sleep duration among Asian preschoolers, but Lin et al [13] found parental education and awareness, among best practices, to be an effective intervention against these effects.

Bangladesh's rising socioeconomic status has contributed to an explosion in digital device access and usage across demographics [14]. Khan and Burton [15] found that almost 80% of Bangladeshi adolescents have high recreational screen time, reported at 4.0 (SD 2.2) hours per day on average, with the mean values of 4.3 (SD 2.4) hours for boys and 3.6 (SD 2.3) hours for girls. High screen time was associated with sleep disturbance and higher family income, among other factors [15]. Anjum et al [16] found a higher incidence of depressive symptoms in adolescents with higher screen time exposure (>2 h per day), alongside other physical and mental health concerns including sleep disturbance and mood disorders prior to the COVID-19 pandemic.

During the COVID-19 lockdown, Bangladeshi children began to spend much more time on the internet, for entertainment, communication, and education [17-19]. Koly and colleagues [20] noted worsening psycho-social health of school-going students in this period, associated with quarantine adaptations and difficulties with online learning. Simultaneously, Rashid

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and colleagues [21] found physical and mental health deterioration among secondary school students, with symptoms including headaches, backaches, visual and sleep disturbance, and depression. During the pandemic, online learning became a necessity, leading to a significant increase in children's digital screen use. While it ensured educational continuity, this shift also contributed to extended screen time, potentially indicating the physical, mental, and emotional health risks associated with excessive screen exposure [4,22].

Following the pandemic, increased digital screen time did not lessen, leading to significant adverse consequences on adolescent health [23,24]. For instance, Shuvo and Biswas [25] note that when electronic device exposure overlaps with eating times and habits, there is an increased likelihood of obesity. Meanwhile, heavier reliance on technology for education, entertainment, and socialization after COVID is associated with increased anxiety, difficulty sleeping, addiction, and various sociobehavioral difficulties [23,24,26].

In Bangladesh, there is a dearth of comprehensive academic research on the effects of screen time on adolescents, despite the fact that there is a substantial amount of empirical evidence around the world [4,22,27-34]. Furthermore, as the results are utilized to create thorough screen-use guidelines, these studies have significant policy ramifications. Furthermore, while parental supervision is crucial in preventing excessive screen time, researchers found that inappropriate methods to discipline children and adolescents may increase long-term screen use and exaggerate other adverse psychosocial effects [24,35]. Therefore, this study aimed to distinguish between the effects of supervised and unsupervised screen time on the physical, mental, and social health of Bangladeshi schoolchildren.

Methods

Study Setting, Participants, and Sampling

This was a cross-sectional descriptive study and adopted a quantitative approach. The survey was conducted between July 2022 to June 2024. We purposively selected 6 schools from the list of all schools in Dhaka North and South city corporations to ensure the equal distribution of the Bangla and English medium schools. Moreover, we considered the socioeconomic, geographic, and feasibility of data collection. During the school selection, with the approval of the school authorities, we considered children aged between 6 to 14 years who were in class 2 to class 8 and who had more than 2 hours of screen time each day as the qualifying criteria for sample inclusion. Smartphones, tablets, laptops, personal computers, gaming consoles, televisions, and portable gaming devices were among the acceptable gadgets. Children with preexisting conditions, such as physical or psychological impairment, were excluded from the study, as this might have influenced the results. We used a stratified random sampling method to recruit a total of 420 students, by including 70 students from each school (ie, 10 students from each grade from grades 2 to 8).

Data Collection Procedure

We collected data through face-to-face interviews with parents and students on school grounds. The day prior to the interview,

study staff scheduled the appointment time with parents, and the class teacher brought the students during the lunch break. A half-hour interview period was allotted for students and an hour for parents. To check for differences in accuracy between staff and trainers (ie, psychologists who trained all the staff on each of the psychometric tools used in this study), 30 pilot tests were performed prior to the start of data collection. Interrater reliability was measured using the Cohen kappa coefficient to quantify the level of agreement between each of the three staff and trainers (n=30 nonstudy participants/staff) for all the Bangla-validated scales. On average, the calculated Cohen kappa values ranged between 0.84 and 0.89 (scores for 30 nonstudy participants/staff-trainer pairs), indicating strong agreement among the staff.

All data collection forms were checked at the field site for completeness, accuracy, and consistency. The quality control team was responsible for regular observations at school, and identical forms and tools were used across the duration of the study. Investigators personally traveled to the sites weekly to ensure proper field implementation.

Study Instruments

Screen Time

A semistructured questionnaire was developed to collect information about screen time from both parents and students. The parents' questionnaires included socioeconomic factors, pattern and quantity of child screen time usage, gadget-using behavior of the children, and parents' mediating role in screen time exposure (supervised vs unsupervised). The student's questionnaire included the type of device use, time and pattern of use, and purpose of device use. Screen time was considered to be any time spent engaging with content in front of a digital device with an electronic screen, including but not limited to iPads, gaming consoles, laptops, smartphones, tablets, and desktop devices. Students were categorized into supervised versus unsupervised based on the self-reporting information regarding the supervision. In this study, supervised screen time is defined as when parents are aware of their child's digital device usage, including what they are doing, how much time they spend, and the type of content they consume. In contrast, unsupervised screen time occurs when parents lack awareness of their child's activities, duration of use, and the content they engage with on digital devices. Similar definitions have been used in other studies [36,37].

Physical Health

Anthropometric measurements (weight and height) were collected from students on school premises during data collection. Measurements were calibrated daily before data collection to ensure standardization. The BMI (kg/m²) was calculated and converted to z-scores, then categorized according to cut-off points given by the World Health Organization BMI-for-age growth chart for ages 5 to 19 years: underweight ($<15 \text{ kg/m}^2$, -1 SD), normal weight ($15 - 25 \text{ kg/m}^2$), overweight ($25 - 30 \text{ kg/m}^2$, +1 SD), obese ($30 - 40 \text{ kg/m}^2$, +2 SD), and morbidly obese ($>40 \text{ kg/m}^2$, +4 SD) [38]. Additional physical health issues, such as blurred vision, headaches, indigestion,

backache, and neck pain, were also asked of the students via a questionnaire. The students' physical health responses were initially categorized into four groups: "No," "Sometimes," "Often," and "Most of the time." These categories were then consolidated into two broader groups: "No" and "Yes," with "Yes" encompassing the responses "Sometimes," "Often," and "Most of the time."

Mental and Social Health

Age-appropriate Bangla-validated versions of the following scales were used to find well-being indicators for children's mental and social health.

Strength and Difficulties Questionnaire

This is a behavioral questionnaire (25 questions) designed to identify a combination of positive and negative attributes across 5 dimensions-emotional symptoms, conduct problems, hyperactivity or attention deficit, peer relationship problems, and prosocial behavior. The sum of the scores of the four negative behavior subscales represents the children's general difficult behavior with a maximum score of 40, whereas the maximum score for prosocial behavior is 10. Gustin and colleagues have verified the Strength and Difficulties Questionnaire (SDQ) against independent clinical diagnoses of Bangladeshi children [39,40].

Spencer Children Anxiety Scale

This scale is used to evaluate symptoms relating to separation anxiety, social phobia, obsessive-compulsive disorder, panic, agoraphobia, generalized anxiety, and fear of injury. Goodman et al have validated the Spencer Children Anxiety Scale (SCAS) as a reliable instrument for Bangla-speaking communities [41].

Pittsburgh Sleep Quality Index

This questionnaire has components spanning several subcategories such as subjective sleep quality, latency, duration, habitual efficiency, disturbances, sleeping medication, and daytime dysfunction. Mamun et al [42] have successfully used the Pittsburgh Sleep Quality Index (PSQI) to identify sleep-related concerns among Bangladeshi students.

Statistical Analysis

Data were entered via IBM SPSS version 20.0 (IBM Corp) and analyzed on Stata version 15.1 (StataCorp LLC). Categorical data were represented as frequency numbers and percentages, while continuous data with reasonably normal distributions were summarized as means and SDs. Nonnormal continuous data were instead summarized as medians and IQRs. Participants were categorized into two main subgroups, supervised and unsupervised. Subsequently, a comparative analysis was performed across various factors, including demographic characteristics, amount of screen time, and health metrics. To assess differences across groups, the chi-squared test for independence was employed for categorical data, and the 2-tailed unpaired t test for differences between proportions was used for continuous data with nearly normal distributions. A significance threshold of P < .05 was used to assess statistical significance.

Ethical Considerations

This study was approved by the Institutional Review Board of icddr,b (protocol number: PR-22002). Written informed consent was obtained from all parents, and confidentiality and anonymity were maintained throughout the study. Children aged above 11 years provided assent in addition to their parents' consent. All the respondents were informed in Bengali about their rights related to their voluntary participation in the study as well as their right to withdraw from the interview at any time during the interview.

Results

A total of 420 students were enrolled based on the screening criteria. Of them, 186 (44%) children were supervised and 234 (56%) children were unsupervised. Table 1 represents the demographic summary statistics of the population. The students were between 6 and 14 years, with a mean age of 10.9 (SD 1.9) years; 207 out of the 420 children (49.3%) were girls. Of the 420 children, 292 (69.5%) belonged to single-family households. In families with 1 - 2 children, 161 out of 288 children (55.9%) were unsupervised, while for families with more than 3 children, 73 out of 132 children (55.3%) were unsupervised.

Table . Demographic and socioeconomic information of study participants.

Characteristics	Overall (N=420)	Supervised (n=186)	Unsupervised (n=234)
Child's age (years)			
Mean (SD)	10.9 (1.9)	11.0 (1.9)	10.8 (1.9)
Child's sex, n (%)			
Male	213 (50.7)	101 (47.4)	112 (52.6)
Female	207 (49.3)	85 (41.1)	122 (58.9)
Family type, n (%)			
Single	292 (69.5)	132 (45.2)	160 (54.8)
Joint	128 (30.5)	54 (42.2)	74 (57.8)
Number of children in the family, n (%)			
1 - 2	288 (68.6)	127 (44.1)	161 (55.9)
≥3	132 (31.4)	59 (44.7)	73 (55.3)
Average monthly income, n (%)			
<bdt<sup>a 50,000 (<us\$ 420)<="" td=""><td>137 (32.6)</td><td>57 (41.6)</td><td>80 (58.4)</td></us\$></bdt<sup>	137 (32.6)	57 (41.6)	80 (58.4)
BDT 50,000 - 100,000 (>US\$ 420 to <us\$ 840)<="" td=""><td>144 (34.3)</td><td>63 (43.8)</td><td>81 (56.2)</td></us\$>	144 (34.3)	63 (43.8)	81 (56.2)
>BDT 100,000 (>US\$ 840)	139 (33.1)	66 (47.5)	73 (52.5)

^aBDT: Bangladeshi taka.

The mean total daily screen time for the entire population was 4.6 (SD 2.3) hours. The large SD relative to the mean indicates widely varying screen habits among the study population. The range of screen time for the unsupervised group was 0.3 - 15 hours and that for the supervised group was 0 - 12 hours. The mean total daily screen time for the unsupervised group was 4.6 (SD 2.4) hours, slightly higher than the supervised group's mean of 4.5 (SD 2.2) hours. These large deviations imply factors other than supervision contribute more to total screen time.

Multimedia Appendix 1 shows the mean daily screen time spent by children categorized by age, sex, and type of school. No significant difference was observed in the mean daily screen time between different age groups (6 - 10 years vs 11 - 14 years) or between male and female participants. However, children attending English medium schools had a significantly higher average daily screen time (5.4 hours) compared to those attending Bangla medium schools (3.6 hours).

Table 2 shows the prevalence of physical symptoms among students with supervised and unsupervised use of digital devices. Overall, out of 420 students, 391 (93.1%) students experienced blurred vision, 341 (81.2%) reported abdominal pain, 336 (80%) had headaches, and 327 (77.9%) experienced dry eyes or soreness. Considering all the health issues, a higher proportion of unsupervised students experienced these problems compared to supervised students. Headaches were significantly more prevalent among the unsupervised group (175/336 children, 52.1%) than the supervised group (161/336 children, 47.9%; P<.003). All the data are shown in Table 2.

Table .	Prevalence of physical	symptoms among study	participants w	ith supervised and	unsupervised us	se of digital screens and	devices.
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Physical symptoms	Frequency (N=420), n (%)	Supervised (n=186), n (%)	Unsupervised (n=234), n (%)	<i>P</i> value
Eye problems	150 (35.7)	64 (42.7)	86 (57.3)	.62
Dry eye or soreness	327 (77.9)	150 (45.9)	177 (54.1)	.22
Blurred vision	391 (93.1)	177 (45.3)	214 (54.7)	.14
Hearing difficulty	14 (3.3)	6 (42.9)	8 (57.1)	.91
Indigestion or gas	276 (65.7)	118 (42.8)	158 (57.2)	.38
Headache	336 (80.0)	161 (47.9)	175 (52.1)	.003
Neck pain	192 (45.7)	86 (44.8)	106 (55.2)	.85
Abdominal pain	341 (81.2)	150 (44.0)	191 (56.0)	.80
Back or any other muscu- loskeletal problem	134 (31.9)	63 (47.0)	71 (53.0)	.44
Diabetes	4 (1.0)	0 (0.0)	4 (100.0)	.07
Change in appetite	204 (48.6)	86 (42.2)	118 (57.8)	.39
Sleep issues	82 (19.5)	32 (39.0)	50 (61.0)	.29

Table 3 shows a mean BMI of 19.3 (SD 4.7) kg/m² for the study population. There was a slight difference in the mean BMI between the supervised (mean 19.6 kg/m², SD 4.9 kg/m²) and unsupervised (mean 19.1 kg/m², SD 4.4 kg/m²) groups (P=.26

indicates statistical insignificance). Overall, out of 420 children, 335 (80.1%) children were healthy, 21 (5%) were underweight, and 42 (10.1%) were overweight/obese. No statistically significant differences were observed in the distribution of BMI between the supervised and unsupervised categories.

Table . Association of BMI with supervised and unsupervised digital screen use.

Characteristics	Overall (N=420)	Supervised (n=186)	Unsupervised (n=234)	<i>P</i> value
BMI, kg/m ²				.26
Mean (SD)	19.3 (4.7)	19.6 (4.9)	19.1 (4.4)	
BMI category, n (%)				.50
Underweight	21 (5.0)	9 (42.9)	12 (57.1)	
Healthy weight	335 (80.1)	143 (42.7)	192 (57.3)	
Overweight	42 (10.1)	21 (50.0)	21 (50.0)	
Obesity	16 (3.8)	9 (56.2)	7 (43.8)	
Severe obesity	4 (1.0)	3 (75.0)	1 (25.0)	

Table 4 shows the association of anxiety with supervised and unsupervised digital screen use. Out of 420 children, 414 (98.6%) children were identified within the normal range. Just 1 of the 6 children fell into the high anxiety range; only 1 was left unsupervised and the other 5 were in the supervised group. Despite the fact that there was a significant difference (P<.05), the small number of individuals in this group could provide an inaccurate correlation. It is recommended to conduct additional research before drawing any conclusions. There were no discernible variations between the supervised and unsupervised proportions for any specific anxiety subcategory on the SCAS.

Multimedia Appendix 2 shows the results of the SDQ scale in the 420 students; of the 420 students, 119 students (28.3%) had conduct problems, 121 students (28.8%) had peer problems, 66 students (15.7%) reported emotional problems, 73 students (17.4%) experienced hyperactivity, and 28 students (6.7%) reported prosocial behaviors. Based on the borderline/abnormal

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results shown in Multimedia Appendix 2, Table 5 was prepared, and it shows the distribution of supervised and unsupervised children categorized as having borderline/abnormal results for digital screen use based on the SDQ subcategories (emotional symptoms, conduct problems, hyperactivity or attention deficit, peer relationship problems, and prosocial behavior).

The percentage of unsupervised children was greater than that of supervised children among those classified as having borderline or abnormal results. The most common abnormality was peer relationship problems among the children. Of the 420 students, 121 (28.8%) had peer relationship problems: 55 students (45.38%) were supervised and 66 students (55.6%) were unsupervised. Less borderline/abnormal results were found considering prosocial behavior. Of the 420 students, 28 (6.7%) were identified with abnormal/borderline results: 11 (39.29%) were supervised and 17 (60.71%) were unsupervised.

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Table . Association of anxiety with supervised and unsupervised digital screen use by using the Spencer Children Anxiety Scale (SCAS).

SCAS	Overall (N=420), n (%)	Supervised (n=186), n (%)	Unsupervised (n=234), n (%)	<i>P</i> value
Overall			·	.05
Normal range	414 (98.6)	181 (43.7)	233 (56.3)	
Elevated range	6 (1.4)	5 (83.3)	1 (16.7)	

Table . Distribution of supervised and unsupervised children categorized as borderline/abnormal for digital screen use based on the Strength and Difficulties Questionnaire subcategories (emotional symptoms, conduct problems, hyperactivity, peer relationship problems, and prosocial behavior).

Category	Supervised (%)	Unsupervised (%)
Emotional symptoms	43.94	56.66
Conduct problems	45.38	54.62
Hyperactivity	47.95	52.05
Peer relationship problems	45.45	54.55
Prosocial behavior	39.29	60.71

Table 6 shows that a majority of children reported good quality of sleep on the PSQI (358/420, 85.2%). Of those who reported bad sleep, the proportions were similar between supervised and unsupervised children (14% of supervised children vs 15.4% of unsupervised children). Nonetheless, a potentially significant result was found on comparing the mean total sleeping durations: supervised children sleep on average for 7.7 (SD 1.5) hours,

compared to 7.4 (SD 1.6) hours for unsupervised children (against an overall mean of 7.6, SD 1.6). However, the *P* value showed borderline significance; furthermore, if the children were subcategorized by the average hours of sleep (>7, 6 - 7, 5 - 6, and <5 hours), no significant difference was found across any subgroup between supervised and unsupervised children.



Table . Association of quality of sleep using the Pittsburgh Sleep Quality Index (PSQI) scale with supervised and unsupervised digital screen use.

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PSQI scale	Overall (N=420)	Supervised (n=186)	Unsupervised (n=234)	<i>P</i> value
Sleep status, n (%)				.69
Good sleep (global PSQI score ≤5)	358 (85.2)	160 (44.6)	198 (55.3)	
Bad sleep (global PSQI score >5)	62 (14.8)	26 (14.0)	36 (15.4)	
Sleep time				.05
Mean bedtime, PM	11:17	11:11	11:21	
Mean wake time, AM	7:19	7:24	7:16	
Total sleeping duration (h), mean (SD)	7.6 (1.6)	7.7 (1.5)	7.4 (1.6)	
Sleep quality, n (%)				.18
Very good	202 (48.1)	82 (44.1)	120 (51.3)	
Fairly good	199 (47.4)	94 (50.5)	105 (44.9)	
Fairly bad	17 (4.0)	10 (5.4)	7 (3.0)	
Very bad	2 (0.5)	0 (0.0)	2 (0.9)	
Sleep latency, n (%)				.85
0	100 (23.8)	41 (22.0)	59 (25.2)	
1 - 2	207 (49.3)	94 (50.5)	113 (48.3)	
3 - 4	105 (25.0)	48 (25.8)	57 (24.4)	
5 - 6	8 (1.9)	3 (1.6)	5 (2.1)	
Sleep duration, n (%)				.06
>7 hours	237 (56.4)	112 (60.2)	125 (53.4)	
6 - 7 hours	123 (29.3)	53 (28.5)	70 (29.9)	
5 - 6 hours	44 (10.5)	19 (10.2)	25 (10.7)	
<5 hours	16 (3.8)	2 (1.1)	14 (6.0)	
Habitual sleep efficiency, n (%)				.40
>85%	393 (93.6)	176 (94.6)	217 (92.7)	
75 - 84%	25 (6.0)	10 (5.4)	15 (6.4)	
65 - 74%	2 (0.5)	0 (0.0)	2 (0.9)	
<65%	0 (0.0)	0 (0.0)	0 (0.0)	
Sleep disturbances, n (%)				.80
0	38 (9.0)	18 (9.7)	20 (8.6)	
1 - 9	364 (86.7)	161 (86.6)	203 (86.8)	
10 - 18	17 (4.0)	7 (3.8)	10 (4.3)	
19 - 27	1 (0.2)	0 (0.0)	1 (0.4)	
Use of sleeping medication, n (%)				.30
Not during the past month	417 (99.3)	186 (100.0)	231 (98.7	
Less than once a week	2 (0.5)	0 (0.0)	2 (0.9)	
Once or twice a week	1 (0.2)	0 (0.0)	1 (0.4)	
Three or more times a week	0 (0.0)	0 (0.0)	0 (0.0)	
Daytime dysfunction, n (%)				.88

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PSQI scale	Overall (N=420)	Supervised (n=186)	Unsupervised (n=234)	<i>P</i> value
0	283 (67.4)	124 (66.7)	159 (68.0)	
1 - 2	121 (28.8)	54 (29.0)	67 (28.6)	
3 - 4	13 (3.1)	7 (3.8)	6 (2.6)	
5 - 6	3 (0.7)	1 (0.5)	2 (0.9)	

Discussion

Principal Results and Comparison With Prior Works

This study enrolled a total of 420 children, with 186 (44%) supervised and 234 (56%) unsupervised children. Unsupervised children had a slightly higher mean screen time of 4.6 (SD 2.4) hours compared to supervised children who had a mean screen time of 4.5 (SD 2.2) hours. Additionally, the study found a higher prevalence of physical symptoms and slightly different BMI distributions among unsupervised children. No significant differences in sleep quality were observed between supervised and unsupervised children, although supervised children slept slightly longer. A greater percentage of unsupervised children were categorized as having borderline or abnormal findings based on the SDQ subcategories (emotional symptoms, conduct problems, hyperactivity or attention deficit, peer relationship problems, and prosocial behavior).

Significant variations depending on the type of education were found in this study, which examined key facets of the role of parental supervision in digital screen use among students in Dhaka city. Although teenagers attending school spent a mean of 4.6 (SD 2.3) hours a day on screens, there was no discernible difference in the amount of time spent on screens between students who were under supervision and those who were not. Nevertheless, when stratified by the type of education, students in Bengali medium schools had screen time of 3.67 hours, while students in English medium schools showed considerably higher screen time (5.46 hours). This discrepancy could have several causes. In Bangladesh, English medium students often come from higher-income households that can afford the higher costs of English medium education, making them more likely to have access to personal digital devices. A similar indication was provided in an article published by The Daily Star [43]. Additionally, English medium students are typically Ordinary level (O level) or Advanced Level (A level) candidates, an internationally recognized qualification that is considered to be the equivalent of Cambridge IGCSE and UK General Certificate of Secondary Education; the preparation for these international-standard examinations necessitates greater screen exposure as part of their learning process [44]. Despite the differences in total screen time, the study did not find any correlations between parental education or income level and screen time supervision. Another study also showed the same findings that no significant association was observed between parental education or income level and screen time supervision [45].

Such trends are concerning given the established negative effects of excessive screen time on adolescent health, including obesity, diabetes, poor sleep, and increased risks of depression and anxiety [5-9]. Effective parental supervision is known to reduce

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screen time and mitigate these adverse effects. Parent-child interaction improved prosocial behavior and reduced psychosocial difficulties while contributing to healthier body mass indices and better sleep [11]. Furthermore, the findings of this study align with the results from previous studies [7, 9]. The empirical evidence found that parental mediation and active participation are associated with improved physical health outcomes, including BMI and sleep duration [7,9]. School-going participants in this study also reported a range of health concerns, with blurred vision, abdominal pain, headaches, dry or sore eyes, and indigestion being the most commonly noted. Such impacts are also reported by several previous studies [46-48]. A notable difference was observed between supervised and unsupervised groups specifically for headaches, with a higher proportion of unsupervised students reporting this issue. A previous study also reported that unsupervised children are more vulnerable to associated health issues [49]. Although supervision did not significantly impact other physical indicators, the findings suggested a potential association with blurred vision and diabetes. However, the small number of patients with diabetes limits the interpretability of these findings. Therefore, further research is needed to explore the effects of different supervision methods on these health concerns and to identify any potential correlations.

In contrast, the statistical significance indicates that factors other than supervision, such as lifestyle, might have a greater impact on other physical issues. For instance, a sizable percentage (28.3%) of kids showed conduct and peer relationship problems when they had results in the borderline or abnormal range on the SDQ. Despite these findings, no significant differences were observed between supervised and unsupervised groups across the SDQ subcategories, suggesting that these behavioral issues may be influenced by factors beyond supervision, including lifestyle and home or school conditions.

Furthermore, we identified a concern that supervision might exacerbate anxiety. This is because, among the 6 children who reported overall anxiety, only 1 was unsupervised. Although the result is statistically significant, this finding should be interpreted with caution due to the small sample size. Collectively, these observations highlight a significant deficiency in effective parental guidance and supervision methods among contemporary urban families in Dhaka. Therefore, further research is needed to explore the specific supervision strategies employed by parents and their impact, with the aim of developing guidelines for healthy technology use.

Finally, we explored a potential correlation between parental supervision of digital screen use and the mean total bedtime based on PSQI data, with the supervised group having slightly more sleep on average compared to their counterpart. However,

when analyzing total sleep duration and examining differences related to supervision across various subgroups, the significance diminished, indicating that the observed differences were not conclusive. Specifically, the proportions of children who slept more than 7 hours were similar between the supervised and unsupervised groups, and these proportions did not differ meaningfully from the overall study sample. Given these borderline findings, further investigation is warranted to explore the potential associations between supervision and sleep patterns.

Limitations

This study has several limitations. First, inconsistencies emerged between the parents' and children's reports, as many parents used a broad definition of "supervised," such as occasional checks or limited awareness of the child's activities on the device. As the children's reports were found to be more reliable predictors, final supervision categorization was based on the children's statements. A similar approach has been followed previously [44]. Second, the study's scope was limited to 6 schools (3 Bangla and 3 English medium schools), which may not be representative of the broader variation between urban and rural settings or differing school resources. Third, data on technological interactions and parental mediation were collected via face-to-face interviews, which may have introduced recall bias. Finally, discrepancies between parent and child reports could not be independently verified. Future research should include diverse populations and settings to provide a more comprehensive understanding of screen time impacts.

Strengths

Despite these limitations, the strength of this study lies in its pioneering exploration of the association of parental supervision with the physical, mental, and social well-being of students in Bangladesh. Additionally, by including students from both Bangla and English medium schools, the study provides valuable comparative insights. The findings are expected to motivate and inform parents, policy makers, and educational authorities, highlighting the need for enhanced supervision and education to promote healthier and more balanced lifestyles for students. Further research is required that may explore causal relationships through experimental or longitudinal designs.

Conclusions

The results of this study enhance our understanding of how to mitigate the negative impacts of unsupervised screen time on students' well-being. Effective guidelines for managing screen use require the involvement of multiple stakeholders: schools, parents, policy makers, and the students themselves. Schools can play a crucial role in educating students about safe screen use and enforcing balanced screen time through workshops and seminars. Parents need to be informed about the risks of excessive screen time and the benefits of active supervision, adopting strategies to enhance their children's well-being. Additionally, accessible mental health services, including counseling and support groups, can help students manage stress and anxiety related to screen time. Conducting further research to develop comprehensive screen time guidelines is essential for promoting the health and well-being of future generations.

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Data Availability

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

Authors' Contributions

SHK contributed to conceptualizing, analyzing, writing, revising, and finalizing the manuscript with the support of TRS, MSH, RH, and FT. All the authors have read, revised, and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Mean daily screen time (hours) by sociodemographic characteristics. [DOCX File, 15 KB - pediatrics_v8i1e62943_app1.docx]

Multimedia Appendix 2

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Distribution of normal and borderline/abnormal responses for the student behavior on the Strength and Difficulties Questionnaire (SDQ) scale.

[DOCX File, 14 KB - pediatrics_v8i1e62943_app2.docx]

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Abbreviations

PSQI: Pittsburgh Sleep Quality Index **SCAS:** Spencer Children Anxiety Scale **SDQ:** Strength and Difficulties Questionnaire

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Assessing the Impact of a Telemedicine Program on Caregivers of Children With Complex Chronic Conditions: Pre-Post Intervention Study

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Abstract

Background: The COVID-19 pandemic was a paradigm shift in global health care. This situation highlighted the role of telemedicine in adapting to the care requirements of pediatric patients and their families by facilitating remote consultations and ensuring continuity of care.

Objective: We aimed to establish the usefulness of a telemedicine program for caregivers of children with complex chronic conditions.

Methods: We performed a quasi-experimental pre-post intervention study of a telemedicine program, regarding health care system use and caregiver quality of life while comparing two periods: before and during the COVID-19 pandemic. This study included caregivers of children with complex chronic conditions followed-up in a specialized unit.

Results: A total of 34 families were included. The mean number of visits per year was higher in the preintervention period for both primary care consultations (P=.03) and hospital-specialized medical consultations (P=.03). The number of emergency room visits per year was lower in the pandemic period compared to the prepandemic period (P=.01). In both groups, an improvement in caregiver quality of life was detected at 12 months (P=.03). However, the Rosenberg self-esteem scale score for the primary caregiver was significantly lower at 3 months compared to the baseline (P=.03).

Conclusions: Our study demonstrates that the use of a telemedicine program resulted in decreased scheduled face-to-face care visits and a reduction in the number of emergency department visits. Regarding the caregiver quality of life, outcomes were poorer among families whose children were affected by neurological conditions or were diagnosed at an older age.

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KEYWORDS

telemedicine; telehealth; complex chronic children; pediatrics complex chronic conditions; palliative care; COVID-19; caregivers; children; pediatrics; chronic; SARS-Cov-2; pandemic; global health; remote consultation; quasi-experimental; quality of life; primary care

Introduction

Technological advances and progress in medicine have reduced infant mortality [1,2]. These survival successes have contributed to an increase in the prevalence of incurable diseases and disability, which leads us to reassess the way we approach and organize health services to adapt them to these new care needs [3,4]. In high-income countries, children with a complex chronic condition (CCC) represent 0.67% - 5% of the pediatric population; however, they consume up to 40% of total health expenditure, involving a high level of care both in and out of hospital, primary care, and non-health services [5-9].

The prevalence of life-threatening or life-limiting illnesses has increased in recent decades, with an estimated 61.1 per 10,000 children aged 1 - 19 years in the United Kingdom. As reported,

approximately 30% of these children have cancer; the remaining 70% comprise a combination of conditions, mainly neurodegenerative, metabolic, and genetic. Of these, 50% children will require the specialized care of a pediatric palliative care unit [10,11].

Therefore, a new strategy is required to transform the current care model, which is focused on treatment-where the patient is a passive subject-into a proactive model more centered on the needs of patients and their caregivers. In this revised model, the patients have more information and autonomy to play an active role in managing the disease [12,13].

In this context, new information and communication technologies (ICTs) provide tools that enable access to a wide range of resources. Numerous studies have endorsed telehealth as a supplementary approach to in-person care for managing chronic diseases [14]. However, the effectiveness of telehealth as a replacement for face-to-face care in patients with chronic conditions remains unclear [15,16].

In 2020, the COVID-19 pandemic transformed medical care through telemedicine with a demand for remote health care and telehealth [17,18]. While the world faced an unprecedented pandemic, patients with chronic diseases required special attention on an ongoing basis and, if warranted, an adaptation of their usual care [19]. This need arose as health care systems were overwhelmed, with most resources diverted to manage COVID-19 patients and their associated complications. The resulting strain on primary and hospital care made in-person evaluations for patients with chronic conditions especially challenging [20].

In complex chronic patient and pediatric palliative care units, telemedicine provides an accessible and equitable tool. With these tools, families can remain in contact with professionals by establishing a schedule for specific services in a time-effective manner and adapted to the stage of the illness [21,22].

Due to the COVID-19 pandemic and considering the vulnerability and fragility of these patients, some of the tools offered by ICT for the continuity of care have become even more useful, as they allow nonface-to-face visits; but with a capacity comparable to face-to-face visits, minimizing the risk of infection, and reducing the need to travel to a medical center [23]. Moreover, these tools may enhance treatment adherence, prevent medication errors, and foster greater engagement in self-care practices [24].

This study aimed to develop and evaluate a telemedicine program for the care of children with CCCs or those receiving palliative care, both before and during the COVID-19 pandemic, within a specialized pediatric palliative care unit.

Methods

Study Design and Setting

We designed a quasi-experimental pre-post intervention study in the Complex Chronic Patient and Palliative Care Unit of a pediatric tertiary hospital.

The study population comprised children with CCCs or those needing palliative care and their families. Inclusion criteria required that children meet the definition of medical complexity algorithm defined by the Seattle Children's Hospital Group and score at least 6,5 points on the PedCom Scale [25,26]. Participants also had to be followed-up in the Complex Chronic Patient and Pediatric Palliative Care Unit of the hospital and had a high level of complexity, defined not only by the identification of the children as complex chronic patients but also by high consumption of resources: two or more hospital admissions, at least one admission to intensive care, or six or more visits to the emergency department in the last twelve months [27]. Patients older than 18 years or those whose families did not provide informed consent were excluded.

Ethical Considerations

The study protocol was in accordance with the Declaration of Helsinki. All caregivers were informed about the study and signed a consent form, with no financial compensation provided. All data were anonymized to ensure confidentiality. This study was approved by the Research Ethics Committee of Malaga in May 2017 (reference: PIN-0287 - 2016).

Telemedicine Program Description

The telemedicine program was remotely managed and controlled by the hospital and its technical support center. It comprised three main functionalities:

- 1. Communication: The technology used was an Android-based smart TV platform connected to a television, which allows access to advanced telecommunication and medical device management services. It allows videoconferencing between patient (through the TV) and hospital (via PC), or between the patient and the medical professional (via PC, tablet, or smartphone), based on session initiation protocol technology (ie, market standard).
- 2. Information and training: Through the platform, families accessed a menu of audiovisual contents. The contents were developed by the professionals of the unit. This includes: information including telephone numbers of interest for caregivers; individualized access to videos, according to specific CCCs, with recommendations, procedures, theoretical and practical workshops including specific training such as nutritional management for patients receiving enteral support, oxygen therapy, or resuscitation, cardiopulmonary and PowerPoint presentations on neonatal techniques and care, secretion aspiration, and monitoring and respiratory care; and information on the current vaccination schedule.
- 1. Health care: The platform allowed clinical assessment via video call, with the option of requesting tests (laboratory and radiological), modification of technological support parameters, and issuing electronic medical prescriptions.

During recruitment, to avoid selection bias caused by the digital divide for families who did not have internet access at home, it was provided through project funding.



Evaluation of the Program

The evaluation of the program was undertaken through the comparison of two one-year time periods; before the pandemic (March 2019 to February 2020) and during the pandemic (March 2020 to February 2021).

Sociodemographic variables described included age, gender, primary caregiver (parent or both parents), number of siblings, place of residence, and country of origin.

- Evaluation of face-to-face health care variables were categorized as follows: (1) scheduled: primary care consultations, hospital outpatient consultations per year, number of outpatient consultations in the Unit, number of home visits made by the Unit, number of scheduled hospital admissions; (2) urgent: number of emergency room visits, and number of urgent hospital admissions.
- Evaluation of telephone health care variables: (1) number of calls from the Unit to caregivers and (2) number of calls from caregivers to the Unit.
- Caregiver reported outcomes: (1) the Rosenberg Self-Esteem Scale [28,29], (2) the Positive and Negative Affect Schedule (PANAS) [30,31], (3) health-related quality of life of primary caregivers (EuroQol-5D-5L) [32], (4) short Zarit Caregiver Burden Interview (ZARIT) scale to assess primary caregiver burden [33,34].

The evaluation of the telemedicine program was carried out with periodic assessments (ie, baseline, 3, 6, and 12 months) of the health care variables and caregiver reported outcomes. The last assessment was carried out 12 months after the start of the intervention. The health care data was collected by telephone and the tests by mail and email.

Data Analysis

Data analysis was performed using free R software (version 4.0.2; R Foundation for Statistical Computing). The Shapiro-Wilk test analysis was performed to determine the normality of the study variables. Data were presented as mean (SD) values in normal distributions or as median (IQR) for non-normal distributions. For independent quantitative variables, Student one-tailed t test was used for normally distributed data, and the Mann-Whitney U test for not normal distributed data. The Wilcoxon signed-rank test was performed to analyze differences in the non-normal distributions, and the paired t test for normal distributed data. To compare qualitative variables, the χ^2 test was used for independent samples and McNemar test for related samples. A P value <.05 was considered statistically significant. Р values were adjusted using the

Benjamini-Hochberg correction to control for multiple comparisons.

Results

Study Population Characteristics

A total of 34 patients were included, ranging in age from 3 months to 14.2 years, with a median age of 4.9 years; 53% (18/34) were female participants. The most common CCC that affected our patients was neurological 73% (n=25), followed by gastrointestinal 71% (n=24), respiratory 50% (n=17), cardiovascular 41% (n=14), and oncological 21% (n=7). In addition, neurological CCCs were also the most frequent primary CCC in 47% (n=16), with cerebral palsy being the most prevalent neurological disease (11/16, 69%).

The primary caregiver was the mother in 82% (n=28) and 47% (n=16) of the families received social assistance; 91% of the families (n=31) received psychological care. A total of 29% (n=10) of the families were from a foreign country and 41% (n=14) had no other children; the number of children per family ranged from 0 to 5, with a median of 1.

Impact of the Telemedicine Program on Health Care Activity During the Pandemic

Regarding scheduled care, bivariate analysis showed that the mean number of visits to primary care consultations per year was higher in the pre-pandemic period (P=.03), as well as more hospital specialty consultations (P=.03) (Table 1).

In terms of emergency care, there were significant differences in the number of emergency department visits per year during the compared to the prepandemic period (P=.01), with fewer visits during the pandemic. No significant differences were found in emergency hospital admissions between the two periods (Table 1).

Regarding telephone care provided by the Unit, we noted a nonsignificant increase in the number of calls made by the Unit during the pandemic (P=.06). However, there was a significant increase in telephone calls made by caregivers to the Unit during the pandemic compared to the pre-pandemic period (P=.003) (Table 2).

There were no significant differences between the mean length of hospital stays (measured in days) before and during the pandemic.

Tables 1 and 2 display the variables related to the health care provided.

Table . Analysis of variables associated with face-to-face health care activity.

Type of care activity	Prepandemic period with telemedicine, mean (SD)	Pandemic period with telemedicine, mean (SD)	<i>P</i> value
Scheduled			
Primary care consultations	9.2 (9.9)	6.6 (5.9)	.03
Scheduled consultations hospital specialties	29.6 (19.2)	23.4 (19.2)	.03
Nurse consultations at CC^{a} and PPC^{b} Unit	8.3 (6.8)	10.1 (9.5)	.54
Pediatrician consultations at CC and PPC Unit	6.7 (5.6)	7.2 (5.6)	.77
Nursing home visits at CC and PPC Unit	3.1 (5.3)	2.4 (4.8)	.20
Pediatrician home visits CC and PPC Unit	2.8 (5.0)	2.1 (4.4)	.09
Scheduled admissions	0.6 (1.0)	0.6 (0.8)	.60
Urgent			
Emergency hospital visits	3.6 (4.0)	2.1 (2.1)	.01
Urgent hospital admissions	1.4 (1.5)	1.2 (1.5)	.19

^aCC: complex chronic.

^bPPC: pediatric palliative care

Table . Analysis of variables related to telephone health care activity.

Type of care activity	Pretelemedicine period, mean (SD)	Pandemic period with telemedicine, mean (SD)	<i>P</i> value
Unit calls to caregivers	36.4 (34)	48 (26)	.06
Caregivers calls to the Unit	6.2 (7.8)	10.5 (9.5)	.003

Impact of the Telemedicine Program on the Caregiver-Reported Outcomes

Significant differences were seen in the visual analogue scale (VAS) of the EuroQol five-dimension (EQ-5D) quality of life test of the primary caregivers at 12 months compared with baseline, with an increase in VAS scores at 12 months (P=.03).

The Rosenberg self-esteem scale scores of the primary caregivers were significantly lower at 3 months than at baseline (P=.03). There was a significant negative correlation between the short Zarit Caregiver Burden Interview (ZARIT) scale for primary caregiver burden at 6 months and the number of siblings (adjusted R^2 =0.37; P=.009). The VAS score of the EQ-5D quality of life scale for primary caregivers at 12 months

correlated negatively and significantly with age at diagnosis of the child's illness (adjusted $R^2=0.24$; P=.04).

The difference in the index value of the EQ-5D quality of life scale for primary caregivers from baseline to 3 months was negatively correlated with the age at patient admission (adjusted R^2 =0.97; *P*=.007).

In the analysis of the relationship between caregiver quality of life and the different types of CCCs, the difference in index value of the EQ-5D quality of life scale for primary caregivers from baseline to 3 months was negatively correlated with neurological disease (adjusted R^2 =0.89; *P*=.03).

Table 3 shows the results of the tests at baseline and at 3, 6, and 12 months.



Table . Analysis of quality of life test results.

Quality of life tests	0 months, mean (SD)	3 months, mean (SD)	6 months, mean (SD)	12 months, mean (SD)	P value
Rosenberg self-esteem scale	29.3 (5.2)	27.3 (6.4)	31.0 (4.2)	33.0 (4.8)	.03
Positive and negative affectivity scales (PANAS)					
Positive affect	29.1 (7.4)	29.5 (7.9)	33.1 (9.4)	33.8 (7.5)	.41
Negative affect	26.8 (8.8)	23.8 (6.8)	24.3 (7.1)	22.8 (6.2)	.34
Health-related quality of life (EuroQol-5D- 5L)					
EQ-5D ^b value	0.814 (0.180)	0.766 (0.151)	0.838 (0.153)	0.838 (0.142)	.053
EQ-5D VAS score	76 (18)	75 (15)	78 (14)	75 (21)	.03
Short ZARIT ^a scale	20.1 (7.0)	24.3 (5.0)	20.8 (5.9)	19.8 (5.7)	.44

^aZARIT: Zarit Caregiver Burden Interview.

^bEQ-5D: EuroQol-five dimension.

Discussion

Principal Findings

The development of telemedicine programs has transformed care for patients with chronic illnesses or those in palliative situations. Several studies including the one by Prabhakaran et al [35], highlights the effectiveness of a mobile health intervention in primary care settings within rural Indian communities. This initiative focused on preventing and managing cardiometabolic conditions, depression, and related risk factors among adults. In pediatrics, evidence-based studies, including the consensus developed by the Italian Societies of Telemedicine, Preventive and Social Pediatrics, and Pediatric Primary Care, among others, have demonstrated the critical role of telemedicine in managing patients with chronic conditions (eg, cardiology, respiratory, or neurology) or those requiring palliative care. These findings underscore the potential of telemedicine to enhance healthcare delivery by facilitating improved collaboration among multidisciplinary professionals and patients, creating innovative opportunities to optimize clinical outcomes and service quality [36].

In our study, the most common condition was neurological, which is the most frequent condition as described in literature indicating that neurological patients are the most prevalent. Our findings are in accordance with prior research, with neurological CCCs being the most frequent, followed by gastrointestinal and respiratory CCCs. Also coinciding with published findings, the mother most often fulfilled the role of the primary caregiver [13,37-41].

During the COVID-19 pandemic, as seen in other studies, a decrease was observed in both scheduled and urgent care for children with CCCs, similar to trends in the general pediatric population and among children with special health care needs [42-49].

The increase in telephone consultations during the pandemic, both initiated by the Unit and caregivers, especially the increase

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in calls from caregivers, may be explained by the decrease in face-to-face care in primary care and in specialized hospital care during this period. This finding highlights the support provided by the Unit via telephone to minimize the impact of the pandemic on children with CCCs, as described in several studies focused on specific care strategies aimed at this particularly vulnerable population [50].

In our study, the absence of significant differences in scheduled or urgent hospital admissions, has been described in other studies on telemedicine in children with CCCs [22]. This may be due to the high complexity of the patients included in this study, where pandemic-related factors may not have influenced the number of hospital admissions or the length of hospital stays.

Several studies have described the importance of the psychosocial needs of children with CCCs and their families and how these needs, especially concerning mental health increased during the pandemic [51,52]. To date, few studies have demonstrated improvements in the quality of life of caregivers from telemedicine programs, often due to the cross-sectional design of studies without multiple cut-off points. Our study highlights the importance of conducting studies that monitor the impact and benefits of these programs throughout the intervention to verify their usefulness [53-55].

In our study, a greater burden on primary caregivers was detected in families with more children, a demographic factor not previously described and one that should be considered to reinforce support for these families.

The quality of life of the primary caregivers measured by the VAS value of the EQ-5D scale at 12 months was poorer in those with children with CCCs diagnosed at an older age. Similarly, we found a negative correlation between the difference in the EQ-5D quality of life scale of the primary caregivers at 3 months, compared to baseline in children with CCCs who were older at admission to the Unit. Our analysis revealed that both the child's age at diagnosis and age at Unit admission were inversely associated with parental quality of life, showing the



most pronounced negative impact at 3- and 12-month follow-up during the pandemic. The influence of the age of the child with a CCC on the quality of life of the primary caregivers during the pandemic has not been examined previously and merits further investigation as a potential modulator of the quality of life of the parents.

Published studies on the impact of neurological diseases have shown an increased family, work, and economic burden on primary caregivers, specifically on caregivers of children with cerebral palsy [56]. In our study, a negative correlation was found between the index value of the EQ-5D quality of life scale of the primary caregiver at 3 months, compared to baseline with neurological CCCs, which was also the most frequent CCC observed.

The observed lower self-esteem among the primary caregivers at 3 months of the telemedicine program during the pandemic setting may be explained by the effects of full confinement, including reduced psychosocial and family support, adaptation of home care with a change in care support, and the increased care burden. This reduction in the quality of life of the primary caregiver at 3 months has not been evaluated in other studies and may be useful for reinforcing psychosocial support to families, considering this period as a turning point in caregiving. Conversely, the observed improvement in VAS of the EQ-5D quality of life test may reflect an increased quality of life at 12 months, which could be attributed to adaptation to the situation as well as decreased isolation measures one year after the pandemic.

It is important to leverage the growth of the ICTs during the pandemic for the benefit of patients, especially those who are most vulnerable and with specific care needs such as children with CCCs. Telemedicine provides equity in care and efforts should be made to evaluate the impact of telemedicine programs in patients, primary caregivers, and health care teams, taking into account the clinical, economic, and quality of life variables in patients and their families monitored over time.

Limitations

The use of telemedicine prior to the pandemic was demonstrated to be effective in children with CCCs, both in reducing the number of emergency department visits and costs [55,57-61]. However, in our study, it was challenging to determine with certainty whether the decrease in urgent or unscheduled care could be attributed to the COVID-19 pandemic or the telemedicine program intervention. During the pandemic, there was a decrease in emergency department visits, as many caregivers were afraid to go to hospitals to avoid infections in their children [43,45]. In addition, we must take into account the decrease in respiratory symptoms due to the confinement and isolation measures described in several studies [45,47,49]. Studies with larger and more homogeneous samples should be carried out after the pandemic to assess whether its effectiveness in terms of care is maintained without the interference caused by the pandemic.

Conclusions

In our study, the use of a telemedicine program during the pandemic resulted in a decrease in scheduled face-to-face care and a reduction in the number of emergency department visits compared to the prepandemic period. Conversely, we observed an increase in telephone support without any impact on hospital admissions. We identified the most vulnerable families in this group of patients, including those with a child affected by a neurological condition, those who had an older child when the disease was diagnosed, and families with a greater number of children. These insights allowed could help guide the redirection of limited resources. Our findings indicated that the telemedicine program was effective in the supporting care of children with CCCs and their families.

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Authors' Contributions

Conceptualization: AMR Formal analysis: ILG, MJPC Investigation: ASC, AGR, ACM, YRT Methodology: ALJ, ILG Resources: ALJ, ILG Writing – original draft: ALJ, AMR, AGR, EGM Writing – review & editing: ALJ, ILG

Conflicts of Interest

None declared.

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Abbreviations

CCC: complex chronic condition EQ-5D: EuroQol five-dimension ICT: information and communication technologies VAS: visual analogue scale

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Development of an eHealth Intervention in Pediatric Home Infusion Therapy: Interview Study of Needs and Preferences of Parents and Health Care Professionals

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Abstract

Background: With the provision of home infusion therapy in children with acute or long-term illness on the rise, eHealth technologies have the potential to bridge the transition between hospital and home. However, eHealth interventions intended to support parents in managing home infusion therapy are sparse. Gaining insight into the needs and experiences of parents and health care professionals is crucial to developing feasible and sustainable eHealth interventions that target their needs. This study describes the first phase of a research study designed to develop and evaluate an eHealth intervention to support home infusion therapy.

Objective: This study aimed to identify the experiences and needs of parents and health care professionals during home infusion therapy and their preferences for digital features in a future eHealth intervention.

Methods: A qualitative study was conducted at 3 pediatric departments at a university hospital in Denmark. We individually interviewed 17 parents of 14 children who had received home infusion therapy with a portable pump. In addition, 5 focus groups were conducted with 15 health care professionals. We conducted a qualitative content analysis of the data, which we collected from February to July 2020.

Results: We identified 6 subthemes that we merged into 3 main themes: increasing safe self-management at home; adapting information and responsibility to individual changing needs; and requesting digital features to ensure skill level, safety, and quality of care. The analysis showed that parents and health care professionals had corresponding needs and preferences, for example, a need for a high sense of safety and easier ways to communicate during home infusion therapy. Both groups emphasized the need for digital features to improve problem-solving and communication as a supplement to existing care to promote a safe environment, self-management, and quality of care. A vital issue was that an eHealth intervention should be aligned with the workflow of health care professionals and comply with regulations regarding confidentiality in communication and data sharing.

Conclusions: Our study highlights the needs that parents and health care professionals have for increased safety and easier access to communication when receiving and providing home infusion therapy. The findings will be used to help develop an eHealth intervention supporting home infusion therapy tailored to individual needs.

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KEYWORDS

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pediatrics; digital; interventions; eHealth; home care; intravenous infusion; qualitative research

Introduction

Home infusion therapy for children with acute or long-term illnesses is becoming increasingly common due to its benefits,

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such as supporting children and their families in maintaining their everyday lives and improving the child's health outcomes [1]. This therapy can be provided by nurses in hospitals or municipalities, home care agencies, or by nonprofessional

caregivers such as parents or guardians. Transitioning care tasks from a hospital to a home setting is complex and requires well-functioning, coordinated collaboration between health care professionals and parents [2]. Parents have reported feeling anxious and insecure if they lack support, experience with, or knowledge about care tasks such as administering medications and observing symptoms that they must manage at the hospital and at home [3]. Furthermore, studies show that parents' administration of oral medication at home is a high-risk area for medication errors [4-7]. Thus, it is vital to ensure that parents are comfortable and confident when managing care tasks at home.

eHealth interventions can be a means to support parents since they provide digital resources for managing home infusion therapy. According to the World Health Organization [8], eHealth can increase communication and data sharing between health care professionals and patients and improve accessibility and patient participation by electronic technologies. The use of eHealth expanded radically during the COVID-19 pandemic [9], but various barriers remain before integration into pediatric clinical practice is completely successful [10-13]. Studies have reported that the use of eHealth in pediatric clinical care can bridge the transition from hospital to home and increase interaction between the two by efficiently and conveniently providing information and communication [14-16]. This helps promote confident self-management among parents in treating and caring for children with various medical needs at home [2,15-17], improve symptom control in the child, and reduce parental worries and insecurity [2,18-22]. However, the availability of eHealth interventions for families of children with acute or long-term health conditions as well as the evidence supporting eHealth in pediatric clinical practice, remains still limited [23-25].

At the outset of this study, children and adolescents were given the opportunity to start antibiotic infusion therapy using a portable pump at a university hospital in Denmark and then continue treatment at home. Parents were trained by nurses and supported with printed materials and resources on the hospital's website. The provision of home infusion therapy began to expand to include other types of medications and delivery methods, thereby placing greater responsibility on the parents. No eHealth interventions were available to support home infusion therapy and there was uncertainty about the extent of parents' and health care professionals' needs and the specific content that they may need for eHealth support. Previous research have shown that extensive support is essential when parents perform caregiving tasks at home [3,26]. However, less is known about how parents and health care professionals employed at hospitals perceive their needs and preferences related to home infusion therapy and eHealth support. According to Medical Research Council's framework [27], exploring the needs of intervention users is a crucial first step in developing an intervention. Applying a participatory design [28], future users are involved to gain an understanding of their situation and respond to their experiences, needs, and preferences. This approach ensures that a future eHealth intervention would target their needs and be sustainably implemented [11,28-30]. Therefore, the aim of this study was to identify the experiences

and needs of parents and health care professionals regarding home infusion therapy, in addition to their preferences for including digital features in the development of a future eHealth intervention.

Methods

Design

An exploratory qualitative design was applied to get relevant input from the users to the future development of a supportive eHealth intervention. This study is a part of the developmental phase of a larger research program with the overall goal of developing and testing an eHealth intervention to support parents and health care professionals during pediatric home infusion therapy. The Medical Research Council's framework for the development and evaluation of complex interventions [27] and a participatory design [28] framed the overall research project. The framework guides researchers through 4 interconnected phases, development, feasibility, evaluation, and implementation. Engaging the users of the eHealth intervention throughout the research study ensured the developmental relevance of our study and its feasibility in clinical practice, improving the probability of successful implementation [26].

Setting

The study was conducted in 3 pediatric departments at a university hospital in Copenhagen, Denmark, 1 specializing in oncology and hematology (20 in-patient beds), 1 in organ and infection diseases (12 in-patient beds), and 1 day hospital (7 beds), with around 2000 combined admissions annually.

Home Infusion Therapy

In 2018, the departments started offering home infusion therapy with portable pumps as an option to children with diagnoses such as cancer or with an acute infection with no underlying condition. The therapy was primarily used for intravenous antibiotic treatment and always initiated during hospitalization at an in-patient ward or in an out-patient setting. The children had a central venous catheter or midline catheter. A nurse informed and trained primarily one of the child's parents before home infusion therapy was initiated and administered the portable pump to the child at the hospital before discharge. The child returned the following day to the hospital to receive a new dose in the pump or to discontinue treatment. The parent's task was to clinically observe the child, the pump and infusion at home, and react if problems arose, such as reactions to the medicine or a pump alarm sounding. If the child had a serious reaction, the parent was instructed to immediately call an ambulance. Health care professionals also taught some parents how to change the pump medication or replace the elastomeric pump with a new one to allow the family to stay at home 1 or 2 additional days before returning to the hospital,

Participants

A purposeful sampling strategy of children, parents, and health care professionals was used to obtain rich and varied data on the home infusion therapy [31]. Inclusion criteria for children were 0 to 18 years of age, having received home infusion therapy with a portable pump with any type of medication,

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having the parent living with the child part or full time, and the parent speaking Danish or English. Most children receiving the therapy had an underlying long-term illness, but children with an acute infection with no underlying condition were also approached. In total, 14 children and their parents were informed about the study, and all agreed to participate. The children were invited to participate in an interview together with their parent, which resulted in 13 children participating, 2 of whom actively joined in. In 3 families, both parents participated and were interviewed jointly or separately (Table 1). Inclusion criteria for health care professionals were: (1) nurse or a physician, (2) working at one of the 3 departments, and (3) had experience with providing home infusion therapy. A total of 15 health care professionals were approached, and all agreed to participate.

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Characteristic			Participant, n
Children (n=14)			
	Age (years)		
		0 - 5	5
		6 - 11	6
		12 - 14	1
		15 - 18	2
	Sex		
		Male	11
		Female	3
	Primary diagnosis		
		Cancer	10
		Congenital lung disease	2
		Congenital autosomal disorder	1
		Stroke caused by virus infection	1
	Ethnicity		
		Danish	11
		Other	3
	Cohabiting with siblings (n)		
		0	2
		1	9
		2 - 4	3
Parents (n=17)			
	Sex		
		Female	12
		Male	5
	Partner relations		
		Cohabiting with partner	16
		Single parent	1
	Age (years)		
		31 - 40	11
		41 - 50	3
		Unknown	3
	Occupational status		
		Employed	5
		Unemployed	1
		Paid leave due to child's illness full time	10
		Paid leave due to child's illness part time	1

Data Collection

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Data were collected from February to July 2020. Parents were interviewed based on a 2-part exploratory semistructured

interview guide. The first part covered experiences and needs regarding home infusion therapy in terms of provision of and responsibility for it, preparation and training, and sense of safety, worries, and challenges. The second part presented concrete

examples of digital features to generate ideas on how technology could address the needs and preferences of the child and parent, in addition to focusing on how an eHealth intervention could support home infusion therapy. We asked which digital features to include, such as possible advantages and disadvantages, experience with digital technologies, and what features are important to have in an eHealth intervention. The eHealth Literacy Framework provided the underlying inspiration for the questions in the second part to understand user needs and prerequisites when new digital health services are introduced [32]. The interviews were conducted by the first author (n=16), at one of the pediatric departments in a meeting room or an in-patient room lasting and lasted 30 to 120 minutes, though 1 was done by phone.

Health care professionals were interviewed in 5 separate focus groups with a semistructured interview guide corresponding to the guide for parents though tailored to their professional role. The focus group interviews, which lasted 60 to 90 minutes, were held in a meeting room at one of the pediatric departments. The interviews were recorded and transcribed verbatim.

Data Analysis

A qualitative content analysis of the transcribed interviews was used comprising a 5-step iterative and inductive approach based on Graneheim and Lundman [33] to identify any patterns and variations in participant experiences. First, 2 authors [HH and MLO] read the text independently to gain an overall understanding. Second, they identified meaning units in terms of words, sentences, and paragraphs that related to the study aim. Next, the meaning units were condensed, organized, and coded using NVivo software (Lumivero). Fourth, the codes were compared with identify similarities and differences, before being organized into subthemes. Finally, the subthemes were compared and analyzed, after which they were merged into main themes. The defined main themes had a consistent pattern of underlying meaning in terms of the condensed meaning units, codes, and subthemes. To strengthen the trustworthiness of the study, the same 2 authors discussed the meaning units, codes, subthemes, and themes throughout the analysis until reaching consensus. Initially, individual and focus group interviews were analyzed separately as 2 datasets. During the data analysis, it became apparent that the subthemes overlapped, and data were analyzed together. In the last phase of the analysis, all authors reflected on and discussed the main themes and subthemes.

Trustworthiness

The authors discussed the analysis, interpretations, and themes at seminars and presentations with key health care professionals involved in home infusion therapy and other researchers to enhance credibility. The authors also discussed their preunderstanding to consider how it may influence data collection and analysis, all of us are experienced in conducting qualitative studies. The first author [HH], who is a nurse, has experience with implementing home infusion therapy at the 3 departments but did not have any clinical contact with the families before the interviews. The health care professionals knew HH, which may have hampered them from freely expressing themselves, but her knowledge of home infusion therapy may also have made them feel confident enough to provide in-depth responses to the interviews.

Ethical Considerations

The Danish Protection Agency approved the study (P-2019 - 392), while approval from the Regional Research Ethics Committees for the Capitol Region of Denmark was not required since it only assesses studies that collect biological material. The study adhered to the Declaration of Helsinki, International Ethical Guidelines for Health-Related Research Involving Humans, and current Swedish and European law. All participants were assured that participation was voluntary and that they could withdraw from the study at any time without affecting their child's treatment or the health care professionals' work. All participants provided written informed consent and were assured confidentiality. When applicable, the children received age-appropriate information about the study based on their cognitive abilities, language skills, and legal guardian's preferences.

Results

Overview

The amount of experience parents and health care professionals had with home infusion therapy ranged from doing it a few to multiple times. The parents expressed that it enhanced their child's well-being and the whole family's due to having a greater opportunity to spend everyday life together more at home. They were willing to take on the additional caregiving tasks and responsibility due to the benefits associated with doing so. The health care professionals also described how the child and family benefited and how important the option of home infusion therapy was.

Three main themes were identified comprising six subthemes: (1) increasing safe self-management at home, (2) adapting information and responsibility to individual changing needs, and (3) requesting digital features to ensure skill level, safety, and quality of care (Textbox 1). The themes and subthemes were bound together in an overarching theme "managing the extended responsibility of home infusion therapy." This theme encompasses the core experience of the increased responsibility parents take on when managing the therapy and the health care professionals being responsible for therapy taking place outside the hospital. Digital features were described as means to support that responsibility.

The first and second themes describe the needs of parents and health care professionals based on current experiences with home infusion therapy, while the third main theme present the digital features proposed to meet the needs of both groups in a future eHealth intervention (Figure 1).


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Textbox 1. Main themes and subthemes.

Overarching theme:

• Managing the extended responsibility of home infusion therapy

Main themes and their subthemes:

- Increasing safe self-management at home
 - Need for standardized information, training, and shared problem-solving
 - Being in control of home infusion therapy and feeling safe
- Adapting information and responsibility to suit individual needs
 - Repeating individualized information and training
 - Desire to share the responsibility
- · Requesting digital features to ensure skill level, safety, and quality of care
 - Access to online one-way communication of knowledge and training
 - Access to interactive communication and support

Figure 1. Digital features proposed by parents and health care professionals for a future eHealth intervention.





Theme 1. Increasing Safe Self-Management at Home

Subtheme: Need for Standardized Information, Training, and Shared Problem-Solving

Overall, parents described that they were confident about the information and training they had received on how to manage home infusion therapy, and they had not experienced any problems with the pump or the child's health. But some felt that the information and training were too sparse. They appreciated the information booklet, even though they did not always have it with them when they needed it. The hospital website provided information and guidelines, but finding either one was

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sometimes difficult and time-consuming if immediate support was required.

Some parents thought that the information and training they received was inconsistent, making both them and their child feel insecure. They requested uniform guidelines and training regardless of which health care professionals or department taught them about managing the care tasks. They also felt unsure if they called for assistance and spoke with a health care professional who lacked the skills to provide support, sometimes forcing families to travel to the hospital.

I felt stressed when it [pump] sounded an alarm that showed 'low reservoir volume'. I think it was actually

when the infusion bag was full. And then I called the ward after trying everything I could do at home. But when you call in the evening, there isn't necessarily anyone at work who knows much about the pump. So, they didn't know what I should do either. [Mother 232]

Health care professionals who seldom had the task of giving parents information and training about managing the portable pump worried about how to maintain their professional skill level, making them feel insecure professionally and concerned about how that could affect the children and parents.

We don't provide home infusion that much at our ward and the more you physically deal with it [pump] in your hands, the better, safer, and more familiar you get with it when you teach the parents. [Health care professional 113]

Subtheme: Being in Control of Home Infusion Therapy and Feeling Safe

The parents described that the pump was easy to manage and that they did not experience many problems related to the pump and infusion, or that their child experienced adverse effects. If a pump alarm went off, they were mostly able to manage the issue at home. They felt particularly worried if an alarm sounded due to air bubbles in the infusion set. In such situations they expressed a need for different interaction than a telephone call with the health care professionals because it had the potential to resolve problems and thereby avoiding a hospital visit.

I think, I think that there's a need for extra support in those kinds of situations when it [pump] acts up. [Mother 73]

Parents described how they wanted to take on responsibility for their child's home infusion therapy as it was a way to have control over their situation. Even though they generally felt secure about the information, training, and support they received, some parents still worried about something unexpected happening, making them feel vulnerable about being home alone without a health care professional nearby. They stated that they would appreciate more support to improve their sense of safety and control of the situation.

The health care professionals also described the need to have more control when discharging a child to home infusion therapy, mentioning that they felt an extended sense of responsibility toward the child and home treatment that they sometimes found difficult to fulfill since they were unable to monitor the child's condition in the same way as at the hospital. The health care professionals lacked having a sense of the family's capacity at home; for example, they could not assess whether the procedures and observations the parents took on had been performed correctly. This lack of control preoccupied them as they worried about the risk of medication errors and adverse events. The health care professionals needed reassurance that the parents had conducted the necessary observations and procedures to help increase their feeling of control concerning the treatment they had initiated, especially because they felt responsible for the child's well-being, treatment, observations, and transferring such specialized care tasks to the parents without their presence to safeguard them at home.

And then there's the issue of whose responsibility it is when you hand it [therapy] over to the parents? Because I agree that they only want the best for their child. There's no doubt about that. [Health care professional 117]

Theme 2. Adapting Information and Responsibility to Suit Individual Needs

Subtheme: Repeating Individualized Information and Training

Parents described feeling mentally burdened by their child's illness, especially those whose child had long-term illness. They had difficulty remembering and comprehending information and training, causing them to request the possibility to repeat information and training once they returned home.

You're bombarded with things that I, as a parent, must be able to gain an overview of, including how the pump works. Then, when you get home you think: "God, what was it that they said about that?" And in that situation, it would be really nice if you could seek help [digitally/online]: "Could you tell me again, what I should do, when I should do this and that?" [Mother 173]

The health care professionals also worried that the parents did not always have the mental surplus to handle new or additional tasks in relation to home infusion therapy. They expressed a need for providing more individualized support to parents at home as they saw the parents' mental surplus as changing over time. It was important for them to ensure that the parents felt safe and were not additionally burdened by managing home infusion therapy.

Maybe we could come by to force them to accept it [home infusion], because we've been used to that. Then there's a psychological aspect to it, where you constantly have to determine where they are in the treatment trajectory: "Do you still feel secure about doing home care?" Because I think the families experience a tremendous number of mental ups and downs. [Health care professional 262]

Subtheme: Desire to Share the Responsibility

The parents described that they would like to involve other caregivers and professionals in the home infusion therapy to share the responsibility, also their child if the child wanted to be involved. Often only one parent was trained to manage the pump and medicine, leaving them with the sole responsibility. One parent said that her partner did not want to help with it due to how unsure it made him feel.

He's perhaps afraid of ending up doing something wrong [with the pump] that may harm our son, which I think might paralyze him a little in terms of his ability to act. [Mother 196]

Another parent described how the partner, who had not been trained at the hospital, panicked at home when an alarm on the



pump went off. Parents also emphasized the need for additional support to facilitate training and guidance at home to increase the sense of safety and control for the child and other caregivers with the therapy and to support shared responsibility. Like the parents, the health care professionals supported and emphasized the need for parents to share the responsibility for managing home infusion therapy, for example, with grandparents and daycare staff.

One of the disadvantages of home treatment is that all of the responsibility lies with one parent, or two, to manage it [the pump]. It's a great deal to have to take care of regularly. [Health care professional 270]

However, the health care professionals found that letting the parents supervise others was challenging because they worried that training others might put an additional burden on the parent or potentially be problematic regarding quality of care and safety.

Theme 3. Requesting Digital Features to Ensure Skill Level, Safety, and Quality of Care

Subtheme: Access to Online One-Way Communication of Knowledge and Training

Parents suggested that online information, guidelines, and instruction videos would be helpful and should be easily accessible in one place, for example, the hospital's website or an app, making it more straightforward and quicker to find information and training, which would potentially allow parents to solve technical problems themselves.

I've actually thought of something that could be really nice, being able to watch a short video, if there's something that's tricky, instead of having to read about it. Because you can't be sure that you'll have the peace of mind to understand it [written information] when you're in the middle of a crisis. [Mother 29]

Sometimes they call and say that they can't find it. They've lost their information material and manual, so they ask: "What should we do when she gets a fever or becomes flush or?" [Health care professional F2]

If information on paper got misplaced or was forgotten, a digital version would always be available. Parents suggested that explanatory instruction videos could be developed to show how to solve the most common problems, for example, removing air bubbles in the infusion set or resolving other practical technical issues related to the pump. The health care professionals supported the idea of having information, guidelines, and instruction videos available online to provide professional reassurance that the parents could find information targeted their needs and skills. They explained that instruction videos could also meet their own needs for maintaining their skill level, along with e-learning. Furthermore, both parents and health care professionals expressed how online material would ensure that the information and skills the parents acquired were aligned with the health care professionals. However, the health care professionals had concerns about how to regularly keep

online material and instruction videos updated based on the newest evidence-based practices.

Parents and health care professionals described how online guidelines and instruction videos could help bolster sharing responsibility for managing home infusion therapy for those who did not receive training at the hospital. Parents also expressed that this would be useful for children interested in self-managing their therapy, also because they were already familiar with using digital platforms with videos. Instruction videos also represent a useful tool for those who learn better visually, just as they can be subtitled or dubbed into different languages, improving access to allow more families to receive home infusion therapy.

Subtheme: Access to Interactive Communication and Support

Parents also mentioned the benefits of video consultations for receiving guidance in managing the pump and resolving any issues with the pump at home to avoid traveling to the hospital. Video consultations would also provide visual advantages that were absent in ordinary telephone conversations in terms of guidance and preventing misunderstandings.

A support feature would be very good to have. If you [nurses] had a smartphone available to make video calls to film what the pump says, because my wife panicked a little bit and the communication on the phone with the nurse [at the hospital] was not that great; the nurse and my wife misunderstood one another. So, I just drove him to the hospital. [Father 112]

Health care professionals also requested the option of using video consultations to reassure parents that their observations were relevant and to guide them in shared problem-solving. Video consultations could potentially improve their sense of safety and professional control by allowing them to assess the child's condition and the parent's management of the therapy.

You're sure that the parents know how to change the infusion bag. And if you're in doubt at home, it's evening and you call and you can't be guided on the phone, then it would be nice be able to see it to avoid any misunderstandings. [Health care professional 208]

However, the health care professionals had concerns. Even though the child was visible on video, they could not use their clinical judgment based on all their senses compared with face-to-face clinical observations at the hospital. They were uneasy about care becoming too digital.

I think it's a good idea [home care], but I also worry about not seeing the children: "How are you doing and how do you look?" Can the parents always assess that? The nursing loses something; it simply becomes too digital. That involves using your eyes, touch, and sense of smell and whatever else we run around doing. [Health care professional 133]

Both parents and health care professionals stressed that the work procedures and settings for digital interactions would require

aligning expectations. For example, video consultations include specific requirements, such as the need for computers with the right equipment, setting up consultations in a confidential setting, and how to manage scheduling consultations, also in the evening and at night, not to mention having skilled health care professionals available to provide support 24/7.

Parents were also interested in being able to send data to the hospital, such as their child's blood pressure or pictures of skin changes to reassure the parents and health care professionals regarding the parents' observations. However, some parents had misgivings about perhaps feeling pressured to provide more data than they could manage. In addition, parents and health care professionals alike were uneasy about when and who was responsible for assessing and reacting to the data at the hospital, and the timespan in which parents could expect to receive an answer. Managing incoming measurements would be required for this to succeed and make all parties feel safer. Furthermore, parents and health care professionals suggested that the parents could also receive notifications to ensure that care tasks like taking their child's temperature and assessing intravenous access were performed at the right time.

Discussion

Principal Findings

We found that parents and health care professionals largely had corresponding needs for safety in home infusion therapy but that their preferences for digital features in a future eHealth intervention to meet those needs were based on different rationalities. It was vital that everyone felt safe about using home infusion therapy, and they suggested various digital features to meet their needs to have consistent knowledge, problem-solving skills, reassurance that the parents could manage the home infusion therapy and their child's well-being, maintain their skill level, and share responsibility with more than one parent. They emphasized the need for an eHealth intervention that provides additional communication support to existing care to enhance safety, self-management, and quality of care.

Comparison With Previous Work

A key finding was how home infusion therapy was linked to the extended responsibility of the parents and health care professionals, the former at home without the presence of a nurse, and that latter in terms of having the professional responsibility without being present in the child's home. We suggest that this extended responsibility generates specific needs and preferences for the digital features a future eHealth intervention should have.

Parents found their responsibilities manageable and felt greater sense of control when they had adequate information and training, along with access to skilled health care professionals when contacting the hospital without these resources, they felt unsure. Two other studies describing the parents' experiences of insecurity and fear of overlooking something important when their child received home intravenous therapy suggested improvements to decrease worries, such as enhanced preparation, alignment of expectations, and accessible visually

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based and text-based information [3,34]. Another study also found that parental management of care for their child after surgery at home felt insecure, for example, they were unable to identify postoperative complications [35]. The information they had received was partially incomplete, and there was a gap in support at home, such as some health care professionals lacking the right knowledge to provide support contacted by parents [35]. Even though the parents in our study had some similar experiences, they were generally satisfied overall but would like to see digital features bolster existing support.

Another aspect of the extended responsibility was the health care professionals' concerns about their ability to clinically assess the child's condition and to know how the parent was managing home infusion therapy. These concerns challenged their professionalism and ethics. For them, the setup comprised nursing at a distance, causing them to worry about how to ensure quality of care. They suggested that various digital features could bridge this distance and had to correspond to the parents' needs. Both parents and health care professionals suggested monitoring, such as sending temperature data to the hospital and notifications to parents to remember tasks. These features would help meet their need for reassurance and increase their sense of safety. One study showed that participants valued notifications as reminders for activities to be carried out at home [36], while another study on designing a home monitoring system for children with a medically complex condition showed how parents preferred to track symptoms to identify early changes in their child's health that could lead to an appropriate intervention [37]. However, parents in our study also worried that they would feel pressured to provide more monitoring and data than they could manage. As a result, adjusting the amount of monitoring and continuously assessing how parents manage at home is important to avoid increased caregiver stress.

The suggestions parents and HCPs provided in our study are comparable with the study by Nkoy et al [37] on the needs of caregivers for designing a home monitoring system for children with a medically complex condition. The parents wanted a mobile health tool that included features to track symptoms and report their child's symptoms that was user friendly, in addition to having the ability to report interventions provided at home, have direct access to hospital through text messaging, and real-time sharing of data, not to mention the capacity to upload a photo or video for the health care professionals [37]. Two studies in which parents managed nursing care for children after surgery or born prematurely developed a successful eHealth tablet for the aforementioned reasons [17,38]. The parents were given an eHealth tablet before their child was discharged from a highly specialized department and that allowed them chat, make video calls, send photos, write daily reports, and get feedback from health care professionals, which facilitated early detection of complications. These features provided support and easy access to communication with health care professionals, creating a sense of security that the parents highly appreciated [17,38]. Due to similarities with our study, this suggest that a corresponding eHealth intervention could support the families and health care professionals in our study.

However, the health care professionals were also concerned that digital features might exacerbate the distance between them

and the family, which is in line with a study on mobile health clinic appointments on parenteral nutrition at home done through a tablet [39]. Parents and health care professionals were very satisfied with how convenient and easy communication was, but the health care professionals reported that the inability to make accurate clinical assessments using the tablet was a significant challenge [39]. Research also shows that another concern is that telemedicine may depersonalize the patient and clinician relationship due to a lack of in-person interaction [11,40]. These key concerns must be taken into consideration when developing an eHealth intervention and will be explored further in the subsequent studies of the development and evaluation of the intervention in this research project.

Another concern was the reservations health care professionals had regarding workflow and setting, for example, how to organize and assess incoming data and chats at all times of day. Furthermore, organizational issues like maintaining confidentiality had to be considered when doing planned and unplanned video consultations. The study with the eHealth tablet showed that parents felt they had to wait too long to receive answers or feedback from health care professionals at the hospital [17]. Another study reported that clinicians emphasized the importance of having clear guidelines for scheduling and use of telemedicine in pediatric emergency settings [11]. Finally, a systematic review on factors concerning the success and failure of eHealth interventions also showed how workflow caused several barriers to success [41]. Accordingly, it is important to consider the needs of health care professionals, as motivating them to use telehealth can otherwise be challenging [42,43].

The extended responsibility that home infusion therapy entails emphasizes the importance of adjusting information and training, in addition to managing the capacity and needs of the individual child and parents. The parents' mental resources varied during their child's treatment, and research shows how parents obtain and act differently regarding health-related information concerning their child [35,44]. Both parents and health care professionals suggested that digital features could support the individualized aspects as the parents could, when necessary, repeat information and training, solve problems, and receive guidance. In addition, the parents and health care professionals in our study were preoccupied with sharing their responsibility with others to avoid distorting the amount of caregiving placed on one parent. Studies show that telemedicine can address these issues, by communication in greater alignment with the parents' own preferences and pace, not to mention that of families who live far from the hospital and wish to avoid the time and expense transportation and parking [17,38,45].

Strengths and Limitations

This study's strengths include its participatory design, which involved families and health care professionals at the beginning of the development process. The demographics and experiences of the sample of children with acute or long-term illness is also varied, just as both mothers and fathers were included, not to mention children to some extent. The child was invited to participate with their parent, and 13 children were present at the interview, 2 of whom participated actively. However, separate interviews would improve our understanding of the child's needs since the parent may withhold experiences and opinions due to the child's presence. Age-specific methods could have been used to involve and interview children, which would have provided additional insights into their unique needs and preferences. Children will be involved and interviewed in the evaluation study of this research project. The study is conducted in a specific geographic and health care setting, which may limit the generalizability of the findings to other countries and settings with different health care systems.

Data were collected during the early phase of the COVID-19 pandemic, and video consultations and other telehealth options were not used at the department on a regular basis at that time. This may have influenced participants' perceptions of eHealth and impacted the results in the sense that their technology readiness was limited. Since then, the use of telehealth has increased extensively in Denmark and abroad, perhaps causing our findings to appear obvious.

Conclusions

Our study highlights the need parents and health care professionals have for increased safety and easier access to communication when receiving and providing home infusion therapy. Their needs and preferences corresponded with each other, and they suggested key digital features for a pediatric eHealth intervention to provide consistent knowledge, skills, and problem-solving during home infusion therapy. The study emphasizes the need to increase access to home infusion therapy by using digital features, and our findings can provide clarity in terms of developing an eHealth intervention to support pediatric home infusion therapy tailored to individual needs.

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Conflicts of Interest

None declared.

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Multilevel Factors and Indicators of Atypical Neurodevelopment During Early Infancy in Japan: Prospective, Longitudinal, Observational Study

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Abstract

Background: The early identification of developmental concerns requires understanding individual differences that may represent early signs of neurodevelopmental conditions. However, few studies have longitudinally examined how child and maternal factors interact to shape these early developmental characteristics.

Objective: We aim to identify factors from the perinatal to infant periods associated with early developmental characteristics that may precede formal diagnoses and propose a method for evaluating individual differences in neurodevelopmental trajectories.

Methods: A prospective longitudinal observational study of 147 mother-child pairs was conducted from gestation to 12 months post partum. Assessments included prenatal questionnaires and blood collection, cord blood at delivery, and postpartum questionnaires at 1, 6, and 12 months. The Modified Checklist for Autism in Toddlers (M-CHAT) was used to evaluate developmental characteristics that might indicate early signs of atypical neurodevelopment. Polychoric or polyserial correlation coefficients assessed relationships between M-CHAT scores and longitudinal variables. L2-regularized logistic regression and Shapley Additive Explanations predicted M-CHAT scores and determined feature contributions.

Results: Twenty-one factors (4 prenatal, 3 at birth, and 14 postnatal) showed significant associations with M-CHAT scores (adjusted *P* values<.05). The predictive accuracy for M-CHAT scores demonstrated reasonable predictive accuracy (area under the receiver operating characteristic curve=0.79). Key predictors included infant sleep status after 6 months (nighttime sleep duration, bedtime, and difficulties falling asleep), maternal Kessler Psychological Distress Scale scores, and Mother-to-Infant Bonding Scale scores after late gestation.

Conclusion: Maternal psychological distress, mother-infant bonding, and infant sleep patterns were identified as significant predictors of early developmental characteristics that may indicate emerging developmental concerns. This study advances our

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understanding of early developmental assessment by providing a novel approach to identifying and evaluating early indicators of atypical neurodevelopment.

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KEYWORDS

early developmental signs; neurodevelopmental screening; risk factors; prediction; early intervention; longitudinal study

Introduction

Early identification of neurodevelopmental disorders and timely intervention are crucial for optimizing developmental outcomes in children [1]. Children exhibit considerable individual differences in their developmental trajectories during the first year of life, particularly in preverbal social behavior skills [2]. These differences have emerged as crucial areas of study in neurodevelopmental research, as some behavioral characteristics observed during infancy may represent early indicators of developmental concerns [3-5]. Similar to how the concept of mild cognitive impairment has facilitated early intervention in preclinical stages of dementia [6], identifying early indicators of developmental concerns may enable more timely and effective support strategies. However, the complex nature of early development, with its inherent variability and multiple influencing factors, has made it challenging to identify and interpret these early indicators reliably.

Multiple factors influence early childhood neurodevelopment, including prenatal conditions such as maternal immune activation [7], stress [8], and nutritional status, as well as postnatal factors including parental depression [9,10] and early life experiences [11]. Recent research has also highlighted the importance of biological factors such as cytokine profiles [12-14] and sleep-wake rhythms [15-18] in early neurodevelopment. While these factors have been studied individually, their complex interactions across time and their cumulative impact on neurodevelopmental trajectories remain poorly understood.

This study is an exploratory longitudinal investigation conducted in Japan, following mothers and children from the perinatal period (20 weeks of gestation) to the end of infancy (12 months of age). Using an innovative explainable artificial intelligence methodology, we aimed to visualize and analyze how various longitudinal factors interact to influence individual neurodevelopmental trajectories during infancy. Specifically, we assessed preverbal social behavior skills at 12 months of age as potential early indicators of developmental concerns using the Modified Checklist for Autism in Toddlers (M-CHAT) [3,5], and systematically evaluated how multiple observed factors throughout the first year of life contributed to these developmental characteristics. This approach enables a comprehensive understanding of the temporal dynamics and relative importance of various factors in shaping early neurodevelopmental trajectories, potentially identifying key time points and factors for early intervention.

Methods

Recruitment

This study is part of an ongoing multicenter Japanese longitudinal research conducted by 6 collaborating institutions-namely, Kyushu University Graduate School of Medicine, Kagawa University School of Medicine, Tohoku University Graduate School of Medicine, Kyoto University School of Medicine, Fukuoka City Children's Hospital, and RIKEN. Pregnant women were recruited between October 2018 and June 2020 at 5 of the collaborating institutions (excluding RIKEN). Overall, 200 women who fulfilled the inclusion criteria (aged ≥ 20 years, pregnant with a gestational period of less than 26 completed weeks, and fetus in stable condition) agreed to participate. The exclusion criteria were the requirement for proxy consent or the inability to provide voluntary consent. These criteria were established by the Ethical Guidelines for Medical and Health Research Involving Human Subjects to ensure that severe comorbidities or extreme factors would not influence the results of this study. Participants were followed up by visiting the affiliated facilities at midgestation (24 - 26 weeks), late gestation (34 - 38 weeks), at birth, and 1 month post partum. Their children were enrolled at birth and followed up by mailing questionnaires at 1, 6, and 12 months of age. By November 2022, a total of 147 participants and their children had completed the 12-month follow-up. Two patients were excluded due to meeting the exclusion criteria for chromosomal abnormalities: 1 with trisomy 21 and another with an unspecified chromosomal abnormality. The third excluded patient was born at 25 weeks' gestation weighing 734 g, thus meeting both the criteria for very low birth weight (<1000 g) and extreme preterm birth (<30 weeks). These 3 cases were consequently removed from the study population. This study was prospectively registered in the UMIN Clinical Trials Registry (UMIN000034837) on November 9, 2018. While registered in a clinical trial registry, this research is an exploratory study, not a clinical trial. It uses nonpredefined analytical methods, which distinguishes it from traditional clinical trials with preset end points and analysis plans. The registration was carried out for transparency, despite the exploratory nature precluding a detailed prespecified analysis plan. This study was reported according to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

Maternal Assessment

Peripheral blood collected at mid- and late gestation and cord blood at birth was used to measure levels of 1,25-dihydroxyvitamin D, 25-hydroxyvitamin D, melatonin, and cytokines (interleukin [IL]-17A, IL-10, IL-1 β , IL-6, and tumor necrosis factor). The participating mothers completed a series of questionnaires at mid- and late gestation and at 1 month

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post delivery (Multimedia Appendix 1). Maternal hematological biomarkers (vitamin D, melatonin, and cytokines) were measured from blood samples collected during prenatal check-ups and from umbilical cord blood at delivery. While prenatal check-ups typically occur during daytime hours, we did not standardize the exact timing of blood collection. Similarly, as birth times vary unpredictably, umbilical cord blood collection times were inconsistent across subjects. Maternal sleep status was evaluated using the Pittsburgh Sleep Quality Index [19] to assess the quality of sleep and the 3D Sleep Scale (3DSS) [20] to assess sleep regularity (the "sleep phase" item). The Edinburgh Postnatal Depression Scale (EPDS) [21] and Kessler Psychological Distress Scale (K6) [22] were used to assess depression and anxiety disorders, respectively, during pregnancy and post partum. The late gestation questionnaire also included the Autism-Spectrum Quotient Japanese short version (AQ-J-10) [23]. At 1 month post partum, the Japanese version of the Mother-to-Infant Bonding Scale (MIBS-J) [24] was used to assess the mothers' feelings toward their babies.

Infant Assessment and Outcomes

When the children were 1, 6, and 12 months of age, mothers completed questionnaires regarding the children's sleep status (Multimedia Appendix 2). To assess early developmental characteristics in infants, we focused on the acquisition of standard preverbal social behavioral skills and the presence of behaviors commonly associated with autism spectrum disorder (ASD). Specifically, we administered the Japanese version of the M-CHAT at 12 months of age to systematically evaluate these early developmental characteristics. The M-CHAT-a parent-completed dichotomous questionnaire designed for children aged 16 - 30 months-is an effective primary screening tool for ASD and other developmental concerns in the general population [3,5]. In our study, we aimed to identify children showing potential developmental concerns at an earlier stage, specifically at 12 months of age. To achieve this, we developed a unique 10-item version of the M-CHAT, informed by age-specific achievement rates observed in a separate observational study of the general Japanese population. Given that prelinguistic social behaviors vary significantly with age, we included in our analysis 4 age-independent ASD-specific behavioral abnormalities (Q11, Q18, Q20, and Q22) and 6 prelinguistic social behaviors (Q1, Q2, Q4, Q10, Q12, and Q14) that are reported to be consistently achieved by 12 months of age in the general population [4]. The items included were as follows: (Q1) "enjoying being swung," (Q2) "interest in other children," (Q4) "enjoying peek-a-boo," (Q10) "eye contact," (Q11) "oversensitive to noise," (Q12) "response to smile," (Q14) "response to name," (Q18) "unusual finger movement," (Q20) "wonder if deaf," and (Q22) "stares at nothing." Children who fulfilled any of the 10 total M-CHAT items (M-CHAT score \geq 1 point) were defined as the M-CHAT positive group.

Statistical Analysis

Descriptive statistics were used to investigate the characteristics of the participating mothers and their infants. Continuous variables—listed as the median and IQR—included maternal age, 1,25-dihydroxyvitamin D, 25-hydroxyvitamin D, melatonin, IL-17A, IL-10, IL-1β, IL-6, tumor necrosis factor, 3DSS (phase), Pittsburgh Sleep Quality Index global score (PSQIG), EPDS, K6, AQ-J-10, MIBS-J, and umbilical artery blood pH. Categorical variables—listed as frequencies and percentages-included the child's sex, maternal smoking history, educational level of parents, annual household income, gestational age at birth, birth weight, Apgar score at 5 minutes, delivery type, answers to sleep-related questions at each period, and the M-CHAT score. Thereafter, the correlation coefficients between the variables were calculated considering the aforementioned categorical variables and 3DSS (phase), PSQIG, EPDS, K6, AQ-J-10, and MIBS-J as ordinal variables. Polyserial correlation coefficients were computed for the relationships between ordinal and continuous variables; further, polychoric correlation coefficients were computed for the relationships between ordinal variables. These polychoric and polyserial correlation coefficients, as well as Pearson correlation coefficients for continuous variable pairs, were calculated using the lavCor function from the lavaan package in R software (R Foundation). Wald tests were performed to assess the statistical significance of each correlation. To address the issue of multiple comparisons arising from these correlation tests, false discovery rate correction [25] was subsequently applied to the resulting P values. This was performed using the p.adjust() function in R software. Adjusted P values (p.adjust) of <.05 were considered statistically significant.

Correlation Analysis

In this study, the relationships between variables affecting the M-CHAT score were represented by network structure. The nodes were variables that showed significant polychoric or polyserial correlations with the M-CHAT score ($|\mathbf{r}| \ge 2$, p.adjust <.05). The nodes were arranged according to the data collection period.

Classification Model for the M-CHAT Positive Group

We implemented a classification model using a logistic regression algorithm with potential regularization in the scikit-learn Python package (version 3.1.2) to predict the M-CHAT positive group in infants aged 12 months. We used features of maternal and child demographics, laboratory values, and questionnaire results from the midgestation to 12 months post partum that exhibited a significant correlation (p.adjust<.05) and $|r| \ge 2$ with the M-CHAT score. This model, overall, used 20 features. The data obtained at 12 months of age had missing values, which were completed with missForest-a modern method based on random forests that efficiently addresses missing data imputation among multivariate data without cross-validating with the test data [26]. This method involves inherent randomness, potentially leading to variability in imputed datasets. In our study, we did not set a fixed seed during the missForest imputation. The mother-child dataset was divided into a training set (N=100) for training the prediction model and a test set (N=44) for evaluating the model's performance by using the train_test_split function in scikit-learn. To address the imbalanced nature of our dataset, we used the "stratify" parameter in the train_test_split function, specifying the binary M-CHAT outcome (positive or negative) as the stratification variable. This approach ensured that the distribution of M-CHAT

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outcomes was maintained across both the training and test sets. The models were optimized by adapting a grid search method for the hyperparameter "C (regularization strength; 10^{-5} , 10^{-4} , 10^{-3} , 10^{-2} , 10^{-1} , 1, 10, 10^2 , 10^3 , 10^4 , or 10^5)," "penalty (norm of regularization; L1, L2, elastic net, or none)," and "solver (algorithm in optimization; "newton-cg," "lbfgs," "liblinear," "sag," "saga")." When specifying elastic net as the penalty, we validated by varying the 11_ratio from 0 to 1 in steps of 0.1. The performance of the logistic regression model was evaluated on the test set after ensuring missing data imputation. The model outputs class probabilities to predict the M-CHAT positive (M-CHAT score≥1) group. The optimal threshold for the model was determined by the Youden index.

The model's performance was evaluated using the area under the receiver operating characteristic and precision-recall curves. The relative importance of each feature for predicting M-CHAT scores was examined and visualized using Shapley Additive Explanations (SHAP) [27]. SHAP is a model-agnostic, game-theoretic, unified method that computes a Shapley value to account for each feature's contribution to a particular forecast. SHAP values are computed using an additive feature attribution method to approximate the Shapley value of the model's conditional expectation function. LinearExplainer [28] was used to calculate SHAP values for the logistic regression model. For the decision plotting that simulates the M-CHAT prediction pathway of each sample using SHAP, we specifically used samples with higher M-CHAT scores (M-CHAT scores 2 - 4) within the M-CHAT positive group to focus on cases that might represent early developmental concerns.

Data analysis was performed using the open-source software R (version 4.1.2) and Python (version 3.8.5; Python Software Foundation). The correlation analysis results were visualized using Cytoscape (version 3.9.1; Cytoscape Consortium).

Ethical Considerations

This study was approved by the Ethics Review Committee on Research Involving Human Subjects at Doshisha University (No. 22063) and, subsequently, by the Ethics Review Committees at each affiliated institution (No. 22064). Written informed consent was provided by each pregnant woman at the time of the visit at the affiliated facility. Data was deidentified immediately upon collection. A secure, separate database is maintained to connect study IDs with participant details, accessible only to authorized personnel. The research description clearly states the following points: (1) women are free to participate in the research and withdraw their consent, (2) refusal of participation in the research has no implications per disadvantages in medical care, and (3) participation in the research entails no increased cost burden or rewards.

Results

Description of the Sample

The characteristics and results for the 144 mother-child pairs included in the final analysis are presented in Table 1 and Multimedia Appendix 2. These maternal background and perinatal data were obtained by combining information from medical records and parents' reports up to the first month postpartum check-up. The median maternal age was 36 (IQR 32-29) years, and 3 (N=144, 2%) mothers had a smoking history during their current pregnancy. The most prevalent educational level for both parents was a university degree (48/144, 33%) mothers and 64/144, 44% fathers). Annual household incomes varied among the participants, with the most common bracket being 4 to 6 million yen (approximately US \$36,000 to US \$56,000, based on a currency exchange rate of US \$1=JP ¥107-112 that was applicable during the study period) per year, reported by 46 (N=142, 32% of the population) families. Of the children, 86 (N=144, 60%) were female, 129 (N=144, 90%) were born at 37 weeks or later, and 3 (N=144, 2%) were born between 30 and 33 weeks. Birth weight ranged from 3000 g to 3999 g in 122 (N=144, 85%) children; all 5-minute Apgar scores were 7 (N=144) or higher. The median umbilical artery blood gas pH was 7.29 (IQR 7.26 - 7.33). The delivery type was vaginal in 87 (N=144, 60%) cases (Table 1). Throughout the pregnancy, the 3DSS (phase) median score was 10 (IQR 9-12). From midgestation to 1-month postpartum, PSQIG exhibited an increasing trend with median scores of 5 (IQR 3-7), 6 (IQR 4.5-9), and 8 (IQR 6-10), respectively. This indicates that mothers' sleep conditions tended to worsen during the period up to 1 month after childbirth. The median EPDS scores were relatively low across all 3 time points: 3 points in midpregnancy, 4 points in late pregnancy, and 2 points at 1 month post partum. Similarly, K6 scores remained low at 1, 2, and 1, respectively. The median AQ-J-10 score at late gestation was 2 (IQR 1-3), and the median MIBS-J score at 1 month post partum was 1 (IQR 0-3; Multimedia Appendix 2).



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Table . Demographic data for the 144 mother-child pairs included in the final analysis.

Characteristics	1 v	Longitudinal group
Maternal age (years; N=144), median (IQR)		36 (32-39)
Child's sex (N=144), n (%)		
	Female	86 (60)
	Male	58 (40)
Maternal smoking status (N=144), n (%)		
	Never or exsmoker	141 (98)
	Current smoker	3 (2.1)
Maternal education (N=144), n (%)		
	Junior high	3 (2.1)
	High school	28 (19)
	Technical college	5 (3.5)
	College	33 (23)
	Junior college	17 (12)
	University	48 (33)
	Master's degree	10 (6.9)
Paternal education (N=144), n (%)		
	Junior high	7 (4.9)
	High school	37 (26)
	Technical college	3 (2.1)
	College	15 (10)
	Junior college	0 (0)
	University	64 (44)
	Master's degree	18 (12)
Annual household income (JP \S^a ; n=142), n (%)		
	<2 million	1 (0.7)
	2 - 3.9 million	29 (20)
	4 - 5.9 million	46 (32)
	6 - 7.9 million	32 (23)
	8 - 9.9 million	19 (13)
	10 - 11.9 million	11 (7.7)
	12 - 14.9 million	1 (0.7)
	15 - 19.9 million	3 (2.1)
Gestational age at birth (wk; N=144), n (%)		
	30 - 32	3 (2.1)
	33 - 36	12 (8.3)
	≥37	129 (90)
Birth weight (g; N=144), n (%)		
	<1500	1 (0.7)
	1500 - 2999	20 (14)
	3000 - 3999	122 (85)
	≥4000	1 (0.7)

Apgar score at 5 min (N=144), n (%)

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Characteristics		Longitudinal group
	7	1 (0.7)
	8	16 (11)
	9	116 (81)
	10	11 (7.6)
Umbilical artery blood pH (n=140), median (IQF	ξ)	7.29 (7.26 - 7.33)
Type of delivery (N=144), n (%)		
	Vaginal	87 (60)
	Cesarean	57 (40)

^aA currency exchange rate of 107-112 JP \cong US \$1 was applicable during the study period.

The Distribution of the M-CHAT Score Among Children Aged 12 Months

The distribution of the M-CHAT scores among the 144 children aged 12 months was as follows: 105 (73%) children scored 0, 30 (21%) scored 1, 5 (3.5%) scored 2, 3 (2.1%) scored 3, and 1 (1%) scored 4. All 6 preverbal social behavior items (Q1, Q2, Q4, Q10, Q12, and Q14) used to score the M-CHAT in this study exhibited achievement rates of 95% or higher. Specifically, for the question on smiling response (Q12), only 1 parent reported that their child did not smile back when smiled at. Similarly, regarding concerns of hearing impairment (Q20), only 1 parent expressed concern that their child might be enduring hearing difficulties. Of the 39 children who scored 1 or more, 29 (74%) received scores for age-independent and ASD-specific behaviors (particularly Q11, Q18, and Q22; Multimedia Appendix 3).

Interrelationships Between M-CHAT Score and Each Variable

To examine the relationship between the M-CHAT score and other variables during each period, polychoric or polyserial correlation coefficients were calculated and presented in a heatmap (Figure 1). Using the correlation heatmap, variables that significantly correlated with the M-CHAT score were identified. The M-CHAT score was positively correlated with maternal serum melatonin levels in midgestation and cord blood IL-1 β ; the M-CHAT score showed a weak positive correlation with cord blood IL-10 (*r*=.18). By contrast, the M-CHAT score exhibited a negative correlation with maternal serum IL-1 β levels in midgestation and cord blood IL-6 levels. The M-CHAT score in late gestation and with K6 and MIBS-J scores at 1 month post

partum. For infant sleep questions, the M-CHAT score was significantly correlated with shorter sleep duration, bedtime, and difficulty in falling asleep (moodiness and required time). Detailed correlation coefficients are presented in Multimedia Appendix 4.

Correlation analysis was performed to determine the interrelationships among factors potentially influencing early developmental characteristics as assessed by M-CHAT scores (Multimedia Appendix 5). Strong positive correlations ($r\approx 1.0$) were found between cord blood IL-6 and IL-1B levels and between weekday and holiday bedtimes of children aged 6 months. Nodes at late gestation, cord blood, and 1 month post partum were strongly and positively correlated with each other within the same observation period. In children aged 6 months, a negative correlation was found between "nighttime sleeping hours" and "bedtime," and a positive correlation was found between "staying awake for ≥ 1 hour at nocturnal awakening" and "takes long (≥1 hour) to fall asleep." A negative correlation was found between IL-1 β levels in the midgestation period and "short sleep duration" in children aged 1 month; a positive correlation was observed between melatonin levels in midgestation and "takes long (≥1 hour) to fall asleep" in children aged 6 months. K6 and EPDS scores in the late gestation were positively correlated with K6 scores in 1 month post partum and also positively correlated with "staying awake for ≥ 1 hour at nocturnal awakening" in children aged 6 months. "Wakes up several times at night, does not sleep and takes several hands" in children aged 1 month was positively correlated with "takes long (≥ 1 hour) to fall asleep" in children aged 6 months. "Bedtime" among children aged 6 months was positively correlated with "bedtime on holidays" among children aged 12 months (Multimedia Appendix 5).



Figure 1. Heatmap of correlations between M-CHAT and each other variable. 1,25(OH)2D: 1,25-dihydroxyvitamin D; 25(OH)D: 25-hydroxyvitamin D; 3DSS: 3D Sleep Scale; AQ-J-10: Autism-Spectrum Quotient Japanese short version; EPDS: Edinburgh Postnatal Depression Scale; IL: interleukin; K6: Kessler Psychological Distress Scale; M-CHAT: Modified Checklist for Autism in Toddlers; MIBS-J: Japanese version of the Mother-to-Infant Bonding Scale; PSQIG: Pittsburgh Sleep Quality Index global score; TNF: tumor necrosis factor.



Assessment and Visualization of Factors Contributing to Early Developmental Characteristics

To assess longitudinal influences associated with early developmental characteristics as measured by M-CHAT scores, we conducted feature importance analysis using SHAP on a logistic regression model with L2 regularization ("C"=0.1, "penalty"="L2," "solver" = "liblinear," area under the receiver operating characteristic and precision-recall curves and the confusion matrix shown in Multimedia Appendix 6). The optimal threshold was determined by the Youden index to be 0.32. The logistic regression model attained reasonable predictive performance (area under the receiver operating characteristic curve=0.79, 95% CI 0.62 - 0.95; Multimedia Appendix 6). While the point estimate falls within the acceptable range (0.7 - 0.8), the CI extends below 0.7, indicating some uncertainty in its discriminative ability. The model's utility should therefore be interpreted within the context of the dataset and application. The SHAP beeswarm plot (Figure 2A) assesses the contribution of each feature of the total sample to the model. The order of the feature values obtained by SHAP and the contribution of each feature is high, and this ranking is relative, for example, it does not indicate which rank is particularly important. When examining variables in order of their contribution strength, we found high contributions from bedtime

at 12 months, nighttime sleep duration and irritability at bedtime at 6 months, and maternal K6 and MIBS-J scores during late pregnancy and 1 month post partum. Specifically, later bedtimes, shorter nighttime sleep duration, higher K6 and MIBS-J scores, and irritability at bedtime promoted classification into the M-CHAT positive group. The characteristics that moderately contributed to such a classification were variables related to the sleep status of children aged 1-6 months and maternal melatonin levels. The 6 characteristics with the lowest influence were predominantly cytokine levels, EPDS score, "wakes up several times at night, does not sleep, and takes several hands" in children aged 1 month, and bedtime for children aged 6 months. The SHAP decision plot (Figure 2B) simulates the decision pathway for predicting classification into the M-CHAT positive or negative (M-CHAT score=0) groups in the order of observation period. All 9 randomly sampled cases with M-CHAT scores of 0 were correctly predicted to be the M-CHAT negative group. In some M-CHAT positive cases, the predictive risk began to increase owing to the deterioration of the maternal K6 and MIBS-J scores and infant sleep status for children aged 6 months. Conversely, there were cases in which the predictive risk did not change for maternal factors but increased rapidly for factors related to the child's sleep after 6 months of age.



Figure 2. (A) SHapley Additive exPlanations (SHAP) beeswarm plot of the logistic regression model. (B) SHAP decision plot of 9 samples with an M-CHAT score of 0 (random sampling) and 9 samples with an M-CHAT score of 2–4, for a total of 18 samples. BT: bedtime; EPDS: Edinburgh Postnatal Depression Scale; FA: fall asleep; IL: interleukin; K6: Kessler Psychological Distress Scale; M-CHAT: Modified Checklist for Autism in Toddlers; MIBS-J: Japanese version of the Mother-to-Infant Bonding Scale; SHAP: Shapley Additive Explanations; SLP: sleeping hours.
 (A) SHAP beeswarm plot



Discussion

Temporal Dynamics of Early Developmental Characteristics: Individual Patterns and Contributing Factors

In recent years, the number of cases of neurodevelopmental disorders has increased rapidly, becoming a significant social concern. While genetic factors have been extensively studied, identifying genes that correlate with symptoms alone is insufficient to understand developmental mechanisms. The clarification of how environmental factors interact with genetic predisposition in the developmental process remains an urgent research priority [29].

In this study, we assessed early developmental characteristics through social behavior patterns and analyzed how these patterns emerge during infancy. The SHAP analysis provided a novel approach to assess and visualize how multiple longitudinal factors contribute to individual neurodevelopmental trajectories. Specifically, our analysis focused on cases showing elevated M-CHAT scores (2 - 4 points), including those exceeding the conventional ASD screening cutoff value (M-CHAT score of 3+). This analysis revealed distinct temporal patterns in the emergence of early developmental characteristics. Some cases showed an increased risk of M-CHAT positive classification during late gestation, primarily associated with elevated maternal K6 scores. Other cases demonstrated increased risk due to disrupted infant sleep patterns after 6 months of age. Additionally, we observed cases where substantial increases in K6 and Mother-to-Infant Bonding Scale (MIBS) scores at 1-month postpartum markedly elevated the predicted probability of M-CHAT positive classification.

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These results indicate that early developmental characteristics associated with elevated M-CHAT scores emerge through several distinct dynamic patterns, involving multiple interacting factors. The SHAP methodology enabled the quantification of each factor's relative contribution to these patterns. Based on our findings, we suggest that targeted follow-up assessments focusing on maternal anxiety disorders in late gestation and infant sleep characteristics at 6 months—particularly sleep duration, bedtime, irritability upon falling asleep, and extended periods of wakefulness—may be particularly valuable for the early identification of developmental concerns.

Temporal Relationships Between Early Developmental Characteristics and Longitudinal Factors

Correlation analysis revealed that relatively strong correlations between factors within the same period were observed between similar factors such as maternal physical and mental status, sleep difficulties in children, and inflammatory cytokines. However, correlations between factors with different observation periods were more limited than correlations within the same period. Our analytical method does not pursue a causal relationship.

Early Sleep Difficulties as Indicators of Emerging Developmental Characteristics

Recent research has established clear interactions between sleep patterns and neurodevelopment in young children. During early brain development, sleep patterns and neural maturation progress in parallel, significantly influencing cognitive performance [16,17]. Notably, studies have demonstrated associations between infant sleep patterns and brain structure, including hippocampal volume [18]. Children who later receive

neurodevelopmental disorder diagnoses often experience more persistent and complex sleep problems compared to their typically developing peers [30]. Several longitudinal studies have identified early sleep difficulties as potential risk indicators for diagnosis of later ASDs [18,30]. Specifically, shorter sleep duration, delayed sleep onset and wake times, and frequent midday awakenings have been associated with an increased likelihood of subsequent ASD diagnosis. The timing of sleep-related interventions appears crucial, with recommendations focusing on the period between 3 and 6 months of age, when circadian rhythms become established in the suprachiasmatic nucleus [15,31]. Our findings align with and extend this literature: M-CHAT scores at 12 months showed significant correlations sleep-related with multiple characteristics, including reduced sleep duration, later bedtime, and difficulties with sleep onset (including irritability and prolonged time to fall asleep). These results suggest that infants showing early signs of developmental concerns, as indicated by elevated M-CHAT scores, may already be experiencing sleep-related challenges. Early identification of these sleep patterns could provide opportunities for targeted interventions, potentially benefiting not only the infant's sleep and neurodevelopmental trajectory but also family functioning and overall cognitive outcomes.

Relationship Between Inflammatory Markers and Early Developmental Characteristics

Increasing evidence suggests that chronic inflammation plays a role in atypical neurodevelopment, although the underlying mechanisms remain unclear. For example, microglia, crucial for brain maturation and function, are increasingly recognized to play a decisive role in various developmental and cognitive conditions [32]. Microglia produce inflammatory mediators and reactive oxygen species, potentially leading to neuronal degeneration, white matter abnormalities, and decreased neurogenesis observed in conditions such as ASD or schizophrenia [32]. The secretion of signaling molecules and cytokines may promote crosstalk between microglia and astrocytes, leading to endothelial dysfunction and blood-brain barrier permeability impairment [33]. Multiple studies have reported increased concentrations of inflammatory cytokines such as IL-6 and IL-1 β and a decrease in anti-inflammatory cytokines (IL-10 and transforming growth factor $[TGF]-\beta$) in the peripheral blood and cerebrospinal fluid of individuals with ASD [12,13,33]. The persistent elevation of these inflammatory cytokines may reflect ongoing inflammatory processes [14].

Maternal infections during pregnancy and early childhood are known to influence early development, and changes in cytokine profiles may be shaped by environmental exposures during prenatal and early childhood periods [32]. Typically, the maternal immune system shifts to a more tolerant state during pregnancy, characterized by a decrease in inflammatory cytokines and an increase in regulatory cytokines [12]. However, mothers whose children later receive neurodevelopmental diagnoses have been reported to have significantly higher levels of various inflammatory cytokines and chemokines, such as IL-1 α , IL-4, IL-6, and interferon [IFN]- γ in serum during midpregnancy [34,35]. Studies have also reported alterations in melatonin secretion in individuals with ASD, particularly decreased secretion of melatonin and its metabolites at night and altered circadian rhythm [33]. Low maternal melatonin levels during pregnancy have been associated with an increased likelihood of subsequent ASD and intellectual disability diagnoses [36], although there is no consensus on this matter. Contrary to previous research, our study found associations between increased melatonin and decreased IL-1 β and M-CHAT scores in midpregnancy. These associations were not observed in maternal blood in late pregnancy. Factors such as the intensity, timing, and duration of maternal inflammatory responses may be crucial for influencing the developing child's brain. Differences in sample processing and clinical sample variation may also contribute to these findings.

Higher levels of IL-1 β in neonatal samples have been associated with an increased likelihood of ASD diagnosis [37]. Moreover, neonatal samples from infants later diagnosed with ASD showed decreased levels of many cytokines (IFN- γ , IL-2, IL-4, IL-6, and IL-10), suggesting reduced immune cell activity in the neonatal period [38]. Interestingly, consistent with previous studies, our analysis found significant correlations between increased IL-1B and decreased IL-6 in cord blood and M-CHAT scores. These results suggest 2 possibilities: first, the cytokine profile in umbilical cord blood samples may predict subsequent developmental characteristics similarly to neonatal samples; second, the M-CHAT assessment at 12 months may effectively identify early developmental concerns before formal diagnostic evaluations. However, these observed relationships between IL-1 β and M-CHAT were derived using polychoric or polyserial correlation analysis, and statistical significance might be lost if other statistical methods accounting for outliers were applied. Given that these cytokine data showed very low predictive contribution to the model, and considering that IL-1 β is a bioactive substance that can be unstable and challenging to measure in blood in clinical settings, the correlations found in this study should be interpreted with caution.

Maternal Psychological Well-Being as a Predictor of Early Developmental Characteristics

Focusing on maternal mental and physical status, it has been previously reported that persistent anxiety during pregnancy is significantly associated with ASD in children [8]; further, persistent depression is associated with developmental delay at 18 months [9]. Our study found correlations between K6, EPDS, and M-CHAT, consistent with previous reports. Notably, we identified a significant positive correlation between MIBS and M-CHAT scores at 1 month post partum. While previous studies have shown strong correlations between MIBS and EPDS from early postpartum through 12 months [10], our study is among the first to examine MIBS scores as an independent predictor of early developmental characteristics. Although enhanced parent-child bonding may not directly improve social functioning in children with ASD [39], our findings suggest that MIBS assessment may be valuable for the early identification of developmental concerns.

Our longitudinal analysis demonstrates that early postnatal maternal psychological measures—including emotional state (EPDS), psychological distress (K6), and MIBS—correlate with infant developmental characteristics as assessed by M-CHAT

scores. These findings emphasize the importance of comprehensive maternal psychological monitoring in the postpartum period. Even when EPDS scores do not indicate clinical depression, attention to other maternal psychological indicators, particularly MIBS and K6 scores, may provide valuable insights for early developmental screening.

Limitations

This study has several limitations. First, the pathogeneses of neurodevelopmental disorders are multifactorial; therefore, the presence of unobserved confounding factors cannot be excluded when interpreting the findings of this study. The interrelationship of various sleep and psychological measures (Pittsburgh Sleep Quality Index, K6, MIBS, EPDS, etc) assessed at different time points may introduce potential biases. Parental ratings of child sleep status are inherently subjective and could be influenced by parents' own psychological stress or sleep issues, potentially affecting the results. Additionally, the collection and measurement of maternal and cord blood biomarkers lack standardized timing protocols and do not account for diurnal variations, necessitating consideration of potential measurement errors in the analysis.

Second, the sample size is small, and the results are preliminary. Future studies should validate these findings using larger samples. Only Japanese participants were included in this study, and no analysis of cultural and social influences due to racial or ethnic differences was conducted. Furthermore, there was considerable variation in the number of mother-child pairs recruited across study sites. While recruitment was not intentionally biased, potential disparities in research resources and physician-patient relationships among facilities may have influenced informed consent rates. Of note is that our longitudinal study may not be fully representative of the Japanese population.

Third, the use of M-CHAT scores at 12 months as an indicator of early developmental characteristics has inherent limitations. While M-CHAT is a validated screening tool, our assessment was based on parent-reported scoring, and due to the short observation period, we were unable to confirm subsequent neurodevelopmental diagnoses. In an ongoing study, we plan to assess ASD using the Kinder Infant Development Scale and Social Responsiveness Scale 2nd edition at 36 months of age.

Conclusions

Understanding the characteristics of early development and their predictors is essential for improving strategies for early detection and support of neurodevelopmental problems.

Our study demonstrates that a systematic analysis of multiple longitudinal factors can reveal important patterns in early development, particularly in preverbal social behaviors as assessed by M-CHAT scores at 12 months. The results indicate that early developmental characteristics are influenced by several key factors, particularly maternal-infant bonding, maternal anxiety, and infant sleep patterns. The temporal dynamics of these relationships suggest that monitoring specific combinations of factors—including maternal psychological well-being and infant sleep patterns. Future studies with larger and more diverse population samples are needed to validate these findings and establish their generalizability for clinical practice.

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Data Availability

The data and code that support the findings of this study are available from the corresponding author, EK, upon reasonable request. The data are not publicly available as it contains information that could compromise the privacy of research participants.

Conflicts of Interest

Y Kimura received collaborative research funding and patent royalties from Atom Medical Inc. All other authors declare that they have no conflicts of interest.

Multimedia Appendix 1

Maternal and infant assessments with questionnaires. [DOCX File, 62 KB - pediatrics v8i1e58337 app1.docx]

Multimedia Appendix 2 Characteristics of participants. [DOCX File, 44 KB - pediatrics_v8i1e58337_app2.docx]

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Multimedia Appendix 3

Distribution of M-CHAT scores for 12-month-old children aged 12 months. M-CHAT: Modified Checklist for Autism in Toddlers. [DOCX File, 98 KB - pediatrics v8i1e58337 app3.docx]

Multimedia Appendix 4

Correlation between the M-CHAT scores and each variable. M-CHAT:Modified Checklist for Autism in Toddlers. [DOCX File, 32 KB - pediatrics_v8i1e58337_app4.docx]

Multimedia Appendix 5 Correlation analysis. [DOCX File, 555 KB - pediatrics v8i1e58337 app5.docx]

Multimedia Appendix 6

Logistic regression model with L2 regularization predicting the DD positive group. DD: developmental diversity. [DOCX File, 269 KB - pediatrics v8i1e58337 app6.docx]

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Abbreviations

3DSS: 3D Sleep Scale **AQ-J-10:** Autism-Spectrum Quotient Japanese short version

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ASD: autism spectrum disorder
EPDS: Edinburgh Postnatal Depression Scale
IFN: interferon
IL: interleukin
K6: Kessler Psychological Distress Scale
M-CHAT: Modified Checklist for Autism in Toddlers
MIBS: Mother-to-Infant Bonding Scale
MIBS-J: Japanese version of the Mother-to-Infant Bonding Scale
p.adjust: adjusted *P* value
PSQIG: Pittsburgh Sleep Quality Index global score
SHAP: Shapley Additive Explanations
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
TGF: transforming growth factor

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Original Paper

Enhancing Access to Mental Health Services for Antepartum and Postpartum Women Through Telemental Health Services at Wellbeing Centers in Selected Health Facilities in Bangladesh: Implementation Research

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Abstract

Background: Globally, 10% of pregnant women and 13% of postpartum women experience mental disorders. In Bangladesh, nearly 50% of mothers face common mental disorders, but mental health services and trained professionals to serve their needs are scarce. To address this, the government of Bangladesh's Non-Communicable Disease Control program initiated "Wellbeing Centers," telemental health services in selected public hospitals.

Objective: This study examines implementation outcomes, including adoption, accessibility, acceptability, feasibility, usefulness, need, experience, perception, and expectations of the Wellbeing Centers, with a focus on antepartum and postpartum women.

Methods: Between January 2023 and August 2024, we interviewed 911 antepartum and postpartum women receiving mental health services and 168 health care providers at 6 Wellbeing Centers in 4 districts in Bangladesh. Data collection involved both quantitative and qualitative methods. Implementation outcomes were measured following the World Health Organization's implementation research framework. Depression and anxiety symptoms were assessed using the Patient Health Questionnaire-9 and Generalized Anxiety Disorder-7 questionnaires. Descriptive statistics and adjusted odds ratios (aORs) with 95% CIs were used to evaluate the implementation outcomes. Qualitative information was obtained through in-depth interviews and key-informant interviews.

Results: Almost all health care providers (165/168, 98.2%) reported that the Wellbeing Centers were feasible to implement in their health facilities; however, about half (84/168, 50%) felt that trained staff to operate them were insufficient. Almost all women agreed that the Wellbeing Centers were acceptable (906/911, 99.8%), useful (909/911, 99.8%), and enhanced access to mental health care (906/911, 99.5%). Patients visiting district-level hospitals had higher odds of access (aOR 1.5, 95% CI 1.1-2.0) to Wellbeing Centers. Moreover, 77.4% (705/911) of women experienced depression symptoms, and 76.7% (699/911) experienced

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anxiety symptoms. About 51.8% (472/911) experienced tiredness or lack of energy, 50.9% (464/911) felt nervous, anxious, or on edge, 57.2% (521/911) felt worried, and 3.8% (35/911) had suicidal ideation almost every day. Patients visiting district hospitals had higher odds (aOR 2.6, 95% CI 1.8-3.78) of depression and anxiety symptoms compared to the patients visiting subdistrict-level hospitals. Decreasing trends in Patient Health Questionnaire-9 scores (from mean 14.4, SD 0.47 to mean 12.9, SD 0.47) and Generalized Anxiety Disorder-7 scores (from mean 13.3, SD 0.49 to mean 12.5, SD 0.48) between 2 counseling sessions indicated improved mental health in the antepartum and postpartum women. The Wellbeing Centers' services were appreciated for their privacy and being free and accessible. However, stigma, postpartum illness, and long waiting times prevented some women from using these services.

Conclusions: To our knowledge, this is the first implementation research assessing telemental health in public health facilities involving trained psychologists and psychiatrists. Our study highlighted the increased accessibility, feasibility, acceptability, and utility of Wellbeing Centers for antepartum and postpartum women in Bangladesh, supporting their scale-up in similar settings.

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KEYWORDS

Wellbeing Centers; antepartum; postpartum; depression; anxiety; implementation

Introduction

Background

Maternal mental health problems are common during pregnancy and after birth [1]. It is recognized as a global public health issue, as approximately 10% of antepartum and 13% of postpartum women experiencing some sort of mental health disorders [2]. The prevalence of maternal common mental disorders is high (49%) in Bangladesh, which underscores a need to screen for depression and anxiety symptoms during pregnancy and postpartum period [3,4]. Around 1 in 5 women experience depressive symptoms during pregnancy, and around 1 in 3 women experience anxiety in rural Bangladesh [4]. In a different study, postpartum women in rural Bangladesh reported that 11% had depressed symptoms, 35% had anxiety symptoms, and 3.4% had both depression and anxiety symptoms [5]. A recent study suggested that postpartum depression symptoms have been more common among impoverished rural mothers during the shutdown in Bangladesh [6-8].

Adverse Effects of Maternal Mental Disorders During the Antepartum and Postpartum Periods

Pregnant women with low education, history of economic difficulties, poor marital relationships, family history of any common mental disorder, poor social and partner support, bad obstetric history, current or previous exposure to violence, preference to have a male child, history of abortions, and disturbed family environment are more likely to report any kind of antepartum and postpartum mental disorders [4,9-13]. Maternal depression may cause negative health-related behaviors and adverse outcomes, including psychological and developmental disturbances in infants, children, and adolescents [14]. Women with severe mental disorders also have increased risks of pre-eclampsia, antepartum and postpartum hemorrhage, placental abruption, impaired intrauterine growth, abortion, and cesarean section, and stillbirths are associated with antepartum and postpartum depression and anxiety [14-19]. Severe mental disorders result in suicide, a leading cause of maternal death in pregnancy and the postpartum period, which contributes to maternal mortality and low quality of life [1,20,21].

Why Videoconference-Based Counseling Is Appropriate as an Intervention for Maternal Mental Disorders in the Context of Bangladesh

Early detection and treatments are necessary to address these maternal mental health issues. Maternal mental disorders are treatable using effective counseling and therapies [22]. However, the availability and access to mental health services are somewhat limited in rural Bangladesh. In addition, the number of available psychologists and psychiatrists is very low. Bangladesh has an estimated 260 psychiatrists, or approximately 0.16/100,000 population, as well as 700 nurses who provide mental health specialty care (0.4/100,000), and 565 psychologists (0.34/100,000) mostly concentrated in urban settings [23]. Providing in-person mental health care with limited capacities such as very low designated government facilities with few specialty service providers is difficult [23].

However, Bangladesh has very good network coverage, which can be used for telehealth counseling services. Telemental health services, which gained popularity during the COVID-19 pandemic, are also commonly used in Bangladesh [24]. Several studies have found that telephone-based treatment significantly improved short-term symptoms and considerably alleviated the advancement of postnatal depression [25,26]. Evidence suggests that digital psychological interventions for mental health problems in developing countries are effective when usual care for mental health problems is minimal [27]. Another study reported that mothers experienced less maternal depression after videoconference-based receiving counseling [28]. Videoconference-based counseling has emerged as a practical and efficient means of providing mental health treatment in resource-limited communities for reducing symptoms of psychiatric disorders and helping to improve quality of life [29-33].

Implementation of Wellbeing Centers in Collaboration With the Non-Communicable Disease Control Program of the Government of Bangladesh

Cognizant of this reality, the Non-Communicable Disease Control (NCDC) program of the government of Bangladesh (GoB) initiated the telemental health service called "Wellbeing Centers" in 6 public hospitals of Bangladesh to provide



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telemental health services with facilitation support from the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). General patients along with women with maternal mental health disorders can take personalized and specialized counseling support from a pool of psychologists and psychiatrists through videoconference counseling at the Wellbeing Centers [34,35]. It is important to know whether these services are adequately benefitting the targeted population in a larger number of facilities for scaling up these Wellbeing Centers in other districts in Bangladesh since no study ever explored it in Bangladesh.

Aims

The primary aim of this study is to assess the implementation outcomes (feasibility, accessibility, adoption, acceptability, usefulness, need, experience, perception, and expectation) of the Wellbeing Centers in selected district and subdistrict hospitals of Bangladesh. We will also explore the prevalence

Figure 1. Study sites. DH: district hospital; UHC: upazila health complex.

of depression and anxiety symptoms in the targeted population as a secondary outcome for demonstrating the need for such mental health care.

Methods

Study Setting

A total of 6 Wellbeing Centers were implemented in district hospitals (DHs) and 4 *upazila* (subdistrict) health complexes (UHCs) in Dinajpur district of Rangpur division and Netrokona district of Mymensingh division. Two other subdistrict-level health care facilities were from Nakla in the Sherpur district and from Chatkhil in the Noakhali district. Selected health care facilities were Dinajpur DH, Netrokona DH, Durgapur UHC, Chirirbandar UHC, Nakla UHC, and Chatkhil UHC (Figure 1). The NCDC program of the Directorate General of Health Services suggested carrying out the Wellbeing Center services in these enlisted 6 health care facilities.



Study Design

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An implementation research study was conducted, where the NCDC program designed, developed, and demonstrated an implementation model to introduce Wellbeing Centers for providing telemental health services. The study used both quantitative and qualitative data collection. Implementation facilitation support was provided, and assessments were

conducted by icddr,b, an international health research organization based in Bangladesh.

Study Participants

Antenatal and postnatal women who visited to the outpatient settings (mainly antenatal care [ANC] and postnatal care [PNC] corner) and received counseling from Wellbeing Centers of the 6 selected health care facilities were enrolled in this study. A total of 911 women in antepartum and postpartum periods

received care from the Wellbeing Centers, and 168 health care facility managers and providers directly involved in the implementation were surveyed and reincluded in this analysis. The health care facility managers and providers included civil surgeons of the corresponding districts, hospital superintendents of the corresponding DHs, subdistrict health and family planning officers of the corresponding UHCs, resident medical officers (RMOs) of corresponding DHs and UHCs, physicians, and gynecological consultants from the outpatient departments.

Development of the Wellbeing Centers at the Health Care Facilities

Overview

The NCDC program of the Directorate General of Health Services, Ministry of Health and Family Welfare of Bangladesh received implementation support from the icddr,b along with other institutions, such as the National Institute of Mental Health (NIMH) and Department of Clinical Psychology, University of Dhaka, to establish the Wellbeing Centers.

Creating a Pool of Psychologists and Psychiatrists

A pool of trained psychologists and psychiatrists has been formed to deliver mental health care services. This pool of psychologists and psychiatrists was guided and mentored by professional bodies from clinical and counseling psychology and psychiatry.

Establishment of the Wellbeing Centers

Equipment and technology recourses included a computer, an internet connection, and a webcam in each Wellbeing Center at the facility. To establish an internet connection, an internet router was provided. In cases of electrifying fall, an uninterrupted power supply was used. Psychologists and psychiatrists and patients were provided with headphones to cancel or isolate ambient noise. With the help of a digital platform, appointments were scheduled. Patients were connected with the psychologists through videoconferencing. In the hospital, a room was allocated for the Wellbeing Center. This room was dedicatedly used for telemental health, maintaining appropriate privacy and confidentiality. The webcam and video monitor were placed at the client's eye level to best approximate a face-to-face interaction.

Training

Health care administrators, expertise in mental health, along with facility managers partnered with icddr,b to facilitate training and workshops for district and subdistrict-level health care providers (such as RMOs, physicians, gynecological consultants, and health workers). Additionally, the implementation support team organized the orientation of both government and program-supported health workers to promote the Wellbeing Center activities. Training content covered the use of depression and anxiety screening tools, patient reception, appointment scheduling, communicable liaison, the integration of mental health services in outpatient settings, effective web-based patient engagement, the use of technology in delivering mental health services, patient referral processes, follow-ups, and crisis management.

Service Provision

At first, women who came to seek health care service at ANC or PNC corners of the health care facilities were referred by the physicians or gynecological consultants to the Wellbeing Centers. Afterward, a health worker screened and redirected women of antepartum and postpartum to a Wellbeing Center and registered the client's through the digital platform using their name and phone number. The health worker noted the availability of psychologists, and an appointment was then fixed. By creating a digital meeting link, the patient's information and schedule were shared with the psychologists. Patients were supported by the health worker to prepare and make necessary arrangements for connecting to the psychologists through videoconference ensuring adequate privacy.

Psychologists assessed clients' mental health disorders using psychometric tools and then provided tailored counseling. Psychologists designed additional management plans and follow-ups based on the clients' improvement dimensions. When counseling proved insufficient to address moderate to severe instances, clients were referred to the NIMH's psychiatrists. Then, the health worker made an appointment and used videoconference-based counseling to connect with the psychiatrist for further treatment. Each client had a second screening by a health worker using the Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder-7 (GAD-7) during follow-up sessions in order to measure the degree of change in their mental condition (Figure 2).



Figure 2. Mental health service delivery mechanism of Wellbeing Centers. ANC: antenatal care; DH: district hospital; PNC: postnatal care; UHC: upazila health complex.



Data Collection

Both quantitative and qualitative methods were undertaken to collect data. Quantitative data were collected using tablets, and qualitative interviews were done using audio recorders. We developed a data entry interface for this implementation research to manage data. A quantitative survey was conducted among women by trained health workers. A structured quantitative questionnaire was used to collect data on demographics [36,37], validate depression and anxiety symptom screening in outpatient settings [38-41], and assess implementation outcomes including acceptability, usefulness, and adoptability [42]. Assessment of feasibility among health facility managers was determined using the World Health Organization's (WHO) improving health system and services for mental health guideline [42]. Qualitative information was received by trained researcher using in-depth interviews (IDIs) and key informant interviews (KIIs). All data collection tools are presented in detail in Multimedia Appendices 1-4. About 10 qualitative IDIs were conducted on experiences, perceptions. and expectations regarding the videoconference-based mental health counseling among women who received ANC and PNC in the health care facilities at the Wellbeing Centers. Moreover, 15 KIIs were conducted among the health care facility managers, RMOs, physicians, psychologists, psychiatrists, and health workers. The number of antepartum and postpartum women who took follow-up sessions was 51.

Study Measures

Basic demographic information included age (years), types of care (ANC and PNC), religion, profession, education (years completed), household income (taka per month), and catchment area (subdistrict and district) were determined. The WHO's implementation research in health care guideline was followed in terms of defining acceptability, usefulness, feasibility, and adoption [42]. Table 1 provides detailed indicator information for all the implementation outcomes assessed in this study.

The PHQ-9 [43] and the GAD-7 scales [44] were used to evaluate depression and anxiety in outpatient settings, respectively [39,41]. The PHQ-9 is a 9-item questionnaire that assesses depression symptoms in a range of 0=not at all to 3=nearly every day. The PHQ-9 score ranges from 0 to 27, with mild, moderate, moderately severe, and severe depression symptoms equating to cutoff values of 5, 10, 15, and 20, respectively. The GAD-7 is a 7-item questionnaire that measures anxiety symptoms on a range of 0=not at all to 3=nearly every day. The GAD-7 scale has a score range of 0 to 21, with mild, moderate, and severe anxiety symptoms equating to cutoff values of 5, 10, and 15, respectively. Figure 3 presents the logical framework of the telemental health intervention in reducing the common mental health disorders among pregnant and postpartum women.



Table 1. Indicators according to the objectives for all the implementation outcomes assessed in the study.

Number	Objectives	Study method	Implementation out- come	Indicators or themes		
1	To assess the feasibility of the Wellbeing Center at the district-level facility	Quantitative	Feasibility	•	Percentage of facility managers who feel that Wellbeing Center is implementable in the facility Percentage of facility managers who feel that they have sufficient trained staff in their facility to implement the Wellbeing Center	
2	To assess the accessibility to mental health care among antenatal and post- natal women by introduc- ing Wellbeing Center's telemental health care	Quantitative	Accessibility	•	Percentage of users who agreed that Wellbeing Center has improved their access to mental health services	
3	To assess the adoption of the Wellbeing Center at district-level facility for antepartum and postpartum women	Quantitative	Adoption	•	Number of women receiving services from the Wellbeing Center	
4	To assess the acceptability of the Wellbeing Center at district-level facility for antepartum and postpartum women	Quantitative	Acceptability	•	Percentage of users who agreed that mental health services from the Wellbeing Center are acceptable to them	
5	To assess the usefulness of the Wellbeing Center at district-level facility for antepartum and postpartum women	Quantitative	Usefulness	•	Percentage of users who agreed that the Wellbeing Center is useful Change in depression and anxiety symptoms scores from first follow-up to second follow-up	
6	To assess the proportion of target women with symp- toms of depression	Quantitative	Need	•	Percentage of users who had depressive symptoms	
7	To assess the proportion of target women with symptoms of anxiety	Quantitative	Need	•	Percentage of users who had symptoms of anxiety	
8	To assess the experience, perception, and expecta- tion about the telemental health counseling at the district-level facility for the antepartum and postpar- tum women	Qualitative	Experience, percep- tion, and expectation	•	Experience, perception, and expectation about the Wellbeing Center	



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Data Analysis

Quantitative Analysis

Stata (version 15.0; StataCorp) was used for this analysis. We have presented descriptive statistics (frequency and percentage) with 95% CIs. For measuring the effect of various factors (age, types of care, religion, profession, education, household income, and catchment area) on the accessibility of the Wellbeing Centers and need-related indicators (depression, anxiety, and both depression and anxiety), 4 separate fitted models were constructed. Multiple logistic regression models were applied to compute the adjusted odds ratios (aORs) with 95% CI. In the adjusted models, accessibility was considered if a woman "strongly agreed" that the Wellbeing Center increased the accessibility of mental health services. Severe depression symptoms were coded as "1," and others (mild, moderate, and moderately severe depression) were coded as "0." For anxiety, severe anxiety symptoms were coded as "1," and mild and moderate anxiety symptoms were coded as "0." When a participant was found to have both severe anxiety and depression, we documented this as the co-occurrence of the 2 conditions using a binary response format (1 and 0). Wald statistics were used to assess the model adequacy. We presented the differences in depressive and anxiety symptoms of antepartum and postpartum women occurring nearly every day using radar plots. At the 5% level of significance, the statistical significance of the estimates has been reported.

Qualitative Analysis

All audio-recorded interviews, supplemented with field notes, were transcribed verbatim. The transcriptions were then read through several times by all the researchers to get more familiar with the data. The transcriptions were manually thematically analyzed using an inductive approach [45,46]. The three stages of the analysis included (1) reading the interview transcripts; (2) highlighting the related words, coding them in relation to

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the text, and thereafter classifying them; and finally, (3) identifying the themes with reflective notes. The data were coded and categorized according to the emerging themes. Data were analyzed by NVivo (QSR International) qualitative data analysis software. To respect the anonymity of each participant, no personal identifying information was presented in the result.

Ethical Considerations

The icddr,b Institutional Review Board granted the study ethics approval (protocol PR-22103). All the eligible women have given written informed consent prior to the enrollment. All data were anonymized or deidentified. No monetary compensation was provided to participants for this research. Consent has been granted from identifiable individual features of research participants or users in any images of the manuscript or supplementary material.

Results

Quantitative Findings

The selection process of the patients from the facilities with Wellbeing Center for antepartum and postpartum women is shown in Multimedia Appendix 5. Between January 2023 and August 2024, 16,203 patients visited the outpatient department, from whom 5863 general patients received services from Wellbeing Centers. Among them, 4450 women visiting the ANC and PNC corners received services from 6 Wellbeing Centers. We have considered only the 911 antepartum and postpartum women who received mental health services at the Wellbeing Center.

Table 2 presents the background characteristics of the antepartum and postpartum women who received services from Wellbeing Centers. The majority of the women were young adults aged 20-24 years. Most of the women (n=817, 89.7%) who received mental health services at the Wellbeing Centers and NIMH were referred during ANC visits. Only 2.2% (n=20)

of the women were involved in any income-generating activities. In total, 54.6% (n=497) of the women completed secondary-level education, and 46.9% (n=427) were from the low-income group. A total of 70.6% (n=643) of the counseling receiving women visited the subdistrict-level facility.

Figure 4 presents the WHO-guided implementation outcomes, feasibility, accessibility, acceptability, usefulness, and need of the Wellbeing Center. Among 168 providers, almost everyone (165/168, 98.2%) reported that the Wellbeing Center is implementable at the facilities. Half of the providers (84/168, 50%) agreed that the facilities have trained staff to maintain the Wellbeing Center. Among the users, almost all antepartum and postpartum women agreed that the Wellbeing Center is increasing accessibility, and it is acceptable and useful for them, as antepartum and postpartum women experience depression and anxiety throughout the period. Around three-fourths of the users had moderate to severe anxiety or depressive symptoms, which demonstrated the need for mental health care.

Figure 5 presents the percentage of women who experienced depressive and anxiety symptoms nearly every day in the past 2 weeks, as indicated by the PHQ-9 and GAD-7 scales. Half of the women (472/911, 51.8%) experienced a lack of energy nearly every day, and 36.6% (333/911) experienced a lack of interest and pleasure. Around one-third of women faced issues with trouble falling asleep or sleeping too much and poor appetite or overeating almost every day. In total, 3.8% (35/911) had suicidal ideation almost every day. Among the anxiety symptoms, 57.2% (521/911) worried too much about different issues, and 50.9% (464/911) experienced nervousness almost every day in the past 2 weeks.

The health care providers reported the need for telemental health in their respective facility: Due to the shortage of well-trained psychiatrists nearby, we have to take treatment from the divisional level health facilities, which is time-consuming and costly. Ensuring proper mental health service district and upazila-level hospital requires service like tele-mental. [KII-15, health worker, Nokla UHC, age 42 years]

Table 3 summarizes the effect of various factors on accessibility and need-related indicators. The odds of increased perceived accessibility were lower among patients receiving PNC compared to ANC with aOR 0.45 (95% CI 0.27-0.74). Women with lower education and lower income had higher perceived accessibility. Patients visiting DHs had higher odds of perceived accessibility (aOR 1.48, 95% CI 1.1-2.0). Patients visiting DHs had 3 times higher odds (aOR 2.58, 95% CI 1.82-3.68) of experiencing both depression and anxiety symptoms, expressing the need for mental health services through the Wellbeing Center.

Figure 6 presents the change in average scores of PHQ-9 and GAD-7 between the first and second counseling sessions of the antepartum and postpartum women. The average PHQ-9 score decreased from 14.4 (SD 0.47) to 12.9 (SD 0.47), and the average GAD-7 score decreased from 13.3 (SD 0.49) to 12.5 (SD 0.48) between these 2 sessions, indicating the usefulness of Wellbeing Center. These changes were statistically significant with P<.001.

The proportion of people taking follow-up counseling is shown in Multimedia Appendix 6. Only 15.1% (51/338 suggestions of follow-up visits) took follow-up counseling among the patients who were suggested a follow-up session.



Table 2. Background characteristics of the antepartum and postpartum women who received services from Wellbeing Centers (N=911).

Background characteristics	Participants, n (%)
Age (years)	
15-19	229 (25.1)
20-24	332 (36.4)
25-29	218 (23.9)
≥30	132 (14.5)
Type of contact care points at the facility	
ANC ^a	817 (89.7)
PNC ^b	94 (10.3)
Religion	
Muslim	848 (93.1)
Other ^c	63 (6.9)
Profession	
Housewife	856 (94)
Involved in income-generation activities	20 (2.2)
Other ^d	35 (3.8)
Education (years completed)	
No education	12 (1.3)
Primary	159 (17.5)
Secondary	497 (54.6)
Above secondary	243 (26.7)
Household income	
Low	427 (46.9)
Middle	217 (23.8)
High	267 (29.3)
Type of facility location	
Subdistrict	643 (70.6)
District	268 (29.4)

^aANC: antenatal care.

^bPNC: postnatal care.

^cHindus, Buddhists, and Christians.

^dUnemployed and unable to work due to disability.



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Figure 4. Implementation outcomes of Wellbeing Centers according to the World Health Organization guidelines.

	0	20	40	60	80	100	Participants	Benchmark
Feasibility (I think this Wellbeing Center is feasible in this health facility; n=168)	98.0				+		Health care provide	r 80
Feasibility (I think this facility has sufficient trained staff to implement Wellbeing Center activities; n=168)	50.0			-	F		Health care provide	r 70
Accessibility (I think this Wellbeing Center has improved my access to mental health services; n=911)	99.0				+	Ľ,	User women	80
Acceptability (Mental health services from this Wellbeing Center are acceptable to me; n=911)	99.9				+	Ľ,	User women	80
Usefulness (I think the Wellbeing Center is useful; n=911)	99.9				+	Ľ,	User women	80
Need: depression (n=911)	77.3		+				User women	40
Need: anxiety (n=911) + Benchmark	76.7		+				User women	40







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Table 3. Factors associated with accessibility (strongly agree) and need (severe depression and anxiety symptoms) of Wellbeing Center.

		Accessibility		Both depression and anxiety		
		aOR ^a (95% CI)	P value	aOR (95% CI)	P value	
Ag	e (years)	·				
	15-19	Reference	Reference	Reference	Reference	
	20-24	1.09 (0.76-1.57)	.63	1.42 (0.90-2.23)	.13	
	25-29	0.78 (0.52-1.17)	.22	1.01 (0.60-1.71)	.97	
	≥30	1.14 (0.72-1.81)	.57	0.87 (0.47-1.60)	.65	
Ty	pe of contact care point at the facility					
	ANC ^b	Reference	Reference	Reference	Reference	
	PNC ^c	0.45 (0.27-0.74)	.002	0.88 (0.48-1.62)	.68	
Re	ligion					
	Muslim	Reference	Reference	Reference	Reference	
	Other ^d	0.56 (0.31-1.01)	.05	0.38 (0.15-0.99)	.047	
Profession						
	Housewife	Reference	Reference	Reference	Reference	
	Involved in incom- generation activities or other	1.04 (0.57-1.92)	.89	1.06 (0.48-2.32)	.89	
Ed	ucation					
	No education or primary	Reference	Reference	Reference	Reference	
	Secondary	0.40 (0.27-0.58)	.001	1.02 (0.64-1.64)	.93	
	Above secondary	0.44 (0.28-0.69)	.001	0.89 (0.51-1.55)	.67	
Ho	usehold income					
	Low	Reference	Reference	Reference	Reference	
	Middle	0.70 (0.49-0.99)	.047	0.97 (0.62-1.51)	.90	
	High	1.12 (0.81-1.56)	.50	1.07 (0.70-1.62)	.76	
Ty	pe of facility location					
	Subdistrict	Reference	Reference	Reference	Reference	
	District	1.48 (1.10-2.00)	.010	2.58 (1.82-3.68)	.001	

^aaOR: adjusted odds ratio.

^bANC: antenatal care.

^cPNC: postnatal care.

^dHindus, Buddhists, and Christians.



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Figure 6. The usefulness of the counseling in reducing the average PHQ-9 and GAD-7 scores (n=51). GAD-7: Generalized Anxiety Disorder-7; PHQ-9: Patient Health Questionnaire-9.



Qualitative Findings

Perception and Experience Regarding Wellbeing Center Services During the Antepartum and Postpartum Periods

Positive Attitude of the Service Providers

The positive attitude of psychologists and health workers of the Wellbeing Centers strengthened the telemental health services compared to other health services. The health workers of the center cordially received the antepartum and postpartum women who were referred by the physicians. During the counseling session, psychologists listened to their problems and issues attentively and provided video counseling, which gives them better feelings about the service at the Wellbeing Center. A pregnant mother mentioned the following:

I feel scared to share my all problems with a physician! I just responded to what the doctor wanted to know. But in the audio-visual call, a counsellor gives a welcoming tone which influenced me to share my mental health issues clearly. [IDI, female, age 32 years]

Cost and Accessibility

Earlier, antepartum and postpartum women who experienced mental health disorders had to get treatment from the regional medical college hospitals or have to go to specialized hospitals. Because of the Wellbeing Center, people can get mental support on their doorstep. From the Wellbeing Center, anyone can get free-of-cost and hassle-free treatment. Those who seek mental health treatment from private hospitals have to spend considerably more money on paying psychiatrist fees, unethical financial gain of clerks, medication, transportation costs, etc. Nevertheless, patients found videoconference-based counseling at the Wellbeing Centers more convenient than the traditional

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treatment system, as they do not require any treatment costs, and it provides easy treatment access at their doorsteps. A service receiver mentioned the following:

If I come here [Wellbeing Center] it will save my money and I get treatment from a good specialist that won't cost me money. [IDI, female, age 22 years]

Privacy and Confidentiality

While the antepartum and postpartum women received counseling, nobody was present in the room to ensure privacy and confidentiality. Service receivers' privacy is a prime concern at the Wellbeing Centers, as patients receive services in a separate room that ensures privacy during the counseling. A service receiver said the following:

During in-person consultations, I did not freely communicate to the doctor [psychiatrist-private chamber] because of the other patient's presence in the waiting area. But in the Wellbeing Center, I do not have worries about violation of [my] privacy while getting audio-visual counseling in a separate room. [IDI, female, age 24 years]

Name

The name of the mental health service center is Wellbeing Center to overcome the stigma and social taboo associated with psychological support needs. Whenever antepartum and postpartum women and their caregivers come to the corner, they do not hesitate to seek care. This may be due to the perception of a safe and supportive space that encourages open discussion of mental health issues without fear of judgment. The term "well-being" did not demonstrate any stigma. A health worker mentioned the following:

We do not use the term mental health corner, instead we use "Mon-Shastho Kendro" [Wellbeing Center] to avoid the stigma. When doctors refer them to the Wellbeing Centerthey do not feel hesitation. [KII, health workers, age 33 years]

Barriers to Using the Wellbeing Center Services

Stigmas and Taboos

During the pregnancy period, mothers experience numerous negative emotions. Though they can understand that their mental condition is changing, they cannot share their problems due to stigmas and taboos. Even more, they do not disclose their mental health problems to their husbands and family members. Fear of family violence and potential disruption of marriage often prevent pregnant women from disclosing their mental health issues. A pregnant mother mentioned the following:

I do not share my problems with my family members, if I share my mental problems with them then they may make any comments on this that will be very frustrating to me. [IDI, pregnant mother, age 29 years]

Postpartum Illness

During the postnatal period, mothers are unable to receive mental health treatment from the Wellbeing Center for their physical illness and lack of support from the family. Moreover, after childbirth, the physician referred the mothers to the Wellbeing Center based on the mental health examination. However, sudden release from the hospital is a reason for not receiving the services. A health worker mentioned the following:

Within the 42 days [postnatal period], mothers were physically sick to come. Those who are referred by the physician, sometimes get a sudden release from the hospital. Therefore, they do not come for mental health services. [KII, health assistant, age 33 years]

Long Waiting Times

During the follow-up visit, antepartum and postpartum women have to wait in the ANC and PNC corner for taking services. Some patients were in a rush to receive the service, but it was not possible to give them an opportunity, as other patients were also on the waiting list. This may be due to the patient load and the ANC and PNC corners operating on a first-come, first-served basis. A pregnant mother mentioned the following:

I feel unsteady while waiting for [receiving] the mental health service. There are only three seats in the waiting room, and three mothers already waiting there to receive the service. Therefore, I and my husband have to stand up for around thirty to forty minutes which causes the irritation. [IDI, pregnant mother, age 18 years]

Discussion

Principal Findings

Our research demonstrated that telemental health services through the Wellbeing Center are feasible, acceptable, useful, and highly needed among women. It has increased accessibility to mental health services to pregnant or postpartum women with a lower level of income and education. The health care providers

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felt a need for more staff with appropriate training to implement this intervention at the hospitals, who are lacking in Bangladesh. The women visiting the DHs have a higher level of depression and anxiety symptoms, demonstrating a critical need for mental health services. Our follow-up assessment scores on depression and anxiety symptoms after the first counseling sessions demonstrated a decrease in the average scores, which indicted the effectiveness of the Wellbeing Centers. The service beneficiaries recommended the intervention because of the positive attitude of the service providers; the services being free of cost, private, and confidential; and its sensitive naming. However, they also mentioned some barriers to receiving care from Wellbeing Centers, which included social stigma, postpartum illness, and long waiting times at the facility to use the service.

To the best of our knowledge, this is the first implementation research that assessed the WHO implementation outcome variables of a facility-based telemental health intervention, the Wellbeing Centers, for antepartum and postpartum women that is operated by the GoB. We have pioneered in proposing an implementation model for mental health care including a pool of trained psychologists and psychiatrists who provided counseling and medications for mental health issues through videoconferencing in the Wellbeing Centers at the public health facilities in Bangladesh.

Some public hospitals in Bangladesh had initiated telemedicine units as a part of their routine care system. However, telemental health services through Wellbeing Centers differ from general telemedicine in several ways. Telemental health often involves specialized platforms designed to provide psychological assessments, therapy, and psychiatric consultations. In contrast, telemedicine includes a broader range of remote clinical services, including primary care, specialist consultations, and follow-up visits. Telemental health is a specialized subset of telemedicine focusing on mental health. While both telemental health and telemedicine use videoconferencing, phone calls, and other digital communication tools, telemental health platforms are tailored to address the unique needs of mental health care, such as ensuring patient privacy and providing a comfortable environment for discussing sensitive issues. This specialization can lead to better patient engagement and satisfaction in mental health care compared to general telemedicine [47]. This type of service is expected to vary according to the differences in context and health systems. Our research focused on the implementation outcomes of telemental health care. This provides evidence to support the scale-up of telemental health care through Wellbeing Centers.

Adoption and Acceptability

A significant proportion of Bangladeshi mothers have common mental health issues during the antenatal and postnatal period [4,48]. Most mental health care facilities are clustered around urban areas, while rural women do not have access to mental health care in Bangladesh. Since maternal mental distress among these rural mothers may cause adverse maternal and child health outcomes, appropriate interventions can address maternal mental distress among the Bangladeshi maternal population. Evidence supports the effectiveness of digital psychological interventions,

especially in low- and middle-income countries where mental disorders contribute significantly to the global burden of disease [49,50]. Globally, these services offer private, personalized support, connecting disparities in mental health care for those facing challenges accessing traditional services or face-to-face services [49]. Global evidence emphasizes the role of telemental health service as an equivalent and effective method, particularly in delivering mental health services to remote areas with limited resources. A significant number of users in our study provided strong evidence on the adoptability and acceptability of the telemental health services through Wellbeing Centers in Bangladesh. Services through Wellbeing Centers minimized travel, offering cost-effective and accessible psychological and psychiatric services.

Feasibility

The health care providers perceived that the telemental support through the Wellbeing Center is highly feasible. However, they also felt that the facilities lacked appropriately trained staff to maintain these centers. Banbury et al [51] stated that staff require comprehensive training to sustain and expand telehealth use in the facilities. These trainings should focus on knowledge, skills, and competencies in using telehealth as well as the broad factors of policies and understanding technologies to support the service providers [51]. Studies have discussed concerns around a lack of appropriate training to be able to conduct remote mental health care effectively and safely [52]. The government should ensure adequate training and supportive supervision for health providers (such as RMOs, physicians, gynecological consultants, and health workers) on mental health disorder assessments of pregnant and postpartum mothers, psychosocial services, as well as information and communication technology to maintain Wellbeing Center activities.

Accessibility

In the context of Bangladesh, mental health services face challenges due to limited resources and a shortage of professionals, relying heavily on the NIMH in Dhaka [53,54]. The new mental health policy of Bangladesh prioritizes community-based services, with nongovernment organizations contributing scalable models, including telemental health initiatives [55,56]. Access challenges still persist despite some voluntary counseling platforms, due to their lack of visibility [57,58]. These programs are not also integrated into the government system. Despite progress and current provisions for service delivery, issues like low help-seeking, inadequate service delivery, and persistent stigma emphasize the need for telemental health services on a larger scale [59]. Integrating telemental health services with these services is essential for improved mental health care [58]. Wellbeing Centers increased perceived accessibility among antepartum and postpartum women. Perceived accessibility was significantly higher among lower socioeconomic groups and lower educated groups. One of the reasons for this could be the free-of-cost facilities at public hospitals that are near their location.

Need

We looked into the need for well-being by looking at the depressive and anxiety symptoms prevalent among our targeted

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patients. Two-thirds of the women who sought services from the Wellbeing Center had moderate to severe indications of depression and anxiety. In addition, we observed a high level of anhedonia or lack of interest and tiredness among the women in the last 2 weeks. These highly prevalent symptoms indicated the need for Wellbeing Centers for the targeted mothers. El Sayed et al [60] reported that fatigue and anhedonia were prevalent and commonly reported in the post-COVID-19 period. A study by Costa et al [61] also reported that the prevalence of perinatal depression increased during the COVID-19 pandemic, which may be due to changes in the profile of specific depressive symptoms. Pearson et al [62] conducted a study where they reported that women experiencing anhedonic depressive symptoms during pregnancy had significantly larger systolic blood pressure responses toward infant distress than nondepressed pregnant women. Special attention should be given to anhedonia and fatigue-related symptoms of perinatal depression to ensure that they are adequately managed.

Among the other depressive symptoms, our finding that 3.8% (n=35) of patients experienced suicidal ideation is a significant concern, reinforcing the need for enhanced mental health interventions in Bangladesh. Scientific studies discussed the complexity of suicidal ideation, noting that it often goes unreported due to stigma and fear of judgment [63]. Suicidal ideation is influenced by a complex interplay of biological, psychological, and social factors. While some biomarkers have been identified to predict the risk of suicide, the underlying causes of suicide remain largely unclear. More research is needed to understand the root causes of suicidal ideation. Digital tools, such as mobile apps and telehealth services, can effectively monitor and reduce suicidal thoughts by providing real-time support [64]. Additionally, telehealth-supported decision-making has been found to significantly reduce suicidal ideation [65].

Our study also found that the level of worry and nervousness in the past 2 weeks was significantly higher among pregnant and postpartum women. More than half of the women experienced these symptoms of anxiety in the past 2 weeks almost every day. Tarafa et al [66] conducted a study in Ethiopia and assessed the factors associated with pregnancy-related anxiety among pregnant women attending ANC follow-up. Unwanted pregnancy, high perceived stress, young age, depression, low income, and poor social support were significantly associated with pregnancy-related anxiety. The overall prevalence of pregnancy-related anxiety in this study was slightly lower 32.7% [66]. It is worth noting that this study assessed only pregnancy-related anxiety while we included both pregnant and postpartum mothers. Appropriate intervention and focus are needed to address these worries and anxieties of pregnant women and postpartum mothers in Bangladesh through Wellbeing Center activities.

We report higher depression and anxiety and perceived accessibility among the women who took Wellbeing Center services at the district-level facilities compared to the subdistrict-level facilities. The reason can be regarded as an indirect effect of urbanization. A recent meta-analysis conducted by Cadman et al [67] assessed the influence of the urban environment in pregnancy and postpartum depression. Exposure

to air pollution and road traffic congestion may increase maternal depression. The urban family structure, with a lack of family support, may also induce higher levels of depressive and anxiety symptoms in Bangladesh. A study conducted on adolescents researched screen-related sedentary behavior, finding that the use of social media caused 2 times higher depression among urban adolescents [68]. A large proportion of our users of Wellbeing Centers were adolescents. Therefore, urgent initiatives should be taken to control the spread of depression and anxiety among the urban population, especially for mothers. In summary, at the district-level facilities, the need for mental health services was higher among the antepartum and postpartum women, which necessitated a strengthened focus on providing equitable services through the Wellbeing Centers in Bangladesh.

Usefulness

While we found the Wellbeing Centers to be feasible and acceptable, our study also indicated small improvements during the follow-up counseling sessions for the targeted patients. A review by Hilty et al [34] reported that telemental health is effective for diagnosis and assessment across many populations, including adults, children, older people, and people of different ethnicities, and for disorders in home and facility settings. This review urged that more research should be conducted on service models, specific disorders, issues regarding culture and language, and cost. Ensuring follow-up visits after the first counseling session is important for the sustained impact of telemental health services. However, we have not observed many women taking follow-up services in our Wellbeing Centers. Special initiatives such as follow-up phone calls or reminders should be ensured to increase follow-up sessions when needed and recommended.

Experience, Perception, and Expectation

Our research explored the experiences and perceptions regarding the Wellbeing Center activities, which revealed several strengths of and barriers to using these services. The users acknowledged the positive attitude and patience of the counselors during the service sessions. In Bangladesh, in-person psychiatric services are expensive and may not be affordable for underprivileged women. The Wellbeing Center services were completely free of cost, which attracted the targeted patients. Furthermore, these Wellbeing Centers ensured the privacy and confidentiality of the patients while providing psychological or psychiatric support. Many women were comfortable while expressing their problems and mental health issues, as they were reassured by this confidentiality. Finally, the women praised the naming of the service, which also addressed the stigma around mental health. The women also mentioned that existing stigmas and taboos on seeking mental health services prevented them from seeking care. However, almost all users of the Wellbeing Centers agreed that these services were acceptable to them. Further research is necessary to understand the actual state of stigma in the community regarding mental health care seeking.

Our quantitative data suggested that more women during pregnancy used Wellbeing Center services compared to postpartum women. Our qualitative finding echoed this finding as women reported postpartum illnesses were a barrier for them to seeking mental health care. Finally, few women mentioned that the long waiting time repelled them to receive services from the Wellbeing Centers. With the high demand and popularity, the system experienced a high patient load and struggled to satisfy all patients with timely services.

Comparison With Prior Studies

Recent studies on telemental health interventions have shown promising results, particularly in the context of the COVID-19 pandemic, which accelerated the adoption of remote mental health care. Research indicates that telemental health, including videoconferencing and phone-based therapy, is generally as effective as in-person care for a variety of mental health conditions [47]. Our research found similar results in terms of feasibility, utility, and effectiveness. A recent systematic review on implementation strategies for telemental health published in 2023 by Appleton et al [52] highlighted that telemental health can improve access to care, especially for individuals in remote or resource-limited areas. Our study echoed them in terms of the role of telemental health support in increasing the accessibility of mental health care in Bangladesh. While most studies on telemental health mentioned positive outcomes, one of the meta-analyses on mobile phone-based telemental health interventions by Goldberg et al [69] suggested that the effectiveness of these interventions can vary based on the specific mental health condition and the technology used. Our study could not compare the efficacy of the Wellbeing Centers compared to other phone-based or community-based methods. We recommend further research and trials to understand the actual benefits of using Wellbeing Centers compared to other types of services.

Strengths

Our study has several strengths, based on which we have identified the major findings discussed earlier. This study was conducted in 6 facilities, which provided us a reasonably large sample of pregnant and postpartum women attending antenatal and postpartum care. It involved a rigorous analysis using WHO-guided implementation variable, which ensured standardization with other global implementation research on telemental health services. Our intervention was provided through the government system; therefore, these findings will be valuable for the GoB for scaling up the intervention to a higher number of facilities. This paper focused on the pregnant and postpartum women. However, the services are also provided to general patients. Therefore, findings might provide additional evidence while assessing the implementation outcomes for general patients.

Limitations

We also acknowledge some limitations of our study. First, this study was conceptualized based on the WHO framework and implementation outcome variables. The WHO's implementation outcome variables may have limited the opportunities of capturing other potential outcome variables that may be important for assessing implementation aspects of the Wellbeing Centers. Second, we acknowledge the fact that we did not randomly select our demonstration sites for Wellbeing Centers. Therefore, the result may not be generalizable to the whole
country. In Bangladesh, there are regional variations that have an impact on access to health care as well as service quality. Our selected sites reasonably capture the variations of the service provision and quality. Third, we also acknowledge that we have selected the DHs based on their functionality. The inclusion of low-performing districts could make our results more generalizable. However, this was not possible because of implementation cost challenges. Fourth, in this analysis, we could not assess the rate of adoption of the Wellbeing Center services, as we could not capture the true denominator of how many women needed mental health support among those seeking ANC or PNC from the facilities. Finally, this analysis only assessed symptoms of depression and anxiety as mental health issue. Other disorders could also have been included to strengthen this study.

Conclusions

This implementation research study demonstrated the feasibility, acceptability, and usefulness of introducing the telemental health service Wellbeing Centers for antepartum and postpartum women at Bangladeshi facilities. We are confident in our conclusions, as we saw the services increased the perceived accessibility of mental health services with minimal influence from other factors. Appropriate staff training is required to maintain these centers. We recommend that psychologists and psychiatrists have patience and a positive attitude while maintaining the privacy of patients during the scale-up of the model. We also recommend future studies on cost-effectiveness and postimplementation follow-up to evaluate the sustainability, effectiveness, and impact over a longer time period. The experiences and learnings from this implementation research can support generating evidence-based decisions related to the introduction and scaling-up of the Wellbeing Centers in Bangladesh and other low- and middle-income countries.

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Authors' Contributions

ATH developed the manuscript as the first author with support from AER. AER and MSS guided ATH in designing the study and developing the manuscript as joint senior authors. SEA and MRA reviewed the results and guided the team in interpreting the results. MHR, RMM, and EA contributed to data management and statistical analyses. MAH conducted the qualitative interviews, and TA, NGU, and PC supported in qualitative data management. SMHI supervised the implementation and field activities. HUA, MKM, JMJ, FS, SAS, FA, and MJB provided guidance in validating the psychological and psychiatric information of the study. MAK and SMMR provided support in developing the intervention strategy. SA, SJ, and AA reviewed the first draft of the paper. All authors contributed to the interpretation of the results and read and approved the final version of the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Quantitative data collection tools to assess depression, anxiety, adoption, accessibility, acceptability, and usefulness for antenatal and postnatal women.

[DOCX File, 38 KB - pediatrics_v8i1e65912_app1.docx]

Multimedia Appendix 2

Data collection tool for feasibility assessment among the health facility managers. [DOCX File, 24 KB - pediatrics v8i1e65912 app2.docx]

Multimedia Appendix 3

Interview guideline for in-depth interviews with antenatal and postnatal women to explore their experiences, perceptions, and expectations regarding the telemental health counseling. [DOCX File, 21 KB - pediatrics_v8i1e65912_app3.docx]

Multimedia Appendix 4

Interview guideline for key informant interviews with the counselors and health care providers to explore their experiences, perceptions, and expectations regarding the telemental health counseling. [DOCX File , 22 KB - pediatrics v8i1e65912 app4.docx]

Multimedia Appendix 5

Flowchart of the selected antepartum and postpartum women. [DOCX File, 50 KB - pediatrics v8i1e65912 app5.docx]

Multimedia Appendix 6 Proportion of users who received follow-up counseling. [DOCX File, 56 KB - pediatrics v8i1e65912 app6.docx]

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Abbreviations

ANC: antenatal care aOR: adjusted odds ratio DH: district hospital GAD-7: Generalized Anxiety Disorder GoB: government of Bangladesh icddr,b: International Centre for Diarrhoeal Disease Research, Bangladesh IDI: in-depth interview KII: key informant interview NCDC: Non-Communicable Disease Control NIMH: National Institute of Mental Health PHQ-9: Patient Health Questionnaire-9 PNC: postnatal care RMO: resident medical officer UHC: upazila health complex WHO: World Health Organization

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Centers in Selected Health Facilities in Bangladesh: Implementation Research

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Pediatric Hearts and Minds: Reimagining Health Education Through Play and Narrative

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KEYWORDS

congenital heart disease; children health literacy; health education; health education interventions; patient-centered care; design; pediatric; PRISMA

As a student advocate actively involved in heart health promotion among youth, I was interested in the study entitled "Exploring Health Educational Interventions for Children With Congenital Heart Disease: Scoping Review" [1]. The authors identified a gap in age-appropriate educational tools for younger children in the interventions, highlighting the importance of using playful, developmentally tailored strategies to engage them in learning about their cardiac condition.

This insight dovetails precisely with the broader realm of pediatric health literacy, wherein the convergence of cognitive development and medical comprehension calls to attention unique barriers. Children with congenital heart disease (CHD) face difficulties in understanding abstract medical concepts and their condition [2]. Considering this, narrative medicine holds great potential in increasing the relatability, digestibility, and applicability of knowledge by reframing biomedical concepts into metaphorical storytelling. Thus, children with CHD may be able to internalize their medical journey in ways that align with their developmental stage and personal experiences, gaining a sense of agency and coherence.

Similarly, the role of ludic and entertaining pedagogical tools emerges as a pivotal mediator of developmental trajectories across cognitive, social, and emotional domains. Health care providers, especially pediatricians and family physicians, must actively ensure that play is healthy and safe [3]. Whether it be a story-driven game or a cardiac-themed toy, interactive tools may significantly advance educational interventions through tangible learning modalities that convert abstract principles into concrete experiences. As such, the cardiac health journey becomes one of engagement, where the child becomes a conscious, active participant in their medical education rather than a mere recipient of information. The teddy bear hospital concept in particular exemplifies this symbiotic relationship between play and education, demonstrating efficacy in reducing children's health care–related anxiety, improving their health care knowledge, and enhancing their well-being through playful role-playing in a health care setting [4]. By softening the edges of medical procedures, this model dismantles the intimidating walls of the clinical environment, transforming it into a less foreign and more approachable space for younger children who are not as impacted by traditional educational interventions.

Yet another crucial dimension of children's play surfaces through physical activity. Children with CHD and their parents recognize the importance of physical activity, but uncertainty in their health environment contributes to inactivity despite minimal professional restrictions [5]. An area ripe for intervention, physical activity guidelines could incorporate real-time feedback mechanisms that build confidence and ensure safety to promote physical exercise as an act of healing and empowerment, rather than a source of anxiety.

In tailoring educational messaging by age, we can raise the effectiveness of CHD interventions, recognizing and respecting that children are not simply "mini teenagers" and much less "mini adults." Such an approach must, therefore, incorporate elements of embodied cognition, experiential learning, and psychological support to create a comprehensive educational framework that addresses the specific cognitive and emotional needs of children with CHD. Only in this way can we create immersive and engaging learning environments that make complex cardiac concepts accessible to the young minds often underrepresented while fostering psychological resilience and physical confidence.



Authors' Contributions

AY wrote, edited, revised, and reviewed this manuscript.

Conflicts of Interest

None declared.

Editorial Notice

The corresponding author of "Exploring Health Educational Interventions for Children With Congenital Heart Disease: Scoping Review" declined to respond to this letter.

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Abbreviations

CHD: congenital heart disease

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Preventing Urgent Pediatric Readmissions: The Need for and Promise of Real-Time Monitoring

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Abstract

Urgent pediatric hospital readmissions are common, costly, and often preventable. Existing prediction models, based solely on discharge data, fail to accurately identify pediatric patients at-risk or urgent readmission. Remote patient monitoring (RPM) leverages wearable technology to provide real-time health data, enabling care teams to detect and respond to early signs of clinical deterioration. Emerging evidence suggests RPM may be a promising strategy to improve pediatric postdischarge outcomes and reduce urgent hospital readmissions.

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KEYWORDS

medical information; remote patient monitoring; RPM; telehealth; pediatric readmissions; patient care management; chronic condition; readmission; disease management; intervention

Introduction

Untreated clinical deterioration in pediatric patients with chronic conditions can lead to urgent hospital readmissions, impacting the health of children, imposing a significant burden on health care systems, and delaying the care of others [1,2]. The rates of pediatric urgent readmissions, unplanned hospitalizations occurring within 30 days of discharge that require immediate medical intervention, vary from 3% to 19% across pediatric hospitals and up to 40% of them may be preventable [2]. The data available at discharge have not proved useful for predicting readmissions, especially for postdischarge causes such as medication-related failures [3]. Remote patient monitoring (RPM) may be a viable approach to detecting the early stages of clinical deterioration that ultimately lead to urgent readmission. A variety of wearable monitors enable the timely identification of deteriorating disease management and interventions to remediate it [4-6]. Used appropriately, wearable technology has the potential to help care teams reduce urgent readmissions. We argue that care models that leverage RPM have the most potential to allow care teams to reduce urgent hospital readmission for patient with chronic disease by

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identifying complications that may otherwise escalate into serious health concerns.

Challenges in Predicting Readmissions

Several studies have shown that predicting urgent pediatric hospital readmissions at the time of discharge is challenging, particularly for general- and for complex-subspecialty patient hospitalizations [2]. Initial efforts in this domain have concentrated on the identification of risk factors using odds ratios from data available at the time of discharge [3]. However, few of these studies have been externally validated or demonstrated to reduce readmissions in practice.

A systematic review of predictive models for 30-day unplanned pediatric readmissions found poor-to-moderate performance across most models [2]. Of the 37 models reviewed, all models except one had an area under the curve (AUC), a flawed but broadly recognized benchmark, below 0.8. The review assessed the quality of these studies to be moderate to low across all domains. Most studies lacked adequate representation of the broader pediatric population, often examining patients from only a single hospital. Many studies lacked sufficient consideration of potential confounders in their analyses.

Tools for predicting unplanned readmissions, such as the High Acuity Readmission Risk Pediatric Screen Tool, LACE (Length of stay, Acuity of admission, Comorbidity, Emergency department use), LACE-SDH (which adds Social Determinants of Health), LACE+, Epic's readmission risk model, and SQLAPE demonstrate only moderate performance, with AUCs ranging from 0.61 to 0.80 [7]. These modest performance metrics likely overstate the usefulness of such models for targeting limited resources to the relatively few patients with high risk of readmission [8]. Existing models likely fail to predict pediatric readmissions effectively because they rely on static data captured at the time of discharge, which does not reflect the evolving nature of recovery. Moreover, many are based on simple scoring systems or regression models that may inadequately account for the complexity of pediatric health trajectories.

It is not surprising that data available at the time of discharge are not sufficient to predict pediatric readmissions. Posthospitalization care is complex and lacks robust quality standards. Up to one-third of pediatric discharges may be associated with discharge-related care failures. Medication adherence serves as a prime example. A study of 157 caregivers revealed that 70% encountered medication-related failures [9]. These findings highlight the pressing need for improved postdischarge monitoring and/or interventions.

RPM

RPM offers promise for preventing readmissions. It is a technology-enabled approach to precision population health that facilitates the continuous capture and transmission of patient health metrics to medical practitioners when patients are not in the clinic. Portable devices have been validated for monitoring activity levels, sleep quality, heart rate, oxygen saturation, blood pressure, and glucose levels. Data from portable devices are often used to help manage chronic disease and detect deteriorating health in pediatric and adult populations [4-6,10,11]. Remote data acquisition and algorithm-supported analyses enable clinicians to detect health deterioration and adverse symptoms or health patterns when patients are not in the clinic. This enables timely investigation by the care team and, when appropriate, interventions to prevent the escalation of minor health concerns into serious complications.

Evidence for the effectiveness of RPM is already emerging in specific pediatric populations. An RPM intervention using continuous glucose monitors (CGMs) in pediatric patients with type 1 diabetes led to significant improvements in glucose control [6]. A small prospective study on pediatric patients receiving automated peritoneal dialysis resulted in a 45% reduction in hospitalization rates, significant increase in ultrafiltration, and significant reduction in systolic blood pressure [12]. RPM for children with single ventricle heart disease is now supported by the American Heart Association, after RPM contributed to mortality reductions of over 40% over an 8-year period [13]. RPM can also lead to more efficient workflows for health care providers, potentially reducing the time spent on routine checkups. For example, the conjunction

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of CGM with an automated tool was associated with improved outcomes and reduced provider screen time [6,14].

Health care systems adopting RPM will need to consider how to integrate workflows into existing clinical systems [15]. Effective implementation may include developing standardized protocols for alert management, integrating multiple monitoring devices into unified systems, and clearly defining care team responsibilities for responding to patient data. Implementing interoperability features that generate reports for inclusion into patients' medical records and import monitoring statistics into electronic medical record flowsheets can streamline clinical workflows [15]. A successful example comes from a CGM-based intervention that used a dashboard to prioritize patients for review, which was later adapted into a nationally available platform for broader adoption [15]. When an RPM system demonstrates efficacy within a single clinic, the standardized approach can facilitate expansion across multiple health care settings, creating opportunities for wider implementation and continuous improvement in patient care.

While RPM offers significant potential, barriers to access may affect its equitable implementation. Digital disparities, including limited internet access and device availability, could restrict RPM use [6,11]. Approximately 20% of US households lack access to a smartphone. In addition, variation in caregiver technological proficiency may affect adherence to monitoring protocols, and limited digital literacy can influence program engagement [11]. Addressing these challenges requires consideration of technology accessibility, device subsidization, user-friendly interfaces, and culturally appropriate education [6,11]. RPM programs "should be designed to accommodate populations with low health literacy and numeracy, with language preferences in mind" [11].

Proof-of-concept studies are necessary to determine how the implementation of RPM can reduce pediatric readmissions in the real clinical setting. Initial studies should focus on the assessment of technical feasibility within existing health care systems along with thoughtful mapping of how RPM would integrate into the clinical workflow of the care of the chronic pediatric patient. As these studies scale, outcome measures should capture not only clinical outcomes, but also include patient-reported outcomes and cost-effectiveness [16]. Pilot studies can then inform the design of larger randomized controlled trials comparing standard discharge protocols to those enhanced with RPM and allow scaling of its implementation [17].

Conclusions

Urgent pediatric hospital readmissions are common and preventable. Existing readmission prediction models are not sufficient to identify the patients at highest risk, especially those associated with care failures. RPM is a promising tool that offers real-time data transmission, streamlined operational procedures, and scalability. As RPM technology becomes more accessible, its potential to transform pediatric postdischarge care and reduce urgent readmissions warrants further investigation. Advancing this work may enable more proactive and effective strategies to improve health outcomes and reduce urgent readmissions.

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Conflicts of Interest

None declared.

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Abbreviations

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AUC: area under the curve CGM: continuous glucose monitor

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LACE: Length of stay, Acuity of admission, Comorbidity, Emergency department use LACE-SDH: Length of stay, Acuity of admission, Comorbidity, Emergency department use–Social Determinants of Health RPM: remote patient monitoring

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A Holistic Digital Health Framework to Support Health Prevention Strategies in the First 1000 Days

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Abstract

The first 1000 days of a child's life, spanning from the time of conception until 2 years of age, are a key period of laying down the foundations of optimum health, growth, and development across the lifespan. Although the role of health prevention programs targeting families and children in the first 1000 days of life is well recognized, investments in this key period are scarce, and the provision of adequate health care services is insufficient. The aim of this viewpoint is to provide a holistic digital health framework cocreated with policy makers, health care professionals, and families to support more effective efforts and health care programs dedicated to the first 1000 days of life as the first line of prevention. The framework provides recommendations for leveraging on behavioral intervention technology and digital therapeutics solutions augmented by artificial intelligence to support the effective deployment of health prevention programs to families. The framework also encourages the adoption of a citizen science approach to co-design and evolve the digital health interventions with all relevant stakeholders in a real-world research perspective.

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KEYWORDS

digital health; digital therapeutics; behavioral intervention technology; prevention; citizen science; first 1000 days

Introduction

The first 1000 days is a continuum that begins with pregnancy and ends at the child's second birthday. It is a unique period laying down the foundations of optimum health, growth, and development across the lifespan [1], but it can also represent a period of potential vulnerability where the way mothers and children are cared for has a profound influence on a child's ability to grow, learn, and thrive [2]. Although the role of the first 1000 days of life is well recognized [2,3], investments in this key period are scarce, and the provision of adequate health care services and interventions is insufficient [1].

In this viewpoint, we address current challenges and opportunities in the development of effective health care interventions for the first 1000 days, by leveraging on a holistic digital health (DH) framework that can help to optimize efforts in the cocreation of these interventions with the support of policy makers, health care professionals, and families. The framework leverages on state-of-the-art approaches and opportunities in the design of behavioral intervention technology (BIT) and artificial intelligence (AI)–augmented digital therapeutics (DTx) for prevention and care, such as the Integrate, Design, Assess, and Share (IDEAS) framework [4] and the DTx Real-World Evidence (RWE) framework [5]. It complements these approaches by stressing the importance of facing the design and validation challenges within a longitudinal perspective based

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on citizen science and real-world evidence, to cocreate and evolve the DH interventions in a more pragmatic and sustainable way.

Health Prevention Strategies and Challenges in the First 1000 Days

The first 1000 days are characterized by 3 main periods of intervention, preconception, pregnancy, and infancy, which are key for ensuring children's healthy growth [1,3]. Health prevention programs and strategies during the preconception period address biomedical, behavioral, and social risks factors that may affect a pregnant woman's health, by providing nutritional and physiological support; identification and prevention of risks, such as toxic exposures [6,7]; and support in the adoption of changes in lifestyle [3]. Health prevention programs and strategies should also be maintained in the interconception period, going from childbirth until the birth of a subsequent child [8]. During pregnancy, the main areas of prevention typically regard nutrition, stress, and exposure to environmental contaminants [3,9]. The Italian Ministry of Health identifies 11 thematic areas that focus on prevention in the first 1000 days, including nutrition, lifestyle, parental literacy and skills, and mental health [10].

In different countries, public health care programs and interventions have been developed to support families in the

first 2 years after birth [11-14], promoting health literacy and behavioral change of parents in key areas such as nutrition, lifestyles, and mental health. Notwithstanding the large amount of data and guidelines supporting the importance of establishing efficient health care services in the first 1000 days, these health prevention strategies have not been efficiently converted into comprehensive and integrated programs enabling adequate support to parents and infants during this period [1,15,16].

In this viewpoint, we advocate that this gap is also due to a lack of deployment of DH solutions that support evidence-based educational and behavioral interventions for families and are designed for being acceptable, inclusive, engaging, equitable, scalable, and sustainable over the lifespan. Recent reviews of health professional-delivered interventions during the first 1000 days have shown that so far, most interventions were delivered in individual or group face-to-face sessions and that optimal intervention, in terms of timing, content, dose, mode of delivery, theory, and active ingredient, have yet to be established [15].

In our vision, DH technologies can play a key role in supporting the deployment of health prevention strategies and programs in the first 1000 days (as the first line of prevention) as well as over the individuals' lifespan. The kind of automation, engagement, and decisions supported by DH empowered by AI are commonly reviewed by domain experts before they can be implemented in a treatment plan, a process called augmented intelligence or intelligence amplification [17], wherein AI technology informs and augments, rather than replaces, health care professionals' experience and cognition [18].

As depicted in Figure 1, prevention programs addressing key areas of intervention, such as nutrition, lifestyle, mental health and well-being, health literacy, and education, may be more effectively translated into behavioral intervention solutions. These interventions should be informed by evidence-based theoretical approaches and a diversity of potential technologies to ensure a scalable, sustainable, accessible, and cost-effective delivery of prevention strategies. To address the challenges of effectively designing such solutions we call for a holistic DH framework helping to combine behavioral, technical, and methodological components in the intervention design process to ensure a translation of health strategies into better prevention and health outcomes for the target populations.

Figure 1. Digital health solutions delivering prevention programs in the first 1000 days and over the lifespan. AI: artificial intelligence.



A Holistic DH Framework for Cocreation With Stakeholders

Opportunities and Challenges of DH Deployment

Recent advances in the development of DH solutions provide unprecedented opportunities for deploying health prevention strategies and programs with the support of BITs or DTx. BITs typically include sensor-trackers (eg, heart rate and step count), AI-augmented chatbots (automated conversational agents), and momentary ecological assessments (which can repeatedly assess individual's behaviors and experience them in real time) [19-21].

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DTx are defined as tools to deliver evidence-based health interventions (using, for example, cognitive behavioral theory as an active ingredient for treatment) through different types of potential technological solutions as excipients (eg, mobile health apps, web apps, chatbots, or virtual reality [VR] environments) [22-24].

Both BITs and DTx are DH solutions that can improve health outcomes, reduce burdens on health care professionals, and increase access to and usability of interventions [25,26]. Common goals of DH include improving lifestyle, by facilitating behavior change in diet, physical activity, or sleep, or improving mental health, such as care for depression, anxiety, or symptoms

of stress. DH solutions are often complex interventions [27], as they can include multiple components, such as goal-setting or problem-solving elements and AI algorithms that adapt provision of support to each person's changing needs. The goal of including these components in DH solutions is that they can simultaneously provide safe, effective, accessible, sustainable, scalable, and equitable support for individual and population health [28]. However, accomplishing an effective integration of these components in DH solutions is very difficult, and recent efforts have been made to provide guidance in the design, development, and assessment of these solutions by leveraging on the evidence offered by real-world data produced over usage of these digital tools, to better understand the trajectories of intervention outcomes over time [5].

The Framework Development

The holistic DH framework (Figure 2) is aimed at supporting the future deployment of DH solutions for prevention in the first 1000 days.

The authors of this paper first conducted a review of state-of-the-art frameworks relevant to inform the design and validation of these solutions. The review identified strengths and limitations of 4 main frameworks commonly deployed in the design of digital interventions: (1) the IDEAS framework, aimed at supporting the development of digital interventions for health behavior change and based on the IDEAS phases [4]; (2) the ORBIT (Obesity-Related Behavioral Intervention Trials) model [29], aimed at guiding the design of evidence-based

behavioral treatments to prevent and treat chronic diseases, based on the 4 phases of design, preliminary testing, efficacy, and effectiveness research; (3) the MOST (Multiphase Optimization Strategy) model [30,31], aimed at optimizing the development of behavioral, biobehavioral, and biomedical interventions; and (4) the DTx RWE framework [5], inspired by ORBIT and based on the 4 phases model of development (design, develop, test, and monitor). The review also included the citizen science approach [32] as a relevant method informing the cocreation of DH solutions with the participation of all stakeholders. Citizen science has been defined as the general public engagement in scientific research activities, when citizens actively contribute to science either with their intellectual effort or surrounding knowledge or their tools and resources [33].

The holistic DH framework was then developed in a 2-way process. First, 1 author (SG) selected the combination of components from the DTx RWE framework and citizen science approach most relevant to provide a comprehensive overview of the research steps to be taken to design and deploy digital interventions for health prevention programs. In a second step, a draft version of the framework was discussed at length in a meeting among the 3 authors (SG, OMI, and SF) and revised based on the feedback provided.

We present the key components of the holistic framework in a case study providing guidance and recommendations for ensuring a more effective deployment of health prevention programs in the first 1000 days by, at the same time, leveraging on the potential of DH solutions.



Figure 2. Holistic DH framework to cocreate with stakeholders. AI: artificial intelligence; DH: digital health; mHealth: mobile health; MVP: minimum viable product; SMART: Specific, Measurable, Actionable, Realistic, Timely; VRE: virtual reality environment.



Application of the Holistic DH Framework

To illustrate the potential of the holistic DH framework in guiding the cocreation of effective prevention programs in the first 1000 days, we present examples of ongoing activities started by our research team in tackling the issues of digitizing prevention programs currently available to citizens in the Trentino region (Italy) for the pregnancy and infancy periods (birth path), working together with health professionals (gynecologists, obstetricians, and pediatricians) at the local health care system, with policy makers at the local Department of Health and Innovation, and with the target user populations (families). The main intervention areas addressed so far regard providing parental literacy to women and families during the first 1000 days (Figure 3), and providing pregnant women with healthy nutrition and psychoeducational DH programs for stress prevention from the 4th month of gestation [34-37]. The overall goal of introducing digital tools to support current prevention programs was to facilitate the adoption of a holistic strategy to target barriers in the delivery of these programs, such as reaching women living in rural areas having difficulties in accessing health care services or belonging to vulnerable populations, but also to improve ongoing prevention programs' development by incorporating holism, precision prevention, timeliness, and cost-effectiveness [19,38].

The design phase for these DH solutions started from a series of participatory sessions with all stakeholder groups (health professionals, policy makers, and families) to achieve an in-depth knowledge of the prevention needs in the target areas and to specify the requirements and prototyping of the DH tools by providing equitable consideration of the different stakeholders' perspectives, as well as building empathy and acknowledgment of any power differential [32].

From a technological point of view, it was decided to realize a secure and privacy-preserving DH platform providing virtual coaching functionalities by means of AI-augmented digital assistants available on mobile app (or coaching avatars in VR) each specialized for delivering DH intervention in a target prevention area.

Chatbot technology, using AI-augmented tools including machine learning and natural language processing, has been introduced into the health sector to address current health care challenges, such as shortage of health care providers and lack of health care access, showing several positive effects in supporting tailored intervention, which is better able to address users' needs over a digital treatment [39].

At the current stage of DH solutions development, a chatbot-based mobile app supporting women and families during the first 1000 days, named TreC-Mamma (Digital Health Research and Digital Health Innovation Lab, Fondazione Bruno Kessler), has already been released, and it is in use by more than 1000 users in the region. The aim of the TreC-Mamma solution is to provide an initial platform for collecting real-world evidence on the impact of DH solutions deployment during the first 1000 days, thus informing the development and refinement

of more advanced AI-augmented digital assistants for the different intervention areas, by relying on a larger involvement and participation of families in the cocreation process. Parallel research activities are ongoing for assessing the developed proof-of-concept DH solution minimum viable products (MVPs) targeting healthy lifestyles and stress prevention during pregnancy. Specifically, virtual coaching on healthy nutrition and physical activity is provided to pregnant women by using microlearning and motivational modules validated by domain experts. For stress prevention, a chatbot-based solution deploying a digitally adapted version of the Self-Help+ protocol developed by WHO (World Health Organization) [40] has been implemented and preliminarily validated with mental health experts.

Small-scale studies are currently running to assess the MVPs' usability, acceptance, scalability, etc for further refinement and optimization based on the attainment of benchmark criteria such as the SMART (Specific, Measurable, Actionable, Realistic, Timely) goals [41]. These studies, typically involving small samples of pregnant women and their families, are also contributing to reinforce their collaboration and interest in the research project goals in the long-term, aiming to minimize the effort requested from citizens if they participate in the cocreation process.

Once the development and optimization phase of the digital assistants is completed, these DH solutions will be integrated into the TreC-Mamma platform and will be available for use by families to undergo more large-scale testing in the form of feasibility pilot trials or effectiveness trials. The ultimate goal of this testing phase is to compare the effects of the DH interventions with standard of care in the local health care system, with other relevant comparators, or by means of randomized controlled trials. In preparation of this testing phase, we are already devising an effective strategy to build trust in the project aim and solutions among families that are using the TreC-Mamma platform, facilitating the collection of their informed consent through the platform (asking them to sign a so-called "agreement with the citizen"), and clearly explaining the type of data and intended use of their data for a dynamic improvement of the platform in a citizen science perspective.

In a more long-term view, the TreC-Mamma platform will allow us to monitor the effects of our released DH interventions to assess whether their positive effects are maintained over real-world usage. In this monitoring phase, additional requirements and needs may arise from families and other stakeholders, leading to improvements and further adaptations of our solutions to fulfill evolving needs to address new areas of prevention or specific needs of target populations. As a positive side effect of deploying our DH solutions for motivating families to practice healthy behaviors in the first 1000 days, we foresee the potential achievement of health improvements in other prevention areas (eg, chronic disease prevention, such as gestational diabetes, type II diabetes, and depression) contributing to the realization of more comprehensive prevention goals and strategies.

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Figure 3. Holistic DH framework applied to *first 1000 days* interventions. AI: artificial intelligence; DH: digital health; mHealth: mobile health; MVP: minimum viable product



Conclusions and Future Work

The holistic framework presented aims to provide guidance in the design and deployment of DH solutions supporting prevention strategies in the first 1000 days. It can be used to realize DH interventions in a more effective and participatory approach, leveraging on the contribution of the different stakeholders. It can help researchers in addressing the complex goal of realizing AI-augmented DH solutions by optimizing the resources available in the design process. This can be achieved by deploying a sociotechnical platform able to facilitate the engagement of citizens in the different stages of the intervention validation, as well as the effective use of real-world data for supporting the evolution and adaptation of the intervention to the target user populations.

Among the strengths of the framework presented is that it sheds light on unprecedented opportunities for deploying DH technologies in the attempt to realize more scalable, sustainable, and cost-effective solutions for prevention. It is also based on a concrete example of ongoing applied research for prevention in the first 1000 days that is supporting the feasibility of the approach proposed. We also believe that the framework illustrated can be of help in designing DH solutions for different application fields targeting health prevention and care with other target populations. By combining real-world evidence with citizen science research, it can help to overcome some limitations of previous DH frameworks like IDEAS by, for example, better supporting multidisciplinary teams' work beyond the initial intervention design and refinement, providing evidence for the adoption of the most effective behavioral strategies as derived from large-scale deployment of the digital solutions, and showcasing the sustainability of the digital solutions deployment, which may facilitate their more structural adoption and support by policy makers and users in the target communities.

However, there are also some limitations involved in the framework adoption and in its generalization to different contexts. Most of the real-world experience reported in the case study presented regards DH solutions design and development, while key outcomes derived from the test and monitor phases are still lacking. Therefore, more validation data on the framework application in real-world settings are needed, and this objective will be part of our future work. In addition, the AI-augmented features recommended to tailor the coaching of the digital assistants to the user needs require considerable design and development efforts, which may consume more tangible and intangible resources [42]. Key ethical considerations should also be considered when applying AI algorithms and techniques in DH solutions development, including bias minimization, transparency, and users' privacy and safety protection [43,44].

Notwithstanding these limitations, we think that grounding DH design efforts in a real-world evidence practice informed by a citizen science approach may contribute to establishing more productive dialogues among the stakeholders involved, as well as to facilitating faster innovation outcomes in the implementation of prevention programs.

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Disclaimer

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence BIT: behavioral intervention technology DH: digital health DTx: digital therapeutics IDEAS: Integrate, Design, Assess, and Share MOST: Multiphase Optimization Strategy MVP: minimum viable product ORBIT: Obesity-Related Behavioral Intervention Trials RWE: Real-World Evidence SMART: Specific, Measurable, Actionable, Realistic, Timely VR: virtual reality WHO: World Health Organization

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Likelihood of Leveraging Augmented Reality Technology to Promote HIV Prevention and Treatment Among Adolescent Girls and Young Women in Cameroon: Cross-Sectional Survey

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Abstract

Introduction: Adolescent girls and young women in sub-Saharan Africa (SSA) represent 4 out of every 5 newly diagnosed HIV cases among adolescent girls and young women globally. Leveraging augmented reality (AR) technology for HIV prevention and treatment holds significant potential among young people. However, there is a knowledge gap regarding the acceptance of AR by adolescent girls and young women in SSA.

Objective: This study aimed to assess the likelihood of adolescent girls and young women in Cameroon using AR for HIV testing, prevention, and treatment. The study findings will lay the groundwork for developing AR-based interventions to prevent and treat HIV in Cameroon and beyond.

Methods: This was a cross-sectional survey conducted in Yaounde, Cameroon, in which 637 adolescent girls and young women were recruited using a combination of multistage cluster and snowball sampling techniques. We used an electronic survey to collect data on participants' knowledge, prior use of AR technology, and likelihood of using AR technology for HIV prevention and treatment, and associated factors. Multivariate ordinal regressions were used to analyze the factors associated with the likelihood of adolescent girls and young women using AR to prevent HIV.

Results: The study showed that 84% (536/637) of adolescent girls and young women had never heard of AR before this study, and only 8% (49/637) had prior experience using AR. Participants' median age was 22 (IQR 21 - 24) years, with the majority (362/637, 56.8%) aged between 21 and 25 years. Despite the low usage rate of AR among participants, there was a high likelihood of using AR to promote HIV prevention and treatment. Specifically, 72% (459/637) of participants reported that they were likely to use AR to visualize the HIV transmission process, while 73% (465/637) and 74% (471/637) reported the likelihood of using AR to learn about pre-exposure prophylaxis (PrEP) and how HIV medication lowers HIV viral load, respectively. More importantly, 54% (342/637) and 50% (319/637) of participants reported that they were extremely likely to use AR to learn the correct way of using condom and self-testing for HIV, respectively. The high likelihood of using AR to prevent and treat HIV was associated with a higher education level (P=.01), having ever tested for HIV (P=.03), and a history of previously using health apps or searching for health information on their phones (P<.001).

Conclusions: The likelihood of using AR technology to promote HIV prevention and treatment is high among adolescent girls and young women in Cameroon. Future research should focus on exploring the preferred features of AR-based digital health interventions and consider methods of implementing them in the context of Cameroon or SSA.

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KEYWORDS

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adolescent; augmented reality; AR; mHealth; mobile apps; HIV/AIDS; PrEP; women; pre-exposure prophylaxis

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Introduction

In sub-Saharan Africa (SSA), the most vulnerable population for HIV is adolescent girls and young women [1]. Among adolescent girls and young women globally, 4 out of every 5 newly diagnosed HIV cases occur in SSA [2,3]. Cameroon, a lower-middle-income country with a population of 29 million, has the highest HIV prevalence rate in West Central Africa. Women, particularly those aged 15 - 49 years, are disproportionately affected by the virus [4-7]. This health disparity among women is related to various factors, including limited access to health care resources, unbalanced power dynamics in sexual communication, reduced awareness of risk behaviors associated with HIV, and the absence of an enabling environment for women [8]. Consequently, the number of new infections among adolescent girls and young women in Cameroon is more than twice that of their male counterparts [9]. To eliminate the burden of HIV, the government of Cameroon has initiated national strategic plans aimed at reducing the HIV incidence by 65% by 2023 [7]. Although Cameroon is making progress in the fight against HIV, with a 50% decrease in HIV prevalence among people aged 15 to 64 years in the past 14 years, the 65% goal has not yet achieved [10]. This shortfall is associated with factors at individual, health system, and structural levels, including delays in diagnosis and linkage to HIV care, as well as insufficient engagement among persons who initiate care [11]. To end HIV in Cameroon, the national strategic plans of Cameroon emphasize the importance of providing adolescents and young people the right skills to protect themselves from HIV [7]. Under this backdrop, it is necessary to develop and test innovative, effective, and culturally appropriate approaches to enhance efforts in fighting against HIV in Cameroon, reduce health disparities, and promote HIV testing and pre-exposure prophylaxis (PrEP) use among adolescent girls and young women [12].

Innovative technologies, such as augmented reality (AR), have been integrated into mobile health (mHealth) interventions to promote user engagement, enhance interactive learning, and provide tailored health information [13]. AR is broadly defined as a technology, usable on devices such as smartphones, tablets, glasses, headsets, and so on, that overlays computer-generated information, such as avatars, images, and sounds, onto the users' real environment in real time to enhance users' interactive experience [13,14]. Additionally, a major technical limitation of conventional HIV prevention strategies is their lack of offering an interactive and immersive environment to enhance users' experience [15-17]. To young people who are more open to technology, AR-based mHealth interventions could offer innovative solutions, through its immersive and interactive qualities, to enhance HIV health education, communication for behavioral change, and reduce stigma. For example, studies have found that AR applications have the potential to significantly increase user engagement, promote information retention, and enhance users' satisfaction [18]. Furthermore, AR-based interventions have the capability to influence people's perceptions of HIV prevention, potentially revolutionizing health education and behavior change initiatives, with youth as the primary target audience [19].

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Despite their potential, most AR-based mHealth interventions have been conducted in high-income countries, leaving insufficient evidence of their applicability in low-income settings [20]. Some AR-based interventions, including "Floating heart" 3D imaging [21], mLearning [22], BodyExplorer [23], and FlexAR [24,25], have demonstrated preliminary but significant outcomes in medical education. However, their application to improve HIV prevention (including condom use and HIV PrEP uptake) is very sparse. Also, implementing AR interventions in resource-limited settings often faces technical challenges, including the need for smartphones with AR capabilities and reliable internet connections. A previous analysis has highlighted a high ownership of smartphones and access to the internet among adolescent girls and young women in Yaounde, Cameroon [17], indicating a favorable environment for implementing digital health interventions like AR-based mHealth programs. Understanding how adolescent girls and young women in Cameroon perceive and engage with AR technology is crucial for designing effective, culturally tailored health interventions. To date, the usability and effectiveness of AR technology in HIV prevention among adolescent girls and young women in Cameroon and the SSA region is unknown. Therefore, this study aimed to assess the likelihood of adolescent girls and young women using AR for the promotion of HIV testing, prevention, and treatment. This study also sought to identify factors associated with the likelihood of adolescent girls and young women adopting AR-based health interventions, informing the design of future AR-based mHealth interventions in Cameroon and the SSA region.

Methods

Study Sample and Data Collection

This was a cross-sectional study conducted from February to June 2023, in which 637 participants were recruited from Yaounde, Cameroon, where a variety of adolescent girls and young women were residing. To be eligible to participate in this study, individuals must be cisgender women aged 18 to 30 years, able to understand the study questions, and mentally healthy enough to voluntarily give informed consent.

The study procedures have been published elsewhere [17]. In brief, participants were recruited using a multistage cluster sampling technique based on Cameroonian health districts and health areas, combined with a snowball sampling technique wherein a consenting participant referred other potential participants. This recruitment method was chosen to ensure the inclusion of participants with diverse demographic backgrounds within Cameroon. Data were collected as pseudonymized data using a survey questionnaire implemented on Yale Qualtrics, a secure electronic survey platform. The Qualtrics questionnaire was administered with the assistance of 2 well-trained enumerators, who could hand their phones to participants to select their own responses, especially for sensitive questions. For reasons of data protection and confidentiality, participants' identifier codes were only known to the 2 enumerators involved in fieldwork and JJNN, who possesses the signed inform consent forms.

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Ethical Considerations

This study received ethical approvals from the Yale University Institutional Review Board (ID: 2000033713) and the Cameroonian Centre Regional Ethics Committee for Human Health Research (initial ID: CE number 02058/CRERSHC/2022, and extension ID: CE number 02058/CRERSHC/2023). Additionally, this study has received administrative authorization from the Cameroonian Centre Regional Delegation for Public Health. Data were pseudonymized and all participants provided informed consent.

Measures

Sociodemographic and Baseline Characteristics

Sociodemographic variables included age, monthly income, educational level, and geographical zone of origin. Other characteristics included sexual orientation, phone ownership and use, awareness of AR, and previous experience with AR. Specifically, phone ownership was measured by the question "Do you own or have access to the following devices on a daily basis (check all that apply: landline telephone, mobile phone without internet access, smartphone, tablet, laptop, and personal computer)?" Participants' awareness of AR was measured by the question "Have you ever heard about Augmented Reality (Yes or No)?" For those who were aware of AR, their previous experience with AR was measured by the question "Have you ever used Augmented Reality (Yes or No)?" For participants who had used AR, a follow-up question was asked to study the features of AR that they used: "Why do you use Augmented Reality in your daily life? Select all that apply (Immersive, interactive, virtual world, embodiment, sensory feedback, other, please specify)."

Likelihood of Using AR

The primary outcome variable was the likelihood of using AR for health purposes, measured as a composite score of 7 subscales. The seven subscales measured the likelihood of leveraging AR to (1) visualize the HIV transmission process, (2) demonstrate the correct way of using a condom, (3) introduce daily PrEP, (4) depict the HIV testing process in a clinical or NGO setting, (5) show the HIV self-testing process, (6) explain the process of receiving HIV treatment, and (7) illustrate how HIV medication lowers the HIV viral load. Participants' responses to each subscale were measured using a 5point Likert scale, ranging from 1 (extremely unlikely) to 5 (extremely likely). For example, the likelihood of leveraging AR to visualize the HIV transmission process was measured by the question: "If we build an Augmented Reality (AR) app for you to visualize the HIV transmission process, how likely would you be to use the AR?" and the likelihood of leveraging AR to demonstrate the correct way of using a condom was assessed by the question: "If we build an Augmented Reality (AR) app demonstrating the correct way of using condom, how likely would you be to use the AR?" A composite score was calculated for each participant as the mean score of the seven 5-point Likert subscales, rounded to the nearest whole number. Specifically, for each of the above subscales, we quantified their responses using a scale ranging from 1 to 5, followed by calculating the

mean of these responses and rounded the results to the nearest whole number within the same Likert scale.

Statistical Analyses

Statistical analyses were conducted using R software version 4.3.1 (R Core Team). Categorical variables were presented as absolute and relative frequencies, as well as cross tabulations of the likelihood categories to use AR. Proportions of the likelihood to use AR for HIV prevention were calculated, where the numerators were the number of participants who selected any of the ordinal response categories (ie, extremely unlikely, somewhat unlikely, neither likely nor unlikely, somewhat likely, and extremely likely), and the denominator was the total number of study participants. To determine factors associated with the likelihood of using AR for health purposes, ordinal logistic regression was applied using the "polr" function. Univariate analyses were initially conducted to identify covariates of interest (with P < .10), which were then put together in a model to adjust for each other's effect in a multivariate analysis. The level of significance for the multivariate analysis was set at 5%. The exhaustive list of independent variables of the univariate analyses include: age group, region of origin, sexual orientation, education level, employment status, monthly revenue, marital status, housing condition, ownership of (or access to) smartphone or tablet with internet, history of health app use or phone for health information search, HIV testing situation, sexually transmitted infection diagnosis within past 6 months, vulnerable sexual behavior and PrEP awareness.

Results

Participant Characteristics

Participants' median age was 22 (IQR 21 - 24) years, with the majority (362/637, 56.8%) aged between 21 and 25 years. Most participants were heterosexual (599/637, 94%), unmarried (485/637, 76.1%), and were unaware of PrEP (519/637). We also found that 93.9% (598/637) of participants had access to a smartphone, 42.4% (270/637) had access to a laptop or personal computer, and 9.9% (63/637) owned a tablet or iPad [17]. Among the 637 participants, 84.1% (n=536) had never heard of AR, and only 7.7% (n=49) had used AR. Among those who had ever used AR, 51% (25/49) used virtual world, 20% (10/49) used embodiment features, 10% (5/49) used interactive elements, 10% (5/49) used sensory feedback, and 8% (4/49) used immersive features.

Likelihood to use AR for Health Purposes and Associated Factors

Overall, the likelihood of using AR for health purposes was high, with 72.8% (464/637) of participants somewhat or extremely likely to use AR, compared to 10.5% (67/637) of participants somewhat or extremely unlikely to use AR. It should be noted that for each of the health purposes, at least 45% (287/637) of participants were extremely likely to use AR, with 53.7% (342/637) preferring to use AR for learning condom use and 50.1% (319/637) preferring to use AR for learning the process of HIV self-testing (Table 1).

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Table . Participants' likelihood to use augmented reality for health purposes (N=637).

Variable	Extremely unlikely, n (%)	Somewhat unlikely, n (%)	Neither likely nor un- likely, n (%)	Somewhat likely, n (%)	Extremely likely, n (%)
Likelihood to use AR ^a if it was built to visual- ize the HIV transmis- sion process	19 (2.9)	55 (8.6)	106 (16.6)	169 (26.5)	288 (45.2)
Likelihood to use AR if it was built to demonstrating the cor- rect way of using con- dom	18 (2.8)	47 (7.4)	80 (12.6)	150 (23.5)	342 (53.7)
Likelihood to use AR if it was built to intro- duce daily PrEP ^b	19 (2.9)	59 (9.3)	96 (15.1)	155 (24.3)	308 (48.4)
Likelihood to use AR if it was built to demonstrate the HIV testing process in a clinical or NGO ^c set- ting	17 (2.7)	60 (9.4)	99 (15.5)	150 (23.5)	311 (48.8)
Likelihood to use AR if it was built to demonstrate the HIV self-testing process	15 (2.4)	58 (9.1)	94 (14.8)	151 (23.7)	319 (50.1)
Likelihood to use AR if it was built to demonstrate the pro- cess of receiving HIV treatment	14 (2.2)	58 (9.1)	97 (15.2)	161 (25.3)	307 (48.2)
Likelihood to use AR if it was built to demonstrate how HIV medication lowers HIV viral load	14 (2.2)	57 (8.9)	95 (14.9)	162 (25.4)	309 (48.5)
Overall likelihood of using AR (a composite score of the above variables)	7 (1.1)	60 (9.4)	106 (16.6)	168 (26.4)	296 (46.5)

^aAR: augmented reality.

^bPrEP: pre-exposure prophylaxis.

^cNGO: nongovernmental organization.

In unadjusted analyses of the ordinal logistic regression (Table 2), increasing likelihood to use AR for health purposes was associated with education level, sexual orientation, access to a smartphone or tablet, previous use of a health app or a phone

for health-related information search, diagnosis of sexually transmitted infection within past 6 months, HIV testing, and awareness of PrEP.



Table .	Factors as	ssociated wi	th participants'	likelihood to use	augmented	reality fo	or health purposes	(N=637).
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Variables	OR ^a (95% CI)	P ^b value	aOR ^c (95% CI)	<i>P</i> value
Education level		<.001		.01
Uneducated or primary	1		1	
Secondary	3.3 (2.16 - 5.01)		2.0 (1.27 - 3.25)	
Higher	3.1 (1.89 - 5.28)		1.6 (0.85 - 2.88)	
Sexual orientation		.02		.047
Heterosexual or straight	1		1	
Bisexual or lesbian or other	0.5 (0.26 - 0.91)		0.5 (0.28 - 1.01)	
Employment status		.08		.24
Unemployed	1		1	
Employed	0.7 (0.5 - 1.04)		0.8 (0.49 - 1.2)	
Phone or Tablet with internet		.002		.48
No	1		1	
Yes	2.7 (1.46 - 4.97)		1.3 (0.65 - 2.46)	
History of health app use or phone health info search		<0.001		<0.001
No	1		1	
Yes	3.6 (2.28 - 4.95)		2.2 (1.41 - 3.42)	
HIV testing		< 0.001		.03
Never	1		1	
>12 months	1.2 (0.85 - 1.71)		1.2 (0.8 - 1.7)	
≤12 months	2.02 (1.4 - 2.89)		1.7 (1.14 - 2.62)	
STI ^d in the past 6 months		.007		.21
No	1		1	
Yes	1.7 (1.15 - 2.42)		1.3 (0.86 - 1.98)	
Aware of PrEP		.002		.18
No	1		1	
Yes	1.9 (1.26 - 2.77)		1.3 (0.88 - 2.06)	

^aOR: odds ratio

^bOnly variables with P<0.1 in univariate analaysis are shown in this table.

^caOR: adjusted odds ratio.

^dSTI: sexually transmitted infection.

Upon adjusting for all key covariates in a multivariate model, an increasing likelihood to use AR for health purposes was independently associated with a higher level of education (P=.01), having used a health-related app before or using a phone to search for health-related information (aOR 2.2, 95% CI 1.41 - 3.42; P<.001), and having tested for HIV, notably less than 12 months ago (aOR 1.7, 95% CI 1.41 - 2.62; P=.03), compared to those who have never undertaken an HIV test. Additionally, a decreasing likelihood to use AR for health purposes was independently associated with participants who identified as sexual minorities (aOR 0.5, 95% CI 0.28 - 1.01; P=.04), compared to heterosexual participants.

Discussion

Principal Findings

The integration of AR into HIV prevention strategies holds promise for enhancing education, improving accessibility, and ultimately reducing the spread of HIV. However, there is a knowledge gap regarding how AR technology, which garners increasing interest worldwide, can be best used for HIV prevention in resource-limited settings. This study seeks to address the literature gap on the feasibility of using AR technology for HIV prevention among adolescent girls and young women in the Cameroonian context. The findings of this study have provided valuable information on the likelihood of Cameroonian adolescent girls and young women to use AR to

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learn about HIV testing, prevention, and treatment. Overall, there was a low prior knowledge of AR among adolescent girls and young women, accompanied by an even lower prior use of AR technology. Despite this, the likelihood of adolescent girls and young women using AR was high, with at least 45% indicating they were extremely likely to use AR interventions for HIV testing, prevention, and treatment, such as acquiring knowledge about HIV transmission, HIV testing, self-testing processes, correct condom use, HIV treatment, daily PrEP, and information on how HIV medication reduces viral load. This finding is particularly significant given that a study conducted in the Northwest region of Cameroon showed a high prevalence of inconsistent condom use among young women with HIV [26]. To end HIV in Cameroon and SSA, more comprehensive educational programs on sexual and reproductive health for adolescent girls and young women, including distribution and empowerment of female condom use, are necessary.

This study also indicated that leveraging AR is worth exploring in Cameroon. Globally, the awareness and use of AR for adolescent girls and young women in resource-limited settings is low compared to their counterparts in high-income settings [27]. This is mainly due to differences in access to AR technology, internet connectivity, and the integration of AR in education and entertainment [27]. Despite this, there have been a few commendable initiatives on the use of AR in SSA, notably in medical training, where it has shown to enhance the learning process and performance through more interactive and engaging experiences [28,29]. These initiatives, along with our study finding on the high likelihood of using AR among adolescent girls and young women, indicate that leveraging AR for HIV prevention in SSA is possible and should be given serious consideration.

This consideration is further justified by the interactive nature of AR technology. Compared with many early mHealth interventions, mobile apps embedded with AR technology can provide an immersive, interactive learning environment for people to receive real-time information, motivation, and behavioral skills. Considering the widespread adoption of smartphones among young people in resource-limited settings and the permeation of digital technologies in developing countries, AR-based mobile apps have significant potential for facilitating behavior change communication in HIV prevention efforts. For example, in a context where the ability of adolescent girls and young women to negotiate condom use during sexual acts is greatly influenced by a lack of comprehensive knowledge on HIV and cultural and social norms [30-32], AR technology, through interactive and educative role-play scenarios, may enhance their ability to effectively negotiate and correctly use condoms. Despite the lack of previous research on AR for HIV prevention among adolescent girls and young women, we believe that the expanded use and integration of technology-delivered interventions, such as mobile apps, websites, live chats, chatbots, vending machines, virtual reality and AR, when guided by theoretical frameworks, can assist adolescent girls and young women in engaging in self-care for HIV testing and prevention [33,34]. For instance, in 2018, the Joint United Nations Programme on HIV/AIDS (UNAIDS) teamed up with Google and Makhulu Media to release a series

https://pediatrics.jmir.org/2025/1/e69471

of virtual reality educational films on HIV testing. These films were distributed in clinics, schools, and communities across South Africa to encourage people to test for HIV, potentially reshaping attitudes and reducing HIV-related stigma [35].

Our study has identified several factors associated with the likelihood of adolescent girls and young women to use AR technology for health purposes. We observed that adolescent girls and young women with at least secondary education level were more likely to use AR for HIV prevention than those with less education. This might be because individuals with higher levels of education tend to have better digital literacy skills as education provides opportunities for engagement with digital technologies and developing necessary digital competencies [36,37]. We also observed that those who had previous exposure to mHealth apps and/or sought health-related information on mobile devices were more likely to accept AR use compared to those who did not use health apps or use their phones for health information inquiries. Given that mobile devices are integrated into everyday life, offering numerous opportunities to enrich the learning experience, prior exposure to smartphones in learning activities might have made them familiar and comfortable with technology-based health interventions [38].

In this study, we also found that adolescent girls and young women who had undergone HIV testing within the past 12 months had a higher likelihood of using AR for HIV prevention compared to those who had never been tested. This increased likelihood might be attributed to the counseling and education services related to HIV testing, which have raised awareness of HIV vulnerability and the preventive behavioral changes that should be adopted, thus increasing their openness to the potential role of AR technology in HIV prevention. Additionally, adolescent girls and young women who identified as sexual minorities (bisexual, lesbian, or other), compared to heterosexual, exhibited lower likelihoods to use AR for HIV-related services. This may be due to a lack of tailored HIV prevention that specifically address the needs and concerns of sexual minorities given the legal and social environment around same-sex relationships in Cameroon. It could also be due to stigma and discrimination based on sexual orientation, which may create barriers to accessing health care services, thus influencing the health care utilization and behavior of young female sexual minorities [39]. Furthermore, cultural and societal norms within certain communities in Cameroon may marginalize such populations [40].

Limitations

Although our study has contributed valuable knowledge to the field of leveraging AR in Cameroon to prevent HIV among adolescent girls and young women, its findings should be applied with consideration of the following limitations. First, although we used multistage cluster sampling that randomly selected 4 health districts followed by the selection of at least 2 health areas from each health district, which increased the representation of adolescent girls and young women from the various regions of Cameroon based in Yaounde, our study sample was ultimately recruited using the snowball technique, relying on referrals from participants' personal networks. This limits the generalizability of our study findings to all regions

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of Cameroon notably semiurban and rural areas which potentially lack the infrastructure to effectively run digital interventions. Second, while investigating their likelihood of using AR technology, we provided participants with an AR definition but did not provide an actual AR device or intervention; therefore, participants' understanding of AR technology might be limited to only a conceptional level rather than with deeper user experience. This might have brought some biases within participant feedback and responses. Nonetheless, building on the findings of this study, our team aims to develop an AR-based mHealth intervention in the future to promote HIV prevention among adolescent girls and young women within the metropolitan cities of Cameroon.

Conclusions

Our study reveals that the likelihood of leveraging AR for HIV prevention among adolescent girls and young women in Cameroon is high, particularly among those with higher educational levels and those who have previously used mobile apps for health purposes. The findings lay the foundation for the necessity of developing and testing AR-based interventions to prevent HIV in Cameroon. These interventions should be based on behavioral theories, Cameroonian culture, and the preferences of adolescent girls and young women in Cameroon.

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Authors' Contributions

Conceptualization & methodology: ZN, IMSB, JJNN; funding acquisition: ZN; project administration: ZN, JJNN, LEN; formal analysis and visualization: ZN, IMSB, JJNN, XZ, SO, YZ; analysis review, revision and validation: ZN, IMSB, JJNN, GB, HY, XZ, SO, YZ, LEN; writing—original draft: ZN, IMSB, JJNN; writing—review & editing: ZN, IMSB, JJNN, GB, HY, XZ, SO, YZ, LEN.

Conflicts of Interest

None declared.

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Abbreviations

AR: augmented reality
mHealth: mobile health
PrEP: pre-exposure prophylaxis
SSA: sub-Saharan Africa
UNAIDS: Joint United Nations Programme on HIV/AIDS

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Integrating Infant Safe Sleep and Breastfeeding Education Into an App in a Novel Approach to Reaching High-Risk Populations: Prospective Observational Study

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Abstract

Background: Sudden unexpected infant death (SUID) is a leading cause of death for US infants, and nonrecommended sleep practices are reported in most of these deaths. SUID rates have not declined over the past 20 years despite significant educational efforts. Integration of prenatal safe sleep and breastfeeding education into a pregnancy app may be one approach to engaging pregnant individuals in education about infant care practices prior to childbirth.

Objective: This study aims to assess whether pregnant individuals would engage with prenatal safe sleep and breastfeeding education provided within a pre-existing pregnancy app. Secondary objectives were to compare engagement among those at high and low risk of losing an infant to SUID and to assess the importance of end user push notifications for engagement.

Methods: This prospective observational study was conducted from September 23, 2019 to March, 22 2022; push notifications were removed on October 26, 2021. TodaysBaby (University of Virginia, Boston University, and Washington University), a mobile health program in which safe sleep and breastfeeding video education was originally provided via texts, was embedded into the MyHealthyPregnancy app (Naima Health LLC). Pregnant mothers who received prenatal care within the University of Pittsburgh Medical Center hospital system were randomized to receive either safe sleep or breastfeeding education beginning at the start of the third trimester of pregnancy and ending 6 weeks post partum. Pregnant persons were designated as high risk if they lived in the 5% of zip codes in Allegheny County, Pennsylvania with the highest rates of SUID in the county. The primary outcome was engagement, defined as watching at least 1 video either in response to a push notification or directly from the app's learning center.

Results: A total of 7572 pregnant persons were enrolled in the TodaysBaby Program—3308 with push notifications and 4264 without. The TodaysBaby engagement rate was 18.8% with push notifications and 3.0% without. Engagement was highest in the initial weeks after enrollment, with a steady decline through pregnancy and very little postpartum engagement. There was no difference in engagement between pregnant persons who were low and high risk. The most viewed videos were ones addressing the use of pacifiers, concerns about infant choking, and the response of the body to the start of breastfeeding.

Conclusions: Integrating safe sleep and breastfeeding education within a pregnancy app may allow for rapid dissemination of infant care information to pregnant individuals. Birthing parents at high risk of losing an infant to SUID—a leading cause of infant death after 1 month of age—appear to engage with the app at the same rates as birth parents who are at low risk. Our data demonstrate that push notifications increase engagement, overall and for those in high-risk zip codes where the SUID education is likely to have the most impact.

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KEYWORDS

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SIDS; infant death; sleep; sudden infant death; US; United States; infant; infancy; baby; prenatal; safe sleep; breastfeeding; infant care; pregnancy; app; randomized controlled study; TodaysBaby; mobile health; mHealth; smartphone

Introduction

Sudden unexpected infant death (SUID) is a leading cause of death among US infants, with nonrecommended sleep practices reported in most of these deaths [1]. After a major decrease in the SUID rate immediately after the American Academy of Pediatrics released its 1992 recommendation that infants be placed on their backs to sleep, the rate has plateaued despite extensive educational efforts [2,3]. There continue to be racial and socioeconomic disparities in SUID, with rates higher among Black infants and infants who live in poverty [4-6]. The disparity can be marked, for instance, in Allegheny County, Pennsylvania in 2017 - 2022; 35% of all SUID occurred in 5.6% (7/124) of zip codes (Berger R, MPH, MD, unpublished data, personal communication, May 2024).

Parental education in the newborn nursery has been an important approach to reducing the risk of SUID [7-9]. Information about modifiable risk factors for SUID, including prone or side sleep position, not breastfeeding, sharing a sleep surface, use of soft bedding, and exposure to nicotine/smoking, alcohol, drugs, and illicit substances, when routinely incorporated into newborn education, can change parental practice [4,10]. In one 4-armed randomized controlled trial of hospital quality improvement (QI) and mobile health (mHealth) in 16 US hospitals, new parents were enrolled in an mHealth program (TodaysBaby; University of Virginia, Boston University, and Washington University). The videos in TodaysBaby were designed with parental input from mothers of young infants (our target population); mothers were involved design of the videos and provided suggestions before and during video production and provided feedback after video production [9]. Participants in the randomized controlled trial were randomized to receive emails or texts with links to short (<2 min) videos about either breastfeeding or safe sleep for 60 days. The videos were aimed at changing attitudes and dispelling misconceptions about safe sleep and breastfeeding. In this study, parents who received only safe sleep messaging were 10 percentage points more likely to use safe sleep practices than parents who received no safe sleep messaging. Additionally, racial and ethnic differences in reported safe sleep practices were eliminated in those who received safe sleep messaging. To our knowledge, this is the only randomized controlled trial evaluating video education as an approach to improving safe sleep practices.

The MyHealthyPregnancy (MHP; Naima Health LLC) app is a commercially available evidence-based patient-facing smartphone app and provider-facing portal developed to monitor and model individual risk during pregnancy and provide easy, actionable feedback to patients. The app also offers connection to relevant resources both within and outside the health care system and notifies the individual's care team if a critical risk (eg, preterm labor and suicidal ideation) is reported through the app. The primary goal of the app is to reduce unwanted outcomes both during pregnancy and in the early period after delivery through more timely risk detection and intervention [11-14]. End users were involved in the design, development, and deployment of the technology and the design approach was grounded in person-centered frameworks to advance reproductive health equity [11,15].

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The primary objectives of this study were to assess whether the TodaysBaby educational program could be integrated into the MHP app, whether users of the app would engage with the TodaysBaby content, and whether there were differences in knowledge and attitudes related to safe sleep among pregnant persons who were assigned to the safe sleep versus breastfeeding education. A secondary objective was to assess whether parents of infants at the highest risk of SUID—as defined by zip code—were similar in their rates of engagement, knowledge, and attitude compared with those living in low-risk zip codes. TodaysBaby was the first infant-specific education to be integrated into the MHP app, which is otherwise entirely focused on pregnant persons' health and pregnancy.

Methods

Overview

Providers at prenatal clinics in the University of Pittsburgh Medical Center (UPMC) health system could prescribe the MHP app (iOS version 1.4.7, Android version 1.8) to pregnant patients at their first prenatal appointment as part of a prenatal care QI initiative sponsored by UPMC and at no cost to the patient. The internal protocol for prescribing MHP was to send a text-based invitation with a unique web link to the patient's phone, which allowed app users to download the app from the Android or Apple app store. App users electronically consented to share identifiable data with their health care provider and anonymized aggregate data for research. An additional specific consent was provided for enrolling in TodaysBaby. Participants did not receive financial compensation for app use or TodaysBaby participation. At the time of consent, patients were randomly assigned to the safe sleep or breastfeeding group in a 2:1 ratio. High-risk patients-defined by zip code as described below-were enrolled in a 3:1 ratio to the safe sleep group.

All participants were recruited during pregnancy at prenatal clinics. While we recognize that pregnant individuals and parents may be of any gender and that transgender men and gender-nonbinary people may also give birth, we did not collect additional information about biological sex or gender identity from participants. We refer to participants as pregnant persons throughout the manuscript.

MHP users completed an initial onboarding process in which they completed questions about demographics, medical history, and baseline risk factors. Throughout the course of their pregnancy, app users were offered the opportunity to answer questions about their experiences and symptoms through app-embedded screeners, questionnaires, and open-ended text entries. Starting at 32 weeks of pregnancy (based on the due date entered by the user), participants started receiving texts with links to videos ("push notifications" or "pushes") at predefined intervals. The decision to start TodaysBaby at 32 weeks was a change from the original TodaysBaby study, in which the education started at the birth of the infant [9]. We chose not to start earlier than 32 weeks to minimize the likelihood of pregnancy loss among study participants.

There were 21 pushes with 18 videos for each group (safe sleep and breastfeeding): 14 pushes in the prenatal period and 7 in

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the postnatal period. A total of 12 short quizzes about intentions related to sleep and breastfeeding were pushed at similar intervals. All videos were also available to all users in both groups at any time in the app's learning center (LC), which was

Textbox 1. Video topics for the safe sleep and breastfeeding groups.

- Importance of sleep position
- Choking and sleep position
- Importance of sleep space
- Bed-sharing
- Handling advice from others
- Mattress safety
- Soft bedding
- Feeding baby in bed
- Pacifiers
- Dangers of smoking
- Infant sleep patterns

Breastfeeding

- Importance of breastfeeding
- How to start breastfeeding
- How often to breastfeed
- Hunger cues
- What to do if baby is always hungry
- Benefits of breast milk
- How long it takes for milk to come in
- Latching on
- Avoiding breast discomfort/pain
- Dealing with fussy baby
- Getting support from others
- Economics of breastfeeding
- Breastfeeding when returning to work

On October 26, 2021, the push notifications and videos were removed; the videos remained in the LC for pregnant persons who downloaded the MHP app.

Ethical Considerations

The project was approved by the UPMC QI Committee (reference number 1613). App users consented the publication of anonymized aggregate data during app onboarding. An additional consent was provided during app onboarding to a subset of MHP users to opt in to participation in the TodaysBaby program.

Statistical Analysis

The number of videos watched via push notification or from the LC was aggregated. Data from the push notifications indicated that some videos were possibly clicked, so the

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a section of the app providing educational articles and video links on a variety of pregnancy-related topics.

The video topics for both the safe sleep and breastfeeding groups are summarized in Textbox 1.

aggregation was done once for definitely clicked videos and separately to include both and possibly clicked videos. Partial viewings of a video were counted as a viewing of that video. Engagement was defined as watching at least 1 video either in the LC or in response to a push notification. A binary indicator of high- versus low-risk zip codes was created.

Descriptive statistics such as frequency and percentages were used to examine demographic factors for the entire sample as well as the high- and low-risk groups. Individual chi-square tests were used to examine 2×2 combinations by group (safe sleep vs breastfeeding), engagement, high-risk zip codes, and frequency of video viewership. A standard of 5% probability of type 1 error was used.

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Results

Overview

Between September 23, 2019, and October 26, 2021, 43% (3635/8453) of pregnant persons who were prescribed the MHP

app enrolled. Of these, 91% (n=3308) consented to receive TodaysBaby content—2407 in the sleep group and 901 in the breastfeeding group. There were no demographic differences between those who did or did not enroll in the MHP app [13]. The demographics of participants who enrolled in TodaysBaby are summarized in Table 1.

Table . Demographics of MyHealthyPregnancy app users who consented to TodaysBaby.

		Overall users (n=3308)	Pregnant person living in a higher SUID ^a rate area in Allegheny County (n=297)	Pregnant person living in a lower SUID rate area in Al- legheny County (n=1562)
Maternal age (years), mean (SD)		29.8 (5.4)	30.3 (5.8)	30.7 (5.1)
Income (US \$), n (%)				
	Under 10,000	282 (8.9)	43 (15.4)	105 (7.0)
	10,000-14,999	147 (4.6)	18 (6.4)	56 (3.7)
	15,000-19,999	107 (3.4)	11 (3.9)	39 (13.3)
	20,000-24,999	137 (4.3)	18 (6.4)	48 (3.2)
	25,000-34,999	233 (7.3)	21 (7.5)	86 (5.7)
	35,000-49,999	274 (8.6)	21 (7.5)	103 (6.9)
	50,000-69,999	351 (11.0)	28 (9.4)	140 (9.3)
	70,000-100,000	640 (20.1)	43 (15.4)	306 (20.4)
	>100,000	1011 (31.8)	77 (27.5)	618 (41.2)
Parity-Nulliparous, n (%)		1793 (54)	166 (56)	885 (57)
Maternal education, n (%)				
	Bachelor degree or higher	1881 (57)	158 (53)	1043 (67)
	Associate degree	356 (11)	29 (10)	137 (9)
	Grade school, some high school, high school, or GED ^b	1025 (31)	101 (34)	362 (23)
	Missing	46 (1)	9 (3)	20 (1)
Smoked tobacco, n (%)		219 (6.6)	20 (6.7)	70 (4.5)
Vaped, n (%)		64 (1.9)	3 (1.0)	24 (1.5)
Used marijuana, n (%)		104 (3)	18 (6.1)	39 (2.5)
Maternal race, n (%)				
	White	2608 (79)	164 (55)	1147 (73)
	Black	351 (11)	91 (31)	210 (13)
	East or South Asian	149 (5)	12 (4)	103 (7)
	Other	176 (5)	25 (8)	90 (6)
	No response	24 (0)	5 (2)	12 (1)

^aSUID: sudden unexpected infant death.

^bGED: General Educational Development.

Engagement

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Video Watching in Response to a Push Notification

Overall, 11% (368/3308) of all participants clicked on at least one of the push notifications they received. Of those who clicked, 53% (194/368) clicked only 1, 26% (94/368) clicked on 2 unique notifications, and the remaining 21% (80/368)

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clicked on 3 or more unique push notifications (maximum 20 push notifications). An additional 36 participants clicked on at least 1 push notification but because they closed the app immediately after clicking on the notification, it is not possible to be sure whether they read the information provided. If the possible clicks are included, then 12.2% (404/3308) of all participants clicked on a push notification. By comparison, 9.0% (300/3308) of users clicked on at least 1 monthly mental health

push notification which was part of the MHP app but not part of TodaysBaby.

Video Watching From the LC

Overall, 10.4% (347/3308) watched at least 1 video directly from the LC and not in response to a push notification; 6.2% (206/3308) watched at least 1 breastfeeding video from the LC, and 7.4% (345/3308) watched at least 1 safe sleep video from the LC.

Overall Engagement Rate

Overall engagement, defined as watching at least 1 video either in response to a push notification or from the LC, was 18.8% (623/3308).

Video Watching

The frequency with which videos were watched ranged from 1% (35/3308) ("why you should not smoke around your baby") to 4.7% (154/3308) ("a reminder about pacifiers"). Over 9% (300/3308) watched at least 1 of 3 pacifier-related videos. Over 98% (613/623) of the watched videos were watched only once (Table 2).

Table . Frequency with which the 10 most popular safe sleep and breastfeeding videos were watched.

Video name	Number of views
A reminder about pacifiers	154
Should I give my baby a pacifier?	106
Will my baby choke on the stomach?	105
Will my body know what to do when I start breastfeeding?	98
Why sleep position matters	97
How often should I feed my baby?	90
What is the safest mattress?	89
How do I know when my baby is hungry	86
What about bedding and bumpers?	84
What makes a baby a good sleeper	70

Timing of Video Watching

Timing of video watching during pregnancy could only be assessed for app users for whom the TodaysBaby integration took place during their first pregnancy with the app. The "weeks gestation" field was not consistently accurate for users who had used the app with previous pregnancies because some had not logged the date when the first pregnancy ended.

Of the 3308, 43% (n=1431) users were using the app for the first time. The mean time during gestation, when videos were watched, ranged from 19 weeks of gestation ("How long should I breastfeed?" and "More about pacifiers") to 32 - 33 weeks ("What can I do when my baby is fussy" and "Breastfeeding can save you time and money"). Many of these videos were watched through the LC before the TodaysBaby curriculum was available (at 32 wk of gestation) on the MHP app.

Engagement Rate After Removal of Push Notifications

From October 27, 2021 to March 22, 2022, after the push notifications were stopped, of the 4264 participants who downloaded the MHP app, 3.0% (n=127) watched any TodaysBaby videos. Overall, 2.0% (n=85) watched at least 1 breastfeeding video, and 2.0% (n=85) watched at least 1 safe sleep video. The use of the LC was also significantly lower among pregnant persons who did not receive pushes versus those who did (127/4264, 3% vs 347/3308, 10.4%; *P*<.001).

Engagement of Participants in High-Risk Zip Codes in Allegheny County

Of the 3308 users, 58% (n=1859) were from Allegheny County; of these, 16% (297/1859) lived in a high-risk zip code and 84% (1562/1859) lived in a low-risk zip code. Demographic characteristics of the TodaysBaby participants from high-risk and low-risk zip codes are found in Textbox 1.

Among those with high-risk zip codes, 219 were randomized to safe sleep and 78 to the breastfeeding group. Overall engagement in this group was 21.5% (62/297), 10.8% (32/297) clicked on at least 1 TodaysBaby push notification, and 12.5% (37/297) watched at least 1 video from the LC. View rates of safe sleep and breastfeeding videos were similar for both high-risk and low-risk groups.

There was no difference in the engagement of users from high-risk and low-risk zip codes, with the push notifications (32/297, 10.8% vs 185/1562, 11.8%; P=.60) or the LC videos (182/1562, 11.6% vs 37/297, 12.5%; P=.70).

Quizzes

Overall, 12.0% (409/3308) of all users took at least 1 of the 12 quizzes. Of those who took at least 1 quiz, 54% (222/409) took only a single quiz. Except for quizzes 1 and 6, the completion rate was very low (Table 3). Quizzes 1 and 6 coincided with the user getting a push notification on the same day related to a change in the stage of fetal development. The push notification on the day of quiz 1 (32 weeks gestation) was "Pregnancy is full of many joys and challenges! Reflect on yours now with

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your mental health check-in" and the one on the day of quiz 6 (35 weeks gestation) was "Welcome to week 35! Time to put that hospital bag next to your door! Visit MHP for a list of

recommended items to pack." There was no difference in response rate between the safe sleep and breastfeeding groups or between high- and low-risk users.

Table . Number of responses to each of the 12 quizzes.

Quiz number	Number of responses
1	279
2	32
3	32
4	44
5	48
6	211
7	62
8	34
9	32
10	25
11	1
12	2

The responses to questions in quizzes 1 and 6 demonstrate that app users plan to breastfeed (83.2%), plan for their baby to sleep in a safe location (97.9%), and plan for their baby to sleep on

his or her back (94.6%) (Table 4). There was no difference in the quiz responses between groups (safe sleep versus breastfeeding or high versus low risk).

Table . Responses to quizzes 1 and 6.

Quiz number and quiz question	Response
Q ^a 1Ques ^b 1: When I first bring my baby home, I plan to breastfeed	83.2% agree or strongly agree
Q1Ques2: When I first bring my baby home, I plan to have him/her sleep in an adult bed	2.1% agree or strongly agree
Q1Ques3: When I first bring my baby home, I plan to place him/her on the side to sleep	5.7% agree or strongly agree
Q1Ques4: When I first bring my baby home, I plan to place him/her on the stomach to sleep	3.9% agree or strongly agree
Q1Ques5: When I first bring my baby home, I plan to place him/her on the back to sleep	94.6% agree or strongly agree
Q1Ques6: When I first bring my baby home, I plan to give him/her a pacifier	34% agree or strongly agree
Q6Ques1: I will be taking a medication or substance that may make me sleep more deeply	10.9% yes or unsure
$Q6Ques 2: I\ am\ currently\ on\ prescribed\ opioids/pain\ medication/methadone\ or\ Subutex/suboxone$	1.9% yes
Q6Ques3: I currently use tobacco products	7.6% yes

^aQ: quiz. ^bQues: question.

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Discussion

Principal Findings

This is the first study, to our knowledge, to evaluate the use of a mobile app as a means of delivering safe sleep education to pregnant persons with the goal of addressing the risk of SUID. While mHealth tools have been used to explicitly encourage

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breastfeeding and other care behaviors, the use of an mHealth tool to address safe sleep is novel [16,17]. Over the past 20 years, the way in which young adults receive information has shifted. Smartphone ownership is ubiquitous among reproductive-aged individuals in the United States, with similar distribution by race and ethnicity [18]. A vast majority of smartphone owners use their phones to access health

information, with pregnancy being one of the most popular health app domains [19-21].

In addition to their popularity as an information source, there are several clear advantages to the dissemination of information through a mobile app. An app allows for the dissemination of information much more broadly and quickly than face-to-face education or information via educational pamphlets. It also provides the opportunity for users to obtain the information at a time and place which is convenient for them and it allows for the education to be provided as many times as desired and for it to be provided in the same way each time. Receiving inconsistent information even within a single setting such as a primary care physician's office or newborn nursery can contribute to misinformation.

Timing of education is also critical. While previous safe sleep and breastfeeding education programs have focused on parents after childbirth, parents make many decisions about sleep and feeding practices during pregnancy. In a study by our group, we found that pregnant mothers often purchased cribs and made decisions about sleep practices in their third trimester (Berger R, MPH, MD, unpublished data, 2021). Much of the safe sleep and breastfeeding education in the health care system takes place in a physician's office or newborn nursery after birth, which may not coincide with when parents or other caretakers want or need to hear this information. For this reason, we included TodaysBaby within the MHP app starting at 32 weeks, which was a change from the original TodaysBaby study, in which the education started at the birth of the infant [9]. Our data demonstrated that many of the videos in the LC center were watched before any of the app users began receiving the TodaysBaby curriculum. The LC provides the opportunity for pregnant persons to find the information they are most eager and willing to learn and may be most amenable to incorporating new information. As a result of this finding, integration of the TodaysBaby curriculum earlier in the pregnancy is a possible future change.

One of the challenges of safe sleep education provided in a physician's office or birthing hospital is that there is a set curriculum; it would be very difficult to tailor education to each parent. In a recent study by our group, parents described interactions with their pediatricians related to safe sleep. Most parents reported that their pediatricians asked if they were practicing safe sleep and if they responded they were, there was no further conversation (Sahud H, unpublished data, personal communication, 2024). Here, an additional advantage of app-based content delivery is that the education can be tailored. Our study showed distinct differences in popularity (as determined by number of views) depending on the topic of the videos. This suggests that parents know the specific topics they are interested in or need additional information about (eg, pacifier use) and may not want to spend time learning about other (potentially already-familiar) infant-related topics even though each of the videos was <2 minutes in length.

This study also allowed us to see the natural engagement rate with the TodaysBaby content when deployed outside the context of a controlled study environment in a nonincentivized manner. Our approach allowed for dissemination to a large number of

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users which would not be possible with an in-person dissemination strategy. Since the field of digital health does not yet have a consensus definition of how to measure and report engagement [22], and very few published studies share engagement rates for specific embedded features and content within a larger intervention (eg, embedding TodaysBaby within the MHP app), it is difficult to interpret our engagement rate of 18.8%. Two studies evaluating specific intervention-embedded content in nonincentivized tool use demonstrated much lower engagement rates (eg, <1% of users completed all modules in 1 mHealth tool; approximately 3.5% completed a single assessment in another) than ours [23,24]. There may be an opportunity to increase engagement by focusing on high-interest video topics and beginning the TodaysBaby curriculum earlier in pregnancy when the overall engagement with the app is higher. Although fewer than half of the videos were watched in response to pushes, when the pushes were removed, the overall engagement dropped from 18% to 3%. Moreover, engagement with quizzes was highest when those quizzes coincided with push notifications containing fetal development information. This suggests that push notifications are critically important to engagement, and push notifications with time-sensitive or high-interest content may be leveraged to engage individuals with aspects of the tool that they would otherwise not seek out. The similar engagement rates between users living in communities with high and low rates of SUID are consistent with other data from the MHP app which has demonstrated that pregnant persons at the highest risk for pregnancy-related complications had similar or higher levels of engagement (Naima Health, unpublished data). This finding has important implications for SUID prevention and potentially for the identification of populations most likely to benefit from access to the MHP app. It is also encouraging that the engagement with videos about maternal health within the MHP app was watched as frequently as videos within the TodaysBaby curriculum since it suggests that mothers are equally willing to watch videos about their baby's health and their own health.

Limitations

There are limitations to this study. Those individuals who downloaded the app may not be representative of the larger pregnant population. For example, these individuals may be more comfortable with seeking out information through technology and may not reflect the population in greatest need of the TodaysBaby information. Because of the low response rate for the quizzes, it was not possible to assess whether engagement with the app correlated with changes in safe sleep or breastfeeding intentions. All participants were English-speaking; there is current work on an app that will be in both Spanish and English (Krishnamurti T, unpublished data, personal communication, June 2024).

Conclusions

Our data demonstrate that it is possible to embed safe sleep and breastfeeding education into an app designed to improve outcomes during pregnancy; that the engagement level is encouraging, especially when compared with other published studies of intervention-embedded education within a health-related app; and that this engagement was equally as
high among pregnant persons at the highest risk of an SUID. Using an app to disseminate information allows for widespread and rapid dissemination and provides users with the opportunity to choose which education they are interested in and when they are interested in receiving it. Simply having access to this education—as was available in the app LC—is not sufficient for engagement, and push notifications are critical for engagement. Future research should focus on assessing whether engagement with the app and TodaysBaby curriculum correlates with changes in safe sleep practices.

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Conflicts of Interest

Naima Health LLC provided the data for this study. The authors did not receive any financial or material compensation for conducting this study. TK is a cofounder and equity holder of Naima Health LLC, but did not receive compensation for conducting this study or disseminating the MyHealthyPregnancy app.

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Abbreviations

LC: learning center mHealth: mobile health MHP: MyHealthyPregnancy QI: quality improvement SUID: sudden unexpected infant death UPMC: University of Pittsburgh Medical Center

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Evaluating the Characteristics and Outcomes of Acute Pharmaceutical Exposure in Children: 5-Year Retrospective Study

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Abstract

Background: Acute pharmaceutical exposure in children can lead to severe health outcomes and contribute to the inefficient use of medical resources.

Objective: This study aimed to investigate the clinical characteristics and outcomes of children with acute pharmaceutical exposure to guide the development of preventive strategies and educational initiatives.

Methods: We analyzed real-world data from electronic medical records of children admitted to the emergency department of a pediatric hospital for acute pharmaceutical exposure between January 2019 and December 2023. Clinical data, including laboratory test results, interventions, and outcomes, were collected. We compared different exposure events and conducted logistic regression analysis to identify risk factors for hospitalization.

Results: A total of 653 children were included in the study. The most common drugs involved in exposure were vitamins (149/653, 22.8%), nonsteroidal anti-inflammatory drugs (92/653, 14.1%), and psychiatric drugs (74/653, 11.3%). In total, 74.3% (469/631) of patients with complete clinical manifestation data showed no symptoms after exposure, and 68.1% (445/653) of patients did not require specific therapy. Toxicology screening was performed for 11% (72/653) of the children, and 69.4% (50/72) of these tests were positive. Independent risk factors for hospitalization included multisystem involvement (odds ratio [OR] 4.575, 95% CI 1.709-12.251, P=.002), psychiatric drugs (OR 6.280, 95% CI 2.189-18.020, P=.001), and intentional poisoning (OR 12.892, 95% CI 2.222-74.796, P=.004).

Conclusions: Children with acute pharmaceutical exposure exhibit diverse clinical characteristics and outcomes, with most requiring no specific treatment. However, immediate toxicology screening and clinical intervention are essential for those exhibiting rapidly developing or multisystem symptoms, as well as those with intentional exposure or exposure to known highly toxic substances. Future pediatric health care policies should emphasize safe storage practices and public education on the prevention of pharmaceutical exposure.

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KEYWORDS

acute pharmaceutical exposure; children; poisoning; characteristics; outcomes

Introduction

Acute poisoning is one of the major public health issues affecting children around the world [1,2]. It can cause severe harm to children and bring immense economic and emotional burdens to their families. As children always lack the ability to metabolize harmful substances, serious physiological and psychological impacts were often observed, even resulting in

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disability or death [3]. According to the World Health Organization (WHO) report, accidental poisoning is a major contributor to accidental injury-related deaths in children, particularly in limited-income countries, where the mortality from poisoning is more pronounced [4]. Recent studies reported a significant decline in overall childhood poison exposures, but a decrease in poisoning-related fatalities was not observed [5]. Surveys in China also indicate that poisoning events still

frequently occurred [5-8]. Meanwhile, acute poisoning has become a common reason for pediatric emergency visits in some regions, accounting for 0.1% - 0.5% of such visits [9,10]. Thus, acute poisoning remains a serious public health concern for pediatrics.

Children, particularly infants and preschoolers, spend the majority of their time at home. Children's strong curiosity, poor discernment ability, and weak protective awareness make them a high-risk group for pharmaceutical poisoning, often leading to acute poisoning incidents. In addition, unsafe storage of pharmaceuticals or chemicals, inadequate child supervision, nonauthoritative parenting, maternal employment, and lack of family support can also lead to pharmaceutical exposure and poisoning in children [11,12]. For example, Song et al [13] analyzed 586 cases of hospitalized children with acute poisoning and found that the main causes of poisoning included medications (37.7%), pesticides (28.5%), and rodenticides (29.9%). Li et al [14] showed that most poisoning incidents among children are accidental, with 70.4% occurring at home. Accidental poisonings are more common in young children, particularly in those aged 1 - 3 years, whereas intentional poisonings are more common among adolescents [15,16]. Furthermore, the clinical manifestations of acute poisoning in children are diverse, and some severe cases presenting consciousness disturbances and circulatory failure can be life-threatening.

Notably, a large proportion of studies focused on pediatric pharmaceutical exposures and related poisoning events have been carried out; however, the epidemiological characteristics and clinical manifestations or outcomes of exposed populations, as well as the toxic substance types and prevention efforts, are often limited to specific research geographical areas, cultural backgrounds, and time periods. Furthermore, with the continuous discovery and development of new drugs, the characteristics of exposed populations are constantly changing, necessitating continuous updates and expansions of the relevant knowledge to meet new challenges for preventing acute poisoning in pediatrics. Additionally, in cases of children with acute pharmaceutical exposure, most parents or caregivers are often unsure whether the drugs are truly dangerous to their children, leading them to immediately take the children to the emergency room. The excessive anxiety and lack of professional knowledge in this population may result in the unnecessary use of pediatric emergency resources. While some exposure incidents indeed require urgent medical intervention, in many cases, the exposure events do not immediately endanger life [17,18].

In light of the aforementioned information, in this study, we retrospectively analyzed the acute pharmaceutical exposure cases from the emergency department of a pediatric hospital located in northern China. By summarizing the epidemiological characteristics and clinical manifestations and outcomes of the patients, this study aims to explore the recent common drugs involved in acute pharmaceutical exposure and the related outcomes, and to propose recommendations for preventing and managing acute pharmaceutical exposure in children.

Methods

Sample Collection

This retrospective study included children with acute pharmaceutical exposure who were admitted to the emergency department of the Capital Center for Children's Health, Capital Medical University between January 1, 2019, and December 31, 2023. All participants were aged 18 years or younger. The inclusion criteria for the patient group were age at assessment between 0 and 18 years, and admission due to pharmaceutical exposure. The exclusion criteria were incomplete records (patients lacking key clinical information such as basic demographic data, type of pharmaceutical substance exposed to, or clinical outcomes), admission due to chronic pharmaceutical exposure, and repeat visits (repeated visit records refer to the follow-up visit records of children with acute pharmaceutical exposure who come to the hospital for further check-ups). Totally, 653 eligible patients were included.

Data Preprocessing and Variables Extraction

For the patients who met the inclusion criteria, more detailed clinical information was extracted from their anonymized electronic medical records. Specifically, the variables directly extracted from the structured fields of the electronic records included age, gender, residence, admission time, types of pharmaceutical substances (eg, vitamins, psychotropic drugs, and nonsteroidal anti-inflammatory drugs [NSAIDs]), reasons for acute pharmaceutical exposure (intentional, suicidal, or accidental ingestion), exposure location, exposure season, methods of arrival, caregiver's education level, and clinical outcomes (discharge without treatment, emergency observation, and hospitalization).

The following variables were manually extracted from the unstructured text in the electronic medical records: clinical manifestations (eg, no symptoms, gastrointestinal symptoms, and neurological symptoms), clinical interventions (eg, no specific therapy, gastric lavage, and specific antidotes), and laboratory test results (routine blood test, biochemical test, coagulation function test, and toxicology screening).

The extraction of unstructured data was performed by 4 pediatric emergency physicians with extensive experience. All physicians underwent training on the data extraction content and methods before the process to ensure the accuracy and consistency of the data collection.

All eligible patients were grouped into the following age categories: infancy (<1 year), toddler (≥ 1 to <3 years), preschool (≥ 3 to <6 years), school age (≥ 6 to <12 years), and adolescence (≥ 12 to <18 years). The pharmaceutical exposure reasons were categorized as intentional and unintentional. The types of drugs involved in acute pharmaceutical exposure were categorized into 13 groups, namely vitamins, NSAIDs (such as ibuprofen and acetaminophen), psychotropic drugs (eg, antidepressant, antiepileptic, and sedative), cardiovascular drugs (eg, antihypertensive and diuretics), antihistamines, respiratory drugs, topical skin drugs, antimicrobial drugs (eg, antibiotic, antiviral, and antifungal drug), endocrine drugs (eg, antidiabetic

and hormone), herbal medicine, digestive drugs, immunosuppressants, and others.

After completing the above variable extraction and transformation, 22 patients lacked clinical manifestation data. For laboratory tests, 435 children underwent routine blood tests (C-reactive protein, white blood cells, and platelets), 437 children underwent biochemical tests (liver enzymes, myocardial enzymes, and renal function), 418 children underwent coagulation function tests, and 72 patients underwent toxicology screening. Except for these, all other variables had no missing values. In this study, we did not perform imputation for the variables with missing values, and we only used the actual valid data for each variable for the following data comparison and statistical analysis.

Statistical Analysis

All analyses were conducted using SPSS (version 26.0; IBM Corp) and Python (version 3.11; Python Software Foundation). The mean level of numerical variables was measured as mean (SD), and differences between different groups were analyzed using 2-tailed *t* tests. Besides, categorical data were measured with frequencies or percentages, and differences between groups were analyzed using the chi-square test, and Fisher exact tests were used when more than 20% of theoretical frequency was less than 5. In addition, univariate and multivariate logistic regression were used and odds ratios (OR) with 95% CIs were calculated to define the risk factors associated with hospitalization for acute pharmaceutical exposure. A *P* value of <.01 was considered statistically significant.

Ethical Considerations

All methods were performed in accordance with the relevant guidelines and regulations. Since we used anonymized data, and this study did not constitute human subject research, the need for written informed consent was waived by the ethics committee of Children's Hospital Affiliated to Capital Institute of Pediatrics, due to the retrospective nature of the study (SHERLLM2024029).

Results

Characteristics of Children With Acute Pharmaceutical Exposure

From January 1, 2019, to December 31, 2023, 653 adequate pediatric patients with acute pharmaceutical exposure were admitted to our pediatric emergency department (PED; Figure 1). The male-to-female ratio among patients was 1.04:1, with a slightly higher proportion of males. The average age of the patients was 4.7 (SD 4.1) years, with toddlers aged 1 - 3 years old accounting for the highest proportion (253/653, 38.7%; Table 1). Analyzing the age distribution by gender, 56.9% (325/571) of the children under 12 years were male and 43.1% (246/571) were female. Among children aged 12 years and older, 11% (9/82) were male and 89% (73/82) were female, which indicated the gender ratio of patients varies across the 2 age groups.

Figure 1. The workflow of sample collection. PED: pediatric emergency department.





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Table . Characteristics of children with acute pharmaceutical exposure admitted to the pediatric emergency department from 2019 to 2023 (N=653).

Demographic characteristics	Participants, n (%)
Sex	
Male	334 (51.1)
Female	319 (48.9)
Age group	
Infant	47 (7.2)
Toddler	253 (38.7)
Preschool	209 (32)
School age	62 (9.5)
Adolescence	82 (12.6)
Residence	
Urban	574 (87.9)
Rural	79 (12.1)
Exposure place	
Home	608 (93.1)
Others	45 (6.9)
Exposure time	
8 AM to 4 PM	231 (35.4)
4 PM to midnight	356 (54.5)
Midnight to 8 AM	66 (10.1)
Exposure season	
Spring	136 (20.8)
Summer	148 (22.7)
Autumn	175 (26.8)
Winter	194 (29.7)
Exposure reason	
Accidental	575 (88.1)
Intentional	78 (11.9)
Caregiver	
Parents	457 (70)
Grandparents	76 (11.6)
None	102 (15.6)
Others	18 (2.8)
Education level of caregiver	
High school or less	112 (17.1)
Undergraduate or vocational college degree	355 (54.4)
Master's degree or above	132 (20.2)
Unclear	54 (8.3)

Most pharmaceutical exposure incidents primarily occurred at home, with the peak period mainly occurring between 4 PM and midnight (356/653, 54.5%). Regarding seasonal variations, the number of children visiting the PED for acute pharmaceutical exposure was highest in winter. The primary caregivers at the time of exposure events were parents, and 54.4% (355/653) of

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XSL•FO RenderX the caregivers were college or undergraduates. In addition, analysis of the exposure reasons showed that 11.9% (78/653) were intentional, while the remaining 88.1% (575/653) were accidental. There were 208 poisoning cases (31.9%) resulting from acute pharmaceutical exposure, with 31.3% (65/208) being intentional and the remaining 68.7% (143/208) accidental. In

our study, the diagnostic criteria for drug poisoning include the presence of corresponding clinical manifestations, abnormal laboratory results indicating organ damage, or toxicology tests showing drug concentrations reaching toxic levels.

In terms of changes over time, the annual number of emergency visits due to acute pharmaceutical exposure fluctuated between 107 and 149 over the past 5 years, with a significant increase

in admissions in 2020 (Figure 2). The number of patients in other years did not show significant differences. This increase in the year 2020 may be attributed to prolonged home stays and heightened parental vigilance during the early stages of the pandemic, which led to more admissions related to acute pharmaceutical exposure. The annual proportion of admissions due to acute pharmaceutical exposure ranged from 0.05% to 0.13% of the total number of PED visits.

Figure 2. The annual number of pediatric patients with acute pharmaceutical exposure and its proportion in the total annual number of emergency department visits.



Types of Pharmaceutical Substances

In this study, the drugs involved in acute pharmaceutical exposure were categorized into 13 groups (Figure 3). Totally, vitamins emerged to be the most common in all patients (149/653, 22.8%), followed by NSAIDs (92/653, 14.1%; Table S1 in Multimedia Appendix 1). Notably, the proportion of

psychotropic drugs is also high (74/653, 11.3%), of which antidepressants accounted for 64.8% (48/74). Besides, cardiovascular drugs (mainly antihypertensive; 56/69, 81.2%) and endocrine drugs (mainly hypoglycemic agents; 11/31, 35.5%) are also common exposure substances (Table S1 in Multimedia Appendix 1).



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Figure 3. The distribution of pharmaceutical substances across different age groups.



Types of pharmaceutical substance

Furthermore, the types of pharmaceutical substances varied across different age groups. NSAIDs (10/47, 21.3%) and topical skin drugs (9/47, 19.1%) were the most common substance in infants. While in toddlers, cardiovascular drugs (44/253, 17.4%), vitamins (42/253, 16.6%), and NSAIDs (38/253, 15%) were more prevalent. Preschool and school-age children were most frequently exposed to vitamins, accounting for 34.4% (72/209) and 40.3% (25/62), respectively. In adolescents, psychiatric medications were the most common type (40/82, 48.8%), followed by NSAIDs (11/82, 13.4%; Table S1 in Multimedia Appendix 1). It is worth noting that there were 29 patients (29/653, 4.4%) involved in multiple drug exposures, and 46.4% (12/29) of them were adolescents.

While the pandemic may have slightly influenced the absolute number of admissions (Figure 2), it did not substantially alter underlying epidemiological trends of pediatric the pharmaceutical exposures (Table S2 in Multimedia Appendix 1). Analysis of the types of pharmaceutical substances across different year groups showed temporal fluctuations. For example, between 2020 and 2022, the proportion of neuropsychiatric drug exposure was higher compared with both 2019 and 2023. Conversely, during the pandemic, the proportion of respiratory system drug exposure was lower than before and

after the pandemic (5.7% vs 12.1% and 12.1%, respectively). However, the types of pharmaceutical substances involved remained largely consistent across these periods (chi-square test, P=.03; Table S2 in Multimedia Appendix 1).

Clinical Manifestations of Acute Pharmaceutical Exposure

In general, for the 631 patients with complete clinical manifestation data, 74.3% (469/631) did not exhibit obvious symptoms after acute pharmaceutical exposure, while the remaining patients showed one or more system involvements. For instance, 13% (82/631) of the patients showed the involvement of the gastrointestinal system, such as nausea, vomiting, abdominal pain, and diarrhea (Table 2). In total, 6.5% (41/631) of patients exhibited neurological symptoms like dizziness, drowsiness, and even coma in some severe cases; these children are mainly associated with excessive use of antidepressants and sedative overdoses. Cardiovascular symptoms were observed in 4.1% (26/631) of the children and manifested as pallor, sweating, and, in some severe cases, hypotension. In addition, multisystem involvement was noted in 9.5% (60/631) of the cases, and dermatological symptoms were observed in 1.4% (9/631) of the cases.



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Table . Clinical manifestations and the abnormal laboratory test results for children with acute pharmaceutical exposure.

Clinical manifestations (n=631)	Participants, n (%)
No symptom	469 (74.3)
Gastrointestinal symptoms	82 (13)
Neurological symptoms	41 (6.5)
Cardiovascular symptoms	26 (4.1)
Dermatological symptoms	9 (1.4)
Hematological symptoms	1 (0.2)
Multisystem symptoms (>2 systems)	60 (9.5)
Abnormal laboratory test results	
Routine blood test (n=435)	
WBC ^a >12×10 ⁹ /L	58 (13.3)
CRP ^b >8 mg/L	31 (7.1)
WBC $\leq 4 \times 10^9 / L$	16 (3.7)
PLT ^c <100×10 ⁹ /L	5 (1.1)
Coagulation function test (n=418)	
Abnormal coagulation index ($PT^d>20$ s or $APTT^e>50$ s or $FIB^f<2$ g/L)	32 (7.7)
Biochemical test (n=437)	
CKMB ^g >3.6 ng/mL	55 (12.6)
ALT ^h >40 U/L	22 (5.0)
Abnormal renal function (urea>7.1 mmol/L or CREA ⁱ >106 µmol/L)	7 (1.6)

^aWBC: white blood cell.
^bCRP: C-reactive protein.
^cPLT: platelet.
^dPT: prothrombin time.
^eAPTT: activated partial thromboplastin time.
^fFIB: fibrinogen.
^gCKMB: creatine kinase (CK)-MB.
^hALT: alanine transaminase.
ⁱCREA: creatinine.

In our study, the majority of patients underwent basic laboratory tests, including routine blood tests, biochemistry tests, and coagulation profiles tests. Among these tested populations, as shown in Table 2, the most frequent abnormalities were white blood cell count elevation (58/435, 13.3%) and myocardial enzyme elevation (55/437, 12.6%). Relatively, creatine kinase-MB was frequent in patients exposed to psychiatric drugs (14/49, 28.6%), cardiovascular drugs (10/38, 26.3%), and antimicrobial drugs (6/27, 22.2%; Table S3 in Multimedia Appendix 1). In the antimicrobial drugs exposure group, the proportion of elevated white blood cells and CRP is high (both are 7/26, 26.9%). In addition, in our study, 72 patients underwent toxicology screening, and the total positive rate was 69.4% (50/72); the positive results indicate drug concentrations exceeding therapeutic levels (Table S4 in Multimedia Appendix 1).

Clinical Interventions and Outcomes of Acute Pharmaceutical Exposure

Before admission, 3.5% (23/653) of the children received emetic treatment, and 1.2% (8/653) of them received drainage from their parents or other caregivers. However, most children with acute pharmaceutical exposure were asymptomatic or showed mild symptoms; 68.3% (446/653) of them did not need specific treatment (discharge after a short observation or without treatment), while the remaining patients received one or more clinical interventions. Gastric lavage was the main treatment strategy for drug removal (145/653, 22.2%), followed by specific antidotes (39/653, 6%) and activated charcoal (38/653, 5.8%). In this study, respiratory support was provided in 1.1% (7/653) of the admitted children when airway protection was necessary due to respiratory or circulatory failure. Extracorporeal techniques like continuous renal replacement therapy,

hemoperfusion, or plasma exchange were used in 0.8% (5/653) of the patients (Table 3).

Table . Clinical interventions and outcomes of patients with acute pharmaceutical exposure (n=653).

Clinical interventions	Participants, n (%)
No specific therapy	445 (68.1)
Gastric lavage	145 (22.2)
Specific antidotes	39 (6.0)
Activated charcoal	38 (5.8)
Induction of vomiting	23 (3.5)
Catharsis	8 (1.2)
Respiratory support	7 (1.1)
CRRT ^a /hemoperfusion/plasma exchange	5 (0.8)
Outcomes	
Discharge without treatment (<6 hours)	446 (68.3)
Emergency observation (≥6 hours)	177 (27.1)
Hospitalization	30 (4.6)

^aCRRT: continuous renal replacement therapy.

Comparison Between Intentional and Unintentional Acute Pharmaceutical Exposures

In this study, 11.9% (78/653) of the children experienced intentional acute drug exposure, with an average age of 13.6 years (Table 4). Of these, 88.5% (69/78) were female and 94.9% (74/78) had a history of depression. Psychotropic drugs were the most common pharmaceutical substances involved in exposure (42/78, 53.2%). In contrast, the average age for unintentional exposures was 3.3 years, with a relatively balanced

gender ratio. For unintentional exposures, vitamins were the most common pharmaceutical substances involved in exposure (125/575, 21.7%). In addition, among patients with intentional exposure, 26 underwent toxicology screening, with a positive rate of 92.3% (24/26), which is significantly higher than the unintentional exposure groups (26/46, 56.5%; P=.004). Intentional exposures resulted in more severe clinical outcomes, with a significantly higher hospitalization rate compared with unintentional exposures (20.5% vs 2.4%, $P=1.486 \times 10^{-8}$). Detailed information is provided in Table 4.



Table . Comparison of patients with intentional and unintentional acute pharmaceutical drug exposure.

Characteristics	Intentional exposure (n=78)	Unintentional exposure (n=575)	<i>P</i> value ^a
Age (years), mean (SD)	13.6 (1.6)	3.3 (2.2)	b
Gender, n (%)			<.001
Male	9 (11.5)	305 (53)	
Female	69 (88.5)	270 (47)	
Patients who were depressed, n (%)	74 (94.9)	0 (0)	
Toxicology screening ^c , n (%)			.004
Positive	24 (92.3)	26 (56.5)	
Negative	2 (7.7)	20 (43.5)	
Multisystem involvement, n (%)			<.001
Yes	22 (28.2)	38 (6.9)	
No	56 (71.8)	515 (93.1)	
Hospitalization, n (%)			<.001
Yes	16 (20.5)	14 (2.4)	
No	62 (79.5)	561 (97.6)	

 ${}^{a}P$ value was calculated with chi-square test, except for comparisons between different hospitalization outcomes, which were calculated with Fisher exact test.

^bNot applicable.

^cThe total number of patients with toxicology screening results was 72.

Factors Influencing Hospitalization for Acute Pharmaceutical Exposure

Univariate analysis indicated that gender, ages 12 - 18 years, multisystem involvement, psychiatric drugs, multiple drug exposures, and intentional exposure were significant risk factors for hospitalization (P<.01; Table 5). The hospitalization rate was significantly higher for females (25/319, 7.8%) compared with males (5/334, 1.5%), patients over 12 years (20/82, 24.4%) compared with those under 12 years (10/571, 1.8%), patients with multisystem symptoms (19/60, 31.7%) compared with

those without (11/593, 1.9%), psychiatric drug exposures (21/74, 28.4%) compared with other drugs (9/579, 1.6%), multiple drug exposures (7/29, 24.1%) compared with single drug exposures (23/624, 3.7%), and intentional poisoning (16/78, 20.5%) compared with accidental ingestion (14/575, 2.4%). For the variables that were significant in univariate analysis, further multivariate analysis was conducted. Further multivariate analysis showed that multisystem symptoms, psychiatric drug, and intentional exposure were independent risk factors for hospitalization (P<.01; Table 5).



Table. Univariate and multivariate logistic regression defined significant risk factors related with hospitalization for children with acute pharmaceutical exposure.

	Hospitalization, n Univar		Univariate analysis ^a	L	Multivariate analysi	is
	No	Yes	P value	Odds ratio (95% CI)	<i>P</i> value	Odds ratio (95% CI)
Sex			.001	5.614 (2.122 - 14.855)	.42	1.709 (0.467 - 6.258)
Female	294	25				
Male	329	5				
Age group (years)			<.001	18.065 (8.091 - 40.330)	.25	0.344 (0.056 - 2.104)
12 - 18	62	20				
<12	561	10				
Multisystem involve	ement		<.001	23.592 (10.522 - 52.897)	.002	4.575 (1.709 - 12.251)
Yes	41	19				
No	560	11				
Types of pharmaceu	tical substances		<.001	25.050 (10.923 - 57.451)	.001	6.280 (2.189 - 18.020)
Psychiatric drug	53	21				
Others	570	9				
Number of drugs			<.001	8.300 (3.220 - 21.398)	.10	2.825 (0.805 - 9.908)
Multiple drugs	22	7				
Single drug	601	23				
Intentional exposure	2		<.001	27.680 (11.439 - 66.980)	.004	12.892 (2.222 - 74.796)
Yes	62	16				
No	561	14				

^aFor univariate analysis, only variables with *P* value <.05 were shown in the table.

Discussion

Principal Findings

This study provides a retrospective analysis of 653 cases with acute pharmaceutical exposure from 2019 to 2023. Our results suggest that toddler and preschool-age groups are more likely to be exposed to drugs. This finding also aligns with Soave et al's [19] study, which reported an average age of 30 months for poisoned children, highlighting the vulnerability of this age group to drug exposure. Following exposure, most children exhibited no symptoms and did not require specific therapy. The most common manifestations were gastrointestinal symptoms, along with elevated white blood cell counts, which were the most frequent abnormal laboratory test results. We also found that multisystem symptoms, psychiatric drugs, and intentional poisoning were associated with hospitalization after acute pediatric pharmaceutical exposure. Notably, female adolescents with mental health issues were more likely to experience intentional exposure, and positive toxicology screening rate, multisystem involvement, and hospitalization incidence were higher in intentional poisoning group [20].

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Regarding regional distribution, this study reveals that 87.9% of the acute pharmaceutical exposure events occurred in urban areas, which could be attributed to the hospital's location. Research from different regions could show significant differences in the incidence and main types of poisoning in children. For example, studies in Zhejiang [7] and southwestern China [14] found poisoning was more common among rural children, with pesticides and insecticides being as the primary toxic substances. This difference may be due to the higher prevalence of agricultural activities and more frequent chemical use in these areas. In addition, 93.1% of pharmaceutical exposure in our study occurred at home, consistent with previous studies [21,22]. Urban families, especially those with young children, often stockpile medications for common illnesses, inadvertently increasing the likelihood of children accessing these drugs. This highlights the importance of safe storage practices at home. In addition, the peak times for exposure incidents were between 4 PM and midnight, likely due to lapses in parental supervision during this period, as children are more likely to access medications after school. Parents, who were the primary caregivers in 57.2% of cases, generally had a college or university degree, reflecting the central role of parents in our

studied area. Despite this, the frequency of pediatric drug exposure suggests a need for greater efforts in educating families about medication safety and preventive measures.

Various studies have indicated that psychiatric medications are commonly associated with acute poisoning in children. For instance, Vilaça et al [23] in Brazil found that anxiolytics (mainly benzodiazepines) were the primary drugs involved in poisoning, followed by analgesics. Anderson et al [24] in the United Kingdom reported that benzodiazepines accounted for 19% of poisoning cases, while Santiago et al [25] in Spain also found that benzodiazepines and detergents were the most commonly involved toxicants. These findings contrast with our results, where vitamins were the most common type of drug exposure, particularly among toddler, preschool and school-aged children. This discrepancy may be due to the fact that caregivers in our study population often keep vitamin supplements at home. However, these vitamins, often presented in candy or liquid form, can attract children and increase the risk of accidental ingestion. Caregivers tend to underestimate the risks associated with vitamins, considering them "harmless," even though high doses of certain vitamins (eg, vitamins A and D) can cause severe toxic reactions. Therefore, it is crucial to educate caregivers on the safe storage and proper use of vitamins. In the infant group, NSAID exposure was relatively high, aligns with other studies [23]. NSAIDs (eg, ibuprofen and acetaminophen) are commonly used to relieve fever and mild to moderate pain, and fever is prevalent among infants, leading to NSAIDs being a staple in homes. This increases the risk of accidental ingestion, with a significant proportion of infant exposure resulting from caregivers misusing doses, leading to overdose and poisoning incidents. In addition, our study also found that exposure events involving psychiatric medications, primarily antidepressants, were most common among adolescents.

It is also worth noting that 11.9% of the children were intentionally exposed to drugs, primarily among adolescents, with females accounting for 89% of this group. Intentional exposure typically involves larger doses or multiple drugs, resulting in more severe symptoms. Similar to previous studies [26,27], the rate of multiple drug ingestion was higher in adolescents, often linked to suicidal or self-harm intentions, reflecting the vulnerability of this age group to mental health issues. Studies from the United States, Singapore, Taiwan, Sri Lanka, and other regions [28-31] also indicate that adolescent girls face greater psychological and social pressures, making them more prone to emotional fluctuations and self-harm behaviors. Addressing intentional drug exposure requires strengthened psychological interventions and social support, especially mental health screening and intervention, to prevent poisoning incidents. Collaboration among schools, families, and society is crucial to help adolescents establish a healthy mental state. Furthermore, multivariate regression analysis identified psychiatric drug exposure, multisystem involvement, and intentional poisoning as key factors influencing hospitalization in children with acute drug exposure. Werner and Platt's study [32] in Brazil also showed that intentionality was associated with hospitalization. For these high-risk children, early identification, close monitoring, and proactive intervention

are essential to optimize treatment and reduce the severity and mortality of poisoning. More research is needed to refine and validate these factors to guide clinical practice and improve early management of acute drug poisoning.

In our study, most children exposed to drugs showed no clinical symptoms, indicating that many ingested drugs were in small doses or of lower toxicity. Symptoms, when present, primarily affected the digestive and nervous systems, followed by the circulatory system, with multisystem involvement in 9.5% of cases. This is consistent with a study in Chongqing, China [13]. Clinical manifestations in children are closely related to the type and dose of ingested drugs. Higher rates of involvement in the digestive, nervous, and circulatory systems are mainly due to the accidental ingestion of NSAIDs, psychiatric medications, and antihypertensive drugs, which are more likely to cause significant clinical symptoms. Laboratory tests are crucial for diagnosing and guiding treatment in children with acute pharmaceutical exposure. In this study, the majority of the children underwent laboratory tests, with common abnormal results including elevated white blood cell counts and myocardial enzymes. The former likely reflects an inflammatory response rather than an adverse drug reaction. Elevated myocardial enzymes suggest potential myocardial damage from acute drug poisoning, particularly with nervous system drugs, antihypertensive drugs, and NSAIDs [33,34], indicating these drugs have a higher likelihood of causing myocardial damage. In addition, some children exhibited coagulation abnormalities, while liver enzyme and kidney function abnormalities were relatively low, suggesting a lower risk of liver and kidney damage in this study. The study also found that almost all asymptomatic children had normal laboratory results, consistent with Wang et al's [35] study in the United States, which found positive results in extensive screening no and electrocardiography tests for asymptomatic children aged 12 years or younger. Therefore, the necessity of these tests in asymptomatic children with accidental drug overdoses remains debatable.

Clinical interventions for suspected drug poisoning include detoxification; specific antidotes; and, in severe cases, extracorporeal techniques such as continuous renal replacement therapy, hemoperfusion, and plasma exchange. However, only 0.8% of patients required these advanced treatments. Managing acute drug exposure in children necessitates a comprehensive approach, considering factors such as toxin type, ingestion time, dosage, clinical symptoms, and laboratory results. Toxicology screening, performed in 11% of cases with a 69.4% positive rate, is essential for identifying toxins and assessing the severity of exposure. Studies have shown that toxicology results can optimize treatment plans, preventing both overtreatment and undertreatment [36]. Despite this, 68.1% of children did not require specific treatment, suggesting a potential overuse of emergency services. Improving parental education and raising public awareness of the risks associated with drug exposure could help reduce unnecessary visits to the emergency department and optimize resource allocation. Most children with mild or no symptoms can be safely managed at home with proper guidance, while moderate to severe cases require medical observation or hospitalization. The average cost of a pediatric

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emergency department visit, including laboratory tests, ranges from ¥1000 to ¥3000 (approximately US \$140-US \$420), placing a financial burden on families and straining hospital resources. This inefficiency may also contribute to delays in care for critically ill patients.

Generally, preventing accidental drug exposure in children is crucial for reducing poisoning incidents, easing emergency department pressure, and optimizing pediatric medical resource use. Families should store medications out of children's reach, preferably in locked cabinets, and avoid placing them in common areas like kitchens and bedrooms. Parents should also refrain from taking or handling medications in front of children to prevent curiosity and mimicry [37]. In addition, caregivers should be educated on recognizing early symptoms of poisoning and proper emergency response methods. Child-resistant packaging should be used to minimize the risk of accidental openings [38]. Public health departments should promote medication safety through community activities, brochures, and media campaigns. Schools should incorporate medication safety into health education curricula to teach children about proper medication use and potential dangers from an early age [39]. A comprehensive, multifaceted approach is essential to reducing unnecessary pediatric poisonings from pharmaceutical exposure.

Limitations

This study has several limitations. First, its single-center design limits the generalizability of the results, and multicenter studies are needed to validate these findings. Second, additional follow-up data are required to explore the long-term effects of pharmaceutical toxic exposures in children. Third, factors such as family health issues, dietary habits, and the pandemic-related lockdown measures were not considered in detail. The increased exposure to neuropsychiatric drugs may be linked to the significant rise in psychological stress faced by children and adolescents during the COVID-19 pandemic. Factors such as prolonged isolation, internet-based learning, and reduced social interactions likely contributed to a surge in anxiety, depression, and other mental health issues, which, in turn, increased the use and exposure to neuropsychiatric drugs. The preventive measures implemented during the pandemic, such as mask-wearing, social distancing, and limited outdoor activities, may have effectively reduced the transmission of respiratory infections, resulting in a decreased incidence of pediatric respiratory diseases and a significant reduction in respiratory drug exposure. Despite these limitations, our study provides valuable insights into the occurrence and outcomes of acute pharmaceutical exposures in children in recent years. Future research with larger sample sizes, longer time spans, and more follow-up data will allow for more comprehensive comparative analysis.

Conclusions

In conclusion, our study offers valuable insights into the epidemiological characteristics and clinical presentations of children with acute drug exposure. It also emphasizes the importance of ongoing education and preventive measures to reduce the risk of drug poisoning in children and optimize the use of emergency medical resources.

Acknowledgments

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Data Availability

The dataset analyzed during this study is not publicly available but could be available from the corresponding author upon reasonable request and with permission of Capital Center for Children's Health, Capital Medical University, by sending a request to the corresponding author.

Authors' Contributions

LYG and conceptualized the study and reviewed the manuscript. ZYD, YNQ, and SZ collected data, performed the analyses, and wrote the manuscript. JTL supervised data collection and data analyses. RT, HW, MYS, and LLW collected and preprocessed data. SL and JL revised the manuscript. All authors approved the final manuscript as submitted.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Supplementary materials on different types of pharmaceutical exposure in different age groups, the distribution of pharmaceutical substances in different year groups, abnormal laboratory test results in different pharmaceutical exposure groups, and positive toxicology screening results in different pharmaceutical exposure groups. [DOCX File, 34 KB - pediatrics_v8i1e66951_app1.docx]

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Abbreviations

NSAID: nonsteroidal anti-inflammatory drug OR: odds ratio PED: pediatric emergency department WHO: World Health Organization

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Original Paper

Efficacy, Feasibility, and Acceptability of an Emotional Competence Tele-Intervention for Mandarin-Speaking Children Aged 5 to 7 Years With Developmental Language Disorder: Pilot Study With an Interrupted Time-Series Design

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Abstract

Background: Children with developmental language disorder (DLD) often experience language difficulties that hinder their ability to acquire emotional competence. Poor emotional competence is associated with emotional and behavioral problems in young children.

Objective: This research involved two studies focusing on (1) the emotional competence of Mandarin-speaking children aged 5 to 7 years with DLD and (2) the efficacy, feasibility, and acceptability of a tele-intervention designed to enhance their emotional competence in Taiwan.

Methods: Five children with DLD from study 1 declined to participate in study 2, the emotional competence tele-intervention, and were excluded from the analysis. We compared the emotional competence of 20 Mandarin-speaking children with DLD to that of 24 children with typical language development (TLD). The children with DLD were, on average, aged 5.79 (SD 0.47) years, whereas the children with TLD were, on average, aged 5.93 (SD 0.31) years. We assessed the children's emotional competence, nonverbal ability, verbal comprehension, vocabulary acquisition, and expressive language skills. In study 2, all children with DLD included in study 1 engaged in an emotional competence tele-intervention. An interrupted time-series design was used to examine their emotional competence. In total, 20 children with DLD provided data on emotional competence evaluated using the Emotional Lexicon Test. These data were individually collected at 3 time points after study 1 (time 1). These phases included baseline (time 1 to time 2), during the tele-intervention (time 2 to time 3), and follow-up (time 3 to time 4), spanning approximately 18 to 20 weeks from time 1 to time 4. Recruitment, retention, and attendance rates were calculated to evaluate the intervention's feasibility, and participant mood was evaluated after each session to calculate the intervention's acceptability.

Results: No significant changes in the children's ability to understand basic or complex emotional terms were observed during the baseline period. However, changes were observed during the tele-intervention period, and these changes remained throughout the follow-up period. With a recruitment rate of 80% (20/25), all participants completed 4 intervention sessions, with retention and attendance rates exceeding 95% (19/20). A total of 90% (18/20) of the participants deemed each session to be acceptable.

Conclusions: Mandarin-speaking children aged 5 to 7 years with DLD exhibited lower emotional competence compared with their counterparts with TLD. Tele-interventions are effective in enhancing the emotional competence of children with DLD, demonstrating feasibility and acceptability for these children and their parents in Taiwan.

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KEYWORDS

language disorder; pediatrics; evidence-based intervention; telemedicine; tele-practice; visual support; mobile phone

Introduction

Background

According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) [1], language disorder (ie, developmental language disorder [DLD]) is a communication disorder that broadly refers to childhood language difficulties and is not associated with any known biomedical condition [2,3]. These language difficulties can hinder children's acquisition of emotional competence, including their understanding of the nature and causes of emotions, their own feelings, their physiological reactions to these feelings, and their cognition surrounding an emotion or emotive event [4-7]. Language is strongly associated with emotional competence, as evidenced in our use of prosody to interpret emotional cues, recognize emotions, and understand what others may feel in various situations [8]. When children experience communication difficulties, their opportunities for social learning diminish, making conversations harder to process, misunderstandings more likely, and participation in discussions or play activities more challenging, which can, in turn, hinder their emotional competence [9]. Language also provides access to mental terms such as think and happy, which help children mentalize and help them identify, understand, express, and regulate their emotions [10]. These capabilities facilitate social interactions and indirectly aid in understanding the mental states of others [11]. Therefore, children with language acquisition difficulties tend to struggle with using these mental terms to learn the emotional or cognitive aspects of theory of mind. Notably, verbal interactions with caregivers play a key role in the development of emotion regulation skills, primarily because discussing emotions helps children connect their emotions to events and learn how to manage these emotions [12]. As children with DLD grow, they struggle to develop the capacity to internally regulate their emotions, with language playing a crucial role in self-reflection, response inhibition, and guiding behavior [13]. Furthermore, in young children with typical language development (TLD), poor emotional competence has been shown to be associated with emotional and behavioral problems [14].

Previous research examining the emotional competence of children with DLD and children with TLD has rarely focused on children who speak Mandarin as their native language [4,11,15]. If studies indicate that the emotional competence of Mandarin-speaking children with DLD lags behind that of their peers with TLD, as is the case for non–Mandarin-speaking children with DLD, this finding will support the presence of cross-linguistic and cross-cultural consistency in the emotional challenges faced by children with DLD. In children with developmental delays, speech and language delays are the most common disabilities [16]. DLD is a highly prevalent neurodevelopmental disability in Mandarin-speaking children [17,18], highlighting the importance of focusing on the emotional competence of this population. Therefore, further research is needed to evaluate the emotional competence of

Mandarin-speaking children with DLD and determine whether early intervention is necessary.

Tele-interventions constitute a promising tool that offers a timely, accessible, and cost-effective solution for overcoming barriers to medical service delivery, such as transportation issues, shortage of skilled therapists, and insufficient facilities in rural areas [19]. This approach is particularly significant given that the special needs of children with DLD living in rural areas are often less adequately addressed than those of children living in urban areas [20]. Adopting tele-practice for early interventions holds great potential to address these disparities and support the development of emotional competence in children with DLD in underserved rural areas [19]. In Taiwan, the procedures, advantages, and challenges associated with implementing such interventions remain unclear. Therefore, in this study, we examined the efficacy, feasibility, and acceptability of emotional competence tele-interventions designed for Mandarin-speaking children with DLD in Taiwan.

Multiple studies have indicated that social stories are an effective means to help children acquire emotional knowledge [21-23]. Social stories have been widely used in clinical practice for children with autism spectrum disorder (ASD) [24]; however, the application of these stories for children with DLD remain understudied. To the best of our knowledge, few studies have focused on children with pragmatic language impairments [25], language impairments [26], and pragmatic disorders with behavioral difficulties [24]. Among the key factors that contribute to the efficacy of a social story is the display of the protagonist's emotional state and social interactions [27], along with labeling affective, physical, and perceptual changes with words describing the protagonist's mental state. These labels help children understand that different experiences can fulfill the same function as long as these experiences are perceived as having the same meaning [28]. The use of visual aids such as pictures or videos can enhance the emotional representation of potential causes, subjective feelings, physiological responses, and cognition during social interactions [29]. Thought bubbles can also be used to clarify the protagonist's emotional state and thoughts within the social context [30,31]. Hence, emotional competence interventions conducted using social stories through remote interfaces, also referred to as social story tele-interventions (SSTIs), are expected to enhance the emotional competence of children with DLD.

Objectives

Preschool and early elementary school are critical periods in the development of a child's emotional competence; the child learns about self-regulation, and their level of emotional competence determines the severity and likelihood of behavioral problems [32,33]. In this research, we examined children in kindergarten and early elementary school. A total of 2 studies were conducted to explore 3 research questions. In study 1, our goal was to determine whether Mandarin-speaking children with DLD in Taiwan differ from those with TLD in emotional competence. We compared Mandarin-speaking children with

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DLD to those with TLD in terms of the size and depth of their understanding of emotional terms at the ages of 5 to 7 years. We hypothesized that Mandarin-speaking children aged 5 to 7 years with DLD would exhibit lower performance in the size and depth of their understanding of emotional terms compared with their counterparts with TLD even with family language characteristics such as maternal educational level accounted for. In study 2, we used an interrupted time-series design to explore two questions: (1) Do SSTIs enhance the understanding of emotional language by Mandarin-speaking children aged 5 to 7 years with DLD relative to their baseline performance (ie, before the intervention)? (2) Are SSTIs a feasible and acceptable intervention for these children in Taiwan? We hypothesized that SSTIs would enhance the emotional competence of Mandarin-speaking children aged 5 to 7 years with DLD and that this tele-intervention would be both feasible and acceptable for them and their parents in Taiwan.

Study 1

Methods

This case-control study was conducted to compare the emotional competence of children with DLD to that of children with TLD.

Participants

A total of 99 children aged 5 to 7 years were recruited from parenting websites and local pediatric clinics in northern and central Taiwan. Figure 1 shows the process of recruitment in study 1. Children with DLD meeting the following matching criteria were included in the study: being within 3 months of the specified age range, having Mandarin Chinese as their native language, and being of the same sex as their matched counterparts. If >1 participant with TLD met these criteria and could be matched with a participant with DLD, they were all included in the analysis. A total of 48 participants with TLD who did not meet the aforementioned criteria and who completed only the in-person evaluation at the preintervention 1 time point (time 1) were excluded from the final analysis. In addition, 2 participants with only a history of late talking who also completed only the in-person evaluation at the preintervention 1 time point (time 1) were excluded from the final analysis. A total of 5 parents refused to participate in the subsequent tele-intervention program. Therefore, of a total of 25 parents of children with DLD, only 20 (80%) participated. Furthermore, ultimately, 44 children were included in the final analysis in study 1: 20 (45%) in the DLD group (mean age 5.79, SD 0.47 years) and 24 (55%) in the TLD group (mean age 5.93, SD 0.31 years).



Figure 1. Flowchart of study 1 and study 2. CLDS-R: Child Language Disorder Scale–Revised; DLD: developmental language disorder; EL: expressive language; ELT: Emotional Lexicon Test; NVI: Nonverbal Index; POST-1: postintervention time point 1; POST-2: postintervention time point 2; PRE-1: preintervention time point 1; PRE-2: preintervention time point 2; SSTI: social story tele-intervention; TLD: typical language development; VAI: Vocabulary Acquisition Index; VCI: Verbal Comprehension Index; WPPSI-IV: Wechsler Preschool and Primary Scale of Intelligence, Fourth Edition.



All participants with DLD had received a diagnosis based on the *DSM-5* criteria at the Early Developmental Evaluation Center, the official institution designated by the Ministry of Health and Welfare of Taiwan for identifying and evaluating children with developmental disorders before the age of 7 years. In Taiwan, the gold standard for diagnosing DLD requires confirmation through a converging evidence approach [34],

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which includes the assessment of delays in receptive and expressive language by board-certified speech and language pathologists using parental reports, standardized tests, and clinical observations. Clinical psychologists are required to confirm the absence of cognitive delays, and child psychiatrists and pediatric neurologists are required to determine whether any observed language delays are due to other

neurodevelopmental (eg, ASD) or neurological (eg, epilepsy) disorders. Establishing a DLD diagnosis through a converging evidence approach in clinical assessments and decision-making scenarios by medical professionals should be considered the gold standard. Participants with TLD had no known developmental or cognitive impairments.

Measurement

Family Characteristics

Data on family characteristics, including paternal and maternal mean age, paternal educational level and marital status, monthly family income, and number of siblings of the child participant, were collected from parent reports.

Child Characteristics

Data on child characteristics, including age, sex, developmental risk factors, and medical diagnoses, were also collected from parent reports. To confirm that the children met the inclusion criteria, their parents provided an early intervention assessment report issued by the Ministry of Health and Welfare. Among the developmental risk factors considered in this study were biological factors (eg, premature birth, low birth weight, genetic disorders, perinatal complications, and neurological conditions) and medical factors (eg, chronic diseases, infectious diseases, and hearing or vision impairments).

Evaluation of Nonverbal Ability

Nonverbal ability was measured using the Mandarin Chinese version of the Nonverbal Index (NVI) of the Wechsler Preschool and Primary Scale of Intelligence, Fourth Edition [35]. The NVI has an internal consistency reliability of 0.94 to 0.96 across various age groups and a test-retest reliability of 0.85 [35].

Evaluation of Language Abilities

A total of 3 dimensions of language abilities were evaluated: verbal comprehension, vocabulary acquisition, and linguistic expressivity. Verbal comprehension and vocabulary acquisition were evaluated using the Mandarin Chinese versions of the Verbal Comprehension Index (VCI) and Vocabulary Acquisition Index (VAI), respectively, of the Wechsler Preschool and Primary Scale of Intelligence, Fourth Edition [35]. The VCI and VAI have internal consistency reliability levels of 0.92 to 0.94 and 0.84 to 0.92, respectively, and both have a test-retest reliability of 0.86 [35]. Expressive language ability was evaluated using the Mandarin Chinese version of the Child Language Disorder Scale-Revised (CLDS-R) [36]. This subscale evaluates expressive language skills across multiple domains. These domains include (1) the ability to retrieve vocabulary or construct short phrases or sentences in response to questions that evaluate knowledge (eg, functions, general information, and analogies) acquired in the classroom and from one's lived environment; (2) phonological working memory, measured through sentence repetition tasks in which children verbally recall sentences of increasing length and grammatical complexity; and (3) narrative skills, evaluated through spontaneous image description and story retelling tasks with or without the aid of sequenced images. The internal consistency reliability of each CLDS-R subscale across different age groups



Evaluation of Emotional Competence

Emotional competence was evaluated using 2 subscales from the Emotional Lexicon Test (ELT) [37]: a depth subscale and a size subscale. Illustrations were drawn without displaying the facial expression of the protagonist to avoid influencing the children's responses. The depth subscale was used to evaluate the depth of understanding of basic emotional terms (BETs) and complex emotional terms (CETs). After the examiner read a story, they asked each child to label the emotional state of the protagonist and state the reasons underlying their responses (ie, explain the reasons underlying the protagonist's feelings in this context). This subscale evaluates the ability of children to retrieve emotional terms through a recall mechanism. Responses are rated depending on their quality on a scale with end points from 0 to 2, reflecting the varying degrees of children's understanding of emotional terms. In terms of interrater reliability, this subscale was evaluated by 2 raters, who reported a 95% agreement. Discrepancies in scores were discussed by the 2 raters to reach a consensus. The size subscale was used to evaluate the size of BETs and CETs. After the examiner read a story, they asked each child to determine which of 2 emotional state terms (eg, joyful vs fearful, scared vs ashamed, and delighted vs sad) better described the protagonist's emotional state. This subscale evaluates the ability of children to recognize emotional terms through a recognition mechanism. Each correct recognition response is assigned a score of 1 point, indicating the size of the child's emotional lexicon. These 2 subscales have been adopted in other emotional lexicon tests [38]. Each subscale consists of 14 cards with short illustrated stories, of which 6 feature basic emotions (joy, sadness, happiness, anger, fear, and disgust) and 8 feature complex emotions (shame, contempt, guilt, hate, envy, jealousy, pride, and loneliness). Hence, the scores on the depth subscale range from 0 to 28 points, and the scores on the size subscale range from 0 to 14 points. Each item in the ELT includes images to convey the story content, which in turn reduces the semantic comprehension load of the participating child. In this study, before the formal items were used, 2 questions and 1 example item were presented to determine whether the children could match the images with the oral content, indicating their understanding of the story. ELT has an adequate to high internal consistency (0.70-0.71) for CETs [39]. Its criterion-related validity scores with the Metacognitive Vocabulary Test and Peabody Picture Vocabulary Test–Revised are 0.80 and 0.74, respectively [40]. In addition, both hard- and soft-copy versions of the ELT were used. The hard-copy version was used for in-person evaluations, whereas the soft-copy version was used for tele-evaluations.

Procedure

After the children arrived at the laboratory with their parents, all parents were informed of the research procedures. All children successfully completed the 2 questions and 1 example item before the administration of the ELT proper, indicating their understanding of the story. All tests were conducted by licensed clinical psychologists and graduate students trained in child psychological assessment.

Ethical Considerations

The study design was approved by the institutional review board of Chung Shan Medical University Hospital in Taiwan (CS2-19046). During the in-person evaluation phase at the preintervention 1 time point (time 1), the researchers outlined the following: (1) study purpose, (2) data handling procedures, (3) privacy measures, and (4) participant rights, including the voluntary nature of participation and withdrawal options. All parents understood and provided their informed consent. This study was conducted in accordance with relevant guidelines and regulations for human participants. Privacy measures included secure data storage with access restricted to research team members only.

Data Analysis

Separate analyses of covariance (ANCOVAs) were conducted to determine the differences in the NVI, VCI, VAI, and linguistic expressivity scores between the 2 groups, with family characteristics used as a covariate. Chi-square and Fisher exact tests were used to compare group proportions with qualitative data for family characteristics (ie, parental educational level and marital status, monthly family income, and whether the child participant had siblings) and child characteristics (ie, sex and presence of developmental risk factors). In addition, a 3-way mixed-model multivariate ANCOVA was conducted, with group (TLD vs DLD) used as the between-group independent variable and emotion (basic vs complex) and understanding (size vs depth) used as the within-group independent variables, with maternal educational level used as a covariate. In case a statistically significant 3-way interaction was observed among group, emotion, and understanding, the simple main effects between TLD and DLD were examined. Effect sizes from ANCOVAs were calculated using the partial η_p^2 , which could be directly translated into a percentage of explained variance. Using the basic framework by Cohen [41], we interpreted these

effect sizes as small ($\eta_p^2=0.01$), moderate ($\eta_p^2=0.06$), or large ($\eta_p^2=0.15$). We also conducted a post hoc power analysis for ANCOVAs using G*Power (version 3.1.5) for a sample size of 44 participants, with $\alpha=.05$ [42]. Post hoc power values of >0.8, between 0.6 and 0.8, and <0.6 were considered high, moderate, and low, respectively. All statistical analyses were conducted using SPSS Statistics (version 25.0; IBM Corp).

Results

Participant Characteristics

Table 1 presents the characteristics of the children and their parents in the TLD and DLD groups. Compared with the TLD group, the DLD group had a lower maternal educational level (N=44, χ^2_1 =5.4, *P*=.04). Previous studies have found that mothers' educational level is related to children's social, emotional, and academic development [43]. Therefore, we controlled for this variable when conducting the ANCOVAs. However, no differences were observed between the 2 groups (*P*>.05) in terms of child characteristics (ie, mean age, sex, and risk factors) and family characteristics (ie, paternal and maternal mean age, paternal educational level and marital status, monthly family income, and whether the child participant had siblings).

Table 2 presents the NVI, VCI, VAI, and oral expression scores of the TLD and DLD groups during the evaluation at the preintervention 1 time point. No significant difference was observed in the NVI between the 2 groups (*P*>.05), as indicated by the ANCOVA results. However, compared with the TLD group, the DLD group exhibited significantly lower levels of verbal comprehension, vocabulary acquisition, and linguistic expressivity ($F_{I, 4I}$ =17.20, 11.89, and 10.91, respectively; *P*<.001, *P*=.001, and *P*=.002, respectively; η_p^2 =0.30, 0.23, and 0.21, respectively; power=0.99, 0.94, and 0.92, respectively).



Table 1. Characteristics of the children and their parents.a

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Variable	TLD ^b (n=24)	DLD ^c (n=20)	P value
Child's age (y), mean (SD)	5.93 (0.31)	5.79 (0.47)	.26
Father's age (y), mean (SD)	40.58 (4.72)	42.05 (5.16)	.34
Mother's age (y), mean (SD)	37.54 (3.75)	39.65 (4.20)	.09
Child characteristics, n (%)			
Sex			.76
Male	17 (71)	15 (75)	
Female	7 (29)	5 (25)	
Developmental risk factors			.15
Yes	13 (54)	15 (75)	
No	11 (46)	5 (25)	
Family characteristics, n (%)			
Father's educational level			>.99
Below university level	3 (12)	3 (15)	
At or above university level	21 (88)	17 (85)	
Mother's educational level			.04
Below university level	1 (4)	6 (30)	
At or above university level	23 (96)	14 (70)	
Parents married and living together			>.99
Yes	22 (92)	17 (85)	
No	2 (8)	3 (15)	
Monthly family income			.14
<nt \$<sup="">d 59,999 (US \$1821.35)</nt>	10 (42)	13 (65)	
≥NT \$ 60,000 (US \$1821.38)	14 (58)	7 (35)	
Child participants having siblings			.50
Yes	8 (33)	4 (20)	
No	16 (67)	16 (80)	

^aAll P values were obtained from ANOVAs or chi-square or Fisher exact tests.

^bTLD: typical language development.

^cDLD: developmental language disorder.



Variable	TLD ^b (n=24), mean (SD)	DLD ^c (n=20), mean (SD)	P value
NVI ^d (CS ^e)	103.71 (9.14)	98.15 (14.79)	.23
VCI ^f (CS)	112.83 (12.67)	93.65 (15.52)	<.001
VAI ^g (CS)	111.63 (11.21)	96.55 (13.92)	.001
$\mathrm{EL}^{\mathrm{h}}(z \operatorname{score})^{\mathrm{i}}$	-0.08 (0.90)	-0.97 (0.61)	.002

Table 2. Nonverbal and language abilities of the participants^a.

^aAll *P* values were obtained from analyses of covariance.

^bTLD: typical language development.

^cDLD: developmental language disorder.

^dNVI: Nonverbal Index.

^eCS: composite score of the Wechsler Preschool and Primary Scale of Intelligence, Fourth Edition, Chinese version.

^fVCI: Verbal Comprehension Index.

^gVAI: Vocabulary Acquisition Index.

^hEL: expressive language.

 ^{i}z score of the Child Language Disorder Scale–Revised, Chinese version.

Emotional Competence Among Children With TLD and DLD

Figure 2 illustrates the size and depth of understanding of BETs and CETs for the TLD and DLD groups during the evaluation at the preintervention 1 time point. It also shows the main effects of emotion (Wilks $\lambda_{1, 41}$ =34.17; *P*<.001; η_p^2 =0.45; power=0.99) and understanding (Wilks $\lambda_{1, 41}$ =72.97; *P*<.001; η_p^2 =0.64; power=0.99). A post hoc analysis revealed that BETs outperformed CETs (*P*<.001), with the number of recognized

emotional terms being greater than that of recalled emotional terms (*P*<.001). A statistically significant 3-way interaction was observed among group, emotion, and understanding (Wilks $\lambda_{1,41}$ =12.39; *P*=.001; η_p^2 =0.23; power=0.66). Simple-simple main effect analysis revealed that the DLD group scored lower than the TLD group in terms of the depth of understanding of BETs and the size and depth of understanding of CETs (*F*_{1,164}=37.20, 11.48, and 6.54, respectively; *P*<.001, *P*<.001, and *P*=.01, respectively; η_p^2 =0.18, 0.07, and 0.04, respectively; power=0.86, 0.43, and 0.26, respectively).

Figure 2. Mean rate of correct answers for basic emotional terms (BETs) and complex emotional terms (CETs) for the typical language development (TLD) and developmental language disorder (DLD) groups during the evaluation at preintervention time point 1 (time 1). The vertical lines represent error bars with 1 SD. The asterisks indicate the significant simple main effects of group, revealing a higher mean rate of correct answers for the TLD group than for the DLD group. **P<.001.



Discussion

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Principal Findings

Few studies have compared the emotional competence of Mandarin-speaking children with DLD to that of children with TLD. In this study, we controlled for child and family

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characteristics in our research design and statistical analysis while comparing children with DLD and TLD. This approach increased the validity of our findings, indicating a lag between children with DLD and those with TLD in terms of emotional competence. It also enhanced the validity of study 2, which

examined the improvement observed in emotional competence among children with DLD after undergoing a tele-intervention.

The size of understanding of BETs among children aged 5 to 7 years with DLD was similar to that among their counterparts with TLD, indicating that children with DLD can understand basic emotional states in typical social scenarios. However, the depth of understanding of BETs among children aged 5 to 7 years with DLD was considerably lower than that among their counterparts with TLD, indicating that the ability of children with DLD to express their emotions through BETs may be limited. In addition, children with DLD were slower in understanding CETs compared with children with TLD in kindergarten and early elementary school years, indicating the delayed development and mastery of such concepts. Overall, our findings are consistent with those of previous studies [5-7,14,44] indicating that Mandarin-speaking children with DLD also exhibit impaired emotional competence. These findings suggest that the lag observed in emotional competence in children with DLD is a universal characteristic across countries and ethnic groups [45]. These findings underscore the importance of early interventions in improving their conceptual knowledge of emotional states.

In this study, children with DLD exhibited language functioning within the low but normal range, although their scores were lower than those of their peers with TLD. The study explored whether these children experienced delays in their lexical, grammatical, or articulatory development. In study 1, all children had been diagnosed with DLD in accordance with DSM-5 criteria at the Early Developmental Evaluation Center, an institution designated by the Ministry of Health and Welfare of Taiwan to evaluate developmental disorders in children aged <7 years. Diagnosing DLD through clinical assessments with a converging evidence approach for clinical decision-making is regarded as the gold standard in Taiwan. In this approach, no single method serves as the deciding factor in making diagnostic decisions regarding the receptive and expressive language skills of individuals with DLD. Converging evidence refers to the concept that multiple pieces of assessment data must align and point in the same direction to support a diagnostic decision [34]. In specific test areas, the cutoff score may vary to maximize sensitivity and specificity in identifying those who are at a high risk of developmental problems. Nevertheless, no consensus has been reached regarding the cutoff values for the VCI, the VAI, and the CLDS-R expressive language subscale required for determining whether a child has DLD. In this study, the VCI, the VAI, and the CLDS-R expressive language subscale were used only to evaluate the language capabilities of children with DLD and compare them to those of children with TLD. Our goal was to determine whether the language capabilities of children with DLD lagged behind those of children with TLD, unlike nonverbal capabilities, for which no differences were observed between the 2 groups. Notably, we did not use the VCI, the VAI, or the CLDS-R expressive language subscale for diagnostic purposes in this study.

According to Bishop [46], DLD involves heterogeneous language features. In this study, we examined only the verbal comprehension, vocabulary acquisition, and expressive language capabilities of children with DLD and did not evaluate their

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speech perception, phonological awareness, or understanding and use of grammar. Therefore, we could not confirm whether children with DLD lag in these language dimensions. In addition, no consensus has yet been reached regarding the definition of DLD in terms of whether receptive or expressive language should be scored at a threshold of <1 or 1.5 SDs in standardized language tests [47]. Of a total of 20 children with DLD, 6 (30%) had received physical therapy, 19 (95%) had received occupational therapy, 18 (90%) had received speech therapy, and 6 (30%) had received psychological therapy, indicating that these children continually underwent systematic structured interventions implemented by medical and professionals to optimize their development during sensitive periods [48-50]. Therefore, although DLD can be qualitatively defined in accordance with the DSM-5 [1] in medical and research contexts, no consensus has yet been established regarding its quantitative definition, including which tests to conduct and which cutoff criteria to apply. Furthermore, each quantitative definition may have unique implications for specific contexts in different countries or cultures, presumably reflecting the use of different measurement tools and cultural perspectives on children's development and delays [51]. Bishop [46] emphasized the importance of establishing a consensus regarding the quantitative definition of DLD to facilitate cross-linguistic and cross-cultural comparisons of the characteristics, developmental changes, and emotional competence of children with DLD over time.

Conclusions

In this study, low power values were observed for the simple-simple main effects of the size and depth of understanding of CETs. According to Ryou et al [52], a lower power value indicates a higher risk of a type II error, also referred to as a false negative, in which a statistical test does not call for the rejection of the null hypothesis when the alternative hypothesis is true. However, our group comparisons for the size and depth of understanding of CETs were significant, with moderate effect sizes. These comparisons mitigated the risk of type II errors in comparison to scenarios in which group differences were not significant. Therefore, increasing the sample size in future studies may aid in achieving more robust results.

Study 2

Methods

In this study, we used a prospective 1-group interrupted time-series research design situated within the context of a response-to-intervention instructional framework [53]. This study comprised a baseline phase, a tele-intervention phase, and a follow-up phase.

Participants

The same 20 children with DLD who participated in study 1 were included in study 2.

SSTI Characteristics

Intervention Sessions

This 6-week emotional competence tele-intervention comprised 2 sessions for parents (first and sixth sessions) and 4 sessions

for children (second to fifth sessions). In the first parent session, the mechanism of SSTIs designed for children to acquire emotional competence skills was introduced, whereas in the last parent session, the SSTIs and children's emotional competence skills acquired during the sessions and on a daily basis were reviewed. No home practice was offered after the 2 parent sessions, and no children were involved in these sessions. Each child's session included the presence of their parents and comprised the following elements: (1) a parent-child interactive game, that is, the finger trap game; (2) a 4-panel physical story comic; (3) a social story video (Multimedia Appendix 1) played for the participating child 3 times; and (4) a talk practice (retelling, prompting, self-narration, and imitation).

In the finger trap game, each parent places their palm facing down, and each child places their index finger underneath their parent's palm. Once a specific word (eg, *three*) is presented in a series of words (eg, *three, four, six, two, three...*), the parent attempts to rapidly close their open palm to catch the child's finger. Two 4-panel physical story comics are presented. The first comic, used in the first and second child sessions, depicts a balloon being blown away by the wind, floating up into a tree,

getting caught on a branch, and popping. The second comic, used in the third and fourth child sessions, depicts a clear, sunny day that later turns cloudy and then rains heavily.

The themes and language content of these intervention sessions corresponded to the titles of 4 researcher-edited social story videos, namely, "Great with others," "Play game," "Grab a toy," and "Give a gift." In these social story videos, external causes lead the protagonist to have an emotional experience. The social stories developed in this study included 4 types of mental state terms: cognitive state terms such as know; desire state terms such as *want*; perceptual state terms such as *feel*; and basic emotional state terms such as *happy*, *sad*, *angry*, and *fear* [54]. Table 3 presents the mental state terms and their frequencies in each social story. Thought bubbles are used to display the beliefs, desires, intentions, knowledge, and moods of the story's protagonist as they arise from the interpretation of environmental cues (Multimedia Appendix 1). As shown in Multimedia Appendix 1, panel 2 displays the mental state for desire, panels 4 and 5 display the mental state for belief, panel 7 displays the mental state for intention, and panels 3 and 6 display the mental states for moods associated with desire and belief.

Table 3. Mental state terms and frequency, words, and length in each social story.

Social story	Mental state terms (frequency)	Words, N ^a	Length (seconds)
Great with others	 Know (n=6) Want (n=6) Feel (n=6) Happy (n=6) Sad (n=6) 	115	95
Play game	 Know (n=6) Want (n=6) Feel (n=6) Happy (n=6) Angry (n=6) 	118	104
Grab a toy	 Know (n=6) Want (n=6) Feel (n=6) Happy (n=6) Fear (n=6) 	112	93
Give a gift	 Know (n=3) Want (n=3) Feel (n=3) Happy (n=3) Sad (n=3) Angry (n=3) Fear (n=3) 	101	91

^aChinese character count.

The following instructions were given to the children for the talking practice. For retelling, the instruction was as follows: "Tell me about the story you just heard." For prompting, the instruction was as follows: "I have a few questions to ask you about this story." For self-narration, the instruction was as follows: "After listening to this story, it's your turn to share a story about how you grabbed a toy with someone." For imitation, the instruction was as follows: "Tell me the story one more time—I'll say a sentence, and then you repeat it."

Each session lasted approximately 40 minutes. A total of 4 sessions were delivered over 4 weeks, with 1 session per week. The quantitative and qualitative aspects of this intervention program are consistent with those outlined by Frizelle et al [55], who emphasized that, in an intervention program, the concept of efficiency is central to "dosage," which includes both quantitative (number of sessions, frequency, and duration) and qualitative (form) constructs.

Tele-Intervention Information and Communications Technology

The technical setup used by the 3 interventionists in their workrooms included a laptop equipped with Google Meet, a broadband internet connection, a web camera, a flexible lighting device to achieve optimal lighting, and a backdrop of an image showing the name of the interventionist to ensure optimal visibility during the tele-intervention sessions. The technical setup used by the participants included their own personal desktop computer or laptop (9/20, 45%), tablet (3/20, 15%), or smartphone (8/20, 40%), all equipped with Google Meet; an internet connection; and a web camera. All parents reported having internet access at their homes (fixed line or 4G or 5G cellular internet). They also reported a sound level of 55 to 65 dB, measured using a sound meter app. Throughout the tele-intervention sessions, the participants were asked to keep the video call in full-screen mode. All interventionists used the screen-sharing tool to present visual stimuli for the social story video and prompt pictures during the talk practice stage.

Measurement

Assessment of Emotional Competence

In this study, the ELT was used to evaluate the emotional competence of children with DLD. The study 1 section provides more details regarding this test.

Assessment of the Feasibility and Acceptability of SSTIs

Feasibility was evaluated based on recruitment, retention, and attendance rates to each session, and acceptability was evaluated based on the outcomes of each session. The participants were asked to either select 1 of 4 affect categories (happiness, anger, fear, and sadness) or remain neutral. Reports of happiness and neutrality were considered acceptable.

Procedure

As shown in Figure 1, the DLD group completed the in-person evaluation at the preintervention 1 time point (time 1). After 5 to 6 weeks, the SSTIs were administered. The parents attended the first parent session, and the ELT was administered during the tele-evaluation at the preintervention 2 time point (time 2). After 1 week, the DLD group received the SSTIs, which lasted 4 weeks (second to fifth session). In the sixth session, the parents were evaluated, and the DLD group was administered the ELT again during the tele-evaluation at the postintervention 1 time point (time 3). Finally, 5 to 6 weeks after time 3, the DLD group was administered the ELT once again during the tele-evaluation at the postintervention 2 time point (time 4). Only 1 participant withdrew from the study during the tele-evaluation at the postintervention 2 time point. The mean number of weeks between time 1 and time 2 and between time 3 and time 4 was similar (P>.05). Figure 1 shows the participant recruitment process. The period from time 1 to time 4 spanned approximately 18 to 20 weeks for each participant with DLD.

Ethical Considerations

This study was conducted in accordance with relevant guidelines and regulations for human participants. Privacy measures included secure data storage with access restricted to research team members only. The study design was approved by the

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institutional review board of Chung Shan Medical University Hospital in Taiwan (CS2-19046).

Data Analysis

When the data suggest a nonlinear relationship, piecewise linear growth models can be used to divide growth trajectories into >2 linear components, such as in interrupted time-series data [56,57]. In this study, we used a piecewise linear growth model with 3 slopes for each outcome: slope 1 to evaluate changes from the preintervention 1 to preintervention 2 time points (baseline), slope 2 to evaluate changes from the preintervention 2 to postintervention 1 time points (tele-intervention), and slope 3 to evaluate changes from the postintervention 1 to postintervention 2 time points (follow-up). We also hypothesized that the tele-interventions would have an effect. Generally, the absence of an intervention effect for baseline and follow-up indicates that emotional competence did not increase during the baseline phase and did not decrease during the follow-up phase. The HLM software (version 7.03; Scientific Software International) [58] was used to fit the piecewise linear growth model. All other analyses were conducted using SPSS Statistics (version 25.0). Estimates of intraclass correlation coefficients (ICCs) are often used to analyze the power of piecewise linear growth models [59]. These coefficients measure the similarity between data points within the same cluster and those in different clusters. They typically range from 0 (no similarity between clusters) to 1 (complete similarity between clusters). ICCs of >0.20 indicate that the model can detect actual differences in growth rates across different time segments [60]. Sufficient power is essential for study accuracy, making piecewise linear growth models suitable for analysis. Effect sizes are typically calculated for each period using the Cohen d for repeated measures [61]. Values of 0.2, 0.5, and 0.8 indicate small, moderate, and large effects, respectively [62]. The Cohen d was calculated using G*Power (version 3.1.5) [63].

Results

Changes in Emotional Competence Among Participants With DLD

In this study, the ICCs for BET size, BET depth, CET size, and CET depth were <0.001, 0.34, 0.30, and 0.46, respectively. The ICCs for BET depth, CET size, and CET depth were >0.20, indicating that the piecewise linear growth model was suitable for analysis. Figure 3 shows the mean change trajectories for the size and depth of BETs and CETs. Table 4 presents the results of multilevel piecewise growth models for estimating mean changes in 4 emotion outcomes in the tele-intervention during the baseline (preintervention 1 to preintervention 2 time points), tele-intervention (preintervention 2 to postintervention 1 time points), and follow-up (postintervention 1 to postintervention 2 time points) phases. Regarding BET size, no statistically significant change was observed during the baseline, tele-intervention, or follow-up phase (P>.05). Regarding BET depth, the rate of correct answers significantly increased during the tele-intervention phase (P<.001), but no significant change was observed during the baseline or follow-up stage (P>.05). Regarding CET size, no statistically significant change was observed during any phase (P>.05). Regarding CET depth, the rate of correct answers significantly increased during the



tele-intervention phase (*P*<.001), but no significant change was observed during the baseline or follow-up phase (*P*>.05).

Figure 3. Mean change trajectories for the size and depth of basic emotional terms (BETs) and complex emotional terms (CETs) during the baseline, tele-intervention, and follow-up phases. D-BET: BET depth; D-CET: CET depth; POST-1: postintervention time point 1; POST-2: postintervention time point 2; PRE-1: preintervention time point 1; PRE-2: preintervention time point 2; S-BET: BET size; S-CET: CET size.



Table 4. Baseline, tele-intervention, and follow-up changes in multilevel piecewise models for emotional terms.

Variable	Size of BET ^a , B (95% CI) ^b	Depth of BET, B (95% CI) ^c	Size of CET ^d , B (95% CI) ^e	Depth of CET, B (95% CI) ^f
Fixed effect				
Intercept	0.93 ^g (0.89 to 0.98)	0.50^{g} (0.40 to 0.61)	0.69 ^g (0.63 to 0.76)	0.15 ^g (0.10 to 0.19)
Baseline	0.03 (-0.04 to 0.09)	0.05 (-0.03 to 0.13)	0.01 (-0.05 to 0.07)	0.00 (-0.05 to 0.05)
Tele-intervention	0.03 (-0.01 to 0.08)	0.21 ^g (0.11 to 0.32)	0.03 (-0.05 to 0.10)	0.07 ^g (0.04 to 0.10)
Follow-up	-0.02 (-0.04 to 0.00)	0.05 (-0.05 to 0.14)	0.001 (-0.09 to 0.09)	0.01 (-0.04 to 0.06)

^aBET: basic emotional term.

^bRandom effect—intercept (U₀): $\chi^2_{19}=15.4$; P>.50.

^cRandom effect—intercept (U₀): $\chi^2_{19}=116.3$; P<.001.

^dCET: complex emotional term.

^eRandom effect—intercept (U₀): $\chi^2_{19}=54.2$; P<.001.

^fRandom effect—intercept (U₀): χ^2_{19} =98.6; *P*<.001.

 $^{g}P < .001.$

Table 5 presents the means and SDs of various emotional term measures at 4 measurement time points. The effect sizes for changes during the baseline period (from the preintervention 1 to preintervention 2 time points) were small (Cohen d=0.00-0.26), indicating that the depth and size of BETs and CETs slightly changed during this period. During the tele-intervention period (from the preintervention 2 to

postintervention 1 time points), large effect sizes (Cohen d=0.88-0.94) were observed for the changes in depth of BETs and CETs, whereas small effect sizes (Cohen d=0.12-0.27) were observed for the changes in size of BETs and CETs. During the follow-up period (from the postintervention 1 to postintervention 2 time points), small effect sizes (Cohen d=0.01-0.39) were observed for the changes in depth and size of BETs and CETs.



Table 5.	Means,	SDs,	and	effect	sizes	for	emotional	term	measures.
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	Rate of correct an- swers (PRE-1 ^a), mean (SD)	Rate of correct an- swers (PRE-2 ^b), mean (SD)	Rate of correct an- swers (POST-1 ^c), mean (SD)	Rate of correct answers (POST-2 ^d), mean (SD)	Effect size, Cohen d		
					Baseline	Tele-intervention	Follow-up
D-BET ^e	0.50 (0.25)	0.55 (0.30)	0.77 (0.19)	0.81 (0.21)	0.26	0.88	0.18
S-BET ^f	0.93 (0.10)	0.96 (0.09)	0.99 (0.04)	0.97 (0.06)	0.19	0.27	0.39
D-CET ^g	0.15 (0.10)	0.15 (0.11)	0.22 (0.13)	0.22 (0.13)	0.00	0.94	0.03
S-CET ^h	0.69 (0.15)	0.71 (0.10)	0.73 (0.20)	0.73 (0.10)	0.14	0.12	0.01

^aPRE-1: preintervention 1 time point.

^bPRE-2: preintervention 2 time point.

^cPOST-1: postintervention 1 time point.

^dPOST-2: postintervention 2 time point.

^eD-BET: depth of basic emotional term.

^fS-BET: size of basic emotional term.

^gD-CET: depth of complex emotional term.

^hS-CET: size of complex emotional term.

Feasibility and Acceptability of SSTIs

Of the 25 parents of participants with DLD, 5 (20%) did not take part in this study. Therefore, the recruitment rate for the program was 80% (20/25). At the preintervention 2, postintervention 1, and postintervention 2 time points, the retention rates were 100% (20/20), 100% (20/20), and 95% (19/20), respectively. During the 4 sessions, the attendance rates were 100% (20/20), 100% (20/20), 95% (19/20), and 100% (20/20). All participants (20/20, 100%) completed the 4 tele-intervention sessions, with only 5% of missing data at the postintervention 2 time point.

During the 4 sessions, the percentages of participants who reported being happy were 90% (18/20), 79% (15/19), 85% (17/20), and 90% (18/20), and the percentages of participants who reported being neutral were 10% (2/20), 11% (2/19), 15% (3/20), and 5% (1/20). Overall, the acceptability rates were 100% (20/20), 89% (17/19), 100% (20/20), and 95% (19/20) during the 4 sessions.

Discussion

Principal Findings

Tele-interventions are not a novel concept in medicine. However, to the best of our knowledge, this is the first study to integrate a social story intervention with a remote format to improve the emotional competence of children with DLD. In this study, a 3-stage process was used to observe changes in emotional terms among children with DLD. We discovered that changes in emotional competence occurred only during the tele-intervention phase, with no changes observed during the baseline phase before the intervention. These effects remained during the follow-up period after the intervention. Overall, this research design enhanced the validity of the results.

Our results indicated that SSTIs helped children with DLD deepen their understanding of BETs. In these SSTIs, 4 BETs were repeatedly used in various social contexts to reflect

different individuals' mental states. This approach enabled the participants to understand that a single emotion word may be applicable to a range of scenarios (ie, unspecific use). The earlier these terms are integrated into the active vocabulary of children, the more their use aligns with that of adults. These findings are consistent with those of Grosse et al [64] indicating that children who learn words about emotions through cross-context scenarios can understand and use such vocabulary as adults. In this study, thought bubbles were used to enhance the children's understanding of representational mental states associated with emotional terms.

Although our intervention was not designed to introduce new CETs, we hypothesized that children with DLD would not seek to increase the size of their CETs and would rather seek to improve their understanding of the CETs that they had already learned. Overall, our findings indicate that SSTIs, which are based on a thorough understanding of BETs, can help children with DLD gain a deeper understanding of the CETs that they have already learned. Further systematic studies of domain-specific vocabulary are required to determine the effectiveness of SSTIs, including the size of emotion vocabulary and the depth of understanding.

Although social stories are often applicable to patients with ASD, similar to the application of such stories to children with ASD, the social stories designed in this study included visualizations of the story context, which can influence social storytelling by reducing extraneous cognitive demands [65]. When social stories are used as an intervention for children with DLD, adjustments may be required depending on the children's language levels. In this study, we used the thought bubbles corresponding to mental state words, which can also be used to clarify the protagonist's emotional state and mental thoughts within a social context. In other words, by making hidden thoughts and feelings explicit, children with DLD can gain a deeper understanding of their own and others' emotions and acquire the emotional language necessary to reflect upon and

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discuss these emotions [66]. Given that children with DLD represent a highly heterogeneous group, when social story interventions are implemented for these children, their language levels must be considered. In other words, the vocabulary, syntactic structures, and story elements included must be carefully planned to ensure that they are within the instructional level and not the frustration level [67]. These strategies have the potential to enhance the expressive language output of children for discussing emotional topics, processing targeted emotional components, and engaging in tele-interventions.

Among the indicators of feasibility for evaluating a pilot program are recruitment, retention, fidelity, acceptability, adherence, and engagement [68,69]. In this study, we evaluated the indicators of recruitment (proportion of parents who were willing to participate), retention (proportion of parents who did not withdraw), and attendance (proportion of parents who attended all 4 sessions). Retention rates are often used as evidence of feasibility in early intervention studies [70,71], particularly for pilot programs [69]. A high retention rate indicates that the program has promise for further development. Future research is required to evaluate the indicators of fidelity, adherence, and engagement to strengthen feasibility assessments.

According to Gartlehner et al [72], clinicians and policy makers tend to differentiate between efficacy and effectiveness. These 2 constructs exist on a continuum where efficacy and efficiency are about whether an intervention functions well under ideal and real-world conditions, respectively. This study was conducted under ideal conditions, supervised by a clinical researcher with expertise in children with DLD. The sample size was small, and the participants were carefully selected—only children with a confirmed diagnosis of DLD were included. The outcomes focused on specific aspects of emotional competence, such as the acquisition of emotional terms, rather than on broader health measures. A short-term intervention was implemented to provide initial evidence of efficacy, with strict protocols for both care providers and families. Future studies should explore the effectiveness of this program for Mandarin-speaking children with DLD, but first, it is necessary to establish the importance of continually evaluating its intermediate- and long-term efficacy. Chorpita et al [73] have argued that, even if >10 successful replications support a particular treatment, this information would not be sufficient to determine whether this treatment is more suitable for a particular child than a treatment supported by only 2 instances of replication assuming the absence of predictors of differences in outcomes. This assumption underscores the importance of conducting effectiveness studies to determine whether intervention programs can be widely implemented in clinical settings. Therefore, future studies should examine our program's real-world effects in hospital settings, including its acceptability, feasibility, and cost versus benefit. They should also explore broader mental health outcomes, such as increased self-regulation or decreased behavioral problems, of tele-interventions designed for Mandarin-speaking children with DLD.

Some parents raised concerns regarding their children facing difficulties focusing on their lessons and interacting with their instructors on-screen. Generally, in-person interventions involve physical contact and social interactions, such as high fives, contingency, eye contact, and joint attention, which can help children focus. In contrast, web-based interactions involve only visual support and behavioral management strategies to keep children engaged [74-76]. Despite these limitations, we discovered that the parents and children who participated in the intervention had high attendance rates and reported positive emotions after the intervention, indicating the feasibility and acceptability of SSTIs among them.

In the past few years, many hospitals were closed to the public because of the COVID-19 pandemic, thus preventing the implementation of in-person interventions. Early interventions for children with developmental delays were also suspended. These measures resulted in an increase in tele-evaluations and tele-interventions in medical scenarios. Although specialized hospitals are currently available for children, tele-practice interventions are particularly valuable for families living in rural areas, who tend to face challenges such as time constraints and lack of transportation. In these areas, enhancing the adoption of tele-practice requires software and hardware support because of these areas' limited internet access and lack of hardware [77]. Currently, Taiwan is striving to expand its 5G infrastructure (through platforms such as OpenGov Asia, the Ministry of Digital Affairs, and ComSoc Technology), particularly in remote areas such as Penghu, to improve digital accessibility and support tele-practice. Enhancing the degree of acceptance among health care professionals and parents is essential for promoting child language development and raising awareness of the benefits of tele-practice [78,79]. Finally, tele-interventions can also be used as a hybrid model in conjunction with in-person services to enhance learning experiences and make efficient use of resources.

This study has some limitations. First, emotional competence was exclusively measured by determining the number of emotional terms that children with DLD were aware of and examining the depth of their understanding of these terms. These measures did not reflect whether the children's emotional regulation strategies or behavioral problems improved as a result of our intervention. Therefore, further studies are required to explore these aspects of emotional competence. Second, the period during which we evaluated the effects of the intervention was short. Therefore, further long-term follow-up studies are required to determine the long-term and cumulative effects of our tele-intervention. Third, although the Italian version of the ELT has demonstrated strong psychometric characteristics [40] and assesses both basic and complex emotional competence in children, the Chinese version of this test lacks support from psychometric data. As in previous studies [38], we evaluated children's understanding of emotion-related words by making them listen to stories and choose the correct terms to determine the quantity of emotion words. We subsequently asked them to explain their choices to gauge their depth of understanding. This approach, which relies on a single test, limits the concept of emotional competence in children. Therefore, future studies should involve various additional measures such as the Emotional Competencies Scale for Young Children [80] or collect data through parent questionnaires or transcript analyses

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to determine whether children use emotion words in different contexts [81,82].

Conclusions

Mandarin-speaking children aged 5 to 7 years with DLD exhibit lower emotional competence than those with TLD even after adjusting for child and family language characteristics. Although DLD can be qualitatively defined in accordance with the DSM-5 [1] in medical and research contexts, no consensus has yet been established regarding its quantitative definition, including which tests to conduct and which cutoff criteria to apply. Therefore, further research is required to establish a quantitative definition for children with DLD across languages and cultures and enable comparisons of emotional competence in children with DLD from different linguistic and cultural backgrounds. In addition, emotional competence tele-interventions effectively improve the emotional competence of children with DLD. They are also feasible and acceptable for both children and their parents. These findings indicate that tele-interventions can be a viable option for individuals who lack access to in-person services due to hospital shutdowns or barriers related to transportation, location, or time. Visual materials such as images and videos of children's interactions, implicit thoughts, and emotions should be used to

understand and discuss emotional situations, with a preference toward realistic content. In addition, the language used in SSTIs should match the language capabilities of children. Although the results of our tele-intervention approach are satisfactory, future studies should explore its effectiveness in hospital settings to determine its real-world impact and examine broader mental health outcomes of tele-interventions for children with DLD. Further research is also required to address unresolved concerns regarding assessment, diagnosis, telephone consultation, internet support systems, and inconsistent intervention outcomes. Addressing these concerns can facilitate the expansion of tele-interventions to enhance other competencies in children with DLD and include a broader population with different medical conditions. Overall, this emotional competence tele-intervention, which can be used on pediatric populations, should be conducted as a participatory process involving children and their parents, with technology used to increase the convenience of the intervention, provided that efficacy is achieved. The findings show that using remote technology in home-based tele-interventions is effective, feasible, and well accepted. These interventions improve emotional skills in children with DLD and help support their parents.

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Conflicts of Interest

None declared.

Multimedia Appendix 1 Example of a social story video. [PNG File , 348 KB - pediatrics v8i1e60333 app1.png]

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Abbreviations

ANCOVA: analysis of covariance ASD: autism spectrum disorder BET: basic emotional term CET: complex emotional term CLDS-R: Child Language Disorder Scale–Revised DLD: developmental language disorder DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition ELT: Emotional Lexicon Test ICC: intraclass correlation coefficient NVI: Nonverbal Index SSTI: social story tele-intervention TLD: typical language development VAI: Vocabulary Acquisition Index VCI: Verbal Comprehension Index

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Body Fat and Obesity Rates, Cardiovascular Fitness, and the Feasibility of a Low-Intensity Non–Weight-Centric Educational Intervention Among Late Adolescents: Quasi-Experimental Study

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Abstract

Background: Obesity rates among Saudi adolescents are increasing, with regional variations highlighting the need for tailored interventions. School-based health programs in Saudi Arabia are limited and often emphasize weight and body size, potentially exacerbating body image dissatisfaction. There is limited knowledge on the feasibility of non–weight-centric educational programs in Saudi Arabia and their effects on health behaviors and body image.

Objectives: This study aimed to (1) assess the prevalence of obesity using BMI-for-age *z* score (BAZ) and fat percentage among Saudi adolescents; (2) evaluate key health behaviors, cardiovascular fitness, and health literacy; and (3) assess the feasibility and impact of a low-intensity, non–weight-centric educational intervention designed to improve knowledge of macronutrients and metabolic diseases, while examining its safety on body image discrepancies.

Methods: A quasi-experimental, pre-post trial with a parallel, nonequivalent control group design was conducted among 95 adolescents (58 boys and 37 girls; mean age 16.18, SD 0.53 years) from 2 public high schools in Medina City, Saudi Arabia. Participants were randomly assigned to either the weight-neutral Macronutrient + Non-Communicable Diseases Health Education group or the weight-neutral Macronutrient Health Education group. Anthropometry (BAZ and fat percentage), cardiovascular fitness, physical activity, and eating behaviors were measured at baseline. Independent *t* tests and χ^2 tests were conducted to compare group differences, and a 2-way mixed ANOVA was used to evaluate the effect of the intervention on macronutrient knowledge and body image discrepancies. A total of 69 participants completed the postintervention assessments.

Results: The prevalence of overweight and obesity based on BAZ was 37.9% (36/95), while 50.5% (48/95) of participants were classified as overfat or obese based on fat percentage. Students with normal weight status were significantly more likely to have had prior exposure to health education related to metabolic diseases than students with higher weight status (P=.02). The intervention significantly improved macronutrient-metabolic knowledge ($F_{1,64}$ =23.452; P<.001), with a large effect size (partial η^2 =0.268). There was no significant change in students' body image from pre- to postintervention (P=.70), supporting the safety of these weight-neutral programs. The intervention demonstrated strong feasibility, with a recruitment rate of 82.6% and a retention rate of 72.6%.

Conclusions: This study reveals a high prevalence of obesity among Saudi adolescents, particularly when measured using fat percentage. The significant improvement in knowledge and the nonimpact on body image suggest that a non-weight-centric intervention can foster better health outcomes without exacerbating body image dissatisfaction. Region-specific strategies that prioritize metabolic health and macronutrient education over weight-centric messaging should be considered to address both obesity and body image concerns in adolescents.

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KEYWORDS

adolescent obesity; macronutrient education; cardiovascular fitness; body composition; health literacy; body image; macronutrient; educational; obesity; weight; overweight; fitness; nutrition; diet; patient education; student; school; youth; adolescent; teenager; metabolic; eating; physical activity; exercise

Introduction

Childhood obesity has become a significant public health concern globally, with projections indicating a continued upward trend in the coming decades. Obesity is expected to rise dramatically among children aged 5 - 19 years, from an estimated 158 million in 2020 to 254 million by 2030 [1], representing a 60% increase over just a decade. Global estimates suggest that the overall prevalence of childhood overweight and obesity could reach 30% by 2030, with boys (34.2%) surpassing girls (27.4%) [2]. This trend is particularly alarming in middle-and high-income countries, where childhood overweight and obesity rates are projected to reach 58.3% by 2030 [2].

In Saudi Arabia, the obesity epidemic has mirrored global trends, with a marked increase in prevalence among both adults and adolescents. National estimates indicate that obesity prevalence among Saudi adolescents ranges from 22.3% to 23.5%, with some studies suggesting that nearly 35% of adolescents are overweight and 20% are obese [3-5]. Although BMI is a common tool for assessing obesity, it has limitations in distinguishing between fat and muscle mass. Notably, recent findings in Saudi Arabia highlight that BMI can underestimate obesity prevalence compared with body fat percentage [6]. For instance, while BMI data indicated an obesity prevalence of 29% (102/348) in men and 53% (314/593) in women, body fat percentage assessments revealed significantly higher rates of 83.9% (292/348) in men and 97.3% (557/593) in women [6]. This underscores the importance of using body fat percentage to provide a more accurate representation of obesity, particularly when evaluating related health risks.

Regional disparities in obesity prevalence further complicate the issue. Urbanized areas in Saudi Arabia report higher rates of obesity, influenced by factors such as physical inactivity, Westernized diets, and socioeconomic conditions [7]. Conversely, rural regions often exhibit lower obesity rates due to more traditional lifestyles that incorporate higher physical activity and different dietary patterns [7]. These regional differences emphasize the need to address physical activity behaviors and dietary habits in specific contexts. While all forms of physical activity are beneficial, current evidence indicates that vigorous-intensity exercise may be particularly effective in improving body composition, cardiorespiratory fitness, and cardiometabolic health markers in adolescents [8,9]. Despite this, there remains a gap in studies exploring the relationship between physical activity behaviors and cardiovascular fitness among adolescents in Saudi Arabia.

Adding to the complexity, decreased health literacy and higher-income levels have been linked to increased obesity rates in Saudi Arabia. This contrasts with trends observed in the United States, where lower-income levels are more commonly associated with higher obesity rates [10,11]. This highlights the crucial role of health literacy as a determinant of obesity prevalence and the importance of tailored educational interventions.

Despite the alarming trends, evidence-based interventions targeting adolescents in Saudi Arabia, particularly late adolescents in school settings, remain limited [12,13]. Schools provide an ideal environment for implementing cost-effective and sustainable obesity interventions, especially when these programs are theory-driven and tailored to meet the specific needs of the target population [14]. A review of the literature shows that only 7 school-based obesity intervention studies have targeted adolescents in Saudi Arabia, with an average age range of 12 - 14 years, and none focusing on high school students [12,13,15]. Furthermore, only 3 of these studies used theory-based approaches [12], and all used weight-centric messaging.

Since 2020, more than 100 organizations worldwide, including scientific societies and academic institutions, have endorsed joint international statements to eliminate weight stigma [16]. Non–weight-centric approaches, which emphasize overall health and well-being rather than solely focusing on weight loss, have gained traction in school-based obesity interventions [17]. These programs encourage healthy behaviors and promote a positive body image without stigmatizing students, addressing the negative outcomes associated with weight stigma such as anxiety, disordered eating, and even weight gain [18,19]. However, designing obesity prevention programs that avoid weight-based stigma remains challenging, prompting calls for expanded research in non-Western cultural settings [16,20].

No study in Saudi Arabia has yet documented the development or efficacy of non-weight-centric interventions. This study focused on Medina City to examine the impact of healthy lifestyle factors on obesity rates among late adolescents and to assess the effectiveness and safety of a low-intensity, non-weight-centric, noncommunicable diseases (NCDs) educational intervention. This regional focus aims to provide insights that can inform targeted, culturally sensitive obesity prevention strategies.

In summary, this study sought to (1) identify the prevalence of obesity using both BMI-for-age z score (BAZ) and body fat percentage among Saudi late adolescents in Medina City; (2) characterize health-related behaviors, cardiovascular fitness, handgrip strength, and health literacy levels; and (3) evaluate the feasibility and safety of a low-intensity health educational intervention aimed at empowering adolescents with improved NCD knowledge while monitoring its effects on body image discrepancy. This research aims to contribute to the development of effective, culturally appropriate interventions that promote adolescent health without reinforcing weight stigma.

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Methods

Design

This study used a quasi-experimental, pre-post trial with a parallel, nonequivalent control group design to assess baseline anthropometry, health-related cardiovascular fitness components, handgrip strength, physical activity, and eating behaviors, as well as the feasibility of a low-intensity, school-based educational intervention aimed at improving critical thinking about the relationship between macronutrients and NCDs among high school students, while tracking safety measures such as body image discrepancy.

Participants

A total of 115 high school students from 2 public schools (1 for males and 1 for females) in Medina City, Saudi Arabia, were invited to participate. These schools were selected by the ministry of education's school health department. Of the invited students, 95 (58 males and 37 females) completed anthropometry and body composition measurements. Baseline surveys were completed by 85 students (53 males and 32 females). Four classes (2 females and 2 males) were randomly assigned to 1 of 2 intervention groups: the Macronutrient+ NCDs Health Education group (n=31) or the Macronutrient Health Education group (n=38).

Intervention: Green Apple

Overview

The LEAF program, an 8-session structured intervention, was developed to enhance critical thinking regarding macronutrients and their relationship to body energy and the prevention of cardiometabolic diseases. For this study, a pilot version, titled Green Apple, was conducted over two 45-minute sessions for female students and one 60-minute session for male students due to scheduling constraints. The intervention was based on best practices derived from evidence-based research into health literacy and behavior change [21]. The program was grounded in the Health Belief Model [22] and Social Cognitive Theory [23], incorporating the Transtheoretical Model for behavior change [24].

These theories provided the framework for understanding how adolescents perceive their risk of NCDs (eg, diabetes, hyperlipidemia, liver disease, stroke, and hypertension) and motivated them to adopt healthier behaviors through education, muscle building, and dietary modifications. The Green Apple program aimed to reduce chronic metabolic NCD risk by promoting visceral fat reduction and muscle building without focusing on weight loss or obesity. Participants were encouraged to follow the MyPlate dietary guidelines [25], emphasizing fiber and whole food consumption and engaging in muscle-building exercises. The program avoided topics related to obesity and sedentary behavior, instead focusing on metabolic health improvements.

Intervention Groups

The Macronutrient+ NCDs Health Education group included 3 educational topics covering nutrition and metabolic diseases

(eg, diabetes and cardiovascular disease), highlighting the impact of macronutrition on metabolic health.

The Macronutrient Health Education group included 2 educational topics focused solely on healthy nutrition principles, dietary guidelines, food groups, and balanced eating.

Both groups received identical macronutrient content.

Measurements

Demographics

Baseline demographic data included age, self-reported weight and height, parental education levels, and monthly family income. Parental education was categorized as high (college degree or above) or low (high school degree or below).

Anthropometry

Body weight and height was measured using a portable digital scale (Omron BF511) to the nearest 100 g and a stadiometer to the nearest 0.1 cm. BMI was calculated as weight (kg) divided by height squared (m²), and BAZs were classified using the World Health Organization 2007 Growth Reference for children and adolescents aged 5 - 19 years [26]. The BAZ categories were thinness ($-3 \le BAZ <-2$), normal weight ($-2 \le BAZ \le+1$), overweight ($+1 < BAZ \le+2$), and obesity (BAZ >+2).

Fat percentage was assessed using a bioimpedance analyzer (Omron BF511). Classification was based on McCarthy's ageand sex-specific fat percentile references, with the 2nd, 85th, and 95th percentiles defining underfat, overfat, and obese, respectively [27].

Cardiovascular Fitness

The Queen's College Step Test, a submaximal exercise test, was used to estimate the maximal oxygen consumption (VO₂max). Participants stepped on a 30.5- cm box at a set rate for 3 minutes [28]. The 30.5-cm step height was chosen for its suitability for adolescents [28]. VO₂max estimation: The pulse rate was measured postexercise using a pulse oximeter, following McArdle's protocol [29]. The equations for estimating VO₂max were as follows: girls: $65.81 - (0.1847 \times \text{pulse rate})$ and boys: $111.33 - (0.42 \times \text{pulse rate})$ [28].

Handgrip Strength

Handgrip strength was measured using a Takei Kiki Kogyo dynamometer, and the highest value from 2 trials for the dominant hand was recorded. Classifications followed age- and gender-specific percentiles [30].

Physical Activity

Physical activity was assessed using the Arab Teen Lifestyle Study physical activity questionnaire subscale [31], calculating total weekly energy expenditure in metabolic equivalent tasks (METs), with vigorous activities (6 METs) and moderate activities (4 METs) expressed in minutes per week.

Eating Habits

Eating habits were evaluated using the Arab Teen Lifestyle Study eating habits subscale, which measured positive eating habits (eg, fruit or vegetable intake) and negative eating habits

(eg, sugary drinks or fast food) based on weekly frequency [31], with a total scores ranging from 0 to 28 for positive habits and 0 to 35 for negative habits.

Sedentary Behavior

Sedentary behavior was measured using the Arabic Sedentary Behavior Questionnaire (SBQ) for weekdays [32]. The questionnaire included 9 items, and a total sitting time was averaged over 5 weekdays. Sitting \geq 7 hours per day was considered highly sedentary [33].

Exposure to NCDs Health Education

Exposure to health education on NCDs was assessed using 4 yes or no questions regarding prior education on chronic diseases. A total score (0 - 4) was calculated.

Macronutrient-NCDs Knowledge

Macronutrient and NCDs knowledge was measured using an 18-item true-or-false quiz developed based on the Green Apple content. A total score (0 - 18) was analyzed, with an urgent need for intervention indicated if 70% or fewer answered correctly, a considered need at 71% - 89%, and no need at 90% or more [34].

Body Image Discrepancy

Body image discrepancy was assessed using 4 body size silhouettes [35]. Participants selected their ideal and perceived current body images, with discrepancies indicating body image concerns. A negative score represented a drive for thinness, while a positive score reflected a drive for increased body weight [36].

Ethical Considerations

The study protocol was approved by the Shaqra University ethics committee (ERC_SU_20230005). Written informed consent was obtained from parents, and student participation was voluntary. To ensure privacy and confidentiality, participant data were anonymized using unique identifiers, and data access was limited to authorized personnel. Baseline assessments were conducted prior to the intervention. The intervention was delivered on different days for males and females due to scheduling constraints. Postintervention assessments for macronutrient-NCDs knowledge and body image discrepancy were conducted, and participants received a key chain medley as a token of appreciation for their involvement.

Statistical Analysis

Overview

Descriptive statistics (means, SDs, and frequencies) were calculated for all variables. Independent *t* tests were conducted to compare males and females and students with and with no overweight or obesity on continuous variables, while χ^2 tests were used for categorical variables. A 2-way mixed ANOVA design was used, with 1 between-subjects factor (intervention type: macronutrient-NCDs vs macronutrient) and 2 within-subjects factors (time: pre-test and post-test) for 2 dependent variables: macronutrient-NCDs knowledge and body image discrepancy. Gender was included as an additional

between-subjects variable to assess potential interactions with time and intervention type.

Statistical significance was set at P<.05. Sample size calculations using G*Power 3.1 indicated a required sample size of 34 participants to detect medium effects (*f*=0.25) with 80% power. Although an initial plan accounted for a 30% attrition rate, the final sample size exceeded the minimum requirement for detecting a medium effect size with 80% power, ensuring sufficient study power.

A 2-way mixed ANOVA was conducted to evaluate the effect of the Green Apple intervention on students' macronutrient-NCDs knowledge scores before and after the intervention and to determine potential gender interaction effects, given the significant difference in mean scores between males and females at preassessment.

Two borderline outliers with studentized residuals of -3.02 and -3.03 were identified but retained in the analysis. The data were normally distributed, as assessed by the Shapiro–Wilk test (*P*>.05). Homogeneity of variances (*P*>.05) and covariances (*P*>.001) were confirmed by Levene test and Box M test, respectively, except for postintervention body image discrepancy, which required Welch ANOVA.

Missing Data

A missing data analysis was conducted, revealing that 4% of data were missing across all items, with a maximum of 7% missing for certain variables (eg, "minutes' walk per day," "number of stairs per day," and "SBQ-listening to music, using computer, crafting"). Little MCAR test was applied to assess the randomness of the missing data, yielding a nonsignificant result (P>.05), indicating that the data were missing completely at random [37]. Expectation-Maximization was used to impute missing data for variables with 5% - 7% missing values. For variables with <5% missing data, series mean and series median imputation methods were used.

Two items from the physical activity scale ("regular dancing" and "house cleaning") were excluded due to cultural factors that led to inconsistent responses between male and female participants. This decision was informed by a review of similar studies conducted in the region [38,39]. Furthermore, family income was excluded from analysis because female students were often unaware of this information, which is considered sensitive, and younger students may not accurately understand their family's financial status [40]. The high absenteeism rate among female students during the intervention (approximately 28%) also contributed to some missing data, consistent with previously reported absenteeism rates in Saudi schools [41].

Results

Baseline Characteristics and Prevalence of Overweight and Obesity

Table 1 shows the baseline characteristics of the 95 participants (37 girls and 58 boys). The mean age of the total sample was 16.18 (SD 0.53) years, with girls having a significantly higher mean age than boys (P<.001). The mean BAZ score for the total sample was 0.44 (SD 1.42), with a significant sex difference

(*P*=.03). Furthermore, girls had a higher mean fat percentage than boys (28.58% vs 22.65%), but this difference was not statistically significant (*P*=.37). The combined prevalence of overweight and obesity based on the BAZ classification was 37.9% (36/95), with 16.8% (16/95) of participants classified as overweight and 21.1% (20/95) of participants classified as obese. When considering fat percentage, the combined prevalence of overfat and obesity was 50.5% (48/95), with 11.6% (11/95) of participants classified as overfat and 38.9% (37/95) of

participants classified as obese. For the BAZ and fat percentage percentile categories, no significant sex differences were observed. Table 2 shows descriptive statistics for the distribution of the participants' weight status (normal BAZ and high BAZ) across different levels. These results suggest that there was no statistically significant relationship between parental education level (both mother and father) and the participants' weight category.

Table . Descriptive statistics based on sex (mean [SD] or fat percentage).

Variables	All (N=95)	Girls (n=37)	Boys (n=58)	Sex (significance) differ- ence ^a
Age (years), mean (SD)	16.18 (0.53)	16.38 (0.64)	16.05 (0.39)	<.001
BMI (kg/m ²), mean (SD)	23.46 (6.07)	23.25 (5.24)	23.59 (6.59)	.05
BAZ ^b , mean (SD)	0.44 (1.68)	0.44 (1.42)	0.44 (1.84)	.03
Fat percentage, mean (SD)	24.96 (9.54)	28.58 (8.62)	22.65±9.44	.37
BAZ percentile, n (%)				.39
Underweight	7 (7.4)	2 (5.4)	5 (8.6)	
Normal weight	52 (54.7)	22 (59.5)	30 (51.7)	
Overweight	16 (16.8)	8 (21.6)	8 (13.8)	
Obese	20 (21.1)	5 (13.5)	15 (25.9)	
Fat percentage percentile, n (%)				.44
Underfat	5 (5.3)	3 (8.1)	2 (3.4)	
Normal	42 (44.2)	16 (43.2)	26 (44.8)	
Overfat	11 (11.6)	6 (16.2)	5 (8.6)	
Obese	37 (38.9)	12 (32.4)	25 (43.1)	
Exposure to metabolic NCDs ^c education, mean (SD) ^d	3.19 (1.006)	3.72 (0.523)	2.87 (1.093)	<.001
Macronutrient-metabolic NCDs knowledge, mean (SD) ^d	10.64 (3.638)	12.13 (2.472)	9.74 (3.943)	.50
Body image discrepancy, mean (SD) ^e	-0.36 (0.94)	-0.69 (0.74)	-0.13 (1.00)	.005

^aIndependent t tests were conducted to compare differences between the 2 groups. Two-sided P values are reported when no significant difference was found between the groups. One-sided P values are reported when the 1-directional hypothesis was supported.

^bBAZ: BMI-for-age *z* score.

^cNCD: noncommunicable disease.

^dThe n values for these data are as follows: All (n=85); Girls (n=32); Boys (n=53).

^eThe n values for these data are as follows: All (n=78); Girls (n=32); Boys (n=46).



Table . Weight category descriptive statistics (mean [SD] or fat percentage).

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	All	Normal BAZ ^a	High BAZ	Significance ^b
Mother's education, n (%)				.99
Low education level	28 (34.6)	18 (34.6)	10 (34.5)	
High education level	53 (65.4)	34 (65.5)	19 (65.5)	
Father's education, n (%)				.07
Low education level	18 (21.7)	8 (15.4)	10 (32.3)	
High education level	65 (78.3)	44 (84.6)	21 (67.7)	
Fat percentage, mean (SD)	24.96 (9.54)	19.53 (6.10)	33.85 (7.16)	<.001
VO ₂ max (mL/kg/min), mean (SD)	53.33 (14.63)	53.68 (14.72)	52.77 (14.67)	.86
VO ₂ max boys (mL/kg/min), mean (SD)	62.65 (10.29)	63.43 (10.69)	61.46 (9.77)	.81
VO ₂ max girls (mL/kg/min), mean (SD)	37.90 (2.87)	38.84 (1.83)	36.10 (3.65)	.014
Handgrip strength max score (kg), mean (SD)	24.49 (7.85)	24.81 (8.81)	23.96 (6.04)	.15
Handgrip strength per- centile, n (%)				.67
Low: ≤20	52 (54.7)	34 (57.6)	18 (50)	
Normal: 21 - 80	35 (36.8)	21 (35.6)	14 (38.9)	
High: >80	8 (8.4)	4 (6.8)	3 (11.1)	
Health-related behaviors based on weight status, mean (SD)				
Vigorous-intensity physi- cal activity (METs ^c min/wk)	2038.91 (2560.25)	2360.92 (2914.76)	1505.56 (1743.45)	.047
Moderate-intensity physi- cal activity (METs min/wk)	1038.90 (1219.13)	1009.073 (1174.13)	1088.286 (1307.99)	.39
Sedentary behavior per day during the week (h/d)	7.28 (3.93)	7.741 (3.11)	7.5064 (3.98)	.34
Positive eating behavior	16.43 (6.30)	16.838 (5.98)	15.7188 (6.84)	.22
Negative eating behavior	15.11 (6.62)	15.160 (6.22)	15.022 (7.34)	.46
Exposure to metabolic NCDs ^d health education topics	3.19 (1.01)	3.36 (0.76)	2.91 (1.28)	.02
Macronutrient-metabolic NCDs knowledge	10.64 (3.64)	10.90 (3.10)	10.13 (4.39)	.16
Need for educational inter- vention assessment, n (%)				.92
Urgent need	59 (69.4)	37 (69.8)	22 (68.8)	
Considered need	26 (30.6)	16 (30.2)	10 (31.3)	
No need	0 (0)	0 (0)	0 (0)	

^aBAZ: BMI-for-age *z* score.

^bIndependent t tests were conducted to compare differences between the 2 groups. Two-sided P values are reported when no significant difference was found between the groups. One-sided P values are reported when the 1-directional hypothesis was supported.

^cMET: metabolic equivalent task.

^dNCD: noncommunicable disease.

Cardiovascular Fitness and Handgrip Strength

Overall cardiovascular fitness levels, as measured using VO₂max, did not significantly differ between individuals in the normal and high body weight categories. The boys in the normal BAZ group had a slightly higher VO₂max (63.43 mL/kg/min, SD 10.69) than the boys in the high BAZ group (61.46 mL/kg/min, SD 9.77). However, this difference was not statistically significant (P=.81). There was a notable and statistically significant difference between the girls in the normal BAZ group (38.84 mL/kg/min, SD 1.83) and those in the high BAZ group (36.10 mL/kg/min, SD 3.65), with a P value of .014. This indicates that girls with overweight or obesity had significantly lower cardiovascular fitness levels than their peers in the normal group, suggesting a potential negative impact of higher body weight on cardiovascular fitness among girls. However, the distribution of handgrip strength categories did not show a statistically significant association with the BAZ classification (*P*=.67) (Table 2).

Health-Related Behaviors Based on Weight Status

Activity Behavior

Participants with a high BAZ had lower levels of METs minutes per week from vigorous-intensity activity (1505.56, SD 1743.45) than those with a normal BAZ (2360.92, SD 2914.76), with a significant difference (P=.047). No significant differences were observed in METs from moderate-intensity activity (P=.39).

Sedentary Behavior

The difference in sedentary behavior between the 2 groups was not statistically significant (P=.68), indicating similar levels of sedentary time regardless of weight status.

Eating Behavior

Positive eating behaviors were marginally lower in the high BAZ group (15.72, SD 6.84) than in the normal BAZ group

(16.84, SD 5.98), but the difference was not statistically significant (P=.23). Furthermore, negative eating behaviors showed no significant differences between the groups (P=.93).

Macronutrient-Metabolic NCDs Knowledge and Need for Intervention

The participants with a normal BAZ reported higher exposure to metabolic NCDs education (3.36, SD 0.76) than those with a high BAZ (2.91, SD 1.28), with a significant difference (P=.02). However, no significant differences were observed in the macronutrient-metabolic NCDs knowledge scores between the 2 groups (P=.16). The majority of the participants were classified as having an urgent need for an educational intervention (59/85, 69.4%), and 30.3% (26/85) were classified as having a need for an intervention, with no statistically significant distribution between the 2 groups (P=.92).

The Green Apple Intervention Effectiveness

The final sample consisted of 69 participants, with 23 females (intervention=13, control=10) and 46 males (intervention=18, control=28).

Effect on Macronutrient-Metabolic NCDs Knowledge

There was a significant main effect of time on students' macronutrient-metabolic NCDs knowledge ($F_{1,58}$ =23.263; P<.001), with a large effect size (partial η^2 =0.286). This indicates that knowledge significantly improved from pre- to postintervention, and the magnitude of the change was substantial. Also, a significant main effect was found for intervention type ($F_{1,58}$ =19.756; P<.001), with a large effect size (partial η^2 =0.254). The Macronutrient + NCDs intervention had a greater effect on improving knowledge (Table 3). The interaction between gender and intervention type was nonsignificant ($F_{1,58}$ =0.002; P=.99), with a very small effect size (partial η^2 =0.00), indicating that the effect of the interventions on knowledge was consistent across genders.

Table . Changes in macronutrient-noncommunicable disease (NCD) knowledge and body image discrepancy across intervention periods.

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	Baseline, mean (SE)	95% CI	Follow-up, mean (SE)	95% CI
Effect on macronutri- ent-metabolic NCDs knowledge				
Nutrition+ NCD	11.16 (0.56)	10.03 to 12.29	13.39 (0.42)	12.55 to 14.24
Nutrition	11.53 (0.55)	10.45 to 12.63	13.04 (0.41)	12.22 to 13.86
Effect on body image discrepancy				
Nutrition + NCD	-0.38 (0.17)	-0.72 to -0.03	-0.53 (0.19)	-0.90 to -0.16
Nutrition	-0.50 (0.167)	-0.84 to -0.17	-0.41 (0.18)	-0.77 to -0.05

Body Image Discrepancy

The effect of time on body image was nonsignificant ($F_{1,58}$ =0.150; P=.70), with a small effect size (partial η^2 =0.003), suggesting no significant change in students' body image from pre- to postintervention. Similarly, the interaction between gender and intervention type was nonsignificant for body image ($F_{1,58}$ =0.182; P=.73), with a very small effect size (partial

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 η^2 =0.002), meaning that the interventions had similar effects on body image for both males and females. The effect of gender on body image was marginally significant ($F_{1,58}$ =6.157; P=.052), with a medium effect size (partial η^2 =0.064), suggesting a slight difference in body image perception between males and females. However, Welch ANOVA was used due to unequal variances between males and females on postintervention body image discrepancy, and the findings suggest that gender does play a

role in postintervention body image, with a statistically significant difference detected between males and females (Welch $F_{1,66.977}$ =5.385; P=.02). This suggests that after accounting for unequal variances (based on Levene test), gender does have a significant effect on postintervention body image.

The Green Apple Intervention Feasibility

The high recruitment rate indicates strong initial interest and willingness to participate in the intervention, with 82.6% (95/115) of invited students enrolling in the study. Nearly 90% (85/95) of the recruited participants were engaged enough to provide comprehensive baseline data. The overall retention rate, based on completion of the pre- and postintervention questionnaires, was 72.6% (69/95). This indicates that a significant majority of the participants remained engaged with the study through to its conclusion, although there was a drop-off of 27.4% (26/95) from baseline to the postintervention phase. This dropout rate highlights some challenges in maintaining participant engagement over the study period. The retention rate was notably higher among male participants (46/58, 79.3%) than among female participants (23/37, 62.2%). This disparity was related to high absenteeism in the female school. Furthermore, one of the key challenges encountered was scheduling conflicts, particularly in the male school. These constraints impacted the intervention delivery, reducing the planned 2 sessions over 2 weeks to a single session on 1 day.

Discussion

Principal Findings

This study aimed to assess the prevalence of obesity among late adolescents in Medina City, Saudi Arabia, using both BAZ and fat percentage, and to evaluate the feasibility and effectiveness of a low-intensity, non–weight-centric educational intervention focused on macronutrient-metabolic disease knowledge. The findings indicate a high prevalence of obesity in this population, surpassing national averages. The Green Apple intervention effectively improved students' macronutrient knowledge without negatively affecting body image discrepancy, demonstrating its potential as a health education tool.

The prevalence of overweight and obesity based on the BAZ classification was 37.9% (36/95), with 21.1% (20/95) classified as obese. When using fat percentage, the prevalence was even higher at 50.5% (48/95), highlighting that BMI alone may underestimate obesity rates. This aligns with regional data, indicating that adolescent obesity trends in Medina reflect broader patterns observed in the western region of Saudi Arabia [7]. The effectiveness of the Green Apple intervention in significantly improving macronutrient-metabolic NCDs knowledge without impacting body image discrepancy underscores the potential for brief educational programs to enhance adolescents' understanding of nutrition and health.

Our study's obesity prevalence rates are consistent with findings from prior research in the western region of Saudi Arabia. For instance, a 2019 study reported a 35.3% (121/342) obesity prevalence among university students in Medina [42], indicating a persistent trend across educational levels. A 2021 study also found a similar overweight and obesity prevalence of 38.5%

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(44,826/116,656) among participants aged 17 - 25 years across different Saudi regions [43]. The higher prevalence of obesity in males (15/58, 25.9%) than in females (5/37, 13.5%) aligns with national data showing higher obesity rates in male adolescents [10].

The use of fat percentage as an additional measure provided a more nuanced understanding, revealing an obesity rate nearly double that of the BAZ classification. This supports prior research suggesting that fat percentage often results in a higher reported prevalence of obesity compared with BMI, sometimes by 1.5-3 times [44-46]. BMI fails to distinguish between muscle and fat mass, making fat percentage a more accurate indicator of obesity [45,46].

The study also identified a significant difference in VO₂max scores between the normal and high BAZ groups among females, with the normal group demonstrating better cardiovascular fitness. This finding suggests an inverse relationship between BAZ and cardiovascular health, emphasizing the importance of maintaining a normal BAZ for better fitness. Similar studies have shown a negative relationship between BMI and cardiorespiratory fitness in Saudi youth aged 8 - 15 years [47]. Furthermore, while the normal BAZ group had higher handgrip strength, there was no significant difference in percentiles between groups, indicating that low muscle strength is common among adolescents regardless of BMI. Previous studies have also reported low muscle strength among Saudi male adolescents aged 17 years [48] and no significant association between BMI and strength in college-aged females [49]. This study is the first to report age- and sex-specific handgrip strength percentiles for this population, an essential aspect for future research [30].

Also, the lack of significant differences in dietary behaviors between weight groups suggests that suboptimal eating habits are widespread. Both groups showed low fruit and vegetable intake and high consumption of sugary drinks, aligning with global patterns [50]. Sedentary behavior was similar between groups, reinforcing the need for targeted physical activity interventions. Our finding that vigorous physical activity correlates with lower obesity rates aligns with the Green Apple program's emphasis on high-intensity activity for metabolic health [51]. Current evidence suggests that vigorous intensity exercise may be particularly effective for improving body composition and health outcomes in adolescents [8,9]. These modalities also show promise for improving adherence. However, proper supervision and safety considerations are important, especially for higher-intensity activities and more research is needed to determine optimal exercise prescriptions and implementation strategies for this age group [8,9].

Our findings further revealed significantly lower exposure to NCD education among students with overweight or obese status compared with those with normal weight, and male students reported lower exposure than females. This could be linked to lower NCD knowledge among male teachers, as suggested by a recent study in Saudi Arabia [52]. The lower awareness about NCDs among young adults highlights the need for targeted interventions to increase education and awareness [53,54]. Early

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education can lead to better outcomes by promoting preventive measures [54,55].

The efficacy of low-intensity, non-weight-centric educational interventions in improving knowledge is crucial for preventing metabolic NCDs. By focusing on macronutrient education without emphasizing weight loss, the Green Apple program demonstrates a promising approach to improving metabolic health in adolescents without affecting body image. Research on educational interventions in Saudi Arabia and Gulf Cooperation Councilcountries is limited, with existing studies primarily focusing on obesity awareness and metabolic NCDs such as diabetes [12,56]. Our study contributes to this field by showing that even low-intensity interventions targeting macronutrient and NCD knowledge can enhance health literacy. Importantly, this study targeted late adolescents, addressing a significant gap as previous research has mainly focused on younger adolescents (aged 12 - 14 years) [12,56]. The Green Apple program, as a pilot derived from the larger LEAF program, suggests a scalable model that integrates educational and behavioral strategies to promote sustainable health improvements by focusing on visceral fat reduction and muscle mass development.

The significant improvement in students' knowledge aligns with recent literature highlighting the importance of early NCD education [57,58]. The observed large effect size (partial η^2 =0.286) further supports the intervention's effectiveness. Contextualizing nutritional information to metabolic health may enhance learning by linking knowledge to practical outcomes. Also, the nonsignificant interaction between gender and intervention type indicates that the content was equally effective for both male and female students, which is significant in a

cultural context where gender-specific education is common [59]. This suggests that balanced content can be effective across genders. Finally, the nonsignificant effect on body image supports literature advocating for weight-neutral interventions to avoid adverse body image outcomes [60]. However, the significant postintervention body image difference between genders highlights the need for considering gender-specific perceptions in future program designs [61].

Limitations and Recommendations

Despite the positive outcomes, challenges such as scheduling and gender-specific retention highlight the need for flexible strategies. Limitations include the relatively small, single-region sample size, which may limit generalizability, and the short intervention period, which may not capture long-term effects. Self-reported data could introduce bias. Future research should involve larger, more diverse samples and longer interventions and consider digital family-based education methods, such as webinars and web-based workshops, to enhance parental involvement [62-64]. Engaging parents in school health education could yield better adolescent health outcomes [63,64].

Conclusions

This study underscores the high prevalence of obesity among Saudi adolescents and highlights the potential of low-intensity educational interventions to improve macronutrient knowledge. By emphasizing metabolic health and muscle building, the Green Apple program offers a promising non–weight-centric strategy for preventing chronic metabolic diseases. Future programs should focus on high-intensity physical activity and neutral weight messaging to address obesity and mental health comprehensively.

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Data Availability

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

Conflicts of Interest

None declared.

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Abbreviations

BAZ: BMI-for-age *z* score **MET:** metabolic equivalent task **NCD:** noncommunicable disease **SBQ:** Sedentary Behavior Questionnaire **VO₂max:** maximal oxygen consumption

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A Primary Care Group Resilience Intervention Promotes Child and Caregiver Behavioral Health

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Abstract

This pilot study of the redesigned Resilience Clinic, a group-based psychoeducational intervention designed to promote relational health and child and family resilience provides preliminary evidence that participation in this intervention is associated with decreased caregiver stress, anxiety, and child behavioral concerns.

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KEYWORDS

parenting education; parent-child relationship; adverse childhood experiences; child behavior; children; caregiver; caretaker; parenting; family; stress; anxiety; behavior; relational health; psychoeducation; psychological education; resilience intervention; group-based; pilot study

Introduction

Since adverse childhood experiences (ACEs) including child maltreatment, family violence, parental substance abuse, and parental mental illness may increase health and behavioral risks [1,2], further research into preventive early childhood interventions, before the onset of ACE-associated sequelae is required [3]. The Resilience Clinic (RC) [4] is a primary care-based group psychoeducational intervention promoting resilience among children exposed to significant adversity. Initially serving children of all ages, this program was redesigned based on significant parent feedback to focus on early childhood (ages 0 - 5); the curriculum incorporates Circle of Security-Parenting (building secure attachment) [5] and Dovetail Learning (mindful stress management) [6] in 6 weekly, hour-long group sessions. This study explored whether participation in RC decreased measures of (1) caregiver stress, anxiety, and depression, and (2) child behavioral challenges.

Methods

This pilot study analyzed pre-post differences in caregiver-reported measures of behavioral health after RC participation. Eligibility criteria included children aged 0 - 5, referred by primary care providers following positive ACE screening; siblings were excluded. Eligible participants were allowed to join the intervention without joining the study.

Study measures included the Child Behavior Checklist (CBCL) for ages 1.5 to 5 years [7] to assess child behavioral challenges, Generalized Anxiety Disorder (GAD-7) [8] for caregiver anxiety, Patient Health Questionnaire (PHQ-8) [9] for caregiver depression, and Perceived Stress Scale (PSS-4) [10] for caregiver stress. Caregivers completed measurements at baseline and 3 months after intervention completion.

To estimate intervention effect sizes, we used Cohen d or (standardized mean difference), for paired samples. Cohen d value cutoffs of 0.2, 0.5, and 0.8 are considered as small, medium, and large effect sizes, respectively. P values were constructed from the Wilcoxon signed-rank test since the variables were not normally distributed, with significance set at P<.05.

This study was approved by the host institution's Institutional Review Board (22 - 37781) as minimal risk research. Signed informed consent was obtained from all participating caregivers. Data was stored on secure institutional servers and deidentified prior to analysis. Participants could receive up to \$190 for completing all study activities.

Results

A total of 28 caregiver/child dyads were recruited; of these, 79% (n=22) preferred Spanish and 14% (n=4) preferred English. Median child age was 4.5 years (IQR 1.66) and 50% (n=14)



were male. Participants who completed both pre and post data collection were included in this analysis.

Three months post-intervention, caregivers reported large reductions in anxiety and perceived stress compared to baseline (Table 1).

Table .	Pre-post	changes	in caregiver	behavioral	health measures.

Construct	Measures	Participants, n ^a (N=28)	Baseline scores median, (IQR)	Post intervention scores, median (IQR)	Cohen $d (SMD)^{b}$	P value
Caregiver anxiety	GAD-7 ^c	16	5.5 (1.75-9.25)	1.0 (0-4.25)	0.86	.01
Caregiver depres- sion	PHQ-8 ^d	4	8.0 (6.5-9.25)	5.5 (3.75-7.25)	0.63	.42
Caregiver-per- ceived stress	PSS)- 4 ^e	18	7.0 (6-8)	4.0 (3-6)	0.92	.02

^aNumber of participants who completed both pre and postdata collection for that measure.

^bSMD: Standardized mean difference.

^cGAD-7: Generalized Anxiety Disorder-7-item.

^dPHQ-8: Patient Health Questionnaire-8-item.

^ePSS-4: Perceived Stress Scale-4-item.

Notably, the decrease in caregiver anxiety (GAD-7: d=0.86, P=.01) and caregiver-perceived stress (PSS-4: d=0.92, P=.02) suggested large and statistically significant intervention effect sizes for parental anxiety and perceived stress among RC participants. The PHQ-8 responses were limited as the full instrument was administered only if the PHQ-2 score exceeded 4, making it difficult to draw conclusions.

Similarly, moderate reductions were seen in postintervention measures of multiple child behavior challenges, including attention problems, aggression, externalizing problems, stress, and overall problems. The decrease in attention problems (d=0.72, P=.05) approached significance. Selected child behavior domains showing moderate postintervention score reduction are listed in Table 2.

All other CBCL domains showed small effect sizes (d<0.5), including emotionally reactive (0.27), anxious depressed (0.12), somatic complaints (0.46), withdrawn (0.36), sleep problems (0.16), internalizing problems (0.32), anxiety problems (0.02), autism spectrum problems (0.48), and oppositional defiant problems (0.40).

Table . Pre-post changes in the Child Behavior Checklist (CBCL).

Child behavior domain	Number of participants, n ^a (N=28)	Baseline scores, medi- an (IQR)	Post-intervention scores, median (IQR)	Cohen d (SMD) ^b	<i>P</i> value
Attention problems	11	62 (57.5-67)	53 (51.5-62)	0.72	.05
Aggressive behaviors	11	64 (51.5-70)	56 (51-61)	0.53	.20
Externalizing problems	11	64 (53-70)	56 (48.5-60)	0.70	.11
Overall problems	11	68 (53.5-72)	58 (49.5-66.5)	0.50	.07
Stress	11	70 (53-72)	53 (52-62.5)	0.74	.09
Depression	11	63 (53-69.5)	56 (50-61.5)	0.52	.09
ADHD ^c	11	64 (59-71)	57 (52-65.5)	0.72	.08

^aNumber of participants who completed both pre and postdata collection for that measure.

^bSMD: Standardized mean difference.

^cADHD: Attention deficit hyperactivity disorder

Discussion

Three months post-intervention, caregivers reported significant reductions in anxiety and perceived stress and moderate reductions in their children's attention problems, aggressive behaviors, externalizing problems, total problems, and stress and depressive problems. The decrease in caregivers' anxiety and perceived stress was significant (P<.05), and the reduction in child attention problems approached significance (P=.05).

These findings suggest that participation in this group resilience intervention may help improve caregiver stress and anxiety and child behavior.

Study limitations include the small sample size and lack of a control group, which make the findings preliminary. Given these promising results, a randomized controlled trial is needed to confirm these intervention effects.

Given the age of these children, when mental health diagnoses are rare, most children would not otherwise be receiving mental health services. This pilot study indicates that similar primary care-based, preventative group interventions may offer meaningful improvements in caregiver and child behavioral health in the context of childhood adversity.

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Conflicts of Interest

None declared.

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Abbreviations

ACE: adverse childhood experiences CBCL : Child Behavior Checklist GAD-7: Generalized Anxiety Disorder -7 item (screening tool for anxiety) PHQ-8: Patient Health Questionnaire (PHQ)-8 item (screening tool for depression) PSS: Perceived Stress Scale RC: Resilience Clinic



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The Effect of COVID-19 on Health Care Utilization Among Children with Medical Complexity: Retrospective Chart Review Study

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Abstract

This study examines the trends, patterns, and potential health disparities in health care utilization among children with medical complexity, before and during COVID pandemic through a retrospective chart review. Our findings show significant differences in the average number of visits per patient over the years and support the adoption of telehealth consultations, while highlighting concerns about demographic disparities.

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KEYWORDS

children with medical complexity; pediatric; children; health care utilization; telemedicine; telehealth; virtual care; virtual health; COVID-19; SARS-COV-2; coronavirus; respiratory; infectious; pulmonary; pandemic; chart review; chart review study; retrospective chart review; retrospective chart review study

Introduction

Children with medical complexity are defined as children and youth with chronic and severe health conditions and substantial functional limitations that require specialized medical services, frequent hospitalizations, and coordinated care from various health care providers [1,2].

Telehealth was one of the efficient and creative solutions for care for children with medical complexity during the pandemic [3]. These children face numerous barriers to health care (eg, multiple visits per day, limited access and availability of clinicians, high cost of transportation, day-to-day life disruptions) [4]. Telehealth visits or remote virtual consultations offered numerous benefits at the onset of the COVID-19 pandemic, such as limited exposure, fewer transfers, and minimum travel for several types of patients and specialists, while also increasing the availability of consultations [5]. This alternative to in-person visits has proven to be effective in resource-limited countries with geographical barriers and has reduced the burden of negative consequences for chronically ill children [6]. After its rapid implementation during the pandemic, the attention has shifted towards equity and safety for children with medical complexity postpandemic, while focusing on clinical model refinement and addressing potential health disparities [7,8]. We explored health care utilization patterns among children with medical complexity over 3 years, before and after the pandemic.

Methods

Study Design and Participants

We performed a retrospective chart review study using data from a large health care setting on the East Coast between January 1, 2019, and December 31, 2021. Patients that were included in the study (N=435) were children with medical complexity (<22 years of age), diagnosed with \geq 3 chronic conditions [9]. All patient mortality cases (n=5) during the selected period were excluded due to incomplete data for comparison.

Ethical Considerations

This study used deidentified chart data retrieved from electronic health records using *ICD-10* codes to identify the population. The data were fully anonymized before analysis, and no personal or identifiable information was accessed. The study was conducted in compliance with all relevant data protection regulations, including the HIPPA (Health Insurance Portability and Accountability Act). Institutional Review Board approval was obtained (IRB ID: Pro2023-0385) from Hackensack Meridian Health.

Data Processing and Analysis

A demographic summary and descriptive statistics were computed to analyze the distribution of demographic variables, years, and health care visit types, including counts, means, and standard deviations. To evaluate associations between these variables, the Pearson χ^2 tests of independence were conducted.



For variables showing significant associations (P<.05), we reported the effect size using Cramer's V [5] to determine the strength of the relationship. Additionally, posthoc pairwise comparisons were performed using χ^2 tests with adjusted significance levels to identify specific category pairs contributing to the observed differences. All analyses were performed using Microsoft Excel and SPSS software (version 29; IBM Corp) to ensure accuracy and consistency.

Table . Demographic summary of patients.

Results

Demographic Summary

Table 1 presents the demographic summary of the patients included in the study.

Variables	Patients, n (%) (N=435)
Age	
Infants (1-2)	55 (12.6)
Children (3-11)	231 (53.1)
Adolescents (12-18)	104 (23.9)
Young Adults (18-21)	45 (10.3)
Race/ethnicity	
Asian	65 (14.9)
Black	65 (14.9)
Hispanic	82 (18.9)
NonHispanic White	85 (29.5)
Other	67 (15.4)
Unknown	71 (16.3)
Insurance method	
Managed Care	302 (69.4)
Private	99 (22.8)
Other	34 (7.8)

Statistical Analysis

Table 2 provides descriptive statistics for the entire dataset. The data reveal that the highest total average was 16.74 appointments per patient before the pandemic in 2019. In 2020, with the onset of COVID-19, telehealth became a viable means of

communicating with patients, while other types of visits and inpatient admissions decreased, resulting in a total average of 10.34 appointments per patient. Although mean of all visit types, including inpatient admissions increased in 2021, they did not return to the 2019 levels, leading to an overall average of 13.22 appointments per patient.



Table . Data description and findings. This table describes the mean and standard deviations of the number of visits for each visit type (telehealth, outpatient, emergency department) and admissions per patient.

Demo-	Visit types
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	Telehealth visits, mean (SD)		Outpatient visits, mean (SD)			Emergency department visits, mean (SD)			Inpatient admissions, mean (SD)							
	2019	2020	2021	P val- ue	2019	2020	2021	P val- ue	2019	2020	2021	P val- ue	2019	2020	2021	P val- ue
Over-	0	2.84	2.01	<.001	6.01	3.50	5.33	<.001	7.31	2.44	3.40	<.001	3.42	1.56	2.48	<.001
all ^a	(0)	(2.02)	(1.41)		(1.98)	(1.09)	(2.31)		(2.28)	(1.70)	(2.21)		(2.30)	(1.11)	(1.69)	
Age ^b				.78				.15				.45				.86
Young	0	2.44	2.22		5.91	3.96	4.91		7.07	2.69	4.07		3.71	1.60	2.27	
adults	(0)	(2.23)	(1.41)		(1.78)	(1.02)	(2.33)		(2.32)	(1.49)	(2.04)		(2.14)	(1.16)	(1.47)	
Chil-	0	2.99	1.99		5.81	3.50	5.37		7.32	2.45	3.42		3.31	1.61	2.45	
dren	(0)	(1.94)	(1.39)		(2.06)	(1.08)	(2.27)		(2.32)	(1.72)	(2.19)		(2.35)	(1.09)	(1.73)	
Ado-	0	3.09	1.99		6.17	3.46	5.35		7.24	2.49	3.21		3.61	1.51	2.52	
les- cents	(0)	(2.07)	(1.43)		(1.94)	(1.10)	(2.37)		(2.25)	(1.67)	(2.23)		(2.35)	(1.12)	(1.70)	
In-	0	2.05	1.98		6.62	3.24	5.45		7.62	2.11	3.11		3.31	1.40	2.73	
fants	(0)	(1.87)	(1.46)		(1.79)	(1.09)	(2.36)		(2.16)	(1.80)	(2.33)		(2.13)	(1.13)	(1.72)	
Raceéth- nicity ^b				.30				.04				.86				.85
Asian	0	2.80	2.26		5.49	3.35	5.51		7.35	2.46	3.52		3.51	1.71	2.71	
	(0)	(2.03)	(1.47)		(1.80)	(1.02)	(2.37)		(2.34)	(1.71)	(2.03)		(2.24)	(1.10)	(1.68)	
Black	0	2.91	2.09		6.46	3.51	5.22		7.22	2.51	3.86		3.37	1.54	2.31	
	(0)	(2.26)	(1.51)		(1.76)	(1.09)	(2.23)		(2.26)	(1.69)	(2.24)		(2.22)	(1.13)	(1.66)	
His-	0	2.52	1.79		5.98	3.45	4.96		7.63	2.66	3.24		3.72	1.61	2.44	
panic	(0)	(1.95)	(1.39)		(1.81)	(1.11)	(2.19)		(2.27)	(1.76)	(2.30)		(2.22)	(1.04)	(1.74)	
Non-	0	2.65	2.02		6.49	3.71	5.38		7.31	2.13	3.40		3.41	1.59	2.35	
His- panic White	(0)	(1.93)	(1.37)		(2.07)	(1.14)	(2.33)		(2.08)	(1.54)	(2.24)		(2.21)	(1.14)	(1.82)	
Other	0	3.30	1.87		5.60	3.66	5.30		7.10	2.57	3.36		3.06	1.57	2.66	
	(0)	(2.04)	(1.28)		(2.11)	(1.05)	(2.41)		(2.57)	(1.79)	(2.31)		(2.42)	(1.05)	(1.67)	
Un-	0	2.97	2.08		5.93	3.31	5.65		7.18	2.35	3.08		3.39	1.32	2.46	
known	(0)	(1.93)	(1.44)		(2.13)	(1.08)	(2.37)		(2.26)	(1.71)	(2.09)		(2.36)	(1.18)	(1.56)	
Insur- ance meth- ods ^b				.86				.44				.43				.17
Man-	0	2.81	1.99		6.06	3.52	5.23		7.32	2.44	3.42		3.39	1.56	2.43	
aged Care	(0)	(2.02)	(1.42)		(1.98)	(1.07)	(2.34)		(2.27)	(1.66)	(2.19)		(2.30)	(1.11)	(1.68)	
Pri-	0	2.78	2.04		5.92	3.59	5.63		7.28	2.38	3.35		3.40	1.49	2.55	
vate	(0)	(1.99)	(1.39)		(1.98)	(1.11)	(2.34)		(2.36)	(1.77)	(2.20)		(2.36)	(1.12)	(1.74)	
Other	0	3.26	2.09		5.85	3.15	5.29		7.29	2.62	3.32		3.74	1.74	2.76	
	(0)	(2.09)	(1.38)		(2.06)	(1.16)	(1.93)		(2.21)	(1.86)	(2.50)		(2.09)	(1.08)	(1.69)	

^aOverall averages for each year with a P value for difference between the years

^bAverages per year for each demographic group with a *P* value for the difference between demographic categories.

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A χ^2 test of independence revealed significant differences between the years for telehealth visits (*P*<.001, Cramer's V=0.612), outpatient visits (*P*<.001, Cramer's V=0.396), emergency department visits (*P*<.001, Cramer's V=0.557), and inpatient admissions (*P*<.001, Cramer's V=0.405).

Among the demographic variables, a significant association was found between race or ethnicity and the number of outpatient visits for three years (P=.04, Cramer's V=0.008). Pairwise comparison for outpatient visits revealed three significant relationships between Asian (P=.02), Hispanic (P=.004), and other patients (P=.02) compared to nonHispanic White patients.

Discussion

Telehealth visits were introduced in 2020, and resulted in a notable decrease in other visit types and inpatient admissions, as reported in other studies [4]. Although 2021 saw an increase in these visit types compared to 2020, they did not return to prepandemic levels observed in 2019. This could be attributed to catch-up visits and admissions that were postponed due to safety reasons during the pandemic [10]. In addition, while many visits can be conducted via telehealth systems, some health care procedures require in-person visits; the safety of these in-person visits improved in 2021.

The reduction in in-person visits after introducing telehealth implementation aligns with another study showing lower hospitalization rates 3 months post discharge when telehealth was used for follow up [11]. Our study also found a reduction in emergency department visits after telehealth introduction, as shown in the literature [8]. Increasing the ease at which a family can access health care via telehealth can avoid some of the in-person struggles faced by families and improve satisfaction with health care interactions.

Our findings show that Asian, Hispanic, and other racial and ethnic groups, have significantly fewer outpatient visits, on average, than nonHispanic White patients. These findings partially align with recent research among Medicaid-insured children with medical complexity, which found that Black nonHispanic and Hispanic children had lower outpatient visit rates than nonHispanic White children [12]. Several reasons may contribute to lower out-patient visits among racial and ethnic minorities, including differential access to care [12], geographical dispersion, a reduced likelihood of receiving specialty referrals from primary care providers, and distrust in the health care system [13]. Significant differences in the number of visits could lead to health disparities, potentially disadvantaging minority groups, and should, therefore, be monitored and addressed.

The COVID-19 pandemic has shown the feasibility of telehealth visits. Although we found disparities based on race and ethnicity in outpatient visits, our findings support equity through telehealth visits for patients and reduced health care utilization. There was no increase in the need for inpatient services when using telehealth visits, which supports the idea that telehealth can be an effective solution for patients. Families can avoid transportation challenges and coordination issues when using telehealth visits.

Our study focuses on changes in health care utilization among children with medical complexity with 3 or more chronic conditions, providing valuable insights into trends within this population. However, we did not account for specific illnesses, clinical outcomes, or the quality of telehealth visits. Additionally, we did not consider environmental factors such as air pollution or pollen exposure, which could significantly influence utilization patterns among children with respiratory or allergic conditions [14]. To deepen our understanding, future research should include control groups or broader pediatric populations to contextualize these observed trends and address potential confounding factors. Additionally, qualitative analyses are needed to explore the reasons behind differences in utilization and disparities, offering a more comprehensive perspective on the challenges faced by this population.

In conclusion, our findings emphasize the need for continued adaptation and support for telehealth services among children, while monitoring demographic disparities in health care access. The introduction of telehealth at the onset of the pandemic coincided with significant decreases in in-person visits and inpatient admissions. Although health care utilization rebound in 2021, it remained below prepandemic levels, suggesting an ongoing adjustment in health care practices. Further, our findings indicate that racial and ethnic disparities persist in outpatient visit patterns. Continued support for telehealth implementation, coupled with targeted efforts to address disparities, are crucial for equitable health care access for all children with medical complexity.

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Authors' Contributions

Conceptualization: IS, KNC, OA, SP Methodology: IS, KNC, OA, SP Writing – original draft: IS, OA Writing – review & editing: IS, KNC, OA, SP



Conflicts of Interest

None declared.

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Abbreviations

HIPPA: Health Insurance Portability and Accountability Act

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Early Digital Engagement Among Younger Children and the Transformation of Parenting in the Digital Age From an mHealth Perspective: Scoping Review

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Abstract

Background: Evidence identifies that excessive screen time consumption during the crucial stage of life (0 - 3 years) significantly affects children's holistic development over time. In today's intricate socioeconomic setting, parents, especially working parents, face challenges in constantly supervising their children's activities, often turning to digital devices as a suitable substitute to keep them occupied. To address these issues, a mobile health (mHealth) app can emerge as a feasible solution to help parents manage digital habits for their infants while minimizing the harmful effects.

Objective: The aim of this scoping review from an mHealth viewpoint is to raise awareness among parents about the detrimental effects of unwarranted screen exposure in children younger than 3 years and recommend effective strategies for redirecting them to alternative developmental activities, promoting balanced digital engagement for their infants and toddlers within their domestic landscape.

Methods: A systematic search of academic databases, including Google Scholar, PubMed, IEEE Xplore, and Elsevier, was conducted. To discover existing child screen monitoring apps, searches were conducted in the Google Play Store and Apple App Store through specific keywords across regional marketplaces. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were followed to organize the literature search process. Data collected from the studies were organized into a predeveloped Excel spreadsheet to facilitate analysis. Synthesized data were scrutinized to detect patterns, variances, and reasonable recommendations.

Results: While parents acknowledge the negative impacts of young children's excessive screen time, their dependence on digital devices survives due to today's modern lifestyle commands. In total, parents' insights were clustered into 9 separate categories, highlighting that parents often believe smart devices are beneficial for their children. A total of 6 intervention approaches for parents and 3 for pediatricians were summarized. A significant finding was parents' unawareness of the association between their own screen time and their toddlers' interactions with screen media. Additionally, parents also perceived existing intervention strategies positively and acknowledged them as helpful solutions. However, they also recognized that inadequate tools and insufficient time for execution caused the gap in these approaches.

Conclusions: The findings of this study underline the need for an empathetic tool to help parents manage their children's screen time efficiently. The development of a holistic mHealth app is presented that considers awareness, practical guidance, and personalized interventions to balance children's digital device use. The proposed solution could incorporate four essential features: (1) screen time tracking and monitoring, (2) a reservoir for parental training and guidelines, (3) an alternative activity advocator, and finally (4) an interactive artificial intelligence assistant. This study provides valuable insights into improving obedience to healthy screen use and fostering a digital ecosystem where technology itself functions as an advocate of child progress, instead of an obligation.

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KEYWORDS

infants and toddlers; screen time; cognitive development; parental ignorance; intervention strategies; mHealth; digital addiction; children; developmental challenge; parents; engagement; decision-making

Introduction

The escalating inclination towards extreme screen time use among children has become a universal problem recently, with evidence pointing to imposing severe impacts on children's early childhood development, for instance, lower academic achievements, increased anxiety, difficulties in language acquisition, and other developmental setbacks [1-4]. The American Academy of Pediatrics (AAP), a leading authority dedicated to safeguarding children's welfare, restricts any form of screen media exposure for children younger than 2 years [5]. Nevertheless, studies have uncovered that almost 68% of children younger than this age bracket often surpass this threshold, spending around 2.05 hours of screen time each day, which is overwhelming [6,7]. In addition, watching television, one of the most conventional modes of screen media, for more than 2 hours per day was observed to be 83% in the United States, 78% in Australia, and 82% in Canada among toddlers aged 2 to 5 years, contributing to a sedentary lifestyle within approximately 34% to 94% of children, which are equally alarming [7,8].

The complex socioeconomic landscape further intensifies this issue, as modern parents face an array of obstructions in constantly monitoring their children's activities. Parents play a central role in influencing their young children's screen time habits, as their screen observation levels and behavior are greatly related to those of their children. Their positive attitudes toward screen time can unconsciously increase screen exposure to their young children, leading to behavioral imitation and delays in developmental outcomes [9]. Contrariwise, research indicates that reduced parental screen time is associated with reduced screen exposure in children younger than 3 years, increasing parent-child interactions that are crucial for early cognitive and emotional development [10]. With the limited scope of supervision, screen devices have emerged as a convenient child supervision tool, performing as a companion for struggling parents, leading to approximately 70% of parents ignoring the

AAP recommendations, unintentionally contributing to the challenge of screen time management [11,12]. These observations highlight a disconnect between existing guidelines for limiting screen time in infants and the practical challenges parents encounter in limiting digital device use, which implies the need for a detailed reassessment of prevailing strategies to promote a balanced lifestyle that is practical for parents and protective of children's optimal growth and developmental needs.

The foundations for effective intellectual and analytical skill advancement are embedded in early childhood, which offspring usually adopt and develop within the initial 3 years of life [13]. However, throughout this critical stage, infants and younger toddlers are also enormously vulnerable to the harmful consequences triggered by long-lasting screen exposure [14]. Evidence implies that consuming a higher rate of screen time negatively impacts children's cognitive growth with a downstream influence on their physical, academic, and psychological outcomes, as illustrated in Figure 1 [15-17]. A psychological study from Korea involving kids between 24 and 30 months of age displayed a proportionate relationship between prolonged screen time and delays in language development and challenge-solving skills [6]. Similarly, higher television exposure at only 29 months of age was correlated with minimum vocabulary acquisition levels at a later age [18]. On the contrary, research has exhibited that watching high-quality programs under parental supervision has advantages, including attention span and vocabulary improvements, compared with children who do not watch such content at all. Such quality content often uses tactics including findable object labeling, proper formatting, the interaction between the child and characters, and a structured program outline, which can help in their developmental benefits [19]. Nonetheless, many of these affirmative statements targeting children younger than 2 years remain unproven, as stated in the 1999 AAP policy announcements [2,20,21]. These opposing outcomes infer a huge gap in our understanding and the need for an adapted rather than a one-size-fits-all answer.



Figure 1. Influence of excessive screen time on early childhood developmental spheres.



Previous studies regarding the potential consequences of screen time have largely targeted the age range of children between 5 and 7 years; nonetheless, limited attention has been given to children between 0 and 36 months. This study argues that instead of completely discarding the abundant presence of screen devices, it is crucial to adopt a parent-centric, rational strategy that aligns with today's contemporary lifestyles. This paper proposes that the development of a mobile health (mHealth) app can enable parents to manage their children's screen time and maintain a balance between technology consumption and mindful parenting. This study aims to acknowledge the research gaps, emphasize the existing blind spots, and offer appropriate solutions. To accomplish this, the paper addresses the following fundamental research questions:

RQ1: How does the absence of knowledge regarding the prospective threats of excessive screen use influence parental decision-making procedures?

RQ2: What alternative approaches have been identified that parents can successfully use to divert their children from unnecessary screen time while reinforcing their intellectual, physical, and emotional expertise in a home-based surrounding?

RQ3: How can these alternate strategies be seamlessly integrated into a holistic approach that mitigates the adverse effects of excessive screen exposure on young children's overall development?

We start by representing a systematic approach to reviewing existing and appropriate literature in the designated field, analyzing their insights, and revealing critical knowledge gaps in parental understanding regarding screen time management. Building on these insights, we present some actionable

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suggestions and explore the capability of developing a mHealth app as a rational tool for parents to help them create a better and healthier digital balance for their children younger than 3 years.

Methods

Overview

Through a structured methodology, broad topics can be investigated and blind spots in the existing literature can be identified [22]. We conducted this research using the methodological framework for scoping reviews proposed by Arksey and O'Malley [23], ensuring a meticulous and transparent approach. The methodological framework of this research is designed to provide a comprehensive understanding of the central research questions by identifying primary studies through different sources. Our framework is divided into 3 distinct phases, covering a thorough scoping criteria, a systematic literature search, and a data synthesis process, which are rigorously carried out to ensure alignment with our research objectives.

Scoping Criteria

In phase 1, we identified studies inspecting the reasoning behind parents' dependence on smart devices, their impact on children's early development, and the viability of alternative intervention activities. The study, furthermore, accounts for parents' misunderstandings regarding the positive effects of screen media consumption on their children's health development, alongside how their own digital habits influence their children's media use patterns. In this research, all contributory studies related to the critical research questions offering insights into the

behavioral and developmental implications of excessive screen use received preliminary approval. This phase was performed to encourage parents' early involvement in using effective solutions, preceding a more thorough investigation of the problem.

Systematic Literature Search

In phase 2, we used a systematic literature search to identify studies that complemented the work done in phase 1 and focused on suggesting, describing, evaluating, and implementing novel insights into mitigating screen dependency on children younger than 3 years. The literature review contained journal papers, peer-reviewed articles, and official reports obtained from academic databases such as JMIR, Google Scholar, IEEE

Table . Search strategy.

Xplore, Elsevier, and PubMed. Advanced search features, such as MeSH terms in PubMed, along with targeted searches including Pediatrics and Parenting, mHealth and uHealth within JMIR were used to recognize the role of child- and parent-centered approaches using mobile apps, information technologies, engineering solutions, and expand the scope of infants and toddlers' health outcomes. We then formulated a series of specified keywords stemming from the research questions to group papers across the abovementioned databases, as detailed in Table 1. Additionally, to gather information on publicly available parental child monitoring mobile apps for smartphones, we conducted searches of the Google Play Store and Apple App Store using keywords like "Family," "Child," and "Safety" across regional marketplaces.

Search approach	Field	Context	Motivation
Primary search term	Screen use and child development	Early childhood screen use	Parental monitoring solutions
Synonyms	"infants," "young toddlers," and "early childhood"	"cognitive growth," "psychological development," "sedentary lifestyle," "screen time," "factors and domi- nance of screen viewing," "risks of extreme screen media," and "alter- nate solutions"	"mHealth," "software system," "software application," and "safety"

Publications were eligible for inclusion if they were written in English, issued in interdisciplinary conference proceedings, satisfactory journals, or as official reports formed by a government constitution. Broad eligibility criteria were used to maximize the possibility of finding appropriate information, such as the studies that demonstrated expertise in child health science and child psychology, explored alternative strategies to reduce screen dependency such as outdoor activity or mHealth apps, and involved in a discussion related to the detection of effects, connections, and solutions for children younger than 36 months. Researchers applied exclusion criteria to ensure consistency in screening and to maximize the possibility of excluding unsatisfactory literature. The exclusion process involved 2 stages of screening, an initial removal of duplicate and irrelevant articles based on titles and abstracts followed by an exclusion of studies that were not peer-reviewed, published in gray literature, and unrelated especially to child cognitive or behavioral growth, resulting in the elimination of approximately 48% publications of the primary pool.

Data Synthesis Procedure

The data synthesis was performed to categorize the selected papers for evidence synthesis and address the research questions briefly. Data collected from the studies included were organized into a predeveloped Excel spreadsheet to facilitate analysis. The extracted data encompassed bibliographical data (eg, author, title, year of publication, DOI), study characteristics (eg, type of study and sample demographics), contextual information (eg, screen media type, parental decision-making factors, perceived developmental impacts), and evaluation criteria (eg, parental behaviors, child performance, intervention strategies, and outcomes such as cognitive, behavioral, physical, and social development). Classification formats were developed to organize the efficacy of interventions (eg, screen time reduction,

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improved parental engagement, and coviewing) and their relevance to developmental outcomes. Data charting involved systematically populating the metadata from each study into predefined categories. Key findings were reviewed to ensure accuracy. The synthesized data underlined crucial insights: parental fallacies regarding screen time, gaps in existing policies, and the necessity for accessible, technology-motivated solutions. This phase highlighted the similarities and discrepancies across selected literature, offering recommendations that address the research questions and confirming that this study's conclusions achieve optimal reliability and scalability in diverse childcare settings.

Results

Overview

This scoping review tries to answer research questions presenting the significance of parental attitudes, perspectives, and practices related to screen use that influence the screen time pattern of their infants and toddlers. This study reveals that parents' lack of awareness regarding their own habits of screen use directly affects their toddlers' relationship with smart devices, impeding their healthy development. Hence, these outcomes highlight the necessity to educate parents on the implications of screen use to promote well-informed decision-making that can draw the odds out of screen device use. The results also highlight the importance of balanced use of screen time by children due to the modern parenting environment. The study selection process is illustrated in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart, as shown in Figure 2, which outlines the records identified, screened, and included in the final analysis.

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Figure 2. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart displaying systematic literature search.



Significance of Consciousness in Parental Decision-Making (RQ1)

The findings from reviewed studies reveal the outcomes related to early childhood screen exposure, highlighting that the majority of parents remain unaware of how their own screen use directly influences the screen time behavior adopted by their infants and young toddlers [11,24]. As the principal guardians and decision makers, parents uphold a momentous role in shaping their children's early interaction with smart devices, who are tremendously susceptible to the potential consequences of excessive screen exposure during this critical development stage [13]. Thus, to construct more rational and informed guidelines regarding screen time limitations, it is essential to further investigate parental decision-making procedures, incorporating their values and theories in today's modern settings. In Table 2, we categorized parents' perceptions towards their positive beliefs in smart devices for their children. The results of children's screen viewing depend heavily on wrong impressions of their parents' decisions regarding the age inappropriateness of content, exposure to background media, allowing screens during mealtimes, and so forth. For example, studies have identified that regularly exposing a toddler to noise made from television or other digital content playing in the background while a child is engaged in another activity can disrupt their focus, reduce verbal interactions, and delay vocabulary growth [15,20,25,26]. Similarly, dependence on any mode of screen device during sleep time often results in reduced parent-child bonds and a disrupted sleep pattern.



Table . Observations of parents as opposed to their actual impact.

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Parents observations	Decision-making factors	Effects on cognitive develop- ment	Additional impacts	Reference
Protected from external world	Parents from unsafe neigh- borhoods prefer providing screen time to keep their toddlers indoors.	 Higher screen dependence at school age Less attention span 	Higher risk of obesityAggressive behavior	[2,27]
Screen media as an educa- tional tool	Confidence that programs that target younger toddlers are educational and enhance child development.	 Decreased child vocal- izations. No considerable linguis- tic abilities Reduced school-con- nectedness 	• Inverse impact on self- esteem.	[2,6,15,28]
Background media use	Children exposed to adult contents (termed as back- ground noise) while being engaged in other activities.	 Delayed vocabulary development because of less "talk time". Reduced focus on intel- lectual tasks. 	 Distraction of children from current activities. Reduced exposure to meaningful family inter- action. 	[15,20,25,26]
Media as a peacekeeper	Parents use screen devices to escape tension and concen- trate on tasks such as food preparation, doing office work, or household duties.	Decreased focus and attention span.Both short and long-term speech delay	 Decreased parent-child interaction. Less time for creative activities. Weakened psychological outcome. 	[11,24,26]
Bedtime media use	Parents comprehending that screen time helps in calming children to sleep.	• Adverse outcome on speech delivery.	Resistance to sleepCondensed sleep length	[20]
Touchscreen benefits for motor development in in- fants	Belief that early touch screen interaction boosts fine motor skill advance- ment.	 Experiencing "video deficit"— difficulties while transitioning from 2D to 3D objects Troubled motor skills. 	 Disrupted mental flexibility. Higher Body Mass Index (BMI) 	[11,14,26]
Use of smart devices as an indication of status	Societal pressure to endless- ly purchase latest screen gadgets to children for sta- tus.	• Delayed cognitive, and verbal advancement.	Limited outdoor play opportunities.Tendency towards a sedentary lifestyle	[2]
Underestimation of media consumption	Parents underestimating their own children's screen viewing length.	Physical changes to brain structureChallenges in informa- tion processing.	Agitated behavioral change.Higher obesity riskReduced sleep duration	[24]
Lack of consciousness of existing recommendations	Confusion or ignorance of existing standards, with a focus only on benefits of physical activity.	 Disproportionate attainment of cognitive indicators. Possibilities of hyperactivity and inattention 	 Health hazards later in life Disrupted sleep and eating routine 	[5]

Table 2 demonstrates that a significant number of parents allow screen time for their children due to an array of familial and societal reasons. Many parents who have newborns and younger toddlers use screen devices as a mode of distraction or a means to prevent conflict, manage household chores, or even put children to sleep. Some of them give their child the latest smart gadgets as a means of maintaining social status because of the perception of these devices as a convenient educational tool, believing screen media literacy will prevent their offspring from falling behind other children in an academic setting, while others

are protective against the outside world and would choose for their children to stay indoors and be secure. Moreover, some parents underestimate their children's screen time entirely, and others are merely oblivious to the recommendations. Such dependence on screen devices has normalized their presence in regular life, advocating to parents that screen use is an innocent and required aspect of advanced upbringing, often obscuring the potential harms associated with screen use which can be serious such as mood fluctuations, sleep difficulties, psychological and physical changes, reduced attention spans, and other health problems. Studies also highlight the influence

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of convincing marketing campaigns that portray screen time as absolutely imperative for educational and entertainment purposes, further concealing the challenges associated with them [28]. These findings highlight the need to promote parental awareness and mindful digital engagement during early childhood. It is therefore crucial to present parents with evidence-based tools that can balance their child's screen use with developmental requirements.

Strategies for Moderating Screen Time in Younger Children (RQ2)

The studies indicate that the continuous presence of smartphones and other smart gadgets within households has become an inherent component in the lives of infants and toddlers [29]. Among this significant population, roughly 72% of children aged 0 - 8 years and 38% of children younger than 2 years have access to some mode of smart devices such as smartphones, iPads, or tablet devices [30,31]. Despite a plethora of studies emphasizing the short-term difficulties during infancy and continuing long-term complications in the subsequent growing phases, such smart devices remain an inevitable part of current parenting due to their ability to attract the minds of children successfully [13]. After acknowledging the consequences, authorities such as the AAP, the US Department of Health and Human Services, the Australian Department of Health and Ageing, and the Canadian Pediatric Society strongly instruct plummeting screen time as one of the significant urgent issues by entirely restraining media use on children younger than 2 years, and instigating rigorous boundaries for those between 2 and 18 years [20]. Figure 3 demonstrates the recommended duration of screen time and other developmentally supportive activities for children stated by AAP to enable healthy behaviors, such as including enough sleep, outdoor activities, and constant physical play that can successfully counterbalance screen exposure.

Figure 3. The advised total amount of screen time, physical/outside activity, and sleep for discrete age groups of children [13,17-20]. AAP: American Academy of Pediatrics.

AAP'S COMPREHENSIVE GUIDELINES FOR SCREEN USE, SLEEP, AND PHYSICAL ACTIVITY ACROSS ALL AGE GROUPS

Address what type of media and how much screen time is appropriate for each child.
 Promote a child's cognitive, physical and mental health

Cultivate healthy lifestyle

AGE GROUP	RECOMMENDED SCREEN TIME	DURATION FOR OUTDOOR ACTIVITY	TOTAL AMOUNT OF SLEEP
0-12 Months	No Screen Media	Not Satisfactory	12-16 h/day
12-24 Months	Minimum screen participation in the presence of a parent	Not Satisfactory	11-15 h/day
2-5 years	At most 1h/day, consumption of high- quality content only	0.5-1 h/day	10-14 h/day
6-12 years	No more than 1h/day and always closely supervise	1h/day	9-12 h/day
13-18 years	Maximum 2h/day with limitations on content	1h/day	8-10 h/day

The results depicted that extreme screen use in a family is strongly associated with a toddler's own screen viewing practices. Given that children younger than 2 years have very limited power over their adjacent surroundings and their actions are merely a replication of what their parents do around them, their screen habits are formed by what they perceive. For instance, studies highlight that if parents engage in more than 4 hours a day watching TV, their toddlers will be 3 times more likely to exceed the same duration [32]. Thus, parents need to regulate their own screen use and model positive examples as they are the chief contributors to their infants' long-term well-being. Childcare providers, more specifically pediatricians, play a fundamental role in supporting well-adjusted screen habits by educating parents and continually supervising parental adherence to the guidelines during scheduled appointments, assuring their proper implementation within households [20,33]. Therefore, intervention strategies should largely entail actions taken by parents as well as childcare providers, as each of them has a unique role in the infant's long-term betterment [33]. Given the increasing impact of modernization within home environments, the following intervention strategies demonstrated in Table 3 provide ideal directions for distinct family perspectives, and it is imperative to implement such principles as references for forthcoming actions. Considering the outcomes of various studies, 6 types of intervention approaches for parents and 3 for pediatricians have been distinguished, along with their expected outcomes as summarized in Table 3.

Table. Intervention strategies and their anticipated outcome.

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Target contributor and recommended intervention strategies	Description	Expected outcome	Reference
Parents			
Restriction on child's screen time	Consistently control screen time throughout the day, avert using any screen de- vice during meals or sleep, and turn off devices while not in use.	 Promote healthy eating behaviors. Enhance language acquisition Better quality of life 	[13,15]
Limit parental screen time	Formulate home-based regu- lations on screen media specifically for parents.	 Reduces screen time of children through model-ing. Increased parent-child connectivity 	[17,34]
Coviewing contents	Parents encourage co- watching high quality con- tent, supervising what their children see and hear.	 Enhances cognitive development. Encourages parent- child interaction Significantly expands vocabulary during in- fancy 	[6,13,24]
Focus on quality over quantity	Promote educational content which uses schemes to assist language training, contains naive story structures and allows child interaction scopes.	 Higher communication skills Increases prosocial behavior. Expands concentration. Encourages positive racial outlook 	[6,13,15,26]
Promote child-directed and age-appropriate media con- tent	Recommend contents for younger children that con- tains longer displays, pro- vides narration hints, label- ing, and structured story- telling.	 Facilitates cognitive understanding. Overcomes "video deficit". Higher school readiness 	[11,17]
Promote a healthy lifestyle.	Include outdoor activity, imaginative play, a regular sleep cycle, and a nutritious diet.	 Promotes locomotive skills, reduces child-hood obesity, and improves metabolic health. Influence adaptive health. 	[35]
Pediatricians			
Set age-appropriate "media limits"	Discuss and enforce screen media restrictions for chil- dren younger than 2 years during scheduled visits.	• Fosters balanced screen behaviors at an initial stage	[20]
Encourage supervised independent play	Inform parents about inde- pendent play when they are unavailable but able to super- vise their child.	• Builds perseverance and problem-solving expertise while remain- ing under surveillance	[20,33]
Explain the value of "unplugged play"	Encourage parents to engage children in hands-on, imagi- native, and performing activ- ities that interest them.	 Encourages creative thinking Expands problem solv- ing skills. 	[3]

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Developing a Holistic Strategy: A Pathway to Expand Children's Cognitive Advancement

Studies indicate that engaged, collaborative, and informed parenting can successfully reverse the detrimental impacts of excessive screen use while fostering complete development [36]. For instance, research has confirmed that the presence of a parent who actively gives statements or explanations on the content their child watches, starting from as early as 6 months, can have a positive impact on the infant's intellectual engagement and attention span [26]. However, modern life often restricts the scope and time for quality parent-child communications, as time-restrained parents face tight spots to implement these policies. Therefore, a balanced solution is needed that moderates the negative impacts of screen time while leveraging the advantages of using several digital tools [37]. As the research team reviewed some existing strategies to help parents balance screen time for their infants and toddlers, studies revealed some parental control mobile apps, such as Google Family Link, Apple Family Sharing, and Microsoft Family Safety, which primarily focus on screen time management for older children. However, these apps provide inadequate guidance for children younger than 3 years, which needs to be addressed through age-appropriate solutions to guarantee healthy early development.

Discussion

Principal Results

This study underlines that excessive screen exposure has extensive consequences on the overall well-being of infants and younger toddlers, putting this phenomenon into a different perspective. The consequences are far more serious, and they are not simply a result of screen exposure but are greatly interconnected with parental personal screen media use, attitudes, behaviors towards technology, and ignorance of the risks posed by digital devices. Parents' reliance on screens-whether as an opportunity of defense against the outside world, a means of distraction, a perceived educational tool, or even a status symbol-plays a critical role in offering their children a smart device. It is undeniable that the presence of smart devices will further reinforce with time, augmenting the urgent necessity for appropriate and practical interventions that encourage mindful digital engagement, particularly in the case of infants and toddlers.

Major intervention strategies identified in this paper include restricting screen time for both parents and their offspring, coviewing age-appropriate programs, and prioritizing nonscreen activities as they promote healthier behavior and increase parent-child connection [13,15,17,34]. More hands-on strategies, such as quality regulation of content, are also essential as younger children often lack the decision-making capabilities of which programs to watch. Therefore, the prevailing guidelines are necessary for a constructive learning experience for the younger generation [14,26]. Pediatricians also play an essential role as part of their responsibility is to advise parents on the best actions required for their children, for instance, inspire parents to establish age-appropriate time limits and suggest both supervised and independent play according to the child's interest. Such pursuits can cultivate a recognition of persistence and broaden their thoughts of the outside world beyond just screens [20,33].

Given the presence of technology in this modern world, it is evident that addressing the challenges related to screen time consumption requires leveraging technology itself. Studies suggest an urgent need for solutions that balance regulatory guidance with sustainable and parent-centric approaches tailored to today's sociocultural and socioeconomic realities [38,39]. Therefore, building on the understanding of the research assembled from an examination of RQ1 and RQ2, we recommend that a mHealth app can be an empathetic, practical, and scalable tool that will make supervising children's screen time easier for today's busy parents. The justification for this app is plain and simple; since digital devices have become an inseparable part of our daily lives and high-tech devices are already accessible to every parent, it would be a logical and feasible decision to leverage them to tackle this issue. Additionally, it would enable parents to oversee the digital ecosystem precisely and cautiously within a household.

The app could be built using the Scrum Agile software development methodology to ensure the progress of the app development process in an incremental and iterative way. Each sprint could drive the systematic execution of planning, design, coding, testing, and review, facilitating efficiency and high-quality outcomes. Backend development could be implemented using the Swift programming language within the Xcode IDE (Apple Inc) to facilitate development, organize events, and enhance data flow. User interface (UI) could be designed by leveraging UIKit and SwiftUI frameworks. Additionally, Swift Package Manager could be leveraged to ensure efficient dependency management, Git for version controlling of the codebase, and Firebase Software Development Kits for documentation and cross-platform app development of the scalable prototype. In delineating the direction for the development of this app, we believe four core components with their prominent features as absolutely principal for creating a holistic framework: (1) screen time tracking and monitoring (could allow parents to monitor screen use across multiple devices and set goals), (2) provision of parental training and guidelines (could provide resources to educate parents, boosting parental self-confidence in their capability for successful screen management), (3) alternative activity advocator (could propose nonscreen pursuits tailored to each child's preferences), and finally (4) interactive artificial intelligence (AI) (could present personalized suggestions to parents, assisting them to address the challenges proactively and reducing screen dependency) (Figure 4).

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Outline of the Key Features

Screen Time Tracking and Monitoring

While it is not realistic for parents to completely eliminate providing their children with screen devices, they can guarantee controlled use [40]. A screen time tracking and monitoring feature can allow parents to track their toddlers' daily screen use by showing detailed data insights across multiple devices [41]. This functionality can be accomplished by applying parental control application programming interfaces (APIs) that supervise and log screen time, along with frameworks like Xamarin or React Native, which can be used for combined codebases. To prevent cognitive fatigue and avoid overstimulation in children from repeated use of the same content, the app can periodically suggest changes in media content after a predefined duration. Younger children can struggle with multilingual content, often overwhelming their learning abilities [42-44]. Recognizing the challenges, the app could offer a language-filtering option that enables parents to streamline content into a single language, supporting early development, early language supporting language development-particularly for children with special requirements. To help parents manage screen exposure effectively, the screen time goals and alerts feature can inform parents with alerts when time limits come closer or are exceeded. Furthermore, a digital reward system can be incorporated to persuade adherence to screen time limits, applied through a gamification reward framework linked to databases to track the improvement. It is well known that prolonged screen exposure at close distances could be extremely detrimental to children's eyesight [45]. A proximity sensor feature could use smartphone infrared sensors to alert parents if devices are held too close to infants' and toddlers' eyes, reducing the risk of eye strain. Both Screen Time API and the UsageStatsManager API can be operated for iOS and Android, respectively, and all the segments can be seamlessly synchronized across various devices using cloud-based services such as Firebase or AWS, confirming convenience and ease of use for parents.

Parental Training and Guidelines

The parental training and guideline feature could perform as an all-inclusive educational resource for parents, so that parents do not feel ignorant. The function can offer reasonable resources such as videos, articles, or infographics to delineate the outcomes of excessive screen time and suggest effective strategies for regulating it, attained using a content management system that handles the content dynamically. To make the app more reachable and user-friendly for parents with varying levels of digital literacy and access to technology, the app could incorporate a LangChain model to provide concise summaries of critical research findings as Daily Educational Push notifications, guiding them to take their next actions. This approach would guarantee that parents have easy access to an ample number of resources, removing the need for independent research and allowing them to make informed decisions regarding their child's screen time. After clicking on the popper notification, parents could be seamlessly redirected to the detailed materials. Real-time updates can be acquired using services, for example, Contentful or Strapi. The platform can connect parents with certified child psychologists or pediatricians through audio or video calls for adapted guidance and strategies on screen time administration, using a booking system and secure calling features such as Twilio API. The blue lights emitted during screen time can significantly disrupt sleep time and sleep quality of infants and toddlers [46]. It is feasible to create collaborative tutorials using libraries such as Intro.js and connect them to the device API to design a scheduled Night mode module that offers step-by-step directions on lowering blue light emission during nighttime gadget use. Finally, a community forum module can facilitate parents in sharing tips, their experiences, hardships, and success stories on monitoring their child's screen time so that they always feel supported in their journey. Both the front and back end of this segment can be developed by using React.js and Node.js, ensuring appropriate authentication, fundamental for this facility to operate.

Alternative Activity Advocator

Nonscreen activities play a vital role in the holistic development of children aged 0 - 3 years, as this period determines future behavioral and health outcomes [47]. While outdoor play promotes physical health and improves motor skills, shared family activities and social interactions improve communication skills [48]. It can be challenging for parents to come up with ideas to lure their kids away from screens. The alternative activity advocator feature can be instrumental in promoting nonscreen engagement for children. Subsections falling within this section can incorporate (1) Shared Family Activities, which could offer constructive, age-appropriate family activities. Existing parental control techniques, such as Google Family Link, Apple Family Sharing, and Microsoft Family Safety, emphasize screen time tracking but do not offer any guidance for alternative activities. The proposed feature could include diverse activity categories based on a child's creative, active, social, and educational interests and recommend tasks accordingly. For instance, interactive activities like listening to nursery rhymes to nurture creativity, baby yoga to encourage physical activity, or a scavenger hunt to build an adventurous mindset [49,50]. Such activities can significantly help children meet milestones, establish a foundation for parent-child bonding, and build their motor, sensory, and communication skills. (2) The next subfeature could suggest the Provision of Digital and Audiobooks, delivering an assorted library of books suitable for a child's age and intensity of reading. The level of engagement will be higher if the picture books include colorful visuals, simple language, and interactive storytelling options to capture the attention of children, particularly infants or younger toddlers [51]. (3) Finally, the app could further incorporate Geolocation-Based Recommendations to identify nearby parks, playgrounds, or family activity centers where parents can arrange playdates with other families [52]. This way, parents can discover safe and engaging environments for their children to socialize with same-age children and develop their social interaction skills at an early age. A decision tree algorithm could be used, driven by data collected through in-app surveys and stored in a NoSQL database like MongoDB for flexibility to attain such distinctive offerings. Activity recommendation algorithms can be used using Python's scikit-learn or comparable libraries. These features would reduce reliance on screens while fostering creativity, physical activity, and real-world interaction in an organized manner.

Interactive AI

The mHealth app can incorporate another innovative attribute by channeling the power of AI to present parents with adapted guidance. An AI-based Content Scheduler can be developed to offer busy parents flexible options for planning their child's activities during mealtimes, play hours, and bedtime, offering real-time support. Automatic AI scheduling could leverage collaborative filtering, content-based recommendations, and context awareness to generate developmentally appropriate schedules. A Parental Advisory AI assistant can be established, using natural language processing libraries such as NLTK or spaCy in Python, incorporated with an AI chatbot framework, for instance, Rasa or Microsoft Bot Framework. Additionally, an AI-assisted Personalized Activity Advocator, leveraging the

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LangChain framework and advanced large language model capabilities, could deliver tailored recommendations for nonscreen activities and developmentally appropriate digital educational content [53-55]. Drawing from user survey data, collaboration history, and professional input, this feature could support the fundamental cognitive development goals for infants and toddlers. Additionally, A/B testing could be used to continuously improve the algorithms based on user feedback, ensuring relevance and accuracy.

To ensure strategic scalability, the app could primarily launch a freemium model, proposing a basic version tailored for home-based ecosystem to allow widespread adoption. Simultaneously, a premium model, available through subscription or payment, could be introduced for daycare or childcare environments, generating sustainable revenue. The basic version can be upgraded to a premium version with a subscription at any time, ensuring accessibility and long-term market success. We believe that by integrating this innovative solution along with all the recommended features, the app will promote healthy cognitive and emotional development, establish positive media habits, and adapt seamlessly to busy family dynamics.

All in all, by leveraging the revolutionary principles of information technology, machine learning, and AI, the proposed mHealth app could become a one-stop solution for confronting the challenges modern parents face in managing screen time for their children younger than 3 years. This novel app can act as an exclusive knowledge hub for screen time management, parenting guidelines, tips, and expert advice. A comprehensive framework, easy-to-understand UI, and integration of advanced functionalities are future ways to maintain the digital lifestyles of toddlers and infants.

Limitations

The outcomes of this research contribute to a deeper understanding of the significant correlation between screen time consumption, parental behaviors, and early childhood development. However, it is compulsory to address specific limitations. Existing studies often fail to consider individual variability among children and different family dynamics, such as socioeconomic factors, parenting styles, and cultural influences. Consequently, this oversight restricts the relevance or applicability of findings across discrete socioeconomic populations. Our research concentrated on general patterns about the effects of screen time without considering different family structures, but recognizes the necessity for future research to further examine these nuances.

The complex and continuously evolving character of the digital landscape presents difficulties in effectively managing screen time. Therefore, the proposed mHealth app, including the existing guidelines, must be pliable and capable of addressing emerging challenges presented to it. Leveraging AI and machine learning to offer continuous updates would provide parents with more control over the watched contents, guaranteeing continual efficacy.

Ensuring user engagement is another challenging procedure. Integrating AI with diverse user input data may demand model

training data adjustments. Future studies could use iterative refinement cycles and investigate additional algorithms to ensure optimal performance. Furthermore, the usability evaluation may reveal unexpected UI challenges. Executing iterative usability testing cycles with small groups could enable mitigating this challenge, allowing for design refinement.

Conclusions

A significant proportion of children begin engaging with smartphones and other screen devices at an earlier stage and for a longer period than childcare authorities advocate. The clear effects of the digital landscape and smart device availability highlighted in this study uncover critical research questions about program content, parental behavior, and the possible direct effects on infants and toddlers; highlighting that there is a pressing need for holistic, evidence-based approaches to address the developmental challenges associated with excessive screen time consumption among children aged 0 - 3 years. In response to this issue, the paper proposes integrating technology into the

solution through a mHealth app constructed to balance the developing requirements of children with the pressures of modern parenting. The novel solution, along with its innovative features, could become a valuable partner in helping parents face repercussions, offering massive support from early childhood. The beneficiaries of this solution are the children themselves, who would obtain immense enrichment in their overall cognitive and emotional advancement through reasonable and practical screen use. The findings should also inspire parents and pediatricians to discuss children's screen habits, warn researchers to unpack the contradictions in the existing literature, and discover potential prospects for defensive interventions. Finally, the paper underlines the importance of further research so that the solutions can appear to be readily applicable and adaptable across all naturalistic home-based settings. With strong potential for commercialization and industry impact, the proposed mHealth app is poised to transform child well-being and promote lasting benefits for families and communities.

Conflicts of Interest

None declared.

Checklist 1 PRISMA checklist. [DOCX File, 544 KB - pediatrics v8i1e60355 app1.docx]

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Abbreviations

AAP: American Academy of Pediatrics
AI: artificial intelligence
API: application programming interface
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
UI: user interface


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Review

Assessing and Enhancing Nutrition and Physical Activity Environments in Early Childhood Education and Care Centers: Scoping Review of eHealth Tools

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Abstract

Background: Early childhood is a critical period for shaping lifelong health behaviors, making early childhood education and care (ECEC) environments ideal for implementing nutrition and physical activity interventions. eHealth tools are increasingly utilized in ECEC settings due to their accessibility, scalability, and cost-effectiveness, demonstrating promise in enhancing educators' practices. Despite the potential effectiveness of these eHealth approaches, a comprehensive collection of available evidence on eHealth tools designed to assess or support best practices for nutrition or physical activity in ECECs is currently lacking.

Objective: The primary objective of this scoping review is to map the range of available eHealth tools designed to assess or deliver interventions aimed at improving nutrition or physical activity in ECEC settings, while evaluating their components, theoretical foundations, and effectiveness.

Methods: This scoping review adhered to the Joanna Briggs Institute methodology, in accordance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) checklist. The objectives, inclusion criteria, and methods for this review were predefined and specified. Eligibility criteria were (1) early childhood educators (population); (2) eHealth (digital) technologies, such as websites, smartphone apps, emails, and social media; and (3) tools designed to assess or deliver interventions aimed at improving best practices for nutrition, physical activity, or both within ECEC settings (context). A search was conducted across 5 electronic databases (PubMed, Scopus, CINAHL Plus, ERIC, and Embase) to identify white literature, and 3 electronic databases (ProQuest, Google Scholar, and targeted Google search), along with hand-searching of reference lists, were used to identify gray literature. All literature was reported in English or French, with the search extending until May 2024. Separate data charting tools were used for white and gray literature.

Results: The search strategy identified 3064 results for white literature, yielding 2653 unique citations after duplicates were removed. Full texts for 65 citations were retrieved and screened for inclusion, resulting in 30 studies eligible for data extraction and analysis. The most common study design was a randomized controlled trial, comprising 16 studies (53%). The largest proportion of studies were conducted in the United States (11 studies, 37%). In total, 19 eHealth tools were identified, targeting nutrition (8 tools, 42%), physical activity (5 tools, 26%), or both nutrition and physical activity (6 tools, 32%). All tools were web based (19 tools, 100%). The gray literature search yielded 1054 results, of which 17 were moved to full-text screening, and 7 met the eligibility criteria for data extraction and analysis. The tools identified in the gray literature originated in Canada (4 tools, 57%) and the United States (3 tools, 43%). The majority targeted nutrition (4 tools, 57%) and were primarily web based (6 tools, 86%), with 1 mobile app (1 tool, 14%).

Conclusions: This scoping review mapped the available eHealth tools designed to improve nutrition or physical activity environments in ECEC settings, highlighting the growing emphasis on web-based tools and the need for psychometric testing.

Future research should systematically evaluate the effectiveness of these tools, particularly those addressing both nutrition and physical activity, to identify the key factors that contribute to long-term behavior change.

Trial Registration: Open Science Framework XTRNZ; https://osf.io/xtrnz International Registered Report Identifier (IRRID): RR2-10.2196/52252

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KEYWORDS

eHealth; early childhood educators; ECE; early childhood education and care; ECEC; knowledge synthesis; digital technology; health technology; digital public health; eating; diet

Introduction

Background

Unhealthy lifestyle factors, such as physical inactivity and unhealthy diets, are primary contributors to the rising incidence of chronic diseases [1-5]. These conditions are recognized as growing global public health problems, leading to significant treatment costs and imposing an economic burden on health systems, individuals, and society as a whole [6,7]. Health behaviors often originate in early childhood and can persist into young adulthood [8]. Research indicates that health behaviors, such as eating habits and physical activity levels, are modifiable risk factors for obesity and chronic diseases [9]. These behaviors often co-occur or cluster together [10,11]. An integrated approach to health promotion, addressing both dietary intake and physical activity simultaneously [10], is therefore essential during early childhood to improve population health across the lifespan.

The early years are a critical period for shaping health behaviors and outcomes [12], with early interventions regarded as an essential component of preventive health [13]. Early childhood education and care (ECEC) settings provide a unique opportunity to reach a large number of children during this pivotal developmental period, making them an ideal setting for behavioral interventions [12,14]. Moreover, early childhood educators, as part of the ECEC environment, are well-positioned to successfully implement nutrition and physical activity behavior interventions [15,16]. Evidence from prior research shows that professional training of early childhood educators in best practices for nutrition and physical activity is associated with improved dietary intake and increased physical activity levels in young children [17-20].

With the widespread use of the internet, online or eHealth interventions have experienced significant growth. eHealth refers to the use of digital technologies, such as the internet, digital gaming, virtual reality, and robotics, for promoting, preventing, treating, and maintaining health [21]. Examples of eHealth technologies include smartphone apps, websites, computer programs, SMS text messaging, and social media platforms [22]. Digital technologies offer several advantages, including lower costs, reduced participant burden, enhanced accessibility, and increased scalability, thereby extending the reach of behavioral interventions [23,24]. Prior research indicates that eHealth interventions within ECEC settings are highly acceptable and effective in improving early childhood educators' knowledge and practices related to nutrition and physical activity [25-27].

Behavior change theories can guide the selection of intrapersonal constructs to target in intervention development, as well as the choice of behavior change techniques to achieve desired behavioral outcomes [28]. Evidence suggests that behavior change interventions, whether internet-based or not, are more effective when guided by a theoretical framework [29]. A meta-analysis [29] found that interventions extensively informed by theory demonstrated larger effects compared with those lacking theoretical underpinnings. The use of theory not only enhances the efficacy of interventions but also facilitates their replication and future development [30]. Consequently, it is crucial to determine whether theory has been applied in the development of eHealth tools.

Recognizing the importance of early learning settings and educators in fostering healthy behavior development in children, researchers have developed, implemented, and evaluated health promotion interventions within childcare settings [31-33]. A preliminary search of PROSPERO, PubMed, the Cochrane Database of Systematic Reviews, and JBI Evidence Synthesis identified several relevant reviews. However, these reviews primarily focused on evaluating the effectiveness of in-person nutrition and physical activity interventions [34,35], interventions conducted in family-based centers [36,37], or those targeting older children and adolescents [33]. No current or in-progress systematic or scoping reviews address eHealth tools for promoting the best nutrition and physical activity practices in ECEC settings.

Objectives

To address this gap in the literature, we conducted a scoping review. This method is used to identify the types of available evidence in a field, explore key characteristics related to a concept, and analyze knowledge gaps [38]. This review aimed to achieve the following objectives: (1) identify existing eHealth tools used to assess or deliver interventions that improve nutrition or physical activity environments in ECEC centers; (2) describe the components of the eHealth tools, including technology type (eg, websites, smartphone apps, social media) and health purposes (eg, nutrition evaluation, physical activity promotion); (3) outline the psychometric properties of the eHealth tools, when applicable; (4) report the theoretical foundations used in developing the eHealth tools; and (5) identify any evidence gaps. The purpose of this study was to map the available evidence on eHealth tools currently used to

assess and support best practices for nutrition or physical activity in ECEC centers.

Methods

Overview

This scoping review followed established methods for such studies [39] and adhered to the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines [40]. Methodological quality or risk of bias was not assessed, as the goal of this review was to provide a broad overview of existing evidence, regardless of methodological approach, to map the available evidence. This is consistent with guidance on scoping review methods [39]. Full details of the methods can be found in our published protocol [41]. The PRISMA-ScR checklist is included in Multimedia Appendix 1 [40].

Selection Criteria

Participants

This review considered studies involving early childhood educators within licensed ECEC programs, whether public or privately operated, providing full-day care for children aged 0-5 years. Studies focusing on educators in family-based settings, preschool programs where children attend for less than 4 hours per day, or before- and after-school care were excluded.

Concept

This review considered studies that explored eHealth tools designed to support nutrition or physical activity environments in the ECEC setting. eHealth tools were defined as digital technologies that (1) assessed or (2) delivered interventions to improve nutrition or physical activity environments and practices. eHealth tools that assessed the ECEC environment were included only if they provided feedback to the ECECs. Additionally, we included only studies where the eHealth tool was the primary component for assessment or intervention.

Context

This review focused on nutrition and physical activity environments in the ECEC setting, considering both the physical and social environments.

Types of Sources

For this scoping review, we considered all study designs, including quantitative, qualitative, mixed methods, protocols, experimental, quasi-experimental, and cross-sectional studies. Systematic reviews and meta-analyses were also included if relevant to the topic, with a primary focus on ECEC settings. Unpublished studies and gray literature were also considered as sources of information.

Search Strategy

Overview

The search strategy was developed in collaboration with 2 research librarians and aimed to capture both white and gray literature to encompass the full range of available eHealth tools.

White Literature

A preliminary limited search of PubMed and Scopus was conducted to identify articles on the topic. The text words in the title and abstract, along with the index terms used to describe the articles, were analyzed to develop a full search strategy for PubMed. This search strategy, incorporating all identified keywords and index terms, was then adapted for each included information source (see Multimedia Appendix 2). The databases searched included PubMed, Scopus, CINAHL Plus (EBSCOhost), ERIC (EBSCOhost), and Embase (OVID). The reference lists of all included sources of evidence were screened for additional white literature. The final search was conducted on October 4, 2023. For each database, a search alert was set up using its alert functions to track any new relevant publications for potential inclusion in the review. The final search alert was reviewed on May 5, 2024, and only 1 additional study was identified. All retrieved white literature was exported into Covidence software (Veritas Health Innovation) for screening and data extraction.

Gray Literature

Following the guidelines outlined by Godin et al [100], we conducted a thorough search of the gray literature to identify nonindexed sources such as dissertation abstracts, government documents, conference proceedings, educational materials, and reports. This was done through searches in (1) the ProQuest Database, (2) Google Scholar, (3) targeted web-based Google searches, and (4) hand searches of the reference lists of all included gray literature to identify additional relevant sources. The final gray literature search was conducted on April 30, 2024. All retrieved documents were exported into Microsoft Excel and assigned a unique identifier for screening and data extraction. Because of the potential volume of gray literature, we limited our review to the first 10 pages from Google Scholar and targeted web-based Google searches, based on title. Additionally, eHealth tools that required payment for access were excluded.

This review included studies and records published in English or French, with no date limitations.

Study Selection

Following the search, all identified records were uploaded into Covidence (for white literature) or Microsoft Excel (for gray literature). Title and abstract screening, full-text screening, and data extraction were performed by 2 independent reviewers (JH and LMZL) according to the inclusion criteria. Reasons for excluding full texts that did not meet the inclusion criteria were recorded and reported in the scoping review. Any disagreements between the 2 reviewers were resolved through discussion, and if consensus could not be reached, a third reviewer (KD) was consulted. The results of the search are reported and presented in a PRISMA-ScR flow diagram (Figure 1 in Results section).

Data Extraction

Separate data extraction charting tools for white and gray literature were developed by the reviewers (Multimedia Appendix 3), as outlined in our published protocol [41]. The extraction tools, used to capture relevant study and eHealth tool characteristics, were piloted before the review to ensure



consistency in information collection. Any disagreements between reviewers were resolved through discussion.

Data Analysis and Presentation

The extracted data were summarized using descriptive statistics (ie, frequency counts). The results were organized by each review question, highlighting study characteristics, eHealth tool characteristics, and the use of a theoretical framework. The findings are presented in a narrative summary, complemented by tables, charts, and illustrations.

Results

Literature Search and Selection Process

The white literature search yielded 3064 results, of which 411 were removed as duplicates. Titles and abstracts for 2653 records were screened for eligibility, and 2588 were excluded. Of the remaining records, 65 full-text articles were reviewed against the eligibility criteria. A total of 30 articles were included for data extraction (Figure 1). The gray literature search yielded 1054 results, of which 7 were removed as duplicates. Titles and abstracts of 1047 records were assessed against the eligibility criteria, and 17 were moved to full-text screening. Of these, 7 met the inclusion criteria and were included in the analysis. The PRISMA flowchart shows the selection process.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart.



Included Records

A total of 30 research studies identified in the white literature were included in this review (Figure 1). Of these, 16 were randomized controlled trials, 6 were protocol studies, 1 was a cross-sectional study, 1 was a nonrandomized experimental study, and 1 was a randomized crossover control trial (Figure 2). Specific characteristics of the included studies are presented in Table 1, which reflects the study design, setting, and outcome measures. The study aims along with additional study details are provided in Multimedia Appendix 4. The largest proportion of studies were conducted in the United States (n=11, 37%) and Australia (n=11, 37%), followed by Canada (n=6, 20%) and

Norway (n=2, 7%; Figure 3). The studies were conducted between 2016 and 2022. The baseline sample size ranged from n=13 to 2932. Of the 10 studies reporting participant sex, females comprised the largest proportion of participants ranging from 85% to 100%, with an average of 96% (Table 1). The mean age of participants ranged from 37.1 to 49.6 years.

A total of 7 records were identified in the gray literature and included in this review (Figure 1). These records represented community-based eHealth outreach initiatives related to nutrition or physical activity support for the ECEC community. Four of these initiatives originated from Canada and 3 from the United States.

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Figure 2. Study designs of research articles identified in the white literature.





 Table 1. Characteristics of included studies from the white literature.

Reference: country	Study design	Study set- ting	Sample size (at baseline)	Sex of overall partic- ipants (% of fe- males)	Participant age (years), mean (SD)	Nutrition or PA ^a outcome measures
Barnes et al [42]: Australia	RCT ^b	Childcare centers	NR ^c	NR	NR	•Improving implementation of targeted healthy eating practices.
						•Child dietary intake of fruit and vegetable servings in care.
						•Child dietary intake of sodi- um, saturated fat, and added sugar in care.
						•Mean servings of fruits and vegetables packed within lunch boxes.
Barnes et al [27]: Australia	RCT	Childcare centers	Total: 22 (inter- vention: 11; con- trol: 11)	NR	Intervention group: supervi- sors 37.68 (5.92) and center cham- pions 44.17	 Implementation of targeted healthy eating practices. Supporting families to pro- vide healthier foods consistent with dietary guidelines.
					(6.40); control group: supervi- sors: 43.91 (10.57)	•Provision of intentional healthy eating learning experi- ences.
						•Using feeding practices that support children's healthy eating.
						•Staff participating in profes- sional development targeting healthy eating.
						•Having a comprehensive written nutrition policy that outlines key healthy eating practices.
Blomkvist et al [43]: Nor- way	Protocol for RCT	Kinder- garten	Total: 46 kinder- gartens (interven- tion: 31; control: 15)	NR	NR	• Primary outcomes: (1) child vegetable intake; (2) chil- dren's level of food neopho- bia; and (3) child dietary habits and food variety.
						• Secondary outcomes: (1) self-reported weight and height; (2) parental and kindergarten staff feeding practices.
Blomkvist et al [44]: Nor- way	RCT	Kinder- garten	Total: 46 kinder- gartens (interven- tion: 31; control:	NR	NR	•Child intake of intervention vegetables and all vegetables combined.
			15)			•Level of child food neopho- bia.
Bruijns ^{d,e} et al [45]: Canada	Pre-post study design	Center- based childcare,	Total: 110 early childhood educa- tors	99.2%	37.1 (9.5)	•Knowledge of PA, out- door/risky play, and sedentary behavior concepts.
		kinder- garten, and				•PA, outdoor/risky play, and sedentary behavior self-effica-cy.
		presention				•Behavioral intention and perceived behavioral control.

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Reference: country	Study design	Study set- ting	Sample size (at baseline)	Sex of overall partic- ipants (% of fe- males)	Participant age (years), mean (SD)	Nutrition or PA ^a outcome measures
Brussoni et al [46]: Canada	Protocol for RCT	ELCC ^f	Total: 324 ECEs ^g and ELCC admin- istrators	NR	NR	•The primary outcome is in- creased tolerance of risk in children's play, as measured by the Teacher Tolerance of Risk in Play Scale.
						•The secondary outcome is self-reported attainment of a self-developed behavior change goal.
Brussoni et al [47]: Canada	RCT	ELCC	Total: 563 educa- tors and adminis- trators (interven-	96.6%	NR	•Primary outcome: change in the total score on the T- TRiPS ^h .
			trol: 281; con- trol: 282)			•Secondary outcome: partici- pants' goal attainment at ei- ther follow-up time point (self-reported behavior change, measured by partici- pants' self-reported progress in attaining the goal they set for themselves).
Chuang et al [48]: United States	RCT	ECE cen- ters	Total: 111 ECE providers (inter- vention: 56; con- trol: 55)	97.3%	43.55 (11.87)	• Psychosocial and behavioral measures: (1) nutrition knowledge, (2) mindful eat- ing, (3) perceived barriers to eating fruits and vegetables, and (4) perceived barriers to promote healthy eating in classroom.
						• Environmental factors: (1) nutrition-related policy and practices at their ECE facili- ties and (2) number of healthy eating-related activities orga- nized for the staff in the ECE center.
						• Individuals behavior: (1) di- etary intake and (2) communi- cation of nutrition information with ECE children and par- ents.
Clark et al [49]: United States	NR	Licensed childcare	Total: 38 child- care providers (intervention: 23; control: 15)	100%	NR	• Knowledge of and attitudes and behaviors toward feeding breast milk, formula, and sol- id food to the infants in their care.
Clarke et al [50]: United States	Protocol	ECE pro- grams	Total: 2932 ECE providers	N/A ⁱ	N/A	• Uptake and perceived useful- ness of on-demand online nu- trition training.
Grady et al [51]: Australia	Nonrandom- ized experi- mental study	Long day care ser- vices	Total: 46 child- care services (in- tervention: 27; control: 19)	NR	Intervention group: 48.44 (10.36); control group: 43.74 (10.48)	• Uptake and use of the menu program: proportion of ser- vices adopting the program and proportion of services us- ing the program as intended.

Reference: country	Study design	Study set- ting	Sample size (at baseline)	Sex of overall partic- ipants (% of fe- males)	Participant age (years), mean (SD)	Nutrition or PA ^a outcome measures
Grady et al [52]: Australia	RCT	Long day care ser- vices	Total: 54 child- care services (in- tervention: 27;	NR	Intervention group: 48.4 (10.4); control	• Primary outcome: the mean number of food groups com- pliant with dietary guidelines
			control: 27)		•Secondary of compliance w guidelines for (2) individual compliance w guidelines, an servings of in groups.	
Green et al [53]: Australia	NR	Long day care, preschool, and occa-	NR	NR	NR	• Nutrition practice achieve- ments such as (1) lunch boxes monitored daily and (2) fruits and vegetables on menu.
		sional care				•PA practice achievements such as (1) tummy time for babies and (2) active playtime for at least 25% of opening hours.
Hazard et al [54] ^e : United States	RCT	Licensed childcare centers	Total: 20 child- care providers	98%	NR	• Evaluation of accessibility, acceptability, and satisfaction of nutrition and online education courses.
Hoffman et al [55]: United States	RCT	Preschools	Total: 11 teachers and 2 site supervi- sors	NR	NR	• Implementation fidelity, acceptability, and feasibility of WE PLAY ^j .
Hoffman et al [19]: United States	RCT	Preschools	Total: 25 teachers (intervention: 11; control: 14)	100%	Intervention group 40.7 (9.0); control group 45.9 (13.2)	 Children's MVPA^k (MVPA accelerometer). Teachers' changes in PA knowledge and attitudes to-
Kempler et al [56]: Australia	Cross-sec- tional study	Childcare services	Total: 64 partici- pants	NR	NR	 Qualitative outcomes explored use and experience with the menu tool.
Kennedy et al [57]: United States	NR	Preschools	Total: 41 teachers	NR	NR	•The percentage of the 60- minute daily goal reached in each classroom.
						•The proportion of students actively participating in MV- PA.
						•The percentage of time spent in MVPA.
						•Teachers' involvement with children during PA opportunities.
						•Child enjoyment (students having fun during the PA opportunities).
Lafave [58]: Canada	Randomized crossover tri- al design	ECEC ¹ centers	Total: 72 educa- tors	100%	NR	• Psychometric evaluation of nutrition and PA assess- ment—online inter- and in- trarater reliability.





Reference: country	Study design	Study set- ting	Sample size (at baseline)	Sex of overall partic- ipants (% of fe- males)	Participant age (years), mean (SD)	Nutrition or PA ^a outcome measures
Lafave et al [59]: Canada	Protocol for quasi-experi- mental study	ECEC centers	Total: 208 educa- tors (intervention: 138; control: 50)	96.2%	40.05 (11.67)	 Food served in the center self-audit, eating environment/mealtime practices self-audit, nutrition education programming self-audit. Mindful eating of educators. Nutrition knowledge, attitude, and behaviors of educators.
						•Observation of nutrition envi- ronment in childcare.
						•Qualitative experiences of the nutrition environment.
						 PA environment self-audit. Physical literacy knowledge, attitude, self-efficacy, and behaviors of educator and professional practices. Objectively measured child PA levels
						•Qualitative experiences of PA environment.
Lee et al [60] ^e : United States	RCT	Licensed childcare centers	Total: 30 ECE or services (interven- tion: 19; control: 11)	NR	Intervention group 47.7 (10.8); control group 49.6 (12.	• Knowledge and awareness of and adherence to Califor- nia's 2010 Healthy Beverages in Child Care Act.
Peden et al [61]: Australia	RCT	ECEC centers	Total: 104 educa- tors	85%	NR	• Qualitative educator com- ments on the experience of the HOPPEL ^m program.
Peden et al [62]: Australia	RCT	ECEC centers	Total: 112 educa- tors	85%	NR	 Changes in center-level healthy eating practices as- sessed using the EPAOⁿ tool. Changes in children's PA assessed using ActiGraph GT1M and GT3X + ac- celerometers.
Reilly et al [63]: Australia	RCT	ECEC services	Total: 1024 ECEC services (intervention: 684; control: 342)	NR	NR	 Intentions to adopt the guidelines. Awareness and reach of the guidelines. Knowledge of the guidelines. Implementation of the guidelines. Barriers to implementing the guidelines.
Saunders et al [64]: United States	NR	Preschools	Total: 818 teach- ers	NR	NR	• Classroom implementation completeness (ie, provision of 300 minutes of PA opportuni- ties) and fidelity (ie, achiev- ing PA fidelity and social en- vironment fidelity).



Reference: country	Study design	Study set- ting	Sample size (at baseline)	Sex of overall partic- ipants (% of fe- males)	Participant age (years), mean (SD)	Nutrition or PA ^a outcome measures
Ward et al [65]: United States	RCT	Full-time and part- time childcare center programs	Total: 33 ECE centers (interven- tion: 18; control: 15)	NR	NR	• Change in centers' nutrition environments: (1) foods pro- vided, (2) beverages provided, (3) feeding environment, (4) feeding practices, (5) menus, (6) education and professional development, and (7) nutrition policy.
Ward et al [25] ⁰ : Canada	RCT	Early	Total: 191 (inter-	NR	NR	•Healthy eating practices.
		centers	control: 89)			•Perceived knowledge about fundamental movement skills.
						•PA practices.
Willis et al [66]: United States	Protocol for RCT	ECE cen- ters	Total: 168 teach- ers	N/A	N/A	•Children's dietary intakes and Healthy Eating Index scores.
						•Teachers' dietary intakes and Healthy Eating Index scores.
						•Anthropometrics measure- ments (children and teachers).
						•ECE center nutrition environ- ment.
						•PA (children and teachers using accelerometers).
						•ECE center PA environment.
Yoong et al [67]: Australia	Protocol for RCT	Childcare services	Total: 54 long- day-care services	N/A	N/A	•Mean number of food groups on childcare service menus that comply with dietary guidelines.
						•Proportion of services that comply with dietary guide- lines for each of the 6 food groups.
						•Proportion of services that meet the recommended num- ber of serves for all of the 6 Australian Guide to Healthy Eating food groups.
						•Child dietary intake.
						•Child BMI.
						•Child health-related quality of life.



Reference: country	Study design	Study set- ting	Sample size (at baseline)	Sex of overall partic- ipants (% of fe- males)	Participant age (years), mean (SD)	Nutrition or PA ^a outcome measures
Yoong et al [68]: Australia	RCT	Childcare centers	Total: 35 child- care centers	NR	NR	•Number of servings of the 5 core and discretionary food groups defined by the Aus- tralian Guide to Healthy Eat- ing consumed in care.
						•Childcare educator-reported child diet quality.
						•Child BMI z-scores.
						•Child health-related quality of life.
						•Child diet outside of care.

^aPA: physical activity.

^bRCT: randomized control trial.

^cNR: not reported.

^dIn Bruijns et al [45], participants included both preservice and in-service ECEs. Only data from in-service ECEs were reported, which aligns with our target population of educators in childcare centers.

^eIn Bruijns et al [45], Hazard et al [54], and Lee et al [60], participants included both center- and family-based childcare. For our purposes, we only included data from center-based childcare (eg, sample size). Gender and age are reported for all participants, as specific breakdowns were not provided.

^fELCC: early learning childcare center.

^gECE: early care and education.

^hTRiPS: Teacher Tolerance of Risk in Play Scale.

ⁱN/A: not applicable.

^jWE PLAY: Wellness Enhancing Physical Activity for Young Children.

^kMVPA: moderate-to-vigorous physical activity.

¹ECEC: early childhood education and care.

^mHOPPEL: Healthy Online Professional Program for Early Learners.

ⁿEPAO: Environmental Policy Assessment and Observation.

^oIn Ward et al [25], the study included both in-person and online intervention groups. Our review focused only on extracting data from the online intervention group.

Figure 3. Country of study from eHealth research identified in the white literature and gray literature.







eHealth Tool Characteristics

The 30 research articles included in the review identified 19 unique eHealth tools, with 12 categorized as intervention-based and 7 as both assessment and intervention tools. The characteristics of these eHealth tools identified in the white literature are summarized in Table 2, with additional details available in Multimedia Appendix 4. Among the 7 eHealth tools incorporating an assessment component, only 1 underwent

evaluation of its psychometric properties. All eHealth tools were delivered via a web-based modality (7/7, 100%).

The characteristics of the eHealth tools identified in the gray literature are summarized in Table 3, with additional details provided in Multimedia Appendix 5. Of the 7 eHealth tools identified, all were intervention-only tools (7/7, 100%). Of these, 6(86%) were delivered via a web-based modality, while 1 (14%) was delivered as a mobile phone app.

Table 2. Characteristics of eHealth tools from included studies identified in the white literature.

eHealth tool	Country: References	Type of eHealth tool	eHealth modality ^a	Target of eHealth tool	eHealth tool component	eHealth tool de- scription	Length of the inter- vention	Theoretical under- pinning
Create Healthy Futures Pro- gram	United States: [48]	Interven- tion	Web based	Nutrition	Healthy eat- ing practices	Self-paced web- based intervention on promoting healthy eating be- haviors for ECE ^b providers	6 weeks	•Social Cognitive Theory •Social Ecologi- cal Model
CHEERS ^c	Canada: [58,59]	Assess- ment and interven- tion	Web based	Nutrition and physical activi- ty	Nutrition and physical activity prac- tices	Online educational modules and com- munities of prac- tice to improve the nutrition and physi- cal activity environ- ment in ECECs ^d	10 months	•Social Cognitive Theory
EATS ^e	Australia: [27,42]	Assess- ment and interven- tion	Web based	Nutrition	Healthy eat- ing practices	The web-based program supports center implementa- tion of targeted healthy eating practices through self-assessment, feedback, and the development of an action plan	6 months	 Social Ecological Framework Behavioral Change Wheel
FoodChecker	Australia: Kem- pler et al [56]	Assess- ment and interven- tion	Web based	Nutrition	Online menu planning	Web-based menu planning tool to support childcare services in plan- ning healthy menus	NR ^f	NR
feedAustralia	Australia: [51,52,67,68]	Assess- ment and interven- tion	Web based	Nutrition	Online menu planning	Web-based menu planning program offering automated real-time assess- ment of childcare menu with feed- back to support the planning of healthi- er menus	12 months	•Technology Ac- ceptance Model •Theoretical Do- mains Frame- work
GO NAP- SACC ^g	United States: [50,65]	Assess- ment and interven- tion	Web based	Nutrition and physical activi- ty	Nutrition and physical activity prac- tices	Suite of online tools to guide ECE programs through a 5-step process to improve their nutri- tion and physical activity-related practices, including (1) self-assess- ment, (2) goal set- ting and action planning, (3) imple- mentation, (4) edu- cation and training, and (5) reasses- ment	4 months	 Social Cognitive Theory DESIGN^h Proce- dure Framework Theories of adult learning in public health practice Behavior change techniques



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eHealth tool	Country: Refer- ences	Type of eHealth tool	eHealth modality ^a	Target of eHealth tool	eHealth tool component	eHealth tool de- scription	Length of the inter- vention	Theoretical under- pinning
GO NAPSACC Cares	United States: [66]	Assess- ment and interven- tion	Web based	Nutrition and physical activi- ty	Nutrition and physical activity prac- tices (center level) + edu- cator's per- sonal diet and physical activity	The traditional GO NAPSACC pro- gram and embed- ded Staff Wellness website that focus on ECE personal healthy behavior change strategies including healthy eating, increased physical activity, and weight manage- ment	6 months	•Social Cognitive Theory •The Social Eco- logical Model
HOPPEL ⁱ	Australia: [61,62]	Interven- tion	Web based	Nutrition and physical activi- ty	Nutrition and physical activity prac- tices	Synchronous and asynchronous on- line professional development to promote physical activity and healthy eating	12 weeks	•Community of Practice •The Guskey model of teacher change
Healthy Start- Départ Santé	Canada: [25]	Interven- tion	Web based	Nutrition and physical activi- ty	Nutrition and physical activity prac- tices	Online modules to improve healthy eating and physical activity practices	4 hours	NR
InfaNET	United States: [49]	Interven- tion	Web based	Nutrition	Infant feed- ing practices	Bilingual (English and Spanish) web- site with childcare- specific infant feeding informa- tion	3 months	•Social Learning Theory
Munch & Move	Australia: [53]	Interven- tion	Web based	Nutrition and physical activi- ty	Nutrition and physical activity prac- tices	Professional devel- opment training for early childhood ed- ucators to support healthy eating and physical activity habits in young children	NR	•The Monitoring Framework
OutsidePlay- ECE risk-re- framing inter- vention	Canada: [46,47]	Interven- tion	Web based	Physical activi- ty	Out- door/risky play	Fully automated web-based interven- tion to reframe ECEs' perception of the importance of outdoor play and its inherent risks and promote a change in their practice in support- ing children's out- door play in EL- CC ^j settings	Up to 100 minutes	 Intervention mapping process Social Cognitive Theory
Online training on healthy bev- erage best prac- tices	United States: [54]	Interven- tion	Web based	Nutrition	Healthy bev- erage prac- tices	Self-paced online modules (English and Spanish) on healthy beverage best practices for	English (29-min- utes); Spanish (37-min-	NR

childcare providers utes)

eHealth tool	Country: References	Type of eHealth tool	eHealth modality ^a	Target of eHealth tool	eHealth tool component	eHealth tool de- scription	Length of the inter- vention	Theoretical under- pinning
Online training on healthy bev- erage policy	United States: [60]	Interven- tion	Web based	Nutrition	Healthy bev- erage prac- tices	Bilingual (English or Spanish) self- paced on-demand online training to increase knowl- edge and adher- ence of childcare providers to healthy beverage practices	30-minutes for the on- line train- ing (+ with or without 6 months of online technical assistance)	 Implementation Science Frame- work Humanistic Learning Theo- ries
Online training to disseminate outdoor free- play informa- tion in relation to COVID-19 guidelines	Australia: [63]	Interven- tion	Web based	Physical activi- ty	Out- door/risky play	e-newsletter or ani- mated video to in- crease ECEC ser- vice intentions to adopt an indoor- outdoor program for the full day and offer more time outdoors	e-newslet- ter (3 min- utes); video (3.5 minutes)	•Model for Dis- semination of Re- search •Interactive Sys- tem Framework
SHAPES-D ^k	United States: [57,64]	Assess- ment and interven- tion	Web based	Physical activi- ty	Physical ac- tivity prac- tices	Self-assessment and online training modules to im- prove instructional physical activity practices and class- room social envi- ronment	12 weeks	NR
Tool to increase children's veg- etable intake and reduce food neophobia	Norway: [43,44]	Interven- tion	Web based	Nutrition	Online menu planning and feeding prac- tices	Access to online menu recipes to in- clude vegetables each week, with or without pedagogi- cal tools (sensory lessons, meal prac- tice, and feeding practices recom- mendations)	3 months	NR
TEACH ¹ e - learning course	Canada: [45]	Interven- tion	Web based	Physical activi- ty	Physical ac- tivity and sedentary be- havior	e-Learning course in physical activity and sedentary be- havior comprising 4 modules	2 weeks	Social Cognitive TheoryThe Theory of Planned Behavior
WE PLAY ^m	United States: [19,55]	Interven- tion	Web based	Physical activi- ty	Physical ac- tivity prac- tices	Online asyn- chronous modules to promote physi- cal activity	4 weeks	Social Cognitive Theory The Theory of Planned Behavior Quality Imple- mentation Frame- work



eHealth tool	Country: References	Type of eHealth tool	eHealth modality ^a	Target of eHealth tool	eHealth tool component	eHealth tool de- scription	Length of the inter- vention	Theoretical under- pinning
Online training on healthy bev- erage policy	United States: [60]	Interven- tion	Web based	Nutrition	Healthy bev- erage prac- tices	Bilingual (English or Spanish) self- paced on-demand online training to increase knowl- edge and adher- ence of childcare providers to healthy beverage practices	30 minutes for the on- line train- ing (+ with or without 6 months of online technical assistance)	Implementation Science Frame- work Humanistic Learning Theo- ries

^aeHealth modality (eg, web, app, or SMS text messages).

^bECE: Early Care and Education.

^cCHEERS: Creating Healthy Eating and Active Environments Survey.

^dECEC: early childhood education and care.

^eEATS: Child Care Electronic Assessment Tool and Support.

^fNR: not reported.

^gNAPSACC: Nutrition and Physical Activity Self-Assessment for Child Care.

^hDESIGN: decide target behavior, explore determinants, select theory-based model, indicate objectives, generate education plans, and nail down the evaluation.

ⁱHOPPEL: Healthy Online Professional Program for Early Learner.

^jELCC: early learning childcare center.

^kSHAPES-Dissemination: Study of Health and Activity in Preschool Environments.

¹TEACH: Training Pre - Service Early Childhood Educators in Physical Activity.

^mWE PLAY: Wellness Enhancing Physical Activity in Young Children.



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Table 3. Characteristics of eHealth tools from included studies identified in the gray literature.

eHealth tool	Author/organi- zation	Country: year	Participant informa- tion	Type of eHealth tool	eHealth modali- ty ^a	Target of eHealth tool	eHealth tool de- scription	Length of interven- tion
A Balanced Day: Tips and Guide- line for Child Care Providers	Hastings Prince Edward Public Health	Canada: NR ^b	Childcare providers	Intervention	Web based	Physical activity	Online interactive modules (videos) on physical activi- ty, sedentary behav- ior, sleep, and health messages for caregivers.	15 min- utes
Boston Healthy Childcare Initiative	The Boston Public Health Commission	United States: NR	Early childhood educators	Intervention	Web based	Nutrition and physical Activity	Online training on evidence-based nu- trition and physical activity best prac- tices in early learn- ing environments.	NR
Child Care Healthy Eat- ing and Ac- tive Living Guidelines Training	Ottawa Public Health	Canada: 2015	Supervisors, child- care providers, and municipal cooks	Intervention	Web based	Nutrition and physical activity	Online training modules on healthy eating practices, environments, and physical literacy.	Part 1: Nutrition: 60 min- utes; part 2: Active living: 30 minutes
Fostering Healthy Eat- ing Habits	BC Provincial Health Ser- vices Authori- ty—Interior Health	Canada: 2016	Childcare providers	Intervention	Web based	Nutrition	e-Learning course on healthy prac- tices and environ- ment.	1 hour
MyPlate on Alexa	United States Department of Agriculture	United States: 2020- 2025	Everyone from parents and care- givers of babies starting at 4 months old through older adults (in- cludes early learn- ing professionals)	Intervention	Арр	Nutrition	An app that pro- vides food and nu- trition tips based on the Dietary Guidelines for Americans.	N/A ^c
Nourished and Active in Early Learning	University of Washington's Center for Public Health Nutrition and Washington State Depart- ment of Health	United States: NR	Early learning pro- fessionals	Intervention	Web based	Nutrition	Online course on healthy eating and beverages compris- ing 6 modules, strategies to sup- port healthy eating, and common chal- lenges.	NR
Nourishing Beginnings	Dairy Farmers of Canada	Canada: NR	ELCC ^d educators and directors as well as ELCC pro- fessors or program directors at col- leges or universi- ties.	Intervention	Web based	Nutrition	Online modules on healthy feeding practices	Module 1: 80 min- utes; module 2: 70 min- utes

^aeHealth modality (eg, web, app, or SMS text messages).

^bNR: not reported.

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^cN/A: not applicable.

^dELCC: early learning in childcare.

Practices Targeted

The majority of eHealth tools identified in the white literature (8/19, 42%) targeted nutrition practices, 6 of 19 (32%) targeted

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both nutrition and physical activity, and 5 of 19 (26%) exclusively addressed physical activity (Figure 4). The duration of intervention implementation ranged from 3 minutes to 12 months. The majority of eHealth tools identified in the gray

literature targeted nutrition (4/7, 57%), followed by tools targeting both nutrition and physical activity (2/7, 29%), and 1 focused solely on physical activity (Figure 4). For both the white (Table 2) and gray literature (Table 3), eHealth intervention tools targeting nutrition primarily addressed best nutrition and

Figure 4. Target of eHealth tool for white and grey literature.



Theoretical Framework of the eHealth Tools

Of the 30 research studies identified in the white literature, 21 reported the use of theoretical models (Multimedia Appendix 4). The most commonly cited theories include Social Cognitive Theory, Social Ecological Model, Theoretical Domain

Framework, Theory of Planned Behavior, Behavior Change Wheel, and Quality Implementation Framework (Figure 5). None of the eHealth tools identified in the gray literature reported a theoretical underpinning (see Multimedia Appendix 5).

feeding practices, healthy eating or beverage practices, and

menu planning. eHealth tools targeting physical activity mainly

focused on best physical activity practices, outdoor play, and

the reduction of sedentary behaviors.



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Figure 5. Theoretical underpinning from studies identified in the white literature search. DESIGN: decide target behavior, explore determinants, select theory-based model, indicate objectives, generate education plans, and nail down the evaluation.



Discussion

Principal Findings

The purpose of this scoping review was to explore the available eHealth tools developed to assess or deliver interventions aimed at improving the nutrition or physical activity environments in ECEC settings. The results of this review provide insights into the digital tools available, outlining their methodological approach and characteristics.

Mapping the included white and gray literature identified 26 eHealth tools, highlighting a growing interest in leveraging digital tools to enhance nutrition and physical environments in early learning settings. Notably, all tools were web based except for 1 delivered via a smart device application. This finding is striking, given the widespread adoption of mobile health apps in health promotion interventions [69,70]. A likely explanation is that the nature and timing of the intervention may influence the choice of eHealth modality. Mobile apps are typically utilized in interventions requiring rapidly changing data and real-time feedback, such as step tracking or patient self-care and symptom management [71,72]. By contrast, interventions targeting nutrition and physical activity practices in educational settings often focus on gradual changes implemented over extended periods. Additionally, mobile apps are generally more expensive to develop and maintain than web-based tools and require regular updates [73]. Furthermore, most educational settings rely on web-based systems and have access to computers and the internet, making web-based platforms a more convenient option for educators while facilitating the implementation of interventions. Lastly, mobile-based interventions are often more prevalent among youth populations (children and adolescents) due to their capacity to incorporate gamification-a popular

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and engaging approach for health promotion interventions within this demographic [74].

The identified eHealth tools employed diverse approaches and strategies to enhance nutrition and physical activity practices. Most tools focused on professional development, offering online modules and self-paced training with both synchronous and asynchronous components to improve educators' knowledge and behaviors related to best practices in nutrition and physical activity. Most of these tools (21/26, 81%) included educational videos to create engaging and interactive content, while just over half (15/26, 58%) incorporated quizzes or evaluation questions to reinforce learning and assess understanding. Additionally, a smaller proportion (10/26, 38%) provided technical support from experts or facilitators to offer guidance and enhance educator engagement. Research suggests that such human support can improve compliance and foster the adoption of new behaviors [75,76]. However, relying on human support may not be a sustainable approach due to the significant resources required and the challenges it poses for scalability [77]. A smaller proportion of tools (3/26, 12%) emphasized menu planning and provided tailored support to aid in the creation of healthier menus. Tools targeting physical activity primarily addressed best practices, highlighted the importance of outdoor and risky play, and aimed to reduce sedentary behaviors. Nutrition-focused tools concentrated on promoting best practices for nutrition and feeding while optimizing eating environments.

Less than one-third (8/26, 31%) of the identified eHealth tools addressed both nutrition and physical activity together. Evidence suggests that multibehavior interventions, which target multiple health behaviors simultaneously, are often more effective in driving meaningful change compared with interventions focused

on a single behavior [78]. Given the interconnected nature of nutrition and physical activity, these behaviors play a crucial role in health and well-being [79,80] and are recognized as leading modifiable factors in the prevention of major chronic diseases [1,2]. Knowing that nutrition and physical activity tend to cluster together, addressing these behaviors collectively might enhance the effectiveness of interventions [11,81-84]. It has also been found that targeting both nutrition and physical activity behaviors can lead to synergistic effects on health outcomes [85-87]. Therefore, tools aimed at improving educators' nutrition and physical activity practices or the nutrition and physical activity environments in early learning centers should target determinants of both behaviors simultaneously.

Another key finding is that, among the 7 eHealth tools incorporating an assessment component, only 1 reported psychometric properties testing. Psychometric evaluations, such as reliability and validity testing, are crucial as they indicate the quality of the tools, ensure their effectiveness for the intended purpose, and support their reproducibility and replicability [88]. The lack of reported psychometric testing may be due to some tools originally being developed in a pen-and-paper format before being adapted to an online format. In the original articles describing the pen-and-paper versions, psychometric testing was reported [89]. However, it is important to recognize that tool validity and reliability are not static characteristics; rather, they are assessments of the tool's instrument scores within the context in which they have been evaluated [90]. It is therefore recommended to conduct and report updated psychometric testing when tools are adapted into digital formats to ensure that the validity and reliability of the results are maintained [91,92].

Among the 30 studies identified in the white literature, the majority (21/30, 70%) incorporated a theoretical framework in their design. The most frequently cited theory was the Social Cognitive Theory, which is commonly used in behavior change interventions, aligning with findings from other reviews [93-95]. A theoretical underpinning is a critical consideration when developing health promotion interventions. It serves as a blueprint for the study, structuring and guiding the intervention planning process, and also helps in understanding the factors that might influence behavior change and need to be targeted [96,97]. Previous reviews have indicated that health interventions grounded in theory are more effective [28] and are associated with positive significant outcomes, larger effect sizes [23,94,98], and the maintenance of behavior change [99]. Hence, future research designing eHealth tools should prioritize the use of theoretical underpinnings to increase effectiveness and ensure replicability. Regarding the gray literature findings, no reports on the theoretical underpinnings or reliability were identified for any of these tools. A possible reason for this could be that the gray literature often targets a general population audience, where the focus is on practical application, whereas in peer-reviewed literature, researchers look for evidence of theoretical grounding to evaluate and further refine or replicate these tools.

Implications/Recommendations

Future research involving the development and implementation of eHealth tools in ECEC settings should emphasize the integration of theoretical frameworks, consider comprehensive multibehavior intervention approaches, incorporate community perspectives in the development process, and prioritize long-term sustainability and scalability, with a focus on implementation and efficacy assessment. Theoretical frameworks provide essential guidance in identifying key determinants of behavior and mechanisms for promoting change. Incorporating theory can enhance the effectiveness of eHealth tools, ensure consistent implementation, and facilitate replicability across different contexts. Multipronged eHealth tools designed to target both nutrition and physical activity can lead to more beneficial outcomes, as these domains are interconnected. To enhance implementation and adoption, it is essential to involve a diverse range of stakeholders, such as educators, parents, and health professionals, in the development process. This ensures that the unique needs and cultural context of the targeted eHealth tool users are addressed. Additionally, researchers should prioritize long-term sustainability and scalability when designing these tools, ensuring that interventions can be maintained and expanded across various settings over time. Finally, the resulting eHealth tools should undergo rigorous testing, including pilot trials, to assess their usability, feasibility, and effectiveness in achieving the intended outcomes. This integrated approach provides a holistic strategy for fostering healthier environments in ECEC settings.

Strengths and Limitations

This review is the first to map and summarize the scope of available evidence on eHealth tools designed to assess or improve nutrition and physical activity environments in early learning settings. The findings from this review can guide future research on the use of eHealth technologies to promote healthy practices in childcare, ultimately contributing to improved children's health behaviors and outcomes. Two librarians with expertise in scoping and systematic reviews assisted in developing and refining the search strategy. The methodology employed facilitated a systematic search of both white and gray literature, ensuring a comprehensive review of available evidence. However, there are some limitations to this scoping review that should be considered. We only considered studies published in English or French, which may have led to the exclusion of relevant research in other languages. Additionally, this scoping review focused solely on full-time day care centers, excluding family-based day care and after-school programs. The primary reason for excluding family-based day cares was the lack of formalized data, and after-school programs were not included as they typically do not cater to children aged 0-5 years. Another limitation encountered during the search for gray literature was the presence of paywalls and restricted access to certain tools, which hindered our ability to fully explore available resources.

Conclusions

This scoping review explored the breadth of evidence on eHealth tools aimed at improving nutrition and physical activity environments in ECEC settings. Future research should conduct

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a systematic review to assess the effectiveness of these tools and identify the specific elements that contribute to a greater impact and sustained behavior change.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews checklist. [PDF File (Adobe PDF File), 258 KB - pediatrics v8i1e68372 app1.pdf]

Multimedia Appendix 2

Search strategy for the databases (PubMed, Scopus, CINHAL Plus [EBSCOhost], ERIC [EBSCOhost], Embase [OVID]). [PDF File (Adobe PDF File), 94 KB - pediatrics_v8i1e68372_app2.pdf]

Multimedia Appendix 3 Data extraction forms for white and gray literature. [PDF File (Adobe PDF File), 73 KB - pediatrics v8i1e68372 app3.pdf]

Multimedia Appendix 4 Extraction sheet results for white literature. [XLSX File (Microsoft Excel File), 66 KB - pediatrics v8i1e68372 app4.xlsx]

Multimedia Appendix 5 Extraction sheet results for gray literature. [XLSX File (Microsoft Excel File), 32 KB - pediatrics_v8i1e68372_app5.xlsx]

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Abbreviations

ECEC: early childhood education and care

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews

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Exploring Health Educational Interventions for Children With Congenital Heart Disease: Scoping Review

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Abstract

Background: Congenital heart disease (CHD) is the most common birth defect, affecting 40,000 births annually in the United States. Despite advances in medical care, CHD is often a chronic condition requiring continuous management and education. Effective care management depends on children's understanding of their condition. This highlights the need for targeted health educational interventions to enhance health literacy among children with CHD.

Objective: This scoping review aims to map and explore existing health educational interventions for children with CHD. The review identifies the types of interventions, target populations, delivery methods, and assessed outcomes. The goal is to consolidate fragmented research, identify gaps, and establish future research agendas.

Methods: Comprehensive searches were conducted in February 2024 using the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) framework across multiple databases: APA PsycINFO, MedlinePlus via Ovid, Web of Science, ACM Digital Library, Scopus, and EBSCOhost (CINAHL Complete, CINAHL Ultimate, Health Source: Nursing/Academic Edition, and ERIC). The search covered health care, design, and human-computer interaction disciplines to capture the interdisciplinary nature of CHD health educational interventions. There was no predefined time limit due to the limited number of relevant studies. Eligible studies were in English, published in peer-reviewed journals, and focused on primary data about educational health interventions for children with CHD. We extracted and synthesized data using thematic analysis.

Results: The review identified 11 studies: 9 randomized controlled trials and 2 observational studies. These used 6 educational strategies: 3D patient-specific models (n=3), habit formation interventions (n=2), empowerment-based health education programs (n=2), rehabilitation interventions (n=2), web-based portals (n=1), and videotape presentations (n=1). Interventions ranged from brief outpatient sessions to 1.5-year programs, with follow-up from none to 24 months. Studies aimed to improve coping, self-management, and knowledge for children with CHD and their families. The most frequently used assessment method was the independent samples *t* test (n=4) for pre- and postassessments, and all 11 studies used questionnaires, 8 of which incorporated qualitative feedback. The target participants for these interventions were children aged 13 years and older (n=3), parents (n=2), and children of various ages and their parents (n=6). Outcomes included improved children's health literacy, reduced parental burden, and increased health care provider efficiency.

Conclusions: This review underscores the critical need for tailored educational interventions for children with CHD. Current research mainly focuses on adolescents and relies heavily on parental involvement, possibly overlooking the specific needs of younger children younger than 13 years of age. It is essential to develop engaging, age-appropriate interventions that actively involve children with CHD in their health care journey. Effective health educational interventions are crucial in empowering these young patients and improving their long-term health outcomes.

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KEYWORDS

congenital heart disease; children health literacy; health education; health education interventions; patient-centered care; design; pediatric; PRISMA

Introduction

Background

Congenital heart disease (CHD) is a structural abnormality in the heart present at birth. It is the most common birth defect, affecting 1.35 million newborns worldwide and around 40,000 births annually in the United States. CHD often leads to other health complications and poses lifelong challenges to affected children, families, and health care systems [1-3]. Improved medical and surgical care have substantially increased survival rates, with up to 90% of children with CHD now surviving through to adulthood [4,5]. Despite improved medical care, CHD is more like a chronic condition that requires early diagnosis, timely treatment, and ongoing management. Figure 1 shows the worldwide prevalence of CHD from 1970 to 2017 and how survival rates in the United States since 1999 impact the need for continuing care [2,5-8]. Effective long-term care requires a comprehensive understanding of the condition by both pediatric patients and caregivers. Traditionally, health care providers have relied on parents to educate their children about their condition, assuming effective transmission of information. This approach often falls short, with parents struggling to comprehend and recall the information provided. Insufficient knowledge leads to extensive education during appointments, causing confusion and anxiety for children with CHD and their families [9-12]. Without proper education, the ability to proactively manage the condition diminishes, potentially leading to worse health outcomes, greater difficulty transitioning to adult care, and increased hospitalizations [4,13]. Accessible health information and organized educational support systems are crucial for improving health education, self-management skills, and health literacy (HL) among pediatric patients and caregivers [2,14].

Figure 1. Worldwide CHD prevalence and the effect of US survival rates on care management. Data were sourced from Boneva et al [8], Liu et al [7], Lopez et al [6]. CHD: congenital heart disease.



Prior Work

HL is defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" [9]. However, there are uncertainties about the best educational and support approaches for improving HL in pediatric patients with CHD. Learning about this complex subject at a young age presents significant challenges. Limited learning opportunities hinder adequate information delivery and understanding [10]. Moreover, current educational materials (eg, pamphlets and postvisit summaries) are often inappropriate for young children and are primarily intended for their caregivers or parents [10,12]. To tackle these challenges, health educational interventions are designed to enhance individuals' knowledge, attitudes, skills, and behaviors to manage their condition [15]. These interventions are crucial for empowering children with CHD to understand their condition, adhere to treatment plans, and navigate the health care system effectively.

Recent focus has highlighted the importance of involving children with CHD and their caregivers in developing and

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executing their care plans through health educational interventions [10,12]. Despite this, the literature on educational interventions for children with CHD remains limited. To our knowledge, no systematic or scoping reviews have been conducted on this topic. Only a few scoping and systematic studies have attempted to understand the experiences of children with CHD, their families, and health care providers in managing CHD [2,16-18]. Furthermore, some studies focus on the coping mechanisms of parents and families of children with CHD rather than on the children themselves [19-21]. Therefore, a scoping review is necessary to consolidate fragmented research, identify existing gaps, and establish a future research agenda [22].

Purpose and Objectives

This scoping review systematically maps and explores existing educational interventions for children with CHD to identify intervention types, target populations, delivery methods, and assessed outcomes. Textbox 1 presents the PICOTS (population, intervention, comparator, outcome, timing, and setting) framework for educational interventions for children with CHD. PICOTS helps clarify and organize research questions. The key questions (KQs) addressed are:

KQ1: What types of educational interventions are available for children with CHD?

KQ2: What are the study designs, target populations, and the roles of various stakeholders in these educational interventions?

KQ3: What outcomes are assessed, and what approaches are used for assessment?

KQ4: What gaps exist in the current literature regarding educational interventions for children with CHD, and what areas require further exploration?

Figure 2 presents the analytical framework for the scoping review. It outlines a structured approach to address KQs concerning CHD and educational interventions for pediatric patients. The review covers intermediate outcomes, including intervention details, study design, stakeholder involvement, and assessed outcomes. The primary outcomes are improved children's HL, reduced parental burden, and enhanced efficiency of health care providers. Suboutcomes related to children's HL enhancement include understanding CHD, self-management or habits, coping or quality of life, empowerment, health care use, and health outcomes. The review also focuses on providing educational, emotional, caregiving, and financial support to reduce parental burden. Additionally, it considers suboutcomes related to saving time or effort, treatment adherence, care coordination, shared decision-making, and patient or family satisfaction to enhance the efficiency of health care providers.

Textbox 1. PICOTS (population, intervention, comparator, outcome, timing, and setting) framework for key questions on health educational interventions for children with congenital heart disease (CHD).

Population

• Children diagnosed with CHD <18 years.

Intervention

• Educational interventions targeting health literacy improvement among children with CHD.

Comparators

• Any comparator (as this is a scoping review).

Outcomes

- Engagement (use and satisfaction).
- Improved health literacy in children with CHD (understanding of CHD, self-management or habits, coping or quality of life, empowerment, health care use, and health outcome).
- Reduced parental burden through effective educational support (educational support, emotional support, and financial support).
- Enhanced health care efficiency by minimizing education needs during medical appointments (saving time or effort, treatment adherence, care coordination, shared decision-making, and patient or family satisfaction).

Timing

No restrictions.

Setting

• All types of studies (as this is a scoping review), including various health care (eg, hospitals and clinics), nonhealth care (eg, school and support community), and home settings.



Figure 2. Logic model for the PICOTS (population, intervention, comparator, outcome, timing, and setting) framework and 4 key questions (KQs).



Methods

Literature Search Strategy

This study used a scoping approach guided by the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) framework [23]. Scoping reviews provide an overview of emerging evidence without aiming to appraise and synthesize results for a specific question. They are useful when it is still unclear what specific research questions a systematic review can address. Additionally, scoping reviews help inform and identify current research practices and methodologies in emerging research fields [22-25]. This research process was structured using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) framework, including four stages: (1) identification of relevant literature searches on various databases using specific keywords, (2) screening the title and abstract of the identified studies, (3) eligibility-full-text review of screened results to eliminate studies outside our intended scope, and (4) inclusion, helped extract relevant data that met the defined criteria [26]. The PRISMA-ScR checklist is available in Multimedia Appendix 1.

Eligibility Criteria

To be included in the review, studies must be written in English and published in a peer-reviewed journal to ensure accessibility and credibility. We only considered studies with a methods section, focusing on primary data and analyses rather than studies like systematic reviews. Our focus was on CHD in pediatric patients younger than 18 years of age, and the studies addressed educational interventions for this demographic, not just HL. We excluded studies that solely targeted parents or caregivers, focused only on health care providers, or related to transition care from pediatric to adult health care, as these areas fall outside our specific review scope. However, we included studies involving parents only when their participation aimed to improve the child's health outcomes, focusing on enhancing the children's educational experience rather than the parents. This selection process ensured that the included studies were directly relevant to pediatric CHD and educational health interventions.

Information Sources and Search

We conducted comprehensive searches across the following bibliographic databases during February 2024 to identify potentially relevant studies without a predefined time limit. Given the initial research indicating a scarcity of relevant studies, we maintained an open search time frame. We gathered relevant studies from APA PsycINFO and MedlinePlus via Ovid, Web of Science, ACM Digital Library, Scopus, and EBSCOhost, including CINAHL Complete, CINAHL Ultimate, Health Source: Nursing/Academic Edition, and ERIC. These databases cover health care, psychology, education, design, and human-computer interaction disciplines. They were selected to reflect the interdisciplinary nature of CHD health educational interventions.

Three main concepts were identified based on the research questions: HL, pediatric, and CHD. Synonyms and related concepts were incorporated to ensure a comprehensive search for related terminologies used in the literature. For example, synonyms of "pediatric" included "child," "children," "toddler," and "preschool," while related concepts like "boy" and "girl" were also included. Given the cross-disciplinary database search, listing each concept's relevant ideas and terms was important. MeSH terms and keywords were tailored to each database's specifications, as detailed in Multimedia Appendix 2. Boolean search strings were formulated using the OR operator for synonyms of the main concepts (ie, "children" OR "child" OR "pediatric") and the AND operator to combine the 3 main concepts (ie, "health literacy" AND "congenital heart disease" AND "pediatric"). The terms were refined through multiple iterations by adding new terms and synonyms or adjusting specificity to enhance the quality of results. For instance, recognizing that the term "health literacy" may be omitted in studies involving health education interventions, alternative terms such as "healthcare knowledge," "health awareness," and "health education" were included. Additionally, we intentionally avoided using "intervention" as a synonym for "health literacy" to ensure that studies focusing on clinical and surgical interventions in CHD were not included (Table 1).



Table 1. Boolean search strings in categories.

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Categories	AND or NOT	Boolean search string
Health literacy	AND	("Health Literacy" OR "Healthcare Literacy" OR "Medical Literacy" OR "Health Understanding" OR "Health Education" OR "Healthcare Education" OR "Health Information Literacy" OR "Medical Comprehension" OR "Healthcare Knowledge" OR "Health Knowledge" OR "Health Proficiency" OR "Health Awareness" OR "Medical Awareness" OR "Health Competency" OR "Health Communication" OR "Information Literacy" OR "Patient Education" OR "Health Pro- motion" OR "Health Teaching")
Pediatric	AND	(Children OR Child* OR Kid OR Kids OR Girl* OR Boy OR Boys* OR Toddler* OR Childhood OR Preschool* OR Pre-school* OR Kindergarten* OR School OR Minors OR Pediatric* OR Paediatric*)
Congenital heart disease	AND	("Congenital Heart Defects" OR "Child Heart Disease" OR "Heart Defects" OR "Congenital Heart Disease" OR "Pediatric Cardiology" OR "Paediatric Cardiology" OR "Cardiac Defect*")

The first author (NB) and a collaborator independently screened the titles and abstracts using the PICO Portal, reaching a consensus on selections for full-text screening and consulting the health librarian for final decisions in disagreements. Before and during the screening process, the first (NB), second (JYS), and last authors (CAL) held weekly meetings to clarify the selection of databases, concepts, and criteria as well as to draft an internal guideline. For example, following our discussions, we added the ACM Digital Library database to broaden our search to include technology-mediated solutions. These meetings continued during data charting and thematic analysis. We also sought guidance from a medical expert, a public health expert, and 2 librarians throughout the review. We used Zotero (Corporation for Digital Scholarship) for reference management and Google Sheets and Microsoft Excel for data abstraction. We established decision rules to guide the coding process and ensure consistency in cases requiring subjective interpretation.

The research team abstracted data on study characteristics: (1) study identification (ie, ID, author or year, country, title, study design, date of study, setting, and objective or purpose), (2) participant details (ie, target population, intervention tested on, sample size, demographic, inclusion or exclusion criteria, and CHD severity), (3) intervention specification (ie, intervention, format, description, comparison, stakeholders' roles, duration, and follow-up), and (4) outcome specification (ie, outcome measures, results, and statistical analysis). Abstraction tables are shown in Tables S1-S5 in Multimedia Appendix 3 [27-37].

Data Synthesis

Due to the heterogeneous nature of the data, the research team used a qualitative approach using affinity diagramming and thematic analysis [38,39]. This approach enabled us to explore the data without predetermined frames and uncover emerging themes to answer our scoping review questions and objectives. We began by categorizing the studies based on the types of interventions they covered. We then performed open coding on all 11 papers to identify the specifications of educational interventions (ie, objectives, strategies, stakeholder involvement, and outcomes) for children with CHD. Through constant comparison and iterative coding, thematic categories emerged. Initially, open coding of studies yielded 43 discrete codes. Subsequently, these codes were iteratively aggregated based on commonalities, resulting in 15 representative codes. Next, affinity diagramming was used to cluster these 15 codes according to similarity, difference, and hierarchy relationships.

This process allowed us to establish high-level themes, refined through constant comparison and iterative coding. The key themes that emerged from the data include (1) types of educational interventions, (2) study design and stakeholder involvement, and (3) evaluation methods and outcome objectives. Each main theme was further divided into 2 subthemes (Textbox 2). This thematic synthesis provided a clear and structured understanding of the educational interventions for children with CHD, covering their implementation and evaluation.

Textbox 2. Identified themes and subthemes.

Types of educational interventions

- Educational strategies and objectives (eg, engaging sessions and disease education)
- Intervention duration (eg, duration and frequency of educational interventions)

Study design and stakeholder involvement

- Study design (eg, observational and randomized controlled trial)
- Target age groups and stakeholder involvement (eg, children and parents)

Evaluation methods and outcome objectives

- Assessed outcomes (eg, health literacy and health outcome)
- Data collection and analysis techniques (eg, questionnaires and interviews)

Results

Selection of Sources of Evidence

The literature search identified 864 records across 5 databases: APA PsycINFO (n=3), MEDLINE (n=235), Web of Science (n=102), ACM Digital Library (n=25), Scopus (n=473), CINAHL Complete (n=11), CINAHL Ultimate (n=11), Health Source: Nursing/Academic Edition (n=3), and ERIC (n=1). After removing 280 duplicates and supplemental materials, 584 records remained for abstract screening. Following abstract and title screening by the research team, 480 records were excluded for not meeting the review criteria. The full texts of the remaining 104 reports were assessed for eligibility. Of these, 93 reports were excluded for various reasons: 31 due to the population mismatch (ie, focusing on parents or caregivers or health care providers, participants aged >18 years, or studying general heart disease), 26 because the intervention was not relevant (ie, no interventions implemented, assessments used as interventions, or noneducational interventions), and 36 were excluded based on the wrong study design (ie, focusing on transitions to adulthood or objectives aimed at parents or health care providers). Finally, 11 reports met all the inclusion criteria and were selected for inclusion in the scoping review. Figure 3 illustrates the results of the literature search and screening. We used the PICO Portal review software to support the screening process. The reasons for exclusion at each stage were clearly documented, ensuring transparency and adherence to the PRISMA guidelines. References for papers excluded in the full-text review can be found in Multimedia Appendix 4.

Figure 3. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram of the literature review process.



Characteristics of Sources Evidence

From 1982 to 2023, 11 studies were reviewed, focusing on educational interventions for pediatric patients with CHD [27-37] (Figure 4). There was a gap in the selected studies from 1982 to 2015. After that, 1 study was published every year until 2023, except for 2016, which had 2 studies [31,34]. Two studies were from the Netherlands in 2017 and 2018 [29,36], while 3

were from the United States in 1982, 2021, and 2022 [33,35,37]. Among these studies were 9 randomized controlled trials (RCTs) [27-32,34-36], with 1 covering both a pilot and RCT [29]. Additionally, 2 were observational studies [33,37]. Even though we searched design, human-computer interaction, and health databases, the studies were published in 9 medical and health-related journals. Two of the reviewed studies were published in the *International Journal of Cardiology* [27,31].

Figure 4. Characteristics of included studies [27-37]. RCT: randomized controlled trial.

Author (year)	Study design	Canada	China	Denmark	England	Finland	France	Netherlands	United States
Uzark et al (1982)	RCT								Pediatric Cardiology
Biglino et al (2015)	RCT				BMJ Open				
Ni et al (2016)	RCT		Journal of Child Health Care						
Klausen et al (2016)	RCT			International Journal of Cardiology					
Etnel et al (2017)	Pilot + RCT							Frontiers in Cardiovascular Medicine	
van der Mheen et al. (2018)	RCT							BMC Pediatrics	
Amedro et al (2019)	RCT						International Journal of Cardiology		
Lemire et al (2020)	RCT	Contemporary Clinical Trials							
Zablah et al (2021)	Observational								Progress in Pediatric Cardiology
Liddle et al (2022)	Observational								Cardiology in the Young
Karikoski et al (2023)	RCT					Caries Research			

Results of Individual Sources of Evidence

Overview

In exploring educational interventions for children with CHD, the first emergent theme is "types of educational interventions," with subthemes of "educational strategies and objectives" and "intervention duration." Educational strategies and objectives refer to the strategies used to support children with CHD and how these interventions address specific objectives, like disease education. Duration presents the timing and duration of these interventions, whether they are 1-time sessions, have follow-ups, or are repeated over time. This theme and its subthemes address KQ1: What types of educational interventions are available for children with CHD?

Educational Strategies and Objectives

Across the reviewed studies, 6 educational strategies were used to support children with CHD and their families (Figure 5). These strategies include the use of 3D patient-specific models, habit formation interventions, empowerment-based health education programs, rehabilitation interventions, a web-based portal, and videotape presentations. 3D patient-specific models are anatomical models created from medical imaging data like computed tomography or magnetic resonance imaging scans, providing a detailed representation of a child's heart. They help visualize and understand complex cardiac structures and treatment plans. Three studies used these models to educate about cardiac anatomy and treatment plans. These models were accompanied by engaging discussions and supplemented with diagrams or images, clarifying complex anatomical structures and treatment options. One of these studies specifically targeted adolescent patients, combining 3D models with tele-education. These interventions offered a visual understanding of the heart's structure and treatment procedures, including cardiac catheterization [28,33,37]. Habit formation interventions aim to instill healthy habits in children with CHD through structured programs. These interventions often involve multiple components, such as printed materials, toolkits, websites, and counseling sessions, to encourage and support the development of these beneficial habits. Two studies focused on these interventions. One aimed at promoting physical activity through a multifaceted intervention, including printed materials, a physical activity toolkit, and a website. The other focused on oral health promotion through counseling, distributing oral hygiene products, and providing written information [30,32].



Figure 5. Educational strategies, objectives, and intervention durations [27-37]. CHD: congenital heart disease; NR: not reported.

Studies	Strategies	Objectives	Purpose	Duration	Follow-up
Biglino et al (2015) Zablah et al (2021) Liddle et al (2022)	3D patient-specific models	- Disease education	Provide a visual understanding of cardiac anatomy and treatment procedures, such as cardiac catheterization.	 Routine outpatient visits Routine outpatient visits 30-minute tele-education 	- NR - NR - NR
Lemire et al (2020) Karikoski et al (2023)	Habit formation interventions	- Self-management skills	Promote physical activity and oral health—2 important habits—among children with CHD.	 6 months (3-day workshop, conference call each month) 1.5 years (sessions at 6, 12, 18 months) 	- 6 months- 24 months
Ni et al (2016) van der Mheen et al (2018)	Empowerment- based health education programs	- Coping strategies - Disease education	Improve caregiving knowledge, caring behaviors, and self-efficacy of parents caring for children with CHD.	 - 40 minutes + 3 monthly each 10 minutes - One-day workshop 	 1 month + 3 months after surgery 6 months
Amedro et al (2019) Klausen et al (2016)	Rehabilitation interventions	 Self-management skills Coping strategies 	Enhance the quality of life, physical fitness, and health-related quality of life in adolescents and young adults with CHD.	- 12 weeks - 52 weeks	- 12 months - 12 months
Etnel et al (2017)	Web-based portal	- Disease education - Physician-patient communication	Improve patient knowledge and involvement and support physician-patient communication in the management of CHD.	- No limit	- 1 month
Uzark et al (1982)	Videotape presentation	 Coping strategies Disease education 	Enhance children's knowledge and coping during hospitalization for cardiac catheterization through visual education.	- 16 min	- 4 to 6 weeks after hospital discharge

Empowerment-based health education programs empower parents and family members by enhancing their knowledge, caregiving behaviors, and self-efficacy in managing a child's CHD. They typically include face-to-face education sessions, workshops, and follow-up support such as telephone calls, helping caregivers feel more confident and competent in their roles. Two studies implemented these programs to improve the caregiving knowledge, caring behaviors, and self-efficacy of parents or family members caring for children with CHD. One offered face-to-face education sessions and follow-up telephone calls, while the other conducted workshops [34,36]. Rehabilitation interventions aim to enhance the physical and psychological well-being of children and adolescents with CHD. These include structured cardiac rehabilitation programs (center or home-based) and eHealth interventions that use technology to improve physical fitness, activity levels, and overall health-related quality of life over an extended period. Two studies explored these interventions. One evaluated the impact of a combined center- and home-based cardiac rehabilitation program on the quality of life of adolescents and young adults with CHD. The other assessed the effects of a 52-week eHealth intervention on physical fitness and health-related quality of life in adolescents with CHD [27,31].

Web-based portals are digital platforms that enhance patient education, engagement, and communication. They provide accessible information about CHD, treatment options, and self-management strategies. These portals also facilitate communication between patients, families, and health care providers, ensuring continuous support and information exchange. Only 1 study assessed the effectiveness of these interventions in improving adolescent patient knowledge and involvement and supporting physicians in communicating with their patients [29]. Videotape presentations prepare children and their families for medical procedures and hospital stays. The videos use engaging, playful, and child-friendly formats, such as fictional or animated characters and stories, to simplify complex medical concepts and make them less intimidating. In 1982, a study evaluated the impact of a 16-minute videotape presentation on children's knowledge and coping skills during cardiac catheterization. The study featured a fictional lion who presented the videotape to guide hospitalized children through the events, sights, sounds, and sensations associated with the cardiac catheterization procedure [35].

Of the 11 studies reviewed, 7 offered disease education using the following methods: 3D patient-specific models, empowerment-based health education programs, web-based portals, and videotape presentations [28,29,33-37]. Four studies

focused on improving self-management skills using 2 strategies: habit formation interventions and rehabilitation interventions [27,30-32]. Five studies aimed to teach coping strategies using 3 approaches: empowerment-based health education programs, rehabilitation interventions, and videotape presentations [27,31,34-36] (Figure 5). It is important to note that some studies addressed more than 1 aspect, which is why the numbers overlap across different categories.

Intervention Duration

The duration of educational interventions varied across the studies, as shown in Figure 5. Some interventions were brief sessions within routine visits, while others lasted up to 1.5 years. Follow-ups also differed. Some interventions had no follow-ups, while others included assessments at intervals of 1 month, 6 months, 1 year, or 2 years.

In total, 2 of 3 studies using 3D patient-specific models were integrated into routine outpatient visits without a specified duration. Another study used digital 3D heart models during a 30-minute tele-education session instead of in person. After the session, patients received a USB drive containing a video of their 3D heart and digital files for potential self-learning, with no follow-up mentioned [28,33,37]. In contrast, habit formation interventions, such as the oral health promotion intervention and a multifaceted physical activity intervention lasted 1.5 years with sessions at baseline, 6, 12, and 18 months, followed by a 24-month follow-up. The multifaceted physical activity intervention spanned 6 months, including a 3-day workshop and monthly conference calls, with a follow-up period of 6 months [30,32].

As part of the empowerment-based health education program, 1 study included a 40-minute face-to-face education session with individualized instructions on the second day after surgery. There were also 2 monthly 10-minute telephone calls after the discharge to discuss the child's care and modify action plans. Subsequent assessments were conducted at 1 month and 3 months after surgery. Another study, the Congenital Heart Disease Intervention Program-Family intervention, involved a 1-day workshop and a 6-month follow-up session and assessment [34,36]. Using the rehabilitation interventions strategy, 1 study implemented the QUALI-REHAB cardiac rehabilitation program, consisting of a 12-week program with 5 days of hospitalization at the rehabilitation center and home-based training. Recall sessions were held every 3 weeks at the center, with a final evaluation at the end of week 12 and a 12-month follow-up period for outcome measurements. Another program, the Paediatric Rehabilitation for Vanguard in Lifeskills (PReVaiL), lasted 52 weeks, with a follow-up assessment conducted after 1 year. Patients received group-based health education sessions lasting 45 minutes and individual counseling sessions lasting 15 minutes [27,31].

Additionally, 1 study introduced a web-based portal during outpatient visits that could be used anytime, with follow-up assessments conducted 1 month after the visit [29]. Finally, 1 study conducted a 16-minute videotape presentation session 1 day before procedures, with a follow-up undertaken 4 to 6 weeks after discharge from the hospital [35]. In total, 3 studies had a 1-month follow-up timeline, while 2 had 6 months and 2 had 1 year.

Study Design and Stakeholder Involvement

Overview

The second emergent theme is "study design and stakeholder involvement," with subthemes of "study design" and "target age groups and stakeholder involvement." Study design focuses on the methodologies used in the studies and the size of participant samples. Target age groups and stakeholder involvement examines the target population's age range and impact on stakeholder roles. It analyzes whether parents, caregivers, or health care providers are involved in delivering or evaluating the intervention and identifies the target population. Together, these address KQ2: What are the study designs, target populations, and the roles of various stakeholders in these educational interventions?

Study Design

In total, 8 of the 11 studies used an RCT design, while 1 study included a pilot phase followed by an RCT [27-32,34-36]. The sample sizes in these RCTs ranged from 53 to 250, with a mean of 126.11 (SD 43.95). The intervention group size ranged from 31 to 125, with a mean of 63 (SD 25.20), and the control group size ranged from 22 to 125, with a mean of 62.78 (SD 24.60).

These RCTs varied in their approach, including prospective randomized clinical trials; questionnaire-based feasibility and acceptability studies; prospective clinical trials; single-center, single-blinded, randomized controlled trials; prospective, multicenter, randomized, controlled, parallel-arm studies; cluster randomized controlled trials; and multicenter stepped-wedge implementation trials. Additionally, 2 studies adopted observational study designs [33,37]. The observational studies explored a single-center cross-sectional study and a prospective pre-post study, with sample sizes of 46 and 22, respectively.

Reviewed studies used diverse settings for their interventions. Three studies implemented interventions across home settings, cardiac clinics, and digital or telehealth platforms [29,32,33]. Another 3 studies implemented interventions at home and children's hospitals [30,34,36]. One study used interventions in home settings, cardiac clinics, and rehabilitation centers [27]. Additionally, 1 study used home settings, rehabilitation centers, and digital or telehealth platforms [31]. In total, 2 studies were conducted at cardiac centers [28,37], while 1 was conducted exclusively at a hospital [35]. The study designs and settings are summarized in Figure 6.
Figure 6. Study design and population characteristics [27-37]. N/A: not applicable; NR: not reported; RCT: randomized controlled trial.

Au	thors and date	Biglino et al (2015)	Zablah et al (2021)	Liddle et al (2022)	Lemire et al (2020)	Karikoski et al (2023)	Ni et al (2016)	van der Mheen et al (2018)	Amedro et al (2019)	Klausen et al (2016)	Etnel et al (2017)	Uzark et al (1982)
Strategy		3D patient-specific models			Habit formation		Empowerment health education		Rehabilitation		Web portal	Videotape
Intervention tested on			Children	Children	Children	Children		Children	Children	Children	Children	Children
			Parent		Parent	Parent	Parent	Parent			Parent	Parent
Study de	RCT studies											
	Prospective randomized clinical trial											~
	Questionnaire-based feasibility study	~										
	Prospective clinical trial						~					
	Randomized clinical trial									~		
	Single-center, single-blinded, RCT							~				
	Prospective, multicenter, RCT, parallel-arm study								~			
	Cluster RCT				~							
	RCT					~						
i	Pilot + RCT											
g n	Multicenter stepped-wedge implementation trial										~	
	Observational studies											
	Single-center cross-sectional study		~									
	Prospective pre-post study			~								
s	Home			~	~	~	~	~	~	~	~	
e	Children hospital	İ			l I	~	~	~	ĺ		İ	~
t t	Cardiac clinic or center	~	~	~	~		İ		~		~	İ
li	Rehabilitation centers	İ			İ		İ		~	~	İ	İ
g	Digital or telehealth	1		~	~					~	~	
	Stakeholders involvement											
	Pediatric patients (children)		~	~	~	~		~	~	~	~	~
P o p u l a t i o n	Parents or caregivers or family	~	~		~	~	~	~	~	~	~	~
	Health care providers	~	~	~	~	~	~	~	~	~	~	~
	Age range											I
	Pediatric patients (children)	6-18 y	1 mo-21 y	13-18 y	5-17 y	0-24 mo	1 mo-5 y	4-7 y	13-25 y	13-16 y	Adolescent	3-12 y
	Parents or caregivers or family	35-51 v	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Sample size											
	Total	103	46	22	200	72	86	90	130	158	250	53
	Intervention group size	45	N/A	N/A	100	35	44	45	65	77	125	31
	Control group size	52	N/A	N/A	100	37	42	45	65	77	125	22

Target Age Groups and Stakeholder Involvement

In the reviewed studies focusing on educational interventions for children with CHD, stakeholder involvement varied depending on the participants' age range. This variation influenced the roles played by different stakeholders, such as parents or caregivers and health care providers, within these interventions.

The primary emphasis of this review was on educational interventions tailored for children with CHD, although not all studies exclusively targeted children as participants. Several studies also included parents of children with CHD within specific age groups to enhance the overall health outcomes for these children. Among the 11 studies examined, 2 exclusively focused on parents [28,34], while 6 involved both parents and children [29,30,32,35-37]. Additionally, 3 studies specifically targeted children aged 13 to 18, 13 to 25, and 13 to 16 years [27,31,33]. The youngest participants in the studies targeting just children with CHD were aged 13 years.

In a study conducted by Uzark et al [35], the researchers assessed the impact of a videotape presentation on the

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knowledge and coping of children with CHD aged 3 to 12 years during hospitalization for cardiac catheterization. The study also targeted the parents of these younger children to improve outcomes for both children and parents. Another study by Biglino et al [28] investigated the effectiveness of 3D patient-specific models of CHD as a communication tool during cardiology consultations for pediatric patients aged 6 to 18 years and their parents. The age range of parents included in this study was 35 to 51 years.

Lemire et al [32] studied children with CHD aged 5 to 17 years and their parents. The intervention aimed to assess whether providing resources and protocols would enable clinicians to counsel about physical activity during every pediatric cardiology appointment. In another study, Karikoski et al [30] targeted children with CHD up to 24 months old and their parents to investigate the effectiveness of repeated counseling provided by a dental hygienist in improving oral health behavior during the first 1000 days of life. They aimed to improve parental hygiene habits with the expectation that it would also enhance young children's hygiene habits.

Ni et al [34] evaluated the effectiveness of an empowerment-based health education program for parents caring for children aged 1 month to 5 years who had undergone corrective surgery for CHD. Their goal was to improve the health outcomes for the children and not the parents. Van der Mheen et al [36] assessed the effects of a program on parental mental health and the psychosocial well-being of children with CHD aged 4 to 7 years. This program also involved siblings to help normalize the child's CHD position within their family dynamic.

In all 11 studies, key stakeholders—children, parents or caregivers, and health care providers—actively participated in the interventions. In total, 8 studies involved all these stakeholders [27,29-32,35-37], while 2 involved parents and health care providers [28,34], and 1 included children and health care providers [33]. The age ranges in these studies varied widely, from birth to 25 years. However, the age range for parents was not consistently provided across the studies. Only 1 study specified the age range for parents as 35 to 51 years, with children aged 6 to 18 years [28]. Figure 6 provides details of population specification, including stakeholder involvement, age ranges, and sample sizes across the reviewed studies.

Evaluation Methods and Outcome Objectives

Overview

Theme 3, "evaluation methods and outcome objectives," includes 2 subthemes: "assessed outcome" and "data collection and analysis techniques." Assessed outcomes discusses the specific objectives and goals the interventions aimed to achieve. Data collection and analysis techniques examines the methods and approaches used to gather and analyze data. Together, these subthemes address KQ3: What outcomes are assessed, and what approaches are used for assessment?

Assessed Outcomes

The outcomes assessed represent the specific objectives the reviewed studies measure to evaluate the effectiveness of their interventions. This scoping review categorized assessed outcomes into three main categories: (1) improved children's HL and outcome, (2) reduced parental burden, and (3) improved efficiency of health care providers. Figure 7 summarizes these categories, demonstrating the varied impacts of interventions on children with CHD, their parents or caregivers, and health care providers.

Improving children's HL involves various suboutcomes. These include understanding CHD, self-management and habits, coping and quality of life, empowerment, health care use, and health outcomes. Two studies evaluated the understanding of CHD, and both reported increased knowledge following the intervention [33,35]. Meanwhile, 3 other studies are still under investigation [29,32,36]. Three studies were conducted on

self-management and habits. In total, 2 showed positive impacts [30,35], while 1 showed no change or impact [31]. Furthermore, 1 study found a relationship between the intervention and self-management and habits, indicating a need for further investigation in future studies [33]. Ongoing research is being conducted in 3 more studies under investigation [27,32,36].

Two other studies assessed coping and quality of life, one showing no change after intervention [31], and one showing improvement [35], while ongoing investigations continue in 4 studies [27,29,32,36]. Regarding empowerment, 2 studies showed improvement [33,35], with ongoing investigations in 2 more studies [29,36]. Health care use was evaluated once, with no observed difference [30]. Health outcomes were assessed in 2 studies, one indicating improvement [34] and the other showing no change [31]. Additionally, 2 studies without assessments reported a relationship between health outcomes and the intervention [30,35], while ongoing investigations are underway in 2 studies [27,36].

Reducing parental burden focused on various suboutcomes, including educational, emotional, caregiving, and financial support. In total, 4 studies assessed educational support, with 3 showing improvement [30,34,37] and 1 showing no change [28]. Two studies evaluated emotional support, both indicating improvement [34,35]. One study identified a relationship between intervention and emotional support without formal assessments [28], while 2 studies are under investigation [29,36]. Three studies assessed caregiver support, all of which showed improvement [30,34,37]. Similarly, 3 studies identified a relationship that needs further assessment [28,33,35], and 2 are still under investigation [29,36]. Financial support was not assessed in any of the reviewed studies.

Furthermore, regarding enhancing the efficiency of health care providers, one study assessed saving time and effort but found no significant time savings [28], while another study on this topic is still ongoing [32]. Treatment adherence was not directly assessed in any reviewed study, although 1 study noted a relationship without formal assessment [37]. Two studies evaluated care coordination, one indicating improvement [37] and another showing no change [30]. In total, 3 studies identified a relationship between the intervention and care coordination but did not conduct formal assessments [28,33,34], and 1 study is currently under investigation [32]. Shared decision-making and patient or family satisfaction were each assessed in 1 study, both showing improvement [33]. However, another study still investigates shared decision-making [29]. Additionally, 3 studies found a relationship between the intervention and shared decision-making [28,34,37], while 1 reported a relationship with patient or family satisfaction [28]. These findings suggest avenues for future research to assess these relationships more deeply.



Figure 7. Evaluation methods and outcomes objectives [27-37]. ANCOVA: analysis of covariance; CHD: congenital heart disease.

 \uparrow denotes positive outcome, \downarrow denotes negative outcome, - denotes no change, \circ indicates a relationship is present but not assessed, NR indicates the statistic is under study and not reported yet, \checkmark indicates the statistic was used in the study and the method.

Authors and date		Biglino et al (2015)	Zablah et al (2021)	Liddle et al (2022)	Lemire et al (2020)	Karikoski et al (2023)	Ni et al (2016)	van der Mheen et al (2018)	Amedro et al (2019)	Klausen et al (2016)	Etnel et al (2017)	Uzark et al (1982)
Strategy		3D patient-specific models			Habit formation		Empowerment health education		Rehabilitation		Web portal	Videotape
Intervention tested on			Children	Children	Children	Children		Children	Children	Children	Children	Children
		Parent	Parent		Parent	Parent	Parent	Parent			Parent	Parent
	Improved children's health literacy an	d outcom	e									
	Understanding of CHD			1	NR			NR			NR	1
	Self-management or habits			0	NR	1		NR	NR	-		1
	Coping or quality of life				NR			NR	NR	-	NR	1
	Empowerment			Ť				NR			NR	1
	Health care use					-						
0	Health outcome					0	1	NR	NR	-		0
t	Reduced parental burden											
c	Educational support	-	Ť	0		1	1	NR			NR	0
0	Emotional support	0					1	NR			NR	1
e	Caregiving support	0	1	0		†	†	NR			NR	0
	Improved health care providers' efficiency											
	Save time or effort	Ŧ			NR							
	Treatment adherence		0									
	Care coordination	0	1	0	NR	-	0					
	Shared decision-making	0	0	1			0				NR	
	Patient or family satisfaction	0		1								
	Repeated measures ANOVA				~		~	~				
	ANCOVA analysis				~					~		~
	Post hoc t test						~					
	Independent samples t test	~				~	~					~
	Wilcoxon signed-rank test		~	~								
	Mann-Whitney U test		~		~	~						
S t	Chi-square analysis (χ ²)	~					~					~
a	Fisher exact test					~						
t	Post hoc power analysis	~										
1	Cohen d							~				
t	Regression analysis							~				ļ
i	Stepwise regression											~
c	Simple logistic regression					~						
	Multiple logistic regression					~						ļ
	Logistic regression				~					~		
	Correlation analysis (r)											~
	Cluster analysis											~
	Weighted Cohen ĸ			~								
M	Software: STATA (ST), SPSS (SP)	(ST)	(SP)		(SP)	(SP)	(SP)			(ST, SP)		
e t	Quantitative questionnaire (ie, pre or post)	~	~	~	~	~	~	~	~	~	~	~
h	Medical record or device				~		~		~			
o d	Qualitative feedback (ie, in-person digital interview, call, focus group)			~		~	~	~		~	~	

Data Collection and Analysis Techniques

Across the 11 reviewed studies, various assessment methods and statistical analyses were used to evaluate the effectiveness of interventions for children with CHD. These methods and analyses provided comprehensive insights into the outcomes measured and the statistical rigor applied.

As a statistical software, SPSS (IBM Corp) was predominantly used in 5 studies [30-32,34,37], reflecting its widespread utility for quantitative data analysis in health care research. Data collection methods varied, with all studies using questionnaires, often administered before and after the intervention. In total, 3 studies relied solely on questionnaires and quantitative methods [28,35,37], while 5 studies integrated questionnaire data with qualitative feedback from in-person or digital interviews, calls, or focus groups [29-31,33,36]. Two studies incorporated medical records or devices alongside questionnaires [27,32], and 1 used

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all 3 methods, including questionnaires, qualitative feedback, and medical records or devices [34].

Statistical analyses used in the reviewed studies to analyze the data included a wide range of methods. The most frequently used statistical analysis method was the independent samples t test, used in 4 studies primarily as pre- and postassessments [28,30,34,35]. Other common analyses included repeated measures ANOVA [32,34,36], analysis of covariance analysis [31,32,35], Mann-Whitney U test [30,32,37], and chi-square analysis [28,34,35], each used 3 times to assess various outcomes. Several studies have also applied regression analysis techniques such as stepwise regression [35], simple logistic regression [30], multiple logistic regression [30], and logistic regression [31,32].

Among the 11 studies, 2 statistical approaches were used in 3 studies [31,33,37]. Notably, 1 study in 1982 used 6 statistical

techniques, including analysis of covariance analysis, independent samples t test, chi-square analysis, stepwise regression, correlation analysis (r), and cluster analysis [35]. Figure 7 provides an overview of the statistical approaches used across the studies, highlighting a range from 2 to 6 approaches per study.

The reviewed studies used various methods and statistical techniques, indicating no single approach to achieving their objectives. The frequent use of quantitative methods, primarily involving stakeholders other than children with CHD, suggests the need for tailored methods and techniques for this patient demographic.

Discussion

Principal Findings

Overview

This scoping review identified 11 studies conducted between 1982 and 2023, focusing on educational interventions for children with CHD. The studies included 9 RCTs and 2 observational studies. These studies used various intervention strategies, durations, study designs, and evaluation methods, offering a comprehensive overview of current research in this field. Six primary types of educational strategies were identified: 3D patient-specific models (n=3), habit formation interventions (n=2), empowerment-based health education programs (n=2), rehabilitation interventions (n=2), web-based portals (n=1), and videotape presentations (n=1). These interventions varied in duration, ranging from brief sessions during outpatient visits to programs lasting up to 1.5 years. Follow-up periods also varied, with 3 interventions having no follow-up, 2 having a 6-month follow-up period, 3 having follow-ups ranging from 4 to 6 weeks, and 1 study having a follow-up period of 24 months. The primary goals of these interventions were to improve the quality of life and coping strategies, self-management skills, and knowledge of children with CHD and their families. Among these studies, 3 interventions specifically targeted children above 13 years of age, 2 focused on parents, and 6 involved both children and parents. The primary statistical method used was the independent samples t test, used in 4 studies for pre- and postassessments. Outcome assessments focused on children's HL, reducing parental burden, and improving the efficiency of health care providers. These findings reveal the potential and the limitations of current health educational interventions, highlighting the need for more child-centric approaches to engage younger patients with CHD.

Limited Interventions for Children With CHD

This scoping review highlights the potential of educational interventions to significantly improve chronic care management for children with CHD and their families, aligning with previous findings [10-13,40-45]. Existing research indicates that well-informed pediatric patients can delay or prevent secondary illnesses, enhance their quality of life, and reduce health care costs [46-50]. However, many children with chronic conditions lack sufficient understanding of their illnesses, leading to confusion, anxiety, and other complications [51-54]. One contributing factor is the reliance on parents by health care

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XSL•F() RenderX providers to educate their children, assuming effective transmission of information [55,56]. Additionally, the development of interventions has mostly neglected children's perspectives, focusing primarily on feedback from health care providers and parents. Younger children face barriers to participation due to limited attention spans, difficulty understanding abstract concepts, and challenges in expressing their needs [57,58]. As a result, interventions typically depend on parental feedback as a proxy for testing and design insights [59].

The review also found that educational materials were predominantly designed for teenagers or parental caregivers, lacking age-appropriate and engaging solutions for children younger than 13 years of age. Among the 11 studies reviewed, only 3 [27,31,33] exclusively targeted children, focusing on those aged 13 years and older, likely due to usability challenges for younger children [58,60-62]. This is the case despite the review's specific focus on educational interventions for children with CHD. The concept that "children are not small adults" is widely acknowledged in pediatric care. It emphasizes that children represent a unique population with their own culture, norms, and complexities [63-65]. This understanding underscores the necessity for developing more inclusive and age-appropriate educational interventions for younger children with CHD.

Limited Engaging Strategies

Among the reviewed studies, 3D modeling emerged as a prominent strategy for educating pediatric patients and their families about CHD [28,33,37]. This approach offers engaging learning and improves communication between families and health care providers. However, despite its interactivity, 3D modeling and the other 5 strategies examined in this review lack engaging, playful interactions. Earlier educational tools, such as videotape presentations featuring friendly and playful characters like a fictional lion, effectively engaged young patients by making complex medical procedures more understandable and less intimidating through storytelling [35].

Playful strategies naturally engage children and facilitate learning through play. By communicating complex health information in an age-appropriate and engaging manner, they make a painful and tedious subject more approachable. In the 1920s, nurses Nightingale and Erikson first recognized the importance of systematizing play sessions to improve children's hospitalization experience and adherence to medical procedures [66-73]. Since then, strategies like pretend play [74,75] and serious games [76,77] have been used for chronic care management, educating children about their conditions, and helping them manage their fears. However, these strategies are rarely used for children with CHD. The evolution of educational interventions from videotape presentations in 1982 to patient-specific 3D printing indicates significant technological advancements. Integrating engaging and playful approaches into current interventions could substantially boost their effectiveness by involving children directly in their health care journey through their own language: play.

Enhancing Methodological Approaches

The majority of the reviewed studies used RCTs [27-32,34-36], reflecting robust methodologies for evaluating educational interventions for children with CHD. However, except for 1 [33], many studies primarily assessed parental outcomes as proxies without adequately evaluating specific outcomes for pediatric patients themselves [28-30,32,34-37]. This highlights a gap in HL measures tailored for children with CHD. While parental involvement is essential, directly assessing children's HL, coping mechanisms, and overall well-being is equally vital.

One notable strength of these studies was the involvement of various stakeholders in intervention delivery, including pediatric patients, parents or caregivers, and health care providers. Eight studies involved all stakeholders, ensuring a comprehensive approach [27,29-32,35-37]. Nevertheless, there is a need for more extensive engagement, particularly with pediatric patients, throughout the intervention's ideation, design, and implementation phases. Early involvement of stakeholders, including children as design partners, enhances the integration of interventions into routine care, ensuring practicality, feasibility, and alignment with clinical needs [58,78-82].

While most studies used questionnaires supplemented by qualitative feedback, there is a major focus on quantitative approaches. Incorporating more qualitative studies in the initial stages could help identify challenges, barriers, and desires more effectively. Unlike quantitative methods, qualitative methods aim to explore, narrate, and explain phenomena, making sense of complex realities. Health interventions could develop as an outcome of qualitative research [83,84]. Statistical analyses were diverse, with the independent samples t test being the most commonly used method, typically involving defined objectives and pre- and postassessment measures. Despite the rigorous methodologies, there was a lack of long-term longitudinal studies to assess the sustained effectiveness of the interventions [85]. Most studies had follow-up periods ranging from 1 month to 1 year, with only 1 study extending to 24 months [30]. This highlights the need for future research to include extended follow-up periods to understand the long-term impact of educational interventions on children with CHD and their families.

By addressing these methodological gaps and expanding stakeholder engagement, particularly with pediatric patients, we can enhance the effectiveness of health educational interventions. Designers, health care providers, and policymakers should prioritize developing and implementing solutions with all stakeholders, not just for them. This collaborative approach can enhance care quality, coordination, and outcomes for children, families, and health care providers.

One effective strategy is to integrate engaging learning tools—both digital and physical—through play. For example, a playful, educational toy similar to Rufus the Bear with Diabetes (Empath Labs), used in diabetes education, can help children manage their health. A comparable toy featuring a simplified heart model allows children to explore their anatomy and medical routines through hands-on play, making complex concepts more accessible. Designed to meet developmental needs, these tools can reduce anxiety, foster independence, and

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help children manage fears through pretend play. By prioritizing children's needs rather than relying on parents to convey information, we ensure that health information remains relatable and engaging. Ultimately, these child-led strategies empower families to build the knowledge and resilience necessary for effectively managing CHD. Such efforts could improve health outcomes during the transition to adulthood, enhance autonomy in managing CHD, and streamline education and health care delivery.

Limitations

This scoping review has offered valuable insights but has limitations. First, the search was limited to English-language publications, which may have excluded relevant studies published in other languages. Second, despite efforts to conduct a comprehensive search, it is possible that some relevant studies were missed, thus introducing selection bias. Finally, the inclusion criteria were restricted to published peer-reviewed studies, which means that relevant gray literature and unpublished studies were excluded, introducing publication bias. It is essential to consider these limitations while interpreting the findings of this scoping review. Additionally, the limited number of studies meeting the inclusion criteria highlights the scarcity of research that focuses specifically on educational interventions for children with CHD. Moreover, the variability in study designs, intervention types, outcome measures, and follow-up periods across the included studies has limited the ability to conduct a meta-analysis and draw definitive conclusions about the effectiveness of educational interventions for children with CHD.

Research Directions

Educational interventions have shown promise in enhancing the quality of life, self-management skills, and knowledge of children with CHD and their families. However, there is a pressing need for further research to develop and evaluate HL-focused pediatric care interventions tailored specifically for patients with CHD younger than 13 years of age. Drawing from successful interventions in this review, such as the approach by Uzark et al [35] that engaged both pediatric patients and parents to enhance understanding and coping during hospitalization, offers a promising framework for younger children with CHD. This playful approach significantly improved HL. empowerment, and self-management skills. While this study focused exclusively on children with CHD and health educational interventions, future research could draw insights from playful interventions designed for other pediatric conditions like cystic fibrosis and diabetes. As part of our multiphase research project, this comparative approach will inform the iterative development of our health education intervention for younger children with CHD and their families.

Additionally, since no studies included in this review used qualitative approaches such as co-design, our research would prioritize integrating such methodologies to involve all stakeholders, including children, early on. This would enhance the relevance and effectiveness of the interventions. Acknowledging challenges and working with all stakeholders toward finding solutions is essential, as simply ignoring the problem will not lead to progress. Involving children as design

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partners, despite all the barriers, can ensure that the interventions are engaging, relevant, and effective in meeting the unique needs of children with CHD.

Conclusions

Educational interventions promise to enhance the quality of life, self-management skills, and knowledge of children with CHD and their families. However, insufficient evidence to support educational interventions for this pediatric population highlights a significant gap in the literature. While this scoping review aimed to identify these gaps, the scarcity of evidence highlights the need for further research. Advocating for such research is crucial to guide designers, health care providers, and policymakers in delivering effective interventions tailored to the specific needs of children with CHD. There is a clear need for more research explicitly addressing pediatric care interventions for children with CHD, focusing on developing age-appropriate, engaging, and engaging educational interventions. Improving HL in pediatric patients can reduce parental educational burden and increase health care provider efficiency by improving communication and patient empowerment.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) checklist. [DOCX File , 109 KB - pediatrics v8i1e64814 app1.docx]

Multimedia Appendix 2 Search strategy. [DOCX File , 23 KB - pediatrics_v8i1e64814_app2.docx]

Multimedia Appendix 3 Study characteristics. [DOCX File , 354 KB - pediatrics v8i1e64814 app3.docx]

Multimedia Appendix 4 Excluded full-text studies. [DOCX File , 34 KB - pediatrics_v8i1e64814_app4.docx]

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Abbreviations

CHD: congenital heart disease
HL: health literacy
KQ: key question
PICOTS: population, intervention, comparator, outcome, timing, and setting
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews
RCT: randomized controlled trial

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