
JMIR Pediatrics and Parenting

Impact Factor (2023): 2.1
Volume 8 (2025) ISSN 2561-6722 Editor in Chief: Sherif Badawy, MS, MD, MBA

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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.

(*JMIR Pediatr Parent* 2025;8:e59489) doi:[10.2196/59489](https://doi.org/10.2196/59489)

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

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 al [23] performed a 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-Schlagel 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

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

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].

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 ($\alpha=.78-.88$) 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 ($\alpha=.76$), 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 ≥ 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.

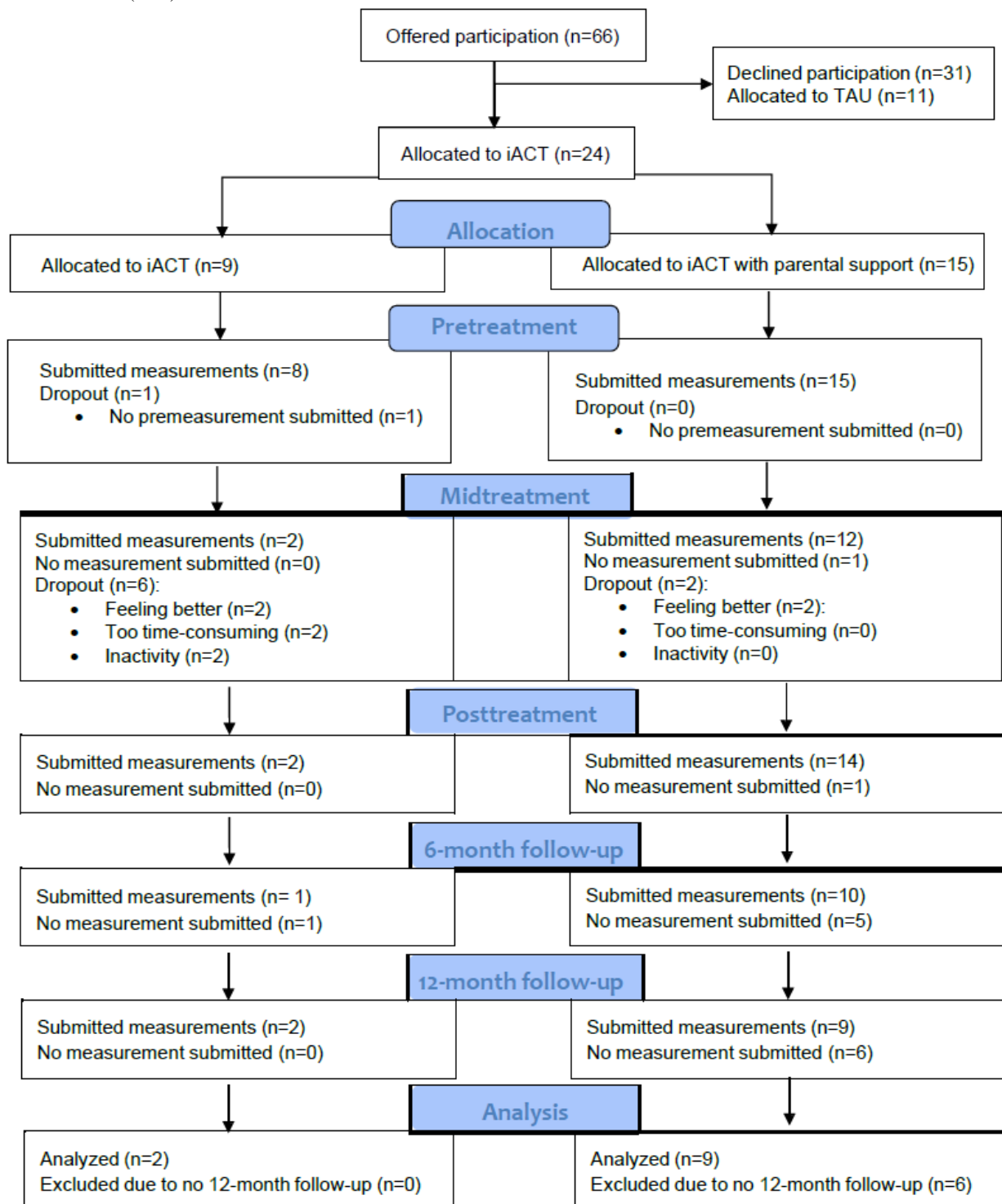
Results

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

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

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.

Table 2. Descriptive statistics for the number of completed modules.

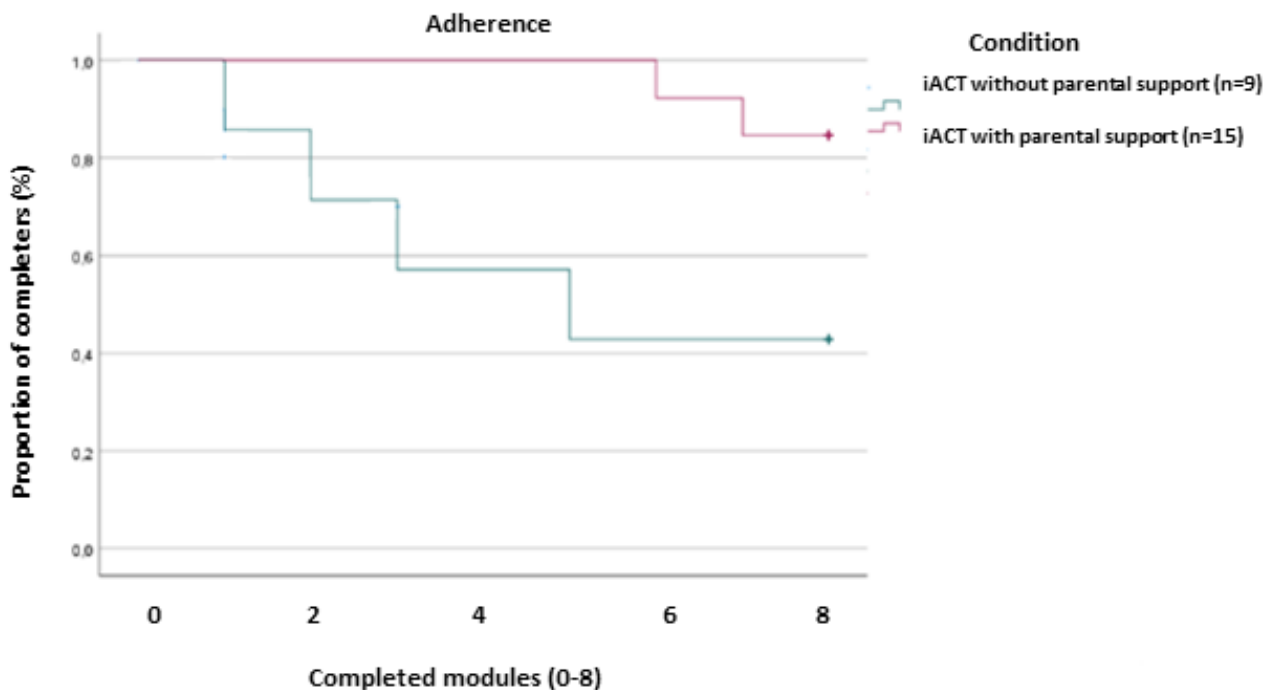
Completed modules or sessions(%)	iACT ^a without parental support (n=9), n (%)	iACT with parental support (n=15), n (%)
<25	2 (22)	0 (0)
25-50	1 (11)	0 (0)
50-75	1 (11)	1 (7)
75-100	5 (56)	14 (93)

^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.



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.

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

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 reported more worry than male participants and that 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

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

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

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.

Acknowledgments

First and foremost, the authors would like to acknowledge Närhälsan and Omtanken, as well as Research and Development Primary Health Care, Region Västra Götaland, Gothenburg, Sweden, for making the Internet Mediated Psychological Treatment-Acceptance and Commitment Therapy (IMPACT) project possible. Furthermore, we would like to thank all health care staff and participants for their time and contributions. Finally, we would like to thank the project managers in Region Västra Götaland. Regional R&D, DNR: 834181 and DNR: 758551 funded the study, received by the second author as the main applicant.

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

Edited by A Serlachius; submitted 01.05.24; peer-reviewed by S Cross, S Sheth - MD; comments to author 05.08.24; revised version received 30.09.24; accepted 01.10.24; published 03.01.25.

Please cite as:

Larsson A, Weineland S, Nissling L, Lilja JL

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

JMIR Pediatr Parent 2025;8:e59489

URL: <https://pediatrics.jmir.org/2025/1/e59489>

doi: [10.2196/59489](https://doi.org/10.2196/59489)

PMID: [39752209](https://pubmed.ncbi.nlm.nih.gov/39752209/)

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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.

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].

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.

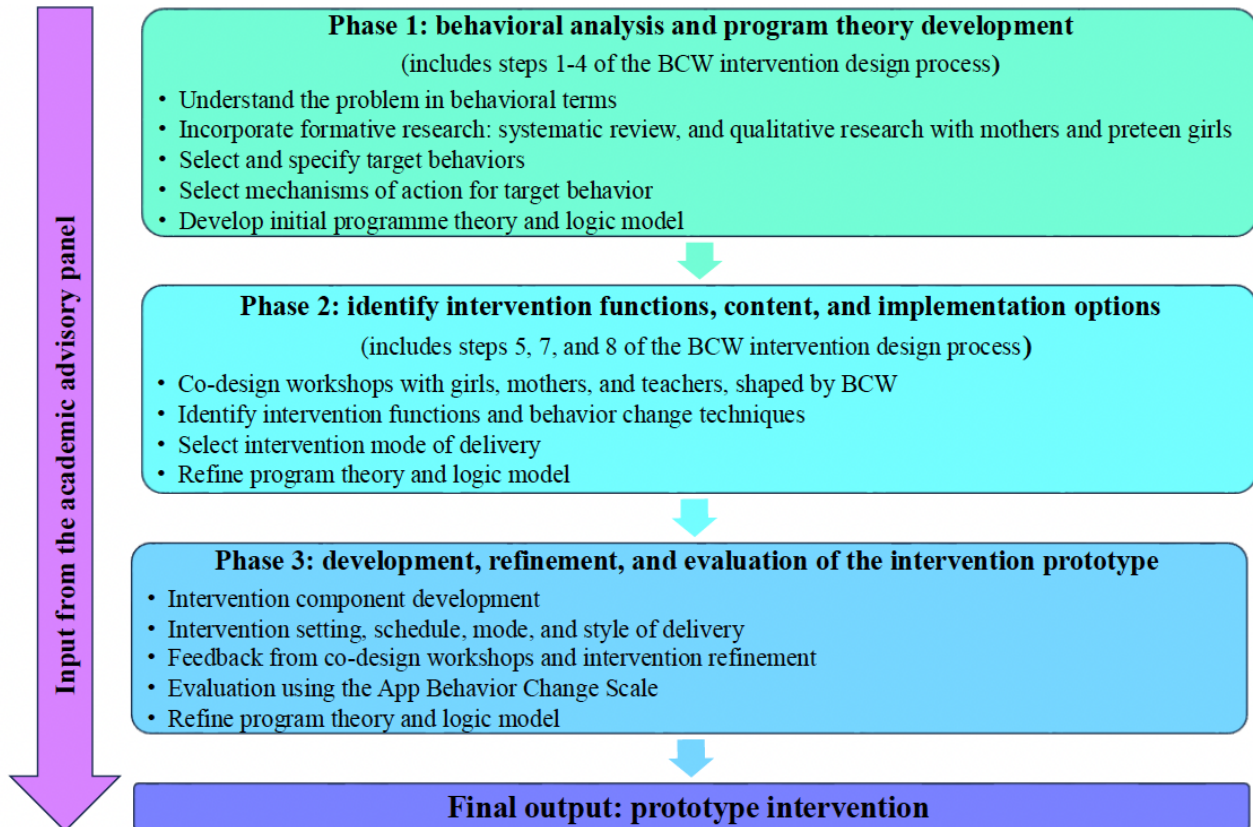
Objectives

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

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](#)).

Table 1. Specification of target behaviors of interest.

	Target behavior 1	Target behavior 2
What behavior	Improve mothers' PA ^a support behaviors (eg, encouragement, 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
<p><i>Knowledge</i></p> <p>Develop mothers' and daughters' understanding of the following:</p> <ul style="list-style-type: none"> 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 	<p><i>Education</i></p> <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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)
<p><i>Skills</i></p> <p>Develop skills to do the following:</p> <ul style="list-style-type: none"> 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 	<p><i>Training</i></p> <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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)
<p><i>Social role and identity</i></p> <ul style="list-style-type: none"> 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 	<p><i>Education</i></p> <ul style="list-style-type: none"> 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 <p><i>Persuasion</i></p> <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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
<p><i>Beliefs about capabilities</i></p> <p>Improve perceived competence in ability to do the following:</p> <ul style="list-style-type: none"> 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 	<p><i>Persuasion</i></p> <ul style="list-style-type: none"> Enhance perceived competence to problem solve, actions plan, select and monitor goals, and self-monitor PA support and PA behaviors Encourage mothers to believe that providing support is possible or daughters to believe that being active is possible, even given constraints of their circumstances <p><i>Enablement</i></p> <ul style="list-style-type: none"> Assist mothers or daughters in problem-solving and action planning to overcome barriers to providing support or being active <p><i>Modeling</i></p> <ul style="list-style-type: none"> Present real-life examples of mothers or preteen girls in similar circumstances 	<ul style="list-style-type: none"> 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:007055) Set graded tasks 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)
<p><i>Beliefs about consequences</i></p> <ul style="list-style-type: none"> Enhance mothers' expectations related to the positive consequences of engaging in selected PA support Enhance mothers' and daughters' expectations related to the positive consequences of engaging in selected PA behaviors 	<p><i>Education</i></p> <ul style="list-style-type: none"> Explore beliefs and attitudes related to PA and the associated health benefits Explore beliefs and attitudes between providing PA support and expected outcomes <p><i>Persuasion</i></p> <ul style="list-style-type: none"> 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 <p><i>Modeling</i></p> <ul style="list-style-type: none"> Provide demonstrations of mothers of teen girls or preteen girls to show the benefits they received as a result of providing support or being active 	<ul style="list-style-type: none"> Inform about health consequences BCT (BCIO:007063) Inform about social consequences BCT (BCIO:007064) Inform about environmental consequences BCT (BCIO:007176) Monitor emotional consequences BCT (BCIO:007066) Demonstrate the behavior BCT (BCIO:007055) Prompt social comparison BCT (BCIO:007073) Present information from credible influence BCT (BCIO:007075)
<p><i>Intentions</i></p> <ul style="list-style-type: none"> 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 	<p><i>Education</i></p> <ul style="list-style-type: none"> Inform about importance of formulating intentions of how and where to provide support or be active <p><i>Persuasion</i></p> <ul style="list-style-type: none"> 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 <p><i>Modeling</i></p> <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Set behavior goal BCT (BCIO:007003) 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	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
<p><i>Goals</i></p> <ul style="list-style-type: none"> 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 	<p><i>Training</i></p> <ul style="list-style-type: none"> Select and review personalized goals related to the target behavior <p><i>Enablement</i></p> <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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)
<p><i>Environmental context and resources</i></p> <ul style="list-style-type: none"> 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 	<p><i>Environmental restructuring</i></p> <ul style="list-style-type: none"> 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 <p><i>Enablement</i></p> <ul style="list-style-type: none"> Provide practical support for mothers and daughters to action plan and problem solve to engage in PA support and PA behaviors 	<ul style="list-style-type: none"> 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)
<p><i>Social influences</i></p> <ul style="list-style-type: none"> 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 	<p><i>Modeling</i></p> <ul style="list-style-type: none"> Provide demonstrations of other mothers and girls describing their experiences for seeking and receiving social support and the benefits they received as a result <p><i>Enablement</i></p> <ul style="list-style-type: none"> Prompt mothers and preteen daughters to seek social support and provide examples of types of social support available to them 	<ul style="list-style-type: none"> 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)
<p><i>Emotion</i></p> <ul style="list-style-type: none"> 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) 	<p><i>Persuasion</i></p> <ul style="list-style-type: none"> Help mothers and daughters recognize the positive feelings associated with providing support or being active <p><i>Enablement</i></p> <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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)
<p><i>Behavioral regulation</i></p> <p>Develop mothers' and daughters' ability to do the following:</p> <ul style="list-style-type: none"> Select and apply PA or PA support behaviors into their daily life Implement tools to monitor PA or PA support progress 	<p><i>Training</i></p> <ul style="list-style-type: none"> Provide means so that mothers and daughters can assess their progress during the intervention and in the future <p><i>Enablement</i></p> <ul style="list-style-type: none"> Provide opportunity, support, and tools to self-monitor PA support or PA behaviors and related habits 	

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
		<ul style="list-style-type: none"> • 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 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 understanding of PA ^a and PA support	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • "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] 	<ul style="list-style-type: none"> • Education • Training
Persuading mothers to support their daughters to be active	<ul style="list-style-type: none"> • Present mothers with examples of other mothers, coaches, teachers, and local sports partnership representatives explaining how, where, and the benefits of supporting daughters to be active • Provide examples of other mothers supporting their daughters to be active, how they overcame 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 	<ul style="list-style-type: none"> • "Or other mummies probably. I think other mummies 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 it...you can challenge your friends or family members and track what you have done." [Sinead, daughter in sixth class] 	<ul style="list-style-type: none"> • Persuasion • Modeling
Practical help for mothers to engage in support behaviors	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • "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 something...Like Netflix." [Imelda, daughter in fifth class] 	<ul style="list-style-type: none"> • Incentivization • Environmental restructuring

	Summary of the recommendations from workshops	Example quotes	Related intervention functions
Social support for mothers	<ul style="list-style-type: none"> • Provide opportunities for mothers to get support from other mothers of preteen daughters, for example, Facebook group • Opportunities to get to know other mothers at daughters' activities 	<ul style="list-style-type: none"> • "every club should have a mummies 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] 	<ul style="list-style-type: none"> • Enablement
Improving daughters' knowledge and understanding of PA	<ul style="list-style-type: none"> • Provide daughters with information and instructions about the different types of PA, the benefits 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 	<ul style="list-style-type: none"> • "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 happening...let the child have their own profile." [Jennifer, daughter in sixth class] 	<ul style="list-style-type: none"> • Education • Training
Persuading daughters to be active	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • "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 become 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] 	<ul style="list-style-type: none"> • Persuasion • Modeling
Practical help for daughters to engage in leisure time PA	<ul style="list-style-type: none"> • Cost of activities is a barrier, so provide opportunities 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 activities • Provide equipment and merchandise for daughters to practice with at home, for example, footballs, basketballs, skipping ropes, T-shirts, jerseys, hoodies, water bottles, and merchandise 	<ul style="list-style-type: none"> • "You can write a to-do list, so that way you can be more motivated to keep on schedule." [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] 	<ul style="list-style-type: none"> • Incentivization • Environmental restructuring
Social support for daughters			<ul style="list-style-type: none"> • Enablement

Summary of the recommendations from workshops	Example quotes	Related intervention functions
<ul style="list-style-type: none"> • 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 activities • Opportunities to get to know other girls at activities. Can be organized by coaches, teachers, and other club members 	<ul style="list-style-type: none"> • “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)	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • Knowledge • Beliefs about consequences • Environmental context and resources
App module 1: getting started	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Knowledge
App module 2: what is PA and why is it important?	<ul style="list-style-type: none"> • 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 congratulations for reaching the end of the module 	<ul style="list-style-type: none"> • Knowledge • Beliefs about consequences
App module 3: what does supporting your daughter to be active involve?	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Knowledge • Beliefs about consequences • Social influences
App module 4: who can help you support your daughter?	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Knowledge • Skills • Identity • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion
App module 6: next steps: planning to support your daughter	<ul style="list-style-type: none"> • 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 self-monitor 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 	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • Includes infographics about the module objectives; recap on maternal PA support behaviors; how to overcome potential barriers to providing support, for example, using if...then 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 	<ul style="list-style-type: none"> • Knowledge • Identity • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion • Behavioral regulation
App module 8: final module	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Knowledge • Beliefs about consequences • Intentions • Social influences • Behavioral regulation
App icon: resources	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Knowledge • Skills • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion
App icon: goals	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Intentions • Goals • Behavioral regulation

	Intervention components, activities, and resources	Mechanisms of action
App icon: trackers history	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Intentions Goals Behavioral regulation
App icon: chat	<ul style="list-style-type: none"> 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 participants for group activities, as per information provided by the research team or as suggested by other participants 	<ul style="list-style-type: none"> Social influences Emotion
Intervention feature: motivational messages	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Beliefs about capabilities Identity Social influences Emotion
Week 8: conclusion of study and group meeting (included after feedback from co-design workshops, session 2)	<ul style="list-style-type: none"> Face-to-face group meeting with mothers to award mothers with a certificate of completion, receive feedback on the intervention, and answer any questions 	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Knowledge • Beliefs about consequences • Environmental context and resources
App module 1: welcome to our study	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Knowledge
App module 2: what is PA?	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Knowledge • Beliefs about consequences
App module 3: why should you be active?	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Knowledge • Beliefs about consequences • Social influences
App module 4: how can you be active?	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Knowledge • Skills • Beliefs about consequences • Intentions • Social influences
App module 5: who can you be active with?	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Knowledge • Beliefs about consequences • Intentions • Social influences

	Intervention components, activities, and resources	Mechanisms of action
App module 6: tips to help you be active	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Knowledge Skills Identity Beliefs about capabilities Beliefs about consequences Intentions Social influences Emotion
App module 7: let us get moving	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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, session 2)	<ul style="list-style-type: none"> 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 if...then 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 	<ul style="list-style-type: none"> Knowledge Identity Beliefs about capabilities Beliefs about consequences Intentions Social influences Emotion Behavioral regulation
App module 9: final module	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Knowledge Beliefs about consequences Intentions Behavioral regulation
App icon: resources	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Knowledge Skills Beliefs about capabilities Beliefs about consequences Intentions Social influences Emotion
App icon: goals	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Intentions Goals Behavioral regulation

	Intervention components, activities, and resources	Mechanisms of action
App icon: trackers	<ul style="list-style-type: none"> Option available for girls to self-monitor their progress of goals set that are paired with a smart-watch 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 	<ul style="list-style-type: none"> Intentions Goals Behavioral regulation
App feature: motivational messages	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Beliefs about capabilities Identity Social influences Emotion
Week 8: conclusion of study and group meeting (included after feedback from the co-design workshops, session 2)	<ul style="list-style-type: none"> Face-to-face group meeting with girls to award girls with a certificate of completion, receive feedback on the intervention, and answer any questions 	<ul style="list-style-type: none"> 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.

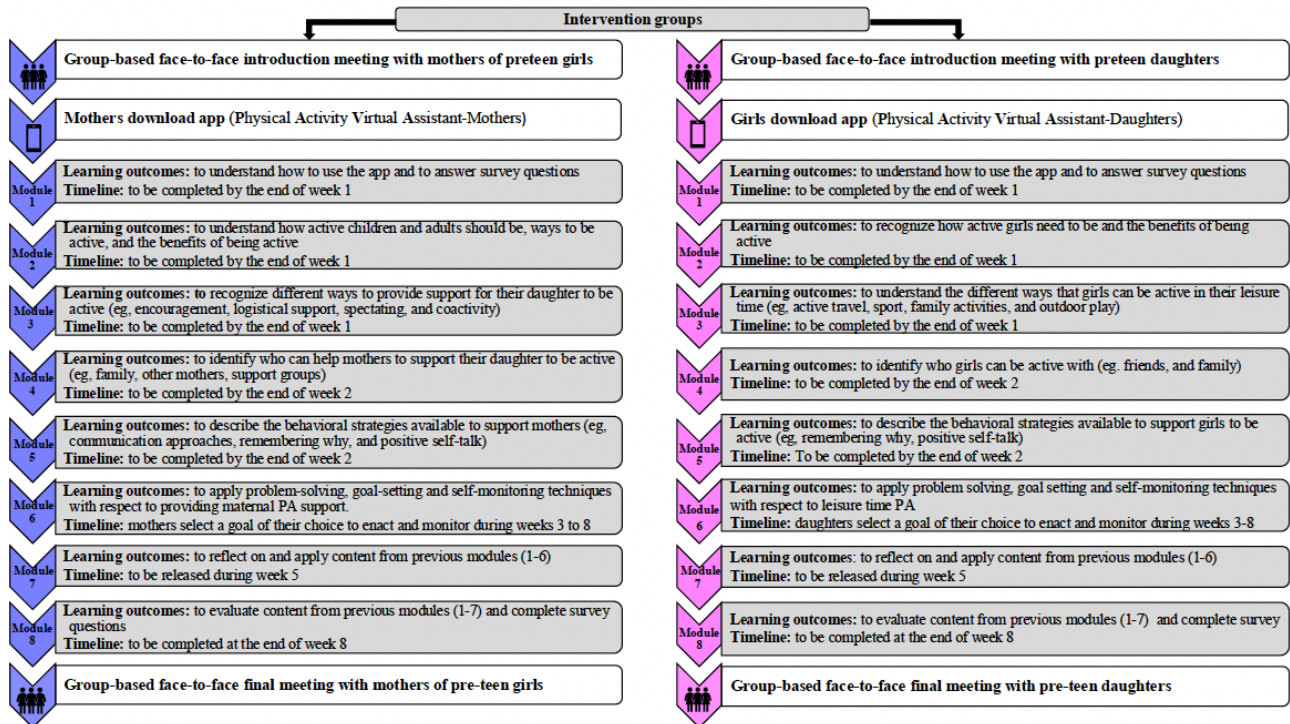


Table 6. Intervention delivery style, illustrating how app features align with the principles of self-determination theory.

App features	Description	Expected benefit
Autonomy-supportive features		
Goal setting	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> This feature helps mothers and daughters stay organized and on track with regard to the target behaviors 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	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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 features		
Self-monitoring	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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 daughters know themselves and understand their personal circumstances that influence the target behavior By entering data into the app, mothers and daughters express their interest in maintaining the behaviors
Activity feedback	<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> 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 features		
Community forum	<ul style="list-style-type: none"> 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 through the group chat feature 	<ul style="list-style-type: none"> Messaging enables mothers and daughters to connect with other participants who face the same challenges They can share experiences, provide and receive support, and experience a sense of belonging and relatedness

App features	Description	Expected benefit
Modeling videos or podcasts	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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

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).

Figure 3. Logic model of the intervention prototype. mHealth: mobile health; PA: physical activity; TDF: Theoretical Domains Framework.

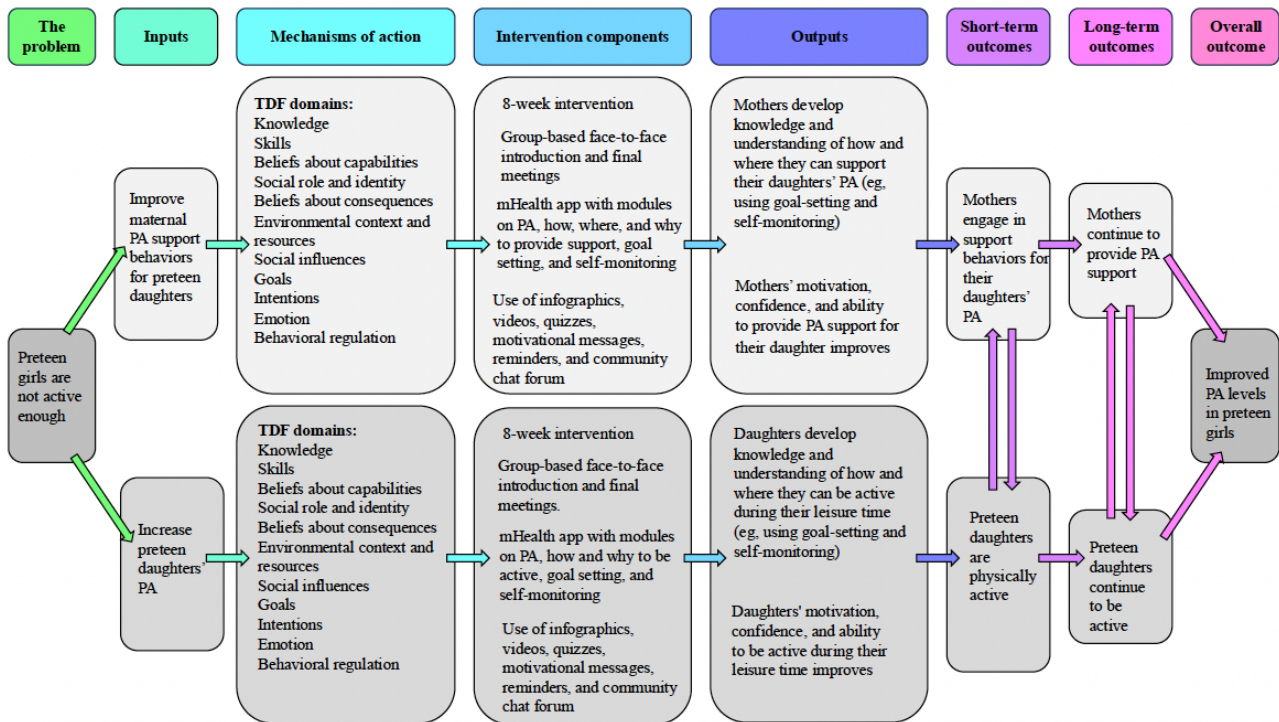


Figure 4. Screenshots from the mothers' mobile app prototype.

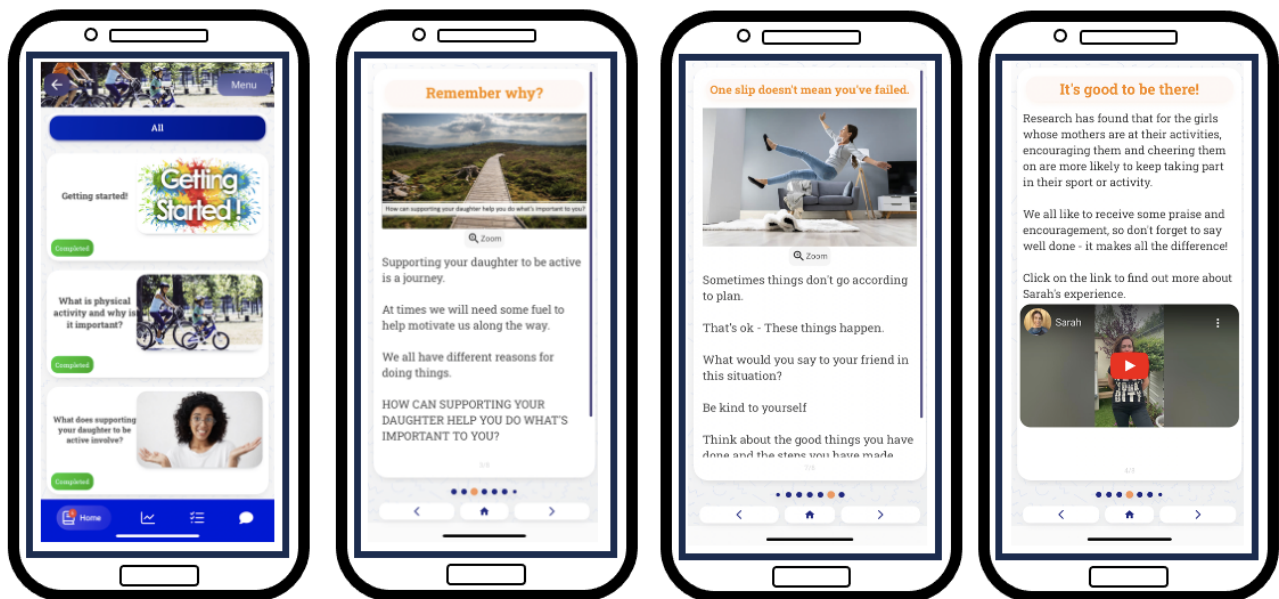
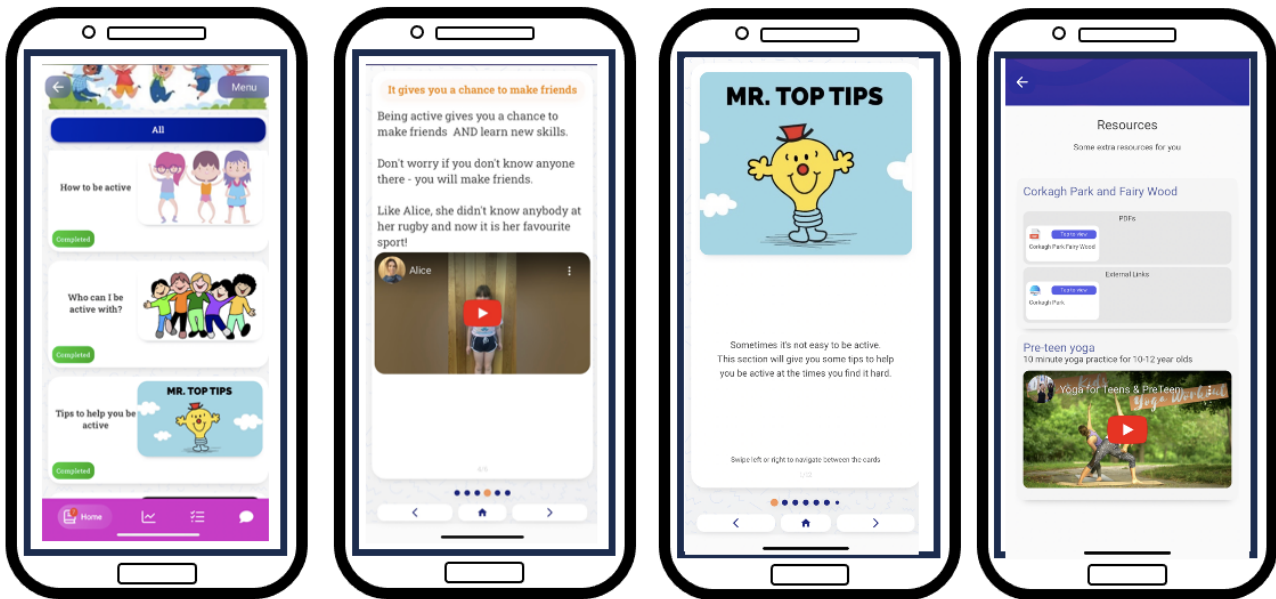


Figure 5. Screenshots from the daughters' mobile app prototype.



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.

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

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 Pfladderer 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.

Acknowledgments

The authors would like to thank the school principal, teachers, mothers, and girls for taking part in the co-design workshops. The authors would also like to thank Amanda Wilms from Pathverse for her help and guidance with using the no-code app development platform.

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.

[\[DOCX File , 19 KB - pediatrics_v8i1e62795_app5.docx \]](#)**References**

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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

Edited by S Badawy; submitted 31.05.24; peer-reviewed by MR Sweeney, S Jiang, E Cowley; comments to author 03.09.24; revised version received 21.10.24; accepted 26.10.24; published 06.01.25.

Please cite as:

Brennan C, ODonoghue G, Keogh A, Rhodes RE, Matthews J

Developing an Evidence- and Theory-Informed Mother-Daughter mHealth Intervention Prototype Targeting Physical Activity in Preeteen Girls of Low Socioeconomic Position: Multiphase Co-Design Study

JMIR Pediatr Parent 2025;8:e62795

URL: <https://pediatrics.jmir.org/2025/1/e62795>

doi: [10.2196/62795](https://doi.org/10.2196/62795)

PMID:

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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

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.

(*JMIR Pediatr Parent* 2025;8:e65912) doi:[10.2196/65912](https://doi.org/10.2196/65912)

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 receiving videoconference-based 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

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

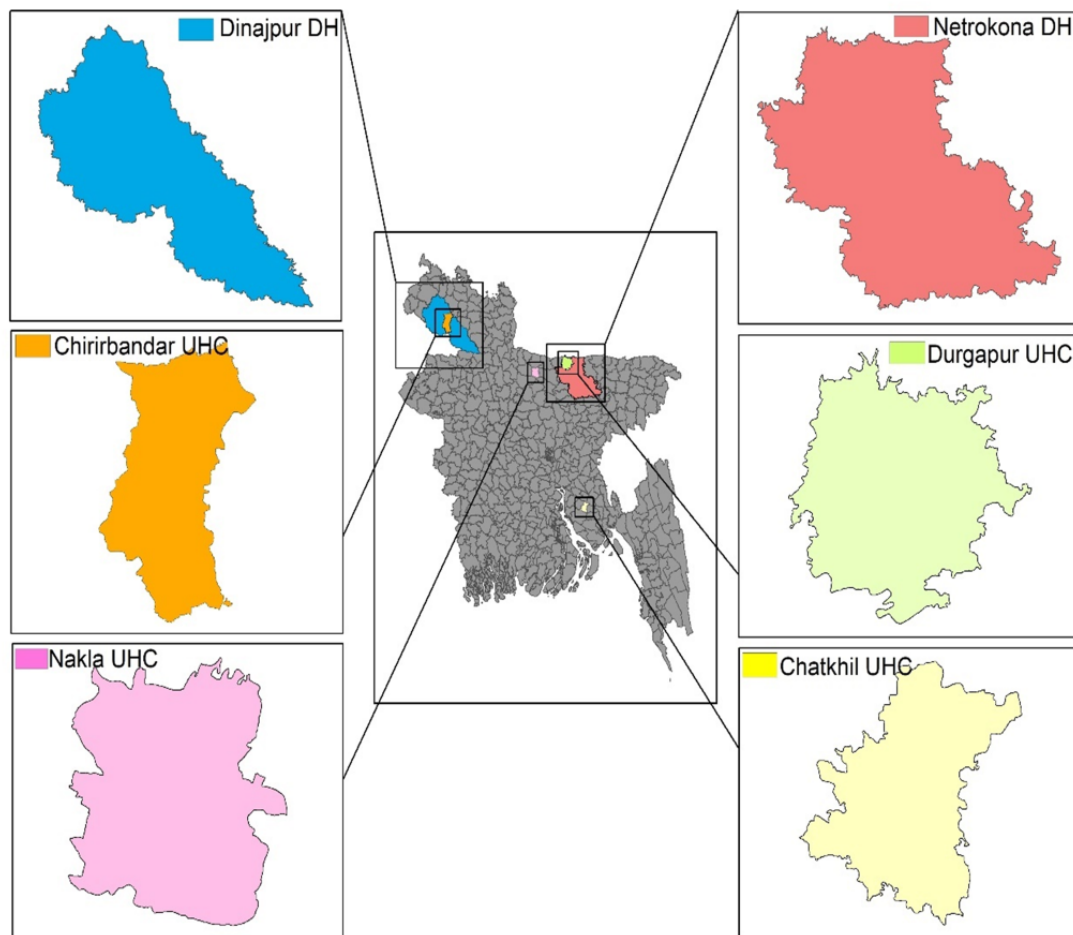
of depression and anxiety symptoms in the targeted population as a secondary outcome for demonstrating the need for such mental health care.

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.

Figure 1. Study sites. DH: district hospital; UHC: upazila health complex.



Study Design

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

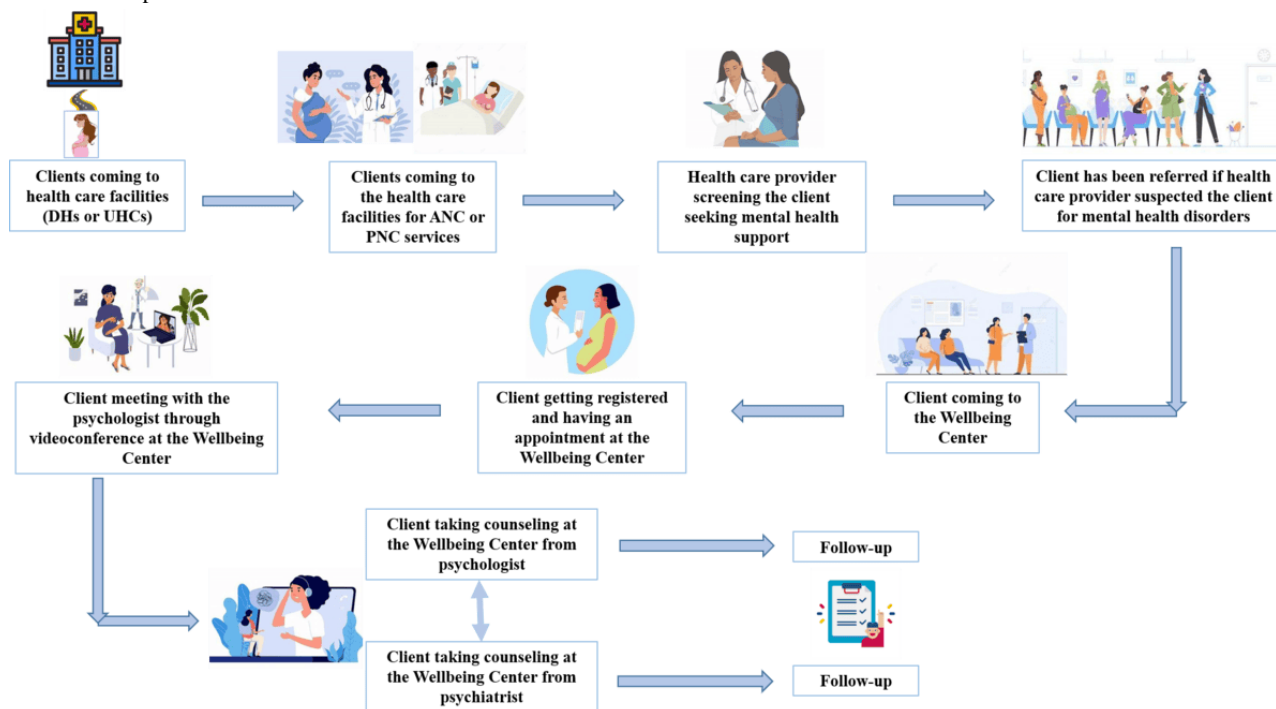
Health care administrators, expertise in mental health, along with facility managers partnered with icddr,b to facilitate training and workshops for district and subdistrict-level health care providers (such as RMOs, physicians, gynecological consultants, and health workers). Additionally, the implementation 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.

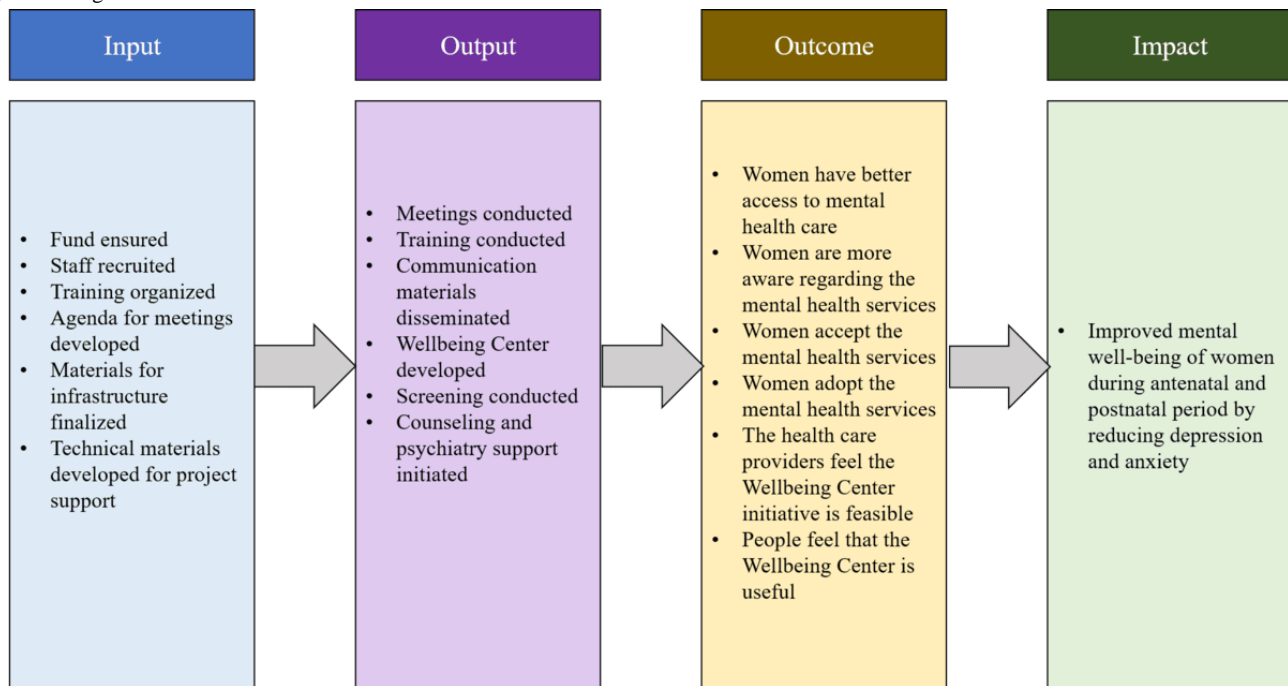
Study Measures

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 outcome	Indicators or themes
1	To assess the feasibility of the Wellbeing Center at the district-level facility	Quantitative	Feasibility	<ul style="list-style-type: none"> 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 postnatal women by introducing Wellbeing Center's telemental health care	Quantitative	Accessibility	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 symptoms of depression	Quantitative	Need	<ul style="list-style-type: none"> Percentage of users who had depressive symptoms
7	To assess the proportion of target women with symptoms of anxiety	Quantitative	Need	<ul style="list-style-type: none"> Percentage of users who had symptoms of anxiety
8	To assess the experience, perception, and expectation about the telemental health counseling at the district-level facility for the antepartum and postpartum women	Qualitative	Experience, perception, and expectation	<ul style="list-style-type: none"> Experience, perception, and expectation about the Wellbeing Center

Figure 3. Logical framework of the telemental health intervention.

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

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 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.

Figure 4. Implementation outcomes of Wellbeing Centers according to the World Health Organization guidelines.

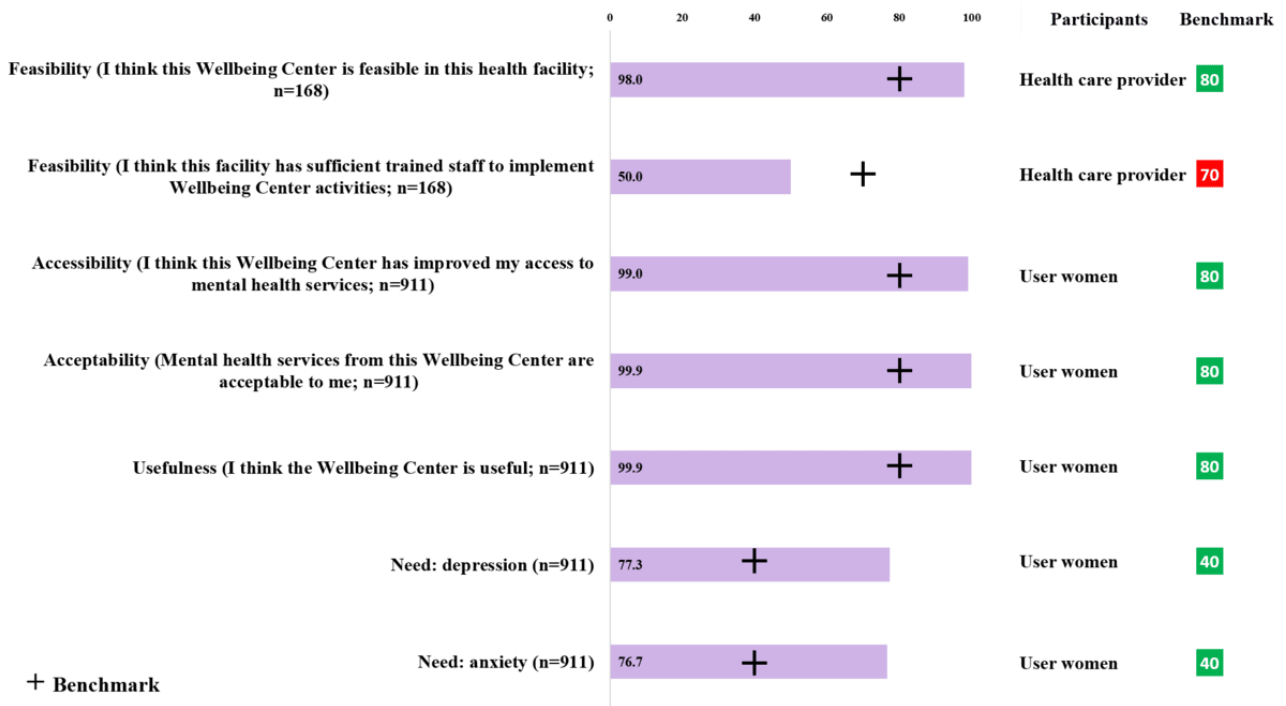


Figure 5. Need for Wellbeing Centers according to the frequency of depressive and anxiety symptoms.

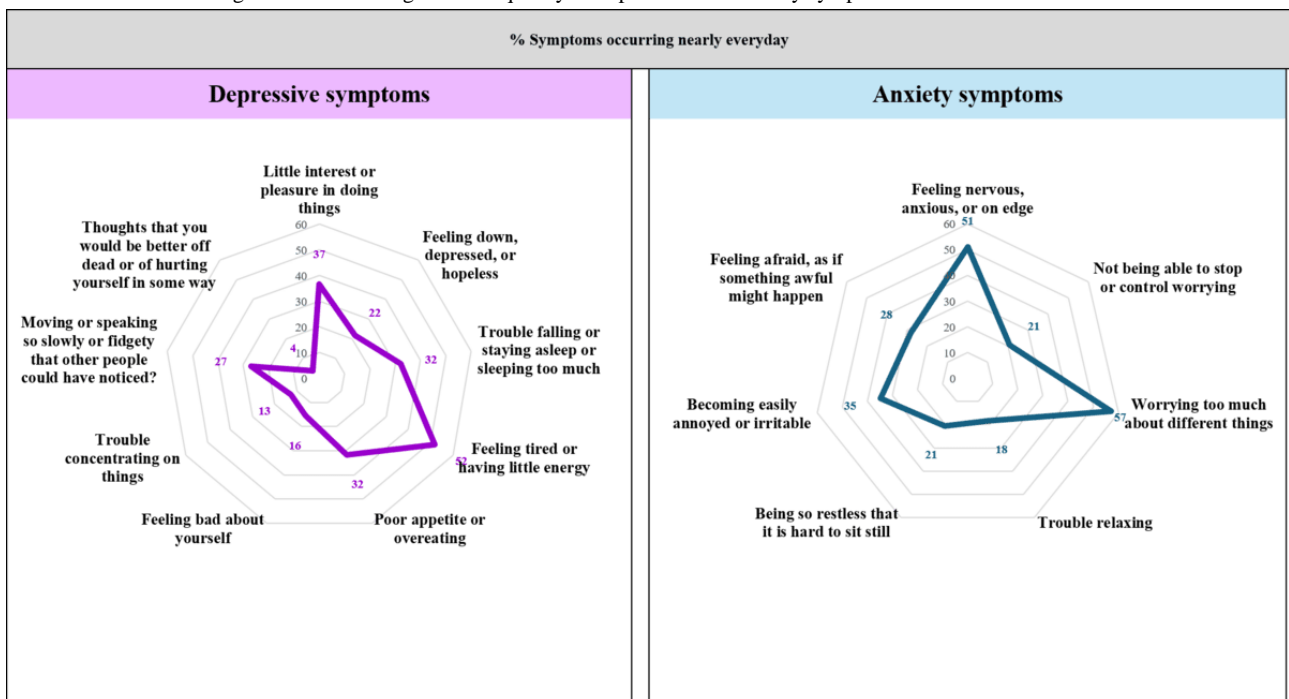


Table 3. Factors associated with accessibility (strongly agree) and need (severe depression and anxiety symptoms) of Wellbeing Center.

	Accessibility		Both depression and anxiety	
	aOR ^a (95% CI)	P value	aOR (95% CI)	P value
Age (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
Type 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
Religion				
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
Education				
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
Household 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
Type of facility location				
Subdistrict	Reference	Reference	Reference	Reference
District	1.48 (1.10-2.00)	.010	2.58 (1.82-3.68)	.001

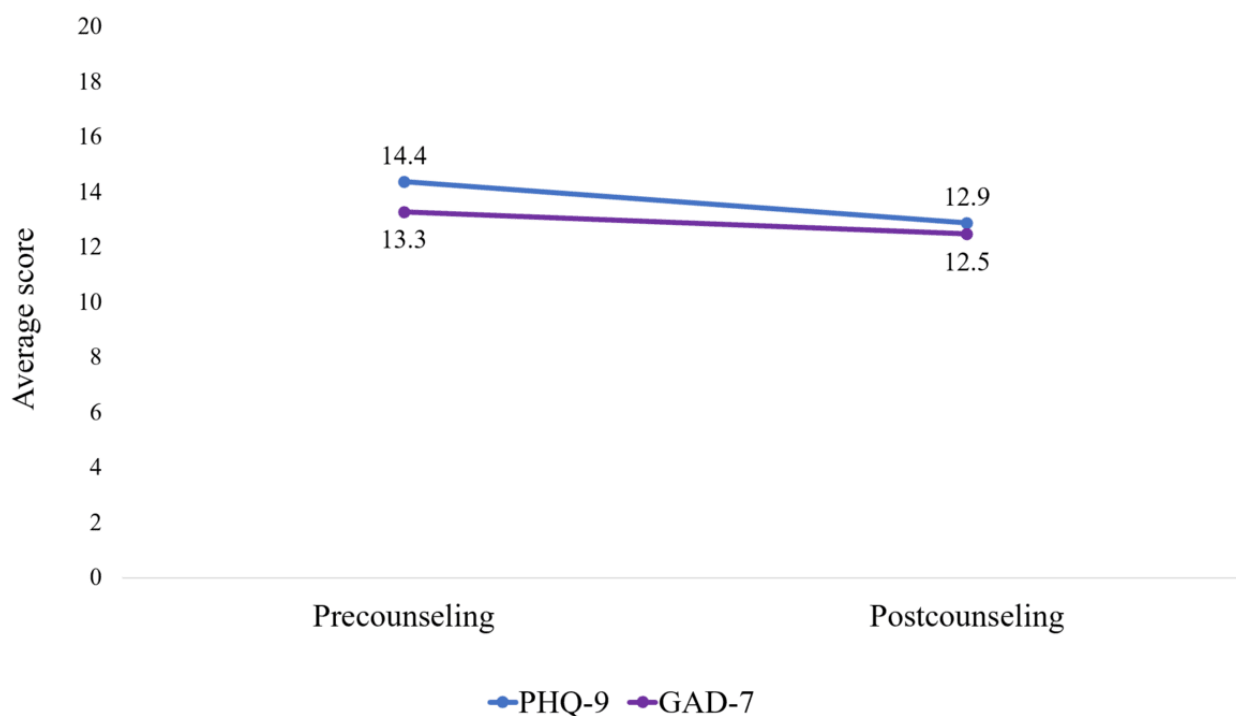
^aaOR: adjusted odds ratio.

^bANC: antenatal care.

^cPNC: postnatal care.

^dHindus, Buddhists, and Christians.

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

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 Center they 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

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

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.

Acknowledgments

This research protocol or activity or study was funded by the Department of Foreign Affairs, Trade and Development through Advancing Sexual and Reproduction Health and Rights (grant SGDE-EDRMS-#9926532, purchase order 7428855, project P007358). The International Centre for Diarrhoeal Disease Research, Bangladesh is also grateful to the governments of Bangladesh and Canada for providing core or unrestricted support.

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

Edited by S Badawy; submitted 30.08.24; peer-reviewed by H Badmus, J Lee; comments to author 09.10.24; revised version received 14.10.24; accepted 26.10.24; published 03.01.25.

Please cite as:

Hossain AT, Rahman MH, Manna RM, Akter E, Islam SMH, Hossain MA, Ara T, Usmani NG, Chandra P, Khan MA, Rahman SMM, Ahmed HU, Mozumder MK, Juthi JM, Shahrin F, Shams SA, Afroze F, Banu MJ, Ameen S, Jabeen S, Ahmed A, Amin MR, Arifeen SE, Shomik MS, Rahman AE

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

JMIR Pediatr Parent 2025;8:e65912

URL: <https://pediatrics.jmir.org/2025/1/e65912>

doi: [10.2196/65912](https://doi.org/10.2196/65912)

PMID:

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Publisher:
JMIR Publications
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