

A Novel Smartphone-Based Application and Supportive Accountability for the Treatment of Childhood Disruptive Behavior Problems: Protocol for a Randomized Controlled Trial

Oliver Lindhiem, Claire S Tomlinson, David J Kolko, Jennifer S Silk, Danella Hafeman, Meredith Wallace, I Made Agus Setiawan, Bambang Parmanto

Submitted to: JMIR Research Protocols
on: October 11, 2024

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript..... 4

Supplementary Files..... 29

 Figures 30

 Figure 1..... 31

 Figure 2..... 32

 Figure 3..... 33

 Figure 4..... 34

 Figure 5..... 35

 Figure 6..... 36

 Multimedia Appendixes 37

 Multimedia Appendix 1..... 38

A Novel Smartphone-Based Application and Supportive Accountability for the Treatment of Childhood Disruptive Behavior Problems: Protocol for a Randomized Controlled Trial

Oliver Lindhiem¹ PhD; Claire S Tomlinson¹ PhD; David J Kolko¹ PhD; Jennifer S Silk¹ PhD; Danella Hafeman¹ MD, PhD; Meredith Wallace¹ PhD; I Made Agus Setiawan¹ PhD, MSc; Bambang Parmanto¹ PhD

¹University of Pittsburgh Pittsburgh US

Corresponding Author:

Oliver Lindhiem PhD
University of Pittsburgh
3811 O'Hara St.
Pittsburgh
US

Abstract

Background: Although evidence-based treatments have been developed for childhood behavior problems, many families encounter barriers to treatment access and completion (e.g., local availability of services, transportation, cost, and perceived stigma). Smartphone-based applications offer a cost-efficient method to deliver content to families.

Objective: The aim of this study is to describe the study protocol for a randomized controlled trial (RCT) of a smartphone-based application designed to reduce disruptive behaviors in young children.

Methods: The current RCT evaluates the effectiveness of the UseIt! mobile health (mHealth) system as both standalone and coach-assisted interventions. A nationwide sample of parents of children ages 5 to 8 years with disruptive behaviors (N = 324 dyads) will be randomly assigned to the standalone app (n = 108), the coach-assisted app (n = 108), or the control app (n = 108). The outcome assessments (post-treatment and 6-month follow-up) include measures of app usage, parenting knowledge, and symptom reduction.

Results: Recruitment of study participants began in December of 2022 and is ongoing. Data collection is projected to be completed by late 2026.

Conclusions: The current study aims to address a gap in the literature regarding the feasibility, effectiveness, and utility of a smartphone-based application that includes a coach-assisted arm. Digital therapeutics have the potential to enhance the reach and scalability of skills-based psychosocial interventions. Findings from the current study will advance scientific knowledge and have implications for clinical practice. Clinical Trial: ClinicalTrials.gov registration number: NCT05647772.

(JMIR Preprints 11/10/2024:67051)

DOI: <https://doi.org/10.2196/preprints.67051>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to all users.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in

Original Manuscript

A Novel Smartphone-Based Application and Supportive Accountability for the Treatment of
Childhood Disruptive Behavior Problems: A Randomized Controlled Trial

Authors: Oliver Lindhiem¹, Claire Tomlinson¹, David J. Kolko¹, Jennifer S. Silk¹, Danella Hafeman¹,
Meredith Wallace¹, I Made Agus Setiawan¹, and Bambang Parmanto¹

¹ University of Pittsburgh

Corresponding Author:

Oliver Lindhiem, PhD
Associate Professor of Psychiatry and Pediatrics
University of Pittsburgh School of Medicine
3811 O'Hara St.
Pittsburgh, PA 15213
Office: 537 Bellefield Towers
Phone: 412-246-5909
Email: lindhiemoj@upmc.edu

Abstract

Background: Although evidence-based treatments have been developed for childhood behavior problems, many families encounter barriers to treatment access and completion (e.g., local availability of services, transportation, cost, and perceived stigma). Smartphone-based applications offer a cost-efficient method to deliver content to families.

Objective: The aim of this study is to describe the study protocol for a randomized controlled trial (RCT) of a smartphone-based application designed to reduce disruptive behaviors in young children.

Methods: The current RCT evaluates the effectiveness of the UseIt! mobile health (mHealth) system as both standalone and coach-assisted interventions. A nationwide sample of parents of children ages 5 to 8 years with disruptive behaviors (N = 324 dyads) will be randomly assigned to the standalone app (n = 108), the coach-assisted app (n = 108), or the control app (n = 108). The outcome assessments (post-treatment and 6-month follow-up) include measures of app usage, parenting knowledge, and symptom reduction.

Results: Recruitment of study participants began in December of 2022 and is ongoing. Data collection is projected to be completed by late 2026.

Conclusions: The current study aims to address a gap in the literature regarding the feasibility, effectiveness, and utility of a smartphone-based application that includes a coach-assisted arm. Digital therapeutics have the potential to enhance the reach and scalability of skills-based psychosocial interventions. Findings from the current study will advance scientific knowledge and have implications for clinical practice.

Trial Registration: ClinicalTrials.gov registration number: NCT05647772.

Key Words: Mobile Health; Disruptive Behaviors, Parent Management Training, Randomized Controlled Trial, Externalizing Behavior



Introduction

Background and Rationale

In the U.S., approximately 1.5 million school-age children meet DSM-5 diagnostic criteria for a disruptive behavior disorder (DBD) [1]. DBDs account for more than half of all mental health referrals for children [2]. Longitudinal studies reveal that these problems in early childhood can be risk factors for persistent problems later in life, including substance use disorders and internalizing disorders, if left untreated [3]. DBDs are typically treated with psychosocial evidence-based therapies [4] that include parent-management training (PMT) skills (e.g., praise, rewards, consequences, time-outs) and cognitive-behavioral therapy (CBT) skills (e.g., problem-solving, emotion labeling) [5]. Meta-analyses point to the substantial effectiveness of these interventions at reducing symptoms and maintaining treatment gains over time [6,7]. Despite the effectiveness of EBTs, many families do not have access to these services, and often stop attending or fail to practice new skills between sessions. Barriers to access include local availability of services, transportation, cost, and perceived stigma. Barriers to non-completion include poor motivation and low engagement, along with competing demands for time, transportation problems, and co-payment costs [8].

The Promise of Digital Therapeutics

Recent advances in technology, in particular mobile health (mHealth) systems, have the potential to overcome these barriers, and promote better data collection for researchers [9]. mHealth technologies, including smartphones, create an opportunity to develop personalized interventions that are delivered to families in their day-to-day settings [10]. A smartphone based mHealth system has numerous potential advantages for improving access to, and engagement in, EBTs for childhood behavior problems. Such applications can deliver content to improve understanding of skills, can provide opportunities for learning through skills practice, and can give feedback to families

regarding areas for improvement [11,12]. In a recent meta-analysis, of 25 clinical trials, mobile technology use was associated with superior treatment outcome across all study designs and types of control conditions, $ES = .34$ [13]. mHealth technologies can also be used to collect data on between-session treatment adherence and skills practice. Evaluating the extent to which patients and families are using the skills they are learning outside of treatment sessions is especially important for psychosocial treatments for disruptive behavior problems which are overwhelmingly skills-based. Remote digital assessments have many advantages over traditional retrospective self-reports including reduced recall bias, the ability to obtain a more representative sample of behavior across situations and contexts, and the ability to track changes in behavior [14–16].

The Role of the Coach in mHealth

There is growing evidence in the field of digital therapeutics that some degree of human interaction is important to sustain app usage and achieve meaningful outcomes [17–19]. Although various models have been proposed, the “Coaching” model affords many of the benefits of human interaction (e.g., support, accountability) at a level of service that remains highly scalable [17]. Mohr’s Supportive Accountability (SA) Model, which is flexible and can be tailored to clinical conditions and service users, details that the intervention is supported by a coach who provides a social presence and accountability to boost motivation and engagement. Effectiveness studies have shown that various paraprofessionals can successfully be trained as coaches for a wide range of interventions and clinical populations [17].

Study Aims and Hypotheses

Primary Aim

We aim to evaluate the effectiveness of the UseIt! mHealth system as both a standalone ($n = 108$) and coach-assisted ($n = 108$) intervention compared to a control app condition ($n = 108$). We expect that 1) the two UseIt! intervention conditions will score higher on parenting knowledge

(primary outcome) and show greater post-treatment reductions in disruptive behavior symptoms (secondary outcome) compared to the control condition, and 2) the coach-assisted UseIt! condition will score higher on parenting knowledge and show greater post-treatment reductions compared to the standalone UseIt! condition.

Secondary Aims

We will also test mechanisms of therapeutic change. In particular, we will test whether gains in knowledge of parenting skills are associated with reductions in disruptive behavior symptoms. Lastly, we aim to evaluate the effectiveness of the components of the UseIt! mHealth system. We will compare app usage across the standalone and coach-assisted conditions and test whether the app usage indices are associated with target engagement, knowledge of parenting skills, and symptom reduction at post-treatment. We expect that families who use the app more often will have higher skill acquisition/utilization scores at post-treatment (“dose” effects) though we do not have specific hypotheses regarding individual app features.

Method

Ethical Considerations

Ethics approval has been obtained from the Institutional Review Board at the University of Pittsburgh (protocol # STUDY22030138).

UseIt! Smartphone Application

The UseIt! system includes a cross-platform mHealth app that runs on both iOS and Android devices. The app is securely connected to a portal where app feature usage is stored. The portal was designed for the research team to track and monitor usage of the app by parents. The app contains six features: (1) a troubleshooting guide that provides detailed skill recommendations for problem situations, (2) a behavior diary for tracking behaviors and skills used each day, (3) a digital library

that provides definitions and instructions for each skill, (4) a point counter for parents to award points to their children, (5) a skills-alarm for reminding parents to practice the various skills, and (6) a timer for use with parenting skills (e.g., time-outs, managing screen time, routines). Users can examine diary entries, view points awarded, and set the skills-alarm through the app. See Figure 1 for a screenshot of the App home page. [Insert Figure 1 here]

Troubleshooting Guide

The UseIt! troubleshooting guide contains information to help parents effectively respond to problem-behaviors. Parents are presented with a list of potential negative behaviors (e.g. bullied or fought). After selecting a behavior, appropriate skill options (e.g. time-out) are displayed with tips to effectively apply each skill. Once a skill has been used and the behavior has stopped, parents are reminded to praise their child for positive behaviors. See Figure 2. [Insert Figure 2 here]

Behavior Diary

The behavior diary cues participants (via a notification) to complete a series of questions about behaviors and PMT/CBT skills used each day. The results are displayed graphically and can be reviewed by the user to track progress over time. This allows the user to keep track of what skills the family has tried for different behaviors (both positive and negative child behaviors) and which ones have been helpful in various contexts. See Figure 3. [Insert Figure 3 here]

Digital Library

The UseIt! digital library provides detailed information about using strategies for positive and negative child behavior. Each skill is defined and presented with tips for how and when to effectively use each skill. The digital library contains more information than the troubleshooting guide and is designed as an information source for reviewing PMT/CBT topics. See Figure 4. [Insert Figure 4 here]

Point Counter

Treatment for disruptive behavior disorders typically includes prizes for treatment adherence, positive behaviors, and skill use. Parents can award points to children for target behaviors (e.g. cleaning dishes) and skill utilization. The UseIt! point counter features an on-screen button (“Give your child a point”) which parents press to reward their child with a point. The feature functions as a digital rewards program that parents can use to keep track of points and reward their children. See Figure 1 for a view of the point counter window.

Skills Alarm

Skills alarms can be set at any time via the app. Users can set dates and times for notifications to activate. These notifications remind parents and children to practice specific skills throughout the week (e.g. “remember to praise your child”). Parents are able to view a list of active and inactive alarms. See Figure 5. [Insert Figure 5 here]

Timer

Timers can be set for use with a variety of skills (e.g., time-outs, screen time management, routines) to promote use of the skills.

Recruitment

We will use a two-pronged recruitment strategy to maximize enrollment. The two recruitment avenues will be: 1) the Clinical and Translational Science Institute (CTSI) patient registry (Pitt+Me®) at the University of Pittsburgh, and 2) BuildClinical. The CTSI patient registry (Pitt+Me®) is an institutional research participant registry that uses enhanced study descriptions and social media to engage the community in research. BuildClinical is a clinical trial recruiting system that helps investigators recruit participants for clinical trials more efficiently. Using study-specific digital advertisements displayed on search engines, health websites, and social media platforms,

BuildClinical generates participant referrals. BuildClinical also provides tools to streamline the recruitment and prescreening process. The platform stores information in a HIPAA compliant manner and allows for remote enrollment.

Participant Eligibility

Inclusion criteria for the current study requires that parents/guardians have 1) a child between the ages of 5 and 8, 2) that child must be above the 90th percentile for Oppositional Defiant Disorder and/or Conduct Disorder on the Vanderbilt Assessment Scale, 3) the child must be in residence with the parent/guardian for at least 80% of the time, 4) parent/guardian must consent to study participation, and 5) parent/guardian must have a smartphone device with daily internet access. Exclusion criteria includes if the child 1) has a known preexisting behavioral or mental health diagnosis requiring alternative treatment (e.g., bipolar disorder, major depression, pervasive developmental disorder) or 2) is currently in treatment for childhood disruptive behavior.

Sample Size Determination

Power analyses were conducted in PASS version 13.0.8 to ensure that the sample size is adequate to test the primary hypotheses with adequate statistical power. All analyses assumed 0.80 power and two-sided tests. Estimated sample sizes are determined based on an assumed 5% attrition/missing data at post-treatment (102 per group) and 10% total attrition at 6-months (97 per group). Using an ANCOVA approach to test for differences across three groups at post-treatment ($n = 108$ each) and assuming $R^2 = 0.20$ from five covariates, we expect 0.80 power ($\alpha = 0.05$) to detect an effect size difference of Cohen's $f = 0.16$ among the 3 groups, $f = 0.14$ ($d = 0.28$) between both UseIt! treatment groups versus the control group, and $f = 0.18$ ($d = 0.36$) between any two groups.

Design

The study is a randomized controlled trial with three conditions. Parents of children aged 5 to

8 (n=324) are randomly assigned to one of three conditions: a standalone UseIt! app condition, a UseIt! app + Coach condition, and a control app condition (Smiling Mind app). Data will be collected via online surveys at baseline, post-treatment (four months after baseline), and at 6-month follow-up. Randomization takes place after the baseline is completed.

Study Conditions

Standalone UseIt! App Condition

Participants are assigned to the UseIt! App as a standalone intervention for four months.

UseIt! App + Coaching Condition

Participants are assigned to the UseIt! App and are provided with an mHealth “Coach” for four months. The primary objective of the coaching condition is to promote engagement with the UseIt! mHealth platform. The mHealth coach will be a bachelor’s-level paraprofessional with a degree in psychology or an allied discipline (e.g., social work) who will provide support to parents in the coach-assisted condition. We selected a bachelor’s-level coach over a Master’s-level coach to enhance the scalability of this intervention condition. The coach will use the Supportive Accountability (SA) coaching model using the training guidelines outlined by Dobke and colleagues [20]. During the intervention phase of the study, parents will be contacted by the coach once per week by phone and also allowed to contact the coach during regular business hours. The coach will provide motivation and accountability but will not provide therapeutic/clinical support. The primary goal of the coach is to increase participant engagement with the UseIt! mHealth system. Specific coaching content/tasks will include, 1) social support, 2) promoting engagement with the app, 3) goal setting 4) monitoring progress, and 5) encouragement/motivation. Parents will be provided with appropriate referrals for any crises. The coach will be instructed to respond to questions that lie outside the domains of motivation and accountability (i.e., content-specific therapeutic support) by

redirecting the parent to the content-specific app features (i.e., Troubleshooting and Library). Only the parent(s) will interact with the coach. To maintain the scalability of the condition, the target time spent with each family will be 15-30 minutes per week. The coach will maintain a “coach-log” to track the frequency, duration, and content of contact with each participant.

Control Condition (Smiling Mind app)

Parents in the control app condition will be assigned to use a mindfulness app called Smiling Mind [21] for four months. We selected a mindfulness app because it is an active control condition, but one that we do not expect to engage the same treatment targets as the UseIt! mHealth system. Meta-analytic findings indicate that mindfulness-based interventions for school-age children are associated with medium to large effect sizes for disruptive behaviors [22]. For parents, dispositional mindfulness has been found to be associated with lower rates of children’s externalizing and internalizing problems [23]; and a mindfulness-based program was associated with decreased parent reports of child ADHD symptoms and decreased parental stress [24]. Other studies with youth found that a combined approach (parent and youth mindfulness training) improved externalizing problems and attention [25]. As an active control condition, we expect that a mindfulness app will likely have some influence on parenting and child behavior. This will provide us with a rigorous control condition while also allowing us to test the specificity of target engagement. We expect the Smiling Mind app will only enhance mindfulness, but not PMT/CBT skills (other than mindfulness). We selected the Smiling Mind app in particular because: 1) it can be downloaded at no cost, 2) it is available for both Android and Apple (iPhone) devices, and 3) app-use can be tracked.

Study Procedures and Randomization

Participants provide their contact information to the Pitt + Me or BuildClinical systems after accessing the study advertisement. Trained research assistants then contact families and conduct the initial screening to determine study eligibility. If determined eligible, a future call is scheduled to

obtain consent from the parent, and assent from the child to participate. After consent, parents are provided a Qualtrics link to complete the initial baseline assessment. After completion of the assessment, families are randomly assigned to Group 1 (standalone UseIt! app; $n = 108$), Group 2 (UseIt! app + coach; $n = 108$), or Group 3 (control app condition; $n = 108$). We use stratified randomization to ensure that the groups are equivalent on key clinical features (screening severity and referral source (i.e., Pitt + Me or BuildClinical)). Parents assigned to the Coach condition will be walked through the initial setup and login process, along with a brief training on how to use the applications over the phone. Families can be set up and trained in approximately 30 minutes. If parents cannot be reached after three weeks, instructions are sent via email. Parents assigned to the standalone UseIt! app condition are sent a tutorial video with the same information. Parents use the app condition assigned for four months before the administration of the post-treatment assessment, via Qualtrics. Six months following the post-treatment assessment, parents again are prompted to complete the 6-month follow-up assessment via Qualtrics. See Figure 6 for the trial flowchart for this study. [Insert Figure 6 here]

Measures

See Table 1 for a summary of study constructs, measures, and assessment timepoints.

Primary Outcome

PMT/CBT Skill Knowledge

The Knowledge of Effective Parenting Test (KEPT[26]) is a 21-item measure of parental knowledge of effective parenting skills. The measure was developed as a potential treatment target for evidence-based psychosocial treatments of disruptive behaviors in children. The KEPT assesses parental knowledge of domains including praise, rewards/point systems, attending and ignoring, commands/expectations, consequences, and time-outs. Parents are presented with a series of video and text-based parenting scenarios and questions with four multiple-choice response options. Scores

range from 0 to 21. The measure has good reliability (Cronbach's $\alpha = .84$). The measure has also demonstrated convergent validity with other measures of parenting knowledge and parenting related constructs (e.g., child behavior, parental psychopathology).

Secondary Outcomes

Symptom Severity

Vanderbilt Assessment Scale-Parent Report (VASPR [27]). The VASPR is a 55-item parent-report screen for Attention-Deficit/Hyperactivity Disorder (ADHD), Oppositional Defiant Disorder (ODD), and Conduct Disorder (CD). It also includes seven items on internalizing symptoms and eight items on school performance and social functioning. Symptom items are rated using a 4-point scale and the performance items are rated on a 5-point scale. The measure has Cronbach's alphas ranging from .79 to .95 and strong evidence of construct validity.

Parenting Practices

The Alabama Parenting Questionnaire (APQ [28]) is a 42-item measure that assesses five dimensions of parenting: (1) positive involvement, (2) monitoring, (3) positive discipline, (4) consistency, and (5) corporal punishment, using a 5-point scale ranging from 1 to 5. The internal consistency of the scale is acceptable with alphas for the five domains ranging up to .80. The measure has well-established construct validity.

Parent Depression

Patient Health Questionnaire-8 (PHQ-8 [29]). The PHQ-8 measures symptoms of depression using a 4-point scale from "not at all" to "nearly every day." Total scores range from 0 to 24. The measure has a reported Cronbach's α of .82 and strong construct validity.

Parent Anxiety

General Anxiety Disorder-7 (GAD-7 [30]). The GAD-7 is a 7-item measure of anxiety. Items are rated on a 4-point scale from "not at all" to "nearly every day." The measure includes an item to

assess the duration of anxiety symptoms. The measure has excellent internal consistency (Cronbach's $\alpha = 0.92$), good test-retest reliability (intraclass correlation = 0.83), and strong convergent validity with other measures of anxiety.

Parenting Stress

The Parental Stress Scale (PSS [31]) is an 18-item measure of stress related to parental experiences. Items are rated on a 5-point scale from "strongly disagree" to "strongly agree". Scores range from 18 to 90. The internal consistency of the scale is acceptable with a Cronbach's α of 0.83, a test-retest reliability of 0.81 (intraclass correlation, ICC), and strong convergent validity of both other parental stress measures (i.e., Parental Stress Index), and other measures related to parenting stress (e.g., loneliness, marital satisfaction, social support).

Social Support

The Social Provisions Scale (SPS [32]) is a 24-item measure that assesses six dimensions of support, including attachment, social integration, opportunity for nurturance, reassurance of worth, reliable alliance, and guidance. The measure uses a five-point scale ranging from 1 to 4, strongly disagree to strongly agree. The measure has been validated across samples, with Cronbach's α s ranging from .65 to .76 for the four subscales, and a total reliability estimate of .91. The measure also demonstrated convergent validity with related measures of social support.

PMT/CBT Skill Use

The Parenting Skill Use Diary (PSUD [33]) assesses daily use of parenting skills in everyday parenting contexts (e.g., child sharing and helping, hitting, fighting). Respondents are presented with a checklist of behaviors to report on for the past week. For each behavior they select, they are next asked to identify which skills (e.g., praise, reward, time-out, loss-of-privilege) they used in responding to the behaviors. The instrument has demonstrated the ability to capture significant between person variability in appropriate PMT skills. A weekly summary score discriminated between parents/guardians whose children screened positive versus negative for Conduct Disorder

(AUC = .72) and Oppositional Defiant Disorder (AUC = .70).

App Use

Parents assigned to both UseIt! conditions (i.e., standalone app and coach conditions) will have their data stored on the secure portal, accessible to the research team. We collect the behavior diary tracked by parents, which displays data on child behavior (both positive and negative) along with CBT/PMT skills. We are also collecting data on time spent on the app along with modules accessed. App usage (e.g., modules used, time spent) is also tracked for the Smiling Mind app (control condition).

Mindfulness

The Mindful Attention Awareness Scale (MAAS [34]) is a 15-item scale designed to assess core characteristics of mindfulness. Parents are asked how often they are engaging in a variety of mindfulness-related behaviors, such as finding it difficult to stay focused on what's happening in the present moment, finding themselves preoccupied with the future or past, and not noticing feelings of physical tension or discomfort until they really grab their attention. The measure's response scale ranges from 1 (almost always) to 6 (almost never). The measure is scored as an average of all 15 items. The measure has adequate validity (Cronbach's alpha = .87 and convergent validity with other measures of mindfulness (e.g., mood disturbances, stress).

Service Use

Service Assessment for Children and Adolescents (SACA [35]) Abbreviated. An abbreviated version of the SACA (25-items) was used to measure mental health service utilization. The SACA asks about various inpatient and outpatient treatment services for mental/behavioral health problems that have been utilized by the child in the past six months [35]. Most items are yes/no questions. The measure is a widely used research tool with strong evidence of reliability and validity.

Supportive Accountability

The Supportive Accountability Index (SAI [36]) is an 8-item measure of how well a given

platform functioned to help keep parents accountable to accomplish a given goal. The measure was included to assess the effectiveness of the Coach in the coach condition of the app in helping to keep parents accountable with skill learning and use. Items are rated on a 1-7 scale, from *strongly disagree* to *strongly agree*. Total scores are summed, ranging from 8-56. The measure has acceptable validity (Cronbach's $\alpha = .68$) and good convergent and divergent validity.

Usability

Post-Study System Usability Questionnaire (PSSUQ [37]). The 19-item PSSUQ will be used to assess overall user satisfaction with the UseIt! apps. Internal consistency of the PSSUQ is excellent ($\alpha = 0.91$ to 0.96).

Technological Literacy

The Technological Self-Assessment Scale (TSAT [38]) is a 13-item parent report screen for technological ability. The measure was created for the current study by the research team to provide an indicator of parent knowledge and experience with their computers and phones. For example, items ask parents if they know how to search for information on the internet, if they have ever downloaded an app, and if they have social media accounts. Items are scored Yes/No, and scores range from 0-13. [Insert Table 1 here]

Data Analyses

Primary Analyses

Our primary analytic strategy will use intent-to-treat (ITT) analyses. We will examine reasons for any missing data and perform multiple imputation (e.g., Multiple Imputation for Chained Equations, MICE [39]) for data missing at random. To evaluate the effectiveness of the UseIt! mHealth system as both a standalone ($n = 108$) and coach-assisted ($n = 108$) intervention compared to a control app condition ($n = 108$), we will regress the primary and secondary outcomes on the study condition. We will also perform *a priori* tests to compare both UseIt! groups to the control and

to compare the coach-assisted and standalone UseIt! groups. Cohen's d effect sizes will be estimated for between-group differences as well as pre-post changes within each group.

Secondary Analyses

We will also test whether gains in knowledge of parenting skills are associated with symptom reduction. We will regress post-treatment knowledge of parenting skills on study condition, pre-treatment knowledge, and their interaction. We will also compare app usage across standalone and coach-assisted conditions and test whether the app usage indices are associated with target engagement and symptom reduction at post-treatment. App usage outcomes will include the number of each of the app features that are utilized, along with frequency and duration (in minutes). We will use generalized linear models with the appropriate link (e.g., log link for count data, identity link for continuous outcomes) to regress each usage outcome on study condition (standalone versus coach).

Results

Study recruitment began in December 2022. As of October 2024, we have recruited approximately half of our intended sample. Recruitment of the full sample ($n=324$) is expected by the end of 2025. Follow-up data collection is expected to be completed by the end of 2026.

Discussion

Mobile health (mHealth) parenting programs have the potential to improve outcomes for parents and children [13]. Further, supportive accountability, defined as a degree of human interaction throughout the program, has the potential to enhance outcomes for mHealth interventions by increasing motivation and engagement [17]. The current study aims to add to the literature base on effective mHealth interventions to treat disruptive behaviors in children. The study will allow us to test the degree to which the UseIt! app can modify parenting (i.e., skill acquisition and utilization) and whether such target engagement is associated with symptom reduction. The UseIt! mHealth

system also allows researchers unique access to data on child behaviors and parent skills tracked on a daily basis. This data will not only allow parents to track behaviors and skills for themselves (allowing parents to visualize progress) but will also allow researchers a system to track change over time. The coaching model used in the study is highly scalable, providing a flexible model of coaching that can be tailored to a variety of clinical conditions and service settings.

In summary, the current study aims to address a gap in the literature regarding the feasibility, effectiveness, and utility of a smartphone-based application that includes a coach-assisted arm for treating disruptive behaviors in young children. Digital therapeutics have the potential to enhance the reach and scalability of skills-based psychosocial interventions, as even small effects can be meaningful on a population level if the intervention can be delivered efficiently on a large scale at a low cost. The UseIt! mHealth system is able to deliver therapeutic content to parents across a variety of settings and has the potential for meaningful impact. Findings from the current trial will advance scientific knowledge and have the potential to enhance clinical practice.

Acknowledgements

This study was supported by grants to the first author from NIH (R01HD106930; R34MH106619; R21HD090145; K01MH093508) and the Klingenstein Third Generation Foundation (Fellowship in Access to Care). The authors would like to thank Abby R. Angus and Emma K. Toevs for study assistance.

Conflicts of Interest: None declared.

References

1. Costello EJ, Mustillo S, Erkanli A, Keeler G, Angold A. Prevalence and Development of Psychiatric Disorders in Childhood and Adolescence. *Arch Gen Psychiatry*. 2003;60(8):837. doi:10.1001/archpsyc.60.8.837
2. Maughan B, Rowe R, Messer J, Goodman R, Meltzer H. Conduct Disorder and Oppositional Defiant Disorder in a national sample: developmental epidemiology. *J Child Psychol Psychiatry*. 2004;45(3):609-621. doi:10.1111/j.1469-7610.2004.00250.x
3. White HR, Xie M, Thompson W, Loeber R, Stouthamer-Loeber M. Psychopathology as a predictor of adolescent drug use trajectories. *Psychol Addict Behav*. 2001;15(3):210-218. doi:10.1037/0893-164X.15.3.210
4. Eyberg SM, Nelson MM, Boggs SR. Evidence-based psychosocial treatments for children and adolescents with disruptive behavior. *J Clin Child Adolesc Psychol*. 2008;37(1):215-237. doi:10.1080/15374410701820117
5. Farris JR, Nicholson JS, Borkowski JG, Whitman TL. Onset and Progression of Disruptive Behavior Problems Among Community Boys and Girls: A Prospective Longitudinal Analysis. *J Emot Behav Disord*. 2011;19(4):233-246. doi:10.1177/1063426610370746
6. Weisz JR, Kuppens S, Ng MY, et al. What five decades of research tells us about the effects of youth psychological therapy: A multilevel meta-analysis and implications for science and practice. *Am Psychol*. 2017;72(2):79-117. doi:10.1037/a0040360
7. Comer JS, Chow C, Chan PT, Cooper-Vince C, Wilson LAS. Psychosocial Treatment Efficacy for Disruptive Behavior Problems in Very Young Children: A Meta-Analytic Examination. *J Am Acad Child Adolesc Psychiatry*. 2013;52(1):26-36. doi:10.1016/j.jaac.2012.10.001
8. Wilder DA, Atwell J, Wine B. The Effects of Varying Levels of Treatment Integrity on Child Compliance During Treatment with a Three-Step Prompting Procedure. *J Appl Behav Anal*.

2006;39(3):369-373. doi:10.1901/jaba.2006.144-05

9. Carl JR, Jones DJ, Lindhiem OJ, et al. Regulating digital therapeutics for mental health: Opportunities, challenges, and the essential role of psychologists. *Br J Clin Psychol.* 2022;61(S1):130-135. doi:10.1111/bjc.12286
10. Lindhiem O, Harris JL. Apps for Mental Health. In: Moreno MA, Radovic A, eds. *Technology and Adolescent Mental Health.* Springer International Publishing; 2018:255-264. doi:10.1007/978-3-319-69638-6_18
11. Reger GM, Hoffman J, Riggs D, et al. The “PE coach” smartphone application: An innovative approach to improving implementation, fidelity, and homework adherence during prolonged exposure. *Psychol Serv.* 2013;10(3):342-349. doi:10.1037/a0032774
12. Pramana G, Parmanto B, Kendall PC, Silk JS. The SmartCAT: An m-Health Platform for Ecological Momentary Intervention in Child Anxiety Treatment. *Telemed E-Health.* 2014;20(5):419-427. doi:10.1089/tmj.2013.0214
13. Lindhiem O, Bennett CB, Rosen D, Silk J. Mobile Technology Boosts the Effectiveness of Psychotherapy and Behavioral Interventions: A Meta-Analysis. *Behav Modif.* 2015;39(6):785-804. doi:10.1177/0145445515595198
14. Bolger N, Davis A, Rafaeli E. Diary Methods: Capturing Life as it is Lived. *Annu Rev Psychol.* 2003;54(Volume 54, 2003):579-616. doi:https://doi.org/10.1146/annurev.psych.54.101601.145030
15. Piasecki TM, Hufford MR, Solhan M, Trull TJ. Assessing clients in their natural environments with electronic diaries: Rationale, benefits, limitations, and barriers. *Psychol Assess.* 2007;19(1):25-43. doi:10.1037/1040-3590.19.1.25
16. Ebner-Priemer UW, Trull TJ. Ecological momentary assessment of mood disorders and mood dysregulation. *Psychol Assess.* 2009;21(4):463-475. doi:10.1037/a0017075
17. Mohr DC, Cuijpers P, Lehman K. Supportive Accountability: A Model for Providing Human

Support to Enhance Adherence to eHealth Interventions. *J Med Internet Res*. 2011;13(1):e30. doi:10.2196/jmir.1602

18. Reynolds J, Griffiths KM, Cunningham JA, Bennett K, Bennett A. Clinical Practice Models for the Use of E-Mental Health Resources in Primary Health Care by Health Professionals and Peer Workers: A Conceptual Framework. *JMIR Ment Health*. 2015;2(1):e6. doi:10.2196/mental.4200

19. Silk JS, Pramana G, Sequeira SL, et al. Using a Smartphone App and Clinician Portal to Enhance Brief Cognitive Behavioral Therapy for Childhood Anxiety Disorders. *Behav Ther*. 2020;51(1):69-84. doi:10.1016/j.beth.2019.05.002

20. Dopke CA, McBride A, Babington P, et al. Development of Coaching Support for LiveWell: A Smartphone-Based Self-Management Intervention for Bipolar Disorder. *JMIR Form Res*. 2021;5(3):e25810. doi:10.2196/25810

21. Smiling Mind. <https://www.smilingmind.com.au/>

22. Klingbeil DA, Fischer AJ, Renshaw TL, et al. Effects Of Mindfulness-Based Interventions On Disruptive Behavior: A Meta-Analysis Of Single-Case Research. *Psychol Sch*. 2017;54(1):70-87. doi:10.1002/pits.21982

23. Bögels S, Hoogstad B, van Dun L, de Schutter S, Restifo K. Mindfulness Training for Adolescents with Externalizing Disorders and their Parents. *Behav Cogn Psychother*. 2008;36(2):193-209. doi:10.1017/S1352465808004190

24. van de Weijer-Bergsma E, Formsma AR, de Bruin EI, Bögels SM. The Effectiveness of Mindfulness Training on Behavioral Problems and Attentional Functioning in Adolescents with ADHD. *J Child Fam Stud*. 2012;21(5):775-787. doi:10.1007/s10826-011-9531-7

25. van der Oord S, Bögels SM, Peijnenburg D. The Effectiveness of Mindfulness Training for Children with ADHD and Mindful Parenting for their Parents. *J Child Fam Stud*. 2012;21(1):139-147. doi:10.1007/s10826-011-9457-0

26. Lindhiem O, Vaughn-Coaxum RA, Higa J, Harris JL, Kolko DJ, Pilkonis PA. Development

and validation of the Knowledge of Effective Parenting Test (KEPT) in a nationally representative sample. *Psychol Assess*. 2019;31(6):781-792. doi:10.1037/pas0000699

27. Wolraich ML, Feurer ID, Hannah JN, Baumgaertel A, Pinnock TY. Obtaining Systematic Teacher Reports of Disruptive Behavior Disorders Utilizing DSM-IV. *J Abnorm Child Psychol*. 1998;26(2):141-152. doi:10.1023/A:1022673906401

28. Frick PJ. The Alabama parenting questionnaire. *Unpubl Rat Scale Univ Ala*. Published online 1991.

29. Kroenke K, Strine TW, Spitzer RL, Williams JBW, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. *J Affect Disord*. 2009;114(1):163-173. doi:10.1016/j.jad.2008.06.026

30. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A Brief Measure for Assessing Generalized Anxiety Disorder: The GAD-7. *Arch Intern Med*. 2006;166(10):1092-1097. doi:10.1001/archinte.166.10.1092

31. Berry JO, Jones WH. The Parental Stress Scale: Initial Psychometric Evidence. *J Soc Pers Relatsh*. 1995;12(3):463-472. doi:10.1177/0265407595123009

32. Cutrona CE, Russell DW. Social provisions scale. *J Abnorm Psychol*. Published online 1987.

33. Lindhiem O, Vaughn-Coaxum RA, Higa J, Harris JL, Kolko DJ, Pilkonis PA. Development and Validation of the Parenting Skill Use Diary (PSUD) in a Nationally Representative Sample. *J Clin Child Adolesc Psychol*. 2021;50(3):400-410. doi:10.1080/15374416.2020.1716366

34. Brown KW, Ryan RM. The benefits of being present: mindfulness and its role in psychological well-being. *J Pers Soc Psychol*. 2003;84(4):822.

35. Stiffman Ar, Horwitz Sm, Hoagwood K, et al. The Service Assessment for Children and Adolescents (SACA): Adult and Child Reports. *J Am Acad Child Adolesc Psychiatry*. 2000;39(8):1032-1039. doi:10.1097/00004583-200008000-00019

36. Meyerhoff J, Haldar S, Mohr DC. The Supportive Accountability Inventory: Psychometric

properties of a measure of supportive accountability in coached digital interventions. *Internet Interv.* 2021;25:100399. doi:10.1016/j.invent.2021.100399

37. Lewis JR. Psychometric Evaluation of the PSSUQ Using Data from Five Years of Usability Studies. *Int J Human-Computer Interact.* 2002;14(3-4):463-488. doi:10.1080/10447318.2002.9669130

38. Technology Self-Assessment Tool (TSAT). The Massachusetts Department of Elementary and Secondary Education. http://www.doe.mass.edu/odl/standards/sa_tool.html

39. Azur MJ, Stuart EA, Frangakis C, Leaf PJ. Multiple imputation by chained equations: what is it and how does it work? *Int J Methods Psychiatr Res.* 2011;20(1):40-49. doi:10.1002/mpr.329

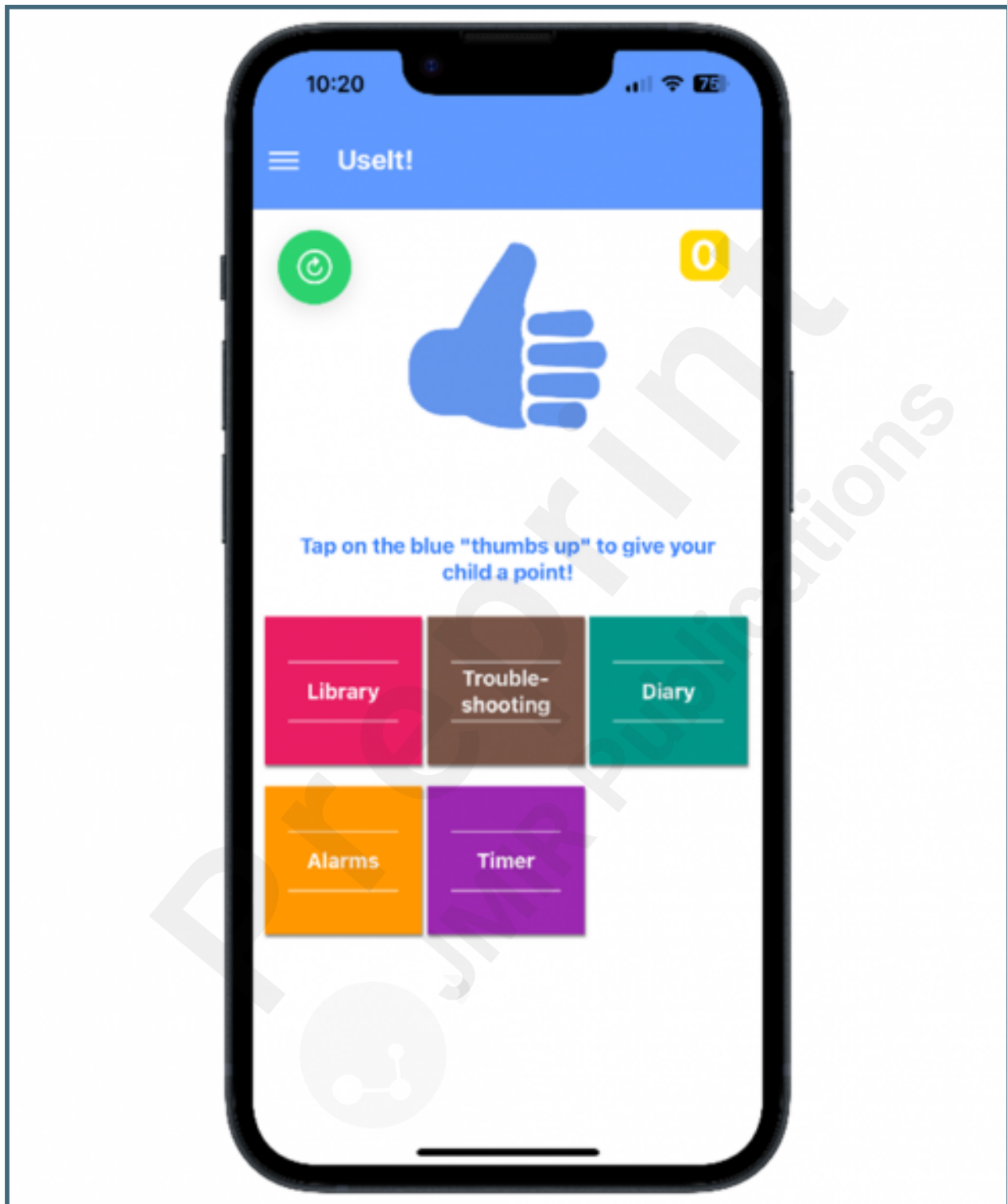
Table 1. Measures

Construct		Measure/Instrument	Timepoint
PMT/CBT	Skill	Knowledge of Effective Parenting Test	
	Knowledge	(KEPT)	All Timepoints
	Symptom Severity	Vanderbilt Assessment Scale	All Timepoints
	Parenting Practices	Alabama Parenting Questionnaire (APQ)	All Timepoints
	Parent Depression	Generalized Anxiety Disorder (GAD-7)	All Timepoints
	Parent Anxiety	Patient Health Questionnaire (PHQ-9)	All Timepoints
	Parenting Stress	Parental Stress Scale (PSS)	All Timepoints
	Social Support	Social Provisions Scale (SPS)	All Timepoints
PMT/CBT	Skill		
	Use	Parenting Skill Use Diary (PSUD)	All Timepoints
	App Use	Automatically Recorded	Active app phase
		Mindful Attention Awareness Scale	
	Mindfulness	(MAAS)	All Timepoints
		Service Assessment for Children and	
	Service Use	Adolescents (SACA)	Six-month follow-up
	Supportive	Supportive Accountability Inventory	Post-treatment (coach
	Accountability	(SAI)	condition only)
		Post-Study Usability Questionnaire	
	Usability	(PSSUQ)	Post-treatment
	Technological	Technology Self-Assessment Tool	
	Literacy	(TSAT)	Baseline

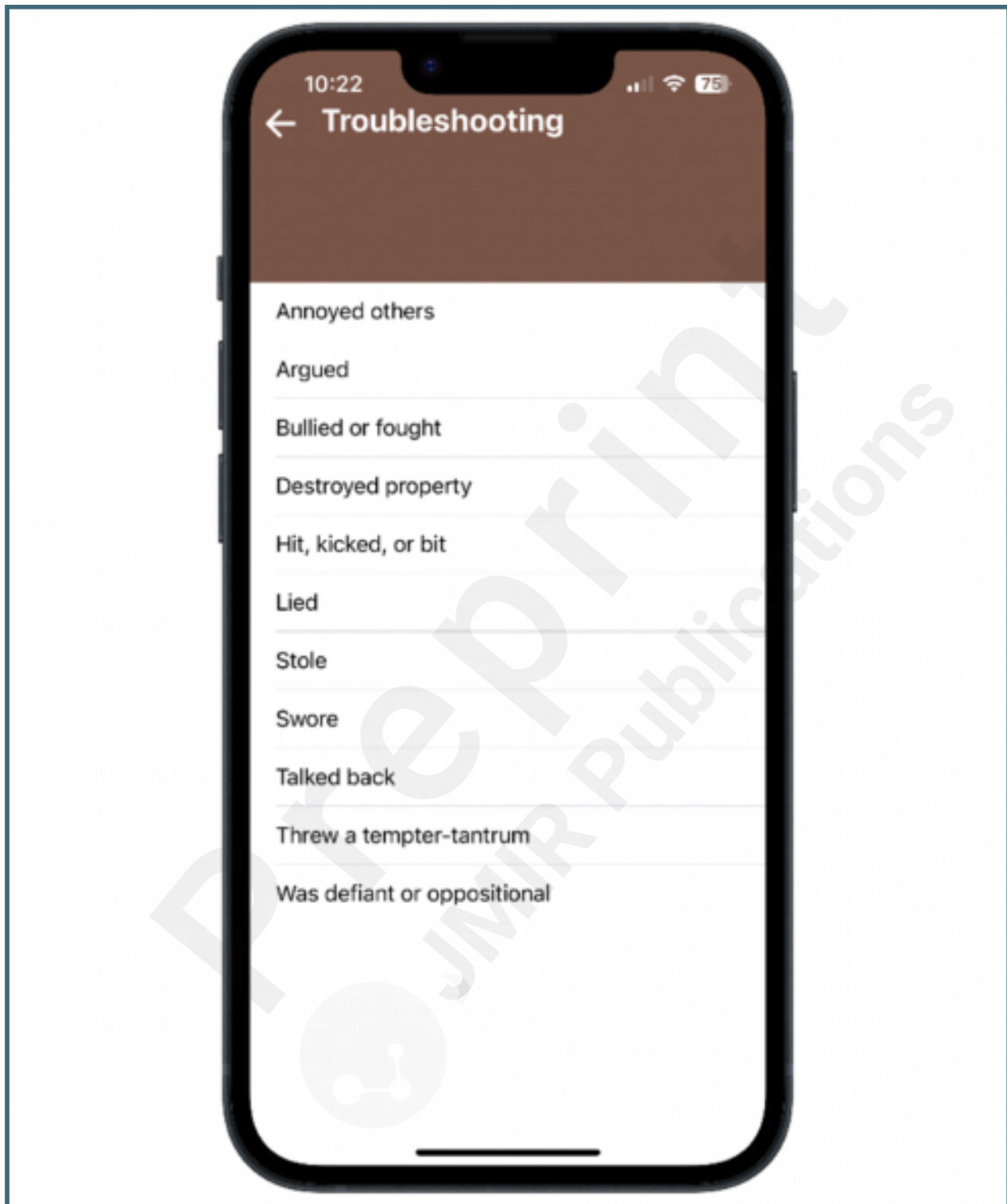
Supplementary Files

Figures

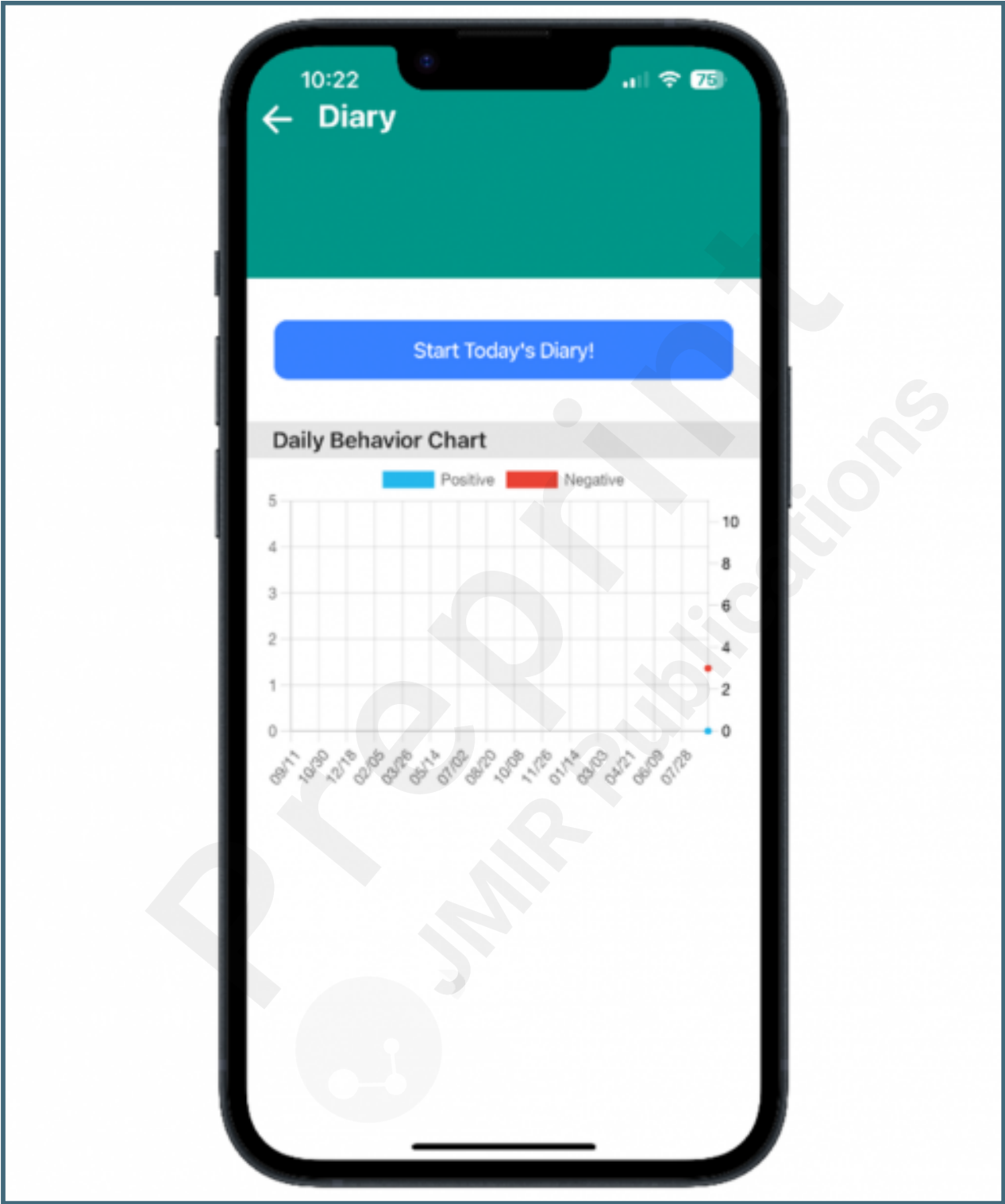
Screenshot of UseIt! Smartphone Application Homepage.



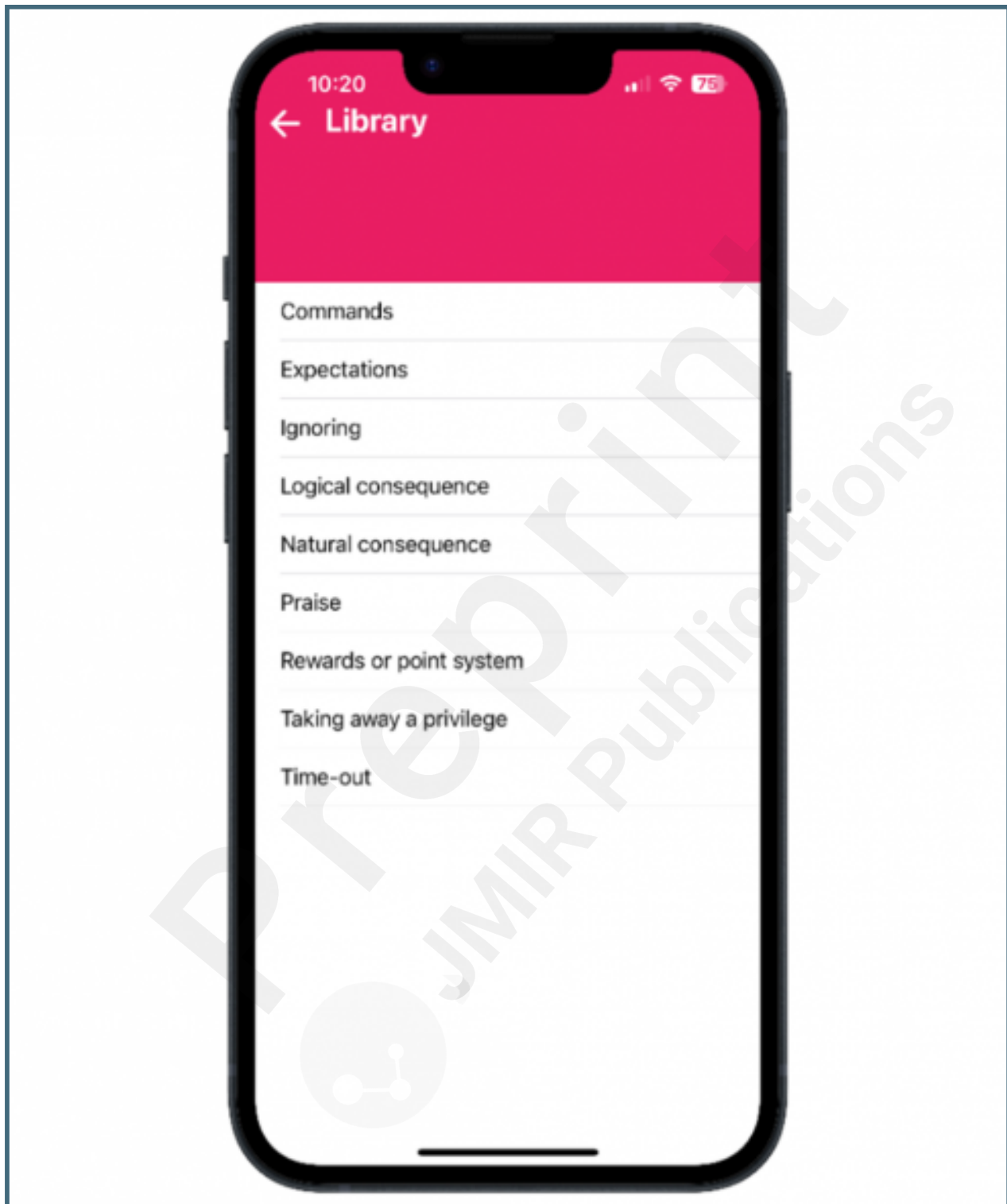
Screenshot of Troubleshooting Guide.



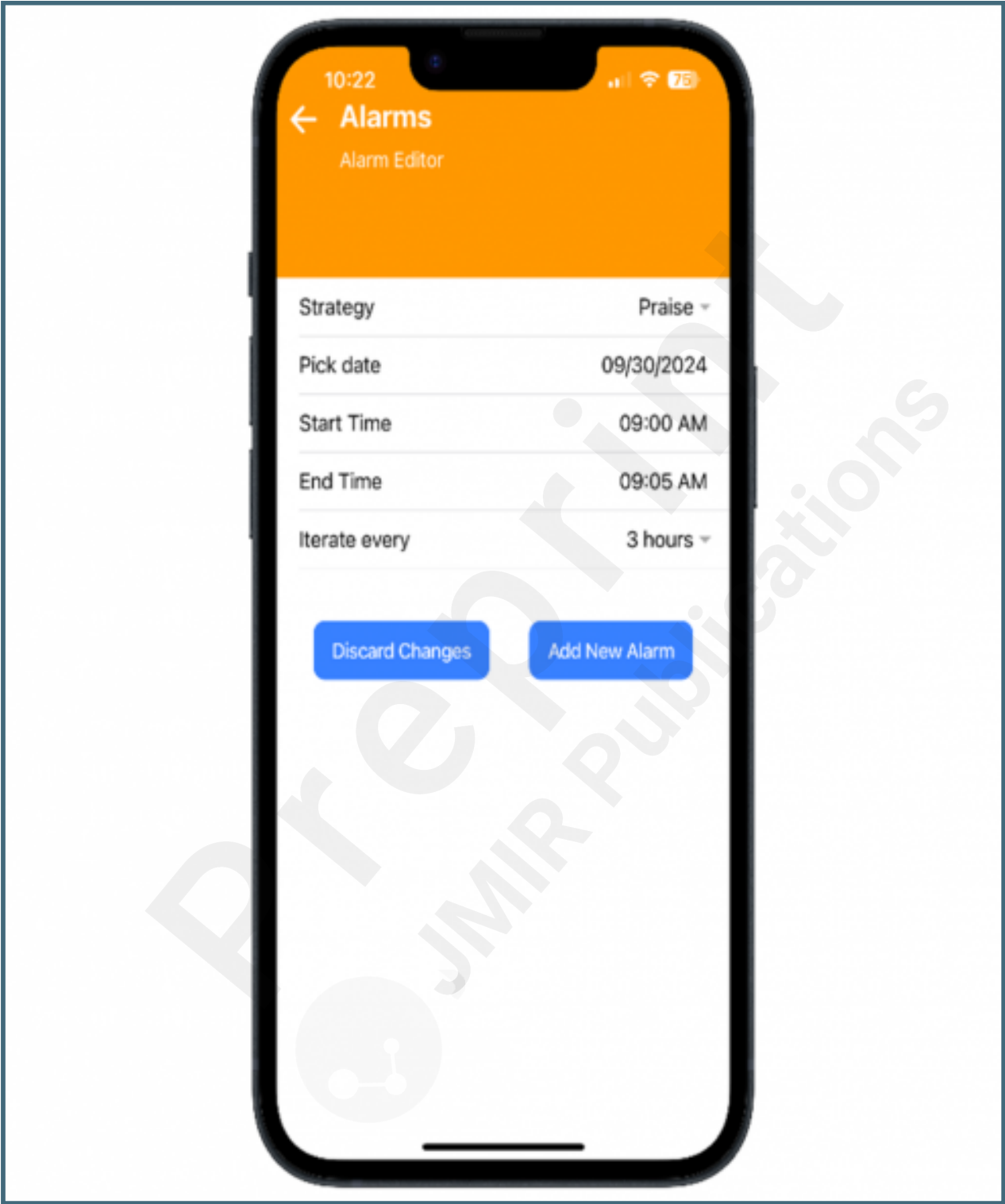
Screenshot of Daily Behavior Chart.



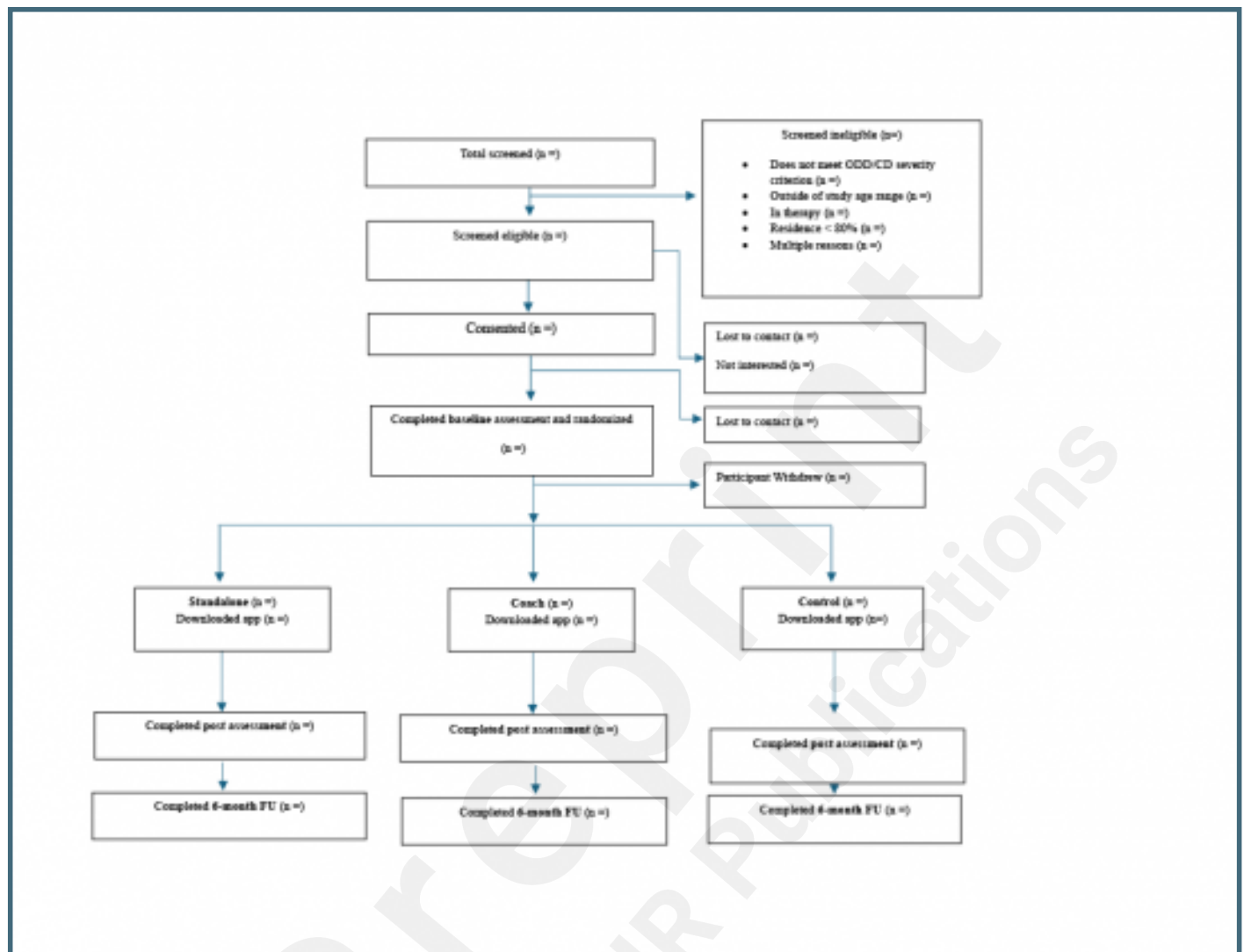
Screenshot of Skills Library.



Screenshot of Skills Alarm.



Study flowchart.



Multimedia Appendixes

Summary statement with peer reviews from NIH. Changes were incorporated from feedback, and the proposal was fully funded.
URL: <http://asset.jmir.pub/assets/115bad4955ffc0cc2390cd9882f56cba.pdf>

