Study Protocol and Statistical Analysis Plan

Mobile Behavioral Parent Training for Childhood ADHD: A Micro-randomized Trial

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Study Protocol

Overview

The current study aims to leverage an established data collection and intervention development smartphone application to develop and pilot a mobile behavioral parent training (BPT) intervention for parents of children with ADHD and academic difficulties. The intervention will target candidate mechanisms of child behavioral and academic success including parenting skills, parent academic management, and engagement with treatment material. mBPT will include: 1) online, asynchronous treatment videos, 2) survey data collection, 3) prompts to complete between session parent practice, and 4) personalized adaptive components to enhance parenting skills.

First, we will determine appropriate tailoring variables and decision rules for intervention personalization (Aim 1). Second(Aim 2), we will conduct a micro-randomized trial to refine the intervention and determine which micro-interventions should be included in the refined intervention. Finally (Aim 3), we will conduct a randomized, controlled pilot trial to compare the mBPT with mBPT combined with personalized, adaptive micro-interventions (JITAI).

The current IRB protocol pertains to the Aim 2 micro-randomized trial.

Procedures: Participants will be children with ADHD and their families. They will be invited to attend a brief virtual or in-person meeting to provide informed consent, complete assessment materials to confirm eligibility, provide baseline measures, and facilitate the child's teacher completing baseline measures of symptoms and impairment. If the child meets eligibility criteria, parents will then be provided access to the developed beta-mBPT program on their smartphones and will agree to be audio-recorded for 60 minutes per day for 28 days. The audio-recordings will be used to trigger immediate, personalized feedback (micro-interventions) to be delivered via phone to the parent--similar to receiving a prompt to stand up when a smartwatch detects that someone has been sitting for a long time. The effects of these micro-interventions on parent and child behavior will be examined. Parents will also have the option to provide more detailed, daily feedback on the application and intervention for a maximum of seven days during the study for additional compensation.

The primary possible risk is loss of confidentiality, and the primary possible benefit is improvement in parent/child relationship and child functioning. If the intervention is found to be effective, this research has the potential to relieve the public mental health burden of childhood ADHD.

Objective and Analyses: We aim to examine the effects of brief, parent-directed micro-interventions sent to a parent's phone while they are interacting with their child. To do this, we will conduct a micro-randomized trial in which parents are randomized to receive or not receive the micro-intervention repeatedly. There will be a total of 9 possible randomization opportunities per participant per day. We will then evaluate whether parent and child behavior

is significantly different when the parent was randomized to receive the micro-intervention (prompt) or not. We hypothesize that following parenting feedback delivered via the phone application, the parent-child interaction will be more positive and less negative compared to when the parent was not provided feedback. We will also examine the usability and feasibility of this intervention method.

Subjects

Duration of Participation: Total active time commitment is estimated to be about 7-8 hours. This includes consent and baseline assessment (60-120 minutes), about 45-60 minutes of intervention engagement weekly over 4 weeks (about 4 hours total), 10 minutes monthly for phone calls (30 minutes total), and 45-60 minutes for post-treatment assessment.

Additionally, there will be approximately 28 hours (one hour per day for 4 weeks) of passive data collection including audio data.

Optional Journaling: Participants will be able to opt-in to provide up to 7 days of journaling (more detailed, daily reports of application use) during the study for additional compensation. This will take approximately 5-10 minutes per day for an estimated 35-70 total minutes during the study.

Justification for Number of Participants: We predict that there will be a medium effect size on parenting skills. A recent meta-analysis (Charach et al., 2013) reported an average effect size of .55 for proximal outcomes (i.e., parenting behaviors) and an average effect size of .75 for distal outcomes (i.e., child behaviors) for parent training studies. Prinz and colleagues (2021) recently reported that online, self-directed BPT was not inferior to in-person treatment, and self-directed parenting programs have been shown to produce medium, positive effects on child behavior (Baumel et al., 2017). Power analysis for the Aim 2 micro-randomized trial was conducted with R (version 4.1.3; MRTSampleSize package). With an estimated 28 days per family in the trial, randomization probability of 50% for receiving a micro-intervention, a decreasing linear trend of micro-intervention effects with a medium effect size, and constant availability estimated to be 60% (given targeted decision points), n = 30 families are needed (Liao et al., 2016), and we aim to recruit n = 33 to ensure sufficient power.

Characteristics of Participants: Study participants will consist of 33 families. Each family will include one child, ages 7-12, with ADHD and up to two caregivers (total of up to 99 people in the study). This population is justified as the treatment being evaluated aims to target parenting among parents of children with ADHD to improve parent skills, functioning, and child functioning. Childhood ADHD is a prevalent, persistent, and impairing disorder, and intervening may improve the outcomes for children with ADHD and their families. Similar interventions have been shown to be effective.

Inclusion and Exclusion Criteria: Inclusion criteria: 1) currently meets DSM-5 diagnostic criteria for ADHD, 2) ages 7 -12, 3) has parent or teacher-rated impairment in homework performance defined as a score of 3 or greater on an Impairment Rating Scale measure (Fabiano et al., 2006)

of homework performance, and 4) has at least one parent or primary caregiver who is willing to participate and is able to access the intervention at home via smartphone. Eligibility for participation will not be affected by current or past pharmacological treatment for ADHD or other diagnoses. Adverse events and changes in treatment will be assessed during monthly phone calls.

This population is justified as the treatment being evaluated aims to target parenting among parents of children with ADHD to improve parent skills, functioning, and child functioning. The age range is when ADHD is most often diagnosed and when parents are most often seeking treatment for their families (Danielson et al., 2019). The intervention will also target homework and academic difficulties at home.

Parental/Child Consent Process: Potential families will be contacted by an experimenter and will be screened via telephone to determine basic eligibility (age, child diagnosis). Families will attend virtual or in-person meeting and provide consent/assent. Families that meet eligibility will be invited to participate and complete questionnaires of study measures.

At the beginning of the visit, study personnel will go over the consent form in detail. All procedures will be clearly explained to caregivers so that they clearly understand (1) what data are being measured and when, (2) any potential risks and benefits, and (3) the limits of confidentiality. After providing written consent, caregivers will also provide consent on the smartphone app. This additional app-based consent form will notify participants of each type of data collected and will request consent and permissions for accessing data on their devices (consent will include adult consent, child assent, and parental consent). We will employ understandable informed consent procedures so that participants can see what data are collected, which will contribute to industry standards for transparency, participant control, and participant ownership of data.

Experimenters will obtain adult consent, parental consent, and child assent for the collection of child data, in line with HHS and OHRS requirements. Children and parents will be approached together. Each parent/caregiver who is participating must provide their own consent to participate. Caregivers will be given the opportunity to read all consent documents and to ask questions and express any concerns. No procedures will be conducted until caregivers have provided both written and app- based consent. Participants will be informed that they can request that any or all of their data be deleted at any time; may listen to, read, and/or delete any recordings or text files that are collected; may skip any questions; and that they can pause or stop their participation at any time (via the mute, pause, and stop data collection functions easily accessible from the app) and/or via contacting study staff via e-mail, phone, or letter.

Description of Compensation or Incentives: Parents will receive a $50 gift card for participating. This can be broken down into $10 per week of sufficient data collection (two-thirds of passive data collected) over 4 weeks with an additional $10 provided if all 4 weeks of data are provided. Parents who opt to participate in the one week of journaling will receive $10

per day that the daily journaling form is completed and submitted for up to $70 in addition to the $50 compensation for the study.

Methods and Activities

Description of Methods and Activities:

1. Parents and children will attend the consent/assent and intake appointment virtually via Zoom or in person. Together with study staff, parents will review the privacy policy for Colliga Apps. Parents will also complete the teacher release form so study staff can request teacher ratings. Parents will indicate on the consent form whether they would like to complete daily journaling for up to seven days during the study.

2. After consent/assent, parents will complete baseline measures on provided iPads or via secure, individual survey links on their own devices. Baseline, parent report measures include: Family Information Form for demographics; disruptive behavior disorders rating scale as a measure of child ADHD symptoms; Homework problems checklist and homework routine measure to measure child behaviors during homework time and the homework routine; Impairment Rating Scale to measure child impairment; Strengths and difficulties questionnaire to measure overall mental health functioning among child participants; Alabama Parenting Questionnaire- short form that measures parenting strategies; Barriers to treatment participation scales to measure reasons for difficulty engaging in treatment; Parent motivation inventory to measure caregiver motivation to engage in treatment; Parenting Stress Index-Short Form to measure parenting stress; Knowledge of Parenting Strategies Scale to measure baseline parenting skills knowledge; Patient Health Questionnaire-9 to assess parent mental health; Adult ADHD Self-Report Scale to measure parent self-report of ADHD symptoms. Ph.D. level psychologist will then conduct a brief, semi-structured interview to determine ADHD diagnosis. The psychologist will also screen for suicidal thoughts and behaviors.

3. Ratings will also be sent to teachers. Teachers will complete ratings of ADHD symptoms, impairment, child difficulties related to mental health, and academic functioning at baseline. ADHD symptoms and impairment ratings inform diagnosis.

4. Participants will be guided on how to download the Colliga App on their phones where all interventions will be housed and where passive audio recording and data collection will occur. They will complete the in-application consent form, and we will also assist them in becoming familiar with the intervention components in the application. We will modify this to be responsive to emergent questions or clarifications as we enroll subjects to ensure procedures are clear and transparent.

5. Four weeks continuous participation: Parents will schedule times for their phone to record for 60 minutes per day for four consecutive weeks (a total of 28 hours of recording). They will also have access to the beta, 4-week version of the mobile behavioral parent training intervention. During the study, the phone will use passively collected data, including audio data, to detect key states (for example, overall negative or positive state). These will be detected

every 6-minutes during audio data collection. Following each 6-minute interval, the parent/child dyad will be randomized to one of three conditions, (1) no intervention; (2) Parenting Behavior Strategy (e.g., suggestion to catch the child being good or provide clear instructions); (3) Parent-Focused Feedback (e.g., feedback regarding positive parenting skill use). Tailoring variables affecting the personalization of the micro-intervention include: sensitivity analysis and key words evaluated in the preceding six minutes. Given one hour per day of recorded interaction, each parent/child dyad will have up to 9 randomization opportunities daily, and will receive an average of 6 micro-interventions each day (if they approve the audio recording).

6. Parents who opt to complete daily journaling for up to 7 days during the four-week study will receive the journaling measure for one week each. This will be planned for the first 7 days of their study enrollment, but can be flexible based on family preference and research staff needs to facilitate staff ensuring daily receipt of journals.

7. Parents will be called at the end of the study to assess for adverse events and will be provided the gift card(s). Measures of symptoms, impairment, family functioning, etc will not be collected at the end of the study given the focus on proximal changes in parent behavior as the primary outcome. Parents will complete the System Usability Survey, Mobile Application Rating Scale, and the Exit Interview to provide information on the usability and feasibility of the application and intervention.

Statistical Analysis Plan

Overview: This study is a micro-randomized trial (MRT) evaluating whether in-the-moment smartphone notifications (personalized parenting suggestions or personalized feedback) improve proximal parenting behavior among caregivers of children with ADHD. During up to two daily audio-recording sessions, caregivers are randomized every 6 minutes to: (a) no notification (50%), (b) suggestion (25%), or (c) feedback (25%). The proximal outcome is a binary indicator of positive parenting sentiment in the subsequent 6-minute window.

Primary Outcome: Binary indicator of positive sentiment (i.e., positive sentiment vs. negative or neutral sentiment) measured in the 6-minute epoch following each randomization decision point in the micro-randomized trial. Additionally, the binary indicator of negative sentiment measured in the 6-minute epoch following each randomization decision point will be examined as an outcome.

Primary Comparison: The marginal causal excursion effect of receiving any active micro-intervention (suggestion or feedback) versus no notification on the proximal binary outcome. Secondarily, we will examine potential effects of micro-intervention type (feedback vs. suggestion/strategy) on sentiment.

Mean Differences: Means and standard deviations for outcome measures by micro-intervention condition are provided in clinicaltrials.gov.

Primary Analysis: A weighted, centered logistic regression model for binary proximal outcomes, implemented using the MRTAnalysis R package (D3C, University of Michigan). The model incorporates known randomization probabilities, participant-level clustering, and time-varying covariates as needed. Availability at each decision point will not be included in models as the participants have indicated availability by starting the recording (i.e., micro-interventions are only delivered within 30 minutes of participant starting audio-recording). The primary coefficient estimates the causal excursion log-odds ratio for active micro-intervention vs. no notification. Analyses are not aimed at determining significance given the small sample size and the pilot nature of the research study. Direction of effects, means, and user feedback and key outcomes.

Secondary Analyses: Moderated causal excursion effects will examine whether treatment effects vary by factors that are static such as child age and oppositional defiant disorder symptoms at baseline, and time-varying moderators including progress in asynchronous treatment (i.e., behavioral treatment modules) and sentiment immediately prior to randomization. All secondary analyses are exploratory.

Missing Data: Decision points without valid audio or outcome coding will be excluded from primary analyses. Sensitivity analyses will be conducted including only micro-intervention instances in which users confirmed micro-intervention receipt on their phone (as well as the no micro-intervention condition). Given availability, missingness is low.

Software: All analyses will be performed in R, using the MRTAnalysis package for estimation of marginal and moderated causal excursion effects for binary proximal outcomes.