Study Protocol and Statistical Analysis Plan

Title: Development of a Mobile App for an Executive Functioning Intervention for Adolescents
NCT04018794

Date: September 9, 2020

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Study Protocol:

Study Start: September 30, 2019
Study Completion: September 1, 2020

Brief Summary: This study develops an initial prototype of a mobile tool that will support clinician-directed behavioral/organizational skills treatment for adolescents with Attention Deficit Hyperactivity Disorder (ADHD) with input guided from key stakeholders.

Abstract/Summary: Attention-Deficit/Hyperactivity Disorder (ADHD) is one of the most common childhood mental health disorders, affecting 7-9% of children and adolescents, and leading to substantial impairment in adolescence. Despite evidence suggesting that behavioral interventions are efficacious, approximately 40-60% of adolescents receiving behavioral treatment show little to no improvement and skills are rarely generalized beyond treatment sessions. Lack of adolescent motivation and engagement, between-session skills use, reward saliency, and family involvement are key contributors to these limited effects. Mobile digital health (dHealth) strategies and gamification techniques, offer unique opportunities for overcoming the barriers of treatments specific to ADHD by using interactive tools to reinforce in-vivo skill practice, providing opportunities for immediate reinforcement, and motivating adolescents with digital rewards. The primary goal of this study is to develop and preliminarily test the integration of a digital health tool into organizational/behavioral skills treatment for adolescents with ADHD by improving executive functioning skills, providing in-vivo skills reinforcement, and monitoring adolescents' skill utilization. This research will use an iterative stakeholder-centered design to develop, refine, and preliminarily test a novel digital health tool, applied as an adjunct to behavioral treatment for adolescents with ADHD (ages 11-15). This includes focus groups with key stakeholders and an open preliminary feasibility trial and usability testing. Data collected from focus groups will inform what content and features could be developed to overcome challenges to adolescent engagement and parent involvement. During the open trial (N=20) we will assess intervention feasibility, usability, and acceptability. During and after the clinical trial, we will collect continuous feedback from users on the usability and utility of the tool. At the end of this study we will complete debugging and programming to maximize usability before a future larger clinical trial.

Study Objectives: The primary objective of the proposed study is to develop and preliminarily test the integration of a digital health tool into organizational/behavioral skills treatment for adolescents with ADHD to support clinician-directed behavioral treatment for adolescents with ADHD by promoting organizational/EF skills utilization, providing in-vivo skills reinforcement, and monitoring adolescents' skill utilization. A two-phase user experience design cycle will be used consisting of initial design and focus groups (Phase 1: Define, 6 months), followed by an open trial with extended formative usability testing and software refinement/debugging (Phase 2: Refine, 6 months). During this open trial (N=20) we will assess intervention feasibility, usability, and acceptability.

Aim 1: Design, build, and refine a mobile app for improving EF skills engagement in behavioral organizational skills treatment for adolescents.

> **Hypothesis 1:** Adolescents, their parents, and SMHPs will rate the intervention as highly feasible, easy to use, acceptable, and responsive to their needs.

Aim 2: Determine the feasibility, acceptability, and usability of the ATOM app.

Hypothesis: Given this is an uncontrolled preliminary feasibility study, descriptive data will be examined for measures of feasibility, usability, user engagement, adherence/ retention, acceptability, and therapeutic process.

Design: Aim 1 (Discovery and Design) will entail iterative software development (6 months) and two focus groups. Facilitating a user-centered design process, we will obtain direct input from a team of end users (8 adolescents, 8 parents, 8 providers) regarding design, content, and functionality. This design will be used to test the central hypothesis that adolescents who use the dHealth tool in treatment will consistently utilize skills between sessions. Following established guidelines for conducting focus groups particularly with adolescents we will include different activity-oriented questions (sticky notes exercises, gameful personas, prototype screenshots, and interactive testing with a tablet) in each group to enrich the data collected and reduce lapses in attention, which is especially relevant for the target population. Qualitative data collected during these sessions including video recordings, written materials (drawings, sticky notes, written ideas), and facilitator notes will be used for transcription, coding, and data analysis. Data from focus groups will inform what content and features could be developed to overcome challenges to adolescent engagement and parent involvement.

Aim 2 (Test) will conduct extended formative usability testing during an open trial with behavioral organizational skills treatment (2 months). We will assess the usability, feasibility, and acceptability of the tool in conjunction with their participation in the HOPS intervention at their school. Inclusion of these stakeholders will allow for an assessment of the tool components during treatment. Adolescents will access the application from their personal device or will be provided with a study tablet if they do not have one (although we expect this to be low based on current participant usage, high national rates (91%), and that the school district has a program that provides tablets to all middle school students. Adolescents will be advised to use the tool daily to practice skills and to access information as needed. Consistent with usability methodology, passive usage analytics will be collected and adolescents, parents, and SMHPs will complete the System Usability Scale at mid-intervention (4-weeks after start) and post-intervention. Participants will be interviewed to provide detailed feedback during and after the open trial to assess reactions to the tool (usability, feasibility, acceptability) to inform refinements and identify barriers and facilitators of use. The end of Aim 2 will also entail debugging and programming to maximize usability before a larger clinical randomized control trial.

Eligibility Criteria: Participants will include 20 young adolescents (ages 11 to 15) with ADHD, and their parents recruited from local schools and the university/medical center clinic. 8 adolescent subjects and their parents will be enrolled to participate in focus group discussions as part of Aim 1 and then 12 additional adolescents and their families will be recruited (for a total of N=20) to participate in the feasibility trial. Participants will also consist of 8 mental health providers (n=8 during Aim 1, of which n=5 will participate in the trial during Aim 2). The primary teachers of the N=20 adolescents participating in the trial will also participate during the trial phase by completing measures about the adolescent before and after the intervention. The entire participant count is based on plans to include 8 adolescents, 8 parents, and 8 mental health providers during the discovery/design phase (Aim 1), and 20 adolescents and their parents plus 5 school mental health providers (SMHPs) schools during the pilot study (Aim 2). Adolescents' eligibility for the study is based on meeting following inclusion and exclusion criteria: a) Inclusion criteria: 1) Youth ages of 11-14 years (6-8th grade) that are attending a participating school2) referred by SMHP as a youth with apparent ADHD-related problems, 3) ≥6 symptoms (item score ≥2) of Inattention or Hyperactivity-Impulsivity on the pooled parent and teacher Vanderbilt ADHD Rating Scale 4) ≥3 on the Impairment Rating Scale by parent and teacher (cross-situational impairment)5) Parent consent and adolescent assent must be

provided; b) Exclusion criteria:1) No presence of conditions that are incompatible with this study's treatment including: Parent or adolescent report of a prior diagnosis of either Autism Spectrum Disorder, Bipolar Disorder, a Dissociative Disorder, Severe visual or hearing impairment, severe language delay or intellectual impairment, or a Psychotic Disorder will be excluded. Rationale: Individuals with these disorders often have very dysregulated behavior and impairments that deviate from the focus of this study. 2) Adolescent is in all-day special education classes or if core classes not in regular education classrooms. Rationale: The vast majority of adolescent with ADHD are served in regular education classrooms and students in full-day self-contained classrooms often have different challenges than students in regular education. 3) Adolescent planning to change (start or stop) psychotropic medication. Note: Adolescents taking medication will be required to meet all entry criteria, including impairment criteria, thus indicating a need for the intervention. Adolescent taking medication for attention or behavior are eligible as long as their medication regimens are stable. Participating parents will also need to be able to read/speak English because all measures are in English, and the intervention will be conducted in English.

Statistical Analysis Plan (SAP):

Analyses Aim 1: Focus group and interview data will be analyzed thematically, following established guidelines for qualitative data analysis and representation procedures. Recordings will be transcribed and open-coded using Transana 3.30 software. Using a content analysis approach, we will condense the data into a thematic framework to generate an independent list of thematic categories and subcategories based on the study team's review of the data. Key themes will inform iterative refinements to the features and functions of the app. Responses will be coded by two independent coders (a third coder is consulted if needed to resolve discrepancies). The codebook will be updated iteratively as new themes emerge. Qualitative data (focus group and interview themes) and quantitative data (ratings) will be used to guide the initial design, development, and refinements.

Analyses Aim 2: For feasibility and acceptability, descriptive statistics of adolescent-reported, parent-reported, and provider-reported satisfaction with intervention structure, length, convenience, and perceived impact on outcomes will be assessed. We will examine means and standard deviations of ratings completed by adolescents, parents, and SMHPs on the Feasibility/Acceptability Questionnaire (ratings of 4 or above are considered good) and System Usability Scale. For usability, the statistical test of choice will be ones ample t-test tested at the nominal alpha 2-tailed = 0.05 level. Usage analytics descriptives (i.e., how often users respond to prompts, access components) will also be examined as an indicator of usability. Representativeness of the sample and enrollment rate of underserved individuals will be assessed to inform potential reach.

Power Analysis: Given the primary goals are to establish feasibility and usability of a dHealth tool for enhancing skills utilization in adolescents, the sample size was set for practical reasons based on our experiences and the resources/timeline allowable with the funding.

Results: Thematic qualitative analyses found students, parents, and school mental health providers prioritized a streamlined interface design for the tool, the use of personalized reminders, progress monitoring graphing tools, visual rewards, and an electronic calendar with prioritized events. Key focus group/qualitative themes from included the stakeholders' prioritization of tools to engage users, personalization capabilities, reminders, and ease of use for all stakeholders. Quantitative usability testing results collected from the open feasibility trial found high overall usability of the intervention digital health tool. Participants rated the tool as highly acceptable, usable, and feasible to implement (System Usability Scale, M= 71.7). Overall usability ratings were high across components (M>=4.3, on a scale of 1=low to 5=high).

Informed Consent Form (ICF):

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Development of a Mobile App for an Executive Functioning Intervention for Adolescents

Research Project Director:	[REDACTED]

Study Coordinator:	[REDACTED]

This is a research study about developing and evaluating a mobile digital application to enhance executive functioning skills including organization, planning, and time management for adolescents participating in intervention for attention and/or executive functioning concerns. The study researchers, [REDACTED], the study project coordinator, or a study clinician from the [REDACTED]will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You and your child are being asked to participate because your child is having attentional, behavioral, and/or academic concerns at school and/or home. Please note that students and families can participate in the study only if their teacher also agrees to participate

Why is this study being done?

The purpose of this phase of the study is to evaluate a mobile digital health tool for supporting intervention focused on improving organization and time management skills for adolescents ages 11 to 15 with difficulties with attention and/or organization. Knowledge from this study will further research on improving interventions for youth with attentional difficulties. This study is sponsored by [REDACTED].

How many people will take part in this study?

A total of 20 families, and participating adolescents' teachers will participate in this study.

What will happen if I take part in this research study?

If you agree to participate, and your child agrees to participate and agrees to the recording of program meetings, the following procedures will occur:

1. First, we will conduct screening procedures to find out if you and your child can participate in the program. You provided your consent for your school and our program staff to share confidential education, psychoeducational and other relevant information about your child and your consent for your child's teacher to complete assessments for the program by

signing the Consent for Release and Exchange of Information form. Screening, which is required for the study, will consist of the following:

- You and your child's teacher will complete ratings of your child's behavior.
- If, based on those ratings, it seems as though your child meets criteria for our study, you and your child will come to your child's school, the [REDACTED] for an evaluation.
- This evaluation will take approximately 30 minutes to complete and will include:
    - Completion of a medical and developmental history and previous service use.
    - Questionnaires for you and your child to complete about your child's functioning.
- You will receive results of your child's screening evaluation, which may be released to your health care provider at your request, but otherwise will not be released.
- If all study criteria are met, your child will be eligible to continue in the study; if study criteria are not met, you will be referred back to your school for other referral options. Information already gathered will be kept by the researchers so that they can report on characteristics of families who consented but did not participate in the study.

2. During this study, approximately 20 children between the ages of 11 to 15 with attention and/or organization concerns will receive an organizational skills intervention program augmented with a mobile application tool. A school counselor, school social worker, or other school mental health provider at your child's school will deliver the intervention to your child. The organizational skills interventions to be delivered to your child will include:
    - Developing a system for organization of bookbag, binder and locker and implementing strategies for homework and time management.
    - The school counselor/school mental health provider will set-up a meeting schedule with your child and will determine when and where he/she will meet with your child based upon your child's needs. It is likely that the school counselor/school mental health provider will meet with your child during school hours twice per week for at least 16 meetings. Each meeting will last no longer than 30 minutes.
    - You (parent) will be asked to attend two sessions with the school counselor and your child. These sessions will be spent updating you on your child's progress and teaching you how to implement the strategies at home.
    - You and your child will be provided access to a mobile application to download on your personal mobile devices (such as smartphones, tablets, laptops) or other computers. The application is designed to augment the meetings and serve as a reference tool for practicing the skills between meetings. You and your child will be asked to use the application tool while participating in the program.
    - When you and your child are using the app during this program, the app will collect data on how you navigate through the features and time spent using the app. The app will also collect data on the points your child earns for practicing organization skills using the skills checklists, responses to the practice plan questions, responses to questions about child's overall progress, as well as information entered into the calendar feature including assignment information and dates. Parents, adolescents, and providers will be able to view a progress monitoring graph that displays the points earned by the adolescent.

3. All sessions will be video recorded for training and research purposes. An expert trainer from [REDACTED]will provide training and consultation to the school counselor during the program. The expert trainer may also observe and provide live support during the sessions remotely via videoconference software. All videoconferencing will take place over a secure internet connection that meets the [REDACTED]HIPAA requirements.

4. All families will participate in a follow-up assessment, about 10-12 weeks after the first assessment. During this assessment, all parents, teachers, and children will complete interviews and questionnaires like those completed at the screening/eligibility assessment.

5. **Study location:** All study procedures will take place either at your child's school or [REDACTED].

Will any video or audiotaping be done during this study?

All sessions will be video recorded and will be secured on password-protected database servers for research and training purposes. The recordings will be identified only by numbers, and none of your names will appear on the electronic file labels. The recordings will be kept indefinitely for research, training, and development purposes. The recording is required for future trainings, analyses, and development of our research. If you or your child decide to withdraw from participating and no longer wish to have your video recordings for research purposes in this study at any point in the future, then his/her image will be blurred from recordings.

What if my child is taking medication for ADHD?

If your child is taking medication, he or she still is eligible for the current project as long as he or she has been taking the same type or dose of medication for the past month (immediately prior to the screening). Your child can continue to take his/her medication as usual throughout his/her participation in the current project.

How long will I be in the study?

The total time commitment for all participating families includes completion of rating scales and participation in two assessments (once at the beginning of this phase of the study and once at the end of the program). The assessments take about 30 minutes for parents and children to complete. Participation in the program involves your child attending up to 16 twice/weekly intervention meetings (up to 30 minutes each session) for eight weeks and two 30-minute meetings between parents, children, and school counselors/mental health providers.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What risks can I expect from being in the study?

- *Potential Risks for Completing Evaluation:* Potential risks include discomfort that some people may feel when being interviewed, observed, or when completing questionnaires about personal matters. Protection against these risks includes highly-trained staff, including licensed child psychologists. The assessments and intervention will be conducted by experienced mental health professionals who are trained to be sensitive to the feelings and well-being of the participants.

- *Potential Risks for Psychosocial Interventions*: As part of participation in this program, participants will be exposed to individual intervention meetings with the school counselor at

their school site. This may be embarrassing or stigmatizing for some families. However, consumer satisfaction from studies of the kind of intervention program we are providing have been positive. All participating parents, children, and school counselors will be instructed about confidentiality and requested that they not reveal the identity of any participants or repeat any personal information provided during these meetings. Protection against these risks also includes use of highly trained staff and availability of child psychologists; all staff will be trained in protecting the confidentiality of patient information.

- *Potential Risks for Using the App*: As part of participation in this program, participants will be asked to use the app to record points from the organizational skills list and answer questions about their progress. Potential risks include experiencing frustration or discomfort with not being able to adhere to the program, experiencing low motivation to use the app, or boredom from using the app. As with any digital application, there is risk of loss of privacy/confidentiality of the child's identity or information collected from the app if the device with the app or the digital copy of the data stored from the app are lost, misplaced, or stolen or if the child's identity and information recorded in the app is otherwise accidentally discovered by anyone else. All participants will be given a username login and password to use to enter the app. Additional protection against these risks include all digital copies of the data will be kept on a secure password-protected server during the study and after its conclusion. The application and all digital copies of the data will not include labels with names, but will be labeled with code numbers only.

- *Potential Risks for audio and video recordings*: Potential risks include discomfort that some people may feel when being recorded. Loss of confidentiality is the major risk if the child's identity accidentally is discovered by anyone viewing or hearing the recordings. Video and audio recordings made during the intervention sessions will be used solely for research and training purposes and will be kept in a secure password-protected website or secure video-streaming program. All digital copies will be kept on a secure password- protected server during the study and after its conclusion. Video and audio recordings will be labeled with code numbers only; labels will not include names.

- For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

There may be no direct benefits to you or your child from participating in this study. However, the information that you provide may help health professionals to design better programs for children, parents, and schools. We cannot and do not promise that you or your child will receive any personal benefit from participating in this study. Potential benefits include possible reduction in attention, behavioral, and/or organizational problems, and improvement in academic functioning as a result of participating in the intervention program. This study will provide careful monitoring of your child's behavior and you may also gain insight into your child through the evaluation procedure.

What other choices do I have if I do not take part in this study?

Your other choices may include not getting the intervention, getting standard intervention for attention and/or organizational problems without being in a study, or taking part in another study. If you decide not to take part in this study, there will be no penalty to you. Your choice will not affect your or your child's care or how you are treated at [REDACTED]. There may be non-study school interventions available to you or your child.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. You will not need to provide additional permission for us to share this de-identified information with other researchers.

Will information about my child and me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Participation in research may involve a loss of privacy, but information about you and your child will be kept as confidential as possible. Neither your name nor your child's name will be used in any published reports about this study. All records will be identified by code number only, and the records will be kept in a locked file cabinet. The key to this file cabinet will be stored in a secure location. You will provide your consent for your school and our program staff to share confidential education, psychoeducational and other relevant information by signing a Consent for Release and Exchange of Information form. Your personal information may be given out if required by law.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the [REDACTED]
- Representatives of the National Institutes of Health
- Representatives of the Sponsor, NIH National Center for Advancing Translational Science
- Representatives of the Food and Drug Administration (FDA)

There are some special circumstances that may invoke breaking confidentiality. Such special circumstances consist of our becoming aware of (a) suicidal or homicidal intent or planning on the part of any participant or family member, or (b) child abuse. All members of the research staff will be trained to immediately page or notify the Principal Investigator (PI) upon discovery of either (a) or (b), and to stay with any participant who is in danger until appropriate care can be provided. The PI will evaluate the situation and take the appropriate steps to resolve the risk, including arranging for any emergency care, warning any potential victim, providing referral to crisis intervention, or making an abuse report to child protective services.

Are there any costs to me for taking part in this study?

No. This research is supported by the [REDACTED]. There will be no cost to you or to your insurance carrier(s) for any of the research procedures described here.

Will I be paid for taking part in this study?

In return for your time, effort and travel expenses, you will be paid $20, in cash, for completing the initial evaluation measures and $30, in cash, for completing the post intervention measures (total $50). You will be paid at the evaluation, and your will be required to sign a receipt for cash received. You child will have the opportunity to earn up to $50 in gift cards based on their work during the intervention program. Your child's teachers will be paid $25 in cash, for completing measures at each of the two evaluations (total $50).

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. **You can contact** [REDACTED]. If you still have questions or concerns after talking to [REDACTED]or if you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at [REDACTED].

CONSENT

You have been given a copy of this consent form to keep. The person who signed below has explained this information to you, and your questions were answered.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You or your child have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate and have your child participate in this study, please sign below.

_____ _____

Date Parent or Legal Guardian Signature for Consent

_____

Name of Parent or Legal Guardian (please print)

_____

Name of Child (please print)

_____ _____

Date Person Obtaining Consent