Reach and Scalability of Digital Therapeutics for Childhood Behavior Problems

NCT05647772

Effective: 10/20/22

UPMC | University of Pittsburgh Medical Center

Western Psychiatric Institute and Clinic

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: Reach and Scalability of Digital Therapeutics for Childhood Behavior Problems

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Sponsor: National Institute of Child and Human Development (NICHD)

Key Study Information: You are being asked to participate in this research study. Research studies include only people who choose to participate. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision. The purpose of this study is to test the effectiveness of a mobile health system

(mHealth) to see if it is an effective way for parents and children with behavior problems to utilize these skills. The study involves a training session on how to use the app, followed by web-based surveys which will be filled out via the Qualtrics system. Parents will be required to fill out these surveys at baseline, at the post assessment (4 months after baseline), and at the follow-up assessment (6 months after the post assessment). Everything will be conducted over the phone or via Qualtrics.

Possible risks and side effects of the study include emotional discomfort, embarrassment and/or frustration while answering questions or using the app. To reduce emotional discomfort and embarrassment throughout the study, families will be reminded that they may skip any question at any time. There is also a small risk of a breach of confidentiality. To minimize this risk, all forms will be deidentified and stored in secure, locked locations. Electronic data will be deidentified, password protected, and placed behind a firewall.

There will be no direct benefit to you from participating in this study. However, the information we obtain from you and others may help us better understand how families use smartphone apps to learn and use new skills and how mobile technology can be used to help parents and children with behavior problems.

We are conducting a research study to help us understand if a smartphone app is an effective way for parents and children with behavior problems to learn and use skills. To accomplish these goals, we will need to see what skills you and your child will learn and use during your time with the smartphone apps, how you used the apps, and how your behaviors change over time. We also need your feedback about how we can improve the apps to better suit the needs of parents and children with behavior problems. You have been asked to participate in this study because you have indicated that your child has mild to moderate behavior problems and you are currently not receiving any other mental health services. We will ask up to 400 parents and their children to take part in this study.

If you and your child agree to participate, we will ask you to use a smartphone application. You will be randomly assigned to download one of two smartphone apps after signing the consent form: the UseIt! app or the SmilingMind app. Regardless of which group you are assigned to, all participants will complete a baseline assessment, a post assessment (four months after baseline), and a follow-up assessment (6 months after the post assessment).

UseIt! App Condition If you are randomly assigned to download the UseIt! app, you will use your own android/iOS device(s). The app is available at no cost for both android and iOS devices, and it will feature digital reminders, a behavioral diary, a troubleshooting guide (to suggest skills), and a library (a general source of information). During this study, we will examine how often you use each feature of the app and how your behavior changes by using the app. We also aim to learn of any difficulties you experience with the app and ways we can improve the app. If you are assigned to the UseIt! app condition, you might also be assigned to a "coach" who will contact you once a week to check in with you on your app use and set goals.

SmilingMind App Condition If you are randomly assigned to download the SmilingMind app, you will use your own android/iOS device(s). The SmilingMind app is a mindfulness app to promote mental wellbeing. The app can be downloaded at no cost, it is available for both Android and iOS devices, and app-use can be tracked. In order to use the app, participants will need to create a user account and log in using a study-specific ID. Families will accept the App Terms (https://app.smilingmind.com.au/home). The research conducted will include data collection and analysis regarding your use of the SmilingMind app. If you agree to participate, SmilingMind will share your information (including name, email address, and data regarding your use of the app) with the University of Pittsburgh research team.

In addition to using the smartphone applications, you will also be asked to complete online questionnaires, which will include multiple choice questions, scenario responses, and family information items (which take approximately 1 hour to complete). The multiple choice questions and scenario responses will relate to how parents and children interact, how parents promote good behavior, and any childhood behavior problems. Scenario responses will present you with a description of common parenting situations. You will be asked to describe how you would respond to the situation. Some questions will also relate to your experiences with the smartphone apps. You will also be asked to complete online behavior diaries (5 – 10 minutes long each night). The behavior diaries will ask you about the behaviors and skills that you used throughout the day. Your responses to assessments and diary entries will only be viewable to research staff. Please see the table below for the assessment schedule and payment plan for the study.

You will be trained over the phone by a member of our study staff, and you will complete your baseline assessment online. This assessment will consist of multiple choice questions and scenario responses (as described in the previous paragraph). The baseline assessment will be completed prior to receiving your training with the app. All other assessments will be sent to you through email and completed online (i.e., you will not travel to our offices for any other assessments).

This is a very low risk study, but you should be aware of risks. The risks associated with this study include the potential for a breach of confidentiality. To reduce the risk of that happening, we will protect the confidentiality of this information. Although every reasonable effort has been taken, confidentiality during Internet communication procedures cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

You may also feel some discomfort or embarrassment discussing personal matters. You may stop answering questions at any time if you are uncomfortable.

You will not receive any direct benefit from participating in this research. However, the information we obtain from you and others may help us better understand how families use smartphone apps to learn and use new skills and how mobile technology can be used to help parents and children with behavior problems.

Your participation in this research study will not cost you any money. Payment for participation is as follows:

Participant Payments	Payment Total
• Up to $20 for completion of the baseline assessment • Up to $40 for completion of the post assessment • Up to $60 for completion of the 6-month follow-up assessment	Up to $120

Participants will receive compensation for all study activities but will not be compensated for using the app. They will only be compensated for assessments completed.

NOTE: Payment for all assessments will be made in the form of a Vincent Payment Card (Mastercard). All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 26% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 74% of the expected payment."

To protect your privacy, we will not link your name to any of the information we obtain, these will be identified only by a code or case number. The information linking these case numbers with your identity will be kept separate from the research records. Online diary data will be collected through the survey system Qualtrics. Data will be stored in secure, password-protected servers and will only be accessible to Dr. Lindhiem and members of his research team. Your identity will not be revealed in any description or publications of this research. Although we will do everything in our power to protect your privacy and the confidentiality of your records, just as with the use of your medical information for health care purposes, we cannot guarantee the privacy of your research records. Authorized representatives from the University of Pittsburgh Office of Research Protections may review your data for the purpose of monitoring the conduct of this study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and child neglect.

Your information collected as a part of this research, after removal of identifiers, could be used for future research studies or distributed to another investigator for future research studies without additional informed consent." Per University of Pittsburgh policy all research records must be maintained for at least 7 years following final reporting or publication of a project. Clinically relevant research results, including individual research results, will not be disclosed to subjects. If these data are shared with other researchers, your identity will not be revealed to those researchers. In unusual cases, your research records may be released in response to an order from a court of law. An exception to confidentiality is information on child abuse and neglect that is obtained during research. If the researchers learn that your child or someone with whom he or she is involved is in serious danger or harm, they will need to inform the appropriate agencies as required by law.

There is the possibility that you may be eligible for other research studies being conducted independently of this one. You may be contacted in person or by mail by members of our research team or their associates to determine your interest in those other studies, but you are never under any obligation to participate in those.

Your participation in this research study is completely voluntary. If you do not agree to participate in this research study, this decision will have no effect on your current or future relationship with the University of Pittsburgh, UPMC or its affiliated health care providers or health care insurance providers. The decision to participate will also have no effect on the services provided by UPMC or its affiliates in any way. **If you decide you no longer wish to participate** after you have signed the consent form, you should contact Dr. Lindhiem or his research

colleagues (412-246-5901). Dropping out from this study will have no effect on your current or future relationship with the University of Pittsburgh or with UPMC or its affiliate health care and insurance operations.

Any identifiable research information recorded for, or resulting from, participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators. A description of this clinical trial will be available on *http://www.clinicaltrials.gov*, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual (412-246-5901) or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By typing my name, I agree to participate in this research study and I agree to and permit my child to participate in this research study. A copy of this consent form will be available for me to print.

Name of Adult Participant:_____

ASSENT

This research has been explained to me and I agree to participate.

Name of Child Participant: _____

PARENTAL PERMISSION

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any part of this research study at any time. Any future questions will be answered by a qualified person or by an investigator listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be answered by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. A copy of this consent form will be given to me/my child.

_____

Name of Child-Subject

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form and typing my name, I give my consent for his/her participation in this research study and provide my authorization for the use of his/her medical records

Parent's or Guardian's Name _____

Relationship to Participant (Child)_____

Date_____

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Name of Person Obtaining Consent_____

Role in Research Study_____

Date_____

VERIFICATION OF EXPLANATION

I certify that I have carefully explained the purpose and nature of this research to the child participant in age appropriate language. S/he has had an opportunity to discuss it with me in detail. I have answered all his/her questions and s/he provided affirmative agreement (i.e., assent) to participate in this research.

Name of Person Obtaining Assent_____

Date_____

If you have any additional questions or concerns about participating in this study, do not select 'I agree to participate.' Call 412-246-5901 and someone from the project staff will clarify any issues you may have.