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

NCT06012851

IRB Approved Parent and Adult Consent Form, IRB Approved Child Assent Form

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ADULT AND PARENTAL CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Mobile behavioral parent training: A micro-randomized trial

SUMMARY INFORMATION

Things you should know about this study:

- **Purpose:** The purpose of the study is to see if a mobile, positive parenting intervention developed to help parents and children with ADHD is effective.
- **Procedures**: If you choose to participate and allow your child to participate, you will be asked to complete surveys about your child and family, complete the study intervention on your phone, and agree to be audio-recorded throughout the study period. Your child will be asked to complete a survey and agree to be audio-recorded throughout the study period. There is also an option for you to complete more detailed daily journals for one week during the study.
- **Duration:** This will take about 4 weeks.
- **Risks**: The main risk or discomfort from this research is potential loss of confidentiality.
- **Benefits:** The main benefits to you and your child from this research are possible improvements in your child's behavior and your stress and family functioning.
- **Alternatives:** There are no known alternatives available to you and your child other than not taking part in this study.
- **Participation:** Taking part in this research project is voluntary.

Please carefully read the entire document before agreeing to participate.

PURPOSE OF THE STUDY

The purpose of this study is to figure out how to make effective treatments for childhood ADHD more available for families. We know that behavioral parent training interventions or positive parenting interventions are helpful for both parents and their children with ADHD. However, it can be difficult to see a behavioral therapist in person. We want to get this effective treatment to more families by delivering it within a phone application. The purpose of this study is to evaluate whether a positive parenting intervention delivered on parents' smartphones is feasible, acceptable, and helpful for families of children with ADHD. We are also interested to learn if receiving in-the-moment support via the phone application is helpful for parents when they are at home with their children. If you choose to participate in this study, you will be given access to the mobile behavioral parent training intervention phone application on your phone. You will also schedule times to be audio-recorded daily for the next 4 weeks. We will use this audio data and other passively collected data (see below) to provide brief, in the moment feedback to you through the phone application. There is also an optional addition to the study where you would

be asked to provide daily journaling about your use of the application for one week of the study for additional compensation. This research is funded by the National Institute of Mental Health (NIMH).

NUMBER OF STUDY PARTICIPANTS

If you decide to be in this study and agree to allow your child to participate in this study, you will be one of 33 families in this research study.

DURATION OF THE STUDY

You and your child's participation will last a total of about 4 weeks. In the mobile application, you will be given access to about four weeks of treatment within brief modules that are completed multiple times per week. You could complete the treatment faster or slower than the estimated weeks or you may not complete the treatment. If you do not complete the treatment, we will still contact you after about 4 weeks to see how you and your child are doing (see procedures below) and provide any compensation. Additionally, you and your child will complete assessments at the beginning of the study totaling about 2 hours. Lastly, you and your child will be audio-recorded at home for about 1 hour per day during the study period- totaling 28 hours of recording. We are using a phone application called 'Colliga Apps' to conduct this study.

PROCEDURES

To be eligible for the study, you must have access to a smartphone, and your child must meet the following criteria:

1. Meets diagnostic criteria for ADHD.
2. Is 7-12 years old.
3. Has difficulty with behavior at home during homework and academic tasks.

If you and your child participate in this study, we will ask you to do the following things:

1. Complete a clinical interview, surveys about your child's symptoms, difficulties, and academics, surveys about your family and your parenting at the beginning of the study.
2. Your child will also complete a survey before the study to see how they are feeling.
3. Your child's teacher will be asked to complete surveys about your child's symptoms, behavior, and academics.
4. Review Colliga App privacy protections and settings with staff.
5. Download the Colliga App mobile application on your smartphone and set it up for data collection. Data to be collected include:
    a. Accelerometer- tells us how fast the phone is moving so that we do not record or send notifications while you are driving.
    b. Screen time and phone pick-ups- this will help us to know how phone use relates to recorded interactions.
    c. App usage- this will help us know how far along you are in treatment and how often you use the treatment information.

6. Be audio-recorded at home during scheduled times for the duration of the study.
    a. Set times for audio recording including when your child is expected to be with you and when they complete homework.
    b. When audio-recordings are scheduled, you will be prompted to approve the recording. The recording will not start until you approve. You will also be able to mute, pause, or stop data collection at any time.
    c. Only start recordings when in a private setting. If you cannot be in a private setting or if someone lives in the home who has not consented, please distribute the Third-Party Recording Notification Handout.
    d. Data from audio recordings include:
        i. Tone, pitch, intensity, voice level
        ii. Words spoken: audio recordings will be transcribed.
7. Use the mobile phone behavioral parent training intervention.
8. Receive a phone call after the study to let us know if there were any difficulties and to coordinate compensation.

Optional:
☐ Complete daily journals about your experience with the phone application for one week (7 days) during the study. See compensation details below.

Treatment:

Mobile behavioral parent training

The mobile behavioral parent training program is a self-guided positive parenting course that includes topics most often included in in-person behavioral parent training. These topics include information about ADHD and families, catching your child being good, differential attention, managing homework time, reward systems at home, and planning ahead. The information is presented in short videos with accompanying text, infographics, brief quizzes, and review. We expect it will take about 4 weeks to complete the treatment. We will walk you through downloading the application and navigating the application today.

In addition, we will use the passive audio recordings during parent/child interactions to send **brief parenting feedback** via the phone application. For example, if the audio recording picks up on a negative tone from parent or child that is out of the ordinary, it may provide a brief suggestion to take a cool down. Similarly, if the audio recording picks up on a lot of positive, supportive words from you, the parent, the phone may provide this feedback so you are able to notice what is going well. The phone application will randomly assign you to one of three options (like flipping a coin) a few times during each audio recording.

1. A <u>suggestion for a parenting behavior</u> such as praise, differential attention, or taking a cool down.
2. <u>Parenting feedback</u> such as letting you know that 7 positive words were counted by the program in the last 10 minutes. This type of feedback can be helpful to recognize progress during treatment and to help parents notice when they might be giving less praise.
3. <u>No intervention</u>. There is a 50% chance that you will not receive a phone prompt in that moment.

These three possibilities are randomly assigned repeatedly each day, and you may receive up to 6 or 7 prompts on a given day. Additionally, you will receive reminders to open the intervention application and complete treatment.

RISKS AND/OR DISCOMFORTS

The primary risk is that you or your child's confidential information may be compromised. It is important to know that the research team has had extensive training in handling confidential information and will take every precaution to ensure the confidentiality of your information. Data collected through the phone application will be stored on a secure server with two-step log-in protection to further minimize the risk of a breach of confidentiality. Please review the attached overview of privacy protection procedures.

BENEFITS

The study has the following possible benefits to you and your child: You will receive access to treatment for your child's ADHD that has been developed based on the best available in-person psychosocial treatments for childhood ADHD. There is no guarantee that these treatments will help you or your child so there is a chance that you may receive no benefit from participating in this study. The study has the following possible benefits to society: We may learn about how to help children with ADHD and their parents when it is difficult to access in person treatment. We may also learn whether brief, in-the-moment parenting feedback is especially helpful for parents.

ALTERNATIVES

There are no known alternatives available to you or your child other than not taking part in this study. Any significant new findings developed during the course of the research which may relate to you or your child's willingness to continue participation will be provided to you.

CONFIDENTIALITY

The records of this study will be kept private and will be protected to the fullest extent provided by law. In any sort of report we might publish, we will not include any information that will make it possible to identify you. Research records will be stored securely, and only the researcher team will have access to the records. However, your records may be inspected by authorized University or other agents who will also keep the information confidential.

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.

This study involves the use of a mobile phone application. Please carefully review the application's privacy policy/terms of use to learn more about how your information on your phone can be used.

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we can't be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative or other proceedings.

There are circumstances where the Certificate doesn't protect against disclosure of your personally identifiable information:

- when the US government is inspecting or evaluating federally-funded studies
- when information must be disclosed to meet FDA requirements (only required for FDA-regulated studies)
- if you give someone written permission to receive research information or you voluntarily disclose your study information
- if the researcher reports that you threatened to harm yourself or others
- in cases of child abuse or vulnerable adult abuse reported by the researcher
- if the investigator reports cases of contagious disease to the state

Confidentiality will be intentionally broken if the study investigators learn about or suspect elder or child abuse or neglect. If we learn about serious harm to you, your child, or someone else, we will take steps to protect the person endangered even if it requires telling the authorities without your permission. If we have reason to believe that your child is being abused, we will report this to the appropriate hotline. In these instances, we would only disclose information to the extent necessary to prevent harm.

Serious adverse events (for example, hospitalization or serious injury) are unlikely. However, please report these events to study investigators as soon as you are able or during monthly phone calls. Investigators will report serious adverse events to the FIU Institutional Review Board within 24 hours of being notified.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US Law. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this website at any time.

USE OF YOUR OR YOUR CHILD'S INFORMATION

Identifiers about you and your child might be removed from the identifiable private information and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Data from this study will be submitted to the National Institute of Mental Health Database (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many National Institute of Mental Health (NIMH) studies is stored and managed. Deidentified study data means that all personal information about you and your child

(such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about mental health more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about mental health and how to help others who have problems with mental health. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you know now that you do not want your data in the NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, this is available on-line at http://nda.nih.gov.

COMPENSATION & COSTS

For the procedures above (1-8), you will receive a payment of $50 for participating in this study (not including optional one week journaling). To receive compensation, at least two-thirds of data must be successfully collected each week. In other words, out of the 7 possible hours of audio-recording each week, at least 4.5 hours needs to be successfully collected. You can receive prorated compensation in the form of $10 per week of complete data with an additional $10 at the end of the study for providing four weeks of complete (meaning two-thirds complete) data.

If you choose to participate in the optional journaling part of the study, you will receive up to an additional $70. You will receive $10 per day of completed journaling. Complete means that you provided the journal about your use of the application before 12:00am on that day.

There may be cost associated with the use of your mobile phone data depending on your data plan. Within the Colliga App phone application, you can select that data only be transferred when connect to Wi-Fi. No additional costs are expected.

RIGHT TO DECLINE OR WITHDRAW

Your participation and your child's participation in this study is voluntary. You and your child are free to participate in the study or withdraw consent at any time during the study. You and your child will not lose any benefits if you or they decide not to participate or if you or your child quits the study early. The investigator reserves the right to remove you from the study without your consent at such time that he/she feels it is in the best interest.

RESEARCHER CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues relating to this research study you may contact Dr. Brittany Merrill at the Center for Children and Families of Western New York, 4600 Main Street, Suite 101, Buffalo NY, (716) 359-5773, brmerril@fiu.edu.

IRB CONTACT INFORMATION

If you would like to talk with someone about your child's rights of being a subject in this research study or about ethical issues with this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION

If you sign this document, you give permission to the health care providers at Florida International University (FIU) Center for Children and Families and the study researchers to use or disclose (release) your child's health information that identifies your child in this research study.

What information may be used and given to others?

The health information that may be used or given to others includes your child's personal and medical information. For example:

- Past and present medical records
- Research records
- Records about your family's study visits

Who will use or receive my child's health information?

The health information listed above will be given to the study researchers. The information may also be given to the study sponsor, the Institutional Review Board (IRB) that reviewed this research, authorized FIU agents, and other federal or state agencies as necessary.

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Why will this information be used and/or given to others?

To do the research, to study the results, and to make sure that the research was done right.

Is my child's health information protected after it has been given to others?

Those persons who receive your child's health information may not be required by Federal privacy laws to protect it and may share your child's information with others without your permission, if permitted by laws governing them.

What if I decide not to give permission to use and give out my child's health information?

You do not have to sign this document, but if you do not, your child will not be able to be in this research study. If you do not sign this document, your child's right to other medical treatment will not be affected.

May I withdraw or revoke (cancel) my permission?

You may change your mind and withdraw or take back your permission at any time. When you withdraw your permission, no new health information identifying your child will be gathered after that date. Information that has already been gathered may still be used and given to others. To withdraw your permission, you must write to: Center for Children and Families of Western New York, 4600 Main Street, Suite 101, Buffalo, NY, 14226 or e-mail brmerril@fiu.edu.

Does my permission have an expiration date?

This permission does not have an expiration date.

PARTICIPANT AGREEMENT

I have read the information in this consent form and agree to allow my child to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. I understand that I will be given a copy of this form for my records.

_____ _____

Signature of Parent/Guardian Date

_____

Printed Name of Parent/ Guardian

_____

Printed Name of Child Participant

_____ _____

Signature of Person Obtaining Consent Date

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CHILD ASSENT TO PARTICIPATE IN A RESEARCH STUDY

Mobile behavioral parent training: A micro-randomized trial

WHY ARE YOU DOING THIS STUDY?

We would like for you to be in a research study we are doing. A research study is a way to learn information about something. We would like to find out more about how to help kids and families spending time together at home.

HOW MANY OTHERS WILL BE IN THIS STUDY?

If you agree to participate in this study, you will be one of about 33 children in this research study.

WHAT WILL HAPPEN IN THIS STUDY?

If you participate in this study, we will ask you to do the following things:

1. Answer some questions about how you're feeling.
2. Be audio-recorded at home for a one hour per day for about 30 days. Audio recording means voices and sounds only. We won't take pictures or record videos of you or your family.

HOW LONG WILL THE STUDY LAST?

Your participation will take about 30 minutes of your time today and require you to be audio-recorded for about one hour per day for the next month (about 30 days).

CAN ANYTHING BAD HAPPEN TO ME?

Some things may make you uncomfortable such as not wanting to be recorded. Your parent can stop the recording at any time by pressing a button on their phone.

CAN ANYTHING GOOD HAPPEN TO ME?

You might like to learn more about research from adults and from being in the study. You might start to do better at home and with homework. Also, you participating might help other families because it will help us (scientists/researchers) learn more about family relationships and how to help families.

DO I HAVE OTHER CHOICES?

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Your other option is to not take part in this study.

WILL ANYONE KNOW I AM IN THE STUDY?

The records of this study will be kept private and will be protected by the researchers. If we learn that you have been hurt or are going to be hurt, we may have to tell someone to make sure you are safe.

WILL I BE GIVEN ANYTHING FOR PARTICIPATING?

You won't be given any payment for participating. You will not need to pay for anything to participate in this study.

WHAT IF I DO NOT WANT TO DO THIS?

You do not have to be in this study if you don't want to and you can quit the study at any time. If you don't like a question, you don't have to answer it and, if you ask, your answers will not be used in the study. No one will get mad at you if you decide you don't want to participate.

WHO CAN I TALK TO ABOUT THE STUDY?

If you have any questions about the research study you may contact Dr. Brittany Merrill at the Center for Children and Families of Western New York, 4600 Main Street, Suite 101, Buffalo NY, (716) 359-5773, brmerril@fiu.edu. If you would like to talk with someone about your rights of being a participant in this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT

This research study has been explained to me and I agree to be in this study.

_____ _____

Signature of Child Participant Date

_____

Printed Name of Child Participant

_____ _____

Signature of Person Obtaining Consent Date