Mindfulness-Based Real-Time fMRI Neurofeedback for Depression

Key Elements

This research study is designed to identify how mindfulness meditation during "neurofeedback" can help decrease depression symptoms. Neurofeedback, which is completed in a Magnetic Resonance Imaging (MRI) scanner, is a non-invasive technique whereby you teach yourself to control certain brain functions. Your child's participation in this study is completely voluntary. If your child chooses to participate, there will be 4 different visits. Some of your child's visits may be conducted remotely using the telephone or HIPAA-compliant video teleconferencing. There will only be one in-person visit. The first sessions will be about 3 hours, and the second session will be about 1 hour. The third session will be about 4 hours. The fourth session will be about 1 hour. Your child will be administered clinical interviews and complete self-report surveys. During session 3, your child will complete self-report surveys, mindfulness training, and an MRI scan. In addition, we also will ask your child to install the Metricwire app on their smartphone. Metricwire will periodically send your child short survey questions to complete.

There is a potential risk that the information we collect could be lost or stolen, or that your child's information could not be kept completely private. However, we have taken many precautions to protect against this outcome, including encrypting the data and storing all electronic information on a password protected server. There also is a risk that some questions may make your child feel uncomfortable, and if so, your child does not have to answer these. Although your child is not likely to benefit directly from this study, others might benefit in the future from what we learn.

Purpose and Overview

Your child is being asked to be in a research study because you and/or your child told us in the phone screen that they may be currently having an episode of feeling very sad or depressed. We are doing this study to learn more about how neurofeedback and mindfulness meditation might improve mental health symptoms. Conducting this study with individuals with current depression will help us better understand mindfulness based real-time neurofeedback as a treatment for depression. This study is funded by the National Institute of Mental Health and the Tommy Fuss Fund and is being done at the New York State Psychiatric Institute, Columbia University Irving Medical Center and at the Northeastern University Biomedical Imaging Center. If you and your child decide to be in this study, they will be one of 90 teens participating. If your child turns 18 while taking part in this study, they will be asked to re-consent.

Voluntary

Your child's participation in this research study is voluntary. You and your child are free to withdraw from the study at any time. If your child decides not to participate or if you decide that you do not wish for your child to participate, or if he or she later decides to stop participating, they will not lose any benefits to which they are otherwise entitled. A decision not to participate or withdraw their participation will not affect their current or future treatment at the New York State Psychiatric Institute, Columbia University Irving Medical Center, or Northeastern University.

The investigators reserve the right to remove your child without your consent or the consent of your child at such time that they feel it is in the best interest of the child.

Alternative Treatments/Alternatives to Participation

Your child can choose not to participate in this study. It is not necessary to participate in this research study to

have an MRI, and the MRI done as part of this study is not the same as one done for medical purposes.

Procedures

If your child agrees to be in the study, we will ask them to do the following things:

1. Complete a total of 4 study visits. The 1st, 2nd, and 4th visits will be conducted remotely over Zoom. The 3rd visit is the in-person MRI visit, which will take place within several weeks of the initial visits and the 4th visit will take place 1 month after the in-person visit.

2. Three visits involve completing interviews and questionnaires (Session 1 = ~3 hours; Session 2 = ~1 hour; Session 4 = ~1 hour).

3. In-person MRI Visit: During the in-person MRI visit (approximately 4 hours) at either: (a) the Columbia University Zuckerman Institute, which is located around 125th Street and Broadway at the Jerome L. Greene Science Center Building on the Columbia University Campus or (b) at the Northeastern University Biomedical Imaging Center, which is located at 805 Columbus Ave, Boston, MA 02120 on the Northeastern University Campus. Your child will: (1) complete self-report questionnaires, (2) complete a brief MRI, (3) complete mindfulness training outside of the scanner, (4) re-enter the scanner for neurofeedback, and (5) complete brief post neurofeedback assessment measures.

    a. <u>MRI Scan.</u> MRI scans allow us to take pictures of your child's brain. When we are ready to take pictures of their brain, we will ask them to lie down on a table that is padded to make it more comfortable. That table can slide into the MRI machine. The MRI machine is shaped like a doughnut, with a round hole in the middle like a tunnel. Once they are lying on the table, we will slide them and the table into the MRI machine. We will give your child ear plugs to block out most of the noise, so it won't be very loud when they are inside. However, they will still be able to hear us giving them directions. When they are in the MRI machine, we will give them a rubber squeeze ball to hold in their hand. If your child squeezes this ball, they will send a signal that tells us they want to stop right away. If they squeeze the ball, we will take them out of the scanner immediately. Your child can ask to stop the scan at any time if they feel uncomfortable. The MRI machine contains a large magnet that can attract metal. So, if they have any metal on or in their body, we must know about it. Before the scan, we will ask them to take off any jewelry or metal and put it into a locker. Also, your child must let us know if they have had any surgeries or metal put in their body. If they wear a patch to take medicine, they will also have to take this off before the scan.

    b. <u>Mindfulness Training.</u> Your child will complete an approximately 45-minute mindfulness training to learn "mental noting," a technique that they will use during neurofeedback. Depending on what is most prominent in their mind at a given moment (e.g., seeing, hearing, feeling, thinking), they would label that experience. For example, if your child noticed that something they were seeing, **they** would silently label that experience "seeing." Your child will be asked to perform a short mental noting session in front of study staff in which he or she will verbalize the mental noting out loud to confirm that they understand the process.

    c. <u>MRI Neurofeedback Task.</u> After mindfulness training, we will ask your child to use mental noting in the scanner. They will receive neurofeedback of their brain in the form of a ball game, which will show them in real time how they activate their brain to achieve different states. They will do this task in the scanner for either 15 minutes or 30 minutes.

4. Pregnancy Testing (participants at the Columbia University site only). If your child is post-menarchal, we must ensure that they are not pregnant before participating in this study. Someone who works on this study will test their urine for pregnancy before MRI scanning If you or your child prefers, they can have their pregnancy test done by their own doctor or a different doctor's office. If the test says that your child is pregnant, they cannot complete the MRI that day. We will tell your child the results of this test and encourage them to discuss the results with you. If your child gives us permission, we also will share the results with you. If your child is thirteen or younger, we are required to report a positive pregnancy test to the appropriate authorities as a possible sexual assault, and we will discuss this with you. Also, we will talk to your child about where they can go to get some help. Additionally, testing urine for pregnancy may not detect a pregnancy for a week or more after conception. Therefore, a negative test does not guarantee that your child is not pregnant. Participants at the Northeastern University site are not required to take a urine pregnancy test – we will ask your child, and if they are pregnant, they cannot complete the MRI scan that day.

5. Metricwire. Your child will download the Metricwire app onto their smartphone and complete a short survey sent to their phone. They will receive this survey multiple times for a one-week period following the baseline assessment, and a one-week period following the MRI scan, and one-week prior to your 1-month follow-up assessment. They will receive 4 surveys per day (7am-10pm); each survey will require 2-3 minutes. Survey prompts will focus on rumination, mindfulness practice, feelings of sadness, and feelings of anxiety.

6. The research team at Columbia University Irving Medical Center and New York State Psychiatric Institute is working in collaboration with Dr. Susan Whitfield-Gabrieli, Principal Investigator of the Northeastern study site. Dr. Whitfield-Gabrieli and her research staff will assist with data collection and analysis.

7. If your child participates, we may contact them in the future about their interest in other studies.

Audio and Video Recordings

Clinical interviews at each assessment may be audiotaped. The audio recordings are needed to ensure reliability of the data collected. They will be reviewed by trained study staff and may be retained for 10 years. If you or your child decides that you no longer would like to participate in the study and would like the recording to be erased, let us know and we will delete the file.

Risks and Inconveniences

The following risks may be associated with your child's participation in this study:

1. During this study, your child will be asked some personal questions, which may cause them to feel different emotions or make them uncomfortable. They are free to skip any questions or to stop the experiment if the questions are upsetting.
2. If your child reports they may hurt themselves, study staff will work with you to get clinical care, which may include emergency services and/or obtaining clinical resources within the community.
3. If your child's participation in this study makes their symptoms worse or makes them feel very upset, a study staff member will stop their participation in the study, and you will be contacted. If a study staff member decides to stop their participation, she or he will explain to you and your child why that decision was made.

4. The information collected over video or phone call, or in-person will be transmitted to servers for storage. There is always the possibility that your child's information could become lost or stolen, or confidentiality could be breached. There is always a risk that your child's information could be hacked. The "Confidentiality" section below explains the steps that we will take to ensure your child's information is kept safe and secure, however, there is a potential risk of identification even with the best practices in place.
5. If at any time your child feels distressed or worse during the study, you should contact your child's doctor or therapist. If you do not have one, please contact the Principal Investigator who will help you find clinical services for your child.
6. Although there have been no reports of any harmful long-term effects caused by MRI magnets of the same or even higher strength, the long-term effects of being placed in a magnet of this strength (3 Tesla) are unknown. We are not aware of any potentially dangerous interactions or hazards associated with the MRI scan except for pacemakers, some types of metallic implants, and medication patches.
7. The MRI scan is not painful, but some people don't like having to lie still inside of the machine. Sometimes, people say that during the MRI scan, they feel a "tingling" or "twitching" feeling. Sometimes, some people feel nervous when they are inside the scanner because the space is small. If your child wants to stop the scan at any time for any reason, they can squeeze the ball in their hand, and we will stop the scan immediately and remove them from the machine. If during your child's participation in the study they feel worse or upset for any reason, a study staff member will stop their participation. If a study staff member decides to stop their participation, they will explain why.
8. Your child may get tired or frustrated while completing the tasks. If they want to stop doing these tasks, just let us know and we will stop.

Benefits

Your child will not receive any direct benefits from participation in this study. This study doesn't provide or replace treatment for depression or any other psychiatric condition. In a broader sense, they will be contributing to the advancement of scientific research to help understand how neurofeedback and mindfulness meditation might improve mental health symptoms.

MRI Scan Results

While MRI scans are sometimes done for clinical purposes, the kind of MRI scan your child will have as part of this study is for research purposes only. This means that the scans are not designed to provide clinical information that might be helpful to your child or their doctor and they may not show problems that would normally be found in an MRI ordered to evaluate a specific medical problem. It is likely that the MRI scan will not have the quality of those done for clinical purposes.

Within a month of the MRI, your child's scan will be read by a neuroradiologist and information about the scan will be shared with you and your child or a physician whom you may designate.

Confidentiality

We will use the information we collect only for scientific, education, or instructional purposes. In any sort of report we might publish, we will not include any information that will make it possible to identify your child as a participant in this study.

The records of this study will be kept private and will be protected to the fullest extent provided by law. We will keep the records of this study confidential in several ways:

1. Research records will be stored securely and only the researcher team will have access to the records.
2. All of your child's study data will be de-identified by using a unique code that is linked to their name, so name and other identifying information (i.e., birthday, address) will not be directly connected to their study materials except on secure databases that only the study team will be able to see. Additionally, de-identified data may be used in future research studies.
3. Assessments that your child completes over video call will be completed using a secured video service (e.g., WebEx, Zoom).
4. Your child's study data will not be shared with individuals outside of the research team. However, records may be reviewed for audit purposes by authorized University personnel or other agents who will also need to adhere to the same rules of confidentiality. Records will be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits). Additionally, de-identified study information may be used in future research studies.

There are limits to confidentiality, specifically when it comes to keeping your child and others safe:

1. If we think that your child is at risk of hurting themselves or others, we will tell their legal guardian(s) so that you can help your child seek immediate care. If their symptoms become more intense, we will stop the study and contact their legal guardian(s). Research staff may not be able to discuss this with your child first. This information would be collected during the clinical assessments.
2. There are times when federal or state law requires that we release your child's records to them. If we learn about serious harm to your child or someone else, we will take steps to protect the person endangered even if it requires telling the authorities without your or your child's permission.
3. Suspected or known neglect or sexual or physical abuse of a child or threatened violence to self or others, will be reported to the appropriate authorities. This includes cases of a positive pregnancy test for youth thirteen years of age or younger.

A clinician on the research team will provide information regarding the results of your child's clinical assessment to you and your child upon request.

Certificate of Confidentiality: This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify your child in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats from you child of harming themselves or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your child's information from being used for other research if allowed by federal regulations.

Researchers may release information about your child when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your child's involvement in this research. It also does not prevent you from having access to your child's own information.

National Institute of Mental Health Data Archive (NDA): Data from this study will be submitted to the NDA. NDA is a data repository run by the National Institute of Mental Health that allows researchers studying mental illness to collect and share de-identified information with each other. A data repository is a large database where information from many studies is stored and managed. De-identified information means that all personal information about research participants, such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

When uploading data to the NDA, your child will be assigned a unique code called a GUID (Global Unique Identifier), which will be submitted to the National Institutes of Health database. Your child's study data will be linked to this GUID, and not to any identifiable information (e.g., name, birthday). This process ensures that all data uploaded to the NDA is de-identified. Through this GUID, your child's study data will be linked to their data from any studies in which they have previously participated, as well as to future studies in which they may participate. Once data is uploaded to the NDA, it cannot be taken back. We affirm that outside researchers may not contact you because of information that has been shared to the NDA. By consenting to participate in this research study, you are permitting us to create a GUID for your child and upload their data to the NDA.

Study Compensation

Clinical Assessments

Your child will receive a payment of $50 for each of the two initial visits, for a total of $100. They will receive a payment of $50 for the 1-month follow-up assessment.

MRI Assessment

Your child will receive a payment of $150 for the MRI assessments. They will also receive $50 for the mindfulness training as well as brief questionnaires before and after the MRI scans. If the scan is stopped early, your child will still receive the entire payment for the MRI portion of this study. Your child will also receive $50 for transportation-related expenses.

Phone Surveys

For one week after your child's baseline assessment, one week after their MRI assessment, and one week before their 1-month follow-up assessment, they will receive surveys every day. For completing each survey, they will receive $1, for up to $28 per one-week survey period. In total, they may earn up to $84.

Total

In total, your child may receive up to $484 for your participation. At the New York-based site, all payments will be given to them on a "ClinCard." "ClinCards" are types of debit cards that will be filled with the payment following each assessment. At the Boston-based site, all payments will be provided by check and a W-2 will be collected.

If your child earns $600 or more for participating in research studies, we are required by law to report your child's earnings to the IRS. Therefore, your child's Social Security Number and amount earned will be reported, and your child will receive the appropriate IRS form at the end of the year in which they were paid. Please note that

payment for this study may affect your child's eligibility for Medicaid and other city and state support services. No information about which study your child participated in will be provided to the IRS.

In Case of Injury

Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research-related injuries.

If you believe that you have sustained an injury as a result of participating in a research study, you may contact the principal investigators to review the matter and to identify medical resources that may be available to you: (a) Dr. Randy P. Auerbach (NYSPI or Columbia University; 646-774-5745; rpa2009@cumc.columbia.edu or (b) Dr. Susan Whitfield-Gabrieli (Northeastern University; s.whitfield-gabrieli@northeastern.edu; 617-373-4793).

Future Studies

Participants may be contacted about their interest in future studies. The sole purpose of this initial contact would be to determine your interest and would not impact your participation in the current study in any way.

Questions

If you have any questions about the purpose, procedures, or any other issues relating to this research study from the New York-based site you may contact Dr. Randy Auerbach (NYSPI/CUIMC) at (646) 774-5745 or rpa2009@cumc.columbia.edu

If you have any questions about this research study from the Boston-based site, you may contact Dr. Susan Whitfield-Gabrieli (Northeastern University) at (617) 373-4793 or s.whitfield-gabrieli@northeastern.edu.

At the New York-based site, if you have any questions about your child's rights as a research participant, want to give feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a group of people that protects the rights of participants in research studies). You may call the NYSPI IRB Office at (646) 774-7155 during regular office hours. At the Boston-based site, you may contact the Northeastern University Institutional Review Board by emailing IRBReview@northeastern.edu.

Documentation of Parental Consent

I give my consent for my child to attend the MRI scan unaccompanied by a parent/guardian. I understand that my child will be accompanied by study staff to the MRI once they have arrived at the scanning facility, and they will complete an MRI screening form: ____ Yes ____ No

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above. I understand that I will receive a copy of this parental permission form.

Print name: _____

Signed: _____

Date: _____

I have discussed the proposed research with the participant's parent/legal guardian including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant and their parent/legal guardian has had an opportunity to ask questions and in my opinion is capable of freely consenting to have their child participate in this research.

Print name: _____
Person Designated to Obtain Consent

Signed: _____

Date: _____