Mindfulness-Based Real-Time fMRI Neurofeedback for Depression

Key Elements

The current 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 participation in this study is completely voluntary. If you choose to participate, there will be 4 different visits. Some of your visits may be conducted remotely using the telephone or HIPAA-compliant video teleconferencing. There will only be one in-person visit. The first session 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. You will be administered clinical interviews and complete self-report surveys. During session 3, you will complete self-report surveys, mindfulness training, and an MRI scan. In addition, we also will ask you to install the Metricwire application on your smartphone. Metricwire will periodically send you short survey questions to complete.

There is a potential risk that the information we collect could be lost or stolen, or that your 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 you feel uncomfortable, and if so, you do not have to answer these. Although you aren't likely to benefit directly from this study, others might benefit in the future from what we learn.

Purpose and Overview

You are being asked to be in a research study because you told us in the phone screen that you may be currently in 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 decide to be in this study, you will be one of 90 teens participating.

Voluntary

Being in this research study is up to you. You can decide not to be in it. If you decide to be in it now, you can change your mind and drop out later. If at any point you want to drop out, you should tell us. We will make sure that you stop the study safely. We also will talk to you about follow-up care if you need it. Your decision will not change the care you get at New York State Psychiatric Institute, Columbia University Irving Medical Center or at Northeastern University now or in the future. There will be no penalty, and you will not lose any benefits.

It is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We also will help arrange other care for you if you need it.

Alternative Treatments/Alternatives to Participation

You 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 you agree to be in the study, we will ask you 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 your 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. You 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. MRI Scan. MRI scans allow us to take pictures of your brain. When we are ready to take pictures of your brain, we will ask you 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 you are lying on the table, we will slide you and the table into the MRI machine. We will give you ear plugs to block out most of the noise, so it won't be very loud when you are inside. However, you will still be able to hear us giving you directions. When you are in the MRI machine, we will give you a rubber squeeze ball to hold in your hand. If you squeeze this ball, you will send a signal that tells us you want to stop right away. If you squeeze the ball, we will take you out of the scanner immediately. You can ask to stop the scan at any time if you feel uncomfortable. The MRI machine contains a large magnet that can attract metal. So, if you have any metal on or in your body, we must know about it. Before the scan, we will ask you to take off any jewelry or metal and put it into a locker. Also, you must let us know if you have had any surgeries or metal put in your body. If you wear a patch to take medicine, you will also have to take this off before the scan.
    b. Mindfulness Training. You will complete an approximately 45-minute mindfulness training to learn "mental noting," a technique that you will use during neurofeedback. Depending on what is most prominent in your mind at a given moment (e.g., seeing, hearing, feeling, thinking), you would label that experience. For example, if you noticed that something you were seeing, you would silently label that experience "seeing." You will be asked to perform a short mental noting session in front of study staff in which they will verbalize the mental noting out loud to confirm that they understand the process.
    c. MRI Neurofeedback Task. After mindfulness training, we will ask you to use mental noting in the scanner. You will receive neurofeedback of your brain in the form of a ball game, which will show you in real time how you activate your brain to achieve different states. You will do this task in the scanner for either 15 minutes or 30 minutes.
4. Pregnancy Testing (participants at Columbia University site only). If you are post-menarchal, we must ensure that you are not pregnant before participating in this study. Someone who works on this study will test your urine for pregnancy before MRI scanning. If you prefer, you can have your pregnancy test done by your own doctor or a different doctor's office. If the test says that you are pregnant, you cannot complete the MRI that day. Also, we can talk to you about where you 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 you are not pregnant. Participants at the Northeastern University site are not required to take a urine pregnancy test – we will ask you and if you are pregnant, you cannot complete the MRI scan that day.
5. Metricwire. You will download the Metricwire app onto your smartphone and complete a short survey sent to your phone. You 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. You 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 you participate, we may contact you in the future about your interest in other studies.

Audio 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 decide 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 related to participating in this study:

1. During this study, you will be asked some personal questions, which may make you feel different emotions or make you uncomfortable. You are free to skip any questions or to stop if the questions are upsetting.
2. If you report that you may hurt yourself, 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 being in this study makes your symptoms worse or makes you feel very upset, a study staff member will stop your participation. Your emergency contact may be contacted. If a study staff member decides to stop your participation, they will explain why that decision was made. If you are receiving treatment during your time participating in this study, you should contact your treatment provider (for example, your therapist) if you ever need help.
4. It's possible that your information could be lost or stolen, or that your information could not be kept completely private. The information collected over video or phone call, or in-person will be transmitted to servers for storage. There is always a risk that your information could be hacked. The "Confidentiality" section below explains the steps that we will take to ensure your 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 you feel distressed or worse during the study, you should contact your doctor or therapist. If you do not have one, please contact the Principal Investigator who will help you find clinical services.
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 you want to stop the scan at any time for any reason, just squeeze the ball in your hand and we will stop the scan and take you out of the machine. If during your participation in the study you feel worse or upset for any reason, a study staff member will stop your participation. If a study staff member decides to stop your participation, they will explain why.
8. You may get tired or frustrated while completing the tasks. If you want to stop doing these tasks, just let us know and we will stop.

Benefits

You will not directly benefit from taking part in this research. This study does not provide or replace treatment for depression or any other mental health condition. In the future, others may benefit from what we learn in this study. In a broader sense, you 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 you 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 you or your 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 scan will be read by a neuroradiologist, a doctor trained to read MRI scans, and information about the scan will be shared with you or a doctor whom you may choose.

Confidentiality

We will use the information we collect only for scientific, educational, or instructional reasons. In any sort of report we publish, we will not include information that will make it possible to identify you 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 safe in several ways:

1. Research records will be stored securely, and only the research team will have access to the records.
2. All of your study data (information collected) will be de-identified by using a unique code that is linked to your name, so name and other information that could be used to identify you (i.e., birthday, address) won't be directly connected to your study materials except in secure databases that only the study team will be able to see.
3. Assessments that you complete over video call will be completed using a secured video service (e.g., WebEx, Zoom).
4. Your identifiable study data won't be shared with people outside of the research team. However, records may be reviewed by authorized University workers or other people who will also follow the same rules of confidentiality. Records will be available to research staff, and to Federal, State and Institutional regulatory workers (people who may review records as part of examining the way the study is being run). Additionally, de-identified study information may be used in future research studies.

There are limits to confidentiality (keeping information private), especially when it comes to keeping you and others safe:

1. If we think that you are at risk for hurting yourself or others, or if your symptoms become worse or more intense, we will stop the study and may contact your emergency contact(s) so that they can help you get immediate care. We may also contact the appropriate authorities to protect the person in danger. Research staff may not be able to talk to you about this first. This information would be collected during the clinical assessments.
2. There are times when federal or state law requires that we release your records. If we learn about serious harm to you or someone else, we will take steps to protect the person in danger even if it requires telling the authorities without your permission.
3. Suspected or known neglect or sexual or physical abuse of a child, or the threat of violence to self or others**,** will be reported to the appropriate authorities.

A clinician on the research team will provide information regarding the results of your clinical assessment 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 you 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 to harm yourself 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 information from being used for other research if allowed by federal regulations.

Researchers may release information about you 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 involvement in this research. It also does not prevent you from having access to your 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, you will be assigned a unique code called a GUID (Global Unique Identifier), which will be submitted to the National Institutes of Health database. Your 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 study data will be linked to your data from any studies in which you have previously participated, as well as to future studies in which you 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 you and upload your data to the NDA.

Study Compensation

Clinical Assessments. You will receive a payment of $50 for each of the two initial visits, for a total of $100. You will receive a payment of $50 for the 1-month follow-up assessment.

MRI Assessment. You will receive a payment of $150 for the MRI assessments. You 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, you will still receive the entire payment for the MRI portion of this study. You will also receive $50 for transportation-related expenses.

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

Total. In total, you may receive up to $484 for your participation. At the New-York based site, all payments will be given to you 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 you earn $600 or more for participating in research studies, we are required by law to report your earnings to the IRS. Therefore, your Social Security Number and amount earned will be reported, and you will receive the appropriate IRS form at the end of the year in which you were paid. Please note that payment for this study may affect your eligibility for Medicaid and other city and state support services. No information about which study you 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 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 Consent

I voluntarily agree to participate in the research study described above. I understand that I will receive a copy of this consent form.

Print name: _____

Signed: _____ *Date:* _____

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

Print name: _____
Person Designated to Obtain Consent

Signed: _____ *Date:* _____