Mindfulness-Based Real-Time fMRI Neurofeedback for Depression

Key Elements

The study tries to find out how mindfulness during "neurofeedback" can help lower sadness. Neurofeedback, which is done in a Magnetic Resonance Imaging (MRI) scanner, is a method where you teach yourself to control certain brain activities. Your participation is up to you. If you choose to participate, there will be 4 different visits. Some of your visits may be done using the telephone or by video calls. 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 complete clinical interviews and questionnaires, which will ask about how you've been feeling. During session 3, you will complete self-report surveys, mindfulness training, and an MRI scan. In addition, we also will ask you to install an app on your smartphone, and we will send you short questions to answer at different times in the study.

There is a 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 steps to keep this from happening, including making sure all data files are saved on a password protected computer. Also, some questions may make you feel uncomfortable, and if so, you do not have to answer these. You are not likely to benefit directly from this study, but others might benefit in the future from what we learn.

Why is this study being done?

You are being asked to be in this study because you told us in the phone screen that you may be having a tough time with feeling sad or down right now. We are doing this study to learn more about how neurofeedback and mindfulness might help people feel better. Doing this study with teens with depression will help us better understand neurofeedback and mindfulness as a potential treatment.

If you decide to be in this study, you will be one of 90 teens participating. 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.

Do I have to be in the study?

No, you can just say no. That will be fine. Being in this 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 so we can make sure that you stop the study safely.

We may ask you to drop out of the study before you finish it. If this happens, we'll tell you why. We'll also help you get care for you if you need it.

You do not have 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 your doctor would ask you to do.

What will happen to me if I'm in the study?

If you are in the study, we'll ask you to do the following things:

1. Complete a total of 4 study visits. The 1st, 2nd, and 4th visits will be conducted over a Zoom video call. The 3rd visit is the in-person MRI visit, which will take place within several weeks of your first visits. The 4th visit will take place 1 month after the in-person visit.
2. Three visits involve completing interviews and questionnaires. (Session 1 takes about 3 hours; Session 2 takes about 1 hour; Session 4 takes about 1 hour).
3. In-person MRI Visit: During the in-person MRI visit (about 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 questionnaires about how you have been feeling, (2) complete a short MRI where you just lie still, (3) complete mindfulness training outside of the scanner, (4) go back into the scanner for neurofeedback, and (5) complete short surveys after neurofeedback. You may only attend the in-person visit without a parent/guardian if your parent/guardian gives their permission for you to do so on the parental permission form. If your parent/guardian does not give their permission for you to attend the scan without a parent/guardian present, your parent/guardian must come with you to the in-person visit.
    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, and you will 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, that will tell us that you want to stop right away. If you squeeze the ball, we will take you out of the scanner right away. 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 method that you will use during neurofeedback. Depending on what you are experiencing 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 do a short mental noting session in front of study staff. Study staff may give more instructions to make sure that the mental noting is done correctly.
    c. MRI Neurofeedback Task. After mindfulness training, we will ask you to use mental noting in the MRI scanner. You will receive neurofeedback of your brain in the form of a ball game, which will show you how you change activity in your brain as these changes are happening. 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 a girl and have had your first period, the doctors who work on this study want to be careful that you are not pregnant before MRI scanning. Someone who works on this study will test your urine for pregnancy before the MRI scan. 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. We will tell you the results of this test and encourage you to discuss them with a parent/guardian. If you give us permission, we will also share the results with your parent. If you are thirteen or younger, we are required to report a positive pregnancy test to the appropriate authorities as a possible sexual assault so we must discuss this with your

parent. Also, we can talk to you and your parents 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 someone becomes pregnant. 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 to complete a short survey sent to your phone. You'll receive surveys for a one-week period after the first assessment, and a one-week period after the MRI scan, and one-week before your 1-month follow-up assessment. You will receive 4 surveys per day (7am-10pm); each survey will take about 2-3 minutes to complete. Questions will be about how you think, mindfulness practice, sadness, and 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.
7. If you take part in this study, we may contact you in the future about your interest in other studies.

What will be recorded?

Clinical interviews at each assessment may be audiotaped. The audio recordings are needed to make sure the data collected is good. They will be listened to by trained study staff and may be kept 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.

Will anything bad happen to me?

These risks may be related to being in the study:

1. You will be asked some personal questions, which may make you feel different emotions or make you uncomfortable. You can skip any questions or to stop at any time you feel this way.
2. If you report that you may hurt yourself, study staff will work with you and your guardian to get clinical care, which may include emergency services and/or getting clinical resources within the community.
3. If during the study you feel worse or upset for any reason, a study staff member will stop your participation. Your legal guardian will be contacted. If a study staff member decides to stop you from participating, they will explain why. If you are receiving treatment during your time in this study, you and your legal guardian should talk to 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 moved to our computers for storage. The "Confidentiality" section below explains the steps that we will take to make sure your information is kept safe and secure. But, there is this possible risk even with the best practices in place.
5. If at any time you feel very upset or worse during the study, you should talk to 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 dangerous 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 do not know of any potentially dangers 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. 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 doing the tasks. If you want to stop doing these tasks, just let us know and we will stop.

Can this study help me?

Being in this study won't directly help you.

This study doesn't replace treatment for problems with depression or any other mental health condition. If you are feeling worse or have an urgent need for help, you should talk to your therapist or physician, or if you need to, go to the nearest emergency room.

In the future, others may benefit from what we learn in this study.

Will I find out what the scan says?

Although MRI scans are sometimes done for clinical purposes, the kind of MRI scan you will have as part of this study is only for research. This means that the scans will not give clinical information that might be helpful to you or your doctor. They may not show problems that would normally be found in an MRI a doctor would ask you to do. It is likely that the MRI scan will not be as good as 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.

Will people know that I am in the study?

We will not tell anyone that you are in this study without you saying that it is okay. The researchers and your parents, will, of course, know.

We'll keep your information safe in these ways:

1. Information will be stored securely. Only the research team will be able to see it.
2. All of your study information will be labeled with unique code and not your name, except on 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 private, secured video service.
4. Your information won't be shared with people outside of the research team. However, records may be looked at by authorized University workers or other people who will also follow the same rules of keeping your information safe and private. Records will be available to research staff, and to Federal, State, and Institutional regulatory workers (people who may look at records to learn about the way the study is being run). Additionally, study information that cannot be connected to you may be used in future research studies.

There are limits to how we are able to keep 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, we'll tell your legal guardian(s) so that they can help you get help right away. If you start feeling worse, we'll stop the study and contact your legal guardian(s). 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'll 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. This includes cases of a positive pregnancy test for youth thirteen years of age or younger.

Finally, a clinician on the research team will give you and your parent/legal guardian the results of your clinical assessment if you ask for this. Additionally, samples collected for pregnancy testing will not be used for commercial profit. This research does not involve any form of gene testing.

Certificate of Confidentiality: This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot give out or use information, documents, or samples that may show who you are in any action or suit unless you say it is okay. They also cannot give 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, which requires someone to go to court.

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 diseases that can be passed between people, 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 give out information about you when you say it is okay. For example, you may give them permission to give information to insurers, doctors or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from choosing to share information about your participation in this research. It also does not stop you from being able to see 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.

Will I get anything if I decide to be in the study?

Assessments. You will get a payment of $50 for the first assessment and $50 for the second assessment. You will also get $50 for the 1-month follow-up assessment.

MRI Assessment. You will get a payment of $150 for the MRI assessments. You will also receive $50 for the mindfulness training as well as short questionnaires before and after the MRI scans. If the scan is stopped early, you will still receive the entire payment for the MRI part of this study. You will also receive $50 for transportation-related expenses.

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

Total. In total, you may get up to $484 for your participation. For participants 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 after each assessment. For participants at the Boston-based site, all payments will be provided by check and a W-2 will be collected.

If you get $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 about 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).

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.

Future Studies

Participants may be contacted about their interest in future studies. The purpose of this first contact would be to see if you are interested and would not change your participation in the current study in any way.

Documentation of Assent

I voluntarily agree to participate in the research study described above. I understand that I will receive a copy of this assent 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:* _____