

UNIVERSITY OF CALIFORNIA SAN FRANCISCO CONSENT TO PARTICIPATE IN A RESEARCH STUDY

For 18-year-old participants
And Parents/Guardians of participants 14-17 years old

Study Title: Neural mechanisms of meditation training in healthy and depressed adolescents: an MRI connectome study R61-R33

When reading this form, please note that the words “you” and “your” refer to the person in the study rather than to a parent/guardian who might sign this form on behalf of the person in the study.

This is a research study to investigate brain changes potentially induced by mindfulness meditation-based training. The study is being led by investigators from the Departments of Radiology and Psychiatry at the University of California, San Francisco (UCSF): Olga Tymofiyeva, Ph.D. and Tony Yang, M.D., Ph.D. The study researchers will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers. You should only agree to participate in the study if you really want to.

Why is this study being done?

The purpose of this study is to see whether a 12-session group program can help young people improve their ability to regulate emotions and whether we can measure potential brain changes that are associated with this improved ability. The study investigators hope such changes can be measured but they do not know it for sure. That is why they are doing the study.

The study is being paid for by a grant from National Institutes of Health (NIH).

How many people will take part in this study?

About 100 young people aged 14-18 years old will take part in the study.

What will happen if I take part in this research study?

If you agree to participate, the following procedures will occur:

First, you will need to have the following “pre-screening” to find out if you can participate in the study:

Phone pre-screening: You will speak to a study staff member to learn about the study and see if you might be interested and eligible to participate. You will be asked questions about your age, your medical and mental health history, and metal implants to see if you can have a brain scan (an MRI). If it appears that you are eligible to participate, you wish to participate you will be invited to schedule the first visit.

First visit: If you schedule the first visit, you will be asked to go to the UCSF’s Mission Bay campus for the MRI scan and attention test. This visit will take approximately 2 hours. At this visit, a study staff member will first review this consent form with you and you will sign this form. The researcher will then go over some questions with you to verify that you are eligible to participate in the study.

1. Questionnaires: You will then be asked to fill out several questionnaires on a computer. They will include some personality, mood, and behavior questionnaires. It will take about 20 minutes. Study staff will be nearby and available to help if you have questions or need help.

2. Magnetic resonance Imaging (MRI) of the head: In this study, your brain will be scanned twice—at your first visit and about 3 months later. Magnetic Resonance Imaging (MRI) will be done on your head. This will involve your lying quietly inside the center of a large, doughnut shaped magnet for approximately 1 hour. Your head will be placed in a special, helmet-like “head-holder” to help you keep your head still. You will be made as comfortable as possible by padding your neck, shoulders, head, and knees. During the scan, the machine takes pictures of your brain. You might be asked to watch a video and do some simple tasks while in the MRI scanner. You can stop the MRI at any time.

Randomization: After these assessments are completed you will be randomly assigned to one of two groups. You will have an equal chance of being assigned to either group. One group will begin with the 12-session training over the following 12 weeks (training group). The other group will wait for 12 weeks without undergoing the training (control group). The participants in the control group will get a chance to do the training after the second MRI has been performed, but this training will be done as part of your regular care, not as part of the study.

Training phase (training group only): If you are assigned to the training group, you will participate in a 12-session training program as follows:

a. **Group classes:** You will participate in the training classes for 12 sessions. In the class, you will learn and practice skills to help you feel calm and relaxed and to regulate your emotions and your attention. You will also learn and talk about stress, as well as what is most important to you. You will learn how the brain functions and how you can increase your sense of well-being. You may do some easy yoga poses. You will have one 90-minute class per week over 12 weeks. There will be about 10-15 other young people in the class with you. Study staff will go over the exact dates of the classes with you. It is understandable that you may have a schedule conflict for one or two of the classes, but you should only participate if you can attend nearly all of the classes (**at least 9 out of 12**).

b. **Audiotaping:** An audio recorder will be placed in front of the class, near the teacher. You will have the option to stop the recorder if you do not want what you say to be recorded.

c. **Home practice:** You will be asked to practice some of the skills that you learn in the class at home for about 10-15 minutes every day. You will receive recorded instructions, which you can download to a phone or computer.

d. **Questionnaires:** Each week of the classes, you will complete a short questionnaire about your opinions about the classes and which parts were most helpful. You will also complete some short questionnaires about how you are doing and feeling. If there have been significant unfavorable changes in your mental or physical health since previous class, our study staff will follow up with you about those changes over the phone.

Waiting period (control group only): If you are assigned to the control group, you will have a 12 week waiting period where you will not complete any study procedures.

Second MRI: After the training (or waiting period if you are in the control group), you will be asked to fill out questionnaires and have an MRI scan again. The procedure will be the same as at the first visit.

Time commitment and Location: You will spend about 36 hours on the training over 3 months if you are assigned to the training group. The classes will take place over Zoom.

Brain scan visits (two times 2 hours) will take place at the UCSF Mission Bay campus.

How long will I be in the study?

You will be in the study for approximately 4 months.

Can I stop being in the study?

Yes. You can decide to stop at any time, for any reason. Just tell the study researcher or staff person right away. Also, the study researchers may stop you from continuing the study he/she if they think it is best for you to stop, or if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

In-class practices and home assignments (training group only): You could experience restlessness or some difficult emotions, like sadness or anger, during some of the class activities or home assignments. If this happens, you can stop the activity and speak to the class leader or study staff by phone or at the next class. The class leader will talk about how to handle difficult emotions that come up during home assignments at the first class, and throughout the course as needed.

In case any participant endorses hurting himself/herself or others, one of the clinicians on our research team would have a private interview with the participant, we would contact his/her personal clinician if contact information had been released to us, and the participant and parent(s)/guardian(s) would have to make a follow-up appointment with their personal clinician (physician or mental health professional).

Home practice (training group only): You may find it difficult to find time to practice the skills you learn in the class at home.

Audio recording (training group only): Your voice may be recorded during class. Some possible risks of this may be - feelings of discomfort, possible risks of privacy (very low risk), feelings of self-consciousness. If you do not wish for your voice to be recorded during class, you can ask to have the recorder stopped when you are speaking.

Brain MRI (both groups):

- Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination, which could in the process possibly harm you. Precautions will be taken to prevent this from happening; loose metal objects, like pocket knives or key chains, are not allowed in the MRI room. You may be asked to change into a hospital gown (pants + a robe) to make sure no metal that might be in your regular clothes is brought into the MRI room. If you have a piece of metal in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have an MRI.
- Having an MRI may mean some added discomfort for you. In particular, you may feel uncomfortable, tired or nervous from lying down in a small space during the MRI. You may be bothered by the loud banging noise that the machine makes. Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear ear plugs. At times during the test, you may be asked to not swallow for a while, which can be uncomfortable.
- There are no known effects from MRI. Some people feel anxious. It is possible that while in the scanner you may experience a headache or nausea or a metallic taste in your mouth. The rapid switching on and off of the magnetic field can cause peripheral nerve stimulation, usually reported as a twitching or painful

feeling. If this happens to you, you can stop the MRI at any time.

- If you have any metal in your body, you should tell the researchers about it. MRI may not be appropriate under some of these circumstances: A cardiac pacemaker; metal fragments in eyes, skin, body; heart valve replacement, brain clips, venous umbrella; being a sheet-metal worker or welder; weakness in brain arteries (aneurism), intercranial bypass, renal, aortic clips; implanted devices such as middle ear, eye, joint or penile implants, joint replacements; hearing aid, nerve stimulator, insulin pump; I.U.D.; being pregnant, suspect being pregnant or trying to become pregnant; shunts/stents, metal mesh/coil implants; metal plate/pin/screws/wires, or any other metal implants; permanent eyeliner/eyebrows; dental braces or retainer; body piercing that cannot be removed.
- Females only: Risks to an unborn baby: If you are female and sexually active, you must use a study-approved birth control method (birth control implant, birth control shot, birth control patch, birth control pill, condom, internal condom, birth control sponge, cervical cap, spermicide, fertility awareness [calendar method], outercourse, abstinence) and agree not to attempt to become pregnant during the study. It is important that you contact the researcher(s) Olga Tymofiyeva at 415-283-5406 or Tony Yang 415-476-7797, if you think you may be pregnant.
- Incidental findings: The MRI scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators and UCSF are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion they may notice a finding on an MRI scan that seems abnormal. If a study physician believes the finding merits further investigation, he or she will contact you to inform of the finding. If you wish, this information will also be provided to your primary care physician. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators and UCSF are not responsible for any examination or treatment that you undertake based on these findings.

Are there benefits to taking part in the study?

If you are assigned to the training group, the classes may help you improve your ability to regulate your emotions. If you are assigned to the control group, there is no direct benefit to you of being in the study; however you will be given the option to take part in the training once your participation in the study is over. The questionnaires and MRI scans may help health professionals better understand how brain changes and how to develop efficient training and treatment programs. Your anonymized MRI data may be used for comparison in several other UCSF studies, contributing to the health professionals' understanding of brain development.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers that Drs. Olga Tymofiyeva and Tony Yang are collaborating with so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Research results: There may be times when researchers using your information may learn new information. The researchers may or may not share these results with you, depending on a number of factors.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include: ***The University of California, The National Institutes of Health.***

For training group participants: The researchers will ask you and the other participants to use only first names during the classes. They will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private.

Research records will be kept as confidentially as possible. All data collected will be coded with a study number (no names will be used). Every reasonable effort will be made to keep your records confidential. All data will be stored in a locked file cabinet only accessible to the study team, and all electronic data will be stored on password-protected computers.

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all procedures and trainings associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?

Training group participants: You will receive up to \$220 in gift cards for completion of the study (\$120 for the two MRIs and an additional bonus of \$100 if you attend at least 9 out of 12 training classes).

Control group participants: You will receive up to \$120 in gift cards for completion of the study (\$120 for the two MRIs).

What if I am injured because I took part in the study?

It is important that you tell the researcher(s) Olga Tymofiyeva at 415-283-5406 or Tony Yang 415-476-7797, if you feel that you have been injured because of taking part in this study. You can also tell the study staff or teacher in person.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415-476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. If you do not want to be in this study, just tell us.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the researcher(s) Olga Tymofiyeva at 415-283-5406 or Tony Yang 415-476-7797. You can also talk to the class leaders. You can ask your questions now or later, any time you like.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Institutional Review Board at 415-476-1814.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You may be told about other research. We may use contact information you give us for us or other UCSF researchers to contact you about other research. Do you agree to give information so that we may find you for later research?

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you do not want to be in this study, please let us know.

If you wish to participate in this study, you should sign below.

Participant name (print)

Date Person Obtaining Consent (signature)

Person Obtaining Consent (print)

OR

The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.

Date _____ Parent or Legal Guardian (signature) _____

Parent/Legal Guardian (print name)

Date _____ Witness/Interpreter – Only required if the Parent/Legal Guardian is a non-English speaker _____