

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

For children 13-17 years old

Study Title: **A Network Approach to Study Brain Plasticity in Youth with Cognitive Training (BrainChange)**

This is a research study to investigate brain network changes induced by Mindfulness Meditation-based training. The study is being carried out by investigators from the Departments of Radiology, Psychiatry, and Pediatrics (Olga Tymofiyeva, Ph.D., Duan Xu, Ph.D., A. James Barkovich, M.D., Eva Henje Blom, M.D., Ph.D., Tony Yang, M.D., Ph.D., Wendy Mendes, Ph.D., and Donna Ferriero, M.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 focus and regulate emotions and whether we can measure the small brain changes that are associated with these improved abilities. 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 grants from UCSF, NIH, Fahs-Beck Fund for Research & Experimentation.

How many people will take part in this study?

About 160 young people aged 10-25 years old will take part in the study.

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

If you agree, and your parent gives permission for you to participate, the following procedures will occur: First, you will need to have the following “screening” to find out if you can participate in the study:

Phone screening: You and your parent/guardian will speak to a study staff member to learn about the study and see if you might be interested and eligible to participate. You and your parent will be asked questions about your age, your 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, and your parent gives permission for you 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 1.5 hours. At this visit, the researcher will first review this consent form with you and your parent/guardian, and you both will sign this form. In

case your parent/guardian cannot be at the first MRI in person, he or she can sign the consent form before the first MRI and mail it to us or have you bring it to the first MRI with you.

1. Computerized Attention Test: You will be asked to do a computerized test of attention. It will take about 20 minutes.

2. Magnetic resonance Imaging (MRI) of the head: In this study, your brain will be scanned three times—at your first visit, 3 months later right before the beginning of the training, and again after the training. 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.

Second MRI (right before the training): After these assessments are completed you will not have to do anything related to this study for 3 months. After 3 months, you will have the second MRI scan and attention test using the same procedure as the first time and shortly after that start the Mindfulness Meditation-based training of attention and emotion regulation.

Training phase: 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-two classes per week over 2-3 months. There are 12 classes total. Classes will be 90 to 120 minutes. There will be about 8-14 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.
- b. Teacher interview: You may be invited to meet individually with the group leader(s) prior to the start of class. The purpose of the interview is for the group leader to meet you and learn your goals for the program.
- c. Orientation Session for parents/guardians: Before the classes begin, your parent/guardian may be invited to an Orientation Session to learn more about the study, how they best can support you during the class and have their questions answered.
- d. 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. After the class, someone will type into a computer a transcription of what is on the recording and will remove any mention of names. The recordings will be destroyed when they have been transcribed and the study is completed.
- e. 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 an mp3 player or computer.

f. Questionnaires: Before the 12-session training program begins and after it ends, you will be asked to complete some personality, mood, and behavior questionnaires. The questionnaires will take approximately 20 minutes. You may be able to complete these questionnaires at home over the internet. In addition, 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. At the end of the 12-session program, you may be asked to participate in a **focus group** with other class members to discuss your class experience. The purpose of these procedures is to get your feedback about the classes so we can make them better.

Third MRI (after the training): After the training, you will be asked to take the attention test and have an MRI scan again. The procedure will be the same as the first and second time. The visit will be at UCSF Mission Bay and will last approximately 1.5 hours.

If you are enrolling at a time point of our study cycle when the first MRI scans have already been performed, you will only undergo two MRI scans: pre- and post-training. If you have not undergone the pre-training MRI, you can still participate in the training as long as there are available spots in the group.

You may be asked to participate in a **physiology testing** session where your body’s physiological responses such as heart rate, breathing rate, your skin’s electrical conductivity (galvanic skin response), and startle eye blink response to seeing images will be recorded for around 15 to 20 minutes.

Six months after the training, you will be asked via email to fill out some personality, mood, and behavior questionnaires. You may also be invited to a **6-month follow-up** meeting, at which we will discuss the effects of the training as well as interesting research findings that your participation contributed to.

Time commitment and Location: You will spend about 36 hours on the training over 3 months. The classes and physiology testing will take place at UCSF Parnassus. Brain scan visits (three times 1.5 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 6 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?

Training group in-class practices and home assignments: 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: You may find it difficult to find time to practice the skills you learn in the class at home.

Audio recording: Your voice may be recorded during class. 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:

- 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; tattoos containing metal pigments.
- Females only: Risks to an unborn baby: If you are female and sexually active, you must use a study-approved birth control method and agree not to attempt to become pregnant during the study. It is important that you contact the Principal Investigator, Dr. Olga Tymofiyeva, 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 your parent to inform them 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?

The classes may help you improve your ability to focus and regulate your emotions. The attention tests, 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 and adolescent depression.

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.

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, or that of your parent/guardian, will not be used.

Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include: *The UCSF Committee on Human Research (for the protection of human subjects in research)*.

The researchers will ask you and the other participants to use only first names during the classes and during the focus group. 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.

What are the costs of taking part in this study?

You will not be charged for the training.

Will I be paid for taking part in this study?

You will receive a \$100 gift card for the successful completion of the training and three MRI scans (\$50 for two scans and no gift card if you did not undergo any scans or just one scan).

We can compensate for up to three hours of parking at the UCSF Mission Bay facility when you come for the scan (by providing you with UCSF parking stickers).

If you participate in the physiology testing session, the focus group, and the 6-month followup, you will get three more \$25 gift cards.

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

It is important that you tell the Principal Investigator, Dr. Olga Tymofiyeva, if you feel that you have been injured because of taking part in this study. Her email is Olga.Tymofiyeva@ucsf.edu and her cell phone number is 415-283-5406. 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 Committee on Human Research 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 858-245-3394. You can also talk to the class leaders. You can ask your questions now or later, any time you like. You can also ask your parents to ask questions for you.

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 Committee on Human Research at 415-476-1814.

You may be told about other research. We may use information you give us to help find you in case you move. People contacted will only be told that this is a study of young people's development; no other information about the study or about you or your parents will be given. Do you agree to give information so that we may find you and/or your parent for later research?

YES

NO

For the parent or legal guardian: You will be invited to be interviewed about the effects the training may have on the participant. If you select the “YES” option below and respond to the invitation, you will be interviewed in person or over the phone for about 30 minutes about your expectations, observations and recommendations related the training your child underwent in this study. This will help us improve the training program. The interview will be recorded for research purposed only with no one possible to identify you and you will have the right to withdraw from the session at any time. Do you agree to participate in the interview?

YES NO

CONSENT

You have been given a copy of this consent form 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, just tell us.

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

 Date Participant's Signature for Assent Participant name (print)

 Date Person Obtaining Consent (signature) Person Obtaining Consent (print)

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/Guardian (print name)