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

For parents of 10-12 year-old children

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

We invite you and your child to take part in a research study that investigates 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., Mai-Lan Ho, M.D., Eva Henje Blom, M.D., Ph.D., Tony Yang, M.D., 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 whether we can measure the small 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 grants from NIH and UCSF.

How many people will take part in this study?

About 30 young people aged 10-18 years old will take part in the study.

What will happen if your child takes part in this research study?

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

**Phone screening:** You and your child 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 child will be asked questions about your child’s age, mental health history and metal implants to see if he or she can have a brain scan (an MRI). If it appears that your child is eligible to participate, wishes to participate, and you give permission for him or her 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 your child’s 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 child, and you will sign this form.
1. Computerized Attention Test: Your child 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 child’s brain will be scanned three times—3 months before the training, right before the training and after the training. Magnetic Resonance Imaging (MRI) will be done on your child’s head. This will involve him or her lying quietly inside the center of a large, doughnut shaped magnet for approximately 1 hour. Your child’s head will be placed in a special, helmet-like “head-holder” to help keep the head still. Your child will be made as comfortable as possible by padding his or her neck, shoulders, head, and knees. During the scan, the machine takes pictures of the brain. Your child may be asked to watch a video and do some simple tasks while in the MRI scanner. He or she can stop the MRI at any time.

**Second MRI (right before the training):** After these assessments are completed your child will not have to do anything related to this study for 3 months. After 3 months, your child 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.

**Training phase:** Your child will participate in a 12-sessions training program as follows:

a. **Group classes:** Your child will participate in the training classes for 12 sessions. In the class, your child will learn and practice skills to help him or her feel calm and relaxed and to control his or her emotions and attention. The participants will also learn and talk about stress, as well as what is most important to them. Your child will learn how the brain functions and how he or she can increase his or her sense of well-being. Your child may do some easy yoga poses. There will be 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 teenagers in the class with your child. 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 one should only participate if nearly all of the classes can be attended.

b. **Teacher interview:** Your child 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 your child and learn his or her goals for the program.

c. **Orientation Session for parents/guardians:** Before the classes begin, you may be invited to an Orientation Session to learn more about the study, how you best can support your child during the class and have your questions answered.

d. **Audiotaping:** An audio recorder will be placed in front of the class, near the teacher. Your child will have the option to stop the recorder if he or she does not want what they 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:** Your child will be asked to practice some of the skills that they learn in the class at home for about 10-15 minutes every day. Your child will receive recorded instructions on a CD;
if preferred, he or she can listen to the instructions by downloading the recording to an mp3 player or computer.

f. Weekly Questionnaires: Each week of the classes, your child will complete a short questionnaire about his or her opinions about the classes and which parts were most helpful. Your child will also complete some short questionnaires about how he or she is doing and feeling. At the end of the 12-session program, your child may be asked to participate in a focus group with other class members to discuss their class experience. The purpose of these procedures is to get your child’s feedback about the classes so we can make them better.

**Third MRI (after the training):** After the training, your child 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.

**Time commitment and Location:** Your child will spend about 36 hours on the training over 3 months. The classes may take place at UCSF Mission Bay or UCSF Parnassus Library. Brain scan visits (three times 1.5 hours) will take place at the UCSF Mission Bay campus.

**How long will your child be in the study?**
Your child will be in the study for approximately 6 months.

**Can your child stop being in the study?**
Yes. You or your child 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 your child from continuing the study if they think it is best for your child to stop, or if your child does not follow the study rules, or if the study is stopped.

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

- **Training group in-class practices and home assignments:** Your child could experience restlessness or some difficult emotions, like sadness or anger, during some of the class activities or home assignments. If this happens, your child 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. Your child may find it difficult to find time to practice the skills he or she learns in the class at home.

- **Audio recording:** Your child’s voice may be recorded during class. If your child does not wish this, he or she can ask to have the recorder stopped when he or she is speaking.

- **Brain MRI:**
  - Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during examination, which could in the process possibly cause harm. 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. If your child has a piece of metal in the body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve...
stimulators, or a pacemaker, he or she will not be allowed into the MRI room and cannot have an MRI.

- Having an MRI may mean some added discomfort for your child. In particular, your child may feel uncomfortable, tired or nervous from lying down in a small space during the MRI. Your child 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 your child will be asked to wear ear plugs. At times during the test, your child 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 your child may experience a headache or nausea or a metallic taste in the mouth. The rapid switching on and off of the magnetic field can causing peripheral nerve stimulation, usually reported as a twitching or painful feeling. If this happens to your child, he or she can stop the MRI at any time.

- If your child has any metal in the body, he or she 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 your child is female and sexually active, she 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 or she thinks she 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 you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your child’s physician. The investigators and UCSF are not responsible for any examination or treatment that your child undertakes based on these findings.

**Are there benefits to taking part in the study?**

The classes may help your child improve his or her ability to focus. The attention tests and MRI scans may help health professionals better understand how brain changes and how to develop efficient training and treatment programs.

**What other choices does my child have if he or she does 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 or your child.
Will information about my child be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. Your child’s personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your or your child’s name and other personal information will not be used.

Organizations that may look at and/or copy your child’s 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 your child and the other participants to use only first names during the classes. They will also ask your child 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 child’s 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?

Each child will receive a $100 gift card for the successful completion of the training and MRI scans.

What if my child is injured because of taking part in the study?

It is important that you tell the Principal Investigator, Dr. Olga Tymofiyeva, if you feel that your child has 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 or your child can also tell the study staff or teacher in person.

**Treatment and Compensation for Injury:** If your child is 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 our rights if my child takes 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 or your child in any way.

If you or your child does 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 Tymofiieva at 415-283-5406 or Eva Henje Blom 415-866-7203. You can also talk to the class leaders. You and your child 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 Committee on Human Research at 415-476-1814.

CONSENT

You have been given a copy of this consent form to keep.

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

If you do not want your child to be in this study, just tell us.
If you give permission for your child to participate in this study, you should sign below.

Date               Parent or Legal Guardian (signature)               Parent/Guardian (print name)

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