CONTROL PARTICIPANT RESEARCH INFORMATION AND CONSENT FORM

Title of Study: Impact of long-term training in meditative practices on the hemodynamic brain response to painful stimuli.

Study Investigators: Richard J. Davidson, Antoine Lutz, David Perlman.

Invitation
You are invited to participate in a research study examining the long-term impact on the brain of meditation. If you choose to participate, this study will involve two visits to the lab for approximately 2 hours each time. During the first visit you will become familiar with the tasks involved in the study. During the second visit you will have your brain scanned by functional magnetic resonance imaging (fMRI). In the scanner you will be asked to do two standard meditation practices while experiencing safe and controlled amounts of pain. Moderate heat sensations will be administered on your palm or wrist while you: a) focus attention on a visual external object, b) maintain a state of unfocused but alert open awareness.

We are looking for up to 60 participants for this study.

Participation in this study is voluntary. The study procedures and the possible risks and benefits are described below. Please read the information carefully and discuss any questions you have before you decide whether or not to join this study.

Purpose
We would like to gain new insights on the long-term impact of meditation on basic pain regulation functions, and on the brain mechanisms involved. In this study, we will compare the pain regulatory processes induced by meditation practices between a group of highly experienced meditators and a control group of inexperienced meditators. We will collect data on your rating of the intensity and unpleasantness of the pain, and on the activity of your brain during the experiment. This will help determine the effects of meditation on pain perception, and what parts of the brain are involved in these effects. In addition, we will look for differences in these effects related to the amount of experience someone has with meditation. We expect that highly experienced meditators will show more activity in their brains related to meditation, and that this will also be related to an improved ability to regulate the experience of pain. We will use the results of this experiment to try to understand how pain regulation processes are flexible skills that can be trained.

Why are you being asked to participate?
We are looking for people inexperienced with meditation who are willing to participate in this research. We need matched subjects who are not claustrophobic, not pregnant, who do not have a history of anxiety disorder and do not have magnetic medical implants such as pacemakers. You are being asked to participate because our screening interview indicated that you meet these criteria.
**What does this study consist of?**

While inside the brain scanner, you will practice two meditation states which cultivate two different cognitive/emotional strategies: a) You focus attention upon an object, in this case an image on the screen, keep it on that object and bring it back to that object when you have been distracted, and b) you do not focus the mind on something, but maintain a present awareness. While you are practicing each of these meditation states, and while you are resting, you will feel short bursts of mildly painful heat. After each burst you will be prompted to rate the intensity and unpleasantness.

The study consists of two visits.

**First visit:**

- We will give you an overview of the study and give you this consent form and the MRI safety screening.
- You will fill out a few short questionnaires about your general emotional state.
- You will perform the thermal pain calibration procedure. In this procedure, we will use the same equipment used in the actual experiment. The stimulator will generate a slowly increasing temperature. When the temperature reaches a level that you consider to be a pain level of 8 on a scale of 0 (no pain) to 10 (unbearable pain), you will hit a button to stop it. This will be repeated several times. The temperature that you consistently rate as 8 will be the highest temperature that you will ever experience in this experiment.
- We will explain the meditation states and the task you are to perform in the experiment.
- You will practice the meditation states and experimental tasks in the scanner simulator. The simulator looks and sounds just like the real MRI scanner. It is used so that you can know how it feels to lie in the scanner and do the tasks and meditation states that you will do on the second visit.
- If you are comfortable with the experiment and wish to continue, we will schedule your appointment for the second visit.

We ask that you practice the meditation practices for 15 minutes each day for one week (7 days) leading up to your second visit. You will be given a printed description of the meditation states to take home with you.

**Second visit:**

- We will give you another safety screening, to make sure you have no magnetic metal objects on you when you go into the scanner.
- We will set up all the equipment used in the experiment, including the scanner, goggles, headphones, breathing and heart-rate monitors, and the pain stimulator.
- You will lie on a table and will be slowly moved to the center of a large metal doughnut-shaped magnet. The MRI machine produces a magnetic field that passes through your body without disturbing any of your body parts. It uses a computer to show us what the inside of your body looks like. Radio signals will also be passed through your body. The MRI machine used in your scan has formal approval from the FDA. We will collect several scans while you are in the machine. You will wear a pair of special eye-tracking goggles through which you will see the cues for what to do, and the rating scales for the experiment. The goggles also have an FDA-approved camera inside of them to record your eye movements. The
information collected from this camera will be stored in either digital or video format. Looking at your eye movements may help us to understand how you feel during the task. Your name will not be associated with information collected from this camera.

Individual scans can last from a few seconds to 20 minutes and you will have to lie still during that time. The entire scanning session may last as long as 1 ½ hours and we will try to keep you comfortable. You will be able to stop the scan at any time. Research staff will be with you during these procedures. At the end of each scan you will be asked to describe briefly the quality of your practice and we will check your comfort level in the scanner.

- During each session you will do two meditative practices. These meditative practices cultivate two cognitive/emotional strategies: a) You focus attention upon an object, in this case an image on the screen, keep it on that object and bring it back to that object when you have been distracted, and b) you do not focus the mind on something, but maintain a present awareness. While you are inside the scanner, you will receive instructions through the headphones to alternate between a neutral state and a particular meditative state. During both the meditative and the neutral states, you will be presented with the painful thermal stimulus. Your task will be to keep practicing even during this stimulus. At the end of each scan you will be asked to describe briefly the quality of your practice and we will check your comfort level in the scanner.

- While you are inside the scanner practicing the various states, you will see pictures that indicate you are about to feel something hot. The heat-generating device is permitted for experimental use by the FDA (under section 510(k)), and has been used safely for almost a decade. It has several features to ensure that the heat produced is safe and well-controlled. If you would like more information on this device, do not hesitate to ask the researchers. The thermal stimuli will start by a 9 to 15 second non-painful ramp-up heat and then will be either warm or hot for 10 seconds. The temperature will never be more than the temperature you rated as a pain level of 8 in the calibration procedure, and the painful heat will never last more than 10 seconds. In addition, the temperature of the stimulus will not be greater than 49°C (120°F), which is considered a safe maximum temperature for hot tap water. You will receive up to 32 bursts of something hot, some of which will be painful and others will not. Following each thermal stimulus you will be asked to rate its painfulness using the same 0-10 scale used in the mock scanner.

What are the costs to me for my participation? Will I be paid for participating?
There will be no cost associated with any part of this study. You will be paid $75 for your participation. If you choose to withdraw from this study after the session in the Simulator Room you will be paid $25. If you wish, we will also provide you with a picture of your brain taken during the MRI.

What are the potential benefits to me for my participation?
There is no direct personal benefit to participating in this study. However, you may find it interesting and informative to participate in research that may contribute to scientific knowledge about the long-term impact of mental training on the brain.
What are the potential risks, discomforts, and inconveniences to me?

• **Painful stimulation:** The painful stimulation, such as the feeling of moderate heat on the palm of your hand, will cause you discomfort but should not injure you or cause any long-term damage. The stimulus will not exceed 49°C (120°F.), which is considered a safe maximum temperature for hot tap water. Although temperatures in this range have been used safely in other research, some minor irritation is possible. One hand will receive stimulation during practice and the opposite hand will be stimulated during testing. You will be given an emergency button in the hand that is not being stimulated which will allow you to stop the study. It may take longer for you to push the emergency button when it is not in your dominant hand (i.e. your writing hand), increasing the risk of any irritation occurring on your dominant hand.

• **MRI brain scanning:** During the MRI portion of the study, some individuals may feel uncomfortable being in an enclosed space, or may be tired and/or may experience physical discomfort from lying still on their back during the scanning session. Some people have also reported tingling or tapping sensations, or muscle twitches in different parts of their body during the imaging procedure. These sensations are not hazardous and should not cause you any discomfort. Occasionally, people who have clasped their hands tightly together during the study have reported a feeling of tingling in their hands and arms. This is also not hazardous; however, to avoid any possible discomfort, you should not clasp your hands together during the study. You are free to stop your participation in the MRI at any time if you feel claustrophobic or uncomfortable, or for any other reason. You will hear loud tapping and pinging noises as the MR machine images your head. Earplugs or headphones will be provided to make this noise less unpleasant, but these earplugs do not completely block the sounds, so that we can still talk to you.

• **Possible discovery of findings related to medical imaging:** There is a remote chance that imaging may reveal unsuspected findings that are of potential medical importance. Therefore, the images obtained during your session will be reviewed by a radiologist (a physician trained in the interpretation of medical images) in order to screen for abnormalities. Such findings can potentially be serious, but this is rare; most often they have little or no medical importance. Occasionally the significance of a finding cannot reliably be determined from the images obtained. Knowing about unsuspected abnormalities on your images may be of some benefit to you, particularly if they are medically important. On the other hand, if the significance of a finding is low or uncertain, there may be little benefit in knowing about it and there may be some risks; for example, it could affect your insurability or employability, or just make you worried.

Whether or not you want to be informed of findings of *unknown or potential* medical significance is up to you. Please indicate your preference by signing your initials on the appropriate blank:

_____ Please inform me of ANY abnormal findings, EVEN IF they are unlikely to pose a risk to my health or if their significance is uncertain.

_____ Please inform my primary physician of ANY abnormal findings, EVEN IF they are unlikely to pose a risk to my health or if their significance is uncertain.

*You will be informed if an abnormal finding of known clinical significance is found on your MRI based on the radiology review.*
**Name of physician to contact**

If you do wish us to report any findings to your physician, you must provide us with the name and location of your primary physician, prior to your scan.

Name of primary physician__________________________________________
City or clinic ______________________________________________________
Health Care Provider ______________________________________________

**Disclaimer**

If you volunteer for this research study, the MRI scan that we will perform is NOT necessarily equivalent to an MRI scan used to diagnose medical problems. Many potentially serious problems may be undetectable on these scans. A negative MRI should not be used to avoid a visit to your primary physician. Should you be having physical symptoms that you are concerned about, you should see your primary physician, who will determine the studies required to arrive at a diagnosis.

**Who should not participate in this study?**

Some subjects should not participate in MR studies. These include persons with metallic implants, such as prostheses or aneurysm clips, or persons with electronic implants, such as cardiac pacemakers. The magnetic field generated by the MR machine can cause a displacement or malfunctioning of these devices. We know of no risks or adverse effects from the radio signals used in this study. Some subjects report some anxiety or claustrophobia in the MR scanner since the head must be placed fully inside the scanner tube. In addition, fatigue and physical discomfort due to the length of the MRI session are possible.

Women who are pregnant must not participate in this study. The potential risks to a fetus from the MRI scan are not known. If you have any reason to suspect that you might be pregnant or become pregnant during the course of this study, you must not participate. You must be right-handed and be free of neurological problems to participate in this study.

**How will I be compensated in the event of injury?**

In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence.

**Is my participation voluntary?**

Yes, your participation in this study is entirely voluntary. You may withdraw from this study at any time. Your decision to withdraw will not affect any benefits to which you are entitled.

Before you sign this form, please ask questions on any aspects of this study that are unclear to you. You may take as much time as necessary to think this over. You are free to withdraw from this study at any time, even after the scanning has begun.

**Will my confidentiality be protected?**

Researchers in this study might use information learned from this research in scientific journal articles or for presentations. None of this information will identify you personally. Any picture or measurement information that is obtained will be identified by a code and not your name.
Contact Information
Please feel free to ask questions before agreeing to participate. Should you choose to participate, you are encouraged to ask questions throughout the study. If you have any questions after participating in the study, please contact the investigator, Dr. Richard Davidson, at (608) 262-8972, or Dr. Antoine Lutz, at (608) 262-8705, alutz@wisc.edu, or David Perlman, at (608) 890-1386, dperlman@wisc.edu.

Authorization: I, ___________________________________, have read the above and decided to participate in the research project described there.

___________________________________________________
Signature of Subject

Date

___________________________________________________
Signature of Person Obtaining Consent

Telephone

Pregnancy Status – Female Participants Only
The regulations for this type of research do not allow the participation of female subjects who are pregnant. Please sign this statement only if you are certain you are not pregnant. If you are not certain, please do not sign this statement.

I confirm that I am not pregnant.

___________________________________________________
Signature of Subject

Date