Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name: _____ **Date:** _____

Subject Initials: _____

Principal Investigator: MARY R. NEWSOME **VAMC:** _____

H-35409 - NEUROIMAGING MEDITATION THERAPY IN VETERANS WITH CO-MORBID MILD TBI AND PTSD

Neuroimaging Meditation Therapy in Veterans with both Mild TBI and PTSD

Background

Many Veterans from Operation Enduring Freedom/Operation Iraqi Freedom/ Operation New Dawn (OEF/OIF/OND) have been diagnosed with posttraumatic stress disorder (PTSD) and mild traumatic brain injury (mTBI). When two conditions occur at the same time, they are said to be co-morbid. In one study of OEF-OIF-OND Veterans, 57.3% of Veterans who had mTBI also had PTSD. Although little is known about how mTBI and PTSD affect each other, especially several years after deployment, one study found that some Veterans with TBI had traumatic stress five years after their brain injury, suggesting the effects of these two conditions together, or co-morbidity, may be long-lasting.

Treatments specifically for Veterans with both mTBI and PTSD are still being developed. It's possible that treatments that improve symptoms in patients with mTBI or PTSD alone may help Veterans with co-morbid mTBI and PTSD. Meditation has been suggested to be effective in Veterans with PTSD and in civilians with TBI, improving their quality of life. A good treatment would also be something that a Veteran could learn and then be able to use at their convenience anytime or anyplace they needed it.

The current study proposes a type of meditation targeted for Veterans, Inner Resources for Veterans (otherwise known as IRV) . In addition to potentially helping to reduce symptoms and to improve function in the brain, IRV would offer Veterans a treatment they could utilize whenever challenging situations occur regardless of where they were. Since the treatment would be relatively cost-free, IRV could also dramatically reduce financial costs.

This research study is funded by Department of Veterans Affairs, Rehabilitation Research & Development

Purpose

The goal of this study is to learn more about how Inner Resouces for Veterans meditation therapy (IRV) helps Veterans with Post Traumatic Stress Disorder (PTSD) and mild traumatic brain injury (mTBI). As you may know, PTSD is a disorder that occurs after exposure to one or more traumatic experiences. People with PTSD may experience anxiety, pay extra attention to their surroundings, involuntarily remember their traumatic experiences, and/or want to avoid situations where these symptoms are increased. MTBI may result from being in a blast explosion, with pressure from the blast potentially disrupting the brain's structure and function.

In this study, we will be looking at the behavioral and neurological changes (changes in the brain) and the reductions in PTSD symptoms that may come from participating in this treatment. We are interested in determining if treatment does reverse changes in the brain caused by PTSD and mTBI. To help us understand changes in how the brain functions, you may complete a functional magnetic resonance imaging (fMRI) scan before and after either a 8-week course of IRV or 8 weeks of education about PTSD

and mTBI. Your participation will help us understand how therapy for PTSD and MTBI impacts the brain's response to emotions and therapeutic processes.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine and Michael E. DeBakey Veterans Affairs Medical Center.

First, we will explain this study, make sure we have answered all of your questions, and complete this consent form. Then, we will ask you some additional questions to make sure that MRI scanning is safe for you. You must be able and willing to complete an MRI scan to participate in the study.

Next, you will be asked to participate in an interview about your PTSD and mTBI symptoms and to fill out some questionnaires. The interview will take between approximately 30 minutes and 4 hours. After the group treatment, when you return for scanning, the interviews will last between 30 minutes and 2 hours. The questionnaires will include statements and questions about different kinds of feelings, experiences, or problems that people sometimes have. Information on alcohol and drug use may be asked.

Before you begin treatment, we will ask you to complete an MRI scan. At this time we will give you a detailed description of what it will be like to be in the scanner and answer any questions you have. The MRI scanner is located at the Michael E. DeBakey VA. The MRI scanner uses a strong magnet and radio waves to obtain a picture of the brain. To be scanned, you will enter a large room where a powerful magnet is located. Before you go into the scanner room, you will be instructed to remove all jewelry and other metal-containing objects. Once in the room with the scanner, you will lie on a narrow table with a plastic-encased metal coil close to your head. Next, the technician will instruct the machine to slide you into a small tunnel approximately 3 feet long and 25 inches wide. Only the top of your body goes into the scanner, so your legs will "stick out" from the scanner tunnel. We will ask you to lie very still for the entire scan, which lasts about 30 minutes. During scanning, the machine produces a loud knocking noise. This is normal. The procedure is non-invasive and involves no medication of any kind. Following the scan, we will ask you to fill out a questionnaire about how you felt while you were in the scanner. If you might have metal in your body but are not sure (for example, if you have welded in the past, you may have small fragments of metal in your eyes without realizing it), before you have an MRI scan, you will be asked to undergo x-ray to identify whether you have metal in your head. A radiologist will look at the x-ray and determine whether it is safe for you to have an MRI or not.

You will have a 50% chance (like the flip of a coin) of being assigned to receive one of two treatments, either Inner Resources for Veterans (IRV), or a PTSD and mTBI Education group. IRV is a meditation intervention specifically adapted for use with Veterans with PTSD. It consists of eight 90-minute group sessions held here at the VA. The first third of each session is spent learning and practicing meditation techniques, the middle third on learning material and group discussion, and the last third practicing

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meditation and talking about your experiences during meditation. You will be asked to complete homework when you're not at the VA. The homework will take 30 minutes a day for 6 days per week. We will give you a week-by-week manual and four 30-minute audio-recordings of guided meditation to help you with your homework. The intervention works mindfulness meditation techniques, including increasing awareness of the moment and of your breathing, imagining peaceful situations, silently repeating words, and letting go of automatic thoughts that you don't want.

The PTSD and mTBI Education group will also consist of eight 90-minute group sessions held here at the VA. You will learn a lot about what causes PTSD and mTBI, how those conditions can change people's lives, and what some of the treatments are for these conditions. People in this group will also perform homework for 30 minutes per day for 6 days a week.

After completing your 8-week course of therapy, we will ask you to fill out several more questionnaires. This is the Posttreatment Assessment. The questionnaires will include statements and questions about different kinds of feelings, experiences, or problems that people sometimes have, and will also ask about your experience in group treatment.

Then approximately four weeks after the Posttreatment Assessment (12 weeks after the start of the study), you will be asked to complete additional questionnaires and to participate in a second fMRI scan. This is the Follow-up Assessment.

We want to make sure that your participation in the study does not cause you distress after the study is over. A member of the clinical research staff will accompany you throughout each visit to our office. If you become upset during any part of the study, this staff member will be available to talk with you to ensure your comfort and safety.

All of your information will be associated with a study ID code and saved on a password-protected server available only to the research team. Your information and answers to questionnaires will not be attached to any of your identifiable information. Except for this consent form, all of your research data is de-identified and stored in a locked file cabinet within a locked office at the Michael E. DeBakey VA. However, consent forms will contain your name and, because this is an intervention study, the last four digits of the social security number will also be recorded on the consent form in order to be able to enter information into your medical chart. All electronic research records are stored on the secure VA server. We maintain a master list of the name of Veterans who participate in the study which are linked to your research data by your coded study ID. This list is stored separately from the research data and is only accessible by the study staff. Only the Principal Investigator (PI), who is the person who is in charge of the study, or the PI's co-investigators, research assistants, and governing bodies/institutions that have legal right to audit will have access to identifiable research data.

Many or all of the sessions will be audio-recorded. The purpose of the recordings is to ensure that the clinicians are providing high treatment quality. The recordings will be reviewed by a rater to assess how well the clinician adhered to the manual that describes how to provide the therapy. The recordings will be kept in a locked filing cabinet and will be reviewed only by the Principal Investigator (or person in charge of the study), or the PI's co-investigators or staff. The recordings will be destroyed at the end of the study.

Confidentiality

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning alcohol abuse
- Specific information concerning drug abuse
- Specific information concerning psychiatry notes
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Partial Social Security # (Last four digits)
- Photographs, videotapes, and/or audiotapes of you

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

The interview will cover a range of topics, including some that are personal in nature. There is a possibility that you may become upset, fearful, or anxious during the interview, because you will be asked some detailed questions about your past traumatic experience(s). These questions may bring about strong memories and feelings you might have about the event(s). In describing an event, it is possible that you may experience a "flashback" or vivid image of the event that brings you back to the time and circumstances of when the event occurred. If you become distressed at any time during the interview, please inform the interviewer so you can take a break. If you feel that you are unable to

continue, the interviewer will stop the interview. In addition, you will be given pager numbers to call if you experience

distress or anxiety after leaving the VA.

Some Veterans may experience some worsening of symptoms before improvements and may feel uncomfortable at first talking in the group setting. If you become distressed at any point during the therapy, please inform the therapist. You can stop participating in the group at any time and seek other treatment with no penalty.

The MRI scanner has been approved by the Food and Drug Administration (FDA) to determine the causes of some medical problems. The magnetic field will affect any metallic object. You should not participate if you have any type of metallic implant in your body, including pacemakers, aneurysm clips, shrapnel, metal fragments, orthopedic pins, screws, or plates, IUD's or piercings that you cannot remove.
If you have any of these, there is a risk that the magnetic field could cause them to move or heat up. Individuals who potentially have metal in their bodies but are not sure, for example, people with a history of welding, will be asked to have an x-ray taken before the scan in order to identify whether there is metal in their bodies. If you receive an x-ray, your participation in this research study involves exposure to radiation. The radiation dose involved in x-rays is 10-20 millirem. We are exposed to radiation every day of our lives from both natural and manmade sources. The average effective dose to a member of the U.S. is about 360 millirem per year. By comparison, the radiation dose that you will receive when participating in this research study is less than the annual amount, and the risk of potential harmful effects is considered to be minimal.

You may experience some muscle discomfort from lying in the scanner. You may also become cold while lying in the scanner. If this happens, we can provide with a sheet or blanket.

Some people become nervous or experience claustrophobia, a fear of enclosed places, in the scanner. If this happens to you, you may ask to be withdrawn and we will do so immediately.

A small number of people experience a sense of dizziness in the magnet. This is due to the magnetic field, and if it disturbs you, you may ask to be withdrawn and we will do so immediately.

If at any time during this study, you feel that anything is causing you anxiety or any other unpleasant sensation, please inform the study staff. The study will be immediately stopped and you will be withdrawn from the scanner.

There is an intercom hooked up so that you can talk to people in the control room between scanning sessions, and an emergency button so that you can be withdrawn from the scanner immediately should you need to.

As with any research, there is always a chance that confidentiality of the collected information may be

breached. However, study staff will store all digital and paper copies of data in a secure location.

If at any time you decide to end your participation in this study, you are free to do so without any penalty. Your medical treatment at the VA will not be affected in any way.

You will be informed of any information that may affect your decision to stay in the study.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

The benefits of participating in this study may be: improvements in your PTSD and mTBI symptoms and comorbid problems such as depression and anxiety. Your participation may also help the investigators better understand the effects of PTSD on the brain and the effectiveness of treatment in helping resolve PTSD symptoms. Eventually, this may also lead to an understanding of how we may treat and ultimately prevent changes in the brain which stem from PTSD and mTBI. It could also eventually help us to improve treatment for other Veterans with PTSD and mTBI. You may also receive a CD with your brain images and a report from a radiologist on the health of your brain. However, you may receive no benefit from participating.

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: The MEDVAMC trauma recovery program offers a variety of treatments for PTSD, including but not limited to Cognitive Processing Therapy, Prolonged Exposure Therapy, PTSD Education Group, and Essential Skills for PTSD.

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not or are unable to comply with study procedures) or because the entire study is stopped.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

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You will be paid after each study visit. You will receive $30 for participation at the PreAssessment Visit (Time 1), $20 at the PostAssessment Visit (Time 2), and $50 at the Follow-up Visit (Time 3). The maximum total amount that you could receive for your participation in this research study is $100 ($30 + $20 + 50).

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, MARY R. NEWSOME, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: MARY R. NEWSOME at 713-791-1414 x25947. Jenny Bannister at 713-791-1414 x23749

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Under Federal Regulations, the VA Medical facility shall provide necessary medical treatment to you as a research subject injured as a result by participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by the Michael E. DeBakey VA Medical Center. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. You do not waive any liability rights for personal injury by signing this form.

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You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. Your participation will not affect the way you now pay for medical care at the VAMC. If you would like to verify the validity of the study and authorized contacts, you may speak with the Michael E. DeBakey Veterans Affairs Medical Center Research Office at 713-794-7918 or 713-794-7566.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

_____	_____
Subject	Date
_____	_____
Investigator or Designee Obtaining Consent	Date
_____	_____
Witness	Date