Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

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Status: Approved
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Approval Period: 3/2/2018 - 3/1/2019

Section Aa: Title & PI

A1. Main Title

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

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

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A5. Funding Source:

Organization: VA CENTRAL OFFICE, RR&D

A6a. Institution(s) where work will be performed:

BCM: Baylor College of Medicine
Michael E. DeBakey Veterans Affairs Medical Center

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:

Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
No

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Approximately 18-22% of Operation Enduring Freedom/Operation Iraqi Freedom/ Operation New Dawn (OEF/OIF/OND) Veterans have been diagnosed with posttraumatic stress disorder (PTSD), and 15-30% of Veterans report mild traumatic brain injury (mTBI). The effects of mTBI and PTSD have been evident since military personnel first came home and continue to be difficult to eradicate. At 3-4 months post-deployment, OIF Veterans with mild TBI (mTBI) were more likely to endorse PTSD symptoms than those without mTBI. The comorbidity may be long-lasting, or at least recurrent, as TBI-related symptoms were strongly associated with traumatic stress five years after injury. In an examination of factors associated with postconcussive symptoms, PTSD was a strong factor. In active duty marines, mTBI during deployment predicted PTSD after deployment, and in a study of OEF-OIF-OND Veterans, 57.3% of those with mTBI had PTSD.

The literature on how mTBI and co-morbid PTSD affect each other and the effects on Veterans several years post-deployment is sparse. Treatment recommendations specific to Veterans with both mTBI and PTSD are in flux, and while treatments address each disorder independently, they may not be effective when the two disorders co-occur. Further impacting successful treatment of Veterans is the fact that many Veterans do not seek treatment, in part due to the distance they travel to obtain VA services and stigma.

Treatments that are accessible and improve symptoms in patients with mTBI and PTSD alone may facilitate rehabilitation in Veterans with co-morbid mTBI and PTSD. Meditation has been suggested to be effective in Veterans with PTSD and in civilians with TBI, improving quality of life. The current study proposes a type of meditation targeted for Veterans, Inner Resources for Veterans (IRV).

Inner Resources for Veterans (IRV) meditation intervention is based on Inner Resources for Stress, an intervention which utilizes mindfulness, techniques that encourage non-judgmental attention to oneself in the present moment. The Inner Resources protocol targets PTSD and has been associated with reduced PTSD and anxiety symptoms, reduced number of depressive symptoms, and depression remissions at a 9-month follow-up, as well as increased perceived self-efficacy. Pilot results of older combat Veterans with PTSD indicated that Inner Resources is a safe, feasible, and acceptable intervention for this population. In a previous study with IRV in veterans at the Michael E. DeBakey VA, the control condition provided education on the symptoms and effects of PTSD. For example, subjects learned to recognize the circumstances that triggered their symptoms, how to identify and participate in healthy activities, and how to monitor their sleep.

In addition to the changes in functional and psychological symptoms and neural pathways, IRV would offer Veterans a treatment they could utilize whenever challenging situations occur regardless of location. Since the treatment would be relatively cost-free after initial training, IRV could also dramatically reduce financial burden to both Veterans and VA. Few treatment studies focusing on Veterans with co-morbid mTBI and PTSD support the innovation of this study, as does generation of community integration data to relate to changes in functional connectivity.

Section D: Purpose and Objectives

Aim. Investigate effects of a meditation intervention designed for Veterans (Inner Resources for Veterans; IRV) on three aspects of rehabilitation in Veterans with both mTBI and PTSD:

Hypothesis 1 (Rehabilitation of Community Integration and Quality of Life): Veterans participating in IRV, relative to an Education Control (EC) group, will exhibit improvements in community reintegration and quality of life after eight weeks of treatment.

Hypothesis 2 (Rehabilitation of Psychological Symptoms): Veterans participating in IRV, relative to an [(EC)] group, will exhibit improvements in PTSD and postconcussive symptoms after eight weeks of treatment.

Hypothesis 3 (Rehabilitation of Neural Networks): Following IRV, functional connectivity in the IRV group will be normalized, e.g., relative to the EC group, Veterans in the IRV group will demonstrate reduced Default Mode Network resting state functional connectivity with lateral prefrontal cortex (LPFC), and increased resting state functional connectivity between the rostral anterior cingulate and amygdala after eight weeks of treatment.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adult (18-64 yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?
Mentally ill

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?
The subjects recruited for the study will be informed of the purpose of the study and the procedures involved. When the researchers explain the experimental procedure and detail any potential risk factors associated with filling out questionnaires, completing the diagnostic interviews, and being inside a Magnetic Resonance Imaging (MRI) scanner, they will be careful to ask if there are any questions and to ask questions to indicate if they are being understood. Participants will be informed that they are under no obligation to participate and that they can discontinue their involvement in the study at any time without penalty. They will be assured that their treatment will in no way be affected by their choice to participate or not to participate, or their choice to withdraw at any time. Only patients who have the cognitive and legal ability to give informed consent for themselves, without a legal

guardian or Legally Authorized Representative, will be included. Much of the study procedures are conducted by mental health professionals who are sensitive to the needs of mental health patients, and they will incorporate those skills into the study procedures, e.g., when subjects fill out assessment questionnaires.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

This is a prospective, randomized, controlled, single-blinded intervention study. Subjects will be randomized to either the IRV Meditation group or the Education Control group and have a 50% chance of being in either group.

Inclusion Criteria:

All subjects will meet the following inclusion criteria: 1. Mild traumatic brain injury (mTBI) as defined by the VA/DoD Clinical Practice Guideline. 2. PTSD as assessed by the Clinician Administered PTSD Scale (CAPS); 3. Aged 18 - 49; 4. Have been referred for treatment by a clinician at the MEDVAMC; 5. Have not previously participated in meditation training.

Exclusion Criteria:

We will exclude subjects who: 1. Meet DSM-IV criteria for drug or alcohol abuse in past 30 days; 2. Have a history of severe TBI based on any of following: (i) Glasgow Coma Score < 8; (ii) alteration of consciousness greater than 24 hours; loss of consciousness greater than 30 minutes; 3. Have current neurological or general medical conditions known to impact cognitive and/or emotional functioning, including but not limited to: epilepsy, Parkinson's disease, Huntington's disease, Alzheimer's disease, stroke, chemotherapy for cancer; 4. Have acute psychological instability as assessed by MEDVAMC clinician or study staff or concurrent diagnosis or

schizophrenia, schizoaffective disorder, delusional disorder, organic psychosis, and subjects taking antipsychotic medication, and 5. Have already completed a course of meditation training.

We may also exclude participants with general contraindications for MRI, including metal in or around the head (e.g., orthodontia, non-removable body piercings, etc.), ferromagnetic material in the body (e.g., non-removable body piercings), or non-MRI compatible medical devices.

F2. Procedure

Overall

Subjects will attend consent and assessment visits prior to being placed in the Inner Resources for Veterans (IRV) meditation intervention or education contol (EC) groups. Before beginning the group and group completion, subjects will also undergo MRI.

Consent

The subjects recruited for the study will be informed of the purpose of the study and the procedures involved. When the researchers explain the experimental procedure and detail any potential risk factors associated with filling out questionnaires, completing the diagnostic interviews, and being inside a Magnetic Resonance Imaging (MRI) scanner, they will be careful to ask if there are any questions and to ask questions to indicate if they are being understood. Participants will be informed that they are under no obligation to participate and that they can discontinue their involvement in the study at any time without penalty. They will be assured that their treatment will in no way be affected by their choice to participate or not to participate, or their choice to withdraw at any time. Only patients who have the cognitive and legal ability to give informed consent for themselves, without a legal guardian or Legally Authorized Representative, will be included.

Assessments

Pretreatment Assessment: Consented Veterans will then participate in a pretreatment assessment sessions that will consist of clinician administered and self-report instruments (e.g., the Structured Clinical Interview for DSM-IV Axis-I Disorders (SCID-I; Steiner et al., 1988; Shear et al, 2000); the Clinician-Administered PTSD Scale (CAPS; Blake et al., 1995; Weathers et al. 2001); the Beck Depression Inventory II (BDI-II; Beck et al., 1996); the PTSD Check List (Weathers et al., 1993); the Neurobehavioral Symptom Inventory (NSI), Trust Inventory, Trail-making task, and Rey Auditory Verbal Learning Test). Information on alcohol and drug use may be asked on the SCID or other form. These questionnaires will take approximately 2.5 hours for subjects to complete. Prior to beginning the interview, subjects will be informed that some of the questions are personal in nature, and that some of the questions may cause them to become upset, particularly PTSD participants when discussing their experiences. In addition, subjects will be reminded that they may take a break whenever necessary and can discontinue the questionnaires if they feel they need to.

Posttreatment Assessment: Approximately two weeks following the final treatment session, participants will complete a posttreatment assessment with a member of the study staff. The measures administered in this assessment will consist of those measures completed in the pretreatment assessment, with the addition of surveys designed to assess participants? therapy experience, e.g., the Client Satisfaction Questionnaire (CSQ).

Follow-up Assessment: Approximately eight weeks after the Posttreatment Assessment, participants will complete a Follow-up assessment with a member of the study staff. The measures administered in this assessment will consist of those measures completed in the pretreatment assessment.

Group Assignment

Following the assessment phase, partipants will be randomized to either the IRV or EC group. The IRV intervention is a manualized meditation intervention that consists of eight 90-minute group sessions. The first third of each session is spent learning and practicing meditation techniques, the middle third on didactic material and group discussion, and the last third practicing meditation and debriefing. Outside of the sessions, subjects

practice approximately 30 minutes a day for 6 days per week. The Education Control group will cover material on PTSD (e.g., the causes, symptoms, and treatment) and will be held in sessions of similar duration.

Pre- and post-treatment fMRI Scans

Before beginning and approximately 12 weeks after completing the IRV intervention or EC groups, participants will be invited to participate in an MRI scan. Study staff will review safety issues related to MRI with the subject and answer any questions. The MRI scanner we will use is a conventional 3.0 Tesla scanner that has been approved for clinical use by the FDA. A mental health provider or trained study staff with experience working with psychiatric populations will be present in the scanner control room throughout the experiment for immediate availability if the patient becomes agitated or frightened. In an effort to reduce the possibility that subjects will be adversely affected by the scanner noise or the appearance of visual stimuli, subjects may be acclimated to the scanner by being permitted to enter it prior to the scan to become familiar with the sounds and enclosed space of the scanner. These habituation procedures have been very successful in terms of stress and movement reduction. Veterans will be informed that if they do not complete the entire scan, they will still be compensated. Should the participant indicate at any time that they choose to discontinue the study, the study will be terminated at no penalty to the subject. Subjects who potentially have metal in their bodies but are not sure, e.g., subjects with a history of welding, will be asked to undergo x-ray in order to identify whether there is metal in their bodies. A radiologist will be asked to review the MRI scans of the subjects and provide reports of his review as a courtesy to the subjects.

Treatment Adherence and Fidelity

Treatment adherence will be assessed by session attendance, recorded at all sessions on the Session Attendance Form, and by the proportion of the recommended 180 minutes per week of meditation practice that each Veteran reports. The IRV Daily Practice Log will be completed for all 8 weekly sessions.

Project Therapists will audio-record all sessions using a digital recorder. These recordings will be stored consistent with MEDVAMC privacy and security requirements. Project Therapists will have weekly 1-hour phone supervision with Dr. Waelde, developer of IRV, to insure treatment fidelity. Approximately 20% of the taped sessions will be assessed for fidelity using fidelity measures provided by an expert IRV Therapist (Dr. Waelde).

All research data is stored as de-identified data with their coded study ID. We maintain a master list of the name of Veterans who participate in the study and their coded study ID. This list is stored separately from the research data and is only accessible by the study staff.

There will be no administration of drugs or placebos or other treatments in any of the visits.

The health records of participants will be flagged to indicate they are in an interventional study that could possibly affect other medical care.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 60 Worldwide: 60

Please indicate why you chose the sample size proposed:

In a meditation study with Veterans that used mantra repetition, a component of IRV, reductions in Posttraumatic Stress Disorder Checklist total scores showed a moderate-to-large effect size, Cohen?s d=0.72 (0.2 is small, 0.5 is moderate, 0.8 is large). A study of loving kindness meditation with Veterans with PTSD reported a large effect size (d=0.89) at a three month post-intervention follow-up. A third meditation study also with Veterans from other

war eras with PTSD showed large effect sizes on CAPS in both Intent to Treat (ITT) (Cohen?s f=0.42, approx. equal to d=0.84) and completer analyses (d=1.24). We more conservatively assume an effect size of d=0.63. At a significance level of 0.05, with 40 patients (20 patients in each group) we will have power of 0.8 to detect the moderate to large effect size of 0.63. Assuming an attrition rate of 33%, 30 subjects are proposed in each group.

Functional Connectivity MRI Power Analysis (Hyp. 3). In the model that power analysis for fMRI SPM Random Effects Analysis was based on, brain signals are modeled by continuously distributed Gaussian kernels of random height and of width, f, in proportion to W, where W is the smoothness of the random field in units of voxels. Based on the pilot fcMRI data, with effect size of d = 0.70, observed W equivalent to [4.9 4.8 4.7] voxels FWHM, observed S = 2023 resels, observed f = 2.72*W, u = 3.167, calculated 2-tailed FWE-corrected cluster k_alpha
(0.05) = 183 voxels, shows that a power of 0.82 would be achieved by 20 subjects per group (after attrition). It should be also be noted that cluster sizes greater than this were observed in our fcMRI pilot data.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

All analyses will be done on an intention-to-treat basis, indicating that all randomized participants and all outcomes will be included in the analysis according to their assigned treatment groups regardless of their adherence to their assigned treatment or their purported relationship to the treatment. Baseline Analysis: Imbalance in groups may occur by chance; we will examine baseline characteristics (e.g., age and psychotropic medication) of participants randomized to the two groups. Chi-square and t-tests will be used to evaluate the differences between groups for categorical and continuous variables, respectively.

Behavioral Outcome Analyses (Hypotheses 1-2). For all outcomes, we will examine the normality of the

distribution of the variable to determine if transformations such as log or inverse might be needed. In order to control for type I error due to multiple comparisons on multiple tests, we will use a rank sum scoring approach. There will be one rank sum score variable for the CAPS (primary outcome measure), and one for psychological tests (secondary outcome measures). The primary analysis is to assess the meditation effect, for which we will use a general linear mixed model, containing terms of treatment, time period, and interaction between time and treatment. The treatment effect will measure differences between the intervention and control groups at baseline, and the time effect will measure whether there was an overall change over time in the outcome. The term of most interest will be the interaction between time and treatment. A secondary analysis will include covariates of age and medication usage Method for Missing data: Because a research assistant verifies completion of each item, missing data are anticipated to be low. We assume any missing data will be missing at random, which can be indirectly verified by comparing the distribution of other important measures between patients with and without complete data. We will apply multiple imputation methods on the missing data and impute the missing data 20 times.

Functional Connectivity Processing and Analyses (Hyp 3). The Functional Connectivity Toolbox (Conn) within SPM8 implemented in Matlab (Mathworks Inc. Sherborn MA, USA) will process and analyze the FC data. Images will be realigned, coregistered, normalized in MNI space, and smoothed with a 6 mm FWHM Gaussian filter. Each subject?s anatomical image will be segmented into gray and white matter (WM) and cerebrospinal fluid (CSF) masks. Physiological noise and movement will be addressed by using WM and CSF masks and realignment parameters as covariates. Data will be band-pass filtered at .008 - .01 Hz. Artifact Detection Toolbox (nitrc.org/projects/artifact_detect/) will repair artifact due to frame-by-frame head movement, i.e., scrub. WFUPickAtlas will create amygdala regions of interest (ROIs). GLM will estimate correlation between ROIs provided by Conn (e.g., ACC, PCC, MPFC), amygdala, and the whole brain in individual and group random effects analyses. Final T maps of between-groups t-tests will test the contrast, (Post_IRV ? Post_EC) MINUS
(Pre_IRV ? Pre_EC) at the different seed regions. Reported clusters will be statistically significant (p=0.05, FWE) at the cluster level of inference, using Random Field Theory correction for multiple comparisons.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

Interviews: During the assessments, subjects will be asked about traumatic experiences that may evoke some anxiety and distress in the subject. If that should happen, subjects will be assured that they are in a safe environment and will be given several options: slow down the pace of the interview, take a break, or discontinue the interview. In addition, prior to the interview, the interviewer will inform participants that some of the questions will be about difficulties they are having or may have had in the past, and that they are free to discontinue the interview or not answer any questions that they feel uncomfortable addressing. Throughout the interview, the interviewer will be mindful of the emotional state of the subject so as to manage any clinically significant distress that could be evoked. In addition, the interviewer will discontinue the interview if it is their judgment that discontinuation is in the interest of the interviewee.

fMRI: The risks associated with fMRI are the same as those with conventional MRI. Movement or heating of metallic implants is a potential risk, and so subjects will be screened to exclude people with metallic implants, fragments, or pacemakers, or any other contraindication for MRI. Individuals who potentially have metal in their bodies but are not sure, e.g., people with a history of welding, will be asked to undergo x-ray before each scan in order to identify whether there is metal in their bodies. The radiation dose involved in x-rays is 10-20 millirem. The average effective dose to a member of the U.S. from natural and manmade sources is about 360 millirem per year. By comparison, the radiation dose that subjects 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.

Some individuals experience claustrophobic reactions in the scanner. Subjects will be informed of this prior to the study, but because it is difficult to predict who will have such a reaction. Any subject experiencing claustrophobia will be removed from the scanner immediately. There is no invasive component to this study, such as IV catheters, and so discomfort, bruising, or infection are not risks. The Siemens 3 T scanner has been approved by the FDA.

Scanner environment: The scanner environment presents an array of sensory inputs. To acclimate vulnerable populations to the scanner environment, the lab has produced sound recordings of all the elements of the scanner suite. These are presented to participants prior to enrollment in the study. These preliminary habituation procedures have been very successful in terms of stress and movement reduction, and we plan to continue to employ them with all Veteran participants. While in the scanner, participants` comfort is continually monitored via an intercom system. Also, an emergency "squeeze bulb" that produces an alerting sound to study staff is provided to all subjects for use in case of significant discomfort. All staff are trained to immediately assess discomfort and discontinue scanning when appropriate and/or requested. At all times during the scanning, participants will be accompanied by a senior staff member with research or treatment experience with psychiatric populations. Subjects may feel startled in response to some visual stimuli and the sound of knocking noises of the scanner. If the subject experiences anxiety or any other unpleasant sensation, the subject may let us know via the continuous wireless intercom connection and/or emergency squeeze bulb we have in place, and the subject will be withdrawn immediately. After the scan, the experimenter will inquire about any concerns subjects may have about the procedure. The experimenter will ask subjects whether they feel comfortable enough to proceed with the study; if not, the experiment will be discontinued without penalty.

Neuroimaging visit: Scanning will be conducted either at the Baylor College of Medicine Human Neuroimaging laboratory or the reseaerch dedicated Seimens 3 T Scanner at the Michael E DeBakey VAMC. A trained staff member will meet the Veteran at the entrance of the scanning facility and accompany the Veteran throughout the time while they are within the neuroimaging facility.

After the end of each experimental session, clinical study staff will provide a thorough study debriefing and compensation, assess participants for emotional distress, and address any remaining questions from the participant. In cases where distress is identified, study staff will notify the PI whowill meet with the participant and de-escalate as necessary. All participants will receive a brief debriefing that will include a description of the longer term goals of the study. All participants will be informed that Dr. Wright Williams (PI) runs an open clinic at the MEDVAMC and is available for consultation should the need arise.

Suicidality: Prior to study inclusion, a pre-test screening will be conducted to assess each prospective participant's suicidal risk/status. On the suicide risk checklist if at least three of the items are endorsed including item 1 at high levels, item 3, item 10, or item 12 then the patient is considered to be at heightened risk and will not be admitted to the study. In this case, the study PI's (Williams, Mott) and the referring VA clinician will be notified immediately.

We will continue to check risk behaviors throughout the examination. We will apply the same threshold criteria used during the pre-screening. Regardless of their affective state, a clinically trained staff member will accompany participants throughout their visit at BCM/VA. If moderate-severe levels of suicidal ideation are indicated, the PI and Co-Is will be alerted immediately. In the event that action is taken to assure the safety of patients, the Veteran's Psychiatrist of Record (POR) will be informed of the event by telephone or pager, in advance of seeing the patient during follow up at the VA. Trained study personnel will remain with patients who have expressed suicidal ideation until they are transferred directly to their POR or the VA clinician designated to receive participants after hours when their POR is not available. For VA patients who indicate severe suicidal ideation, he/she will be brought to the VA Emergency Room and we will notify their POR. After hours, the NPOD for Psychiatry will be contacted to alert them that the patient is being brought in. In addition to these procedures, the BCM/VA staff are trained to identify early signs of distress. Despite our best efforts to minimize affective distress, specific testing procedures may evoke distress in some participants. Distressed participants may experience anxiety, dissociation, or anger. These affective states may be reflected in the following observable signs: (a) anxiety: rapid breathing, sweating, trembling, tension, flushed face, crying; (b) dissociation: glassy eyes, vacant stare, non-responsive to communication, confusion; and (c) anger: tension, extreme agitation, clenched fists, raised voice, verbal hostility, physical aggression. We will tailor the specific interventions we use to stabilize a distressed participant to the particular manifestation of their distress. We will manage these reactions by applying emotion stabilization techniques recommended by the National Center for PTSD. These techniques are drawn from empirically supported approaches that are effectively help most distressed individuals manage their distress, for example: a) maintaining a calm, even voice with the patient; b) showing empathy and understanding of patient's reactions and perceptions; c) applying relaxation breathing techniques; d) applying grounding techniques to orient patient to time and place of testing; e) asking the patient about techniques learned at the MEDVAMC and applying those techniques. In general, a warm, collaborative approach will be used by BCM/VA staff to ensure the participant's experience of safety. This flexible approach will follow the participant's own adaptive coping approaches and be guided by the assistance of Drs. Williams and Mott when needed. If this initial intervention does not reduce the Veteran?s distress within several minutes, testing will be interrupted to allow the veteran more time to relax and regain their composure. After a rest period of up to 30 minutes, the participant will be asked whether he wishes to resume the study. He will be assured that discontinuing the study will have no adverse effects on their participation in alternate studies or treatment at the MEDVAMC. If the participant declines further testing, testing will cease and the PIs will be informed of the incident to determine an appropriate course of action. Additionally, the veterans POR will be informed of the event by telephone or pager, in advance of seeing the patient during follow up at the VA.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work. It is possible that subjects will not receive a benefit from treatment or even will get worse. However, research indicates that many, although not all, Veterans who complete the meditation intervention may experience a

reduction in their symptoms of PTSD and comormid psychological problems (as stated in section below), e.g., anxiety, depression.

Describe potential benefit(s) to society of the planned work.

PTSD affects over 7.5 million Americans in a given year and many more people world-wide. If effective, this treatment may become a viable treatment for Veterans with PTSD, thereby increasing their breadth of treatment options and access to care. In addition, we seek to document the effectiveness of treatment by using

neurobiological markers. This should also deepen our understanding of the neurobiological alterations induced by trauma and the contributions they make to symptom severity, comorbid psychological problems, and our expectations for recovery.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

The potential long-term benefits to society could be large, given the tremendous amount of personal suffering and loss of productivity that currently occur as a direct result of severe trauma. In addition to providing therapy for the patients, any new insights into human stress reactivity could potentially result in improved treatment either for these subjects or other Veterans who are obtaining treatment for PTSD. The study may also contribute to the development of more targeted treatment options. The scientific understanding that we will gain is also of general value to society, although it is always difficult to predict exactly what practical benefits will ensue as a result of new scientific knowledge. Considering that the risks to the subjects are small, the risk-to-benefit ratio is high.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

Yes

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

A partial waiver of HIPAA authorization is being requested to allow screening of potential participants prior to consent. Participants will not be enrolled without HIPAA authorization.

A partial waiver is also being requested to look up potential subject's diagnosis information in CPRS.

Explain why the research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals.

We will review medical records in order to identify potential subjects. No PHI will be removed from the CPRS files. Pre-screening of chart enables assurance that all criteria are met.

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.

We will review medical records in order to identify potential subjects. No PHI will be removed from the CPRS files. Pre-screening of chart enables assurance that all criteria are met.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.

We will need to have access to protected health information to correctly identify the study patients. It would be cost-prohibitive (more than the small grant can afford) and time consuming to bring subjects in for consent if they don't have the diagnoses required for the study.

Many of the potential subjects who participate in the phone screening could easily be determined to be ineligible via a CPRS review therefore reducing the burden on potential subjects

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure. An adequate plan exists in order to protect health information identifiers from improper use and disclosure, because patients PHI will not be recorded or kept unless they are enrolled in the study. Once enrolled, participant¿s information will only be recorded under their study ID. PHI collected from the chart for screening purposes will not be kept in any form, and used for viewing purposes only, to ensure eligibility criteria. Information collected and used following enrollment will be recorded on study CRF¿s per protocol and entered via the electronic database system identified in the protocol.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

Adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule, because: The PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

Yes

Specific information concerning drug abuse:

Yes

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
Yes

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
No

Partial Social Security # (Last four digits):
Yes

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

Other:
No

Will additional pertinent information be provided to subjects after participation?
No

If No, explain why providing subjects additional pertinent information after participation is not appropriate.
Since this waiver is for identification purposes only, there would not be information to disclose to subjects.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

Yes

Explain how the research involves no more than minimal risk to the participants, and the specifics demonstrating that the research does not involve procedures for which written consent is normally required outside of the research context.

We are requesting permission to waive documentation of consent to complete a telephone-based basic screening. If the telephone-based basic screening indicates that participants may be eligible for the study, they will be invited to complete the in-person screening interview at the MEDVAMC. We will provide a highly abbreviated screen over the phone to reduce travel burden on possible participants, some of whom may live in rural locations, who do not meet basic eligibility criteria. Therefore, participants asked to travel to the MEDVAMC will be more likely to meet the following eligibility criteria: 1.) Mild traumatic brain injury (mTBI) as defined by the VA/DoD Clinical Practice Guideline and 2.) PTSD as assessed by the Clinician Administered PTSD Scale (CAPS).

During the screening, potential subjects will solely be asked about the presence or absence of symptoms of mild traumatic brain injury and PTSD and will not be required to discuss specific traumatic experiences that may evoke some anxiety and distress in the subject. However, if subjects should become anxious or distressed, they will be given several options: slow down the pace of the screening, take a break, or discontinue the screening. In addition, prior to the screening, the interviewer will inform participants that some of the questions will be about difficulties they are having or may have had in the past, and that they are free to discontinue the screening or not answer any questions that they feel uncomfortable addressing. Throughout the screening, the interviewer will be mindful of the emotional state of the subject so as to manage any clinically significant distress that could be evoked. In addition, the interviewer will discontinue the screening if it is their judgment that discontinuation is in the interest of the interviewee.

Any notes taken by the interviewer will be immediately shredded after the screening when eligibility is determined. The telephone-based screening questions will not be recorded in the research database and will solely be used to determine basic eligibility criteria. The waiver affords practicability of carrying out the study while not presenting greater than minimal risk and because information will not be recorded, will not adversely affect the rights and welfare of the subject.

J2. Consent Procedures

Who will recruit subjects for this study?

PI

PI's staff

Third Party: MEDVAMC Mental Health providers

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Many subjects will be Veterans receiving mental health services at the Michael E DeBakey VAMC and will be recruited through referral from clinicians. Recruitment will involve reaching participants through physician and health care provider?s offices. Health care providers will inform potential participants about the study, and if interested, the participant will fill out a form that provides the researchers with the participant's contact information. Using advertisements, referrals, and electronic or phone contact with veterans support groups, veterans may also be recruited off campus, e.g., from local universities and veterans' groups, or from the Traumatic Brain Injury Center of Excellence at the MEDVAMC.

Once potential participants provide interest in participating in the study, (either by filling out a form to provide the researchers their contact information or by calling in response to an advertisements), they will complete a telephone-based basic screening interview. A telephone script will be used to explain the research project to all potential subjects. Potential participants will be asked whether they are interested in the study and whether they consent to completing the basic phone screen. If they consent to proceeding with the basic screen, the date of verbal consent will be recorded in the study database. The telephone-based screening questions will not be

recorded in the research database and will solely be used to determine basic eligibility criteria. We will provide the basic screen over the phone to reduce travel burden on possible participants who do not meet basic eligibility criteria. If the initial screen indicates the patient may be eligible for the study, they will be invited to complete the in-person screening interview at the MEDVAMC.

Either the PI or the PI's research assistant will conduct the informed consent process to enroll patients in the study. Following consent, the PI or research assistant will conduct the screening interview with a questionnaire inquiring into demographic variables, medical history, and contraindications to magnetic resonance imaging. Any questions that potential participants have will be answered by study staff.

The contents of the consent form will be reviewed with each potential participant and any questions participants have will be answered prior to providing consent. If participants are ineligible for participation based on their screening interview information or choose not to participate in the study, initial screening interview information linked to subject identity will be destroyed. Study staff will emphasize to all participants that they may withdraw from the research at any time with no adverse consequences and will be compensated for their participation in the study up to that point.

TRP Clinicians will be informed of the study and may choose to refer individuals to the study if they believe a patient may be eligible and appropriate for participation. All subjects receiving medical care will be informed that their treatment will not be affected by their choice to participate or not to participate. Staff of the study will contact the subject?s treating clinician and confirm that their participation in the study does not pose an increased medical or behavioral risk to the participant. Subjects interested in the study may fill out a physician's office form to be contacted by the researchers.

A partial waiver of HIPAA authorization is being requested to allow screening of potential participants prior to consent. Participants will not be enrolled without HIPAA authorization.

Are foreign language consent forms required for this protocol?

No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?

No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?

Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse:

Yes

Specific information concerning drug abuse:

Yes

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

Yes

Demographic information (name, D.O.B., age, gender, race, etc.):

Yes

Full Social Security #:

No

Partial Social Security # (Last four digits):

Yes

Billing or financial records:

No

Photographs, videotapes, and/or audiotapes of you:

Yes

Other:

No

At what institution will the physical research data be kept?

Michael E. DeBakey VA Medical Center in rooms 6C-162 and 6C-113.

How will such physical research data be secured?

Subjects will be assigned a coded study ID. All paper records and recordings from the study will be identifiable only by this subject number and will be kept in a locked file cabinet in the PI's locked office, room 6C-113 and 6C 162 in the main MEDVAMC hospital building (Building 100).

At what institution will the electronic research data be kept?

Michael E. DeBakey VA Medical Center, Baylor College of Medicine. Electronic data will be stored on S:/Research/Newsome,Mary/SPIRE_H-35409. Audio recordings will be made with an Olympus DS-7000 digital voice recorder with data encryption, as suggested by ISO. The recorder meets FIPS-140-2 encryption

requirements. The recorder will be stored in a locked cabinet in 6C-162. The audio files will be stored on L:/Research/Newsome,Mary/SPIRE_H-35409.

Non-sensitive (de-identified data) will be securely uploaded and stored on VINCI. Please see attachment in Section S on VINCI.

Non-sensitive (de-identified) neuroimaging data will be uploaded to BCM BigFile and sent to co-I Olivia Haller for

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):

Yes

Such electronic research data will be secured via Other:

Yes, (describe below):

A copy of subjects' non-sensitive research data without any identifiable information will be transferred via CD to study co-investigators at Baylor College of Medicine. MRI imaging data will be kept and analyzed on password

protected secure storage and server BCM network. All 18 HIPAA identifiers will be removed prior to sending data outside the VA. Additionally, a digital key associating de-identified imaging data to de-identified behavioral data will be kept within a database on the VA secure server.

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

Yes, identify the classes of the persons:

People who ensure quality from the institutions where the research is being done, federal and other regulatory agencies will have access to all of the research data.

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

PHI will not be transmitted to sponsors or collaborators outside MEDVAMC or BCM. All PHI will stay at MEDVAMC or BCM. Non-sensitive (de-identified data) will be securely uploaded and stored on VINCI. Please see attachment in Section S on VINCI. Non-sensitive data will be transferred to collaborators at Colgate University

(Olivia Haller) or University of Southern California (Emily Dennis) through BCM's BigFile or Box. Non-sensitive, de-identified data may be accessed and analyzed via the BCM network. The MEDVAMC Privacy Officer will be asked to review the data prior to transferring the data.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

The PI, Co-I, research assistants, and governing bodies/institutions that have legal right to audit will have access to identifiable research data. People who ensure quality from the institutions where the research is being done, federal and other regulatory agencies will have access to all of the research data.

The purpose of collecting information covered under 38 U.S.C. 7332 is to conduct scientific research and no personnel involved in this study will identify, directly or indirectly, any individual patient or subject in any report of such research.

It is understood by the PI that data will not be used or shared with others outside the scope of the research study as documented in the protocol approved by the IRB and MEDVAMC R&D Committee.

Removal of access to research study data will be accomplished for all study personnel when they are no longer

part of the research team.

The coded study ID is a number unrelated to any identifiable patient information. Data will be identified only by this number and will not contain any HIPAA identifiers. Consent forms will contain the subject's name and last four digits of the social security number as the last four digits of the social security number may be used to access and enter information into subjects' health records for this intervention study.

PI will transfer non-sensitive (no identifying information) data from a BCM laptop (with CRIS-CAT installed) to the L drive using a VA flash drive. A digital file of the video and audio recordings will be stored on the L drive on a password protected VA server and accessed only on password protected computers.

Audiotapes of the therapy sessions will be made in order to check that the therapist is adhering to the protocol. These audiotapes will be recorded by an Olympus DS-5000iD Digital Voice Recorder. The PI or designated research staff will capture video data using Sony HandyCam #DCR-SX85 and the data will be transferred to the VA network in accordance with VA IT/security standards and procedures .

Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery,

device, drugs, etc). If appropriate, discuss the availability of financial counseling. Subjects will not be responsible for research related costs.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

100

Distribution Plan:

Subjects will be paid after each study visit. Participants 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). If a participant attempts the scan session but does not complete it, they will still receive payment. The maximum total amount that subjects could receive for their participation in this research study is $100 ($30 + $20 + 50).

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug that is not approved by the FDA?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

No

Section Q. Consent Form(s)

None

Section R: Advertisements

Mode of Advertising: Newspaper

Exact language of Advertisement:

Meditation Therapy for the Treatment of PTSD and mTBI using Functional MRI 8 week research study with compensation

Eligibility: • OEF/OIF/OND Veterans • Diagnosis of PTSD & Mild Traumatic Brain Injury • Between 18-49 years old • No current serious medical conditions • Free from metal in body • Not claustrophobic • Enrolled in or willing to be enrolled in VA

Requirements of program: • Screening • Pre & post treatment assessments and MRI brain scans • 8-week meditation or PTSD education group

Possible benefits: • Practice relaxed alertness • Reduce PTSD symptoms • Improve sleep, decrease pain, reduce depression & anxiety

Compensation up to $110 and receive images of your brain!

Study Coordinator

Jenny Bannister (713) 791-1414 Ext. 23749

Study is funded by the Department of Veterans Affairs—Rehabilitation Research & Development Service

Mode of Advertising: Radio

Exact language of Advertisement:

Meditation Therapy for the Treatment of PTSD and mTBI using Functional MRI 8 week research study with compensation

Eligibility: • OEF/OIF/OND Veterans • Diagnosis of PTSD & Mild Traumatic Brain Injury • Between 18-49 years old • No current serious medical conditions • Free from metal in body • Not claustrophobic • Enrolled in or willing to be enrolled in VA

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Study Coordinator

Jenny Bannister (713) 791-1414 Ext. 23749

Study is funded by the Department of Veterans Affairs—Rehabilitation Research & Development Service

Mode of Advertising: Bulletin Board

Exact language of Advertisement:

Meditation Therapy for the Treatment of PTSD and mTBI using Functional MRI 8 week research study with compensation

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Study Coordinator

Jenny Bannister (713) 791-1414 Ext. 23749

Study is funded by the Department of Veterans Affairs—Rehabilitation Research & Development Service

Mode of Advertising: Internet

Exact language of Advertisement:

Meditation Therapy for the Treatment of PTSD and mTBI using Functional MRI 8 week research study with compensation

Eligibility: • OEF/OIF/OND Veterans • Diagnosis of PTSD & Mild Traumatic Brain Injury • Between 18-49 years old • No current serious medical conditions • Free from metal in body • Not claustrophobic • Enrolled in or willing to be enrolled in VA

Requirements of program: • Screening • Pre & post treatment assessments and MRI brain scans • 8-week meditation or PTSD education group

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Compensation up to $110 and receive images of your brain!

Study Coordinator

Jenny Bannister (713) 791-1414 Ext. 23749

Study is funded by the Department of Veterans Affairs—Rehabilitation Research & Development Service

Mode of Advertising: BCM Clinical Trials Website

Exact language of Advertisement:

Meditation Therapy for the Treatment of PTSD and mTBI using Functional MRI 8 week research study with compensation

Eligibility: • OEF/OIF/OND Veterans • Diagnosis of PTSD & Mild Traumatic Brain Injury • Between 18-49 years old • No current serious medical conditions • Free from metal in body • Not claustrophobic • Enrolled in or willing to be enrolled in VA

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