Study Title: Neurofeedback for PTSD

NCT Number: NCT03482466

Document Date: IRB Approved on 8/20/2021

Compare

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-38715
Status: Approved
Initial Submit Date: 6/6/2016
Approval Period: 9/30/2020 - 9/29/2021

Section Aa: Title & PI

A1. Main Title

PTSD VIRTUAL WORLD FMRI TRAINING

A2. Principal Investigator

Name:	RAMIRO SALAS	Phone:	713-798-3502
Id:	690935	Fax:	713-798-4488
Department:	PSYCHIATRY & BEHAVIORAL SCIENCES	Email:	rsalas@bcm.tmc.edu
Center:		Mail Stn:	BCM350

A3. Administrative Contact

Name:	FRANK F VELASQUEZ	Phone:	713-798-0117
Id:	172146	Fax:	713-798-4089
		Email:	ffvelasq@bcm.tmc.edu
		Mail Stn:	BCM350

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

A4. Co-Investigators

Name:	M WRIGHT WILLIAMS	Phone:	713-794-7629
Id:	014678	Fax:	
Department:	PSYCHIATRY & BEHAVIORAL SCIENCES	Email:	wrightw@bcm.edu
Center:		Mail Stn:	BCM350
Name:	DAVID RESS	Phone:	713-798-3973
Id:	182661	Fax:	
Department:	NEUROSCIENCE	Email:	ress@bcm.tmc.edu
Center:		Mail Stn:	BCM240
Name:	LIA SMITH	Phone:	713-798-3502
Id:	208368	Fax:	
Department:	PSYCHIATRY & BEHAVIORAL SCIENCES	Email:	lias@bcm.edu
Center:		Mail Stn:	BCM350
Name:	ANDREW FLOREN	Phone:	214 314 2895
Id:	Non-Baylor	Fax:	

Institution: UT Austin
Address: One University Austin TX 78712
Email: andrewfloren@gmail.com

Name: BRUCE NAYLOR
Id: Non-Baylor
Institution: University of Texas at Austin
Address: Department of Computer Sciences The University of Texas at Austin, Austin TX 78712
Phone: 214 314 2895
Fax:
Email: naylor@austin.utexas.edu

A5. Funding Source:

Baylor College of Medicine (Internal Funding Only)

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

A9. ClinicalTrails.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?
No, this clinical is not a clinical trial, or does not meet the definition of an Applicable Clinical Trial, or does not need to be registered under the terms and conditions of an award, or is not a clinical trial with results intended to be reported in an journal belonging to the ICMJE. Registration is not required.

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Post traumatic stress disorder is a common occurrence in US armed force veterans. One of the most commonly used therapeutic approaches is exposure therapy, where patients are exposed to memories of traumatic events in the hope that the memory becomes desensitized over time. Although successful in many cases, exposure therapy is far from being useful in every patient. In addition, little is known about the brain mechanisms at play, which hinders our ability to improve the therapeutic effects. We plan to use a novel exposure approach that combines several state-of -the -art techniques: we will use a "virtual world" approach to exposure, and will use real-time functional MRI to be able to analyze brain activity while the patient is exposed to trauma-associated virtual situations (see Rothbaum et al., Virtual reality exposure therapy for combat-related posttraumatic stress disorder,Ann N Y Acad Sci. 2010 Oct;1208:126-32; Roy et al., Heart rate response to fear conditioning and virtual reality in sub threshold PTSD, Stud Health Technol Inform. 2013;191:115-9). The real-time analysis will use a machine-learning approach to determine brain states. This information will feed into the appearance of the virtual world such that the patient may eventually gain strategies that allow for bringing oneself to a state of non-stress.

Section D: Purpose and Objectives

We aim to improve the treatment of PTSD using a combination of virtual worlds and neuro-feedback. Virtual worlds have been used to successfully treat PTSD induced by combat experience for a subset of the population. The primary approach is called extinction therapy, in which carefully controlled stimuli is used to evoke the associative memory of the original trauma. By maintaining the intensity of the patient response at a level the patient can comfortably tolerate, the sensitivity for triggering the traumatic response as well as the strength of the response can be gradually reduced with repeated treatments. However, given the variety of patient responses, modulating the stimulus optimally over the course of a treatment session is elusive. What is required is a real-time neuro-feedback system that can continually measure the degree of traumatic state of the patient, and then automatically control the stimulus to maintain the stress response within an effective therapeutic range. The purpose of this pilot project is to approach this goal by applying recent basic research we have conducted jointly at UT Austin and BCM on analyzing brain states using fMRI data with machine learning algorithms while exposing the subject to real-time virtual worlds. This pilot will extend that work to real-time neuro-feedback applied to treatment of PTSD. Using fMRI for neuro-feedback, rather than the much more common EEG, should enable a significantly increased accuracy in the assessment of the patient¿s current neuro-cognitive state. It should also lead to a better understanding of the neurophysiology during a stress response, e.g. which brain regions are most involved. This is not necessarily the same as which brain regions are the most active. Our analysis technique takes the next step by measuring the degree to which brain regions are critical to discriminating between different brain states, such as threatened versus safe.

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?

Patients will be assessed by a clinician as competent and stable enough to understand and sign the consent form, to be exposed to a virtual world with war scenes, and to be scanned in an MRI machine.

Informed consent will be obtained according to federal regulations and BCM policies. The investigational nature and objectives of the trial, the procedures involved and their attendant risks and discomforts will be carefully explained to the patient prior to enrollment. Confidentiality will be protected within the limits allowed by law. It will be emphasized that the study is completely voluntary. Adequate time will be allowed to decide on their participation status. Questions and concerns will be addressed thoroughly.

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.

Subjects will be PTSD patients deemed stable enough to go through these procedures unharmed. There is no placebo group, and all patients will undergo similar protocols. All subjects will first be trained in the stimulus in an office equipped with the Virtual Iraq (software Bravemind or similar) stimulus equipment. This first session will establish stimulus criteria that will later be used during exposure to similar stimuli while being scanned with MRI. Subjects will be given real-time feedback during these sessions in an effort to train them to reduce their stress level. We hypothesize that this treatment will allow PTSD patients to learn how to bring their brain activity to a "non-threatened" state on demand, whenever they are confronted with stressful situations in real life.

Inclusion Criteria:

Adult veteran patients suffering from post traumatic stress syndrome as assessed by a clinician will be included. A score of 2 or 3 on the Clinician-Administered PTSD Scale (CAPS) will be required. For testing of procedures, healthy controls will also be included.

Exclusion Criteria:

1. Claustrophobia (this would make lying in the scanner very uncomfortable). 2. Pregnant (the patient will be queried on pregnancy status at each visit, if patient reports being pregnant she will be discontinued from the study). 3. Contraindications to MRI: pacemaker, aneurysm clips, neurostimulators, cochlear implants, metal in eyes, steel worker, or other implants. 4. History of head injuries resulting in loss of consciousness > 30 minutes. Non-fit to be scanned for any other reason, as assessed by a psychiatrist. 5. A CAPS score or 0 or 1 (not enough symptoms to need treatment) or 5 (for possible safety reasons).

F2. Procedure

Subjects will be first assessed and screened for eligibility and safety. As part of the screening process, a CAPS-5 PTSD clinician administered assessment will be administered. This administration may be recorded for validity purposes, in which chase data would be stored using a VA-approved secure portable USB device. These data will be destroyed at the conclusion of the study. Study participants will sign VA forms 10-3203 and 10-5345 for these purposes. The next step is an evaluation in a specially-equipped lab of appropriate stimulus parameters to evoke a stress response in each subject. The subject will interact with an audiovisual stimulus called Virtual Iraq, a commercially available virtual-world environment. The interaction involves passive view of a virtual town with an appearance similar to those found in Iraq. Events will occur in the stimulus designed to evoke stress, such as smoke, explosions, or the appearance of enemy combatants. The level of stress elicited by the virtual world will be manipulated using controls in the stimulus package specifically designed to vary threat levels. Patients will undergo this training in the presence of an experienced PTSD therapist, who will gradually guide the patient through a gamut of stress levels that remains at tolerable levels. Calm environments (such as a nice beach) will also be explored by the participants. Once we verify that all subjects can be safely exposed to this virtual world, they will be scanned using functional MRI under stimulus conditions that vary over a gamut of conditions varying from non-threatening to strongly threatening. The MRI scanner we will use differs from conventional scanners only in that the magnet strength is 3 T, rather than the more typical 1.5 T magnets used in routine clinical scanning. The subject will enter a large room where a powerful magnet is located. Subject will be instructed to remove all jewelry and other metal-containing objects. The subject will then be placed on a narrow table with plastic-encased metal coil close to the head. Next, the subject will be slid into a small tunnel approximately 6 feet long and 24 inches in diameter. The duration of the scan is approximately 70 minutes. A small mirror with a filter holder to enable 3D stimulation will be positioned above the subject's head so they can view a 3D LCD display at the opposite end of the scanner. After the subject is positioned, the table will move the subject into the scanner itself. Subjects will wear MR-compatible headphones for audio stimulation, and for voice-communication with a technician or investigator. They will also be given a pneumatic squeeze ball which they will instructed to use to signal that scanning should be stopped at any time. Subjects will participate in 3--8 scanning sessions. Brain imaging data will be collected and analyzed using machine learning techniques to discriminate a range of brain states varying from ¿non-threatening¿ to ¿highly threatening¿. The first 1--2 sessions will be used to ¿train¿ a software analysis program to recognize the subject¿s brain states. Once these two states have been determined, subjects will be scanned during 1--6 feedback sessions, using similar stimulus conditions, but this time a "thermometer" will display, in real time, the current brain state threat level. Subjects will be instructed to use their mind to bring the thermometer toward the "non-threatening" state. Once the subject is able to move the thermometer toward sufficiently non-threatening "temperatures" the display will briefly change to a pleasing and comfortable image to provide positive feedback. Data storage in a VA repository will be a requirement of the study. Data will be stored in a VA repository (a folder within the S drive in which the imaging data will be stored) on the S drive. This repository is only not to lose data possibly necessary in the future analysis. It will not be released to other investigators unless thei have their own IRB approval prior to coming and asking for these data, including if the investigators of this study decide to do any further research unrelated to this study protocol. Participants will be free to withdraw their data from the study at any point.

Data analysis: During the training sessions we will use the imaging data in real time to feedback information about the brain state (where in a continuum from CALM to STRESS the participant is a each moment) for the participant to use mental strategies (think happy thoughts, breath deeply, imagine a quiet place, etc) to try to bring the thermometer toward CALM. As the thermometer moves to CALM, the environment will be manipulated toward less stressful images and sounds. We hypothesize that over time, participant's brains will accommodate to expect that these mental strategies effectively change the environment toward being calmer and safer. This may translate into such strategies becoming more and more useful in real life. The main data to be analyzed will be whether PTSD symptoms (as measured by questionnaires) decrease over time.

In an exploratory manner, some participants may explore the Virtual Iraq (and calm environments) while wearing a commercially available one-electrode eeg. This is similar to headphones and gives an eeg signal that will be analyzed to study the possibility of discerning the signal while under stress (Virtual Iraq) and calm epochs. This will last no more than 15 minutes and data will be analyzed for each individual, solely to verify feasibility for future studies.

Section G: Sample Size/Data Analysis

G1. Sample Size

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

Local: 35 Worldwide: 35

Please indicate why you chose the sample size proposed:

There is no data available to calculate sample size. This will be a pilot to study the possibility that the proposed approach merits further study.

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?

The primary outcome will be clinical data from CAPS scores before and after the procedure.

In addition, we will use activity monitors (similar to a commercially available FitBit) that will be used by subjects from at least a week before the study starts, to at least a week after the last MRI session. This will allow us to study not only diurnal activity, but also quality of sleep, a major problem for PTSD patients.

Finally, we will use general linear model analysis on aggregate data to determine if there are specific brain regions in which activity is higher or lower during the two brain states (Threat and Non-Threat). This data may render information important to design and improve PTSD therapy (pharmacological or otherwise) in the future.

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:

Risks associated with fMRI These 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. Some individuals experience claustrophobic reactions in the scanner. Subjects will be informed of this prior to the study. 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. However, there may be additional risks associated with scanning at 3 T compared to the conventional clinical scanners in the 1.5-2.0 T range. These include: 1. Effect of the static field. There is no conclusive evidence for irreversible or hazardous bioeffects to acute, short-term exposures of humans up to 2.0 T (Shellock and Kanal, 1996). Studies have indicated some side-effects at 4.0 T, namely unusual sensations including nausea, vertigo, and metallic taste (Schenck, 1991). However, there is no evidence that this is either irreversible or harmful. If subjects experience unusual sensations, they will be withdrawn. 2. Effect of the gradient field. MRI operates by rapidly changing small additional fields, called gradients. This will induce small electrical currents in any conductor, and thus could theoretically induce mild peripheral nerve stimulation. However, this is not substantially different at higher magnetic fields since the gradients are separate from the main magnet. There is no evidence that the effect of the gradients is any different at 3 T than at 1.5 T. However, if subjects experience peripheral nerve stimulation, e.g. tingling or twitching, they will be withdrawn. 3. Effect of the RF electromagnetic field. The higher magnetic field strength requires that higher RF frequency pulses are used to excite the protons in the subject's brain. The limits of RF energy that can be safely given to humans has been clearly defined by the FDA: a. The exposure to RF energy below the level of concern is an SAR of 0.4 W/kg or less averaged over the body, and 8.0 W/kg or less spatial peak in any 1 g of tissue, and 3.2 W/kg or less average over the head; or b. The exposure to RF energy that is sufficient to produce a core temperature increase of 1 degree C and localized heating to no greater extent than 38 degree C in the head, 39 degree C in the trunk, and 40 degree C in the

extremities, except for patients with impaired systemic blood flow and/or perspiration. We will adhere to the recommendations for the head. The scanner has a large monitor indicating the RF power level which can be limited to a specific maximum.

Risks associated with trauma exposure PTSD patients may feel stress and anxiety when exposed to "Virtual Iraq". However, we will avoid recruiting patients with a caps score higher than 3, which will minimize the possibility of a serious reaction to the scenes. In addition, PTSD patients are routinely exposed to therapies in which stressful events are recalled (including Virtual Iraq, which we will use in this application), usually with positive consequences. Patients will be debriefed and asked how they are doing. If they report extreme anxiety or agitation they will need to be held until they feel better.

The eeg pilot (to be performed only on some participants as a pilot to study the possibility of using eeg in the future in similar protocols) adds no risk to the protocol. The eeg electrode to be used feels just like wearing headphones. There is no known risk associated to wearing the electrode, which is sold and marketed as a toy suitable even for children.

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 these procedures result in individual personal strategies to avoid feeling stress in PTSD patients. This is exactly what we want to measure. Patients will also receive a small monetary compensation.

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

The potential benefits to society are quite large: If our trial is successful, this method could result in a major improvement on exposure therapies, and in the acquisition of a large body of knowledge in terms of the brain mechanisms of PTSD and its recovery.

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

The risks are minimal, being that the MRI is very safe (we have scanned thousands of patients with no adverse events) and exposure therapy has been performed in thousands of veterans.

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 waiver of consent and HIPAA authorization are requested in order to conduct chart review to determine participant eligibility. Participant eligibility will be determined by presence or absence of current PTSD diagnosis. Chart review will only be conducted for study candidates whom have expressed interest in the study and have provided verbal consent to verify current PTSD diagnosis (yes/no) via medical chart review. Once a trained member of the study staff has confirmed the presence of a current PTSD diagnosis, we will move to informed consent for the study itself.

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.

This research involves no more than minimal risk. Information obtained during chart review will not be recorded and will not affect participants enrolled in the study. Study candidates will be asked for verbal consent to verify that they have a current PTSD diagnosis (yes/no) via chart review.

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

The waiver will only be used to verify study candidates that have a current PTSD diagnosis (yes/no). Knowledge will be obtained by a trained member of the research staff that has pre-existing access to clinical records at the Michael E. Debakey VA medical center. This knowledge will not be recorded and will not affect the care of study candidates at the

Michael E. Debakey VA medical center. Study candidates will be asked for verbal consent to verify that they have a current PTSD diagnosis (yes/no) via chart review. Upon verifying that the interested study candidate has a current PTSD diagnosis (yes/ no), the study candidate will be contacted via phone by the same trained study staff member to schedule an in-person meeting with said study staff member to review the consent form for the current study.

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.

The use of the waiver will be used to verify study eligibility for study candidates that have already verbally expressed their interest to participate in the current study and whom have verbally consented for a trained member of the study staff to verify that they have a current PTSD diagnosis (yes/no) via chart review.

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.

Information obtained during chart review will not be recorded on any study materials.

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.

Identifiers will not be recorded.

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.

PHI will not be reused or disclosed 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:

No

Specific information concerning drug abuse:

No

Specific information concerning sickle cell anemia:

No

Specific information concerning HIV:

No

Specific information concerning psychiatry notes:

No

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

No

Full Social Security #:

No

Partial Social Security # (Last four digits):

Yes

Billing or financial records:

No

Photographs, videotapes, and/or audiotapes of you:

No

Other:

No

Will additional pertinent information be provided to subjects after participation?

Yes

If Yes, explain how subjects will be provided additional pertinent information after participation.

Following participation in the study, study participants will be debriefed. At that time, study participants may request a copy of the data that they provided during the study.

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.

A waiver of consent will only be used to ask the study candidate a series of MRI safety questions and to determine whether the study candidate has a current PTSD diagnosis (yes/no). Only verbal consent will be used for that. Once we have demonstrated that it would be safe to scan a person, then we will move to informed consent for the study itself.

J2. Consent Procedures

Who will recruit subjects for this study?

PI

PI's staff

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.

PTSD patients will be identified by clinicians at MEDVAMC, who will refer them to the investigators of the study and their staff. Study candidates may indicate their interest in the study and sign up to be contacted for the study at VA sponsored research events. Study staff may access electronic medical records of interested study candidates to ensure PTSD diagnosis (yes/no). Then, study staff will contact interested study candidates via phone or in person to verify that subjects do not have any MRI contraindications. Subjects without MRI contraindications will then be consented during an initial screening session prior to beginning any virtual reality training. During the screening season, study staff will discuss study participation with subjects, including an explanation of the purpose, procedures, risks, benefits, and alternatives. Furthermore, study staff will answer any questions the subject may have prior to enrolling in the study and signing the consent form.

A verbal consent procedure will be used to verify MRI safety. This will be done using a verbal consent script. Prior to asking for verbal consent for the MRI contraindications, we will briefly inform the subject about the overall study¿s purpose (see section S) followed by the MRI safety screen. If passed, we will then move onto informed consent. This verbal consent will simply state that we need to make sure it is safe to undergo the MRI scan procedure before we move to informed consent and a more detailed explanation of the study.

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:
No

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:
No

Other:
No

At what institution will the physical research data be kept?
BCM, MEDVAMC (MEDVAMC Building 110, room 207)

How will such physical research data be secured?
Physical research data will be kept at the PI's lab, in a keyed cabinet inside a keyed room: MEDVAMC Building 110, room 207.

Video recordings of CAPS-5 interviews will be recorded for validity purposes. These will be stored on a VA-approved secure portable USB device. This device will also be kept at the PI's lab, in a keyed cabinet inside a keyed room: MEDVAMC Building 110, room 207. Video recordings of CAPS-5 interviews will be destroyed at the conclusion of the study.

At what institution will the electronic research data be kept?
BCM and MEDVAMC (S Drive: Research\Salas\H-38715)

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):
S Drive: Research\Salas\H-38715

Video recordings of CAPS-5 interviews will be recorded for validity purposes and will be stored on a VA-approved secure portable USB device. This device will also be kept at the PI's lab, in a keyed cabinet inside a keyed room: MEDVAMC Building 110, room 207. Video recordings of CAPS-5 interviews will be destroyed at the conclusion of the study.

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.

Only non-identifiable data pertaining to demographic information, drug abuse, and alcohol abuse will be moved outside BCM, except for data to be kept at MEDVAMC drive S. Data will be de-identified prior to transmission. Data will be transmitted using a VA-approved secure portable USB device or via secure/encrypted e-mail.

Will you obtain a Certificate of Confidentiality for this study?

No

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

As with most human research, loss of confidentiality is always a risk. Every effort will be made to maintain confidentiality, including removing identifiers from data as soon as possible.

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.

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.

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.

There is no cost for patients.

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:

440

Distribution Plan:

Study participants will receive $50 per scanning session (8 total) and $40 for screening, for a possible total of $440 if all sessions are done. Subjects will be paid for each portion of the study as they complete it.

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?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

No

Section Q: Consent Form(s)

PTSD MRI virtual world exposure

Section R: Advertisements

Mode of Advertising: Other: Flier

Exact language of Advertisement:

A Study of the Effectiveness of Virtual Reality for PTSD Using Functional MRI Why?

Traumatic experiences have a profound impact on the lives and well-being of the people who experience them. Trauma can produce changes in the brains of Veterans exposed to them. However, little is known about the brain mechanisms at play following exposure to trauma, which hinders the development of effective treatments.

In this study, we use state-of-the-art technologies to investigate brain states following traumatic experiences. Using a unique combination of functional MRI, virtual reality, and neuro-feedback, this study aims to analyze stress responses following traumatic experiences to improve treatments for PTSD.

Will I be compensated?

You will receive $40 for the screening session and $50 per scanning session ($40 per scan with $10 for parking; up to 8 total), for a possible total of $440 if all sessions are completed.

Where are we?

CAMRI (Scanning sessions) Baylor College of Medicine 1 Baylor Plaza Suite S104 Houston, TX 77030

Michael E. DeBakey VA Medical Center (Screening sessions) 2002 Holcombe Blvd Houston, TX 77030

If you would like to participate please contact:

Lia Smith Research Coordinator

(817) 382-2430 Lia.Smith@bcm.edu

Who can participate? Veterans who: Have PTSD, as assessed by a study clinician Are 18-64 years old Speak English as their primary language

Who can't participate? Anyone who: Is claustrophobic Is currently pregnant, or becomes pregnant during the course of the study Has any contraindications to MRI, such as a pacemaker, aneurysm clips, neurostimulators, cochlear implants, metal in eyes, or other implants, or previous steel working experience Has had a head injury resulting in loss of consciousness for more than 30 minutes Is not fit to be scanned for any other reason

What do participants do?

Initial screening: We first provide an overview of each part of the study, and answer any questions you may have. We will then ask you some questions and determine whether you can qualify for the interview/questionnaire portion of the study.

Interview and questionnaires: Next, you will participate in a structured interview regarding past and present difficulties you may have had. You will also be asked to complete some questionnaires. The purpose of this interview and the questionnaires is to determine that you qualify for the study. This visit lasts between 2-4 hours.

Virtual reality training sessions: Veterans will participate in 1-2 functional magnetic resonance imaging (fMRI) sessions at the Core for Advanced Magnetic Resonance Imaging (CAMRI) at Baylor College of Medicine. During these sessions, you will be exposed to a virtual reality combat scenario while your brain activity is monitored. Information will be collected throughout the scanning session about your stress response to various stimuli. Sessions last about 1-2 hours. fMRI is non-invasive and should not cause discomfort. Unlike x-rays or CT scans, fMRI does not involve exposure to radioactive material.

Study: PTSD Virtual World fMRI Training

Feedback sessions: Next, Veterans may participate in up to 6 feedback sessions. Similar to the training sessions, you will view virtual reality combat scenarios while your brain activity is monitored in a fMRI machine. During these sessions, however, you will be provided constant feedback on your stress levels to help you bring your stress levels down. We anticipate these sessions to last about 1-2 hours.

Ongoing assessment: Veterans will fill out a number of self-report questionnaires throughout the course of the study. You will also be given 1-2 wearable sensors to monitor your sleep quality, heart rate, and physical activity during the course of the study.

Mode of Advertising: BCM Clinical Trials Website

Exact language of Advertisement:

Research Study for US veterans suffering from PTSD. We are investigating how the brain functions in PTSD and how to modulate its activity. If interested, please call (817) 382-2430 or email lia.smith@bcm.edu. Compensation available.