

Study Title: Neurofeedback for PTSD

NCT Number: NCT03482466

Document Date: IRB Approved on 8/20/2021



Subject Name: _____ Date: _____

Subject Initials: _____

Principal Investigator: RAMIRO SALAS VAMC: _____

H-38715 - PTSD VIRTUAL WORLD FMRI TRAINING

PTSD MRI virtual world exposure**Background**

You are invited to take part in a research study related to treating post traumatic stress disorder among veterans. You have been identified and recommended for this study based on a diagnosis of post traumatic stress disorder from your doctor, or self-identified as having post-traumatic symptoms. Post traumatic stress disorder is common among veterans. One treatment that is used is "exposure therapy." In this type of therapy, the patient "re-lives" a traumatic event, often making the traumatic memory less severe. We will use brain imaging and virtual reality (Virtual Iraq, in which you would be "driving" in a computer-simulated Iraq landscape) to study whether information from your brain activity can be used to help improve your condition. Please read this information and feel free to ask any questions before you agree to take part in the study.

Purpose

This research protocol will study the possibility that using brain imaging and exposure to a virtual environment (simulated driving in a computer) at the same time can result in a therapeutic effect for patients suffering from PTSD.

Briefly, veterans suffering from PTSD will be shown the software "Virtual Iraq" in which military scenes from Iraq are shown (driving a Humvee through Iraq, seeing smoke columns, or hearing war-like sounds). The level of threat of the scenes will be modified by the brain activity of the volunteer, in real time. If the volunteer is able to "calm down" brain activity (for example by thinking pleasant thoughts) then the scene will turn less threatening (war-like sounds will disappear, for example). We hope that this training will allow volunteers to use those same strategies in real life to decrease PTSD symptoms.

Procedures

The research will be conducted at the following location(s):

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

Procedures include:

- 1) a screening session in which we will make sure that you qualify for the study and that it will be safe for you to be a volunteer in the study. This includes virtually "driving" or "walking" in Iraq, in the computer. Other calmer environments will also be visited, such as a nice beach.
- 2) A brain imaging MRI session (this may need to be repeated) in which you will be exposed to Virtual Iraq and calmer environments again, while brain images are taken at the same time.
- 3) Possibly, up to seven additional MRI sessions in which a signal from your brain activity will be displayed on the screen. You will be able to modify the scenes by "changing" your brain activity (for example, by thinking pleasant thoughts, etc).

Your participation will last about 10 weeks, with one visit per week: screening (day 1), possibly 8 MRIs (once a week), and study end. You will wear an activity monitor (similar to a wristwatch) at some point through the study, for 2-3 days, because we want to monitor your activity levels and sleep quality.



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You may be asked to also look at the virtual environments while wearing a one-electrode eeg (a device similar to headphones, with a small electrode lightly placed on your forehead and another electrode on your ear). The electrode is completely harmless and can barely be felt on the skin.

Your confidentiality will be kept by removing identifiers (such as names, phone numbers, etc) from your data. Those identifiers will be confidentially kept and will only be accessible by our trained staff. No identifiable information will leave the MEDVAMC/Baylor College of Medicine. A requirement of the study is to store your data in a secure VA repository for future use in research. This repository is simply a computer folder with files regarding the research: images of your brain, information about the virtual environment (similar to a game, we will collect images from your brain while you "drive" in a computer animation depicting Iraq), and other information such as your PTSD symptoms, etc. This will only be used from investigators in our group, will be coded you could only be identified by name by accessing both the repository and the code. We will not share this data with other investigators. You are free to remove your data from the repository if you wish to do so (call or email Dr. Salas: 832-274-5340 or rsalas@bcm.edu).

Confidentiality

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

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

Use or Disclosure Required by Law

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

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

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



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Potential Risks and Discomforts

There are no known risks involved with this procedure. The scanner is twice the strength of most standard MRI machines, but it has been approved by the Food and Drug Administration (FDA) for diagnostic purposes. There is no evidence that it is harmful in any way. The one-electrode eeg poses no health risk and is commonly used by many people to monitor brain states.

The magnetic field will affect any metallic object. You should not participate if you have any type of metallic implant in your body, including pacemakers, aneurysm clips, shrapnel, metal fragments, orthopedic pins, screws, or plates, IUD's, or piercings that you cannot remove. If you have any of these, there is a risk that the magnetic field could cause them to move or heat up.

You may experience some muscle discomfort from lying in the scanner. You may also become too hot or too cold, in which case you may ask for a sheet. There is an intercom hooked up so that you can talk to people in the control room while you are in the scanner. Some people become nervous or claustrophobic in the scanner. If this happens to you, you may ask to be withdrawn and you will be withdrawn from the magnet immediately. A small number of people experience a sense of dizziness in the magnet. This is due to the magnetic field, and if it disturbs you, you may ask to be withdrawn and you will be withdrawn immediately.

The exposure to a virtual environment with possibly traumatic scenes may produce discomfort. However, similar types of "exposure" have proven therapeutic in similar settings.

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

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand the brain mechanisms of PTSD, which in the long term will help create better medication for a PTSD. .

Alternatives

You may choose to not participate in this study.

Subject Costs and Payments

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



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A total of up to \$440 (\$40 for screening (one) and \$40 per MRI session (up to 8 scanning sessions) will be paid to you as you complete each session of the study. An additional \$10 for parking will be paid to you at each MRI session (for a total of \$50 per MRI session).

Subject's Rights

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

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

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

The investigator, RAMIRO SALAS, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: RAMIRO SALAS at 713-798-3502 during the day and RAMIRO SALAS at 832-274-5340 after hours.

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

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



VA RESEARCH CONSENT FORM

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

If your child is the one invited to take part in this study you are signing to give your permission. Each child may agree to take part in a study at his or her own level of understanding. When you sign this you also note that your child understands and agrees to take part in this study according to his or her understanding.

Please print your child's name here _____



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

Subject Date_____
Investigator or Designee Obtaining Consent Date_____
Witness Date