University of Southern California
School of Social Work
Center for Innovation on Research with Military Families and Veterans (CIR)

**INFORMED CONSENT FOR NON-MEDICAL RESEARCH**

**Train Your Brain Clinical Trial**



You are invited to participate in a research study conducted by Dr. Jeremy Goldbach at the University of Southern California because you are aged 18-65 and have been previously diagnosed with PTSD. This study is funded by Tel Aviv University. Your participation is voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether to participate. Please take as much time as you need to read the consent form. You may also decide to discuss participation with your family or friends. If you decide to participate, you will be asked to sign this form. You will also be given a copy of this form.

**PURPOSE OF THE STUDY**

The purpose of this study is to determine the benefits of a novel brain guided virtual reality intervention in reducing PTSD symptoms as compared to another evidence-based approach for the same symptoms. Therefore, while we cannot guarantee this, we believe that participation may result in fewer PTSD symptoms for you. The training will be done using virtual reality and psychophysiological equipment called an electroencephalogram (EEG). This research study will take place over 4 to 6 months and will involve 2 baseline measurement appointments, 15 neurofeedback training sessions, and 2 post-experiment data collection appointments.

**STUDY PROCEDURES**

If you volunteer to participate in this study, you will be asked to complete questionnaires about your emotions, stressful experiences you have had, and associated anxiety. You will complete these measures on four occasions: today, in about seven (7) weeks, after the completion of all 15 neurofeedback sessions, and at a 3-month follow-up.

You will also be asked to wear a Fitbit on your wrist, which looks much like a watch, throughout the week in order to collect data on your sleep duration and quality. We will collect sleep data for 3-7 nights on 3 separate occasions: after this initial session, after the 7$^{th}$ week session, and after the completion of the neurofeedback sessions. Your Fitbit data will be downloaded onto a computer, and no other data will be used for study purposes; you will not have access to view your study data. Additionally, you will not be responsible for any loss or damage to the Fitbit device.

We will use the Clinician Administered PTSD Survey (CAPS), a structured 30-45 minute interview, to confirm current symptoms of PTSD. The audio from this clinical interview will be

recorded to provide clinical supervision of the interview process. If you have any issues with this interview being recorded, you may opt out of having the interview recorded.

In addition to completing the clinical interview, self-report questionnaires, and wearing the Fitbit, you will be randomly assigned, like flipping a coin, to one of two groups. There is no intention in the group you are placed, as it is entirely random. All groups will receive the regular treatment they may be currently receiving from their mental health professionals (e.g., pharmacological treatment or psychotherapy, for instance). In other words, no outside treatment will be withheld. The random assignment is done by the computer, so the research assistant will not know which group you have been assigned to.

Regardless of the group you are assigned, you will be asked to meet with us a total of 19 times, at the best time that works for your schedule. At this first visit, you will complete the study assessments mentioned above and receive a fitbit to gather your sleep data. After returning the fitbit at your second visit, you will then return 7 weeks later and retake the assessments. The purpose of these first visits is to detect natural variances in your baseline measurements that may occur over time. At the visit in the 7$^{th}$ week, you will also begin the neurofeedback training sessions. You will complete 15 training sessions one to two times per week with each session lasting 40 minutes. The study measures will be taken again after completing all neurofeedback sessions and at a 3-month follow-up to identify the possible benefits of the neurofeedback treatment.

During the neurofeedback sessions, you will play a virtual reality video game while wearing an EEG cap. The EEG cap is similar to swimming cap worn on your head, with plastic placements holding the EEG electrodes. Before placing the electrodes on, a conductive gel will be used in order to enable contact between the scalp and the electrode, and to allow a proper recording of neuro-electrical signals. At the end of the session you will be provided with the necessary equipment to clean the gel from your hair.

Following the placement of the EEG cap you will start the neurofeedback virtual reality training. During the game your brain activity, as measured online by the EEG, will be reflected to you by the *unrest* level of a group of virtual characters in a virtual hospital waiting room. Unrest manifests itself so that during baseline, the animated scenario is noisy (people shouting and crying) and the characters behave impatiently, trying to reach the admission desk and complain to the helpless secretary. This unrest level corresponds modulations in your brain activity as recorded on-line. The higher the recorded brain signal is, the more agitated the room will be. Your goal will be to find the mental state that will cause a decrease in the recorded EEG signal thus corresponding to an ease in the unrest level of the animated scenario (i.e., resulting in game characters sitting down calmly). Instructions are intentionally unspecific, allowing you to adopt the mental strategy that you will subjectively find most efficient.

The neurofeedback (NF) will follow a similar block design differing only in the number of cycles. Each cycle consists of one rest block (60 seconds), one NF block (180 seconds) and one

wash-out block (30 seconds). During rest blocks you will be instructed to passively view the interface animation. At this time the animation is not influenced by your brain activity. During NF blocks you will be instructed to ease the waiting room unrest level as explained above.

If you are placed in the second group, you will play the game exactly the same way as the first group; however, the brain signals that are monitored online are slightly different. Neurofeedback for the first group will focus on down regulation of limbic activity (a deep-brain activity found related to PTSD) using a novel development. For the second group, neurofeedback will focus on down regulation of alpha waves relative to theta waves (A/T), a state known to reflect relaxation.

During neurofeedback sessions 11-15, two additional cycles will take place, in which you will attempt to downregulate your brain without any feedback present for one minute each. This will help to determine whether or not you have acquired the ability to regulate your mental state. At these sessions, you will still complete five cycles of the Waiting Room scenario.

After completing all 15 neurofeedback sessions, two reassessment appointments will be scheduled. The first will take place the following week, during which you will recomplete the assessments administered at the beginning of the trial. The second reassessment will take place three months after neurofeedback completion, and you may choose to complete a brief online survey or have an in-office visit to complete the full study assessment for greater compensation.

**RE-SCHEDULING APPOINTMENTS**

It is important that you complete all of your scheduled appointments. It is your responsibility to cancel or reschedule your appointment at least 24-hours ahead of your scheduled appointment.

To cancel or reschedule your appointment, please contact the USC Train Your Brain staff at (424) 261-4968 by text/call or vetnfb@usc.edu by email.

If you fail to notify the USC Train Your Brain staff of a cancellation at least 24 hours in advance on three or more occasions, we may reassign your appointment time to another participant or terminate your participation.

**POTENTIAL RISKS AND DISCOMFORTS**

Potential risks and discomforts to this study include the discomfort of being exposed to a potentially anxiety-provoking situation in the virtual reality game. To alleviate the risk, trained staff will be on-hand to answer any questions and process any discomforts with you at the time of the study. Furthermore, there may be some discomfort in answering questions about your emotional state. If you feel distressed, or the researcher working with you determines you are at risk, we will stop the session and connect you immediately with a clinical social worker or mental health specialist on site, as your safety is of primary concern. There will be no costs to you as a participant for participation, or for meeting with a mental health professional should you request it.

The EEG equipment is non-invasive; however, it will be attached to your head for each training session. At the end of each session, you will be given supplies to clean the contact point of the EEG to your hair. There may be a small amount of the gel left behind, however there is no risk to you for this procedure.

**POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY**

You may not directly benefit from your participation in this study; it is hoped that by learning to self-regulate brain activity previously found to underlie some of the symptoms in PTSD, you will feel an ease in these symptoms. Furthermore, participants from prior research conducted in different institutions have reported an improved sense of control on their own emotional state following brain training. It is hoped that the results of this study will be used to benefit future combat forces and individuals afflicted with PTSD, by training them with new ways to handle stressful situations.

**PAYMENT/COMPENSATION FOR PARTICIPATION**

You will receive cash worth up to $210 for your participation in the study and up to $140 in cash for transportation reimbursement. You will receive $30 at the end of your first session; $10 after returning your fitbit, $30 at the 7th week session, $10 for the second fitbit return, $30 at the 8th neurofeedback session, $50 at the end of the final session (session 15), and either $10 for completing an online survey or $50 for a full in-person interview at the 3-month follow-up. You will receive the compensation, as long as you are present for that session. If you do not complete the study, you will keep the payments that you have received up until that point in your participation.

If you drive to USC and require parking, your parking will be purchased by our study funds in advance of your visit. If you use public transportation, you will be given $10 cash.

**CONFIDENTIALITY**

We will keep your records for this study confidential as far as permitted by law. The members of the research team, the funding agency and the University of Southern California's Human Subjects Protection Program (HSPP) may access the data. The HSPP reviews and monitors research studies to protect the rights and welfare of research subjects. The Department of Defense (DOD) or Federal representatives may also access research records for the purpose of protecting human subjects.

The data will be stored in a locked office and/or on a secure computer which is encrypted, at USC.

Identifiable information, such as this consent document, your name, and contact information, will be kept separate from your responses. Identifiable information will be destroyed at the end of the study; the remaining (de-identified) data will be retained indefinitely and may be used in future research studies. If you do not want your data retained for future use, you should not participate in this study.

When the results of the research are published or discussed in conferences, no identifiable information will be used.

**CERTIFICATE OF CONFIDENTIALITY**

Any identifiable information obtained in connection with this study will remain confidential, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care). A Certificate of Confidentiality has been received from the Federal Government for this study to help protect your privacy. This certificate means that the researchers can resist the release of information about your participation to people who are not connected with the study, including courts. The Certificate of Confidentiality will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others.

**PARTICIPATION AND WITHDRAWAL**

Your participation is voluntary. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you fail to notify the USC Train Your Brain staff of an appointment cancellation at least 24 hours in advance on three or more occasions, we may terminate your participation.

**ALTERNATIVES TO PARTICIPATION**

You do not need to participate in the present study. There are many other studies currently going on at USC that you may participate instead of the present study.

**EMERGENCY CARE AND COMPENSATION FOR INJURY**

**For Civilian Participants**: If you are injured as a direct result of research procedures you will receive medical treatment; however, you or your insurance will be responsible for the cost. The University of Southern California does not provide any monetary compensation for injury.

**For Veteran Participants**: If you are hurt or get sick because of this research study, you can receive medical care at an Army hospital or clinic free of charge. You will only be treated for injuries that are directly caused by the research study. The Army will not pay for your transportation to and from the hospital or clinic. If you have questions about this medical care, talk to the principal investigator for this study, contact Jeremy Goldbach, Ph.D. at (213) 821-6460. If you pay out-of-pocket for medical care elsewhere for injuries caused by this research study, contact the principal investigator. If the issue cannot be resolved, contact the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of the Staff Judge Advocate (legal office) at (301) 619-7663/2221.

**INVESTIGATOR'S CONTACT INFORMATION**

You can ask any questions that you have about the study at any time. You may contact Jeremy Goldbach, Ph.D. at (213) 821-6460 with any questions, concerns or complaints about the research or your participation in this study.

**RIGHTS OF RESEARCH PARTICIPANT – IRB CONTACT INFORMATION**

If you have questions, concerns, or complaints about your rights as a research participant or the research in general and are unable to contact the research team, or if you want to talk to someone independent of the research team, please contact the University of Southern California Institutional Review Board (USC IRB), 1640 Marengo Street, Suite 700, Los Angeles, CA 90033-9269, (323) 442-0114 or irb@usc.edu.

**SIGNATURE OF RESEARCH PARTICIPANT**

I have read the information provided above. I have been given a chance to ask questions. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

_____

Name of Participant

_____ _____

Signature of Participant Date

**SIGNATURE OF INVESTIGATOR**

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____

Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date