Enhancement of PTSD Treatment With Computerized Executive Function Training

NCT #: NCT03260127

Consent form last approved on 08/13/2020

Title of Study:	
Enhancement of PTSD Treatment with Computerized Executive Function Training	
Principal Investigator: Laura Crocker, Ph.D.	**VAMC:** VA San Diego Healthcare System
Subject Name:	**Date:**

1) Purpose of this research study

Laura Crocker, Ph.D. and her colleagues are conducting a research study to find out how to more effectively treat posttraumatic stress disorder in Veterans who are also having thinking difficulties. You have been asked to participate because you are an OEF/OIF Veteran who likely has both PTSD and some problems with thinking, such as attention or memory difficulty. You will be randomly assigned to receive one of two types of computer game training. Some participants will be assigned to play the specific computerized tasks that we are studying to see whether playing improves individuals' thinking skills. Other participants will be assigned to a comparison group who will play computerized games and puzzles. Everyone will receive PTSD therapy after the computer game training portion of the study. There will be approximately 200 participants at this VA site. This research is being funded by the Department of Veterans Affairs.

2) How long the study will take

Your participation in the study will include 16 appointments over approximately a 3 month period, which will be a combination of remote and in-person visits. You will be asked to complete three assessments that will be split into two parts. The first part will take approximately three hours to complete via remote methods (telehealth communication software, phone, email, and/or mail). The second part of the three assessments will be an in-person appointment at the VA and will take approximately 1 hour. You will also be asked to complete a 1 hour in-person MRI brain scan at the beginning of the study. In addition, you will participate in telehealth or phone appointments for the PTSD treatment portion of the study for 1 hour on 12 occasions. A portion of your participation in the study over the 3 months will be completed at home on your own time, involving 6 weeks of computer game training for 30 minutes a day, 5 days a week. Your participation will conclude after 16 appointments.

The entire study with all participants will take about 5 years.

3) What will happen to you in this study

If you agree to be in the study, the following will happen to you:

a. The remote appointments will take place via VA approved telehealth communication software, phone, email, and/or mail.
b. You will undergo three separate **comprehensive assessments** that will take approximately four hours to complete each time, three hours for the remote portion of the assessment and 1 hour for the in-person portion at the VA Medical Center. These will occur on your first appointment, immediately after the completion of 6 weeks of computer game training, and then immediately after PTSD treatment. There will be

cognitive assessment which includes measuring thinking, learning, memory, and problem-solving abilities. These are paper and pencil tests. These tasks take about two hours. There will also be a psychiatric and functioning assessment which asks about your experiences with trauma, current symptoms, daily functioning, and quality of life. These assessments take about one to two hours.

b. After the first assessment, you will undergo an **MRI scan** that takes pictures of your brain, which will take place at the UCSD Keck functional MRI center. The scan will last approximately one hour. The MRI scan will involve having you lay quietly inside the center of a large, doughnut-shaped magnet. Your head will be placed in a special, helmet-like "head holder" to help you keep your head still. Before being scanned, the operator will provide you with instructions and conduct a pre-scan metal screen. Should the metal screen come up positive, for your own safety, you will not be scanned. More than one set of pictures will be taken, and the operator will need to make sure that your head is optimally positioned in the machine. During the scan, you will be completing cognitive tasks through the use of an MRI-safe button box.

At this time it is unknown whether or not there are potential risks to a fetus from exposure to magnetic fields (MRI). If you are a female of child-bearing potential, the researchers will provide you with a pregnancy test to self-administer after coming in to the research lab.

c. After the initial assessment and MRI visit, you will complete 6 weeks of **computer game training** at home on your own time. You will be randomly assigned to one of two training conditions. Each condition will consist of approximately 30 minutes a day of training for 5 days a week for the 6 weeks. During this time, research staff will be in touch to check in on your progress and answer any questions you may have. Some participants will be randomly assigned to a group that will play the specific computerized tasks that we are studying to see whether playing improves individuals' thinking skills. Other participants will be randomly assigned to a comparison group who will play other computerized games and puzzles. You will have a 50/50 chance of being in either computer game condition. You will not be told which group you are in prior to the end of your participation in the study.

d. After the 6 weeks of computer game training and a second comprehensive assessment, you will receive **PTSD therapy** via telehealth or phone. This therapy is called Cognitive Processing Therapy (CPT) and is a type of cognitive behavioral therapy intended to reduce symptoms of PTSD that has been shown in previous research to be very helpful. This is a 12-session, twice-weekly individual treatment with each session lasting 60 minutes. This is one of the standard treatments for PTSD offered at the VA clinics. Everyone will receive CPT, regardless of the type of game training you participate in.

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e. Information about medications and your medical history will be taken from your medical record.

f. Because this project utilizes the resources of the Veterans Affairs San Diego Healthcare System (VASDHS), your name, social security number, and other demographic information may be entered into the VASDHS confidential computer system, and a record of your research visits may be kept on the system.

g. Your PTSD therapy (CPT) sessions will be audio recorded for treatment fidelity monitoring purposes.

h. We ask that you do not participate in any other treatment for PTSD or thinking difficulties while you are enrolled in the study but participation in this study will not preclude mental health care related to other conditions or other medical care as usual. You can and should continue to take any prescribed medications.

4) Which procedure(s) or treatment(s) are done for research only

All procedures, including assessments, MRI, computer training, and treatments described for this study are done for research only. However, CPT is the standard of clinical care for PTSD.

5) RISKS <u>reasonably</u> to be expected

Participation in this study may involve some added discomforts. The procedures used are likely to cause:

a. Fatigue and/or boredom. You may find some of the tests during the assessments or computer games to be boring or cause fatigue. Frequent rest intervals will be available during the assessments to reduce fatigue, and the neuropsychological tests and computer games have been designed to be as interesting as possible.

b. There are no known adverse effects from exposure to magnetic fields. However, the MRI imager makes a loud, banging noise while it is taking pictures. Earplugs and headphones will be provided to you to protect against the loud banging noise of the machine. A physiological reaction (muscle twitching) can occur in some individuals during certain imaging sequences if their position in the scanner forms a circuit (e.g., connected hands). Therefore, during parts of the scan, you will be asked not to cross your arms. Dizziness can occur in some individuals due to rapidly switching gradients. Some patients undergoing this procedure become anxious. If this happens to you, you can stop the procedure at any time. You may experience some discomfort and fatigue from lying still in a confined space during imaging. If you have any metal clips or plates in your body or a pacemaker, you should tell the investigator about it. MRI may not be appropriate under certain conditions: A cardiac pacemaker; metal fragments in eyes, skin, body; heart valve replacement, brain clips, venous umbrella; being a sheet-metal worker or welder;

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aneurysm surgery, intercranial bypass, renal aortic clips; prosthetic devices such as middle ear, eye, joint or penile implants, joint replacements; hearing aid, neurostimulator, insulin pump; shunts/stents, metal mesh/coil implants; metal plate/pin/screws/wires, or any other metal implants; permanent eyeliner, eyebrows.

c. There is the possibility of an abnormal finding on the MRI scan. However, the MRI scans are not being done for clinical purposes, and the MRI scan procedure is not sufficient for the clinical diagnosis of a possible brain disorder. The purpose of this scan is not to diagnose abnormalities, but on rare occasions a finding is observed that might be clinically important. A clinician will observe your data in order to screen for any abnormalities that would exclude you from the study. Should there be cause for concern, with your permission, this information will be forwarded to your primary care physician for follow-up.

d. Women of child-bearing potential: At this time it is unknown whether or not there are potential risks to a fetus from exposure to magnetic fields (MRI). Women of child-bearing age will be asked to take a pregnancy test and only those women who have a negative test may participate in this part of the research.

e. Increased stress level. Participating in treatment for PTSD is often difficult and can lead to temporary increases in emotional discomfort. Any such reaction normally subsides as the skills taught in treatment are learned. Study staff are trained to handle any distress that arises and emergency and after hours contacts are available to offer treatment or make emergency referrals if necessary. Some of the questions you will be asked are personal and may cause you to feel uncomfortable. You may request to stop the interview or to not answer any question that makes you uncomfortable.

f. Increased risk for COVID-19 infection. In-person visits, while shortened to reduce exposure, still increase risk for COVID-19 infection. However, VASDHS requires social distancing and the use of personal protective equipment (PPE) by participants and study staff during these visits to mitigate risk of infection. Study staff will regularly disinfect surfaces and equipment used by participants, as well as practice frequent hand washing and sanitization. All participants will also be required to go through COVID-19 screening 24-48 hours prior to their in-person visit and again when they arrive at the VA San Diego Medical Center to reduce the chance of infection between participants and staff.

Other potential risks of this study include:

Loss of confidentiality: As a result of participation in this project, there is a very small risk that sensitive information (e.g., psychiatric information which you have provided) could become known outside the research setting. If this is compromised it could affect your employability, insurability, and/or social standing. To minimize this risk, your name will not be on any of your data; instead your name will be replaced with a code. All of your data will be kept in locked cabinets or in databases behind secure firewalls.

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Unforeseeable RISKS
Because this is an investigational study there may be some unknown risks that are currently unforeseeable. You will be informed if the researchers learn of any change in the amount of risk to you.

6) BENEFITS reasonably to be expected.
There may or may not be a direct benefit to you from these procedures. You may notice positive changes in your mood, thinking abilities, and quality of life. The investigator, however, may learn more about treatments for Veterans with both PTSD and thinking difficulties.

7) Voluntary nature of participation and right to withdraw without penalty.
Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled.

8) Alternatives to the research procedure or treatment
If you choose to not participate or withdraw from participation in this study you will be offered the option to enter standard clinical CPT or other mental health treatment done with no research component. There may be risks associated with standard treatments for your condition. You should review the risks of standard treatments with your condition with your health care provider.

9) Procedure for the orderly termination of a volunteer's participation
If you decide that you no longer wish to participate in this study please call Dr. Crocker or her study staff or contact in person Dr. Crocker or her study staff. You should participate in a final visit if you decide to stop your participation in this study so that the investigators can ensure your health and well-being.
Your participation in this study may be stopped if the investigator decides that stopping is in your best interest. The investigator has the right to end your participation in this study if it would be dangerous for you to continue or if you do not follow study procedures as directed by the study staff. Should you express thoughts or behaviors that indicate you plan to harm yourself or others or if more significant mental health concerns are discovered, clinical interventions to ensure your safety and mental health stability will be implemented. This may make it necessary for you to temporarily withdraw from the study. You can choose to re-enter the study when these issues are resolved if study and clinical staff agree.

10) Information learned from the study will be shared with you
While you are a participant in this study you will be told if any important new information is found that may affect your wanting to continue.

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If the results of this research might influence your medical care after you have completed your participation, the investigators will contact you to let you know these results.

11) Care provided if you are injured as a result of this study

The VA will provide necessary medical treatment should you be injured as a result of participating in this study and following study procedures. You will be treated for the injury by the VA at no cost to you or your insurance but no additional compensation is available.

12) Privacy and confidentiality

Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. The research does involve collecting your social security number for review of your electronic medical record (CPRS), for entering study visit notes into CPRS, and for your payment for your participation.

Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in a secure VASDHS location, or as files behind the secure VASDHS computer firewall.

Data from the online computer tasks you will be asked to complete will also use a code and will not contain any personal or identifying information. This data will be stored on a secure server that is accessible to the research team and will be transferred to a secure VASDHS server.

All data available to these companies will be completely free of any identifying information such as names and unique subject identification numbers.

Any presentations or publications from this information will not identify you.

We will keep confidential all research and medical records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, the Federal Office of Human Research Protections, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board, the UCSD Center for Functional MRI (Keck Center), and federal compliance officers may look at or copy portions of records that identify you.

13) Payment

Costs to you or your insurance

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There will be no costs to you or your insurance for any procedures or testing done only as part of this research study. If you receive a bill for services that you think could be related to your participation in this study, you should contact Dr. Crocker.

Medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

Payment for participating

You will be compensated $30 for the initial assessment, $20 for the MRI scan, $50 for the second assessment after the computer game training, and $70 for the final assessment after the PTSD therapy. If you complete at least 80% of the computer game training, you will receive an additional $30. Therefore, the total possible compensation for your time and travel is $200 if you complete all portions of the study.
This payment will be made directly to your bank account using electronic funds transfer. If you currently have a debt to the Federal Government, your debt may be subtracted from your funds transfer payment for study participation.

14) Additional Information
The VA San Diego Healthcare System provides oversight and resources for this study. Financial support for this study is provided by Department of Veterans Affairs Rehabilitation Research & Development Service.

Clinical Trial: A description of this clinical trial will be available on http:\\www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Future Use of Data
We will retain deidentified data from this study for analysis and future presentations and publications of the results. The data will be stored in secure office at the VA and only study staff will have access to it.

Re-contact.
You may be eligible to participate in other studies as well. If you are interested in finding out about other research, please check the box below:

☐ _____ (check and initial here) I consent to being contacted by phone for possible participation in future studies.

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15) RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above. **You have been informed that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.**

In the event of illness or injury that you believe to be related to the study, or have questions about this research, you can call Dr. Crocker at 858-642-6484 during the day, or leave a message after 5:00 PM. If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel you can contact the Research Compliance Officer at 858-642-3817, VA Research Service at 858-642-3657, VA Regional Counsel at 858-642-1540, or the VASDHS Human Research Protection Program at 858-642-6320.

_____ has explained the study to you and answered all of your questions. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You will receive a copy of this consent form and a copy of the Health Insurance Portability and Accountability Act (HIPAA) Authorization that you signed. You will also receive a copy of the California Experimental Subject's Bill of Rights.

By signing this form you indicate that you have been informed of your rights as a research subject, and that you voluntarily consent to participate in this study. You have been informed what the study is about and how and why it is being done.

_____ _____
Subject's Signature Date

_____ _____ _____
Signature of Researcher obtaining consent Name (print) Date