Title of Study:
Cognitive Training as a Novel Neuroscience-based Treatment for PTSD

Principal Investigator:	**VAMC:**
Jessica Bomyea, Ph.D.	VA San Diego Healthcare System

Subject Name:	**Date:**

1) Purpose of this research study

Jessica Bomyea, Ph.D, is conducting a research study to examine the effects of a new, computer-based, cognitive training program on posttraumatic stress disorder (PTSD) symptoms. This study aims to evaluate the usefulness of the program for improving memory and attention and decreasing symptoms related to PTSD. Symptom outcomes of the cognitive training program will be compared to those of a similar cognitive program that is believed to have little to no effect on symptoms. You have been asked to participate because you (1) are a Veteran who meets DSM-5 criteria for Posttraumatic Stress Disorder (PTSD), (2) are between the ages of 2155, (3) are willing to attend assessment and treatment sessions (4) and are intending to remain in the San Diego geographical area for the duration of this study. There will be approximately 130 participants in this study.

2) How long the study will take

Your participation will require approximately 19 over a four month period. Three of these visits will be assessments that will last an average of 4 hours each. The remaining 16 visits will be for the purpose of completing the computerized cognitive program only and will last approximately 20-30 minutes each. The total time required for participation is approximately 19-20 hours. The entire study will take five years to complete.

3) What will happen to you in this study

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

1. You will be asked to complete a clinical interview regarding any trauma-related symptoms you may be experiencing in order to determine if you are eligible to participate in the remainder of this study. If you are not eligible to participate in the remaining parts of the study, the information obtained from you in the interview will be omitted from this study and destroyed to protect your privacy. If your responses indicate that you *are* eligible to complete the remaining parts of this study, you will be asked to continue.

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2. You will be asked to answer a series of questionnaires about your mental health history, how you feel, and experiences that you have had. You may skip any question(s) you wish. An interviewer will also ask you questions about symptoms of anxiety and other psychological distress that you may have experienced. If you have a strong negative reaction to the

   questions about your mental health history or are having thoughts of suicide, you will be evaluated and immediately referred to a clinical psychologist for care in accordance with symptom severity.

3. Portions of the assessments may be audio-recorded so that they may be reviewed by supervisors to ensure assessments are being administered properly. Audio recording is optional and does not affect your enrollment in the study. Please initial one of the options below to indicate your choice:

   _____ I would like to participate in having portions of my assessments audio recorded
   _____ I would **not** like to participate in having portions of my assessment audio recorded

4. You will be asked to participate in several different computer-based tasks that measure your reaction time and response accuracy. These computer tasks will take approximately 30 minutes. You may take breaks between the computer tasks. You will also be asked to complete a task that measures your level of anxiety in different situations (i.e., when monitoring your thoughts about a traumatic event). Assessments of the frequency of these types of thoughts will also be taken.

5. You will be asked to complete computerized and/or paper-and-pencil tests that assess your familiarity with words, your ability to problem-solve, complete patterns, learn new motor skills, and attend to new visual information.

6. A picture of your brain will be obtained using a magnetic resonance imaging (MRI) scanner.
   a. During the MRI scan, you will be placed in a large donut-like machine.
   b. Your head will be placed in a helmet-like holder that allows us to take images of your brain.c. The scan will take approximately 1 hour.

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7. During the scanning session, you will be asked to complete computerized tasks. These tasks will include doing one or more of the following: (1) looking at pictures or movie clips of emotional faces or scenes, (2) solving problems, (3) making decisions based on personal preferences, or (4) remembering pieces of information for a short period of time.

8. You will be randomly assigned to one of two groups. The group you are assigned to will determine which type of computer-based program you will complete. Group One will receive the computer-based program that is designed as a training intervention, and Group Two will receive the computer-based non-treatment (placebo). You will not know which group you

   have been assigned to until the end of the study.

9. After you have been randomly assigned to a group, you will be asked to participate in sixteen computer-based treatment sessions. These sessions will occur twice a week over a period of eight weeks and will last approximately 30 minutes each. During your computer sessions, you will be asked to remember words or letters and decide whether sentences make sense. Completing these tasks does not require any computer skills.

10. You will be asked if you are interested in receiving information regarding additional research opportunities. If you are, you will be contacted by phone or mail and given information about other studies. Whether or not you choose to participate in these studies is entirely your choice. Participation in other research studies will not affect your ability to continue in the current study. Please initial one of the lines below:

    _____ I am interested in getting information about additional research studies.
    _____ I am **not** interested in getting information about additional research studies.

11. Information from your medical record may be utilized as noted in the HIPAA Authorization.

12. If you are a female and capable of child-bearing, a urine-based pregnancy test will be administered prior to your MRI scan in order to be as sure as possible that you are not pregnant. It is important to be as sure as possible that you are not pregnant, because it is currently unknown whether or not exposure to the magnetic fields from an MRI scanner is a risk to a fetus. Only those women who have a negative pregnancy test result may participate

in the study. You will be given a pregnancy test by the researchers to self-administer prior to the MRI scan.

13. At the time of your first visit, the research team will determine if you are appropriate for the MRI based on the absence of the following conditions: cardiac pacemaker, metal fragments in eye, skin, body; heart valve replacement, brain clips, venous umbrella, being a sheetmetal worker or welder, aneurysm surgery, intracranial bypass, renal, aortic clips; prosthetic devices such as middle ear, eye, joint, or penile implants, joint replacements; hearing aid, neurostimulator, insulin pump; I.U.D; being pregnant or trying to become pregnant; shunts/stents, metal mesh/coil implants; metal plate/pin/screws/wires, or any other metal implants; permanent eyeliner, eyebrows, some tattoos; or any other conditions that would make it unsafe to scan you in the MRI (including concerns regarding the risk of COVID19 transmission). If you are found to have any of the aforementioned objects or conditions, you will not be scanned but you may continue with other portions of the study.

The study will take place at the San Diego VA Healthcare facilities and the UCSD Keck Center for Functional MRI, which is approximately ½ mile from the VA hospital. You may be offered the option of completing assessments and computerized training via the telephone and using remote telehealth technologies, rather than completing visits in-person, if it is deemed to be in your best interest to do so (e.g., to satisfy social distancing requirements due to COVID-19 concerns).

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

The goal of this study is to examine the effects of cognitive training on PTSD symptom outcomes. This program may reduce symptoms, but is not a psychotherapy or pharmacotherapy, and is not related to typical care within the VA. All procedures are performed for research purposes.

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

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

a. restlessness, anxiety, or fatigue in some people while filling out questionnaires.
b. temporary discomfort while being asked personal questions about anxiety, depression, and negative life experiences (for example: “Have you ever experienced a traumatic or life-threatening event?”).

c. temporary discomfort or frustration while being asked to complete challenging computer tasks that ask you to remember many items at a time.
d. anxiety in some people during the MRI scan due to limited space within the scanner and head holder. Keep in mind that you may stop the scan at any time by pressing a button that will immediately notify investigators that you would like to exit.
e. emotional discomfort or agitation while in the scanner due to tasks that may be emotional in nature or challenging. You may terminate the scan if you become overly emotionally affected.
f. muscle aches due to lying on your back for 1 hour in the scanner.
g. discomfort due to banging noises that the MRI scanner makes while taking pictures. You will be asked to wear earplugs in order to minimize the risks of these loud noises to your hearing.
h. muscle twitches during the scanning procedure.
i. risk to the health of a fetus. Because it is currently unknown whether or not exposure to magnetic fields can cause harm to a fetus, women of child-bearing age will be asked to take a pregnancy test. Only those women who have a negative test may participate in the research.

j. risk to the health and safety of a participant who may be ineligible for MRI. For this reason, all subjects will be thoroughly screened for the presence of MRI contraindications before scanning. If you have any metal parts, clips, or plates in your body or a pacemaker, you should tell the investigator. Subjects with MRI contraindications will not be scanned and will not be able to remain in the study.
k. damage to your personal reputation, ability to become or remain employed, or exposure to criminal or civil liabilities, or other unforeseen consequences, if your confidential information were to accidentally become public- e.g. whether you have used illegal substances. To minimize this risk, all of your data will be anonymized and kept in locked cabinets or in databases with secured passwords. The study investigators have conducted this research for over 8 years and have not encountered such problems.

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.

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6) BENEFITS reasonably to be expected
You may experience a decrease in symptoms as a result of treatment during your participation. Furthermore, the results of this study will provide information to help inform novel treatments for individuals experiencing psychological symptoms in the aftermath of a traumatic event. We cannot guarantee, however, that you will receive any benefits from participating in this study.

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
There are alternative treatments for PTSD. These include cognitive-behavioral and talk therapy, as well as medications that have been shown to reduce PTSD symptoms.

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. Jessica Bomyea at (858) 552-8585 x 2872.

Your participation in this study may be stopped if the investigator decides that stopping is in your best interest.

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. 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. You will be treated for the injury by the VA at no cost to you or your insurance but no additional compensation is available.

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12) Privacy and confidentiality

All of the information about you obtained during this study will remain confidential and will be disclosed only with your written permission. A brief record of your study visits will be entered into the VA Computerized Patient Record System. Authorized research personnel may access information contained in the VA Computerized Patient Record System, solely for the purposes of scheduling MRI scans at the VASDHS and for screening and determining study eligibility. Your SSN will be required for payment.

We will keep confidential all research and medical records that identify you to the extent allowed by law. Your research records will contain no names and will be labeled with a code number. The list that matches your name to the code number will be kept in a locked file in a locked office. The research records will be kept only as paper records in a secure VASDHS location, or as digital files behind the secure VASDHS computer firewall. None of the presentations or publications based on the data collected through this study will identify you. To minimize risk of confidentiality loss during procedures delivered remotely (e.g., phone assessments), you will be asked to complete all activities in a private environment where others cannot see or hear you. However, there are some circumstances in which we may have to show your information to other people. For example, the Federal Office of Human Research Protection, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board, the Food and Drug Administration, and federal compliance officers may look at records that identify you. The UCSD Keck Center for functional MRI may be able to view de-identified MRI scans of your brain.

During the course of your participation in this study, if there is any indication of suicidal ideation or that you may pose a threat to yourself, you will be contacted by a licensed, clinical member of the research staff or be asked to visit the VA emergency department. You will be asked questions regarding your intent to harm yourself and, at the discretion of the clinician, appropriate actions will be taken to ensure your well-being if it is determined that your immediate safety is in jeopardy. Questions regarding suicidal thoughts and actions are components of the self-report surveys that you will be asked to fill out, as well as parts of the clinical interviews that you will undergo. This information will be handled under the same privacy and confidentiality standards as the rest of your research data, unless it is determined that immediate medical or mental health attention is required. Research staff is legally required to report known reasonable suspicion of abuse to a child, elder, or disabled adult. Staff is also

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legally required to report serious threats of physical violence against a reasonably identifiable victim or victims to law enforcement and the victim(s).

13) Payment

Costs to you or your insurance

There will be no costs to you or your insurance for any procedures or testing done 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. Jessica Bomyea at (858)552-8585 x 2872.

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 copayments if your VA-eligibility category requires co-payment for VA services.

Payment for participating

For completing the first round of assessments (prior to treatment), you will receive $100. For completing the second round of assessments (after treatment), you will receive $100. For completing the third round of assessments (2 months after treatment), you will receive $50. If you complete all three research visits and the treatment, you will receive a $50 bonus. You will receive a total of $300 for completing the entire study. You will also receive a T-shirt with a brain picture for completing the entire study.

You will receive $30 if you arrive for your first visit and it is determined that you are not eligible to participate in the remainder of the study. The most common reason for this determination is that information comes to light which renders it unsafe for you to continue.

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 payment for study participation.

In addition, travel reimbursement will be provided to subjects who are unable to participate because of travel expense incurred. Travel reimbursement will be provided at the VA listed reimbursement rate (https://www.va.gov/health-care/get-reimbursed-for-travel-pay/#reimbursed-expenses-and-rates). This website will be referred to every time travel reimbursement is required to ensure participants are being reimbursed at the proper rate.

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Subjects can also request a digital non-PHI image of their brain which we will send over VA-approved encrypted software.

14) Additional Information

1. Support for this study is provided by the Department of Veterans Affairs.
2. In the case that the research team is not able to contact you via your primary telephone number, would you be willing to provide information for an alternative contact person?

☐ **Yes** ☐ **No**

_____ _____

Alternate Contact Person Alternate Contact Number

May we leave a message?

☐ **Yes**
☐ **No**

The VA San Diego Healthcare System provides oversight and resources for this study.

Sometimes over the course of a research study, research personnel may encounter incidental findings. An incidental finding is a previously undiagnosed medical or psychiatric condition that is discovered unintentionally. Research personnel are not trained to diagnose potential abnormalities. In such a case, a qualified medical professional will be consulted. If this condition requires further medical evaluation or treatment, you will be notified.

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 if you have questions about this research, you can call Dr. Bomyea at (858)552-8585 x 2872. If you have

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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 858-6423817, 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 if you desire one. 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

If consent is obtained using telehealth technology, the researcher's initials certify they have:
____ Identified the individual
____ Reviewed the informed consent with the potential participant
____ Answered any questions about the study
____ Confirmed that the participant is willing to participate in the trial with verbal confirmation
____ Observed that the participant sign a copy of the informed consent document