# Tuning Up Memory-related Brain Potentials using Real-time Neurofeedback in Older Veterans

NCT04446481

April 19, 2022

Participant Name: _____ Date:_____

Title of Study: _Tuning up memory-related brain potentials using real-time neurofeedback in older veterans___

Principal Investigator: __Y Jiang, Ph.D._____ VA Facility: __Sleep Clinic_____

**WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?**

You are being invited to take part in a research study. This aim of this study is to investigate state of the art neurofeedback training to boost memory performance in Veterans. It is being funded by the
Department of Veterans Affairs. By doing this study, we hope to learn how to apply this intervention drugfree to improve Veterans memory functions and use as a potential treatment for mild cognitive impairment due to traumatic brain injury or pain. This initial information is to give you key information to help you decide whether to participate. We have included detailed information in the "RESEARCH DETAILS" section. Feel free to ask the research team questions at any time. Taking part in this study is completely voluntary. If you decide to take part, your signature on this consent form will show that you received all of the information below and have addressed any concerns you have with a member of the study team.

**WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?**

You will be one of the 10 Veterans expected to participant to this study. You will be asked to sit comfortably in a chair while wearing a headset with special sensors that lay closely on your scalp and may mess up your hair a little. The device is called an encephalogram (EEG) and is connected wirelessly to a computer. It reads your brainwaves during a simple memory task and sends them to a computer where they will be recorded. You will be wearing the headset throughout the session and your brain activity will be recorded. It is important to know that ***the sensors only read the brain waves*****;** ***there is no electricity running to the brain*****.** The entire training will last 6-8 weeks, about two sessions a week (30-45 minutes per session).

**WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?**

The proposed brain training with neurofeedback, a non-pharmacological (drug free) treatment to improve memory, is a potential new effective cognitive rehabilitation for Veterans with combat stress.

**WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?**

For a complete description of risks, refer to the Detailed Consent.

The study requires you repeated visits to the VA sleep center clinic, Building 17, Sousley Campus, for 6-8 weeks (twice a week). If you have difficulty in time and transportation, you may choose not to participate. You cannot participate in this study if

you are under the age of 18 and are unable to speak and read English proficiently, nor if you have a neurological or psychiatric disorder, have had a head injury within the past 3 months, take benzo-related medications, are pregnant or breastfeeding.

For a complete description of alternative treatment/procedures, refer to the Detailed Consent.

**DO YOU HAVE TO TAKE PART IN THE STUDY?**

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you chose not to volunteer.

**WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?**

The people in charge of the study are Yang Jiang, Ph.D. and Sylvia Cerel-Suhl, MD. of the Lexington VA Health Care System. You will also be working with research coordinator Grace Markowski, B.S. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, please call us at the 859-233-4511 ext. 2617 or ask for the Sleep Center and leave us a message.

## RESEARCH DETAILS

**WHAT IS THE PURPOSE OF THIS STUDY?**

By carrying out this study, we hope to learn how to apply a non-drug intervention to improve Veterans memory functions and use as a potential treatment for mild cognitive impairment due to traumatic brain injury or pain. Many veterans report problems with thinking and memory. We aim to use our neurofeedback system to modulate brain activity in veterans potentially improving cognitive functioning.

**HOW LONG WILL I BE IN THE STUDY?**

Your participation in the first session should take about 1 hour, because we will calibrate your personalized brain signals, and will discover your brain's preferred way to be rewarded. The following sessions (twice a week) will last about 30 minutes. The entire training will last 6-8 weeks because some individuals may lose the effectiveness when stopping prematurely. Total 12-16 sessions.

**WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?**

If you decide to participate in this study, you will come to *the Sleep center Clinic at the Lexington VA Leestown Road, known as Sousley campus Station*. You will be asked to sit comfortably in a chair while wearing a headset with special sensors that lay closely on your scalp and may mess up your hair a little. The device is called an encephalogram (EEG) and is connected wirelessly to a computer. It **reads your brainwaves** and sends them to a computer where they will be recorded. You will be wearing a headset throughout the session and your brain activity will be recorded.

1. Before training
    a. While wearing the EEG headset you will perform a simple task that requires you to remember simple pictures to test your memory. Written and verbal instructions will help you through this picture-matching task that involves looking at pictures and pressing buttons on a keyboard.
    b. When you feel comfortable with this task, we will ask you to complete it while we record your brain activity. You will then be asked to sit quietly for a short period with your eyes open or closed while the EEG records your brainwaves.
2. Neurofeedback training.
    a. You will complete the picture-matching task again with a new set of images. When you get it right, you will hear sounds that are pleasing or enhanced images to "reward your brain".
    b. You will be asked to sit quietly for a short period with your eyes open or closed while the EEG records your brainwaves.

Finally, to test if the neurofeedback training has improved your attention and memory, you will be given other questionnaires / neuropsychological tests for about 30 mins. For instance, "What is (are) your reason(s) for coming in today (especially related to brain function – thinking, memory, attention, lapses in awareness, neurological problems, etc)?", or "Would you describe your current level of stress as higher than normal, normal, or less than normal? (Circle the best choice)". All procedures are being done solely for the purpose of this research study.

**WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?**

Recording of your brain activity with a wireless device is not associated with any known risks to your health. Performing the tasks is in no way harmful to you. Placement of the EEG headset will most likely mess up your hair and you will be given time to correct

this prior to leaving. However, to the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life. The procedures in this study may cause all, some, or none of the risks or side effects listed below.

| Possible Risk/Side Effect | How often has it occurred? | How serious is it? | Can it be corrected? |
|---|---|---|---|
| Messy hair | It almost always occurs | Not serious | Yes |
| Scalp irritation | It occurs rarely | Not serious | Yes |
| Boredom | It may occur to some | Not serious | Yes |
| Breach of Confidentiality | It has never occurred in our practice, but is a possible risk | This could affect your ability to receive insurance | Yes |
| Redness under electrode | It may occur | Not serious | Yes |
| Mild tingling sensation | It may occur | Not serious | Yes |
| Itching sensation | It may occur | Not serious | Yes |

Photography, audiotaping, or videotaping

There will be no photographs, audio tapes, or video tapes made of you as part of this study

Blood or Saliva collection

There will be no collection of blood or saliva as part of this study.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

**FOR IRB USE ONLY**

**PI/SC Approval Date:**

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

**WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?**

We can't promise that you will get any personal benefit from taking part in this study. Some people have found the testing challenging and interesting. In addition, recent literature has pointed to short-term benefits of cognitive enhancement. Your willingness to take part, however, may in the future help doctors better understand how neurofeedback can be used to improve cognition and aid in the treatment of patients with cognitive impairment.

**WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?**

Participation in the study is completely voluntary. There is currently no known effective drug treatment for mild cognitive impairment. You may discuss these options with your doctor on alternative options to boost your memory, such as traditional cognitive training, reading, and exercise.

**HOW WILL MY PRIVATE INFORMATION BE PROTECTED?**

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

Identifiers will be removed from the identifiable private information or identifiable biospecimens that are collected. After that removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative,

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

While this study is being conducted, Drs Cerel-Suhl & Jiang will have access to your research related health records.

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

**HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)**

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the VA Cooperative Studies Program (CSPCC); CSP Clinical Research Pharmacy Coordinating Center (CSPCRPCC); CSP Site Monitoring; Auditing and Review Team (SMART); CSPCC's Human Research Committee (HRC); Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility, or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Drs. Sylvia Cerel-Suhl, Yang Jiang and the research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment, or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

**WHAT IS THE COST TO ME IF I TAKE PART IN THIS STUDY?**

You and/or your insurance will NOT be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are Not part of this study.

**Payment Offered for Participation:**

Participants who agree to join this study will be compensated for transportation and other inconvenience due to participation of this study.

You will receive a $20 each session. The payment will be electronic transfer.

**WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?**

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment in accordance with applicable federal regulations (38 CFR 17.85) at no cost to you.

The Lexington VAHCS will provide medical care if you get hurt or get sick as a result of taking part in this study. The necessary care must be provided in a VA medical facility unless an exception is granted. In cases of exceptions, the Lexington VAHCS Director may contract for such care. Exceptions include situations where a VA facility is not capable of furnishing economical care, situations where a VA facility is not capable of furnishing the care or services required and situations involving a non-veteran research subject. Treatment for research-related injuries will be provided at no cost to you. However, this does not apply to treatment for injuries that result from noncompliance by a research subject with study procedures. If a research subject needs treatment in a

medical emergency, the Lexington VAHCS may provide reasonable reimbursement for emergency treatment in a non-VA facility.

A co-payment from you may be required for medical care and services provided by the Lexington VAHCS that are not for research-related injuries.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call *(List local site contacts)*

DURING THE DAY:

Lexington VA Healthcare Sleep Center 859-233-4511 ext. 2617

AFTER HOURS:

Sylvia Cerel-Suhl, M.D. 859-351-9201

Emergency and ongoing medical treatment will be provided as needed.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form

**DO I HAVE TO TAKE PART IN THE STUDY?**

Participation is voluntary; refusal to participate in the study involves no penalty or loss of benefits to which you are otherwise entitled. It is up to you to decide whether or not to take part in this study. If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable. If you decide to take part, you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. If you don't take part or decide to withdraw, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

You can stop or withdraw from the study at any stage. The investigator may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data.

**WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?**

If you have questions about this study, please call 859-233-4511 ext. 2617 or ask for Sleep Center. Sylvia Cerel-Suhl, MD, Yang Jiang, Ph.D, and Grace Markowski, BS., will answer your questions. If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Lexington VAHCS IRB at 859-233-4511 x4927 if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

**WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?**

Sometimes during the course of a research study, new information becomes available about the training (e.g. newer or better program becomes available) that might change a person's decision to stay in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your research doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue.

**WHO COULD PROFIT FROM THE STUDY RESULTS?**

There is no profit to the investigator and real or apparent conflicts to disclose.

**FUTURE USE OF DATA AND RE-CONTACT**

Only De-identified data will be stored for analysis at the Aging, Brain and Cognition Laboratory, Department of Behavioral Science, University of Kentucky College of Medicine. Dr. Yang Jiang and lab members will have access to the de-identified EEG data. (Re: The VHA Handbook 1200.12).

The researchers will not contact you after the study. You will be re-contact only if you initiate the contact, e.g. seeing the benefit of the program.

**AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY**

Dr./Mr./Ms._____ _____
has explained the research study to you. 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 have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

| **I agree to participate in this research study as has been explained in this document.** | | |
|---|---|---|
| _____ Participant's Name | _____ Participant's Signature | _____ Date |
| _____ Name of person obtaining consent | _____ Signature of person obtaining consent | _____ Date |

**FOR IRB USE ONLY**

**PI/SC Approval Date:**