Neurophysiology Markers of PTSD's Presence, Severity and Therapy Outcome

NCT04209387

Februrary 11, 2021

Participant Name: Last, First, MI suffix Date:

Title of Study: Neurophysiology Markers of PTSD's Presence, Severity and Therapy

Principal Investigator: Mo Modarres, PhD VA Facility: ENRM Bedford VA

Sponsor of Study: VA RR&D

We are asking you to choose whether to volunteer for a research study. This consent form will give you information about the study to help you decide whether you want to participate. Taking part in this study is completely voluntary.

SUMMARY OF IMPORTANT INFORMATION

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

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

You are invited to be in a research study looking into whether a person's brain activity may be used to develop new and more accurate and faster ways of detecting PTSD and response to treatment. It is being funded by the Department of Veterans Affairs. By doing this study, we hope to develop new measures that can be used to develop better ways of PTSD treatment .

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

If you participate in the study, you will come to the VA on 4 days, several weeks apart. Each time you will:

- Complete questionnaires about your daily activity, mood, and sleep quality (2 hrs.)
- Have your brain activity measured (takes about 30 min)
- Try to take a nap while recording your brain activity (1-2 hrs.)
- Have your brain activity recorded while home and asleep while wearing brain recording equipment (6-10 hrs.)
- Arrange to return the brain recording equipment.

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

Your participation in the study will help us develop better methods for measurement of PTSD that will help to develop more effective PTSD treatment in the future.

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

You might choose not to volunteer if:

(1) You are uncomfortable wearing an electrode cap while sleeping.

(2) You are uncomfortable answering some or all of the surveys and questionnaires that ask you to rate your mood and symptoms.

5. 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 choose not to volunteer.

6. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of the study is Mo Modarres, PhD of the ENRM Bedford VA. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: 216-496-6169.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to improve the accuracy and speed of the detection of PTSD and measurement of PTSD symptoms. The information obtained in this study will be used in the future to improve treatment of PTSD.

HOW LONG WILL I BE IN THE STUDY?

You will be studied on four days over a 4-5-month period, and the duration of each day of the study is as follows:
(1) Time to complete the questionnaires and surveys is 2 Hrs.
(2) Time to take a nap with EEG electrodes at the VA is 1-2 hours
(3) Full-night sleep at your home: 6-10 hrs.

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

In this study, we will measure your brain activity during awake and sleep periods using a cap that is attached to your head by chin straps. The cap contains multiple electrodes (up to 64) that are attached to the head surface using electrode paste. The electrodes are only able to record your brain acitivity. You will be also asked to answer surveys and questionnaires to be filled by you and the research assistant. questionnaires will ask information such as your age, gender, race, ethnicity, and employment status. We will also ask you about prior history of mental health treatment, and current medications. Other surveys will ask you questions about your mood, sleep, physical health, and quality of life. A study team member will administrate all of the tests. **You are free to skip any questions that you would prefer not to answer.**

Sleep Studies.
For these tests, you will be asked to wear an electrode cap, attached to a small brain monitoring (EEG) box (about the size of a deck of cards), and try to fall asleep at the ENRM research laboratory during the day of your test (Nap). After completion of the nap study, the cap will remain on your head and you will take it home to sleep with it at night. The sleep protocol is as follows:

- On the day of your test at ENRM VA, a study team member will place the electrode cap on your head, secure it with a chin strap, and will then attach the electrodes to the cap using a paste. The paste will be placed between your scalp and the electrode and is used to get a

better measurement of your brainwaves (cleaner signal with less noise). The paste can be washed out your hair with shampoo. This attachment procedure will take about 30 minutes.

- You will then lay down on bed or sit on a comfortable recliner at the ENRM research lab.
- The study team member will turn off the light and leave the room and you will be asked to close your eyes and attempt to fall asleep. This nap study will last between 1-2 hours (depending if you manage to stay asleep for up to 2 hours).
- Following the end of the nap study, the electrode cap will remain on your head but will be detached from EEG box.
- You will take the EEG device home with you and that night before your regular sleep time, you will attach the electrode cap to the EEG box.
- You will then sleep at normal sleep time.
- Over-night live support will be available; you can call the sleep technician during the night in case of any difficulty with the continuation of the study.
- Upon waking up in the morning, you will detach the electrode cap from the EEG box, remove the electrode cap and clean your hair and head/face surface area with soap/shampoo and warm water to remove the electrode paste.
- At some point during the day, a technician from ENRM VA will arrange with you to retrieve the electrode cap and EEG box.

Study Times
The protocol will consist of four study visits within a 4-5-month period.

The following are what we ask of you if you agree to participate:

- Complete your questionnaires as instructed.
- Perform home sleep studies as instructed.
- While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS OF TAKING PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

- Questionnaires: Some people become uncomfortable at being asked questions about their mood and symptoms; if, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.
- Sleep Studies: Attachment of the electrode cap and wearing the device during sleep might cause skin irritation (because of electrode paste), and overall excessive interference with your comfort. What you will be doing in this study is same as a regular sleep study

performed at a doctor's office and the risk will be minimized by following procedures used in routine clinical sleep studies (including attachment and detachment procedures). In case of a situation where wearing the electrode cap interferes with your sleep, you will be advised to remove the electrode cap and wash the site of electrode attachment with shampoo and warm water and continue your normal sleep without the device.

- Unanticipated breach of confidentiality: This is highly unlikely risk as your data will be de-identified and a code that can be used to link your data to you will be kept separately from the other data in a double locked format (locked in a cabinet within a locked room).
- Risk of COVID-19 Exposure: Coming into the hospital/lab for a research EEG test may increase the risk of COVID-19 exposure. The exposure risk would be the same with clinical EEG appointments and we are taking the necessary precautions to minimize this risk. Lab staff will be tested for COVID-19 on a bi-weekly basis and will be in full appropriate PPE (including mask, face shield or goggles, gown, and gloves) during all in-person interactions. Upon arrival in the lab, you will be given a surgical mask and hand sanitizer. Lab staff will also screen you again and take your temperature to ensure safety before entering the lab for the research assessment. The lab space and all surfaces and equipment will be thoroughly cleaned and sanitized before and after each visit. This plan was developed following the guidelines of labs currently conducting clinical EEG assessments at VA hospitals.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with your conditions by developing a more precise and accurate method of evaluating PTSD severity and improving the outcome of the treatment

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Your research records will be kept as confidential as possible. Only a code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.) The master list linking names to code numbers will be kept separately from the research data. All research information will be kept in locked files or behind the VA firewall at all times. If results of this study are reported in journals or at meetings, you will not be identified by name or by any other means without your specific consent. The PI and the Research Health Specialist will have possession of questionnaires, and sleep data. All data will be kept in accordance with VA regulations.

Only the PI will have access to the information gathered in this study unless required by law. Federal Agencies such as the Office for Human Research Protection (OHRP), Government Accountability Office (GAO) and Food and Drug Administration (FDA) may have access to the records.

Identifiers might be removed from the identifiable private information that are collected. After that removal, the information 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.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

There are no costs to you for participating in this study. You will receive compensation for taking part in the study.

You will either receive a payment voucher or a gift card for the amount of $100.00 for each test day, which amount to a total of $400.00. If you withdraw from the study, you will be compensated for all of the study parts that you have completed by the time of your withdrawal.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this research study is voluntary. You may refuse to participate and your refusal to participate will involve no penalty or loss of benefits to which you are entitled. You may also discontinue participation at any time without penalty or loss of benefits to which you are entitled.

If you are a VA employee, your refusal to take part in the study will in no way influence your employment, ratings, or subsequent recommendations.

Please note that for data already collected prior to your withdrawal, 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.

FUTURE USE OF DATA

With your approval, the data you provide may also be included in a future EEG data repository at the VA Hospital in Bedford, MA. All data will be securely stored and maintained according to VA regulations and only approved researchers will have access to this data. Any future use of the data will be reviewed and approved by an EEG data repository committee. The creation and management of this data repository will be approved by the hospital Research and Development Committee before any of the data from this study will be stored in it for future use. Approval for future use of your EEG data is optional and prohibiting future use will not prevent you from participating in this study.

☐ Approve ☐ Disapprove

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

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call (216) 496-6169 during the day, and after hours call 781-687-2000 and have the doctor on call paged.

VA Medical Facilities shall provide, or arrange for, necessary medical treatment to a research subject injured as a result of participation in a research project. This does not apply to treatment for injuries due to non-compliance by the subject with the study procedures.
No money has been set aside for compensation in case of injury as a result of participating in this study however I have been told that I would still have the right to file any legal action.

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

If you have any questions about the research, you may contact Dr. Mo Modarres at 216-496-6169. If you have any questions, concerns, or complaints 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 Coordinator, Denise Carr at 781-687-2839, and the information will be given to the Institutional Review Board. This is the Board that is responsible for overseeing the safety of human participants in this study.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A member of the study team 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. You also confirm that you have read this consent, or it has been read to you. A copy of the consent will be given to you.

I agree to participate in this research study as has been explained in this document.		
Participant's Name	Participant's Signature	Date