4/25/2025

Study Title: Assessing an electroencephalography (EEG) biomarker of response to transcranial magnetic stimulation for major depression

NCT Number: NCT05008198

VA Central IRB
DEPT. OF VETERANS AFFAIRS

Participant Name: _____ Date:_____

Title of Study: Assessing an electroencephalography (EEG) biomarker of response to transcranial magnetic stimulation for major depression

Principal Investigator: [LOCAL SITE PI] VA Facility: [LOCAL SITE FACILITY]

Principal Investigator for Multisite Study:

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by Clinical Science Research & Development (CSR&D). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn how an electroencephalography (EEG) (which measures the electrical activity of your brain) can be used to predict how well an individual with Major Depressive Disorder (MDD; depression) will respond to Transcranial Magnetic Stimulation (TMS) treatment.

You were selected as a possible participant in this study because you are a Veteran who will be receiving TMS for MDD. Your participation in this research will last about 6 to 8 weeks. Most study visits will occur during your regular TMS treatment visits.

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

By participating in this study, you will be helping our understanding of who will most benefit from receiving TMS treatment. Your participation may help us to learn more about the how individuals with MDD respond to TMS treatment. For a complete description of benefits, refer to the Detailed Information section of this consent.

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

You may not want to participate in this study if you think you may not have the extra time after the end of your weekly TMS treatment (day 5) or at the beginning of your weekly TMS treatment to do the extra research activities. For a complete description of risks, refer to the Detailed Information Section of this 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 choose not to volunteer.

Participant Name: _____ Date:_____

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Principal Investigator for Multisite Study:

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is _____ at the [*insert name of VA facility.*]
If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: {*PI or LSI contact information as applicable*}.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to learn whether or not an EEG can predict which individuals respond and which individuals do not respond to TMS treatments.

HOW LONG WILL I BE IN THE STUDY?

We expect 600 Veterans who are receiving transcranial magnetic stimulation (TMS) for treating major depressive disorder at 10 Veteran Administration Medical Centers to enroll in this study. The initial 5 sites will enroll 80 participants per site (20 participants per year for 4 years). The additional 5 sites will enroll 40 participants per site (20 participants per year for 2 years). This research study is expected to take approximately five (5) years to complete. Your participation is expected to last throughout the course of your TMS treatment, around 6-8 weeks and will involve 7 study visits. Each study visit will last approximately 60 minutes.

Participant Name: _____ Date:_____

Title of Study: Assessing an electroencephalography (EEG) biomarker of response to transcranial magnetic stimulation for major depression

Principal Investigator: [LOCAL SITE PI] VA Facility: [LOCAL SITE FACILITY]

Principal Investigator for Multisite Study:

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

SCREENING/BASELINE VISIT (Visit 1) – occurs within 1 week of starting your TMS treatments.

If you choose to participate, after you sign this form, the following procedures will take place:

- We will review the answers to the questionnaires you completed during your initial TMS clinic visit.
- You will complete questionnaires that ask about your mood, past stressful situations, and mental health treatment history.
- If you qualify to participate in the study, you will have the baseline EEG

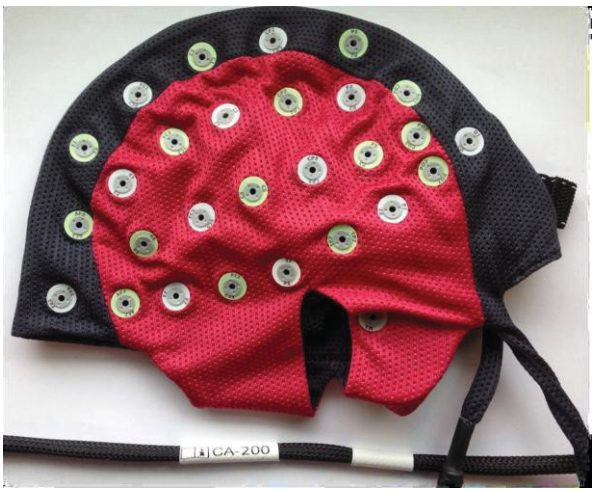

Figure: EEG Cap

EEG Visits (visits 2 – 7)

Within 1 to 3 days after every 5th TMS treatment you will:

- Meet with the research coordinator
- Have an EEG
- You will complete questionnaires that ask about your mood.

If you complete all EEGs, you will complete a total of 7 EEGs.

What is involved in an Electroencephalography (EEG)?

For each EEG visit, an EEG cap (like a swim cap) will be placed on your head by a study staff member (see Figure). The cap uses a gel type solution that will be injected with a blunt needle through the holes in the cap. We may need to gently rub your scalp under the electrodes to maximize the quality of the recording. This will take about 10-15 minutes. You will be asked to sit still for about 10-15 minutes while the EEG is being recorded. During some of this time, you will be asked to keep your eyes open and to look at a cross on a computer screen. At other times, you will be asked to close your eyes. The entire EEG recording session will last about 30 minutes.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Follow the instructions of the investigators and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the research study staff to reschedule as soon as you know you will miss the appointment.
- Ask questions as you think of them.
- Tell the research staff if you change your mind about staying in the study.
- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. 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 POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Risks of an EEG: An EEG is a non-invasive procedure with no known risk to participants.

Risk of Discomfort: The EEG cap may cause some discomfort. To help decrease the risk of discomfort from the cap before the test begins, the research staff will ensure the cap is fitted properly and confirm with you that you are comfortable.

Occasionally some emotional discomfort may occur while you are filling out questionnaires about your mood, past stressful situations, and mental health treatment history. At any time, you can choose not to answer any questions. To minimize potential problems of emotional distress, the procedures will not begin until you are comfortable with the room and the research staff. At any time that you feel uncomfortable filling out the questionnaires or need to stop or take a break please make the research staff aware.

Risks to women of childbearing potential

If you are pregnant or currently breast-feeding, you may participate in this study, as an EEG has no known risks to you, your fetus or your breastmilk.

Risks of tiredness and boredom

There is a risk that the additional time at your TMS treatments to complete the study procedures will cause you to get tired and bored. To help decrease this, when possible, we will let you take breaks during the study visit.

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.

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?

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.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Every effort will be made to maintain the confidentiality of your study records. The data from the study may be published; however, you will not be identified. Your identity will remain confidential unless disclosure is required by law.

You will be assigned a code number. The questionnaire data will be put into a secure database that will contain your number only. The key linking the code numbers with study participants' names will permanently reside on a secure server with restricted access limited to the investigator and study team members.

The information acquired from and about you in the study will be kept behind a locked door, in a locked file cabinet by study staff. Only investigators and study team members will have access to the information, except as otherwise noted in this form. Your name and other identifying information will be on this consent form. These documents will be kept in a locked cabinet separate from your responses to the questionnaires and procedures.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, the Food and Drug Administration, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. Destruction of all

research records pertaining to this study will be in accordance with the Federal Policy of the Department of Veterans Affairs and will be retained for a minimum of 6 years after the end of the study.

Other researchers may request to use your EEG data collected from this study to do more research. The purpose would be to learn more about how EEG data predict how an individual will respond to other treatments for MDD. We will only share your information from this study with other researchers if their research is approved by a committee that protects the rights and safety of patients in research. All personal identifiers will be removed from the data before it is shared. After this removal of personally identifiable information and personal health information, the data 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.

We will include information about your study participation in your medical record.

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 results. You can search this website at any time.

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

You 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.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

Yes, you will be paid $25.00 for your time and effort for each study visit for a total up of to $175.00. Additionally, you will be paid up to [LOCAL SITE DOLLAR AMOUNT UP TO $50.00] to offset travel costs to each research visit. This travel payment will be paid regardless of your decision to consent to study participation. Payment will be made available by Department of Veterans Affairs via electronic funds transfer or via gift card. Due to limitations in the Financial Management System, payments made to subjects through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount. Your SSN will be used for this purpose in reimbursement.

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

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you or your insurance unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

No additional payments by the VA are planned. By signing this form, you do not lose any of your legal rights or release the VA Medical Center from its duty to provide proper medical care.

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:

Dr./Mr./Ms. _____ at _____ and

AFTER HOURS:

Dr. /Mr./Ms._____ at _____.

DO I HAVE TO TAKE PART IN THE STUDY?

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and stop your participation at any time. If you decide to withdraw from the study, you will not lose any benefits to which you would otherwise be entitled, and your decision will not affect your ability to receive medical care for your condition.

If you choose to withdraw from the study, you will still be able to continue to receive your TMS treatments.

You may contact study personnel at any time if you would like to withdraw from the study. Contact information can be found in the section below titled, “Persons to Contact About This Study” If you withdraw, study personnel may continue to review the study data already collected prior to your withdrawal, but they cannot collect further information about you, except from public records.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: **06/13/2025**
Per PI Amendment 04
LSI Approval Date: **N/A**

LSI Verification Date: **N/A**

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The research study staff may also withdraw you from the study without your consent for one or more of the following reasons:

- failure to follow the instructions of the study staff
- if the study staff decide that continuing your participation could be harmful to you
- if the study is cancelled
- for other administrative reasons
- or for other unanticipated circumstances

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

If you have any questions, complaints, or concerns about this study, you may contact the study investigator at your VA Medical Center or the Research Coordinator during regular business hours.

The Investigator is [local PI]

The Research Coordinator is [local study coordinator]

You may also call the VA Medical Center's Patient Advocate at [number here]

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 VA Central 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 VA Central IRB toll free at 1-877-254-3130 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?

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

It is possible that, based on information gained from this study, the researchers may have serious concerns (relating to matters such as severe depression, physical abuse, etc.) about

your health and/or safety; in such a case, the researchers may contact you and provide a referral for your care.

FUTURE USE OF DATA

Health information collected from you during this study will be deidentified and stored on a secure password protected computer at VA Palo Alto Health Care System, Palo Alto California.

Your EEG data will be deidentified and stored on a VA approved secure password protected cloud storage solution. You will sign a separate form giving us permission to keep your health information.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ _____ *(or you can indicate a study role that has been delegated by the PI/SC or LSI to obtain informed consent)* 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 in 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. *(Include if applicable:* A copy of this signed consent will also be put in your medical record.*)*

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

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LSI Approval Date: **N/A**

LSI Verification Date: **N/A**