Effects of Neuromodulation and Cognitive Training for Suicide in Veterans (ENACTS)

NCT05231213

November 14, 2024

Participant Name: _____ Date: _____

Title of Study: __ Effects of Neuromodulation and Cognitive Training for Suicide in Veterans (ENACTS)_____

IRBNet protocol # 1672669

Principal Investigator: __Casey S. Gilmore, PhD_____ VA Facility: _Minneapolis VA___

KEY SUMMARY INFORMATION ABOUT THIS STUDY

INTRODUCTION

You are being asked to participate in a research study. The box below highlights some key information that you should know about the project, and more detailed information is provided on the following pages. Before you decide whether to participate, please ask questions about any of the information you do not understand.

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. Whether or not you decide to participate, treatment at the VA for which you are eligible will not be affected, and refusal to participate does not involve any penalty or loss of benefits to which you're entitled.
- **Purpose**. The purpose of this research is to investigate if transcranial direct current stimulation (tDCS) can increase the effectiveness of cognitive training to enhance cognition and affect Veterans' help-seeking and suicide risk during the transition period from inpatient to outpatient care.
- **Duration.** It is expected that your participation will last two months.
- **Procedures and Activities.** You will be asked to complete one baseline session and 10 stimulation sessions over the course of five days while you are in inpatient care. Also, you will be asked to return to the VA at 1 month and 2 months following your discharge from inpatient care. Stimulation sessions will include administering tDCS while you complete cognitive training tasks on a computer. Throughout the course of the study, you will be asked to complete several assessments including interviews, questionnaires, and cognitive functioning tasks and electro- encephalography (EEG; a measure of brain activity). During the one month following discharge, you will be asked to complete three surveys per day either on an app developed by the VA, mPRO, that you will download to your smartphone or other device, or using links to surveys sent to your device through Qualtrics. You will also be provided a wearable activity tracker.
- **Risks.** Some of the foreseeable risks or discomforts of your participation include stress and discomfort answering personal questions about your health symptoms, feelings, past experiences, family history, and suicidal thoughts and behavior. There is also a risk of skin irritation associated with the Garmin activity tracker. Risks associated with tDCS include light itching, burning, or tingling under the electrodes, headache, fatigue, and nausea and rarely skin burns and sudden changes in mood.
- **Benefits**. There may be no direct benefit to you from being in the study. The knowledge gained from this study may benefit others in the future.

- **Alternatives.** You do not have to participate in this study. As an alternative to participation, you could consult with your mental health provider.

DETAILED INFORMATION ABOUT THE STUDY

What is research?
One purpose of this informed consent document is to provide clear information about the activities involved with this study. There are important differences between research and treatment plans:

- The goal of *clinical care* is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.
- The goal of *research* is to learn new things that may help groups of people in the future. Research teams learn things by following the same plan with many study participants, so they do not usually make changes to the plan for one person. You may or may not be helped by volunteering for a research study.

How many people will be studied?
We expect about 38 people will participate in the study at the Minneapolis VA.

What happens if I say "*Yes, I want to be in this research*"?
- You will be asked to complete one baseline session, 10 stimulation sessions, and one mid-intervention session over the course of five days while you are in inpatient care.
- You will be asked to return to the VA at 1 month and 2 months following your discharge from inpatient care. While an in-person follow-up visit is preferred, if you are unable to return for an in-person visit you will have the option to do a video or phone call.
- tDCS (stimulation) involves applying a weak electrical current to the scalp. This study will use the TaskFlow-TES or Neuroelectrics Starstim device to apply stimulation. These devices are experimental and deliver the same type of stimulation. A device will be assigned to you based on availability at your time of enrollment.
- You may receive real (active) or fake (sham) stimulation. The type of stimulation you receive will be chosen by chance, like flipping a coin. You will have an equal chance of being given either type of stimulation. Neither you nor the study doctor will know which stimulation you are receiving.
- You will be asked to complete cognitive training tasks on a computer while you receive stimulation.

- We will ask you for the contact information of two family members, friends, etc. We may contact them in the case that we are unable to contact you to schedule follow-up sessions or if we cannot get ahold of you in a crisis or emergency situation.

During the baseline and follow-up sessions, you will complete 1) questionnaires about your thoughts, behaviors, and symptoms, and 2) computer-based assessments measuring your speed of processing, memory, and decision-making, and 3) EEG, which measures brain activity by wearing a cap on your head that contains electrodes.

For 30 days following your discharge from inpatient care, you will be asked to answer three brief surveys each day using either an app developed by the VA, mPRO, that you download to your smartphone or other device, or using links to surveys sent to your device through Qualtrics. You will receive three daily reminders to your phone/device, one in the morning and one in the evening, to answer the surveys.

You will be asked to wear an activity tracker (Garmin Vivosmart 4) on the wrist of your non-dominant hand until your last follow-up session where you will return the tracker to study staff. The activity tracker has an application (Garmin Connect) that will track your sleep, activity, and stress levels to see if the study intervention is affecting those measurements. You will be asked to download the application to your personal smartphone, accept the End User License Agreement (EULA), set-up your own account, and share the data collected on your account with the study team. The study team will provide you with instructions on this process and can assist you, as needed.

The table below outlines the schedule for the study.

Visits and Assessment Schedule:

Visit	**Activities**	**Length of Visit**
Session 1 (Inpatient)	Informed Consent Process Computer Assessments Questionnaires EEG	2 ½ hours
Sessions 2 - 11 (Inpatient)	Inpatient EMA Questionnaire + tDCS + Cognitive Training Session 5 only – Computer Assessments Questionnaires	1 hour each (2 times per day for five days = 10 total sessions)
Session 12 (Inpatient)	Computer Assessments Questionnaires EEG	70 minutes
Sessions 13 & 14 (1 month and 2 months follow-ups) - In-person at the VA	Computer Assessments Questionnaires EEG	1 ¾ hours
Ecological Momentary Assessment (EMA) and wearable activity tracker	3 surveys each day on your phone for 30 days	5 - 10 minutes per survey

What happens if I say "Yes" but change my mind later?
You can end your study participation at any time without penalty or loss of VA benefits or other benefits to which you are entitled. The investigator may continue to review data already collected for the study prior to your withdrawal, but cannot collect further information, except from public records, such as survival data. Also, your participation may be terminated by the investigator without your consent at any time.

What are the risks of being in this study?

The study involves the use of private medical records. The use of protected health information may be associated with negative feelings about sharing medical history. The assessments (interviews and questionnaires) used in the study will involve questions about health symptoms, feelings, past experiences, and family history. Discussion of these topics could cause stress and/or discomfort. You can skip any questions on the questionnaires that you are uncomfortable answering. You could also experience temporary feelings of stress or mental fatigue due to the cognitive tasks and EEG.

tDCS (Stimulation)

There is currently no evidence of serious side-effects related to tDCS. Listed below are mild side effects that typically go away after stopping tDCS:

- Light itching, burning, or tingling under the electrodes (68 out of 100 people)
- Fatigue (20 out of 100 people)
- Headache (13 out of 100 people)
- Nausea (2 out of 100 people)

Rare adverse events could include skin burns and sudden changes in mood. You may choose to discontinue stimulation at any time during the session if you are experiencing excessive discomfort or side effects.

We will also ask you about any suicidal thoughts and behaviors you may be experiencing. This may result in increased thoughts of suicide or increased risk of suicide attempt. The research team may not be able to keep confidential any disclosure or endorsement of thoughts to harm yourself or others. In the event that you tell the research staff that you are thinking about harming yourself or others, or you answer yes to a question about having thoughts about suicide, the research staff may ask you more questions about the thoughts. Depending on how intense your thoughts are or how much you feel like hurting yourself or others, the research staff may provide you with referrals for treatment, work with you to contact your personal physician, trusted family member, or mental health professional to discuss your thoughts of harming yourself, or work with you on a plan that may include getting you to a medical facility for safety.

During the course of the study, we will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What if my test results show something unexpected?
There is a possibility that the study tests/procedures may discover that you have a potential abnormality that we did not expect to see. This is what is called an "incidental finding." Study procedures are done for research purposes only. They are designed to answer research questions, not to medically examine you or provide a clinical diagnosis. If we see something unusual, we will inform you so you can obtain appropriate follow-up evaluation by your physician. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

Will I be paid for being in the study?
If you agree to take part in this research study, we will pay you $25 following the first inpatient session (session 1), and $50 following the post-intervention session (session 12). You will also be paid 50¢ for each of the 90 EMA surveys (3 per day for 30 days = $45) completed, and a $1 per day bonus if you complete two EMA surveys each day ($30). Finally, you will be paid $75 following successful completion of the study ($30 after attending the 1-month and $45 after attending the 2-month follow-up visits). The maximum amount of compensation that you can receive is $225. You will be paid via debit card or electronic funds transfer at the completion of each visit.

Compensation for participation in research is considered taxable income. If you receive $600 or more in any one calendar year, the VA is required to report this information to the Internal Revenue Service (IRS). FORM 1099 (Miscellaneous Income) will be issued to you and a copy will be sent to the IRS.

Are other procedures or treatments available if I don't participate in this study?
You do not have to participate in this study. As an alternative to participation, you could consult with your mental health provider.

Will it cost me anything to participate in this research study?
There is no cost to you or your insurance for taking part in this study. All the study costs, including procedures related directly to the study, will be paid for by the VA Medical Center. There should be no additional medical costs to you for taking part in this study. However, clinic visits may result in transportation costs and possible wages lost due to time missed from work.

Use of Identifiable Private Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us permission to use your information, including health information in your medical records that can identify you. Only IRB-approved study personnel will have access to your personally identifiable information. These data are stored in locked file cabinets within locked research study offices at the MVAMC or VA computer servers behind the VA firewall. Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all identifying information has been removed.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. The results of this study may be published or presented, but your identity and records will not be revealed unless required by Federal Law. 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 MVAHCS IRB, our local Research and Development Committee, Food and Drug Administration (FDA), and other study monitors may look at or copy portions of records that identify you. Because of the need for these inspections, absolute confidentiality cannot be guaranteed.

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

Employees as Research Subjects
If you are a VA employee, you are considered a class of research subjects with special protections. Your decision to participate in this study should be free from pressure or coercion to participate. The research team will secure your information according to VA data security and privacy policies. Every effort will be made to prevent access by your supervisor and co-workers, but accidental disclosure or release of your private information could potentially occur. Refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress, as applicable.

Will I receive research test results?
Most tests done in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results.

Who could profit from the study results?
The TaskFlow-TES platform being used for this study was developed by Dr. Kelvin Lim, Co-Investigator on this study, and his team. They are currently seeking a patent for the platform.

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.

If you are injured from this research study, treatment will be available, including first aid, emergency treatment and follow-up care, as needed, by the VA Medical Center. In the event you cannot reach a VA facility, the VA will pay for necessary medical care for any injury or illness directly related to your participation in this research study.

You should immediately report any injuries resulting from your participation in this study to Dr. Casey Gilmore at 612-629-7466 or the Call Center at 866-414-5058 during the day, or the VA Nurse Line at 866-687-7382 on evenings and weekends. If you do not live in the metropolitan area, you may call the toll-free number: 1-866-414-5058.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE 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 IRB office at (612) 629-7387. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Patient Representative at (612) 725-2106 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

Participant Name: _____ Date: _____

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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. 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 form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

FOR IRB USE ONLY

PI/SC Approval Date: