Effects of tDCS Paired with Cognitive Training on Brain Networks Associated with Alcohol Use Disorder in Veterans

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Study Title: Effects of tDCS Paired with Cognitive Training on Brain Networks Associated with Alcohol Use Disorder in Veterans	
Principal Investigator: Kelvin O. Lim, MD	
Protocol #: VAM-19-00460	**ICF Version Date: 08/01/2025**

INTRODUCTION

You are being asked to participate in a research study that is being funded by the VA Clinical Science Research & Development (CSR&D). The box below highlights some key information that you should know about the study, 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. 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 in alcohol use disorder and improve treatment outcome.
- **Duration.** It is expected that your participation will last three months.
- **Procedures and Activities.** You will be asked to complete one baseline session, 10 stimulation sessions over the course of three weeks and two follow-up sessions occurring one-month and two-months after the completion of the stimulation sessions. 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. If eligible, you will also be asked to complete two magnetic resonance imaging (MRI) scans of the brain; the first scan will occur before the stimulation sessions begin and the second scan will occur after the stimulation sessions are finished.
- **Risks.** Some of the foreseeable risks or discomforts of your participation include: 1) risks associated with MRI including metal objects turning into projectiles, claustrophobia, hearing damage, nerve stimulation, and disruption and/or heating of implanted devices, and 2) risks associated with tDCS including light itching, burning, or tingling under the electrodes, headache, fatigue, and nausea and rarely skin burns, a shock, seeing lights, 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. Additionally, the study may be terminated without your consent.

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Detailed Information about this Research 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 120 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 tDCS (stimulation) sessions over the course of three weeks, and two follow-up sessions occurring one-month and two-months after the completion of the stimulation sessions. These stimulation sessions will occur at the Minneapolis VA Medical Center or at your home.
  - tDCS (stimulation) involves applying a weak electrical current to the scalp. This study will use the Soterix (1x1 mini-CT) device or the TCT tDCS device to apply stimulation. This device is investigational. This means the device is not approved by the FDA for how it is being used in the study.
  - 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.
- If eligible, you will be asked to complete two magnetic resonance imaging (MRI) scans of your brain. The first scan will occur before the stimulation sessions begin and the second scan will occur after the stimulation sessions are finished. MRI scans will occur at the University of Minnesota's Center for Magnetic Resonance Research.
  - MRI uses a strong magnet and radiofrequency magnetic fields to take images of your body. The scanning process is similar to an x-ray or CT scan, but MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA) like x-rays or CT scans.
  - During the MRI scan, you will lie down on a bed and the bed will slide into the scanner. You will be asked to either simply lie still while the scan is taking place or perform a cognitive task.

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- If research staff suspect you have undocumented metal fragments in your eyes or head, you will be asked to complete an x-ray prior to the MRI scan to verify safety.

- Throughout the course of the study, you will be asked to complete: 1) interviews regarding your physical and mental health including substance use, 2) questionnaires about your thoughts, behaviors, and symptoms, 3) computer-based assessments measuring your speed of processing, memory, and decision-making 4) breathalyzer and saliva drug screen.
- If you are a female of childbearing age/potential, you will be asked to complete a urine pregnancy screen.

Visits and Activities Chart:

Visit	Activities	Location	Length	Pay
Visit 1	Consent, Interviews, Questionnaires, Columbia-Suicide Severity Rating Scale (C-SSRS), Pregnancy Screen (if applicable), Cognitive Functioning Assessments, tDCS Equipment Provided	Minneapolis VA Medical Center (MVAMC)	3 hours	$60
Visit 2 MRI*	MRI, Saliva Drug Screen, Breathalyzer	CMRR	2 hours	$40
Visit 3	tDCS, Cognitive Training, Remote Session Orientation	Home or MVAMC	75 minutes	$30
Visit 4	tDCS, Cognitive Training	Home or MVAMC	1 hour	$20
Visit 5	tDCS, Cognitive Training	Home or MVAMC	1 hour	$20
Visit 6	tDCS, Cognitive Training	Home or MVAMC	1 hour	$20
Visit 7	tDCS, Cognitive Training	Home or MVAMC	1 hour	$20
Visit 8	tDCS, Cognitive Training	Home or MVAMC	1 hour	$20
Visit 9	tDCS, Cognitive Training	Home or MVAMC	1 hour	$20
Visit 10	tDCS, Cognitive Training	Home or MVAMC	1 hour	$20
Visit 11	tDCS, Cognitive Training	Home or MVAMC	1 hour	$20
Visit 12	tDCS, Cognitive Training, Questionnaires, Cognitive Functioning Assessments, tDCS Equipment Returned	MVAMC	3 hours	$60
Visit 13 MRI*	MRI, Saliva Drug Screen, Breathalyzer	CMRR	2 hours	$40
Visit 14 One-Month Follow-Up	Questionnaires, Cognitive Functioning Assessments, Columbia-Suicide Severity Rating Scale (C-SSRS)	MVAMC	2 hours	$40
Visit 15 Two-Month Follow-Up	Questionnaires, Cognitive Functioning Assessments, Columbia-Suicide Severity Rating Scale (C-SSRS)	MVAMC	2 hours	$40
Total			**23.5 Hours**	**$ 470**

* MRI visits will not be administered if you have a contraindication for MRI or when safety cannot be confirmed.

Equipment: You will be provided with or asked to use the following equipment during the study: personal Wi-Fi or internet connection if choosing remote option, study laptop, and study tDCS equipment. We will assist you with set-up, training, and practice on all the equipment. The equipment must be returned to the VA at your in-person Visit 12. All provided study equipment must be returned to the VA if you do not complete the study.

What is expected of me if I take part in this study?

- Complete all study procedures, as instructed.
- Keep the tDCS device in a safe place for your use only and away from children.
- Keep your study appointments. If you miss an appointment, please contact the team to reschedule as soon as you know you will miss the appointment.
- Tell the investigator or research staff if you believe you may be pregnant.
- Tell the research staff if you change your mind about staying in the study.
- Return the study equipment (laptop, tDCS device, tDCS headbands, laptop case) to the study team at Visit 12 or when you end your study participation.
- Ask questions as you think them.
- While participating in this research study, do not take part in any other research project without approval from the study team. 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 those of the other studies.

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. If you end your study participation, information about you that has already been collected may not be removed from the study database. All study equipment must be returned to the study team at the Minneapolis VA Medical Center.

What are the risks of being in this study?
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.

The study involves the use of private (medical or educational) records. The use of protected health information may be associated with negative feelings about sharing medical/educational history. You may experience mild stress and/or discomfort with completing interviews/questionnaires and could also experience temporary feelings of stress or mental fatigue due to the cognitive tasks used in this study. You can skip any questions you are uncomfortable answering or any tasks that you are uncomfortable completing; however, this may affect your continuation in the study.

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, sudden changes in mood, and sensations of a shock and seeing lights (this occurs in less than 1% of subjects). To date, only one participant has experienced a rare shock event. You may choose to discontinue stimulation at any time during the session if you are experiencing excessive discomfort or side effects. Participants who experience serious adverse events will be immediately withdrawn from the study.

MRI

The risks associated with MRI scans are:

- Projectiles: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk, we ask that participants remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and by controlling access to the scanner.
- Claustrophobia: The scanner is a long narrow tube that may cause some people to feel claustrophobic.
- Hearing Damage: The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if you do not wear hearing protection. Hearing protection is required and is provided by the MRI operator.
- Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable please notify the MRI operator.
- Disruption of Devices: Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If you have any implanted device, notify the MRI operator.
- Heating of Devices: The radiofrequency waves used in MRI can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. You will be asked to remove these items if possible. If they cannot be removed, you will be asked to provide more information to allow MRI staff to be able to make determination on the safety of proceeding with the scan.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. The University of Minnesota's Center for Magnetic Resonance Research requires information regarding the manufacturer/model of medical implants; participants who received implants outside of the VA may be asked to complete a Release of Information in order to obtain the needed information.

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During the MRI scan, you will be in constant contact with the MRI operator and should notify them immediately, via the squeeze ball, if you notice anything unusual, become claustrophobic, think that your hearing protection is not adequate, or if you experience nerve stimulation that is uncomfortable.

In addition, there is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. These symptoms, if present, subside shortly after leaving the MRI scanner. If any sensations experienced during participation cause discomfort or pain, notify the MRI operator right away. The MRI will be discontinued, and you will be taken out of the magnetic field.

The risks of exposure to high magnetic fields are unknown for fetuses. Therefore, if you are a female who is capable of becoming pregnant, and you have any reason to believe that you might be pregnant, you should not participate in this study.

The MRI measurements made for this research project are for research purposes only. Clinical MRI measurements are made using different MRI scanner settings than those used in this research study. Therefore, the MRI data collected for this study will not be interpreted by a neuroradiologist as the research scans differ from a standardized set of clinical MRI scans.

X-Rays (if applicable)
As part of this study, you may be asked to complete an x-ray prior to your MRI scan if research staff suspect that you may have acquired undetected metal fragments in part or parts of your body. This procedure involves exposure to ionizing radiation. Everyone receives about 300 mrem of unavoidable radiation each year from space and from naturally occurring radioactive materials in the environment. The amount of radiation exposure you will receive depends on the portion of your body that needs an x-ray (abdomen = 70 mrem, head or chest = 10 mrem, arms or legs = 1 mrem or less). Research staff will inquire about any other studies or medical procedures involving radiation that you have been exposed to within the past 12 months or may be exposed to in the upcoming 12 months. The x-ray procedure used in this study may involve unknown risks to an infant, embryo, fetus, or nursing infant; therefore, if you are pregnant, planning to become pregnant, or nursing, you will not be asked to participate in the x-ray portion of this study.

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 including MRI 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.

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Will I be paid for being in the study?
If you agree to take part in this VA-funded research study, you will be compensated approximately $20 per hour for your time and effort (see chart on page 3 for a breakdown). Payment will be made through electronic funds transfer (EFT) in which funds are deposited into your bank account, or a debit card in which funds are placed on a card. Payments will occur within 4 weeks of the completion of Visit 13, and each follow-up visit (Visits 14 and 15). You will only be compensated for visits you attend.

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 may choose to not participate in the study. As an alternative to participation, you could consult with your mental health provider. Several AUD treatments exist. You may choose to enroll or continue with treatment for AUD at your local VA Health Care System. You may also seek medication help from a psychiatrist or seek therapy from a trained clinician. You may choose to seek no treatment at all.

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, frequent clinic visits may result in transportation costs and possible wages lost due to time missed from work.

Use of Identifiable Private Information or Identifiable Specimens
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. 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. Organizations that are required by law to provide oversight of research projects may review your records. This includes several federal agencies, the VA's Research & Development Committee, the Institutional Review Board, and the Food and Drug Administration (FDA). The sponsor or sponsors of the research project

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will also be allowed to review your medical records. 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 Participants
If you are a VA employee, you are considered a class of research participants 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.

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 research team will not contact you or share your individual test results.

What happens if I am injured while participating in this research?
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 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.

Should an injury occur, the sponsor will voluntarily provide medical care or reimburse you for emergency medical care provided elsewhere. You do not give up any legal rights or release the VA from any liability by signing this form.The sponsor will cover reasonable medical expenses for necessary treatment if you are injured by the properly performed study procedures and have not caused the injury by failing to follow the directions of the study doctor or study staff.

You should immediately report any injuries resulting from your participation in this study to the study coordinator at 612-467-4140 or Dr. Kelvin Lim at 612-467-3323 during the day, or the VA operator at 612-725-2000 during evenings or weekends. If you do not live in the metropolitan area, you may call the toll-free number: 1-866-414-5058.

Right of Investigator to Terminate My Participation
Your participation in the study may be discontinued at any time without your consent by the investigator, Institutional Review Board, or the sponsor. This could happen if you do not meet study criteria, if you do not follow study procedures, or if in the investigator's opinion it would be detrimental to you and/or staff for you to continue. You will be notified of your termination and will be given appropriate resources to reach out for care.

Notification of Significant New Findings?

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

Whom do I contact if I have questions, concerns, or feedback about my experience?
You are encouraged to contact the Patient Representative at (612) 725-2106 if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

If you wish to verify the validity of the study and its authorized contacts, call the Patient Representative or contact the IRB office at (612) 629-7387.

I have reviewed the information provided in this document. My questions have been answered and I voluntarily consent to participate in this study. I understand that I have not given away any of my legal rights by signing this form.

Participant's Signature: _____ Date: _____

Witness Signature: _____ Date: _____

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