CONSENT TO PARTICIPATE IN RESEARCH

Title: Remotely supervised tDCS combined with cognitive training to improve complex attention in Active Duty Service Members and Veterans with mild TBI
Principal Investigator: Lars Hungerford, PhD, ABPP-CN

You may be eligible to take part in this research study. This form gives you important information about the study. Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalty.

1. **Introduction of the study**
   You, (*insert participant's name*), have been asked to voluntarily participate in a research project entitled, "Remotely Supervised tDCS Combined With Cognitive Training to Improve Complex Attention in Active Duty Service Members and Veterans With Mild TBI" being conducted at the Naval Medical Center San Diego (NMCSD) by researchers from Traumatic Brain Injury Center of Excellence (TBICoE), and the Minneapolis VA Healthcare System (MVAHCS). This research is funded by the Department of Defense (DoD).

2. **Why is the study being done?**
   You are being asked to take part in this research study because you are an Active Duty Service Member who sustained a mild TBI and are currently experiencing symptoms related to attention, concentration, or other related thinking processes. The purpose of this research study is to test new methods for treatment of cognitive symptoms related to mild TBI.

3. **How long will you be participating in the study?**
   Your individual participation will take place at NMCSD and at home and will occur over a total of 8 weeks. You will complete assessments in the first week (week 0), again at week 3 (1 week after treatment), and at week 8 (6 weeks after treatment). Each assessment will last about 3 hours. In week 0 and week 3 you may also complete an MRI of about 60 minutes. In between week 0 and week 3 sessions, you will complete 10 RS-tDCS+ sessions lasting approximately 50 minutes. In between the week 3 and week 8 sessions, you will be asked to answer a brief survey three times per week that will be texted or emailed to you. You will receive a notification reminder to your phone/device on the days that you need to answer the surveys. Overall, your total participation time in this research project will be approximately 23 hours.

4. **What is involved in the study?**
   - You will give us information about yourself such as military and employment status, medical and educational history, date of birth, and contact information.
   - We will review your medical history to confirm possible history of brain injuries and other information used to determine whether you are eligible to participate.
   - You will complete tasks and answer questions to measure your thinking abilities. You will also answer questions about your thoughts, feelings, and symptoms you may be experiencing.
   - You will do tasks on a computer while your eye movements and brain activity (EEG) are recorded.
   - You will complete one pre-treatment visit, 10 remotely-supervised transcranial direct current stimulation with cognitive training (RS-tDCS+) sessions at home, a post-treatment visit, answer a brief survey on your phone 3 times per week for 6 weeks, and a 6-week follow up visit.
     - Transcranial direct current stimulation (tDCS) involves applying a weak electrical current to the scalp. We will be using the Soterix (1x1 mini-CT) device to apply the stimulation. This device is experimental.

- You may be randomly selected (50% chance, like a coin flip) to complete two 3T Magnetic Resonance Imaging (MRI) scans; these will occur during the week of your pre-treatment session (in-person Visit 1, week 0) and your 1-week post-treatment session (in-person Visit 2, week 3). The MRI scans will result in pictures of your brain that are similar to x-rays without exposure to radiation. These pictures will be used to measure the structure and activity of certain brain regions. During the MRI scans, you will be asked to lie down on a bed, and the bed will slide into the scanner, which is a tunnel that is open on both ends. You will be asked to simply lie still while the scan is taking place.

  The in-person research office visits will be conducted at NMCSD, and the MRI scans will take place at the University of California, San Diego Center for Functional Magnetic Resonance Imaging (CFMRI). Only MRI scans will be performed at UCSD CFMRI and no other information or study-related data will be shared with the UCSD CFMRI team.

5. What is the experimental part of the study?

The experimental part of this study is the use of *active* RS-tDCS to treat the cognitive effects of mild TBI. Participants in the study will be divided into two groups based on randomization, a process similar to flipping a coin. Neither you nor the study investigator will choose, or know, which group you are in.

a. The experimental group will receive *active* RS-tDCS while completing computerized cognitive training on BrainHQ.
b. The control group will receive *sham* (placebo) RS-tDCS while completing computerized cognitive training on BrainHQ.

6. How many people will take part in the study?

Overall, there will be about 160 people taking part in the study, over a period of four years. All volunteering participants for this study will be Active Duty Service Members or Veterans recruited from NMCSD or MVAHCS.

7. What are the risks of the study?

We expect no greater than minimal risks or discomforts related to your participation in this study. This means that risks or discomforts, beyond those risks associated with any underlying medical condition which you might have or associated with standard health care which you might be receiving during the course of your participation in this study, are felt to be no greater than the "normal" risks of day-to-day life.

You will be asked some questions about your health. It is possible that study questions or tasks might make you upset or uneasy. If this happens, remember that you will not need to respond to any questions or do any tasks that make you feel upset or uneasy. You may also stop at any time without penalty.

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

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

You may choose to discontinue stimulation at any time during the session if you are experiencing excessive discomfort or side effects.

Sham RS-tDCS+ is a simulation, therefore you will feel the same sensation as what you would feel if you receive the active RS-tDCS+. Sham RS-tDCS+ is inactive and harmless.

EEG. The EEG is a painless procedure with no known risks. The EEG will only measure electricity coming from your brain. The EEG does not conduct any electricity to your brain.

MRI Scans. If you are selected to do an MRI exam, it is possible that you may experience fatigue and discomfort due to lying motionless. The MRI scan could also make you feel claustrophobic. Incidental findings on your MRI scan may require referral for further evaluation and/or additional imaging and laboratory testing. In rare cases, Limited Duty (LIMDU) or Medical Boards/Physical Evaluation Board (MEB/PEB) referral may be initiated to assess fitness for continued active-duty service [low-risk; chance of immediate harm.]

If we feel it is needed or you request it, we will provide you with referrals to a mental health care provider for evaluation or treatment at your option. These referrals may be provided if a licensed member of the study team judges that you may benefit from these services based upon evidence of mental health difficulties. Immediate referral to a mental health professional will take place if we feel that you are in danger of harming yourself or others. However, this study is not intended to diagnose or treat any conditions. Non-referral does not imply the absence of a mental health condition.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

8. Are there benefits to taking part in the study?

Your participation in this research may or may not be of direct benefit to you personally. However, others may benefit in the future from the information learned during this study. The treatments used in this study are designed to help people with mild TBI. Also, results of this study may help the investigator develop tools for improved treatment of mild TBI.

9. What other options are there?

If you choose to take part in the study, you will be asked not to partake in other cognitive training or brain stimulation until the study is over. You can keep taking part in other treatments that do not involve cognitive training or brain stimulation. You can withdraw from the study if you change your mind.
Choosing not to participate in this research study is also an option. If you choose not to take part in this study, you may already be eligible to receive other cognitive treatments from your medical providers. Talk to your doctor if you have any questions about other cognitive treatments that may be available to you.

10. Will I be paid to participate?

If you are an Active Duty Service Member, you will only be eligible for payment if you complete the study requirements during off-duty hours. If you are randomly selected to complete the MRI portion of the study, the maximum compensation is $568. If you are not randomly selected to complete the MRI portion of the study, the maximum compensation is $418. Compensation will be issued in the form of gift cards. The compensation amount for each study activity is outlined below.

Visit Type	Payment	Quantity	Total
Visit 1: Consent, baseline assessment	$100.00	1	$100.00
Pre-Treatment MRI	$75.00	1	$75.00
At-home Treatment	$10.00	10	$100.00
Visit 2: Post-Treatment MRI	$75.00	1	$75.00
Post-Treatment in-person assessments	$100.00	1	$100.00
EMA ($1 per survey x 3 per week x 6 weeks)	$1.00	18	$18.00
Visit 3: 6-week follow-up	$100.00	1	$100.00
Non-MRI Participant			$418.00
MRI Participant			$568.00

If you request it, a letter of appreciation can also be issued to you at the end of your participation in the study.

11. What if I am injured as a result of participation in this study?

If you suffer any injury directly related to your participation in this research study, immediate medical attention is available at NMCSD or at another closer medical treatment facility, if applicable. Any injury resulting from your participation in this study will be evaluated and treated in keeping with the benefits or care to which you are entitled under applicable Navy, other Department of Defense, and other state or Federal regulations.

12. What about confidentiality?

In all publications and presentations resulting from this research study, information about you or your participation in this project will be kept in the strictest confidence and will not be released in any form identifiable to you personally. However, authorized personnel from NMCSD, MVAHCS, Traumatic Brain Injury Center of Excellence (TBICoE), U.S. Army Medical Research and Materiel Command (USAMRMC), and the Food and Drug Administration (FDA), where applicable, may have access to your research file in order to verify that your rights have been adequately protected.

Information that identifies you will be used in this study and shared with the study investigators, NMCSD IRB, TBICoE, and USAMRMC. A breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft or could result in embarrassment. However, the research team will make every effort to protect your private health information and guard against any loss of privacy.

Procedures to protect the confidentiality of the data in this study include but are not limited to: Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in a secure location, or as files behind the secure computer firewall. Identifiers might be removed from the identifiable private information that is 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.

Per 21 CFR 50.25, a description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

Coded data from this study will be submitted to the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. FITBIR is a computer system run by the National Institutes of Health that allows researchers studying TBI to collect and share information with each other. With an easier way to share data, researchers hope to learn new and important things about TBI more quickly than before.

During and after the study, the researchers will send information about your health and behavior to FITBIR. However, before they send it to FITBIR, they will remove information such as name, date of birth, and city of birth, and replace that information with a code/number. Other researchers nationwide can then file an application to obtain access to your study data for research purposes. Experts who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with FITBIR. However, the information provided to FITBIR might help researchers around the world treat future adults with TBI so that they have better outcomes. FITBIR will report on its website about the different studies that

researchers are conducting using FITBIR data, but FITBIR will not be able to contact you individually about specific studies. If you would like more information about FITBIR, please visit https://fitbir.nih.gov.

PATIENT AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH (HIPAA)
(In Keeping with the Health Insurance Portability and Accountability Protection Act)

What is Confidentiality of records all about?
The Naval Medical Center San Diego makes every effort to maintain the confidentiality of protected health information we obtain about you. However, we cannot absolutely guarantee confidentiality because other people may need to see your information during this research study. Most people and organizations will protect the privacy of your information, but may not be required to do so by the law. Also, if the results of this research study are presented at meetings or are published, your name will not be used.

What is HIPAA all about?
The Health Insurance Portability and Accountability Act (HIPAA) requires that we get your permission to use protected health information about you that is either created by or used in connection with this research study. This permission is called an Authorization. The information we use includes your entire research record and supporting information from the tDCS device and other testing.

What will we do with this information?
Your protected health information will be collected and used during the research study to determine research results, and to possibly develop new treatments and procedures to treat TBI.

Data collected during this study will also be shared with the entities listed below. Your name and personally identifying information will be removed before the data are shared so that the shared data will not contain any information that could identify you. The information may also be reviewed when the research study is audited for compliance. When the study is over, you have the right to see the information and copy it for your records.

Who will we share your information with?
Your information may be shared with any of the following:

- The sponsor of the study: U.S. Army Medical Research and Materiel Command (USAMRMC).
- Representatives of the DoD.
- Other research investigators, from Minneapolis Veterans Healthcare Administration Hospital, participating in this research study.
- State and Federal agencies that have authority over the research, the Naval Medical Center San Diego, or patients. Good examples are: the Department of Defense, the Department of Health and Human Services (DHHS), Defense Health Agency (DHA), and the Office of Human Research Protections (OHRP).
- Accrediting agencies, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
- Medical providers who may not be involved directly in the research study, but who may become involved in your care, if it is possibly related to treatment.
- Members of the research team who work for the Traumatic Brain Injury Center of Excellence (TBICoE).
- Members of the research team who are employed by General Dynamics Information Technology (GDIT).
- The Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system.

FITBIR was developed to share data across the entire TBI research field. It is a central repository for data from TBI studies built by the National Institutes of Health (NIH) and the Department of Defense (DoD). FITBIR will receive and store coded data only, including clinical assessment data, neuroimaging data, and any demographics and medical record data that are collected for this study.

What if you want to revoke or cancel away your Authorization?

If you decide to participate in this research study, your Authorization for this study will not expire unless you revoke or cancel it in writing to the principal investigator. If you revoke your Authorization, you will also be removed from the study, but standard medical care and any other benefit to which you are entitled will not be affected in any way.

13. Incidental findings.

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

You do not have an option to decline receiving information about an incidental finding. A qualified person (usually a member of the research team) will talk to you if there is an incidental finding.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

An incidental finding may cause you to feel anxious.

Since an incidental finding may be part of your medical record, you could face greater difficulty in getting health or life insurance

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. If you are a DOD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

14. Whom do I call if I have questions?

Principal Investigator (PI)

The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Lars Hungerford, PhD, ABPP-CN
Phone: (619) 532-5715
Mailing Address: 34800 Bob Wilson Drive, San Diego, CA 92134

NMCSD Human Research Protection Program (HRPP) Office

The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.
Phone: (619) 532-5524

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:
Institutional Review Board or NMCSD Clinical Investigation Department: (619) 532-6099
NMCSD: (619) 532-9927

15. What are my rights as a participant?
Your participation in this project is entirely voluntary and your decision not to participate will involve no penalty or loss of benefits to which you are entitled under applicable regulations. If you choose to participate, you are free to ask questions or to withdraw from the study at any time. If you should decide to withdraw from the research project, you will notify Dr. Lars Hungerford (NMCSD) at (619) 532-5715 to ensure your timely removal from the study. Your withdrawal will involve no prejudice to your future health care or any loss of rights or benefits to which you are otherwise entitled. Any new significant findings developed during the course of this study, which might affect your willingness to continue participation, will be communicated to you.

16. Can I be terminated from the study?
The investigator may terminate your participation in this study for the following reasons: failure to comply with study procedures; the study investigators are unable to get a hold of you for 7 days; the investigator determines that it is in your best interest; the study is discontinued.

17. Signature
You are making a decision whether or not to participate in the research project above. Your signature indicates that you have had this information presented to you, have had the opportunity to ask questions about the research and your participation, and agree to participate in the study.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information have been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Dat