Study Document

Study Title: Role of Transcranial Direct Current Stimulation to Decrease Impulsivity and Compulsivity in Individuals with Obesity
Short Title: tDCS for Impulsivity and Compulsivity in Obesity
NCT: NCT04405089
Document Type: Informed Consent Form
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INTRODUCTION

It is important that you read and understand the following explanation of the proposed research study before you agree to participate. This consent form describes:

- The purpose,
- The description of the study,
- The benefits,
- The risks and/or discomforts (including any potential for pain),
- Steps taken to decrease or eliminate the risks, discomforts, or possible pain,
- Any other treatments that may be available, and
- Confidentiality and use of research results.

Whether you decide to participate or not, treatment at the VA for which you are eligible will not be affected.

This consent form may contain words you do not understand. Please ask the study doctor or the study staff to explain any words or information unclear to you.

PURPOSE OF THE STUDY

You are being asked to voluntarily participate in a research study to find out if transcranial direct current stimulation (tDCS) coupled with executive function brain training decreases impulsive behaviors, such as out-of-control eating, in people who have obesity being followed in the Minneapolis VAMC Move Mass program. As a secondary aim, we will look at whether tDCS when coupled with the brain training helps with weight loss in people in this program attempting to lose weight in a structured behavior-modification based program offered by the program. You have been asked to participate in this study because you have obesity and are in the Move Mass weight loss program. Your participation is expected to last about 4 months, and approximately 50 people will be enrolled in the study at this site.

DESCRIPTION OF STUDY

This study is conducted by Drs. Sibley, Billington, and Lim at the Minneapolis VA Medical Center. The following information describes what will happen while you participate in the study: As a participant, you will be asked to complete one initial visit (Visit 1), followed by 1 session a day (Visits 2-6) for 5 days (1 full week of daily visits), followed by a visit about 8 weeks after Visit 6 (Visit 7), and a final visit (Visit 8) which is about 8 weeks after Visit 7. Between Visits 6 and 8 you would participate in the Behavior Modification Structured Module in our Weight Loss Program. The Behavior Modification Module is part of the regular care we offer in our weight

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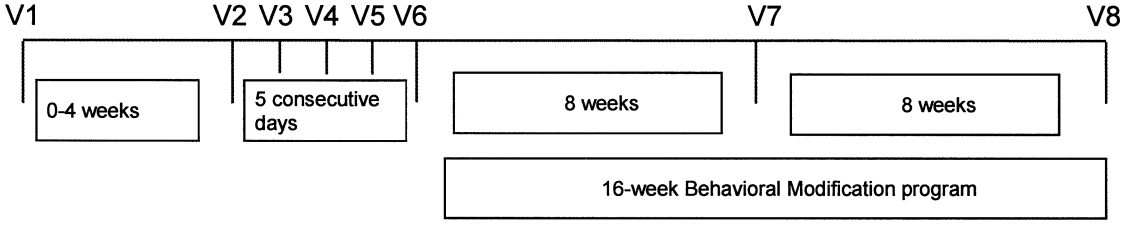
loss program, it consists of 8 in-person group classes, each one lasting about one hour, every other week but other procedures described in this consent form are for research purposes.

This figure summarizes the Visit schedule:



Study Visit Details:

Screening visit (Visit 1 [V1]) -

Medical records will be reviewed for eligibility, a urine pregnancy test will be collected (if applicable), blood draw (about 1-2 teaspoons), history and physical will be done. Computerized and/or paper brain games that consist of cognitive tests to assess your memory and attention, 2 questionnaires and a brain injury interview will be done. This visit is expected to last up to about 2 hours

tDCS session visits (V2-6):

At these visits we will do the tDCS sessions. tDCS involves applying a weak electrical current to the scalp. This device has been approved by the FDA for investigational purposes.

You will receive either active tDCS or sham tDCS. During the active tDCS, stimulation occurs throughout the entire time; whereas, during sham tDCS, stimulation occurs during the first 30 seconds, and then is turned off. You will be randomly assigned to the type of tDCS stimulation, with a 50% chance of getting either active tDCS or sham tDCS. We will disclose the type of intervention you received at the end of your participation in the study.

These visits will occur over 5 sequential weekdays, 13 minutes of stimulation, with a 20 minute stimulation break followed by another 13 minutes of stimulation. You will complete brain training games during the entire 46 minutes. With Visit 6, we will collect your weight and you will repeat an additional brain game that was done at the beginning of the study so this visit will be a little longer than the others. These visits are expected to last about 1 to 1 ½ hours.

Visit post Behavioral Modification Class Completion and Final Visit (V7 and V8):

These visits will be identical to V1 with the exceptions that the history and physical, blood draw, and brain injury interview will not be repeated, and that one of the questionnaires is only repeated at the final visit. Although the physical will not be conducted, we will weight you at both follow up visits. These visits are expected to last between 1 and 2 hours.

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Its is recommended to not adjust obesity medications once you have enrolled in the study, but if you need to stop or adjust medications due side effects, alert study staff so they can document the change.

ALTERNATIVES(OTHER AVAILABLE TREATMENTS)

MOVE MASS Program
Subjects may continue in the MOVE MASS program which standard of care including pharmacotherapy and lifestyle modification.

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.

RISKS AND/OR DISCOMFORTS

tDCS is a non-invasive brain stimulation technique that rarely results in harmful events. Listed below are mild side effects that typically go away after stopping tDCS.

- Light itching under the electrode at the beginning of the administration
- Headache
- Fatigue
- Nausea

There is currently no evidence of serious side effects.

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

In addition, this study also involves the use of private (medical) records. The use of protected health information may be associated with negative feelings about sharing the history.
There may be other unknown side effects that could occur. You may experience mild stress or mental fatigue due to the decision-making tasks used in the study. You may skip any questions on the questionnaires that you are uncomfortable answering.

A small amount of blood is drawn at the beginning of this study. You may have pain or bruising at the venipuncture site.

If you become pregnant during the study, we will no longer continue the tDCS stimulation so please contact study staff listed below in "Compensation for any Injuries" section.

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EMPLOYEES AS RESEARCH SUBJECTS

If you are a VA employee you are considered a special class of research subject who deserves special protections: 1) Your decision to participate in this study should be free from pressure or coercion to participate. 2) The VA research team will work to secure your information according to VA data security and privacy policies and every effort will be made to keep your information from your supervisor and co-workers. However, accidental disclosure or release of your private information could occur during the conduct of this study.

COMPENSATION

Due to the commitment of time, you will be compensated for their study participation at a rate of $15 per hour. If you complete only part of a visit you will be compensated at a rate of $10per hour, prorated for the time spent in that visit. You will be paid at the visit or a check will be mailed after the visit.

CONFIDENTIALITY AND USE OF RESEARCH RESULTS

The results of this study may be published or presented but your identity and records will not be revealed unless required by Federal Law. A Federal Law allows the U.S. Food and Drug Administration, Office for Human Research Protections, Government Accountability Office and other Federal agencies, the Research and Development Committee and/or the Institutional Review Board (IRB)/Human Studies Subcommittee of the VA Medical Center to review records. By participating in this research, you have also agreed to allow the sponsor or sponsors of the research project to review your medical records. Because of the need for these inspections, absolute confidentiality cannot be guaranteed.

COSTS TO YOU FOR PARTICIPATING

There is no cost to you for taking part in this study. All of the study costs 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.

MEDICAL CARE IF YOU ARE INJURED

In case 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

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directly related to your participation in this research study. If you receive this type of medical care, you must contact the Research Investigator for this study. You can find contact information in the section of this consent titled "Compensation for Any Injuries".

COMPENSATION FOR ANY INJURIES

You have not released the VA Medical Center from liability by signing this form. This includes but is not limited to: 1) free medical care other than as described in this consent form, 2) payment of lost wages, or 3) compensation for pain and suffering. Compensation for those items from the VA may be available under applicable Federal Law. You should immediately report any injuries resulting from your participation in this study to Dr. Shalamar Sibley at (612) 467-1727 during the day and during the evenings or weekends, by calling the VA operator at (612) 725-2000 and ask to have the metabolic attending on call paged. Tell the operator you are in a research study. If you do not live in the metropolitan area, you may call the toll-free number: 1-866-414-5058.

NEW INFORMATION

You will be given any new significant information which is discovered during the course of this study which may influence your willingness to continue the study.

OTHER INFORMATION

Unanticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent could include: if the study is terminated early, if the subject does not follow instructions, or if the investigator feels it is not in the best interest of the subject to continue You have a right to withdraw from the research at any time. Payment will be made for the sessions that were completed. No further follow up would be necessary.

A description of this clinical trial will be available on https://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.

RESEARCH SUBJECT'S RIGHTS: I have read or have had read to me all of the above. _____ *(Name of person obtaining consent)* has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available. **I understand that I do not have to take part in this study and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.**

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The results of this study may be published but my identity and records will not be revealed unless required by law.

I authorize the use of my bodily fluids and substances, or tissues.

I have been informed that because this study involves articles regulated by the FDA (Food and Drug Administration), the FDA may choose to inspect research identifying me as a subject of this investigation.

In case there are medical problems or questions, concerns, or complaints, I have been told I can call Dr. Shalamar Sibley at (612) 467-1727 or the Study Coordinator at (612)467-5203 during the day and the VA operator at (612) 725-2000 after hours and ask to have the metabolic attending on call paged. I will tell the operator I am in a research study. If I do not live in the metropolitan area, I may call the toll-free number: 1-866-414-5058.

If any medical problems occur in connection with this study the VA will provide emergency care.
If I have any questions about the rights of a research subject, or would like to:

- obtain information
- discuss problems or concerns, or have questions about this study
- offer input regarding this research study

and would like to speak to an individual who is not part of the research team of this study, I may contact the Patient Representative at (612) 725-2106. If I wish to verify the validity of the study and its authorized contacts, I may call the patient representative or contact the IRB office at (612) 629-7387.

CONTACT REGARDING FUTURE STUDIES

May we contact you about future studies that you may be interested in participating in?
Please **initial** item 1 or 2 below:

1. _____ Yes, you may keep my contact information and contact me about future studies. Your contact information will be stored in a secure database under the VA firewall and will be managed by Dr. Sibley.
2. _____ No, you may not keep my contact information and contact me about future studies.

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My questions have been answered and I voluntarily consent to participate in this study. By signing this form, I have not given away any of my legal rights, which I have as a subject of this research study. I will receive a signed copy of this consent form.

Subject's Signature	Date
Signature of Person Obtaining Consent	Date
Printed Name of Person Obtaining Consent	

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