Medical University of South Carolina

Accelerated High-Dose Transcranial Direct Current Stimulation (tDCS) for Depression: An Open-Label Outpatient Pilot Study

ClinicalTrials.gov Identifier (NCT Number): NCT

SPONSOR / COLLABORATORS:

Medical University of South Carolina (MUSC)
City College of New York (Collaborating Investigator: Marom Bikson, PhD)

PRINCIPAL INVESTIGATOR:

Mark S. George, MD
Distinguished Professor, Psychiatry, Radiology, and Neuroscience
Medical University of South Carolina
Study Lead: Clayton Olash, MD
Psychiatry Resident
DART Fellow

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Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

Study Title: **Accelerated High-Dose tDCS for Depression: An Open-Label Outpatient Pilot Study**

SUMMARY

You are being asked to take part in this research study. Participation is voluntary. The purpose of this study is to see if giving a type of brain stimulation, called transcranial direct current stimulation (tDCS), at higher strength can be done safely and is comfortable for people with depression. We will also look at whether it may improve mood.

Your participation will last about one week of in-person visits. You will have a screening and first stimulation day, followed by four more daily treatment visits. You will also have one brain scan, called a Magnetic Resonance Imaging (MRI) scan, which uses a magnet to take pictures of your brain. About four weeks after the last treatment, you will complete a short follow-up visit virtually. You may experience a reduction in depressive symptoms because of participating in this study, though this cannot be guaranteed. The data gained from this study may lead to new innovative treatments for depression in the future. Your participation is voluntary, and if choose not to participate or to withdraw at any time, standard treatments for depression, such as medication or psychotherapy, remain available to you.

During the study, you will answer surveys about mood and mental health, complete an MRI scan, and have supervised sessions of tDCS. Some people may feel mild side effects such as tingling on the scalp, skin redness, headache, or fatigue. More serious side effects are rare, but seizures, mood changes, and heart changes are possible. You will be monitored closely, and you will be told who to contact if you experience any problems.

A. PURPOSE OF THE RESEARCH

You are being asked to participate in this study because you fit our inclusion criteria and could be a good candidate. This study is being done to test a form of brain stimulation called transcranial direct current stimulation (tDCS). tDCS uses a device to send a low electrical current through electrodes placed on the scalp. This device is investigational, meaning it has not been approved by the Food and Drug Administration (FDA) for treating depression, although similar devices have been studied before.

This is a small early study being done only at MUSC to see if the treatment is safe, tolerable, and practical to use. We will also look at whether it may help improve depression symptoms.

About 20 participants will be enrolled at MUSC. The study team is not being paid by any company to run this project. The principal investigator in this study is Mark George, MD.

B. PROCEDURES

If you agree to be in this study, the following will happen:

Screening and Eligibility

You will have the following tests and procedures to make sure that you are eligible:

- You will be asked about your medical history, mental health history, and current medications (about 30 minutes).
- You will have a brief physical examination, including a skin check, to make sure it is safe for you to participate.
- You will complete questionnaires about mood and related symptoms (about 30 minutes).
- If you are able to become pregnant, you will provide a urine sample for a pregnancy test (about 10 minutes).

Study Device

- This study uses an investigational tDCS device. The device used in this study is called a "high-capacity tDCS system." It is a modified version of a device already used in many research studies around the world. This device sends a very small electrical current through soft pads, called electrodes, that stick to the skin on your forehead. The current is measured in milliamps (mA) — one milliamp is one-thousandth of an amp, which is a very small amount of electricity. For comparison, the device in this study uses up to 6 milliamps, which is much lower than the amount of electricity in a household outlet. The special "high-capacity" pads are designed to spread the current out more evenly. This helps make the stimulation more comfortable and reduces the chance of skin redness or irritation. These pads and this device have already been tested in healthy volunteers at the same levels we are using here, and they were found to be safe and well-tolerated. This study will test whether this approach is also safe and comfortable for people with depression. The use of this device at higher intensity (6 mA) is investigational and not FDA-approved.

Study Procedures

- **Safety Run-In (first 3 participants only):** For the first three participants, we will start with lower levels of stimulation and increase gradually. This helps us check for safety before everyone receives the higher level of stimulation. On Day 1, you will receive three stimulation sessions: 20 minutes at 2 mA, 20 minutes at 4 mA, and 20 minutes at 6 mA, each separated by 30 minutes of rest. On Day 2, your skin will be checked, and you will receive two 20-minute sessions at 6 mA separated by a 30-minute rest. Each of these visits will take about 3 hours.

- **Main Protocol (all participants):** If no serious side effects are observed in the safety run-in, all participants will receive 20 minutes of stimulation at 6 mA, twice per day, separated by at least 30 minutes, for five consecutive days. Each daily visit will take about 1.5 to 2 hours.
- **Questionnaires:** You will complete questionnaires about depression, pleasure, and mindfulness before and after stimulation (about 30 minutes each time).
- **Follow-Up:** You will be asked to complete questionnaires at four weeks after the last stimulation, which will be conducted remotely (about 30 minutes each follow-up).
- **MRI:** At one point during the study (the timing of which is at your discretion), you will undergo a structural MRI scan (about 30 minutes). This scan is for research only and not for medical diagnosis or treatment. If incidental findings are seen, the study team will not evaluate or treat them. Magnetic resonance imaging (MRI) uses a magnet and radio waves to make diagnostic medical images of the body. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will hear a loud machine-like noise.

C. DURATION

Participation in the study will take 6 in-person visits over one week, plus one virtual follow-up at four weeks.

D. RISKS AND DISCOMFORTS

- With this form of tCDS there are potential risks and discomforts, including:
  Mild sensations such as itching, tingling, or warmth under the electrodes during stimulation.
- Headache, fatigue, or lightheadedness during or after stimulation.
- Temporary skin redness or irritation at the electrode sites.
- Rarely, temporary changes in mood or anxiety.
- If the participant is or becomes pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which are currently unforeseeable
- Seizure
- Heart-related changes such as low blood pressure or slow heart rate
- Questionnaires: You may experience some mild discomfort while answering some of the questions in the questionnaire part of the study, as they ask about personal topics.
- The experimental treatments may have unknown side effects.
- There is a risk of loss of confidentiality of your information that is used in this study.
- With respect to the MRI: There have been no ill effects reported from exposure to the magnetism or radio waves used in this test. A known risk is that the magnet could attract certain kinds of metal. Therefore, we will carefully ask you about metal within your body (this includes certain dyes found in tattoos). If there is any question about potentially hazardous metal within your body, you will be excluded from participation in this research study. We will also keep the examining room locked so that no one carrying metal objects can enter while you are in the scanner. Please inform the study staff if you have a history of claustrophobia

(extreme anxiety in close spaces). This may also be a contraindication to participation in the study.

- If a serious adverse event does occur, you will be able to contact the Principal Investigator, Dr. Mark George, at his phone number: 843.876.5142..

E. MEDICAL RECORDS AND CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

F. BENEFITS

You may experience a reduction in depressive symptoms as a result of participating in this study. However, we cannot guarantee any benefit. The information gained from this study may help develop new treatments for depression in the future.

G. COSTS

There will be no additional cost to you for procedures required in this research study. All routine clinical care that the Sponsor is not paying for that you would have undergone without participation in the study will be billed to you/your insurance company.

Some insurance plans will not pay for these services for people taking part in research studies. You will be responsible for any charges that your insurance does not cover including co-payments and deductibles.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $_280____ for participation in this study. If you do not complete the study, you will receive $__40___for each completed visit. There will be 7 total visits including the virtual follow up visit, and completion of each visit will result in 40$ being paid to the participant.

Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet.

ClinCard is administered by an outside company called Greenphire. Greenphire will be given your name, address, SSN and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study that you are participating in.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your participation is voluntary. You may choose not to participate or to withdraw at any time without any penalty or loss of benefits to which you are otherwise entitled. If you choose not to participate, standard treatments for depression, such as medication or psychotherapy, remain available to you.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you.

K. DISCLOSURE OF RESULTS

Research test results, including MRI scans, will not be returned to you or your medical providers.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

- The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits.

However, you will not be allowed to be a participant in this research study.
You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study.

However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.
If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

M. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

N. CLINICAL TRIALS.GOV

A description of this clinical trial 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.

O. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.
The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact **Mark George, MD at (**843.876.5142.**).** I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.
If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a paper copy of this form for my own records.

Standard Signature Block for Enrolling Adult Participants

Signature of Participant	Date	Name of Participant

Signature of Person Obtaining Consent	Date