

**Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT**

**Effects of transcranial Direct Current Stimulation and Brief Cognitive Intervention
on Pain Tolerance**

A. PURPOSE AND BACKGROUND:

You are being asked to volunteer for a research study. This research is sponsored by the Medical University of South Carolina. The purpose of this study is to determine whether a new medical technology in combination with brief cognitive intervention can temporarily alter pain tolerance level. The new technology is called Transcranial Direct Current Stimulation. Transcranial Direct Current Stimulation (tDCS) is a minimally-invasive technique (i.e., it does not involve any surgical procedures, additional medication or sedation, or needles) that uses a very small amount of electricity to temporarily stimulate specific brain areas in awake people. The electrical current passes through the skin, scalp, hair and skull and can temporarily increase or decrease activity in areas of the brain that are thought to be involved in pain perception. Some preliminary studies suggest that tDCS may be effective in decreasing pain. However, tDCS is not approved by the FDA as a treatment for pain problems.

The investigator in charge of this study is Dr. Jeffrey J. Borckardt, and this study will involve approximately 360 volunteers.

B. PROCEDURES:

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

1. You will complete several self-report screening measures designed to assess your mood, pain history, and anxiety. Additionally, you will be interviewed by one of the researchers about your medical history including history of seizures, implanted medical devices, skin conditions and history of brain injuries. All women of child-bearing age who are sexually active and are unsure of whether or not they could be pregnant will be provided with a pregnancy test before being able to participate in the study.
2. If you are eligible for participation, you will be scheduled for 1 visit to MUSC and you will be randomly assigned to one of three tDCS groups (anodal, cathodal or sham). This means that you have a 33% chance of being in each stimulation group. You will also be randomly assigned to one of four cognitive behavioral therapies paired with one of the three stimulation groups. Therefore there are twelve possible treatment options to which you can be randomly assigned. Neither the researchers nor you will make the choice of which group to which you are assigned. In the four types of cognitive intervention you will be provided with information related to the pain tolerance task and will later answer questions about that information.
3. Regardless of which group you are in, after completing the initial questionnaires you will undergo a laboratory pain assessment. The laboratory pain assessment involves the use of a small device that is attached to the underside of your forearm. The device is controlled by a computer and can be set to produce different temperature stimulations. The researcher will attach the device (called a thermode) to your arm. The thermode will heat up very slowly and you will be asked to press a button when you can no longer tolerate the heat. The thermode is

programmed to stop heating when it approaches a temperature that might cause tissue damage.

4. Next, the researchers will take some head measurements and apply a saline-soaked sponge electrode to your forehead. Another will be placed on your upper-arm/shoulder. The electrodes will be held in place with a Velcro band.

5. You will then either receive 20 minutes of anodal, cathodal, or “sham” tDCS along with a cognitive intervention, and the researchers will measure your pain tolerance using the thermode every 5 minutes in the same manner as before.

6. After the tDCS, you will undergo an identical laboratory pain assessment to the one before the tDCS treatment.

7. At the end of the appointment you will be asked about any side-effects and you will be asked questions about your experience of the stimulation. You will also fill out a short questionnaire asking you questions about the information you learned about during the 20 minutes of intervention.

C. DURATION:

Your total participation time will be about 1 hour over the course of one appointment. The screening and consent portion of the study will take about 20-minutes, and the tDCS procedures will take about 40 minutes.

D. RISKS/DISCOMFORTS:

Potential Risks of tDCS:

tDCS has been found to be safe in humans with mild side-effects such as tingling sensations under the sponge electrodes (experienced by 70% of tDCS patients), moderate fatigue (35%), and light itching sensations under the sponges (30%). These side-effects typically disappear within the first few minutes of tDCS treatment for most participants.

After tDCS, the incidence of side-effects is lower than other brain stimulation techniques (i.e. transcranial magnetic stimulation) but include headache (12%), nausea (3%) and insomnia (<1%). There is no evidence to date suggesting that tDCS causes seizures, and it is currently being used as a method to reduce seizure frequency in epileptic patients. However, there is a very small possibility that tDCS could induce a seizure in some participants.

Some mild skin irritation can occur after tDCS treatment. If tDCS is delivered at 20 minutes per day, every day for 4 or more days in a row, mild skin burns have been reported. However, these burns have all been reported to heal without scarring within 1 to 3 weeks following the end of tDCS treatment. We will only be delivering one tDCS session in this study. Further, we will be using a more sophisticated electrode configuration that we believe to be safer and less uncomfortable than traditional sponge electrodes. Further, we will provide you

with vitamin-E lotion to apply to your skin after the tDCS treatment.

tDCS is thought to be safe, with no potential for brain damage, and has been used extensively in humans and other animals. There have been no reports of long-term changes in cognitive function (memory, attention, etc) in tDCS studies. However, tDCS is an experimental procedure and may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

Safety in case of pregnancy:

This protocol will exclude pregnant women. The risks of using tDCS with pregnant women are currently unknown. If you are pregnant, or think you might be pregnant at any point during this study, please inform the investigators and the tDCS will be discontinued immediately. All women of child-bearing age who are sexually active will be provided with a pregnancy test before being able to participate in the study.

Potential Risks of Cognitive Intervention:

There are no known risks to the cognitive intervention that you will receive. However, there is always a minimal risk of emotional discomfort or distress emerging as a result of learning new information about pain and ways of coping with painful stimuli.

Potential Risks of Laboratory Pain Procedures:

Risk of tissue damage, burning or scarring:

The procedures proposed in this study are widely used in research and clinical evaluation procedures and have been shown to be safe. For thermal pain procedures, the stimulator will be set with a limit of 52°C which is well below the threshold for causing any damage to subject's skin or nerve endings. However, it is not unusual to experience some tenderness, redness or inflammation in the heated skin area after completion of the thermal pain procedures. These symptoms subside within a few hours with no intervention. In very rare cases of people with highly sensitive skin, mild blistering has occurred.

Risks regarding Confidentiality:

Despite efforts to maintain subjects' anonymity and confidentiality, there is always some minimal risk of people other than the study investigators gaining access to your health information. Every effort will be made to ensure that your health information will be collected and stored in a manner that ensures the highest level of protection of confidentiality.

E. BENEFITS:

There are no direct benefits to you for participating in this study. However, it is hoped that the information gained from the study will help in the treatment and management of chronic pain.

F. COSTS:

You will not be charged for any of the study treatments or procedures.

G. COMPENSATION:

You will be paid \$40 in cash for your participation in this study at the end of the appointment.

H. ALTERNATIVES:

This is not a treatment study. You have the option of not participating in this trial if you choose.

I. NEW INFORMATION:

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

J. STUDENTS:

All MUSC students are eligible to participate in this research study. Your participation or discontinuance will not constitute an element of your academic performance nor will it be a part of your academic record at this Institution.

K. EMPLOYEE PARTICIPATION:

All MUSC employees are eligible to participate in this study. Your participation or discontinuance will not constitute an element of your job performance or evaluation nor will it be a part of your personnel record at this Institution.

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. 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 Dr. Borckardt at (843)792-3295. I may contact the Medical University of SC Hospital Medical Director (843) 792-9537 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 copy of this form for my own records.

If you wish to participate, you should sign below.

Signature of Person Obtaining
Consent

Date

Signature of Participant

Date

