

Medical University of South Carolina CONSENT TO BE IN A RESEARCH STUDY

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“The Effects of Cognitive Behavioral Therapy and Transcranial Direct Current Stimulation (tDCS) on Fibromyalgia Patients”

A. PURPOSE AND BACKGROUND

You are being asked to volunteer for a research study. This research is sponsored by the National Institutes of Health (NIH) and the Medical University of South Carolina (MUSC). The purpose of this study is to determine whether a new medical technology, called Transcranial Direct Current Stimulation (tDCS), can help reduce chronic pain due to fibromyalgia when applied in combination with cognitive behavioral therapy (“talk therapy”). 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 with pain reduction. Some preliminary studies suggest that tDCS may be effective in reducing fibromyalgia and altering pain perception in both healthy adults and in patients with various types of pain conditions. However, tDCS is not approved by the FDA as a treatment for pain conditions.

You are being asked to participate in this study because you are between the ages of 21-85 and may meet criteria for these conditions. The investigator in charge of this study is Jeffrey J. Borckardt, Ph.D. This study will involve approximately 72 volunteers with chronic pain due to fibromyalgia and will be conducted in Charleston, SC.

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 pain history, level of depression and anxiety.
Additionally, you will be interviewed by one of the research team members about your medical history including history of seizures, implanted medical devices, skin conditions and history of brain injuries.
2. You will be permitted to continue your current pain treatments (including medications), but will be asked not to change the treatment regimen during your enrollment in the study.



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3. If you are a woman who is able to become pregnant, the study team will perform a urine pregnancy test. If the pregnancy test is positive you will not be eligible to participate in the study.
4. You will be randomized to one of two groups; neither the researcher nor you will make the choice of which group you are assigned. The two groups are A and B. If you are randomized to Group A, you will meet with a clinician for 6 sessions of cognitive behavioral therapy for pain and you will receive real tDCS. If you are randomized to Group B, you will meet with a clinician for 6 sessions of cognitive behavioral therapy for pain and you will receive sham tDCS (this is not real stimulation).
5. You will be given a paper diary to record your daily pain, mood, sleep and activity levels. You will also be scheduled to undergo Quantitative Sensory Testing (QST), which will take place in the Brain Stimulation Laboratory in the Institute of Psychiatry at MUSC. QST evaluates your response to pain by using a heat stimulator on your arm and a blunt tip needle that will be pressed into various skin areas that are thought to be uniquely sensitive in patients with fibromyalgia.
6. During the treatment phase, you will receive 6, 60 minute therapy sessions of CBT for pain. These treatment sessions will take place in the Behavioral Medicine Clinic located on the 1st floor of the Institute of Psychiatry at 67 President St. Charleston, SC. During each of these CBT therapy sessions, you will undergo approximately 30 minutes of either real or sham tDCS over the left DLPFC. You will also be asked to fill out questionnaires about your mood, sleep, activity levels, and quality of life at each session.
7. When conducting a tDCS session, the investigators may pre-treat your skin with a small amount of mild pain-reducing cream. Small sponges will be soaked in a sterile solution of 0.9% sodium chloride insulated by a latex casing.

The sponges will be placed over the area of your scalp corresponding to your group. The sponges will be held in place by a Velcro headband. After stimulation, the investigators may apply a vitamin-E/Aloe cream to the skin to reduce problems associated with skin drying.

8. You may experience 30 minutes of mild, constant stimulation through the sponges. Some people experience a mild tingling or itching under the sponges during the stimulation. Some people feel tired, some feel nothing at all.
9. After a 2-week baseline phase, you will undergo QST and then start the manualized CBT intervention with simultaneous tDCS (real or sham; randomized and masked).



You will undergo 1 session per week for ~6 weeks. After the last session, you will undergo another QST session. You will continue to complete the electronic pain diaries throughout the treatment as well as a 4-week follow-up phase. At 1, 3 and 6 months, you will return to the lab to complete follow-up questionnaires.

C. DURATION

Your participation in the study will involve 12 appointments (baseline visit, 6 therapy sessions, 2 QST sessions, 3 follow-up appointments). The baseline assessment may last up to three hours. The therapy sessions are 1 hour each. The follow up sessions will last approximately one to two hours. The QST sessions will last approximately 45 minutes each.

Project staff will contact you to schedule appointments and provide reminders for those appointments. We will ask for your phone number, email, and mailing address to contact you. Any contact associated with the study will simply remind you of the time and date of an appointment and will not include information indicating that this study is related to psychiatric or pain research.

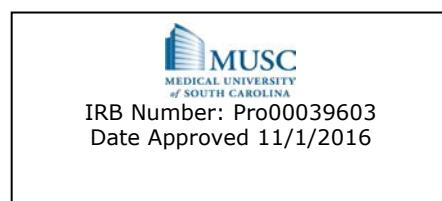
D. RISKS/DISCOMFORTS

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%).

After tDCS, the incidence of side-effects is lower, but include headache (12%), nausea (3%) and insomnia (<1%). There is no evidence to date suggesting that tDCS causes seizures. This technique is currently being used as a method to reduce seizure frequency in epileptic patients. However, there is at least a theoretical possibility that tDCS could induce a seizure in some patients, thus if you have epilepsy or are taking medications known to lower seizure threshold, you will not be eligible for participation in this study.

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 problems have only been seen when the electrode sponges are soaked in certain types of liquid, none of which will be used in this study. Further, these problems have only been seen when the skin is not treated with moisturizer creams after stimulation. The investigators will apply a vitamin-E/Aloe cream to your skin after each stimulation session. Lastly, these rare instances of burns reported in the research literature have all been reported to heal without scarring within 1 to 3 weeks following the end of tDCS.



treatment. Because we are using liquids that have not been associated with skin irritation, and because we will be applying a moisturizing cream after each treatment, we believe that the risk of mild burns is very minimal. Further, if the investigators detect any evidence that you are developing a skin irritation in response to the treatment, the treatment will be discontinued.

tDCS is thought to be safe, with no potential for brain damage, despite extensive use 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.

Potential for allergic reaction:

Some people report allergic contact dermatitis as a result of exposure to creams such as Benzocaine and Vitamin-E lotion. Dermatitis is described as inflammation of the skin and may present as an itchy rash. The rash may be treated with corticosteroid creams (such as hydrocortisone), antihistamines, or wet compresses. If contact dermatitis develops, the investigator will immediately remove any cream from your skin and apply a wet compress.

Risks regarding Confidentiality:

All study records will be placed in a locked, secure, limited access location. Your participation in the study and the information you provide will be treated as confidential. In order to protect your confidentiality, the information we collect will contain your code number and not your name. Codes linking numbers and names will be kept in a locked secure location and will not be accessible to anyone outside the research team. There is a risk of a loss of confidentiality of your personal information as a result of participation in this study.

You should know that if you threaten to harm yourself or others, or give information about child or elder abuse, this information will be reported to appropriate clinical staff and other persons outside the research program as necessary to protect you and others.

Even without your consent, suspected or known abuse or neglect of a child, disabled or elder abuse, or threatened violence to self or others may be reported to appropriate authorities.

Randomization Risk:

As there is a 50/50 chance of you receiving either the real or sham stimulation, there is the risk of being assigned to the sham group, which may not receive a benefit.



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E. BENEFITS

You may (or may not) experience a reduction in pain as a result of participating in this trial. It is hoped that the information gained from the study will help in the treatment of future patients with chronic pain conditions.

F. COSTS

There are no costs to you for your participation. You will not be required to pay for medical care or services.

G. COMPENSATION

Compensation will be in the form of cash. You will receive \$40 for the baseline visit; \$20 for each therapy session; \$75 for each follow-up visit; and \$25 for each QST procedure. For each daily diary, you will receive \$1. Thus, the total amount subjects may receive for participation in this study is \$519.

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.

H. ALTERNATIVES

tDCS is not approved by the FDA as a treatment for pain. This treatment study is being conducted to determine the effectiveness of tDCS for pain. If you choose not to participate in this study, you could receive other treatments for your conditions. We will be happy to provide referrals for other treatment clinics and health care providers in the community if you would like. 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 this study, you will be notified.



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J. RELEASE OF MEDICAL RECORDS TO ANYONE OTHER THAN THE INVESTIGATORS

If for any reason you would like your medical records released to anyone other than the study investigators, you will be asked to sign a release of information form. You will also sign a Health Insurance Portability and Accountability Act (HIPAA) authorization to use or disclose your protected health information for research purposes.

K. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance nor will it be part of your academic record at this Institution.

L. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute any element of your job performance or evaluation nor will it be part of your personnel record at this Institution.

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 any time.

M. OTHER INFORMATION

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 Jeffrey J. Borckardt, Ph.D. I may contact the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment.

If I have any questions, problem, 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 offered a copy of this form for my own records.

If you wish to participate, you should sign below.

Signature of **Participant** Date

Signature of **Person Obtaining
Consent** Date