Coversheet

Study Title: tDCS and Metacognitive Strategy Training in Stroke

NCT Number: 2076763

Consent Approval Date: 10/09/2024

Written Consent to Participate in a Research Study

Project Title: Pilot Testing of tDCS and Metacognitive Strategy Training in Chronic Stroke
Principal Investigator Name: Anna E. Boone, PhD
Sponsor: College of Health Sciences; Roger S. Williams Grant
IRB Assigned Project Number: 2076763

Key Information About the Study

You are being asked to participate in a research study. The purpose of the research study is being conducted evaluate the feasibility of combining two approaches to stroke rehabilitation. You are being asked to complete cognitive and functional assessments at two different time points and to participate in a total of 12 intervention sessions (described below). Possible benefits include improved ability to do day to day activities that you value. Some possible risks may include boredom or frustration while completing the assessments and the potential for a breach of confidentiality.

Please read this form carefully and take your time. Let us know if you have any questions before participating. The research team can explain words or information that you do not understand. Research is voluntary and you can choose not to participate. If you do not want to participate or choose to start then stop later, there will be no penalty or loss of benefits to which you are otherwise entitled.

Purpose of the Research

You are being asked to participate in this study because you sustained a stroke more than 6 months ago. The purpose of the study is to determine the effects of combining two approaches, transcranial direct current stimulation (tDCS) and metacognitive strategy training, on the functioning of individuals living with the long-term effects of chronic stroke.

What will happen during the study?

You will be asked to complete the following activities.

Pre-intervention testing: Come to our research lab at the University of Missouri to complete a brief cognitive assessment (Montreal Cognitive Assessment), a brief questionnaire on depressive symptoms (Patient Health Questionnaire-9), a brief language screening (National Institute of Health Stroke Scale language item), and a brief brain stimulation safety screening. This will determine your eligibility for the study. If you are eligible and wish to participate you will then be asked to complete about 2 hours of functional assessments, cognitive assessments, and self-report questionnaires.

Intervention: Then, you will be asked to complete a 4-week intervention with three, one-hour sessions each week. Each intervention session will begin with low-current brain stimulation that has been deemed a non-significant medical risk. The brain stimulation will involve placing

IRB Approval Date: Oct 09, 2024; Written Consent Form ID #742085; Annual Update ID #438440

two electrodes on the scalp toward the front and side. The brain stimulation will be conducted for 20 minutes at the beginning of each session. It may produce some tingling or itching sensations, but should not be painful. You will randomly receive active or sham (e.g. fake) stimulation. Following each brain stimulation session, you will be asked to complete a brain stimulation sensations questionnaire to identify sensations you experienced during the brain stimulation. You may stop the stimulation at any point if you feel uncomfortable or need a break. If at any point you wish to stop the stimulation, inform the researcher with you. For the remainder of each session, you will be randomized to either (1) practice tasks that you wish to improve upon with cognitive strategy (e.g. problem-solving) usage or (2) computer-based cognitive training.

Post-testing: After the four weeks of intervention, you will be asked to complete about two hours of post-intervention assessments including the same assessments from the beginning of the study.

Your participation is expected to last 6 weeks.

Transcranial Direct Current Stimulation (tDCS) is a non-invasive type of brain stimulation that passes a weak electrical current (generated by 9-volt batteries) into the area of your brain responsible for movement. This current will be passed between two electrodes (small metal discs) housed in saline- soaked sponges that we will apply to your head. You might feel a slight tingling or itching sensation at the beginning of the stimulation.

- o tDCS is considered investigational, which means it has not been approved by the U.S. Food and Drug Administration to be used to investigate how the central nervous system works.
- o The actual current entering your brain during tDCS is very small. tDCS has been used safely in hundreds of experimental investigations.
- o The effects of tDCS are temporary, and it is not known to cause any permanent effects, either beneficial or harmful. Please report any adverse effects that you may experience during simulation to the therapist so they can monitor these symptoms, or discontinue the study.
- o The application of tDCS may cause you some temporary discomfort: you may notice some mild itching or tingling, fatigue, or a headache.

What are the expected benefits of the study?

You may or may not benefit as a result of your participation in the study. Information learned from the study may help other people in the future. If you agree to take part in this study, you may potentially experience an improvement in your ability to participate in everyday life activities and your self-efficacy to manage your chronic health conditions.

What are the possible risks of participating in this study?

While in the study, you are at risk for minor scalp sensations of tingling or itching. You may also experience boredom or frustration while completing the assessments. Another potential risk associated with this study is the rare risk of breach of confidentiality, although our research team has taken every precaution to minimize this risk. You should discuss these with the investigator

IRB Approval Date: Oct 09, 2024; Written Consent Form ID #742085; Annual Update ID #438440

should they occur. Although there are no known effects of the intervention on pregnancy, participants who are pregnant will not be allowed to participate in the study as a precaution. Should a participant become pregnant during the intervention, there may be risks which are currently unforeseeable.

To help lower these possible risks, we will exclude participants who are or who are trying to become pregnant, offer breaks in assessment administration as needed, and monitor sensations experienced as a result of the brain stimulation.

We will tell you about any new important information we learn that may affect your decision to continue to participate in this study.

If you are pregnant or become pregnant while in this study, there may be risks to you, the embryo or fetus that we do not know yet. This study uses self-report to confirm that participants are not pregnant, if you are female, sexually active, and of childbearing age, we encourage abstinence during the intervention phase of this study.

What other choices do I have if I don't want to be in this study?

You are not required to be in this study. You can simply choose not to participate. You can look for other research projects you may be interested in instead of this study.

Will I receive compensation for taking part in this study?

You will be compensated for taking part in this study. For your time and effort, you will receive $50 for each of the two assessment time points (pre-intervention, post-intervention). Additionally, you will be compensated for travel for each visit (up to $25).

We will need your Social Security Number in order to pay you. Any payment may need to be reported as income on your tax return. If you are not a resident/citizen (non-resident alien) of the United States, you will need to work with the MU Nonresident Tax Specialist at 573-882-5509.

Are there any costs for participating in this study?

You should not expect any additional costs by participating in this study.

Other costs to you from being in this study may include transportation, parking, childcare, and/or time off work.

You should discuss any questions about costs with the researchers before agreeing to participate.

Will information about me be kept private?

The research team is committed to respecting your privacy and keeping your personal information confidential. We will make every effort to protect your information to the extent allowed by law. Your records will be given a code number and will not contain your name or other information that

IRB Approval Date: Oct 09, 2024; Written Consent Form ID #742085; Annual Update ID #438440

could identify you. The code number that connects your name to your information will be kept in a separate, secure location.

When the results of this research are shared, we will remove all identifying information so it will not be known who provided the information. Your information will be kept as secure as possible to prevent your identity from being disclosed.

We may share what we collected from you as part of this research, after removing your identifiers, for future research without additional informed consent from you.

It is possible that your medical and/or research record, including sensitive information and/or identifying information, may be inspected by the the Food and Drug Administration (FDA) in the course of carrying out their duties. If your record is inspected or copied by the study sponsor (and/or its agents), or by any of these agencies, the University of Missouri will use reasonable efforts to protect your privacy and the confidentiality of your medical information.

What if I am injured during the study?

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury.

The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri.

In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

Who do I contact if I have questions or concerns?

If you have questions about this study or experience a research-related injury, you can contact the University of Missouri researcher at (573)882-7023 or booneae@umsystem.edu.

If you have questions about your rights as a research participant, please contact the University of Missouri Institutional Review Board (IRB) at 573-882-3181 or muresearchirb@missouri.edu. The IRB is a group of people who review research studies to make sure the rights and welfare of participants are protected.

If you want to talk privately about any concerns or issues related to your participation, you may contact the Research Participant Advocacy at 888-280-5002 (a free call) or email muresearchrpa@missouri.edu.

IRB Approval Date: Oct 09, 2024; Written Consent Form ID #742085; Annual Update ID #438440

Do I get a copy of this consent?

You will receive a copy of this consent for your records.

We appreciate your consideration to participate in this study.

Consent Signatures

Subject's Signature	**Date**

Investigator Authorized to Obtain Consent	**Date**

IRB Approval Date: Oct 09, 2024; Written Consent Form ID #742085; Annual Update ID #438440