**Northeastern University, Department of Electrical and Computer Engineering**
**Protocol Title:** TDCS to Improve Motivation and Memory in Elderly (TIME)
**Principal Investigator:** Sumientra Rampersad

***Informed consent to participate in a research study***

We are inviting you to take part in a research study, which is described in this form. This study was designed and is executed by researchers from Northeastern University and Massachusetts General Hospital. This study is funded by the National Institute on Aging. You may ask the researchers any questions that you have. Your participation is voluntary. You may not personally benefit from the study, but your participation could help others as a result of knowledge gained from this research. If you decide to participate, you will be asked to sign this statement and you will receive a copy to keep. You may terminate your participation in this study at any time.

***Key information***

- Your consent is being sought for participation in a research project and your participation is voluntary.
- The purpose of this research is to better understand cognitive functioning in older adults and how to support successful aging.
- The anticipated amount of time for the study is a total of 13 hours in the lab across 7 visits, of which 5 visits are held on consecutive weekdays.
- The procedures that you will be asked to complete include:
    - Answering questions about your background, completing eligibility screening and filling out questionnaires. The screening session will be audio-recorded for analysis purposes only.
    - Laying in an MRI scanner and non-invasively have images taken of your brain.
    - Wearing a cap holding multiple electrodes on your head and receiving non-invasive electric brain stimulation, known as transcranial direct current stimulation (tDCS).
    - Participants will be randomly assigned to one of four study groups and may receive either tDCS or sham stimulation (a placebo treatment). During the study, neither you nor the experimenter will know which type of stimulation you will receive, so as not to bias the study in any way.
- The risks and discomforts in this study are minimal. There is a possibility that some of the questions you will be asked might make you feel uncomfortable. You are free to refuse to answer any question.
    - tDCS: You may feel a slight itching or tingling around the electrode locations, which is normal and typically does not last after the experiment. Although this method is non-invasive and no serious problems or side effects have been reported, there is a small chance that you feel a burning sensation around the electrodes, feel fatigued, get a headache, or temporarily feel un-concentrated during or a few hours after the experiment. In case you feel uncomfortable for any reason, you can ask to stop the experiment immediately.
    - MRI: Please take note that some subjects have experienced claustrophobia while in the MRI. If at any time you wish to discontinue the scan, you may do so by notifying the experimenter.
- There will be no direct benefit to you from being in this study. Your participation may help others in the future because of knowledge gained from this study.

***Why am I being asked to take part in this research study?***

You are being asked to participate in this study because you are a right-handed healthy adult aged 65-80 years old, with normal or corrected vision, who can read and speak fluent English.

***Why is this research study being done?***

The main purpose of this research is to study age-related cognitive abilities, such as memory function, and how we may be able to improve these using noninvasive brain stimulation. We are interested in seeing how the brain engages in cognitive activities before and after brain stimulation. The brain stimulation technique used in this research is transcranial direct current stimulation (tDCS). This is a method to safely and noninvasively stimulate the brain. We will use magnetic resonance imaging (MRI) and standard behavioral tests, such as tests of motivation and memory function, to assess cognitive abilities before and after stimulation.

***What will I be asked to do?***

If you choose to sign this consent form, we will continue today's session with a standard neuro-psychological screening and a set of questionnaires, which takes about 3 hours. This screening will be used to evaluate whether you can participate in the study, which we aim to let you know within one week. We will use an audio recording of this session to evaluate the screening; this recording will be destroyed once the study ends. If you are included, you will be asked to return for 5 visits in one week (one per day on Monday to Friday). This includes two measurement sessions (Mon, Fri: 2.5 h) and five stimulation sessions (daily) of 45 minutes each. Before and after every session, you will fill out several short questionnaires.

*Baseline and follow-up measurement sessions:* We will acquire structural and functional MR images, which takes approximately 30 minutes in total. MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. You will be asked to lie still on a long narrow bed inside a large magnet while the machine gathers data. You will not feel the magnetic field, but you will hear repetitive tapping noises that arise from the scanner. We will provide earplugs or headphones that you will be required to wear. The space within the magnet in which you lie is somewhat confined. After scanning has finished, you will be brought to a different room. Here, you will perform a memory task in which you will first be shown matching pairs of images and later asked which pairs belong together. After the task, you will self-report on expanded effort and will solve a series of anagrams.

*Stimulation sessions*: In each of five sessions, you will receive 20 minutes of tDCS. Including preparation and cleanup, each session takes about 45 minutes. We start each session with cleaning specific locations on your scalp using alcohol and scrub gel. A researcher will place a cap holding multiple electrodes on your head and will insert gel into the electrodes to ensure a good connection. The electrodes are connected by wires to a box that generates weak currents (2 mA). During the 20 minutes that you receive tDCS, you will sit still in a quiet room.

It is likely that you will feel some itching on your scalp under the electrodes. After each session, you will have to wash the gel from your hair; you may do so in our lab or at home. You will be randomly assigned to one of four study groups and may receive either tDCS or sham stimulation (a placebo treatment). During the study, neither you nor the experimenter will know which type of stimulation you will receive, so as not to bias the study in any way. You will be informed about your group assignment after your final session. The number and location of electrodes varies across conditions. Depending on your group assignment, you may be asked to participate in one additional 30-minute MRI session. It is important that you tell the researcher about any possible adverse effects you may experience. Those may include, but are not limited to, the effects described below.

***Will there be any risk or discomfort to me?***

As a result of your participation in this study, you are at risk for side effects listed in this section. You may discuss these with the investigator and with your regular doctor, if you choose to do so. If it any point during a session you feel uncomfortable, the session can be stopped immediately.

tDCS: *More Common:* 1) sensations under the electrodes (20-70% of subjects undergoing noninvasive current stimulation feel sensations under the electrode, such as mild tingling, itching, or pinching; 10-20% of subjects feel discomfort, mild pain, or slight burning; sensations can sometimes continue throughout and for a brief period following stimulation, but usually fade shortly after the start of stimulation), 2) skin irritation, 3) moderate fatigue (35%), 4) headache (10-15%), 5) difficulties in concentration (11%), 6) visual sensations such as a flash of light or flickering (5%). To reduce sensations under the electrodes, we will slowly increase the current from zero to 2 mA.

*Less Common:* Nausea or nervousness (less than 5%). If you feel dizzy, lightheaded, that you might vomit or pass out, immediately tell the researcher. The study will be stopped immediately and you will be monitored until feeling better.

*Rare:* Seizure is a theoretical possibility, but tDCS has not been known to cause a seizure.

*Pregnancy:* The effects of tDCS on the developing fetus are not known; therefore, you cannot participate in this study if you are pregnant.

MRI: The MRI scanner uses a very strong magnet that will attract some metals and affect some electronic devices. For instance, if you have a pacemaker, metal implants, bullet pieces, insulin pumps or any other metal such as metal clips or rings inside your body, you cannot have an MRI. During the scan, you will lie in a small closed area inside a large magnetic tube; you should not participate if you are scared or anxious in small places. The MRI scanner makes loud banging noises while taking a measurement, so ear plugs or headphones will be used to reduce the noise. Tattoos could become warm and irritated during the scan and remain so for several days. There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan; this is not unexpected and should not be painful. Dizziness or nausea may occur if you move your head rapidly within the magnet. While the MR images in this study are not formally reviewed by a radiologist, if in the course of processing the images we notice any abnormality that would be possibly important to your health, we will notify you.

Cognitive testing**:** You may feel fatigued or frustrated during the cognitive tasks. You will be allowed breaks at several points during the session.

***Where will this take place and how much of my time will it take?***

Experiments will take place in the Interdisciplinary Science & Engineering Complex (ISEC) of Northeastern University, which is located at 805 Columbus Ave, Boston MA. You should expect to spend around 13 hours in the lab. All sessions take place on Monday to Friday during business hours.

***Will I benefit by being in this research?***

There will be no direct benefit to you from being in this study. Your participation may help others in the future because of knowledge gained from this study.

***Who will see the information about me?***

Your identity will not be known to anyone except the researchers in this study. All data will be labeled with your unique code and the code-identity pairing information will be kept secure in a computer separate from data and media. In rare instances, authorized people may request to see research information about you and other people in this study. This is done only to be sure that the research is done properly. We would permit people who are legally authorized by organizations such as Northeastern

University, Massachusetts General Hospital, the National Institutes of Health or the FDA to see this information. Some or all data collected from your sessions may be made available to other researchers to help achieve faster progress in the field. The data will be anonymized such that your identity cannot be associated with it.

***Future use of data.***
Your de-identified information could be used for future research **without additional informed consent.**

***If I do not want to take part in the study, what choices do I have?***
You may choose not to participate in this study.

***What will happen if I suffer any harm from this research?***
No special arrangements will be made for compensation or for payment for treatment solely because of your participation in this research.

***Can I stop my participation in this study?***
Your participation is completely voluntary and you may terminate at any time without any consequences.

***Who can I contact if I have questions or problems?***
You may contact Dr. Sumientra Rampersad, the principal investigator at Northeastern University, via phone (617-379-2452) or via email (rampersad@northeastern.edu).

***Who can I contact about my rights as a participant?***
If you have questions about your rights as a participant, you may contact Nan Regina, Director of Human Subject Research Protection (360 Huntington Avenue, Northeastern University, Boston, MA 02115) via email (n.regina@northeastern.edu) or phone (617-373-4588). You may call anonymously if you wish.

***Will I be paid for my participation?***
Yes, you will be compensated for your time up to $260. This breaks down as follows:

- $50 for screening
- $15 for each of 3 MRI scanning sessions
- $20 for each of 2 cognitive testing sessions
- $15 for each of 5 stimulation sessions
- $50 study completion bonus

If you complete the entire study following the requirements as scheduled, your total compensation will be $260. If you do not complete the study, whether this is by your own choice, by exclusion after the screening session, or by study termination due to non-compliance, you will be compensated for every session that you completed; you will not receive the completion bonus.

***Is there anything else I need to know?***
If you do not comply with the study protocol, investigators may prematurely terminate your participation in the study. You will always be compensated for the sessions you completed.

**I agree to take part in this research.**

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|---|---|
| **Signature of person agreeing to take part** | **Date** |
| **Printed name of person above** | **Participant ID** |

☐ **I agree to be contacted for follow up or for future research studies.**

**Contact information (email or phone)**

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|---|---|
| **Signature of person who explained the study to the participant above and obtained consent** | **Date** |

**Printed name of person above**