

Temple IRB Approved**07/30/2014**

Title of research study: Transcranial Direct Current Stimulation Investigations of Cognition

Investigator and Department:

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Why you are being invited to take part in a research study

You are invited to participate in a research study involving transcranial direct current stimulation (tDCS), a technique by which small electric currents are applied to the scalp. The study will test whether very small amounts of electricity applied to the scalp and transmitted to the underlying cortex, affect a person's ability to perceive, attend to, decide about, or remember different things such as words, letters, and objects. We may assess your speed, accuracy, and your self reports. To do this, we will study the effects of tDCS on your ability to perform such tasks as remembering, naming, reaching, or depressing key as quickly as possible. The purpose of this research is to learn about the specific brain regions that are involved in these behavioral tasks.

Who can I talk to?

Subject Initials: _____

Date: _____

If you have questions, concerns, or complaints, or think the research has hurt you, contact the research team or Dr. Olson, at iolson@temple.edu or (215) 204-1708.

This research has been reviewed and approved by an Institutional Review Board. You may talk to them at (215) 707-3390 or e-mail them at: irb@temple.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why are we doing this research?

We hope to learn more about cognition and action in the brain by measuring things like memory and attention.

How long will the research last?

Different experiments under this protocol require different amounts of time. Some experiments involve only 2 sessions of 1 hour each, others may involve 10 or 20 1-hour sessions. Visits will be scheduled at your convenience. You will always be free to stop any study at any time.

How many people will be studied?

We expect about 200 people will be in this research protocol.

What happens if I say yes, I want to be in this research?

If you decide to participate, Dr. Olson, Dr. Chein or a certified researcher will describe the procedures to you. All study procedures will take place on Temple University's main campus. You will be asked to perform a variety of behavioral tasks before, during or after tDCS. The specifics of the task will differ but none of the tasks are painful or risky. For example you might be asked to remember letters and spatial locations and recall them at a later time. In another task you might be asked to reach with your hand to pick up or point to an object such as a cup or pen.

A second component of the study is brain stimulation with tDCS. In this technique a small direct current (approximately 1 to 2.0 milliAmps) is delivered to the scalp for up to 20 minutes. The current is approximately what one might expect from a 9 volt battery. The amount of current to be delivered will be at a level that is a small fraction of the limit that has been determined to be safe in animals. Many experiments will also include a sham stimulation condition, in which a small current will be delivered only at the beginning of the test. The current is produced by a small portable machine that is connected by thin wires to two saltwater soaked pads that are placed on your head and held in place with a strap. The location of the salt-water soaked pads will vary depending on the experiment but one pad is likely to be on your forehead and another at a different location on your scalp. The pads will be active for 10-20 minutes, depending on the study. You will probably feel tingling of your scalp at the start of the current; this is normal and expected. You are consenting to participate in one experiment

Subject Initials: _____

Date: _____

that may have multiple sessions. Should you desire, you will also be able to participate in other experiments with tDCS; in the event that you participate in another experiment, the new experiment will be described and you will be asked to sign another Informed Consent document.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for completing the experimental tasks.

What happens if I say no, I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you. It will in no way affect your relationship with the study researcher.

There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future. The research team will not be disappointed or angry should you choose to not participate.

What happens if I say yes, but I change my mind later?

You agree to take part in the research now and if you stop at any time, it will not be held against you. Again, it will in no way affect your relationship with the study researcher.

Is there any way being in this study could be bad for me?

Behavioral Testing

The behavioral tasks involve minimal risk. You may be asked to perform a task that is difficult or irritating, you may find the task too annoying or frustrating to continue.

Transcranial Direct Current Stimulation

In published studies using this technique there have been no reported significant side effects from tDCS. This means that tDCS has never been associated with seizures, loss of consciousness, or weakness, numbness or pain that did not go away. The most commonly reported side effects of tDCS are a mild tingling in the skin underlying the electrodes, itching under the electrode, and mild pain. Some subjects report feeling fatigued after tDCS. Finally, there is a chance the machine could cause a small electrical shock, like that caused by static electricity. The amount of tDCS we will employ is well within a threshold that is considered safe. In many experiments you will be asked to undergo tDCS on multiple occasions. There is no evidence that repeating tDCS is associated with increased risk. For the sake of caution, however, you will not be permitted to have tDCS more than once daily and no more than five times in one week. This device has been used in 1,000 studies involving humans. There is no evidence that the device causes long-term effects. However, it is not completely certain that long-term effects will not be seen.

Pregnancy

There is no known risk to a mother or fetus from tDCS however the safety of the technique in pregnant women has not been fully studied. To err on the side of caution, women who know they are pregnant

Subject Initials: _____

Date: _____

should not participate in this study.

Will being in this study help me any way?

There is no benefit to you. However, your participation could help us understand more about what parts of the brain are important for cognition, action, and perception. The studies that we do with tDCS may offer insights that may ultimately lead to techniques to improve brain function or treat brain problems. tDCS has been demonstrated to improve performance of normal subjects and may have benefits for clinical populations.

What happens to the information we collect?

Every effort will be made to limit the viewing of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. For example, though the study team has put in safeguards to protect your information, there is always a potential risk of loss of confidentiality.

Organizations that may inspect and copy your information include the IRB, Temple University, Temple University Health System, Inc. and its affiliates, and other representatives of these organizations, and the Office of Human Research Protections.

Federal law provides additional protections of your personal information. These are described in an attached Authorization document. You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. By signing this document you are permitting the research team to use and disclose personal health information collected about you for research purposes as described above.

Can I be removed from the research without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval.

The sponsor can also end the research study early.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

If you are injured as a result of your participation in this research study, seek immediate medical care. However, there is no commitment by Temple University, Temple University Health System or its subsidiaries to provide monetary compensation or free medical care to you in the event of a study-related injury. By signing this consent form, you are not waiving any of the legal rights that you otherwise would have as a participant in a research study. If you have questions about the study or a research-related injury, please contact Dr. Ingrid Olson at (215) 204-7318 or email her at iolson@temple.edu.

Subject Initials: _____

Date: _____

Reimbursement

To show our appreciation for your time, we will pay you from \$15 per hour. If you decide to withdraw from the study before the study is over, your compensation is prorated for the amount of time you have spent with us. If you must travel more than 1 mile to be in our study, we will reimburse you for transportation.

In longer studies you may receive additional payment (a “completion bonus”, equivalent to \$1.50 per day of successive visits) upon completion of all study sessions.

Participating in Future Research Studies

We may want to contact you in the future to see if you would be interested in participating in another research study and/or to obtain additional information related to your participation in this study. Please indicate by initialing on the line in the next paragraph below if you are willing to be contacted. Please know that you can amend your answer below at any time without prejudice to you or your relationship with the study, Temple University, or the Study doctor and team.

Initial your choices

Yes, I agree to be contacted about future research studies.

OR

No, I do not want to be contacted about future research studies.

Yes, I agree to be contacted to obtain additional information related to my participation in this study.

OR

No, I do not want to be contacted to obtain additional information related to my participation in this study.

Subject Initials: _____

Date: _____

Your signature below indicates that:

- Someone has explained this research study to you.
- You freely volunteer to be in this research study.
- You can choose not to take part in this research study and it will not affect your care.
- You can agree to take part in this study now and later change your mind. Your decision to leave the study will not affect your care.
- You have been offered the opportunity to ask questions and all your questions have been answered.

Your signature documents your permission to take part in this research.

Signature of subject

Date

Printed name of subject

Signature of person obtaining consent

Printed name of person obtaining consent

Subject Initials: _____

Date: _____