The University of New Mexico Health Sciences Center
Consent to Participate in Research

Transcranial Direct Current Stimulation for Treatment of Deficits After Traumatic Brain Injury

Introduction

You are being asked to participate in a clinical trial that is being done by Davin Quinn, M.D., who is the Principal Investigator and sponsor, and his associates from the Department of Psychiatry and the UNM Center for Brain Recovery and Repair. The funding source for this study is the National Institutes of Health (NIH) and the National Institute of Neurological Disorders and Stroke (NINDS).

Purpose of the Research

This research is studying how traumatic brain injury (TBI) affects mood, and the way the brain solves problems ("executive function," i.e., remembering things, choosing things)., We will be studying how an intervention called TDCS (Transcranial Direct Current Stimulation) affects moods and problem solving after a mild to moderate TBI. We use TDCS to slightly change the way the brain works for a short period of time. TDCS accomplishes this by delivering a very weak electrical current through your scalp and into your brain. TDCS is not yet approved for use by the FDA.

To see whether TDCS is working, we will use several methods to assess the brain. These include computerized and paper and pencil tests of memory and attention. You may be asked to have your brain waves measured (EEG). You may also be asked to undergo magnetic resonance imaging (MRI) exams. The MRI and EEG give us a picture of your brain and which parts are active while you rest or do tasks. These scans are non-invasive and performed while you lay inside a very strong magnet.

Because we do not know if TDCS is helpful for symptoms after TBI, we need to compare it to a version of TDCS that has no effects. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin.

Inactive TDCS feels like real TDCS but it is not. It is a dummy or pretend stimulation. It has no effect on a person because it is not powerful enough. Sometimes when we want to know whether a new treatment is good, we give some people the active TDCS and some people the pretend or dummy TDCS. For the research to be good, it is important that you do not know whether you have been given the real TDCS or the pretend or dummy TDCS. This is one of the best ways we have for knowing what the TDCS we are testing really does.

Participants in one group will be given TDCS that is known to have effect on the brain, while participants in the other group will be given TDCS that feels like it is having effect, but is actually having no effect. It is important that neither you nor we know which of the two kinds of TDCS you are given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might

happen. We will then compare which of the two groups has the best results. You will have a 50% chance of getting effective TDCS.

The study team will be looking after you and the other participants very carefully during the study. If we are concerned about what the TDCS is doing, we will find out which kind of TDCS you are getting and make changes. If there is anything you are concerned about or is bothering you about the research, please talk to us or one of the other researchers.

Participant Selection

You are being asked to participate in this study because you are an adult between the ages of 18 and 55, may have suffered a mild or moderate traumatic brain injury, have the ability to consent to a research study, are not pregnant, are not a UNM employee, and have no history of any other neurological or brain disorder or psychosis.

There are no known risks of TDCS to pregnant mothers or their developing fetuses. However, if you are pregnant at this time, then you should not be in the study. If you are not pregnant, you should use two forms of birth control during the first month of the study. If you are unsure whether you are pregnant or not, you may have a urine pregnancy test done to make sure you are not pregnant. You do not have to have a pregnancy test if you don't want to, but you will not be allowed to be in the study.

I am not pregnant at this time. _____ Initials

I am pregnant. _____ Initials

I am not sure if I am pregnant. . _____ Initials Test Result:

Voluntary Participation

Your participation in this research study is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at UNM will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered at UNM for TBI and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Information on the Trial Intervention

The intervention we are testing in this research is called transcranial direct current stimulation. It has been tested before with people who have severe brain injuries as well as healthy people. We now want to test TDCS on people who have mild to moderate traumatic brain injury compared to healthy people.

The TDCS machine is made by the company NeuroConn. You should know that a common side effect of TDCS is a tingling or itching sensation. Some participants in the research will not be given TDCS that is known to affect the brain. Instead, they will be given TDCS in such a way that it will have no effect the brain. There is the same risk of itching or tingling with this kind of TDCS.

This form will explain the research study, and will also explain the possible risks as well as the possible benefits to you. We encourage you to talk with your family and friends before you decide to take part in this research study. If you have any questions, please ask one of the study investigators.

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 at any time.

What will happen if I decide to participate?

If you agree to participate, the following things will happen:

- MEDICAL HISTORY AND SCREENING FORMS: You may be asked to complete several short screening forms that ask you about things like your medical history, the hand you use to perform various tasks, how many years of education you've had, what medications you take, etc.

- MEDICAL RECORDS: You may be asked to sign a release of medical information allowing the investigators to look at your medical records at UNM for information about your traumatic brain injury, such as hospital visits, treatment notes, and brain scans. You may also be asked to sign a release of medical information for records at non-UNM hospitals.

- PROBLEM SOLVING TESTS: You may be asked to perform some paper and pencil tests and computer tests that measure your ability to do such things as reading lists of words, and drawing lines between numbers and letters. In addition, you will also complete a questionnaire that asks you about your moods and how you feel about certain things such as sadness and how anxious you are in general. You will complete these tests at various times during the study, such as on the first day, on the 10th day, or on the 30th day.

- EEG RECORDING: You may be asked to undergo EEG. EEG records the electrical activity of your brain at rest and while you work on a set of tasks. EEG setup takes between 10 and 30 minutes. Electrodes will be applied to your head and sides of your face using a special conductive gel For the EEG, you will sit in a comfortable chair in a special room. These will be held in place with a cap or sticky tape. We use these electrodes to monitor your brain activity your eye movements, your head position, and your heartbeat. During the scan, you may be shown pictures and words and will be asked to make decisions about the information presented in them. When the scan is over, all of the electrodes will be removed and you will have the

opportunity to wash off the gel using our sink. The EEG will take between 1 and 2 hours per session. EEG does not cause any sensations or discomfort.

- MRI RECORDING: You may be asked to undergo MRI before and after brain stimulation. You will lie down on a table and will then be placed into a long donut-shaped magnet. During the study you will hear loud rapping and knocking noises coming from the magnet. You may feel warm during this procedure. In order to obtain good pictures, it is important that you do not move during the procedure. Although you should not talk during the MRI procedure, you will be able to talk with the technician during breaks or in case of emergency by pressing a call button or similar device. During the scan, you may be shown pictures and words and will be asked to make decisions about the information presented in them. We will record your brain activity with the MRI equipment while you do these tasks. We will also obtain structural and chemical information about your brain during this exam, using MRI and spectroscopy scans. The MRI will take about 1.5 hours to complete, including preparation and removal from the scanner. The MRI will be performed at the Mind Research Network which is located in the same building across the hall from our testing rooms.

- The EEG and MRI scans are being done to answer research questions, not to examine your brain for medical reasons. Please note that the results from the scans and neuropsychological tests will not be made available to you. This MRI scan is not a substitute for a clinical MRI scan (the type a doctor would order). The research scan may not show problems that would be picked up by a clinical MRI scan. However, all research MRI scans will be read by a neuroradiologist (a doctor with experience reading MRI scans). When your scan is read, you will receive an email letting you know you can download your MRI report from the Participant Portal Homepage. If you do not need an email, do not have an email or do not want an email your scan information will be sent to your address on record. If we find an abnormality that requires urgent follow-up, we may also mail a copy of the report to you, or contact you and your doctor (with your permission) by phone to help answer questions. Our Medical Director and the research team are always available to answer any questions you may have about your scan.

- TDCS DURING PROBLEM SOLVING TASKS*:* You may be setup to receive TDCS up to 10 times, on separate days. Two saline-soaked or gel-soaked sponges will be placed on your scalp and/or upper arm. The sponges are connected to wires which will deliver a very weak electrical current for a few seconds or up to 30 minutes, which may briefly result in a tingling feeling at the electrode sites. While receiving TDCS, you may be comfortably seated in front of a personal computer or a screen while you solve memory tasks such as pushing a button for a certain letter, or answering if a box was in the same place as before. During TDCS, we will repeatedly ask you to fill out a questionnaire which asks you to rate the feelings you are having while receiving TDCS. After the TDCS is removed, you may be asked to complete the questionnaire once more,

including some questions about your mood. In the very unlikely case that our tests show that you have any leftover effects of stimulation, we will inform you immediately. You will be given the opportunity to relax for 15 minutes, and then will be asked to answer the mood question once more.

- TELEPHONE INTERVIEW: At 6 months and 1 year after the TDCS, we may call you to conduct a brief interview about your mood and your quality of life. This will take approximately 10 minutes. At the beginning of the study we will ask for your contact information (phone, address, email, fax) as well as contact information for someone else who knows you, so that we can reach you at 6 months and 1 year after the TDCS.

At the beginning and end of the stimulation trial, the session may last up to 5 hours, or may be spread out over several days. On stimulation days (anywhere from 1 to 10 sessions), each session may last 1 hour. If you are asked to return at one month, the session may last 3 hours. If you receive a phone call on the 6th month and 12th month, the phone calls may last 10 minutes.

We would also like to request your permission to store all of the data that was collected in the current experiment in the UNM Center for Brain Recovery and Repair database for future research. The stored information would include basic information such as your age and gender, personal health information, and test results that were collected about you during the course of this experiment. This information will be handled with the same care and confidentially as it is for the current study. You have the right to withdraw your information for recruitment and/or research purposes from the UNM Center for Recovery and Repair database at anytime following your participation in this study. To do so, please contact either the PI of this study or the UNM Center for Brain Recovery and Repair directly. Please circle and initial your choice.

Store my data in the UNM Center for Brain Recovery and Repair database for future unspecified research.

YES _____ Initials

NO _____ Initials

There is also the possibility that you may qualify to participate in future related studies. Please circle one of the choices below if you would like Davin Quinn or one of his associates at the UNM Center for Brain Recovery and Repair or UNMH to contact you in the future about other related studies.

YES - Please contact me about related studies in the future. _____ Initials

NO - Please do not contact me about related studies in the future. _____ Initials

How long will I be in this study?

Participation in this study may take up to 25 hours of your time over 13 in-person visits and 2 follow-up phone calls over a period of 1 year.

What are the risks or side effects of being in this study?

- The risks of TDCS for people with TBI and without TBI are approximately the same. At the beginning of TDCS most people feel a tingling sensation that is present for a short period of time. Also, most people feel a warming sensation on the scalp that disappears after awhile. TDCS is known to be a safe procedure for several hundred patients at UNM, but in a few cases (1%) subjects have reported minor skin burns at the electrode spot. For example, a few subjects who had recently shaved their heads have reported transient redness and irritation at the stimulating electrode site. Prior to stimulation, your scalp will be checked for any redness or recent shaving of the head. If any of these are seen, we will pause or stop your participation in the study. You will be encouraged at the beginning of and throughout the TDCS procedure to report any pain or problems at the electrode sites that you may encounter throughout the procedure. Any problems, or evidence of redness or pain of the scalp, will result in the immediate stopping of stimulation.

- As with any contact between persons and electrical apparatuses, there is a slight possibility of electrical shock. To our knowledge, no studies have reported any electrical shock resulting from TDCS, and we do not expect this event to occur in our experiment.

- TDCS uses rubber electrode holders. If you think you may be sensitive or allergic to rubber or latex, please tell us before the start of the experiment.

- A few people in other studies have experienced drowsiness, excitement, or dizziness after TDCS.
- EEG: There is a very small possibility that if you have sensitive skin (e.g., contact dermatitis) you may experience some skin irritation from the EEG gel or metal sensor. Throughout the sessions, assistants will be attending to you to keep you from becoming uncomfortable.
- Some individuals may experience discomfort (such as nervousness or embarrassment) when answering questions on the questionnaires.

- Participation in this study may produce emotional stress, behavioral fatigue, or inconvenience.

- As with any scientific study, there is the possibility of unforeseen risk not mentioned in this consent.
- There are no known long-term, adverse effects from MRI imaging. However, since the effect of MRI upon early development of the fetus is unknown, females who are pregnant should not be studied. If you are a woman 18 years of age or older and there is a possibility that you may be pregnant, you will be asked to take a urine pregnancy test before being allowed to participate in the study. Rarely, large or recent tattoos can heat up during an MRI scan and cause skin irritation like a sunburn, so the MRI technologist will want to see any tattoos you have prior to the scan.
- An MR scanner acts like a large magnet, so it could move iron-containing objects in the room during the examination. Loose metal objects, like pocket knives or key chains, are not allowed in the MRI room. If you have a piece of metal in your body, such as a pacemaker, nerve stimulator, or certain metal surgical implants, you will not be allowed into the MRI room and cannot have an

MRI. Because the MRI scanner moves metals, you will be asked to change into clean hospital scrubs before the scanning begins to ensure that there is no metal in your clothing. Having an MRI may mean some added discomfort to you. In particular, you may be bothered by feelings of claustrophobia (fear of closed spaces) and by the loud banging noise during the study. Headphones will be provided for your safety and comfort. There is a speaker in the MRI scan room, as well as a window that allows the operator to view you during data collection. This allows the assistants to hear and see you at all times to ensure that you are comfortable and to allow them to respond if you are uncomfortable. You will be able to communicate with the study staff at all times and may ask to stop the study at any point.

- Due to the very high sensitivity of MRI in detecting abnormalities, there is a risk of false-positive findings, identifying something on imaging studies that may or may not be important. This may result in anxiety and additional testing, possibly including a recommendation for clinical scans at your cost. The radiology report or other study data will not be put into your medical record unless you provide it to your physician. If the radiology report becomes part of your personal medical record, it may or may not have an effect on getting health insurance or life insurance in the future.
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For more information about risks and side effects, you may ask one of the research team members.

What are the benefits to being in this study?

If you are a subject with a TBI, there may be a mild temporary benefit to you from participating in this study that lasts for a few days to a few weeks. Your mood may temporarily improve if you are depressed, and your ability to solve problems may temporarily improve. Your quality of life may improve slightly. If you are in the control group, there may be less chance you will receive these benefits. If you are a healthy subject without a TBI, you may also experience a mild temporary benefit in your mood and problem solving. It is hoped that information gained from this study will help us better understand how TDCS affects brain functioning after a traumatic brain injury, and how it may be used in the future to treat brain disorders.

What other choices do I have if I do not want to be in this study?

You do not have to participate in this study. You have the option of stopping your participation at any time. If you wish to have treatment for problems with moods and problem solving, we will refer you

to the UNM Mental Health Center or a clinic of your preference, which is the standard of care for these kinds of issues.

How will my information be kept confidential?

We will take measures to protect your privacy and the security of all your personal information, but we cannot guarantee confidentiality of all study data.

Information contained in your study records is used by study staff and, in some cases it will be shared with the sponsor of the study. The University of New Mexico Health Institutional Review Board (IRB) that oversees human subject research, the US Food and Drug Administration (FDA) and/or other groups may be permitted to see your records. There may be times when we are required by law to share your information. However, your name will not be used in any published reports about this study. A copy of this consent form will be kept at the UNM Center for Brain Recovery and Repair.

Information collected as part of this study, including questionnaires, health data, and test results, will be labeled with a subject number rather than your name. All of your identifying information will be removed from the data anywhere that it is stored, so that it cannot be linked back to you, without access to a separate database which contains keys for linking personal information to the subject number. This database will be kept in a separate secure location, in a locked file cabinet in a locked office, or in a password-protected computer file in the UNM Center for Brain Recovery and Repair. This information will also be stored securely in restricted and protected databases according to Mind Research Network information security policies. Upon study completion, all linking information will be destroyed. Davin Quinn and his associates will have access to your study information. If you would like to withdraw from the study all of your information held at the UNM Center for Brain Recovery and Repair will be destroyed.

Some of the information that this study will find out about you is considered sensitive, because it has to do with your psychological well-being and mental health. To help us further protect the confidentiality of your data, the investigators have been granted a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however upon request of DHHS or other federal agencies for audit or program evaluation purposes. You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy and the confidentiality of your data. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm of yourself or others.

Because the information about your performance in the study is for research purposes and not medical purposes, it will not be released to you, unless your primary care provider (PCP) requests a report. We will only do this if you give permission for us to release this information to your provider.

YES – My PCP is allowed to receive a copy of my results __ _____ Initials

NO – Do not send a copy of my results to my PCP . _____ Initials

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm of yourself or others.

What are the costs of taking part in this study?

You will not be charged for any of the experimental study procedures or treatments, including the MRI scan. The costs of tests done for research purposes will be covered by the study. If incidental findings from the study result in the need for further evaluation/treatment, then you or your insurance company will be responsible for any clinical evaluation/treatment that may be needed.

What will happen if I am injured or become sick because I took part in this study?

If you are injured or become sick as a result of this study, UNMHSC will provide you with emergency treatment, at your cost. No commitment is made by the University of New Mexico Health Sciences Center (UNMHSC) to provide free medical care or money for injuries to participants in this study.

If you do not have insurance, you may be responsible for these costs. You will also be responsible for any co-payments or deductibles required by your insurance.

It is important for you to tell your doctor immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the Human Research Review Committee (HRRC) at the University of New Mexico Health Sciences Center, Albuquerque, New Mexico 87131, (505) 272-1129 for more information.

Will I be paid for taking part in this study?

In return for your time and the inconvenience of participating in this study, you will receive $20/hour in the form of a cash card.

Compensation is considered taxable income. Amounts of $600 or more will be reported by UNM to the Internal Revenue Service (IRS).

How will I know if you learn something new that may change my mind about participating?

You will be told of any significant new findings that become known during the course of the study, such as changes in the risks or benefits resulting from participating in the research or other choices that might change your mind about participating.

Can I stop being in the study once I begin?

Your participation in this study is completely by choice. You will be asked at various times during the study if you wish to continue or if you wish to stop. You have the right to choose not to participate or to withdraw your participation at any point in this study without affecting your future health care or other services to which you are entitled. You may request that your data not be included in the study any longer. The Principal Investigator may at any time withdraw you from the study in order to protect your health and safety.

HIPAA Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)

As part of this study, we will be collecting health information about you and sharing it with others. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)

By signing this Consent Document, you are allowing the investigators and their team to use your protected health information for this study. This information may include: results of physical exams, medical, neurological, and psychiatric history, medication lists, laboratory tests, brain scans and brain wave scans, and information from clinic visits and hospital visits.

In addition to researchers and staff at UNM and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send letter notifying them of your withdrawal to: Davin Quinn, MD

2600 Marble Avenue NE
UNM Psychiatric Center
Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

Refusal to Sign
If you choose not to sign this consent form and authorization for the use and disclosure of your PHI, you will not be allowed to take part in the research study.

Whom can I call with questions or complaints about this study?
If you have any questions, concerns or complaints at any time about the research study, Davin Quinn, M.D., or his associates will be glad to answer them at (505)272-4763, Monday through Friday, 9am - 4 pm. If you would like to speak with someone other than the research team, you may call the UNMHSC HRRC at (505) 272-1129.

If you would like to speak with someone other than the research team, you may call the UNM Office of the IRB at (505) 277-2644.

Whom can I call with questions about my rights as a research subject?
If you have questions regarding your rights as a research subject, you may call the UNMHSC HRRC at (505) 272-1129. The HRRC is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human subjects. For more information, you may also access the HRRC website at http://hsc.unm.edu/som/research/hrrc/.

CONSENT
You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this consent form, you are not waiving any of your legal rights as a research subject.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to participate in this study. A copy of this consent form will be provided to you.

_____	_____	_____
Name of Subject (print)	Signature of Subject	Date

INVESTIGATOR SIGNATURE
I have explained the research to the subject and answered all of his questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

_____
Name of Investigator/ Research Team Member (type or print)

_____	_____
(Signature of Investigator/ Research Team Member)	Date