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

Metaplasticity in the human motor cortex: validation of an experimental design and comparison of motor outcome measure sensitivity to change

12/16/2016

Introduction

You are being asked to participate in a research study that is being done by Dr. Sarah Pirio Richardson from the Department of Neurology who is the Principal Investigator and Dr. Davin Quinn who is the Co-Principal Investigator from the Department of Psychiatry. This research is studying how the brain regulates its activity in response to noninvasive neurostimulation. Noninvasive neurostimulation means that we apply either a weak electrical stimulation (TDCS) or a magnetic pulse (TMS) to the scalp to affect the brain.

Plasticity is a process in the brain that allows us to learn, to remember and to change our behaviour. In some diseases, plasticity (or the ability of the brain to adapt) changes and patients may have difficulty remembering or learning new things. In other diseases, plasticity can become uncontrolled and patients may have too many movements or thoughts, which can interfere with their daily living. In this study, we are trying to learn how the healthy brain controls plasticity so that if we understand better the normal brain processes, we can work to restore these in patients who have diseases that affect plasticity.

You are being asked to participate in this study because you are a healthy person of at least 18 years of age with no current psychiatric or neurological disorders and meet the inclusion/exclusion criteria. Sixteen people will take part in this study at the University of New Mexico.

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.

What will happen if I decide to participate?

If you agree to participate, the following things will happen as part of the screening/randomization process:

- If you are a female of childbearing potential, you will be given a urine pregnancy test to determine if you are eligible to have TMS. This will be done at each study visit with confirmation that the test is negative prior to treatment.
- You will be asked to give a detailed medical history, including whether you have a history of seizure disorder, pacemaker, medical implants or other criteria that would be unsafe for TMS treatment. We will also ask about current medication use, and current drug use or dependence.
- You will have a physical examination and your basic demographic information will be recorded.
- You will be randomized into a study regimen. This means that neither you nor the investigate will be able to determine what intervention you receive. Instead you are randomly assigned, similar to a flip of a coin, to a different order of interventions. This ensures that each treatment option is fairly represented in this research.
- After that three study visits, each separated by one week, will be scheduled.

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

- After informed consent, you will be seated in a comfortable chair. Surface EMG leads will be applied to clean and prepped skin over the right hand.
- The handheld transcranial magnetic stimulation (TMS) coil will be held on the top left-hand side of the head around the ear area to determine intensity thresholds and to get baseline measurements.
- You will be asked to do a simple task with your right hand for several minutes.
- You will then have 10 minutes of TDCS applied. Two saline-soaked, very thick 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 10 minutes, which may briefly result in a tingling feeling at the electrode sites. The TDCS may be active (real) or may be a sham. Sham means that the TDCS will look and feel real but will not have a treatment effect. Sham is used to help make sure we understand the real treatment effect by taking into account any "placebo" effect.
- The handheld TMS coil will be held again on the top left-hand side of the head around the ear area to determine intensity thresholds and to get measurements.
- You will be asked to do a simple task with your right hand for several minutes.
- You will then have repetitive rTMS over the left-hand side of the head for 15 minutes. A short magnetic pulse will occur every few seconds. You will hear a clicking sound (earplugs will be provided) and may feel a mild "flick"-like sensation on the scalp.
- Again, the handheld TMS coil will be held on the top left-hand side of the head around the ear area to determine intensity thresholds and to get measurements.
- You will be asked to do a simple task with your right hand for several minutes.

How long will I be in this study?

Participation in this study will take a total of 1-2 hours over a period of 3 days over 3 weeks.

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

- **Risks of Research:** A potential loss of confidentiality, which could result in stress, emotional distress, inconvenience and possibly loss of privacy.
- **TDCS:** 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.
- **TMS:** TMS is a safe procedure that has been used on many people to study the brain. Most people do not find the stimulation painful, but occasionally strong contractions of scalp muscles can cause some discomfort of headache. If you find the procedure too uncomfortable, you may discontinue it at any time. Headaches usually go away promptly with non-prescription medication. The noise of the TMS magnet may affect hearing, so you will be fitted with earplugs to wear during TMS. Magnetic stimulation will not be performed in people who have pacemakers, implanted pumps or stimulators, or who have metal objects inside the eye or skull. Please inform the investigators if you have any of these or known hearing loss. This study

employs paired pulse TMS, which is of equivalent safety to previous studies employing paired pulse TMS. The risk of inducing a seizure with single, or paired-pulse, TMS is considered very low. Seizures from single/paired-pulse TMS have only been reported in subjects with medically-intractable epilepsy very rarely (0.0-3%). Safety studies using TMS in patients with neurological disorders have demonstrated no permanence. Risks to a fetus are not known. If you are pregnant prior to treatment, you will not be able to participate in this study. However, if you become pregnant during the follow-up period, after the TMS interventions, you can remain in the study if you choose.

There are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study.

What are the benefits to being in this study?

There will be no benefit to you from participating in this study. However, it is hoped that information gained from this study will help in the understanding of how healthy brains regulate plasticity and may help us to design new therapies for people with brain diseases.

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

Participation in this study is completely voluntary, and you do not have to choose to participate.

How will my information be kept confidential?

We will take measures to protect 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 Sciences Center Human Research Review Committee (HRRC) that oversees human subject research, and the Food and Drug Administration and/or other entities may be permitted to access 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 in your medical record.

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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 Institutional Review Board (IRB) that oversees human subject research and/or other entities may be permitted to access 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.

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Information and clinical data collected as part of the study will be labeled with your initials and a study number; information (without your name) will be entered into a computer database/locked file cabinet in

the office of the Principal Investigator or their research staff. Data will be stored for six years and then be destroyed.

What are the costs of taking part in this study?

You will not be charged for any study procedures or treatments. The costs of the TDCS and rTMS required by the research will be covered by the study.

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.

In the event that you have an injury or illness that is caused by your participation in this study, reimbursement for all related costs of care will be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

It is important for you to tell the investigator 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 be paid $20 through a merchandise card for each of the first 2 study visits and $30 through a merchandise card for the third study visit (a total up to $70 in merchandise cards if you complete the study). If you do not complete the study, you will be paid for each study visit you completed as above.

Compensation is considered taxable income. Amounts of $600 or more will be reported to 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 informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

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 other authorized personnel to use your protected health information for the purposes of this study. This information may include: medical history and results of physical exam.

In addition to researchers and staff at UNMHSC 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:

Sarah Pirio Richardson

MSC 10 5620

1 University of New Mexico

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 PHI, you will not be allowed to take part in the research study.

Can I stop being in the study once I begin?

Your participation in this study is completely voluntary. 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.

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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, Dr. Sarah Pirio Richardson, or his/her associates will be glad to answer them at 505-272-8740.

If you would like to speak with someone other than the research team, you may call the UNMHSC HRRC at (505) 272-1129.

Whom can I call with questions about my rights as a research participant?

If you have questions regarding your rights as a research participant, 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 participants. For more information, you may also access the HRRC website at http://hsc.unm.edu/som/research/hrrc/.

CONSENT

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.

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

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

INVESTIGATOR SIGNATURE

I have explained the research to the participant and answered all of his/her 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