UT Austin IRB Approved
Submission ID:STUDY00000896-MOD09
Date Approved:1/10/2024

The University of Texas at Austin

Consent to Participate in Research

Basic Study Information

Title of the Project: Brain state-dependent enhancement of post-stroke hand function

Principal Investigator: Sara Hussain, PhD
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Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

Important Information about this Research Study

Things you should know:

The purpose of the study is to study the effects of a non-invasive brain and nerve stimulation procedure on hand function. In order to participate, you must be at least 18 years old and have experienced a stroke at least 6 months ago. You must not have any contraindications to the procedures performed in this study. We will review all eligibility criteria with you before your participation.

This study involves three separate experiments. You may participate in one, two, or all experiments. This form will provide information for Experiment 2 only. If you choose to participate in Experiment 2, you will be asked to visit the laboratory on up to three separate days, for up to 6 hours each day. At least 24 hours will elapse between laboratory visits. You may have the opportunity to participate in Experiment 3 in the future. You may also participate in Experiment 2 more than once.

Risks and discomforts from research during Experiment 2 involve mild headache and a stinging/tingling sensation.

Participation in this study may temporarily improve your hand functioning. Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information will be described later in this form. Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

What is the study about and why are we doing it?

After stroke, people often have difficulty using their hands. Non-invasive brain and nerve stimulation may help people regain some function of their hands, but the benefits are small and it doesn't work for everyone. In this study, we are testing the effects of a brain and nerve stimulation procedure on hand function. Our hope is that this procedure can in the future be used to help people who have had a stroke regain function of their hands.

What will happen if you take part in this study?

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You are being asked to participate in Experiment 2.

Information on study procedures:

- *Clinical assessments:* We will perform a few clinical assessments of motor function, mental function, and disability to make sure you are eligible for this study. During these assessments, you will be asked to perform a series of movements and answer some basic questions.

- *Transcranial magnetic stimulation (TMS):* For transcranial magnetic stimulation (TMS), a wire coil is held on the scalp or spine. A brief electrical current passes through the coil and creates a magnetic pulse that affects brain and nerve activity. You will hear a click and may feel a pulling sensation on the skin beneath the coil. There may be a twitch in the muscles of the face, arm, or leg. We may ask you to tense certain muscles or perform simple actions during TMS.

- *Peripheral nerve stimulation (PNS):* Nerves will be stimulated by applying a small electrical pulse through metal disks (electrodes) on the skin of wrist and shoulder area. The stimulus produces a stinging or tingling sensation and the muscle will twitch. You might experience some pain during the nerve stimulation. If you find PNS too uncomfortable, you may choose not to complete this procedure.

- *Electromyography (EMG):* Electromyography (EMG) measures the electrical activity of muscles. For EMG, small metal disks (electrodes) will be attached to the skin of your hand and wrist. Your muscle activity will be recorded using these disks. The electrodes will be placed in between your thumb and pointer finger and on the back of the stroke-affected hand.

  Electroencephalography (EEG): Electroencephalography (EEG) records the electrical activity of the brain ("brain waves"). For EEG, small metal disks (electrodes) will be placed on your scalp using gel and a swim-type cap. Your scalp may be lightly abraded using a blunt needle. Your brain waves will be recorded using these disks.

If you agree to take part in Experiment 2, you will be asked to visit the lab on up to three separate days.

You will be asked to complete the following activities on Day 1:
- Answer some questions about your health to determine eligibility (~10 minutes)
- Complete some clinical assessments of motor and mental function (~45 minutes)
- Have EMG and PNS electrodes attached to your wrist, hands, and shoulder area (~10 minutes). These will stay in place throughout the experiment on Day 1.
- Have TMS applied to your scalp (~30 minutes). Afterwards, we will remove the TMS coil from your scalp.
- Have PNS applied to your shoulder and wrist (~20 minutes). This involves passing electrical currents through the electrodes that are already in place. If you find this procedure too uncomfortable, you may choose not to complete it.
- Afterwards, all electrodes will be removed.

On Days 2 and 3, you will be asked to complete the following activities:

- Answer some questions about your health to determine your continued eligibility (~10 minutes)
- Have EEG electrodes attached to your scalp (~1 hour). These will remain in place throughout the experiment on Day 2.
- Have EMG and PNS electrodes attached to your wrist, hands, and shoulder area (~10 minutes). These will remain in place throughout the experiment on Day 2.
- Have TMS applied to your scalp (~10 minutes). Afterwards, we will remove the TMS coil from your scalp.
- Have PNS applied separately to your shoulder and wrist (~10 minutes). This involves passing electrical currents through the electrodes that are already in place. If you find this procedure too uncomfortable, you may choose not to complete it.
- Have TMS applied to your scalp (~40 minutes). Afterwards, we will remove the TMS coil from your scalp.
- We may also record EEG signals while you rest quietly (~5 minutes each). This will be done using the EEG electrodes that are already in place.
- Have TMS applied to your scalp (~40 minutes). Afterwards, we will remove the TMS coil from your scalp.
- Have TMS and PNS applied to your scalp, shoulder, and wrist at the same time (~1 hour). This involves passing electrical currents through the electrodes that are already in place. Afterwards, the TMS coil will be removed from your scalp and all remaining electrodes will be removed. If you find this procedure too uncomfortable, you may choose not to complete it.

How long will you be in this study and how many people will be in the study?

If you participate in Experiment 2, your participation will last for up to 6 hours on each day, for a maximum of 18 hours. If we encounter technical difficulties, you may be asked to return for up to an additional two days, for up to 6 hours each day. Afterwards, your participation will be complete. Overall, up to 135 people will be in this study.

What risks and discomforts might you experience from being in this study?

There are some risks you might experience from being in this study.

Likely (more than a 50% chance this will happen):

1. You may become tired or sore during the clinical assessments of motor and mental function
2. Attaching the EEG electrodes to your scalp may be uncomfortable
3. You may find removing the EEG gel from your hair after the experiment annoying
4. PNS often causes a tingling or stinging sensation

Occasional (between a 1-10% chance that this will happen):

1. Your skin may become irritated from the adhesives used to attach the EMG electrodes to your skin
2. You may experience mild scalp or face muscle contraction during TMS. This can cause a headache

Rare risks (less than a 1% chance risk this will happen):

1. TMS has caused brief seizures in a very few people who previously had a stroke or brain injury
2. You may experience a breach of confidentiality

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in this study.

How could you benefit from this study?

For Experiment 2 of this study, we do not anticipate any improvements in motor function. However, others might benefit from your participation in this study because it will help us develop new treatments to help people who have had a stroke be able to move their hands better.

What will happen to the samples and/or data we collect from you?

As part of Experiment 2 of this study, we will collect information about your motor and mental function, recordings of your brain activity using EEG, and recordings of your muscle activity using EMG.

How will we protect your information?

We will protect your information by removing your name from all data obtained in this study. Instead, we will use a coding system (for example, Participant # 21). Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**.**

If you have an adverse reaction to any of the procedures performed in this study, we may share information about your health with emergency medical personnel.

Information about you may be given to the following organizations:
• Representatives of UT Austin and the UT Austin Institutional Review Board
• Officials of the Department of Health and Human Services or the Federal Food and Drug Administration

We will share your data or samples with other researchers for future research studies that may be similar to this study or may be very different. The data or samples shared with other researchers will not include information that can directly identify you.

We plan to publish the results of this study. To protect your privacy, we will not include any information that could directly identify you.

A description of this study will be available on http://www.ClinicalTrials.gov as required by U.S. law. This web site will not include any 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.

With your permission, we may share your name and contact information with other researchers at UT Austin so that they may contact you about other research studies for which you may

qualify. Please initial one of the spaces below to indicate whether or not you provide your permission to share your name and contact information for this purpose.

_____ I provide my permission for the research team to share my name and contact information with other researchers at UT Austin.

_____ I do not provide my permission for the research team to share my name and contact information with other researchers at UT Austin.

If you later decide that you do not want to share your name and contact information any longer, please contact the study team in writing to withdrawal your authorization. Contact information for the study team can be found at the end of this form.

What will happen to the information we collect about you after the study is over?

We will keep your research data to use for future research. Your name and any other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

How will we compensate you for being part of the study?

You will receive $15 for each hour of participation. Compensation will be pro-rated on a 30-minute basis. Compensation will be provided by cash and rounded to the nearest dollar. For example, if you participate for 3.5 hours, you will receive $53 of compensation.

You will have the option to bring an escort with you to your sessions. This escort can be a family member or friend. If you choose to bring an escort with you, the escort will receive 50% of the amount of compensation you receive for your participation per session, rounded to the nearest dollar.

We will also provide you with a $25 transportation stipend per session to offset the costs of traveling to and from the laboratory.

If you withdraw from the study, you will be compensated for the time you completed. Payment will occur after your participation is complete. You will be responsible for any taxes assessed on the compensation.

Who will pay if you are hurt during the study?

In the event of a research-related injury, it is important that you notify the Principal Investigator of the research-related injury immediately. You and/or your insurance company or health care plan may be responsible for any charges related to research-related injuries. Compensation for an injury resulting from your participation in this research is not available from the University of Texas at Austin.

You are not waiving any of your legal rights by participating in this study.

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What are the costs to you to be part of the study?

To participate in the research, you will need to pay for any parking or transportation.

What other choices do you have if you do not take part in this study?

There is no direct benefit from participating in this study. You may choose not to participate.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

The Food and Drug Administration requires that we keep record of your involvement with the study. Even if you leave the study, we must keep the data we have already collected.

Is it possible that you will be asked to leave the study?

You may be asked to leave the study if the research team determines that it is unsafe for you to continue.

Is it safe to start the study and stop before you are finished?

You are always free to stop participating in the study if you would like. Your decision to stop participating will not affect your standard medical care or any other benefit you would receive if you were not in a research study.

Contact Information for the Study Team

If you have any questions about this research, you may contact the Principal Investigator:

Sara J Hussain, PhD
Phone: (512) 232-2686
Email: sara.hussain@austin.utexas.edu

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

The University of Texas at Austin

Please reference the protocol number found at the top of this document.

Your Consent

Before agreeing to be part of the research, please be sure that you understand what the study is about. By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
Signature Date

_____
Signature of person obtaining consent Date