The University of Texas at Austin

Consent to Participate in Research

Basic Study Information

Title of the Project: Brain state-dependent enhancement of hand function in healthy humans

Principal Investigator: Sara Hussain, PhD
Assistant Professor, Department of Kinesiology and Health Education
University of Texas at Austin

Study Sponsor: National Institutes of Health

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 a healthy adult older than 18 years of age. 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 two 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 two days for up to 6 hours each day. At least 24 hours will elapse between each of your laboratory visits. You may have the opportunity to participate in Experiments 1 and/or 3 in the future.

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

There is no direct benefit for participating in this study. 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:

- *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, back, 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.

- *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. Your muscle activity will be recorded using these disks.

- *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 brain waves will be recorded using these disks.

- *Demographics survey:* You will also be asked to complete a short survey that asks you about your demographic background, including age, gender, race, ethnicity, and other questions.

If you agree to take part in Experiment 2, you will be asked to visit the lab on up to two days. You will be asked to complete the following activities:

- Answer some questions about your health to determine eligibility (~ 10 minutes)
- Have EEG electrodes attached to your scalp (~ 1 hour). These electrodes will remain in place throughout the study.
- Have EMG and PNS electrodes attached to your wrist, hands, and shoulder area (~ 10 minutes). These electrodes will remain in place throughout the study.
- Have TMS applied to your scalp (~ 60 minutes)
- Have PNS applied separately to your shoulder and wrist (~ 10 minutes)
- Have TMS applied to your scalp (~ 40 minutes)
- Have TMS and PNS applied to your scalp, shoulder, and wrist at the same time (~ 40 minutes)
- Have all EEG and EMG electrodes removed (~ 5 minutes).

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 up to two days, for a total of up to 12 hours. If we encounter technical difficulties, you may be asked to return for a third day of up to 6 hours. Afterwards, your participation will be complete. Overall, up to 90 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. Attaching the EEG electrodes to your scalp may be uncomfortable
2. You may find removing the EEG gel from your hair after the experiment annoying
3. 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, face, or back muscle contraction during TMS. This can cause a headache

We 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?

Although you will not directly benefit from being in this study, others might benefit because it will help us develop new treatments to help people who have had a stroke 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 brain activity recordings using EEG and muscle activity recordings 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**.**

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. After publication, the information that can directly identify you and the code key linking your identifiable information to the coded data will be destroyed.

Under certain situations, we may break confidentiality. If during the study we learn about elder abuse or neglect, we will report this information to the appropriate authorities including the police and/or the Texas Department of Family and Protective Services.

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
- Study sponsor or representatives of the study sponsor

To help protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide information, documents, or samples that may identify you as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers, or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

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. For example, if you participate for 3.5 hours, you will receive $52.50 of compensation. Compensation will be provided by cash or Venmo.

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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.

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

To participate in the research, you may 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.

If you decide to withdraw before this study is completed, the data we have collected so far will be retained.

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.

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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

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

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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