Neuroplasticity Associated with Extended Daily Use of a Sensorimotor Priming Vibration System to Improve Hand Function After Stroke

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Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT
Neuroplasticity Associated with Extended Daily Use of a Sensorimotor Priming Vibration System to Improve Hand Function After Stroke

SUMMARY

You are being asked to consent to participate in a research study. Your consent is voluntary. The purpose of this study is to determine if continuous use of TheraBracelet in the home has a clinically meaningful effect in stroke survivors. TheraBracelet is an imperceptible vibration applied to the wrist, intended to assist with hand sensation and dexterity. The participation will last 4 months. You will be asked to wear the TheraBracelet watch on your affected wrist for at least 8 hours/day for a month. The watch will provide either treatment vibration or no vibration. Potential risks include irritation or discomfort from the watch or the vibration. The potential benefit is that the vibration, if received, may help hand functional recovery, although this cannot be guaranteed. The knowledge regarding the potential of using vibration to augment recovery may guide rehabilitation for stroke survivors in general. You will be asked to come to the laboratory 6-9 times during the4 months you are enrolled for an evaluation of your limb function and brain activity. If upper limb rehabilitation therapy is the standard of care suggested by your healthcare provider, you may receive the prescribed therapy and not participate in this study. Your brain will be evaluated using MRI (Magnetic Resonance Imaging) and TMS (Transcranial Magnetic Stimulation). The purpose of the MRI is to verify which regions of your brain have been affected by stroke. TMS will be used to assess how your stroke has affected the excitability of your brain. For safety, you will complete screening for MRI and TMS. If you have any contraindications associated with MRI or TMS (i.e. metal in your body, implanted medical device, epilepsy, etc.), you have will have the option of continuing in the study, but will not complete MRI or TMS.

A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study because you have experienced a stroke at least six months ago and have an upper extremity sensory impairment. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of this study is to determine if continuous use of TheraBracelet in the home has a clinically meaningful effect in stroke survivors. TheraBracelet is a imperceptible vibration applied to the wrist, intended to assist with hand sensation and dexterity. This device has not been approved by the FDA. The study is sponsored by the Medical University of South Carolina (MUSC) Center of Biomedical Research Excellence funded by the National Institutes of Health (NIH) and MUSC College of Health Professions. The investigator in charge of this study is Na Jin Seo, Ph.D. The study is being done at one site. Approximately 40 people will take part at MUSC.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You will complete a safety screening as a precautionary measure to identify any contraindications to testing procedures such as TMS (Transcranial Magnetic Stimulation) and

MRI (Magnetic Resonance Imaging). These include the presence of any metal in your body and history of epilepsy and concussion. You may still be eligible to participate in this study if you have any of these contraindications; however, you will be excluded from participating in these tests. The risks associated to pregnant women are unknown. If you are pregnant, think you are pregnant, or are trying to get pregnant please notify study staff. If you are pregnant, we will not include you in these tests. If you are a woman and of childbearing age, you will be asked to take a pregnancy test. This is to make sure that you are not put at risk during any parts of the study.

2. Your movement and sensation will be assessed. For movement assessment, you will be asked to move your hand and arm in specific ways as best as you can and move objects in different sizes and shapes around the table with the hand as quickly as possible. For sensation assessment, you will be asked if you can feel a small touch on your fingertips. You will be asked if you have any sense of numbness. These results will determine if you are eligible for the study.
3. If you are eligible for the study, you will be randomly assigned to one of two groups. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice of which group to which you are assigned. The two groups are Group A (people in this group will receive vibration at the wrist that they cannot feel) and Group B (placebo, this group will not receive vibration).
4. For both groups, you will be asked to wear a wrist vibration device at least 8 hours/day everyday for one month. You will be asked to come to the laboratory weekly during this one month and 3 months afterwards, for a total of 9-13 times.
5. In between weekly visits to the laboratory, you will practice specific hand/arm tasks at home that will help increase use of the hand/arm in activities of daily living. You will meet with study personnel to discuss the details of this task practice.

The following evaluations will occur at each weekly visit and last approximately 2 hours:

Clinical Assessments: We will assess your hand/arm movement ability and finger sensation as described above (clinical hand function). This evaluation may take half an hour and will be videotaped. A member of our research team will score these assessments by viewing the video at a later date.

Transcranial Magnetic Stimulation (TMS): Excitability of the neurons in your brain will be assessed using TMS and electrical nerve stimulation together. TMS is a noninvasive brain stimulation device. We will ask you to wear an elastic cap (like a swimmer's cap) on your head. You will then be asked to sit in a cushioned chair and rest while holding a light grip. TMS will be delivered at this time. During this time, a clicking sound will be audible as the paddle produces magnetic energy which you may feel as a light tap against your scalp. The magnetic pulse stimulates the brain nerves controlling your hand. Therefore you may or may not feel your hand muscle briefly twitch depending on the strength of the TMS pulse. You might also feel your facial muscles twitch slightly just around your eye. This twitch is a result of the TMS directly stimulating the facial nerves and muscles that run directly under your scalp. The TMS pad may be moved around your head until the best position is located to give a contraction of the hand muscle. This contraction will be measured by a muscle activity sensor that will be placed on your hand skin with a sticky pad and/or tape. TMS will be given together with electrical nerve stimulation. The nerve stimulation is noninvasive. An electrode pair will be placed on your wrist and deliver a small current. You may feel tingling of your wrist or hand. This evaluation may take a

half an hour.

Device Use Log: You will be asked to write down when you put on and take off the device each day. You will be asked to return this log to study staff at each weekly visit.

The following assessments will occur three times during the study period:

Electroencephalogram (EEG): During this assessment you will wear a cap containing electrodes on your head. The electrodes will record your brain activity during this assessment. These electrodes contain gels which can make your hair messy. You may want to bring a hat to wear after this assessment. You will be seated and either receive light touches on your fingertip or pinch using a small amount of force (as in holding a pen) when cued. This evaluation may take approximately 40 minutes.

Movement Analysis: This is an evaluation of the geometry of your arm movement using a computerized motion analysis system. We will first attach small square lighted markers to your trunk, arms, and hands using hypoallergenic tape. The lighted markers are detected by sensors on the walls of the laboratory. During testing you will sit on a study bench while gripping and object and lifting it off the table. You will repeat this task 5 times. This evaluation will last approximately 15 minutes.

Accelerometer: You will be asked to wear an accelerometer on each wrist for 3 full days after your first visit, immediately after one month of wearing TheraBracelet, and at follow-up. This device measures your activity (similar to tracking your steps) throughout the day.

The following assessment will occur only once and last approximately 30 minutes:

MRI:
In addition, you will receive a Magnetic Resonance Imaging (MRI) exam. This MRI exam includes an anatomical scan to specify the stroke-affected brain areas and the area of the brain that we will stimulate using transcranial magnetic stimulation (TMS) for the next evaluation. For the MRI exam, you will lie down on a narrow bed which will then be placed in a tunnel that is 6 feet by 22 inches wide and open at each end. You will lie there quietly for about 20 min, during which time you will hear a loud noise. You may feel warm during this procedure. This evaluation will be performed once during the study.

You may be withdrawn from the study without your consent if the researchers believe it is in your best interest or if you fail to follow study procedures.

Due to COVID-19, some participants may be assessed over the phone only, and may continue with the home intervention (home exercise and watch) while being monitored via weekly phone calls until they could come to the laboratory for full assessments.

C. DURATION

Participation in the study will take 9-13 visits over a period of 4 months.

D. RISKS AND DISCOMFORTS

1. **Loss of confidentiality:** Researchers will take appropriate steps to protect any information

collected about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. The data from your test results will be de-identified once it has been collected and before it is stored. This means your individual results would not be able to be linked to you by others who review the results of this research.

2. **Randomization:** You will be assigned to a treatment program by chance. The treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

3. **Vibration:** If you are in the group that receives vibration, prolonged vibration may numb although it is very unlikely because the vibration you will receive is very small to the extent that it is imperceptible.

4. **TMS:** Transcranial Magnetic Stimulation (brain stimulation): Historically, transcranial magnetic stimulation has been thought to increase a chance of inducing an epileptic seizure in a small population of people. However, more recent extensive review studies suggest such concerns would not be applicable to the current uses of magnetic stimulation. You cannot participate if you have any implanted biomedical devices in or above the chest (e.g., pacemakers, cochlear implants, etc.). There is also a possibility that you may experience a mild short-lasting headache after the experiment. Some other common minor short-term side effects include: scalp discomfort at the stimulation site, tingling or twitching of facial muscles, lightheadedness, and discomfort from stimulation noise. Uncommon but theoretically possible side effects include: seizures, hearing loss, and cognitive impairment. To avoid these uncommon and more serious side effects, the exclusion criteria of this study exclude individuals with epilepsy and metal implants. Please let us know if the headaches cause you to want to withdraw from these experiments. Safety of TMS in pregnancy is unknown. If you are potentially pregnant, you should not have the TMS stimulation. You will have to pass a TMS screen to decrease the risk of adverse events.

5. **EMG**: The use of tape or other adhesives to secure EMG sensors during testing may cause mild skin irritation.

6. **MRI**: Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination, which could in the process possibly harm you. Precautions have been taken to prevent such an event from happening; 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 fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have a MRI. However, you may still be eligible to complete the other parts of the study. Having a MRI may mean some added discomfort to you. In particular, you may be bothered by feelings of claustrophobia and by the loud banging noise during the study. Temporary hearing loss has been reported from the loud noise. This is why you will be asked to wear earplugs. At times during the test, you may be asked not to swallow for a while, which can be uncomfortable. The risks to pregnant women are unknown. We ask that you please report to the study team if you are pregnant. If you are pregnant, we will not test you for MRI.

7. **EEG**: It may be uncomfortable to wear a head cap attached with a bundle of wires during

evaluation. Also, the gel used for the electrodes will get your hair messy. The gel is washed off with shampoo.

Unknown Risks: The experimental treatments may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Information about your study participation will not be in your MUSC medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

E. BENEFITS

There may be no benefit from participating in this study. The potential benefit to you is that the therapy you receive may help you gain your hand function, although this cannot be guaranteed. The vibration

you may receive may prove to increase the therapy outcome than the therapy itself without vibration or than other available treatments, although this cannot be guaranteed.

F. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $15 per TMS evaluation (for a total of 6 times), $15 per EEG evaluation (for a total of 3 times), $10 per full clinical evaluation (for a total of 3 times), $10 per movement analysis (for a total of 3 times), and $15 for the MRI evaluation. There will be a total of 9-13 visits. If you complete all evaluations, you will receive a total of $210. You will be paid only for the evaluations that you complete. If you stop participating in the study, you will keep the payments you already received and will not receive additional payments.

I. ALTERNATIVES

Your alternative is to not participate in this study. Participation in this research means that you will not receive other upper limb rehabilitation therapy other than the home task practice prescribed in this study. If the standard upper limb rehabilitation therapy is suggested by your healthcare provider, you may receive the standard therapy and not participate in this study.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

We would like to include data collected in this study and from other stroke related studies you may participate in with the Registry for Stroke Recovery (RESTORE-Pro00037803). RESTORE provides MUSC's stroke recovery research community with a database containing information on research participants including stroke type, disability status, and demographics to assist in recruitment. By including data from this study in RESTORE, MUSC researchers will have access to a more complete database with key elements of physical function characteristics for more targeted recruitment efforts in the future. Additionally, this could reduce the burden placed on subjects by reducing the duplicative efforts of collecting common data and assessments requested by multiple studies and storing them in one centralized and secure location.

If you consent to participate in RESTORE your data from this study, including your personal health information, will be included in the registry. You will be asked to sign a Release of Study Records Form to share data from other stroke related studies in which you have participated. If you authorize this release your information from those studies will become part of the RESTORE registry study

K. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

L. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

M. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

N. CLINICAL TRIALS.GOV

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.

O. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance

company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact **Dr. Na Jin Seo at 843-792-0084**. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

Please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date

Participant's Personal Representative (if applicable):

_____

Name of Personal Representative *(Please print)*

_____

Signature of Personal Representative Date