# Title: Cognitive Priming to Boost Stroke Telerehabilitation Outcomes

NCT Number: 06555302

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**Medical University of South Carolina**
**CONSENT TO BE A RESEARCH SUBJECT**

**TITLE OF RESEARCH: Cognitive Priming to Boost Stroke Telerehabilitation Outcomes**

**Concise Summary**

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to see if adding cognitive rehabilitation (training to improve thinking abilities) to an occupational therapy (OT) telerehabilitation program for arm/hand function improves daily functioning for people with stroke.

You will complete 13 treatment sessions. These sessions will take place over a video visit using your device (phone, tablet, or computer). Each session will last about 1 hour. Sessions will focus on either cognitive training, OT, or a combination of the two. A caregiver or friend may be required to be with you during each session for your safety. You will also complete 2 assessment visits, one pre-treatment and one post-treatment. We will test your thinking abilities, arm/hand movement, balance, ability to perform daily activities, and overall well-being.

There may be no direct benefit for participating in this study. However, we hope that the information gained from the study will help in the treatment of future patients with stroke. The risks of this study include loss of confidentiality, muscle pain, fatigue, emotional discomfort, or falling. The study team members are licensed and experienced OTs and psychologists. We will do everything possible to assure that you are safe.

If you are interested in learning more about this study, please continue to read below.

## A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As the study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you have had a stroke. The study is being done at MUSC. The study is sponsored by the National Institutes of Health. The investigator in charge of this study is Dr. Stephanie Aghamoosa. Approximately 20 people will take part in this study.

The goal of this study is to test if adding cognitive training to occupational therapy (OT) telerehabilitation improves daily function for people with stroke. Both the cognitive training and OT are being studied as part of the research. Cognitive training involves teaching strategies to improve your thinking, memory, focus, and planning. OT involves practicing arm and hand movements that were impacted by your stroke. In this study, you will learn these skills and apply them to your daily life.

## B. PROCEDURES

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

1. **Pre-Treatment Visit (2-3 hours):** A research team member will schedule a pre-treatment appointment which can take place virtually or at MUSC research space. The appointment will last 2-3 hours. If you decide you would like to split up this visit, you can schedule two pre-treatment appointments. At this visit you will be asked to:
    a. Provide information about yourself (examples: your age, your gender, etc.) and your stroke (examples: time since your stroke, location of stroke). We may also look in your medical chart to collect information about your stroke.
    b. Complete interviews, tests, and surveys about your balance, thinking skills, arm movement skills, and ability to do daily life activities.
    c. Work with your occupational therapist to plan your goals for the telerehabilitation sessions.
    d. Schedule 13 telerehabilitation sessions over the next 8 weeks on days and at times that are good for you.
2. **Telerehabilitation Sessions (45-75 minutes each):** You will complete 13 total sessions over 8 weeks (first 5 weeks: 2 sessions/week; last 3 weeks: 1 session/week). If you need to miss sessions, you may schedule make-up sessions with the therapist. This could extend the 13 sessions over an additional week (9 weeks). You will interact with the therapist through a video call on your phone, tablet, or computer. During each session, you will engage in cognitive training, OT, or a combination of the two. Both cognitive training and OT are being studied as part of the research. The content will be:
    - Sessions 1-4 will focus on cognitive training (strategies to improve with your thinking, memory, focus, and planning).
    - Sessions 5-10 will provide additional cognitive training and begin your OT exercises (practicing arm/hand movements).
    - Sessions 11-13 will review cognitive training skills and focus on your OT exercises.
3. **Post-Treatment Visit (1.5 hours):** You and the therapist will schedule a final appointment that may take place virtually or at MUSC research space. This will occur after you complete the 8 weeks of telerehabilitation visits. You will repeat some of the tests and surveys that you completed during the first appointment.

If you are uncomfortable at any point during the sessions, you can choose to take a break or stop. If you get tired, or if the research team member believes that you are getting tired, you can pause for a rest or you can choose to stop the session and reschedule to finish session on a different day.

## C. DURATION

This study will last up to 11 weeks. Typically, you will complete all 15 study visits over 10 weeks: 2 assessment sessions (pre- and post-treatment) and 13 telerehabilitation sessions. If you miss telerehabiliation sessions, make-up sessions could extend participation up to 11 weeks.

## D. RISKS AND DISCOMFORTS

Physical Risk/Discomfort: It is possible that you could experience minor mental fatigue from engaging in the cognitive training sessions. You may also experience minor muscle pain and/or fatigue from participating in the OT sessions because you will be moving and exercising the arm made weakest by your stroke. This is the same risk as if you were attending OT at your local hospital or clinic. The muscle pain and/or fatigue should go away within a few hours after you stop the session. If your pain does not go away, the therapist will stop the therapy sessions.

It is possible that you could fall during an OT session when you stand and/or move around to do activities. During the first visit, you will complete assessments of your balance and thinking skills. The results of those tests will be used to help determine your risk of falling. If you have moderate or high risk of falling, you will be required to have another person with you during all OT activities that entail standing and/or walking. During the telerehabilitation sessions, your caregiver or a trusted friend should stand and walk with you.

Psychological Risk and/or Emotional Distress or Discomfort: Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.

Loss of Confidentiality: There is a risk of a loss of confidentiality of your personal information that is used in this study.

## E. MEDICAL RECORDS AND/OR 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.

## F. BENEFITS

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with stroke. This study will help the researchers learn more about how cognitive training and OT impact stroke rehabilitation.

## G. COSTS

There will be no cost to you as a result of participation in this study. Your normal cellular data and usage rates will apply if you use a personal device to join the remote visits.

## H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $50.00 for each assessment visit, or a total of $100.00 for completing the full study. Payment for your participation will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card, and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. The money will be added to the card throughout the study. Details of the debit card system are explained on an additional sheet that will be mailed to you.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

## I. ALTERNATIVES

If you choose not to participate in this study, you could receive other treatments for your condition. The standard therapy for your condition is outpatient occupational therapy. Engaging in outpatient occupational therapy does not prevent you from participating in this study. Your alternative is to 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.

If you agree, the data collected and generated from this study will be shared to the Registry for Stroke Recovery (RESTORE-Pro#00037803) by the subject's registry ID. Sharing data from this study with the registry will allow for more targeted recruitment efforts in the future and allow researchers at MUSC to have a more complete registry with key stroke recovery elements including common data and physical function characteristics that are applicable to multiple studies. MUSC researchers and collaborating facilities will be able to query data sets to learn more about recovery of subjects after their stroke through institutionally managed secure servers that will assure HIPAA privacy and security compliance.

____Yes, I agree to share my data with RESTORE

____No, I do not agree to share my data with RESTORE

## K. DISCLOSURE OF RESULTS

If you would like a copy of your test results, please ask one of the study team members. A printed copy of the results will be mailed or emailed to you.

## L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

## M. 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.

## N. 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

## MUSC STANDARD PARAGRAPHS:

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 investigators associated with this study, the sponsor, 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 that you are injured as a result of participation in this study, 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. 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 **Stephanie Aghamoosa (843) 792-2956**. 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.

_____ _____
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

Relationship: ___ Spouse ___ Parent ___Next of Kin ___Legal Guardian* ____ DPOA for Healthcare*

**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf of the patient)*