Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: *Impact of Intense Physical Therapy on Functional Mobility Outcomes in the Acute Stroke Population - Phase II*
NCT06042179

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. This research study is looking at the impact of increased frequency of Physical Therapy (PT) services on patient outcomes in the acute stroke population. If you agree to participate, you will be assigned, by chance to either the standard of care physical therapy or one of three treatment groups- an increased frequency group, an increased intensity group OR a combined increased frequency and intensity group. We are unable to predict which group you will be assigned to. The standard of care PT group will receive standard of care PT (3-5 sessions per week). The increased frequency group will receive increased frequency of physical therapy services (twice a day for the first 3-5 days of admission followed by daily treatments). The intensive therapy group will receive a physical therapy treatment approach that increases the difficulty of each session, daily. The combined increased frequency/intensity group will receive increased frequency of physical therapy services (twice a day for the first 3-5 days of admission followed by daily treatments) with the use of enhanced difficulty throughout each session. Your ability to get out of bed, transfer to a different surface and walk after receiving PT will be examined. The study will last throughout your inpatient hospital admission and data will be collected at your 30-day post stroke outpatient clinic follow up.

The potential benefit to you is that the increased frequency of physical therapy you receive may prove to be more effective than the current standard of care, although this cannot be guaranteed. We also hope that the information gained from the study will help the field of stroke rehabilitation. The greatest risks of this study include the possibility of injury during physical therapy and loss of confidentiality. You do not have to participate in this study to have your condition treated. If you choose not to participate, you will receive usual standard of care physical therapy. If you are interested in learning more about this study, please continue reading below.

A. PURPOSE OF THE RESEARCH

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 what amount of physical therapy is beneficial in the hospital setting after suffering a stroke. You are being asked to participate in this study because you have experienced a stroke. The study is sponsored by the NIH through the COBRE Center for Stroke Recovery and

Research. The investigator in charge of this study at MUSC is Dr. Christine Holmstedt. Approximately 168 people will take part in this study.

B. PROCEDURES

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

1) The researchers will check your medical records to gather information about your health including: demographic information, current diagnoses, information about your stroke, treatments you received for your stroke, and results of your physical performance tests.
2) If your medical record indicates that you are eligible for the study, you will be randomly assigned to one of four groups, like drawing numbers from a hat. The four groups are the frequent PT group, the intense PT group, the frequent AND intense combined PT group, and the standard of care PT group.
3) If you are randomized to the frequent PT groups, will receive PT services 2 times per day for 3 out of your first 5 days of hospital admission and daily for the remainder of your hospitalization; sessions will be 20-50 minutes in duration. These PT sessions will include working on getting you out of bed, transferring from your bed to a chair, working on balance, strengthening the side of your body affected by your stroke, learning how to walk again and/or how to use a wheelchair if unable to walk.
4) If you are randomized to the intense PT group, you will receive PT services daily with treatment sessions being more difficult than the typical therapy session because during each PT session, the things that are difficult for you will be made even more difficult (by adding resistance or other challenges) in order to increase the intensity of the session.
5) If you are randomized to the frequent AND intense combined PT group you will receive PT services 2 times per day for 3 out of your first 5 days of hospital admission and daily for the remainder of your hospitalization; sessions will be 20-50 minutes in duration and will focus on increasing the intensity of services by making difficult tasks more difficult with the addition of resistance or challenging your balance.
6) If you are randomized to the standard of care group, you will receive the normal amount of PT services 3-5 times per week throughout admission and you will be assisted and facilitated to perform the difficult tasks without the component of an added challenge. Sessions will be 20-50 minutes in duration.
7) You will have assessments done that will look closely at your balance, ability to get out of bed, stand and walk. During these assessments you will be asked to try and stand up, to try and stand on one foot, and to try and pick an item up off of the floor. These assessments will be obtained from the medical chart for initial PT evaluation and will be performed for research on day three of hospitalization, discharge from the hospital and 30-day stroke clinic follow up.
8) You can ask to end PT sessions early and you can choose to stop participating in the study at any time.

C. DURATION

Participation in this study will span your inpatient hospital admission on the Vascular Neurology/Stroke Service and will end after your 30-day outpatient stroke clinic follow-up.

D. RISKS AND DISCOMFORT

Unknown Risks

- The experimental treatments may have unknown side effects.
- 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.

Risk of Intensive PT

- Falls, decreased blood flow to your brain, worsening weakness and/or worsened stroke.
    - The research team will monitor your blood pressure before each PT session to make sure it is safe for you to continue.

Loss of Confidentiality

- A confidentiality breach is also a risk associated with this research.
    - The research team will make every effort to protect your confidentiality as a result of your participation in this study by de-identifying all data and keeping it in a secure or password protected location.

Risk of Randomization

- 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.

The researchers will let you know if they learn anything during the course of the study that might make you change your mind about participating in the study.

E. MEDICAL RECORDS & CERIFICATE 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 except if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you are an MUSC patient, you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law; however, there is the possibility that your research information will be disclosed. 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 or 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

The potential benefit to you is that the treatment you receive may prove to be more effective than the other study treatment or than other available treatments, although this cannot be guaranteed. The treatment provided for the intense physical therapy group may improve your independence, your ability to stand, walk or get around and may lead to a shorter hospital length of stay.
It is hoped that the information gained from the study will help in the treatment of future patients with conditions like yours and that it will help the researcher learn more about physical therapy approach to mobility post stroke.

G. COSTS

There will be no additional cost to you for procedures required in this research study. All routine clinical care that you would have undergone without participation in the study, including testing and procedures, will be billed to you/your insurance company. All study-related tests and procedures (additional 3 PT sessions over the first three days of admission for patients in the frequent or frequent/intense treatment group) will be paid for by the Sponsor. You will be responsible for any charges that your insurance does not cover including copayments and deductibles. Some insurance plans will not pay for these services for people taking part in research studies.

H. PAYMENT TO PARTICIPANTS

You will not be paid for participating in this study.

I. ALTERNATIVES

If you choose not to participate in this study, you will receive standard clinical physical therapy during your hospital stay.

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.

K. DISCLOSURE OF RESULTS

Results of the study will not be shared with the individual subjects.

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;
- 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
    - National Institutes of Health or Other governmental offices, such as a public health agency or as required by law;
    - IRB approved Investigators requiring your data for their research projects.

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 is 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

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.

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.
If you are unable to physically sign this consent form but would like to participate, you may make a mark in the signature area, and we will have a witness sign on your behalf.

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. Christine Holmstedt at 843-792-3020. 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)*

Witness (if applicable):

_____

Name of Witness *(Please print)*

_____

Signature of Witness Date