Research Protocol Title

Impact of Intense Physical Therapy on Functional Mobility Outcomes in the Acute Stroke Population - Phase II

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1.0 Objectives and Specific Aims

Goal: *To evaluate the impact of increased frequency and intensity of Physical Therapy (PT) services on patient outcomes in the acute stroke population.*

Aim I: To determine whether increasing the frequency of Physical Therapy services post-acute stroke is superior to standard of care physical therapy services; measured by a change in functional outcomes, hospital length of stay, 30 day follow up.

Hypothesis I: We hypothesize that patients receiving an increased frequency of PT services will demonstrate higher degree of improvement on the Activity Measure for Post-Acute Care (AMPAC) and Postural Assessment Stroke Scale (PASS) from admission to time of discharge from the hospital and at 30-day follow up. We also expect lower overall Modified Rankin Scale (mRS) scores for the increased frequency PT group compared the usual care PT group at 30 days post stroke.

Aim II: To determine whether increasing the intensity of Physical Therapy services post-acute stroke is superior to standard of care physical therapy services; measured by a change in functional outcomes, hospital length of stay, 30 day follow up.

Hypothesis II: We hypothesize that patients receiving an increased intensity of PT services will demonstrate higher degree of improvement on the AMPAC and PASS from admission to time of discharge from the hospital and at 30-day follow up. We also expect lower overall mRS scores for the increased frequency PT group compared the usual care PT group at 30 days post stroke.

Aim III: To determine whether increasing the intensity of Physical Therapy (PT) services post-acute stroke is superior to increasing the frequency of PT services; measured by a change in functional outcomes, hospital length of stay, 30 day follow up.

Hypothesis III: We hypothesize that patients receiving an increased intensity of PT services will demonstrate higher degree of improvement on the AMPAC and PASS from admission to time of discharge from the hospital and at 30-day follow up. We also expect lower overall mRS scores for the increased intensity PT group compared the increased frequency PT group at 30 days post stroke.

Aim IV: To determine whether increasing the intensity and frequency of PT services post-acute stroke is superior to increasing only the intensity of PT services; measured by a change in functional outcomes, hospital length of stay, 30 day follow up.

Hypothesis IV: We hypothesize that patients receiving an increased frequency AND intensity of PT services will demonstrate higher degree of improvement on the Activity Measure for Post-Acute Care (AMPAC) and Postural Assessment Stroke Scale (PASS) from admission to time of discharge from the hospital and at 30-day follow up. We also expect lower overall Modified Rankin Scale (mRS) scores for the combined increased intensity AND frequency PT group compared the usual care PT group OR either of the treatment groups alone at three months post stroke.

2.0 Background

The Department of Physical Therapy in conjunction with the Comprehensive Stroke Center at the Medical University of South Carolina (MUSC) seeks support for developing an evidence-based approach for the mobilization of patients within the first 24 hours of admission for an acute stroke and for increasing the frequency and intensity of acute PT services while inpatient. This evidence will prepare physical therapists and guide practice in the delivery of acute stroke mobilization in the hospital setting to optimize length of stay, disposition planning, and enhance long term recovery outcomes.

Our research hopes to challenge the clinical paradigm regarding the possibility of decreased functional outcomes with early mobilization post stroke. We acknowledge that acute stroke patients may not be able to tolerate an extensive early mobility program but may benefit from shorter more frequent sessions of therapy early in their recovery. Throughout the literature, there are clinical practice guidelines for both the inpatient rehabilitation and outpatient therapy sectors and post stroke recovery. Little is known about the contribution of therapy services in the acute hospital setting and therapy's impact on long term functional gains. The goal of this project is to determine the appropriate dosage of post stroke mobility in the acute care hospital setting.

The objective is to determine if changing one component of the overall mobility dosage, adjusting frequency or intensity, will improve patient outcomes. Phase I of this study, performed at MUSC from June 2021-June 2022, demonstrated improved functional mobility outcomes at hospital discharge for patients who received a combination of both increased frequency and intensity of PT services compared to the standard of care approach. Phase II aims to determine if these promising results can be attributed to increased frequency, increased intensity or a combination of frequent and intense PT sessions. As a comprehensive stroke center, MUSC strives to provide the best of patient care by committing to a higher standard of clinical service utilizing evidence-based practice to improve patient outcomes.

3.0 Innovation of Intervention to be Studied

Early mobilization is a widely accepted pillar of acute hospital physical therapy services. In most populations, early mobility is regarded as safe, feasible, and yields positive results.[6] A considerable amount of clinical and scientific literature has evaluated and upheld the positive effect of early mobility on patient safety, ICU delirium, duration of mechanical ventilation, hospital length of stay, functional mobility, ambulation ability, and mortality. However, most of the research in the field of early mobilization has focused on intensive care patients with multiple medical comorbidities.[7]

The consideration of an acute stroke diagnosis in relation to the approach of acute care PT and "early mobility" is limited. The AVERT trial was novel in opening the doors to evaluate physical therapy's approach to acute stroke care on dedicated stroke units. This research proved critical since earlier research surmised that complications of immobility could be estimated to account for as many as 51% of death in the first 30 days post stroke.[8] The results of the AVERT trial raised concern that very early mobilization may cause changes in cerebral blood flow and blood pressure leading to worsened stroke outcomes, increased mortality and increased rate of falls during early mobility.[9]

From the publication of the AVERT trial, there has been a rise in clinical interest regarding the correlation of early mobility and improved functional outcomes post stroke with the biggest question remaining- how early is too early and how much is too much? The majority of physical therapy studies in the acute stroke population have only examined the optimal time to begin mobilization post admission to the hospital.[9] We hypothesize that the approach of shorter, more frequent sessions of intense quality therapy services will negate the post stroke cerebral perfusion factor. Thus, allowing patients to progress functional mobility with improved tolerance to therapy sessions, frequent repetition, as well as implementation of motor learning principles to ensure carryover by providing distributed over massed practice.

The research in the field of neuroplasticity and neuro rehabilitation illustrates the importance of high intensity, repetitive and aggressive approaches for motor recovery, however, most of this research has been performed in the subacute stroke population. Error augmentation training is one way to increase the difficulty of a task to enhance motor learning.[10] In the current research, error amplification training was found to induce more robust aftereffects of locomotion training as compared to assistive training.[10] Thus, error augmentation/ amplification may be one approach to increasing the intensity and complexity of the task without changing the task itself. For acute stroke patients in the hospital setting- error augmentation can be implemented by targeting the patients post stroke deficits by emphasizing them. If a patient has a hemiparetic limb- error augmentation would include resisting and challenging the movement of that limb rather than facilitating and assisting with the movement of that limb. For patients whose stroke did not cause hemiparesis but rather balance impairments, narrowing the base of support or dynamically resisting balance in the direction of a patient's lateral lean can also amplify and augment their error. The celebrated motor learning theory, "The Challenge Point Theory" states that learning is maximized when the task difficulty is appropriate for the individual skill level of the performer[11]; this theory leaves us with hope that increasing the challenge of mobility tasks in the acute hospital setting may be beneficial to increasing the success and progress of functional mobility.

Rather than decreasing the time to upright mobility, it may be beneficial to examine the effect of short sessions of more frequent challenging mobilization in these patients, within the early stages of their hospitalization. If, as assumed, a prolonged duration of upright sitting posture has a negative effect on cerebral blood flow[12] it may be possible to gain the positive effects of early mobility by continuing to provide PT services while combating the negative effects of cerebral perfusion by returning all patients to a <30-degree position in bed following therapy services within the first 24 hours of acute stroke admission. This study aims to examine the approach of increased frequency and intensity of physical therapy services as a way to gain the benefits of the publicized early mobility approach, while weighing the concerns raised by previous trials and decreasing amount of time left upright to combat negative effects of cerebral perfusion on the ischemic penumbra. A study similar to our Phase I approach, performed in Taiwan in 2021, demonstrated that survivors of acute stroke who receive up to 2 rehabilitation sessions per day for 5 d/wk. early in their hospitalization have better functional recovery at 3 months after stroke.[13] Phase I of "Impact of Intense Physical Therapy on Functional Mobility Outcomes in the Acute Stroke Population" demonstrated a significant improvement in functional mobility scores for acute stroke patients mobilized early, frequently and intensely compared to their counterparts in the standard of care arm of the study. The treatment arm progressed on the Postural Assessment Scale for Stroke (PASS) and the Activity Measure for Post-Acute Care (AMPAC). The PASS improved in the experimental group from admission to discharge 6.28 points while the standard of care change was 1.82 points; there was a main effect for interaction ($p=0.0001$). The AMPAC improved in the experimental group from admission to discharge 3.13 points while the standard of care change was 1.48 points; there was a main effect for interaction ($p=0.01$). PASS and AMPAC scores were maintained in both groups at 90 days post-stroke. The level of disability measured by the Modified Rankin Score (mRS) decreased for both groups at 90 day follow up and the length of hospital stay was decreased by 1.5 days in the treatment arm. There was one significant adverse event in the experimental group during the first 30 days post-stroke- due to significant atherosclerosis and perfusion dependence. This patient was removed from the study secondary to having a carotid stent placed. Because of this adverse event, patients who

require stenting procedures were added to the list of exclusion criteria for Phase II. Given the feedback on AVERT results assuming that most negative outcomes were for the patients with hemorrhagic stroke, not ischemic stroke- Phase II of this study will also exclude all hemorrhagic stroke patients. We demonstrated in phase I that patients may benefit from shorter more frequent sessions of therapy early in their recovery with an emphasis on facilitating error to progress seated postural control, motor recruitment strategies, and transfer training delivered in separate sessions- allowing for time outside of therapy to be spent in a less than 30-degree position for the first 24 hours of hospital admission to optimize cerebral perfusion. During phase I, the treatment arm was seen both frequently and intensely. Phase II of this study is hopeful to determine whether the improvements in functional mobility during Phase I should be attributed most to an increase in intensity, an increase in frequency or whether the combination of frequent and intensive therapy is truly best practice for acute post stroke PT services in the hospital setting.

4.0 Approach

The purpose of this study is to determine what amount of physical therapy is beneficial in the hospital setting after suffering a stroke. Stroke continues to be a leading cause of disability and death worldwide. Improvements in research, acute stroke treatments, and health care accessibility have resulted in a decreased mortality rate of stroke patients and have increased the need for rehabilitation services to optimize functional gains post-acute stroke. Across most acute health conditions, increased physical therapy (PT) in the hospital environment has been shown to reduce length of stay and improve quality of life. However, the dose-response relationship is not well established in acute stroke patients. There is conflicting literature regarding the safety of early mobility within the first 24 hours post admission to the hospital for an acute stroke. Phase I of this study was performed at MUSC from June 2021-June 2022 with promising results of improved functional mobility outcomes with early intervention of Physical Therapy post stroke. Phase II aims to evaluate whether the dosage of increased frequency or increased intensity of Physical Therapy services led to the promising outcomes and functional improvements which the first study demonstrated.

We propose to enroll 168 individuals with acute stroke admitted to MUSC and randomize them into increased frequency, increased intensity, increased frequency and intensity combined and usual care PT treatment groups. This study will be designed as a randomized control trial. Patients who agree to participate, will be assigned (at random) to either a treatment arm which will receive either more frequent therapy services, more intense therapy services (increased intensity by incorporating error augmentation training), a combination of frequent and intense therapy services (frequent bouts of error augmentation training) or to the control group (treatment as usual) which will receive the standard amount of therapy services currently provided in the hospital setting (~3-5 times per week). Error augmentation training is an approach that targets what is difficult for the patient and makes it even more difficult, increasing errors to enhance adaptation. By studying the balance, walking and success of patients in the treatment groups compared with the standard of care group- we hope to better understand the contribution of intense PT services, frequency PT services, or a combination of intense and frequent PT services on a patient's independence post stroke. We know from phase I of this study that patients provided with a combination of increased frequency and intensity of PT services demonstrated significant functional improvements (measured by PASS and AMPAC) at

time of hospital discharge and a decreased length of hospital stay when compared to the standard of care PT group. Phase II will help us determine if these promising results can be best attributed to the intensity and error augmentation training portion of PT services, to the frequency of PT services, or to a combination of both frequent and intense PT services post stroke in the acute hospital setting.

5.0 Study Endpoints

Physical Performance and Functional Measures: PASS scores & AMPAC scores on evaluation, day three, discharge, and 30-day follow up. Discharge disposition recommended vs ultimate discharge disposition, hospital length of stay, and 30-day readmission. The primary outcome is a change in functional mobility measure- the Postural Assessment Scale for Stroke from PT evaluation to discharge from hospital.

6.0 Setting

This research will be conducted on the inpatient stroke service at MUSC (ED, 9E, 9W, 8W, ICU) as soon as possible after admission, ideally within the first 24 hours of the patient's admission to the vascular neurology service for an acute stroke. Follow up values will be collected at post discharge neurology clinic (either in person or through password protected zoom call, or doxy.me) by a member of the study team. Adverse events will be documented in the patient's medical chart and research record and the primary investigator will direct and oversee services provided.

7.0 Enrollment

Goal enrollment is 168 participants.

Potential subjects will be identified via chart review on admission to the stroke service and appropriateness of enrollment will be decided by PI based on discussion with the patient's clinical care team. The patient will then be approached on the inpatient stroke service, provided information about the study by a study team member at bedside and have time to ask questions before consent is obtained by a study team member. The PI/study team will already be part of these patients' clinical care and the PT or nurse practitioner obtaining consent will be an approved member of the study team on the eIRB application.

Inclusion/exclusion criteria will be determined based on patient chart review in Epic, once PT consults are received (consults are automatically triggered on admission to the acute stroke service). Thorough chart review and discussion with patient's medical team will serve as a means of determining patient eligibility. Both treatments as usual and experimental group patients will meet the same eligibility criteria and will be randomized to their treatment after consent is obtained.

Inclusion Criteria:

Acute stroke
NIH Stroke Scale score of 2-18 with motor involvement
Age 18-80yo
Medical stability for increased therapy services, determined by Stroke Service NP (no significant uncontrolled fluctuation in vital signs, blood pressures or seizure like activity).
Ability to give informed consent

Oriented x 4 and able to follow commands

Exclusion Criteria:
Medical instability or cerebral perfusion dependence, requiring bed rest
Pregnancy (noted in chart)
Inmates (noted in chart or visible by guards present at bedside)
Known & Current COVID-19 infection (PCR positive labs)
Dialysis (noted in chart & performed while inpatient)
External Carotid Stenting Procedure
Hemorrhagic Stroke

8.0 Informed Consent

To conduct this research, we will require a signed informed consent from all patients. Consent will be obtained by PI, Co-I and study personnel. The PI/study team will already be part of these patients' clinical care and the PT or nurse practitioner obtaining consent will be an approved member of the study team on the eIRB application. The signed informed consent is necessary to be randomized to one of four study groups. A written copy of the consent form will be provided to the patient by a study member at bedside, on the inpatient stroke service. The participant will be given the opportunity to read the consent, their questions will be answered, and they will be provided with a copy of the consent document. Capacity to consent will be determined by the patient's primary medical team. For patients who are unable to physically sign their name (secondary to weakness or hemiparesis from stroke), they may use make a mark on the consent and there will be a witness to the consent process.

9.0 Study Design

This study will be designed as a randomized control trial with a 1:1:1:1 randomization. This study will utilize a stratified block randomization design and stratifying on the 4 NIHSS categories to randomly allocate a participate to a treatment group, while maintaining a balance across treatment groups. All patients will be identified and consented as soon as possible, ideally within 24 hours of admission to the stroke service. Patient's blood pressures will be obtained prior to PT treatment to ensure safety of mobilization. If systolic blood pressure is above 220mmHG, therapy services will not be performed at that time and therapist will follow up later in the day once patient is medicated for hypertension by nursing staff.

If a patient is randomized to the frequent physical therapy treatment group, they will receive PT services 2x/day for 3 out of the first 5 days of hospital admission and daily for the remainder of their hospitalization. Sessions will be 20-50 minutes in duration, based on patient tolerance. These PT sessions will include working on getting out of bed, transferring from bed to a chair, working on balance, strengthening the side of the body affected by the stroke, learning how to walk again and/or how to use a wheelchair if unable to walk.

If a patient is randomized to the intense physical therapy treatment group, they will receive PT services daily with treatment sessions being more difficult than a standard therapy session. During each PT session, the things that are difficult for the patient will be made even more difficult (by adding resistance or other challenges) in order to increase the intensity of the session. This is known as "Error Augmentation training" and will be implemented to target at least 3 post stroke deficits identified on evaluation.

If a patient is randomized to the frequent AND intense physical therapy treatment group they will receive PT services 2x/day for 3 out of the first 5 days of hospital admission and daily for the remainder of the hospitalization. Sessions will be 20-50 minutes in duration (based on patient tolerance) and will focus on increasing the intensity of services by making difficult tasks more difficult with the addition of resistance or other challenges. This is known as "Error Augmentation training" and will be implemented to target at least 3 post stroke deficits identified on evaluation.
If a patient is randomized to the standard of care group they will receive the normal amount of PT services one a day, three to five days week for 20-50minutes throughout admission. The patient will be assisted to perform transfers and mobility tasks with a PT providing facilitation to assist the patient without the component of an added challenge.
Functional measures such as PASS, AMPAC, mRS will be collected on initial PT evaluation, day three of treatment and discharge from the acute care hospital. These measures will be collected again in the outpatient neurology clinic (or virtually via Zoom or Doxy.me) at 30 day follow up appointment. Study procedures will end after 30 day follow up appointment is completed.
Participants can ask to end PT sessions early if they become uncomfortable or do not want to do them.

10.0 Data

Patient data will be collected from their medical record. Data collected from Epic/patient's MUSC EMR will be coded in the research database. Data collected include:

1. Demographics: sex, age, race

2. Stroke risk factors: history of HTN, HLD, A-fib, or DM

3. Stroke specifics: type of stroke (hemorrhagic vs ischemic), location of stroke, stroke severity (measured by NIHSS & MRS), time of symptoms to presentation, intervention (tPA or thrombectomy) and complications

4. Physical Performance and Functional Measures: Postural assessment stroke scale scores on evaluation, day three and 30 day follow up. Discharge disposition recommended vs ultimate discharge disposition, hospital length of stay.

11.0 Data Management

Paper consent will be stored in a locked cabinet in the PT department. All data management will be conducted using the REDCap platform developed and housed at MUSC. All other collected data will be stored electronically in the MUSC OCIO approved secure SharePoint system. Access to this database will be restricted based on netID permissions to a secured server and will only be accessible to IRB study personnel. Identifying information will be removed from the primary database. Identifying information will be stored in a separate file with a unique identifier assigned to the patient to link the two datasets.

Our data and safety monitoring plan will be continuous, close monitoring by the study investigator/co-investigators of all participants. The PI and Co-I's will meet every 25 patients to discuss data and safety monitoring. During these meetings we will look for any negative trends

in the data we have collected (vitals, NIH stroke scale- i.e., stroke severity, and functional mobility scores) that could indicate adverse events and provide a timely summary report of adverse events to the IRB/NIH.

Any reportable safety events that are unexpected, serious or may be related to the subjects' participation in this research will be reported to the MUSC IRB in accordance with their policies.

Once the Principal Investigator (PI) determines that an adverse event meets the IRBs' reporting requirements, the PI will report the SAE, and related safety information, to the IRB. For reasons of confidentiality, subjects' names will not be included in the report. If the adverse event results in the need to revise the informed consent, or other study documents, the PI will submit a study amendment to the IRB. Any trend in a type of adverse event will be relayed to the IRB as soon as the trend is noted. All events that do not meet the criteria of significant or trending, will be recorded in a summary form and included at the close of the study. Per consistency with the NIH guidelines- all serious and significant adverse events involving risks to a participant or suspension/termination of IRB approval for this study will be immediately reported to the sponsor.

12.0 Outcomes and Analysis

Goal enrollment is 168 participants. Based on the past literature, in similar populations the standard deviation of PASS measurements is at the most 7.20.[5] Using this, with a sample of 42 patients in each group, with 95% confidence at the end of the study we can estimate this difference within a margin of error of 2.8.

The primary out come measure will be the change in postural assessment stroke scale scores from time of PT evaluation to hospital discharge. A factorial design will allow for a test of intensity (vs control) and duration (vs control) through pooling across treatment arms. Using the table below, margins (A+C, B+D, A+B, C+D) need to each be 104 given a mean difference of 2.8, standard deviation of 7.2, 80% power and 5% type I error. Given that this is an early phase study, we can increase the type I error to 10% which would decrease the overall sample size needed to 168 patients (42 per arm) whilst still maintaining 80% power.

	Low Intensity	High Intensity	Totals
Low Duration	A	B	A+B
High Duration	C	D	C+D
Totals	A+C	B+D	A+B+C+D

We are planning to conduct the analysis using intention to treat paradigm. In a preliminary analysis we will compute all summary statistics. Initial plots, such as spaghetti plots, will be used to guide our analyses. A general linear mixed model approach will be used to analyze all the outcomes. This model will account for the correlations between time points using either a compound symmetric or spatial structure for the covariance matrix. Post-hoc analyses using Tukey type adjustments will be performed to obtain least squares estimates of the differences between the two randomized groups. Although the study is powered based on only the primary

outcome (PASS), we will apply multiple comparisons adjustments for the rest of the outcomes, using Bonferroni corrections. We will test for the assumptions using diagnostic procedures and take appropriate actions if needed. Also, we will define an outcome to be 'favorable' or 'unfavorable' based on a threshold and apply generalized linear mixed models with logistic link and repeat the analyses. We will attempt to minimize drop- outs but in case of missing data, we will assume Missing at Random or Missing Completely at Random. If necessary, we will perform multiple imputations. For all analyses, we will use SAS, (MIXED, GLIMMIX, MI and MIANALYZE).

13.0 Risks, Discomforts and Potential Harms

Early mobilization in the acute stroke population may pose risks including but not limited to falls, decreased cerebral perfusion, worsening weakness and/or worsening stroke. The research team will monitor blood pressures before each PT session to make sure it is safe for the individual to participate. A confidentiality breach is also a risk associated with this research. However, no paper records will be stored or reviewed other than consent forms and only coded data will be used for the analysis. Identifying information will be removed from the primary database. Identifying information will be stored in a separate file with a unique identifier assigned to the patient to link the two datasets.

The PT treatment each participant receives may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments. The experimental treatments may have unknown side effects. The researchers will inform patients immediately if they learn anything during the course of the study that might make the patient change their mind about participating in the study.

Within the first 24 hours post admission for stroke, ALL patients will be returned to a semi-supine position with the head of bed angle <30-degrees to minimize the risk of decreased cerebral perfusion, which is standard of care. Despite the fact that the treatment group will be seen at an increased frequency for PT services- we will not increase their duration of upright within the first 24 hours of admission, which was thought in the previous AVERT trial to be the cause of poor outcomes. Thus, all patients will participate in PT services but will be placed back in a semi-supine position, less than 30-degrees following upright mobility.

The PI and Co-I's will meet every 25 patients to discuss data and safety monitoring. During these meetings we will look for any negative trends in the data we have collected (vitals, NIH stroke scale- i.e., stroke severity, and functional mobility scores) that could indicate adverse events and provide a timely summary report of adverse events to the IRB/NIH. If at any time, there is an adverse event (i.e.: worsened stroke or death) directly related to PT services at an increased frequency and intensity- the PI and/or Co-I's will alert the IRB immediately.

Precaution will be taken to lessen the probability of risks; despite increased frequency of treatments, duration of upright will still be approached cautiously within the first 24 hours s/p admission for stroke for cerebral perfusion. ALL stroke patients will be returned to semi-supine position within 24 hours of admission for acute stroke and maintain head of bed <30 degrees except for medication, meals, and therapy. They will only be upright for therapy services, medications, and meals- but will not be left in an upright seated position. Therapy will be

stopped if patient deemed medically unstable for increased frequency of treatments by the Stroke NP, Attendings, Fellow, or PI; this decision will be documented via "bed rest" orders in the patient's electronic medical chart, so that the study team is aware to avoid progressive frequent upright mobilization.

Phase I of this study raised concerns regarding the risk of hypotension in patients' status post external carotid stenting procedure and those patients were removed from the study secondary to medical instability and hypotension. Because of this, we will exclude patients who undergo external carotid stenting from participation in Phase II of this study. The American Association for Neurology also released clinical practice guidelines, attributing the negative effects of the AVERT trial to the hemorrhagic stroke population and warning against early mobility post hemorrhagic stroke. For this reason, we will only include ischemic strokes in Phase II of this study.

14.0 Withdrawal of Subjects

Subjects will be withdrawn from the research without their consent with the occurrence of worsening medical status, medical instability that limits ability to progress mobility or transfer to the ICU. For subjects who request to withdraw from the research trial, investigators may retain and analyze already collected data relating to that subject.

15.0 Potential Benefits

The potential benefit to patient's is that the treatment they receive may prove to be more effective than the other study treatment or than other available treatments, although this cannot be guaranteed. Certain treatment arms may increase a patient's independence and may lead to a shorter hospital length of stay and improved functional mobility outcomes (i.e.: regaining the ability to stand and walk).

It is hoped that the information gained from the study will help in the treatment of future patients with similar conditions and that it will help the researcher learn more about physical therapy approach to mobility post stroke.

15.0 Sharing of results with subjects:

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

16.0 Significance

The Department of Physical Therapy in conjunction with the Comprehensive Stroke Center at the Medical University of South Carolina (MUSC) seeks support for developing an evidence-based approach for the mobilization of patients within the first 24 hours after an acute stroke admission and for increasing the frequency and intensity of acute PT services while inpatient. This evidence will prepare physical therapists and guide the practice in the delivery of acute stroke mobilization in the hospital setting to optimize length of stay, disposition planning, and enhance long term recovery outcomes. As a comprehensive stroke center, MUSC strives to provide the best of patient care by committing to a higher standard of clinical service, providing a framework to improve patient outcomes, and organizing teams within the continuum of care-

therapy included. A cohesive approach to mobilization in the hyper acute phase of stroke may impact patient outcomes across the continuum of care.

The critical barrier to progress of our current knowledge is the lack of implementation of randomized controlled therapy trials in the hospital setting. Funding from the Acute Care Research grant for salary support, patient treatment costs and supportive personnel will allow us to address these very important questions regarding the appropriate PT approach to patients admitted to the hospital with a stroke. It is an honor to be a practicing clinician who is provided with the support and ability to partake in the research that shapes our field. The proposed project has completed a successful Phase I which demonstrated improved functional gains with increased frequency and intensity of therapy services post stroke. The evaluation of these early, intense and frequent therapy services with an acknowledgement of the importance of cerebral perfusion will assist in developing the interventions that will drive the hyperacute field of neurorehabilitation.

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