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Title: Telehealth After Stroke Care (TASC): Integrated multidisciplinary access to post-stroke care

Study Purpose and Rationale:

Improvements in stroke prevention, acute treatment, and organized systems of care for acute stroke are all contributing to declines in stroke mortality observed over the past decade. However, with increasing survival after stroke and expected increases in stroke related to population aging, the prevalence of stroke is projected to increase by 3.4 million in 2030. Despite these projections, there has been little research on post-acute care models for stroke survivors. Stroke incidence, mortality, and recurrence vary by race. African Americans, Hispanic Americans, and American Natives have higher risk of stroke than Caucasian Americans. Projected increases in stroke prevalence also vary by racial and ethnic category, with the largest rises expected in men and women of Hispanic ethnicity and African American race. Systems of care for stroke survivors must be developed with mechanisms to identify stressors and address racial disparities in stroke outcomes. Hypertension is the most important modifiable risk factor for stroke. Small reductions in systolic BP after stroke (5 mmHg) are associated with greater than 20% reduction in recurrent stoke risk. However, available data suggests that hypertension remains poorly controlled after the incident stroke. Among published studies, race, socioeconomic status, medication adherence, self-efficacy, marital status, and level of independence have been associated with BP control. The most effective interventions for BP control in the general population of African Americans target more than one barrier to control, and little is known regarding Hispanic Americans. Telehealth and tele-monitoring have shown benefit for improving BP control in the general population. Successful interventions include those that incorporate a team-based approach to care, and those that utilize telehealth and home BP monitoring. Among stroke patients, isolated behavioral and educational interventions have not been shown to impact BP control. Organizational interventions, such as those incorporating collaborations among multidisciplinary teams, providing integrated care service with quality management show mild improvements in BP control. To our knowledge, no studies providing accessible integrated care including telehealth and remote BP monitoring with multidisciplinary teams have been conducted and shown to reduce racial disparities in post-stroke BP control, and examine health outcomes. A multidisciplinary team approach that integrates care within a telehealth intervention has potential to improve BP control and reduce racial disparities in care. As the prevalence of post-stroke survivors increases, there is a need to develop efficient and effective post-stroke care; one that not only addresses the most important modifiable risk factor to prevent recurrent stroke but enhances medication self-efficacy and access to care in the highest risk populations. An integrated care model that provides health self-management, home BP monitoring and easy access to a multidisciplinary team including nursing, pharmacy and stroke neurologists to facilitate adherence to treatment may improve post-stroke outcomes. Telehealth has been identified as a low-cost, easy access to care method, with potential for geographically wide networks.

Study Design:

We plan to develop and integrate a telehealth intervention that incorporates evidence-based strategies for BP control, and enables self-efficacy through remote BP monitoring, education, and multidisciplinary care inclusive of pharmacy and nursing. In this pilot trial, we will compare early post-stroke BP management using an integrated multidisciplinary telehealth model, Telehealth After Stroke Care (TASC), to usual care with a primary outcome of BP control defined by the mean 24-hr blood pressure through remote monitoring at 3 months and survey patient reported outcomes. We will identify stroke patients hospitalized for ischemic and hemorrhagic stroke. A study investigator will approach the patient and introduce the study and if the participant is interested informed consent will be obtained. We will conduct the surveys in all ischemic and hemorrhagic stroke patients who agree to participate. If informed consent is obtained, the study investigator will ask the patient to complete the surveys and they will be recruited to follow up after hospitalization and randomized to TASC integrated multidisciplinary care or usual post stroke follow up. NYP will provide home blood pressure monitoring

kits to patients randomized to the TASC arm for the first three months and a telehealth satisfaction survey will be completed at the end of the study by both groups. We will be collecting information on demographic and clinical characteristics in addition to the surveys and blood pressure results in a REDCap database.

Statistical Procedures:
All data will be combined, coded, and kept secure in a secure database such as REDCap. As this is a preliminary trial with a small sample, estimates derived will be used to plan the subsequent larger confirmatory trial. Descriptive statistics will characterize the randomized patients completing surveys and outcome assessments. Generalized linear modeling will evaluate the primary clinical outcome (BP <140/90 mmHg) 90 days post discharge as a function of treatment, race and the interaction of treatment and race. Moderating effects of race will also be evaluated for the secondary outcome. Survey results will be analyzed with Chi-square to determine the proportion of yes and no answers. The open-ended answers within the survey will be assessed to determine if central themes can be determined from the answers.

Protections in place to safeguard participants' privacy while information is being collected:
All materials will be collected and stored in a locked office in the Neurological Institute. Electronic data will be stored on the encrypted neurology server. Surveys in the hospital will be conducted privately. Telehealth visits will be provided by a secure Telehealth system. The patients will be aware of their right to refuse to participate in services delivered via telemedicine and the alternatives and potential limitations of participating in a telemedicine visit versus a face-to-face visit. The patients will also be informed of the surveyor’s and/or provider’s current location and the names of all persons participating in the telemedicine service and their role in the encounter.

Study Procedures:
In this pilot trial, we will compare early post-stroke BP management using an integrated multidisciplinary telehealth model, Telehealth After Stroke Care (TASC), to usual care with a primary outcome of BP control defined by the mean 24-hr blood pressure through remote monitoring at 3 months and survey patient reported outcomes. Participants randomized to only the standard usual care will receive a one and three month post stroke follow up appointment post discharge and no 24 hr blood pressure remote monitoring. We will identify stroke patients hospitalized for ischemic and hemorrhagic stroke. After obtaining permission from the patient's treating Physician, the study investigator will approach the patient and introduce the study and if the participant is interested informed consent will be obtained. We will conduct the patient reported outcomes surveys in all ischemic and hemorrhagic stroke patients who agree to participate. If informed consent is obtained, the study investigator will ask the patient to complete the surveys. They will be recruited to follow up after hospitalization and randomized to TASC integrated multidisciplinary care through telehealth visits with remote blood pressure monitoring or usual post stroke follow up. NYP will provide home blood pressure monitoring kits to patients randomized to the TASC arm for 3 months and at three months in the control group. A telehealth satisfaction survey will be completed at the end of the study in both groups. Information on demographics and clinical characteristics will be obtained from the medical records and entered into a REDCap database.

How participants will be recruited:
Any person over the age of 18 who is hospitalized for an ischemic or a hemorrhagic stroke and has hypertension will be considered for this study. People who are unable to consent will not be considered. The patient’s primary treating physician will be asked for permission to approach the patient. If yes, the

treating Physician will approach and ask the potential participant if they would be interested in participating in a research survey. A study team member then will approach the stroke patient and describe the study. A study team member will obtain one on one verbal consent to participate in the study. Informed Consent Process will begin with a concise and focused presentation of the key information about the research study. Potential subjects will have an opportunity to discuss the information provided. Informed Consent Process presents information in sufficient detail relating to the research study. We plan to enroll subjects in their primary language. The informed consent process will be conducted in Spanish or English corresponding to subject's language preference. For participants fluent in Spanish, A bilingual study coordinator fluent in both Spanish and English will facilitate the conversation during the consent process with the research team and participant.
Target enrollment: 50

How participants' written consent will be obtained:
Informed consent will be obtained by a member of the research team. Recruitment will take place in the in-patient Stroke unit at New York- Presbyterian/Columbia University Medical Center. All stroke in patients who meet the criteria will be considered for the study and approached for participation during their inpatient stay. The criteria for being considered for the study include (1) stroke patient at CUIMC, (2) over the age of 18, (3) presence of hypertension (by clinical history or hospital BP 140/90 on two occasions), (4) patient is conscious and able to consent. The criteria will be verified by the treating stroke physician. A study team member will explain the purpose of the study, ask the patient if they would like to participate, and then conduct the informed consent process. The patient reported outcome surveys can be conducted as an interview for patients who are not able to read, whether due to literacy or due to stroke symptoms. The survey will be available on an iPad to enter responses. People who are not able to consent for themselves, who are unconscious, or who have stroke symptoms influencing their ability to communicate will not be approached for the study.

Research Question(s)/Hypothesis(es):
Primary Aims:
1. To develop and establish feasibility of the TASC model.
Hypothesis: A multidisciplinary platform including nursing, pharmacy and physician care will enhance clinical processes and health outcomes.
2. To obtain preliminary evidence of efficacy of an integrated telehealth approach to blood pressure management after stroke.
Hypothesis: Remote BP monitoring and telehealth visits with a multidisciplinary approach will enhance BP control and promote self-efficacy.
Secondary Aims: To explore the effect of the TASC intervention on patient-reported outcomes.

Potential Risks:
A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. However, we do not expect more than minimal risk. All data will be collected on standardized data collection forms and/or entered in REDCap, a secure database with webserver access and data back-up and recovery. Hard copies of surveys will be stored securely in locked locations and electronic data will be stored on encrypted neurology servers. Only private investigators and trained data abstractors will have access to the database containing patient information. For all patients completing the Depression tool survey and who endorse or experience emotional distress, we will provide a referral for a mental Health professional and alert their primary care provider if they have one and are interested in treatment. They will be provided with a list of mental health resources in the community.

Potential Benefits:
Potential benefits for patients include improved access to care and blood pressure management given structured and evidence-based assessment and monitoring for post stroke outcomes.