Title Stroke Telemedicine Outpatient Program (STOP) for Blood Pressure Reduction

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Protocol Version 1.6

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Population:	Patients discharged home from Memorial Hermann Hospital
Number of Sites:	One – UT Houston
Study Duration:	30 months
Subject Duration:	6 months

Background and Significance

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.[1] However, with increasing survival after stroke and expected increases in stroke incidence related to population aging, the prevalence of stroke is projected to increase by 3.4 million in 2030.[1, 14] Despite these projections, there has been little research on post-acute care models for stroke survivors.

Stroke incidence, mortality, and recurrence vary by race.[1, 15] African Americans, Hispanic Americans, and American Natives have higher risk of stroke than Caucasian Americans.[8-11, 16] 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.[14] Systems of care for stroke survivors must be developed with mechanisms to identify and address racial disparities in stroke outcomes.

Hypertension is the most important risk factor for ischemic stroke and hemorrhagic stroke.[1] Small reductions in systolic BP after stroke (5 mmHg) are associated with greater than 20% reduction in recurrent stoke risk.[3] However, available data suggests that hypertension remains poorly controlled after the incident stroke. A report from the Reasons for Geographic and Racial Differences in Stroke **(REGARDS)** observational study revealed that risk factor awareness and control were poor in participants who self-reported a history of stroke.[5] Only 66.7% of stroke survivors had controlled BP, and African American stroke survivors were more likely to have undiagnosed hypertension and uncontrolled hypertension (among those treated) than White stroke survivors. Baseline visit data from the Secondary Prevention of Small Subcortical Strokes **(SPS3)** trial support REGARDs data. Among US participants, 44% of ischemic stroke survivors had controlled BP three months after stroke and African Americans were more likely to have uncontrolled BP.[7] Investigators from The Differences in the Imaging of Primary Hemorrhage based on Ethnicity or Race **(DECIPHER)** project reported poor BP control 30 days and 1 year after hemorrhagic stroke.[6] In this study, BP was controlled (less than 140/90) for 47.2% of participants at 30 days and for 41.7% one year after stroke, and BP control was poor in African Americans.

Factors associated with BP control in African Americans have been studied extensively. These include social and economic factors, condition and therapy-related factors, health care system and clinician factors, patient-related factors, and patient-physician relationship factors.[17, 18] Uncontrolled BP may be specifically related to medication cost, access to healthcare, access to providers, medication complexity, patient beliefs and perceptions, patient educational achievement and socioeconomic status, patient response to and side effects of medications, sodium intake, patient depression and demoralization, perceived racism and discrimination, social networks and support, physician prescribing practices, physician communication and empathy, neighborhood segregation, and others.[18-25]

There are fewer studies of uncontrolled BP in stroke survivors overall, but among published studies, race, socioeconomic status, medication adherence, self-efficacy, marital status, and level of independence have been associated with BP control.[5, 7, 26-28] Access to care, medication adherence, and medication prescribing patterns do not fully explain disparities in BP control in stroke survivors. Among 2972 insured stroke survivors followed in the Kaiser Quality Improvement in Stroke Prevention **(QUISP)** study, odds of BP control in African Americans was 41% less than that observed in White Americans despite similar rates of medication adherence and attendance at outpatient visits and higher median number of medications.[29] Disparities in control may be explained by physiologic factors such as duration of hypertension, differential response to medications according to race, and medical comorbidities such as sleep apnea and chronic kidney disease.[30-33] The presence and differential impact of post-stroke depression, cognitive impairment, social isolation, and caregiver burden may add to the complexity of BP control in hypertensive stroke survivors.

The most effective interventions for BP control in the general population of African Americans target more than one barrier to control. Successful interventions include those that incorporate a team-based approach to care, that utilize a pharmacist or health professional other than the primary care provider, and those that utilize telehealth and home BP monitoring.[21, 24, 34-39] Among stroke patients, isolated behavioral and educational interventions have not been shown to impact BP control.[12] Organizational interventions, such as those incorporating collaborations among multidisciplinary teams, integrated care services, revision of pharmacists' roles, and/or knowledge and quality management protocols show evidence supporting mild improvements in BP control.[13, 40] To our knowledge, no studies have shown benefit for reducing disparities in BP control among stroke survivors.

We will implement a pilot trial of a telehealth intervention for BP control at the Memorial Hermann Hospital-TMC campus focusing on patients at highest risk for uncontrolled blood pressure. The intervention will address general and stroke-related factors associated with racial disparities in BP control. We will assess feasibility of implementation of the trial and will use the measures and outcomes assessed in the pilot to examine knowledge gaps.

Specific Aims

Aim 1 will focus on the identification of hospitalized ischemic and hemorrhagic stroke patients at risk for uncontrolled BP after hospital discharge.

- We will develop a checklist to be completed by the discharge nurse navigator or social worker for early identification of stroke inpatients at risk for uncontrolled BP. The checklist will include existing information from the patient medical record (race and insurance) and clinical information including stroke type and etiology in order to document the presence of known risk factors for uncontrolled BP. Key known risk factors include uninsured status, Medicaid payer status, hypertensive intracerebral hemorrhage, small vessel ischemic stroke, and patients on ≥ 2 hypertensive medications. The checklist will be used to determine which patients should be screened for study eligibility.

Aim 2 will shift from the planning portion of the study to the pilot trial, which will simulate a larger trial and allow evaluation of intervention components and outcome measures and estimation of effect sizes and attrition rates.

- Aim 2a: To examine the suitability of key study components and outcome measures intended for a future larger trial, we will randomize 50 patients to the intervention and 50 patients to usual care. We will determine the proportion of randomized patients who complete the intervention visits, the proportion of patients (by group) who complete the outcome assessments, and barriers to intervention and 6-month outcome assessment completion.
- Aim 2b: To examine the suitability and ease of use of the telehealth tool and effectiveness of components of the intervention, we will develop a CRF to capture patient feedback to be integrated into the design of the future, larger trial.
- Aim 2c: To estimate key parameters needed to adequately power a larger randomized trial, we will calculate the effect of the intervention on the ambulatory systolic blood pressure at 6 months relative to usual care; the probability using Bayesian methods that this effect size exists; the enrollment rate; and the attrition rate.

Study Procedures:

Eligibility Criteria

Ischemic and hemorrhagic stroke patients (N=100) identified as potentially eligible by the checklist (at least one of the following high risk criteria: uninsured, Medicaid payer status, small vessel ischemic stroke, hypertensive ICH, planning on discharging on ≥2 hypertension medications) will be eligible if they also meet the following inclusion criteria: age ≥ 18; presence of hypertension (by clinical history or hospital BP ≥130/80 mmHg on two occasions); plan to discharge home after stroke; ability to provide consent (patient or caregiver); ability to communicate in English. Exclusion criteria will include modified Rankin scale > 4 at the time of enrollment (severe disability), life expectancy < 1 year or terminal illness, eGFR < 30 at time of discharge, pregnancy, symptomatic flow limiting carotid stenosis without plan for intervention; urine toxicology positive for cocaine or methamphetamine or history of use; long-term BP goal ≥ 130/80 mmHg according to clinical team; and inability to comply with study procedures * (severe expressive language impairment, deafness, blindness, or other physical; cognitive; or social issues limiting ability to adhere to procedures).

Screening and Randomization

Sequential eligible patients will be approached prior to discharge to assess their interest in participating in the trial. Informed consent will be obtained from patients. Caregivers will provide consent for patients with aphasia who are otherwise eligible. Baseline assessments of socioeconomic status (education and income), medication adherence, medication adherence self-efficacy, cognition, and social support will be completed prior to randomization. We will use an internet-based system to randomize patients (1:1) to intervention versus usual care using a block design with permuted blocks of 2 to 4. The randomization allocation sequence will be developed by a statistician not involved in enrollment procedures. We will stratify based on insurance status (insured vs uninsured) and race (African American vs other) to assure that groups are balanced with respect to baseline risk. Consort criteria for the design of parallel group randomized trials will be followed.

Intervention

Components of the telehealth intervention will target behaviors associated with racial disparities (African American focused) in BP control. At the time of discharge, intervention patients will receive a package containing an iPad (with a data plan) and a blue tooth enabled blood pressure monitor that allows automatic transmission of encrypted BP data to the study team (QardioARM). [39] Patients will be allowed to use their own smart device if it is compatible with the BP device). Patients and/or caregivers will be instructed in use of equipment and the first video telehealth visit will be arranged. They will complete questionnaires including a depression screen, a dietary assessment, a cognitive screen, and a sleep apnea screen prior to discharge. Patients will receive a phone call at 72 hours by the discharge nurse navigator or social worker (standard of care) to assure that they have received their medications and follow-up appointments. The first telehealth visit will occur 7 days after discharge. A stroke prevention-trained nurse practitioner **(NP) or MD,** social worker **(SW),** and pharmacist will attend this video telehealth visit. The NP will review the participant's hospital records and depression, dietary, and sleep apnea screens, will reinforce the care plan based on patient-specific needs. The NP or MD will counsel patients on salt reduction, the Mediterranean diet, and the importance of diet and exercise for stroke prevention. The NP (or MD) and pharmacist will review the BP data to determine the need for medication adjustment. The pharmacist will discuss side effects and

interactions. Treatment of hypertension and selection of BP lowering medications will be in accordance with latest published guidelines for BP management.[42]. The SW will assess the need for medication assistance and other resources. The care plan will be shared with primary care providers **(PCP)** and patients will be referred to a PCP if they do not have one. The SW will assist uninsured patients in applying for Texas County Indigent Care programs.

Participants will be prompted to transmit BP logs through the telemonitoring device every 2 weeks until average BP is < 130/80, then monthly thereafter. Uncontrolled BP will prompt a call from the pharmacist to discuss medication adherence and the need for further titration. Subsequent video telehealth visits for intervention patients will be attended by the NP (or MD) and pharmacist 1 month, 3 months, and 5 months after enrollment. Care plans will be reviewed and medication and lifestyle adherence will be assessed. Medications will be adjusted as appropriate. Participants will complete electronic health care utilization and recurrent vascular CRFs using the iPad at 3 months and 6 months (final outcome) Participants will receive educational messaging once every other week throughout the study period. Messages will be sent to the participants' cellular phones. The messages will contain one of the following: a reminder to monitor BP, information from about lifestyle and diet for BP reduction, or a message from the pharmacist about medication adherence. Final outcome assessments (detailed below) will occur at 6 months.

Uninsured Patients (5/8/2019):
An Internal Medicine Consultant will be utilized as an advisor when complex medical non-neurologic issues arise for patients who do not yet have a primary care provider. The consultant will join the telehealth visits as appropriate to provide recommendations for management of complex medical issues that can be managed in the ambulatory setting.

Usual Care (Control) Group

Participants randomized to usual care will complete questionnaires including a depression screen, a dietary assessment, a cognitive screen, and a sleep apnea screen prior to discharge. A summary of the assessments will be given to the patient and they will be instructed to follow-up with their PCP and to monitor their BP. They will be contacted by the discharge nurse navigator or social worker at 72 hours to as per usual care to determine if they have received their medication and made their appointments. They will be offered a standard of care hospital follow up appointment with a stroke neurologist or nurse practitioner at the clinic. The RC will contact participants at 30-days, 90-days, 150-days to encourage continued participation. The RC will complete a telephone CRFs to obtain information about readmissions, hospital visits, and recurrent vascular events at 30 days and 90 days. Final outcome assessments (detailed below) will occur at 6 months.

Weekend and Holiday Discharges (Both Groups)

Eligible patients may be consented during the week but subsequently discharged on a weekend or holiday when study staff are not available to deliver equipment or provide counseling. Patients will be randomized on the day of discharge, however, if they are randomized to the intervention group, the telemonitoring equipment will be sent to them (in person or via Fedex) on the first business day after discharge. The pharmacist will provide counseling about discharge medications on the first business day after discharge. The nurse navigator or social worker call will take place at 72 hours after discharge as per usual.

Variables and Outcome Assessment
Baseline demographic and clinical characteristics will be abstracted from inpatient charts, supplemented by a study CRF collected prior to randomization. Demographic variables will include age, sex, self-reported race, self-reported ethnicity, level of education, household income, insurance status, and marital status. Clinical variables will include stroke subtype, stroke etiology, prior stroke or TIA, treatment with IV tPA, endovascular therapy, admission National Institutes of Health Stroke Score, pre-stroke modified Rankin scale, presence of stroke risk factors (hypertension, diabetes mellitus, tobacco use, hyperlipidemia, obstructive sleep apnea, atrial fibrillation, coronary artery disease, systolic heart failure, substance abuse) other medical co-morbidities (obesity, chronic kidney disease), Barthel Index at baseline, Body Mass Index (BMI) at discharge, and the number of BP medications at discharge. Psychological, cognitive, and behavioral variables will include depression (Patient Health Questionaire-9); anxiety (Generalized Anxiety Disorder-7); cognitive impairment (Montreal Cognitive Assessment), self-efficacy (Medication Adherence Self-Efficacy Scale - MASES); medication adherence (Morisky Medication Adherence Scale - MMAS); and social support (Stroke Social Network Scale).[43-47]

Primary Clinical Outcomes
The primary clinical outcome will be the daytime ambulatory systolic blood pressure at 6 months. Secondary clinical outcomes will include the following: daytime ambulatory diastolic blood pressure, nighttime ambulatory systolic and diastolic blood pressure; BMI at 6 months; recurrent vascular event rate (stroke, myocardial infarction, acute cardiac death); and acute healthcare utilization rate (hospital readmission and acute care visits to emergency room and/or urgent care).[42] The 6- month behavioral outcomes will include change in self-efficacy for taking medication as prescribed, medication adherence, and caregiver burden. Patient satisfaction will be assessed using scores obtained from the Patient Telemedicine Satisfaction Survey.[48]

Outcome Assessments
All enrolled patients will have final 6-month outcomes either in-clinic or by home visit with the research coordinator. Final BP will be assessed using a validated ambulatory blood pressure monitor (ABPM). The patient will be fitted with the ABPM at the final visit and will receive a Fedex envelope in which to return the ABPM after 24 hours. Weight and height will be assessed for BMI. Final healthcare utilization and recurrent vascular event CRFs will be completed and behavioral outcomes will be assessed using MASES, MMAS, and the Zarit Caregiver Burden Questionnaire.[44, 45, 50] Satisfaction with telehealth visits will be assessed using the Telemedicine Satisfaction Survey (intervention arm). Patients will be compensated for final study visits ($50).

Sample Size Estimation and Statistical Approach

Sample size estimates are based on feasibility of recruitment in a 1 year study period and anticipated attrition rates, based on our experience recruiting similar patient populations. Estimates derived from the current pilot trial in the form of posterior distribution will form the basis for simulations in planning the subsequent, larger, confirmatory trial.

Descriptive statistics will characterize the proportion of randomized patients completing assessments at baseline, 7 days (intervention), 1 month (intervention), 3 months (intervention), 5-months (intervention) and 6 months (all). Tabulation of obstacles to the intervention and completion of the outcome assessments will permit appropriate revision of the intervention for the subsequent, larger confirmatory trial. Descriptive statistics will characterize scores on the Telemedicine Satisfaction Questionnaire. Inspection of patterns of patient responses to specific

items will permit modification of the telemedicine approach for the subsequent, larger, confirmatory trial. Generalized linear modeling will evaluate the primary clinical outcome difference in ambulatory daytime systolic BP between the two groups 6 months post-discharge as a function of treatment, race, the interaction of treatment and race, the interaction of insurance status and race. Secondary analyses will evaluate nighttime systolic, and daytime and nighttime diastolic ambulatory BP, BMI, recurrent vascular event rate, acute healthcare utilization rate, self-efficacy, medication adherence, and caregiver burden.

Risks and Benefits:

Usual care participants may be at higher risk for complications associated with elevate blood pressure, especially if they do not establish care with a primary provider. However, this is not more risk than what occurs typically. In fact, they will be offered a standard of care hospital follow up visit with the clinic and with 6 month study blood pressure assessments, usual care patients may have more MD contact, and opportunities for referral to primary care, than typical.

There is potential for adverse effects associated with aggressive blood pressure reduction. We have chosen a conservative and currently AHA recommended BP goal and will monitor for hypotension, syncope, and falls that may result from hypotension. These are included these as safety outcomes.

Participants may be burdened by numbers of surveys and telephone calls. We will give breaks and minimize number of forms requested to obtain necessary data. Telephone calls will be brief.

Another potential risk of this study is breach of confidentiality. This risk will be minimized with confidentiality measures described below.

All patients, including usual care group, may benefit from ambulatory blood pressure assessments and communication with primary care providers about risk factor goals.
More patients will be given access to specialty care (uninsured and underinsured) than would be typically.

Costs, Reimbursement, and Compensation:
Participants will receive 50 dollars for time and travel associated with the 6-month visit. They will also receive a parking voucher at for their 6 month visit.

Human Subject Issues:
Consent will be obtained from patients and authorized representatives.

Patient Confidentiality and Data Safety:
Patients will be assigned a code which will be kept in a password protected excel spreadsheet with patient name, date of initial hospital visit, and medical record number. Clinical data will be entered into RedCAP using patient code. Only the Principle investigator and data abstractors will have access to the codebook with patient identifiers.

The file containing PHI will be deleted 5 years after completion of the study.

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