Rationale and Design of the Hispanic Secondary Stroke Prevention Initiative:  
A Community Health Worker Intervention among Latino Patients at Risk of Recurrent Stroke

Olveen Carrasquillo, MD, MPH
BreAnne Young, MSPH, Stuti Dang, MD, MPH
Orieta Fontan
Natalie Ferras, MS, MHC
Jose Romano, MD
Sonjia Kenya, EdD, MS, MA

1Department of General Medicine, University of Miami Miller School of Medicine, Miami, FL
2Division of Geriatrics & Palliative Medicine, University of Miami Miller School of Medicine,
3Department of Neurology, University of Miami Miller School of Medicine, Miami, FL

Corresponding Author:
Olveen Carrasquillo, MD, MPH
Don Soffer Clinical Research Center
University of Miami Miller School of Medicine
1120 NW 14th St, Suite 962
Miami, FL 33136
P: 305.243.5505; F: 305.243.7096
E: oc6@med.miami.edu

Running Title: Hispanic Secondary Stroke Prevention RTC
Word Count: 4,973
Rationale and Design of the Hispanic Secondary Stroke Prevention Initiative:
A Community Health Worker Intervention among Latino Patients at Risk of Recurrent Stroke

ABSTRACT

Background: Hispanic-Latino populations face a disproportionate stroke burden, and are less likely to have sufficient control over stroke risk factors in comparison to other ethnic populations. A promising approach to improving chronic health outcomes has been the use of Community Health Workers (CHWs). Objective: This study aims to evaluate their effectiveness in a randomized controlled trial setting. Methods: The Hispanic Secondary Stroke Prevention Initiative is an Randomized Clinical Trial of 300 Latinos from South Florida whom have experienced a stroke within the last 5 years. Participants randomized into the CHW intervention arm receive health education and assistance with healthcare navigation and social services through home visits and phone calls. Results: Outcomes at 12 months include changes in systolic blood pressure, LDL, HbA1c, and medication adherence. Conclusions: HiSSPI is one of the first RTCs to examine CHW-facilitated stroke prevention and will provide rigorous evidence on the impact of CHWs on secondary stroke risk factors among Latinos having had a stroke.

Funding: The project is supported by an award from the National Institute on Minority Health and Health Disparities R01MD009164

Trial Registration: The protocol is registered in ClinicalTrials.gov: NCT02251834

Keywords: Hispanic; Latino; Stroke; Health Care Support; Community Health Workers; Randomized Trial; Health Care Disparities
INTRODUCTION

Background

With 795,000 annual cases, stroke is a leading cause of death and the single greatest cause of preventable adult disability in the United States [1]. Medical costs, medication, and lost productivity resulting from stroke cost an estimated $34 billion annually [1]. Moreover, as our population ages, the stroke incidence is expected to increase dramatically. By 2035, an additional 3.7 million people are expected to suffer from a stroke, resulting in a two-fold increase in healthcare costs [2].

Nearly 23% of stroke cases are recurrent strokes [1], and the risk of recurrence ranges from 14 to 40% within a five-year period following the first attack [3]. Further, the adverse impact of recurrent stroke is more devastating than the first-time attack; the fatality rate during the first 30 days after a recurrent stroke is more than double the fatality rate among first-time stroke victims [4]. Research indicates that a majority of recurrent stroke cases can be prevented by better control of modifiable risk factors [5]. However, Hispanics (a term we used interchangeably with Latinos) face a disparate burden of stroke and stroke risk factors in comparison to non-Hispanic whites [6,7,8]. For example, hypertension, diabetes, and limited physical activity account for more strokes among Hispanics than any other racial or ethnic group [9,10,11].

Hispanics are also less likely to receive evaluation or treatment for hypertension or diabetes and are also less likely to maintain their treatment regimens after diagnosis [10,12,13]. Socioeconomic barriers such as lack of insurance, limited language, competing demands, and inadequate care access also disproportionately impact the Hispanic population which further compound their health risks [14,15].
Prior Work

A promising approach to improving disease outcomes among Hispanics has been the use of Community Health Workers (CHWs)\[15\]. CHWs are trusted members of a target community who understand the local health beliefs and recognize the social and historical experiences shaping their communities \[15,16\]. They serve as links between their communities and the healthcare system, acting as patient advocates, delivering prevention education and counseling services, and linking people to the appropriate care facilities \[17\]. There has been increasing evidence on CHWs for a variety of preventive and chronic conditions \[16\], including knowledge and behaviors aimed at vascular risk factors and self-management \[18,19,20\]. While more limited, randomized studies have also shown CHW interventions can improved physiological outcomes such as glycemic control \[21\].

Another approach of increasing interest in addressing disparities has been use of mobile health devices and technologies (mHealth). These approaches allow clinicians and researchers to provide health services through platforms such as text messaging, web-based services and dedicated phone apps \[22\]. With over 80% of minority adults having a cellular phone for phone calls or text messaging \[23\] mHealth technologies are a potentially cost-effective way of delivering some health services to underserved populations \[24,25,26\].

Study Goals

Combined CHW interventions and mHealth approaches may be one potentially innovative approach to address care of Hispanic stroke patients. To examine the impact of such an approach in prevention of secondary stroke among Latinos, we designed a clinical trial consisting of a combined CHW and mHealth intervention. We examine the
effectiveness of such a combined intervention in lowering of systolic blood pressure (SBP), which is the most important modifiable risk factor for recurrent stroke.

METHODS

Overview and Conceptual Design

The Hispanic Secondary Stroke Prevention Initiative (HiSSPI) is a randomized single-blind parallel controlled trial of 300 Latino patients who have experienced an ischemic or hemorrhagic stroke in the last 5 years. The study examines the impact of a combined one-year CHW and text messaging intervention on reducing risk factors for a recurrent stroke. The theoretical foundation of the HiSSPI study is grounded in the Chronic Care Model, an organizational framework for restructuring chronic disease management to create partnership between health systems and communities [27]. The focus of our design emphasizes a community-based approach to successfully linking individuals in underserved populations with effective healthcare services [16,28]. The study was reviewed and approved by the University of Miami Institutional Review Board.

Study Setting

The study takes place in Miami-Dade County, where Latinos compromise 68% of the population [28,29]. Unlike other parts of the country, the Latino population of the county is highly diverse, having ethnic origins from most countries in Latin-America. As an example, Miami-Dade has the highest number of Cubans, Columbians, Hondurans and Peruvians in the US. [30].

For this study, patients are recruited from two health systems in Miami’s Civic Center Health District: the University of Miami Health System (UHealth) and Jackson Health System (JHS). UHealth is a private, University-owned not-for-profit healthcare system, and
JHS is a public safety-net hospital system. Both are quaternary care institutions and major teaching sites for the University of Miami Miller School of Medicine. Additionally, both systems are Florida-designated Primary Stroke Centers and combined see over 1,000 stroke admissions per year.

**Hiring and Training of CHWs**

The lead CHW for HiSSPI (OF) is a Florida-certified CHW with several years of experience [31]. She has worked with our team on a previous diabetes intervention study [21]. In selecting additional CHWs to work on HiSSPI, we prioritize candidates with knowledge of the local community and prior experience in service delivery (e.g. social, medical, education, consumer) to Latino populations. Other important selection criteria include maturity, communication skills, and prior positive work evaluations. CHWs also need to meet the basic requirements to be a Florida-certified CHW. A personal vehicle and valid driver’s license are also required.

For HiSSPI training, CHWs need to complete “Promoting Healthy Choices and Community Changes,” a three-hour online training provided by the Department of Health and Human Services Promotores de Salud Health Initiative [32]. This four-part learning program gives CHWs health training on reaching vulnerable, low-income and underserved members of Latino and Hispanic populations. For the cardiovascular disease specific training, we use CHWs training materials from the CDC and NHLBI, as well as our own CHW training material [33,34,35]. Additional training on stroke and stroke prevention is also provided by the stroke neurologist on our team (JR).

CHWs also receive ongoing training, including continuing education modules on topics such as motivational interviewing, clinic and insurance navigation, cardiovascular
disease care, and social support resource navigation. Additionally, weekly meetings are held with a CHW supervisor to obtain performance feedback and discuss individual cases. CHWs are further required to complete all UM/NIH required training in human subject’s research and HIPPA, as well as specific research training we developed for CHWs [36]. Table 1 provides additional details on these training modules.

Table 1. Description of HiSSPI Community Health Worker training components.

<table>
<thead>
<tr>
<th>Training</th>
<th>Session Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Miami Basic Research Training</td>
<td>- Collaborative Institutional Initiative Training</td>
</tr>
<tr>
<td></td>
<td>- Human Subjects Research</td>
</tr>
<tr>
<td></td>
<td>- Health Information Privacy</td>
</tr>
<tr>
<td></td>
<td>- REDCap (Research Electronic Data Capture) Database Software Training</td>
</tr>
<tr>
<td>Community Health Worker Certification</td>
<td>- 500 clock hours of formal work and/or volunteer experience providing community health worker services in any of the following domains of practice within the last 5 years:</td>
</tr>
<tr>
<td></td>
<td>- Communication and Education: Tasks related to community and education</td>
</tr>
<tr>
<td></td>
<td>- Resources: Tasks related to linking community members with available health/social services</td>
</tr>
<tr>
<td></td>
<td>- Advocacy: tasks related to advocating for the community’s health/social service needs</td>
</tr>
<tr>
<td></td>
<td>- 30 clock hours of content specific training as follows:</td>
</tr>
<tr>
<td></td>
<td>- Communication and Education: 4 hours</td>
</tr>
<tr>
<td></td>
<td>- Resources: 4 hours</td>
</tr>
<tr>
<td></td>
<td>- Foundations of Health: 4 hours</td>
</tr>
<tr>
<td></td>
<td>- Professional Responsibility: 4 hours</td>
</tr>
<tr>
<td></td>
<td>- Electives (may related to any of the performance domains): 10 hours</td>
</tr>
<tr>
<td>Department of Health &amp; Human Services Office of Minority Services</td>
<td>- Promotores de Salud Health Initiative – “Promoting Healthy Choices and Community Changes”</td>
</tr>
<tr>
<td></td>
<td>- Unit A: Understanding Health Decisions</td>
</tr>
<tr>
<td></td>
<td>- Unit B: Helping People Make Health Choices</td>
</tr>
<tr>
<td></td>
<td>- Unit C: Understanding Changes in the Community</td>
</tr>
<tr>
<td></td>
<td>- Unit D: Health People Make Changes in the Community</td>
</tr>
</tbody>
</table>
Additional Training

- FL CHW Coalition – PCORI Partnership to Train Community Health Workers in Patient Centered Research, 7 hours
  - Patient-Centered Outcomes Research: Rationale, definitions, role of CHWs
  - Clinical Trials: Types, randomization
  - Data Collection Methods: Qualitative and quantitative methods, avoiding bias
  - Informed Consent Process
  - Study Protocol and Reporting: Working in a research team
  - Disseminating Study Results: To study participants, how CHWs can contribute to research manuscripts
  - Ethics: Institutional Research Boards, privacy and confidentiality, professional boundaries

- NIH CHW Health Disparities Initiative Health Education Materials & Resources
  - Su corazón, su vida: Manual del promotor y promotora de salud
  - Healthy Heart, Healthy Homes series
  - Salud para su Corazón: Bringing Heart Health to Latinos - A Community Program Guide for Latinos
  - Approaches to Enhance Learning: Using Adult Learning and Popular Education with the NHLBI Heart Health Curricula (webinar)
  - Improving Heart Health with Community Health Workers, Promotores, and Community Educators (webinar)

Study Participants

Inclusion and Exclusion Criteria

Eligible patients are Miami-Dade residents ages 18 or older, who self-identify as Hispanic or Latino, and whom were admitted to the stroke service for an intra-cerebral hemorrhage or ischemic hemorrhagic stroke. Initially the study was designed to recruit patients having had a stroke admission within the last month but a year after the study began, inclusion criteria were expanded to any patient having had a documented admission for stroke with the within the last 5 years.

As the study is aimed at preventing a secondary stroke, the focus is on stroke patients whose initial stroke was not very severe. Stroke severity is assessed using the modified Ranking Scale (mRS) [37,38]. This scale evaluates a stroke patient’s degree of
disability that resulted from the stroke. Patients can score on a range from 0 (no residual symptoms) to 6 (death). For study eligibility patients, must have a modified Rankin Scale (mRS) score no greater than 3 which means they may have up to a moderate disability from the stroke but can still walk without assistance. Patients who have any immediate and/or life-threatening morbidity (e.g. active cancer), an arm circumference greater than 47cm (automated cuffs are unreliable at greater arm widths), or who are currently enrolled in another stroke, cardiovascular, or diabetes study, were excluded from the study.

Recruitment

Participant Selection

Study recruitment uses a multi-modal approach. One approach is having study coordinators track and review data on all stroke admissions at both JMH and UHealth. Study coordinators approach patients, describe the study in person while patients are in the hospital, provide interested participants with brochures detailing the study program, and collect detailed contact information. When not possible in person, this is done after discharge by phone.

As noted above, a year after the study began recruitment, inclusion criteria were expanded to any patient having had a documented admission for stroke with the within the last 5 years. This allowed coordinators to recruit from the stroke clinic through provider referrals. It also allowed for recruitment from an existing stroke registry. Patients enrolled in others stroke projects were also referred to us after they completed participation in their other studies.”

Consent & Enrollment
Identified participants are contacted by phone to assess their interest in participation, evaluate their study eligibility and answer any questions. If the patient is interested and qualifies for participation, they are scheduled for a baseline appointment at the Clinical Research Center at University of Miami. At the appointment, the study is again explained and informed consent is obtained. Vital signs and bloodwork are collected, and a baseline questionnaire is subsequently administered. The project coordinator orally administers the survey and records participant responses into an electronic data management system (REDCap) via laptop computer [39]. To ensure accuracy, baseline sessions are also audio recorded and periodically reviewed for concordance with the data electronically entered.

The full baseline process takes approximately 90-minutes to complete. Participants receive $50 compensation to cover cost of travel and other incidentals following once they have completed full assessment. Upon completing baseline, participants are randomized into one of two research arms by the project biostatistician.

**Randomization & Blinding**

Patients are randomized in a 1:1 ratio to the enhanced care group or the CHW intervention group within each hospital. Within each site, every eligible patient receives a unique study subject ID and pre-specified assignment that corresponds to the ID through randomization. The principal investigator and the program clinical coordinator are blinded to study allocation; however, both participants and CHWs are aware of the group to which each participant was randomized.

**Control Arm – Enhanced Usual Care**
Patients randomized into this group receive enhanced usual care. Depending on the stroke severity, patients at both facilities are either discharged home or to a short-term rehabilitation facility. Prior to release, the patient’s nurse or case manager ensures the patient is scheduled for follow-up with their primary care provider (PCP) and a neurologist; patients lacking a PCP are provided with a list of potential follow-up care facilities and information on how to schedule an appointment.

For this project, participants in the control group also receive health education materials every four months, including the following: “Lo que necesita saber sobre los ataques cerebrales,” an NINDS brochure which explains the causes of stroke, the associated risk factors, and strategies for prevention [40]; “Cómo prepararse para una cita con el medico” a booklet that provides guidance, strategies and tips to Latino patients on ways to better communicate with their physician [41]; and an NHLBI bilingual Latino recipe cookbook, “Platillos Latinos” [42].

**Community Health Worker Intervention**

Participants randomized into the intervention group are assigned to a CHW who provides 12 months of personalized health management support tailored to the unique needs of each patient. Through home-visits and phone contact, CHWs empower patients with skills to manage their health, including medication adherence, physical activity, nutrition, and mental well-being.

**Intervention Enhancement Phase (Months 1-4)**

Conceptually, we divided the CHW intervention in the two phases - the enhancement phase which consists of individualized health education and the maintenance phase. The enhancement phase occurs during the first four months and includes home visits and
phone calls. Although the number of home visits and phone calls is based on individualized decisions, as a rough estimate we plan five home visits in this four-month period and 2-3 phone calls per month. In this phase, the CHW helps the participant identify the issues that may affect his or her overall health and well-being. These can include direct influences, such comorbid health conditions and behavioral risk factors, or more indirect influences, such as socioeconomic status and social context, poor health literacy, barriers in communication, and limited experience navigating the healthcare system. Once these barriers are identified, participants can then develop structured goals and methods for overcoming these obstacles in a manner that aligns with their needs and preferences.

The CHW guides participants through this process by developing individualized health and well-being plans. This includes orienting participants on the principles of self-management and engaging them in a problem-solving process that sets priorities for immediate problem resolution. To ensure participants achieve their personal health goals regarding stroke risk and related risk factors, each CHW is tasked with a number of roles including, but not limited to, health and behavior counseling/coaching, medical service navigation (e.g. scheduling appointments, sending reminders, providing guidance through the health system bureaucracy, etc.), and social support (e.g. identifying local social resources programs such as immigration services, tenant advocacy, and domestic violence programs.). A major component of health education consists of blood pressure home self-monitoring. For participants who do not have a home blood pressure meter, CHWs provide one at no cost to them.

*Maintenance Phase (Months 4-12)*
During the maintenance phase, participants are expected to independently maintain progress on their patient navigation activities and individual lifestyle intervention goals. CHWs contact participants by phone weekly to check on their progress, including the status of participant action plans, updates on lifestyle modifications, and addressing new problems that may have developed. Participants also initiate contact with CHWs when in need of additional support.

Phone calls are also used for patient navigation purposes, including to remind participants of their next doctor’s appointment and facilitate patient contact with their provider offices when needed. Home visits can also occur during this period to ensure participants are meeting their outlined goals. During the final contact, participants are notified that the intervention is concluding and that they will be contacted in the coming weeks to complete their follow-up visit at the University of Miami Clinical Research Center.

**Mobile Technology Component**

The mobile health (mHealth) component of HiSSPI intervention is led by a telehealth expert (SD) in conjunction with the external vendor, GenerationOne [43]. The vendor uses a proprietary mHealth Connect platform that is compatible with most modern cell phones (including basic cellphones and smartphones) and carrier cellphone plans. It allows for messaging through either a web browser or using standard text messages. During outreach and subsequently during informed consent participants are made aware that if randomized to the intervention, they would have the option of also participating in the (mHealth) component of HiSSPI. After the initial CHW home visit, participants are asked if they wish to participate in this component of the intervention. If participant does not have a phone and wishes to participate, CHWs assist in helping them obtain a low-cost phone such as
those offered through the federal Lifeline Program (if income eligible). Participants can also designate their primary care giver and/or close relative to serve as their proxy for receiving messages and providing mHealth information.

Using the mHealth Connect software, we developed a set of project specific user-friendly query routines and informational tips sent to enrolled participants on a daily basis using a 61-day looping routine. The query routines include decision branching logic that allows the system to interact with the participant based on information they provide. Responses from participants are recorded into a clinical dashboard where the CHW is able to track and follow responses and trends for their assigned patients. In addition, the CHWs receive alerts if their participant answers a question out of the expected pre-defined “normal” range. Participants can choose their preferred time to receive these daily questions.

One important component of the queries are those where participants are asked to enter their blood pressure. This data is processed and organized into three response categories – high risk (requires immediate attention, SBP > 180), moderate risk (requires attention, SBP > 140), and low risk, or normal (SBP < 120). For high risk participants, the system alerts the patient to contact their physician or CHW and further sends the patient’s name to the CHW so they are aware that the patient requires a call that same day. In consultation with project physicians (OC), CHWs decide a plan of action for such participants. This may include emergency room referral.

Participants in the moderate risk are provided with automated feedback. The data also alerts CHWs of participants that may require additional follow-up. This information is valuable in helping CHWs further pinpoint the areas of concern thereby creating a more
focused and effective intervention strategy. For example, this may include calling participants and asking about medication adherence or recent changes in diet. When needed, CHWs can also alert the patients’ health care provider about patent BP readings which remain high over several days. They can also help obtain urgent appointment for such patients to see their PCP. CHWs and study team staff do not engage in medication management. Rather, when needed, they facilitate contact and interaction with the participants PCP who then decides if medication changes are needed.

Training of participants in the mHealth intervention is done by the CHWs. The training includes how to interface with the study’s text support system, how to submit daily blood pressure readings and how to use the various medication, diet, and physical activity reminders built into the system. In general, training of participants takes less than 60 minutes but varies depending on the patients’ baseline level of mobile phone use. Participant caregivers are also invited to participate in the training so that they may also be able to assist in the device usage or in some cases become the primary user of the technology for the participant.

With respect to data privacy, users are assigned a unique name for identifying and tracking user identity and the server does not transmit or store any identifying information. In addition, user sessions are terminated after 15 minutes of inactivity. Data within the database server is encrypted using Transparent Data Encryption which protects data at rest and data that is being transmitted over an electronic communications network using 256-bit encryption.

Data Management
Survey data is collected on laptop computers connected to REDCap [33], a secure cloud-based web application for data capturing in both online and offline settings managed by the University of Miami. On a monthly basis, data is reviewed by the study statistician for missing or out of range values and potential inconsistencies. As needed, these discrepancies are reviewed with the study team and statistician.

Sample Size & Statistical Power

We reviewed stroke and cardiovascular intervention programs to estimate the sample size required for this study. Sample size consideration and power analyses were performed based on the primary outcome variable of systolic blood pressure (SBP). Using a standard deviation (SD) of 21 mmHg and with an alpha significance level of 0.05 and using a two-sided t test analyses we estimate that 150 participants per study arm (300 participants total) can detect a minimum difference of 8-mmHg between groups with 91% power. For our secondary outcome of LDL, we will have 80% power to detect a minimum LDL difference of 13 mg/dL given SD = 39 mg/dL. For adherence to antiplatelet/anti-thrombotic therapy, we will have 83% power to detect a 15% difference in adherence among the intervention versus control group.

RESULTS

Primary Outcome

The primary outcome is systolic blood pressure (SBP), measured using the Omron HEM-705CP automated oscillometric device (Lake Forest, IL, USA). Three readings are taken according to the American Heart Association guidelines and the average of the last two readings is used as the blood pressure measurement [44]. The study is powered to test
the hypotheses that at one year the systolic blood pressure (SBP) of participants enrolled in the intervention will be 8-mmHg lower than those in the control (see below).

**Secondary Outcomes**

Secondary outcomes are low-density lipoproteins (LDL), HbA1c (for diabetic participants), and adherence to anti-platelet or anti-thrombotic medications (for ischemic/embolic stroke patients). To assess LDL and HbA1c, a certified phlebotomist obtains 10 cc of blood. Samples are spun and delivered to the University of Miami Diabetes Research Institute for lipid profiling. HbA1c analyses are performed via latex agglutination, and LDL is estimated using the Friedewald equation [45]. For those with triglycerides greater than 400, a direct LDL measurement is performed. Self-reported medication adherence is assessed using a Medication Adherence Scale (MMAS) [46].

**Confounding Variables**

Potential confounders of our primary and secondary outcomes include socio-demographics (age, sex, income, and educational attainment), health insurance status, depression (Center for Epidemiological Studies Depression Scale) [47]; acculturation (modified Marin-Marin scale) [48,49]; health literacy (Short Assessment of Health Literacy SAHL-S&L, validated in both English and Spanish) [50]; body mass index (BMI); and functional status (modified Rankin score) [44].

**Mechanistic Variables**

Mechanistically, we expect the CHW intervention to be successful in BP management through two primary pathways. One is through better medication management. Although the intervention team is not involved in managing medications, our behavioral intervention can result in improved medication management through either increased medication
adherence or by ensuring patients have appropriate and timely follow-up with their existing PCPs who manage medications. The second is through lifestyle changes, primarily diet and exercise.

To conduct potential exploratory analyses of how the intervention may have resulted in improved outcomes, we are collecting data on potential mediators including medication adherence, medication intensification, salt intake, physical activity, provider visits and salt intake. This will allow us to examine the degree to which any improvements in BP were mediated by changes in these variables. We are also collecting detailed data on service intensity. We can then examine the correlations between BP control and items such as number of home visits, telephone calls, and group visit participation. Similarly, items in the cellphone intervention can also be correlated with BP control, such as the number of days in which BP values were uploaded or frequency of text messaging responses. A summary of variables being collected is shown in Table 2.

Table 2. List of variables and measures included in HiSSPI baseline survey.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Measures/ methods</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Outcomes:</strong> Blood Pressure</td>
<td>OMRON HEM-705CP, validated oscillometric device</td>
</tr>
<tr>
<td><strong>Secondary Outcomes:</strong> LDL</td>
<td>Roche Cobas c501 (Freidwald eq), also registry</td>
</tr>
<tr>
<td>HbA1C</td>
<td>Bio-Rad D-10 Latex agglutination, also from registry</td>
</tr>
<tr>
<td>Adherence anti-platelet/thrombotic medsbc</td>
<td>Medication Adherence Scale</td>
</tr>
<tr>
<td><strong>Exploratory Outcomes:</strong> Quality of Lifede</td>
<td>EuroQual (NINDS CDE core)</td>
</tr>
<tr>
<td>Visits to providersfg</td>
<td>AHRQ MEPS Survey</td>
</tr>
<tr>
<td><strong>Hospitalization / Stroke Admissionshi</strong></td>
<td>MEPS and NOMAS Questions</td>
</tr>
<tr>
<td><strong>Mechanistic Variables (mediators)</strong></td>
<td></td>
</tr>
<tr>
<td>BP Behaviors Complianceik</td>
<td>Hill Bone Scale (salt intake &amp; BP med adherence)</td>
</tr>
<tr>
<td>Fruit and Vegetable Intakeim</td>
<td>BRFSS (as a very rough marker of any diet change)</td>
</tr>
<tr>
<td>Medication Intensification</td>
<td>MHHI Medication Intensification Criteria</td>
</tr>
<tr>
<td>Physical Activityn</td>
<td>International Physical Activity Questionnaire, CDE</td>
</tr>
<tr>
<td><strong>Co-Variates (moderators)</strong></td>
<td></td>
</tr>
</tbody>
</table>
Statistical Analysis

The distribution of baseline values and outcomes will be examined for each arm. The intervention effects on outcomes (SBP, LDL, HbA1c) will be evaluated using linear regression models for continuous variables as a function of intervention status, as well as with categorical classification variables to index time intervals pre- and post-intervention. We will use statistical tests of the estimates of the regression parameters from this model to compare the major outcomes before and after the intervention groups in the full sample, as well as between intervention groups. Adherence to antiplatelet/antithrombotic therapy adherence will also be evaluated using logistic regression models as a function of intervention status. Covariates which will be included in the models will include age, sex, BMI, and educational attainment. Relationships between the outcome variables and other potential co-variates such as income, health insurance status, health literacy, functional status will be explored to determine their potential inclusion in final models.

DISCUSSION

Limitations

One study concern relates to study attrition. In a prior diabetes study, we experienced 21% attrition [21]. As figure 1 shows, even with such attrition, we would have > 80% power to detect an SBP difference of 8mmHg. However, in that study patients were
younger and a much more geographically mobile group than stroke survivors. Thus, for
HISPPI we expect an attrition rate of about 10%. Analytically, attrition will be handled by
examining baseline characteristics of completers and non-completers, and testing patterns
of attrition for randomness or ignorability. If the pattern of missing data is non-ignorable,
one approach is using baseline values carried forward. However, baseline values carried
forward may not be the best method and sensitivity analyses will be considered using
different approaches: such weighted generalized estimating equations (using the inverse
probability of dropout), multiple imputation, and propensity scores.[51,52]

As noted above, Miami has a diverse Latino population of both Caribbean and
Central/South Americans facing numerous distinct barriers to quality stroke care. Thus, it
is an ideal location from which to generate findings that generalize to the US Latino
population. In addition, initially we also considered having Puerto Rico as another
recruitment site. This site would allow us to test the intervention in a more homogenous
Latino population where barriers such as immigration status and language are mitigated.
Unfortunately, budgetary constraints did not allow us to include this site.

Lastly, a gap in the CHW literature is that few studies model the costs and benefits of
CHW programs. Our proposed intervention is approximately $2,000 patient. While this
figure pales in comparison to the cost of a subsequent stroke, of key importance to
policymakers would be a formal cost effective (CE) analysis. Although a formal CE analysis
is not part of the protocol, as part of the survey instrument we will be collecting quality of
life data using a standardized health state instrument (EQ5) and collecting data on health
care utilization and hospitalizations. If linked to expenditure data, such data would allow
for a future CE evaluation.
Conclusions

Results collected from the HiSSPI will provide important information on the effectiveness of a combined CHW and MHealth intervention on recurrent stroke risk among Hispanic-Latino populations. The study highlights the innovative role CHWs play in chronic care delivery, and our findings will further gauge the feasibility of this framework in the existing health care system using mobile technologies which may be more scalable options for chronic disease management.

CONFLICTS OF INTEREST

The authors report no financial conflicts of interest in this work.
REFERENCES


31. Certified Community Health Worker (CCHW) - Florida Certification Board. Florida Certification Board. 2018. Available at:


38. Wilson J, Hareendran A, Grant M, Baird T, Schulz U, Muir K, Bone I. Improving the Assessment of Outcomes in Stroke: Use of a Structured Interview to Assign Grades on
the Modified Rankin Scale. Stroke 2002;33(9):2243-2246.

doi:10.1161/01.str.0000027437.22450.bd.


**APPENDIX**

**Figures**

Figure 1. Statistical power and least detectable differences in HiSSPI for systolic blood pressure.
Abbreviations

AHRQ MEPS: Agency for Healthcare Research & Quality Medical Expenditure Panel Survey

NOMAS: Northern Manhattan Stroke Study

BRFSS: Behavioral Risk Factor Surveillance System

MMHI: Miami Healthy Heart Initiative

IPAQ: International Physical Activity Questionnaire

NINDS CDE: Neurological Disorders and Stroke Common Data Elements

SAHL- S&L-18: Short Assessment of Health Literacy- Spanish and English

CES-D: Center for Epidemiologic Studies Depression

MRS: modified Rankin Scale

Instruments & Measures (Tables)


