

# Practice-based Trial of Home BP Telemonitoring Among Minority Stroke Survivors: Successes, Challenges and Recruitment Lessons Learned

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# Study Aims

- **Primary Aim:** To evaluate the comparative effectiveness of two telemonitoring interventions on SBP reduction and stroke recurrence in high-risk Black and Hispanic stroke survivors
  - Home BP Telemonitoring (HBPTM)
  - HBPTM + Nurse Case Management (HBPTM+NCM)
- **Hypothesis 1A & 1B:** Compared with HBPTM alone, HBPTM+NCM will be associated with:
  - Greater SBP reduction at 12 months
  - Lower stroke recurrence rates at 24 months

# Study Aims

- **Secondary Aim:** To compare the cost-effectiveness of HBPTM+NCM versus HBPTM alone
- **Exploratory Aim:** To test potential patient- and provider-level mediators of treatment effects:
  - Change in other stroke risk factors (lipids, blood glucose)
  - Change in health behaviors (diet, physical activity, medication adherence)
  - Antihypertensive medication intensification

# HHC House Calls Telehealth Program

Home BP readings  
≥3 days/wk (am,  
pm) for 12 months



Critical alerts  
monitored and  
addressed

- 20 NCM calls
- Mo. 1-2: weekly
  - Mo. 3-4: biweekly
  - Mo. 5-12: monthly

BP summary reports mailed to patients monthly to share with provider(s)

# Study Overview

- **Design:** Multi-site, practice-based, two-arm RCT
- **Sample:** 450 Black and Hispanic stroke survivors with high BP from Stroke Centers and primary care practices within NYC Health and Hospitals Corporation (HHC) and other NYC hospitals
- **Methods:**
  - Both groups receive 12 months of intervention
  - Study visits & EHR review at Baseline, 6M, 12M
  - EHR review & phone contact only at 24M

# Eligibility Criteria

## Inclusion

- Age 18 or older
- Black or Hispanic
- English or Spanish speaking
- Ischemic or hemorrhagic stroke in past 1-12 months
- Modified Rankin Scale score  $\leq 3$
- Avg screening SBP  $\geq 130$  mmHg
- Plans to continue receiving care at site for next 2 years

## Exclusion

- Deemed unable to comply with study protocol
- Cognitive dysfunction
- Significant speech impairment
- Significant psychiatric comorbidity
- End-stage renal disease or dialysis
- Pregnant women
- Upper arm circumference  $\geq 52$ cm
- Participation in other clinical trials
- Relocating out of area or extended travel during study period

# Challenge: Recruiting Sites

- **Requirements:**
  - High volume of Black/Hispanic stroke patients
  - Collaborator willing to serve as site PI
    - Complete required trainings
    - Submit IRB applications, modifications, continuations
  - Site/site PI willing and able to provide:
    - Patient lists (ongoing, filtered by basic eligibility criteria)
    - Space
    - Access to patients (EHR access, introductions)
    - Help with volunteer process

# Successes: Recruiting Sites

- Started with sites with established relationships
  - Professional connections
  - Previous study sites
- Negotiated terms; requests vary by site:
  - Salary support/subcontract
  - Per-patient enrollment compensation
  - Training/mentoring of residents, junior faculty
  - Co-authorship on publications



# Challenge: Activating Sites

- Multi-layered IRB process
  - NYU IRB (all sites)
  - BRANY
  - HHC approvals (ReaSOOn)
  - Non-HHC site-specific approvals
- Volunteer approvals and EHR access
  - Applications; reference letters; site-specific trainings (in-person); medical and security clearance
  - No reciprocity among HHC hospitals
  - Restrictions on volunteers (number, duties); need flexibility to staff multiple sites with limited budget

# Successes: Activating Sites

- Closed a site with many barriers to focus on better sites
- Obtained stroke volume data from NYC DOH to help plan staffing and target new sites

Site	IRB Initiated	All IRB approvals obtained	NYU research staff approved at site	Patient lists obtained	Recruitment started
<b>Active Sites</b>					
Jacobi	Sept 2013	Nov 2013	Dec 2013	Jan 2014	Jan 2014
Bellevue	Feb 2014	Apr 2014	Apr 2014	Feb 2014	April 2014
CUMC	May 2014	Sept 2014	Oct 2014	Oct 2014	Oct 2014
Kings County	June 2014	Oct 2014	Oct 2014	Sept 2014	Oct 2014
Woodhull	May 2014	July 2014	Sept 2014	Jan 2015	June 2015
Harlem	June 2014	Dec 2014	Nov 2014	April 2015	April 2015
<b>Future Sites</b>					
SUNY Downstate	June 2014	Pending	Aug 2014	Pending	Pending contract
Lincoln	Dec 2014	Pending	Pending	Pending	Pending
Lutheran	June 2015	Pending	Pending	Pending	Pending

# Challenge: Identifying Patients

- First step at each site: obtain list of discharges over previous year (GWTG; hospital database)
  - Lack of centralized stroke center makes it difficult to identify patients; some hospitals cannot filter lists by race/ethnicity or other key criteria → low yield
- Inpatients: rely on sites to introduce RAs
- Outpatients: screen appointment lists of target clinics (e.g., stroke, general neurology, rehab)
- Pre-screen EHRs → list of initially eligible patients

# Challenge: Approaching Patients

- Stroke patients in NYC have low follow-up rates (with primary care, neurology), no regular PCPs
  - Increased efforts to meet inpatients before discharge
  - Look for stroke patients coming to other clinics
- Many initially eligible patients missed due to IRB restrictions (could not meet in-person)
  - PI visiting sites to increase engagement and support
  - Worked with IRBs on site-specific procedures; obtained approval for less restrictive approach at some sites

# Challenge: Approaching Patients

- Approach process varies by site:
  - CUMC IRB requires PCP to approve patients and mail opt-out letter to introduce study
  - NYU IRB requires provider to make first contact with patient
  - BRANY IRB allows us to obtain permission from providers, then we directly contact patient

# Challenge: Low Enrollment Rate

- BP control at screening higher than expected (50%)
  - Re-screen patients who narrowly miss BP cutoff
  - Dropped second BP screening visit
  - Lowered SBP threshold from  $\geq 140$  to  $\geq 130$  mm Hg
- Competition with other studies for stroke patients
  - Attempting to develop rotation for prioritizing studies

# Challenge: Retention

- Mobility of NYC population: frequent moves within the city; frequent phone number changes; some Hispanic patients spend months in home countries
  - Obtain multiple alternate contacts
  - Detailed inquiry about upcoming plans
- Many patients report difficulty completing visits due to finances, transportation issues
  - Increased financial incentives
  - Obtained IRB approval to do home visits
  - Can complete part of study visits by phone

# Study Flow Chart

