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Home Blood Pressure Telemonitoring and Nurse Case Management in Black and Hispanic Patients With Stroke: A Randomized Clinical Trial

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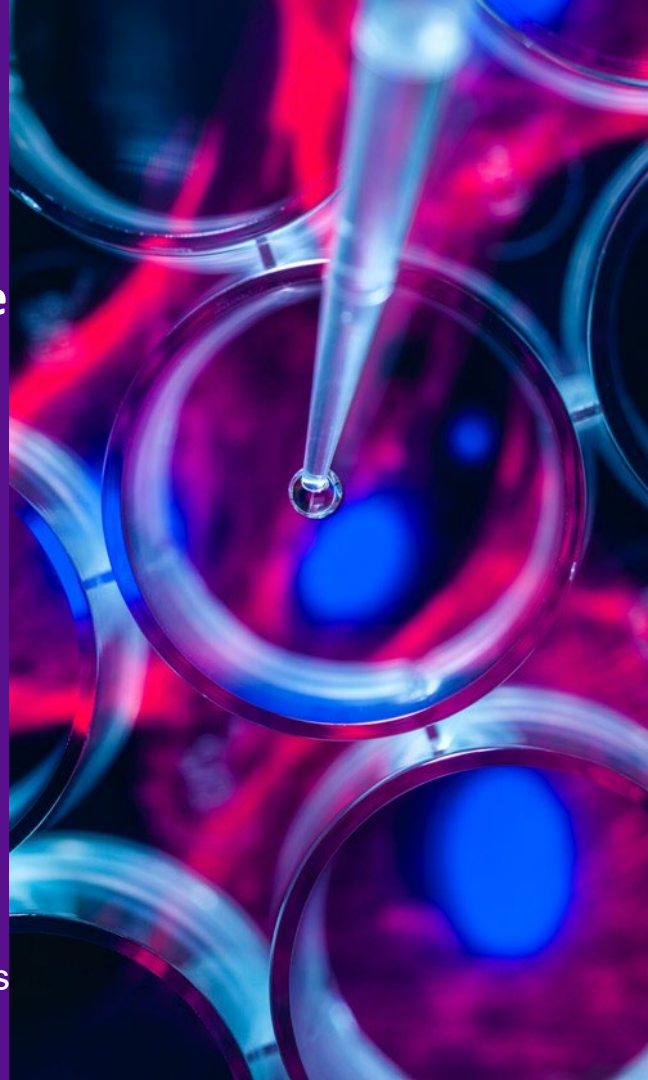

NIH DCRI Collaboratory Grand Rounds
December 12, 2024

Expertise

Expertise

Health Equity; Implementation Science; Pragmatic Practice-based Trials; and Global Health

Research Focus

Strategies to narrow the racial gap in hypertension-related morbidity & mortality in the United States and Africa

Clinical Focus

Director, Hypertension Clinic, Bellevue Hospital

National Recognition & Honors

Member, National Academy of Medicine

Member, U.S. Preventive Services Task Force

Numerous scientific honors and mentoring awards

Served on NIH/Fogarty International Center Board

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Disclosures

- Funding received from National Heart, Lung & Blood Institute
  - UH3HL151310, R01HL117323, R01HL157091, R01HL147811,and UH3HL154498
- Information presented at this talk is largely based on findings from the NYU-Columbia University Center for Stroke Disparities Solutions (U54NS081765: Ogedegbe & Williams)
- American Heart Association Health Equity Research Network (HERN)

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Premise

- Blacks and Hispanics have poorer stroke outcomes than Caucasians.
- HTN is a major predictor of racial disparities in stroke outcomes in the U.S
- HTN control in stroke survivors is key to secondary stroke prevention.
- Home BP Telemonitoring (HBPTM) and Nurse Case Management (NCM) have proven efficacy in addressing multilevel barriers to HTN control.
- However, their effectiveness remains untested in stroke patients; and their implementation is sub-optimal in Blacks and Hispanics.

Sheinart KF et al. Stroke recurrence is more frequent in Blacks and Hispanics. Neuroepidemiology. 1998;17:188–98
Lisabeth LD et al. Ethnic differences in stroke recurrence. Ann Neurol. 2006;60:469–75.
Morgenstern LB et al. Excess stroke in Mexican Americans compared with non-Hispanic Whites: the Brain Attack Surveillance in Corpus Christi Project. Am J Epidemiol. 2004;160:376–83.

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Research Question

- **Question:** What is the *comparative effectiveness* of HBPTM alone versus HBPTM plus telephone-based NCM among Black and Hispanic stroke survivors with uncontrolled hypertension?
- **Primary Outcomes:**
  - Within-patient change in systolic BP from baseline to 12 months
  - Rate of recurrent stroke at 24 months
- **Primary hypothesis:** Addition of tailored NCM to HBPTM will lead to greater reduction in SBP and stroke recurrence than HBPTM alone at 12 and 24 months, respectively.

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Spruill et al. Trials (2015) 16:97
DOI 10.1186/s13063-015-0605-5

TRIALS

STUDY PROTOCOL Open Access

Comparative effectiveness of home blood pressure telemonitoring (HBPTM) plus nurse case management versus HBPTM alone among Black and Hispanic stroke survivors: study protocol for a randomized controlled trial

Tanya M Spruill[1*], Olajide Williams[2], Jeanne A Teresi[3,4], Susan Lehrer[5], Liliana Pezzin[6], Salina P Waddy[7], Ronald M Lazar[2], Stephen K Williams[1], Girardin Jean-Louis[1], Joseph Ravenell[1], Sunil Penesetti[1], Albert Favate[8], Judith Flores[9], Katherine A Henry[8,10], Anne Kleiman[11], Steven R Levine[12,13,14], Richard Sinert[15], Teresa Y Smith[15], Michelle Stern[16], Helen Valsamis[12,17] and Gbenga Ogedegbe[1]

Multisite Practice-based, Comparative Effectiveness 2-arm RCT

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Study Sites

Comprehensive Stroke Centers and Primary Care Practices in New York City

1. Three academic medical centers
   - NYU Langone Health
   - Columbia University Medical Center
   - SUNY Downstate Medical Center

2. Six Public Hospitals from Health & Hospital Corporation
   - Lincoln Hospital, Bellevue Hospital
   - Kings County Hospital, Woodhull Hospital
   - Jacobi Medical Center, Harlem Hospital Center

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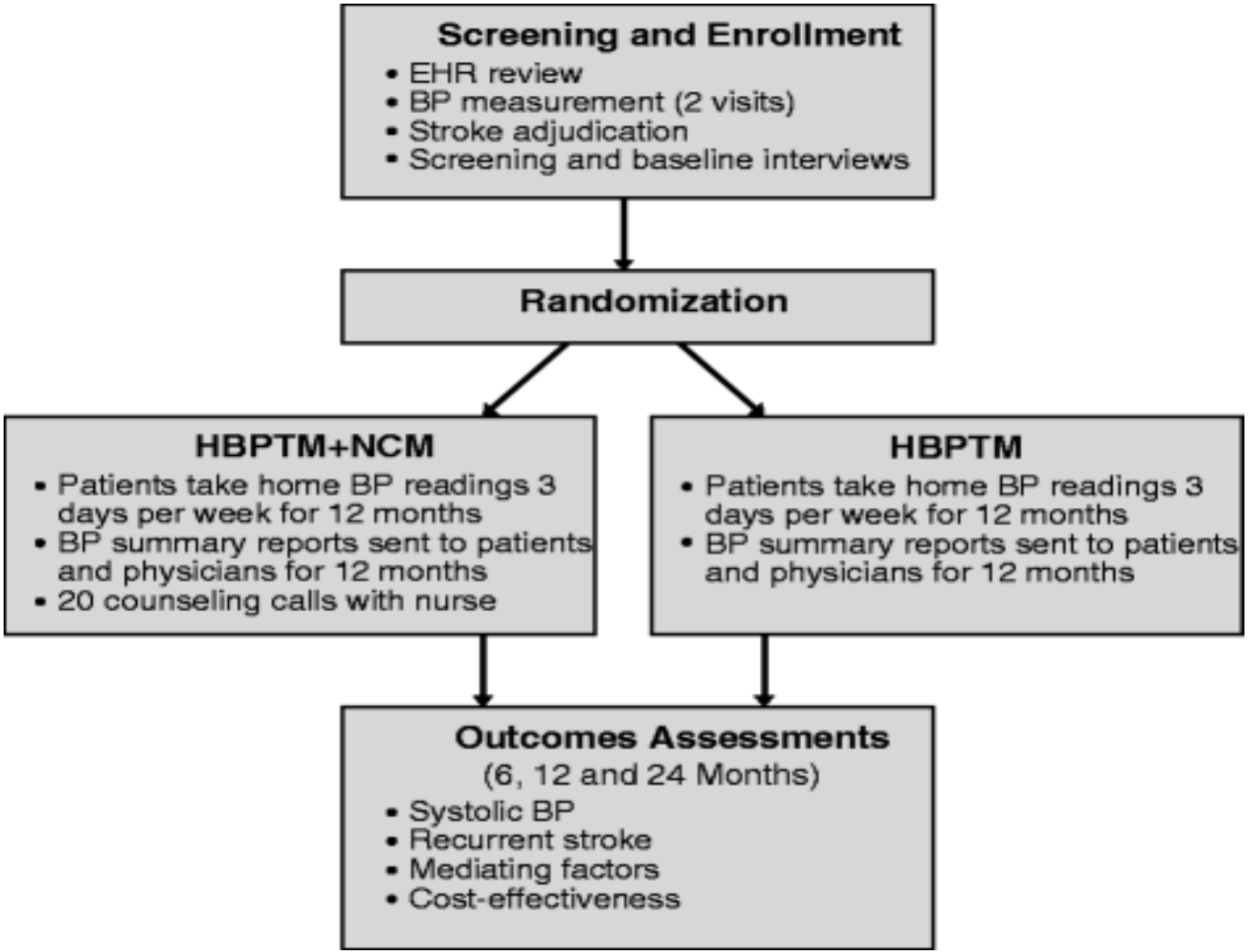

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Description of Interventions

HBPTM

- Home BP monitoring ≥ 3 days/week for 12 months
- Home BP readings transmitted wirelessly to secure server
- Reports sent to physician one week before each clinic appointment

HBPTM + NCM

- Evaluate patients' profiles from EHR and patient self-report
- Counsel patients on targeted lifestyle behaviors (diet, physical activity, medication adherence)
- Review and advise patient on their home BP data

Schedule of NCM Telephone Calls

Months 1-2: weekly

Months 3-4: biweekly;

Months 5-12: monthly

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HBTM+NCM Intervention

HBPTM readings ≥3 days/week for 12 months

20 NCM calls over 12 months

Critical BP alerts are monitored and addressed

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

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Spruill, T.M., *et al. Trials* **16,** 97 (2015)

Eligibility criteria

Inclusion

- Age 18 or older
- English or Spanish speaking
- Ischemic or hemorrhagic stroke in past 1-12 months
- Modified Rankin Score ≤ 3
- Screening SBP ≥ 140 mmHg on two visits within a 2-week period
- Received care at recruiting hospital >6 months and plans to continue for next 2 years

Exclusion

- Deemed unable to comply with study protocol
- Cognitive dysfunction
- End-stage renal disease or dialysis
- Pregnant women
- Upper arm circumference ≥ 52cm (limit for extra-large BP cuff)
- Relocating out of area or extended travel during study period

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JAMA

QUESTION In Black and Hispanic stroke survivors with uncontrolled hypertension, does home blood pressure telemonitoring (HBPTM) plus nurse case management (NCM) result in greater systolic blood pressure reduction than HBPTM alone?

CONCLUSION Findings from this study support implementation of a NCM-enhanced HBPTM program for management of hypertension.

POPULATION

250 Men
200 Women

Black and Hispanic adults with uncontrolled hypertension

Mean age: 61.7 years

LOCATIONS

8
Stroke centers and ambulatory practices in the US

INTERVENTION

450 Patients randomized

224

NCM plus HBPTM

HBPTM plus 20 counseling calls over 12 months

226

HBPTM alone

12 Home BP measurements per week for 12 months, with results transmitted to a clinician

PRIMARY OUTCOMES

Change in systolic BP at 12 months and rate of recurrent stroke at 24 months

FINDINGS

Systolic BP change and recurrent stroke rate

NCM plus HBPTM

Systolic BP change:	Recurrent stroke rate:
−15.1 mm Hg (95% CI, −17.2 to −13.0)	4.0% (9 of 224 patients)

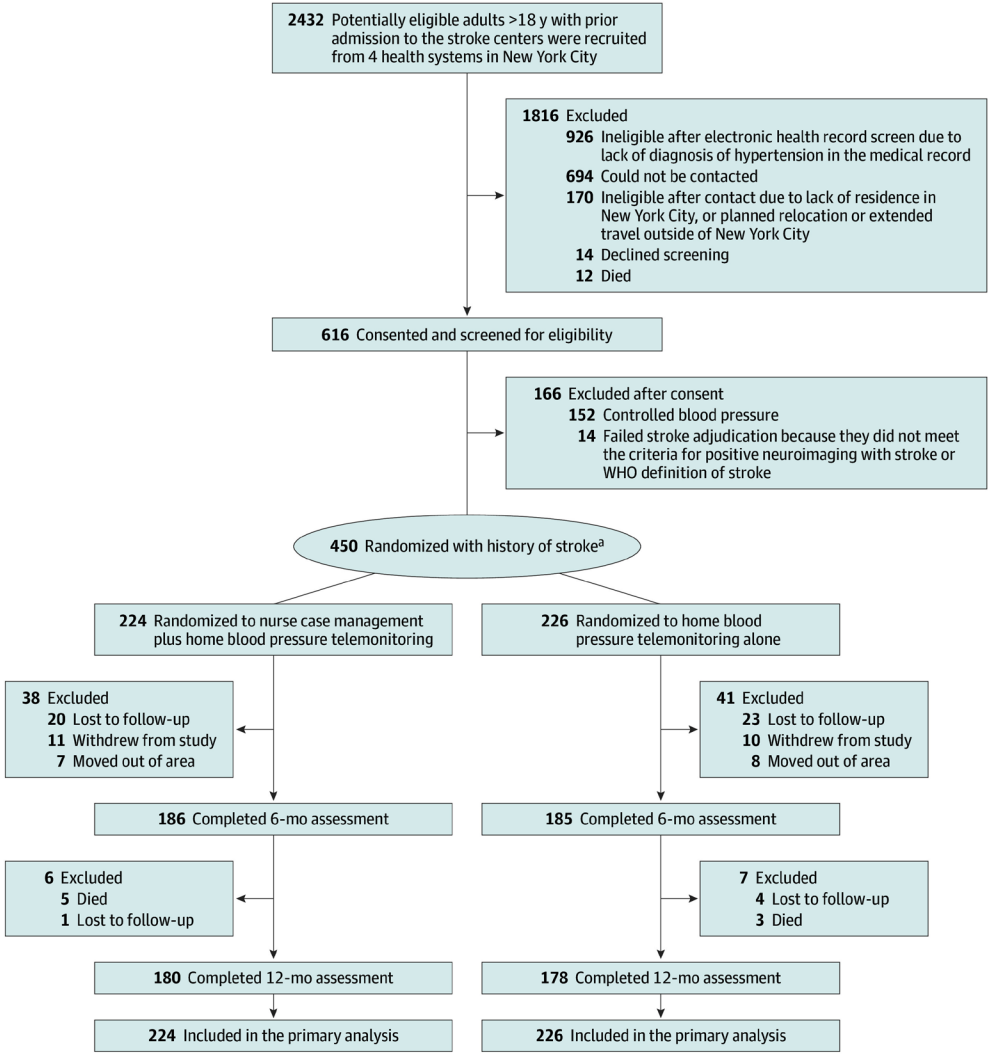
HBPTM alone

Systolic BP change:	Recurrent stroke rate:
−5.8 mm Hg (95% CI, −7.9 to −3.7)	4.0% (9 of 226 patients)

Between-group difference in systolic BP reduction, adjusted for physician clustering,

−8.1 (95% CI, −11.2 to −5.0)

Ogedegbe G, Teresi JA, Williams SK, et al. Home blood pressure telemonitoring and nurse case management in Black and Hispanic patients with stroke: a randomized clinical trial. *JAMA*. Published June 6, 2024. doi:10.1001/jama.2024.6609



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Baseline Demographic Characteristics	TOTAL (N=450)	HBPTM (N=226)	HBTM+NCM (N=224)
AGE, Mean (SD)	61.7 (11.0)	61.1 (10.5)	62.3 (11.5)
SEX, Female (%)	44.4	42.0	46.9
RACE, Black (%)	51.3	46.9	55.8
LEVEL OF EDUCATION, ≥High School (%)	51.1	45.3	56.9
EMPLOYMENT STATUS, Employed (%)	18.1	20.0	16.1
YEARLY FAMILY INCOME, <$24,999 (%)	72.2	72.6	71.9
LANGUAGE, English (%)	61.8	59.7	63.8
MARITAL STATUS (%)			
Single/Never Married	27.4	27.6	27.2
Married/Domestic Partnership	42.1	41.8	42.4

Baseline Clinical Characteristics	TOTAL (N=450)	HBPTM (N=226)	HBTM+NCM (N=224)
Systolic BP, Mean (SD)	149.02 (14.81)	148.03 (14.39)	150.03 (15.20)
Diastolic BP, Mean (SD)	87.82 (12.52)	87.95 (12.72)	87.69 (12.34)
BMI, Obese (>=30) (%)	45.8	45.1	46.5
STROKE TYPE, Ischemic (%)	76.4	77.0	75.9
MODIFIED RANKING SCORE, Mean (SD)	1.68 (1.05)	1.68 (1.06)	1.67 (1.04)
Positive Diagnosis of Diabetes (%)	48.0	49.6	46.4
CIGARETTE SMOKING STATUS (%) Currently Smokes	14.4	11.5	17.4
DRINKING STATUS (%) Currently Drinks	29.6	30.5	28.7
CHARLSON COMORBIDITY INDEX (%)			
No Comorbid Conditions	20.0	15.6	24.3
1-2 Comorbid Conditions	49.3	50.0	48.6
≥3 Comorbid Conditions	30.7	34.4	27.0

Table 2. Longitudinal Descriptive Statistics by Treatment Group and Model Results for Systolic Blood Pressure (SBP)

Outcome	Home blood pressure telemonitoring plus nurse case management (n = 224)			Home blood pressure telemonitoring (n = 226)			Absolute difference in difference (95% CI)	*P* value
	Baseline	Final	Difference (95% CI)	Baseline	Final	Difference (95% CI)		
Primary outcomes								
SBP at 12 mo (95% CI), mm Hg[a]	148.3 (146.3 to 150.3) [n = 224]	133.2 (131.0 to 135.4) [n = 180]	−15.1 (−17.2 to −13.0)	147.1 (145.1 to 149.1) [n = 226]	141.3 (139.1 to 143.5) [n = 178]	−5.8 (−7.9 to −3.7)	−8.1 (−11.2 to −5.0)	<.001
Recurrent stroke at 24 mo, No. (%)[b]	0	9 (4.0)		0	9 (4.0)			>.99
Post hoc outcome								
SBP at 6 mo (post hoc)	148.3 (146.3 to 150.3) [n = 224]	140.7 (139.1 to 143.4) [n = 186]	−7.6 (−9.4 to −5.8)	147.1 (145.1 to 149.1) [n = 226]	144.2 (142.5 to 145.9) [n = 185]	−2.9 (−4.7 to −1.1)	−3.4 (−5.8 to −1.1)	.002

[a] Sample size and model-adjusted means and 95% CIs are reported for the SBP outcome. A repeated-measures linear mixed model, adjusting for clustering within primary care physician and assuming a compound symmetry covariance structure, was used for the SBP analysis.

[b] Sample size and percentages are reported for the recurrent stroke at 24 months outcome. Fisher exact *P* value reported for comparison of recurrent stroke at 24 months between treatment groups.

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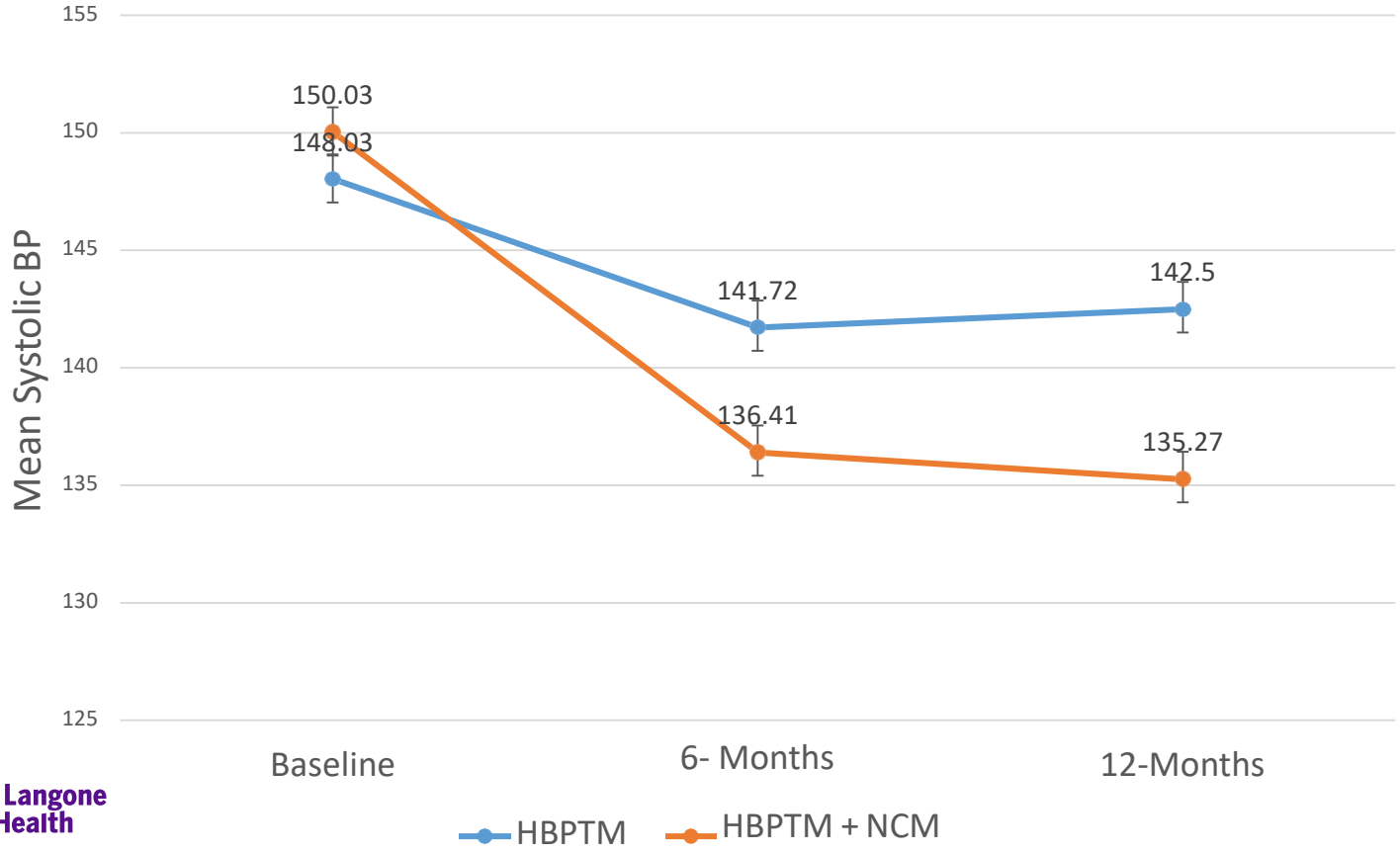
Primary Outcome: Within-patient change in systolic BP from baseline to 12 months



Both groups experienced significant SBP reduction at both time points

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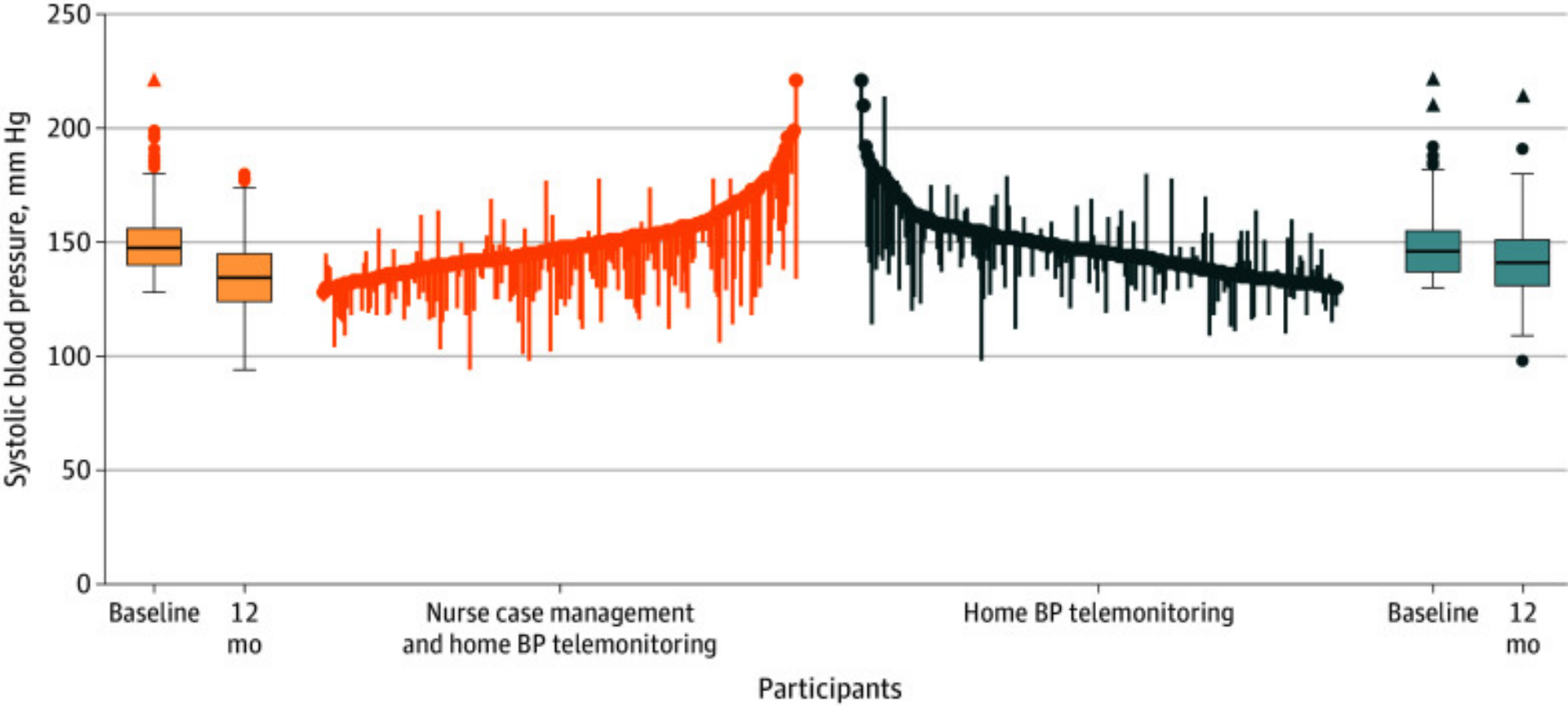

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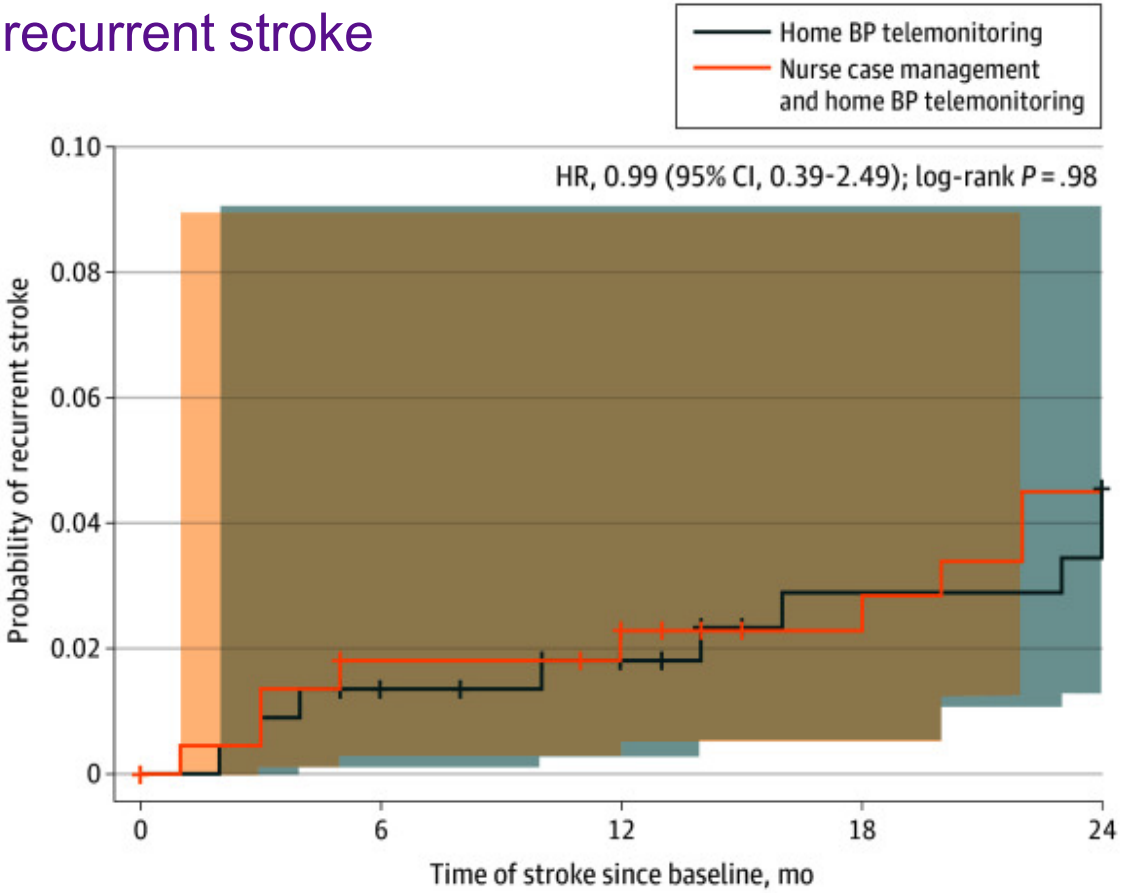
Primary Outcomes: Rate of recurrent stroke at 24 months



No. at risk					
Home BP telemonitoring	226	217	212	175	174
Nurse case management and home BP telemonitoring	224	214	210	175	171

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Conclusion

- A telehealth intervention which combines HBPTM with NCM led to greater SBP reduction than HBPTM alone.
- These findings provide strong empirical evidence for widespread implementation in low-income stroke survivors with multiple comorbidity
- Policy makers now have the needed evidence to implement these strategies in minority patients with stroke and uncontrolled hypertension.
- Effectiveness of HBPTM+NCM in secondary stroke prevention warrants further investigation.

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Implementation Challenges of HBPTM in Low-income and Minoritized Patient Populations

- Coverage of HBPM is variable amongst private payers and Medicaid programs
  - There are currently no national coverage determinations (NCD) or local coverage determinations (LCD) that address use of home BP monitors.
  - CMS recently finalized an NCD for use of ABPM, it does not extend coverage to HBPM.
- Once HBPM is obtained by patient, clinical support services for use is lacking.
- Poor access to Internet service to transmit HBPM data to the clinic for virtual care.
- Lack of a private space in which to conduct the virtual appointment
  - Multigenerational household does not allow privacy – lack of privacy
- Direct integration of data from home BP monitors directly into most EMRs is lacking
- Poor integration of clinical decision support

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Thank you

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