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Authors

Cheng, Eric M
Cunningham, William E
Towfighi, Amytis
et al.

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Efficacy of a Chronic Care Based Intervention on Secondary Stroke Prevention among Vulnerable Stroke Survivors: A Randomized, Controlled Trial

Eric M Cheng, MD, MS[1], **William E Cunningham, MD, MPH**[1], **Amytis Towfighi, MD**[2], **Nerses Sanossian, MD**[3], **Robert J Bryg, MD**[4], **Thomas L Anderson, MD**[5], **Frances Barry, MA**[1], **Susan M Douglas, MD, JD**[1], **Lillie Hudson, PA**[1], **Monica Ayala-Rivera, MA**[1], **Jeffrey J Guterman, MD, MS**[6], **Sandra Gross-Schulman, MD, MPH, RN**[6], **Sylvia Beanes, MPA**[7], **Andrea S Jones**[8], **Honghu Liu, PhD**[1,9], and **Barbara G Vickrey, MD, MPH**[1,10]

[1]UCLA David Geffen School of Medicine, Los Angeles, CA

[2]Rancho Los Amigos Natl Rehabilitation Center, Downey, CA

[3]Keck Med of USC, Los Angeles, CA

[4]Olive View-UCLA Medical Center, Sylmar, CA

[5]Harbor-UCLA Medical Center, Torrance, CA

[6]Los Angeles County Department of Health Services, Sylmar, CA

[7]American Heart Association, Los Angeles, CA

[8]Healthy African American Families Phase II, Los Angeles, CA

[9]UCLA School of Dentistry, Los Angeles, CA

[10]Icahn School of Medicine at Mount Sinai, New York, NY

Abstract

Background—Disparities of care among stroke survivors are well-documented. Effective interventions to improve recurrent stroke preventative care in vulnerable populations are lacking.

Methods and Results—In a randomized controlled trial, we tested the efficacy of components of a chronic care model–based intervention versus usual care among 404 subjects having an ischemic stroke or transient ischemic attack within 90 days of enrollment and receiving care within the Los Angeles public healthcare system. Subjects had baseline systolic blood pressure (SBP) >120 mm Hg. The intervention included a nurse practitioner/physician assistant care manager, group clinics, self-management support, report cards, decision support, and ongoing care coordination. Outcomes were collected at 3, 8, and 12 months, analyzed as intention-to-treat, and employed repeated-measures mixed-effects models. Change in SBP was the primary outcome. LDL reduction, antithrombotic medication use, smoking cessation, and physical activity were

Corresponding author: Eric M Cheng, MD, MS, UCLA Neurology BOX 951769, C-247 RNRC Los Angeles, CA 90095-1769, Tel: 310-206-7671, Fax 310-794-7716, echeng@mednet.ucla.edu.

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secondary outcomes. Average age was 57 years old; 18% were African-American race;69% were Hispanic ethnicity. Mean baseline SBP was 150 mm Hg in both arms. SBP decreased 17 mm Hg in the intervention arm and 14 mm Hg in the usual care arm; the between-arm difference was not significant (-3.6 mm Hg, 95% CI -9.2,2.2)). Among secondary outcomes, the only significant difference was that persons in the intervention arm were more likely to lower their LDL under 100 md/dL (2.0 OR, 95% CI (1.1,3.5)).

Conclusions—This intervention did not improve SBP control beyond that attained in usual care among vulnerable stroke survivors. A community-centered component could strengthen the intervention impact.

Clinical Trial Registration—https://clinicaltrials.gov/ct2/show/NCT00861081

Keywords

stroke; secondary prevention; risk factors; care coordination

Stroke remains one of the leading causes of death and disability. Of the 795,000 strokes in the United States that occur each year, about one-quarter are secondary strokes. [1] The strongest predictor of a stroke is a prior history of stroke. [2] The risk of stroke can be greatly reduced through better control of atherosclerotic risk factors, particularly hypertension. [2] A Cochrane review identified 26 randomized-controlled trials of care interventions that targeted control of risk factors among stroke survivors. [3] They reported that multidisciplinary teams and integrated care services may have a meaningful effect on risk factor control, but they were not sufficiently powered to reach a definitive conclusion.

The need to improve stroke prevention care is especially pressing among African-American and Hispanic populations. [1] Among survivors with stroke, African-Americans and Hispanics have worse access to physicians [4] and are less likely to receive appropriate stroke preventive services. [5] The prevalence of stroke among Hispanics in Los Angeles County is elevated, reflecting an excessive burden of risk factors. [6] Recently completed studies of stroke care interventions indicate that these vulnerable populations are receiving increasing attention.[7-9]

The Chronic Care Model (CCM) guides the design of many interventions to improve care for patients with chronic disease. [10] The six CCM components are self-management support, clinical information systems, delivery system redesign, decision support, health care reorganization, and community resources. Coordination of patient care is based on the CCM component of delivery system redesign, as well as supporting patient self-management to improve self-efficacy. [10, 11]

We designed SUSTAIN (Systemic Use of STroke Averting INterventions) by leveraging a successful in-hospital stroke prevention program [12] and adding outpatient care interventions guided by the CCM to improve adherence to guideline-recommended care after hospital discharge in resource-constrained settings. We then conducted a randomized-controlled trial to test the efficacy of SUSTAIN among persons with a recent ischemic stroke or TIA in a large county safety net health system.

Methods

Setting, eligible subjects

We previously reported on the design of the study.[13] Briefly, the setting of this study is all four county hospitals that anchor care for patients in the Los Angeles County Department of Health Services public healthcare system (LAC-DHS), which serves the largest, most ethnically diverse county in the United States.

We identified potential subjects through outpatient clinics, admission diagnosis logs, and the stroke Inpatient Clinical Pathways implemented at LAC-DHS. The enrollment period was January 2010 to August 2012. Inclusion criteria included a TIA or ischemic stroke within the prior 90 days and an average systolic blood pressure (SBP) ≥ 120 mm Hg, as obtained by the RA according to a protocol. Subjects were English-speaking or Spanish-speaking.

Eligible subjects who consented to study participation were administered a baseline survey and examination by a research assistant (RA). After collection of the baseline study data, the RA called a central research staff member. Prior to initiation of trial enrollment, a statistical programmer created randomization tables using an allocation ratio of 1:1, a block size of 4, and stratified by each of the 4 sites and by the language in which the survey was conducted (English or Spanish). The central research staff member identified the next available assignment in the appropriate table and relayed the assignment to the RA. Subjects randomized to the intervention arm were told they would be contacted by a care manager. Subjects randomized to the usual care arm were given an American Heart Association (AHA) brochure about reducing the risk of heart attack and stroke. [14] Subjects randomized to either arm of SUSTAIN were eligible for the same usual care as patients with a recent stroke or TIA in LAC-DHS, which consisted of at least one scheduled appointment to the outpatient neurology clinic, followed by a plan to rapidly transition care to a primary care provider.

Intervention

The research team collaborated with three community organizations whose missions were congruent with the goal of reducing the risk of stroke in underserved minority communities of Los Angeles: the AHA, Partners in Care Foundation,[15] and Healthy African-American Families. [16] Working together, we developed an intervention designed to be implemented and maintained in LAC-DHS. The intervention care managers were nurse practitioners (NPs) or physician assistants (PAs). Care managers followed the algorithms (see Supplemental Material) we developed based on existing guidelines and recommendations for modifying medications relevant to stroke risk factors,[2,17] as well as tobacco cessation, physical activity, depression, and medication adherence. These protocols were implemented in an existing health information technology/chronic disease registry program by LAC-DHS and included medications covered by the LAC-DHS formulary. These protocols reminded the care managers about scheduled visits, pharmacy refills, and laboratory testing and also informed care managers about whether subjects had achieved goal physiologic measurements so that they could intervene to better control risk factors.

Each subject randomized to the SUSTAIN intervention was scheduled to attend group clinics at the medical facility 2, 5, and 10 months after enrollment (Figure 1). Separate group clinics were scheduled for subjects who spoke English or Spanish. The first group clinic focused on stroke education, the second group clinic focused on self-management, and the third group clinic reinforced content presented at prior group clinics. Following each group clinic, there were brief one-on-one sessions with the care manager to individualize and reinforce content presented in the group session. Group clinics took about 8 hours in total to plan, schedule and coordinate with study team and participants. The group sessions themselves were scheduled for 2 hours.

Subjects in the SUSTAIN intervention were also scheduled to a regular clinic with the care manager at months 1 and 7 months after enrollment (Figure 1). During these individualized sessions, subjects were given a customized report card on his or her current versus optimal control of key stroke risk factors. Subjects reviewed the report card and were instructed to bring a blank report card to future primary care provider visits to facilitate active engagement by these clinicians in delivering stroke preventive services. We provided subjects with a blood pressure monitor (Omron HEM-711 DLX) for home use and trained them in how to use it. [18] The care manager followed home blood pressure measurements on telephone calls and at individual visits. Individual sessions were scheduled for one hour.

In addition, the care manager scheduled telephone care coordination calls starting at one week after hospital discharge, and between group clinics and individualized visits. The care managers called the participants at least monthly. Protocols on care coordination were followed if a problem was identified, such as a missed appointment or missed prescription refill. The care manager needed to be comfortable initiating, titrating, and discontinuing medications over the telephone without the presence of a physician on the call, such as a mid-level provider.

Outcome Measures

Interviews to assess outcome measures were conducted in person by a blinded RA at baseline, 3 months, and 12 months, and by phone at 8 months. The outcomes include blood pressure, cholesterol levels, smoking status, whether taking antithrombotic medication, physical activity levels, as well as the occurrence of new strokes and myocardial infarction events. [2] At each in-person assessment, blood pressure measurements were obtained and averaged from each subject using the Omron HEM-907XL.[19] We also calculated the 10-year risk of cardiovascular events, [20] acknowledging that this model was originally used to predict primary cardiovascular events and not stroke recurrence. We also collected demographic data, stroke severity, [21] level of disability [22], and stroke knowledge.[23, 24] We assessed health care utilization, perceptions of health care, [25] competing needs for obtaining health care, [26] social support,[27] and life chaos.[28] At the 8 month phone call, we assessed for the occurrence of strokes and myocardial infarction, smoking, exercise habits, current medications, competing needs, access to care, and life chaos.

To improve retention, contact information and back-up contact information was confirmed during every interaction with subjects. Subjects in both arms were paid up to $115 in addition to transportation costs for the collection of study outcome measures across all time

points. Efforts were made to arrange study outcome visits on the same day as therapy or clinic follow up visits.

Analytic sample size, statistical power, and enrollment sample size

Our sample size calculation and power analyses were based on the primary outcome of SBP.[29-3132] Using a Type I error of 0.05, a Type II error of 0.1 (or power of 90%), and a two-sided test, 132 subjects in each treatment arm would enable detection of a difference of 8 mm Hg in SBP between the two treatment arms, corresponding to an effect size of 0.5. Using a conservative estimate of a 65% study sample retention rate, the target number for enrollment was 205 in each treatment arm for a total of 410. While we enrolled 410 study participants, after we closed enrollment, 6 of these individuals were identified as ineligible. Our final study sample was thus 404.

Analysis

We compared the distributions of baseline characteristics between the usual care and intervention arms. Continuous measures were compared using the two group t-test, and ordinal or non-Gaussian continuous variables were compared using the Wilcoxon rank sum test. Nominal categorical variables were compared using a Chi-square test or a Fisher's exact test.

Changes in outcomes from baseline to 12-months, within each arm and between arms, were compared using repeated-measures mixed-effects models (PROC MIXED for continuous measures and PROC GENMOD for categorical measures, expressed as odds ratios) using an intention to treat analysis. The covariance-variance structure of these types of models takes into consideration the correlations between the outcomes collected for the same individual over multiple time points. For each outcome, two covariance structures were modelled: Autoregressive (assumes measurements for the same individual become less correlated as they move further apart) and Compound Symmetry (assumes the correlation between observations is constant, regardless of the time lapse between measurements). For each outcome, the model with the lowest Akaike Information Criteria (AIC) was selected. [33] The p-value is the interaction term of time multiplied by study arm.

The primary outcome of SBP was analyzed as a continuous variable. In sensitivity analyses, it was also analyzed as a dichotomous variable using 130 mm Hg and 140 mm Hg as cutoffs. While the original design paper set a threshold of 120 mm Hg, [13] subsequent research articles raised concerns on whether 120 mm Hg was too low a target. [34, 35] We also performed subgroup analyses of SBP by site, race/ethnicity, and language. Secondary outcomes include changes in LDL as a continuous measure and attainment of LDL < 100 mg/dL as a categorical measure; smoking cessation, physical activity, 10-year risk of a cardiovascular event, and taking antithrombotic medication. Our analyses of cholesterol are based on contemporaneous guidelines about cholesterol treatment to LDL targets. These guidelines have been replaced by current guidelines that recommend treatment by high-potency statins regardless of LDL values.[36]

We also performed post-hoc analyses to provide data for conducting future trials in the same setting. First, we identified predictors of retention in the study. Second, we identified

predictors of participating in group clinics, which is one of the featured components of the intervention. Third, we examined clinical outcomes of stroke/TIA so that we can calculate the sample size of future trials that would be sufficiently powered to detect differences in those outcomes.

Institutional Review Board approvals were obtained at University of California, Los Angeles and at each of the four county hospitals. This study is listed in the Clinical Trial Registration as NCT00861081.

Results

Among 1476 persons approached, 622 were eligible, and 407 enrolled in the study (Figure 1). The three most common reasons for ineligibility were hemorrhagic stroke (N=274), speaking a language other than English or Spanish (N=100), or age younger than 40 (N=85). Setting of enrollment was collected at three participating hospitals, and over 95% of the 329 subjects from those hospitals were enrolled prior to hospital discharge. There are no significant differences in any demographic and sociodemographic characteristics between the two study arms ($p>0.05$; Table 1). The average age of subjects is 57 years. Over two-thirds of the subjects were of Hispanic ethnicity. Majorities of subjects were born outside of the United States and predominantly spoke a language other than English. Over one-third did not attend high school.

There are no significant differences for baseline stroke risk factors and potential mediators for any characteristic between the two study arms ($p>0.05$; Table 2). Mean baseline SBP was 150.3 mm Hg in the usual care arm and 149.5 mm Hg in the intervention arm. Very high proportions of both arms were non-smokers at baseline. The majority of subjects had a mild stroke as defined by a National Institute of Health Stroke Scale (NIHSS) ≤5 and did not have significant disability as defined by a modified Rankin scale score of either 0 or 1.

There were 82% of subjects in the usual care arm and 83% of subjects in the intervention arm who completed the 12-month survey (Supplemental Table 1). There are no significant differences in the baseline characteristics between subjects who completed the 12-month survey and those who did not.

The primary outcome of SBP changed significantly within the intervention arm by -17.3 (95% confidence interval (CI) -21.6,-12.9)) mm Hg, and within the usual care arm by-13.7 (95% CI (-17.4,-10.0) mm Hg (Table 3). The improvement of SBP in the intervention arm was not different from that in the usual care arm (-3.6 mm Hg (95% CI (9.3,2.2)). Sensitivity analyses using SBP as categorical variables at 130 mm Hg and 140 mmHg thresholds showed similar results (Table 3). Subgroup analyses by site, race/ethnicity, and language revealed that the two subgroups of English-speaking study participants and of African-American study participants each had significantly greater lowering of their SBP in the intervention arm compared to the usual care arm (Supplemental Table 2). Of note, African-Americans had a higher baseline SBP than other subgroups. ““Consistent with the results on the primary outcome of BP, the proportions of both arms with BP medication intensification

was much higher at 12 months compared to baseline in both arms, but not significantly different from each other at either baseline or 12 months (p=0.12).

Among secondary outcomes, improvements from baseline over time were seen in both arms for LDL, taking antithrombotic medication, and 10-year risk of a cardiovascular event. Figure 2 shows that most of the improvements in outcomes occurred in the first 3 months with smaller changes in outcomes occurring between the 3 and 12 month time points.

Comparing the two arms to each other, the intervention arm had better improvement than the usual care arm for the categorical measure of LDL < 100 mg/dL (odds ratio2.095% CI (1.1 to 3.5), Table 3)). There were no significant between-arm differences for other outcomes (Table 3 and Supplemental Table 3).

The number of visits to a mid-level provider over 12 months were higher in the intervention arm than in the usual care arm (2.2 vs 0.7, p<0.05). The number of total outpatient visits to all providers was not different between the two arms (14.0 visits in usual care arm versus 18.6 visits in intervention arm, p=0.11).

In terms of data on extent of implementation of the intervention, Figure 3 shows participation in group clinics among those randomized to the intervention group. While 56% of the subjects attended at least two group clinics, 28% did not attend any group clinic. There was no overall association between number of group clinics attended and improvements in SBP (p=0.66) nor greater knowledge of stroke risk factors (p=0.37). In Supplemental Table 4, the only baseline characteristic that predicted greater participation in group clinics was being born outside of the United States (p<0.01). In exploratory post-hoc analyses, subjects who reported on the 3-monthsurvey that they missed health care appointments because they did not have a way to get there or were taking care of somebody else were significantly less likely to participate in group clinics (results not shown). Compared to the usual care arm, subjects in the intervention arm were more likely to report having a BP monitor in the home (98% versus 65%, p<0.001) and having used the home BP monitor during the study period (58% versus 25%, p<0.001)

Finally, we counted clinical outcomes in preparation for future sample size power calculations. We found that fewer subjects self-reported stroke or TIA in the intervention arm compared to the usual care arm (22 events (12%) versus 39 events (22%), p=0.01). However, over half of self-reported events in both arms were not corroborated in a medical record review at the four hospitals. There was no difference in medical record corroborated stroke and TIA between the two arms (7 events (3%) in the intervention group versus 11 events (6%) in the usual care arm, p=0.30). We did not have access to medical record data of study participants for care received outside of the four participating hospitals.

Discussion

We designed a CCM-based intervention and then conducted a randomized controlled trial among multi-racial/multi-ethnic vulnerable population receiving care in a county safety net health system to test its efficacy on secondary stroke prevention. We were able to achieve high rates of retention in the study. There were improvements over time from baseline in

vascular risk factor control in both arms, with the exception of non-smoking status and physical activity, both of which were relatively high at baseline. However, there was no greater improvement in SBP observed in the intervention arm relative to the usual care arm, and the only secondary outcome that showed better improvement in the intervention arm was lowering LDL below 100 mg/dL. African-Americans did improve their SBP in the intervention arm compared to usual care. The intervention may have been more effective in this subgroup due to the higher initial severity of SBP.

The magnitude of SBP improvement in both arms was greater than that reported in studies listed in two meta-analyses, which did not identify studies with improvement in SBP over 10 mm Hg.[3, 37] One potential explanation is that we enrolled subjects very shortly after stroke onset. SBP is highest in the acute stroke setting and naturally declines afterward. In addition, permissive hypertensive practices that are typically implemented upon hospital admission may elevate SBP even further. Using SBP near the onset of stroke as our baseline value could result in a greater than expected magnitude of SBP lowering compared to studies in which baseline SBP is measured further from stroke onset, such as after hospital discharge.

Even though substantial improvement of SBP was observed among both arms, there remains considerable room for improvement because about one-third of subjects still had an SBP >140 mm Hg one year after their stroke. Subjects in this trial had a mean age of 57 years, which is considerably younger than other studies. As a comparison, the population-based study of the Brain Attack Surveillance in Corpus Christi (BASIC) found that Mexican American stroke survivors had a mean age of 69 years and non-Hispanic whites had a mean age of 76 years. [38] The subjects in our study likely have a longer remaining lifespan than typical stroke survivors and would particularly benefit from aggressive strategies to reduce the recurrence of stroke.

There are several possible reasons why we did not observe a difference between the two arms for the primary outcome. First, there may be contamination of care in the usual care arm. Because we randomized patients instead of sites, physicians at LAC-DHS could manage patients in both arms of the study. Second, there may have been a Hawthorne effect among usual care arm participants, particularly because all subjects had their BP pressure measured during face-to-face outcome assessments at 3 months and at 12 months. We considered withholding BP measurement results from participants to minimize attention to this as a study outcome, but ultimately decided that was unethical. Third, patients randomized to the intervention arm did not fully participate in all scheduled intervention activities. Stroke intervention intensity can be measured by total number of contacts. [3] At least one-quarter of subjects randomized to the intervention arm did not attend a single group clinic and reported that transportation and competing needs to care for others were potential barriers to participation. To overcome these barriers, we modified the secondary stroke prevention program to emphasize further the self-management and community resources components of the chronic care model and are testing it under an NIH-funded U54 Stroke Prevention/Intervention Research Program (SPIRP) grant.[39] Intervention components beyond the SUSTAIN NP/care manager visits include home visits by community health workers (CHWs), mobile health applications for care coordination and patient/family

education, and Chronic Disease Self-Management Programs delivered by CHWs in the community rather than solely at the medical center facility.[40]

Regarding generalizability, the components of the model that we perceive as generalizable to other settings and populations include the care coordination and the proactive follow-up, and incorporating algorithms for guidance on medication management. Group clinics might work better among under-resourced populations in areas having useable public transit with disability access, compared to our setting of Los Angeles County. Shifts in healthcare payment to value-based payment approaches should incentivize uptake of a model that is found effective at improving quality of care and has substantial emphasis on elements that are not reimbursed under traditional fee-for-service payment approaches.

We have three recommendations for researchers conducting interventions in safety net systems. First, researchers need to earn the trust of partnering organizations and patients by assuring they remain committed to addressing their needs after the study is completed. Second, care managers were frequently asked by patients to help navigate a complex health system, which reduced the amount of time available for protocol-outlined tasks such as medication management. Third, researchers should establish health information technology systems to standardize collection of data and monitor adherence to intervention protocols, being mindful of the available technology and the constraints of needing to get the study into the field.

Conclusions

We successfully designed and tested components of a Chronic Care Model-based stroke prevention intervention among multi-racial/multi-ethnic vulnerable population receiving care in a county safety net health system. However, this intervention did not improve stroke risk factor control beyond what was attained in usual care among vulnerable stroke survivors. We have identified barriers to implementing a secondary stroke prevention program and have leveraged this experience to guide further modification of the care intervention for future testing in this setting where we have demonstrated the ability to conduct randomized trials.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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What is Known

- Effective interventions to redress racial ethnic disparities in recurrent stroke risk are lacking
- Chronic Care Models are a guide to designing effective interventions to improve care for patients with chronic disease

What The Study Adds

- We successfully designed and tested a stroke prevention intervention based on components of a Chronic Care Model among a multi-racial/multi-ethnic vulnerable population receiving care in a county safety net health system.
- With the exception of attaining LDL below target levels, this chronic care model intervention did not improve stroke risk factor control beyond that attained in usual care among vulnerable stroke survivors.
- A community-centered component could strengthen the intervention impact.

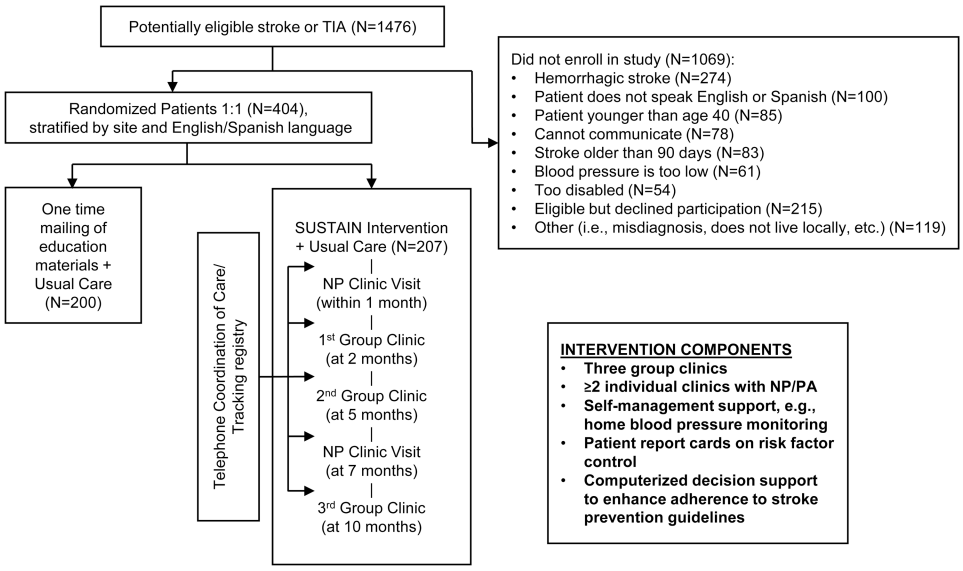

Figure 1. Design of the study

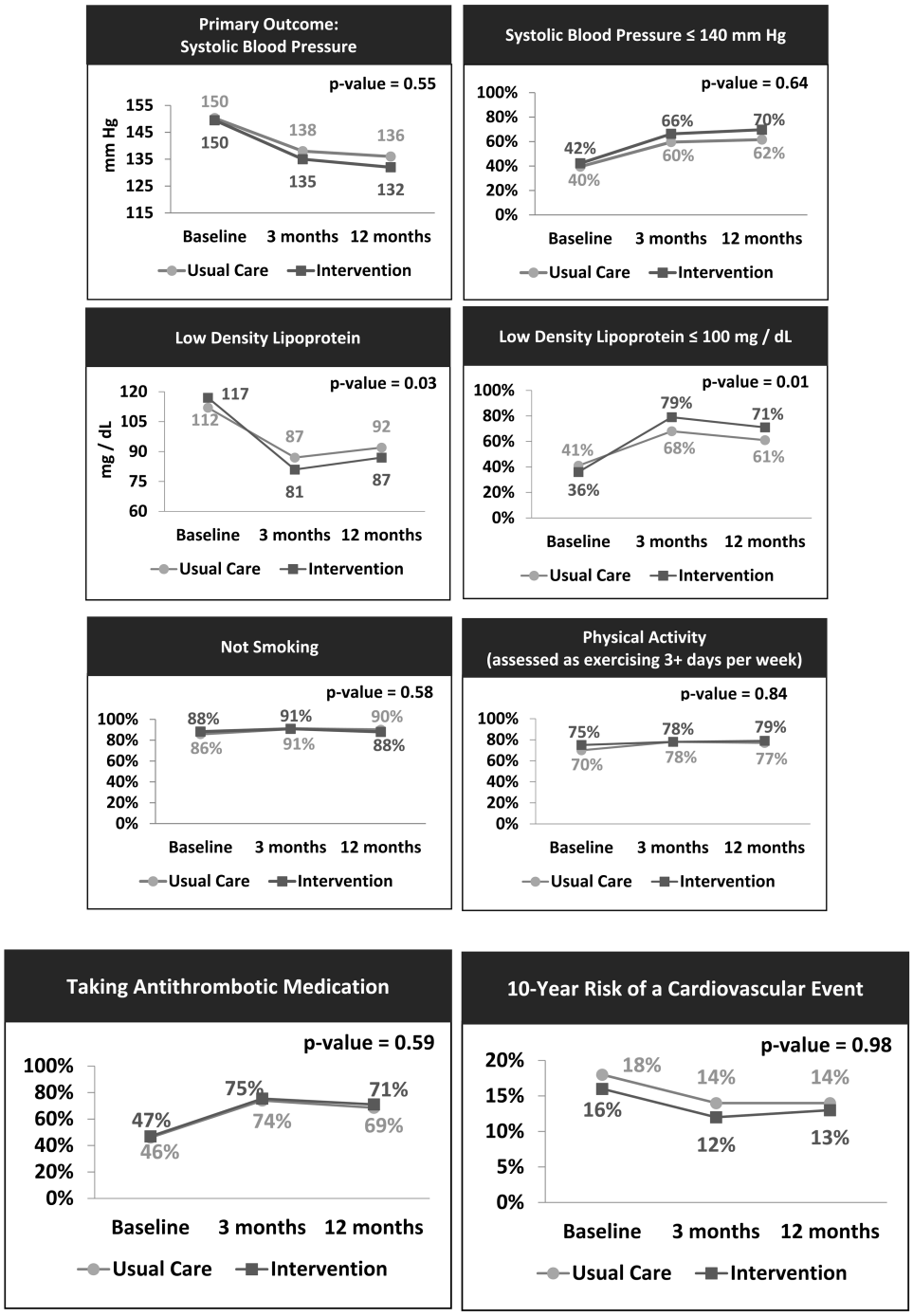

Figure 2.

Trends in primary and selected secondary outcomes by study arm. p-value is the interaction term for three time points (baseline, 3 months, 12 months) * study arm in a repeated measures mixed-effects model. For the outcome of taking antithrombotic medication, we added an additional time point of 8 months.

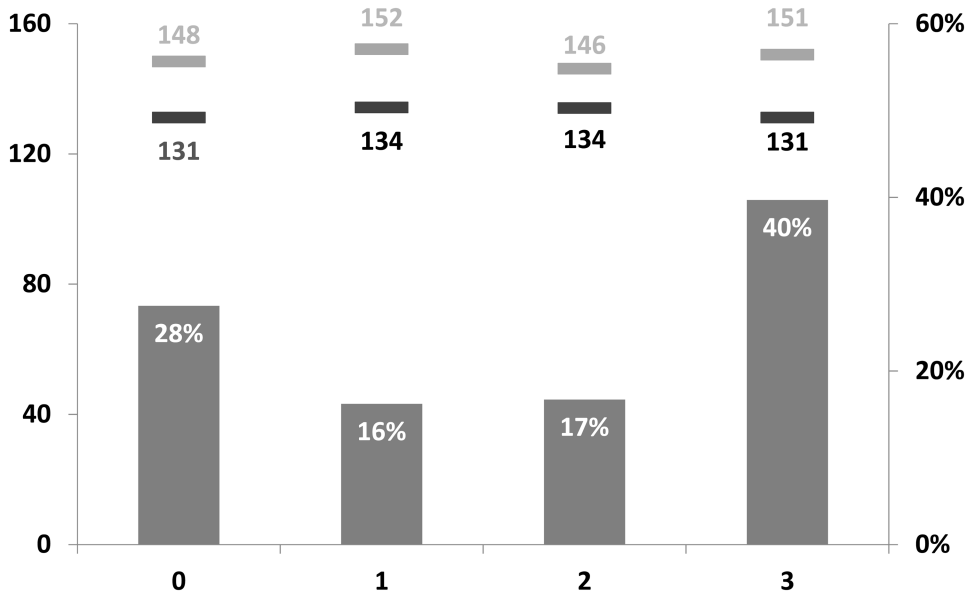

Figure 3. Participation in group clinics among subjects randomized to intervention

Table 1

Demographic, sociodemographic characteristics (N=404).

	Usual Care (n=200)	Intervention (n=204)
Age, years, mean (standard deviation)	57.6 (7.3)	57.1 (7.0)
Male, n (%)	116 (58.0)	128 (62.7)
Race / Ethnicity, n (%) *(excludes unknown)*		
Non-Hispanic African American	33 (16.5)	26 (12.8)
Non-Hispanic Asian / Pacific Islander	20 (10.0)	21 (10.3)
Non-Hispanic Caucasian	13 (6.5)	11 (5.4)
Non-Hispanic Other	1 (0.5)	3 (1.5)
Hispanic	133 (67.2)	142 (70.0)
Born in the United States, n (%)	48 (24.0)	47 (23.0)
Predominant language spoken, n (%)		
English	63 (31.5)	63 (30.9)
Spanish	120 (60.0)	118 (57.8)
Other	17 (8.5)	23 (11.3)
Living with a least one adult, n (%)	172 (87.3)	170 (85.9)
Education, n (%)		
Some college	72 (36.0)	63 (31.7)
At least high school graduate or equivalent	38 (19.0)	35 (17.6)
Some high school	23 (11.5)	27 (13.6)
8th grade or less	67 (33.5)	74 (37.2)

p-value >0.05 for all comparisons between usual care and intervention

Table 2
Baseline stroke risk factors and potential mediators (N=407)

	Usual Care (n=200)	Intervention (n=204)
Baseline stroke risk factor status		
Systolic blood pressure		
Average (mm Hg), mean (std)	150.3 (20.9)	149.5 (21.7)
≤ 130 mm Hg, n (%)	37 (18.5)	41 (20.1)
≤ 140 mm Hg, n (%)	79 (39.5)	86 (42.2)
Low-density lipoprotein		
Average (mg/dL), mean (std)	111.7 (39.6)	117.3 (39.7)
≤ 100 mg/dL n (%)	78 (41.3)	71 (35.5)
Smoking status: currently smoking, n (%)	28 (14.4)	23 (11.7)
Physical activity: exercise 3 or more days per week, n (%)	140 (70.0)	153 (75.0)
10-year risk of a cardiovascular event, mean (std)	18.2 (13.1)	16.1 (11.9)
Mediators of outcome		
NIH stroke scale (NIHSS), n (%)		
Mild (NIHSS 0-5)	115 (57.5)	111 (54.4)
Moderate (NIHSS 6-14)	74 (37.0)	79 (38.7)
Severe (NIHSS 15-24)	11 (5.5)	14 (6.9)
Modified Rankin scale, n (%)		
0: No symptoms	43 (21.5)	45 (22.1)
1: No significant disability despite symptoms	62 (31.0)	63 (30.9)
2: Slight disability	40 (20.0)	30 (14.7)
3: Moderate disability	35 (17.5)	36 (17.6)
4: Moderately severe disability	18 (9.0)	29 (14.2)
5: Severe disability	2 (1.0)	1 (0.5)
Knowledge about stroke signs and risk factors, n (%)		
Does not know any risk factors	29 (14.5)	27 (13.2)
Knows 1+ risk factor	171 (85.5)	177 (86.8)
Knows 2 +risk factors	151 (75.5)	155 (76.0)
Knows 3+ risk factors	105 (52.5)	104 (51.0)
Deferred health care because of a competing need, n (%)	69 (36.7)	57 (29.1)
Life chaos scale (6-30; higher scores indicate greater life chaos), mean (std)	15.1 (5.7)	15.5 (5.8)
Social support (0-100; higher scores indicate more social support), mean (std)	59.6(28.4)	58.8 (27.8)

p-value >0.05 for all comparisons between usual care and intervention

Table 3

Primary and secondary outcomes among baseline and intervention arms

Outcome	Control arm (n=200)		Intervention arm (n=204)		
		Change from baseline		Change from baseline	Differences in changes from baseline between control and intervention arms* (95% CI)
SBP, mm Hg, mean (std) (primary outcome)					
Baseline	150.3 (20.9)		149.5 (21.7)		
1 year	136.1 (20.8)	-13.7 mm Hg (-17.4,-10.0)†	132.3 (20.5)	-17.3 mm Hg (-21.6,-12.9)†	-3.6 mm Hg (-9.3,2.2)
SBP≤ 130 mm Hg, n (%)					
Baseline	37 (18.5)		41 (20.1)		
1 year	69 (43.4)	3.4 OR (2.2,5.2)†	89 (53.9)	4.7 OR (3.0,7.3)†	1.4 OR (0.7,2.6)
SBP≤ 140 mm Hg, n (%)					
Baseline	79 (39.5)		86 (42.2)		
1 year	98 (61.6)	2.5 OR (1.7,3.6)†	115 (69.7)	3.2 OR (2.1,4.8)†	1.3 OR (0.7,2.3)
LDL, mg/dL, mean (std)					
Baseline	111.7 (39.6)		117.3 (39.7)		
1 year	92.3 (41.1)	-21.0 mg/dL (-29.1,-12.9)†	86.8 (38.9)	-31.2 mg/dL (-38.6,-23.9)†	-10.2 mg/dL (-21.1,-0.6)
LDL≤ 100 md/dL, n (%)					
Baseline	78 (41.3)		71 (35.5)		
1 year	83 (61.0)	2.2 OR (1.5,3.3)†	110 (70.5)	4.3 OR (2.8,6.7)†	2.0 OR (1.1,3.5)†
Not Smoking, n (%)					
Baseline	166 (85.6)		174 (88.3)		
1 year	147 (90.2)	1.6 OR (1.0,2.5)	150 (88.2)	1.0 OR (0.6,1.6)	0.6 OR (0.3,1.3)
Physical activity, assessed as exercise 3+ days per week, n (%)					
Baseline	140 (70.0)		153 (75.0)		
1 year	125 (76.7)	1.4 OR (0.9,2.2)	135 (79.4)	1.3 OR (0.8,2.1)	0.9 OR (0.5,1.8)
Taking antithrombotic medication, n (%)					
Baseline	92 (46.0)		96 (47.1)		

Outcome	Control arm (n=200)		Intervention arm (n=204)		
		Change from baseline		Change from baseline	Differences in changes from baseline between control and intervention arms* (95% CI)
1 year	137 (68.5)	2.6 OR (1.7,3.8)†	147 (71.0)	2.9 OR (1.9,4.4)†	1.1 OR (0.6,2.0)
10-year risk of a cardiovascular event, %, std)					
Baseline	18.2 (13.1)		16.1 (11.9)		
1 year	13.7 (9.7)	-3.5% (-5.3,-1.7)†	13.1 (9.2)	-4.2 % (-5.8,-2.7)†	0.8 (-3.1,1.6)

*Repeated-measures mixed-effect models included baseline, 3-month, 12 month values. For antithrombotic medication and exercise outcomes, values were also collected at 8-months and included in the models. For categorical variables, the results are reported as odds ratios (OR)

†indicates p<0.05