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Designing and Evaluating Health Systems Level Hypertension Control Interventions for African-Americans: Lessons from a Pooled Analysis of Three Cluster Randomized Trials

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Abstract

Objectives—African-Americans (AAs) have a high prevalence of hypertension and their blood pressure (BP) control on treatment still lags behind other groups. In 2004, NHLBI funded five

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CONFLICT OF INTEREST

The authors confirm that this article content has no conflict of interest.

SUPPLEMENTARY MATERIAL

Supplementary material is available on the publisher's web site along with the published article.

projects that aimed to evaluate clinically feasible interventions to effect changes in medical care delivery leading to an increased proportion of AA patients with controlled BP. Three of the groups performed a pooled analysis of trial results to determine: 1) the magnitude of the combined intervention effect; and 2) how the pooled results could inform the methodology for future health-system level BP interventions.

Methods—Using a cluster randomized design, the trials enrolled AAs with uncontrolled hypertension to test interventions targeting a combination of patient and clinician behaviors. The 12-month Systolic BP (SBP) and Diastolic BP (DBP) effects of intervention or control cluster assignment were assessed using mixed effects longitudinal regression modeling.

Results—2,015 patients representing 352 clusters participated across the three trials. Pooled BP slopes followed a quadratic pattern, with an initial decline, followed by a rise toward baseline, and did not differ significantly between intervention and control clusters: SBP linear coefficient = -2.60 ± 0.21 mmHg per month, $p < 0.001$; quadratic coefficient = 0.167 ± 0.02 mmHg/month, $p < 0.001$; group by time interaction group by time group $\times$ linear time coefficient = 0.145 ± 0.293 , $p = 0.622$; group $\times$ quadratic time coefficient = -0.017 ± 0.026 , $p = 0.525$). Results were similar for DBP. The individual sites did not have significant intervention effects when analyzed separately.

Conclusion—Investigators planning behavioral trials to improve BP control in health systems serving AAs should plan for small effect sizes and employ a “run-in” period in which BP can be expected to improve in both experimental and control clusters.

Keywords

African-Americans; hypertension control; cluster randomized trial; effect size; health disparities; health systems interventions; high blood pressure; minority health; practice-based research network (PBRNs)

INTRODUCTION

Hypertension is a major cardiovascular risk factor affecting almost one-third of adults in the United States [1] African-Americans have between a 1.5 and 2 times higher prevalence of hypertension than other groups, depending on the age group and gender being compared. After age 60, more than 80% of African-Americans are hypertensive [2]. Because of the high prevalence of hypertension in middle aged and older Americans, especially in African-Americans, the effective treatment of hypertension is one of the most important responsibilities of the health care system.

In spite of greater gains in awareness and treatment among African-Americans than other population subgroups over the past several decades, the proportion of African-Americans that achieve control BP on treatment still lags behind non-Hispanic whites [1]. Even in the setting of a clinical trial (ALLHAT), control to the target blood pressure of 140/90 mmHg was achieved in only 60.9% of African-Americans compared to 68.2% of non-African-Americans during the Year 5 Health Center visit ($p < .001$), with greater differences seen in the ACE-inhibitor lisinopril arm (54% vs 65%; $p < .001$) than in the diuretic chlorthalidone (64% vs 70%; $p < .001$) or calcium-channel blocker amlodipine (62% vs 68%; $p < .001$) [3, 4].

The potential public health benefits of controlling hypertension, particularly in African-Americans [4], have motivated ongoing research to address the gap between recommended treatment goals and the proportion of treated patients who actually achieve the treatment goals. The accumulated results of patient level, provider and health system level and family and social level intervention research to improve hypertension control over the past three decades still leave many questions unanswered about what elements are necessary to achieve a clinically significant improvement in blood pressure control in health care settings [5]. Walsh *et al.* [6] evaluated published quality improvement interventions through 2003 that reported blood pressure outcomes. Of the 57 studies included, 47 included a combination of these strategies. The authors found that interventions that included team change, such as creation of a multidisciplinary team or institution of a case management model, resulted in the largest reduction in systolic (9.7 mmHg) and diastolic (4.2 mmHg) BP and was the only strategy that had a clearly significant effect on both systolic and diastolic pressure. Interventions that evaluated clinician reminders and clinician education alone did not show a significant pooled benefit for BP reduction.

Fahey *et al.* [7] examined RCT's that tested "models of care" to improve BP control in ambulatory settings. In general, the interventions assessed in the review did not produce clear results. Many of the classes of interventions yielded heterogeneous results that did not permit statistical pooling of the effects. In an update of this systematic review published in 2010 [8], the authors added self-monitoring of blood pressure as a strategy. The updated review confirmed the earlier finding that the organizational approach of regular monitoring of hypertension control with vigorous intensification of treatment as tested in the Hypertension Detection and Follow-up Program (HDFP) [9, 10] yielded the greatest reductions in BP. Self-monitoring, and nurse- or pharmacist-led care showed small positive effects, and the authors recommended further evaluation of these approaches.

Medication adherence may be a significant factor in explaining residual uncontrolled hypertension in patients on antihypertensive treatment [11]. Schroeder *et al.* [12] examined interventions to improve adherence to anti-hypertensive pharmacotherapy in ambulatory settings. The types of interventions tested included education of caregivers and patients, simplification of dosing regimens, involvement of allied health professionals, special monitoring, motivation (i.e., financial incentives, reminder packages, reminder aids). The authors found that simplification of dosing regimen increased adherence ranging from 8 to 19.6 percent. There was inconclusive evidence for the effect of motivational interviewing and more complex interventions. Education alone appeared largely unsuccessful. An effect on both adherence and blood pressure was only observed in seven out of 58 interventions. A trial published after the cutoff for inclusion in the review by Schroeder *et al.* [12] showed that motivational interviewing delivered over a 12-month period improved medication adherence in an African-American clinic population [13].

The studies discussed above suggest that structured education programs alone, or provider interventions alone, are unlikely to be effective approaches to further improvements in hypertension control. Furthermore, they do not address the question of whether specific subsets of interventions are more effective than others in eliminating the disparity in levels of blood pressure control achieved in African-Americans on treatment.

In September 2004, NHLBI funded five projects that aimed “to evaluate clinically feasible interventions to effect changes in medical care delivery leading to an increase in the proportion of African American patients whose BP was controlled” [14]. The RFA that solicited the multi-component proposals (RFA HL–04–007) indicated that interventions targeted only to the individual patient level would not be viewed as competitive. The funded projects were designed independently by the teams of investigators from different institutions. However, the teams formed a collaboration before and during implementation of their respective projects to explore commonalities in choice of primary and secondary outcome measures, planned intervention components, and to share problems and experiences during the implementation phase. When the projects were completed, three of the groups agreed to pool their raw data and perform a combined analysis of their trial results in order to assess the magnitude of any observed effects with each type of intervention, and to evaluate the implications of the findings for the design of future health system based research to improve hypertension control. Of the two groups not included in the pooled analysis, one did not complete data collection [15]. The second involved a setting, study population, and intervention delivery that was so different from the others that inclusion in the pooled analysis was not deemed appropriate [16, 17]. In this paper we report the results of the combined analysis of three of the five trials [18–20] and discuss their implications in light of the accumulated literature on BP control interventions.

METHODS

Individual Trial Characteristics

The methodologies of the three trials included in this analysis have been reported in detail previously [21–23]. Although the interventions tested in the trials were different, the target populations for each were African-Americans with uncontrolled hypertension, defined according to the consensus guidelines in effect at the time of trial implementation—i.e., SBP < 140 mmHg and DBP < 90 mmHg, with the lower thresholds of 130 mmHg and 80 mmHg if the individual had diabetes or kidney disease. The participants were identified and recruited from clinical populations. Two of the trials were conducted in the New York metropolitan area, and the third was carried out in Houston, Texas. We will refer to the three different trials as New York Visiting Nurse (NYVN) [18, 21], New York Community Health Centers (NYCHC) [20, 22], and Houston Clinics (HC) [19, 23].

The main features of the trial designs are summarized in Table 1. All of the trials had components that, through direct or indirect effects, were designed to: 1) improve patients’ adherence to medication and lifestyle advice; 2) encourage providers to increase treatment intensity to achieve the recommended treatment targets of SBP < 140 mmHg and DBP < 90 mmHg, or < 130 mmHg and < 80 mmHg if diabetes or renal insufficiency is present [24].

Individual Trial Results

The NYVN investigators published an interim analysis of 3-month results that showed a non-significant intervention effect in the entire sample, but a significant increase in the proportion of patients with severe hypertension at baseline (SBP ≥ 160 mmHg or DBP ≥ 100 mmHg) whose blood pressure was controlled [18]. This result occurred in the arm that

involved intensive nurse-delivered, home-based counseling, monitoring and feedback, compared to usual care or a less intensive intervention of education with instructions on self-monitoring. As reported below the 12-month outcome was negative.

For the pre-specified primary outcome of BP control at 12 months using research measurements obtained with an automated device (BPT_{ru}), the NYCHC investigators did not find a significant difference between the intervention group (49.3%) and usual care (44.5%); OR, 1.21; 95% CI, 0.90 – 1.63; $p=0.21$) [20]. With respect to BPs measured in the CHC by staff using routine care measures, including non-automated devices (“office BPs”), the investigators found a statistically significant treatment effect, although this was not the primary pre-specified outcome. From baseline to 12 months, office SBP decreased 8.4 mmHg and 3.4 mmHg at the intervention and usual care sites respectively ($p=.006$ for treatment effect). From baseline to 12 months, office DBP decreased 6.1 mmHg and 3.2 mmHg at the intervention and control sites respectively ($p=.03$ for treatment effect). At 12 months, the rate of office BP control was 40.9% and 31.0% at the intervention and control sites, respectively ($p=0.09$).

The HC group did not find a significant difference between the groups in the proportion of patients who met control targets based on office blood pressure after a predefined minimum follow-up period of 24 months (35.0% in the intervention group and 31.9% in the control group, $p=.39$) [19]. However, they observed significant quadratic trends in both SBP and DBP favoring the intervention group after approximately 18 months of follow-up ($p=0.048$ for SBP and $p=0.001$ for DBP).

Modeling of Pooled Effects

The pooled analysis of blood pressure outcomes in the three trials had two main goals: 1) to determine whether relatively small intervention effects that were not significant in the individual trials could be detected in the larger pooled sample which has greater statistical power to detect small differences; and 2) to determine whether the magnitude of the intervention effect differed for any of the sites. The collaborators recognized that there was significant heterogeneity among the types of interventions tested, as well as among clinicians and patients. However, they felt that the comparability of the target population, and the general focus of the interventions on encouraging physicians to seek lower control targets and patients to increase adherence to recommended medication and lifestyle regimens justified a pooling of results.

As noted in Table 1, the measurement of the primary BP outcome differed across sites. At NYVN, the measurements were obtained in the patient’s home by trained Research Assistants (RAs) using a validated automated device (Microlife Model 3AA1–2). The nurse interventionist did not see the RA measurements, but relied on a combination of periodic in-home visits and self-report to monitor the patient’s BP. Likewise, the RA measurements were not reported to the patient’s primary care provider, but patients were coached to discuss their home BP monitoring results with their providers. At NYCHC, the pre-specified primary outcome was a BP measurement with a validated, automated device (BPT_{ru}) obtained by a trained RA in the CHC setting. These measurements did not necessarily coincide with a regular office visit, and NYCHC physicians did not see the RAs BP

measurements. However, NYCHC staff also collected the office BP measurements recorded in patient's charts on any visit made during the follow-up period. At the HC site, the primary outcome was based on routine office BP recorded in the patient's medical record at the time of their regular visits. At baseline, and at as many follow-up visits as possible, the HC RAs also obtained a research BP under standard conditions using a validated automated device. At NYCHC, 7 percent (571/7918) of the follow-up office and research BP measurements occurred on the same day, and at HC, 29 percent (871/2961) occurred on the same day.

The NYVN trial had three arms, as described in Table 1. However, in interim analyses, no differences were observed between the basic nurse intervention and usual care. Since the two other trials had only two arms, we decided to include only participants exposed to the usual care and augmented arms in the pooled analysis. Thirty-seven percent of the participants in the HC trial were not self-identified African-Americans, and these were also excluded from the pooled analysis.

The modeling technique that is most suited to the structure of the data generated in these studies is mixed effects longitudinal linear regression. This approach permits adjustment for multiple levels of nested data, and an unbalanced number of observations within patients and practices over the follow-up period. This analytical approach has been applied recently to assess intervention effects in a weight loss and blood pressure self-management intervention [25]. In these models, the linear regression coefficients represent the average change, or slope, in the dependent variable for an individual subject (in our case, SBP and DBP) in relation to specified independent variables, after taking into account the random variation in intercepts and slopes of the clusters in which the individuals are nested. Because of the different sources of BP measurements available in the study, and the use of clinic blood pressure as the primary outcome measure at one site (HC); we decided to include all available measurements in the models. In the number of cases noted above, two types of measurements (research and clinical) were obtained on the same day. The primary endpoint at NYVN and NYC was assessed at 12 months post-enrollment, and hence, the BP measurements from HC collected more than 12 months after enrollment were excluded. Modeling was carried out using SAS Proc Mixed. STATA 10 *xtmixed* procedure was used to produce fitted graphs of BP trends.

We assessed the overall effect on SBP and DBP of being assigned to the intervention group. In this model, age, sex, education level, history of diabetes, BP measurement method, and study group assignment (intervention or control) were included as fixed effects. Other potential covariates, such as employment status or a broader range of comorbidities were not measured consistently across the three sites, and were thus not included as adjustment variables. The random effects were the study site, randomization cluster, and patient-specific intercepts and slopes. The interaction of study group assignment by months since enrollment was used to assess whether the slope of blood pressure change differed significantly by study group assignment. Since other investigators had found non-linear changes in blood pressure over time during behavioral interventions, we also tested a quadratic term for time. Since the sample size at each site varied considerably, we weighted each observation in the regression models by the inverse of the proportion of patients contributed by the site. We used the same modeling approach for assessing effects at the individual study site level.

RESULTS

Table 2 provides a summary of individual participant characteristics at each site, unadjusted for clustering. The participants at NYVN were on average 8–10 years older than those at the other two sites. The samples also differed significantly with regard to proportion of patients with a high school education or less, proportion with diabetes, and proportion with severe hypertension at enrollment (defined as SBP ≥ 160 mmHg or DBP ≥ 100 mmHg). Although the mean number of antihypertensive medication in the patient's regimen reached statistical significance in the cross-site comparison, the absolute difference was very small. Differences in the proportion of patients whose regimen included a diuretic did not differ significantly.

Uncontrolled hypertension was a stated patient inclusion criterion across the sites. The research staff SBP measurement was higher at the NYVN site, as would be expected, given the higher age of that patient sample. Research SBPs at the NYC and HC sites were nearly identical. The research DBP varied across the three sites by small, albeit statistically significant amounts. Office staff measured SBP and DBP were not available for NYVN. The office SBP was similar in the NYCHC and HC samples, but DBP was significantly higher at NYCHC. Notably, the office SBPs and DBPs were lower than the research measurements at both sites.

Table 3 presents the pooled modeling results for SBP and DBP, and the fitted curves for these models are shown in Figs. 1 and 2. For both outcomes, the interaction of intervention group assignment by time was not significant; indicating that the cumulative change in BP did not differ between the intervention and the control groups. The coefficients for linear decline per month of follow-up were -2.60 mmHg for SBP ($p < .001$) and -1.46 mmHg for DBP ($p < .001$). The quadratic term for time was also significant, with regression coefficients of $.167$ mmHg SBP ($p < .001$) and $.09$ mmHg DBP ($p < .001$) for each month squared. The coefficient for measurement method was statistically significant, reflecting a difference of -1.476 mmHg SBP ($p = .002$) and -1.192 mmHg DBP ($p < .001$) for an office measurement compared to a research measurement.

DISCUSSION

The pooled effect of intervention group participation in three cluster-randomized trials to improve BP control in African-Americans was not significant for SBP or DBP over a 12-month time frame. None of the individual trials had a significant overall intervention main effect during this interval. Small BP differences favoring the intervention condition at individual sites did not result in a statistically significant effect in the pooled analysis. The trials included large sample sizes. The interventions were (i) designed by experienced investigators, (ii) grounded in established theoretical behavioral change frameworks, (iii) delivered in practice-based settings, and (iv) used a combination of research and office-based (pragmatic) BP measures. This lack of intervention impact on a significant public health parameter in a high risk population group deserves a careful analysis of potential explanations for the results observed at 12 months.

It is notable that, in spite of different intervention approaches, all three trials manifested a similar pattern of blood pressure change over a 12-month period. This pattern was characterized by an initial, parallel BP decline in both intervention and control groups, followed by an upward trend toward the baseline levels in both groups. We examined other BP control behavioral intervention trials to assess the extent to which the BP trends in our trials differed from others. Elmer *et al.*, in an 18-month follow-up of the Premier trial participants [26], reported -7.8 mmHg drop in SBP at six months and -9.9 mmHg SBP drop at 18 months in hypertensives assigned to the least intensive of the three intervention arms (advice only). A quadratic trend for both SBP and DBP is apparent in both of the two more intensive intervention conditions: SBP change of -12.5 mmHg at six months to -11.4 mmHg at 18 months in “Established” group which received counseling to lose weight, increase physical activity and reduce sodium and alcohol intake; SBP change of -14.2 mmHg at six months to SBP of -11.0 at 18 months in Established + a high fruit, vegetable and dairy, and low saturated fat (DASH diet) group. The DBP patterns were somewhat different — DBP continued to fall in advice only and in the established groups, but remained at the same level at 18 months in the DASH group as was achieved at six months.

Svetkey *et al.* [27] tested, in a 2×2 factorial design, an 18-month patient behavioral intervention, a physician quality improvement intervention, and the two combined. In the control group (no patient or physician intervention), SBP declined by 6.7 mmHg at six months and 7.5 mmHg at 18 months. DBP declines of 3.6 mmHg and 4.9 mmHg, respectively, were seen in the control group. While statistically significantly, greater drops were seen in the patient intervention and patient + physician intervention arms at six months. These differences were attenuated and are no longer statistically significant compared to the control group at 18 months. The net maximum differences in BP achieved between intervention and control groups at six months were 3 mmHg systolic and 1.8 mmHg diastolic. Uncontrolled hypertension was not a selection criterion for this study.

Bosworth *et al.* [28] randomized individual hypertensive patients to four conditions: behavioral counseling, home BP monitoring, both, usual care. There was no change in BP in the usual care group over 24 months. Each individual intervention group had a quadratic trend in BP change, with an initial drop followed by a return to base levels. The combined intervention group reduced and maintained BP improvements at 24 months. Selection criteria did not require that patients be uncontrolled.

The trial funded by the same NHLBI RFA but not included in the pooled analysis, tested an intervention delivered by trained pharmacist-technician teams in 28 chain pharmacies located in predominantly African-American neighborhoods in a Midwestern state [16, 17]. Participants with uncontrolled hypertension were recruited through screenings at each pharmacy. The intervention consisted of scheduled visits with in-pharmacy counseling to help participants improve their medication adherence and pharmacist feedback to patients and physicians. The intervention period for each participant was six months, and outcome measurements were obtained at six and 12 months. The control group received printed material regarding ways to control BP. The investigators reported significant improvements in refill adherence in the intervention group at both measurement points [17]. At 12 months, statistically significant declines in both SBP and DBP were observed in both the control and

intervention groups. The SBP decline was significantly greater in the intervention compared to the control group (-13.64 mmHg vs -8.30 mmHg $p=.004$), but the DBP decline was not (-8.57 mmHg vs. -7.14 mmHg in intervention vs control groups, $p=.20$).

These studies suggest that BP improvements in the usual care or minimal intervention group are common, but not universal. Likewise, a reversion of the initial BP decline in intervention groups to baseline levels over time is the norm, rather than the exception. There has been surprisingly little attention in the hypertension control behavioral and health system literature to the BP changes in the control or placebo group. These individuals cannot be masked as to treatment allocation, and most study protocols calls for obtrusive physical and psychosocial measures, which may in themselves motivate additional attention to blood pressure control.

Although the initial decline in BP seen in all the settings may be in part due to regression to the mean as participants were selected on the basis of elevated BP measures, this statistical phenomenon does not explain the subsequent increase in BPs toward their baseline levels. Indeed, in the Systolic Hypertension in the Elderly (SHEP) study, which targeted a group with elevated SBP, the regression effect seen in the placebo group was maintained over the duration of this masked, placebo controlled drug trial [29].

It is possible that the absence of significant intervention effects in our trials may be attributable, in part, to the selected, high risk population of African-Americans living in urban environments. The participants in these trials were recruited in health care settings and were not highly selected research study volunteers. A possible lesson from the experience in these trials is that well-accepted behavioral strategies targeting patients and/or providers, when adapted for incorporation into routine care delivery processes, may not be sufficient to induce lasting, significant changes in BP levels of uncontrolled hypertension.

As interest increases in translating the results from efficacy trials of lifestyle change into clinical practice, the pragmatic, cluster randomized, multi-factorial trial has become more common. Experimental design considerations for such projects are complex. They frequently require multiple intervention sites and/or treatment conditions, and large patient sample sizes to account for clustering effects and/or relatively small effect sizes. Since it is difficult to mask treatment allocation from either patients or providers who participate in behavioral interventions, the threats to internal validity of the study identified by Cook and Campbell in their classic text may explain the non-significant effect sizes observed [30]: diffusion or imitation of treatments, compensatory equalization of treatments, or compensatory rivalry by respondents receiving less desirable treatments. These validity threats may become even more acute in cluster randomized designs, in which both clinicians and patients are targeted for intervention. If both groups of subjects are aware that they are under observation for achievement of a particular outcome, this may, in itself, have a sufficiently strong impact on behavior to result in outcomes similar to those in the more intensive, active intervention groups.

One additional observation from our pooled analysis deserves close attention—that is, the difference between the office and research measurements. The bias toward lower office

measurements compared to research measurements was observed at both sites where the two types of measurements were recorded. The office measurements were obtained by the medical assistant staff and recorded in the vital signs section of the visit record, as is customary in nearly all primary care settings. No formal documentation of the type of devices used at the multiple office settings that participated in this trial was kept, but the investigators were aware that a variety of devices were in use at different settings, that devices were subject to various calibration activities and frequencies, and that readings were taken by staff with different training and skills in BP measurement. The finding reinforces the need for standardization of blood pressure measurement in health care delivery settings in order to promote the accurate assessment of blood pressure and BP control rates. In addition, the substantial difference in effect size observed in one of the trials (NYCHC) with research compared to office BP measurements raises important methodological questions about the appropriate choice and measurement of outcomes for interventions that attempt to alter physicians' behavioral responses to an office-based BP measurement.

A limitation of our analysis is that the planned duration of the intervention varied across the three sites. At NYVN, the primary outcome was assessed at 12 months. At NYCHC there was an a priori planned examination of the intervention at 12 months, but observation activities continued for 24 months, with a final outcome assessment at that point. At HC, intervention conditions were put into place in the Health Centers and continued for up to 36 months, with a minimum exposure for each patient of 24 months. Since NYVN did not have observations beyond 12 months, we had to limit the pooled analysis to this 12-month interval. As reported in the main outcomes paper, when examined over a longer time period, the quadratic trend in the HC sites significantly favored intervention clinics [19]. However, the observation of the short term decline in BP in both intervention and control conditions, followed by a rise toward baseline, was remarkably consistent across the sites. This leads us to conclude that BP control behavioral interventions in cluster randomized designs should allow for the initial improvement in BP in all participants, and the behavioral interventions should be designed to sustain or continue the improvements initially observed. Additionally, multifactorial interventions that are practical for implementation in routine care must plan for relatively small effect sizes on the order of 3–4 mmHg. In spite of the limitations, this combined analysis can provide valuable lessons for investigators planning future health system-based interventions to improve hypertension control in urban, high-risk populations.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Fig. 1. Pooled SBP trends over 12 months. Curves fit by the mixed effects regression model in Table 3. p for linear time $\times$ group interaction=.62; p for quadratic time $\times$ group interaction=.53.

Fig. 2. Pooled DBP trends over 12 months. Curves fit by the mixed effects regression model in Table 3. p for linear time $\times$ group interaction=.39; p for quadratic time $\times$ group interaction=.67).

Table 1

Trial characteristics.

Site	Design	Number of Participants	Intervention(s)	Duration of Exposure to Intervention	Primary Endpoint	Secondary Endpoint(s)	Time from Enrollment to Primary Endpoint Assessment
NYVN	3 arms, randomized by nurse (n=312)	845 African-Americans with a diagnosis of hypertension referred for home nursing care after hospital discharge Powered to detect 20% in proportion controlled	1) <i>Basic</i> Intervention (nurse clinical reminders) 2) <i>Augmented</i> Intervention (basic plus transition to an ongoing HTN home program) 3) Usual Care TARGET: Care management, patient Adherence	3 months	Proportion of patients with BP controlled based on RA measurement	Systolic and Diastolic BP measured by RA in patient's home	12 months
NYCHC	2 arms, cluster-randomized by Health Center (n=30)	1058 African-Americans with uncontrolled hypertension recruited from Health Centers. Powered to detect 4 mm Hg for SBP and 3 mm Hg for DBP	1) Provider education and feedback + patient education, self-monitoring and behavioral counseling; 2) Usual Care TARGET: Provider Practice, Patient Adherence	12 months	Proportion of patients with BP controlled based on RA measurement	Systolic and diastolic BP recorded in medical record at last visit	12 months
HC	2 arms, cluster-randomized by Health Center (n=10)	665 (398 African-Americans) with uncontrolled hypertension recruited from primary care Health Centers Powered to detect 20% in proportion controlled	1) Availability of 24-hr ABPM, electronic pill counts, and lifestyle assessment/counseling to reduce uncertainty about need for intensification 2) Usual Care TARGET: Provider Practice	24–36 months	Proportion of patients with BP controlled at last visit based on routine Office BP measurement	Systolic and diastolic BP recorded in medical record at last visit	Average 24 Months

Table 2

Sample characteristics at baseline.

Patient Characteristics	NYVN (n=578)	NYCHC (n=1039)	HC (n=398)	p
Age	63.9 (11.1)	56.4 (12.1)	54.6 (10.9)	<.001
Sex (% female)	66.8	71.4	71.4	.125
Education (% High School graduate or less)	67.8	72.0	56.0	<.001
Diabetes (%)	57.6	36.3	45.0	<.001
Severe Hypertension (% with SBP 160 mmHg or DBP 100 mmHg)	52.9	45.1	62.6	<.001
Mean Number of Antihypertensive Medications (SD)	2.3 (1.2)	2.2 (1.0)	2.4 (1.2)	.002
On a Diuretic (%)	51.6	55.1	58.5	.093
Maximum Number of Blood Pressure Measurements During Study (Health Center and or Research)	3	25	24	
Total Number of Research BP Measurements	1405	3714	851	
Blood Pressure at Baseline (mmHg)	SBP DBP	SBP DBP	SBP DBP	p _{SBP} p _{DBP}
RA Research	155.1 (19.8)	151.1 (16.8)	151.5 (20.3)	<.001
Office Measurement	NA	148.5 (18.4)	148.1(20.4)	.756
			86.3 (13.4)	.002

Table 3

Results of pooled multilevel modeling of intervention effect *.

	Systolic Pressure			Diastolic Pressure		
	Coefficient	Std. Err.	p	Coefficient	Std. Err.	p
Age	.189	.030	<.001	-.294	.017	<.001
Sex (female=reference)	.043	.743	.954	2.407	.421	<.001
Education (some college=reference)	.942	.781	.228	-.602	.439	.171
Diabetes (yes=reference)	-1.082	.684	.114	2.585	.388	<.001
Study Group (Control=reference)	-.876	.995	.379	.137	.509	.788
Measurement Method (Research=reference)	-1.476	.359	<.001	-1.192	.213	<.001
Follow-up Month	-2.600	.211	<.001	-1.460	.125	<.001
Follow-up Month Squared	.167	.019	<.001	.090	.011	<.001
Study Group * Follow-up Month (linear slope of BP trend in intervention and control groups)	.145	.293	.622	-.148	.173	.393
Study Group * Follow-up Month Squared (quadratic trend difference in intervention and control group)	-.017	.026	.525	.006	.016	.670
Constant	139.61	2.73		103.59	1.399	
<i>Covariance Parameters</i>						
Cluster	12.816	4.020	<.001	1.090	.579	.030
Pt Level Intercept	115.19	6.320	<.001	36.939	2.067	<.001
Pt Level Slope	.788	.104	<.001	.179	.032	<.001
Site	10.080	10.864	.177	1.82	2.083	.191

* Modeling results for each individual site are shown in Supplementary Tables 1–3.