CLINICAL RESEARCH STUDY

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Racial Differences in Two Self-Management Hypertension Interventions

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ABSTRACT

BACKGROUND: Only one half of Americans have their blood pressure controlled, and there are significant racial differences in blood pressure control. The goal of this study was to examine the effectiveness of 2 patient-directed interventions designed to improve blood pressure control within white and non-white subgroups (African Americans, 49%).

METHODS: Post hoc analysis of a 2 by 2 randomized trial with 2-year follow-up in 2 university-affiliated primary care clinics was performed. Within white and non-white patients (n = 634), 4 groups were examined: 1) usual care; 2) home blood pressure monitoring (3 times per week); 3) tailored behavioral self-management intervention administered via telephone by a nurse every other month; and 4) a combination of the 2 interventions.

RESULTS: The overall race by time by treatment group effect suggested differential intervention effects on blood pressure over time for whites and non-whites (systolic blood pressure, $P = .08$; diastolic blood pressure, $P = .01$). Estimated trajectories indicated that among the 308 whites, there was no significant effect on blood pressure at 12 or 24 months for any intervention compared with the control group. At 12 months, the non-whites (n = 328) in all 3 intervention groups had systolic blood pressure decreases of 5.3 to 5.7 mm Hg compared with usual care ($P < .05$). At 24 months, in the combined intervention, non-whites had sustained lower systolic blood pressure compared with usual care (7.5 mm Hg; $P < .02$). A similar pattern was observed for diastolic blood pressure.

CONCLUSION: Combined home blood pressure monitoring and a tailored behavioral phone intervention seem to be particularly effective for improving blood pressure in non-white patients.

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KEYWORDS: Adherence; Clinical Trial; Disparities; Hypertension; Lifestyle; Self-management

Hypertension affects approximately 75 million individuals in the United States and is an important modifiable risk factor for stroke, renal disease, and cardiovascular disease.[1] Despite effective therapies, only 50% of patients with hypertension achieve their target blood pressure.[2] Hypertension is particularly burdensome among African Americans;[3] African Americans have higher average blood pressures compared with whites.[1] The racial differences in hypertension and diseases attributed to hypertension account for 15% of the overall difference in mortality between African

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Americans and whites.[4] Cross-sectional analysis of nationally representative samples of African American and white adults who participated in the National Health and Nutrition Examination Survey (NHANES) 1999-2002 and NHANES III conducted in 1988-1994 indicated that hypertension prevalence increased significantly from 35.8% to 41.4% among African Americans and from 24.3% to 28.1% among whites. Disparity in blood pressure control among treated cases increased, with 59.7% of treated whites and 48.9% of treated African Americans reaching blood pressure goals in NHANES III ($P < .001$).[5] Race is an independent predictor of uncontrolled blood pressure even after controlling for important comorbidities such as diabetes.[6,7] The efficacy of lifestyle interventions for lowering blood pressure is at least as great among African Americans as it is among other racial/ethnic groups.[8] Although improving the equity of healthcare is one of the key components of quality improvement,[9] it is unclear which components will reduce the significant disparity between African Americans and whites.

CLINICAL SIGNIFICANCE

- Non-white patients in the 3 intervention arms had significant systolic blood pressure decreases relative to usual care in the first 12 months.
- Only the combined intervention was effective for improving blood pressure in non-white patients in a 24-month period.
- Tailored hypertension lifestyle interventions combined with home blood pressure monitoring may reduce health care barriers and decrease health disparities among non-white patients with hypertension.

We conducted post hoc analyses among a racially and economically diverse sample of patients who received primary care for hypertension in 2 diverse primary care sites in a university health system. The main study findings have been published.[10] The current study examines the effectiveness of 3 interventions compared with usual care on systolic and diastolic blood pressures in a 24-month period within white and non-white patient subgroups: 1) home blood pressure self-monitoring only, 2) nurse-administered tailored behavioral self-management intervention only, and 3) a combination of home blood pressure monitoring and tailored behavioral intervention.

MATERIALS AND METHODS

Setting

The study took place at 2 university-affiliated general internal medicine clinics in Durham, North Carolina.

Patient Eligibility

Potentially eligible study patients were identified through weekly data extractions from the Duke University Health System's billing and appointment database for the study primary care clinics. Initial inclusion criteria were: 1) having a diagnosis of hypertension at least 12 months before the data pull date (*International Classification of Diseases 9th Revision* code of 401.0, 401.1, or 401.9); 2) being enrolled with a primary care physician at the clinic of interest for at least 12 months; 3) having received a hypertensive medication prescription (in the previous year); 4) having a scheduled non-laboratory primary care physician appointment during the next 30 days; and 5) residing in 1 of 32 specified zip codes in the areas surrounding Duke University Health System.

Exclusion criteria applied before randomization were: 1) having a diagnosis of dementia, Parkinson's disease, atrial fibrillation, or end-stage renal disease; 2) residing in a nursing home or receiving home health care; 4) being hospitalized for a stroke or heart attack, undergoing surgery for blocked arteries, or being diagnosed with metastatic cancer in the previous 3 months; 3) having poor vision or difficulty hearing on the telephone; 6) having difficulty understanding English; 4) participating in another blood pressure study; 5) having a spouse participating in the current study; and 6) having an arm circumference > 17 inches or wrist circumference > 8.5 inches.

Subjects were considered excluded from the remainder of the study for the following events, and we used their available data up to the point of the following events occurring: 1) no longer receiving most medical care at the Duke clinics; 2) being treated with dialysis in the past 6 months; 3) having received an organ transplant in the past 6 months; 4) residing in a nursing home or receiving home health care; or 5) being diagnosed with pulmonary hypertension in the past 6 months. See Figure 1 for numbers excluded by intervention and race subgroups.

Study members mailed qualifying patients a letter from the patients' primary care providers providing information about the study and stating that the study team may contact them to participate in the study. Research assistants made weekly screening phone calls to patients from a randomly ordered list of eligible patients with upcoming clinic appointments.

Overall, 2060 letters were mailed to patients inviting them to participate in the study. Research assistants attempted to contact 1728 of potential participants by phone. A total of 656 participants enrolled and consented; the remaining 1072 participants did not consent for the following reasons: had disconnected phones or incorrect phone numbers, were ineligible, declined to participate, and were not included primarily because of scheduling conflicts. Twenty additional patients were excluded at the time of the baseline interview because of arm size ($n = 18$), poor vision ($n = 1$), and not currently taking hypertensive medication ($n = 1$) (see Figure 1 for study flow).

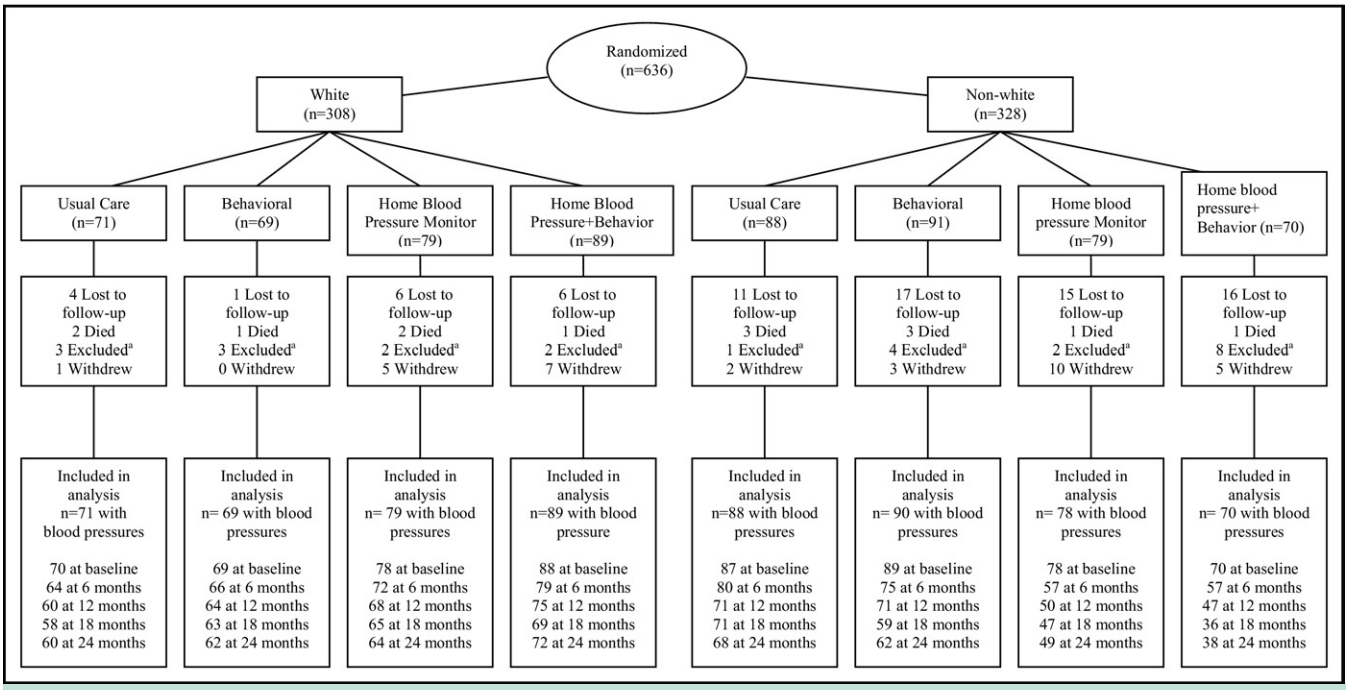

Figure 1 Take Control of Your Blood Pressure recruitment flowchart. [a]No longer receiving care at Duke clinics, receiving dialysis, received organ transplant, residing in nursing home or receiving home health care, no phone, or had pulmonary hypertension.

Patient Randomization

The remaining 636 eligible patients were randomized to 1 of 4 arms: usual care, tailored behavioral phone intervention alone, home blood pressure monitor alone, or both tailored behavioral phone intervention and home blood pressure monitor. Randomization was stratified by enrollment site (2 primary care clinics) and literacy status (≥9th vs <9th grade as determined by the Rapid Estimate of Adult Literacy in Medicine (REALM[11]) during the baseline interview. Site and literacy levels were used for stratification purposes because of concerns of potential site differences and prior literature suggesting that literacy may influence self-management interventions.[12,13] Within each stratum, patients were randomized using consecutively numbered envelopes. Participants were reimbursed $25 for the baseline visit and for each of the 4 subsequent 6-month blood pressure measurements ($125 total). The study was approved by the Duke Institutional Review Board, and all patients provided written informed consent. There were no study-related adverse events in any intervention group.

Interventions

Tailored Behavioral Self-Management Intervention. The behavioral intervention was tailored to individuals on the basis of their circumstances and needs.[14] Patient factors targeted in the tailored intervention included perceived risk of hypertension, memory, literacy, social support, patients' relationships with their health care providers, and side effects of hypertension medication therapy. In addition, the intervention focused on improving adherence to the following 5 hypertension recommendations: the Dietary Approaches to Stop Hypertension dietary pattern,[15-18] weight loss in the overweight,[19,20] reduced sodium intake,[20,21] regular moderate-intensity physical activity,[22,23] and moderation of alcohol intake.[24] In the hypertension perceived risk module, African Americans received specific information indicating that as a group, African Americans were approximately 2 times more likely to develop high blood pressure than Caucasians; that high blood pressure is generally more severe and occurs 5 to 10 years earlier in African Americans than other groups; and that African Americans tend to be more affected by salt intake than other races.

The intervention was delivered by a nurse during bimonthly telephone calls. All information was presented in an easily understood format with a Flesch–Kincaid readability[25] score of<9th grade. These encounters included a core group of modules potentially implemented during each call (eg, medication) plus additional modules activated at specific intervals (eg, diet, hypertension knowledge).[26]

The nurse underwent training in aspects of motivational interviewing[27] and in the specific procedures developed for this study. Maintaining or developing motivation and overcoming resistance are key issues for individuals attempting to initiate and change behaviors, and these were a focus of the nurse training. To ensure fidelity of the intervention, periodic intervention logs were examined.

Home Blood Pressure Monitoring Intervention. Patients randomized to the home blood pressure monitor interventions received an Omron HEM 773AC arm monitor (arm

circumference 9 -17 inches) or Omron HEM 637 wrist monitor (Omron Healthcare Inc, Bannockburn, Ill) if arm circumference was >17 inches and wrist circumference was ≤8.5 inches. Patients whose arm or wrist sizes did not fit into these categories at baseline were excluded from the study. Research assistants trained patients in the proper use of the home blood pressure devices. At each 6-month outcome assessment, patients reviewed their home blood pressure assessment procedures and were retrained if their procedures were incorrect. Patients were asked to take their blood pressures 3 times per week, on 3 separate days at the same time of day, and to record their values in a log. Patients were asked to mail their logs in every 2 months to the study coordinator using study preaddressed, stamped envelopes.

Combined Intervention. Patients randomized to the combined intervention received a home blood pressure monitor, training on its use, and bimonthly nurse-administered behavioral self-management intervention. The nurse did not examine home blood pressure values or use the home blood pressure values to adjust the intervention.

Usual Care. Patients randomized to usual care received their hypertension care from their primary care provider. They were not provided home blood pressure monitors by the study, nor did they have access to the nurse-administered behavioral intervention.

Study Measures

Baseline. Patient information, including age, self-described race, diagnosis of diabetes, and level of education, was obtained from patients during a face-to-face baseline interview. Financial status was assessed by asking patients to report whether they had enough money after paying bills for special things; enough to pay the bills, but not purchase extra things; enough money to pay bills by cutting back on things; or difficulty paying bills no matter what is done.[28] The latter 2 categories were categorized as inadequate income. The REALM[29] was used to measure health-related literacy. Health literacy was evaluated as a dichotomous variable with low literacy defined as REALM score 0 to 60 (<9th grade level) and adequate literacy defined as REALM score 61 to 66 (>9th grade level).[30]

Study Outcomes: Systolic And Diastolic Blood Pressures

The primary outcome of the study was systolic blood pressure measured at each time point (baseline, and 6, 12, 18, and 24 months of follow up) over the 24 months. Blood pressure was measured using a digital sphygmanometer (BpTRU automated noninvasive blood pressure monitor, Model BPM-100; Coquitlam, BC, Canada). The readings were taken by a research assistant who was blinded to the patient's randomization assignment. Two blood pressure readings were taken: the first after patients were seated and had rested in a quiet room separate from the clinical practice site, for at least 5 minutes, and the second 30 seconds after the first. The mean blood pressure reading taken at each of the 5 visits was used as the outcome. Diastolic blood pressure was a secondary outcome.

Analyses

The primary goal was to compare the effects of the intervention arms to usual care within white and non-white patient subgroups. For both systolic and diastolic blood pressures, general linear models (PROC MIXED in SAS, version 9.2; SAS Institute Inc, Cary, NC) were used to estimate trajectories over the entire study period by intervention arm and race subgroups. Exploratory analyses indicated that both systolic and diastolic blood pressures had quadratic shapes in which improvements in blood pressures were greatest during the first half of the study. The final model included a common intercept for white patients, a common intercept for non-white patients, and the following interaction terms: intervention arm by time (where time was coded as 0, 6, 12, 18, and 24 months), intervention arm by time-squared, and each of these terms interacted with race to estimate the differential intervention trajectories for white and non-white patients. Estimates and confidence intervals from this model were then used to test for blood pressure differences in the intervention groups relative to usual care at 12 and 24 months within white and non-white subgroups. An unstructured covariance was included to account for patients' repeated measurements over time.

Patients were analyzed on the basis of initial randomization group (intention to treat); 634 patients were included in the analyses. All available data, including data from participants who subsequently discontinued the study, were used for analyses. Our analysis techniques assumed the probability of dropout may depend on covariates in the model (ie, race and intervention group) or participants' previous responses but not on current or future responses.[31]

RESULTS

There were 308 white and 328 non-white patients. The majority of non-white patients were African American (95%). As shown in Table 1, baseline mean systolic blood pressure was 128.3 mm Hg (standard deviation [SD] = 19.0) for non-white patients and 121.5 mm Hg (SD = 15.6) for white patients; baseline diastolic blood pressure was 73.7 (SD = 10.5) for non-white patients and 68.8 (SD = 10.6) for white patients. Non-whites were younger, were more likely to be female, were not married, had lower levels of education and literacy, and had less income. In terms of behaviors, non-whites had higher body mass index and were more likely to report medication nonadherence than their white counterparts.[32]

Intervention Effects

The overall race by time by treatment group effect (6df test) suggested likely differential intervention effects over time

Table 1 Take Control of Your Blood Pressure Study Baseline Sample Characteristics, Overall and Stratified by Race

Baseline Characteristics*	Total (n = 636)	Non-white (n = 328)	White (n = 308)	*P* Value†
Demographics				
Age, mean (SD)	61 (12)	59 (12)	63 (12)	<.0001
Non-white race				–
American Indian/Alaskan Native	–	1%	–	
Asian	–	2%	–	
African American	–	95%	–	
Other	–	2%	–	
Hispanic	1%	2%	1%	.45†
Male	34%	27%	41%	.0003
Married	50%	35%	67%	<.0001
Lives alone	26%	26%	25%	.79
Completed ≤12 y of school	36%	50%	22%	<.0001
Low literacy level (<9th grade; REALM score ≤ 60)	27%	45%	8%	<.0001
Employed	39%	37%	42%	.26
Inadequate income‡	19%	28%	9%	<.0001
No weekly aerobic exercise lasting ≥ 20 min	23%	25%	20%	.13
Currently smokes	16%	21%	12%	.002
Mean BMI (SD)	32.1 (8.2)	33.7 (8.8)	30.5 (7.3)	<.0001
Self-reported medication	36%	49%	21%	<.0001
Non-adherence§				
Insurance				<.0001
Commercial	39%	34%	45%	
Medicaid	17%	27%	6%	
Medicare	41%	35%	48%	
Uninsured	3%	5%	2%	
Medical history				
Started taking blood pressure medication > 5 y ago	60%	66%	54%	.001
Parent or sibling has hypertension	77%	84%	70%	.001
Diabetic	36%	45%	26%	<.0001
Blood pressure‖				
Systolic, mean mm Hg (SD)	125 (18)	128 (19)	121 (16)	<.0001
Diastolic, mean mm Hg (SD)	71 (11)	74 (10)	69 (11)	<.0001
Blood pressure control	80%	72.5%	88%	<.0001

BMI = body mass index; SD = standard deviation.

*All data except blood pressure were patient reported. When missing values existed, they were included in the calculation of percentages.

†Cochran–Mantel–Haenszel chi-square *P* value for general association between non-whites and whites; for the Hispanic variable, the Fisher exact test was used.

‡Inadequate income defined as reporting difficulty paying bills no matter what was done or having money to pay the bills only because cut back on things.

§Self-reported adherence was assessed using a 4-item measure based on the Morisky scale.[42] Response options ranged from strongly agree (1) to strongly disagree (4). A summary binary variable was created by coding those who responded strongly agree, agree, or "don't know" to any of the 4 questions as nonadherent; otherwise, patients were coded as adherent.

‖When patients had multiple blood pressure readings during their baseline visit, mean systolic and diastolic readings were used as the baseline blood pressure values.

for white and non-white patients for both systolic blood pressure ($P = .08$) and diastolic blood pressure ($P = .01$). Estimated trajectories with confidence intervals are shown in Figure 2A and B. The estimated trajectories for white patients (Figure 2B) show similar patterns of change among the usual care, home blood pressure monitoring, and combined arms. Among white patients, mean systolic blood pressure was not significantly different at 12 and 24 months for intervention arm patients compared with usual care patients (Table 2). A similar pattern was observed for diastolic blood pressure except that white patients in the behavioral only group had a significantly higher mean diastolic blood pressure at 12 months when compared with the usual care group ($P = .03$).

In contrast, several interesting blood pressure patterns occurred among non-white patients. The estimated trajectories for non-white patients (Figure 2A) shows that all intervention groups improved during the first half of the study, but by the end of the study, only patients in the combined arm continue to show improvement. At 12 months, among non-whites, all intervention groups had significantly lower mean systolic blood pressure (all $P < .05$) compared with

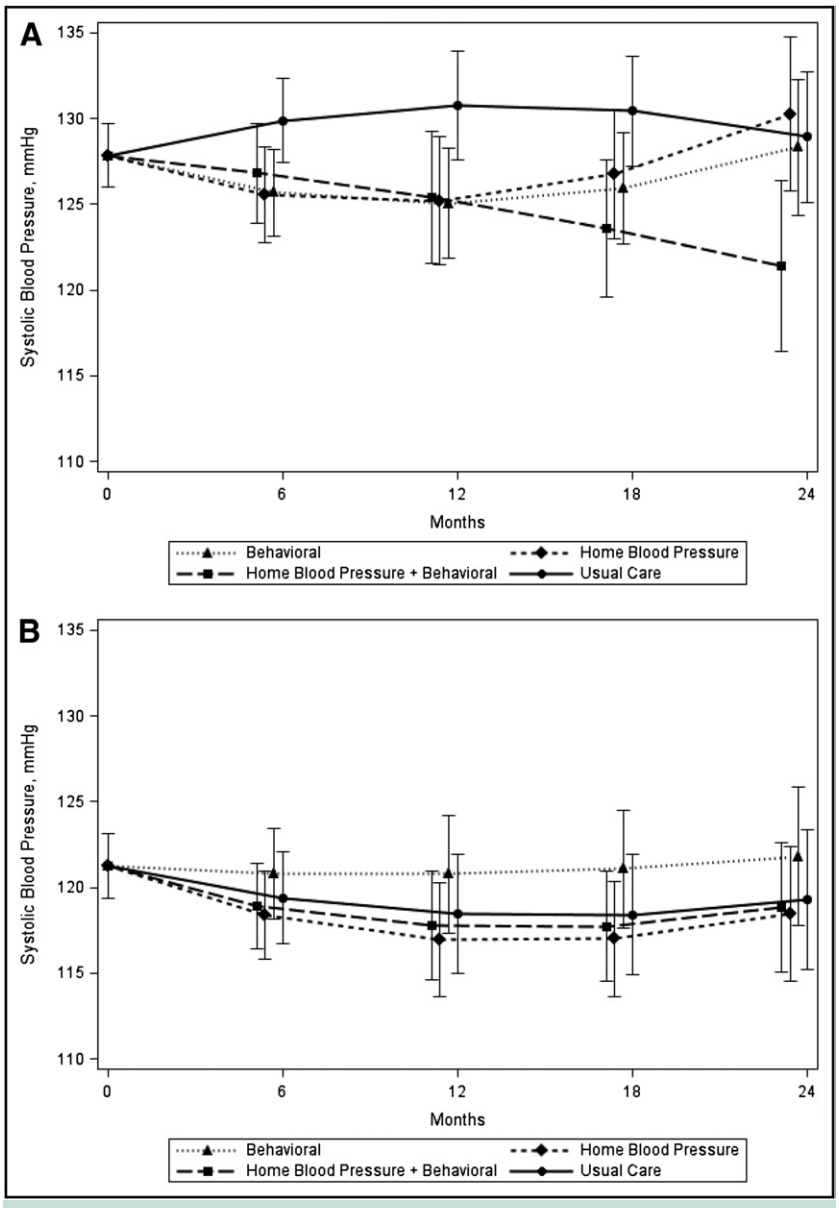

Figure 2 **A,** Changes in systolic blood pressure from baseline to 24 months, by intervention group for non-whites. **B,** Changes in systolic blood pressure from baseline to 24 months, by intervention group for whites.

the usual care group; estimated differences ranged from −5.3 to −5.7 mm Hg. However, at 24 months, only those non-white patients in the combined arm continued to have lower systolic blood pressure compared with the usual care group (−7.5 mm Hg; 95% CI, −13.7 to −1.4; $P = .02$). A similar pattern was observed for diastolic blood pressure among non-white patients. At 12 months, all intervention groups compared with usual care had significantly lower mean diastolic blood pressure (all $P < .05$); estimated differences ranged from −2.7 to −3.7 mm Hg. Again, compared with usual care, only patients in the combined group continued to have lower mean diastolic blood pressure at 24 months (−3.5 mm Hg; 95% CI, −7.0 to −0.1 mm Hg; $P = .04$) (Table 2).

DISCUSSION

In post hoc analyses, our data suggest a potential difference in treatment response to a self-management intervention between white and non-white patients. Non-white patients in the nurse behavioral, home blood pressure monitoring, or combined intervention groups had statistically significant systolic blood pressure decreases by 5.3 to 5.7 mm Hg relative to usual care in the first 12 months, but these improvements were sustained only in the combined behavioral and home monitoring arm (7.5 mm Hg improvement at 24 months) compared with usual care. For whites, we did not observe a significant decrease in blood pressure for any of the intervention groups over the 24 months relative to usual care.

Table 2 Estimated Differences (95% Confidence Interval) in Blood Pressure Between Take Control of Your Blood Pressure Intervention and Usual Care Groups at 12 and 24 Months for Race Subgroups

Outcome/Subgroup/Time Period	Behavioral vs Usual Care	Home Blood Pressure Monitor vs Usual Care	Home Blood Pressure Monitor and Behavioral vs Usual Care
Systolic blood pressure			
White			
12 mo	2.3 (−2.4 to 7.0)	−1.5 (−6.1 to 3.2)	−0.7 (−5.2 to 3.9)
24 mo	2.5 (−3.1 to 8.1)	−0.8 (−6.4 to 4.7)	−0.4 (−5.9 to 5.0)
Non-white			
12 mo	−5.7 (−10.0 to −1.4)	-5.5 (−10.3 to −0.8)	−5.3 (−10.1 to −0.5)
24 mo	−0.6 (−6.0 to 4.8)	1.3 (−4.4 to 7.1)	−7.5 (−13.7 to −1.4)
Diastolic blood pressure			
White			
12 mo	2.9 (0.4 to 5.4)	0.1 (−2.4 to 2.6)	1.3 (−1.2 to 3.7)
24 mo	2.0 (−1.2 to 5.1)	0.1 (−3.0 to 3.2)	0.5 (−2.5 to 3.5)
Non-white			
12 mo	−3.3 (−5.6 to −0.9)	−3.7 (−6.2 to −1.1)	−2.7 (−5.3 to −0.2)
24 mo	0.6 (−2.4 to 3.6)	−0.6 (−3.9 to 2.6)	−3.5 (−7.0 to −0.1)

We propose one potential explanation for our findings that the combination of blood pressure monitoring and nurse-administered bimonthly telephone behavioral intervention was most effective for non-whites and led to clinically and statistically significant improvements. First, consistent with a growing body of literature, lifestyle interventions seem to be as efficacious, if not more, among African Americans compared with whites.[33] There is excellent evidence demonstrating that sodium reduction leads to significant reductions in blood pressure in most patients, but an even greater decrease in both systolic and diastolic blood pressures among African Americans (–8.0 and –4.5 mm Hg, respectively) compared with whites (–5.1 and –2.2 mm Hg, respectively).[34] In addition, the Dietary Approaches to Stop Hypertension dietary pattern leads to a reduction in systolic blood pressure and diastolic blood pressure for most patients but a significantly greater reduction in systolic blood pressure among African Americans with hypertension (–13.2 mm Hg) compared with hypertensive whites (–6.3 mm Hg).[18] In recent "real-life" effectiveness trials, behavioral interventions designed to increase adoption of healthy lifestyles have been effective among African Americans, but generally less so than in whites.[35,36]

STUDY LIMITATIONS

This study has several potential limitations. Data were limited to only whites and non-whites seen in 2 community clinics in one geographic area and therefore may not generalize to other settings. Furthermore, our study was not designed to detect treatment differences in patient subgroups; therefore, our ability to provide definitive evidence of a differential treatment response by race was somewhat limited, especially among small subgroups such as whites with poor blood pressure control. In addition, the highest rates of dropout were observed in non-white patients in the combined intervention group. Although our analysis used all available data and is valid if all predictors of missing data were included in the model (ie, the missing data assumption of ignorability), the results could be biased if our model was misspecified or if we failed to measure and include other important predictors of dropout.[37] Finally, the comprehensive nature of the self-management intervention makes it difficult to discern which aspects of our intervention were the most beneficial.

CONCLUSIONS

The African American population is far from homogeneous, and each African American patient should be treated as an individual. Nonetheless, the rate of cardiovascular disease is 65% greater in African Americans than in whites,[38] the risk of coronary heart disease is 50% greater,[39] stroke is 200% greater,[40] hypertension-related end-stage renal disease is 320% greater,[40] and congestive heart failure is 2000% greater.[41] Thus, interventions targeting cardiovascular disease and hypertension that potentially reduce health care barriers and provide improved quality of care among non-whites may directly address one of the most important health disparities in the United States today.

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