Nurse-led Disease Management for Hypertension Control in a Diverse Urban Community: a Randomized Trial

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BACKGROUND: Treated but uncontrolled hypertension is highly prevalent in African American and Hispanic communities.

OBJECTIVE: To test the effectiveness on blood pressure of home blood pressure monitors alone or in combination with follow-up by a nurse manager.

DESIGN: Randomized controlled effectiveness trial.

PATIENTS: Four hundred and sixteen African American or Hispanic patients with a history of uncontrolled hypertension. Patients with blood pressure $\geq 150/95$, or $\geq 140/85$ for patients with diabetes or renal disease, at enrollment were recruited from one community clinic and four hospital outpatient clinics in East and Central Harlem, New York City.

INTERVENTION: Patients were randomized to receive usual care or a home blood pressure monitor plus one in-person counseling session and 9 months of telephone follow-up with a registered nurse. During the trial, the home monitor alone arm was added.

MAIN MEASURES: Change in systolic and diastolic blood pressure at 9 and 18 months.

KEY RESULTS: Changes from baseline to 9 months in systolic blood pressure relative to usual care was -7.0 mm Hg (Confidence Interval [CI], -13.4 to -0.6) in the nurse management plus home blood pressure monitor arm, and $+1.1$ mm Hg (95% CI, -5.5 to 7.8) in the home blood pressure monitor only arm. No statistically significant differences in systolic blood pressure were observed among treatment arms at 18 months. No statistically significant improvements in diastolic blood pressure were found across treatment arms at 9 or 18 months. Changes in prescribing practices did not explain the decrease in blood pressure in the nurse management arm.

CONCLUSIONS: A nurse management intervention combining an in-person visit, periodic phone calls, and home blood pressure monitoring over 9 months was associated with a statistically significant reduction in

systolic, but not diastolic, blood pressure compared to usual care in a high risk population. Home blood pressure monitoring alone was no more effective than usual care.

KEY WORDS: hypertension; randomized trial; minority; nurse management; home blood pressure monitor.

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INTRODUCTION

Hypertension affects 65 million Americans,¹ and the cardiovascular consequences of hypertension contribute to significant racial disparities in health. Cardiovascular disease accounts for 34% of the difference in expected life-years between blacks and whites, with hypertension alone accounting for 15%.² Although proven-effective lifestyle modifications³⁻⁵ and numerous pharmacologic agents⁶ exist, rates of blood pressure (BP) control among patients who are treated for hypertension remain suboptimal. In a nationally representative study, 65% of non-Hispanic white, 64% of Mexican-American, and 58% of non-Hispanic black patients who were taking antihypertensive medication had their BP below the recommended 140/90.⁷

A number of clinician-related and patient-related factors underlie poor BP control in minority communities. Patient self-care behaviors that contribute to low BP control include diet^{8,9} and exercise behavior¹⁰ that result in a high rate of overweight and obesity in minority communities, and non-adherence to medications,^{8,11,12} which some studies suggest is a greater problem for black patients. Clinician factors such as a satisfaction with an elevated BP^{13,14}; a failure to make medication changes when BP is elevated^{15,16}; and low expectations for BP control for low-income patients¹⁷ may also contribute to poor BP control.

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Chronic disease management programs may be an effective means of ameliorating these barriers to better BP control. Although randomized trials have yielded mixed results, meta-analyses suggest disease management for hypertension is generally effective.^{18–20} Interventions that target the specific needs of the target population are likely to be more successful; this is perhaps especially true in minority communities,²¹ which must overcome specific economic, language and cultural barriers to better BP control.

We conducted a randomized controlled effectiveness trial of a nurse based intervention tailored to the specific needs of black and Hispanic patients in East and Central Harlem, New York City who had treated but uncontrolled hypertension. The trial had three arms: a nurse management intervention, a home blood pressure monitor intervention, and usual care. Patients in the nurse group received a face-to-face counseling session with a trained nurse, a home blood pressure monitor, and regular telephone follow-up with the nurse over 9 months. Patients in the home blood pressure monitor arm received home monitors, but no interaction with a nurse. The primary outcome was blood pressure reduction at 9 months.

METHODS

Development of the Intervention

Clinician surveys, analyses of medical charts, and focus groups with patients with hypertension were conducted to identify modifiable barriers to better BP control. In the focus groups, patients reported a lack of confidence in their ability to maintain a low salt diet, in part because lifestyle recommendations were difficult to follow in the context of their family and social lives.⁹ Surveys found that clinicians had good knowledge of BP targets and recommended therapy,¹⁷ however a review of medical charts for 99 consecutive patients with uncontrolled hypertension found significant clinician inertia. Patients had a mean 6.6 visits per year, and BP was uncontrolled at 80% of those visits, but clinicians made changes to medication or referred the patient to a dietician or specialist in only 50% of those visits, and frequently cited patient non-adherence to medication in the chart.

The nurse intervention was designed to address these barriers. To improve self-care behaviors, a registered nurse provided face-to-face counseling with the patient. This counseling stressed vigilance in BP monitoring using the home BP monitor and BP diaries, gave strategies to improve medication adherence, and provided instructions to patients on how to read food labels on foods important to this community to better monitor salt and fat intake. Counseling was also provided on reducing smoking and alcohol intake. Regular telephone follow-up reinforced these messages. To address clinician inertia, nurses con-

tacted patients' clinicians to discuss problems with specific medications, especially those with side-effects that affected adherence, and arranged any prescription changes. A cardiologist monitored the nurse's work, initially in weekly and then biweekly meetings.

Patients in the home BP monitor group received information on its use and a pamphlet on strategies for controlling BP, but no follow-up with the nurse. Patients in the usual-care group received only the pamphlet, and continued to receive regular visits with their clinicians.

Settings and Recruitment

One federally qualified health center and all four hospitals in Harlem collaborated in the trial. The hospitals included one large private academic medical center (1,171 beds), two medium-sized municipal hospitals (286 and 363 beds), and one private community hospital (200 beds). All are not-for-profit institutions.

Patients eligible for the trial were self-described black or Hispanic adults ≥ 18 years; English-speaking or Spanish-speaking; community-dwelling at enrollment; had received care for at least 6 months in a general medicine, geriatrics, or cardiology clinic or office at a participating site; had uncontrolled hypertension ($\geq 140/90$ or $\geq 130/80$ for patients with diabetes or renal disease) recorded in the medical chart for their last two clinic visits, and $\geq 150/95$ ($\geq 140/85$ for patients with diabetes or renal disease) confirmed at recruitment. Exclusion criteria were pregnancy; renal dialysis; terminal illness; and medical conditions that prevented a patient's interacting with the nurse, including blindness, deafness, and cognitive impairment. Clinicians gave permission to recruit patients. No clinician refused permission to recruit his/her patients. The Institutional Review Boards (IRBs) for each site approved the study.

Bilingual recruiters screened charts for patients who had next day appointments in medicine or hypertension clinics at each site and approached eligible patients at the scheduled appointments. BP was measured in each arm with patient seated with feet on the ground. If no significant difference in BP was noted, the measurement was repeated in the dominant arm. After measuring the patient's BP, the recruiter conducted the baseline patient survey, and then called a project coordinator who conveyed the treatment assignment.

Randomization and Treatment Groups

The project's statistician used a computer-generated random-number sequence without blocking or stratification to generate randomized treatment assignments, and concealed these assignments in sealed opaque envelopes.

This trial was initiated as one of several studies in a program project grant, and was supplemented by funds from

a later center grant. This sequential funding process resulted in a three phase recruitment process. In the first phase, recruitment was restricted to usual care and nurse management arms in order to more fully fund other projects in the program. In the second phase, after additional funds were earned from the center grant, we added the home BP monitor arm, and recruited patients to all three arms. After the 120th patient was assigned to the nurse management arm, we initiated the third phase in which all subsequent patients were randomized to either the home BP monitor arm or usual care group. Because of this irregular recruitment process, patients from clinics that were added later in the study were more likely to be randomized to the BP monitor or usual care arms. Clinics in Harlem differ substantially in patient demographics, especially ethnicity. Consequently, to report differences between the nurse group and usual care, only those usual care patients who were recruited contemporaneously with the nurse management patients are used. Similarly, outcomes for home BP monitor patients are compared with those of contemporaneously recruited patients who were randomized to usual care. This results in 71 usual care patients serving as controls for both the nurse and home BP monitor groups.

Outcomes and their Measurement

The primary outcome was BP at 9 months, at the conclusion of the nurse intervention. We also measured BP at 18 months to assess whether any intervention effects were sustained. Research personnel who were blinded to treatment assignment met patients at the recruitment site at 9 and 18 months to record patient BPs. The same make of a validated²² sphygmomanometer (Omron HEM-712C) was used for all BP measurements.

We measured deaths recorded in the National Death Index plus deaths reported by patients' families. Since nurse management, home BP monitoring, and usual care involved only services delivered in routine practice, the study did not monitor adverse effects. As required by the academic center's IRB, we informed the IRB about hospitalizations and deaths. None was deemed intervention-related.

We administered patient surveys to assess how patient self-care behaviors changed between baseline and 9-month follow-up, and to measure self-reported medication adherence using a variation of the Morisky scale that was validated for use in a demographically similar population.²³ Patients were asked at baseline and 9 months validated questions²⁴ on difficulty controlling weight; reducing stress, smoking, alcohol, dietary salt or fat; and measuring their BP at home.

Statistical Analysis

We calculated that a sample size of 120 patients per treatment arm would have 80% power to detect a 5 mm/Hg difference

in the systolic BP between treatment arms at 9 months, assuming a rate of loss-to-follow-up of 20%.

For the primary outcome we report both complete-case and multiple-imputed results. For the complete-case analysis, we estimated linear regressions where the dependent variables were systolic and diastolic BP at follow-up, respectively. Independent variables included treatment assignment and pre-specified variables believed to be correlated with follow-up BP. These included patient baseline BP, age, gender, race/ethnicity (Non-Hispanic black, Hispanic black, Hispanic non-black), education, and body-mass index; and indicators for recruitment site, recruitment interview conducted in Spanish, insufficient health literacy,²⁵ and chart documented diagnoses of alcohol abuse, coronary artery disease, diabetes, depression, psychiatric diseases, and renal disease. We report the coefficient on treatment assignment as the adjusted difference in BP.

For the multiple imputed results, we used imputation by chained equations²⁶ as implemented by the "ice" command in Stata 10²⁷ to generate ten imputations for each missing BP measurement. The imputation equations were similar to those described above, but with the addition of a variable derived from BP measurements abstracted from the patients' charts. Briefly, we abstracted BPs recorded during routine outpatient visits during the trial and estimated a linear mixed model of chart-based BPs as a quadratic function of time, with random intercepts and random coefficients on time to account for patient-specific trends in BP. We calculated the patient-specific fitted value of this equation at $t=9$ and 18 months, and included them as independent variables in the imputation equation as estimates of what each patient's BP was on days when the patient had follow-up appointments. Simulations demonstrated that this procedure produces unbiased estimates of missing BP measures that had lower variance than estimates that did not use chart data.

RESULTS

We recruited 416 patients; 71 patients in usual care served as control subjects for both the nurse and home BP monitor groups. Patient characteristics were balanced between intervention groups and contemporaneously recruited usual care patients. Loss to follow-up (28% at 9 months) was substantial but did not differ by treatment group ($p=0.956$) (Fig. 1). The study sample was 59% Non-Hispanic black, 37% Hispanic, and 4% black Hispanic (Table 1). Deaths (8 over 18 months) were rare and did not differ statistically significantly by treatment group ($p=0.453$).

At nine months, systolic BP was statistically significantly improved in the nurse arm compared with usual care (Table 2). The nurse intervention ended at 9 months, and by 18 months, the difference in BP was not statistically significant, although this was due less to deterioration of gains in the nurse group than to continued reductions in BP

Figure 1. Study flow chart. Legend: Patients were recruited in three phases. In the first, recruitment was restricted to usual care and nurse management arms. In the second, the home blood pressure monitor arm was added and patients were recruited to all three arms. After the 120th patient was assigned to the nurse management arm, the third phase was initiated in which all subsequent patients were randomized to either the home blood pressure monitor arm or usual care group.

in the usual care group. There were no statistically significant differences in BP between the home BP monitor group and usual care at 9 or 18 months. Rates of BP control—defined as $\leq 140/90$ or $\leq 130/80$ for patients with diabetes or renal disease—improved from 0% at baseline to as high as 56% for the nurse group at 18 months, but were not statistically significantly different by treatment group. Accounting for lost to follow-up using multiple imputation generally confirms the complete case analysis (Table 2 column 5).

Figure 2 shows that systolic BP was lower in the nurse group not because of large drops in BP but because a larger percentage of patients had some reduction in BP since baseline. Eighty-one percent of patients in the nurse group had lower BPs at 9 months than at baseline, compared to 65% of usual care patients ($p=0.018$). No significant differences in this statistic were found between the home BP monitor and usual care groups. Figure 3 shows the percentage of patients who had changes in medication

Table 1. Characteristics of Patients by Treatment Group

	Total	Nurse management versus Usual Care		Home BP Monitor versus Usual Care	
		Usual Care	Nurse	Usual Care	BP Monitor
Count	416	118	120	129	120
Mean Systolic BP, mm Hg (sd)	153 (16.8)	152 (15.3)	152 (13.4)	153 (18.4)	155 (18.7)
Mean Diastolic BP, mm Hg (sd)	86.0 (13.4)	86.2 (13.7)	85.8 (14.0)	85.8 (13.5)	86.3 (12.9)
Mean Age, years (sd)	60.8 (11.6)	61.2 (12.0)	60.5 (11.1)	61.0 (11.8)	61.3 (11.7)
Hispanic, % (n)	36.5 (152)	39.0 (46)	34.2 (41)	42.6 (55)	34.2 (41)
Black, % (n)	59.1 (246)	55.1 (65)	60.8 (73)	55.0 (71)	63.3 (76)
Black Hispanic, % (n)	4.33 (18)	5.93 (7)	5.00 (6)	2.33 (3)	2.50 (3)
Female, % (n)	70.9 (295)	68.6 (81)	62.5 (75)	75.2 (97)	79.2 (95)
Interviewed in Spanish, % (n)	30.8 (128)	36.4 (43)	25.8 (31)	37.2 (48)	27.5 (33)
Education, % (n)					
Less than High School	53.7 (220)	52.1 (61)	51.7 (62)	53.1 (68)	58.6 (68)
High School Degree	27.6 (113)	30.8 (36)	27.5 (33)	31.3 (40)	20.7 (24)
Greater than High School	18.8 (77)	17.1 (20)	20.8 (25)	15.6 (20)	20.7 (24)
Inadequate Health Literacy, % (n) †	43.5 (181)	48.3 (57)	38.3 (46)	49.6 (64)	42.5 (51)
BMI Category, % (n)					
Normal	10.8 (45)	7.6 (9)	12.5 (15)	7.0 (9)	13.3 (16)
Overweight	81.7 (340)	83.9 (99)	80.0 (96)	84.5 (109)	80.0 (96)
Underweight	1.0 (4)	1.69 (2)	0.9 (1)	0.8 (1)	0.8 (1)
Missing	6.49 (27)	6.78 (8)	6.67 (8)	7.75 (10)	5.83 (7)
Alcohol abuse, % (n)	6.25 (26)	5.08 (6)	6.67 (8)	6.20 (8)	5.83 (7)
Coronary Artery Disease, % (n)	19.5 (81)	19.5 (23)	21.7 (26)	16.3 (21)	20.0 (24)
Diabetes, % (n)	51.4 (214)	55.1 (65)	47.5 (57)	57.4 (74)	50.8 (61)
Depression, % (n)	17.5 (73)	14.4 (17)	13.3 (16)	14.7 (19)	25.8** (31)
Psychiatric disease, % (n)	12.7 (53)	11.9 (14)	10.8 (13)	11.6 (15)	12.5 (15)
Renal disease, % (n)	17.1 (71)	12.7 (15)	15.0 (18)	17.1 (22)	19.2 (23)

*Note: 71 usual care patients serve as control for both Nurse Management and Home Blood Pressure Monitor only groups because they were recruited during times when patients were being randomized to all three treatment groups

** $p=0.029$

† STOHFLA score (0–16)

Table 2. Change in Systolic and Diastolic Blood Pressure from Baseline and Percent Controlled at 9 and 18 months for Patients in the Nurse Management Compared with Usual Care (top panel) and Home Blood Pressure Monitor Group Compared with Usual Care (bottom panel)

	Complete case analysis			Multiple imputation of missing BP
	Usual Care (sd) [n]	Nurse Management (sd) [n]	Adjusted difference [†] from usual care (95% CI)	Difference from usual care (95% CI)
Systolic BP, mmHg				
Change at 9 months	−8.1 (21.7) [n=83]	−15.8 (21.0) [n=85]	−7.0 (−13.4, −0.6)	−8.2 (−14.2, −2.3)
Change at 18 months	−14.4 (19.7) [n=79]	−14.5 (21.8) [n=79]	0.7 (−5.5, 7.0)	−0.4 (−6.9, 6.1)
Diastolic BP, mmHg				
Change at 9 months	−9.1 (12.0) [n=83]	−10.6 (14.9) [n=85]	−1.5 (−5.2, 2.2)	−1.5 (−5.0, 2.1)
Change at 18 months	−8.4 (11.3) [n=78]	−8.7 (12.8) [n=79]	−0.6 (−4.0, 2.7)	−1.3 (−4.9, 2.2)
BP Controlled [‡] , %				
At 9 months	41%	47%	5.6 (−11.4, 22.6)	9.6 (−4.4, 23.5)
At 18 months	48%	56%	7.5 (−11.8, 26.8)	6.6 (−7.5, 20.6)
	Usual Care (sd) [n]	Home BP Monitor (sd) [n]	Adjusted difference [†] from usual care (95% CI)	Difference from usual care (95% CI)
Systolic BP, mmHg				
Change at 9 months	−11.7 (22.8) [n=96]	−13.1 (26.2) [n=88]	1.1 (−5.5, 7.8)	1.2 (−5.4, 7.7)
Change at 18 months	−13.9 (24.5) [n=93]	−10.4 (29.2) [n=86]	4.7 (−2.6, 12.0)	4.9 (−1.7, 11.6)
Diastolic BP, mmHg				
Change at 9 months	−6.6 (13.1) [n=96]	−8.3 (12.2) [n=88]	−1.5 (−5.2, 2.2)	−0.7 (−4.6, 3.2)
Change at 18 months	−6.8 (13.3) [n=92]	−8.2 (13.6) [n=86]	−1.5 (−5.2, 2.2)	−1.6 (−5.3, 2.2)
BP Controlled, %				
At 9 months	41%	44%	1.7 (−15.1, 18.5)	1.2 (−12.9, 15.2)
At 18 months	49%	42%	−7.7 (−25.2, 9.9)	−4.4 (−18.4, 9.6)

† Adjusted difference for blood pressure is the coefficient on treatment assignment from a linear regression of follow-up BP on treatment assignment, BP at baseline, recruitment site indicators, and age, gender, race, Hispanic ethnicity, BMI, insufficient health literacy, interviewed in Spanish, and chart documented diagnoses of alcohol abuse, coronary artery disease, diabetes, depression, psychiatric diseases, or renal disease. Negative numbers reflect larger reductions in BP in the intervention group compared to usual care. Adjusted difference for % BP controlled is derived from a logistic regression of the same form with controlled BP (BP <140/90 or <130/80 for patients with diabetes or renal disease) as the dependent variable. For control, a positive number reflects improved rates of control

Abbreviations sd = standard deviation n = count

Figure 2. Systolic blood pressure at baseline, 9 and 18 months for patients in the usual care and nurse management groups (top panel) and usual care versus home BP monitor groups (bottom panel), by whether the blood pressure improved or worsened between baseline and 9 months. Lighter lines represent individual blood pressures at baseline, 9 and 18 months. Darker lines represent group mean blood pressures at those months.

prescribed from baseline to termination of intervention at 9 months, usual care versus intervention groups.

More patients in the nurse group had doses of medications decreased or discontinued by 9 months (Table 3). One self-care behavior, difficulty in measuring BP at home, declined substantially in both the home BP monitor and the nurse groups compared to usual care (Table 3). Changes since baseline in self-reported medica-

tion adherence did not differ statistically significantly across treatment groups.

DISCUSSION

Nurse management using one in-person counseling session, home blood pressure monitoring and periodic telephone

Figure 3. Percentage of patients who had changes in medication prescribed from baseline to termination of intervention at 9 months, usual care versus intervention groups. Legend: none.

contact over 9 months was effective in reducing systolic, but not diastolic, blood pressure among black and Hispanic patients with treated but uncontrolled hypertension in a diverse urban community. The 8.2 mm Hg reduction in systolic BP in the nurse group over usual care was similar to the 9.1 mm Hg reduction among treated patients in a meta-analysis of 792 trials of antihypertensive medications.²⁸ If sustained over 10 years for a patient age 60–69, this represents a 30% and 23% reduction in the ten-year stroke and ischemic heart disease mortality rate,²⁹ respectively. Whether these benefits would accrue to nurse-management patients is open to question because, as discussed below, while BP in the nurse group remained below baseline at 18 months, BP in the usual care group showed a difficult-to-explain reduction at 18 months as well. Nevertheless, the result of this trial convinced one of the participating clinics to implement the nurse management program.

Patients given only a home BP monitor showed decreases in BP at 9 months that were not statistically significantly different from those in usual care. BP in all three groups declined throughout the study. At 18 months—9 months after the nurse intervention ended—BP in the nurse group remained low, but was not statistically significantly different from usual care.

Compared to patients in usual care, patients in the nurse and home BP monitor groups reported statistically significant decreases in the difficulty of measuring their BP at home (Table 3, column 5). We found no evidence of medication intensification in the charts, or of improvements in self-reported medication adherence or health behaviors in patient surveys. At baseline, most patients reported good medication adherence, which suggests a ceiling effect may have limited our ability to detect changes in these measures. In addition, significant loss-to-follow-up contributed to low power to detect subtle difference in patient-reported measures.

Comparison to Other Studies

Our findings regarding nurse management are generally consistent with other randomized trials. Meta-analyses of nurse- or pharmacist-based interventions for controlling hypertension found heterogeneous but generally positive findings,¹⁸ with a range of differences from usual care in mean BP from −12 to 0 mmHg. The more limited benefit of home BP monitoring alone is also consistent with meta-analyses that find small though significant benefits of home BP monitoring,³⁰ and two recent trials that showed that adding counseling from a nurse or pharmacist to home BP monitoring resulted in significant improvement over home BP monitoring alone.^{31,32}

The present study differs from previous trials in several important respects. Ours is one of the few care management trials that specifically targeted African American and Hispanic patients with uncontrolled hypertension. Hill and colleagues found significant effects on BP of intensive care management by a nurse and community health worker team for young African American men with hypertension,³³ although these patients were recruited from the community and, unlike the present trial, much of the improvement in BP might be attributed to the high percentage of patients who were untreated at baseline.

Limitations

Four limitations should be noted. First, our attempt to expand the scope of the study by adding a treatment arm had some untoward consequences. Patients recruited later in the study were demographically dissimilar to patients recruited earlier in the study because recruitment at one site expanded later in the study. This created treatment

Table 3. Patients' Self-Care Behaviors at Baseline and 9 months, Nurse Management Versus Usual Care (top panel) and Home Blood Pressure Monitor Versus Usual Care (bottom panel)

	Usual Care		Nurse Management		% Change due to nurse management† (95% CI)
	Baseline (n=118)	9 Months (n=83)	Baseline (n=120)	9 Months (n=85)	
Self-reported adherence with medications					
How often do/are you‡...					
Forget to take meds, %	36.8	33.8	35.0	33.3	-8.2 (-24.3, 7.9)
Careless about taking meds, %	20.9	25.9	11.7	18.4	-5.8 (-18.4, 6.9)
Skip taking meds when I feel better, %	14.7	19.8	12.6	19.5	1.1 (-11.0,13.2)
Skip taking meds when I feel sick, %	7.76	10.0	10.1	8.05	-2.2 (-10.7, 6.3)
Skip taking meds for any reason, %	17.2	30.0*	23.5	26.4	-5.7 (-20.0, 8.5)
Adherence score§, mean (sd)	0.96 (1.30)	1.16 (1.58)	0.93 (1.38)	1.05 (1.39)	-0.2 (-0.6,0.2)
Any difficulty with self-care behaviors					
How difficult is it for you to ...					
Control your weight, %	63.6	68.7	68.1	68.6	-4.6 (-19.6, 10.5)
Keep a low salt diet, %	39.0	48.2	45.0	48.9	-3.6 (-19.7,12.5)
Keep a low fat diet, %	44.1	36.1	44.2	50.6	13.0 (-3.0, 28.9)
Exercise, %	69.5	68.7	66.4	69.3	1.4 (-12.6, 15.4)
Not smoke, %	23.1	25.3	24.4	23.9	-12.0 (-28.5,4.4)
Not drink too much alcohol, %	7.63	7.23	10.2	10.2	2.8 (-5.1,10.7)
Control stress, %	62.9	63.4	65.3	60.2	-3.0 (-17.9,11.8)
Measure BP at home, %	60.9	50.0	60.8	27.3*	-23.8(-38.7,-9.0)
	Usual Care		Home BP Monitor		% Change due to home BP monitor† (95% C.I.)
	Baseline (n=129)	9 Months (n=96)	Baseline (n=120)	9 Months (n=88)	
Self-reported Adherence with medications					
How often do you‡...					
Forget to take meds, %	38.3	36.8	39.3	45.6	8.7 (-6.4,23.9)
Careless about taking meds, %	15.0	25.5	18.8	23.9	-3.3 (-15.9, 9.3)
Skip taking meds when I feel better, %	16.5	13.7	12.8	11.2	-1.0 (-10.2, 8.2)
Skip taking meds when I feel sick , %	8.66	6.38	11.2	13.5	6.0 (-2.5,14.5)
Skip taking meds for any reason, %	26.0	27.7	24.1	22.5	-5.7 (-18.4, 6.9)
Adherence score, mean (sd)	1.03 (1.40)	1.07 (1.39)	1.03 (1.42)	1.16 (1.35)	0.1 (-0.3,0.5)
Any difficulty with self-care behaviors					
How difficult is it for you too...					
Control your weight, %	65.1	68.8	68.6	68.9	-2.7 (-16.8,11.4)
Keep a low salt diet, %	42.6	42.3	40.8	44.4	0.4 (-14.7,15.6)
Keep a low fat diet, %	43.4	35.1	36.1	40.4	6.0 (-8.6,20.5)
Exercise, %	69.8	68.0	71.4	62.9	-5.0 (-19.0, 9.1)
Not smoke, %	21.9	21.6	28.3	31.1	-1.7 (-18.5,15.1)
Not drink too much alcohol, %	5.43	6.19	9.2	13.3	5.2 (-2.8,13.2)
Control stress, %	63.8	60.4	65.5	71.9	12.4 (-1.5,26.3)
Measure BP at home, %	66.7	62.2	72.6	31.1*	-35.2 (-50.2, -0.1)

* $p < 0.05$

†Marginal effect of the intervention on the probability of a positive response at 9-month follow-up, from a logistic regression that controlled for response at baseline

‡Responses from a 5-point scale (0 = never, 1 = a little of the time, 2 = some of the time, 3 = most of the time, 4 = all of the time). Figures are the percent of patients with a response > 0

§The score for each patient is the sum of the item scores

|| Responses from a 5-point scale (0 = not at all difficult, ..., 4 = extremely difficult). Figures are the percent of patients with response > 0

groups that were comparable only when compared to contemporaneously recruited patients, and made direct comparisons of outcomes between nurse management and BP monitor arms improper. In addition, control patients recruited later in the study had statistically insignificant but nevertheless lower BP at 9 and 18 months compared to usual care patients recruited earlier in the study. This contributed to the null findings of the BP monitor group,

and may reflect a spillover effect of the intervention. For example, clinicians may have perceived a benefit to the home BP monitors used in the nurse group and prescribed them more frequently for their patients in usual care. Thus, a cautious interpretation of the findings regarding home BP monitoring is warranted.

Second, there is an unexplained decrease in mean BP in the usual care arm at 18 months that contributed to null

differences among treatment arms at 18 months. In addition to a spillover effect of the intervention, a Hawthorne effect may have come into play, in that by 18 months, study personnel had contacted usual care patients three times in-person to measure BP, and an additional two times by phone to administer brief surveys.

Third, despite our determined efforts, loss-to-follow-up was substantial, although in line with similar studies.^{31,33,34}

We used appropriate statistical techniques to address loss-to-follow-up, and found no evidence from BP measures taken from medical charts that BP from patients who failed to return for follow-up study measurement differed significantly from those who did.

Fourth, the only statistically significant mechanism to explain why systolic BP was lower in the nurse group at 9 months compared to usual care was reduced difficulty in measuring BP at home. Frequent contact with a trained nurse may have provided the social support needed to improve healthy behavior, including adherence to medications and confidence in self-care, in ways that are difficult to measure, especially given the reduced power associated with loss-to-follow-up.

CONCLUSION

For African American and Hispanic patients with uncontrolled hypertension, the combined effect of a home blood pressure monitor plus follow-up by a nurse manager over 9 months was associated with a statistically significant reduction in systolic, but not diastolic, blood pressure compared to usual care. Home blood pressure monitoring without nurse follow-up was no more effective than usual care.

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