A Multimodal Blood Pressure Control Intervention in 3 Healthcare Systems

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Objective: To determine if a multimodal intervention composed of patient education, home blood pressure (BP) monitoring, BP measurement reporting to an interactive voice response (IVR) phone system, and clinical pharmacist follow-up improves BP control compared with usual care.

Study Design: Prospective study with patient enrollment, medication consultation and adjustment, remote BP monitoring, and follow-up at 6 months.

Methods: This randomized controlled trial was conducted at 3 healthcare systems in Denver, Colorado, including a large health maintenance organization, a Veterans Affairs medical center, and a county hospital. At each site, patients with uncontrolled BP were randomized to the multimodal intervention vs usual care for 6 months, with the primary end point of BP reduction.

Results: Of 338 patients randomized, 283 (84%) completed the study, including 138 intervention patients and 145 usual care patients. Baseline BP was higher in the intervention group vs the usual care group (150.5/89.4 vs 143.8/85.3 mm Hg). At 6 months, BPs were similar in the intervention group vs the usual care group (137.4 vs 136.7 mm Hg, $P = .85$ for systolic; 82.9 vs 81.1 mm Hg, $P = .14$ for diastolic). However, BP reductions were greater in the intervention group vs the usual care group (–13.1 vs –7.1 mm Hg, $P = .006$ for systolic; –6.5 vs –4.2 mm Hg, $P = .07$ for diastolic). Adherence to medications was similar between the 2 groups, but intervention patients had a greater increase in medication regimen intensity.

Conclusions: A multimodal intervention of patient education, home BP monitoring, BP measurement reporting to an IVR system, and clinical pharmacist follow-up achieved greater reductions in BP compared with usual care.

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For author information and disclosures, see end of text.

Uncontrolled hypertension is associated with increased risk of myocardial infarction, stroke, kidney failure, and heart failure.[1] Randomized controlled clinical trials have shown the benefit of blood pressure (BP) lowering for reducing these adverse events.[2] Yet, hypertension remains uncontrolled in a large proportion of treated patients.[3] Some interventions to improve hypertension control have demonstrated reductions in BP, but the interventions are often complex and difficult to implement in routine clinical practice.[4] Furthermore, it cannot be assumed that interventions shown to work in one healthcare setting will be transportable and effective in a different healthcare setting.

The objective of the Improving Blood Pressure in Colorado study was to evaluate a multimodal intervention across 3 distinct healthcare settings. The intervention was composed of patient education, home BP monitoring, and BP measurement reporting to an interactive voice response (IVR) phone system, and clinical pharmacist management of hypertension with physician oversight. This was a practical clinical trial comparing the intervention plus usual care vs usual care alone for patients having diagnosed hypertension and uncontrolled BP. Our hypothesis was that patients randomized to the intervention plus usual care would have greater reductions in BP at 6 months compared with patients randomized to usual care alone (clinicaltrials.gov identifier: NCT00520988).

METHODS

Study Settings

This study was conducted at 3 healthcare systems located in metropolitan Denver, Colorado, including Denver Health and Hospitals, Veterans Affairs Eastern Colorado Healthcare System, and Kaiser Permanente Colorado. Denver Health and Hospitals is a safety-net health system that provides services to a large proportion of indigent, vulnerable, and minority populations in the city and county of Denver.[5] Veterans Affairs Eastern Colorado Healthcare System serves more than 60,000 Colorado veterans through its medical center in Denver and 8 outpatient clinics located throughout eastern Colorado. Many veterans live in rural Colorado communities with limited access to healthcare. Kai-

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ser Permanente Colorado is a nonprofit managed care organization that cares for more than 500,000 patients in the Denver-Boulder–Colorado Springs metropolitan areas through 2 contract hospitals and 20 outpatient clinics. Kaiser Permanente Colorado provides care to more than 60,000 Medicare, Medicaid, or dually eligible Medicare-Medicaid patients.

Take-Away Points

This practical clinical trial implemented across 3 healthcare systems showed that a multimodal intervention composed of patient education, home blood pressure (BP) monitoring, BP measurement reporting to an interactive voice response system, and clinical pharmacist management of hypertension led to greater BP reductions compared with usual care.

- This difference was likely due to greater therapy intensification (number and intensity of hypertension medications) in the intervention group, as adherence was comparable between the 2 study groups.
- These findings suggest that encouraging self-care through home BP monitoring and using clinical pharmacists to initiate and titrate antihypertensive medications with physician oversight can improve BP levels.

Patient Population

We performed population screening of potentially eligible patients using electronic BP data available within each healthcare system. Eligible for study participation were patients with hypertension who were taking 4 or fewer antihypertensive medications and who had elevations in 2 of the 3 most recent electronic BP measurements (>140 mm Hg for systolic or >90 mm Hg for diastolic; for patients with diabetes mellitus or chronic kidney disease, >130 mm Hg for systolic or >80 mm Hg for diastolic). Potentially eligible patients were contacted by phone and were invited for an initial (baseline) study enrollment clinic visit.

At the enrollment clinic visit, the patient's BP was measured using techniques recommended in the seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.[6] Three BP measurements were obtained 1 minute apart using an electronic BP cuff (BPM-100 professional BP monitor [A/A grade from the British Hypertension Society]; VSM MedTech Ltd, Coquitlam, British Columbia, Canada), and the average of the latter 2 BPs was calculated. Patients whose averaged BP exceeded 140 mm Hg for systolic or 90 mm Hg for diastolic (or >130/80 mm Hg for patients with diabetes or chronic kidney disease) and who consented to participate in the study were randomized to the intervention or to usual care. Patients whose averaged BP levels were below the cutoffs were ineligible for the study.

A block randomization design was used to ensure balance within healthcare systems. A random allocation sequence was computer generated using stratified randomization with an allocation ratio of 1:1 (intervention to usual care). We used commercially available statistical software (SAS RANUNI function; SAS Institute Inc, Cary, North Carolina) to generate the assignment list for each stratum according to site (Denver Health and Hospitals, Veterans Affairs Eastern Colorado Healthcare System, and Kaiser Permanente Colorado). The sequence was concealed until the intervention and usual care groups were assigned at the baseline visit. Patients randomized to usual care were educated about hypertension using a National Institutes of Health booklet on hypertension entitled *Your Guide to Lowering Blood Pressure* (http://www.nhlbi.nih.gov/health/public/heart/hbp/hbp_low/hbp_low.pdf) and were instructed to follow up with their primary care provider to get their BP under control.

Intervention

Four main components of the multimodal intervention were the following: (1) patient education, (2) home BP monitoring, (3) home BP measurement reporting to an IVR phone system, and (4) clinical pharmacist management of hypertension with physician oversight. After randomization to the intervention, patients were educated about hypertension using a National Institutes of Health booklet on hypertension (*Your Guide to Lowering Blood Pressure*), instructed about use of the IVR phone system, and trained on using an electronic BP cuff (UA-767; LifeSource, Milpitas, California) to monitor home BP.

Patients were instructed to measure their BP 3 to 4 times per week and were encouraged to measure their BP on different days of the week and at various times of the day. Patients were asked to report their BP measurements to the IVR phone system on a weekly basis. During the IVR call, patients were prompted to input their systolic and diastolic BP readings for the week using the touch-tone keypad of their phone. The average of the inputted measurements was calculated, and patients were given feedback on whether their BP measurements were at goal at the end of the call. In addition, patients were offered an opportunity to listen to educational messages or to request a call from the clinical pharmacist to answer questions.

Next, the clinical pharmacist reviewed the reported home BP measurements. For patients whose home BP measurements were above guideline-recommended treatment goals, clinical pharmacists reviewed medication adherence, made adjustments to antihypertensive medication regimens as appropriate, and provided counseling on healthy therapeutic lifestyle changes. For patients with essential hypertension, average home readings with systolic BP exceeding 135 mm Hg or diastolic BP exceeding 85 mm Hg triggered a clinical pharmacist

intervention. For patients with diabetes or chronic kidney disease, average home readings with systolic BP exceeding 125 mm Hg or diastolic BP exceeding 75 mm Hg triggered a clinical pharmacist intervention.

The clinical pharmacists practiced under preapproved drug therapy management protocols. The clinical pharmacist intervention varied based on the level of BP elevation, and clinical judgment was used to determine the intervention implemented (eg, patient counseling or education, dose adjustment, and addition of new medication). The clinical pharmacist discussed these changes with the patient during phone visits. The patient's primary care provider was notified of any medication changes through progress notes entered into the electronic medical record available within each of the healthcare systems, via a phone call, or both. Patients who did not enter any BP measurements into the IVR system after 10 days received an automated reminder call, followed by a call from the pharmacist 4 days later if necessary. Overall, 94% of intervention patients uploaded BP measures at least 1 time during the study period.

Primary Outcomes of BP Control and Change in BP

Primary study outcomes were (1) the proportion of patients who achieved guideline-recommended BP goals (ie, <140/90 mm Hg [or <130/80 mm Hg for those with diabetes or chronic kidney disease]) and (2) the change in systolic and diastolic BPs between the enrollment visit and the 6-month follow-up visit.

Intervention and usual care patients returned after 6 months for an end-of-study clinic visit to obtain 3 in-person BP measurements using the same standardized research methods used at the baseline enrollment visit. The research assistant who obtained the BP measurements was blinded to patient study group assignment.

Secondary Outcomes of Therapy Intensification and Medication Adherence

The secondary outcome of intensity of hypertension medication regimen was based on patient report of medication regimen (specific medication and dosage) at the enrollment visit and at the 6-month follow-up visit, with confirmation by reviewing the pharmacy list available through the site's electronic medical record or the pill bottles that patients brought to the visits. Each antihypertensive medication was categorized as low, moderate, or high intensity corresponding to a score of 1, 2, or 3 points based on the dosage prescribed (**Appendix**). For example, lisinopril at less than 20 mg was classified as low intensity (1 point), lisinopril at 20 to 40 mg as moderate intensity (2 points), and lisinopril at greater than 40 mg as high intensity (3 points). This algorithm was reviewed by a panel of internists and cardiologists not involved with the study and was believed to have face validity. For each patient, an average intensity score was derived based on the sum of the medication intensity score divided by the number of antihypertensive medications prescribed.

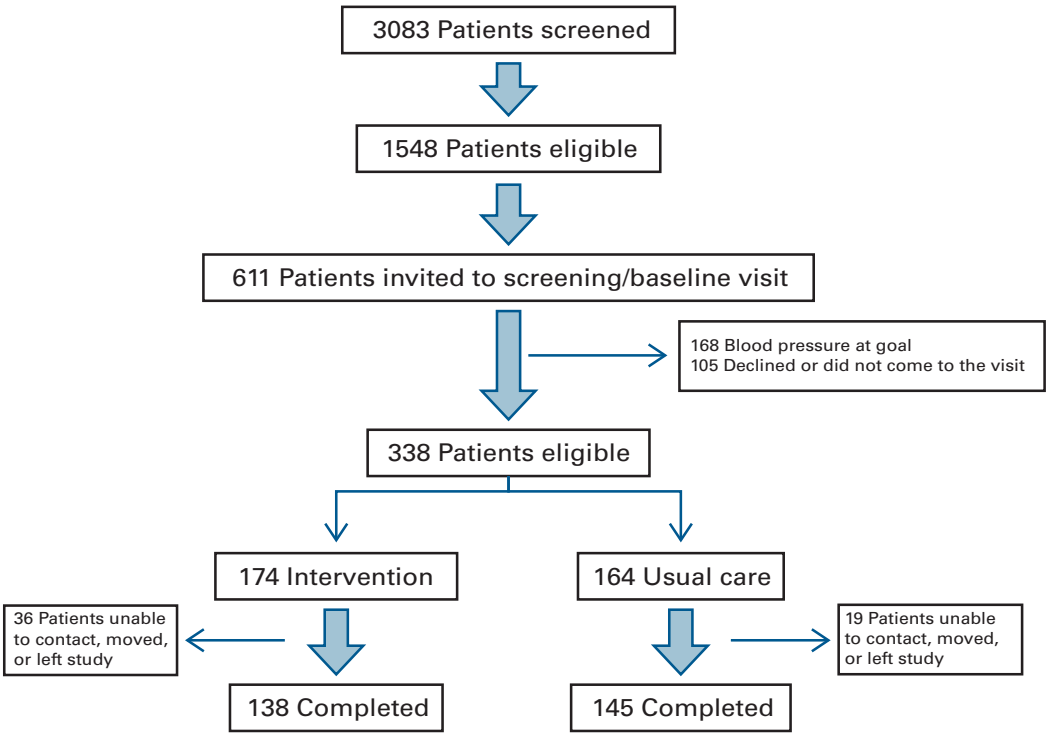
To assess the secondary outcome of medication adherence during the study, only Veterans Affairs Eastern Colorado Healthcare System and Kaiser Permanente Colorado patients were included because those sites had comparable automated pharmacy data that included all medications dispensed and sold within each of the respective healthcare systems. A medication possession ratio (MPR) was calculated based on the total number of days supplied for each filled antihypertensive medication divided by the period for which the medication was prescribed. For patients using multiple antihypertensive medications during this time, adherence to each medication was averaged to derive a summary adherence measure. Classes of antihypertensive medications considered included β-blockers, dihydropyridine calcium channel blockers, nondihydropyridine calcium channel blockers, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, α-blockers, and diuretics. Patients were categorized as adherent vs nonadherent using MPR cutoffs of at least 0.80 vs less than 0.80, consistent with the literature.[7]

Statistical Analysis

Our primary analyses applied intent-to-treat principles to patients who completed the end-of-study visit. Follow-up was attempted for all patients, and all patients who completed follow-up in their randomized intervention assignment were included, regardless of whether they used the IVR phone system or interacted with the study pharmacist. Baseline characteristics and BP, MPR, and therapy intensification outcomes were compared using *t* test for continuous variables and χ^2 test for categorical variables.

In secondary analyses, we assessed the association between medication intensity, medication adherence, and BP control. Because there was an interaction between medication intensity and medication adherence, we constructed separate models for the association between BP control and medication intensity among patients who were adherent vs nonadherent. In addition, a stratified analysis of change in BPs was conducted for patients with baseline systolic BP of at least 150 mm Hg vs less than 150 mm Hg. Finally, regression analyses that included site as a covariate were conducted. In this analysis, the outcomes of the intervention group vs the usual care group were similar to those noted in the primary analysis and are not presented in detail. All analyses were performed using commercially available statistical software (SAS version 9).

Figure 1. Patient Flow Diagram



RESULTS

Figure 1 shows the flow of patients through the initial screening, baseline visit, randomization, and 6-month follow-up phases of the study. Of 338 patients enrolled in the study, 283 (84%) completed the 6-month visit. Reasons for not completing the 6-month visit included failed contact attempt, moved from the area, and declined further participation in the study. There were no significant differences in the baseline demographic and clinical characteristics of patients who did vs did not complete the 6-month visit, although patients who did not complete the study had higher baseline systolic and diastolic BPs.

Baseline demographic and medical history characteristics of patients completing the 6-month visit in the intervention and usual care groups were comparable (Table). The mean age was 62 years; one-third of patients were female, and two-thirds were of white race/ethnicity. Slightly more than 50% of patients had diabetes or chronic kidney disease. At baseline, the mean (SD) BPs were significantly higher for 138 intervention patients vs 145 usual care patients (150.5 [19.5] vs 143.8 [16.8] mm Hg, P <.01 for systolic; 89.4 [13.6] vs 85.3 [11.1] mm Hg, P = .02 for diastolic).

At 6 months, the mean (SD) BPs were similar in the intervention group vs the usual care group (137.4 [19.4] vs 136.7 [17.0] mm Hg, P = .85 for systolic; 82.9 [12.9] vs 81.1 [11.7] mm Hg, P = .14 for diastolic). There was no difference between the intervention group vs the usual care group in the proportions achieving BP goal (36.0% vs 35.2%, P = .89).

Evaluating the changes in BP, greater reductions were experienced by intervention patients vs usual care patients in systolic BP (−13.1; 95% confidence interval [CI], −16.5 to −9.7 mm Hg vs −7.1; 95% CI, −9.8 to −4.4 mm Hg; P = .006) and in diastolic BP (−6.5; 95% CI, −8.5 to −4.6 mm Hg vs −4.2; 95% CI, −5.9 to −2.5 mm Hg; P = .07; Figure 2). The differences in BPs for intervention patients compared with usual care patients were −6.0 (95% CI, −10.4 to −1.7) mm Hg for systolic and −2.3 (95% CI, −4.9 to −0.2) mm Hg for diastolic. When the analysis was stratified by baseline systolic and diastolic BPs, among patients with a baseline systolic BP of 150 mm Hg or higher, there was a statistically significant difference in the change in systolic BP between baseline and 6 months for intervention patients vs usual care patients (−23.3 vs −15.1 mm Hg, P = .047). There was no statistically significant difference among patients with a baseline systolic BP of less than 150 mm Hg.

At baseline, the mean (SD) number of antihypertensive medications (2.1 [1.0] vs 2.1 [1.1], P = .99) and the mean (SD) intensity of the hypertension regimen (3.2 [1.9] vs 3.3 [1.9], P

Table. Baseline Characteristics of the Study Population

Characteristic	Intervention Group (n = 138)	Usual Care Group (n = 145)	*P*
Age, mean (SD), y	65.1 (11.1)	66.7 (12.2)	.23
Male sex, %	66.7	62.8	.49
Race/ethnicity, %			
White	65.9	64.8	.84
Hispanic	18.1	16.6	.37
Married, %	47.1	49.0	.75
≤High school education, %	21.7	24.1	.63
Diabetes or chronic kidney disease, %	52.2	58.6	.27
Never drink alcohol, %	18.1	22.8	.33
Current smoker, %	13.0	11.0	.60
Never exercise, %	10.1	6.9	.33
Blood pressure, mean, mm Hg			
Systolic	150.5	143.8	<.01
Diastolic	89.4	85.3	.02
No. of antihypertensive medications, mean (SD)	2.1 (1.0)	2.1 (1.1)	.99
Current medications, %			
β-Blockers	40.0	46.9	.23
Angiotensin-converting enzyme inhibitors	58.7	50.3	.16
Angiotension II receptor blockers	10.9	17.2	.12
Calcium channel blockers	23.9	24.1	.96
Thiazides	33.3	42.8	.10

= .39) were comparable between the intervention group and the usual care group. At 6 months, the intervention group vs the usual care group had a greater increase in the number of hypertension medications (change of 0.3 vs 0.1, P = .05) and a higher intensity of hypertension medication regimens (change of 0.6 vs 0.2, P = .008). For Veterans Affairs Eastern Colorado Healthcare System and Kaiser Permanente Colorado patients (n = 224), there was no significant difference between intervention patients vs usual care patients in the mean (SD) MPR (0.85 [0.19] vs 0.84 [0.19], P = .88) or in the proportion of patients categorized as being adherent (69.9% vs 69.4%, P = .93).

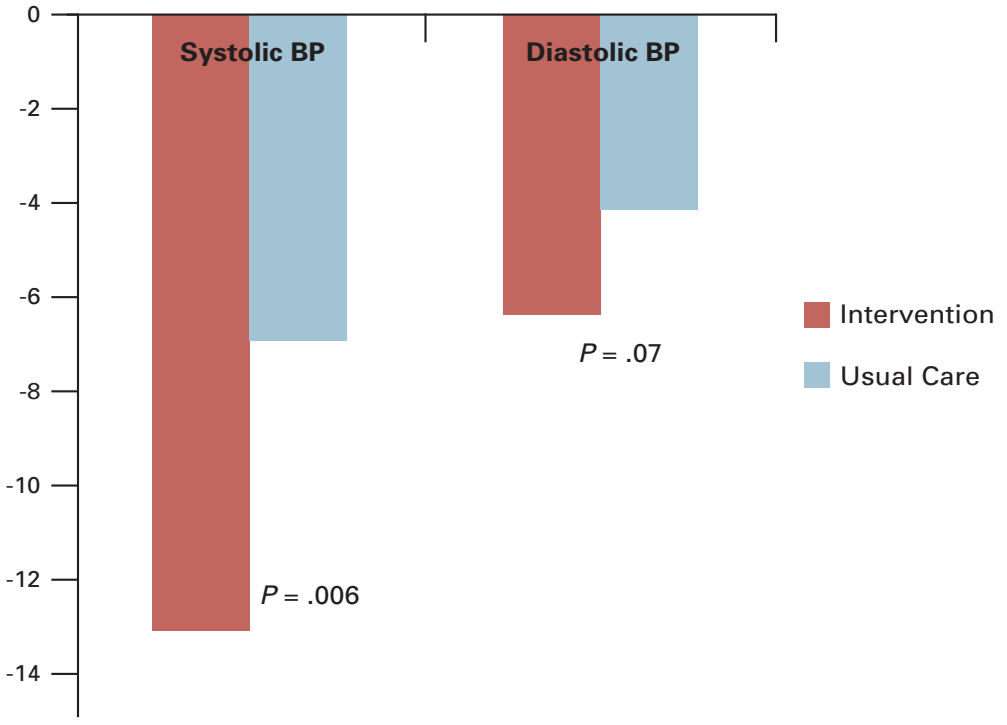
Finally, we assessed the association between medication intensity, medication adherence, and BP control. Among patients who were nonadherent (MPR, <0.80), medication intensity was not associated with BP control (P = .32). However, among patients who were adherent (MPR, ≥0.80), increasing medication intensity was associated with BP control (parameter estimate, −2.2; P = .04), suggesting that uptitration of medications does not affect BP control when patients are nonadherent to their BP medications.

DISCUSSION

This practical clinical trial implemented across 3 healthcare systems showed that a multimodal intervention composed of patient education, home BP monitoring, home BP measurement reporting to an IVR phone system, and clinical pharmacist management of hypertension led to greater BP reductions compared with usual care. This difference was likely due to greater therapy intensification (number and intensity of hypertension medications) in the intervention group, as adherence to hypertension medications was comparable between the 2 study groups. These findings suggest that encouraging self-care through home BP monitoring and using clinical pharmacists to initiate and titrate antihypertensive medications with physician oversight can improve BP levels.

The results of this study add to the literature on the value of technology to help promote self-care and to improve BP control.[4,8-12] We were able to use simple phone-based IVR technology to allow patients to stay connected to the healthcare system and to implement this technology across 3 distinctly different healthcare settings. Patients were able to

Figure 2. Reduction in Systolic and Diastolic Blood Pressures (BP) for the Intervention and Usual Care Groups



get prompt feedback about their BP levels after entering their measurements into the system. In addition, they received follow-up calls from the clinical pharmacist if their BP readings remained above guideline-recommended goals. Prior assessments of technology interventions have used the Internet or personal digital assistant devices and have generally been successful. However, these technologies may not be readily available to all patients with hypertension, and most of these investigations were performed within a single healthcare system,[4] limiting the generalizability of the findings. In our study, patients could access the IVR system through a landline phone or cell phone, which increases the generalizability of our results to other healthcare settings because most patients have access to a phone. The generalizability of the study results also is enhanced by the inclusion of a broadly representative population of patients with uncontrolled hypertension that included participants with diabetes and chronic kidney disease, populations that have been excluded in prior intervention studies.

Our use of additional personnel dedicated to hypertension management to improve BP control reinforces findings of a meta-analysis by Walsh et al[13] on quality improvement strategies for hypertension management. In our study, we further identified the potential mechanism for this improvement by demonstrating greater therapy intensification in the intervention group compared with the control group. We had anticipated that the intervention might also lead to better medication adherence; however, there was no difference in adherence between the 2 study groups as measured by MPR. A potential explanation for the lack of difference in adherence to hypertension medications may be that adherence in both groups was higher than that reported in prior observational investigations of routine clinical practice.[14] Furthermore, our ability to assess adherence was limited by the short 6-month time frame and the challenge in using pharmacy refill data to assess adherence during periods when changes to the antihypertensive medication regimen were common.[14]

We acknowledge several additional limitations. The therapy intensification score was developed post hoc; however, this algorithm was reviewed by a panel of internists and cardiologists who were not involved with the study and was considered to have face validity. In addition, higher intensity medication regimens were associated with better BP control among patients adherent to their hypertension medications. Also, our study was conducted primarily in integrated healthcare settings, and the results may not be applicable to other settings, although these 3 sites care for diverse patient populations and the study conducted follow-up using widely available phone technology. Because the baseline BP in the intervention group was higher than that in the control group, the greater decrease in BP in the intervention group may be in part because of regression to the mean. While there were

significant reductions in systolic BP during the study period, the duration of the intervention effects after ending participation in the study is unknown. Finally, the study intervention focused primarily on use of home BP monitoring to guide treatment intensification of patients with uncontrolled hypertension. Future studies focusing on strategies to improve adherence to prescribed therapy may lead to even better BP control.

In conclusion, the addition of a multifaceted intervention to usual care composed of patient education, home BP monitoring, BP measurement reporting to an IVR system, and clinical pharmacist management of hypertension led to greater BP reductions among patients with uncontrolled hypertension. These findings were primarily driven by higher-intensity treatment regimens. The next challenge is to see if interventions such as that described herein can be implemented among a broader population of patients with uncontrolled hypertension and to assess the sustainability and cost-effectiveness of these interventions.

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Appendix. Intensity of Antihypertensive Medications

Drug	Daily Dose (mg)			Maximum Dose According to MICROMEDEX[a]
	Low (1 Point)	Moderate (2 Points)	High (3 Points)	
Atenolol	<50	50 to 100	>100	100
Metoprolol	<100	100 to 300	>300	450 mg for metoprolol tartrate, 400 mg for metoprolol succinate
Carvedilol	25	>25 to 50	>50	50
Labetalol hydrochloride	200	>200 to 400	>400	400
Diltiazem	<240	240 to 360	>360	540
Verapamil	<240	240 to 360	>360	480
Felodipine	≤5	>5 to 10	>10	10
Amlodipine	≤5	>5 to 10	>10	10
Hydrochlorothiazide	≤25	>25 to 50	>50	100
Triamterene	≤25	>25 to 50	>50	100
Furosemide	40	>40 to 80	>80	80
Lisinopril	<20	20 to 40	>40	80
Enalapril maleate	<20	20 to 40	>40	40
Losartan potassium	<50	50 to 100	>100	100
Irbesartan	150	>150 to 300	>300	300
Terazosin hydrochloride	≤5	>5 to 20	>20	40
Prazosin hydrochloride	≤3	>3 to 20	>20	20
Hydralazine	≤100	>100 to 300	>300	300
Clonidine	≤0.2	0.2 to 0.6	>0.6	0.6 mg/d for patch, 2.4 mg for pills
Monoxidil	10	>10 to 40	>40	100
Acebutolol	400	>400 to 800	>800	1200
Doxazosin mesylate	≤4	4 to 8	>8	16
Fosinopril sodium	<20	20 to 40	>40	80
Nebivolol	5	>5 to 40	>40	40
Nifedipine	60	>60 to 120	>120	120 mg for extended release
Propranolol hydrochloride	80	>80 to 160	>160	640 mg for immediate release, 160 mg for long acting
Spironolactone	50	>50 to 100	>100	400
Olmesartan medoxomil	20	21 to 40	>40	—
Captopril (based on total dose for the day)	75	76 to 300	>300	—
Nisoldipine	20	21 to 40	>40	—

[a]Thomson Reuters (Healthcare) Inc, Greenwood Village, Colorado.