

## Original Investigation

# Effect of Home Blood Pressure Telemonitoring and Pharmacist Management on Blood Pressure Control

## A Cluster Randomized Clinical Trial

Karen L. Margolis, MD, MPH; Stephen E. Asche, MA; Anna R. Bergdall, MPH; Steven P. Dehmer, PhD; Sarah E. Groen, PharmD; Holly M. Kadmas, PharmD; Tessa J. Kerby, MPH; Krissa J. Klotzle, PharmD; Michael V. Maciosek, PhD; Ryan D. Michels, PharmD; Patrick J. O'Connor, MD, MPH; Rachel A. Pritchard, BA; Jaime L. Sekenski, BS; JoAnn M. Sperl-Hillen, MD; Nicole K. Trower, BA

**IMPORTANCE** Only about half of patients with high blood pressure (BP) in the United States have their BP controlled. Practical, robust, and sustainable models are needed to improve BP control in patients with uncontrolled hypertension.

**OBJECTIVES** To determine whether an intervention combining home BP telemonitoring with pharmacist case management improves BP control compared with usual care and to determine whether BP control is maintained after the intervention is stopped.

**DESIGN, SETTING, AND PATIENTS** A cluster randomized clinical trial of 450 adults with uncontrolled BP recruited from 14 692 patients with electronic medical records across 16 primary care clinics in an integrated health system in Minneapolis-St Paul, Minnesota, with 12 months of intervention and 6 months of postintervention follow-up.

**INTERVENTIONS** Eight clinics were randomized to provide usual care to patients (n = 222) and 8 clinics were randomized to provide a telemonitoring intervention (n = 228). Intervention patients received home BP telemonitors and transmitted BP data to pharmacists who adjusted antihypertensive therapy accordingly.

**MAIN OUTCOMES AND MEASURES** Control of systolic BP to less than 140 mm Hg and diastolic BP to less than 90 mm Hg (<130/80 mm Hg in patients with diabetes or chronic kidney disease) at 6 and 12 months. Secondary outcomes were change in BP, patient satisfaction, and BP control at 18 months (6 months after intervention stopped).

**RESULTS** At baseline, enrollees were 45% women, 82% white, mean (SD) age, 61.1 (12.0) years; mean systolic BP, 148 mm Hg; diastolic BP, 85 mm Hg. The proportion of patients with BP control at both 6 and 12 months was significantly greater in the telemonitoring group than in the usual care group.

BP control	Telemonitoring Intervention		Usual Care		Differential Change From Baseline, % (95%CI)	P Value
	No.	% (95% CI)	No.	% (95% CI)		
6 and 12 mo	113	57.2 (44.8-68.7)	58	30.0 (23.2-37.8)	27.2 (13.4-40.0)	.001
6 mo	148	71.8 (65.6-77.3)	89	45.2 (39.2-51.3)	26.6 (19.1-33.1)	<.001
12 mo	141	71.2 (62.0-78.9)	102	52.8 (45.4-60.2)	18.4 (7.9-27.0)	.005
18 mo	135	71.8 (65.0-77.8)	104	57.1 (51.5-62.6)	14.7 (7.0-21.4)	.003

Compared with the usual care group, systolic BP decreased more from baseline among patients in the telemonitoring intervention group at 6 months (−10.7 mm Hg [95% CI, −14.3 to −7.3 mm Hg];  $P < .001$ ), at 12 months (−9.7 mm Hg [95% CI, −13.4 to −6.0 mm Hg];  $P < .001$ ), and at 18 months (−6.6 mm Hg [95% CI, −10.7 to −2.5 mm Hg];  $P = .004$ ).

**CONCLUSIONS AND RELEVANCE** Home BP telemonitoring and pharmacist case management achieved better BP control compared with usual care during 12 months of intervention that persisted during 6 months of postintervention follow-up.

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**Author Affiliations:** HealthPartners Institute for Education and Research, Minneapolis, Minnesota (Margolis, Asche, Bergdall, Dehmer, Maciosek, O'Connor, Pritchard, Sekenski, Sperl-Hillen, Trower); HealthPartners, Health Improvement, Minneapolis, Minnesota (Kerby); HealthPartners, Clinical Pharmacy, Minneapolis, Minnesota (Groen, Kadmas, Klotzle, Michels).

**Corresponding Author:** Karen L. Margolis, MD, MPH, HealthPartners Institute for Education and Research, PO Box 1524, MS 2111R, Minneapolis, MN 55440 ([karen.l.margolis@healthpartners.com](mailto:karen.l.margolis@healthpartners.com)).

**H**igh blood pressure (BP) is the most common chronic condition for which patients visit primary care physicians, affecting about 30% of US adults, with estimated annual costs exceeding \$50 billion.<sup>1,2</sup> Decades of research have shown that treatment of hypertension prevents cardiovascular events; and many well-tolerated, effective, and inexpensive drugs are readily available.<sup>3</sup> Although BP control has improved during the past 2 decades, it is controlled to recommended levels in only about half of US adults with hypertension.<sup>4</sup>

Many types of interventions have been tested to improve BP control. Even though most studies showed modest improvements in BP, recent systematic reviews summarizing more than 3 decades of research concluded that the most potent methods to improve BP involve a reorganization of clinical practice and empowerment of nonphysician practitioners to adjust antihypertensive therapy.<sup>5-7</sup> Nurses and pharmacists are both effective in team-based care for hypertension.<sup>7,8</sup>

Home BP monitoring also has been identified as a useful adjunct to team-based care for hypertension.<sup>9</sup> Measurement of BP in a patient's home predicts cardiovascular risk better than office BP measurement,<sup>10</sup> and telemonitoring eliminates underreporting of high home BP readings.<sup>11</sup> Several recent studies<sup>12-16</sup> suggest that a combined intervention of telemedicine with nurse- or pharmacist-led care may be effective for improving hypertension management, but none included postintervention follow-up. Also, previous studies excluded patients with comorbidities and more severe hypertension. The objective of the Home Blood Pressure Telemonitoring and Case Management to Control Hypertension (HyperLink) study was to determine the effect and durability of home BP telemonitoring with pharmacist case management in patients representative of the range of comorbidity and hypertension severity in typical primary care practices.

## Methods

### Design, Setting, and Patients

A 2-group cluster randomized clinical trial, HyperLink, was conducted at HealthPartners Medical Group, a multispecialty practice in the Minneapolis-St Paul, Minnesota, metropolitan area that is part of an integrated health system. The trial's rationale and design have been described in detail.<sup>17</sup> The study protocol was approved by the HealthPartners institutional review board.

Electronic medical records were used to identify adult patients who had elevated BP (systolic BP [SBP]  $\geq 140$  mm Hg or diastolic BP [DBP]  $\geq 90$  mm Hg, hereafter abbreviated  $\geq 140/90$  mm Hg) at the 2 most recent primary care visits in the previous year (Figure). Patients meeting these criteria received up to 2 recruitment mailings followed by telephone calls to nonresponders. Patients who responded were screened for eligibility by telephone and in the research clinic.

During the research clinic screening, patients had to have uncontrolled BP ( $\geq 140/90$  mm Hg or  $\geq 130/80$  mm Hg if diabetes or chronic kidney disease was present)<sup>3</sup> based on the average of 3 automated measurements taken using a standard-

ized protocol.<sup>17</sup> All patients provided verbal consent to the telephone screening and signed a full informed consent form at the beginning of the research clinic visit. All recruitment occurred between March 2009 and April 2011.

Medical exclusion criteria included stage 4 or 5 kidney disease or ratio of albumin to creatinine of 700 mg/g or greater; acute coronary syndrome, coronary revascularization, or stroke within past 3 months; known secondary causes of hypertension; pregnancy; New York Heart Association class III or IV heart failure; or known left ventricular ejection fraction of less than 30%. We also required a landline telephone initially, but near the end of recruitment patients with only a cellular telephone were permitted to enroll.

Of 21 HealthPartners primary care clinics in 2009, 16 had a medication therapy management pharmacist onsite at least once weekly.<sup>18</sup> At these clinics, there was a clinical practice agreement between pharmacists and primary care physicians that allowed pharmacists to prescribe and change antihypertensive therapy within specified parameters. The 16 study clinics were matched by size and clinic-level BP control at baseline and then randomly assigned to either the telemonitoring intervention (n = 8) or usual care (n = 8).

Four doctoral pharmacists worked in the intervention clinics. Each pharmacist received 8 hours of formal training on the study protocol and was observed conducting a telephone visit on 2 occasions to verify fidelity to the intervention. Patients were linked to their clinic by self-report and then assigned to a treatment group. All consenting patients and pharmacists were blinded before randomization, but were informed of their treatment assignment postrandomization.

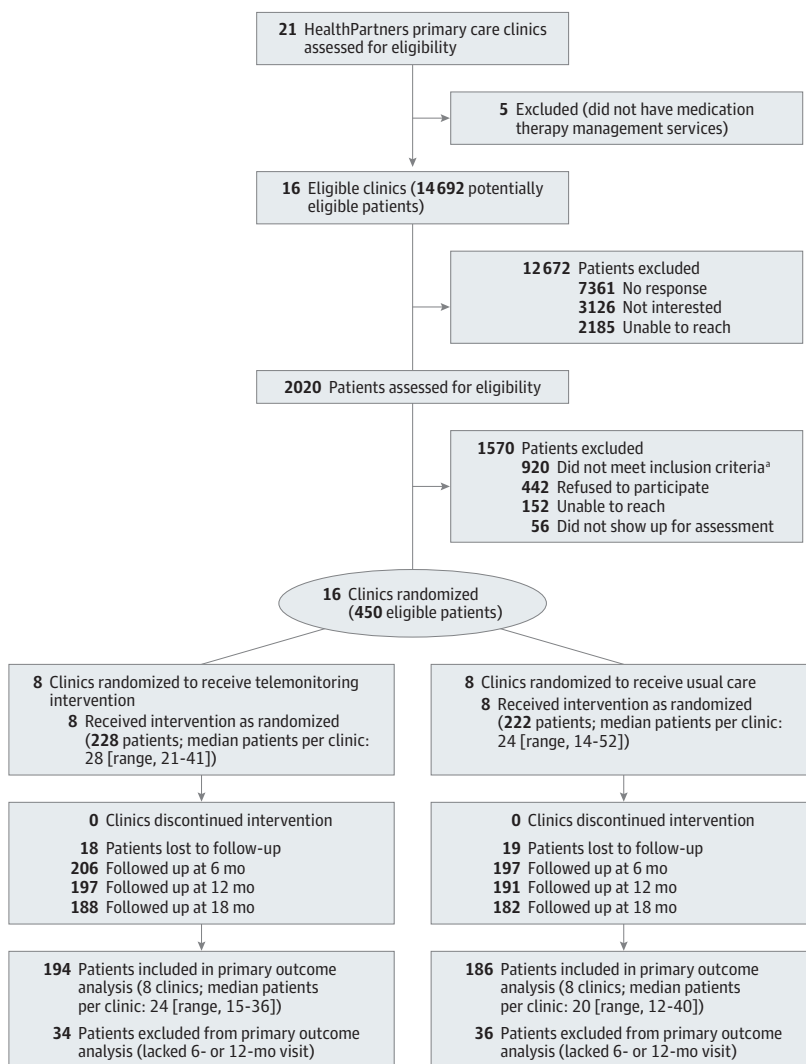
### Interventions

Each intervention patient received a home BP monitor (A&D Medical 767PC automated oscillometric) that stored and transmitted data to a secure website via modem (AMC Health). Pharmacists met with patients for a 1-hour, in-person visit, during which they reviewed the patient's relevant history, covered general teaching points about hypertension, instructed the patients on using the home BP telemonitoring system, and provided patients with an individualized home BP goal 5 mm Hg lower than their clinic BP goal (ie,  $<135/85$  mm Hg or  $<125/75$  mm Hg for patients with diabetes or chronic kidney disease).<sup>19,20</sup>

Patients were instructed to transmit at least 6 BP measurements weekly (3 in the morning and 3 in the evening). During the first 6 months of the intervention, patients and pharmacists met every 2 weeks via telephone until BP control was sustained for 6 weeks, and then frequency was reduced to monthly. During intervention months 7 through 12, telephone visits occurred every 2 months. After 12 months, patients discontinued use of the telemonitors, returned to the care of their primary physicians, and no longer received support from a study pharmacist. A previous analysis<sup>21</sup> found that patients sent at least 6 BP measurements in 73% of the weeks during the first 6 months of the intervention and 88% of telephone visits were conducted.

During telephone visits, pharmacists emphasized lifestyle changes and medication adherence. They assessed and adjusted antihypertensive drug therapy based on an algo-

Figure. Participant Recruitment, Enrollment, and Follow-up



<sup>a</sup>Of the 920 who did not meet inclusion criteria, 652 did not have elevated blood pressure, 126 did not have a landline telephone, 107 had medical exclusions, and 35 changed clinics or were not study clinic patients.

rhythm (eTables 1 and 2 in Supplement) using the percentage of home BP readings meeting goal.<sup>17</sup> If at least 75% of readings since the last visit met the BP goal, no medication changes were generally suggested. If fewer than 75% of readings met the BP goal, the algorithm recommended treatment intensification. Regardless of BP control, if patients experienced adverse effects, the dosage would be lowered or the drug was switched. Pharmacists communicated with patients' primary care teams through the electronic medical record following each visit.

During the study period, usual care patients worked with their primary care physicians as they had in the past. This could include referral to a medication therapy management pharmacist for consultation (1-2 visits without telephone follow-up or prolonged monitoring) and conventional home BP measurement.

**Outcomes**

The primary outcome was the proportion of patients with controlled BP (ie, <140/90 mm Hg or <130/80 mm Hg if diabetes

or chronic kidney disease was present) at both the 6- and 12-month clinic visits. Other outcomes included change in SBP and DBP at each time point, patient satisfaction with care, and BP control at 18 months (6 months of postintervention follow-up). Outcomes related to BP were based only on BP measurements taken at research clinic visits.

All patients visited a research clinic for study screening and enrollment, and at 6, 12, and 18 months postbaseline for follow-up. Research staff were not blinded to study group, but were trained to treat patients in both groups identically. Demographic data were collected at baseline, including sex, self-identified race/ethnicity (white, black, Asian, Hispanic, or other), education level, household income, and marital status. Blood pressure was measured at each research visit using a standardized technique with an automated monitor identical to the home BP device. Three measurements were averaged. The number and type of BP medications were inventoried and self-reported adherence was recorded using the 4-item scale (modified for BP medications) by Morisky et al.<sup>22</sup>

Survey data collected at research visits included quality of life and general health measured by the Medical Outcomes Study Short Form 12 questionnaire (version 2); and self-efficacy for managing BP was measured by a 13-item subset of questions assessing perceived self-efficacy.<sup>13,23</sup> Six items were selected from the Consumer Assessment of Healthcare Providers and Systems adult survey (version 4) regarding satisfaction with care.<sup>24</sup>

Safety was assessed at each research visit by collecting all reports of hospitalizations and reports of emergency department, urgent care, and same-day medical visits for problems related to elevated BP, hypotension, fainting, loss of consciousness, and allergic reactions. Medical records of events were reviewed by a physician unrelated to the study with experience assessing adverse events for trials. The severity of the event and probability of its relationship to the study treatment were assessed using 5-point scales.

### Direct Program Cost Estimate

All patient encounters with study pharmacists were logged in a database. The pharmacist recorded time spent during encounters with patients, previsit time reviewing BP telemonitoring data and preparing for the telephone call, and postvisit time documenting the encounter. Monthly time logs were used to reimburse the pharmacy department for the participation of their staff in the study. The price for home BP telemonitoring was negotiated prior to the start of the trial, with a fixed per-patient enrollment fee and a monthly telemonitoring rate based on the 12-month intervention period. The program cost estimates excluded patient time, pharmacy, laboratory tests, and nonstudy encounters.

### Sample Size and Statistical Analysis

This study was powered at 80% (2-sided test a level of .05) to detect a difference in the proportion of patients with controlled BP at both 6 and 12 months in 40% receiving usual care and 60% receiving the telemonitoring intervention. The sample size was based on recruitment of 450 patients from 16 clinics, of whom 405 (90%) would complete the 6-month clinic visit and 360 (80%) would complete both the 6- and 12-month clinic visits.

Generalized linear mixed models with a logit link and a random intercept for clinic were used to test the effect of the intervention on the binary outcomes of BP control at 6, 12, and 18 months and at composite time points of 6 and 12 months, and 6, 12, and 18 months. For continuous and binary measures obtained over time, general and generalized linear mixed models were used with a time (baseline, 6 months, 12 months, 18 months) × study group interaction term and an additional random term to model the repeated measures from baseline to 6, 12, and 18 months, assuming data were missing at random.

To account for missing data on continuous outcomes, maximum likelihood-based ignorable methods were used that yield valid inference when the outcome data are missing at random. Sensitivity analyses were conducted, adjusting for race and hypertension treatment, which showed some imbalance by study group. All analyses were 2-sided and *P* values of less than .05 were considered statistically significant. Multiple com-

parisons of BP control and changes in BP were controlled for using the Holm step-down procedure. Corrections for multiple comparisons were not conducted for other outcomes.

## Results

In total, 14 692 potentially eligible patients were identified using electronic medical record data (Figure). Of those, 2020 expressed interest in participating and agreed to be screened by telephone; 650 patients did not complete screening. Of the 1370 who completed screening, 920 were excluded, mostly for nonelevated BP. In total, 450 patients were enrolled and linked to their primary care clinic by self-report. Of these, 228 patients were assigned to the telemonitoring intervention and 222 patients were assigned to usual care.

The mean (SD) research clinic follow-up time from baseline visit to 6 months was 187.7 (16.9) days, baseline to 12 months was 368.7 (17.3) days, and baseline to 18 months was 547.7 (15.0) days. Missing a research clinic visit at 6, 12, or 18 months was not associated with study group, baseline SBP or DBP level, or baseline BP medication adherence (data not reported).

At baseline, the 450 participants had a mean (SD) age of 61.1 (12.0) years, 45% were women, and 82% were white (Table 1). Nearly half (48%) had earned a college degree. Many patients had comorbid conditions, including obesity (54%), diabetes (19%), chronic kidney disease (19%), or a history of cardiovascular disease (10%). At baseline, mean BP was 148/85 mm Hg and patients reported taking a mean (SD) of 1.5 (1.2) antihypertensive drug classes. There were significantly more Hispanic patients in the usual care group (*P* = .009). Patients in the telemonitoring intervention group were somewhat more likely to report receiving hypertension care at baseline (*P* = .07).

The proportions of patients attending follow-up visits were 90% for the telemonitoring intervention and 89% for usual care at 6 months, 86% in both groups at 12 months, and 82% in both groups at 18 months (Figure). By study design, all patients had uncontrolled BP at baseline. Among the 380 patients attending both the 6- and 12-month visits, the proportions of patients with controlled BP at both visits were 57.2% (95% CI, 44.8%-68.7%) in the telemonitoring intervention group and 30.0% (95% CI, 23.2%-37.8%) in the usual care group (*P* = .001; Table 2). Under the assumption that all 70 patients with neither a 6-month nor a 12-month visit had uncontrolled BP at both time points, BP was controlled at both 6 and 12 months in 48.5% (95% CI, 37.0%-60.1%) of the telemonitoring intervention group and 25.1% (95% CI, 20.0%-31.0%) of the usual care group (*P* = .001).

At 6 months, BP was controlled in 71.8% (95% CI, 65.6%-77.3%) of the telemonitoring intervention group and 45.2% (95% CI, 39.2%-51.3%) of the usual care group (*P* < .001). At 12 months, BP was controlled in 71.2% (95% CI, 62.0%-78.9%) of the telemonitoring intervention group and 52.8% (95% CI, 45.4%-60.2%) of the usual care group (*P* = .005). At 18 months, BP was controlled in 71.8% (95% CI, 65.0%-77.8%) of the telemonitoring intervention group and 57.1% (95% CI, 51.5%-62.6%) of the usual care group (*P* = .003).

Table 1. Baseline Characteristics of Patients<sup>a</sup>

	All (N = 450)	Telemonitoring Intervention (n = 228)	Usual Care (n = 222)
Age, mean (SD), y	61.1 (12.0)	62.0 (11.7)	60.2 (12.2)
Female sex	201 (44.7)	103 (45.2)	98 (44.1)
Race/ethnicity			
White	368 (81.8)	191 (83.8)	177 (79.7)
Black	53 (11.8)	24 (10.5)	29 (13.1)
Asian	7 (1.6)	4 (1.8)	3 (1.4)
Other <sup>b</sup>	22 (4.9)	9 (4.0)	13 (5.9)
Hispanic	10 (2.2)	1 (0.4)	9 (4.1)
Education level <sup>c</sup>			
≤High school or GED	76 (17.4)	36 (16.3)	40 (18.6)
Some college or technical school	151 (34.6)	72 (32.6)	79 (36.7)
4-y College degree	82 (18.8)	46 (20.8)	36 (16.7)
>4-y College degree	127 (29.1)	67 (30.3)	60 (27.9)
Paid work status <sup>c</sup>			
Full-time	176 (40.5)	86 (38.9)	90 (42.1)
Part-time	53 (12.2)	28 (12.7)	25 (11.7)
Not working	43 (9.9)	20 (9.1)	23 (10.8)
Retired	163 (37.5)	87 (39.4)	76 (35.5)
Married or living with partner <sup>c</sup>	301 (69.2)	160 (72.4)	141 (65.9)
Household income, \$ <sup>c</sup>			
<30 000	65 (17.0)	34 (18.2)	31 (15.9)
30 000-49 999	63 (16.5)	27 (14.4)	36 (18.5)
50 000-99 999	150 (39.3)	69 (36.9)	81 (41.5)
≥100 000	104 (27.2)	57 (30.5)	47 (24.1)
Body mass index <sup>c,d</sup>			
Normal (18.5-24.9)	66 (14.9)	36 (16.1)	30 (13.6)
Overweight (25-29.9)	137 (30.9)	71 (31.7)	66 (30.0)
Obese (≥30)	241 (54.3)	117 (52.2)	124 (56.4)
Smoked in last 30 d <sup>c</sup>	49 (11.0)	24 (10.7)	25 (11.4)
Comorbidities affecting BP goal			
Diabetes	86 (19.1)	46 (20.2)	40 (18.0)
Chronic kidney disease	84 (18.6)	47 (20.6)	37 (16.7)
Diabetes or chronic kidney disease	146 (32.4)	81 (35.5)	65 (29.3)
History of cardiovascular disease <sup>e</sup>	43 (9.6)	23 (10.1)	20 (9.0)
Estimated GFR <60 mL/min/1.73 m <sup>2c</sup>	71 (15.9)	39 (17.1)	32 (14.6)
Ratio of urine albumin to creatinine ≥30 mg/g <sup>c</sup>	88 (19.6)	46 (20.2)	42 (19.1)
Received medical care for hypertension in past 12 mo <sup>c</sup>	279 (63.3)	151 (67.4)	128 (59.0)
Antihypertensive drug classes			
0	118 (26.2)	54 (23.7)	64 (28.8)
1	116 (25.8)	56 (24.6)	60 (27.0)
2	115 (25.6)	63 (27.6)	52 (23.4)
3	78 (17.3)	42 (18.4)	36 (16.2)
≥4	23 (5.1)	13 (5.7)	10 (4.5)
Antihypertensive drug classes, mean (SD)	1.5 (1.2)	1.6 (1.2)	1.4 (1.2)
BP, mean (SD), mm Hg			
Systolic	147.9 (13.0)	148.2 (12.9)	147.7 (13.2)
Diastolic	84.7 (11.6)	84.5 (11.7)	84.9 (11.5)

Abbreviations: BP, blood pressure; GED, general equivalency diploma; GFR, glomerular filtration rate.

<sup>a</sup> Values are expressed as number (percentage) unless otherwise indicated.

<sup>b</sup> Includes American Indian, mixed race, or other.

<sup>c</sup> Missing data for between 2 and 18 patients.

<sup>d</sup> Calculated as weight in kilograms divided by height in meters squared.

<sup>e</sup> Indicates patients who have ever had a myocardial infarction, stroke, heart bypass surgery, cardiac stent, or balloon angioplasty.

Among the 362 patients attending all clinic visits at 6, 12, and 18 months, the proportions of patients with controlled BP at all visits were 50.9% (95% CI, 36.9%-64.8%) in the telemonitoring

intervention group and 21.3% (95% CI, 14.4%-30.4%) in the usual care group (*P* = .002). Under the assumption that all 88 patients with 1 or more missing visits had uncontrolled BP at those

Table 2. Composite and Blood Pressure (BP) Control

	Telemonitoring Intervention		Usual Care		Differential Change From Baseline, % (95% CI)	P Value <sup>a</sup>
	No. of Patients	% (95% CI)	No. of Patients	% (95% CI)		
Composite BP control						
At 6 and 12 mo	113	57.2 (44.8-68.7)	58	30.0 (23.2-37.8)	27.2 (13.4-40.0)	.001
At 6, 12, and 18 mo	96	50.9 (36.9-64.8)	42	21.3 (14.4-30.4)	29.6 (13.1-46.0)	.002
BP control						
At 6 mo	148	71.8 (65.6-77.3)	89	45.2 (39.2-51.3)	26.6 (19.1-33.1)	<.001
At 12 mo	141	71.2 (62.0-78.9)	102	52.8 (45.4-60.2)	18.4 (7.9-27.0)	.005
At 18 mo	135	71.8 (65.0-77.8)	104	57.1 (51.5-62.6)	14.7 (7.0-21.4)	.003

<sup>a</sup> Study group difference for composite BP control and at each individual time point.

Table 3. Blood Pressure (BP) Reduction From Baseline

	Telemonitoring Intervention		Usual Care		Differential Change From Baseline, Mean (95% CI)	P Value <sup>a</sup>
	Mean (95% CI)	Reduction From Baseline, Mean (95% CI)	Mean (95% CI)	Reduction From Baseline, Mean (95% CI)		
Systolic BP, mm Hg						
At baseline	148.2 (146.3 to 150.0)		147.7 (145.8 to 149.5)			
At 6 mo	126.7 (124.4 to 129.0)	-21.5 (-23.9 to -19.1)	136.9 (134.6 to 139.2)	-10.8 (-13.3 to -8.3)	-10.7 (-14.3 to -7.3)	<.001
At 12 mo	125.7 (123.4 to 128.0)	-22.5 (-25.1 to -19.9)	134.8 (132.5 to 137.2)	-12.9 (-15.5 to -10.2)	-9.7 (-13.4 to -6.0)	<.001
At 18 mo	126.9 (124.3 to 129.4)	-21.3 (-24.2 to -18.4)	133.0 (130.4 to 135.5)	-14.7 (-17.6 to -11.8)	-6.6 (-10.7 to -2.5)	.004
Diastolic BP, mm Hg						
At baseline	84.4 (82.3 to 86.6)		85.1 (82.9 to 87.3)			
At 6 mo	75.0 (72.9 to 77.2)	-9.4 (-11.1 to -7.6)	81.7 (79.5 to 84.0)	-3.4 (-5.2 to -1.5)	-6.0 (-8.6 to -3.4)	<.001
At 12 mo	75.1 (72.8 to 77.4)	-9.3 (-11.0 to -7.7)	80.8 (78.5 to 83.2)	-4.3 (-5.9 to -2.7)	-5.1 (-7.4 to -2.8)	<.001
At 18 mo	75.1 (73.0 to 77.2)	-9.3 (-11.7 to -7.0)	78.7 (76.6 to 80.9)	-6.4 (-8.7 to -3.9)	-3.0 (-6.3 to 0.3)	.07

<sup>a</sup> Calculated using time × study group interaction term, indicating differential reduction from baseline by study group.

time points, BP was controlled at all visits in 40.9% (95% CI, 29.7%-53.1%) of the telemonitoring intervention group and 17.2% (95% CI, 11.9%-24.3%) of the usual care group ( $P = .002$ ).

The mean difference in SBP change between the telemonitoring intervention group and the usual care group was -10.7 mm Hg (95% CI, -14.3 to -7.3 mm Hg) at 6 months ( $P < .001$ ); -9.7 mm Hg (95% CI, -13.4 to -6.0 mm Hg) at 12 months ( $P < .001$ ); and -6.6 mm Hg (95% CI, -10.7 to -2.5 mm Hg) at 18 months ( $P = .004$ ) (Table 3). The mean difference in DBP change between the telemonitoring intervention group and the usual care group was -6.0 mm Hg (95% CI, -8.6 to -3.4 mm Hg) at 6 months ( $P < .001$ ); -5.1 mm Hg (95% CI, -7.4 to -2.8 mm Hg) at 12 months ( $P < .001$ ); and -3.0 mm Hg (95% CI, -6.3 to 0.3 mm Hg) at 18 months ( $P = .07$ ). Inclusion of Hispanic ethnicity and receiving care for hypertension in the past 12 months at baseline as covariates in the models predicting BP control and change in BP values showed trivial differences in the model coefficients and  $P$  values (data not reported).

The mean number of antihypertensive medication classes increased from 1.6 (95% CI, 1.4-1.8) at baseline to 2.2 (95% CI, 2.0-2.4) at 6 months in the telemonitoring intervention group, and from 1.4 (95% CI, 1.2-1.6) at baseline to 1.6 (95% CI, 1.4-1.8) at 6 months in the usual care group ( $P < .001$ ; Table 4), with similar differences persisting through 18 months. Between baseline and 6 months, self-reported adherence to hyperten-

sion medications increased among patients in the telemonitoring intervention group and decreased among patients in the usual care group ( $P = .04$ ), but did not differ significantly between groups at 12 and 18 months.

About half of all patients used a home BP monitor in the past 12 months at baseline, and there was little change among the usual care patients. During the 12-month intervention, home BP monitor use was nearly universal in the telemonitoring intervention group, but decreased to 71% (95% CI, 63.0%-78.6%) at 18 months.

Among patients receiving any medical care in the previous period, overall satisfaction with care was similar in both groups. Satisfaction items concerning clinicians listening carefully, explaining things clearly, and respecting what the patient said showed larger improvements among patients in the telemonitoring intervention group than in the usual care group at 6 months, but not at 12 or 18 months. Functional status did not differ by study group.

Self-efficacy questions indicated telemonitoring intervention patients were substantially more confident than usual care patients that they could communicate with their health care team, integrate home BP monitoring in their weekly routine, follow their medication regimen, and keep their BP under control. Telemonitoring intervention patients self-reported adding less salt to food than usual care patients at all time points, but other lifestyle factors did not differ.

Table 4. Other Study Outcomes<sup>a</sup>

	Telemonitoring Intervention				Usual Care			
	At Baseline (n = 228)	At 6 mo (n = 206)	At 12 mo (n = 197)	At 18 mo (n = 188)	At Baseline (n = 222)	At 6 mo (n = 197)	At 12 mo (n = 191)	At 18 mo (n = 182)
<b>Medical history</b>								
No. of hypertension medication classes <sup>b</sup>	1.6 (1.4 to 1.8)	2.2 (2.0 to 2.4)	2.2 (2.0 to 2.4)	2.2 (2.0 to 2.4)	1.4 (1.2 to 1.6)	1.6 (1.4 to 1.8)	1.6 (1.4 to 1.8)	1.7 (1.5 to 1.9)
Change from baseline <sup>b</sup>		0.66 (0.53 to 0.78) <sup>c</sup>	0.63 (0.49 to 0.77) <sup>c</sup>	0.62 (0.46 to 0.77) <sup>d</sup>		0.16 (0.04 to 0.29)	0.22 (0.07 to 0.36)	0.26 (0.10 to 0.42)
Prescribed any hypertension medications <sup>e</sup>	76.8 (66.1 to 84.9)	94.5 (88.9 to 97.4)	94.6 (89.2 to 97.4)	94.9 (89.4 to 97.6)	73.0 (61.2 to 82.1)	79.3 (68.6 to 87.0)	80.3 (70.6 to 87.3)	81.1 (71.2 to 88.1)
Change from baseline <sup>e</sup>		17.7 (13.0 to 20.3) <sup>d</sup>	17.8 (13.3 to 20.7) <sup>d</sup>	18.1 (13.5 to 20.8) <sup>f</sup>		6.3 (-2.1 to 12.7)	7.3 (-0.8 to 13.8)	8.1 (-0.3 to 14.2)
Perfect self-reported adherence to hypertension medication <sup>g,h</sup>	66.7 (58.5 to 74.0)	77.4 (70.2 to 83.3)	68.6 (60.6 to 75.6)	71.6 (63.3 to 78.6)	66.9 (58.1 to 74.6)	61.0 (51.9 to 69.4)	63.7 (54.8 to 71.7)	62.6 (53.1 to 71.3)
Change from baseline <sup>e</sup>		10.7 (1.5 to 17.9) <sup>f</sup>	1.9 (-8.5 to 10.8)	4.9 (-5.4 to 13.3)		-5.9 (-17.8 to 4.8)	-3.2 (-14.9 to 7.0)	-4.3 (-16.2 to 6.2)
Used home BP monitor in past 12 mo at baseline or in past 6 mo <sup>e</sup>	50.6 (42.4 to 58.8)	94.1 (89.1 to 96.9)	95.4 (90.7 to 97.7)	71.4 (63.0 to 78.6)	42.8 (34.7 to 51.3)	43.7 (35.2 to 52.6)	42.8 (34.9 to 51.2)	50.7 (41.7 to 59.7)
Change from baseline <sup>e</sup>		43.5 (38.7 to 46.2) <sup>c</sup>	44.8 (40.0 to 47.0) <sup>c</sup>	20.8 (11.8 to 28.5)		0.9 (-8.4 to 10.6)	0 (-10.3 to 10.2)	7.0 (-2.6 to 17.0)
<b>Satisfaction with care<sup>b</sup></b>								
Overall rating of health care <sup>b,i</sup>	4.3 (4.2 to 4.4)	4.6 (4.4 to 4.7)	4.5 (4.4 to 4.6)	4.5 (4.4 to 4.7)	4.3 (4.1 to 4.4)	4.4 (4.2 to 4.5)	4.4 (4.3 to 4.6)	4.4 (4.3 to 4.5)
Change from baseline <sup>b</sup>		0.27 (0.16 to 0.39)	0.22 (0.08 to 0.35)	0.26 (0.13 to 0.38)		0.11 (-0.01 to 0.23)	0.18 (0.14 to 0.32)	0.15 (0.03 to 0.28)
Clinicians listened carefully <sup>b,j</sup>	3.5 (3.4 to 3.6)	3.7 (3.6 to 3.8)	3.6 (3.5 to 3.8)	3.6 (3.5 to 3.8)	3.5 (3.4 to 3.7)	3.5 (3.4 to 3.7)	3.6 (3.5 to 3.7)	3.7 (3.5 to 3.8)
Change from baseline <sup>b</sup>		0.20 (0.11 to 0.31) <sup>d</sup>	0.13 (0.03 to 0.23)	0.13 (0.01 to 0.24)		0.01 (-0.10 to 0.11)	0.05 (-0.05 to 0.15)	0.12 (0.01 to 0.22)
Clinicians explained things clearly <sup>b,j</sup>	3.7 (3.6 to 3.7)	3.8 (3.7 to 3.9)	3.8 (3.7 to 3.8)	3.7 (3.6 to 3.7)	3.6 (3.5 to 3.7)	3.6 (3.5 to 3.7)	3.7 (3.6 to 3.8)	3.7 (3.6 to 3.8)
Change from baseline <sup>b</sup>		0.12 (0.02 to 0.22) <sup>f</sup>	0.09 (-0.01 to 0.19)	0.09 (-0.01 to 0.19)		-0.03 (-0.13 to 0.07)	0.10 (0.01 to 0.20)	0.13 (0.02 to 0.23)
Clinicians respected what patient said <sup>b,j</sup>	3.6 (3.5 to 3.7)	3.8 (3.7 to 3.9)	3.8 (3.6 to 3.9)	3.7 (3.6 to 3.9)	3.7 (3.6 to 3.8)	3.7 (3.6 to 3.9)	3.7 (3.6 to 3.8)	3.7 (3.6 to 3.9)
Change from baseline <sup>b</sup>		0.19 (0.10 to 0.28) <sup>f</sup>	0.14 (0.05 to 0.23)	0.11 (-0.02 to 0.24)		0.02 (-0.07 to 0.12)	0.01 (-0.08 to 0.11)	0.07 (-0.06 to 0.20)
Clinicians spent enough time with patient <sup>b,j</sup>	3.4 (3.3 to 3.6)	3.6 (3.5 to 3.8)	3.6 (3.4 to 3.7)	3.6 (3.5 to 3.7)	3.5 (3.4 to 3.7)	3.6 (3.4 to 3.7)	3.6 (3.5 to 3.8)	3.7 (3.5 to 3.8)
Change from baseline <sup>b</sup>		0.20 (0.07 to 0.31)	0.11 (-0.03 to 0.25)	0.17 (0.06 to 0.28)		0.04 (-0.08 to 0.17)	0.13 (-0.01 to 0.27)	0.15 (0.03 to 0.26)
Had problems getting needed care <sup>b,j</sup>	1.7 (1.5 to 1.9)	1.9 (1.6 to 2.1)	1.9 (1.6 to 2.1)	1.8 (1.5 to 2.1)	1.9 (1.6 to 2.1)	2.0 (1.8 to 2.3)	1.9 (1.7 to 2.2)	1.9 (1.7 to 2.2)
Change from baseline <sup>b</sup>		0.15 (-0.09 to 0.39)	0.15 (-0.15 to 0.45)	0.07 (-0.22 to 0.35)		0.18 (-0.07 to 0.43)	0.04 (-0.26 to 0.35)	0.05 (-0.24 to 0.34)
<b>Physical and mental function</b>								
SF-12 physical <sup>b,k</sup>	48.0 (45.8 to 50.2)	47.5 (45.2 to 49.8)	47.2 (44.8 to 49.5)	47.4 (45.1 to 49.7)	47.3 (45.1 to 49.6)	46.2 (43.9 to 48.5)	46.6 (44.3 to 49.0)	46.6 (44.2 to 48.9)
Change from baseline <sup>b</sup>		-0.50 (-1.56 to 0.56)	-0.84 (-2.00 to 0.32)	-0.54 (-1.77 to 0.69)		-1.17 (-2.26 to 0.07)	-0.72 (-1.90 to 0.45)	-0.82 (-2.09 to 0.45)
SF-12 mental <sup>b,k</sup>	52.2 (50.7 to 53.8)	52.5 (51.0 to 54.0)	52.1 (50.4 to 53.8)	53.7 (52.3 to 55.1)	51.2 (49.6 to 52.8)	51.3 (49.8 to 52.9)	50.5 (48.8 to 52.3)	51.8 (50.3 to 53.2)
Change from baseline <sup>b</sup>		0.25 (-0.88 to 1.38)	-0.05 (-1.83 to 0.78)	1.51 (-0.18 to 2.40)		0.09 (-1.08 to 1.26)	-0.78 (-2.11 to 0.55)	0.50 (-0.83 to 1.84)
<b>Self-efficacy</b>								
Can communicate with nurse or pharmacist <sup>b,l</sup>	4.4 (4.3 to 4.5)	4.5 (4.4 to 4.6)	4.4 (4.3 to 4.5)	4.5 (4.4 to 4.7)	4.4 (4.3 to 4.5)	4.4 (4.2 to 4.5)	4.4 (4.2 to 4.5)	4.5 (4.3 to 4.6)
Change from baseline <sup>b</sup>		0.09 (-0.01 to 0.18)	-0.02 (-0.14 to 0.11)	0.12 (0.02 to 0.21)		-0.03 (-0.12 to 0.07)	-0.02 (-0.15 to 0.11)	0.05 (-0.05 to 0.15)

(continued)

Table 4. Other Study Outcomes<sup>a</sup> (continued)

	Telemonitoring Intervention				Usual Care			
	At Baseline (n = 228)	At 6 mo (n = 206)	At 12 mo (n = 197)	At 18 mo (n = 188)	At Baseline (n = 222)	At 6 mo (n = 197)	At 12 mo (n = 191)	At 18 mo (n = 182)
Can communicate with health care team <sup>b,i</sup>	4.4 (4.2 to 4.5)	4.5 (4.3 to 4.6)	4.4 (4.2 to 4.5)	4.5 (4.4 to 4.6)	4.4 (4.2 to 4.5)	4.3 (4.2 to 4.4)	4.4 (4.3 to 4.6)	4.5 (4.3 to 4.6)
Change from baseline <sup>b</sup>		0.08 (-0.02 to 0.18) <sup>f</sup>	-0.02 (-0.13 to 0.10)	0.11 (-0.01 to 0.21)		-0.06 (-0.16 to 0.04)	0.07 (-0.04 to 0.18)	0.09 (-0.01 to 0.20)
Can integrate home BP monitoring in weekly routine <sup>b,i</sup>	4.6 (4.4 to 4.7)	4.7 (4.5 to 4.9)	4.2 (4.0 to 4.4)	4.0 (3.8 to 4.2)	4.5 (4.3 to 4.6)	3.8 (3.6 to 4.0)	3.7 (3.5 to 3.9)	4.0 (3.8 to 4.2)
Change from baseline <sup>b</sup>		0.16 (-0.04 to 0.37) <sup>c</sup>	-0.34 (-0.54 to 0.14) <sup>d</sup>	-0.51 (-0.72 to 0.30)		-0.69 (-0.90 to 0.48)	-0.77 (-0.97 to 0.57)	-0.50 (-0.71 to 0.28)
Can follow medication regimen <sup>b,i</sup>	4.7 (4.6 to 4.9)	4.8 (4.7 to 4.9)	4.7 (4.6 to 4.8)	4.8 (4.7 to 4.9)	4.7 (4.6 to 4.8)	4.5 (4.4 to 4.6)	4.6 (4.5 to 4.7)	4.6 (4.5 to 4.7)
Change from baseline <sup>b</sup>		0.05 (-0.05 to 0.15) <sup>f</sup>	-0.08 (-0.20 to 0.05)	0.05 (-0.06 to 0.16)		-0.15 (-0.26 to 0.04)	-0.09 (-0.21 to 0.04)	-0.07 (-0.19 to 0.04)
Can keep BP under control <sup>b,i</sup>	3.8 (3.7 to 4.0)	4.2 (4.1 to 4.4)	4.2 (4.0 to 4.3)	4.3 (4.2 to 4.4)	3.9 (3.7 to 4.0)	3.9 (3.7 to 4.0)	3.9 (3.7 to 4.0)	4.0 (3.9 to 4.1)
Change from baseline <sup>b</sup>		0.40 (0.24 to 0.55) <sup>d</sup>	0.34 (0.19 to 0.50) <sup>d</sup>	0.47 (0.30 to 0.63) <sup>f</sup>		0.01 (-0.15 to 0.16)	0.01 (-0.14 to 0.17)	0.15 (-0.02 to 0.32)
<b>Lifestyle change</b>								
Smoked in past 30 d <sup>e</sup>	7.0 (2.2 to 19.9)	5.5 (1.7 to 16.5)	6.1 (2.0 to 16.8)	4.4 (1.3 to 14.0)	10.3 (3.5 to 26.7)	10.7 (3.6 to 27.9)	9.0 (3.2 to 23.1)	9.7 (3.2 to 25.6)
Change from baseline <sup>e</sup>		-1.5 (-4.1 to 3.2)	-1.0 (-4.7 to 3.5)	-2.6 (-5.1 to 1.6)		0.4 (-4.3 to 8.4)	-1.3 (-5.9 to 5.6)	-0.6 (-4.9 to 7.2)
Add salt daily after served at table <sup>e</sup>	21.1 (15.3 to 28.3)	10.3 (6.4 to 16.3)	10.4 (6.1 to 17.1)	12.3 (7.8 to 18.9)	19.4 (13.8 to 26.6)	18.9 (13.1 to 26.4)	20.9 (3.7 to 15.1)	19.3 (13.3 to 27.2)
Change from baseline <sup>e</sup>		-10.8 (-14.9 to -4.4) <sup>f</sup>	-10.7 (-14.8 to -4.1) <sup>f</sup>	-8.8 (-13.5 to -1.6)		-0.5 (-8.2 to 6.9)	1.4 (-5.8 to 10.2)	-0.2 (-7.0 to 8.7)
Add salt daily when preparing food <sup>e</sup>	27.3 (20.6 to 35.2)	15.3 (10.2 to 22.1)	13.4 (8.7 to 20.1)	13.8 (9.3 to 20.2)	23.3 (17.0 to 31.0)	25.4 (18.5 to 33.7)	24.6 (17.9 to 32.8)	23.3 (17.2 to 30.8)
Change from baseline <sup>e</sup>		-12.0 (-17.3 to -4.7) <sup>f</sup>	-13.9 (-18.6 to -6.7) <sup>f</sup>	-13.5 (-18.4 to -6.2) <sup>f</sup>		2.1 (-5.5 to 11.5)	1.3 (-6.3 to 10.5)	0 (-8.3 to 9.4)
≥7 Alcohol drinks/wk <sup>e</sup>	20.4 (13.6 to 29.5)	16.7 (10.6 to 25.3)	18.2 (11.5 to 27.7)	15.8 (9.8 to 24.4)	18.4 (11.9 to 27.3)	15.0 (9.2 to 23.4)	13.1 (7.7 to 21.3)	13.0 (7.7 to 21.1)
Change from baseline <sup>e</sup>		-3.7 (-9.5 to 4.3)	-2.2 (-8.5 to 6.1)	-4.6 (-10.5 to 3.1)		-3.4 (-8.9 to 4.3)	-5.3 (-10.1 to 2.1)	-5.5 (-11.0 to 1.6)
Body mass index <sup>b,m</sup>	31.3 (30.2 to 32.5)	31.4 (30.2 to 32.5)	31.6 (30.4 to 32.7)	31.6 (30.5 to 32.8)	31.7 (30.5 to 32.8)	31.7 (30.5 to 32.9)	31.7 (30.5 to 32.9)	31.5 (30.4 to 32.7)
Change from baseline <sup>b</sup>		0.05 (-0.20 to 0.31)	0.27 (-0.01 to 0.55)	0.36 (0.03 to 0.68) <sup>f</sup>		0.04 (-0.22 to 0.30)	0.05 (-0.23 to 0.33)	-0.15 (-0.48 to 0.18)
Physical activity meets CDC guidelines <sup>e,n</sup>	34.3 (25.4 to 44.5)	39.6 (29.9 to 50.3)	43.1 (34.1 to 52.6)	36.5 (28.2 to 45.7)	32.3 (23.5 to 42.6)	30.7 (21.9 to 41.3)	39.9 (31.0 to 49.4)	37.7 (29.1 to 47.3)
Change from baseline <sup>e</sup>		5.3 (-3.6 to 15.0)	8.8 (-0.5 to 18.7)	2.2 (-6.6 to 12.0)		-1.6 (-9.7 to 7.9)	7.5 (-1.6 to 17.4)	5.3 (-4.4 to 14.8)

Abbreviation: BP, blood pressure.

<sup>a</sup> Model-based results from general and generalized linear mixed models predicting outcome from study group, time, and group × time interaction. The P values indicated in footnotes c, d, and f were calculated using the time × study group interaction term, indicating differential change by study group from baseline to 6 months, baseline to 12 months, or baseline to 18 months.

<sup>b</sup> Values expressed as mean (95% confidence interval).

<sup>c</sup> Comparison yielded a P value of less than .001.

<sup>d</sup> Comparison yielded a P value of less than .01.

<sup>e</sup> Values expressed as percentage (95% confidence interval).

<sup>f</sup> Comparison yielded a P value of less than .05.

<sup>g</sup> Limited to 330 patients at baseline, 336 at 6 months, 332 at 12 months, and 317 at 18 months. Assigned a score between 0 and 4 based on 4 questions about nonadherence. Each positive response is 1 point; on scale of 0 to 4, 0 is perfect self-reported adherence.<sup>22</sup>

<sup>h</sup> Limited to patients who reported receiving health care in past 12 months at

baseline (n = 425), in past 6 months at 6-month clinic visit (n = 334), in past 6 months at 12-month clinic visit (n = 303), and in past 6 months at 18-month clinic visit (n = 272). Includes selected items from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey.<sup>24</sup>

<sup>i</sup> Data are from the CAHPS survey; items answered were scored on a scale of 0 to 5, with 0 indicating the worst and 5 the best.

<sup>j</sup> Data are from the CAHPS survey; items answered were scored on a scale of 1 to 4, with 1 indicating never, 2 for sometimes, 3 for usually, and 4 for always.

<sup>k</sup> Data are from the Medical Outcomes Study Short Form 12 (SF-12) survey; items were scored on scale of 0 to 100, with 100 indicating highest levels of health.<sup>23</sup>

<sup>l</sup> Items answered were scored on scale of 1 to 5, with 1 indicating not confident and 5 indicating very confident.<sup>13</sup>

<sup>m</sup> Calculated as weight in kilograms divided by height in meters squared.

<sup>n</sup> Based on US Centers for Disease Control and Prevention (CDC) guidelines for moderate intensity physical activity in adults.



There were 109 adverse events reported, 60 in usual care and 49 in the telemonitoring intervention. Most events were noncardiovascular hospitalizations. There were 2 allergic reactions attributed to BP medicine in usual care patients. There were 7 events related to hypotension, dizziness, or loss of consciousness (6 in the telemonitoring intervention group and 1 in the usual care group), and 5 events related to hypertension (4 in the usual care group and 1 in the telemonitoring intervention group).

All the hypotension-related events in the telemonitoring intervention group occurred among patients with the lower BP goal of less than 130/80 mm Hg due to having either diabetes or chronic kidney disease. Other cardiovascular events included: 7 strokes (5 in the usual care group and 2 in the telemonitoring intervention group), 3 transient ischemic attacks (all in the usual care group), 2 episodes of atrial fibrillation (1 in the usual care group and 1 in the telemonitoring intervention group), 1 myocardial infarction (in the usual care group), 1 episode of angina (in the telemonitoring intervention group), and 2 cardiac bypass surgeries (both in the usual care group).

Direct program costs per patient in the intervention group were \$1045 during the 12-month intervention period. About half (48%) of program costs were for care management services and the remainder were for telemonitoring services; however, the study received discounted pricing for research from the telemonitoring vendor. In the telemonitoring intervention group, all 228 patients used pharmacist services, with a mean (SD) of 11.4 (3.9) visits and each visit lasting 34.2 minutes per encounter; and 217 used telemonitoring services, with a mean (SD) of 9.8 (2.5) months of actual use. Under prevailing market rates and this level of telemonitoring use, we estimate that direct program costs would total about \$1350 per patient.

## Discussion

Our results show that compared with usual primary care, home BP telemonitoring with pharmacist management resulted in large improvements in BP control and substantial decreases in BP during 12 months. Compared with usual care patients, telemonitoring intervention patients had greater antihypertensive medication intensification and better self-reported adherence to antihypertensive medication and sodium restriction. The intervention also improved some aspects of patient satisfaction and appeared to have an acceptable level of safety.

Unique features of our study were the primary outcome of composite BP control at 6 and 12 months, the maintenance intervention from months 6 to 12, and the extended postintervention follow-up at 18 months. We selected a composite primary outcome because early and persistent BP control is likely to be more effective for prevention of cardiovascular events than intermittent control. Although BP control in both groups was lower for the composite measure than at single time points, the telemonitoring intervention group had 25% to 30% higher absolute BP control rates compared with the usual care group.

We observed maintenance of the level of BP control achieved at 6 months in the telemonitoring intervention group through 18 months. In contrast, BP control gradually im-

proved in the usual care group, but still remained substantially lower than the telemonitoring intervention group by an absolute 15% by 18 months.

Improvement in the usual care group over time has been observed in other studies.<sup>16</sup> Although we did not find significant changes in antihypertensive treatment, lifestyle, or self-reported medication adherence in the usual care group, the measures reported herein may not have captured subtle changes that resulted in improved BP over time. Data on the long-term effectiveness of team-based care and home BP monitoring interventions beyond 12 months are limited and conflicting, and no study has measured postintervention outcomes with rigorous research-quality BP measures.<sup>7-9,14,16,25-28</sup> Our study shows that high levels of BP control can be maintained with a less intensive intervention and persist for at least 6 months after the intervention is stopped.

The HyperLink study included several of the 6 domains designated by the chronic care model,<sup>29</sup> which is a framework for organizational changes to improve chronic illness care through delivery system redesign, clinical information systems, and self-management support. HyperLink's design also was based on 3 decades of quality improvement trials for hypertension care showing that organizational interventions, including nonphysician hypertension care, achieved the largest BP reductions.<sup>5-8,25,30-36</sup>

In most cases, the interventions in these studies included a nurse or a pharmacist and were called team change, team-based care, case management, disease management, or nurse- or pharmacist-led care. In a 2006 meta-analysis<sup>5</sup> of the studies, average SBP/DBP decreased by 10/4 mm Hg, and the absolute proportion of patients achieving BP control improved by 20%. The most successful interventions did not depend on the physician responding to recommendations. A recently updated meta-analysis<sup>7</sup> that included 31 additional studies confirmed these findings, and although SBP/DBP reductions were smaller (6/2 mm Hg), the benefits extended to improving other cardiovascular risk factors (lipid levels and glycemic control).

Other strategies in previous research associated with large BP improvements include patient self-management and self-monitoring with resources or devices that enhance patients' abilities to manage their condition.<sup>5,30,32,37-39</sup> Home BP monitoring with or without additional support was the subject of several recent comprehensive evidence reviews<sup>6,9,35,40,41</sup> that concluded home monitoring alone results in small BP reductions at 6 months compared with usual care (SBP/DBP reductions of 3/2 mm Hg), but evidence regarding longer-term efficacy is lacking. In contrast, improved BP outcomes were more robust in high-quality studies combining home BP monitoring with some additional support intervention for up to 12 months (SBP reductions of 3-9 mm Hg and DBP reductions of 2-4 mm Hg).<sup>9</sup>

The combination of home BP monitoring and team-based hypertension care has been the subject of several high-quality studies. A recent study by Green et al<sup>13</sup> using secure e-mail to convey home BP data to pharmacists found BP and BP control improvements compared with usual care over 12 months that were quite similar to those observed in Hyper-

Link, but the study excluded patients with diabetes, chronic kidney disease, or cardiovascular disease. In another recently published study conducted in a managed care setting,<sup>42</sup> patients randomly assigned to home BP telemonitoring combined with pharmacist-led care had 13-mm Hg greater reductions in SBP than usual care during a 6-month period.

Artinian et al<sup>12</sup> studied 387 urban blacks with uncontrolled BP randomly assigned to community nurse-managed telemonitoring or usual care. At 12 months, intervention patients had a 5-mm Hg greater reduction in SBP, but DBP and BP control did not differ. A British study of patients with uncontrolled BP while taking up to 2 antihypertensive drugs randomized patients to usual care or an intervention combining home BP telemonitoring and self-titration of medications.<sup>15</sup> Systolic BP decreased by 6 mm Hg more in the intervention group after 12 months and most patients in the intervention made at least 1 medication change.

Another recent study<sup>16</sup> among US veterans compared usual care with a BP telemonitoring intervention composed of various types of nurse management. The largest effect was observed for a combined behavioral and medication management intervention in the post hoc subgroup with inadequate BP control at baseline (SBP was 15 mm Hg lower at 12 months and 8 mm Hg lower at 18 months, both significantly different than usual care).

It is important to consider intervention costs in addition to effectiveness. We project that direct program costs would total \$1350 per patient using current market rates when patients are given up to 12 months of access to BP telemonitoring. This is quite similar to the cost estimate for 18 months of combined behavioral and medication management for hypertension in the BP telemonitoring trial conducted among veterans.<sup>16,43</sup> It may be possible to reduce total program costs through better targeting of patients, negotiating volume discounts, and by individual tailoring of the intervention; for example, telemonitoring could be replaced with a standard home BP monitor after a patient demonstrates that he/she has reached and sustained home BP goals. We plan future analyses that will take into account indirect costs during 18 months and long-term cost savings from averting hypertension-related adverse events.

Some limitations of HyperLink should be considered in interpreting the results. Although the study aimed to enroll a broad population, only about 1 in 7 patients solicited by mail for participation responded; and of those screened, only about 1 in 4 was eligible. Participants were generally well-educated with high income levels; and perhaps reflecting the study population's interest in hypertension, about half had used a home BP monitor during the year prior to the study. HyperLink was conducted in 1 integrated health care system, but the findings are in agreement with studies conducted in Washington, Colorado, Michigan, and North Carolina in a variety of health care settings. As in any multicomponent intervention, it is difficult to separate how much of the intervention effect is attributable to the telemonitoring and pharmacist case management.

In addition, the study was not blinded, which could have had an effect on the reporting of subjective outcomes and adverse events. However, BP was measured using automated devices with a standard protocol and is unlikely to have been biased. Last, although BP improvement was substantial and a full cost analysis is under way, no study has yet conducted a thorough cost-effectiveness analysis of this type of intervention. Lack of information on long-term effects, reimbursement mechanisms, and return on investment have been identified as barriers to implementation.<sup>7,9</sup> We hope to address these issues when a planned long-term follow-up study is completed.

## Conclusions

We conclude that BP telemonitoring and pharmacist case management was safe and effective for improving BP control compared with usual care during 12 months; and improved BP in the intervention group was maintained for 6 months following the intervention (18 months). HyperLink included patients with a much wider range of hypertension severity and comorbidity than have been enrolled in previous trials. If these results are found to be cost-effective and durable during an even longer period, it should spur wider testing and dissemination of similar alternative models of care for managing hypertension and other chronic conditions.

### ARTICLE INFORMATION

**Author Contributions:** Dr Margolis had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Study concept and design:** Margolis, Kerby, Maciosek, O'Connor.

**Acquisition of data:** Margolis, Bergdall, Groen, Kadrmas, Kerby, Klotzle, Michels, O'Connor, Pritchard, Sekenski, Trower.

**Analysis and interpretation of data:** Margolis, Asche, Bergdall, Dehmer, Maciosek, O'Connor, Sperl-Hillen.

**Drafting of the manuscript:** Margolis, Asche, Bergdall, Dehmer, Kadrmas, O'Connor, Sperl-Hillen, Trower.

**Critical revision of the manuscript for important intellectual content:** Asche, Bergdall, Dehmer, Groen, Kerby, Klotzle, Maciosek, Michels, O'Connor, Pritchard, Sekenski, Sperl-Hillen.

**Statistical analysis:** Asche, Dehmer, Trower.

**Obtained funding:** Margolis, Kerby, Maciosek.

**Administrative, technical, or material support:** Margolis, Bergdall, Groen, Kerby, Klotzle, Maciosek.

**Study supervision:** Margolis, Bergdall, Kerby, Maciosek.

**Conflict of Interest Disclosures:** The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Drs Margolis, Dehmer, Maciosek, O'Connor, and Sperl-Hillen, Mr Asche, and Mss Bergdall, Kerby, Pritchard, Sekenski, and Trower reported receiving grant support administered through HealthPartners Institute for Education and Research for work on HyperLink. Dr O'Connor also reported receiving payment for lectures from the State of Montana Diabetes Program, the Centers for Disease Control and Prevention, and Peking University; has a patent pending for diabetes clinical decision support; and

has received reimbursement for travel from the American Diabetes Association, the International Diabetes Federation, the National Institutes of Health, and the International Conference on Diabetes and Depression. Dr Sperl-Hillen also reported being listed as an inventor on US patent No. 8,388,342 B2 issued in 2013 entitled "Disease Treatment Simulation." She is eligible to receive revenue in the future per HealthPartners Institute for Education and Research intellectual property policy. To date, she has received no payment for this role. HealthPartners Institute for Education and Research has recently entered into a royalty-bearing license agreement with a third party to commercialize the simulated learning technology for the purpose of broader dissemination. Dr Sperl-Hillen will serve as a nonpaid director on the board of directors for that licensee. No other author reported disclosures.

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