

Do the Benefits of Participation in a Hypertension Self-Management Trial Persist After Patients Resume Usual Care?

Matthew L. Maciejewski, PhD; Hayden B. Bosworth, PhD; Maren K. Olsen, PhD; Valerie A. Smith, MS; David Edelman, MD, MHS; Benjamin J. Powers, MD, MHS; Miriam A. Kaufman, MSW; Eugene Z. Oddone, MD, MHS; George L. Jackson, PhD, MHA

Background—Hypertension self-management has been shown to improve systolic blood pressure (BP) control, but longer-term economic and clinical impacts are unknown. The purpose of this article is to examine clinical and economic outcomes 18 months after completion of a hypertension self-management trial.

Methods and Results—This study is a follow-up analysis of an 18-month, 4-arm, hypertension self-management trial of 591 veterans with hypertension who were randomized to usual care or 1 of 3 interventions. Clinic-derived systolic blood pressure obtained before, during, and after the trial were estimated using linear mixed models. Inpatient admissions, outpatient expenditures, and total expenditures were estimated using generalized estimating equations. The 3 telephone-based interventions were nurse-administered health behavior promotion, provider-administered medication adjustments based on hypertension treatment guidelines, or a combination of both. Intervention calls were triggered by home BP values transmitted via telemonitoring devices. Clinical and economic outcomes were examined 12 months before, 18 months during, and 18 months after trial completion. Compared with usual care, patients randomized to the combined arm had greater improvement in proportion of BP control during and after the 18-month trial and estimated proportion of BP control improved 18 months after trial completion for patients in the behavioral and medication management arms. Among the patients with inadequate baseline BP control, estimated mean systolic BP was significantly lower in the combined arm as compared with usual care during and after the 18-month trial. Utilization and expenditure trends were similar for patients in all 4 arms.

Conclusions—Behavioral and medication management can generate systolic BP improvements that are sustained 18 months after trial completion.

Clinical Trial Registration—URL: <http://www.clinicaltrials.gov>. Unique identifier: NCT00237692. (*Circ Cardiovasc Qual Outcomes*. 2014;7:269-275.)

Key Words: blood pressure ■ group processes ■ health care costs ■ outcomes assessment (health care) ■ veterans

Interventions that combine self-management (SM) support and individualized medical management theoretically represent a potentially sustainable intervention for patients with hypertension if they retain and apply skills learned in such interventions after returning to usual care. The longer-term clinical and economic benefits of SM interventions remain largely untested because only 5 prior studies tracked clinical outcomes after completion of SM trials in patients with hypertension. Results from the United Kingdom Prospective Diabetes Study (UKPDS)¹ found that the clinical benefits of tight blood pressure (BP) control were not sustained ≤ 10 years after trial completion.

Editorial see p 205

The Steno-2² follow-up study of patients with diabetes mellitus and microalbuminuria and 3 follow-up studies of pharmacist interventions for patients with hypertension suggested that SM interventions had long-lasting effects.³⁻⁵ These long-term clinical benefits may translate into reductions in healthcare utilization and costs, but no prior trial has reported long-term economic outcomes once patients return to usual care.

The purpose of this article is to examine clinical and economic outcomes 18 months after completion of an 18-month

Received April 25, 2013; accepted December 18, 2013.

From the Center for Health Services Research in Primary Care, Durham Veterans Affairs Medical Center, Durham, NC (M.L.M., H.B.B., M.K.O., V.A.S., D.E., M.A.K., E.Z.O., G.L.J.); Division of General Internal Medicine (M.L.M., H.B.B., D.E., E.Z.O., G.L.J.) and Departments of Psychiatry and Behavioral Sciences and School of Nursing (H.B.B.) and Biostatistics and Bioinformatics, Duke University, Durham, NC (M.K.O.); and St. Luke's Health System, Boise, ID (B.J.P.).

The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs, the United States government, or Duke University.

The Data Supplement is available at <http://circoutcomes.ahajournals.org/lookup/suppl/doi:10.1161/CIRCOUTCOMES.113.000309/-DC1>.

Correspondence to Matthew L. Maciejewski, PhD, Durham Veterans Affairs Medical Center, HSR&D Service (152), 508 Fulton St, Durham, NC 27705. E-mail matthew.maciejewski@va.gov

© 2014 American Heart Association, Inc.

Circ Cardiovasc Qual Outcomes is available at <http://circoutcomes.ahajournals.org>

DOI: 10.1161/CIRCOUTCOMES.113.000309

WHAT IS KNOWN

- Hypertension self-management has been shown to improve short-term blood pressure control in a range of patient populations.
- The effect of hypertension self-management on disease control in the longer term is largely unknown, and the effect on long-term health expenditures is entirely unknown.

WHAT THE STUDY ADDS

- This article evaluates the effect of hypertension self-management 18 months after patients return to usual care on completion of a randomized trial.
- This article also reports on the effect of hypertension self-management on glycemic and lipid control in a sample of veterans with hypertension.

hypertension SM (HSM) randomized trial of 591 patients with hypertension in which behavioral management and medication management showed significant systolic BP (SBP) improvements at 12 months, but not at 18 months, particularly among those with poor baseline BP control who showed the most improvement at 18 months.⁶ If the clinical benefits of HSM trials are sustainable or clinical benefits translate into decreased expenditures, payers may find HSM interventions to be a financially viable strategy to improve health and health care of patients with hypertension.

Methods

Study Design and Study Population

The trial design and primary results were published previously.⁶⁻⁸ In brief, the trial evaluated 3 telephone-based interventions through a 4-group design: (1) nurse-administered, physician-directed medication management intervention using a validated clinical decision support system; (2) nurse-administered, behavioral management intervention; (3) combined behavioral management and medication management intervention; and (4) usual care. Interventions were activated based on home BP measurements collected via telemonitoring. Potentially eligible individuals were selected from primary care patients in Durham Veterans Affairs Medical Center ambulatory care clinics. Eligible patients had a diagnosis of hypertension, were using a BP-lowering medication, and had inadequate BP control ($>140/90$ mmHg for all patients) based on the mean of the prior 12 months of clinic BP recordings. We excluded patients who received dialysis; had a serum creatinine >2.5 or no documentation of renal function; ever received an organ transplantation; were hospitalized for stroke, myocardial infarction, or coronary artery revascularization within 3 months of contact; had a diagnosis of metastatic cancer or dementia; lacked a home telephone; resided in a nursing home; received home health care; or had severely impaired hearing or speech. Patients providing written informed consent were randomized to 1 of 4 arms, with randomization stratified by diabetic status.

As in the original trial, we conducted analyses on the entire study sample and stratified analyses separately for those whose study-measured BP was in control at baseline and those whose study-measured BP was out of control at baseline.⁶ Despite inclusion criteria requiring patients to have had inadequate BP control based on the mean of the prior 12 months of BP recordings obtained from the electronic medical record, 59% ($n=348$) at baseline were in control (study mean SBP= 117.9 mmHg; study mean diastolic BP= 71.6 mmHg) using a standardized method of assessing BP (ie, systematic assessment in a quiet room by a trained research assistant). The

Durham Veterans Affairs Medical Center Institutional Review Board approved both the clinical trial and these follow-up analyses.

Intervention

Telemedicine and Home BP Monitoring

Patients randomized to any 1 of 3 intervention arms were provided a home BP monitor. Patients were advised to take their BP once every other day; readings were transmitted automatically.⁸ Home SBP averages 6 to 8 mmHg lower than values obtained during a routine clinic visit,⁹ so intervention trigger alerts were based on a 2-week average home BP of $\geq 135/85$ mmHg for patients without diabetes and $\geq 135/80$ mmHg for patients with diabetes.¹⁰ If an intervention was activated, a patient's home BP was reassessed again at 6 weeks before triggering the intervention again. If 3 BP values were not transmitted during a 2-week period, a research assistant contacted patients to remind them to use the equipment and answer any questions regarding the equipment. Patients who maintained adequate BP control did not activate the intervention but triggered a contact every 6 months to reinforce positive behavior.

Behavioral Management Intervention

The behavioral management intervention consisted of 11 tailored health behavior modules focused on improving HSM, including the following⁷: hypertension knowledge including medication side effects, medication memory, resources to improve healthcare access, and patient-provider relationship. Patients were also provided evidence-based recommendations regarding salt intake, weight, stress reduction, smoking cessation, and alcohol use. Verbal information was reinforced with mailed handouts. The nurse used intervention software that contained predetermined scripts and patient-specific tailored algorithms for the modules. Each encounter consisted of 3 to 4 modules and lasted 12 to 14 minutes.

Medication Management Intervention

On triggers in the medication management intervention, a nurse provided a study physician with a medication change recommendation based on the decision support software.¹¹ The study physician reviewed the patient's BP, medication, and adherence (based on patient report and prescription refill data) with the nurse and decided whether to change hypertension medication. The nurse communicated recommended changes to the patient, while the study physician electronically prescribed the medication and generated a note in the patient's medical record that was cosigned by the patient's primary care provider. The nurse called the patient 3 weeks after the medication change to obtain reports of adverse effects and address patient questions.

Combined Intervention and Usual Care

Patients in the combined arm received each intervention component described above. Usual care patients received no contact with the intervention nurses and did not receive home telemonitoring equipment, but they received primary care and management of hypertension according to the discretion of their primary care provider.

Study Outcomes

We compared clinical and economic outcome trends between patients in the 4 arms 12 months before, 18 months during, and 18 months after trial completion. The primary clinical outcome from the original study and this follow-up study was BP control ($\leq 140/90$ mmHg for individuals without diabetes mellitus and $\leq 130/80$ mmHg for individuals with diabetes mellitus).¹² The secondary clinical outcome was SBP. Unlike the primary trial analysis that used study-specific clinical measurements obtained by trial staff during study visits, the current study used clinical measurements from the Veterans Affairs (VA) electronic health record (EHR) taken during any outpatient visit in the 48-month observation period. BP readings taken on the same day as an inpatient admission were excluded. We used the mean of multiple BP readings taken on the same day, so patients only had 1 BP outcome per day.

The economic outcomes included probability of ≥ 1 inpatient admissions, outpatient expenditures, and total expenditures in VA in each

of 8 six-month intervals making up the 48-month observation period. Expenditure and admission outcomes were obtained from Decision Support System data, which generate expenditure estimates for each outpatient visit, inpatient admission, dispensed medication, and other healthcare products and services provided in the VA.^{13,14} VA outpatient expenditures were aggregated for all outpatient services, and total expenditures were aggregated from outpatient and inpatient expenditures. The unit of analysis in the economic analysis was the person/half-year, and expenditures were inflation adjusted to 2010 dollars.

Statistical Analysis

Clinical Outcomes

Patients had a varying number of clinic-based BP assessments that were captured at different time intervals in the VA EHR. Thus, it was not possible to examine actual BP values at the same time intervals for all patients, so we generated descriptive penalized splines over the 48-month observation period to understand mean BP control and SBP trends. There were natural transition points at baseline and trial conclusion, so piecewise quadratic mixed-effects models were fit for each outcome. These models had separate quadratic functions for the pretrial, trial, and post-trial study periods, with time terms coded continuously as the number of weeks from baseline and centered at the transition points.¹⁵ Treatment by time interactions allowed us to estimate differential BP trends for the 3 intervention arms versus usual care.

For the analysis of the primary outcome of BP control, a logistic piecewise quadratic mixed-effects regression model was used to estimate differences in BP control for each of the intervention arms relative to usual care. Model parameters, described above, were estimated using maximum likelihood via an adaptive quadrature method (SAS v9.2 PROC NLMIXED). A patient-level random effect was included in the model to account for the correlation of repeated measurements over time. Marginalized estimates and corresponding confidence intervals (CIs) for the proportion in BP control for the usual care and each intervention group were calculated at 6-month intervals after initiation of the intervention to estimate the relative improvement in proportion of patients with BP control.¹⁶

For the secondary analyses, we examined the intervention group effect on mean clinic SBPs over time. The linear piecewise quadratic mixed-effects model for SBP included the fixed-effects terms described above and patient-level random effects for intercept as well as linear slope, quadratic time slope, and the correlations (ie, variance-covariance matrix) between intercept and slopes. Mean differences between each intervention arm relative to usual care were calculated at 6-month intervals after intervention initiation, along with corresponding 95% CIs, using SAS ESTIMATE statements in PROC MIXED (v9.2). We then examined the intervention group effect on mean clinic SBPs over time within the subgroup of patients with controlled BP at baseline and separately for the subgroup of patients with uncontrolled BP at baseline using a similar model described above.

Economic Outcomes

Using generalized estimating equations with a binomial distribution and logit link function (SAS v9.2 and Stata version 11), we modeled the probability of ≥ 1 inpatient admissions during 8 half-year time points (2 before, 3 during, and 3 after the trial). We did not conduct regression analysis of inpatient expenditures because too few patients were admitted. Outpatient and total expenditures were modeled using generalized estimating equations. All 3 economic outcome models included treatment arm, indicators for each half-year time period, and the interactions of treatment and time period for the 5 half-year periods after intervention initiation. CIs for the differences in expenditures between arms were derived from model estimates using the delta method.

Role of the Funding Source

The Quality Enhancement Research Initiative and Health Services Research and Development Service of the US Department of Veterans Affairs had no role in the design, conduct, collection, management, analysis, or interpretation of the data, or in the preparation, review, or approval of the article.

Results

Patient Characteristics

The trial randomized 591 of 1893 potentially eligible patients between May 2006 and July 2009. Given the availability of VA medical record data on all patients, we modeled clinical and economic outcomes data on the 591 patients initially enrolled in the trial. Of the 591 study patients, 48% were blacks, and 92% were men (Table 1).

Primary Outcome: BP Control

The 591 patients had a mean of 21.1 SBP values taken during routine clinic visits during the 48-month observation period. The estimated improvement in BP control relative to usual care at 12 months after trial completion (30 months postrandomization) was statistically significant in the medication management arm and the combined arm at 6.6% (95% CI, 0.7% to 12.6%) and 10.1% (95% CI, 4.2% to 16.0%), respectively (Figure 1, Table 2). Eighteen months after trial completion (36 months postrandomization), a higher statistically significant proportion of patients in the behavioral arm (17.1%; 95% CI, 6.9% to 27.4%), the medication management arm (20.2%; 95% CI, 9.7% to 30.6%), and the combined arm (20.4%; 95% CI, 10.0% to 30.8%) had estimated BP improvements compared with usual care.

Systolic Blood Pressure

Estimated trends in clinic SBP values found improvements for patients in the combined arm at 6 months (-2.0 mmHg; 95% CI, -3.6 to -0.4) and at 12 months (-2.6 mmHg; 95% CI, -4.7 to -0.4) of the 18-month trial compared with usual care (Figure 2, Table 2). Eighteen months after trial completion, estimated mean SBP was statistically improved for patients in the behavioral arm (-5.0 mmHg; 95% CI, -9.5 to -0.5) and the combined arm (-5.5 mmHg; 95% CI, -10.0 to -1.0) relative to usual care.

Among the individuals with adequate BP control at baseline ($n=348$), estimated mean SBP was stable over time, and there were no differences between the intervention arms and usual care during the 18 months of the study and in the 18 months after the trial (results not shown). For individuals with poor BP control ($n=243$), in the combined arm, SBP statistically decreased by 5.3 mmHg (95% CI, -9.1 to -1.5) at 18 months (ie, the end the trial) and 5.0 mmHg (95% CI, -9.6 to -0.3) at 24 months, 6.5 mmHg (95% CI, -11.7 to -1.3) at 30 months postrandomization (12 months after completion of the trial), and 10.0 mmHg (95% CI, -17.8 to -2.2) at 36 months postrandomization (18 months after completion of the trial) relative to usual care (Figure 3, Appendix I in the Data Supplement). No significant differences were found for the other arms relative to usual care after trial completion.

Economic Outcomes

At baseline, trial end at 18 months, and 18 months after trial completion, the estimated probability of inpatient admission was similar for patients in all arms (Table 3). Estimated mean outpatient expenditures and estimated mean total expenditures were also similar for patients in the 18 months during the trial and the 18 months after trial completion. In subgroup

Table 1. Hypertension Intervention Nurse Telemedicine Study Baseline Sample Characteristics

Baseline Characteristics	Total (n=591)	Usual Care (n=147)	Behavioral Management Intervention (n=148)	Medication Management Intervention (n=149)	Combined Intervention (n=147)
Demographics					
Age, y, Mean SD	64 (10)	64 (10)	63 (11)	64 (10)	63 (11)
Race					
White	49%	50%	53%	49%	44%
Black	48%	48%	45%	48%	52%
Other	3%	1%	3%	3%	5%
Male	92%	96%	92%	93%	86%
Married	66%	65%	71%	65%	61%
Completed <12 y of school	13%	10%	14%	12%	18%
Low literacy level (<9th grade; REALM score ≤60)	38%	45%	39%	32%	37%
Employed	35%	35%	34%	34%	35%
Current smoker	21%	22%	19%	20%	22%
Body mass index	30.3 (5.3)	30.0 (5.5)	30.6 (5.6)	30.2 (5.0)	30.6 (5.1)
Medical history					
>10-y history of high blood pressure	75%	71%	76%	77%	74%
Diabetic	43%	44%	44%	43%	40%
No. of hypertension medications, mean (SD)*	2.4 (1.2)	2.5 (1.2)	2.4 (1.2)	2.3 (1.1)	2.4 (1.1)

*Means are for the n=507 Veterans Affairs (VA) patients whose prescribed hypertension medication fills, as recorded in the national VA database, overlapped with their baseline interview date. Note that the percentages for race do not add to 100% due to rounding. REALM indicates Rapid Assessment of Adult Literacy in Medicine.

Reproduced with permission from Bosworth et al.⁶ Copyright ©2011 American Medical Association. All rights reserved. Authorization for this adaptation has been obtained both from the owner of the copyright in the original work and from the owner of copyright in the translation or adaptation.

analyses of patients with poor BP control at baseline, the estimated probability of inpatient admission, estimated mean outpatient expenditures, and estimated mean total expenditures were similar for patients in all arms (Appendix I in the Data Supplement).

Discussion

This is one of the few articles to conduct long-term follow-up of clinical outcomes after completion of an HSM trial and the first to examine whether clinical benefits translate into

reductions in health expenditures after patients return to usual care. We observed that an intervention combining behavioral and medication management significantly improved BP control during the 18-month trial, and these statistically significant improvements were sustained 18 months after trial completion, particularly for patients with inadequate BP control at baseline. Patients may have realized BP benefits after the trial ended because they were able to effectively execute the behavior changes taught to them in the behavioral management intervention. We should note that these improvements were driven by worsening control in the control arm, not by continued better control in the treatment arm. Health expenditures were similar for all patients, so the clinical benefits did not translate into lower health expenditures. The null expenditure finding is not surprising, given that condition improvements large enough to reduce utilization and expenditures typically take years to manifest.

The clinical results are consistent with 2 prior cluster randomized trials that examined clinical outcomes 18 months after completion^{3,4} of physician–pharmacist collaboration interventions to improve hypertension,¹⁷ which focused primarily on medication intensification.¹⁸ In the first study, the mean adjusted SBP was 8.7 mm Hg (95% CI, 4.4 to 12.9) lower for the intervention group at the conclusion of the 9-month trial, and SBP control was greater (89% versus 53%; $P<0.0001$) in intervention patients.³ After trial completion, 104 of these 179 patients were reconsented to evaluate SBP values 18 months after trial completion.³ By 18 months after the trial, BP control deteriorated to 59% and 31% in the intervention and control groups, respectively ($P=0.0048$). In the second study, the

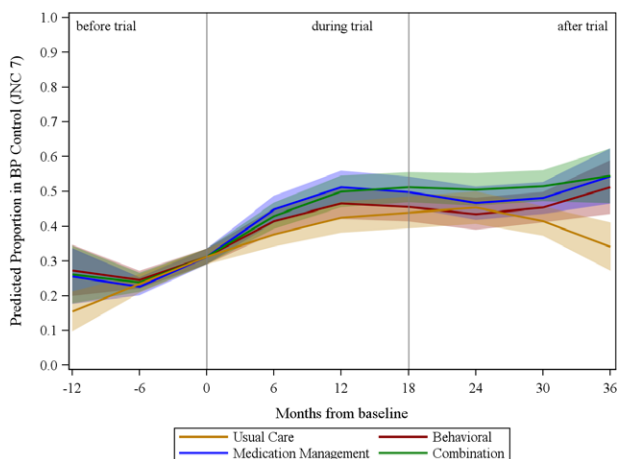


Figure 1. Estimated probability of blood pressure control before, during, and after trial completion. JNC 7 indicates Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure.

Table 2. Estimated Differences in Proportion of Patients With In-Control BP and Estimated Differences in Systolic BP (mm Hg), Overall Sample (95% CI)

Outcome/Time Period	Behavioral Arm vs Usual Care	Medication Management vs Usual Care	Combined Arm vs Usual Care
Adequate blood pressure control (entire sample, n=591)			
During trial			
6 mo	3.8% (−0.5% to 8.2%)	7.1% (2.6% to 11.7%)	5.3% (0.9% to 9.8%)
12 mo	4.0% (−1.8% to 9.8%)	8.8% (2.8% to 14.8%)	7.4% (1.4% to 13.4%)
18 mo	0.1% (−5.5% to 5.7%)	4.4% (−1.4% to 10.2%)	5.8% (0.02% to 11.5%)
After trial completion			
24 mo	−1.8% (−8.0% to 4.4%)	5.1% (−1.2% to 11.4%)	5.1% (−1.2% to 11.4%)
30 mo	3.9% (−1.8% to 9.7%)	6.6% (0.7% to 12.6%)	10.1% (4.2% to 16.0%)
36 mo	17.1% (6.9% to 27.4%)	20.2% (9.7% to 30.6%)	20.4% (10.0% to 30.8%)
Systolic blood pressure (entire sample, n=591)			
During trial			
6 mo	−0.57 (−2.11 to 0.97)	−1.41 (−2.98 to 0.16)	−2.02 (−3.60 to −0.44)
12 mo	−0.34 (−2.45 to 1.77)	−1.40 (−3.55 to 0.74)	−2.57 (−4.73 to −0.41)
18 mo	0.70 (−1.52 to 2.91)	0.02 (−2.23 to 2.27)	−1.65 (−3.91 to 0.61)
After trial completion			
24 mo	1.03 (−1.52 to 3.57)	1.03 (−1.56 to 3.62)	−0.98 (−3.56 to 1.60)
30 mo	−0.86 (−3.62 to 1.90)	−0.19 (−2.99 to 2.61)	−2.27 (−5.06 to 0.53)
36 mo	−4.97 (−9.45 to −0.50)	−3.64 (−8.16 to 0.88)	−5.51 (−10.04 to −0.98)

BP indicates blood pressure; and CI, confidence interval.

mean adjusted difference in SBP was 11.1 mmHg in favor of the intervention group at the conclusion of the 6-month trial, and SBP control was greater (65% versus 29%; $P < 0.0001$) in intervention patients than control patients.⁴

Our study demonstrates the promise of linking EHR data to trial participants to conduct long-term follow-up studies without patient contact through surveys or interviews. Within-trial SBP measures in the 2 prior pharmacist interventions were research measurements obtained during study visits, whereas SBP measures after the trial were abstracted from clinic values entered into medical records. The UKPDS¹ and Steno-2² follow-up studies required direct patient contact to obtain SBP values, which is much more costly than extraction of EHR data routinely collected at clinic visits. In this study,

all SBP measures before, during, and after trial completion were obtained from clinic values captured in the VA EHR, so the use of a single source (clinic) of BP measures in this study reduced the cost of data capture and likely stabilized the measurement error compared with prior studies that linked research and clinic measurements.

This study also demonstrates the challenge of using EHR data to conduct long-term follow-up studies. Measurement and estimation of outcomes after the trial are complicated by the lack of EHR-based measures at consistent intervals for all patients (as is done via study-specific assessments in trials), potential coding mistakes in clinic-based measures, and inherent within-patient variability. Clinic BP measurements have substantial variability and are subject to measurement error

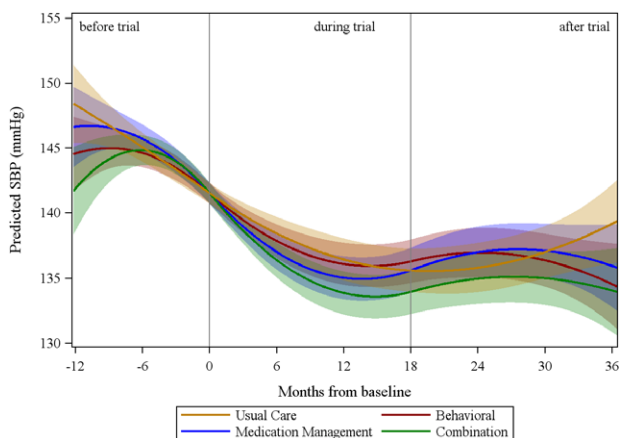


Figure 2. Estimated systolic blood pressure (SBP) with 95% confidence regions before, during, and after trial completion (n=591).

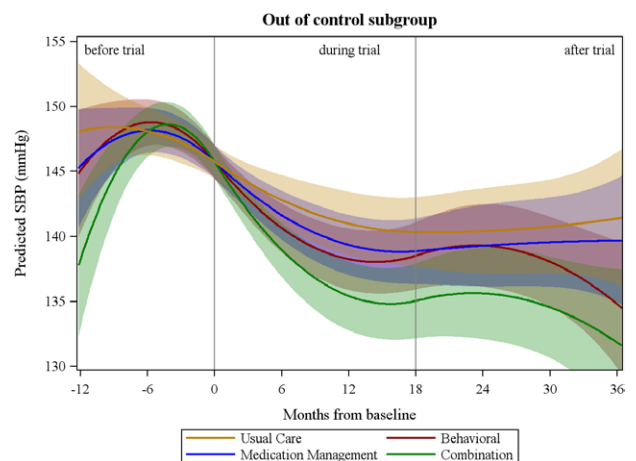


Figure 3. Estimated systolic blood pressure (SBP) with 95% confidence regions among the subgroup with inadequate BP control at baseline (n=243).

Table 3. Estimated Differences in Inpatient Utilization, Outpatient Expenditures, and Total Expenditures (95% CI) Between HINTS Intervention and Usual Care Groups

Outcome/Time Period	Behavioral Management vs Usual Care	Medication Management vs Usual Care	Combined vs Usual Care
Probability of inpatient admission (entire sample, n=591)			
During trial			
1–6 mo	–0.015 (–0.072 to 0.042)	–0.0004 (–0.059 to 0.059)	–0.009 (–0.067 to 0.049)
7–12 mo	–0.027 (–0.097 to 0.043)	–0.050 (–0.116 to 0.016)	–0.067 (–0.129 to –0.006)
13–18 mo	–0.007 (–0.060 to 0.047)	–0.026 (–0.074 to 0.021)	0.035 (–0.026 to 0.096)
After trial completion			
19–24 mo	0.007 (–0.053 to 0.067)	–0.017 (–0.072 to 0.037)	0.013 (–0.047 to 0.073)
25–30 mo	–0.058 (–0.119 to 0.002)	–0.044 (–0.108 to 0.019)	–0.023 (–0.090 to 0.044)
31–36 mo	0.005 (–0.057 to 0.066)	–0.028 (–0.083 to 0.026)	–0.007 (–0.066 to 0.051)
Outpatient expenditures (entire sample, n=591)			
During trial			
1–6 mo	–\$97 (–\$951 to \$756)	\$243 (–\$621 to \$1108)	–\$353 (–\$1061 to \$355)
7–12 mo	\$403 (–\$444 to \$1249)	–\$28 (–\$806 to \$750)	\$309 (–\$580 to \$1199)
13–18 mo	\$143 (–\$898 to \$1184)	–\$457 (–\$1320 to \$407)	–\$69 (–\$1236 to \$1098)
After trial completion			
19–24 mo	–\$1151 (–\$2697 to \$396)	–\$1470 (–\$3022 to \$82)	\$37 (–\$1885 to \$1960)
25–30 mo	–\$1265 (–\$3268 to \$738)	–\$1375 (–\$3315 to \$565)	–\$604 (–\$2705 to \$1497)
31–36 mo	–\$137 (–\$1628 to \$1354)	–\$588 (–\$1845 to \$670)	\$179 (–\$1180 to \$1538)
Total expenditures (entire sample, n=591)			
During trial			
1–6 mo	–\$158 (–\$2202 to \$1887)	\$1041 (–\$2325 to \$4407)	–\$548 (–\$2410 to \$1313)
7–12 mo	\$1179 (–\$1103 to \$3462)	\$1694 (–\$1605 to \$4994)	\$1186 (–\$1201 to \$3572)
13–18 mo	\$382 (–\$1776 to \$2539)	–\$375 (–\$2505 to \$1755)	\$269 (–\$1476 to \$2014)
After trial completion			
19–24 mo	–\$877 (–\$5948 to \$4194)	–\$3375 (–\$7417 to \$667)	–\$748 (–\$5278 to \$3782)
25–30 mo	–\$2190 (–\$8499 to \$4120)	–\$4436 (–\$8569 to –\$303)	–\$3009 (–\$7213 to \$1195)
31–36 mo	\$3237 (–\$2838 to \$9312)	–\$977 (–\$2715 to \$761)	\$309 (–\$1643 to \$2262)

Confidence intervals (CIs) for the differences in expenditures between arms were derived from model estimates using the delta method. HINTS indicates Hypertension Intervention Nurse Telemedicine Study.

that may have biased between arm differences toward the null, unlike the main trial analysis that used multiple BP measurements using a standard protocol during study visit.^{19–21} Although the original study results⁶ based on research BP measurements were generally consistent with these results based on clinic BP measurements, estimated BP differences at 18 months between the combined arm and usual care differed between the 2 modes of measurement. In the combined arm, improvements in BP control were greater when estimated using research measurements compared with clinic measurements (7.7% versus 5.8%), as were SBP improvements (–3.6 versus –1.7 mmHg). We were able to compare estimated treatment effects between research BP measurements and clinic measurements captured in an EHR because we conducted analyses consistent with the original study.⁶ Researchers interested in conducting follow-up studies after trial completion would be well served to conduct analyses consistent with the original trial analyses, as we did here, to enable comparability between sources of clinical data and between short- and long-term outcomes.

Even though the clinical benefits of this HSM intervention did not translate into economic benefits, this analysis addresses a question of great interest to payers. The business case for

dissemination of interventions that are shown to be effective in randomized trials becomes even stronger if the economic benefits of intervention participation are sustained beyond immediate exposure to the intervention. This is critical because most health systems have limited capacity for continued provision of SM and disease management programs. Instead, programs must prioritize patients or provide brief interventions to more patients, and this analysis suggests that the clinical benefits of this intervention accrued to the subset of patients with poor BP control at baseline. Identification of interventions with sustained benefits may enable broader reach to more patients in addition to targeting of high-risk patients.

This study is subject to several limitations. This study may not generalize because the study sample included veterans who received primary care at 1 Veterans Affairs Medical Center. The VA is an integrated health system with a long history of a sophisticated EHR. However, the potential for new delivery systems further integrating provider organizations (eg, Accountable Care Organizations)²² and the effort to move all US health care to EHRs may extend the generalizability of studies like ours. Reflecting the VA population,²³ trial participants were mostly men and had lower socioeconomic status

than non-VA patients with diabetes mellitus and hypertension, so treatment effects may vary by patient risk.

Future research should examine the long-term benefits of participation in different types of chronic disease intervention trials to determine whether clinical and economic outcomes of alternative interventions persist after trial completion. Such analyses would strengthen the business case for broader dissemination of interventions found to be effective in single sites or small samples. These analyses will be increasingly possible with wider EHR adoption and as pressure continues to grow to effectively bend the cost curve.

Sources of Funding

This research was funded by the Quality Enhancement Research Initiative of the VA Health Services Research & Development Service (RRP-09-407). The Hypertension Intervention Nurse Telemedicine Study was funded by VA Health Services Research & Development (IIR-04-426). Dr Bosworth is supported by a Research Career Scientist Award from the VA (RCS-08-027). Dr Maciejewski is supported by a VA Health Services Research & Development Research Career Scientist Award (RCS-10-391).

Disclosures

Dr Bosworth has received consultation funds from Pfizer and MeadWestVaco. Dr Maciejewski has received consultation funds from Daichi Sankyo, Takeda Pharmaceuticals, Novartis, and the Surgical Review Corporation and owns stock in Amgen due to his wife's employment. The other authors report no conflicts.

References

- Holman RR, Paul SK, Bethel MA, Neil HA, Matthews DR. Long-term follow-up after tight control of blood pressure in type 2 diabetes. *N Engl J Med*. 2008;359:1565–1576.
- Gaede P, Lund-Andersen H, Parving HH, Pedersen O. Effect of a multifactorial intervention on mortality in type 2 diabetes. *N Engl J Med*. 2008;358:580–591.
- Carter BL, Doucette WR, Franciscus CL, Ardery G, Kluesner KM, Chrischilles EA. Deterioration of blood pressure control after discontinuation of a physician-pharmacist collaborative intervention. *Pharmacotherapy*. 2010;30:228–235.
- Wentzlaff DM, Carter BL, Ardery G, Franciscus CL, Doucette WR, Chrischilles EA, Rosenkrans KA, Buys LM. Sustained blood pressure control following discontinuation of a pharmacist intervention. *J Clin Hypertens (Greenwich)*. 2011;13:431–437.
- Green BB, Anderson ML, Ralston JD, Catz SL, Cook AJ. Blood pressure 1 year after completion of web-based pharmacist care. *JAMA Intern Med*. 2013;173:1250–1252.
- Bosworth HB, Powers BJ, Olsen MK, McCant F, Grubber J, Smith V, Gentry PW, Rose C, Van Houtven C, Wang V, Goldstein MK, Oddone EZ. Home blood pressure management and improved blood pressure control: results from a randomized controlled trial. *Arch Intern Med*. 2011;171:1173–1180.
- Bosworth HB, Olsen MK, Dudley T, Orr M, Goldstein MK, Datta SK, McCant F, Gentry P, Simel DL, Oddone EZ. Patient education and provider decision support to control blood pressure in primary care: a cluster randomized trial. *Am Heart J*. 2009;157:450–456.
- Bosworth HB, Olsen MK, McCant F, Harrelson M, Gentry P, Rose C, Goldstein MK, Hoffman BB, Powers B, Oddone EZ. Hypertension Intervention Nurse Telemedicine Study (HINTS): testing a multifactorial tailored behavioral/educational and a medication management intervention for blood pressure control. *Am Heart J*. 2007;153:918–924.
- Weisser B, Mengden T, Düsing R, Vetter H, Vetter W. Normal values of blood pressure self-measurement in view of the 1999 World Health Organization-International Society of Hypertension guidelines. *Am J Hypertens*. 2000;13:940–943.
- Staessen JA, Thijs L. Development of diagnostic thresholds for automated self-measurement of blood pressure in adults: First International Consensus Conference on Blood Pressure Self-Measurement. *Blood Press Monit*. 2000;5:101–109.
- Goldstein MK, Coleman RW, Tu SW, Shankar RD, O'Connor MJ, Musen MA, Martins SB, Lavori PW, Shlipak MG, Oddone E, Advani AA, Gholami P, Hoffman BB. Translating research into practice: organizational issues in implementing automated decision support for hypertension in three medical centers. *J Am Med Inform Assoc*. 2004;11:368–376.
- Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL Jr, Jones DW, Materson BJ, Oparil S, Wright JT Jr, Roccella EJ, National Heart, Lung, and Blood Institute Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; National High Blood Pressure Education Program Coordinating Committee. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. *JAMA*. 2003;289:2560–2572.
- Maciejewski ML, Maynard C. Diabetes-related utilization and costs for inpatient and outpatient services in the Veterans Administration. *Diabetes Care*. 2004;27(suppl 2):B69–B73.
- Phibbs CS, Barnett PG, Fan A, Harden C, King SS, Scott JY. *Research Guide to Decision Support System National Cost Extracts*. Menlo Park, CA: Health Economics Resource Center of Health Services Research & Development Service, Department of Veterans Affairs; 2010.
- Witte JS, Greenland S. A nested approach to evaluating dose-response and trend. *Ann Epidemiol*. 1997;7:188–193.
- Hedeker D, Gibbons RD. *Longitudinal Data Analysis*. Wiley-Interscience: Hoboken, NJ; 2006.
- Carter BL, Bergus GR, Dawson JD, Farris KB, Doucette WR, Chrischilles EA, Hartz AJ. A cluster randomized trial to evaluate physician/pharmacist collaboration to improve blood pressure control. *J Clin Hypertens (Greenwich)*. 2008;10:260–271.
- Von Muenster SJ, Carter BL, Weber CA, Ernst ME, Milchak JL, Steffensmeier JJ, Xu Y. Description of pharmacist interventions during physician-pharmacist co-management of hypertension. *Pharm World Sci*. 2008;30:128–135.
- Powers BJ, Olsen MK, Smith VA, Woolson RF, Bosworth HB, Oddone EZ. Measuring blood pressure for decision making and quality reporting: where and how many measures? *Ann Intern Med*. 2011;154:781–788.
- Appel LJ, Miller ER III, Charleston J. Improving the measurement of blood pressure: is it time for regulated standards? *Ann Intern Med*. 2011;154:838–840.
- Graves JW, Bailey KR, Grossardt BR, Gullerud RE, Meverden RA, Grill DE, Sheps SG. The impact of observer and patient factors on the occurrence of digit preference for zero in blood pressure measurement in a hypertension specialty clinic: evidence for the need of continued observation. *Am J Hypertens*. 2006;19:567–572.
- Berwick DM. Making good on ACOs' promise—the final rule for the Medicare shared savings program. *N Engl J Med*. 2011;365:1753–1756.
- Morgan RO, Teal CR, Reddy SG, Ford ME, Ashton CM. Measurement in Veterans Affairs Health Services Research: veterans as a special population. *Health Serv Res*. 2005;40(5 pt 2):1573–1583.