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Economic Evaluation of Home Blood Pressure Monitoring With or Without Telephonic Behavioral Self-Management in Patients With Hypertension

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Abstract

Background—The Take Control of Your Blood Pressure trial evaluated the effect of a multicomponent telephonic behavioral lifestyle intervention, patient self-monitoring, and both interventions combined compared with usual care on reducing systolic blood pressure during 24 months. The combined intervention led to a significant reduction in systolic blood pressure compared with usual care alone. We examined direct and patient time costs associated with each intervention.

Methods—We conducted a prospective economic evaluation alongside a randomized controlled trial of 636 patients with hypertension participating in each study intervention. Medical costs were estimated using electronic data representing medical services delivered within the health system. Intervention-related costs were derived using information collected during the trial, administrative records, and published unit costs.

Results—During 24 months, patients incurred a mean of \$6965 (SD, \$22,054) in inpatient costs and \$8676 (SD, \$9368) in outpatient costs, with no significant differences among the intervention

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groups. With base-case assumptions, intervention costs were estimated at \$90 (SD, \$2) for home blood pressure monitoring, \$345 (SD, \$64) for the behavioral intervention (\$31 per telephone encounter), and \$416 (SD, \$93) for the combined intervention. Patient time costs were estimated at \$585 (SD, \$487) for home monitoring, \$55 (SD, \$16) for the behavioral intervention, and \$741 (SD, \$529) for the combined intervention.

Conclusions—Our analysis demonstrated that the interventions are cost-additive to the health care system in the short term and that patients' time costs are nontrivial.

Keywords

Costs and Cost Analysis; Hypertension; Patient Compliance

Introduction

More than 1 in 4 adults in the United States have hypertension.1 Although there is little disagreement that hypertension is an important risk factor for cardiovascular morbidity and mortality, more than two thirds of patients with hypertension in the United States have poor control of their blood pressure.2⁻⁶ Numerous medications and health behaviors have been shown in clinical trials to reduce blood pressure.7 However, many patients in clinical practice do not adhere to prescribed medication regimens, and many more have difficulty making and sustaining behavioral lifestyle changes to successfully manage high blood pressure.

The Take Control of Your Blood Pressure (TCYB) trial tested a multicomponent behavioral lifestyle intervention, patient self-monitoring, and both interventions combined compared with usual care alone among patients with a diagnosis of hypertension in an ambulatory setting. The primary end point of the trial was blood pressure control at 6-month intervals over 24 months. One of the secondary goals was to estimate the costs associated with the interventions.

From the perspective of the health care system, with blood pressure reduction as a goal, understanding the relationships between interventions and medical costs and their effects on blood pressure is necessary in making informed program funding decisions. From the perspective of the patient, time is a limited resource that should be expended on activities that yield improvements in health outcomes. To provide an evidence base for evaluating these tradeoffs, we estimated costs associated with the interventions, evaluated their impact on medical resource use and costs, and aligned these estimates with the measured impact on blood pressure observed during the trial's 2-year follow-up period.

Methods

The TCYB trial employed a 2-by-2 factorial design to evaluate the impact of a home blood pressure monitoring intervention and a nurse-administered, tailored behavioral intervention, separately and combined, on blood pressure during 24 months of follow-up. Details of the study design and the interventions have been reported previously.8⁹ The trial randomly assigned 636 patients with hypertension to the 4 study groups in 2 community-based primary care clinics in a large academic health system.

Blood pressure was measured at baseline and at 6-month intervals for 24 months. Patients who were randomly assigned to home blood pressure monitoring received approximately 10 minutes of training by a research assistant and were given electronic blood pressure measurement devices to use at home. The patients were asked to record their blood pressure

The behavioral intervention was administered by a nurse during 12 bimonthly telephone encounters. These encounters included a core set of survey modules that could be activated during each call (eg, medication and side effects) plus additional modules activated at specific intervals (eg, diet, hypertension knowledge). For each call, the nurse used a computer program designed to tailor the questions and information presented to each patient and to store patient-specific information. This program also recorded the duration of each call.

The institutional review board of the Duke University Health System approved the study. All patients provided written informed consent.

Medical Resource Use and Costs

We conducted the economic evaluation from the societal perspective. We discounted costs incurred beyond the first year by 3% and report all costs in 2008 US dollars.

We obtained data on medical resource use and costs from the health system in which the study was conducted. One data set contained information about all hospitalizations, outpatient visits, treatments, laboratory tests, and procedures. Another data set contained information about physician fees for all inpatient and outpatient care. In this study, we defined outpatient resource use as outpatient encounters involving unique visits for medical services, procedures, and tests performed at outpatient clinics in the health system. In the first data set, we derived costs (including direct and overhead costs) from the health system's cost accounting system (Transition Systems, Inc, Boca Raton, Florida). In the data set representing physician services, we used total reimbursement amounts for all services. We used the Consumer Price Index for Medical Care10 to update medical costs incurred during the study to 2008 values. Information on outpatient medications was not collected for patients randomized to home monitoring or usual care, and these data were not available electronically. Thus, our analysis does not include medication costs.

Patient Time

Home Blood Pressure Monitoring—Patient time associated with home blood pressure monitoring consisted of the time spent training to use the device, biannual assessments of technique, and the time spent monitoring blood pressure at home. Study personnel estimated that the initial training lasted approximately 10 minutes and that each 6-month check lasted approximately 5 minutes. For an estimate of time spent at home, at 12 and 24 months, patients were asked to report the amount of time they spent on blood pressure monitoring each week (≤ 15 minutes, 16 to 30 minutes, 31 to 45 minutes, 46 to 60 minutes, and > 60 minutes). We used the midpoint of each response option to extrapolate annual estimates, and we set responses of more than 60 minutes per week at 60.

Behavioral Intervention—The number of minutes spent by patients on the telephone for nurse-initiated and patient-initiated calls was electronically tracked in the study database. For each patient, we summed the number of minutes during the study period.

Valuing Patient Time—We assigned values to patient time associated with home blood pressure monitoring and the behavioral intervention using the 2006 average hourly wage of \$19.29,11 which we updated to the 2008 value of \$20.06 using employer cost data from the US Bureau of Labor Statistics.12 We assumed that out-of-pocket expenses were zero for all interventions.

Intervention Costs

Home Blood Pressure Monitoring—Variable costs for blood pressure monitoring included costs for the blood pressure monitor (\$77) and batteries (\$3) and time spent on initial training and reassessments of technique valued at the mean wage (including fringe) reported for licensed practical nurses (\$24.66 in 2008).11[,]12 We assumed there were no overhead costs associated with these assessments because neither additional space nor office equipment would be required to integrate these activities into routine care.

Behavioral Intervention—The primary cost component of the behavioral intervention was compensation for the nurse who administered the intervention. To calculate overhead costs for the base-case analysis, we applied a "bottom-up" approach. With this approach, we accounted for start-up costs and ongoing fixed costs that were independent of the number of patients participating (Table 2). Because the computer software developed for TCYB is available for dissemination, we assumed zero cost for the program. Variable costs, representing marginal costs for each additional patient receiving the intervention, were limited to the costs of patient education materials, available from administrative trial records (Table 2).

To estimate the fixed costs associated with each telephone encounter in the base-case analysis, we assumed that 7 patient encounters could be completed during each 6-hour workday. This assumption implies that each encounter takes approximately 51 minutes, inclusive of preparation, note taking, discussion with the patient, mailing of patient education materials, and associated activities. The assumption of 7 encounters per day was supported by trial records, which showed that the average number of encounters completed per day during the busier months of the trial ranged from approximately 5 to 7. Because the study nurse was occasionally involved in other non-encounter activities (eg, staff meetings, administrative activities associated with the study), we used the upper end of the range. This number is also consistent with the nurse's estimate of a reasonable number of encounters per day. As the final step, we applied the estimated cost per encounter to the patient-level data and added variable costs for each patient to represent the total cost of delivering the intervention.

Statistical Analysis

We used chi-square tests to compare the proportions of patients hospitalized and negative binomial regression models to compare counts of outpatient encounters, hospitalizations, and inpatient days between the intervention groups and the usual care group. We compared mean estimates of total costs between the intervention groups and the usual care group using the nonparametric bootstrap method by calculating bias-corrected 95% confidence intervals for differences in costs.13

Sensitivity Analysis

We performed 3 sets of sensitivity analyses to evaluate the impact of applying different assumptions to estimate the cost per patient encounter for the behavioral intervention. First, as an alternative strategy for estimating overhead costs, we used a "top-down" approach whereby we applied the overhead rate used by the health system for federal grants (54%) to the nurse's annual salary.

In the next 2 approaches, we applied the overhead costs used in the base-case analysis. In one analysis, instead of assuming that the nurse would complete 7 encounters daily, we assumed that the nurse would complete all encounters for all 319 patients receiving the behavioral intervention in 24 months (hereafter termed the 24-month approach), the time period during which most patients were participating in the trial. In the final analysis, we

used a "maximum efficiency approach" in which we counted only the nurse's time spent on the phone with patients to deliver the intervention.

Results

Among the 636 patients randomly assigned, 475 (75%) completed 24 months of follow-up. Mean systolic blood pressure in the usual care group was largely unchanged between baseline (124.2 mm Hg) and 24 months (123.8 mm Hg).14 Table 3 reports mean blood pressure change at 12 and 24 months in each intervention group relative to the usual care group. At 24 months, compared with the usual care group, mean systolic blood pressure decreased by 0.6 mm Hg (P = .69) in the home monitoring arm, increased by 0.6 mm Hg (P = .67) in the behavioral intervention arm, and decreased by 3.9 mm Hg (P = .01) in the combined intervention.

Medical Resource Use and Costs

During 24 months of follow-up, approximately 1 in 5 patients was hospitalized (home blood pressure monitoring, 22.1%; behavioral intervention, 21.9%; combined intervention, 19.5%; usual care, 22.6%; P = 0.91), with the majority (56.9%) being hospitalized once. The mean number of total inpatient days per patient was lowest in the combined intervention group, but none of the intervention groups differed significantly from usual care (home blood pressure monitoring, 2.7 days; behavioral intervention, 2.8 days; combined intervention, 2.2 days; usual care, 2.5 days; $P \ge .55$).

Patients in the combined intervention group had a mean of 18.5 (SD, 17.4) outpatient encounters during the follow-up period (P = 0.18 compared with usual care), approximately 2 more than patients in the home monitoring group (16.6 [SD, 14.5]; P = .93 compared with usual care), the behavioral intervention group (16.6 [SD, 12.5]; P = .96 compared with usual care), and the usual care group (16.5 [SD, 14.2]). Median estimates were 14 for the combined intervention, 13 for home blood pressure monitoring, 15 for the behavioral intervention, and 13 for usual care.

Point estimates of mean inpatient costs were lowest in the combined intervention group (Table 4), and point estimates of mean outpatient costs were highest in this group. Compared with the usual care group, mean total medical costs were \$947 higher in the home monitoring group, \$910 higher in the behavioral intervention group, and \$626 higher in the combined intervention group (Table 3). However, there was an appreciable degree of variability across the cost estimates, and none of the comparisons were statistically significant.

Patient Time

Among the 244 patients (77.0%) in the home blood pressure monitoring group who reported time spent monitoring and recording blood pressure at 12 months, the mean time spent per week was 20.9 (SD, 15.4) minutes. Extrapolating over a mean follow-up period, patient time for home blood pressure monitoring was 31.8 hours.

On average, each telephone encounter lasted 15.9 minutes (SD, 7.2). Altogether, patients spent an average of 2.74 hours (SD, 0.84) on the phone across all encounters.

Sensitivity Analysis

With the top-down approach for estimating overhead plus other base-case assumptions, the cost to provide each encounter was an estimated \$45.50 (compared with the base-case estimate of \$31.09 per encounter). With the 24-month approach, the cost per encounter was

an estimated \$28.42; with the maximum efficiency approach, the estimate was \$9.94 per encounter.

Discussion

The American Heart Association, the American Society of Hypertension, and the Preventive Cardiovascular Nurses Association recently joined efforts in calling for increased use of and reimbursement for home blood pressure monitoring.15 Although the authors of this call to action discuss reimbursement issues relevant to providers and patients, they note that there is little evidence regarding the impact of self-monitoring on costs. Our cost assessment helps to fill this knowledge gap.

Clinical results from the TCYB trial demonstrated that neither the behavioral intervention nor the self- monitoring intervention provided significant improvements in systolic blood pressure over 24 months compared with usual care.14 However, in combination, these interventions resulted in a 3.9/2.2 mm Hg decrease in systolic/diastolic blood pressure and 11% improvement in blood pressure control compared with usual care. We estimated the per-patient cost of providing the combined intervention to be \$416 over 24 months, consisting of \$90 for home monitoring and \$326 for the behavioral intervention. Given the estimated patient time cost of \$741, the total cost of the combined intervention was \$1157 over 24 months. Combining these results, the incremental 2-year cost per 1-point reduction in systolic blood pressure was \$107 in direct medical costs and \$297 when including patient time costs.

In comparison with many published studies of behavioral interventions, we attempted to capture all personnel and overhead costs and to represent the variability of the intervention costs from patient to patient.16 Our costing strategy contrasts with cost estimation methods in which the intervention costs were limited to the salaries of the persons involved based on an estimate of average time spent providing the intervention.17,18 Such economic evaluations assume maximum efficiency with no downtime for preparation, note taking, missed calls, scheduling, and other administrative tasks. In our sensitivity analysis evaluating a maximum efficiency scenario, we found that the estimated cost to provide each encounter (\$10) was approximately one third of the cost we applied in the base-case analysis (\$31). Furthermore, our estimated costs included overhead costs, whereas other economic evaluations have excluded these costs, perhaps because provision of the intervention would be expected to use existing resources (eg, existing computer and phone line) for which additional costs would not be incurred.17-21 In addition, we provide a transparent account of intervention costs. The use of commercial charges as estimates of intervention costs limits the transparency of other studies.22⁻²⁴ Finally, even in studies in which a comprehensive costing approach was undertaken, relatively little methodological detail was provided.25,26

Whether medical practices or health plans prefer to use the base-case estimate of \$416 (2year cost), the lowest estimate of \$124, or something in between, these costs are nontrivial, especially given the high prevalence of hypertension. The affordability of providing these services is a critical consideration. However, the true potential value of this intervention is driven by the health outcomes afforded by a 3.9/2.2 mm Hg reduction in systolic/diastolic blood pressure compared with usual care. During 5 years of follow-up in high-risk patients with hypertension (mean systolic/diastolic blood pressure at baseline, 146/80 mm Hg), investigators in the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) reported a 2/0 mm Hg reduction in systolic/diastolic blood pressure with chlorthalidone vs lisinopril and significantly lower risks of combined cardiovascular events, stroke, coronary revascularization, and heart failure.27 In the blood pressure reduction arm of the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT-BPLA), blood pressure values

in patients randomly assigned to an amlodipine-based regimen were 2.7/1.9 mm Hg lower on average throughout the 5.5 years of follow-up compared with patients assigned to an atenolol-based regimen.28 ASCOT-BPLA also demonstrated significant reductions in cardiovascular events, procedures, and stroke, and showed a significant reduction in all-cause mortality.

An economic evaluation based on ASCOT-BPLA estimated that the gain in life expectancy or quality-adjusted life expectancy with the amlodipine regimen was approximately 0.1 year. 29 Extending a benefit of this magnitude to the estimated cost of the combined intervention in TCYB results in an incremental cost-effectiveness ratio of \$4169 per life-year saved. If we assume that the interventions had to be maintained to achieve the survival benefit, extrapolating estimated annual intervention costs of \$211 over 12 years (remaining average survival) produces an incremental cost-effectiveness ratio of approximately \$23,000 per life-year saved.

The Panel on Cost-Effectiveness in Health and Medicine recommends that patients' time be counted as a cost in cost-effectiveness analysis.30 However, other economic evaluations of home monitoring and patient education interventions have excluded patients' time costs. $26\cdot31^{-3}4$ A remarkable finding from our analysis was that patients' time costs associated with home monitoring during 24 months (\$585 with single intervention, \$687 with the combined intervention) were greater than the providers' costs in each of the individual interventions (\$90, \$345) and in the combined intervention (\$416). In the TCYB trial, if patient time costs were included, the incremental cost-effectiveness ratios would increase to \$11,570 per life-year saved using 2-year cost estimates and \$64,000 per life-year saved when extending (and discounting) costs over 12 years.30

Limitations

Our reliance on electronic data from a single health system was both a strength and a limitation. Although the data were comprehensive, medical care provided outside of the health system was not represented. However, for inclusion in the trial, patients were required to receive most of their medical care through the health system. In addition, our study did not include medication costs. To the extent that medication adherence increased with the study interventions relative to usual care, total incremental costs associated with these interventions would increase.

Despite the robustness of the data on medical resource use and costs, the relatively small sample sizes in the trial provided little statistical power to detect significant cost differences (approximately 10% power to detect a \$1000 difference in outpatient costs). We used the nonparametric bootstrap method to represent this uncertainty in our results.

Conclusions

The TCYB study demonstrated statistically and clinically significant reductions in blood pressure with a tailored behavioral intervention when combined with home blood pressure monitoring. However, these interventions are cost-additive to the health care system. Thrice-weekly blood pressure monitoring resulted in patient time costs that surpassed the cost of the intervention. Future studies of blood pressure monitoring could seek to determine whether less frequent monitoring and/or less intensive nurse interventions would provide similar benefits.

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Participant Characteristics and Summary Clinical Results

Characteristic	Group				
	Home Blood Pressure Monitoring	Behavioral Intervention	Combined Intervention	Usual Care	
Age, mean (SD), y	62 (12)	60 (13)	61 (12)	62 (12)	
Male, %	29	33	38	36	
Race, %					
African American	48	52	43	54	
Caucasian	50	43	56	45	
Other	2	5	1	2	
Risk factors, %					
Current smoker	14	18	16	18	
Diabetes mellitus	36	36	32	40	
Inactive lifestyle ^a	29	16	26	20	
Married, %	52	46	52	51	
Employed full- or part-time, %	38	45	38	36	
Low literacy, % ^b	28	28	27	27	
Baseline systolic blood pressure, mean (SD), mm Hg	126 (15)	124 (18)	126 (20)	124 (18)	
Baseline diastolic blood pressure, mean (SD), mm Hg	72 (11)	71 (10)	72 (12)	70 (10)	

 a Defined as less than 20 minutes of aerobic exercise per week.

 $^b\mathrm{Defined}$ as a score of 60 or less on the Rapid Estimate of Adult Literacy in Medicine.

Unit Costs for the Behavioral Intervention

Item	Unit Cost	Source	Total Cost
		Fixed Costs	
Start-up costs ^a			
Desktop computer with monitor	\$900	http://www.officedepot.com/a/products/101335/HP-Pavilion-Desktop-Computer-Bundle-With/With/With/With/With/With/With/With/	\$180/y
Fax, printer, copier, scanner	\$1150	http://www.officedepot.com/a/products/389405/Xerox-Phaser-multifunction-color/	
Telephone	\$18	http://www.officedepot.com/a/products/504336/GE-Corded-Speakerphone-With-Memory-White/With-Weith-With-Memory-White/With-Weith-Weith/With-Weith	\$3.60/y
Chair	\$140	http://www.officedepot.com/a/products/525369/Office-Brand-Pillow-Mesh-Fabric-Chair/	\$28/y
Desk	\$130	http://www.officedepot.com/a/products/850987/Office-Dawson-Computer-Desk-x-59/	\$26/y
File cabinet	\$140	http://www.officedepot.com/a/products/679024/Office-Brand-Vertical-Letter-File-Light/	\$28/y
Ongoing Fixed C	Costs		
Office space (64 sq ft)	\$24/sq ft/y	http://www.lincolnharris.com/Properties/?Type=2	\$1536/y
Telephone service with voice mail (small business rate)	\$55.75/mo	https://smallbusiness.bellsouth.com/newlocal/step02LS.asp	\$669/y
Personnel Costs			
Nurse salary and fringe	\$51,703/y	Administrative records, 5 days per week, 6 hours per day	\$51,703/y
Fixed cost per year			\$54,404/y
		Variable Costs ^b	
Toner	\$0.12/page	Administrative records, 61.4 color pages per patient: http://www.office.xerox.com/latest/OPBFS-13.PDF	
Paper	\$0.023/page	Administrative records, 61.4 color sheets per patient: http://www.officedepot.com/a/products/565565/Inkjet-Paper-8-x-24-98/	
Postage stamps	\$0.39/unit	Administrative records, 9.1 stamps per patient	\$10.53/patien
Envelopes	\$0.1399/unit	Administrative records, 3 envelopes per patient	\$0.42/patient
Variable cost per patient			\$19.71/patien

 a Assumed that costs were allocated over 5 years at a 0% discount rate and with no residual value.

 ${}^{b}\mathrm{Variable}$ costs for producing and mailing patient education materials.

Differences in Mean Costs and Blood Pressure Change From Baseline Between Interventions and Usual Care

Cost Category	Intervention, Mean Difference (95% CI), \$				
	Home Blood Pressure Monitoring	Behavioral Intervention	Combined Intervention		
Systolic blood press	sure, mm Hg*				
12 months	-3.7 (-6.1 to -1.2)	-1.6 (-3.9 to 0.7)	-3.3 (-5.7 to -0.8)		
24 months	-0.6 (-3.6 to 2.3)	0.6 (-2.2 to 3.4)	-3.9 (-6.9 to -0.9)		
Diastolic blood pressure, mm Hg*					
12 months	-3.1 (-4.4 to -1.8)	-1.4 (-2.6 to -0.1)	-2.2 (-3.5 to -0.8)		
24 months	-1.2 (-2.9 to 0.4)	0.4 (-1.1 to 1.9)	-2.2 (-3.8 to -0.6)		
Inpatient care	1194 (-3546 to 6496)	1020 (-3062 to 5225)	-201 (-3917 to 5042)		
Outpatient care	-247 (-2452 to 2101)	-110 (-2170 to 1798)	828 (-1602 to 2963)		
Total medical cost	947 (-4457 to 7371)	910 (-4162 to 5749)	627 (-4384 to 6198)		
Total cost (case 5)	1622 (-3806 to 8000)	1310 (-3721 to 6204)	1784 (-3197 to 7383)		

Abbreviation: CI, confidence interval.

 † Estimates are based on a general linear model with an unstructured covariance matrix. General linear models were used to estimate changes in blood pressure over time and to test for blood pressure differences in the intervention groups relative to usual care at 12 and 24 months. Confidence intervals were derived from 1000 bootstrap samples to represent the relative change in blood pressure between each of the intervention groups and the usual care group at 12 and 24 months.14

Medical, Patient Time, and Intervention Costs During 24 Months

Cost Category	Group					
	Home Blood Pressure Monitoring	Behavioral Intervention	Combined Intervention	Usual Care		
Inpatient care, \$						
Mean (SD)	7656 (28,309)	7482 (19,853)	6261 (22,015)	6642 (16,600)		
Median (IQR)	0 (0–633)	0 (0–1596)	0	0 (0–1273)		
Outpatient care, \$						
Mean (SD)	8311 (10,156)	8448 (7683)	9386 (9791)	8558 (9708)		
Median (IQR)	5178 (2545–10,310)	6229 (3482–10,632)	6302 (3074–10,897)	6221 (2821–11,573)		
Total medical cost	ts, \$					
Mean (SD)	15,967 (31,516)	15,930 (23,043)	15,647 (25,479)	15,020 (22,309)		
Median (IQR)	5945 (2904–18,173)	6658 (3496–17,903)	7103 (3343–18,158)	6757 (3109–14,257)		
Intervention cost,	\$*					
Mean (SD)	90 (2)	345 (64)	416 (93)	0		
Median (IQR)	90 (90–90)	357 (326–387)	448 (416–478)	0		
Patient time cost,	\$					
Mean (SD)	585 (487)	55 (16)	741 (529)	0		
Median (IQR)	276 (267–804)	55 (46-64)	803 (319–870)	0		
Total costs, \$						
Mean (SD)	16,642 (31,507)	16,330 (23,029)	16,804 (25,521)	15,020 (22,309)		
Median (IQR)	6865 (3537–18,449)	7102 (3936–18,319)	8633 (4557–18,966)	6757 (3109–14,257)		

Abbreviation: IQR, interquartile range.

Costs for the combined intervention were slightly lower than the sum of the single-modality interventions because patients in the combined intervention spent, on average, less time on the phone with the nurse as part of the behavioral intervention (2.69 hours vs. 2.79 hours). Patient time costs, however, were greater in the combined intervention group compared with the sum of the single-modality interventions because patients in the combined intervention reported greater amounts of time spent on monitoring and recording their blood pressure at home (11.46 hours vs. 9.75 hours).