Effectiveness of Home Blood Pressure Monitoring, Web Communication, and Pharmacist Care on Hypertension Control

A Randomized Controlled Trial

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Context Treating hypertension decreases mortality and disability from cardiovascular disease, but most hypertension remains inadequately controlled.

Objective To determine if a new model of care that uses patient Web services, home blood pressure (BP) monitoring, and pharmacist-assisted care improves BP control.

Design, Setting, and Participants A 3-group randomized controlled trial, the Electronic Communications and Home Blood Pressure Monitoring study was based on the Chronic Care Model. The trial was conducted at an integrated group practice in Washington state, enrolling 778 participants aged 25 to 75 years with uncontrolled essential hypertension and Internet access. Care was delivered over a secure patient Web site from June 2005 to December 2007.

Interventions Participants were randomly assigned to usual care, home BP monitoring and secure patient Web site training only, or home BP monitoring and secure patient Web site training plus pharmacist care management delivered through Web communications.

Main Outcome Measures Percentage of patients with controlled BP (<140/90 mm Hg) and changes in systolic and diastolic BP at 12 months.

Results Of 778 patients, 730 (94%) completed the 1-year follow-up visit. Patients assigned to the home BP monitoring and Web training only group had a nonsignificant increase in the percentage of patients with controlled BP (<140/90 mm Hg) compared with usual care (36% [95% confidence interval {CI}, 30%-42%] vs 31% [95% CI, 25%-37%]; $P=.21$). Adding Web-based pharmacist care to home BP monitoring and Web training significantly increased the percentage of patients with controlled BP (56%; 95% CI, 49%-62%) compared with usual care ($P<.001$) and home BP monitoring and Web training only ($P<.001$). Systolic BP was decreased stepwise from usual care to home BP monitoring and Web training only to home BP monitoring and Web training plus pharmacist care. Diastolic BP was decreased only in the pharmacist care group compared with both the usual care and home BP monitoring and Web training only groups. Compared with usual care, the patients who had baseline systolic BP of 160 mm Hg or higher and received home BP monitoring and Web training plus pharmacist care had a greater net reduction in systolic BP (–13.2 mm Hg [95% CI, –19.2 to –7.1]; $P<.001$) and diastolic BP (–4.6 mm Hg [95% CI, –8.0 to –1.2]; $P<.001$), and improved BP control (relative risk, 3.32 [95% CI, 1.86 to 5.94]; $P<.001$).

Conclusion Pharmacist care management delivered through secure patient Web communications improved BP control in patients with hypertension.

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HYPERTENSION IS ONE OF THE leading causes of death worldwide.[1] Almost 1 in 3 US adults has hypertension, defined as a sustained systolic and diastolic blood pressure (BP) of 140 and 90 mm Hg or higher, respectively.[2,3] Lowering BP with antihypertensive medications decreases mortality and major disability from cardiovascular and renal disease. Hypertension, however, remains inadequately treated in the majority of affected individuals.[4-6] In recent meta-analyses[7,8] of quality-improvement strategies to lower BP, those targeting patients (education and self-monitoring) or adding a health care team member, such as a nurse or a pharmacist, to focus specifically on hypertension had the largest reductions in BP. Optimal methods for integrating these strategies into routine care were less certain.

Electronic medical records (EMRs) and secure patient Web sites increas-

See also p 2896 and Patient Page.

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ingly let patients view portions of their medical record, access health care services, and communicate with their health care team online. More than 75% of adults nationally have Internet access[9] and most want to use the Internet to contact physicians, make appointments, refill prescriptions, and receive laboratory results.[10] However, little is known about the effectiveness of Web services in the care of chronic conditions.

Web-based care might be particularly suitable for improving hypertension care. Conventional office BP measurement is subject to error and bias[11-13] and physicians often make medication decisions based on 1 or 2 office measurements despite the known variability of BP.[14] Self-monitoring of BP by patients provides similar accuracy, is less expensive, and provides direct feedback as to BP control.[14,15]

We hypothesized that hypertension care could be provided asynchronously and remotely over the Web without in-person clinic visits. A 3-group randomized controlled trial, the Electronic Communications and Home Blood Pressure Monitoring (e-BP) study was designed to test whether hypertension control improved with home BP monitoring and training to use patient Web services only or with home BP monitoring and Web training plus care management by a pharmacist over the Web.

METHODS

Design

A complete description of the design and methods of the e-BP study has been published elsewhere.[16] The e-BP study was a 3-group randomized controlled trial designed to compare 2 interventions to improve hypertension control. Patients who had uncontrolled hypertension and were taking antihypertensive medication were randomly assigned to usual care, home BP monitoring and secure patient Web services training only, or home BP monitoring and Web training plus pharmacist care management delivered through Web communications.

The study design was based on the Chronic Care Model.[17] The model specifies 6 domains: self-management support, clinical information systems, delivery system redesign, decision support, health care organization, and community resources. According to the model, paying attention to these domains and integrating them can produce system changes in which informed patients interact collaboratively with prepared practice teams.

The primary study outcomes were change in systolic and diastolic BP and the percentage of patients with controlled BP (<140/90 mm Hg) at 12 months. Secondary outcomes included changes in the number of classes of antihypertensive medications, aspirin use, body mass index (calculated as weight in kilograms at baseline divided by height in meters squared at baseline; and weight in kilograms at the follow-up visit divided by height in meters squared at baseline), physical activity, health-related quality of life, satisfaction with the health plan, and use of health care services from baseline until the 12-month follow-up. The institutional review board and a data and safety monitoring board approved the protocol and monitored adverse events. The trial was conducted from June 2005 to December 2007.

Setting

The trial was a single-site study conducted at 10 medical centers within Group Health, a large, nonprofit, integrated group practice that provides both medical coverage and care to more than 540 000 residents of Washington State and Idaho. A commercially available EMR integrated with patient Web site services was available at all Group Health–owned primary care clinics and hospitals at the beginning of the study. Patient Web services include the ability to refill medications, make appointments, view portions of his or her EMR (current health conditions, laboratory test results, clinic visit summaries, and lists of allergies, immunizations, and medications), and use secure messaging to contact health care team members.[18]

Recruitment and Baseline Assessment

Clinical and administrative data sources were used to identify patients aged 25 to 75 years with a hypertension diagnosis and taking antihypertensive medications, with no diagnoses of diabetes, cardiovascular or renal disease, or other serious conditions. Research assistants telephoned potential participants to confirm eligibility, including the ability to use a computer, regular access to the Web, an e-mail address, and willingness to attend screening visits and obtain all their antihypertensive medications at Group Health–owned pharmacies. Eligible and willing patients were invited to 2 screening visits at their clinic in which a research assistant measured BP using the validated Omron Hem-705-CP (Omron Healthcare, Kyoto, Japan) upper arm automated monitor.[19,20] If mean diastolic BP (last 2 of 3 BP recordings, with the first measurement dropped) was between 90 and 109 mm Hg or mean systolic BP was between 140 and 199 mm Hg at both screening visits, the participant was eligible for the study and written informed consent was obtained.

To ensure blinding for the primary outcomes (changes in systolic and diastolic BP and control of BP) at baseline, BP measurements from both screening visits (4 measurements total) were averaged and recorded before consent and randomization. Baseline height, weight, and self-reported data also were obtained prior to randomization. Randomized patients only attended 1 more study-related clinic visit at 12 months so blinded outcome assessments could be obtained. Study interventions were provided via the secure patient Web site.

Randomization

A single-blind block, independent randomization design was used to ensure balance within medical centers and baseline systolic BP measurements. The subgroup of patients with systolic BP between 160 and 199 mm Hg were stratified into a separate subgroup to ensure equal numbers in the 3 study

groups. Within these 2 groups, patients were randomly assigned in sequential blocks of 3, 6, or 9 to the 3 study groups. To ensure the research assistant was blinded to study group assignment during initial training interventions, random assignment occurred in 2 steps. After consent, the research assistant opened a sequentially numbered opaque envelope with the preassigned random study group allocating patients to either the usual care group or the combined intervention group. After receipt of the BP monitor and Web training, a second opaque envelope was opened assigning them to home BP monitoring and Web training only or home BP monitoring and Web training plus pharmacist-assisted care.

Interventions

Before randomization, all participants were registered to use Group Health's secure patient Web services if they had not already done so. Patients in all groups also received Group Health's hypertension pamphlet *High Blood Pressure and You*, which describes definitions for BP control, the importance of medication and lifestyle behaviors that influence BP and cardiovascular risk (ie, sodium intake, weight, and physical activity), and Group Health's pamphlet *The No-Waiting Room*, which describes the patient Web site and utilities available to registered users. After the first randomization, those assigned to usual care were told their BP was not in control and were encouraged to work with their physician to improve it. Those assigned to the other 2 study groups received additional interventions.

Training for Home BP Monitoring and Patient Web Site

Patients assigned to active interventions were first given a home BP monitor (the validated Omron Hem-705-CP), with the cuff size based on upper arm measurements[19,20] and training on its use, demonstrating that they could use it without help. They were instructed to use this monitor to check their BP at least 2 days per week with 2 measurements each time. They were told the goal for average home systolic and diastolic BP was 135 and 85 mm Hg or less, respectively, and lower than the goal for clinic measurements for systolic and diastolic BP of less than 140 and 90 mm Hg (based on observational data demonstrating that BP readings in individuals tend to be about 5 mm Hg lower when taken at home).[21] Second, they received training on how to use the Web site. They received a tour of the different utilities (secure e-mail, refilling medications, viewing portions of their medical record, use of the health library, and links to Group Health and community resources for lifestyle and behavioral change).

After the initial training, the second opaque envelope was opened and patients assigned to home BP monitoring and Web training only were told that their BP was not controlled and advised to work with their physician to improve this. They were given the following verbal and written instructions:

> As a participant in Group 2, you have two additional resources (the home BP monitor and MyGroupHealth) to help manage your high blood pressure. We encourage you to use the MyGroupHealth website. It gives you access to a suite of online services so you can e-mail your doctor, refill prescriptions, request appointments, get test results, and look up health information. Sending a message to your provider on MyGroupHealth is an easy way to report your home BP readings.

Those assigned to home BP monitoring and Web training plus pharmacist care were told a pharmacist would be assisting them to improve their BP control via home BP monitoring and Web communications.

Home BP Monitoring and Web Training Plus Pharmacist Care Intervention

Three Group Health pharmacists performed all pharmacy interventions. They were clinical pharmacists with experience and time separate from front-line customer service to assist with team-based care management activities (such as collaborating with physicians and patients to ensure adequate lipid lowering in patients with cardiovascular disease). They received 2 half-days of additional training on evidence-based care of hypertension, the stepped medication protocols used in the intervention based on the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure[3] and Group Health guidelines, and patient-centered techniques for addressing behavioral issues related to adherence and lifestyle change. The e-BP study interventions were included in the pharmacists' usual daily activities and, depending on their average patient load (about 50 patients each), took them from 2 to 8 hours per week.

The pharmacist welcomed the patient to the study with a secure message and informed the patient's physician of his or her participation with a staff message. The pharmacist also arranged a time for 1 planned telephone visit to obtain a more detailed medication history and review allergies, intolerances, and cardiovascular risk factors. At the end of the telephone call, the pharmacist introduced the patient to the action plan. Used for Web communications, the action plan was a template with the following 5 components: instructions for home BP monitoring; a list of current medications; at least 1 patient-selected lifestyle goal(s) from the list in the Group Health hypertension pamphlet (such as increasing physical activity); recommended medication changes based on the stepped medication protocols; and the follow-up plan. Each patient and his or her physician received an electronic copy of the action plan.

All planned communications then occurred over the Web every 2 weeks until BP was controlled (mean home systolic BP $<$135 mm Hg and diastolic BP $<$85 mm Hg) and less often thereafter. Patients were asked to provide BP measurements, concerns about medications, and progress related to their lifestyle goal(s). Pharmacists responded

with specific recommendations (including medication changes) and patients were encouraged to provide feedback and collaboratively change the action plan. All clinical concerns or potential deviations from the medication protocol were referred back to the patient's physician. All secure messages between pharmacists and patients and staff messages between the pharmacist and the patient's physician were part of the EMR.

Blinded Outcome Assessments

At the 12-month follow-up visit at the patient's clinic, trained research assistants blinded to the patient's study group measured BP using the same protocol as at baseline. Automated databases were used to obtain use of antihypertensive medications, with 5 predefined classes: diuretics, angiotensin-converting enzyme inhibitors and angiotensin receptor blockers, calcium channel blockers, β-blockers, and others (α-blockers, hydralazine, minoxidil, clonidine, reserpine, guanethidine, and methyldopa, which were used infrequently). Use of a medication class was defined as patient procurement of a 60-day or longer supply of medication during a 182-day period.

Aspirin use was measured by self-report at baseline and at 12-month follow-up. Health-related quality of life was measured using the Short Form 12.[22,23] Body mass index was calculated from height and weight at baseline and weight at the follow-up visit. Physical activity was measured using the Stages of Change questionnaire by Marcus et al.[24] Satisfaction with the health plan was assessed using the Consumer Assessment of Healthcare Providers and Systems instrument.[25]

Secure message use was measured by the number of message threads between providers (physicians, nurses, or pharmacists) and patients. A message thread is defined as an initial message sent by either the patient or the provider and the series of subsequent replies from both parties.[26] Use of outpatient primary and specialty care, emergency department, hospital services, and telephone encounters was obtained from clinical and administrative databases that Group Health maintains.

Demographic characteristics and prior use of home BP monitoring were collected at the time of the telephone survey. When participants chose more than 1 category for race, coding precedence was given to black, Asian, other, and white categories, in that order. The National Heart, Lung, and Blood Institute required the collection of this information and submission of quarterly enrollment reports by race and Hispanic ethnicity. Also, blacks are disproportionately affected by hypertension. We attempted to recruit as many blacks and other ethnic minority groups as possible to increase the external generalizability of our study findings.

Sample Size

The study was designed to enroll 780 patients equally to each of the 3 intervention groups. The sample size was powered to detect clinically meaningful differences in mean changes in systolic BP of 4 mm Hg and diastolic BP of 3 mm Hg between usual care and home BP monitoring and Web training plus pharmacist care at 12-month follow-up. It was assumed that home BP monitoring and Web training plus pharmacist care was equivalent to home BP monitoring and Web training only in the sample size calculations; therefore, power was determined for only 1 comparison.

This sample size provided 80% and 86% power to detect differences in systolic and diastolic BP, respectively, and assumed a normal approximation to compare 2 independent means, an SD for systolic BP of 14.5 mm Hg and an SD for diastolic BP of 10 mm Hg, and an 80% follow-up rate. This sample size provided 80% power to detect an 11.7% improvement in BP control in home BP monitoring and Web training plus pharmacist care compared with usual care at 12-month follow-up and assumed that 20% of the usual care group would attain BP control at 12-month follow-up due to regression to the mean and changes in treatment regimen, 80% follow-up, and normal approximation without the continuity correction. The sample size did not take into account adjustment for precision variables in our primary analyses; therefore, this calculation was conservative.

Statistical Analysis

TABLE 1 presents summary statistics (frequencies, means, and standard deviations) for baseline patient characteristics (age, sex, race/ethnicity, education, employment, number of hypertension medication classes, tobacco use, body mass index, exercise, having a home BP monitor prior to study enrollment, clinic, and baseline systolic and diastolic BP), stratified by intervention group. To assess for any differences among the intervention groups by baseline characteristics, Pearson χ^2 test for categorical variables[27] and F tests for continuous variables were performed.[28,29]

Following the a priori primary analysis plan, the differences among intervention groups and continuous primary outcomes were evaluated using linear regression models adjusted for baseline outcome measures (eg, systolic and diastolic BP at baseline for the outcomes of systolic and diastolic BP at 12-month follow-up) and baseline characteristics that were significantly related at the α level of .10 to either the outcome of interest or the intervention groups. All statistical tests were performed using F tests. To protect against multiple comparisons, the Fisher protected least-significant difference approach was used.[30] This approach makes pairwise comparisons among the 3 treatment groups only if the overall F test is significant. Prespecified secondary analyses also were presented for unadjusted linear regression models.

For the binary primary outcome, BP control (systolic BP <140 mm Hg and diastolic BP <90 mm Hg), generalized linear models were applied with a log link and robust sandwich variance estimator using modified Poisson regression.[31] Logistic regression models were not used because controlled BP was not rare. Baseline characteristics were adjusted for in the same manner

as for continuous outcomes. All *P* values for binary outcomes are from a χ^2 test. Prespecified unadjusted analyses also are presented as a proportion controlled with the Wald 95% confidence interval (CI).[32]

For the primary outcomes, the planned analyses on the subgroup of participants with baseline systolic BP of 160 mm Hg or higher also were repeated to assess the intervention's effectiveness for more extreme hypertension. Secondary outcomes followed a similar modeling scheme to the primary analyses except all analyses were unadjusted. All secondary outcome analyses were conducted on the subset of patients who attended a 12-month follow-up visit.

All analyses were performed using the statistical package R version 2.6.1 (R Foundation for Statistical Computing, Vienna, Austria),[33] except for the modified Poisson regression, which was generated using SAS version 9 (SAS Institute Inc, Cary, North Carolina). All reported *P* values and 95% CIs are 2-sided. All analyses assumed intention-to-treat principles (ie, comparing patients in the groups to which they were originally randomly assigned). Follow-up was attempted for all patients, and all patients who completed follow-up in their randomized intervention assignment were included, regardless of whether they received the intervention, or subsequently withdrew or deviated from the protocol.[34]

Our primary analyses apply intention-to-treat principles to those patients with complete follow-up. Those analyses for any baseline covariates that may influence the outcome were adjusted to remove potential bias due to loss to follow-up, which was low. Because the loss to follow-up was only 6%, these procedures introduce less bias than the alternative of imputing missing values, which would preclude adjusting for baseline covariates. Nonetheless, a sensitivity analysis also was performed using the last-observation-carried-forward assumption (ie, those patients who were lost to follow-up had the same BP as was observed at baseline).

RESULTS

The FIGURE shows the flow of participants through the study. Letters were mailed to 9298 patients with an *International Classification of Diseases, Ninth Revision,* diagnosis of hypertension. Of those contacted by telephone and answering the telephone survey questions, 1510 of 7279 patients (20.7%) were ineligible because they did not have access to either a computer, the Internet, or an e-mail address. Of those remaining eligible after being contacted by telephone, 2937 of 5535 patients (53.1%) agreed to a screening appointment. Of those who had a screening appointment and had their BP measured, 1567 of 2573 patients (60.9%) had controlled hyperten-

Table 1. Baseline Characteristics of Patients in the Electronic Communications and Home Blood Pressure Monitoring Trial

Characteristic	No. (%) of Patients[a] Total (N = 778)	Usual Care (n = 258)	BP Monitoring and Patient Web Services Training Only (n = 259)	BP Monitoring and Patient Web Services Training + Pharmacist Care[b] (n = 261)	*P* Value[c]
Age, mean (SD), y	59.1 (8.5)	58.6 (8.5)	59.5 (8.3)	59.3 (8.6)	.41
Female sex	406 (52.2)	141 (54.7)	119 (45.9)	146 (55.9)	.05
Race[d]					
White	644 (82.8)	214 (82.9)	223 (86.1)	207 (79.3)	.34
Black	61 (7.8)	22 (8.5)	18 (6.9)	21 (8.0)	
Asian	29 (3.7)	8 (3.1)	9 (3.5)	12 (4.6)	
Other	44 (5.7)	14 (5.4)	9 (3.5)	21 (8.0)	
Education					
≤12 y or GED	62 (8.0)	22 (8.5)	19 (7.3)	21 (8.0)	.11
Some post–high school	324 (41.6)	117 (45.3)	110 (42.5)	97 (37.2)	
4-y college degree	195 (25.1)	48 (18.6)	72 (27.8)	75 (28.7)	
Graduate school	197 (25.3)	71 (27.5)	58 (22.4)	68 (26.1)	
Employment					
Full-time	435 (55.9)	158 (61.2)	130 (50.2)	147 (56.3)	.13
Retired	270 (34.7)	75 (29.1)	103 (39.8)	92 (35.2)	
Part-time	51 (6.6)	16 (6.2)	21 (8.1)	14 (5.4)	
Other[e]	22 (2.8)	9 (3.5)	5 (1.9)	8 (3.1)	
Antihypertensive medication classes					
0	28 (3.6)	13 (5.0)	5 (1.9)	10 (3.8)	.16
1	366 (47.0)	127 (49.2)	120 (46.3)	119 (45.6)	
2	261 (33.5)	89 (34.5)	86 (33.2)	86 (33.0)	
≥3	123 (15.8)	29 (11.2)	48 (18.5)	46 (17.6)	
Current smoker	52 (6.8)[f]	20 (8.1)	14 (5.5)	18 (6.9)	.51
Body mass index[g]					
Normal (18.5-24.9)	54 (7.2)	16 (6.5)	14 (5.6)	24 (9.5)	.37
Overweight (25-29.9)	237 (31.6)	72 (29.4)	84 (33.3)	81 (32.1)	
Obese (≥30)	458 (61.1)	157 (64.1)	154 (61.1)	147 (58.3)	
Already had home BP monitor	437 (56.2)	137 (53.1)	160 (61.8)	140 (53.6)	.08
BP, mean (SD), mm Hg					
Systolic	151.9 (10.3)	151.3 (10.6)	152.2 (10.0)	152.2 (10.4)	.55
Diastolic	89.1 (8.0)	89.4 (8.0)	89.0 (7.9)	88.9 (8.1)	.74

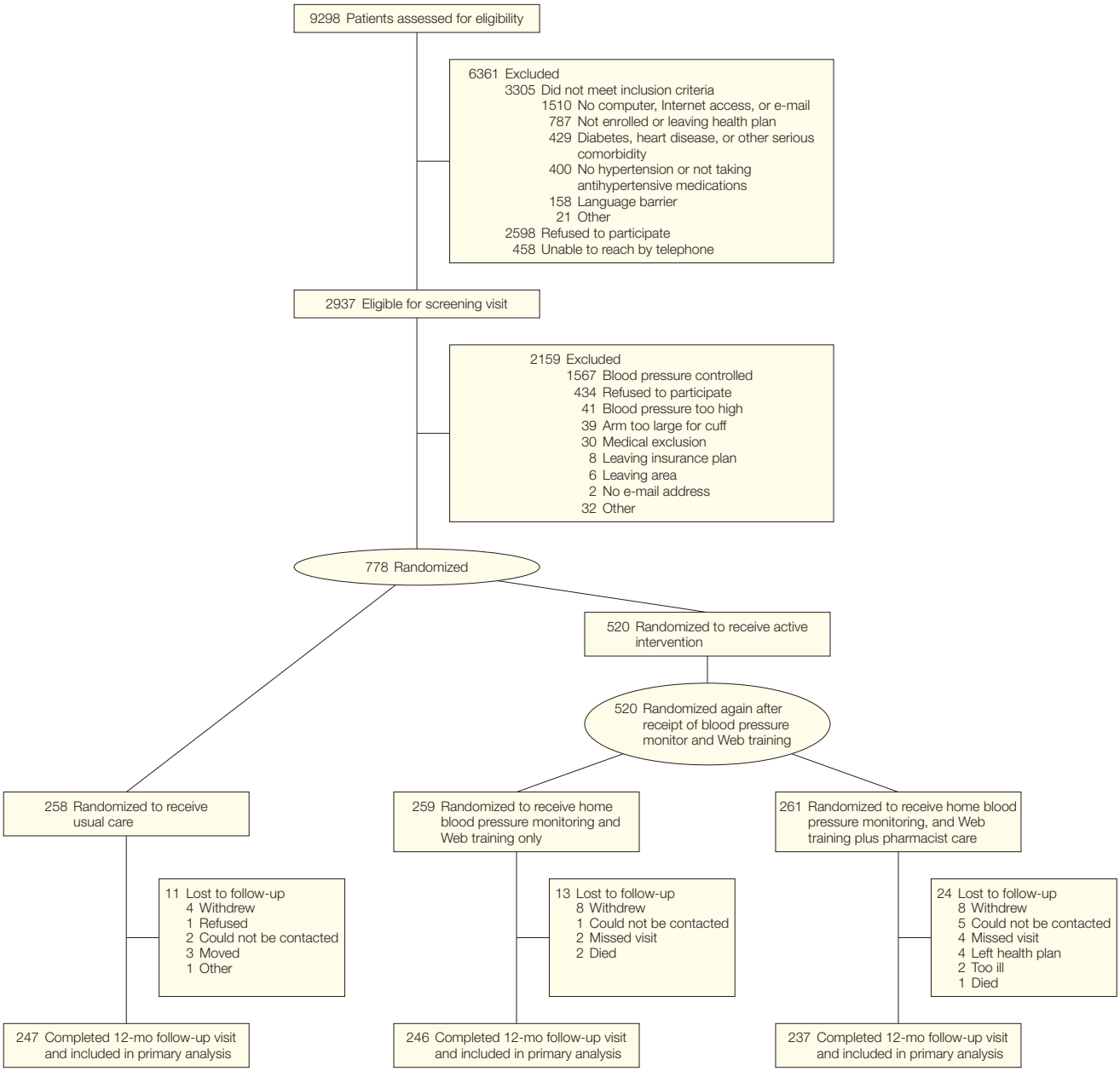
Abbreviations: BP, blood pressure; GED, general equivalency degree.
[a] Unless otherwise indicated.
[b] Indicates pharmacist care management delivered through Web communications.
[c] *P* value from an *F* test for continuous outcomes and χ^2 test for binary outcomes comparing a difference between any of the 3 study groups.
[d] Or refused to say. When participants chose more than 1 category for race, coding precedence was given to black, Asian, other, and white categories, in that order.
[e] Or refused to say.
[f] Missing data for 15 patients.
[g] Calculated as weight in kilograms divided by height in meters squared. Missing data for 29 patients.

sion and also were ineligible. Of those agreeing to a screening appointment and eligible after the visit, 778 of 1212 patients (64.2%) provided consent to participate in the e-BP study. A total of 778 computer-able patients with uncontrolled essential hypertension were enrolled from 10 medical centers, of whom 730 (94%) completed the 12-month follow-up visit. Completion rates did not differ significantly by study group and were higher than the assumed 80% follow-up rate in the sample size determination.

Patient Characteristics

Demographic characteristics of the study groups were comparable at baseline ($P > .10$), except for sex and already having a home BP monitor (Table 1). To account for these differences, these variables were adjusted for

Figure. Flow of e-BP Trial Patients Through Recruitment, Intervention, and Blinded Follow-up Assessments



All patients were encouraged to have a 12-month follow-up visit, regardless of intervention participation. Patients were randomized again to ensure blinding during baseline home BP monitor and Web training. e-BP indicates Electronic Communications and Home Blood Pressure Monitoring.

in the primary analyses. Overall, racial minorities were better represented than is typical for Group Health and the surrounding Puget Sound area. By definition, all 778 patients had uncontrolled hypertension; 347 (44.6%) had elevated systolic BP only, 59 (7.6%) had elevated diastolic BP only, and 372 (47.8%) had combined systolic and diastolic BP elevation. The mean (SD) BP at baseline for the study population was 151.9 (10.3) mm Hg for systolic and 89.1 (8.0) mm Hg for diastolic. Baseline BPs were similar in all 3 groups. For the prespecified subgroup with baseline systolic BP of 160 to 199 mm Hg, the mean (SD) for systolic and diastolic BP was 167.6 (6.2) mm Hg and 90.7 (8.3) mm Hg, respectively.

Primary Outcomes

Compared with patients receiving usual care, the BP control (defined as systolic BP <140 mm Hg and diastolic BP <90 mm Hg) of the home BP monitoring and Web training only group did not improve; however, they did have a significant improvement and a modest reduction in systolic BP (difference between adjusted mean change, –2.9 mm Hg [95% CI, –5.4 to –0.4]; $P=.02$). The addition of Web-based pharmacist care to home BP monitoring and Web training resulted in 25% more patients with controlled BP (56% [95% CI, 49%-62%]) compared with those receiving usual care (31% [95% CI, 25%-37%]; $P<.001$) and 20% more patients with controlled BP compared with the home BP monitoring and Web training only group (36% [95% CI, 30%-42%]; $P<.001$).

Compared with the usual care group, adjusted analyses found a 1.8 times increase in BP control for the group receiving home BP monitoring and Web training plus pharmacist care (RR, 1.84 [95% CI, 1.48 to 2.29]; $P<.001$) and a 1.2 times increase for the group receiving home BP monitoring and Web training only (RR, 1.22 [95% CI, 0.95 to 1.56]; $P=.20$) (TABLE 2). Compared with usual care, greater reductions in systolic BP occurred in the group receiving home BP monitoring and Web training plus pharmacist care (difference between adjusted mean change, –8.9 mm Hg [95% CI, –11.4 to –6.3]; $P<.001$) and in the group receiving home BP monitoring and Web training only (difference between adjusted mean change, –6.0 mm Hg [95% CI, –8.5 to –3.5]; $P<.001$). The group receiving home BP monitoring and Web training plus pharmacist care also had a significant decrease in diastolic BP compared with the group receiving usual care (net change, –3.5 mm Hg [95% CI, –4.9 to –2.1]; $P<.001$). For the subgroup with baseline systolic BP of 160 mm Hg or higher, the group receiving home BP monitoring and Web training plus pharmacist care had 3.3 times more patients with BP in control (RR, 3.32 [95% CI, 1.86 to 5.94], $P<.001$), lower systolic BP of –13.2 mm Hg (95% CI, –19.2 to –7.1; $P<.001$), and lower diastolic BP of –4.6 mm Hg (95% CI, –8.0 to –1.2; $P<.001$) compared with usual care.

In a sensitivity analysis using baseline BP values for those who did not complete follow-up (6% of study population), there were no major changes in the results. The results for the home BP monitoring and Web training plus pharmacist care group are still significantly better than those for the home BP monitoring and Web training only group and the usual care group, although the differences among the groups are slightly attenuated (TABLE 3).

Secondary Outcomes

At baseline, patients took a mean of 1.6 antihypertensive medication classes. At 12 months, the mean (SD) number of antihypertensive medication classes filled of 1.94 (0.91) in the home BP monitoring and Web training only group significantly increased compared with 1.69 (0.91) in the usual care group ($P<.01$). The group receiving home BP monitoring and Web training plus pharmacist care had an increase in the mean (SD) number of antihypertensive medication classes filled of 2.16 (0.93), which was significantly greater than both the usual care group ($P<.001$) and the home BP monitoring and Web training only group ($P<.01$) (TABLE 4).

Aspirin use for the group receiving home BP monitoring and Web training plus pharmacist care significantly increased by 1.3 times (RR 1.3; 95% CI, 1.1-1.5) compared with the usual care group and by 1.2 times (RR, 1.2; 95% CI, 1.1-1.4) compared with the home BP monitoring and Web training only group. Aspirin use did not significantly change for the group receiving home BP monitoring and Web training only compared with the usual care group. Body mass index, physical activity, health-related quality of life, and satisfaction with the health plan did not differ among the 3 groups.

Secure Messages and Other Health Care Use

In the 12 months after randomization, the mean (SD) number of message threads (defined as a secure message and subsequent responses) was 22.3 (10.2) in the group receiving home BP monitoring and Web training plus pharmacist care compared with 2.4 (4.6) in the usual care group and 3.3 (7.4) in the home BP monitoring and Web training only group because the pharmacists regularly initiated these threads. The mean (SD) number of patient-initiated threads increased significantly to 2.7 (7.1) threads in the home BP monitoring and Web training only group compared with 1.8 (4.2) threads in the usual care group ($P=.01$) and to 4.2 (6.0) threads in the home BP monitoring and Web training plus pharmacist care group compared with both the usual care group ($P<.01$) and the home BP monitoring and Web training only group ($P<.01$).

At 12 months, with the 1 planned telephone encounter excluded, telephone encounters also were higher in the group receiving home BP monitoring and Web training plus pharmacist care by a mean (SD) of 7.5 (9.3) compared with 3.8 (5.0) in the home BP monitoring and Web training only group ($P<.001$) and 4.0 (4.8) in the usual care group ($P<.001$). Primary care visits did not differ among patients in the usual care, home BP monitoring and Web training only, and home BP monitoring and Web training plus

pharmacist care groups (with 3.2, 3.0, and 3.2 visits, respectively, over 12 months). There also were no significant differences among patients in any group with respect to inpatient and urgent care or emergency use at 12 months. There was a modest but significant decrease in the percentage of patients with office visits to a specialist during the 12-month period in the group receiving home BP monitoring and Web training plus pharmacist care ($P = .04$) relative to baseline and to patients in the other groups.

Serious Adverse Events

Three people died during the study; 2 died of cancer-related complications in the group receiving home BP monitoring and Web training only and the third died of cardiac arrest in the group receiving home BP monitoring and Web training plus pharmacist care. Seven patients had nonfatal cardiovascular events: 2 in the usual care group, 4 in the home BP monitoring and Web training only group, and 3 in the home BP monitoring and Web training plus pharmacist care group. The data and safety monitoring board and the investigators attributed none of the deaths, cardiovascular events, or other hospitalizations to study participation.

COMMENT

The results of this study indicate that Web-based pharmacy care improved BP control. Our intervention was particularly effective for those with higher systolic BP (≥160 mm Hg at baseline), which is typically more difficult to treat and associated with increased cardiovascular risk.[35]

Our study findings support previous research that demonstrates encouraging patients to participate more actively in their own care, combined with care management,[36] including assisted patient review of paper medical records,[37,38] leads to improved health outcomes. Our intervention extends this work by connecting patients and care managers through a shared EMR over the Web. In our study, providing home BP monitors and Web training alone did not significantly improve BP control, despite trends in that direction. These results are consistent with recent meta-analyses[7,8,39,40] showing care delivered by an ancillary care provider, such as a nurse or pharmacist, resulted in larger

Table 2. Primary Outcomes at 12 Months for All Patients Completing Follow-up in the Electronic Communications and Home Blood Pressure Monitoring Trial

	Outcomes for Patients Completing 12-mo Follow-up (n = 730)				*P* Values for Difference Between Groups[c]		
		BP Monitoring and Patient Web Services Training					
	Usual Care (n = 247)	Only (n = 246)	+ Pharmacist Care[a] (n = 237)	Overall *P* Value[b]	Usual Care vs Only[d]	Usual Care vs + Pharmacist Care[a]	Only[d] vs + Pharmacist Care[a]
Systolic BP (95% CI)							
Unadjusted mean	146.3 (144.5 to 148.2)	143.8 (141.9 to 145.6)	137.9 (136.0 to 139.8)	<.001	.06	<.001	<.001
Adjusted mean change[e]	−5.3 (−7.1 to −3.5)	−8.2 (−10.0 to −6.4)	−14.2 (−16.0 to −12.4)	<.001	.02	<.001	<.001
Diastolic BP (95% CI)							
Unadjusted mean	85.7 (84.5 to 86.9)	84.5 (83.3 to 85.7)	81.6 (80.4 to 82.9)	<.001	.18	<.001	<.001
Adjusted mean change[e]	−3.5 (−4.5 to −2.5)	−4.4 (−5.4 to −3.4)	−7.0 (−8.0 to −6.0)	<.001	.21	<.001	<.001
BP controlled (95% CI)[f]							
Unadjusted proportion	0.31 (0.25 to 0.37)	0.36 (0.30 to 0.42)	0.56 (0.49 to 0.62)	<.001	.20	<.001	<.001
Adjusted RR[g]	1 [Reference]	1.22 (0.95 to 1.56)	1.84 (1.48 to 2.29)	<.001	.20	<.001	<.001
	Subanalysis of Patients With Systolic BP at Baseline ≥160 mm Hg (n = 150)						
	(n = 51)	(n = 47)	(n = 52)				
Systolic BP (95 % CI)							
Unadjusted mean	152.4 (148.2 to 156.6)	151.0 (146.6 to 155.4)	139.8 (135.6 to 144.0)	<.001	.64	<.001	<.001
Adjusted mean change[e]	−14.4 (−18.6 to −10.1)	−17.8 (−22.2 to −13.4)	−27.6 (−31.8 to −23.4)	<.001	.30	<.001	.002
Diastolic BP (95 % CI)							
Unadjusted mean	84.4 (81.6 to 87.2)	83.8 (80.9 to 86.7)	81.0 (78.2 to 83.8)	.21	.78	.10	.10
Adjusted mean change[e]	−5.6 (−8.0 to −3.2)	−6.3 (−8.8 to −3.8)	−10.2 (−12.6 to −7.8)	.02	.70	.01	.03
BP controlled (95%CI)[f]							
Unadjusted proportion	0.20 (0.11 to 0.33)	0.26 (0.15 to 0.40)	0.54 (0.40 to 0.67)	<.001	.20	<.001	<.001
Adjusted RR[g]	1 [Reference]	1.88 (0.94 to 3.78)	3.32 (1.86 to 5.94)	<.001	.08	<.001	.05

Abbreviations: BP, blood pressure; CI, confidence interval; RR, relative risk.
[a] Indicates pharmacist care management delivered through Web communications were received in addition to BP monitoring and patient Web services training.
[b] *P* value from an *F* test for continuous outcomes and χ^2 test for binary outcomes comparing a difference between any of the 3 study groups.
[c] *P* value from a Wald *t* test for continuous outcomes and a Wald *z* test for binary outcomes comparing a difference between the 2 intervention groups.
[d] Indicates only BP monitoring and patient Web services training were received.
[e] Indicates the estimated mean change in 12-month outcome from baseline in a linear regression model adjusted for baseline outcome, sex, already having a home BP monitor before trial, and clinic while assuming mean baseline covariate values.
[f] Defined as systolic and diastolic BP lower than 140 and 90 mm Hg, respectively.
[g] Indicates estimated RR comparing each intervention group with usual care for the outcome of controlled BP in a modified Poisson regression model adjusted for body mass index, sex, already having a home BP monitor before the trial, baseline systolic BP, and clinic.

decreases in BP than did home BP monitoring and patient education interventions alone.

This study has several limitations. Our intervention was limited to those with uncontrolled essential hypertension, and patients were required to have computer, Internet, and e-mail access. Letters were sent to more than 9000 patients with a diagnosis of hypertension, but more than two-thirds of them were ineligible. Patients without computer access (21%) were more likely to be older, belong to racial or ethnic minority groups, and have less education, suggesting a digital divide. This gap between persons with and without access to the Internet may narrow with time as the population ages, but some patients are likely to remain without access to care over the Web.[41] Patients also were ineligible if they had diabetes, heart disease, or other serious diseases because we wanted to keep medication protocols simple for this first test of Web-based care. Patients also had better BP control than expected, with 60.9% having controlled[5,6] hypertension at the recruitment screening visits. These rates of control are better than those published in the peer-reviewed literature,[4] but similar to those reported by the National Committee for Quality Assurance Health Plan Employer Data and Information Set.[42] The e-BP study began shortly after implementation of the EMR, and there were not enough clinic BP measurements in the EMR for us to use these to preidentify patients more likely to have uncontrolled BP. However, now most Group Health adult patients have BP measurements in the EMR, and these could be used to refine recruitment strategies.

We also did not control for the greater attention that the patients in the home BP monitoring and Web training plus pharmacist care group received. Patients in the home BP monitoring and Web training only group might have had similar reductions if we had e-mailed additional reminders to send BP measurements to their physician. We also do not know whether BP control will be maintained after the end of pharmacy support. Additionally, the health plan's characteristics may have influenced the results. Patients in this study received care in a large integrated group practice, in which Group Health was both the insurance plan and the health care de-

Table 3. Sensitivity Analysis at 12 Months for All Patients Assuming Those Not Completing Follow-up Had Baseline Blood Pressure Measurement in the Electronic Communications and Home Blood Pressure Monitoring Trial

	Outcomes for All Patients at 12 mo (N = 778)				*P* Values for Difference Between Groups[c]		
		BP Monitoring and Patient Web Services Training					
	Usual Care (n = 258)	Only (n = 259)	+ Pharmacist Care[a] (n = 261)	Overall *P* Value[b]	Usual Care vs Only[d]	Usual Care vs + Pharmacist Care[a]	Only[d] vs + Pharmacist Care[a]
Systolic BP (95% CI)							
Unadjusted mean	146.5 (144.7 to 148.3)	144.2 (142.4 to 146.0)	139.1 (137.3 to 140.9)	<.001	.08	<.001	<.001
Adjusted mean change[e]	−5.1 (−6.9 to −3.4)	−7.8 (−9.5 to −6.1)	−12.9 (−14.6 to −11.2)	.002	.03	<.001	<.001
Diastolic BP (95% CI)							
Unadjusted mean	86.0 (84.9 to 87.2)	84.9 (83.7 to 86.1)	82.7 (81.5 to 83.9)	<.001	.17	<.001	<.001
Adjusted mean change[e]	−3.3 (−4.3 to −2.4)	−4.1 (−5.1 to −3.2)	−6.2 (−7.2 to −5.3)	<.001	.26	<.001	.003
BP controlled (95% CI)[f]							
Unadjusted proportion	0.29 (0.24 to 0.35)	0.34 (0.29 to 0.40)	0.51 (0.45 to 0.57)	<.001	.23	<.001	<.001
Adjusted RR[g]	1 [Reference]	1.19 (0.93 to 1.52)	1.74 (1.39 to 2.18)	<.001	.18	<.001	<.001
	Subanalysis of Patients With Systolic BP at Baseline ≥160 mm Hg (n = 162)						
	(n = 54)	(n = 50)	(n = 58)				
Systolic BP (95% CI)							
Unadjusted mean	153.2 (149.0 to 157.4)	152.0 (147.6 to 156.4)	142.5 (138.4 to 146.6)	<.001	.71	<.001	<.001
Adjusted mean change[e]	−13.9 (−18.1 to −9.7)	−16.3 (−20.7 to −11.9)	−25.0 (−29.1 to −21.0)	<.001	.46	<.001	.005
Diastolic BP (95% CI)							
Unadjusted mean	85.2 (82.4 to 87.9)	84.1 (81.2 to 87.0)	82.3 (79.6 to 85.0)	.35	.62	.15	.15
Adjusted mean change[e]	−5.3 (−7.7 to −3.0)	−5.9 (−8.3 to −3.5)	−9.0 (−11.2 to −6.8)	.06	.75	.03	.07
BP controlled (95% CI)[f]							
Unadjusted proportion	0.19 (0.10 to 0.31)	0.24 (0.14 to 0.38)	0.48 (0.36 to 0.61)	.001	.40	.001	.01
Adjusted RR[g]	1 [Reference]	1.73 (0.85 to 3.51)	3.10 (1.73 to 5.58)	<.001	.13	<.001	.04

Abbreviations: BP, blood pressure; CI, confidence interval; RR, relative risk.
[a] Indicates pharmacist care management delivered through Web communications were received in addition to BP monitoring and patient Web services training.
[b] *P* value from an *F* test for continuous outcomes and likelihood ratio χ^2 test for binary outcomes comparing a difference between any of the 3 study groups.
[c] *P* value from a Wald *t* test for continuous outcomes and a Wald *z* test for binary outcomes comparing a difference between the 2 intervention groups.
[d] Indicates only BP monitoring and patient Web services training were received.
[e] Indicates the estimated mean change in 12-month outcome from baseline in a linear regression model adjusted for baseline outcome, sex, already having a home BP monitor before the trial, and clinic while assuming mean baseline covariate values.
[f] Defined as systolic and diastolic BP lower than 140 and 90 mm Hg, respectively.
[g] Indicates estimated RR comparing each intervention group with usual care for the outcome of controlled BP in a modified Poisson regression model adjusted for body mass index, sex, already having a home BP monitor before the trial, baseline systolic BP, and clinic.

Table 4. Secondary Outcomes at 12 Months for All Patients Completing Follow-up in the Electronic Communications and Home Blood Pressure Monitoring Trial

	Missing Data, No. of Patients	Mean (SD)[a] At 12-mo Follow-up				Differences Between Intervention Groups, Mean Difference or RR (95% CI)[c]		
				BP Monitoring and Patient Web Services Training				
		Baseline	Usual Care	Only	+ Pharmacist Care[b]	Usual Care vs Only[d]	Usual Care vs + Pharmacist Care[b]	Only[d] vs + Pharmacist Care[b]
No. of antihypertensive medication classes	0	1.64 (0.85)	1.69 (0.91)	1.94 (0.91)	2.16 (0.93)	0.3 (0.1 to 0.4)[e]	0.5 (0.3 to 0.6)[f]	0.2 (0.1 to 0.4)[e]
Aspirin use, No. (%)	38	338 (48.8)	124 (53.0)	131 (56.0)	149 (66.5)	1.1 (0.9 to 1.2)	1.3 (1.1 to 1.5)[e]	1.2 (1.0 to 1.4)[g]
Body mass index	34	32.3 (6.5)	32.5 (6.5)	32.5 (7.0)	31.6 (6.2)	0 (–1.1 to 1.2)	–0.9 (–2.1 to 0.3)	–0.9 (–2.1 to 0.3)
Active, No. (%)	49	464 (68.1)	158 (68.4)	173 (73.9)	155 (71.8)	1.1 (1.0 to 1.2)	1.0 (0.9 to 1.2)	1.0 (0.9 to 1.1)
Quality of life (1-100 scale)								
General health	38	67.1 (20.4)	66.7 (20.4)	66.6 (20.9)	66.6 (22.2)	–0.1 (–4.0 to 3.7)	–0.1 (–4.0 to 3.8)	0 (–3.9 to 3.9)
Physical health	44	80.6 (27.0)	78.1 (27.7)	77.7 (30.3)	81.0 (26.5)	–0.4 (–5.6 to 4.7)	2.8 (–2.3 to 8.0)	3.3 (–1.9 to 8.5)
Emotional health	39	71.6 (16.8)	71.5 (17.7)	72.1 (16.8)	71.7 (19.7)	0.5 (–2.7 to 3.8)	0.1 (–3.2 to 3.4)	–0.4 (–3.7 to 2.9)
CAHPS (0-10 scale)	65	7.9 (1.5)	8.1 (1.5)	8.1 (1.5)	8.3 (1.4)	0 (–0.3 to 0.3)	0.2 (–0.1 to 0.5)	0.2 (0 to 0.5)

Abbreviations: BP, blood pressure; CAHPS, Consumer Assessment of Healthcare Providers and Systems; CI, confidence interval; RR, relative risk.
[a] Unless otherwise indicated.
[b] Indicates pharmacist care management delivered through Web communications were received in addition to BP monitoring and patient Web services training.
[c] Mean difference if outcome is continuous and RR if outcome is binary.
[d] Indicates only BP monitoring and patient Web services training were received.
[e] Significant at $P < .01$ level.
[f] Significant at $P < .001$ level.
[g] Significant at $P < .05$ level.

livery system. Group Health's medical centers were paperless; orders, laboratory test results, medications, and patient encounter notes were part of the EMR and had already used clinical pharmacists for team-based care management. Patients had prescription drug coverage and received medications for a copayment from Group Health pharmacies. Independent group practices or those in an insurance plan network might have greater difficulties in providing these integrated services.

However, our study also has several strengths. To our knowledge, this is the first large randomized controlled trial to test the use of care management over the Web, including a preexisting EMR shared between patients and providers (physicians, nurses, or pharmacists) and additional Web services, to improve chronic disease treatment outcomes. Use of patient Web sites is consistent with the Institute of Medicine *Crossing the Quality Chasm* report, which states that an essential element for the transformation of health care is continuous access (24 hours per day/7 days per week) to health care.[43]

To our knowledge, this also is the first randomized controlled trial that has applied the Chronic Care Model to the care of hypertension. Systematic reviews have shown that use of this model can lead to improved health outcomes for other chronic conditions.[44,45] Uncertainty persists regarding how best to deliver this model and whether all 6 domains are required.

In the e-BP study, a low-intensity, self-care management intervention that did not include ongoing care management support led to some increases in Web communications and the number of classes of antihypertensive medications used, and a modest reduction in systolic BP. Adding pharmacist care allowed the Chronic Care Model to be integrated, with further increases in secure messaging, more antihypertensive medication classes being added, and larger reductions in both systolic and diastolic BP. We believe the pharmacists were successful because they provided planned care to a defined population, consistently applied stepped medication protocols, and used comprehensive information systems, a patient-shared EMR, and Web communications to collaborate with patients and their physicians.

CONCLUSION

Our findings demonstrate the effectiveness of using home BP monitoring combined with pharmacy care over the Web to improve BP control for patients with essential hypertension. More studies are needed to determine whether similar care can be applied to other chronic diseases, be implemented in other settings, and decrease costs.

Author Contributions: Drs Green, Cook, and Carrell had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Green, Fishman, Catz, Carlson, Thompson.
Acquisition of data: Green, Fishman, Catz, Carrell, Tyll.
Analysis and interpretation of data: Green, Cook, Ralston, Fishman, Catz, Carlson, Carrell, Larson, Thompson.
Drafting of the manuscript: Green, Cook, Ralston, Fishman, Catz, Tyll, Larson.
Critical revision of the manuscript for important intellectual content: Green, Cook, Ralston, Fishman, Catz, Carlson, Carrell, Tyll, Larson.
Statistical expertise: Cook, Fishman.
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Study supervision: Green, Carlson, Tyll, Larson, Thompson.

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†Deceased.

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