

Home Monitoring Service Improves Mean Arterial Pressure in Patients with Essential Hypertension

A Randomized, Controlled Trial

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Background: Technological advances in the distribution of information have opened new avenues for patient care. Few trials, however, have used telemedicine to improve blood pressure in patients with essential hypertension.

Objective: To determine the efficacy of a telecommunication service in reducing blood pressure.

Design: Randomized, controlled trial.

Setting: University-affiliated primary care outpatient clinics.

Patients: 121 adults with essential hypertension who were under evaluation for a change in antihypertensive therapy.

Intervention: A home service consisting of automatic transmission of blood pressure data over telephone lines, computerized conversion of the information into report forms, and weekly electronic transmission of the report forms to physicians and patients.

Measurements: 24-hour ambulatory blood pressure monitoring at baseline and exit. The primary end point was change in mean arterial pressure from baseline to exit.

Results: Mean arterial pressure decreased by 2.8 mm Hg in patients receiving the home service and increased by 1.3 mm Hg in patients receiving usual care ($P = 0.013$ for the difference). Mean diastolic blood pressure decreased by 2.0 mm Hg for home service but increased by 2.1 mm Hg for usual care ($P = 0.012$ for the difference). Mean systolic blood pressure decreased by 4.9 mm Hg for home service and 0.1 mm Hg for patients receiving usual care ($P = 0.047$ for the difference). Among African-American patients, mean arterial pressure decreased by 9.6 mm Hg in those receiving home service and increased by 5.25 mm Hg in those receiving usual care ($P = 0.047$). Part of the decrease in blood pressure for home service was due to more frequent changes in the type or dose of antihypertensive medications.

Conclusion: This telecommunication service was efficacious in reducing the mean arterial pressure of patients with established essential hypertension.

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Although the use of telecommunication systems in medicine has been increasing, few trials have assessed the efficacy of such technology for improving blood pressure in patients with essential hypertension (1, 2). Friedman and colleagues (1) found that when hypertensive patients used a telephone-linked computer system to report blood pressure, diastolic blood pressure decreased significantly. Bondmass and colleagues (2) also found a significant decrease in both diastolic and systolic blood pressure, although their trial lacked controls. In these studies and in other trials of home monitoring, self-report of blood pressure was the basic mechanism for transmission of information to physicians (1–8). This may have consequences for patient care, since it has recently been shown that patients often erroneously report blood pressure, especially patients whose blood pressure is uncontrolled (9). Johnson and

colleagues (9) found that in approximately 20% of instances, self-report of blood pressure differed from the electronic reading by more than 10 mm Hg.

Another limitation of previous trials is accurate assessment of the outcome. In some studies, the outcome was determined by one or two blood pressure readings taken during an office visit or by a technician in the home setting (1, 4–7). Only one study of 31 patients used automatic ambulatory blood pressure monitoring (ABPM) to assess usual blood pressure at baseline and exit (3). Twenty-four-hour ABPM recordings yield a more reliable assessment of usual blood pressure levels during the course of daily activities (10).

To improve on the previous studies, we designed a randomized, controlled trial that used 24-hour ABPM measurements at baseline and at exit to determine change in blood pressure more accurately. The interven-

tion was a service provided to physicians that used electronic transmission of results and did not rely on self-report of blood pressure.

METHODS

Study Protocol

From May 1999 to April 2000, five internists from the Department of Medicine at the State University of New York Upstate Medical University in Syracuse recruited patients from internal medicine outpatient practices affiliated with the general medicine division. Outpatients seen by these physicians were covered by private insurance plans or Medicare. Eligible patients were adults who had previously received a diagnosis of essential hypertension and were under evaluation for a change in antihypertensive therapy because of 1) elevated blood pressure (systolic pressure ≥ 140 or diastolic pressure ≥ 90 mm Hg) despite current antihypertensive therapy, 2) undesirable side effects of current antihypertensive medication, or 3) office systolic pressure of at least 180 mm Hg or diastolic pressure of at least 110 mm Hg with no current use of antihypertensive medication.

For patients with diabetes mellitus, heart disease, stroke, nephropathy, peripheral arterial disease, or hypertensive retinopathy, an office systolic pressure of at least 130 mm Hg or an office diastolic pressure of at least 85 mm Hg was a criterion for eligibility. Patients who were younger than 18 years of age, were pregnant, had secondary hypertension, or did not have the mental or physical capacity to monitor blood pressure at home were excluded.

All patients were informed of the study procedures, the risks and benefits of participation, confidentiality, rights, and personnel to contact for additional information. The institutional review board at Upstate Medical University approved the trial, and all patients gave written consent before participation.

Patients received printed educational materials on nonpharmacologic approaches to blood pressure control from the National Heart, Lung, and Blood Institute (11). These approaches included reducing weight, increasing physical activity, and changing diet if necessary. At baseline, height and weight were recorded at the clinic for all patients. Body mass index was calculated as kg/m^2 . Printed information on the treatment of hypertension from the Sixth Report of the Joint National

Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (National High Blood Pressure Education Program) (12) was available at each clinical site as a reference for physicians and clinical staff.

Study Group Assignment

We conducted a randomized trial with concurrent controls. The two study groups were home service and usual care. To ensure an equal number of patients in both study groups, we used a blocking procedure with random permuted blocks of varying size to reduce predictability. Randomization was stratified by the number of prescription medications patients were taking (0 to 2 or ≥ 3) at study entry, which served as a general indicator of morbidity. Sequentially numbered, sealed, opaque envelopes were used for assignment. The randomization procedure was concealed to physicians and clinical research staff, but physicians, investigators, and patients were aware of group assignment when randomization was complete. In addition, adherence to the protocol was monitored independently of the clinicians. A priori sample size was calculated to detect a mean (\pm SD) difference in blood pressure of 3 ± 5 mm Hg between the two study groups. This yielded 60 patients per group with 90% power ($\alpha = 0.05$ [two-tailed]).

Intervention

The intervention was a telecommunication service consisting of three components: automatic blood pressure recording at home, central processing, and electronic reports provided weekly to the primary physician and patient. We used a home blood pressure monitoring device that transmitted data over analog telephone lines (Model 52500, Welch Allyn, Inc., Skaneateles Falls, New York) and was validated according to the standards of the American National Standard Institute, Inc., and the Association for the Advancement of Medical Instrumentation (13). The oscillometric device (16.26 cm \times 10.92 cm \times 6.6 cm) had a digital display for blood pressure and pulse and used automatic pressurization and exhaust for cuff inflation and deflation. Patients were instructed to take their blood pressure three times in the morning before eating or drinking and three times in the evening before going to bed. After each reading, the device automatically dialed the Service and

Support Center at Welch Allyn and transmitted the data. Patients were asked to conduct this routine at least three days each week for a minimum of 8 weeks and could take additional readings if they desired. A computer program was developed to display the results in a report form, which was then faxed to each patient's physician. The report form contained information on the mean systolic pressure, mean diastolic pressure, and heart rate (overall, morning, and evening). It also graphed the pressure by date and displayed individual readings in tabular form. Both physicians and patients received a report form each week, as well as a summary report form at the end of the trial. When physicians received report forms that indicated elevated pressure, they adjusted antihypertensive medications through a telephone call, an office visit, or both. At the time of the trial, the service cost \$24.95 per month.

Patients assigned to usual care were treated for hypertension according to the guidelines of the Joint National Committee on Prevention, Detection, and Treatment of High Blood Pressure (12).

Questionnaire Information

Information about patients' medical histories, past diagnoses of disease, and use of medications was obtained from questionnaires. The Baecke questionnaire of habitual physical activity was used to assess usual activity levels (14). Subscales included a work index, a sports index, and a nonsports leisure index, as well as a total physical activity score. Dietary intake was estimated by using the Block screening questionnaire, which consists of two subscales: intake of highly saturated fatty foods and intake of fruit, vegetables, and high-fiber grains (15). Questions about smoking and stress were taken from the previously validated Health Habits and History Questionnaire (16). The study questionnaire was collected at the time of the second 24-hour ambulatory readings.

Outcome Measures

The primary end point was the change in mean arterial pressure during the trial (baseline to exit) for home service compared with usual care. A clinical research nurse (the study manager) fitted participants with a 24-hour ABPM device at baseline and at exit. The nurse gave the patients detailed instructions for using the device. The ABPM device automatically recorded

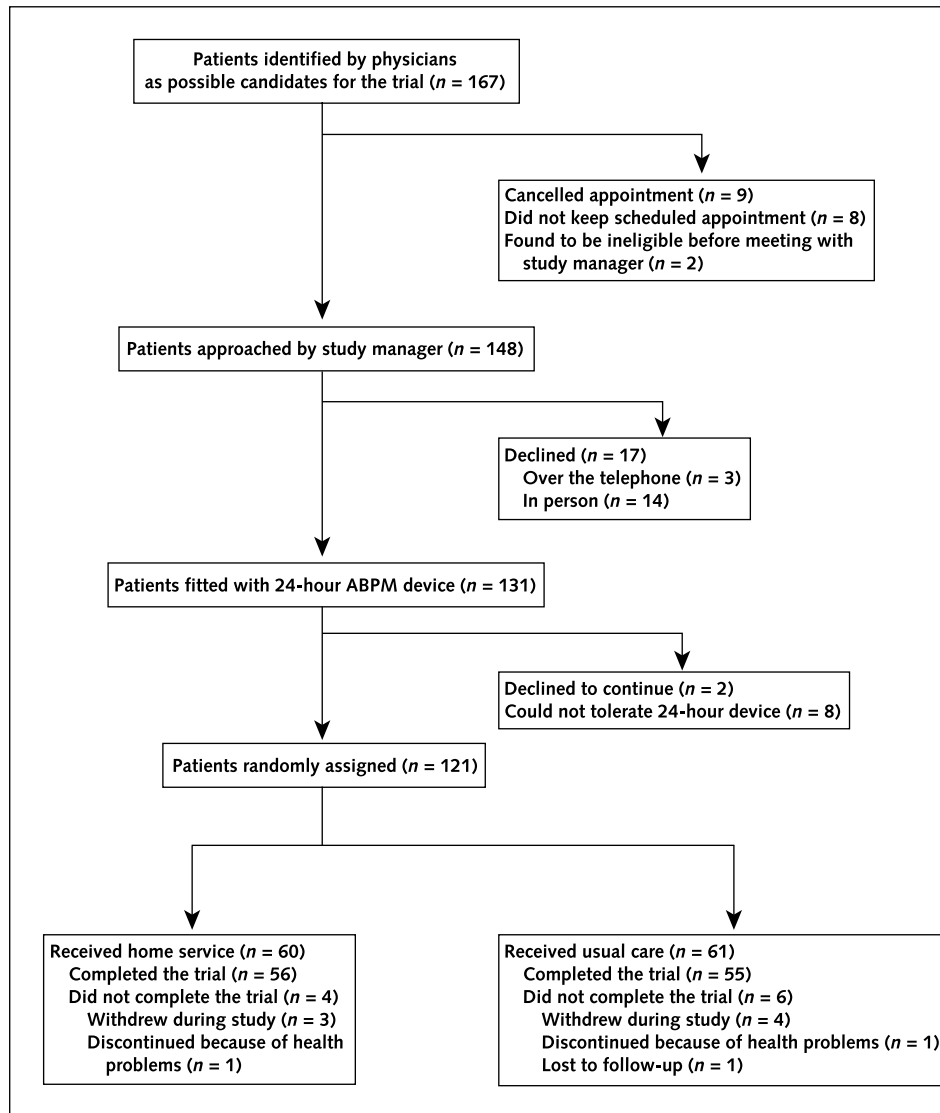
blood pressure every half-hour from 7:00 a.m. to 11:00 p.m. and every hour from 11:00 p.m. to 7:00 a.m. Information from baseline and exit ABPM readings was given to physicians only after the patient exited the trial. All blood pressure measurements indicated in this report refer to these 24-hour readings. Means and SDs were recorded for systolic pressure, diastolic pressure, arterial pressure, and heart rate by using 24-hour ABPM. Mean arterial pressure was measured as (diastolic pressure + 1/3 [systolic pressure - diastolic pressure]). The ABPM device also recorded the percentage of readings above the desired target levels (≥ 140 mm Hg systolic or ≥ 90 mm Hg diastolic for patients without target organ damage; ≥ 130 mm Hg systolic or ≥ 85 mm Hg diastolic for patients with target organ damage).

Patients were scheduled to remain in the trial for a minimum of 8 weeks. During the sixth and seventh weeks, appointments were made to schedule second 24-hour ABPM sessions. For both the home service and usual care groups, the median time from baseline to exit was 11 weeks. The final patient receiving usual care exited at 20 weeks, and the final patient receiving home service exited at 28 weeks.

Statistical Analysis

All information was entered into an Excel database (Microsoft Corp., Redmond, Washington) and was manually rechecked for errors. Statistical analyses were conducted by using STATISTICA software (StatSoft Inc., Tulsa, Oklahoma). Initially, univariate analyses were performed to determine the distribution of the variables and presence of outliers. Paired *t*-tests were used to compare mean baseline and exit pressures, while *t*-tests for independent samples were performed to assess differences in means between the two study groups. Change in pressure was measured by subtracting the baseline mean value from the exit mean value. The Pearson chi-square test was used for hypothesis testing of categorical data when the expected number in each cell exceeded five; otherwise, the Fisher exact test was used. The Mann-Whitney U test was used to compare groups with non-normally distributed data. Analysis of covariance was performed to assess first-order interactions between group assignment and demographic variables, comorbid conditions, and number of medications. We also adjusted for such covariates as age, sex, ethnicity,

Figure 1. Patient accrual.



ABPM = ambulatory blood pressure monitoring.

body mass index, smoking status, intake of high-fat foods, physical activity, family history of cardiovascular disease, physician, and time of follow-up. Logistic regression was used to determine odds ratios with adjustment for potential confounding factors, as described. The α value was set at 0.05 (two-tailed). To calculate the number needed to treat for benefit, systolic and diastolic blood pressure were binary coded (any decrease in mm Hg/no decrease in mm Hg from baseline to exit). All analyses were conducted by using the intention-to-treat principle.

Role of the Funding Source

This study was funded by Welch Allyn, Inc. Welch Allyn did not participate in the study design, implementation, or data analysis and had no role in the decision to publish the results.

RESULTS

From May 1999 through April 2000, 167 patients with hypertension were identified by the five participating physicians as possible candidates for the trial. Figure 1

Table. Characteristics of Patients Receiving Home Service and Those Receiving Usual Care*

Characteristic	Home Service	Usual Care
Mean age \pm SD, y	62.6 \pm 10.0	60.3 \pm 11.9
Sex, n (%)		
Men	26 (43.3)	34 (55.7)
Women	34 (56.7)	27 (44.3)
Ethnicity, n (%)		
White	46 (80.7)	52 (91.2)
African American	7 (12.3)	4 (7.0)
Other	4 (7.0)	1 (1.8)
Cigarette smoking, n (%)		
Current	4 (7.3)	9 (16.4)
Former	23 (41.8)	28 (50.9)
Never	28 (50.9)	18 (32.7)
Medical history, n (%)		
Cardiovascular disease	7 (13.0)	11 (20.0)
Stroke or carotid surgery	5 (9.3)	7 (12.7)
Chronic bronchitis, emphysema, or chronic obstructive pulmonary disease	7 (13.0)	8 (14.6)
Diabetes	13 (22.8)	15 (26.3)
Mean body mass index \pm SD, kg/m ²	31.5 \pm 7.6	28.9 \pm 5.2
Mean total physical activity score \pm SD†	7.32 \pm 1.27	7.77 \pm 1.52
Mean intake of highly saturated fatty foods \pm SD‡	15.1 \pm 7.1	14.2 \pm 7.2
Stress, n (%)§		
Every day	8 (15.1)	5 (9.3)
Several times a week	11 (20.8)	9 (16.7)

* Information collected at the time of the second 24-hour ambulatory reading.

† Based on the Baecke questionnaire (14). Higher scores indicate greater activity.

‡ Based on the Block screening questionnaire (15). A higher score indicates greater intake.

§ In response to the question "How often do you feel under stress that makes you tense or worried; or causes such physical problems as stomach or back trouble, headaches, or trouble sleeping?"

indicates the steps taken during accrual. One hundred twenty-one patients were found to be eligible, consented to participate, and were randomly assigned (60 to home service and 61 to usual care). Of those randomly assigned, 93% receiving home service and 90% receiving usual care completed the trial. Ten patients did not complete the entire trial; that is, they finished the initial 24-hour session of ABPM but did not complete the exit session of ABPM. These 10 patients were included in the data analysis as treatment failures (no change in pressure from baseline to exit), according to the intention-to-treat principle. At baseline, the mean number of readings taken with the ABPM device over the 24-hour period was 37.6 in the home service group and 38.9 in the usual care group. At the conclusion of the trial, the mean number of readings was 37.5 in the home service group and 38.1 in the usual care group.

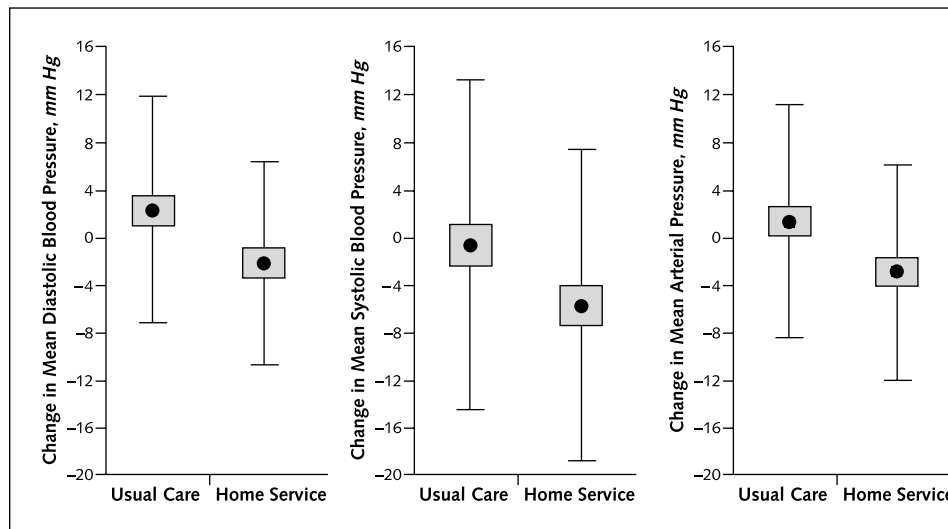
Characteristics of the study participants are given in the Table. Ages of the patients ranged from 34 to 86

years, with an overall mean of 61.5 years. There were some differences between the two groups for the variables listed; however, only the difference in body mass index was statistically significant. Patients receiving home service, on average, were more overweight than patients receiving usual care ($P = 0.038$). In addition to the characteristics listed in the Table, alcohol intake was similar in both groups, and patients in both groups had a mean of 7.5 hours of sleep per night.

Figure 2 shows the results for the main outcome variables. Mean diastolic, systolic, and arterial pressures decreased in patients who received home service. Mean systolic blood pressure decreased by 4.9 mm Hg (95% CI, -1.61 to -8.12 mm Hg; $P = 0.005$) from baseline to exit. Mean diastolic blood pressure decreased by 2.0 mm Hg (CI, 0.14 to -4.04 mm Hg; $P = 0.072$), and average mean arterial pressure decreased by 2.8 mm Hg (CI, -0.59 to -5.05 mm Hg; $P = 0.016$) from baseline to exit. In contrast, patients who received usual care exhibited a 2.1-mm Hg increase in mean diastolic blood pressure (CI, -0.21 to 4.37 mm Hg; $P = 0.08$), a 0.1-mm Hg decrease in mean systolic blood pressure (CI, -3.43 to 3.17 mm Hg; $P > 0.2$), and a 1.3-mm Hg increase in average mean arterial pressure (CI, -1.01 to 3.67 mm Hg; $P > 0.2$). We found statistically significant differences between the home service and usual care groups when the changes in pressure from baseline to exit were compared. Statistically significant differences were seen for mean diastolic pressure (difference, 4.1 mm Hg [CI, 0.93 to 7.13 mm Hg]; $P = 0.012$), mean systolic pressure (difference, 4.8 mm Hg [CI, 0.10 to 9.37 mm Hg]; $P = 0.047$), and mean arterial pressure (difference, 4.1 mm Hg [CI, 0.91 to 7.38 mm Hg]; $P = 0.013$).

When the outcome was coded as "improved" (that is, a decrease in pressure from baseline to exit) compared with "did not improve," patients who received home service were 2.32 (CI, 1.05 to 5.15) times more likely to have improved diastolic blood pressure than patients receiving usual care. Patients in the home service group were 2.52 (CI, 1.13 to 5.64) times more likely to have improved systolic blood pressure than those in the usual care group. Adjustment for age, sex, ethnicity, body mass index, smoking status, intake of fatty foods, physical activity, and family history of cardiovascular disease did not appreciably change these odds ratios (2.86 for diastolic pressure and 2.62 for systolic pressure). The

Figure 2. Change in mean diastolic, systolic, and arterial pressures from baseline to exit using 24-hour ambulatory monitoring in patients receiving home service and those receiving usual care.



Data points represent the mean, shaded areas represent the mean \pm SE, and error bars represent the mean \pm SD. $P = 0.012$, 0.047 , and 0.013 for differences in mean diastolic, systolic, and arterial pressure, respectively, between patients receiving usual care and those receiving home service.

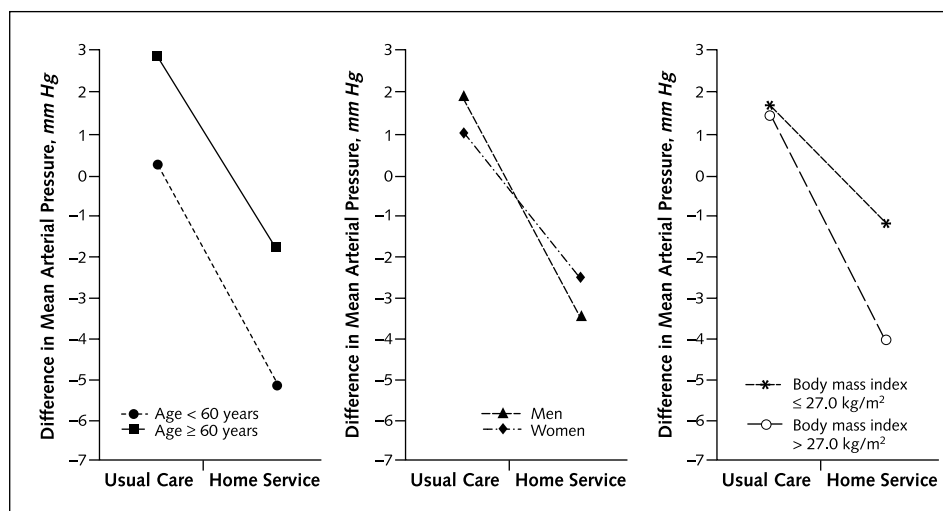
number needed to treat to reduce either diastolic or systolic blood pressure was five.

The decrease in blood pressure with home service was evident in both men and women (Figure 3), in both younger and older patients (<60 years of age vs. ≥ 60 years of age), and in patients in each ethnic group. The difference in mean arterial pressure was particularly evi-

dent in African-American patients. Among these patients, mean arterial pressure decreased by 9.6 mm Hg in the home service group and increased by 5.25 mm Hg in the usual care group ($P = 0.047$).

Figure 3 also shows the change in average mean arterial pressure according to body mass index (≤ 27 kg/m² vs. >27 kg/m²). A treatment effect was seen in

Figure 3. Difference in mean arterial pressure from baseline to exit using 24-hour ambulatory monitoring in the usual care and home service groups according to age, sex, and body mass index.

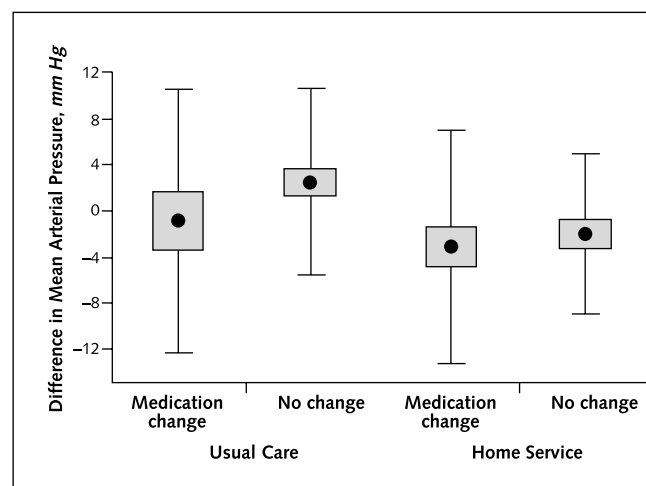


both groups. The data suggest that home service may be more effective in obese patients, although the interaction term was not statistically significant (interaction term, -2.719 [CI, -9.334 to 3.896]; $P = 0.422$); mean arterial pressure decreased by 4.0 mm Hg in the home service group and increased by 1.3 mm Hg in the usual care group. Likewise, the data suggest a considerable treatment effect in patients with angina, although a larger study is needed to confirm this. Among patients with angina, mean arterial pressure increased by 10.0 mm Hg in the usual care group and decreased by 6.5 mm Hg in the home service group (interaction term, 13.967 [CI, -2.009 to 29.943]; $P = 0.090$).

The main effect (difference in average mean arterial pressure for home service vs. usual care) was statistically adjusted for demographic and lifestyle factors. When data were adjusted for age, sex, and ethnicity, mean arterial pressure decreased by 3.0 mm Hg in those receiving home service and increased by 1.4 mm Hg in those receiving usual care, a statistically significant difference ($P = 0.013$). When adjusted for age, sex, ethnicity, body mass index, smoking status, intake of high-fat foods, physical activity, and family history of cardiovascular disease, the difference in mean arterial pressure from baseline to exit was -2.8 mm Hg in those receiving home service and 1.1 mm Hg in those receiving usual care. The difference between home service and usual care remained statistically significant ($P = 0.044$). The findings also remained statistically significant after adjustment for the total number of medications currently prescribed (antihypertensive and other drugs).

The percentage of readings during the 24-hour ambulatory period that were above the target values for systolic blood pressure and diastolic blood pressure (that is, ≥ 130 and ≥ 85 mm Hg, respectively, for patients with target organ damage and ≥ 140 and ≥ 90 mm Hg, respectively, for patients without) was also recorded for both study groups. For patients receiving home service, the above-target levels decreased by 6.3% for diastolic pressure and by 8.1% for systolic pressure from baseline to exit. For patients receiving usual care, the above-target levels increased by 5.6% for diastolic pressure and decreased by 0.5% for systolic pressure. The difference between the above-target percentages for diastolic pressure in the two study groups (-6.3% vs. 5.6%) was statistically significant (difference, 11.9 percentage points [CI, 3.6 to 20.1 percentage points]; $P = 0.006$). The

Figure 4. Difference in mean arterial pressure from baseline to exit using 24-hour ambulatory monitoring in the usual care and home service groups according to change in antihypertensive medication.



Data points represent the mean, shaded areas represent the mean (\pm SE), and error bars represent the mean (\pm SD).

difference between the above-target percentages for systolic pressure in the usual care and home service groups was 7.6 percentage points (CI, -0.6 to 15.8 percentage points).

Heart rate was also measured with the 24-hour ABPM device. Mean heart rate decreased in both study groups. A nonsignificant difference in heart rate was seen when patients who received home service were compared with patients receiving usual care (change in mean heart rate, -0.90 beats/min for home service and -0.18 beats/min for usual care; $P > 0.2$).

To determine whether the decrease in mean arterial pressure was due to differences in the use of medications during the trial, changes in type or dose of medication were recorded. **Figure 4** shows the differences in mean arterial pressure for patients who changed type or dose of antihypertensive medication during the trial. Regardless of study group, mean arterial pressure decreased from baseline to exit in patients who had a medication change. Medication changes, however, were more common in the home service group than in the usual care group. During the course of the trial, medication dose changed in 20 patients in the home service group (33.3%) and 4 patients in the usual care group (6.6%) ($P < 0.001$). The type of antihypertensive medication changed in 24 patients in the home service group

(40.0%) and 17 patients in the usual care group (27.9%) ($P = 0.159$). When a covariate was added to the analysis of covariance model indicating a change in type or dose of medication, the F statistic decreased from 6.256 to 4.572. **Figure 4** also suggests that change in medication was not the only reason for decreases in pressure. In the home service group, mean arterial pressure decreased in patients with and without a medication change.

We did not find a statistically significant difference in the median number of office visits between patients who received the home service and those who received usual care (in both groups, the median number of visits was one). In addition, 73.2% of patients receiving home service and 60.0% of those receiving usual care had at least one office visit during the trial. However, a significant difference was seen in the median length of follow-up time for home service compared with usual care (79 vs. 72 days, respectively). When follow-up time was added as a covariate to the analysis of covariance model, the results for the main end points were similar ($P = 0.009$ for difference in mean arterial pressure, $P = 0.006$ for difference in diastolic pressure, and $P = 0.050$ for difference in systolic pressure). In addition, when only patients who participated in the trial for 4 months or less were included in the analysis, the main outcomes remained statistically significant; differences between the two study groups for mean arterial, diastolic, and systolic pressures yielded P values of 0.023, 0.024, and 0.047, respectively.

Patients were generally satisfied with their medical care. In both groups, 94% of the patients indicated that they agreed or strongly agreed with the statement “I feel that I am receiving good medical care.” In response to the statement “I feel that my doctor had all the information needed to diagnose or treat me,” 96% of the home service group and 89% of the usual care group agreed or strongly agreed. Each physician who participated in the study had approximately the same number of patients receiving home service and usual care. There was no significant effect modification by physician, and the significance of the results did not change when physician was added as a covariate.

DISCUSSION

In this randomized, controlled trial, a telecommunication service was efficacious in decreasing blood pressure in patients with established hypertension. Blood

pressure decreased in patients who used the service, while hypertension worsened in patients receiving usual care. The results were similar regardless of whether pressure was measured by a change in mean 24-hour ABPM readings or by the percentage of blood pressure readings above the target levels. Moreover, the results remained significant after adjustment for various cardiovascular risk factors. Regression to the mean probably does not explain our findings, since multiple blood pressure measurements were used and controlling for baseline blood pressure did not change our results.

Our trial had two main strengths. The intervention did not rely on self-report of blood pressure, and repeated measurements (that is, 37 to 39 readings) at baseline and exit were used to assess usual blood pressure during normal activities. Friedman and colleagues (1) likewise conducted a randomized, controlled trial of a telecommunication system and found that the mean diastolic blood pressure decreased by 5.2 mm Hg in the intervention group, compared with 0.8 mm Hg in the usual care group. Their intervention, however, was subject to the possible bias of self-report. Patients first measured their blood pressure with an automated sphygmomanometer, then telephoned to report their readings by using a touch-tone keypad.

In an uncontrolled trial using a pretest–post-test design, Bondmass and colleagues (2) assessed the usefulness of a transtelephonic monitoring system in managing blood pressure in 33 African-American patients. They found that both mean systolic and diastolic blood pressure significantly decreased within 1 to 3 months. Our study also found benefits in this population. Among African-American patients, mean arterial pressure decreased by almost 10 mm Hg in those receiving home service and increased by more than 5 mm Hg in those receiving usual care. Use of such technology in this population should be investigated further with a larger sample size, particularly since hypertension is considerably more prevalent in African-American patients, affecting approximately one in every three adults (17).

The beneficial effect of home service was due in part to more frequent changes in type or dose of antihypertensive medications. However, mean arterial pressure also decreased in patients receiving home service who did not change antihypertensive medications. Although the mechanisms for this effect are not known, possible reasons include patient-initiated changes in lifestyle fac-

tors or improved adherence to existing prescriptions for antihypertensive medications. The home device had a large, visible display of the pressure readings, and the patient, as well as the physician, received weekly reports.

Accurate and timely information is an essential cornerstone for the provision of quality medical care. Technological advances, which assist physicians in obtaining this information, must be tested and, if efficacious, be made available. Our results suggest that this telecommunication service may be a useful adjunct to antihypertensive therapy and warrants investigation in larger study samples.

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