Effect of Home Blood Pressure Telemonitoring With Self-Care Support on Uncontrolled Systolic Hypertension in Diabetics

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Abstract—Lowering blood pressure reduces cardiovascular risk, yet hypertension is poorly controlled in diabetic patients. In a pilot study we demonstrated that a home blood pressure telemonitoring system, which provided self-care messages on the smartphone of hypertensive diabetic patients immediately after each reading, improved blood pressure control. Messages were based on care paths defined by running averages of transmitted readings. The present study tests the system's effectiveness in a randomized, controlled trial in diabetic patients with uncontrolled systolic hypertension. Of 244 subjects screened for eligibility, 110 (45%) were randomly allocated to the intervention (n=55) or control (n=55) group, and 105 (95.5%) completed the 1-year outcome visit. In the intention-to-treat analysis, mean daytime ambulatory systolic blood pressure, the primary end point, decreased significantly only in the intervention group by 9.1±15.6 mm Hg (SD; $P<0.0001$), and the mean between-group difference was 7.1±2.3 mm Hg (SE; $P<0.005$). Furthermore, 51% of intervention subjects achieved the guideline recommended target of <130/80 mm Hg compared with 31% of control subjects ($P<0.05$). These improvements were obtained without the use of more or different antihypertensive medications or additional clinic visits to physicians. Providing self-care support did not affect anxiety but worsened depression on the Hospital Anxiety and Depression Scale (baseline, 4.1±3.76; exit, 5.2±4.30; $P=0.014$). This study demonstrated that home blood pressure telemonitoring combined with automated self-care support reduced the blood pressure of diabetic patients with uncontrolled systolic hypertension and improved hypertension control. Home blood pressure monitoring alone had no effect on blood pressure. Promoting patient self-care may have negative psychological effects. **(*Hypertension*. 2012;60:00.)**

Key Words: home blood pressure ■ hypertension ■ diabetes mellitus ■ blood pressure ■ self-care ■ depression

Lowering blood pressure (BP) reduces the risk of cardiovascular and renal disease.[1] However, in the majority of hypertensive patients, particularly those with diabetes mellitus, BP is poorly controlled,[2] despite excellent access to health care and frequent visits to the physician.[3] Such results spurred development of chronic care models that engage patients in their own care.[4]

Home BP monitoring promotes self-care, improves BP control, and is endorsed by several prominent organizations as an adjunct to hypertension treatment.[5] A recent meta-analysis suggested that adding telemonitoring to self-measurement of BP is even more effective in reducing BP.[6] In the telemonitoring studies, however, a physician or member of the healthcare team reviewed the transmitted data and contacted the patients to adjust antihypertensive treatment.[7–13] Thus, it is unclear whether the better outcome was related to the use of a telemonitoring system or the increased involvement of healthcare providers in the treatment process.

Previously we reported the development of a home BP telemonitoring system that provided self-care messages on the smartphone of patients immediately after each reading.[14] Messages were based on care paths defined by running averages of transmitted readings. The system was designed to

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A.G.L. had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. None of the other authors has real or perceived conflicts of interest related to the study.

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eliminate the need for a health provider to review home BP readings before management decisions were made. In a pilot study, the system was highly effective in lowering the BP of hypertensive diabetic patients.[14] This study extends our preliminary work by comparing its effectiveness in a randomized, controlled trial to home BP monitoring without self-care support. The psychological effects of promoting patient self-care were also examined.

Methods

Study Design

The study was a prospective, randomized, open, blinded primary end-point trial, conducted in the offices or clinics of physicians practicing in metropolitan Toronto. Men and women, ≥30 years of age, with diabetes mellitus were recruited from family physicians' office or hospital-based speciality clinics and advertisements in public areas of hospitals. All of the potential participants underwent 24-hour ambulatory BP monitoring using the validated oscillometric SpaceLabs 90207 recorders (SpaceLabs Healthcare, Inc, Issaquah, WA). The recorders were programmed to measure BP at 20-minute intervals during the day and every 30 minutes at night. Participants were instructed to record the time they went to sleep at night and awoke in the morning. Individuals fulfilling the study's eligibility criteria were randomly allocated to home BP monitoring with or without self-care support. Group allocation schedule was based on blocks of 4 and 6 patients randomly arranged and administered by a person not directly involved in the study. Research ethics board of the 5 participating hospitals approved the study protocol by June 2008, and all of the participants gave written informed consent. The trial was completed in June 2010.

Study Subjects

Diabetic patients with uncontrolled systolic hypertension, defined as a mean daytime systolic BP of ≥130 mm Hg on ambulatory BP monitoring, were eligible unless they had severe or end-stage organ disease (liver, kidney, heart, and lung), a history of diabetic ketoacidosis, any illness with expected survival <1 year, severe cognitive impairment, mental illness or disability, clinically significant cardiac arrhythmia, symptomatic orthostatic hypotension, or were pregnant, unsuitable for participation in the opinion of their primary care physician, or not fluent in English. Subjects were not required to be familiar with computers or have access to the Internet. All of the eligible subjects were asked to monitor their BP at home daily for 7 days, taking 2 readings in the morning and 2 readings in the evening using a validated Bluetooth-enabled home BP device (Life Source UA-767, A&D Medical, San Jose, CA). The device was paired with a smartphone that automatically transmitted every reading to a central server for processing and storage. At the end of 7 days they returned the equipment to the study staff. Control group subjects were then issued with an identical-appearing home BP device without built-in Bluetooth capability for use during the study. Each participant provided medical and demographic information, identified their primary care physician, and completed the Anxiety Sensitivity Index,[15] Hospital Anxiety and Depression Scale,[16] and comfort with self-measurement of BP questionnaires. The former 2 measures have previously undergone psychometric validation,[15,16] and the internal reliability of the scale items of the latter measure, which was created purposely for the study, was excellent (α of 0.86 within our sample).

Telemonitoring Self-Care Support System

We designed, developed, and piloted the system with no commercial support.[14] The patient component consisted of a custom software application running on a BlackBerry smartphone (Research In Motion, Inc, Waterloo, Ontario, Canada) that was paired with a Bluetooth-enabled home BP monitoring device. BP readings were automatically transmitted by the smartphone to application servers, which processed the information for trends and applied decisions rules. The reporting and alerting component of the system sent a self-care message to the screen of the patients' smartphone immediately after each reading. Messages related to the control of hypertension were based on care paths defined by running averages of transmitted readings. They instructed patients whose BP fell outside the target range (predefined low and high values) to take additional BP readings, which were then used to provide advice on the urgency to make a follow-up visit with their physician. The message to patients whose BP was within the target range indicated that their hypertension was under control and that they should continue to monitor their BP as recommended. Nonadherence to the preset home BP measurement schedule triggered an automated voice message that was sent to the patients' home telephone, requesting them to check the smartphone for a message. Critical alerts were automatically sent to their physician's office by fax whenever BP readings exceeded predetermined threshold values. Simultaneously an automated voice message was left on the patients' home telephone advising them to check their smartphone for a message, which instructed them to contact their doctor immediately for advice. On the day before the office visit to their physician, patients called a dedicated telephone number to initiate the automated process to fax a 1-page patient summary report to their physician. This process could also be initiated by the physicians' office. The summary report contained a graphic presentation of readings with dates, the current 30-day average of transmitted BP readings, the previous 30-day average, and the number of readings used to derive the averages. There were no treatment recommendations. All of the electronic transmissions were encrypted and deidentified to ensure confidentiality of the personal health information.

Study Protocol

Participants in both groups were taught how to measure their BP correctly, instructed to measure their BP 2 days per week twice in the morning and twice in the evening, provided with a validated home BP monitoring device with appropriate-sized upper arm cuff, and given a booklet with detailed information on the self-measurement of BP, treatment of hypertension, and goals of therapy. Their primary care physician was given an outline of the study's objectives and BP treatment goal, asked to provide relevant medical information, and given a copy of the 24-hour ambulatory BP monitoring report. In both groups, treatment decisions, including medication adjustments and changes in lifestyle, were made by the patients' primary care physician.

Self-care support patients were taught how to use the telemonitoring system, review past readings on their smartphone and the study-specific Web site (these activities were optional), and generate a 1-page patient summary report. They were instructed to take their smartphone to all doctor visits. The patient's physician was shown the patient summary report, asked to indicate the low and high threshold BP values for critical alert messages (default options were provided), and taught how to change the threshold values. Optionally, they were shown how to visit the study's password-protected Web site. The research team did not contact the subjects in either group or their physician during the course of the study.

End Points

End point assessments were undertaken 1 year after randomization. The primary end point was the change in mean daytime ambulatory systolic BP. Secondary end points included changes in 7 days of home BP readings, psychological questionnaire responses, and prescribed antihypertensive medications. BP control was defined as <130/80 mm Hg on 24-hour ambulatory BP monitoring. Information on the number of hypertension-related office visits made by patients during the study year was gathered from the billing records of their physicians supplemented in cases of missing data by patient self-report. Information on the dates and number of transmitted readings, reminder messages, and alerts was ascertained from data in the application servers. Full adherence with the home BP measurement schedule (100%) in the self-care support group was defined as a minimum of 8 readings

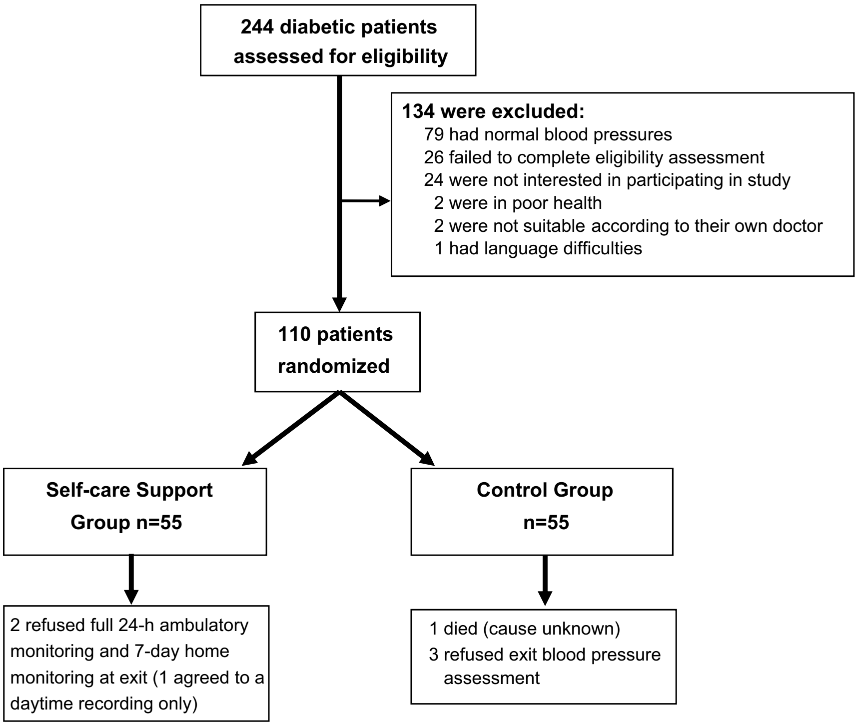

Figure. Flowchart of study subjects.

per week. No information on home BP monitoring use in the control group was collected.

Statistical Methods

The study was designed to have a statistical power of 80% to detect a 4-mm Hg reduction in mean daytime systolic BP in the self-care support group, as compared with control group, using a 2-tailed test with an α level of 5%. In the calculation we used an SD of the difference of 7.16 mm Hg that was obtained by pooling estimates of studies that reported it on repeated ambulatory BP monitoring on 2 separate occasions. Assuming a 10% dropout rate, we estimated a total sample size of 113 patients (56 per group). To fully exploit the repeated BP measurements in the ambulatory recordings and home BP assessments, a mixed-model ANCOVA was used to assess continuous variables, using baseline BP and body mass index as continuous variables and group membership as a discrete variable. We specified random subject effects and fixed treatment effects. Linear contrasts were used to test for group differences. BP status (controlled or not controlled) was analyzed using logistic regression with baseline BP and body mass index as continuous covariates and group membership as a discrete variable. We compared the distribution of the number of medications in the 2 groups using the Wilcoxon signed-rank test. Because of violations in normality distributions, the Hospital Anxiety and Depression Scale depression scores were normalized using a square-root transformation. All of the individuals with partial or complete outcome data were included in the final analysis. Results are expressed as means and SD, median and interquartile range, or proportions, unless otherwise specified. A 2-sided P value <0.05 was considered statistically significant.

Results

Study Participants

Of 244 diabetic patients screened for uncontrolled systolic hypertension, 110 subjects fulfilled the trial's eligibility criteria and were randomized to the self-care support group (n=55) or control group (n=55). Reasons for ineligibility and failure to complete the study are outlined in the flowchart of the study population (Figure). There were 96 family physicians and 16 specialists involved in providing care to study subjects.

Baseline Characteristics

The demographic and clinical characteristics of study participants at entry are listed in Tables 1 and S1 (please see the online-only Data Supplement). There were no significant differences between groups for these features apart from a borderline higher percentage of subjects with dyslipidemia in the self-care support group. There was also no difference in the mean number of antihypertensive medications per patient (Table 1) or drug classes (Table S2).

Blood Pressure

At 12 months, mean daytime ambulatory systolic BP, the primary end point, decreased significantly only in the self-care support group by 9.1±15.6 mm Hg (SD; $P<0.0001$), and the mean between-group difference was 7.1±2.3 mm Hg (SE; $P<0.005$). There was also a significant decrease in mean daytime diastolic BP, 24-hour BP, and night-time BP from baseline in the self-care group and no significant changes in the control group (Table 2). The same results were observed using 7 days of self-measured BP at home instead of ambulatory BP monitoring as the outcome measure (Table S3). Furthermore, 51% of self-care support subjects achieved the guideline recommended target of <130/80 mm Hg compared with 31% of control subjects ($P<0.05$).

Intervention Effects

There were no significant changes or between-group differences in the total number of antihypertensive medications at exit (−0.15±1.19 in self-care support group and

Table 1. Baseline Characteristics

Variable	Control Group (n=55)	Self-Care Support Group (n=55)
Age, y	63.1±9.0	62.7±7.8
Men, %	62	49
BMI, kg/m^2	29.8±5.5	31.9±7.9
Ethnicity, %		
White/European	60.0	70.9
African/West Indian	18.1	14.6
Asian	12.7	7.2
Hispanics	1.8	5.5
Others	7.4	1.8
Systolic blood pressure, mm Hg		
24-h	139.9±10.6	139.4±11.6
Daytime	142.6±10.2	142.7±10.9
Nighttime	132.8±14.8	130.8±16.4
Diastolic blood pressure, mm Hg		
24-h	75.4±8.7	73.9±10.6
Daytime	77.9±9.2	76.3±10.5
Nighttime	69.6±9.5	67.7±12.1
On antihypertensive drugs, %	89.1	89.1
Mean No. of antihypertensive drugs per patient, n	2.36±1.54	2.55±1.64
Hemoglobin A1C	0.075±0.012	0.074±0.015
Antihyperglycemic agents, n (%)	54 (98.2)	53 (96.4)
Cardiovascular disease, %		
Stroke or transient ischemic attack	7.4	5.5
Coronary artery disease	14.5	9.1
Peripheral vascular disease	0.0	5.5
Serum creatinine, μmol/L	88.9±31.0	101.0±58.6
Urine albumin/creatinine, g/mol	30.7±107.2	33.2±77.1

0.00±1.26 in control group) or specific drug classes (Table S4). In addition, there was no significant difference in the number of visits to family physicians or combined visits to family physicians and specialists (median number of 6 in self-care support group and 7 in control group), even when the small percentage of self-reported data was excluded (Table 5S). Information on the experience of using the self-care support system is summarized in Table S6. Of the total (critical and noncritical) alerts, 75.3% were sent because average BP readings were above pre-established threshold values (Table S7). There were 3 high and 2 low critical alerts.

Psychological Variables

Psychological variables at baseline and outcome are summarized by group in Table 3. Using the self-care support system did not affect anxiety but worsened depression (P=0.014), and the between-group effect on depression was significant (P=0.032). Comfort with home BP monitoring decreased significantly in both groups (P<0.001), with no between-group difference.

Discussion

The study demonstrated that home BP telemonitoring combined with self-care support reduced the BP of diabetic patients with uncontrolled systolic hypertension and improved hypertension control. Our system was fully automated, and self-care messages, which were sent immediately after each BP reading, were based on care paths defined by running averages of transmitted readings. The BP results confirmed our pilot study findings[14] and were the same whether 24-hour ambulatory BP monitoring or 7-day home BP measurements were used to assess outcome. In the self-care support group, 51% achieved the guideline-recommended BP target of <130/80 mm Hg,[1] which was substantially higher than that of 37.5% among treated hypertensive diabetic patients in a recent BP survey in the United States.[2]

Patients with chronic conditions inevitably engage in self-care activities.[4] In the case of hypertension, this may take the form of self-measuring BP, making lifestyle changes, or experimenting with prescribed treatment. However, for self-care activities to be effective they need to be based on reliable information and a meaningful collaboration with healthcare providers in an overarching framework of maintaining autonomy.[4] Our study confirmed this precept. We found, as have others, that better hypertension control can be achieved when self-measurement of BP is part of a plan that increases patient

Table 2. Change in Ambulatory Blood Pressure From Baseline to Outcome

Variable	Control Group (n=51), Mean±SD, H_0:Δ_c=0	Self-Care Support Group (n=54), Mean±SD, H_0:Δ_s=0*	Between Group Comparisons Mean±SE, H_0:Δ_s= Δ_c
Systolic blood pressure			
24-h	−1.7±12.1, P=0.33	−8.7±14.7, P<0.001	6.8±2.4, P=0.005
Daytime	−1.5±12.2, P=0.38	−9.1±15.6, P<0.001	7.1±2.3, P=0.003
Nighttime	−2.3±14.9, P=0.29	−6.7±15.9, P=0.003	4.7±2.8, P=0.098
Diastolic blood pressure			
24-h	−1.1±6.8, P=0.24	−4.2±9.3, P=0.002	3.6±1.3, P=0.006
Daytime	−1.3±6.6, P=0.16	−4.6±9.2, P<0.001	3.9±1.3, P=0.003
Nighttime	−1.5±9.1, P=0.26	−2.9±10.7, P=0.051	2.3±1.6, P=0.16

*One patient in the self-care support group agreed to have a daytime ambulatory recording only.

Table 3. Change in Psychological Variables From Baseline to Outcome

Variable, Mean±SD	Control Group	Within-Group Effect Over Time	Self-Care Support Group	Within-Group Effect Over Time	Between-Group Comparisons
HADS, anxiety	(n=48)		(n=51)		
Baseline	6.6±4.69	t(47) = 0.33, P=0.74	6.0±3.27	t(50) = −0.33, P=0.75	F(1, 96) = 0.09, P=0.76
12-mo	6.4±4.90		6.1±3.77		
HADS, depression	(n=48)		(n=51)		
Baseline	4.7±4.23	t(47) = 0.61, P=0.55	4.1±3.76	t(50) = −2.54, P=0.014	F(1, 96) = 4.76, P=0.032
12-mo	4.5±4.43		5.2±4.30		
ASI, anxiety	(n=47)		(n=49)		
Baseline	26.0±14.89	t(46) = 2.22, P=0.032	22.4±11.47	t(48) = 0.59, P=0.56	F(1, 93) = 0.41, P=0.52
12-mo	23.0±14.55		21.6±11.25		
Comfort with BP self-monitoring	(n=47)		(n=47)		
Baseline	49.6±13.00	t(46) = 4.01, P<0.001	50.7±10.28	t(46) = 3.66, P=0.001	F(1, 91) = 0.81, P=0.37
12-mo	40.8±18.63		44.3±15.85		

HADS indicates Hospital Anxiety and Depression Scale; ASI, Anxiety Sensitivity Index; BP, blood pressure.

engagement in making management decisions. Previous studies achieved good results by directly linking home BP monitoring with some form of regular professional supervision, such as telecounseling[8] or implementing action plans established by a pharmacist,[9] nurse,[10–12] or family physician.[7,13] These interventions required a health professional to examine all of the transmitted readings for trends and extreme values and to contact patients with a management plan. In this study we were able to independently test the contribution of home BP telemonitoring by automating these activities, including the process of responding immediately to critical BP alerts.

Our study was not specifically designed to study the mechanisms accounting for the better hypertension control. Telemonitoring certainly promotes self-care, may improve medication adherence,[17] and has been used successfully to intensify antihypertensive drug treatment.[9,13] However, several telemonitoring studies, including our own, have shown that better outcomes can be achieved without a change in the number or types of antihypertensive medications prescribed or in the proportion of subjects whose treatment was adjusted during the study.[8,10,17] In one study this improvement was related to better adherence to antihypertensive medications.[17] Another study showed a decrease in BP in the home monitoring service group irrespective of whether there was a medication change.[7] It seems likely that multiple factors, which have not yet been systematically evaluated, are playing an important role in reducing BP and achieving target.

In keeping with other home BP monitoring studies of 1-year duration,[18–20] we found that self-measurement of BP on its own failed to lower BP. This finding is not unexpected based on results of attitude surveys of primary care physicians and patients on home BP monitoring. In a survey conducted several years ago, American physicians indicated their reluctance to use home BP monitoring results as the primary means of making management decisions.[21] In Ontario, only 19% of physicians preferred home BP monitoring to office or ambulatory readings to guide treatment decisions.[22] In France, only 36% of general practitioners who encouraged their patients to do home BP monitoring actually used the readings to adjust antihypertensive treatment.[23] Furthermore, the attitude of French physicians did not change from 2004 to 2009, despite strong recommendations of national and international guideline committees to incorporate home BP monitoring into making treatment decisions.[5] Patients also have an ambivalent attitude toward home BP monitoring. Although the majority of patients have access to a home BP monitoring device and are encouraged by their physician to use them, only a third actually communicated the results to their doctor. Even more disturbingly, ≈40% of those with alarming readings did nothing specific about the results.[21] These findings suggest that the use of home BP monitoring in ongoing clinical management of hypertension is still not well accepted by physicians and that home BP monitoring without linkage to an effective support system does not provide any direct benefits for patients.

A potential disadvantage of home BP monitoring is the possibility that patients may become preoccupied with measuring their BP or for those with an anxiety disorder their symptoms may worsen.[5] Like others,[13] we found no change in anxiety score with telemonitoring. However, we did observed a significant increase in depression score in the self-care support group. The clinical significance of this observation is unclear. The discrepancy between the anxiety and depression effects might suggest that the depression effect is a chance finding. However, it is known that selective self-focused attention to bodily symptoms can have unexpected negative psychological consequences.[24] It is possible that the intervention contributed to depression by increasing participants' attention to their hypertension, even if there was evidence of improved BP control. Future studies will need to first replicate our finding and, if confirmed, to find ways to mitigate the effect.

The study's limitations need acknowledgement. First, interventions were not masked. However, the same results were obtained using 2 different methods to assess BP outcomes. Second, the results may not be generalizable to hypertensive patients at lower risk for cardiovascular disease or whose hypertension is easier to control. Third, the study was not designed to examine in detail mechanisms accounting for the better outcome in the self-care support group. This now needs to be undertaken. Fourth, the study did not measure adherence to the recommended home BP measurement schedule in the control group, record office BP readings, or assess changes in weight and hemoglobin A1C. Finally, there was no formal cost-effective analysis. Nonetheless, in designing the system, we used commercially available hardware and communicated directly with patients as cost-saving measures.[14] In the future, even greater savings may be achieved by using the patients' own smartphone, as smartphones are on track to outnumber conventional cell phones in the United States in 2012.[25]

Perspectives

Home BP telemonitoring combined with automated self-care support significantly reduced uncontrolled systolic hypertension in diabetic patients without the use of more or different antihypertensive medications or additional clinic visits to physicians. The mechanisms accounting for the improvement need to be explored further. Home BP monitoring without linkage to a patient support system had no effect on BP. The finding that promoting self-care may have negative psychological effects requires further study. A major reason for the failure of physicians to fully endorse the use of home BP monitoring is the possibility of adverse behavioral effects associated with its use.[21–23] Finally, despite reminder messages, there was a decline over time in the number of BP readings per week in the self-care support group, suggesting a fatigue effect with this intervention. The finding highlights the need for changes in or additions to the current system to counter this negative trend.

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References

1. America Diabetes Association. Standards of medical care in diabetes-2011. *Diabetes Care*. 2011;34(suppl 1)S11–S61.
2. Ong KL, Cheung BMY, Man YB, Lau CP, Lam KSL. Prevalence, awareness, treatment, and control of hypertension among United States adults 1999–2004. *Hypertension*. 2007;49:69–75.
3. Hyman DJ, Pavlik VN. Characteristics of patients with uncontrolled hypertension in the United States. *N Engl J Med*. 2001;345:479–486.
4. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. *JAMA*. 2002;288: 2469–2475.
5. Parati G, Pickering TG. Home blood-pressure monitoring: US and European consensus. *Lancet*. 2009;373:876–878.
6. Agarwal R, Bills JE, Hecht TJW, Light RP. Role of home blood pressure monitoring in overcoming therapeutic inertia and improving hypertension control. *Hypertension*. 2011;57:29–38.
7. Rogers MAM, Small D, Buchan DA, Butch CA, Stewart CM, Krenzer BE, Husovsky HL. Home monitoring service improves mean arterial pressure in patients with essential hypertension: a randomized, controlled trial. *Ann Intern Med*. 2001;134:1024–1032.
8. Artinian NT, Flack JM, Nordstrom CK, Hockman EM, Washington OGM, Jen K-LC, Fathy M. Effects of nurse-managed telemonitoring on blood pressure at 12-month follow-up among urban African Americans. *Nurs Res*. 2007;56:312–322.
9. Green BB, Cook AJ, Ralston JD, Fishman PA, Catz SL, Carlson J, Carrell D, Tyll L, Larson EB, Thompson RS. Effectiveness of home blood pressure monitoring, web communication, and pharmacist care on hypertension control: a randomized controlled trial. *JAMA*. 2008;299: 2857–2867.
10. Parati G, Omboni S, Albini F, Piantoni L, Giuliano A, Revera M, Illyes M, Mancia G. on behalf of the TeleBPCare study group. Home blood pressure telemonitoring improves hypertension control in general practice: the TeleBPCare Study. *J Hypertens*. 2009;27:198–203.
11. Shea S, Weinstock RS, Teresi JA, Palmas W, Starren J, Cimino JJ, Lai AM, Field L, Morin PC, Goland R, Izquierdo RE, Ebner S, Silver S, Petkova E, Kong J, Eimicke JP, for the IDEATel Consortium. A randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved patients with diabetes mellitus: 5 year results of the IDEALTel Study. *J Am Med Inform Assoc*. 2009;16:446–456.
12. Rinfert S, Lussier M-T, Peirce A, Duhamel F, Cossette S, Lalonde L, Tremblay C, Guertin M-C, LeLorier J, Turgeon J, Hamet P, for the LOYAL Study investigators. The impact of a multidisciplinary information technology-supported program on blood pressure control in primary care. *Circ Cardiovasc Qual Outcomes*. 2009;2:170–177.
13. McManus RJ, Mant J, Bray EP, Holder R, Jones MI, Greenfield S, Kaambwa B, Banting M, Bryan S, Little P, Williams B, Hobbs FDR. Telemonitoring and self-management in the control of hypertension (TASMINH2): a randomised controlled trial. *Lancet*. 2010;376: 163–172.
14. Logan AG, McIsaac WJ, Tisler A, Irvine MJ, Saunders A, Dunai A, Rizo CA, Feig DS, Hamill M, Trudel M, Cafazzo JA. Mobile phone-based remote patient monitoring system for management of hypertension in diabetic patients. *Am J Hypertens*. 2007;20:942–948.
15. Peterson RA, Reiss S., *Anxiety Sensitivity Index Manual,* 2nd ed. Worthington, OH: IDS Publishing Corporation; 1992.
16. Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale: an updated literature review. *J Psychosom Res*. 2002;52:69–77.
17. Friedman RH, Kazis LE, Jette A, Smith MB, Stollerman J, Torgerson J, Carey K. A telecommunications system for monitoring and counselling patients with hypertension: impact on medication adherence and blood pressure control. *Am J Hypertens*. 1996;9:285–292.
18. Staessen JA, Hond ED, Celis H, Fagard R, Keary L, Vandenhoven G, O'Brien ET, for the Treatment of Hypertension Based on Home or Office Blood Pressure (THOP) Trial investigators. Antihypertensive treatment based on blood pressure measurement at home or in the physician's office. *JAMA*. 2004;291:955–964.
19. Verberk WJ, Kroon AA, Lenders JWM, Kessels AGH, van Montrans GA, Smit AJ, van der Kuy P-HM, Nelemans PJ, Rennenberg RJMW, Grobbee DE, Beltman FW, Joore MA, Brunenberg DEM, Dirksen C, Thien T, de Leeuw PW, for the home versus office measurement, reduction of unnecessary treatment study investigators. Self-measurement of blood pressure at home reduces the need for antihypertensive drugs: a randomized, controlled trial. *Hypertension*. 2007; 50:1019–1025.
20. Godwin M, Lam M, Birtwhistle R, Delva D, Seguin R, Casson I, MacDonald S. A primary care pragmatic cluster randomized trial of the use of home blood pressure monitoring on blood pressure levels in hypertensive patients with above target blood pressure. *Fam Pract*. 2010;27:135–142.

21. Cheng C, Studdiford JSA, Diamond JJ, Chambers CV. Primary care physician beliefs regarding usefulness of self-monitoring of blood pressure. *Blood Press Monit*. 2003;8:249–254.
22. Logan AG, Dunai A, McIsaac WJ, Irvine MJ, Tisler A. Attitudes of primary care physicians and their patients about home blood pressure monitoring in Ontario. *J Hypertens*. 2008;26:446–452.
23. Boivin J-M, Tsou-Gaillet T-J, Fay R, Dobre D, Rossignol P, Zannad F. Influence of the recommendations on the implementation of home blood pressure measurement by French general practitioners: a 2004–2009 longitudinal survey. *J Hypertens*. 2011;29:2105–2115.
24. Schwarzer R, Wicklund RA, eds. *Anxiety and Self-Focussed Attention.* Chur, Switzerland: Harwood Academic Publishers; 1991.
25. Entner R., Smartphones to overtake feature phones in U.S. by 2011. http://blog.nielsen.com/nielsenwire/consumer/smartphones-to-overtake-feature-phones-in-u-s-by-2011/. Accessed June 10, 2011.

Novelty and Significance

What Is New?

- Research included development of a fully automated self-care support system for home BP monitoring.
- We focused on using smartphone technology to facilitate self-care support.
- We also focused on assessing the psychological effects of promoting self-care.

What Is Relevant?

- Control of hypertension is still poor among hypertensive diabetic patients.
- Improving BP control significantly reduces cardiovascular disease risk.
- Self-care support is a key component of chronic disease models.

Summary

New system improved hypertension control of diabetic patients with uncontrolled systolic hypertension. Home BP monitoring alone had no effect on BP. Promoting patient self-care may have negative psychological effects.

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EFFECT OF HOME BLOOD PRESSURE TELEMONITORING WITH AUTOMATED SELF-CARE SUPPORT ON UNCONTROLLED SYSTOLIC HYPERTENSION IN DIABETIC PATIENTS

Short title:

Telemonitoring with automated self-care support

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Table S1. Additional information on baseline characteristics

Variable	Control group n=55	Self-care support group n=55
Current smokers, %	7.3	3.6
Dyslipidemia, %*	74.1	89.1
Lipid-lowering medications, n (%)	39 (70.9)	38 (69.1)
Aspirin, n (%)	32 (58.2)	30 (54.5)

* indicates statistically significant difference (p-value = 0.037)

Table S2. Number of antihypertensive drugs of each class at baseline, by group

Drug class	Number of drugs	Control group n=55	Self-care support group, n=55	p-value*
All antihypertensive drug, n (%)	0	6 (10.9)	6 (10.9)	0.39
	1	13 (23.6)	10 (18.2)	
	2	9 (16.4)	6 (10.9)	
	3	16 (29.1)	18 (32.7)	
	4	3 (5.5)	10 (18.2)	
	5	7 (12.7)	1 (1.8)	
	6	0 (0.0)	3 (5.5)	
	7	1 (1.8)	1 (1.8)	
Angiotensin converting enzyme inhibitors, n (%)	0	20 (36.4)	22 (40.0)	0.56
	1	33 (60.0)	33 (60.0)	
	2	2 (3.6)	0 (0.0)	
Angiotensin receptor blockers, n (%)	0	39 (70.9)	34 (61.8)	0.37
	1	16 (29.1)	22 (38.2)	
Beta blockers, n (%)	0	37 (67.3)	36 (65.5)	0.92
	1	18 (32.7)	19 (34.5)	
Calcium channel blockers, n (%)	0	26 (47.3)	28 (50.9)	0.68
	1	28 (50.0)	27 (49.1)	
	2	1 (1.8)	0 (0.0)	
Diuretics, n (%)	0	32 (58.2)	26 (47.3)	0.18
	1	20 (36.4)	22 (40.0)	
	2	3 (5.5)	7 (12.7)	
Nitroglycerin, n (%)	0	54 (98.2)	55 (100)	0.75
	1	1 (1.8)	0 (0.0)	
Smooth muscle blockers, n (%)	0	55 (100)	54 (98.2)	0.75
	1	0 (0.0)	1 (1.8)	
Alpha-agonists, n (%)	0	53 (96.4)	52 (94.5)	0.84
	1	2 (3.6)	3 (5.5)	
Alpha-blockers, n (%)	0	52 (94.5)	49 (89.1)	0.41
	1	3 (5.5)	6 (10.9)	

* exact Wilcoxon test (mid-p corrected)

Table S3. Change in 7-days of self-measured blood pressure at home from baseline to outcome

Variable		**Control group n=51 mean±sd**	**Self-care support group n=53 mean±sd**	**Between group comparisons mean±se, H_0:$\Delta_s = \Delta_c$**
Systolic blood pressure	Baseline	139.7±14.1	138.7±14.6	9.0±2.4
	Outcome	139.1±15.7	129.6±13.71	$p<0.001$
	Change (Δ)	-0.5±12.7	-9.1±13.9	
	H_0: Δ=0	$p=0.77$	$p<0.001$	
Diastolic blood pressure	Baseline	76.4±9.4	76.3±11.1	4.0±1.3
	Outcome	75.7±10.8	71.7±9.1	$p=0.004$
	Change (Δ)	-0.7±6.5	-4.6±8.1	
	H_0: Δ=0	$p=0.44$	$p<0.001$	

Table S4. Comparison between groups of change in number of antihypertensive drugs

Variable	Change from baseline (number of drugs)	Control group (n=51)	Self-care support group (n=54)	p-value
All antihypertensive drugs, n	-5	1	0	0.33
	-4	0	1	
	-3	3	3	
	-2	0	1	
	-1	6	8	
	0	25	29	
	+1	12	10	
	+2	4	1	
	+3	0	1	
	mean ± sd	0.00 ± 1.26	-0.15 ± 1.19	
Angiotensin converting enzyme inhibitors, n	-1	9	10	0.62
	0	38	42	
	+1	4	2	
	mean ± sd	-0.09 ± 0.48	-0.15 ± 0.45	
Angiotensin receptor blockers, n	-1	1	3	0.32
	0	45	48	
	+1	5	3	
	mean ± sd	+0.07 ± 0.33	0.00 ± 0.33	
Beta blockers, n	-1	5	2	0.36
	0	46	52	
	+1	0	0	
	mean ± sd	-0.09 ± 0.29	-0.04 ± 0.19	
Calcium channel blockers, n	-1	4	3	0.75
	0	44	47	
	+1	3	4	
	mean ± sd	-0.02 ± 0.36	+0.02 ± 0.36	
Diuretics n	-2	0	2	0.24
	-1	1	5	
	0	40	38	
	+1	10	8	
	+2	0	1	
	mean ± sd	+0.16 ± 0.42	+0.02 ± 0.68	
Nitroglycerin, n	-1	1	0	0.38
	0	50	53	
	+1	0	1	
	mean ± sd	-0.02 ± 0.13	+0.02 ± 0.13	
Smooth muscle blockers, n	-1	0	1	0.75
	0	51	53	
	+1	0	0	
	mean ± sd	-	-0.02 ± 0. 13	

Alpha-agonists, n	-1	1	0	0.75
	0	50	54	
	+1	0	0	
	mean ± sd	-0.02 ± 0.13	-	
Alpha-blockers, n	-1	3	2	0.95
	0	45	50	
	+1	3	2	
	mean ± sd	0.00 ± 0.33	0.00 ± 0.27	

Table S5a. Number of general practitioner (GP) Visits

Variable		Control Group n=49	Self-care Support Group n=51	p-value*
GP Visits	median	6	4	0.19
	IQR†	3-8	3-7	
GP+Other Caregiver Visits	median	7	6	0.63
	IQR	5-9	4-9	

* exact Wilcoxon test; † IQR = interquartile range

Table S5b. Number of GP Visits (excluding self-reported data†)

Variable		Control Group n=47	Self-care Support Group n=45	p-value*
GP Visits	median	6	4	0.16
	IQR	3-8	3-7	
GP+Other Caregiver Visits	median	7	6	0.63
	IQR	5-9	4-9	

* exact Wilcoxon test

† the number of GP visits for eight patients with self-reported data did not differ significantly from the 92 patients with data was provided by the GP (median 5 vs 5, p=0.82). Similarly there was no difference when the number of other caregiver visits were included (median 5 vs. 6.5, p=0.69).

Table S6. Information on the use of the telemonitoring self-care support system

Variable	Result
Number of readings per week per patient, mean ± sd	10.8 ± 6.7
Number of subjects with decreasing trend in self-measurement of blood pressure, n (%)	40 (72.7)
Adherence rate with home blood pressure measurement schedule*, as % per week, mean ± sd	65.4 ± 30.0
Overall slope of adherence to self-measurement blood pressure schedule, as % per week ± se	-1.8 ± 0.4
Total number of alerts per patient, mean ± sd	1.9 ± 3.9
Alerts to patients	1.8 ± 3.7
Critical alerts to physicians	0.1 ± 0.4
Number of measurement reminders per patient per 4 weeks, mean ± sd	1.8 ± 0.9
Proportion of patients calling the server to send a fax to their own doctor, %	85.5
Number of fax reports sent to doctors per patient, mean ± sd	3.3 ± 3.6

* full adherence (100%) was defined as a minimum of 8 readings per week

Table S7. Alerts to patients and physicians in the self-care support group*

Alerts	Range Minimum Maximum	Mean ± SD
Total alerts	0 to 18	1.91 ± 3.88
Alerts to patients	0 to 16	1.82 ± 3.69
Alerts to physicians	0 to 2	0.09 ± 0.35
Total high alerts	0 to 18	1.44 ± 3.70
To patients only	0 to 16	1.38 ± 3.51
To physicians only	0 to 2	0.05 ± 0.30
Total low alerts	0 to 9	0.47 ± 1.67
To patients only	0 to 9	0.44 ± 1.56
To physicians only	0 to 1	0.04 ± 0.19

* alerts were automatically sent if average blood pressure exceeded pre-established threshold values; high alerts, if values were above the threshold, and low alerts, if values were below the threshold.