A pilot study of hypertension management using a telemedicine treatment approach

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We recruited 78 men and 94 women to investigate if the proportion of subjects with well-controlled home blood pressure levels could be increased when treatment was guided by smartphone-based telemonitoring. All patients were prescribed one to three antihypertensive drugs. The Accumbo smartphone telemonitoring application was downloaded to the Iphones of the participants and home blood pressure information was gathered from semi-automatic oscillometric blood pressure-recorders by Bluetooth. The study physician adjusted the medications based on home blood pressure for 3 months. home blood pressure was controlled (<135/<85 mmHg) in 55 participants at baseline and in 56 subjects after 3 months (Chi-square $P = 0.91$). The 117 patients with initially uncontrolled home blood pressure had a drop in home blood pressure (from 138.0 ± 9.0/91.3 ± 6.5 mmHg to 133.4 ± 8.0/88.6 ± 6.1 mmHg, $P < 0.001$) and prescribed antihypertensive drugs increased from 1.71 ± 0.94/day to 2.00 ± 0.92/day, $P < 0.0001$. Thus, while the proportion of participants with controlled home blood pressure remained unchanged, the home blood pressure levels were lowered in participants who had uncontrolled home blood pressure at study start. *Blood Press Monit* **25: 18–21**

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Introduction

Blood pressure (BP) values obtained by self-measurement at home have been shown to predict cardiovascular prognosis equally well as, or better than, measurements obtained in the clinic in observational studies [1–7]. In recent trials, in which the target BP was set to be lower in the home BP (HBP) measurement group than in the office BP (OBP) measurement group, treatment titration according to HBP led to lower ambulatory day-time SBP [8] and to lower OBP [9]. Less is known, however, about the impact on BP control of HBP combined with telemonitoring provided via smartphone applications. Therefore, the primary aim of the present non-controlled pilot study was to investigate whether 3 months of HBP measurements combined with telemonitoring provided via a smartphone application increased the proportion of patients with controlled hypertension (HBP < 135/85 mmHg).

Methods

Recruitment took place in Stockholm in May 2018 through Facebook and Instagram. Inclusion criteria were: age 35–70 years, diagnosed primary hypertension prescribed with 1–3 antihypertensive drugs/day, Iphone owner with access to electronic ID (Swedish BankID). Exclusion criteria were: secondary hypertension, previous stroke, previous myocardial infarction, heart failure, cardiac arrhythmia, severe renal failure, dementia, diabetes mellitus or on-going pregnancy. Patients were given a validated and CE-labeled Bluetooth-equipped oscillometric BP monitor with individually adjusted cuff size (Truly Instrument Limited, Hong Kong, China). On the same day as blood and urine samples were collected, the laboratory personnel instructed the patients how to measure BP in the right arm in the sitting position after 5 minutes of rest and compared this initial BP reading with that of an Omron M6 Comfort monitor (Omron, Kyoto, Japan). If readings differed >7 mmHg, the study monitor was replaced.

For the first 2 weeks of the trial, participants were asked to measure HBP on at least 7 days in the morning (before breakfast) and at least 7 days in the evening. The patient could graphically see the changes of HBP and there was also a color-graded gauge meter. The study physician (M.C.) had access to these data and based the treatment on the trends of HBP changes. The physician could be alerted through automated notifications in case of exceedingly high (>190 SBP or >115 mmHg DBP) or low levels (SBP < 110 mmHg). By the chat function in the smartphone, the patients could contact the study physician at any time. The physician usually responded within 24 hours on weekdays.

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All patients received individualized lifestyle advices. If mean BP values were above target, defined as ≥135 mmHg systolic or ≥85 mmHg diastolic, the medications were adjusted and follow-up was planned 2 weeks later. The patients could also be referred for extra laboratory tests if necessary. If seated BP was indicative of hypotension (SBP < 110 mmHg), or if dizziness was reported, patients were asked to perform measurements after 1 and 3 minutes in upright position. In participants who had not performed at least three HBP measurements during the last week of the trial, we used the average of the last three available measurements obtained during the last month as an estimate for achieved final HBP. An anonymized questionnaire about the experience of using the Accumbo hypertension management system was sent to the participants at study end.

Statistical analyses

Statistical estimates were calculated using IBM SPSS Amos 25 software (IBM Corporation, Somers, New York, USA).

Ethics

The study was approved by the Regional Ethics Committee of Linköping and performed in accordance with the Declaration of Helsinki of 1975. The ClinicalTrials.gov ID number was NCT03908710.

Results

There were 429 subjects who responded to the initial invitation, and 179 initiated the study. The final cohort, who participated the full duration of the trial, consisted of 172 subjects (78 men and 94 women; Table 1). Mean BP did not differ between the first BP measurement with the reference Omron M6 device and the Accumbo monitor at the start of the trial (Accumbo: 134.0 ± 16/88.2 ± 11 mmHg, Omron M6: 134.5 ± 15/88.5 ± 11 mmHg, P = 0.35 for systolic and P = 0.58 for DBP, n = 156). The correlation coefficients (r) between the BP measured with the Accumbo and Omron M6 devices were 0.91 (P < 0.0001) for SBP and 0.82 (P < 0.0001) for DBP. The mean HBP during the first week of the trial was 132.2 ± 12/86.7 ± 9.0 mmHg and the participants were prescribed 1.69 ± 0.86 antihypertensive drugs/day on average (Table 1). On average, the physician (M.C.) sent 8.4 ± 4.1 messages to the patients (range 2–22), whereas the patients sent 5.8 ± 4.8 (range 1–24) messages to the physician.

Average HBP was at target (<135/85 mmHg) in 55 participants (31.9%) during the first week. At the end of the trial there were 56 subjects (32.5%) with average HBP at target (Chi-square, P = 0.908). Mean systolic, but not DBP, was reduced when levels at start were compared with those at the end of the trial in the total cohort (from 132.2 ± 12/86.7 ± 9.0 mmHg to 130.5 ± 12/86.0 ± 7.1 mmHg, P = 0.015 for SBP and P = 0.22 for DBP, respectively; Table 1). The number of antihypertensive drugs prescribed/day increased from 1.69 ± 0.86/day to 1.87 ± 0.88/day, P < 0.0001.

The 117 patients with baseline HBP above target had their BP lowered (from 138.0 ± 9.0/91.3 ± 6.5 mmHg to 133.4 ± 8.0/88.6 ± 6.1 mmHg, P < 0.001 for SBP; Fig. 1, and P < 0.0001 for DBP, respectively) and their number of prescribed antihypertensive drugs/day increased significantly (from 1.71 ± 0.94/day to 2.00 ± 0.92/day, P < 0.0001).

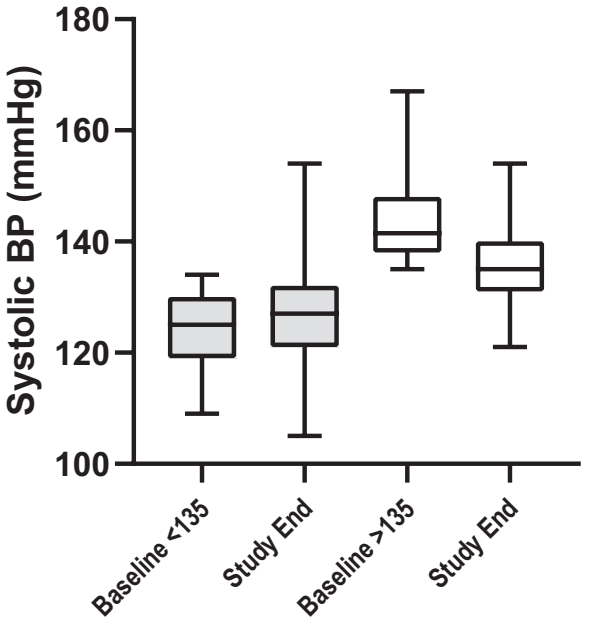
The 55 patients who had HBP at target (<135/85 mmHg) during the first week displayed increased average BP at the end of the trial (from 120.0 ± 5.8/76.7 ± 3.8 mmHg to 124.1 ± 6.9/80.3 ± 5.8 mmHg, P < 0.0001 for SBP; Fig. 1, and P < 0.0001 for DBP, respectively) and prescribed

Table 1 Baseline characteristics of the participants and effects of intervention on home blood pressure and amount of prescribed antihypertensive drugs

Variable	Baseline	Three months	*P* value
Sex (males/females)	78/94		
Age (years)	56.3 ± 7.1		
BMI (kg/m^2)	27.7 ± 4.4		
Waist (cm)	98.3 ± 14		
Total group BP (mmHg)	132.2 ± 12/86.7 ± 9.0	130.5 ± 12/86.0 ± 7.1	0.015/0.22
BP above target (mmHg), n = 117	138.0 ± 9.0/91.3 ± 6.5	133.4 ± 8.0/88.6 ± 6.1	<0.001/<0.0001
Controlled BP (mmHg), n = 55	120.0 ± 5.8/76.7 ± 3.8	124.1 ± 6.9/80.3 ± 5.8	<0.0001/<0.0001
Plasma creatinine (μmol/l)	71.0 ± 13		
Total cholesterol (mmol/l)	5.6 ± 0.92		
LDL cholesterol (mmol/l)	3.6 ± 0.90		
HDL cholesterol (mmol/l)	1.6 ± 0.42		
Triglycerides (mmol/l)	1.7 ± 0.95		
Fasting blood glucose (mmol/l)	5.78 ± 1.2		
Smoking (never/former/current)	90/77/5		
Liquorice use (never/seldom/often)	30/105/36		
Antihypertensive drugs (no/day)	1.69 ± 0.86	1.87 ± 0.88	<0.0001
BP above target drugs (no/day)	1.71 ± 0.94	2.00 ± 0.92	<0.0001
Controlled BP drugs (no/day)	1.64 ± 0.68	1.58 ± 0.74	0.26

BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

Fig. 1



Box plot (median and range) of SBP changes in participants at goal (<135 mmHg, gray box) at baseline or above goal at baseline (≥135 mmHg, white box).

number of antihypertensive drugs/day did not change (from 1.64 ± 0.68/day to 1.58 ± 0.74/day, $P = 0.26$). This group of patients also included nine patients in which the antihypertensives were reduced due to hypotension.

Overall, 166 of the patients filled out the questionnaire. The treatment and service during the trial was rated as 'very good' by 107 participants (65%), 'fairly good' by 54 participants (33%), 'not bad/not good' by three participants (2%) and 'rather bad' by one participant (1%). Sixty-eight percent reported that they found the device 'very ease' to use, 21% responded 'fairly easy', 6% responded 'neither easy nor difficult', 4% responded 'fairly difficult' and one participant (1%) responded 'very difficult'.

A questionnaire about perceived care was answered by 156 participants. Fifty-eight (37%) rated the care quality as 'very high', 53 (34%) rated it as 'fairly high', 41 (26%) rated it as 'neither low nor high' and four (3%) rated it as 'fairly low'.

Discussion

HBP measurement combined with telemonitoring and BP management provided via a smartphone application did not alter the rate of HBP control in this prospective pilot trial. The finding that almost one-third of the patients were at target HBP already at baseline may have contributed to this neutral finding. However, we did note a mean SBP reduction of about 5 mmHg in patients with baseline HBP above target. We believe that this was achieved both by an increased amount of antihypertensive medication, and also by enhanced communication between physician and patients which facilitated a healthy lifestyle. Some previous trials of telemonitoring in patients with hypertension have reported larger reductions of SBP, possibly due to higher baseline BP levels [9–12].

HBP monitoring as part of hypertension management is now recommended in European as well as American guidelines [13,14] and there is a growing interest in telemedicine as part of the management of hypertension [15]. An analysis of smartphone-based applications for hypertension management showed that only 3% of commercially available apps had been developed by healthcare professionals, and that less than 2% targeted both physicians and patients [16]. The present study represents an effort to develop an evidence-based telemedicine solution for hypertension management, with the aim not only to allow patient tracking of BP, but to increase and enhance the interaction between patients and physicians.

The findings of this study should be interpreted in the light of some study-limitations. First, this proof-of-concept trial did not include a control group. Therefore, we cannot rule out that our finding of BP reduction in patients with initially too high BP and BP increase in patients with initially too low BP had been influenced by the 'regression to the mean' phenomenon. Second, medical decisions were made by one single physician with special interest in hypertension which makes it difficult to generalize the findings to a conventional primary health care setting.

To summarize, we prospectively evaluated HBP levels in patients with treated hypertension who used a telemedicine healthcare management system which allowed continuous communication between physician and patient via a smartphone application. Although HBP control did not improve in the total cohort, we found improvements in the patients with poor control, while too low BP values were avoided in patients with initial hypotension in this pilot-study.

Acknowledgements

Conflicts of interest

M.W. has served on advisory boards or lectured for MSD, Lilly, Novo Nordisk and Sanofi, and has organized a professional regional meeting sponsored by Lilly, Rubin Medical, Sanofi, Novartis and Novo Nordisk. M.C. has organized professional meetings and lectured for Lilly, Novo Nordisk, Sanofi, Roche, Novartis and AstraZeneca and is a minority shareholder in Accumbo AB. G.D. has served on advisory boards or lectured for Novartis and Novo Nordisk. F.H.N. has served on advisory boards or lectured for MSD, Lilly, Novo Nordisk, AstraZeneca, Amgen, Boehringer Ingelheim, Accumbo and Sanofi.

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