

ORIGINAL ARTICLE

Short-term telemedical home blood pressure monitoring does not improve blood pressure in uncomplicated hypertensive patients

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Telemonitoring of home blood pressure measurements (TBPM) is a new and promising supplement to diagnosis, control and treatment of hypertension. We wanted to compare the outcome of antihypertensive treatment based on TBPM and conventional monitoring of blood pressure. Participants were recruited from a prevalence study among citizens aged 55–64 years in the municipality of Holstebro, Denmark. The study was a randomized, controlled, unblinded 3 months' trial. In the intervention group, antihypertensive treatment was based on TBPM with transmission of the measurements and subsequent communication by telephone or e-mail. In the control group, patients received usual care. Primary outcome was reduction in daytime ambulatory blood pressure measurements (ABPM) from baseline to 3 months' follow-up. Of 375 participants randomized, primary outcome data were available for 356 (95%). In both groups, daytime ABPM decreased significantly. The decrease in daytime ABPM in the intervention group was systolic/diastolic, $-8 \pm 12 / -4 \pm 7$ mm Hg. This did not differ significantly from the control group's $-8 \pm 13 / -4 \pm 8$ mm Hg. An equal number of participants obtained normal daytime ABPM, in the intervention group 17% (31/175) versus control 21% (37/181), $P=0.34$. We found that both TBPM patients and controls achieved a significant blood pressure reduction in this randomized, controlled, unblinded 3-month trial. We found no difference in blood pressure reduction or number of patients reaching blood pressure goals. Further information and education of some general practitioners seem to be relevant regarding blood pressure management and control of hypertension.

Journal of Human Hypertension (2017) 31, 93–98; doi:10.1038/jhh.2016.43; published online 23 June 2016

INTRODUCTION

Clinic-based hypertension management may lead to overtreatment of some patients and undertreatment of others, owing to the white-coat and masked hypertension phenomena.¹ Home blood pressure monitoring has been recommended for the diagnosis of hypertension as well as monitoring.^{1,2} Recent studies suggest that home blood pressure measurement is even superior to ambulatory blood pressure measurements.^{3,4} However, hypertensive patients often misreport their home blood pressure readings.^{5,6} Telemedical home blood pressure measurements (TBPM) supplemented by other interventions like pharmacist co-management, team care, patient self-titration and so on has shown improved blood pressure control.^{7–9} Most hypertensive patients are diagnosed, treated and controlled by general practitioners (GPs). A telehealth system that transmits the TBPM readings to the electronic patient record eliminates patients' misreporting of their blood pressure values, but it is not known whether TBPM alone improves the treatment of hypertension.

The aim of this study was to compare the outcome of antihypertensive treatment in patients aged 55–64 years based on transmission of TBPM with usual care by GPs.

MATERIALS AND METHODS

Design

This study was designed as a randomized, controlled, unblinded study of 3 months' duration; comparing the outcome of antihypertensive treatment

monitored by TBPM (intervention group) and conventional blood pressure monitoring.

Participants

The participants were recruited between March 2011 and September 2014 from a prevalence study¹⁰ in the municipality of Holstebro, which has 57 000 inhabitants. Inclusion criteria in the previous population study were age 55–64 years, registered address in the municipality of Holstebro and enrolment at a practice of one of the GPs who had agreed to participate. Exclusion criteria were unwillingness to participate or incapability to do TBPM measurements. Inclusion criteria in the present study were a sufficient number of TBPMs (≥ 12 , day 2 and 3), TBPM $\geq 135/85$, hypertension confirmed by daytime ambulatory blood pressure measurements (ABPM) $\geq 135/85$ (TBPM and daytime ABPM $\geq 130/80$ if diagnosed diabetes, chronic kidney disease or prior stroke) and electrocardiogram-verified sinus rhythm. Exclusion criteria were unwillingness to participate and normotension by the ABPM measurements.

Randomization

Randomization was performed using a block randomization procedure for every 10 numbers in order to obtain equal numbers in each study arm. The patients were allocated to treatment via a computer-generated randomization sequence conducted by the hospital pharmacy. Participants were randomized to TBPM or conventional blood pressure monitoring (controls).

Number of participants

A power calculation indicated that a sample of 169 patients in each group was necessary to detect a 2-mm Hg difference in daytime ABPM with an assumed s.d. of 8 mm Hg and a power of 90% at a significance level of 5%

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Received 30 December 2015; revised 27 April 2016; accepted 12 May 2016; published online 23 June 2016

Effect variables

Primary outcome was defined as difference in daytime ABPM from baseline to follow-up between intervention and control group. Secondary outcome was difference in number of patients reaching target blood pressure of daytime ABPM <135/85 (daytime ABPM <130/80 if diagnosed diabetes, chronic kidney disease or prior stroke).

Procedure

The citizens and GPs of Holstebro were invited. Names and addresses were drawn from the Civil Registration System of Central Region Denmark. It contains information on the GPs, whom the citizens attended at the time of the drawing. All patients registered with one particular practice, were drawn at a time. In this way, the drawings were from an actual dynamic population aged 55–64 years during the whole time of recruitment.¹¹ The patients were sent an invitation letter, and a reminder was sent, if it was not answered within 2 months. Participants who changed registration with a GP were only invited once. The Municipal Preventive Care Centre managed all appointment and equipment logistics.

By use of TBPM all participants were asked to do three blood pressure measurements at home with an interval of 1 min in the morning before breakfast and drug intake if treated, three measurements before supper and three measurements before going to bed. The home blood pressure was calculated as the average of all measures on day 2 and 3. A valid report had 12 or more measures on day 2 and 3. After 3 days, the participants returned the equipment. If the home blood pressure was above threshold the patient was invited to have a supplementary 24-h ABPM. Measurements were taken every 15 min during daytime and every 30 min overnight. The monitoring cuff was wrapped around the non-dominant arm and the patient was asked to keep the arm still during the measurements. If daytime ABPM was above threshold and the patient accepted participation in the 3 months' project, they were randomized to either TBPM or conventional blood pressure monitoring (controls). Within a few days the participants were given an appointment at their GP to have blood samples taken and for the planning of the project period. In the TBPM group the patients did home measurements for 3 days every second week. The average of all measures excluding day 1 was sent to the GPs. In the control group the GPs were asked to do blood pressure controls as close to their normal routine as possible. In both groups the GPs were instructed to follow current guidelines regarding blood pressure levels and pharmacological/non-pharmacological treatment of hypertension. At the end of the 3-month period all patients returned to the Municipal Preventive Centre for a follow-up consultation including a 24-h ABPM.

Devices

In the first part of the study, we used A&D 767PlusBT (A&D Company Limited, Tokyo, Japan)¹² blood pressure monitors for TBPM. We used A&D cuffs, sizes depending on the patient's upper arm. Data were sent using a Tunstall RTX3371 telehealth monitor (Tunstall Healthcare A/S, Noerresundby, Denmark), with Global System for Mobile communication/General Packet Radio Service (GSM/GPRS) communication with a central server. A summary report was extracted from the Tunstall Triagemanager software. Because of a planned integration of the electronic patient records at the GPs' offices and at the hospital we had to change telehealth monitor and subsequently the blood pressure monitor. In the second part, we used Omron 705IT (Omron Healthcare, Kyoto, Japan)¹³ blood pressure monitors for TBPM measurements. We used Omron cuffs, sizes depending on the patient's upper arm. Data were sent using a Numera telehealth (Numera, Seattle, WA, USA) monitor with GSM/GPRS communication with a central server. The mean of TBPM measurements was sent to the GP's electronic patient record using the Danish MedCom standard. A summary report could be extracted from the Columna Citizen Platform (Systematic A/S, Aarhus, Denmark). The A&D 767PlusBT and the Omron 705IT have both been clinically validated according to the British Hypertension Society protocol and rated A/A.^{12,13} A&D TM-2430 was used for the 24-h ABPM. Cuff sizes depending on the patients' upper arm. The heart rhythm was monitored for 30 s with a handheld electrocardiogram monitor (MD100B) to exclude atrial fibrillation.

Ethics

All participants were given oral and written information about the project. All gave written consent. The study was approved by the committee of Multipractice Studies in General Practice (MPU 1-2011). The study was approved by the Scientific Ethical Committee of Central

Region Denmark (j.no.: M-2011013) and by the Danish Data Protection Agency (j.no.: 2011-41-5704).

Statistics

Continuous variables were reported as means with s.d.'s or medians with interquartile range, depending on whether the data were normally distributed or not. Categorical variables were reported as percentages. Students unpaired t-test was used for parametric, continuous variables. Independent samples Mann-Whitney U-test was used for nonparametric, continuous data. χ^2 -test was used for categorical variables. McNemars test was used for paired, categorical variables. Multiple regression was used for construction of a multivariate model including effect of TBPM, sex, prior diagnosis of hypertension and GP setting. All predictors were forced into the model simultaneously. A two-tailed P-value <0.05 was considered significant in all analysis. Statistical analyses were done using the IBP-SPSS version 20 (Armonk, NY, USA).

RESULTS

Demographics

The 40 GPs in the municipality of Holstebro are organized in 18 different offices. All but 1 practice (2 GPs) agreed to participate in the study. From the 17 practices, we invited all citizens aged 55–64 years, that is, 6405 citizens, ending up with 3159 (49%) attenders and 3246 (51%) non-attenders (Figure 1). Sufficient measurements of TBPM were done in 3102 individuals. Patients who had elevated TBPM ($n=1078$) were invited to have a confirmatory 24-h ABPM. Elevated daytime ABPM being found in 425 participants, and 375 agreed on participating in the present study and were randomized. During the study 19 withdrew consent. The remaining 356 participants (95%) had a follow-up 24-h ABPM performed (175 in the TBPM group and 181 in the control group). No difference was found in the numbers of consultations between the TBPM and the control group, 2.94 (95% confidence interval (CI): 2.68, 3.17) versus 2.96 (95% CI: 2.73, 3.19). Neither did we find difference in the number of phone calls, 0.15 (95% CI: 0.08, 0.22) versus 0.21 (95% CI: 0.14, 0.30). In the TBPM group email communication between the GP and the

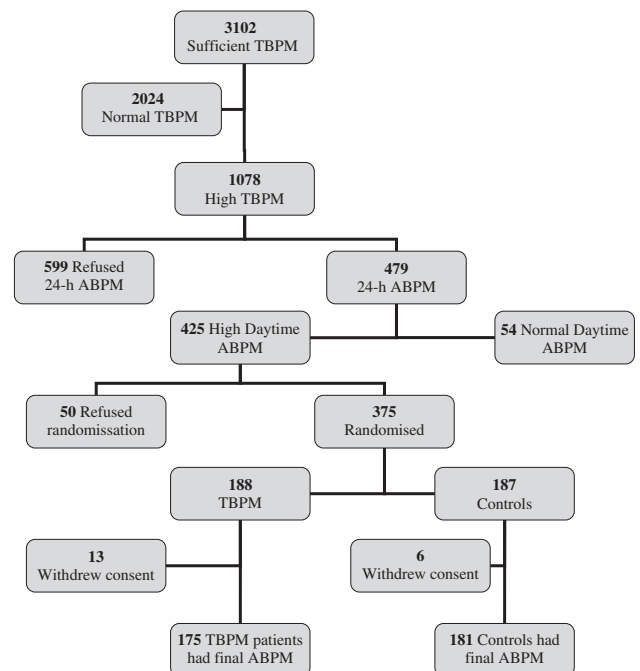


Figure 1. Flow diagram for the study participants. A full colour version of this figure is available at the *Journal of Human Hypertension* journal online.

Table 1. Demographics and clinical data

	TBPM group (n = 175)	Control group (n = 181)	P-value
Female	75 (43%)	87 (48%)	NS
Age, mean (s.d.), years	60.5 (2.6)	60.4 (2.9)	NS
Height, mean (s.d.), cm	171.2 (8.1)	171.4 (9.0)	NS
Weight, mean (s.d.), kg	84.4 (15.9)	82.5 (15.5)	NS
Body mass index, mean (s.d.) ^a	28.7 (4.6)	28.0 (4.6)	NS
Waist circumference, mean (s.d.), cm	100.3 (13.4)	98.1 (11.8)	NS
OBP, systolic, mean (s.d.), mm Hg	154.6 (18.9)	151.1 (19.2)	NS
OBP, diastolic, mean (s.d.), mm Hg	93.2 (10.5)	92.3 (9.7)	NS
TBPM, systolic, mean (s.d.), mm Hg	144.4 (11.5)	145.0 (12.5)	NS
TBPM, diastolic, mean (s.d.), mm Hg	88.6 (7.8)	88.8 (6.8)	NS
Known with hypertension ^b , n (%)	84 (48%)	81 (45%)	NS
Diabetes ^b , n (%)	12 (7%)	13 (7%)	NS
No diagnosis of diabetes, but HbA1C above threshold, n (%)	7 (4%)	3 (2%)	NS
Kidney disease ^b , n (%)	0	0	
History of coronary heart disease ^b , n (%)	4 (2%)	10 (6%)	NS
History of stroke ^b , n (%)	7 (4%)	6 (3%)	NS
Current smoker ^b , n (%)	27 (16%)	35 (20%)	NS
Tobacco consumption among smokers ^{b,c,d} , median (IR)	17.5 (10)	17 (10)	NS
Alcohol consumption ^{b,c,e} , median (IR)	4 (9)	5 (9)	NS
Physical exercise ^{b,c,f} , median (IR)	10 (22.9)	11 (16)	NS
Haemoglobin, mean (s.d.), mmol l ⁻¹	9.0 (0.7)	9.4 (6.3)	NS
HbA1C ^c , median (IR), mmol mol ⁻¹	37 (5)	37 (5)	NS
Total cholesterol, mean (s.d.), mmol l ⁻¹	5.6 (1.0)	5.6 (1.1)	NS
HDL cholesterol, mean (s.d.), mmol l ⁻¹	1.4 (0.4)	1.5 (0.4)	NS
LDL cholesterol, mean (s.d.), mmol l ⁻¹	3.5 (0.9)	3.4 (1.0)	NS
Creatinine, mean (s.d.), μmol l ⁻¹	78 (14)	76 (14)	NS
Urine ratio of albumin/creatinine ^c , median (IR), mg g ⁻¹	6 (10)	8 (9)	NS

Abbreviations: HbA1C, haemoglobin A1C; HDL, high-density lipoprotein; IR, interquartile range; LDL, low-density lipoprotein; n, Number of participants; NS, nonsignificant; OBP, office blood pressure; TBPM, telemedical blood pressure monitoring. Significance level was $P < 0.05$. ^aCalculated as weight in kilograms divided by height in metres squared. ^bSelf-reported data. ^cData are not normally distributed, reported as medians. ^dNumber of cigarettes per day. ^eAlcohol units per week (one unit equals 12 g of alcohol). ^fHours of light exercise per week.

patient was used, 0.64 (95% CI: 0.43, 0.85) versus 0.14 (95% CI: 0.08, 0.21).

Clinical data

The TBPM and the control group did not significantly differ in any baseline characteristics (Table 1). In the TBPM group 48% were known with hypertension (self-reported), in the control group 45%. Current smoker was reported for 16% versus 20%, with a median tobacco consumption of 17.5 versus 17 cigarettes per day. Mean total cholesterol was 5.6 mmol l⁻¹ in both groups. Mean creatinine was 78 versus 76 μmol l⁻¹. In both groups 7% had diabetes. Haemoglobin A1C was above the threshold for diabetes in 10 participants with undiagnosed diabetes. No patients had previously diagnosed chronic kidney disease.

Primary outcome

The daytime ABPM reduction in the TBPM group after 3 months (systolic/diastolic, $-8 \pm 12 / -4 \pm 7$ mm Hg) did not differ significantly from that in the control group (systolic/diastolic, $-8 \pm 13 / -4 \pm 8$ mm Hg), as shown in Table 2. Nor did the nighttime reduction differ between the TBPM and the control group.

Secondary outcome

The proportion of patients reaching blood pressure targets was not significantly different between the TBPM group (17%, $n = 17$) and the control group (21%, $n = 21$) as shown in Table 2.

Subgroup analysis

Medication. No significant difference between the two groups was observed in the use of different antihypertensive drugs, neither at baseline nor at follow-up (Table 3). In both groups, we found a significant increase in the number of patients treated with

angiotensin-converting enzyme inhibitor, angiotensin receptor antagonist, calcium channel blocker and thiazide diuretics, as shown in (Table 3). At baseline 59% in the TBPM group and 61% in the control group did not receive any antihypertensive medication. In both groups we saw a significant increase in the number of patients receiving antihypertensive medication. At follow-up, the number of patients not receiving any antihypertensive medication was reduced to 23% in the TBPM group and 22% in the control group.

A&D 767PlusBT versus Omron 705IT

No difference was found between the TBPM and the control group regarding blood pressure values or achievement of target values when either blood pressure monitors were used.

Multivariable model

The number of participants per practice ranged from 3 to 45. When using a multivariate model with systolic and diastolic blood pressure as dependent variables and TBPM, sex, prior diagnosis of hypertension according to the self-reported questionnaire and practice setting (centre effect) as independent variables, we found no significance of the partial regression coefficients for any variables (Table 4).

DISCUSSION

We found that both TBPM patients and controls achieved a significant blood pressure reduction in this randomized, controlled, unblinded 3-month trial. We found no difference in blood pressure reduction or number of patients reaching blood pressure goals. Receiving a TBPM report every second week did not improve the treatment of hypertension in general practice.

Table 2. Mean systolic and diastolic blood pressure at baseline and after 3 months in the telemedical home blood pressure group (TBPM) and the control group

	Baseline			3 months			Change within groups		
	TBPM (n = 175)	Control (n = 181)	P-value	TBPM (n = 175)	Control (n = 181)	P-value	TBPM	Control	P-value
Number of antihypertensive drugs, mean (range)	0.7 (0, 4)	0.7 (0, 4)	NS	1.4 (0, 5)	1.3 (0, 5)	NS			
Daytime ABPM, systolic, mean (s.d.)	151 (11)	152 (11)	NS	142 (11)	144 (12)	NS	-8 (12)	-8 (13)	NS
Daytime ABPM, diastolic, mean (s.d.)	89 (7)	90 (7)	NS	85 (7)	86 (7)	NS	-4 (7)	-4 (8)	NS
Night time ABPM, systolic, mean (s.d.)	128 (15)	130 (14)	NS	122 (13)	124 (15)	NS	-6 (13)	-7 (14)	NS
Night time ABPM, diastolic, mean (s.d.)	75 (9)	76 (7)	NS	72 (7)	72 (8)	NS	-3 (7)	-4 (8)	NS
Achieved target blood pressure				17% (n = 31)	21% (n = 37)	NS			

Abbreviations: ABPM, ambulatory blood pressure monitoring; NS, nonsignificant; TBPM, telemedical blood pressure monitoring. Target blood pressure < 135/85 (< 130/80 if diabetic, history of stroke or chronic kidney disease). Students *t*-test was used for the comparisons of blood pressure levels. Pearson's χ^2 -test was used in analysis of the number of patients achieving target blood pressure. Significance level was $P < 0.05$.

Table 3. Comparison of antihypertensive treatment in telemedical group (TBPM) and control group

	Baseline			3 months		
	TBPM	Control	P-value	TBPM	Control	P-value
No antihypertensive treatment	59% (n = 102)	61% (n = 111)	NS	23% ^a (n = 40)	22% ^a (n = 39)	NS
Angiotensin-converting enzyme inhibitor	12% (n = 21)	14% (n = 26)	NS	38% ^a (n = 66)	38% ^a (n = 68)	NS
Angiotensin receptor antagonist	12% (n = 20)	8% (n = 14)	NS	22% ^a (n = 38)	21% ^a (n = 38)	NS
Calcium channel blocker	16% (n = 28)	14% (n = 25)	NS	31% ^a (n = 54)	28% ^a (n = 51)	NS
Thiazid	18% (n = 31)	17% (n = 30)	NS	31% ^a (n = 55)	29% ^a (n = 52)	NS
Alphablocker	0	2% (n = 3)	NS	0	2% (n = 3)	NS
Betablocker	12% (n = 20)	9% (n = 17)	NS	13% (n = 23)	11% (n = 20)	NS
Furosemide	2% (n = 3)	1% (n = 2)	NS	2% (n = 4)	1% (n = 1)	NS
Spirolactone	1% (n = 1)	0	NS	1% (n = 1)	1% (n = 1)	NS
Amiloride	0	0		1% (n = 1)	0	NS

Abbreviations: NS, nonsignificant; TBPM, telemedical blood pressure monitoring. Data are reported as percentage (number) of study participants. Pearson's χ^2 -test was used for analysis of between the TBPM and the control group. McNemars test was used for the paired comparison between baseline and 3 months' values. Significance level was $P < 0.05$. ^aSignificant difference between baseline and 3 months' follow-up.

Comparison of TBPM studies is difficult because of their heterogeneity. Only about one-tenth of the published studies are randomized and controlled trials.¹⁴ A recent meta-analysis found that TBPM improved systolic office blood pressure (OBP) by 4.71 mm Hg and diastolic OBP by 2.45 mm Hg.¹⁵ In studies assessing ABPM instead of OBP, the reduction was smaller but still significant; systolic 3.48 mm Hg and diastolic 1.43 mm Hg.¹⁵ Other interventions like patient education may improve the TBPM treatment of hypertension.¹⁶ Self management of hypertension using a simple drug titration plan in combination with TBPM was assessed in the TASMINH2 trial.¹⁷ Compared with usual care, the intervention resulted in significant reductions in systolic blood pressure, 3.7 mm Hg at 6 months and 5.4 mm Hg at 12 months. Especially, studies with a long follow-up have shown effect on blood pressure, like the HyperLink study using a multifaceted approach in a cluster randomized design.¹⁸ After 12 months they found a 11.3-mm Hg systolic difference in blood pressure reduction. After 6 months another primary-care study found a mean difference in daytime ABPM of 4.3 mm Hg systolic and 2.3 mm Hg diastolic.¹⁹ Studies focusing on the TBPM without interventions show a more moderate effect on the blood pressure.^{20,21} We found no difference in blood pressure reduction or number of patients reaching blood pressure goals using a mean TBPM every second week. In the literature clinical inertia and patients' adherence to therapy seem the biggest challenges in optimizing the treatment of hypertension.^{22,23} As we found that only about one-fifth reached the target blood pressure, it appears

very unlikely that a change in patients' behaviour when participating in a study (Hawthorne effect) should have eliminated possible significant differences between the TBPM and the control group. At the time of inclusion, the mean number of antihypertensive drugs used per patient was only 0.7 indicating that the population was not a group of patients with resistant hypertension. The mean number of antihypertensive drugs doubled during the study (to 1.3 and 1.4) leaving room for further improvement in the treatment.

In the previous prevalence study we found that the blood pressure was well controlled in about half of patients with hypertension, which is comparable to the US population.²⁴ In 2009, the Kaiser Permanente Northern California increased the overall hypertension control from 44 to 80% through a large-scale hypertension programme.²⁵

We found no difference between TBPM-monitored patients and controls regardless of whether patients had known or newly detected hypertension. We would expect TBPM to be a useful tool in the titration period, but no apparent effect was seen in this short-term study. It is surprising that only about one-fifth of newly and previously diagnosed patients reached the blood pressure targets. By inviting all patients from a prior prevalence study with elevated blood pressure we believe selection bias to be eliminated. Despite the precise TBPM measurements clinical inertia might still be an important challenge in reaching blood pressure targets.

Table 4. Multivariate model exploring effect of TBPM, sex, prior diagnosed hypertension and GP setting

	B	s.e. B	β	P-value
<i>Systolic BP, model 1</i>				
Constant	-7.87 (-9.65, -6.08)	0.91		0.001
TBPM/control	-0.32 (-2.86, 2.23)	1.30	-0.01	0.81
<i>Systolic BP, model 2</i>				
Constant	-6.97 (-10.17, -3.76)	1.63		0.001
TBPM/control	-0.27 (-2.83, 2.29)	1.30	-0.01	0.84
Male/female	-0.32 (-2.89, 2.25)	1.31	-0.01	0.81
Diagnosed/not prior diagnosed HT	-0.93 (-3.52, 1.66)	-0.93	-0.04	0.48
General practitioner	0.04 (-0.31, 0.22)	-0.04	-0.02	0.74
<i>Diastolic BP, model 1</i>				
Constant	-3.75 (-4.88, -2.62)	0.58		0.001
TBPM/control	-0.25 (-1.86, 1.37)	0.82	-0.02	0.76
<i>Diastolic BP, model 2</i>				
Constant	-3.86 (-5.88, -1.83)	1.03		0.001
TBPM/control	-0.23 (-1.85, 1.40)	0.82	-0.02	0.78
Male/female	-0.50 (-2.13, 1.13)	0.83	-0.03	0.55
Diagnosed/not prior diagnosed HT	0.24 (-1.40, 1.88)	0.83	0.02	0.78
General practitioner	0.04 (-0.13, 0.20)	0.09	0.02	0.68

Abbreviations: BP, blood pressure; GP, general practitioner; HT, hypertension; TBPM, telemedical blood pressure monitoring. 95% confidence intervals in brackets. Systolic: model 1, $R^2=0.00$ (adjusted $R^2=0.00$); model 2: $\Delta R^2=0.00$ (adjusted $\Delta R^2=-0.01$). Diastolic: model 1: $R^2=0.00$ (adjusted $R^2=0.00$); model 2: $\Delta R^2=0.00$ (adjusted $\Delta R^2=-0.01$).

In the first part of the study an A&D 767PlusBT was connected to a transmitting hub, in the last part we used Omron 705IT with another hub. Both devices have been clinical validated,^{12,13} but never compared head to head in a clinical setting. No difference was found between the TBPM and the control group regarding blood pressure values or achievement of target values when either blood pressure monitor was used. Thus, the change in equipment does not seem to have influenced our results.

The multivariate analyses showed no significant effect on the independent variables, that is, TBPM, gender, previously diagnosed hypertension, on the dependent variables as systolic and diastolic blood pressure. However, blood pressure management and control considerably between different GPs. Thus, further information and education of some GPs seem to be relevant regarding blood pressure management and control of hypertension.

Our study has five key strengths. First, it is one of the largest randomized studies regarding TBPM and the first to report a software ability of electronic transmission of blood pressure data right into the GP's electronic patient record.¹⁵ Second, patients were treated by their GP as most hypertensive patients are. Third, the randomized patients were recruited from a prior prevalence study, thus avoiding referral bias. Recruitment bias was reduced by the fact that all but one practice (two GPs) agreed to participate in the study and no study-specific additional payment was offered. Fourth, we used ABPM as the effect measure and not OBP as most TBPM studies. All patients who had had an elevated TBPM were invited to have a supplementary ABPM. Only when daytime ABPM also was elevated, the patients were randomized. Fifth, only 5% ($n=19$) did not show up for the follow-up ABPM measurement.

Our study has six key limitations. First, we changed the blood pressure monitor and telemedical software platform in order to integrate the TBPM values into the electronic patient record at the GP's office and at the hospital, but no difference in blood pressure reduction was found between the TBPM and the controls using either device. Second, all patients with elevated blood pressure were invited to participate regardless of the level of blood pressure and their cardiovascular risk profile. Thus, some patients began antihypertensive treatment after consulting their GP, because of a marginally elevated blood pressure. Third, the study was unblinded for the GPs as well as the patients. This could introduce a significant bias and changes in health-related behaviours. Fourth, no alarm limits were applied to the electronic transmission of data to the GPs. Applying alarm limits might increase clinical vigilance. Fifth, in the control group, we asked the GPs to do the blood pressure controls as close to their normal routine as possible, thus we did not register changes in OBP or TBPM neither did we register number of titration procedures. Sixth, we focused on the level of blood pressure reduction in ABPM during a 3-month period. This could have been too short a period to show a superiority of TBPM. A more intensive patient-GP communication may be necessary for the improvement of blood pressure. According to the registrations by the GPs only a fraction of TBPM received every second week was communicated to the patient. In the future we need studies powered to detect impact on hard end points by system-wide, multi-faceted telemonitoring programmes.

In conclusion, we found that both TBPM patients and controls achieved a significant blood pressure reduction in this randomized, controlled, unblinded 3-month trial. We found no difference in blood pressure reduction or number of patients reaching blood pressure goals. Although our multivariate analysis did not demonstrate a centre effect, blood pressure management and control deviated considerably between different GPs.

What is known about the topic?

- Home blood pressure is better correlated with cardiovascular risk factors than office blood pressure.
- Patients prefer home rather than ABPM for their out-of-office blood pressure evaluation.
- TBPM supplemented by other interventions has shown improved blood pressure control.

What this study adds?

- As an isolated tool TBPM did not improve blood pressure control during a 3-month period.
- Receiving a TBPM report every second week did not improve the treatment of hypertension in general practice.
- Clinical inertia might still be an important challenge in reaching blood pressure targets.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ACKNOWLEDGEMENTS

We thank participating citizens and the general practitioners Ulla and Jakob Hoffmann-Petersen; Helle Bondesen and Jacob Houe; Marianne and Bent Conrad Pedersen; Susanne Schovsbo; Jørgen Buch, Dorte Navntoft and Ole Mecklenborg; Mette Damgaard and Lotte Jakobsen; Poul Erik Hven; Kirstine Albrechtsen, Karen Schou and Pernille Tørring; Michael Poulsen, Agathe Mierzwinska and Niels Christian Bentsen; Annette Fleng and Jes Sørensen; Peder Kirkegaard; Anne Kristensen, Lene Kristensen, Tove Holm, Claus Larsen and Kurt Ebbensgaard; Tina Høst and Finn Olsen; Trine Overgaard and Anders Nissen; Ken Hermansen; Christian Thomsen; Laila Andersen, Poul Bøge, Rita Christiansen, Allan Raft, Audun Bosnes and Tina Lunderoff. We thank study nurses Karen Markussen, Inge Winther and Mona Godtkjær, and

laboratory technicians Susan Milton Rasmussen, Lisbeth Mikkelsen, Anne Mette Ravn, Kirsten Nygaard and Henriette Simonsen for skilful assistance. We thank Janni Maigaard Jensen MD, PhD for helpful assistance during the recruitment. We thank Ellen Greve and Jesper Ejstrup from the municipal preventive care centre for enthusiastic support. ClinicalTrials.gov identification number is NCT02531347. The study was funded by the Tryg Foundation, Municipality of Holstebro, Central Denmark Region and Research Fund of Central Denmark Region.

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