

**Does self-monitoring and self-management of blood pressure after stroke or TIA
improve control? TEST-BP, a randomised controlled trial**

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Abbreviated title:

Self-monitoring Blood Pressure after Stroke

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Key Words

Blood pressure self-monitoring, stroke, cerebrovascular disease.

Abstract

The therapeutic benefit of self-monitoring blood pressure in stroke patients is uncertain. We investigated the effect of self-monitoring, with or without guided antihypertensive management, compared to usual care in patients with a recent cerebrovascular event. No between-group differences in blood pressure at outcome were found, but blood pressure self-monitoring and management was well tolerated.

Introduction

Hypertension is the most important modifiable risk factor for primary and secondary stroke prevention, even modest reductions in clinic blood pressure (BP) of approximately 10/5mmHg being associated with a 30% risk reduction [1]. Despite the existence of effective treatments, rates of BP control post-stroke are poor, a recent cohort reporting only 16% of patients achieving clinic BP \leq 130/80mmHg six months after their event [2]. Studies suggest that self-BP monitoring (SBPM) may improve BP control, its use resulting in lower BP levels and increased achievement of targets compared to usual management, particularly if combined with complementary strategies, such as telemonitoring of results, or guided antihypertensive self-management [3]. However, studies to date have not addressed the use of SBPM in high-risk groups. Here we report the results of the TEST-BP trial, which aimed to determine whether SBPM with or without guided self-management of BP treatment resulted in lower BP levels and better control than usual care in hypertensive patients with a recent stroke or transient ischaemic attack (TIA).

Methods

TEST-BP was a randomised, blinded end-point, parallel group controlled trial (ClinicalTrials.gov reference no. NCT02947490). Summary methods are described, with full methodology available (online supplement). Eligible patients were adults with a recent mild/moderate stroke or TIA, all requiring BP treatment for secondary prevention. Patients with life expectancy below six months or cognitive impairment were excluded. Ethical approval for the trial was granted (Research Ethics Committee East of England – Norfolk (ref: 11/EE/0147)). All participants provided written informed consent. At enrolment, participants were randomised via a concealed web-based system to Treatment As Usual (TAU), Self-MONitoring only (S-MON), or Self-monitoring with guided self-MANagement of BP (S-MAN).

Ambulatory BP monitoring ((ABPM) Spacelabs 90207 monitor, Spacelabs Healthcare Ltd. (UK), Hertford, UK), undertaken as per guidelines [4], was performed at baseline and six months in the three groups. BP management for TAU participants was by their General Practitioner (GP) only. The intervention groups performed self-monitoring, as per guidelines [4], at six weeks, three and five months post-randomisation. S-MON patients used a validated monitor (Omron 705IT, Omron Healthcare UK Ltd., Milton Keynes, UK) with readings passed to the GP for management. S-MAN patients used a validated monitor (A&D UA-767PBT, A&D Instruments Ltd., Abingdon, UK) with telemonitoring (iModem; Netmedical, Utrecht, Netherlands), readings going directly to the trial team. Changes to antihypertensive treatment in S-MAN group were made jointly by the patient and the supervising stroke trial clinician, but informing the patient's GP. British guidelines current at trial inception recommended a secondary stroke prevention target clinic BP of $\leq 130/80$ mmHg, with out-of-office BP targets adjusted down by 10/5mmHg due to expected differences in measurement methods [5], so out-of-office target BP was $\leq 120/75$ mmHg.

The primary outcome was difference in daytime ambulatory systolic BP (SBP) at six months. Secondary outcomes were (i) differences in mean daytime ambulatory diastolic BP (DBP) at six months, (ii) differences in antihypertensive medication changes, (iii) adverse events.

Participants with <14 daytime ABPM readings or non-compliant with self-monitoring were excluded from analysis. To detect a difference in mean daytime ambulatory SBP of 6mmHg, with a power of 0.8 at the 5% significance level, assuming a standard deviation of 10.3mmHg for daytime ABPM [6], required 48 participants per group.

Outcomes Analysis

Data were analysed using SPSS version 23.0 on an intention to treat (ITT) basis. Continuous data are presented as mean (standard deviation) or mean (95% confidence interval (CI)), discrete data as median (interquartile range (IQR)). Independent samples t-tests assessed between-group differences in mean BP at outcome and Chi-squared tests assessed proportions of participants who were normotensive at outcome and proportions of participants who had medication changes. Mann-Whitney U tests assessed between-group differences in medication changes. Each intervention group was compared separately to control, with exploratory comparison of the intervention groups only where both were significantly different to control, to reduce the risk of a false positive outcome and to eliminate potential bias from using distinct control groups [7]. Sensitivity analysis accounting for missing ABPM data was conducted after imputation by predictive mean matching.

Results

Recruitment ran from 20th December 2012 to 14th March 2016, ending when target numbers were achieved. Progress through the trial is shown in **Figure 1**, with baseline demographics in **Table I**.

There were no significant between-group differences in the primary outcome of mean daytime ambulatory SBP at six months (difference TAU minus S-MON 2.69mmHg [95% CI -2.59 to 7.97, p=0.31], TAU minus S-MAN 3.00mmHg [95% CI -2.53 to 8.54, p=0.28]) or in mean daytime ambulatory DBP (**Table II**). SBPM did not result in more participants achieving target BP (daytime ABPM \leq 120/75mmHg) (TAU 12/52 [23%], S-MON 8/51 [16%], S-MAN 13/51 [26%], p>0.05). Subgroup analysis of those with uncontrolled baseline BP (daytime ABPM >120/75mmHg) gave similar results (data in online supplement), as did the sensitivity analysis.

A greater proportion of S-MAN participants had their antihypertensive therapy adjusted compared to control (TAU 31% vs. S-MAN 63% p=0.001), though there was no difference with S-MON (31% vs. 43% p=0.19). The difference with S-MAN was driven by a greater number of dose increases (TAU vs. S-MAN p=<0.0001). The number of dose decreases, additional, or discontinued medications did not differ.

Ninety-two percent of SBPM recording sets were completed. Only one participant was non-compliant with self-monitoring. In comparison, most TAU participants consulted their GP once during the trial (median 1.0, IQR 0.0-2.0). Rates of reported side effects were similar in all groups and no major adverse events were recorded.

Discussion

Our findings, in agreement with comparable studies, showed that SBPM alone, or combined with telemonitoring and guided therapy management, did not result in lower BP levels or improved BP control at six months compared to usual care, despite good adherence. In a trial of SBPM alone vs. usual care in hypertensive stroke patients, clinic BP at six or 12 months was not significantly different with intervention [8]. Post-hoc analysis suggested a benefit in participants with baseline clinic BP >140/90mmHg, but we did not find this. Similarly, when investigating SBPM with guided self-management vs. usual care in a mixed high-risk population, intervention did not result in lower clinic BP at 12 months in the subgroup with stroke/TIA [9]. Conversely, a feasibility study of SBPM telemonitoring vs. usual care post-stroke reported ambulatory SBP reductions of 10.1mmHg at six months with intervention compared to 3.8mmHg with control [6]. The only meta-analysis to assess patients with cerebrovascular disease as a subgroup found no benefit with intervention, though this finding may reflect small numbers and few trials employing SBPM with additional strategies [3].

SBPM cannot intrinsically lower BP; rather its effect is mediated through therapeutic intensification [8-10], as we found, which is less likely to occur in patients with controlled BP. Alternatively, patients with physical (or cognitive) disability post-stroke may gain less benefit from SBPM due to therapeutic inertia, as noted by Kerry et al. [8]. These findings suggest that not all patients post-stroke will benefit from SBPM.

Strengths of this study include the use of the gold-standard ABPM for the BP outcome measure [4], differentiating it from most similar studies and reducing measurement and observer bias, and the simultaneous comparison of two interventions of differing intensity.

The main limitation is the smaller between-group BP difference than planned in our sample size calculation, hence our study may be underpowered to make firm conclusions about the significance of a more modest, but potentially clinically important SBPM effect. Secondly, our self-monitoring target may have been too low (just 10 participants reached target BP on the final self-monitoring), with recent comparisons suggesting that out-of-office values are on average 4/3 mmHg lower than clinic measurements [11]. Thirdly, although most participants had baseline daytime ABPM above our defined target, mean BP levels were approximately 135/75mmHg and all participants were on treatment, potentially limiting the benefit of the interventions. Finally, the use of different home monitors may have introduced measurement bias, though we would stress that both are validated.

In summary, SBPM with or without guided self-management of antihypertensive therapy was safe and well tolerated, but did not improve overall BP control in these post-stroke participants. The small reductions in BP demonstrated with SBPM in this trial may still be clinically significant and warrant further investigation to identify potential subgroups where such therapy may be clinically beneficial.

Source of funding

TEST-BP was funded by the National Institute for Health Research (NIHR) Research for Patient Benefit Programme (RfPB) (grant reference PB-PG--0909-20246). This paper presents independent research funded by the NIHR under the RfPB. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Declarations of Interest: none

Author Contributions: All authors contributed significantly to the research and have approved the final manuscript.

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Table I: Comparison of baseline characteristics between the three trial groups in TEST-BP.

Values presented are mean (SD) or frequency (%).

		Treatment as usual N=52	Self- monitoring only N=51	Self-monitoring and self- management N=51
Age (years)		72.3 (9.8)	74.5 (9.6)	73.8 (10.7)
Sex	Male	34 (65%)	33 (65%)	34 (67%)
Ethnicity	White	51 (98%)	50 (98%)	51 (100%)
	Black	1 (2%)	0 (0%)	0 (0%)
	Asian	0 (0%)	1 (2%)	0 (0%)
Diagnosis	TIA	34 (65%)	33 (65%)	34 (67%)
	Stroke	18 (35%)	18 (35%)	17 (33%)
Baseline clinic blood pressure (mmHg)	SBP	152.4 (18.1)	154.5 (18.3)	148.3 (21.3)
	DBP	82.4 (12.0)	87.2 (9.8)	81.7 (13.1)
Baseline clinic blood pressure ≤130/80mmHg		2 (4%)	2 (4%)	6 (16%)
Baseline daytime ambulatory blood pressure (mmHg)	SBP	134.4 (14.3)	135.3 (14.7)	133.7 (13.0)
	DBP	75.4 (9.5)	76.6 (8.0)	75.9 (8.5)
Baseline daytime ambulatory blood		6 (12%)	8 (16%)	7 (14%)

pressure \leq120/75mmHg				
First self-monitored blood pressure (mmHg)	SBP	-	142.5 (14.5)	138.4 (16.6)
	DBP	-	77.8 (7.6)	78.8 (9.7)
Past Medical History	Hypertension	36 (69%)	33 (65%)	40 (78%)
	Transient ischaemic attack	38 (73%)	31 (61%)	37 (73%)
	Stroke	19 (37%)	20 (39%)	21 (41%)
	Ischaemic heart disease	8 (15%)	11 (22%)	13 (26%)
	Diabetes	15 (29%)	10 (20%)	12 (24%)
	Chronic kidney disease	2 (4%)	2 (4%)	2 (4%)
Montreal cognitive assessment score		26.0 (3.0)	25.7 (2.9)	24.9 (3.7)
Number of baseline antihypertensives		1.6 (0.8)	1.4 (0.8)	1.9 (1.0)
Antihypertensive medications	ACE inhibitor or angiotensin receptor blocker	36 (69%)	37 (73%)	43 (84%)
	Beta blocker	17 (33%)	9 (18%)	12 (24%)
	Calcium channel blocker	23 (44%)	16 (31%)	24 (47%)
	Diuretic	8 (15%)	5 (10%)	12 (24%)

Alpha blocker	2 (4%)	4 (8%)	2 (4%)
Other	-	-	4 (8%)

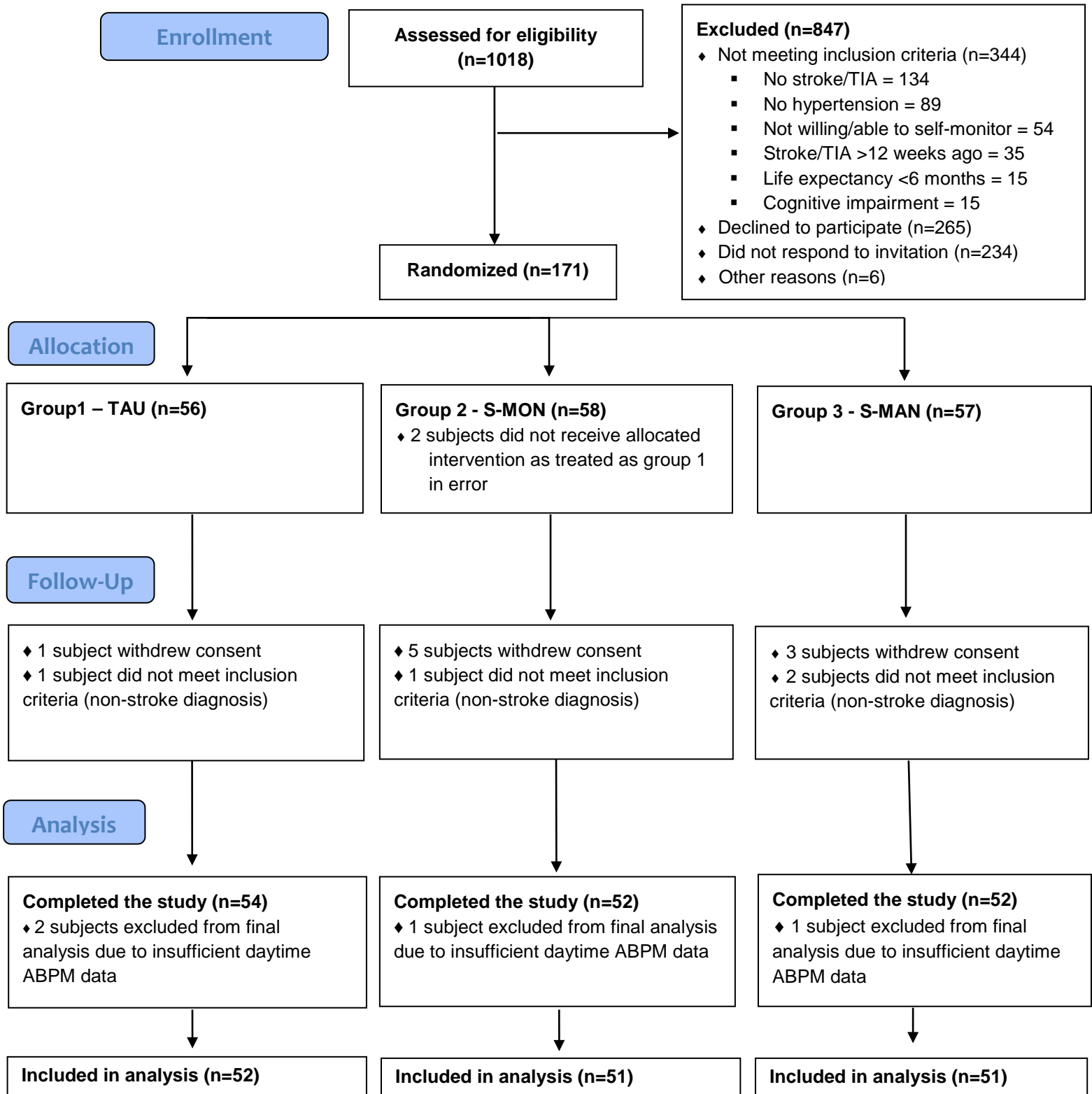
Table II: Ambulatory systolic and diastolic blood pressure at six months for each trial arm and the between-group differences. Values presented are mean (SD) for within-group blood pressure levels and mean (95% confidence interval) for between-group differences.

	TAU	S- MON	S- MAN	Difference TAU vs S- MON	P value	Difference TAU vs S- MAN	P value
Daytime ambulatory systolic blood pressure (mmHg)	130.8 (15.5)	128.2 (11.2)	127.8 (12.7)	2.69 (-2.59 to 7.97)	0.31	3.00 (-2.53 to 8.54)	0.28
Daytime ambulatory diastolic blood pressure (mmHg)	72.3 (10.2)	73.5 (7.6)	74.3 (10.5)	-1.18 (-4.70 to 2.34)	0.51	-2.03 (-6.08 to 2.03)	0.32

Figure Legends

Figure 1: CONSORT flow diagram.

Fig. 1: CONSORT Flow Diagram



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Expanded Methods

The Trial of the Effectiveness of Self-monitoring and Treatment of Blood Pressure following stroke or TIA (TEST-BP) was a randomised, blinded end-point, parallel group controlled trial (ClinicalTrials.gov reference no. NCT02947490). Participants were aged 18+ years with a history of mild/moderate stroke (National Institute of Health Stroke Scale (NIHSS) <15) or TIA between 72 hours and twelve weeks post-event and requiring treatment for hypertension (defined as being on antihypertensive medications prior to the cerebrovascular event or having untreated BP \geq 140/90mmHg from the mean of three clinic readings at screening). Participants also had to be willing to undertake SBPM with or without guided self-management and undergo two periods of ambulatory BP monitoring (ABPM). None of the participants had undertaken self-BP measurement prior to study entry. Patients with life expectancy below six months or established cognitive impairment were excluded. Ethical approval for the trial was obtained from the Research Ethics Committee East of England – Norfolk (ref: 11/EE/0147) and the trial was conducted in accordance with the principles of the Declaration of Helsinki. The trial protocol is publicly available on the ISRCTN website (<http://www.isrctn.com/ISRCTN86192648>).

Eligible participants were identified from inpatient and outpatient stroke services at the Norfolk and Norwich University Hospital. Patients willing to participate provided written informed consent before being randomised in a 1:1:1 ratio, to Treatment As Usual (TAU), Self-MONitoring only (S-MON), or Self-monitoring with guided self-MANagement of BP (S-MAN). An interactive web randomisation system using a computer generated randomisation list was built into the web-based trial database. The list was concealed from the

research team and provided non-stratified group allocation with a block size of six.

Participants and the trial nurses/clinician were not blinded to group allocation, but those analysing the outcome data were.

All subjects underwent baseline ABPM (Spacelabs 90207 monitor, Spacelabs Healthcare Ltd. (UK), Hertford, UK) set to measure BP every 20 minutes from 0700-2200 and hourly overnight (2200-0700) following NICE guidelines [1]. TAU participants' subsequent BP management was by their General Practitioner (GP). Participants in the intervention groups received face-to-face, written, and audio-visual instruction on self-monitoring from the trial nurse. Self-monitoring over seven days was performed at six weeks, three and five months post-randomisation. Two measurements were taken in the morning and evening for seven consecutive days with a target of $\geq 75\%$ of all possible self-readings, additional readings being requested if that was not achieved. Measurements were taken in a seated position after five minutes rest, using the non-dominant arm, and were taken before meals and antihypertensive medications. The S-MON group used a validated British Hypertension Society (BHS) approved monitor with integrated memory and printer (Omron 705IT, Omron Healthcare UK Ltd., Milton Keynes, UK). Results were collected by the trial team and relayed directly to the participant's GP for review without any treatment recommendations, though target BP levels were suggested as below. The S-MAN group used a different BHS validated home monitor to S-MON in order to incorporate telemonitoring of results into this intervention arm, thereby increasing the intervention intensity in conjunction with the guided self-management of antihypertensive treatment. S-MAN participants used a validated BHS approved monitor (A&D UA-767PBT, A&D Instruments Ltd., Abingdon, UK) with linked Bluetooth modem (iModem; Netmedical, Utrecht, Netherlands) that automatically transmitted readings to the trial team. Any changes to antihypertensive treatment were suggested at the end of the seven-

day monitoring period by the supervising trial clinician (a stroke physician) based on agreed target BP levels described below. Decisions were discussed with the participant by telephone and individualised so that they could be self-implemented without contacting their GP for an additional prescription where possible. Any recommended changes were also sent to the patient by letter at the same time, with a copy sent to their GP. Telephone follow-up was conducted by the trial nurses 2-3 days after any changes to ensure that the participant was happy with the new regime. BHS guidelines that were current at the time of the trial design recommended a target clinic BP of $\leq 130/80$ mmHg for patients with a previous stroke or TIA [2]. They also recommended that out-of-office BP targets should be adjusted down by 10/5mmHg to allow for the expected difference in out-of-office readings compared to clinic readings. Target BP for both self-monitoring groups in this trial, if tolerated, was therefore $\leq 120/75$ mmHg, taking the mean of all self-measurements. This target was in keeping with the design of other trials of self-monitoring in general hypertensive patients [3]. For consistency, the same threshold was used to define BP control on daytime ambulatory measurements.

At six months, the primary end-point measure of daytime ambulatory systolic BP (SBP) was taken. Secondary outcomes were (i) differences in mean daytime ambulatory diastolic BP (DBP) at six months, (ii) differences in antihypertensive medication changes, (iii) adverse events. Additional secondary outcomes presented in this online supplement were (i) between-group differences in mean night-time SBP and DBP, (ii) between-group differences in mean 24 hour SBP and DBP, (iii) between-group differences in mean daytime ambulatory SBP and DBP at six months in participants with daytime ABPM $\geq 120/75$ mmHg, (iv) between-group differences in mean daytime ambulatory SBP and DBP at six months in participants with stroke vs. TIA.

Minimum required numbers of 48 per group were based on a sample size calculation to detect a difference in mean daytime ambulatory SBP of 6mmHg, with a power of 0.8 at the 5% significance level, assuming a standard deviation of 10.3mmHg for daytime ABPM [4].

Participants were excluded from analysis if there were <14 daytime ABPM measurements or if they failed to comply with self-monitoring.

Outcomes Analysis

Data were analysed using SPSS version 23.0 on an intention to treat basis. Continuous data are presented as mean (standard deviation (SD)) or mean (95% confidence interval (CI)), discrete data as median (interquartile range (IQR)). Independent samples t-tests were used to assess between-group differences in mean BP at outcome. Chi-squared tests were used to assess proportions of participants who were normotensive at outcome and proportions of participants who had medication changes during the trial. Mann-Whitney U tests were used to assess between-group differences in changes in medication use. For all tests each intervention group was compared to the control group separately, with exploratory comparison of the intervention groups only where both were significantly different to control. This approach was taken to reduce the risk of a false positive outcome and to eliminate bias that may occur if comparing the interventions with distinct control groups [5]. Planned subgroup analyses of baseline hypertensive vs. normotensive (threshold 120/75mmHg from daytime ABPM) and stroke vs. TIA were performed using a linear model with a test for interaction for SBP and DBP at six months. Due to the small number of participants with missing ABPM data a sensitivity analysis was conducted after imputation of missing values. Predictive mean matching was used, with mean baseline clinic BP and baseline daytime ABPM as variables for imputing missing baseline ABPM values, and mean baseline clinic BP and outcome daytime ABPM as variables for imputing missing outcome ABPM values.

Additional Results

Supplementary Table I: Night-time and 24 hour ambulatory systolic and diastolic blood pressure at six months for each trial arm and the between-group differences. Values presented are mean (SD) for within group blood pressure levels and mean (95% confidence interval) for between group differences.

	TAU	S-MON	S-MAN	Difference TAU vs S- MON	P value	Difference TAU vs S- MAN	P value
Night-time ambulatory systolic blood pressure (mmHg)	122.6 (14.1)	119.3 (15.6)	120.1 (18.1)	3.36 (-2.56 to 9.28)	0.26	2.52 (-3.92 to 8.97)	0.44
Night-time ambulatory diastolic blood pressure (mmHg)	65.4 (9.8)	66.3 (10.0)	66.7 (10.1)	-0.89 (-4.82 to 3.05)	0.66	-1.29 (-5.23 to 2.66)	0.52
24 hour ambulatory systolic blood pressure (mmHg)	129.5 (15.2)	126.5 (11.3)	126.2 (13.2)	2.95 (-2.29 to 8.20)	0.27	3.25 (-2.33 to 8.82)	0.25
24 hour ambulatory diastolic blood pressure (mmHg)	71.3 (10.2)	72.3 (7.6)	72.9 (10.1)	-1.03 (-4.55 to 2.48)	0.56	-1.62 (-5.58 to 2.34)	0.42

Supplementary Table II: Ambulatory systolic blood pressure (SBP) and diastolic blood pressure (DBP) at six months for each trial arm and the between-group differences in participants with controlled or uncontrolled baseline blood pressure (threshold daytime ambulatory blood pressure $\leq 120/75$ mmHg) with a test for interaction. Values presented are mean (SD) for within-group blood pressure levels and mean (95% confidence interval) for between-group differences.

	TAU	S-MON	S-MAN	Difference TAU vs. S-MON	P value*	Difference TAU vs. S-MAN	P value*
Uncontrolled SBP	133.1 (14.8)	130.1 (9.5)	130.1 (12.0)	2.97 (-2.24 to 8.18)	0.34	3.02 (-2.64 to 8.68)	0.68
Controlled SBP	113.7 (8.7)	117.6 (14.3)	113.9 (6.4)	-3.96 (-18.38 to 10.46)		-0.19 (-9.39 to 9.00)	
Uncontrolled DBP	73.2 (10.3)	74.2 (7.7)	75.3 (10.9)	-1.01 (-4.83 to 2.80)	0.55	-2.09 (-6.53 to 2.34)	0.91
Controlled DBP	65.7 (7.5)	69.8 (6.2)	68.4 (4.8)	-4.08 (-12.06 to 3.89)		-2.76 (-10.36 to 4.83)	

*based on interaction test

Supplementary Table III: Ambulatory systolic blood pressure (SBP) and diastolic blood pressure (DBP) at six months for each trial arm and the between-group differences in participants diagnosed with stroke or TIA with a test for interaction. Values presented are mean (SD) for within-group blood pressure levels and mean (95% confidence interval) for between-group differences.

	TAU	S- MON	S- MAN	Difference TAU vs. S-MON	P value*	Difference TAU vs. S-MAN	P value*
Stroke SBP	129.4 (13.6)	126.2 (8.9)	123.5 (8.4)	3.22 (-4.57 to 11.01)	0.88	5.92 (-1.92 to 13.75)	0.46
TIA SBP	131.6 (16.5)	129.2 (12.3)	130.0 (13.9)	2.38 (-4.74 to 9.49)		1.59 (-5.82 to 8.99)	
Stroke DBP	70.8 (10.7)	73.1 (8.4)	72.2 (9.7)	-2.22 (-8.75 to 4.30)	0.67	-1.40 (-8.43 to 5.63)	0.84
TIA DBP	73.1 (10.0)	73.7 (7.3)	75.4 (10.9)	-0.64 (-4.91 to 3.63)		-2.29 (-7.37 to 2.78)	

*based on interaction test

Table IV: Rates of the most commonly reported side effects (those reported by >25% of participants in total) at six months, assessed using the revised illness perception questionnaire. Values presented are frequency (%). There were no significant differences between groups.

Side Effect	Treatment as usual (N=52)	Self-monitoring only (N=51)	Self-monitoring and self-management (N=51)
Fatigue	22 (42%)	22 (43%)	23 (45%)
Pain	20 (39%)	17 (33%)	26 (51%)
Breathlessness	21 (40%)	17 (33%)	18 (35%)
Stiff joints	18 (35%)	16 (31%)	19 (37%)
Leg/ankle swelling	12 (23%)	18 (35%)	15 (29%)
Cough	16 (31%)	16 (31%)	14 (28%)
Sleep disturbance	15 (29%)	14 (28%)	16 (31%)
Dizziness	14 (27%)	11 (22%)	20 (39%)
Pins and needles	15 (29%)	15 (29%)	14 (28%)
Dry mouth	13 (25%)	12 (24%)	16 (31%)
Loss of strength	15 (29%)	12 (24%)	13 (26%)

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