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Research Letters

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 ≤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 ≤130/80mmHg, 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 ≤120/75mmHg.

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 ≤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.

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Declarations of Interest: none

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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 ≤120/75mmHg				
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.

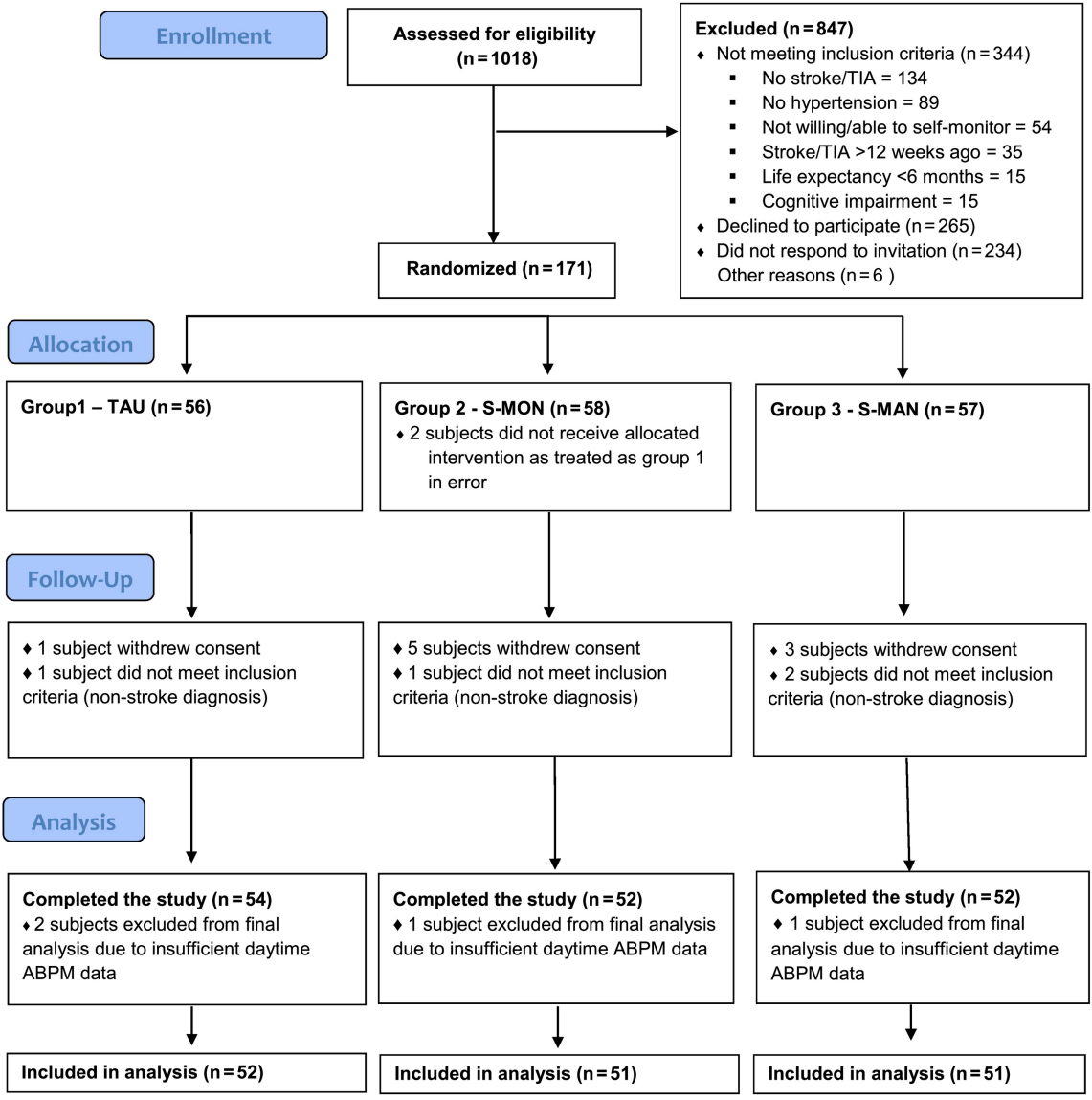
Enrollment
Assessed for eligibility (n = 1018)
Excluded (n = 847)
Not meeting inclusion criteria (n = 344)
No stroke/TIA = 134
No hypertension = 89
Not willing/able to self-monitor = 54
Stroke/TIA >12 weeks ago = 35
Life expectancy <6 months = 15
Cognitive impairment = 15
Declined to participate (n = 265)
Did not respond to invitation (n = 234)
Other reasons (n = 6)
Randomized (n = 171)
Allocation
Group1 – TAU (n = 56)
Group 2 - S-MON (n = 58)
2 subjects did not receive allocated intervention as treated as group 1 in error
Group 3 - S-MAN (n = 57)
Follow-Up
1 subject withdrew consent
1 subject did not meet inclusion criteria (non-stroke diagnosis)
5 subjects withdrew consent
1 subject did not meet inclusion criteria (non-stroke diagnosis)
3 subjects withdrew consent
2 subjects did not meet inclusion criteria (non-stroke diagnosis)
Analysis
Completed the study (n = 54)
2 subjects excluded from final analysis due to insufficient daytime ABPM data
Completed the study (n = 52)
1 subject excluded from final analysis due to insufficient daytime ABPM data
Completed the study (n = 52)
1 subject excluded from final analysis due to insufficient daytime ABPM data
Included in analysis (n = 52)
Included in analysis (n = 51)
Included in analysis (n = 51)

Figure 1