ORIGINAL RESEARCH ARTICLE

Self-Monitoring and Management of Blood Pressure in Patients with Stroke or TIA: An Economic Evaluation of TEST-BP, A Randomised Controlled Trial

Lois G. Kim[1,2] · Edward C. F. Wilson[1,3] ⬤ · William J. Davison[4] · Allan B. Clark[5] · Phyo K. Myint[6] · John F. Potter[4]

Abstract

Background Prevention of secondary stroke following initial ictus is an important focus of after-stroke care. Blood pressure (BP) is a key risk factor, so usual care following stroke or transient ischaemic attack includes regular BP checks and monitoring of anti-hypertensive medication. This is traditionally carried out in primary care, but the evidence supporting self-monitoring and self-guided management of BP in the general population with hypertension is growing.

Objective Our objective was to estimate the cost effectiveness of treatment as usual (TAU) versus (1) self-monitoring of BP (S-MON) and (2) self-monitoring and guided self-management of anti-hypertensive medication (S-MAN).

Methods This was a within-trial economic evaluation of a randomised controlled trial estimating the incremental cost per 1 mmHg BP reduction and per quality-adjusted life-year (QALY) gained over a 6-month time horizon from the perspective of the UK National Health Service (NHS).

Results Data were evaluable for 140 participants. Costs per patient were £473, £853 and £1035; mean reduction in systolic BP (SBP) was 3.6, 6.7 and 6.1 mmHg, and QALYs accrued were 0.427, 0.422 and 0.423 for TAU, S-MON and S-MAN, respectively. No statistically significant differences in incremental costs or outcomes were detected. On average, S-MAN was dominated or extended dominated. The incremental cost per 1 mmHg BP reduction from S-MON versus TAU was £137.

Conclusion On average, S-MAN is an inefficient intervention. S-MON may be cost effective, depending on the willingness to pay for a 1 mmHg BP reduction, although it yielded fewer QALYs over the within-trial time horizon. Decision modelling is required to explore the longer-term costs and outcomes.

✉ Edward C. F. Wilson
ed.wilson@uea.ac.uk

1 Cambridge Centre for Health Services Research, Institute of Public Health, University of Cambridge School of Clinical Medicine, Forvie Site, Cambridge, UK

2 Cardiovascular Epidemiology Unit, Department of Public Health and Primary Care, Strangeways Research Laboratory, Wort's Causeway, Cambridge, UK

3 Health Economics Group, Norwich Medical School, University of East Anglia, Norwich, UK

4 Ageing and Stroke Medicine, Norwich Medical School, University of East Anglia, Norwich, UK

5 Medical Statistics Group, Norwich Medical School, University of East Anglia, Norwich, UK

6 Ageing Clinical and Experimental Research (ACER), Institute of Applied Health Sciences, University of Aberdeen, Aberdeen, UK

1 Introduction

Prevention of stroke recurrence following initial stroke or transient ischaemic attack (TIA) is an important focus for secondary prevention, the risk being substantially reduced by good blood pressure (BP) control [1–3]. Usual care following stroke and TIA therefore includes regular BP checks and monitoring of anti-hypertensive medications, which are usually carried out in primary care.

In recent years, evidence supporting the use of self-monitoring and guided management of BP in the general population with high BP has been growing [4, 5]. Several studies have reported benefits in terms of BP reductions and improved control, and this approach therefore offers a potential opportunity to not only translate these benefits to patients with a history of stroke or TIA but also to reduce the primary care burden associated with after-stroke care. Since no consensus yet exists regarding whether specific subgroups (such as those with a history of stroke/TIA) benefit

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Key Points for Decision Makers

On average, over a 6-month time horizon, self-management of anti-hypertensive medication is not an efficient intervention. The incremental cost per 1 mmHg blood pressure (BP) reduction for self-monitoring of BP versus treatment as usual (TAU) was £137.

Point estimate quality-adjusted life-years (QALYs) accrued were very similar, although TAU had the highest point estimate.

As future cardiovascular events will be a major driver of QALYs, decision modelling is required to explore longer-term costs and outcomes.

from this strategy, or whether guided self-management in conjunction with self-monitoring offers a superior approach to self-monitoring alone [6], it remains important to evaluate these strategies in specific subpopulations of interest.

TEST-BP (Trial of the Effectiveness of Self-monitoring/Treatment of BP after stroke; ClinicalTrials.gov reference NCT02947490) was a randomised controlled trial that assessed the benefits in terms of BP reduction and reaching target levels using these approaches in patients following stroke or TIA. The trial reported small and statistically non-significant improvements in systolic BP (SBP) over 6 months in patients using both self-monitoring of BP and self-monitoring plus guided management of their anti-hypertensive medications compared with usual care [7]. Although BP reduction and control rates were not statistically significantly different between the interventions, these results demonstrated that this approach to after-stroke BP care was both safe and well-tolerated (only 2% of patients receiving the intervention did not comply with the BP measurement protocol) among patients with stroke or TIA. Self-monitoring and guided self-management were associated with significantly greater increases in anti-hypertensive drug use than was usual treatment.

In this study, we estimated the within-trial cost effectiveness of self-monitoring and self-management of BP in patients with a history of stroke or TIA. We used patient data from TEST-BP to combine information about the SBP reduction benefits and the associated costs to assess the short-term cost effectiveness of these interventions.

2 Methods

2.1 Clinical Study

Full details of the results of TEST-BP have been published elsewhere [7]. In brief, 171 community-dwelling adults in England with a recent mild or moderate stroke or TIA requiring anti-hypertensive treatment to prevent recurrence were randomised into the three arms of the trial between December 2012 and March 2016, of whom 154 were included in the final outcomes analysis: (1) treatment as usual (TAU, $n = 52$), (2) self-monitoring of BP (S-MON, $n = 51$), (3) self-monitoring of BP plus guided management of anti-hypertensive medications (S-MAN, $n = 51$). A target BP of ≤ 130/80 mmHg was used for office measurement, adjusted downwards to 120/75 mmHg for out-of-office measurement in the intervention groups (S-MON, S-MAN). This was to counteract the so-called 'white coat' effect of BP measurement [8]. Daytime ambulatory BP monitoring values were used to provide BP measurements (study primary outcome) at baseline and 6-month follow-up. The intervention for both S-MON and S-MAN groups comprised self-monitoring over a 7-day period, taking two readings in the morning before treatment and two again about 12 h later using validated monitors at 6 weeks, 3 months and 5 months after baseline. Self-recorded values were passed to the general practitioner (GP) in the S-MON group by post/telephone and directly to the study team in the S-MAN group by telemetry, with a paper copy to the patient's GP; the S-MAN group then received guidance from the study clinician regarding possible adjustments to their medications and jointly agreed on any changes without the need for a face-to-face appointment with their GP. Medication management in the TAU and S-MON groups was carried out by the GP with no input from the trial team. Data on changes in treatment, GP visits and adverse events were recorded at each study visit in TAU and S-MON at the beginning and end of the trial.

2.2 Health Economic Measurements and Analysis

Profiles as per the three-level EuroQoL-Five Dimensions (EQ-5D-3L) instrument were collected at baseline and 6-month follow-up and converted to utilities using UK-specific preference weights [9]. Quality-adjusted life-years (QALYs) over the follow-up period were then calculated as the area under the curve using linear interpolation between the two timepoints. Comparisons of QALYs between groups were adjusted for baseline utility [10].

Costs were calculated by extracting resource-use quantities from the patient-completed resource-use questionnaires and multiplying them by unit costs taken from standard national health service (NHS) sources for 2017/18 [11, 12]. Unit costs are reported in the online appendix. Where appropriate, costs were adjusted to year 2017/8 values using the hospital and community health services pay and prices index [13] (to 2016) and the new health services index [11]. Anti-hypertensive medication costs were calculated using frequency and dose of prescription alongside data on pack

size and cost relevant for the NHS [14, 15]. To minimise respondent burden, a maximum of one medication per category (α-blockers, β-blockers, calcium channel blockers, diuretics, angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers, and other anti-hypertensive medications) was recorded at baseline, 6 weeks, 3 months, and 5 months and at 6-month follow-up, with usage assumed constant between timepoints. The cost of the intervention included purchase price of the BP monitor and associated software costs, two nurse home visits incorporating time spent training patients in their use (nurse time and mileage costs applied) and telephone charges to remind patients to monitor their BP and to discuss treatment changes in the S-MON and S-MAN arms [11]. Prices for monitors and associated software (€, year 2012/3 values) were converted to £ at the historic rate (2012) of €1: £0.833, before being adjusted to year 2018 values. The economic evaluation was conducted from the perspective of the NHS over a time horizon of 6 months (within-trial evaluation). No discounting was applied because of the short time horizon of the study. Data were analysed with Stata v16.0 (Stata Corp LLC, College Station, TX, USA).

We report mean (95% confidence interval [CI]) change in SBP from baseline, QALYs accrued and cost per patient, with increments $\pm$ 95% CI reported compared with TAU. Primary analysis was based on as-treated groups; a sensitivity analysis was then carried out based on intention to treat (ITT). Point estimate incremental cost-effectiveness ratios (ICERs) are reported taking into account dominance and extended dominance, with uncertainty in the ICERs reported via cost-effectiveness acceptability curves (CEACs) and frontiers, showing the probability that each of the interventions is the most cost effective at various thresholds of willingness to pay (WTP) per point reduction in SBP. CEACs were calculated using 10,000 bootstrapped samples of the dataset. As the quantity of missing data was relatively low (approximately 10%; see Sect. 3), we report complete case analysis only (i.e. no adjustments for missing data).

3 Results

We excluded 14 participants (as-treated groups: one TAU, eight S-MON, five S-MAN) from the economic evaluation because their care resource-use data were incomplete. In total, 140 participants were analysed (51 TAU, 43 S-MON, 46 S-MAN), with a further five patients (two TAU, two S-MON, one S-MAN) excluded from the QALY analysis because of missing utility data.

Table 1 shows the mean resource use and costs in each group, categorised by costs relating directly to the invention, primary/community care use, secondary care use and anti-hypertensive medications. Mean overall costs were £473 for

TAU, £853 for S-MON and £1035 for S-MAN. Differences were not statistically significant (all $p \geq 0.2$).

Table 2 presents the key outcomes relating to the economic evaluation. The incremental cost per additional 1 mmHg SBP reduction with S-MON compared with TAU was £137. S-MON dominated S-MAN (i.e. on average, it was both more effective and less expensive). Figure 1 shows the net benefit for each randomised group over a range of WTP values per 1 mmHg SBP reduction, evaluated at the mean baseline SBP. This suggests that TAU is the preferred approach at WTP values < £137 for 1 mmHg SBP reduction; at higher values, S-MON is the preferred approach. Figure 2 shows the corresponding CEACs. For the ITT analysis, S-MON had the highest probability of cost effectiveness as long as the WTP for a 1 mmHg SBP reduction was > £196. For the analysis based on QALYs, TAU dominated both the S-MON and the S-MAN treatment strategies. Figures 3 and 4 show the net benefit and CEAC plots, respectively, corresponding to this analysis: TAU was the most cost-effective option, with very high certainty over this limited timeframe.

4 Discussion

In terms of BP reduction, on average, S-MON cost £137 per 1 mmHg SBP reduction over 6 months compared with TAU. When taking an ITT approach, the ICER was £196 per 1 mmHg SBP reduction. S-MAN was not an efficient option, yielding poorer outcomes and higher costs than S-MON. This was mostly due to the increased intervention cost, but the higher point estimate cost of anti-hypertensives is worth noting: the S-MAN group tended to use larger doses of medication and more different agents than the S-MON group, but these did not result in better BP control (at least within the 6-month trial time horizon) [7]. When considering cost effectiveness in terms of QALYs, TAU dominated both S-MON and S-MAN because point estimate QALYs were lower than TAU. However, we urge caution in interpreting these results: QALY accruals will be driven much more strongly by future cardiovascular events, which cannot be captured within a 6-month time horizon. Combining our results with longer-term prognoses may yield increased QALYs through reduced BP, but decision modelling is required to confirm or refute this.

TEST-BP was restricted to the post-stroke and TIA subpopulation, so may be expected to provide slightly different estimates of the cost effectiveness of these interventions than studies carried out in other populations. One randomised trial of self-monitoring of BP compared with usual care in the wider hypertensive population reported that self-monitoring was cheaper because of reduced medication costs [16]. However, in that study, the self-monitoring target BP was not adjusted down,

Table 1 Mean resource use and associated cost by group, over the 6-month follow-up period (for those not lost to follow-up)

Intervention	TAU (N=51)		S-MON (N=43)		S-MAN (N=46)	
	Contacts	Cost	Contacts	Cost	Contacts	Cost
Total cost		0		185		379
Primary and community care						
GP—surgery	1.5 ± 1.4	56 ± 51	1.8 ± 2.4	67 ± 89	1.6 ± 2.4	59 ± 87
GP—phone	0.02 ± 0.1	0.16 ± 1.13	0.2 ± 0.5	1.32 ± 4.30	0.1 ± 0.5	0.88 ± 3.90
GP—home	0	NA	0	NA	0	0 ± 0
Nurse—surgery	0.8 ± 0.9	9.15 ± 9.79	1.3 ± 4.1	14.13 ± 44.01	0.6 ± 1.6	6.60 ± 17.04
Nurse—phone	0.02 ± 0.1	0.10 ± 0.70	0	NA	0	0 ± 0
Nurse—home	0	NA	0.8 ± 4.6	9.08 ± 50.39	0	0 ± 0
Health visitor—surgery	0	NA	0	NA	0	0 ± 0
Health visitor—phone	0	NA	0	NA	0	0 ± 0
Health visitor—home	0	NA	0	NA	0.1 ± 0.9	6.72 ± 45.60
Physiotherapist—surgery	0.2 ± 1.4	12.13 ± 72.60	0.2 ± 1.0	9.59 ± 49.36	0.2 ± 1.5	11.21 ± 76.01
Physiotherapist—phone	0	NA	0	NA	0	0 ± 0
Physiotherapist—home	0	NA	0.05 ± 0.3	2.40 ± 15.72	0.2 ± 0.9	10.09 ± 48.14
OT—surgery	0.3 ± 1.5	14.15 ± 77.21	0	NA	0	0 ± 0
OT—phone	0	NA	0	NA	0	0 ± 0
OT—home	0.02 ± 0.1	1.01 ± 7.22	0.05 ± 0.3	2.40 ± 15.72	0.02 ± 0.1	1.12 ± 7.60
Other—surgery	0.3 ± 1.5	16.17 ± 76.11	0.07 ± 0.3	3.60 ± 17.41	0.2 ± 0.9	8.97 ± 46.50
Other—phone	0	NA	0	NA	0	0 ± 0
Other—home	0.04 ± 0.2	2.02 ± 10.11	0	NA	0	0 ± 0
Total cost		111 ± 242		110 ± 157		104 ± 181
Secondary care						
Outpatient appointment	0.6 ± 1.4	76 ± 172	0.9 ± 1.6	108 ± 194	0.7 ± 2.3	90 ± 285
Day-case procedure	0.1 ± 0.5	73 ± 340	0.07 ± 0.3	52 ± 191	0.1 ± 0.7	81 ± 547
Inpatient admission	0.06 ± 0.2	195 ± 787	0.1 ± 0.4	385 ± 1294	0.1 ± 0.5	360 ± 1596
Total cost		343 ± 948		544 ± 1458		530 ± 1919
Anti-hypertensive medication						
Total cost		19 ± 27		14 ± 19		21 ± 26
Grand total cost		473 ± 1045		853 ± 1458		1035 ± 1953

Data are presented as mean ± standard deviation; costs are presented as £

GP general practitioner, *NA* not applicable, *OT* occupational therapist, *S-MAN* self-monitoring and guided self-management of anti-hypertensive medication, *S-MON* self-monitoring of blood pressure, *TAU* treatment as usual

which may have influenced treatment costs. Furthermore, primary and secondary care costs were not included, and details on the methods used to compare costs between groups were not given. A systematic review of self-monitoring with telemonitoring by Omboni et al. [17], again in the wider hypertensive population, incorporated a cost-effectiveness analysis. Six studies were analysed, and the authors reported that the cost of self-monitoring with telemonitoring was greater than that of usual care by around €660, with a cost per 1 mmHg SBP reduction of €406. However, there was substantial heterogeneity between the studies, with only three reporting on medical costs in addition to intervention costs, and a wide range of follow-up durations. Along with the difference in population studied, this likely accounts for the differences from our findings.

A key strength of our study was the use of ambulatory BP monitoring for the outcome measure, as opposed to clinic BP measurement used in other studies [18, 19], thus decreasing the influence of the natural variability in BP measurement and reducing the risk of measurement bias [20]. Another strength was the simultaneous comparison of two intervention strategies, this being the first health economic evaluation of guided self-management exclusively in a stroke/TIA population.

The major limitation of this study was that it only provided a short-term perspective on the benefits and costs associated with these interventions, focusing on the impact on BP. Studies with durations > 24 months have shown that the benefits of BP self-monitoring in terms of control decreased with time [21]. However, even modest BP reductions may

Table 2 Key costs and outcomes results for economic evaluation

Costs and outcomes	TAU	S-MON	S-MAN
Primary analysis: SBP	*N* = 51	*N* = 43	*N* = 46
Mean reduction in SBP	3.6 (0.2 to 7.0)	6.7 (3.1 to 10.4)	6.1 (2.6 to 9.7)
Incremental reduction in SBP[a,b]	NA	2.8 (− 1.6 to 7.1)	2.7 (− 1.5 to 7.0)
Mean total cost	473 (186 to 760)	853 (417 to 1289)	1035 (471 to 1599)
Incremental cost[b]	NA	380 (− 254 to 1013)	562 (− 61 to 1184)
Incremental cost per 1 mmHg reduction in SBP[a,c]	NA	137[b]	Dominated[d]
Sensitivity analysis: ITT	*N* = 49	*N* = 45	*N* = 46
Mean reduction in SBP	3.3 (− 0.1 to 6.7)	6.9 (3.3 to 10.4)	6.1 (2.6 to 9.7)
Incremental reduction in SBP[a,b]	NA	2.5 (− 1.9 to 6.9)	2.6 (− 1.7 to 6.9)
Mean total cost	408 (222 to 776)	905 (450 to 1359)	1035 (585 to 1484)
Incremental cost[b]	NA	495 (− 135 to 1124)	625 (− 1 to 1250)
Incremental cost per 1 mmHg reduction in SBP[a,c]	NA	196[b]	1113[d]
Secondary analysis: QALYs	*N* = 49	*N* = 41	*N* = 45
Mean QALYs[e]	0.427	0.422	0.423
Cost per QALY[c,e]	NA	Dominated	Dominated

Data are presented as means (95% confidence interval), costs are presented in £ and reductions are presented in mmHg

ITT intent to treat, *NA* not applicable, *QALY* quality-adjusted life-year, *SBP* systolic blood pressure, *S-MAN* self-monitoring and guided self-management of anti-hypertensive medication, *S-MON* self-monitoring of BP, *TAU* treatment as usual

[a]Adjusted for baseline SBP

[b]Compared with TAU, after adjustment for baseline SBP

[c] Willingness-to-pay value at which the incremental net benefit was 0

[d]Compared with S-MON
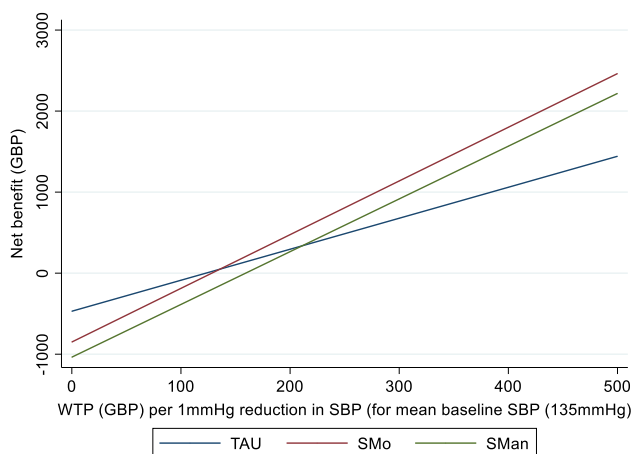
[e]Evaluated at mean baseline utility (0.847)

Fig. 1 Net benefit for a range of values of WTP per 1 mmHg SBP reduction, by randomised group. *GBP* Great British pounds, *SBP* systolic blood pressure, *SMan* self-monitoring and guided self-management of anti-hypertensive medication, *SMo* self-monitoring of blood pressure, *TAU* treatment as usual, *WTP* willingness to pay

Fig. 2 Cost-effectiveness acceptability curves based on SBP reduction, by randomised group. *GBP* Great British pounds, *SBP* systolic blood pressure, *SMan* self-monitoring and guided self-management of anti-hypertensive medication, *SMo* self-monitoring of BP, *TAU* treatment as usual

translate into sizeable risk reductions in terms of secondary stroke prevention [1]. Therefore, the relatively small reductions observed in the TEST-BP trial may convert into larger benefits in the longer term. Health economic modelling work
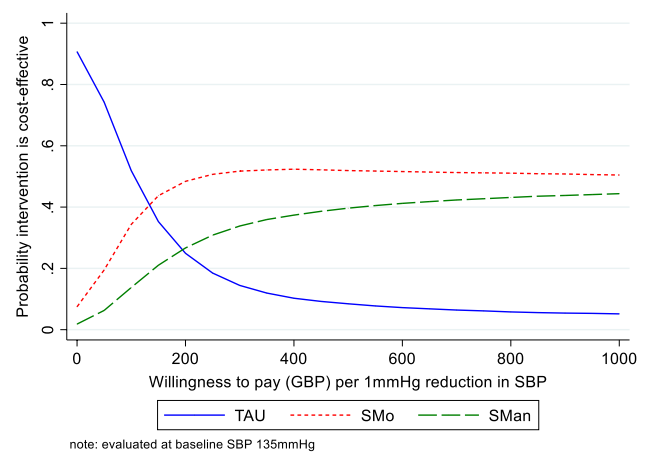
would be needed to formally assess the long-term cost effectiveness of these interventions in patients with stroke or TIA, though this would necessarily require a range of assumptions regarding the conversion of reductions in short-term SBP into lifetime QALYs, as has been implemented in the
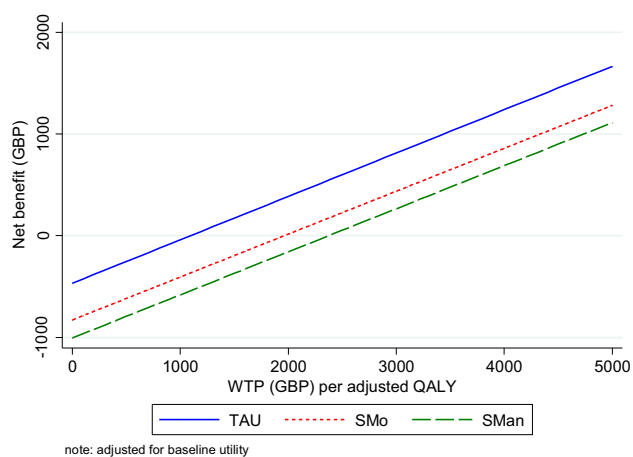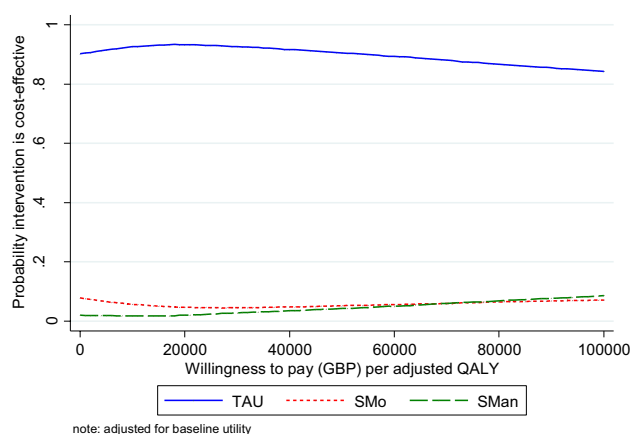
Fig. 3 Net benefit for a range of values of WTP per QALY, by randomised group. *GBP* Great British pounds, *QALY* quality-adjusted life-year, *SMan* self-monitoring and guided self-management of anti-hypertensive medication, *SMo* self-monitoring of blood pressure, *TAU* treatment as usual, *WTP* willingness to pay

Fig. 4 Cost-effectiveness acceptability curves based on QALYs, by randomised group. *GBP* Great British pounds, *QALY* quality-adjusted life-year, *SMan* self-monitoring and guided self-management of anti-hypertensive medication, *SMo* self-monitoring of BP, *TAU* treatment as usual

general hypertensive population [22]. It should be noted that studies of 12–24 months' duration tend to report a sustained effect from self-monitoring, but other data suggest this may diminish over the longer term [21].

Another limitation of our analysis is potential overestimation of the cost of BP monitors. A monitor is likely to last more than the 6-month time horizon of this study. However, amortising the purchase price over a longer period would not materially change our results: S-MAN would still be dominated by S-MON, and the ICER of S-MON versus TAU would be lower (more cost effective).

Finally, we reported per-protocol analyses as our primary analysis because this represents costs and outcomes for patients who actually completed the interventions, but this is of course at risk of bias. We therefore also reported the ITT analysis.

Despite the growing body of evidence demonstrating the effectiveness of self-monitoring BP in various populations, few studies have carried out economic evaluations of this approach to date. Kaambwa et al. [22] reported a long-term cost-effectiveness analysis of the TASMINH2 trial, which examined the use of telemonitoring and self-monitoring of BP measurements in patients with hypertension. This analysis suggested that lifetime cost effectiveness was around £1600 per QALY in men and £5000 per QALY in women based on a continued BP reduction of 6.4 mmHg and 4.4 mmHg, respectively.

5 Conclusions

Self-management of BP is unlikely to be cost effective. A self-monitoring strategy costs an extra £137 per 1 mmHg SBP decrease over a 6-month time horizon. Decision modelling is required to project these findings to a lifetime horizon to explore whether it may yield further benefits in terms of reduced stroke recurrence and other cardiovascular impacts.

Compliance with Ethical Standards

Conflict of interest AC, WD, LK, PM and JP have no conflicts of interest that are directly relevant to the content of this article. EW has received travel expenses from the funder to attend study meetings.

Ethical approval Ethical approval for the trial was granted by the Research Ethics Committee East of England—Norfolk (ref: 11/EE/0147), and the study was performed in accordance with the ethical standards of the Declaration of Helsinki. All participants provided written informed consent.

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