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Telemonitoring and self-management in the control of hypertension (TASMINH2): a cost-effectiveness analysis

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Abstract

Aims: Self-monitoring and self-titration of antihypertensives (self-management) is a novel intervention which improves blood pressure control. However, little evidence exists regarding the cost-effectiveness of self-monitoring of blood pressure in general and self-management in particular. This study aimed to evaluate whether self-management of hypertension was cost-effective.

Design and methods: A cohort Markov model-based probabilistic cost-effectiveness analysis was undertaken extrapolating to up to 35 years from cost and outcome data collected from the telemonitoring and self-management in hypertension trial (TASMINH2). Self-management of hypertension was compared with usual care in terms of lifetime costs, quality adjusted life years and cost-effectiveness using a UK Health Service perspective. Sensitivity analyses examined the effect of different time horizons and reduced effectiveness over time from self-management.

Results: In the long-term, when compared with usual care, self-management was more effective by 0.24 and 0.12 quality adjusted life years (QALYs) gained per patient for men and women, respectively. The resultant incremental cost-effectiveness ratio for self-management was £1624 per QALY for men and £4923 per QALY for women. There was at least a 99% chance of the intervention being cost-effective for both sexes at a willingness to pay threshold of £20,000 per QALY gained. These results were robust to sensitivity analyses around the assumptions made, provided that the effects of self-management lasted at least two years for men and five years for women.

Conclusion: Self-monitoring with self-titration of antihypertensives and telemonitoring of blood pressure measurements not only reduces blood pressure, compared with usual care, but also represents a cost-effective use of health care resources.

Keywords

Hypertension, telemonitoring, self-management, cost-effectiveness

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Introduction

Raised blood pressure remains a key factor in determining lifetime risk of cardiovascular disease, the largest cause of morbidity and mortality worldwide, yet only about a half of people on treatment for hypertension have their blood pressure controlled to recommended levels.[1-3] This difficulty in achieving control is despite significant advances in the evidence base for both lifestyle and pharmaceutical interventions.[4,5] Therefore, there is a potentially important role for novel interventions to lower blood pressure, particularly in primary care, where most hypertension management takes place.

One such approach is patient self-management, which has gained widespread use in other chronic conditions such as diabetes[6] and anticoagulation control.[7] Self-management comprising self-monitoring and self-titration of antihypertensive medication has recently been shown to reduce blood pressure but prior to implementation the implications of the additional requirements (training, monitoring equipment) on costs and cost-effectiveness need to be evaluated.[8]

Previous work has largely evaluated the cost-effectiveness of self-monitoring of hypertension. The results of these evaluations have been inconsistent and have not been extrapolated to the longer term.[9–15] One study reported trial costs of self-monitoring with a behavioural self-management intervention and then conducted an informal cost-effectiveness analysis with results expressed in terms of costs per life year.[10] To our knowledge, no studies to date have examined the long-term cost-effectiveness of self-monitoring combined with self-titration in hypertension.

This study aimed to assess the long-term cost-effectiveness of self-monitoring with self-titration of antihypertensives and telemonitoring of blood pressure measurements, hereafter simply referred to as self-management of hypertension or intervention, in comparison with usual hypertension care. A model-based probabilistic cost-effectiveness analysis was undertaken extrapolating from cost and outcome data collected from the first major randomised controlled trial (RCT) of such self-management (TASMINH2).[8]

Methods

The TASMINH2 trial

The methodological details of this prospective RCT have been reported elsewhere.[16] Briefly, primary care physicians identified potential participants using electronic searches of clinical records from 24 general practices in the West Midlands, United Kingdom (UK) between March 2007 and May 2008.[17] To be eligible, patients had to be aged 35–85, have a blood pressure at baseline of over 140/90 mmHg, be receiving treatment for hypertension with two or fewer antihypertensive drugs and be willing to self-monitor and self-titrate medication. Patients following the self-management pathway were trained by members of the TASMINH2 research team for 1–1.75 h in the use of an automated sphygmomanometer (Omron 705IT, Omron Healthcare Europe, Hoofddorp, Netherlands) and associated equipment to take and transmit blood pressure readings.[8] Home targets were adjusted from 140/90 mmHg by 10/5 mmHg to take into account lower home blood pressure.[8] Patients used a colour traffic light system to code these readings as green (below target but above safety limit), amber (above target but below safety limits) and red (very high or very low). On the basis of their readings and following an initial consultation with their primary care physicians, patients could make antihypertensive medication changes without needing to re-consult.[8] All drug choices were left to the Primary Care Physician, who was free to use any antihypertensive drug. For usual hypertension care, patients received an annual hypertension review as per UK national guidelines.[18,19] Follow-up was for 12 months and the trial was powered to detect a 5 mmHg difference in systolic blood pressure. The trial found that intervention patients had a 5.4/2.7 mmHg reduction in blood pressure compared with usual care after 12 months, used more medication and most made at least one change to their treatment.[8]

Development of the cost-effectiveness model

Using a cohort Markov model (with extrapolation from the trial data), we estimated the long-term cost-effectiveness of self-management of hypertension compared with usual care in patients with treated but poorly controlled hypertension. The model was built in TreeAge Pro 2009[20] using previously documented methods.[21,22] Briefly, this entailed dividing a patient's possible course of disease progression into a number of health states with transition probabilities assigned for the movement between these states over a discrete time period called the Markov cycle. Long-term costs and health outcomes were assessed by attaching estimates of resource use and health outcomes to the states in the model and then running the model over a large number of cycles.

In the model, the progress of a hypothetical cohort of hypertensive patients moving along the two alternative pathways of care as received in the trial was compared. The model distinguished between men and women. Health resources use was as observed in the trial, with subsequent clinical pathways designed to mirror the natural progression of the condition in the population (see below).

Model-based predictions of costs and outcomes were compared for the intervention and usual care groups in a cost-utility analysis (CUA) from the UK National Health Service (NHS) perspective.

Model structure and inputs

The structure of the Markov model is shown in Figure 1. Only health states for the 'self-management of hypertension' arm are shown but these are identical to those in the 'usual care' arm. In broad terms, individual patient data were used from the TASMINH2 trial,[8] supplemented by the best available estimates from published sources, where necessary. The starting age of the patient cohorts on entry into the model was 66 years.[8] The time horizon for the model was 35 years, which was the maximum patient lifetime assumed in the analysis.

The Markov process for each arm began with the initial 'well' health state, representing individuals with stable but poorly controlled hypertension. Patients could remain in the 'well' state or move to one of four possible acute health states, namely stroke, myocardial infarction (MI), angina and heart failure (HF).[23] Individuals that survived an acute phase in any of the four health states naturally progressed into a chronic phase where quality of life was lower than in the 'well' state (see Table 2 for utilities). Individuals in a chronic health state remained in that state for the rest of their lives unless they died before the end of the time horizon for the model. The risk of secondary events was not modelled and a cycle length of one year was used.

Transition probabilities governing movement between the five states were obtained from published sources[24-31] and are shown in Table 1. Initially, the mean 10-year cardiovascular (CV) risk for each patient cohort was calculated using the Framingham equation.[23] This risk estimate was then converted into an annual probability, and split between the four possible CV events The weight attributed to each type of event was determined by CV risk profiles measured within the Framingham study,[23] with coronary heart disease (CHD) further sub-divided into MI, HF and angina, using published data on the breakdown of CHD events.[32] Annual risks of CV events increased with the age of the cohort they were applied to.

Age-related relative risks of having a CV event following use of antihypertensive drugs, together with associated reductions in blood pressure (BP), were obtained from Law et al.[4] This information was then used to extrapolate from the 12 month reductions in blood pressure recorded in the TASMINH2 trial (17.8 mmHg and 11.4 mmHg for the intervention and control arms respectively for men and 17.2 mmHg and 12.8 mmHg for the intervention and control arms for women[8]) to the age-related relative risks subsequently used in the model. The base case assumed that the 12-month difference in BP between self-management and usual care was maintained over the lifetime of the model, as were the costs of the intervention and this assumption was then tested in sensitivity analyses (see below). The extrapolated relative risk for CHD was also assumed for MI, angina and HF using data on the breakdown of CHD events from Wood et al.[32] Risk rates used are shown in Table 1.

Resource use and costs

All costs are reported in UK pounds (and euros) at 2009/10 unit prices and, where appropriate, were discounted at 3.5% as recommended by the UK National Institute for Health and Clinical Excellence.[33] Resource use and subsequent costs per patient obtained from the TASMINH2 trial were applied to the initial health state in the model. Total costs per patient in the trial were calculated as the sum of the costs of inpatient and outpatient visits, primary care consultations, drugs, equipment and training. Equipment and training costs (£230 (€267)) were annuitised at 3.5% and based on a lifetime of five years.[33,34] Replacement costs for the equipment and costs of additional training were included at five yearly intervals over the lifetime of the model. Costs for the acute and chronic states were obtained from a number of other sources.[35-38] All cost data are shown in Table 2.

Utility values

All utility scores, which reflect the health-related quality of life associated with each health state in the model, are shown in Table 2. The starting quality of life (QoL) values for individuals in the model were obtained from UK age- and sex-specific QoL estimates.[39] Utilities for any acute state occurring thereafter were applied midway through that one-year cycle and those for the subsequent chronic state at the start of the next cycle. Utility values for all health states were obtained from Cooper et al.[38] Future health state utilities were modelled as multiplicative values of the UK age- and sex-specific QoL estimate[39] and that of the particular health state.

Analysis

Analyses were undertaken from a UK NHS perspective and the primary result reported in terms of the incremental cost per quality adjusted life year (QALY).[34] Probabilistic analyses were used in the base case based on 50,000 Monte Carlo simulations. Gamma distribution were fitted to all costs used in

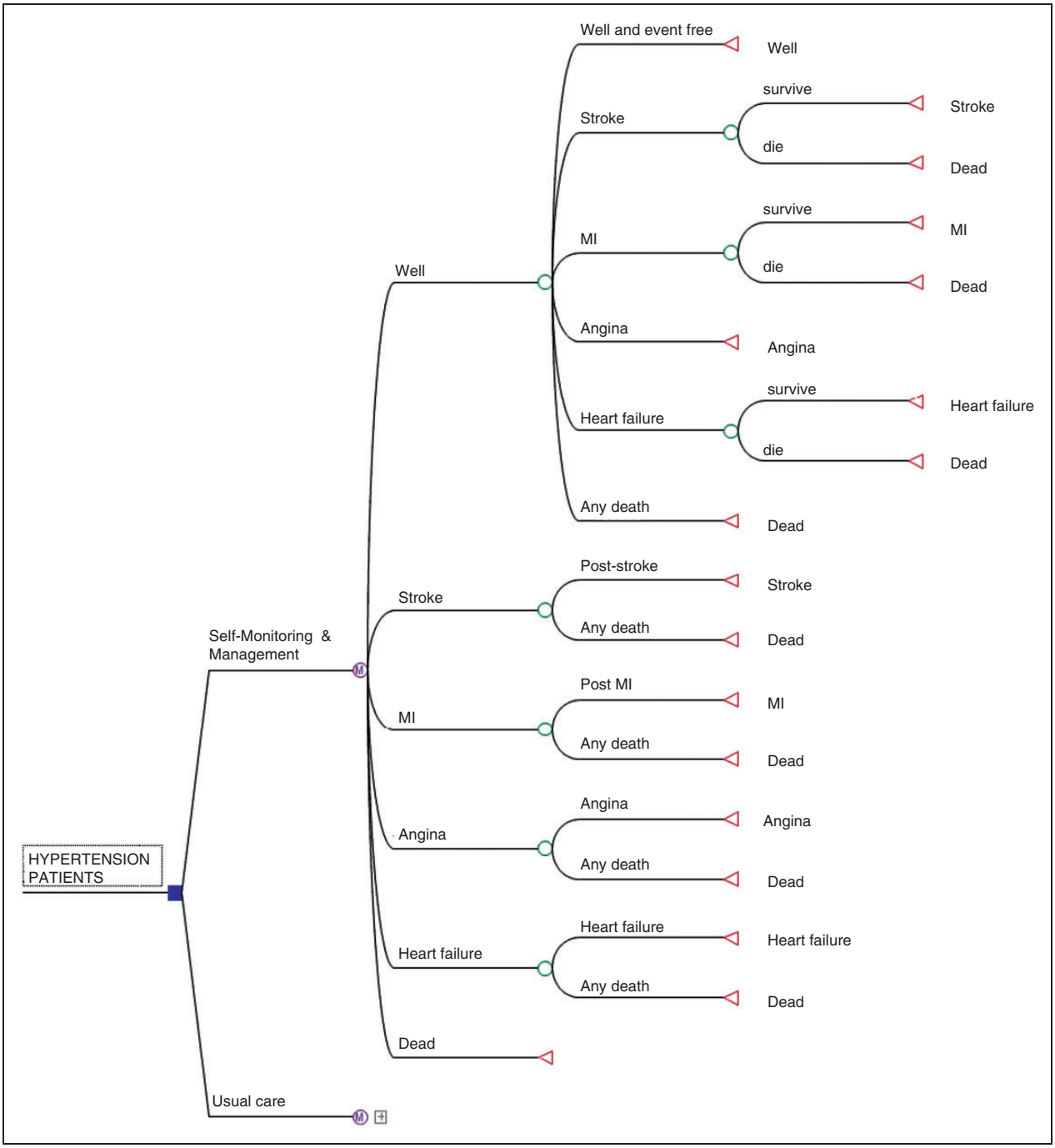

Figure 1. The structure of the Markov model used to conduct the cost-effectiveness analysis. Only health states for the 'self-management of hypertension' arm are shown but these are identical to those in the 'usual care' arm; [+] means 'same structure but with appropriate changes in parameter estimates'. The Markov process for each arm began with the initial health state 'well', representing individuals with stable but poorly controlled hypertension. Patients could remain in the 'well' state or move to one of four possible acute health states, namely stroke, myocardial infarction (MI), angina and heart failure. Individuals that survived an acute phase in any of the four health states naturally progressed into a chronic phase. Individuals in a chronic health state remained in that state for the rest of their lives unless they died before the end of the time horizon for the model.

Table 1. Estimates of blood pressure reductions, risk rates, probabilities and distributions used in the reference case and sensitivity analyses

Description	Estimate[a]	Distribution[b]	Source
Men			
12 month blood pressure reductions – systolic			
Self-monitoring arm	17.8 (14.5, 21.2)	Lognormal	TASMINH2 trial[8]
Usual care arm	11.4 (8.1, 14.7)	Lognormal	TASMINH2 trial[8]
Risks			
One year risk of angina[c]	0.020 (0.020, 0.020)	Lognormal	Anderson et al.[31] andTASMINH2 trial[8]
One year risk of HF[c]	0.006 (0.005, 0.006)	Lognormal	Anderson et al. [31] and TASMINH2 trial[8]
One year risk of MI[c]	0.014 (0.013, 0.015)	Lognormal	Anderson et al.[31] and TASMINH2 trial[8]
One year risk of stroke[c]	0.009 (0.009, 0.010)	Lognormal	Anderson et al.[31] and TASMINH2 trial[8]
Relative risk reductions			
Angina, HF and MI events by age (self-monitoring arm)[d]			
66–69 years	0.57 (0.55, 0.60)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
70–79 years	0.64 (0.60, 0.65)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
>79 years	0.70 (0.65, 0.74)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
Stroke events by age (self-monitoring arm)[e]			
66–69 years	0.47 (0.43, 0.51)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
70–79 years	0.53 (0.50, 0.57)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
>79 years	0.70 (0.64, 0.75)	Lognormal	Law et al.[4] (4) and TASMINH2 trial[8]
Angina, HF and MI events by age (usual care arm)[d]			
66–69 years	0.70 (0.68, 0.73)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
70–79 years	0.75 (0.73, 0.77)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
>79 years	0.80 (0.77, 0.83)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
Stroke events by age (usual care arm)[e]			
66–69 years	0.62 (0.59, 0.65)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
70–79 years	0.68 (0.65, 0.71)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
>79 years	0.80 (0.76, 0.83)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
Women			
12 month blood pressure reductions – systolic			
Self-monitoring arm	17.2 (13.5, 21.0)	Lognormal	TASMINH2 trial[8]
Usual care arm	12.8 (9.1, 16.5)	Lognormal	TASMINH2 trial[8]
Risks			
One year risk of angina[c]	0.010 (0.010, 0.010)	Lognormal	Anderson et al.[31] and TASMINH2 trial[8]
One year risk of HF[c]	0.003 (0.003, 0.003)	Lognormal	Anderson et al.[31] and TASMINH2 trial[8]
One year risk of MI[c]	0.007 (0.007, 0.008)	Lognormal	Anderson et al.[31] and TASMINH2 trial[8]
One year risk of stroke[c]	0.005 (0.005, 0.005)	Lognormal	Anderson et al.[31] and TASMINH2 trial[8]
Relative risk reductions			
Angina, HF and MI events by age (self-monitoring arm)[d]			
66–69 years	0.59 (0.56, 0.61)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
70–79 years	0.65 (0.61, 0.66)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
>79 years	0.71 (0.66, 0.75)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
Stroke events by age (self-monitoring arm)[e]			
66–69 years	0.48 (0.44, 0.52)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
70–79 years	0.54 (0.51, 0.58)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
>79 years	0.71 (0.65, 0.76)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
Angina, HF and MI events by age (usual care arm)[d]			
66–69 years	0.67 (0.65, 0.70)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
70–79 years	0.73 (0.70, 0.74)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
>79 years	0.78 (0.74, 0.81)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
Stroke events by age (usual care arm)[e]			
66–69 years	0.59 (0.56, 0.62)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
70–79 years	0.65 (0.62, 0.68)	Lognormal	Law et al.[4] and TASMINH2 trial[8]
>79 years	0.79 (0.78, 0.81)	Lognormal	Law et al.[4] and TASMINH2 trial[8]

(continued)

Table 1. Continued

Description	Estimate[a]	Distribution[b]	Source
Men and women			
Increased risk of death from events			
Increased risk of death from angina	2.19 (2.05, 2.33)	Lognormal	NCGC[24]
Increased risk of death from HF	2.17 (1.96, 2.41)	Lognormal	De Guili et al.[25]
Increased risk of death from MI	2.68 (2.48, 2.91)	Lognormal	Bronnum-Hansen et al.[26]
Increased risk of death from stroke	2.72 (2.59, 2.85)	Lognormal	Bronnum-Hansen et al.[26]
Probability of death for those who have suffered an event			
Probability of death from HF	0.17 [$r=68$, $n=396$][f]	Beta	Mehta et al.[28]
Probability of death from MI	0.52 [$r=351$, $n=675$][f]	Beta	Volmink et al.[29]
Probability of death from stroke	0.23 [$r=125$, $n=545$][f]	Beta	Bamford et al.[30]

[a]Figures in round parentheses are 95% confidence interval limits; [b]Distributions used in probabilistic sensitivity analysis; [c]These baseline risk values were calculated from 10 year risk values in Anderson et al.[31] and split among five disease using probabilities from D'Agostino et al.[23]; [d]The relative risk for having a coronary heart disease event was also applied to angina, heart failure (HF) and myocardial infarction (MI) events; [d,e]Age-related relative risks were extrapolated from Law et al.[4] based on 12 month blood pressure (BP) reductions of 17.8 mmHg in the intervention arm and 11.4 mmHg in the control arm for men and 17.2 mmHg in the intervention arm and 12.8 mmHg in the control arm for women (from TASMINH2 trial[8]), hence the difference in the values of the relative risk reductions. In the base case, BP reduction in both arms for men and women was assumed to be maintained over the lifetime of the model; [f]Figures in square brackets are occurrences (r) and population size (n).

the model for consistency. Lognormal distributions were used for 12 month blood pressure reductions, the increased risks of death from any of the conditions, for the one year risk of experiencing an event and for the age-dependent relative risks associated with each of the events. Beta distributions were used to model the probability of dying from any of the cardiovascular events as well as the uncertainty around the utility values. The parameters used for these distributions are shown in Tables 1 and 2. Cost-effectiveness planes (CEPs) and cost-effectiveness acceptability curves (CEACs) were constructed.[40,41]

Uncertainty in the model results was assessed using sensitivity analyses. These involved varying the time horizon for the model from a lifetime time horizon to between five and 30 years. This time horizon was chosen to represent a plausible range within which the cost-effectiveness of the intervention could be assessed. In further sensitivity analyses, the assumption regarding the long-term effectiveness of the intervention was tested by assessing the impact of reductions in effectiveness after the initial year of the study: a 20% reduction in blood pressure lowering in the intervention arm meant that the blood pressure difference between the two arms dropped from 6.4 mmHg to 2.8 mmHg for men and from 4.4 mmHg to 1.0 mmHg for women, while reductions of 36% and 26% modelled the impact of a complete loss of incremental effectiveness of the intervention for men and women, respectively. These reduced effects were applied at three arbitrarily chosen time periods: in the second, fifth and 15th year of the intervention. Extra time periods relating to the effect of the 26% reduction for women (in the third and sixth year of the intervention) were also included to show points at which the intervention became cost-effective when assessed against the threshold of £20,000–£30,000 (€23,000–€35,000)/QALY gained, which is the conventional criterion adopted by decision makers in the UK.[33]

Results

The mean lifetime costs and QALYs are presented in Table 3. For men, self-management of hypertension, when compared with usual care, was associated with higher mean costs of £383 (€446) (self-management £7090 *vs.* usual care £6707) and QALY gains of 0.24 (9.16 *vs.* 8.92, respectively) giving an incremental cost-effectiveness ratio (ICER) of £1624 (€1891)/QALY gained. In the female subgroup, self-management of hypertension, when compared with usual care, was associated with much higher mean cost difference of £576 (€671) (self-management £7296 *vs.* usual care £6720) and QALY gains of 0.12 (10.57 *vs.* 10.46, respectively) giving an ICER of £4923 (€5733)/QALY gained.

Figure 2(a) and (b) presents the CEPs for men and women respectively while (c) and (d) present the CEACs, again for men and women respectively. The CEPs and CEACs all compare self-management of hypertension with usual care. The CEPs show the joint distribution of the mean incremental costs and mean QALYs gained with most results in the north-east and south-east quadrants. The CEACs show that the probability of self-management of hypertension being cost-effective compared with usual care was at least 99% for both men and women if decision makers were willing to pay at least £20,000 (€23,000) per QALY gained.[40] At lower thresholds, however, the probability of the intervention being cost-effective

Table 2. Estimates of utilities, costs and distributions used in the reference case and sensitivity analyses

Description	Estimate	Distribution[a]	Source
Men			
Age-related utilities			
66–74 years	0.78 (0.019)[b]	Beta	Kind et al.[39]
75 + years	0.75 (0.027)[b]	Beta	Kind et al.[39]
Utility for initial (well) health state			
Starting age 66 years	0.78 (0.019)[b]	Beta	Kind et al.[39]
Women			
Age-related utilities			
66–74 years	0.78 (0.016)[b]	Beta	Kind et al.[39]
75 + years	0.71 (0.019)[b]	Beta	Kind et al.[39]
Utility for initial (well) health state			
Starting age 66 years	0.78 (0.019)[b]	Beta	Kind et al.[39]
Men and women			
Utilities for acute disease health states			
Angina	0.77 (0.038)[b]	Beta	Cooper et al.[38]
HF	0.68 (0.020)[b]	Beta	Cooper et al.[38]
MI	0.76 (0.018)[b]	Beta	Cooper et al.[38]
Stroke	0.63 (0.040)[b]	Beta	Cooper et al.[38]
Utilities for long-term (chronic) disease health states			
Angina	0.88 (0.018)[b]	Beta	Cooper et al.[38]
HF	0.68 (0.020)[b]	Beta	Cooper et al.[38]
MI	0.88 (0.018)[b]	Beta	Cooper et al.[38]
Stroke	0.63 (0.040)[b]	Beta	Cooper et al.[38]
Costs for the initial (well) health state (UK £)[c]			
Self-monitoring arm	£475 (413, 597)[d] SE = 27	Gamma	TASMINH2 trial[8]
Usual care arm	£370 (239, 393)[d] SE = 47	Gamma	TASMINH2 trial[8]
Costs for acute disease health states (UK £)			
Angina	£2,521	Gamma[e]	Palmer et al.[36]
HF	£1,860	Gamma[e]	Department of Health[35]
MI	£1,763	Gamma[e]	Palmer et al.[36]
Stroke	£8,316	Gamma[e]	Youman et al.[37]
Costs for long-term (chronic) disease health states (UK £)			
Angina	£556	Gamma[e]	Cooper et al.[38]
HF	£556	Gamma[e]	Cooper et al.[38]
MI	£556	Gamma[e]	Cooper et al.[38]
Stroke	£2,555	Gamma[e]	Youman et al.[37]

[a]Distributions used in probabilistic sensitivity analysis; [b]Standard error; [c]Total costs included costs of drugs, outpatient visits, inpatient visits, GP visits and the intervention (equipment and training). The cost difference between self-monitoring and usual care was driven by cost of the intervention; [d]95% confidence interval; [e]As only point estimates were obtained for these costs, the standard error was assumed to be equal to the mean as has been done elsewhere[38,51]; HF: heat failure; MI: myocardial infarction

Table 3. Cost-effectiveness results (based on probabilistic analysis and sensitivity analysis involving changing time horizons)

Time horizon	Costs/QALYs	Intervention group	Control (usual care) group	Difference	ICER
Men					
Base case results					
	Mean total health care costs	£7090	£6707	£383	
Lifetime					£1624
	Mean QALYs gained	9.16	8.92	0.24	
Changing the time horizon					
	Mean total health care costs	£7046	£6674	£372	
30 years					£1635
	Mean QALYs gained	9.11	8.88	0.23	
	Mean total health care costs	£6891	£6550	£341	
25 years					£1660
	Mean QALYs gained	8.93	8.30	0.17	
	Mean total health care costs	£6479	£6201	£279	
20 years					£1690
	Mean QALYs gained	8.46	8.30	0.17	
	Mean total health care costs	£5615	£5430	£185	
15 years					£1659
	Mean QALYs gained	7.50	7.39	0.11	
	Mean total health care costs	£4181	£4109	£72	
10 years					£1247
	Mean QALYs gained	5.88	5.83	0.06	
	Mean total health care costs	£2203	£2260	–£56	
5 years					SM[a]
	Mean QALYs gained	3.45	3.43	0.02	
Women					
Base case results					
	Mean total health care costs	£7296	£6720	£576	
Lifetime					£4923
	Mean QALYs gained	10.57	10.46	0.12	
Changing the time horizon					
	Mean total health care costs	£7197	£6639	£558	
30 years					£5108
	Mean QALYs gained	10.44	10.33	0.11	
	Mean total health care costs	£6921	£6407	£514	
25 years					£5547
	Mean QALYs gained	10.07	9.98	0.09	
	Mean total health care costs	£6331	£5892	£439	
20 years					£6349
	Mean QALYs gained	9.31	9.24	0.07	
	Mean total health care costs	£5321	£4990	£331	
15 years					£7532
	Mean QALYs gained	8.02	7.97	0.04	
	Mean total health care costs	£3870	£3680	£190	
10 years					£8726
	Mean QALYs gained	6.12	6.09	0.02	
	Mean total health care costs	£2011	£2002	£10	
5 years					£1635
	Mean QALYs gained	3.50	3.50	0.01	

[a]Where the abbreviation for the self-management of hypertension arm (SM) is given instead of an ICER, it means that SM dominates usual care, that is, is less costly and more effective.; ICER: incremental cost-effectiveness ratio; QALY: quality adjusted life year

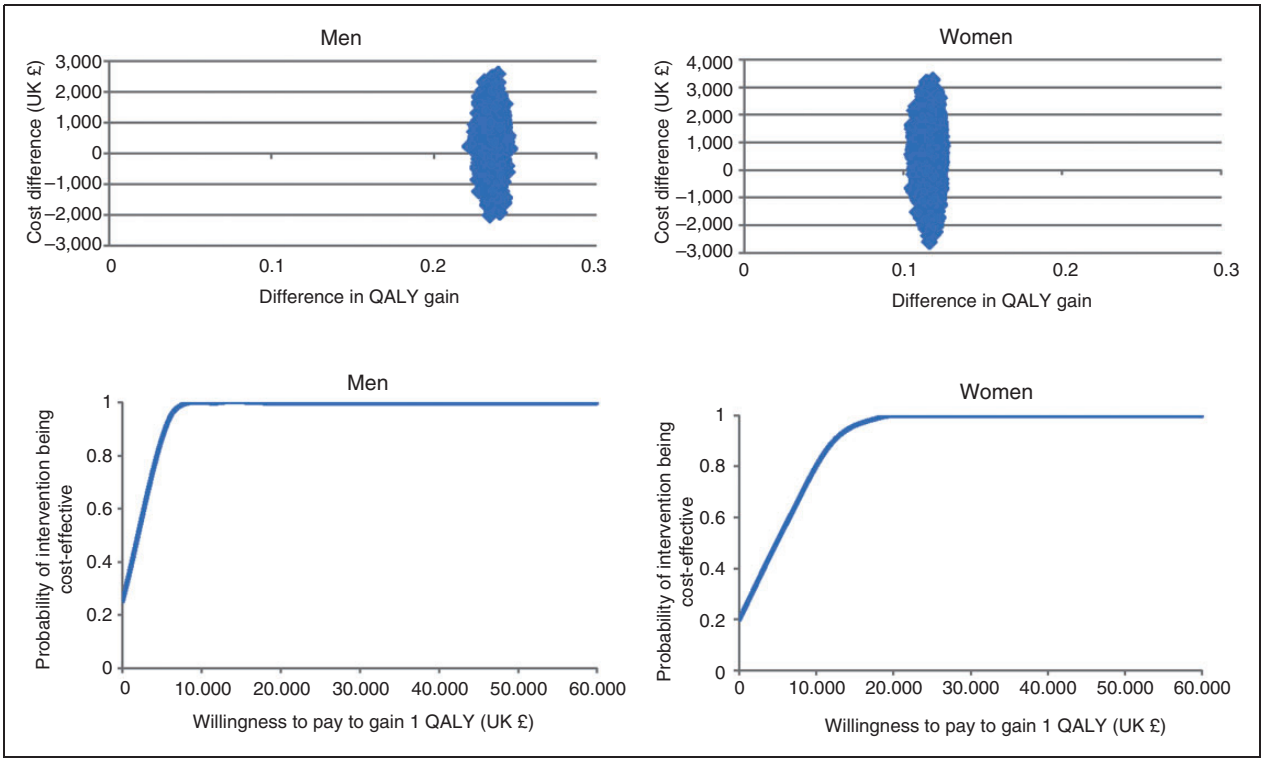

Figure 2. Cost-effectiveness plane of self-management of hypertension versus usual care and the Cost-effectiveness acceptability curve of self-management of hypertension versus usual care. (a) and (b) are cost-effectiveness planes showing the relationship between the incremental cost and incremental quality adjusted life years (QALYs) of self-management of hypertension compared with usual care. They show that most results are in the north-east and south-east quadrants. (c) and (d) depict the cost-effectiveness acceptability curve of self-management of hypertension versus usual care. They shows that the probability of self-management of hypertension being cost-effective compared with usual care was at least 99% if decision makers were willing to pay at least £20,000 (€23,000) per QALY gained for women or at least £8000 (€9280) for men. This probability dropped to 50% at around £5000 (€5800) per QALY gained for women and at around £4000 (€4640) per QALY gained for men.

compared with the control was lower, dropping to 50% at around £4000 (€4640) per QALY gained for men and £5000 (€5800) per QALY gained for women.

Table 3 shows that the ICERs for all time horizons considered for both men and women were below £20,000 (€23,000) per QALY gained. The other sensitivity analyses conducted involved modelling a declining impact of the intervention on BP reduction following the first year of the intervention (Table 4). When a 20% decline in effectiveness of the intervention was applied two, five and 15 years after the start of the intervention for both men and women, all ICERs remained below £20,000 (€23,000). All ICERs again remained below £20,000 (€23,000) when a 36% decline in effectiveness of the intervention was applied at two, five and 15 years after the start of the intervention for men. When a 26% decline in effectiveness of the intervention was applied at two, three, five, six and 15 years after the start of the intervention for women, ICERs dropped to below £20,000 (€23,000) after five years.

Discussion

Statement of principal findings

The primary analysis shows that for both men and women, self-monitoring and self-titration of antihypertensive medication is cost-effective compared with usual hypertension care, provided decision makers are willing to pay at least £1600 (€1800) per QALY for men or £4900 (€5700) per QALY for women, both of which are well within the cost-effectiveness criteria applied in the UK.[33] Despite self-management being more costly than usual care, it was associated with better QoL due to reduced CV events. No evidence was found that it was associated with deleterious direct effects on QoL.[8]

Varying the time horizons of the model from the lifetime (35 years) period used in the base case analysis and assuming a threshold of £20,000–£30,000 (€23,000–€35,000)/QALY[33,42] showed that self-management of hypertension was still more cost-effective than usual care at all time periods. Similarly, provided the effects of the BP reduction observed through self-management (6.4 mmHg systolic for men and 4.4 mmHg for women)

Table 4. Cost-effectiveness results of declining impact of self-monitoring on blood pressure reduction

Time horizon	Costs/QALYs	Intervention group	Control (usual care) group	Difference	ICER
Men					
20% decline[a] in impact of intervention on BP reduction applied in the second year of the intervention					
	Mean total health care costs	£7168	£6707	£461	
Lifetime					£3652
	Mean QALYs gained	9.16	8.92	0.13	
20% decline[a] in impact of intervention on BP reduction applied in the fifth year of the intervention					
	Mean total health care costs	£7155	£6707	£448	
Lifetime					£1635
	Mean QALYs gained	9.07	8.92	0.14	
20% decline[a] in impact of intervention on BP reduction applied in the 15th year of the intervention					
	Mean total health care costs	£7112	£6707	£405	
Lifetime					£1999
	Mean QALYs gained	9.13	8.92	0.20	
36% decline[b] in impact of intervention on BP reduction applied in the second year of the intervention					
	Mean total health care costs	£7235	£6707	£528	
Lifetime					£15,911
	Mean QALYs gained	8.96	8.92	0.03	
36% decline[b] in impact of intervention on BP reduction applied in the fifth year of the intervention					
	Mean total health care costs	£7213	£6707	£506	
Lifetime					£7742
	Mean QALYs gained	8.99	8.92	0.07	
36% decline[b] in impact of intervention on BP reduction applied in the 15th year of the intervention					
	Mean total health care costs	£7133	£6707	£426	
Lifetime					£2504
	Mean QALYs gained	9.09	8.92	0.17	
Women					
20% decline[a] in impact of intervention on BP reduction applied in the second year of the intervention					
	Mean total health care costs	£7357	£6720	£637	
Lifetime					£15,798
	Mean QALYs gained	10.50	10.46	0.04	
20% decline[a] in impact of intervention on BP reduction applied in the fifth year of the intervention					
	Mean total health care costs	£7347	£6720	£628	
Lifetime					£12,429
	Mean QALYs gained	10.51	10.46	0.05	
20% decline[a] in impact of intervention on BP reduction applied in the 15th year of the intervention					
	Mean total health care costs	£7315	£6720	£596	
Lifetime					£6659
	Mean QALYs gained	10.55	10.46	0.09	
26% decline[b] in impact of intervention on BP reduction applied in the second year of the intervention					
	Mean total health care costs	£7378	£6720	£658	
Lifetime					£44,423
	Mean QALYs gained	10.47	10.46	0.01	
26% decline[b] in impact of intervention on BP reduction applied in the third year of the intervention					
	Mean total health care costs	£7371	£6720	£651	
Lifetime					£27,801
	Mean QALYs gained	10.48	10.46	0.02	
26% decline[b] in impact of intervention on BP reduction applied in the fifth year of the intervention					
	Mean total health care costs	£7367	£6720	£647	

(continued)

Table 4. Continued

Time horizon	Costs/QALYs	Intervention group	Control (usual care) group	Difference	ICER
Lifetime					£24,420
	Mean QALYs gained	10.48	10.46	0.03	
26% decline[b] in impact of intervention on BP reduction applied in the sixth year of the intervention					
	Mean total health care costs	£7363	£6720	£643	
Lifetime					£14,208
	Mean QALYs gained	10.50	10.46	0.05	
26% decline[b] in impact of intervention on BP reduction applied in the 15th year of the intervention					
	Mean total health care costs	£7323	£6720	£604	
Lifetime					£7683
	Mean QALYs gained	10.54	10.46	0.08	

[a]A 20% decline in the impact of the intervention (from 17.8 mmHg to 14.2 mmHg for men and from 17.2 mmHg to 13.8 mmHg for women) meant that the difference in the effects between the two trial groups dropped from 6.4 mmHg to 2.8 mmHg for men and from 4.4 mmHg to 1.0 mmHg for women, that is, 12 month BP reduction in the usual care arm was 11.4 mmHg for men and 12.8 mmHg for women.; [b]A 36% decline in the impact of the intervention for men (from 17.8 mmHg to 11.4 mmHg) and a 26% decline in the impact of the intervention for women (from 17.2 mmHg to 12.8 mmHg) implied that there was no difference at all between the two trial groups in terms of effectiveness, that is, 12 month BP reduction in the usual care arm was 11.4 mmHg for men and 12.8 mmHg for women.; ICER: incremental cost-effectiveness ratio; BP: blood pressure; QALY: quality adjusted life year

lasted at least two years for men or five years for women, the intervention was cost-effective.

Strengths and limitations

This study used cost and outcome data from the first major RCT of self-management, which had high levels of follow-up and data capture.[8] The use of a Markov model overcame limitations associated with within-trial analyses, specifically allowing the modelling of effects on long-term events allowing assessment of the long-term cost-effectiveness beyond the trial period.

Adverse effects such as anxiety or drug side effects were not modelled as robust data on the consequences of these on QoL were not available, although no difference in anxiety and minimal increased side effects were observed in the trial.[8] Additional costs of monitoring potential side effects were not captured by the primary care resource data collection. A potential weakness was that effectiveness of the intervention after the year of the study was unknown: the BP curves were still diverging at that point.[8] Another study found a different self-management intervention to last for at least two years and persisting differences in outcome have been seen elsewhere despite cessation of interventions.[43,44] The base case therefore assumed that the effects of the intervention persisted after the year of study. Sensitivity analyses modelled the effect of various potential reductions in efficacy of the intervention. This is important as the model parameters were obtained from TASMINH2 participants who may well have achieved better results than a more general population as they were taking part in a trial. The results remained robust to such reduction in efficacy, provided that some element of effectiveness was maintained for at least two years for men or five years for women after the start of the intervention (i.e. one or four years in addition to the year observed in the underlying trial for men and women, respectively).

While the Framingham risk score[31] is not based on contemporary data, it is still the recommended and most widely used system.[45] For the purposes of the model, we made a further assumption that CHD was further subdivided into MI, HF and angina events using additional estimates from the literature. Any inaccuracies in the equation should not have affected the results as CV risk was estimated in the same way for both intervention and control but may have reduced the size of the ICERs observed. Risk reductions were applied to all CV events, and were associated with the average reduction in BP in each trial arm, using estimates from Law et al.[4] Although some clinical states affected by BP (such as renal failure) were not modelled, our analysis included common types of CV morbidity and mortality influenced by BP and the addition of additional health states would have reinforced the results. The use of QoL measures in cost-effectiveness analyses is standard methodology but is subject to potential bias. Data on QoL at baseline came from the UK population norms[39] but for the different health states came from other published sources, which may have led to some variability in terms of the way QALYs were calculated. Again, because these were applied to both groups, bias would have been reduced. Finally, the model has the structural limitation of not considering secondary events (including progression of disease). This is a conservative assumption as reduction of BP would be expected to reduce these in

addition to the primary events considered, hence self-management may be more cost-effective than found.

Comparisons with other studies

This is the first economic analysis of self-monitoring and self-titration of hypertensive medication. A US randomised trial comparing usual care with twice weekly self-monitoring found a reduction in costs but not BP in the intervention group.[9] However, the increased cost of medical care in the US and the age of the study mean that these results are not immediately transferable outside of that setting.[9] Reed et al. found that a tailored behavioural self-management intervention combined with home BP monitoring led to statistically and clinically significant reductions in BP but raised costs to the health-care system.[10,44] An informal estimate with a shorter time horizon of 12 years estimated an ICER of approximately $23,000 per life-year saved.[10] A trial of self-monitoring in practice waiting rooms found that this intervention was not significantly more expensive than usual care.[11] Fukunaga established that self-monitoring of hypertension was cost-effective, although this was in terms of the detection of 'white coat' hypertension.[12] A Danish study found that the cost savings of home telemonitoring of BP due to lower consultation and medication costs were negated by the cost of the telemonitoring equipment with uncertainty around the cost-effectiveness results.[13] A final study comparing cost-effectiveness of different adherence-improving interventions for antihypertensive and lipid-lowering treatment found that self-monitoring, in combination with reminders and educational materials, was more cost-effective than usual care but less cost-effective than pharmacist/nurse management.[14]

In other clinical areas, economic analyses have reached varying conclusions: self-management of anticoagulation was not cost-effective under conventional criteria due to increased costs with equivalent efficacy,[38,46] whereas self-management of asthma was associated with both increased effectiveness and lower costs.[47] Richardson and colleagues showed that a generic, lay administered self-management course for chronic disease was cost-effective.[15] Uncertainties in the data underline the importance of accompanying implementation of self-management with ongoing cost-effectiveness evaluation to ensure that the results are replicated outside of trial conditions.

Clinical Implications

The introduction of new technologies into health systems requires robust evidence of both effectiveness and cost-effectiveness. Previous work has shown the former[8] and this paper provides data on the latter which should encourage commissioners of health to consider the utilisation of self-management of hypertension in daily practice. Whilst self-management may be appropriate for only a minority of individuals with hypertension, the numbers of people affected both in the UK[2] and worldwide[48-50] mean that many millions of people could benefit from the implementation of this technology.

Conclusions

The results of this model-based economic evaluation suggest that, irrespective of sex, self-monitoring with self-titration of antihypertensives is a cost-effective strategy in the long term, resulting in QALY gains as well as lower BP provided that the BP reduction seen in the TASMINH2 trial lasts at least two years with ongoing self-management for men or five years for women.[8] Self-management of hypertension represents an important new addition to the management of hypertension in primary care.

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Conflict of interest

None declared.

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