Telemonitoring and self-management in the control of hypertension (TASMINH2): a randomised controlled trial

Richard J McManus, Jonathan Mant, Emma P Bray, Roger Holder, Miren I Jones, Sheila Greenfield, Billingsley Kaambwa, Miriam Banting, Stirling Bryan, Paul Little, Bryan Williams, F D Richard Hobbs

Summary

Background Control of blood pressure is a key component of cardiovascular disease prevention, but is difficult to achieve and until recently has been the sole preserve of health professionals. This study assessed whether self-management by people with poorly controlled hypertension resulted in better blood pressure control compared with usual care.

Methods This randomised controlled trial was undertaken in 24 general practices in the UK. Patients aged 35–85 years were eligible for enrolment if they had blood pressure more than 140/90 mm Hg despite antihypertensive treatment and were willing to self-manage their hypertension. Participants were randomly assigned in a 1:1 ratio to self-management, consisting of self-monitoring of blood pressure and self-titration of antihypertensive drugs, combined with telemonitoring of home blood pressure measurements or to usual care. Randomisation was done by use of a central web-based system and was stratified by general practice with minimisation for sex, baseline systolic blood pressure, and presence or absence of diabetes or chronic kidney disease. Neither participants nor investigators were masked to group assignment. The primary endpoint was change in mean systolic blood pressure between baseline and each follow-up point (6 months and 12 months). All randomised patients who attended follow-up visits at 6 months and 12 months and had complete data for the primary outcome were included in the analysis, without imputation for missing data. This study is registered as an International Standard Randomised Controlled Trial, number ISRCTN17585681.

Findings 527 participants were randomly assigned to self-management (n=263) or control (n=264), of whom 480 (91%; self-management, n=234; control, n=246) were included in the primary analysis. Mean systolic blood pressure decreased by 12·9 mm Hg (95% CI 10·4–15·5) from baseline to 6 months in the self-management group and by 9·2 mm Hg (6·7–11·8) in the control group (difference between groups 3·7 mm Hg, 0·8–6·6; p=0·013). From baseline to 12 months, systolic blood pressure decreased by 17·6 mm Hg (14·9–20·3) in the self-management group and by 12·2 mm Hg (9·5–14·9) in the control group (difference between groups 5·4 mm Hg, 2·4–8·5; p=0·0004). Frequency of most side-effects did not differ between groups, apart from leg swelling (self-management, 74 patients [32%]; control, 55 patients [22%]; p=0·022).

Interpretation Self-management of hypertension in combination with telemonitoring of blood pressure measurements represents an important new addition to control of hypertension in primary care.

Funding Department of Health Policy Research Programme, National Coordinating Centre for Research Capacity Development, and Midlands Research Practices Consortium.

Introduction

Raised blood pressure remains a key risk factor for cardiovascular disease, the largest cause of morbidity and mortality worldwide, yet only about half of people on treatment for hypertension have their blood pressure controlled to current recommended levels.[1,2] This difficulty in achieving control is despite substantial advances in the evidence base for both lifestyle and pharmaceutical interventions.[3,4] Therefore, there is a potentially important role for novel interventions to lower blood pressure, especially in primary care, where management of hypertension mainly takes place.

One such approach is patient self-management, which has gained widespread use in other chronic conditions such as diabetes[5] and anticoagulation control.[6] Prerequisites for self-management are the ability and willingness of a patient to self-monitor. Several randomised controlled trials have shown that self-monitoring of blood pressure can lead to blood pressure control that is at least as good as office-monitored blood pressure; it can also result in slightly better control, perhaps as a result of better adherence to treatment.[7,8] Patient management with self-titration (ie, adjustment) of antihypertensive drugs has previously only been tested on a small scale in 31 individuals with chronic stable hypertension from primary and secondary care clinics:[9] a bespoke drug titration schedule incorporating current drugs resulted in a lower daytime ambulatory mean arterial pressure of 2·9 mm Hg at 8 weeks compared with usual care.

Another new approach is telemonitoring, whereby readings made at home are relayed to a health-care professional who can take appropriate action. This strategy shows some promise in heart failure, where it is

Lancet 2010; 376: 163–72

Published Online July 8, 2010 DOI:10.1016/S0140-6736(10)60964-6

See Comment page 144

Primary Care Clinical Sciences (Prof R J McManus FRCGP, E P Bray PhD, R Holder BSc, M I Jones PhD, S Greenfield PhD, M Banting MSc, Prof F D R Hobbs FRCGP), **and Health Economics Unit** (B Kaambwa PhD), **University of Birmingham and National Institute for Health Research (NIHR) National School for Primary Care Research, Birmingham, UK; General Practice and Primary Care Research Unit, Institute of Public Health, University of Cambridge, Cambridge, UK** (Prof J Mant MD); **Centre for Clinical Epidemiology and Evaluation, Vancouver Coastal Health Research Institute, and School of Population and Public Health, University of British Columbia, Vancouver, BC, Canada** (Prof S Bryan PhD); **School of Medicine, University of Southampton and NIHR National School for Primary Care Research, Southampton, UK** (Prof P Little MD); **and Department of Cardiovascular Sciences, University of Leicester and Leicester NIHR Cardiovascular Biomedical Research Unit, Glenfield Hospital, Leicester, UK** (Prof B Williams MD)

Correspondence to: Prof R J McManus, Primary Care Clinical Sciences, Primary Care Clinical Sciences Building, University of Birmingham, Edgbaston, Birmingham B15 2TT, UK
r.j.mcmanus@bham.ac.uk

associated with lower rates of hospital admission and reduced mortality compared with usual care.[10] A systematic review in 2007 found 14 studies that assessed telemonitoring for hypertension, of which only three were randomised controlled trials. These studies showed that home telemonitoring for hypertension can produce reliable and accurate data, and is well accepted by patients.[11] In the setting of self-management, telemonitoring adds a safety net by which researchers and clinicians can be reassured that patients are not ignoring very high (or low) readings.

The Telemonitoring and Self-Management of Hypertension Trial (TASMINH2) assessed whether self-management of hypertension, consisting of self-monitoring of blood pressure and self-titration of antihypertensive drugs, combined with telemonitoring of home blood pressure measurements could lead to substantial reductions of blood pressure sustained for 1 year.

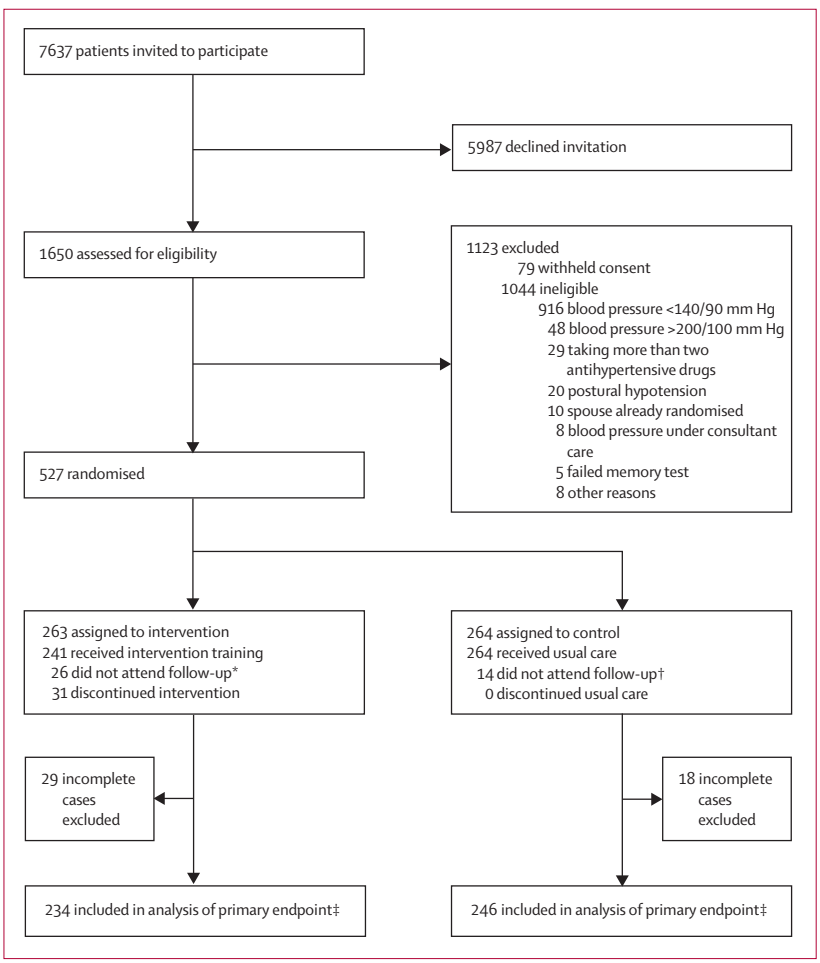

Figure 1: **Trial profile**
*Two patients in the intervention group did not attend follow-up at 6 months but did attend at 12 months. Two patients attended follow-up but had no data for blood pressure. †Three patients in the control group did not attend follow-up at 6 months but did attend at 12 months. ‡Patients who attended follow-up visits at 6 months and 12 months and had complete data for the primary outcome.

Methods

Study design and participants

TASMINH2 was a prospective, randomised open trial with automated ascertainment of endpoint. The protocol of the trial has been published elsewhere.[12] Potential participants were identified by their own family doctor by use of electronic searches of practice clinical record systems in 24 general practices in the West Midlands, UK, between March, 2007, and May, 2008.[13]

Patients were eligible for enrolment if they were aged 35–85 years, receiving treatment for hypertension with two or fewer antihypertensive drugs, had a blood pressure at baseline of more than 140/90 mm Hg, and were willing to monitor their own blood pressure and self-titrate medication. The age range for eligibility had been increased from 35–75 years to 35–85 years after 3 months when it became apparent that older patients were able to undertake the trial procedures and there were concerns about recruitment. Exclusion criteria were blood pressure more than 200/100 mm Hg, postural hypotension (>20 mm Hg systolic drop), terminal disease, dementia, score of more than ten on the short orientation memory concentration test,[14] hypertension not managed by their family doctor, or spouse already randomised to study group. Potentially eligible patients were invited by means of a letter and accompanying information sheet to attend a baseline clinic at their practice held by the research team.

Eligibility was confirmed and written informed consent obtained from all participants at the baseline visit. The study was approved by Sandwell and West Birmingham Local Research Ethics Committee (reference 05/Q2709/103).

Randomisation and masking

Participants were enrolled and followed up by the research team who assigned them to intervention or control (1:1 ratio) on the basis of a computer-generated allocation sequence via the internet with telephone back-up. Randomisation was stratified by general practice with minimisation for sex, baseline systolic blood pressure (≤150 mm Hg *vs* >150 mm Hg) and presence or absence of diabetes or chronic kidney disease.

Neither participants nor investigators were masked to group assignment in this open trial. Outcome measurement was not blinded but used the automatic mode of the sphygmomanometer to measure blood pressure without the need for intervention by the investigator other than to place the cuff and switch the device on.

Procedures

All participants received information based on literature produced by the British Hypertension Society about non-pharmacological interventions to reduce blood pressure. All participating family doctors were given a copy of current National Institute for Health and Clinical Excellence (NICE) guidelines.[15] Participants allocated to control

received usual care for hypertension. In the UK, national guidelines recommend (and performance-related pay rewards) an annual review to monitor blood pressure, provide support, and discuss lifestyle, symptoms, and medication.[15,16] After randomisation, all participants in the control group were asked to attend for a review by their family doctor. No specific instructions were given to the clinicians about the content of this visit other than to review medication. Thereafter, care was at the discretion of the family doctor.

Patients assigned to the intervention group were invited to two training sessions run by the research team. Participants were trained to monitor their own blood pressure for the first week of each month with a validated automated sphygmomanometer (Omron 705IT; Omron Healthcare Europe, Hoofddorp, Netherlands) and to transmit blood pressure readings to the research team by means of an automated modem device (i-modem; Netmedical, De Meern, Netherlands), which was connected to the sphygmomanometer and plugged into a normal telephone socket like an answerphone.[17] Two self-measurements were made each morning with a 5-min interval and the second reading acted upon. A colour traffic light system was used by participants to code these readings as green (below target but above safety limit), amber (above target but below safety limits) and red (outside of safety limits; see webappendix for coding chart). A month was deemed to be "above target" if the readings on 4 or more days were above target.

Titration schedules consisting of two changes or increases in medication were agreed between participants in the intervention group and their family doctor at a review visit after training and included the option of renal monitoring for angiotensin-converting enzyme inhibitors. The family doctor received no specific instruction from the research team about suitable medication changes other than receiving the NICE guidelines.[15] If patients had two consecutive months of readings above target, they were instructed to make medication changes in accordance with the titration schedule by requesting a new prescription without seeing their family doctor. After each set of two changes had been implemented, patients returned to their family doctor for a further titration schedule if blood pressure remained above target. Monthly summaries of each patient's blood pressure readings were sent to their family doctor. Patients with internet access could view their own readings via a dedicated internet site.

Target blood pressures for home readings were based on the then current UK NICE guidelines for hypertension and diabetes, adjusted down by 10/5 mm Hg in accordance with the recommendations of the British Hypertension Society (home readings tend to be lower than office readings). Home targets were therefore 130/85 mm Hg for patients without diabetes and 130/75 mm Hg for patients with diabetes.[15,18,19] In the absence of national recommendations for self-monitoring of blood pressure in patients with chronic kidney disease, this subgroup of patients was assigned the same target as those with diabetes. Safety limits of readings greater than 200/100 mm Hg or systolic blood pressure less than 100 mm Hg triggered the patients to request a blood pressure check by the practice and a toll-free telephone number was provided for any trial-related queries. Intervention by the research team on the basis of telemonitored blood pressure results was limited to checking that patients had followed the safety advice for high or low readings by means of a telephone call.

	Intervention (n=234)	Control (n=246)
Age (years)	66·6 (8·8)	66·2 (8·8)
Men	110 (47%)	115 (47%)
Systolic blood pressure (mm Hg)	152·1 (11·9)	151·8 (11·9)
Diastolic blood pressure (mm Hg)	85·0 (8·5)	84·5 (9·6)
Ethnic origin		
White	223 (95%)	238 (97%)
Black	5 (2%)	2 (1%)
Asian	4 (2%)	6 (2%)
Other	2 (1%)	0
Body-mass index (kg/m²)	29·6 (5·8)	30·0 (5·4)
Marital status: married	174 (74%)	188 (76%)
Occupation		
Professional/managerial and technical	110 (47%)	109 (44%)
Skilled manual and non-manual	73 (31%)	90 (37%)
Partly skilled and unskilled	13 (6%)	17 (7%)
Unemployed/unwaged	38 (16%)	30 (12%)
IMD 2007 score*	16·7 (13·3)	17·3 (14·0)
Current smoker	19 (8%)	14 (6%)
Anxiety score (STAI-6)†	10·1 (3·3)	9·7 (3·1)
Past medical history		
Coronary heart disease	22 (9%)	24 (10%)
Cerebrovascular disease	12 (5%)	9 (4%)
Diabetes	18 (8%)	17 (7%)
Chronic kidney disease	17 (7%)	27 (11%)
Atrial fibrillation	19 (8%)	18 (7%)
Number of antihypertensive drugs	1·50 (0·53)	1·54 (0·51)

Data are mean (SD) or number (%). *Index of multiple deprivation (IMD) 2007 scale ranges from 0·37 to 85·46. †Six-item version of the State-Trait Anxiety Inventory (STAI-6) scale ranges from 6 to 24. Data for STAI-6 were missing for four patients in the intervention group and six patients in the control group.

Table 1: **Baseline characteristics of 480 complete cases (unadjusted)**

See **Online** for webappendix

Outcomes

The primary outcome for the study was change in mean systolic blood pressure between baseline and each follow-up point (6 months and 12 months). Follow-up visits were undertaken by members of the research team in the patient's general practice. At baseline and follow-up visits, blood pressure was measured systematically after 5 min

	Mean blood pressure (mm Hg)			Mean difference from baseline (mm Hg)		Effect size (mm Hg)	
	Baseline	6 months	12 months	6 months	12 months	Baseline to 6 months	Baseline to 12 months
Systolic blood pressure; unadjusted							
Intervention	152·1 (150·6 to 153·6)	139·0 (137·0 to 141·0)	134·9 (132·6 to 137·1)	−13·1 (−10·9 to −15·3)	−17·2 (−14·8 to −19·7)	3·7 (0·6 to 6·8)	5·5 (2·2 to 8·8)
Control	151·8 (150·3 to 153·3)	142·4 (140·2 to 144·6)	140·1 (138·0 to 142·2)	−9·4 (−7·2 to −11·6)	−11·7 (−9·5 to −13·9)	..	..
Systolic blood pressure; adjusted*							
Intervention	151·9 (150·8 to 153·1)	138·8 (136·6 to 141·0)	134·7 (132·3 to 137·0)	−12·9 (−10·4 to −15·5)	−17·6 (−14·9 to −20·3)	3·7 (0·8 to 6·6)	5·4 (2·4 to 8·5)
Control	152·0 (150·9 to 153·2)	142·6 (140·5 to 144·8)	140·3 (138·0 to 142·6)	−9·2 (−6·7 to −11·8)	−12·2 (−9·5 to −14·9)	..	..
Diastolic blood pressure; unadjusted							
Intervention	85·0 (83·9 to 86·1)	79·6 (78·4 to 80·9)	77·4 (76·1 to 78·6)	−5·4 (−4·3 to −6·5)	−7·6 (−6·5 to −8·8)	1·3 (−0·3 to 2·8)	2·7 (1·1 to 4·3)
Control	84·5 (83·3 to 85·7)	80·3 (79·0 to 81·7)	79·5 (78·1 to 80·9)	−4·1 (−3·0 to −5·3)	−5·0 (−3·8 to −6·1)	..	..
Diastolic blood pressure; adjusted*							
Intervention	85·2 (83·8 to 86·5)	79·8 (78·3 to 81·3)	77·5 (76·0 to 79·1)	−5·2 (−3·9 to −6·5)	−7·5 (−6·0 to −9·0)	1·3 (−0·3 to 2·6)	2·7 (1·1 to 4·2)
Control	84·7 (83·4 to 86·0)	80·6 (79·1 to 82·0)	79·8 (78·3 to 81·3)	−3·9 (−2·7 to −5·2)	−4·8 (−3·4 to −6·3)	..	..

Data are mean (95% CI). *Adjusted for sex, general practice, baseline systolic blood pressure more than 150 mm Hg, and diabetes and chronic kidney disease status.

Table 2: **Systolic and diastolic blood pressure in intervention and control groups**

rest with a validated electronic automated sphygmomanometer (BP TRU BPM 100 or 200; BP TRU Medical Devices; Coquitlam, BC, Canada).[20] Six blood pressure readings were taken at intervals of 1 min. The mean of the second and third readings was used for the primary outcome. No changes were made to study outcomes after commencement of the trial.

Medications prescribed were recorded from the electronic patient record with confirmation from the patient. Side-effects were measured by use of standard questionnaires and anxiety was measured by the six-item version of the state scale of the State-Trait Anxiety Inventory.[21,22]

At the end of the trial, patients were asked to rank their preference for method of blood pressure monitoring by choosing between measurement by a doctor, measurement by a nurse, self-monitoring in the practice, or self-monitoring at home.

Statistical analysis

On the assumption of an SD of 15 mm Hg, and 20% dropout based on the results of our previous self-monitoring trial,[23] a sample size of 239 participants per group was required to detect a blood pressure difference of at least 5 mm Hg between groups with 90% power. The study was powered on the primary analysis alone.

All randomised patients who attended follow-up visits at 6 months and 12 months and had complete data for the primary outcome were included in the analysis, without imputation for missing data. A mixed model method was used to compare systolic blood pressure at baseline, 6 months, and 12 months between the intervention and control groups. The primary analysis was adjusted for general practice (as a random effect), and the covariates baseline systolic blood pressure more than 150 mm Hg, sex, and diabetes or chronic kidney disease status. The effect of any significant differences was further investigated by examination of the individual changes in systolic blood pressure between baseline and the follow-up points at 6 months and 12 months. Normally distributed errors were assumed and residuals were checked for normality by the Kolmogorov-Smirnov test. A sensitivity analysis considered the effect of missing values by use of three approaches: replacement by multiple imputation, by the mean of series, and by the last available value. Predefined subgroups for the primary analysis were based on blood pressure target, age (65 years as threshold), sex, baseline systolic blood pressure (150 mm Hg threshold) and index of multiple deprivation 2007 score (IMD 2007; this factor was added to the analysis plan before analysis). Secondary analyses used similar techniques to investigate change in diastolic blood pressure, side-effects, and anxiety. For number of medications and use of specific medications, generalised linear models were used when adjusting for the covariates mentioned previously. Unadjusted tests and CIs were computed with assumption of Poisson and Binomial distributions, respectively. Bootstrapping for CIs was undertaken for the utility data (EuroQol Group 5-Dimension Self-Report Questionnaire score [EQ-5D]), because these data were skewed.[24] Analyses were done with Minitab version 15 and SPSS version 17.

This study is registered as an International Standard Randomised Controlled Trial, number ISRCTN17585681.

Role of the funding source

The sponsors of the study had no role in study design, data collection, data analysis, data interpretation, writing of the report, or in the decision to submit for publication. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Figure 1 shows the trial profile. 527 patients from 24 general practices (range 8–56 patients per practice) were randomly assigned to study group, of whom 480 (91%) attended follow-up visits at 6 months and 12 months and had complete data for the primary outcome (complete cases). Two patients attended follow-up but had no data for blood pressure because of intolerance to measurement in one case and a machine error in the other. Table 1 shows baseline characteristics of the complete cases. Incomplete cases were similar to complete cases in terms of age, sex, baseline systolic blood pressure, and presence of diabetes but had a higher mean IMD 2007 score (21·7 [SE 13·2] *vs* 17·0 [13·6]).

Each patient in the intervention group took a median of 152 blood pressure readings and 194 (74%) completed more than 90% of the expected number of readings during the trial. 60 (23%) patients recorded at least one blood pressure reading outside the study limits (>200/100 mm Hg or systolic <100 mm Hg). Nine (3%) patients were contacted by telephone by the research team in response to high or low telemonitored readings (when the patient had not contacted the research team and it was not clear that blood pressure had settled on repeated measurement). 22 (8%) patients assigned to the intervention group did not complete training and a further 31 (12%) patients ceased self-management before the follow-up at 12 months.

Overall, blood pressure changed significantly in the intervention group compared with the control group (p=0·002; table 2). Reduction in mean systolic blood pressure from baseline was greater in the intervention group than in the control group by 3·7 mm Hg (95% CI 0·8–6·6; p=0·013) at 6 months and by 5·4 mm Hg (2·4–8·5, p=0·0004) at 12 months.

Treatment effect was not modified by patient characteristics (figure 2) apart from social deprivation: a greater reduction in systolic blood pressure was seen in patients with a low IMD 2007 score (5·3 mm Hg, 95% CI 1·9–8·8, at 6 months; 7·0 mm Hg, 3·5–10·6, at 12 months) than in those with a high IMD 2007 score (–0·4 mm Hg, –5·9 to 5·2, at 6 months; 1·6 mm Hg, –4·4 to 7·6, at 12 months; p=0·05 and p=0·08, respectively, for the comparison of change at 6 months and 12 months between the two groups).

The sensitivity analysis for missing values showed small changes in effect size in either direction dependent on the method used: multiple imputation (mean difference between groups in systolic blood pressure at 12 months: 5·9 mm Hg, 95% CI 2·8–9·1), replacement by the mean of series (5·9 mm Hg, 2·8–8·9), and carry forward from last available value (4·9 mm Hg, 1·8–8·0). The primary analysis was repeated with the mean of readings 2–6 rather than readings 2 and 3 to assess the effect of habituation to blood pressure measurement on results. Although baseline blood pressure in this sensitivity analysis was lower than that in the primary analysis, the effect size in terms of the greater decrease in blood pressure drop in the intervention group was similar (3·4 mm Hg, 0·7–6·2, at 6 months and 5·2 mm Hg, 2·3–8·0, at 12 months).

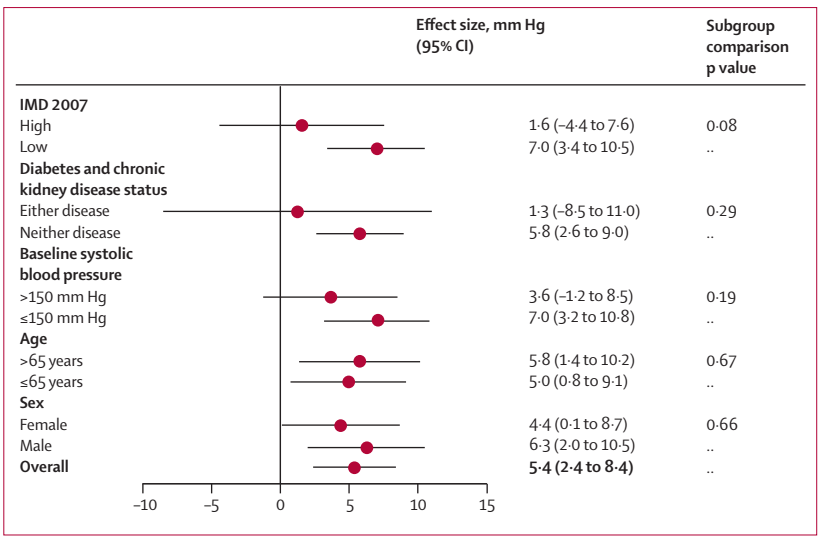

Figure 2: **Effect size by subgroup for systolic blood pressure over 12 months**
Effect size=intervention (reading at baseline minus reading at 12 months) minus control (reading at baseline minus reading at 12 months). Reading=mean of second and third systolic blood pressure measurements (in mm Hg). IMD=index of multiple deprivation.

The pattern of the trend over time for mean diastolic blood pressure was not significantly different between the intervention and control groups (p=0·092). The mixed model analysis did not show a significant difference in the magnitude of reduction between the intervention and control groups in diastolic blood pressure from baseline to 6 months (1·3 mm Hg, 95% CI –0·3 to 2·6; p=0·108) but did between baseline to 12 months (2·7 mm Hg, 1·1–4·2; p=0·001).

Of the 210 (80%) patients who self-managed their hypertension for the full 12 months of the study, 148 (70%) made at least one medication change (median 1, IQR 0–2). Patients in the intervention group were prescribed 0·32 (0·21–0·43) additional antihypertensive drugs compared with control at 6 months (p=0·001) and 0·46 (0·34–0·58) additional antihypertensive drugs at 12 months (p=0·001). These findings are reflected in a change from baseline to 6 months and 12 months in the number of antihypertensive drugs prescribed per patient in the intervention group compared with the control group, with more participants prescribed three or more drugs and fewer a single agent in the intervention group than in the control group (figure 3). Increase in prescriptions of thiazides and calcium antagonists from baseline to 12 months was greater in the intervention group than in the control group (table 3).

During the year, patients in the intervention group attended a mean 3·2 (95% CI 2·9–3·5) primary care

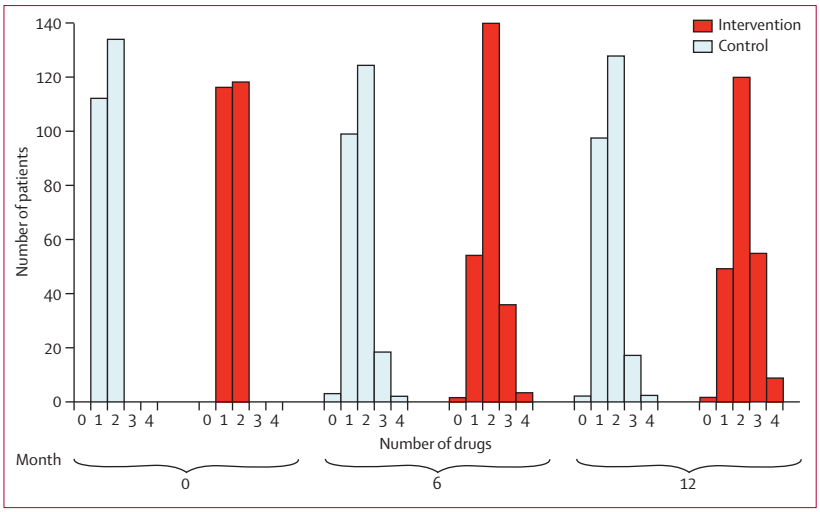

Figure 3: **Number of antihypertensive drugs prescribed by randomisation group and follow-up point**

consultations that included blood pressure measurement or management compared with 3·5 (3·2–3·7) in the control group (χ^2=3·0, p=0·08 for the comparison).

Table 4 shows the most frequent side-effects in the two groups. Leg swelling was more frequent in the intervention group than in the control group. Anxiety score did not differ between groups at baseline or over time (mean anxiety score at 12 months 9·4, 95% CI 9·0–9·9, in the intervention group *vs* 9·0, 8·6–9·5, in controls; change from baseline to 12 months 0·6, 0·1–1·1, in the intervention group *vs* 0·7, 0·1–1·1, in controls). Quality of life as measured by the EQ-5D increased in the intervention group over time, but the difference between intervention and control groups was not significant (table 5).

After 12 months, 166 (71%) of 234 patients in the intervention group ranked self-monitoring as their preferred method of blood pressure monitoring compared with 103 (43%) of 242 in the control group (p<0·0001).

Discussion

This study shows that self-management of hypertension, consisting of regular self-measurements of blood pressure and a simple predetermined titration plan for antihypertensive drugs, is more effective in lowering systolic blood pressure than is usual care during 1 year. The absolute reduction in blood pressure (5·4/2·7 mm Hg) is equivalent to a reduction in risk of stroke of more than 20% and in coronary heart disease of more than 10%.[3] Subgroup analyses were not powered a priori, but no clear differences were seen between subgroups apart from a greater reduction in systolic blood pressure in patients with a low index of multiple deprivation than in patients with a high level of deprivation.

The greater reduction in blood pressure in the self-management group was probably mediated via increased use of medication, particularly calcium antagonists and thiazides, reflecting the NICE guidelines.[15] Alternative explanations could include the blood pressure targets used, the effect of self-monitoring per se, the additional effect of telemonitoring, or other effects from lifestyle changes. However, the effects recorded in this trial are greater than those reported in systematic reviews that did not differentiate between the effect of self-monitoring and that of any associated co-intervention.[7] The home target for blood pressure in this trial was in accordance with British Hypertension Society recommendations; the target was lower, however, than the European Society of Hypertension and US consensus conference recommendations, which were published after recruitment for the trial had ended. Evidence for setting such therapeutic targets is not yet clear but targets used in this study were in line with contemporary standards.[25] Change in behaviour leading to beneficial effects on blood pressure is possible but other investigators have shown that intensive behavioural intervention is needed to achieve smaller reductions in blood pressure than those seen in the self-management group in this trial.[26]

Telemonitoring was used to check that participants had adhered to safety advice. However, few patients needed telephone reminders to take action for high or low readings. Participating practices received monthly summaries of mean blood pressure measurements but the emphasis was on self-management, unlike in other trials that used technology to prompt physician or nurse intervention.[10,11] The increasing capacity for integration of home blood pressure measurements into the electronic patient record might drive increased use of telemonitoring (personal communication, MacGinnis G, Assistive Technology, NHS Technology Office, Leeds, UK).

Change in diastolic blood pressure did not differ significantly between intervention and control groups overall although the change between baseline and 12 months was significant. This finding might be caused by lack of power. Mean blood pressure in the control group dropped by 12·2/4·8 mm Hg from baseline to 12 months, which could have masked the true effect size of the intervention, and was probably caused by regression to the mean and an increase in medication use, particularly thiazides. Similar reductions have been seen in placebo-controlled trials of antihypertensive drugs in which inclusion was on the basis of blood pressure, for example a 13 mm Hg systolic reduction in the control group of the Syst-Eur trial.[27]

The self-management intervention was not associated with increased anxiety or frequency of most side-effects. However, frequency of leg swelling was higher in the intervention group than in the control group, which was probably caused by increased use of calcium antagonists in the intervention group. Quality of life was similar in intervention and control groups despite

	Baseline	6 months	12 months	p value for overall trend comparison*	p value for comparison at 6 months†	p value for comparison at 12 months†
Antihypertensive drugs						
Intervention	1·5 (1·4–1·7)	1·9 (1·8–2·1)	2·1 (1·9–2·3)	<0·0001	<0·0001	<0·0001
Control	1·5 (1·4–1·7)	1·7 (1·5–1·8)	1·7 (1·5–1·8)	..	..	..
Thiazide						
Intervention	86 (36·8%)	118 (50·4%)	124 (53·0%)	0·045	0·042	0·020
Control	91 (37·0%)	107 (43·5%)	107 (43·5%)	..	..	..
β blocker						
Intervention	41 (17·5%)	44 (18·8%)	42 (17·9%)	0·026	0·012	0·350
Control	45 (18·3%)	36 (14·6%)	40 (16·2%)	..	..	..
Angiotensin-converting enzyme inhibitor						
Intervention	94 (40·2%)	113 (48·3%)	113 (48·3%)	0·258	0·067	0·251
Control	108 (43·9%)	114 (46·3%)	117 (47·6%)	..	..	..
Angiotensin-receptor blocker						
Intervention	46 (19·7%)	60 (25·6%)	67 (28·6%)	0·132	0·173	0·023
Control	41 (16·7%)	48 (19·5%)	48 (19·5%)	..	..	..
Calcium-channel blocker						
Intervention	73 (31·2%)	105 (44·9%)	118 (50·4%)	<0·0001	0·0023	<0·0001
Control	73 (29·7%)	80 (32·5%)	76 (30·9%)	..	..	..

Data are mean number of drugs (95% CI) or number of patients (%). Denominators for the percentages are 234 for the intervention group and 246 for the control group. *Comparison of trend over time between intervention and control adjusted for general practice, sex, baseline systolic blood pressure more than 150 mm Hg, and diabetes and chronic kidney disease status. †Comparison of change from baseline to 6 months or 12 months between intervention and control adjusted for general practice, sex, baseline systolic blood pressure more than 150 mm Hg, and diabetes and chronic kidney disease status.

Table 3: **Prescription of antihypertensive drugs**

increased use of medication in the intervention group. 80% of patients continued to self-manage their hypertension up to 12 months, which compares favourably with drug treatment for hypertension, for which cumulative incidence of discontinuation of new antihypertensive medication was 29% after 1 year in a large database study.[28] At the end of the trial, patients who self-managed their hypertension rated self-monitoring of blood pressure as more preferable to measurement by a doctor, measurement by a nurse, or self-monitoring in the practice.

The study was not blinded but the primary endpoint was measured with automated sphygmomanometers that allowed consecutive blood pressure readings to be taken without the need for intervention from the researcher once the cuff was in place and the machine turned on. The sensitivity analysis that used the mean of multiple blood pressure measurements to reduce the impact of the alerting response to blood pressure measurement gave similar results to the primary analysis albeit at lower absolute blood pressure, which suggests that habituation to blood pressure measurement in the intervention group did not affect the results.

Follow-up was achieved in more than 90% of patients in both groups, but it is possible that those lost to follow-up had worse blood pressure control than did those who attended study visits. Patients in the intervention group were less likely to attend follow-up than were controls, which might reflect the additional burden associated with self-management. Additionally, patients who were lost to follow-up had higher IMD 2007 scores than did those who were included in the analysis, which is notable in view of the apparent reduction in effect in patients with higher scores. However, overall, the sensitivity analyses suggest that these missing values are likely to have made little difference to the primary outcome.

	Intervention (n=234)	Control (n=246)	p value
Stiff joints	95 (41%)	104 (42%)	0·709
Pain	89 (38%)	84 (34%)	0·375
Fatigue	84 (36%)	78 (32%)	0·332
Swelling of legs	74 (32%)	55 (22%)	0·022
Sleep difficulties	72 (31%)	80 (33%)	0·680
Dry mouth	68 (29%)	59 (24%)	0·208
Feeling flushed	61 (26%)	57 (23%)	0·461
Cough	61 (26%)	60 (24%)	0·672
Breathlessness	53 (23%)	59 (24%)	0·730
Sore eyes	48 (21%)	58 (24%)	0·419

Table 4: **Most frequent symptoms or side-effects at 12 months**

The cost-effectiveness of the intervention will clearly be important and will be reported separately. Increased drug prescription and the cost of the intervention will need to be considered against the effect size. Importantly, consultation rate was not increased in the intervention group compared with the control group although training of patients for self-management will obviously require increased input from primary care staff.

	Baseline	6 months	12 months	Adjusted mean difference from baseline		Effect size	
				6 months	12 months	Baseline to 6 months	Baseline to 12 months
EQ5D; unadjusted							
Intervention	0·809 (0·781 to 0·837)	0·819 (0·789 to 0·850)	0·833 (0·805 to 0·861)	0·010 (–0·013 to 0·032)	0·024 (0·002 to 0·047)	0·010 (–0·024 to 0·043)	0·028 (–0·011 to 0·060)
Control	0·847 (0·819 to 0·876)	0·848 (0·818 to 0·877)	0·844 (0·814 to 0·873)	0·000 (–0·028 to 0·026)	–0·004 (–0·030 to 0·020)	..	..
EQ5D; adjusted*							
Intervention	0·801 (0·767 to 0·834)	0·812 (0·777 to 0·847)	0·826 (0·792 to 0·859)	0·011 (–0·013 to 0·034)	0·024 (–0·001 to 0·049)	0·011 (–0·023 to 0·045)	0·027 (–0·004 to 0·065)
Control	0·841 (0·809 to 0·874)	0·842 (0·807 to 0·876)	0·838 (0·805 to 0·871)	0·000 (–0·023 to 0·023)	–0·003 (–0·027 to 0·021)	..	..

Data are mean (bootstrapped 95% CI). EQ-5D=EuroQol Group 5-Dimension Self-Report Questionnaire score. *Adjusted for sex, general practice, baseline systolic blood pressure more than 150 mm Hg, and diabetes and chronic kidney disease status.

Table 5: **Quality of life as measured by EQ-5D**

Generalisability is a key issue in all research. This trial was undertaken within primary care, the principal setting for management of hypertension, but only recruited a small proportion of potentially eligible individuals, as has been seen in other studies of self-management.[29] Patients receiving more than two antihypertensive drugs were excluded, meaning that around 20% of those potentially eligible were excluded. This exclusion criterion was pragmatic to ensure that patients would have scope for additional medication. Median deprivation score was lower than that for the West Midlands as a whole (19·9; calculated from publically available data[30]) and ethnic minorities were under represented. Therefore, despite the success of the intervention, self-management will not be suitable for all patients. However, even if only 20% of individuals with hypertension self-managed their disorder, this proportion would still represent around 4% of the UK population—ie, more than 2 million individuals.

The only other previous study that investigated self-management of hypertension in the form of self-titration was a Canadian study, which used a fixed titration regimen, had short follow-up (8 weeks), and randomised only 31 patients.[9] Although the primary outcomes in the Canadian study are not directly comparable with those of this trial (ambulatory blood pressure monitoring *vs* office blood pressure measurements), both studies have reported a greater decrease in blood pressure in patients who were assigned to self-management of hypertension than in controls. Self-management of hypertension consisting of lifestyle interventions and self-monitoring of blood pressure has also been reported: Bosworth and colleagues[26] undertook a 2×2 factorial trial of a nurse-led behavioural intervention with or without self-monitoring of blood pressure compared with usual care and reported that the combined intervention group had improved blood pressure control (systolic and diastolic) after 24 months. Neither individual intervention affected control of blood pressure at 24 months, although self-monitoring reduced systolic and diastolic blood pressure and the behavioural intervention reduced diastolic blood pressure at 12 months.[26] Current studies are assessing telemonitoring of blood pressure with a nurse-led behavioural intervention or nurse-led medication management, or both,[31] and self-titration of antihypertensive drugs with weekly health coach support for compliance and self-titration.[32]

This study accords with the wider published work on self-monitoring of hypertension, which suggests that this strategy has a greater effect on blood pressure control when used in combination with other co-interventions.[7] Two studies that included self-monitoring of hypertension but not self-management merit particular mention: Staessen and colleagues[33] reported that physician adjustment of antihypertensive medication according to self-monitored blood pressure resulted in worse blood pressure control with less prescribed medication than when adjustment was based on clinic readings; this finding was probably a result of setting the same target blood pressures for both groups. More recently, Green and colleagues[34] compared self-monitoring of blood pressure in conjunction with a secure patient web-based system with or without pharmacist support including an action plan. These investigators reported a significant reduction in systolic blood pressure from usual care, with the combined intervention resulting in substantially better blood pressure control, which was not seen in the self-monitored group without pharmacist input. They used self-monitoring on 2 days per week every week and set a lower goal for home readings than for clinic readings (135/85 mm Hg *vs* 140/90 mm Hg).[34] The pharmacist-led intervention resulted in a similar increase in use of antihypertensive drugs (0·5, 95% CI 0·3–0·6) to that seen in the self-management group in this study (0·46, 0·34–0·58), but almost doubled the number of telephone contacts as well as the expected increase in website use compared with usual care. Face-to-face consultation rate was not affected in either study.

In related work, self-monitoring of blood glucose concentration has proved variably effective and probably of limited clinical benefit unless accompanied by feedback or used in conjunction with therapy modification.[35] A systematic review found that best possible self-management of

asthma medication can be achieved by either self-adjustment following a written action plan or by regular medical review.[36] A further review showed that self-testing of international normalised ratio and self-adjustment of warfarin resulted in at least as good control of anticoagulation compared with usual care by family doctors or a specialist service.[6] A common theme from this evidence is the importance of self-management interventions that empower patients to self-titrate their own medication.

Self-management of hypertension resulted in significant and worthwhile reductions in blood pressure that were maintained at 6 months and 12 months compared with usual care. These findings seem to be the result of an increase in the number of antihypertensive drugs prescribed according to a simple titration plan. Thus, self-management represents an important new addition to the control of hypertension in primary care.

Contributors

RJM led the study and wrote the first draft of the report. RH and BK undertook the analyses. All authors participated in design, execution, and oversight of the study. All authors had access to the data, commented on subsequent drafts, and approved the final submitted version. RJM will act as guarantor and made the final decision to submit for publication.

Midlands Research Practices Consortium (MidReC) Investigators

Lead general practitioners and practices: M V Hirsch (Bellevue Medical Centre, Birmingham), S Chudley (Jiggins Lane Medical Centre. Birmingham), D G B Taylor (Woodland Road Surgery, Birmingham), P Giddings (Goodrest Croft Surgery, Birmingham), P B Saunders (Ridgacre House Surgery, Birmingham), K Ladha (The Dovecote Surgery, Birmingham), H Dau (Tudor Practice, Sutton Coldfield), H Stokes-Lampard (Cloisters Medical Practice, Lichfield), L Miller (Sherwood House Medical Practice, Birmingham), M Webb (Grove Road Surgery, Solihull), M Wilkinson (The Harlequin Surgery, Birmingham), J Barnham (Harborne Medical Practice, Birmingham), N Speak (Manor Practice, James Preston Health Centre, Sutton Coldfield), L Lumley (Greenridge Surgery, Birmingham), J Tyler (Warley Medical Centre, Oldbury), I Morrey (Churchfields Surgery, Bromsgrove), E Hamnett (Lordswood House Medical Practice, Birmingham), S Carvell (Worcester Street Surgery, Stourbridge), J C Desveaux (Four Oaks Medical Centre, Sutton Coldfield), A B Skilbeck (Kingswinford Health Centre, Kingswinford), E Leyton (Shirley Medical Centre, Solihull), J P Q Ward (Woodgate Valley Health Centre, Birmingham), N Chauhan (River Brook Medical Centre, Birmingham), P Clarke (Yardley Wood Health Centre, Birmingham).
MidReC research nurses: Pat Marsh, Rachel Iles, Peter Bradburn, Sharon Jones.

Conflicts of interest

RJM is funded by an National Institute for Health Reserch (NIHR) Career Development Fellowship. He received a consultancy fee from Tplus Medical (2006) to advise on telemonitoring services. FDRH has received limited research support in terms of blood pressure devices from Microlife and BpTRU. All other authors declare that they have no conflicts of interest.

Acknowledgments

This study received joint funding from the Department of Health Policy Research Programme, National Coordinating Centre for Research Capacity Development, and Midlands Research Practices Consortium (MidReC). Service support costs were obtained from the Department of Health in collaboration with MidReC. Support was received from the Primary Care Clinical Research and Trials Unit (PCCRTU) and the Midlands Research Practices Consortium (MidReC). The Departments of Primary Care in Birmingham and Southampton also receive funding from NIHR National School for Primary Care Research. This research would not have been possible without the help of the participating patients and practice staff. We thank the particular input of trial secretaries Amanda Davies and Sheila Bailey.

References

1 Craig R, Mindell J, eds. Health survey for England 2006. London: Her Majesty's Stationery Office, 2006.
2 NHS Information Centre. Quality and outcomes framework 2008/09. Online GP practice results database. http://www.qof.ic.nhs.uk/ (accessed April 24, 2010).
3 Law MR, Morris JK, Wald NJ. Use of blood pressure lowering drugs in the prevention of cardiovascular disease: meta-analysis of 147 randomised trials in the context of expectations from prospective epidemiological studies. *BMJ* 2009; **338:** b1665.
4 Dickinson HO, Mason JM, Nicolson DJ, et al. Lifestyle interventions to reduce raised blood pressure: a systematic review of randomized controlled trials. *J Hypertens* 2006; **24:** 215–33.
5 McAndrew L, Schneider SH, Burns E, Leventhal H. Does patient blood glucose monitoring improve diabetes control? A systematic review of the literature. *Diabetes Educ* 2007; **33:** 991–1011.
6 Levi M. Self-management of anticoagulation. *Expert Rev Cardiovasc Ther* 2008; **6:** 979–85.
7 Bray EP, Holder R, Mant J, McManus RJ. Does self monitoring reduce blood pressure? Meta-analysis with meta-regression of randomized controlled trials. *Ann Med* 2010; published online May 27. DOI:10.3109/07853890.2010.489567.
8 Ogedegbe G, Schoenthaler A. A systematic review of the effects of home blood pressure monitoring on medication adherence. *J Clin Hypertens (Greenwich)* 2006; **8:** 174–80.
9 Zarnke KB, Feagan BG, Mahon JL, Feldman RD. A randomized study comparing a patient-directed hypertension management strategy with usual office-based care. *Am J Hypertens* 1997; **10:** 58–67.
10 Polisena J, Tran K, Cimon K, et al. Home telemonitoring for congestive heart failure: a systematic review and meta-analysis. *J Telemed Telecare* 2010; **16:** 68–76.
11 Pare G, Jaana M, Sicotte C. Systematic review of home telemonitoring for chronic diseases: the evidence base. *J Am Med Inform Assoc* 2007; **14:** 269–77.
12 McManus RJ, Bray EP, Mant J, et al. Protocol for a randomised controlled trial of telemonitoring and self-management in the control of hypertension: telemonitoring and self-management in hypertension. [ISRCTN17585681]. *BMC Cardiovasc Disord* 2009; **9:** 6.
13 McManus RJ, Ryan R, Jones M, Wilson S, Hobbs FR. How representative of primary care are research active practices? Cross-sectional survey. *Fam Pract* 2008; **25:** 56–62.
14 Katzman R, Brown T, Fuld P, Peck A, Schechter R, Schimmel H. Validation of a short orientation-memory-concentration test of cognitive impairment. *Am J Psychiatry* 1983; **140:** 734–39.
15 NICE. CG34 hypertension (persistently high blood pressure) in adults—NICE guideline. 2006. http://guidance.nice.org.uk/CG34 (accessed April 24, 2010).
16 British Medical Association, NHS Employers. Quality and outcomes framework guidance. http://www.bma.org.uk/employmentandcontracts/independent_contractors/quality_outcomes_framework/qof0309.jsp (accessed April 24, 2010).
17 Coleman A, Freeman P, Steel S, Shennan A. Validation of the Omron 705IT (HEM-759-E) oscillometric blood pressure monitoring device according to the British Hypertension Society protocol. *Blood Press Monit* 2006; **11:** 27–32.
18 NICE. NICE Guideline CG66: type 2 diabetes: the management of type 2 diabetes (updated May 2008). http://www.nice.org.uk/CG66 (accessed April 24, 2010).
19 Williams B, Poulter NR, Brown MJ, et al. Guidelines for management of hypertension: report of the fourth working party of the British Hypertension Society, 2004-BHS IV. *J Hum Hypertens* 2004; **18:** 139–85.
20 Mattu GS, Heran BS, Wright JM. Overall accuracy of the BpTRU—an automated electronic blood pressure device. *Blood Press Monit* 2004; **9:** 47–52.
21 Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the Spielberger State-Trait Anxiety Inventory (STAI). *Br J Clin Psychol* 1992; **31:** 301–06.

22 Moss-Morris R, Weinman J, Horne R, Buick D. The revised illness perception questionnaire (IPQ-R). *Psychol Health* 2002; **17:** 1–16.

23 McManus RJ, Mant J, Roalfe A, et al. Targets and self monitoring in hypertension: randomised controlled trial and cost effectiveness analysis. *BMJ* 2005; **331:** 493.

24 Barber JA, Thompson SG. Analysis of cost data in randomized trials: an application of the non-parametric bootstrap. *Stat Med* 2000; **19:** 3219–36.

25 Staessen JA, Thijs L, Ohkubo T, et al. Thirty years of research on diagnostic and therapeutic thresholds for the self-measured blood pressure at home. *Blood Press Monit* 2008; **13:** 352–65.

26 Bosworth HB, Olsen MK, Grubber JM, et al. Two self-management interventions to improve hypertension control: a randomized trial. *Ann Intern Med* 2009; **151:** 687–95.

27 Staessen JA, Fagard R, Thijs L, et al, for the Systolic Hypertension in Europe (Syst-Eur) Trial Investigators. Randomised double-blind comparison of placebo and active treatment for older patients with isolated systolic hypertension. *Lancet* 1997; **350:** 757–64.

28 Burke TA, Sturkenboom MC, Lu Se, Wentworth CE, Lin Y, Rhoads GG. Discontinuation of antihypertensive drugs among newly diagnosed hypertensive patients in UK general practice. *J Hypertens* 2006; **24:** 1193–200.

29 Fitzmaurice DA, Murray ET, McCahon D, et al. Self management of oral anticoagulation: randomised trial. *BMJ* 2005; **331:** 1057.

30 Office for National Statistics. Neighbourhood Statistics. http://neighbourhood.statistics.gov.uk/ (accessed June 26, 2010).

31 Bosworth HB, Olsen MK, McCant F, et al. Hypertension Intervention Nurse Telemedicine Study (HINTS): testing a multifactorial tailored behavioral/educational and a medication management intervention for blood pressure control. *Am Heart J* 2007; **153:** 918–24.

32 Bennett H, Laird K, Margolius D, Ngo V, Thom DH, Bodenheimer T. The effectiveness of health coaching, home blood pressure monitoring, and home-titration in controlling hypertension among low-income patients: protocol for a randomized controlled trial. *BMC Public Health* 2009; **9:** 456.

33 Staessen JA, Den Hond E, Celis H, et al. Antihypertensive treatment based on blood pressure measurement at home or in the physician's office: a randomized controlled trial. *JAMA* 2004; **291:** 955–64.

34 Green BB, Cook AJ, Ralston JD, et al. Effectiveness of home blood pressure monitoring, web communication, and pharmacist care on hypertension control: a randomized controlled trial. *JAMA* 2008; **299:** 2857–67.

35 Clar C, Barnard K, Cummins E, Royle P, Waugh N. Self-monitoring of blood glucose in type 2 diabetes: systematic review. *Health Technol Assess* 2010; **14:** 1–140.

36 Powell H, Gibson PG. Options for self-management education for adults with asthma. *Cochrane Database Syst Rev* 2003; **1:** CD004107.