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Primary care

Targets and self monitoring in hypertension: randomised controlled trial and cost effectiveness analysis

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Abstract

Objectives To assess whether blood pressure control in primary care could be improved with the use of patient held targets and self monitoring in a practice setting, and to assess the impact of these on health behaviours, anxiety, prescribed antihypertensive drugs, patients' preferences, and costs.
Design Randomised controlled trial.
Setting Eight general practices in south Birmingham.
Participants 441 people receiving treatment in primary care for hypertension but not controlled below the target of < 140/85 mm Hg.
Interventions Patients in the intervention group received treatment targets along with facilities to measure their own blood pressure at their general practice; they were also asked to visit their general practitioner or practice nurse if their blood pressure was repeatedly above the target level. Patients in the control group received usual care (blood pressure monitoring by their practice).
Main outcome measures Primary outcome: change in systolic blood pressure at six months and one year in both intervention and control groups. Secondary outcomes: change in health behaviours, anxiety, prescribed antihypertensive drugs, patients' preferences of method of blood pressure monitoring, and costs.
Results 400 (91%) patients attended follow up at one year. Systolic blood pressure in the intervention group had significantly reduced after six months (mean difference 4.3 mm Hg (95% confidence interval 0.8 mm Hg to 7.9 mm Hg)) but not after one year (mean difference 2.7 mm Hg (– 1.2 mm Hg to 6.6 mm Hg)). No overall difference was found in diastolic blood pressure, anxiety, health behaviours, or number of prescribed drugs. Patients who self monitored lost more weight than controls (as evidenced by a drop in body mass index), rated self monitoring above monitoring by a doctor or nurse, and consulted less often. Overall, self monitoring did not cost significantly more than usual care (£251 ($437; 364 euros) (95% confidence interval £233 to £275) versus £240 (£217 to £263).
Conclusions Practice based self monitoring resulted in small but significant improvements of blood pressure at six months, which were not sustained after a year. Self monitoring was well received by patients, anxiety did not increase, and there was no appreciable additional cost. Practice based self monitoring is feasible and results in blood pressure control that is similar to that in usual care.

Introduction

Hypertension is a key risk factor for cardiovascular disease, the leading cause of death worldwide.[1] Use of antihypertensive drugs leads to a significant reduction in both stroke and coronary heart disease risk and is cost effective, especially for individuals at highest risk of cardiovascular events.[2 3] This potential benefit from drug treatment is reflected in recent hypertension guidelines, which recommend treatment targets of 140/85 mm Hg or below.[4 5] However, international community based surveys show that in many countries only a minority of people treated for hypertension are controlled to these levels.[6]

Most patients with hypertension receive treatment in primary care and so it is here that potential reasons for this shortfall must be sought. These may include clinical inertia and excessive workloads on the part of physicians[7 8]; unmet information needs and poor adherence to antihypertensive treatment by patients[9 10]; and differing thresholds at which health professionals and patients would choose to start treatment.[11]

Self monitoring of blood pressure has the potential to improve blood pressure control at modest cost: a recent systematic review of home monitoring found a lowering of systolic blood pressure of about 4 mm Hg.[12] However, most included trials were inadequately powered with short (six months or less) follow-up, none was performed in the United Kingdom, and only one study evaluated costs.[13] Community based self monitoring, where patients have access to blood pressure measurement facilities without the need to see a health professional, has the potential to provide the benefits of home monitoring (reduction of the white coat effect, more readings, and improved control) without requiring the purchase of a blood pressure machine for all patients.[14 15]

We aimed to assess whether blood pressure control in primary care could be improved with the use of patient held targets and self monitoring in a practice setting and to assess the impact of these on health behaviours, anxiety, prescribed antihypertensive treatment, patients' preferences, and costs.

Methods

Participants

We recruited participants from eight primary care practices in Birmingham through the Midlands Research Practice Consortium between September 2001 and April 2002. The practices were selected so that there would be two from each quartile of the Townsend score (a measure of socioeconomic deprivation).[16] A computer search identified patients aged 35-75 receiving treatment for hypertension. Those with at least one blood pressure reading greater than 140/85 mm Hg in the previous year were invited to attend a study clinic run by the principal investigator (RJMcM). If their blood pressure at this clinic was in the range 140/85 mm Hg to 200/100 mm Hg they were eligible for the study. All patients provided written informed consent before entry to the study.

Assignment and blinding

Randomisation was stratified by practice and diabetic status; we used a random number generator to produce a series of blocks of random size.[17] Allocations were transferred to opaque envelopes that were held centrally and opened by the trial secretary in response to a telephone call. In one practice, owing to an error in the blocking process, three people with diabetes were allocated to the control rather than intervention group. The study was unblinded.

Intervention

Patients randomised to intervention were asked to attend their practice every month to measure their own blood pressure using validated electronic blood pressure machines (Omron M5-I[18]). They did not need an appointment, and they did the monitoring in the waiting room or in a side room, depending on facilities at the practice. They were given about 10 minutes of instruction at baseline on how to use the electronic sphygmomanometers and a five minute refresher session at a six month follow-up. Reception staff were also trained to provide support to patients as required.

The patients in the intervention group each received a record card showing the blood pressure target they should aim for (the British Hypertension Society's treatment targets—at that time—of 140/85 mmHg (140/80 mm Hg for those with diabetes)).[4 19] The cards had space for recording monthly blood pressure readings as well as advice that patients should attend their general practitioner or practice nurse if they recorded blood pressures above target on successive months—or earlier in the case of very high readings. Central telephone support was available.

Frequency of monitoring of patients in the control group was at the discretion of the general practitioner. All control patients received an information sheet on self help measures to lower blood pressure based on a fact sheet published by the British Hypertension Society (www.bhsoc.org). Responsibility for changes to treatment remained with the general practitioner for both the intervention and control group.

Data collection

All baseline data and measurements were recorded before randomisation. Patients were followed up by a researcher (RJMcM or RAO) in their own surgeries six months and one year after randomisation. All primary and secondary end point data were collected at each follow-up visit.

At follow-up sessions, blood pressure was measured with a validated automated sphygmomanometer (Omron 705CP) in the left arm three times at five minute intervals after 10 minutes rest, with the patient seated. We used the mean of the three readings in the analysis. We measured anxiety using the short form of the Spielberger state anxiety inventory[20] and used previously validated questionnaires for alcohol consumption[21] and exercise[22] to measure lifestyle factors. We assessed addition of salt to food by using questions drawn from a validated questionnaire.[23] We calculated body mass index using electronic scales (Seca 880, Vogel and Halke, Hamburg) and a portable height meter. At each follow up visit we collected data on prescribed antihypertensive drugs from the practice computer systems. We asked participants to rank four methods of blood pressure measurement according to preference—namely, by a doctor, by a nurse, self measurement at the surgery, and self measurement at home.

Analysis

The primary outcome was change in systolic blood pressure between baseline and the two follow-up sessions. A power calculation suggested that if 434 patients were followed up, it would be possible to detect a 5 mm Hg difference with a power of 90% and significance level of 5%, assuming a standard deviation of 16 mm Hg. We analysed the data with the statistical software SPSS (version 10) on an "intention to treat" basis using the "complete case" method with sensitivity analysis around assumptions for missing values.[24] We used the GLM (general linear model) repeated measures technique to examine within subject differences in systolic blood pressure between baseline and the two follow-up sessions. We adjusted the primary analysis for practice (nested within intervention) and diabetic status by including these as fixed effects in the model along with any baseline differences with potential effects on outcome.

We also used the GLM repeated measures technique for the secondary outcomes—to analyse changes in diastolic blood pressure, anxiety, body mass index, and patients' preferences. Changes over time between intervention and control with respect to exercise (three times or more a week), alcohol (>21 or >14 units a week for men and woman respectively), smoking (yes or no), and addition of salt to food were assessed using logistic regression, taking into account repeated measures and adjusting for practice, diabetic status, and sex.

Costing

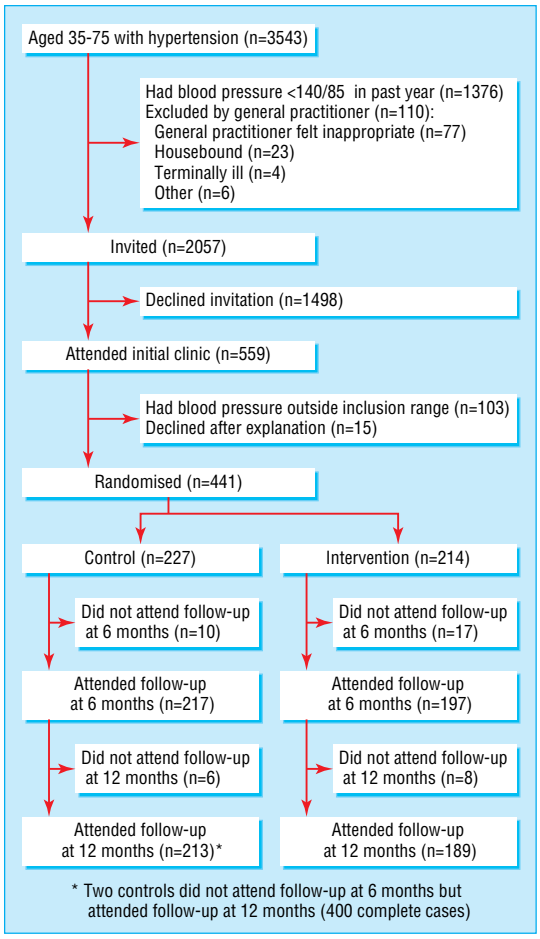
During the trial we collected data on the number of consultations for hypertension (with both general practitioners and practice nurses and defined as consultations with Read codes for hypertension or where blood pressure was recorded or where free text explicitly mentioning hypertension management was included), drug treatment, referrals for hypertension, and intervention costs (for equipment and training). Equipment costs were discounted at 3.5% (a year) over a five year life.[25] We assumed that consultations had standard UK costs (£16 ($28; €23) for a general practitioner and £8 for a practice nurse)[26]; we took treatment costs from the *British National Formulary*[27]; and we priced referrals at the rate for a general medical outpatient clinic (£104).[28] Cost data were bootstrapped (1000 samples) to estimate confidence intervals.

Results

In all, 441 people were randomised, of whom 400 (91%) attended follow-up at both six and 12 months (complete cases). The figure shows flow through the trial, and table 1 shows baseline details of complete cases. In all, 74% of participants in the intervention group measured their own blood pressure at least eight times over 12 months (prespecified as the definition of adequate compliance), and the median number of self measurements over a year was 11. Owing to the baseline difference in sex and the potential effect on outcome, sex was included in the model as prespecified in the analysis plan.

Primary outcome (systolic blood pressure)

The GLM repeated measures—taking into account intervention group, practice (nested within intervention), sex, and diabetic status—showed a significant difference in systolic blood pressure over time between intervention and control ($F(2, 762) = 3.7$; $P = 0.02$). Further analysis of this change in systolic blood pressure showed a significant difference between groups in favour of the intervention between baseline and six month follow-up (mean difference in change 4.3 mm Hg (95% confidence interval 0.8 mm Hg to 7.9 mm Hg); $F(1, 381) = 8.2$;



Flow of participants through the trial

P=0.004) but not between six months and one year (−1.6 mm Hg (−5.3 mm Hg to 2.2 mm Hg); F (1, 381) = 1.0; P=0.33) (table 2). The intervention group experienced a greater fall in blood pressure in the first six months, but from a higher baseline. Mean systolic blood pressure at six and 12 months was similar in the two groups.

Secondary outcomes

Diastolic pressure did not change significantly over time between the groups (F (1.9, 737.9) = 0.08; P= 0.91) (fractional degrees of freedom result from adjustments made when Mauchly's test for sphericity was significant) (table 2). The groups did not differ over time for anxiety, smoking, exercise, salt intake, or number of prescribed drugs (tables 3 and 4). Body mass index reduced significantly more over time in the intervention group than in the control group (F (1.6, 590.9) =6.010; P=0.005). Most of the reduction occurred in the first six months of the study: with the repeated measures comparisons, the change between baseline and six months is significant (F (1, 370) =10.3; P= 0.001) whereas that between six months and one year is not (F (1, 370) =0.58; P=0.45). Reported alcohol intake reduced significantly in the intervention group compared with the control group in the first six months but not thereafter (P=0.03 and P=0.56 respectively).

Table 5 shows patients' preferences at the end of the study for method of blood pressure measurement. The ranking was significantly different between the intervention and control groups (F (2.1, 820.5) = 37.4; P<0.001). Patients in the intervention group ranked home measurement highest, followed by self measurement in the surgery. Those in the control group ranked measurement by a doctor highest, followed by nurse measurement.

Table 1 Baseline characteristics of 400 complete cases (unadjusted). Values are numbers (percentages) of participants, unless stated otherwise

Attribute	Intervention (n=189)	Control (n=211)
Mean (SD) age (years)	62.8 (8.5)	62.4 (9.9)
Male	98 (52)	90 (43)
Mean (SD) systolic blood pressure (mm Hg)	157.9 (15.7)	155.0 (13.6)
Mean (SD) diastolic blood pressure (mm Hg)	88.7 (7.3)	88.0 (7.9)
Ethnic group*:		
White	180 (95)	195 (92)
Black or Black British	7 (4)	13 (6)
Asian or Asian British	2 (1)	3 (1)
Mean (SD) body mass index (kg/m^2)	30.5 (5.3)	29.5 (5.5)
Current smokers	23 (12)	24 (11)
Men drinking >21 or women >14 units of alcohol a week	28 (15)	14 (7)
Exercise ≥3 times/week	52 (28)	53 (25)
Mean (SD) anxiety score†	9.8 (3.0)	9.3 (3.0)
History of coronary heart disease	31 (16)	27 (13)
History of diabetes	25 (13)	34 (16)
Mean (SD) No of antihypertensive drugs	1.8 (0.9)	1.9 (0.9)
Currently working	51 (27)	61 (29)

*According to 2001 United Kingdom census criteria. White includes White British or White Other. Black or Black British includes those of Caribbean, African, or Black Other ethnicity. Asian or Asian British includes those of Indian, Pakistani, Bangladeshi or Asian Other ethnicity (see www.statistics.gov.uk/census2001/census2001.asp).
†On the state trait anxiety inventory (scores range from 6 to 24: the higher the score, the higher the anxiety).

Sensitivity analysis

Missing values analysis on the primary outcome of systolic blood pressure found that for substitution of missing values by either the mean of the series or by the last recorded value for an individual, the change in systolic blood pressure in the first six months remained significant (P=0.03 in both cases), but the overall difference between the groups over time was no longer significant (P=0.11 (substitution by mean of series) and P=0.10 (substitution by last recorded value)).

Cost effectiveness

Table 6 shows the cost and effectiveness results. The intervention group consulted less frequently than the control group, and the drug costs did not differ significantly between the two groups. The reduction in consultation rate observed in the intervention group reflected fewer consultations in which blood pressure monitoring alone took place. Intervention costs (£26.80 per patient) were dominated by the cost of general practitioners' time in training staff and patients (£25.40), with discounted equipment costs relatively trivial (£1.39). The incremental cost effectiveness ratio for practice based self monitoring—that is, the cost per additional 1 mm Hg reduction in blood pressure—was £5.10, with confidence intervals that crossed zero (table 5).

Discussion

In this study, giving patients their own blood pressure targets and encouraging them to monitor their own blood pressure resulted in a significant reduction in blood pressure at six month follow-up but not thereafter, compared with patients whose monitoring was left to the discretion of their practice. Self monitoring did not increase anxiety, and patients in the intervention group ranked this method more highly than monitoring by the general practitioner or nurse (in contrast to the control group).

Table 2 Mean systolic and diastolic blood pressure (mm Hg)

	Unadjusted			Adjusted*			Adjusted mean difference (95% confidence interval) *†	
	Baseline	6 months	12 months	Baseline	6 months	12 months	Baseline to 6 months	Baseline to 12 months
Systolic (mm Hg)								
Intervention	157.9	144.5	149.0	159.3	144.5	149.5	4.3 (0.8 to 7.9)	2.7 (–1.2 to 6.6)
Control	155.0	144.7	148.4	156.1	145.6	149.0		
Diastolic (mm Hg)								
Intervention	88.7	83.2	83.0	87.4	82.4	82.1	–0.4 (–2.4 to 1.7)	0.1 (–2.3 to 2.4)
Control	88.0	83.3	83.4	86.6	81.3	81.5		

*Adjusted for practice (nested within intervention), diabetic status, and sex.
†Difference between change in intervention blood pressure and change in control blood pressure. Positive values show greater change in intervention.

Table 3 Secondary outcomes: anxiety, body mass index, and number of prescribed medications

	Unadjusted			Adjusted*			Adjusted mean difference (95% confidence interval)*†	
	Baseline	6 months	12 months	Baseline	6 months	12 months	Baseline to 6 months	Baseline to 12 months
State anxiety inventory score‡								
Intervention	9.8	9.6	9.5	10.0	9.7	9.6	0.4 (–0.3 to 1.1)	0.3 (–0.4 to 0.9)
Control	9.3	9.3	9.1	9.2	9.3	9.1		
Body mass index								
Intervention	30.5	30.1	30.2	31.8	31.1	31.3	0.7 (0.3 to 1.1)	0.6 (0.1 to 1.1)
Control	29.5	29.4	29.4	29.9	30.0	30.0		
No of prescribed drugs								
Intervention	1.8	2.0	2.0	1.9	2.0	2.0	0.0 (–0.2 to 0.1)	–0.1 (–0.2 to 0.1)
Control	1.9	2.0	2.0	2.0	2.1	2.1		

*Adjusted for practice (nested within intervention), diabetic status, and sex.
†Difference between change in intervention outcome and change in control. Positive values show greater change in intervention.
‡Scores range from 6 to 24 (the higher the score, the higher the anxiety).

Costs of self monitoring were not significantly greater than usual care as equipment costs were trivial and the additional time required for training patients in self monitoring was balanced by a reduced consultation rate.

Body mass index was significantly reduced in the intervention group, suggesting a mechanism of blood pressure reduction through a healthier lifestyle. Of the health related behaviours examined, only alcohol intake changed significantly between the two groups (in the first six months only).

Possible biases

That the study was unblinded will have had minimal effect on the primary outcome as blood pressure was recorded in a standardised fashion by a single individual using a print-out of an automated sphygmomanometer. However, greater familiarity with automated sphygmomanometers in patients in the intervention group might have led to a reduced "white coat" effect at follow-up, thereby causing an artefactually greater reduction in blood pressure in the intervention group.

The study used individual rather than cluster randomisation, so there is a possibility of "contamination" of the control group, in that blood pressure monitors were available in the waiting room. However, all participants were asked whether they had monitored their blood pressure on additional occasions (that is, outside the requirements of the study), and we found no evidence that control patients had done so (data available on request). We failed to obtain complete follow-up data for 41 (9%) participants, but sensitivity analysis indicated that this is unlikely to have had an important effect on the results.

The intervention was of relatively low intensity. More frequent measurement of blood pressure, particularly in the initial phases of adjustment of drug treatment, might have led to better blood pressure control. Monthly measurement was chosen as being frequent enough to allow action based on readings within an appropriate timescale while not being too onerous for patients. The latter was important given the aim of studying self measurement of blood pressure in a community setting rather than at home.

In adopting a health service perspective, we did not take into account additional patient costs. A recent analysis suggested that an average attendance at a primary care centre costs about £5 and therefore if individuals were to measure their own blood pressure at their practice on eight occasions annually this would have a notional cost for each individual of £40.[29] Given that the automated sphygmomanometers used in the study now cost around £50 and might be expected to have a useful life of five

Table 4 Secondary outcomes: health behaviour. Values are numbers (percentages) of participants, unless stated otherwise

				P value for change	
	Baseline	6 months	12 months	Baseline to 6 months	Baseline to 12 months
Exercise*					
Intervention	51 (28)	69 (37)	59 (32)	0.53	0.49
Control	53 (25)	80 (38)	59 (28)		
Salt†					
Intervention	152 (80)	148 (78)	136 (72)	0.82	0.11
Control	170 (81)	167 (79)	164 (78)		
Alcohol‡					
Intervention	28 (15)	21 (11)	17 (9)	0.03	0.56
Control	15 (7)	21 (10)	10 (5)		
Smoking§					
Intervention	23 (12)	25 (13)	27 (14)	0.10	0.50
Control	24 (11)	20 (9)	22 (10)		

For all health behaviours except exercise, n=189 (intervention) and 211 (control); for exercise, owing to missing values, n=185 (intervention) and 208 (control).
All patients were advised to exercise at least three times a week, stop adding salt to food, drink less than 21 (males) or 14 (females) units of alcohol and stop smoking if they were smokers.
*Exercising ≥3 times a week. †Adding salt to food or cooking. ‡Drinking >21 (men) or 14 (women) units a week. §Smoking ≥1 cigarette a day.

Table 5 Patients' ranking of methods of blood pressure measurement at end of study*

	Doctor	Nurse	Self measurement at home	Self measurement in surgery
Intervention group				
Mean ranking	2.59	2.56	1.98	2.46
Median ranking (interquartile range)	3 (1-4)	3 (2-3)	1 (1-3)	2 (2-3)
Control group				
Mean ranking	1.91	1.96	2.71	3.07
Median ranking (interquartile range)	2 (1-3)	2 (1-2)	3 (1-4)	3 (3-4)

The two participants who did not attend the first follow-up but attended the second, are included in this analysis.
*Methods were ranked 1 to 4 (1=prefer most, 4=prefer least).

years, if a societal perspective were taken, then patients might reasonably request home monitoring rather than the centralised model used in this study.

Comparison with other studies

We believe this study to be the first randomised controlled trial in the United Kingdom to evaluate the effect of self monitoring of hypertension and the first randomised controlled trial anywhere to use a community clinic setting for self measurement. Cappuccio and colleagues in a recent systematic review identified 18 randomised controlled trials involving self monitoring at home.[12] This meta-analysis found reductions in systolic blood pressure of 4.2 mm Hg (95% confidence interval 1.5 mm Hg to 6.9 mm Hg) and in diastolic blood pressure of 2.4 mm Hg (1.2 mm Hg to 3.5 mm Hg). However, only one of the studies included self monitoring over 12 months or more with sufficient participants to detect changes in blood pressure of the size found in the meta-analysis: Soghikian and colleagues studied 430 people with uncomplicated hypertension who monitored their own blood pressure at home for a year in the setting of the Kaiser Permanente medical care programme.[13] They found that blood pressure control was similar for self monitoring and usual care and that overall costs were similar too; savings were apparent in terms of consultations and laboratory tests associated with hypertensive care, which cancelled out the increased costs of monitoring. Other studies of self monitoring are not comparable with our study owing to small size, use of manual rather than automated self monitoring equipment, or use of extensive cointerventions.[12]

Little and colleagues in the United Kingdom have evaluated the acceptability to patients of measuring their own blood pressure both at home and in a surgery setting.[30] In that study, blood pressure was measured in various settings and included self measurement; the participants ranked home monitoring as more acceptable than other methods of blood pressure measurement—which we also found in the intervention group in our study. The control participants in our study, however, preferred measurement by a doctor or nurse, and so our results suggest that experience of self monitoring influences patients' views. Given the relatively low proportion (27%) of potentially eligible subjects responding to the study invitation, more success in recruiting individuals to self monitoring may require "taster" sessions to allow people to see what they are letting themselves in for.

Table 6 Costs and effects of self monitoring compared with usual care (adjusted effects). Values are per patient per year (95% confidence interval)

	Practice based self monitoring	Control (usual care)
Mean No of consultations for hypertension	3.6 (3.2 to 4.0)	4.4 (4.0 to 4.9)
Mean drug costs for hypertension (£)	174 (162 to 189)*	180 (164 to 196)*
Intervention costs (£)	27	
Mean cost (£)	251 (233 to 275)*	240 (217 to 263)*
Mean effect (mm Hg)	9.9 (5.8 to 13.9)	7.1 (3.4 to 10.8)
Mean incremental cost effectiveness ratio(£/mm Hg)	5.1 (–7.2 to 19.1)*	

*Boot strapped confidence intervals.

What is already known on this topic

Home monitoring by hypertensive patients results in small but significant reductions in blood pressure, though the studies with such findings have largely been underpowered with inadequate length of follow up

No published randomised studies have evaluated self monitoring outside the home

What this study adds

Small early reductions of blood pressure are achieved by self monitoring in a community setting, but these are not maintained long term

The reductions seem to result from non-pharmacological mechanisms rather than more intensive treatment

Self monitoring is feasible in a community setting, highly acceptable to hypertensive patients, and cost effective in the United Kingdom

Conclusion

Blood pressure can be controlled to the same degree with either practice based self monitoring or usual care. This confirms that community based self monitoring has the potential to bring the benefits of home monitoring to individuals without the means to purchase their own equipment. Self monitoring of blood pressure results in worthwhile and significant improvements in systolic blood pressure at six months. How this early improvement might be maintained requires further study. Self monitoring has negligible costs, reduces practice consulting rates, is acceptable to (and preferred by) patients and does not increase anxiety. If the training associated with self monitoring were performed by non-medical or lay individuals then cost savings might be possible. In an average practice, a few practice based automated sphygmomanometers would be sufficient for the hypertensive population. General practitioners should offer this option to their hypertensive patients.

We thank the partners, staff, and participants at the eight practices that took part in the study (Greenridge Surgery, Bellevue Medical Centre, Goodrest Croft Surgery, Harborne Medical Practice, Ridgacre House Surgery, Sherwood House Medical Practice, Woodgate Valley Health Centre, and Woodland Road Surgery). The practices were all part of the Midlands Research Practice Consortium, which assisted in practice recruitment and in securing Support for Science funding. We also thank Roger Holder for advice on the analysis and Ms Emelda Kiely for secretarial support.

Contributors: RJMcM had the original idea, recruited the practices and patients, led the study clinics, and wrote the first draft of this paper. JM and FDRH helped to oversee the trial progress, do the analysis, and write the manuscript. HMP and SB provided specialist expertise on psychological and economic aspects respectively. RAO and RJMcM collected and entered the data. RJMcM and AR did the analyses. All authors participated in the development of the protocol, have access to the original data, contributed to subsequent drafts of the paper, and approved the final version.

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study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the paper for publication.

Competing interests: FDRH sits on the boards of the British Cardiac Society, the British Society of Heart Failure, and the Primary Care Cardiovascular Society; he is chairman of the Secondary Prevention Board of the British Heart Foundation and serves on the European Society of Cardiology Working Group for Heart Failure. He has received travel sponsorship and honorariums from a number of multinational biotechnology and pharmaceutical companies with cardiovascular products for plenary talks and attendance at major cardiology scientific congresses and conferences. To the best of his knowledge, none of these interests conflicts with the work contained in this paper.

Ethical approval: Ethical approval was received from South Birmingham (ref 5694) and Sandwell (ref SEC 320/060701) Local Research Ethics Committees.

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