

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) (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 reduces stroke and coronary heart disease risk.^{2,3} However, although recent hypertension guidelines recommend treatment targets of 140/85 mm Hg or below,^{4,5} international community based surveys show that in many countries only a minority of people treated for hypertension are controlled to these levels.⁶

Self monitoring of blood pressure has the potential to improve blood pressure control at modest cost: a recent systematic review found a lowering of systolic blood pressure of about 4 mm Hg.⁷ However, most included trials were inadequately powered with short follow-up.⁸

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 on health behaviours, anxiety, prescribed antihypertensive treatment, patients' preferences, and costs.

Methods

We recruited participants from eight primary care practices in Birmingham between September 2001 and April 2002. The practices included two from each quartile of the Townsend socioeconomic deprivation score.⁹ Patients aged 35-75 receiving treatment for hypertension and with at least one blood pressure reading greater than 140/85 mm Hg in the previous year were examined: those with blood pressure in the range 140/85 mm Hg to 200/100 mm Hg were eligible for the study. Randomisation was stratified by practice and diabetic status, with concealed allocation to treatment groups. The study was unblinded.

Intervention

Patients randomised to intervention were asked to attend their practice every month to measure their own

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blood pressure using electronic blood pressure machines. They were instructed how to do this at their first visit. They received a record card showing their blood pressure target (140/85 mmHg (140/80 mm Hg for those with diabetes)).⁴⁻¹⁰ 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.

Control group patients were monitored at the discretion of the general practitioner and received an information sheet on self help measures to lower blood pressure.

Data collection

Patients were followed up at six months and one year after randomisation. At follow-up sessions, a researcher (RJMCM or RAO) measured blood pressure and used validated questionnaires to assess anxiety,¹¹ alcohol consumption,¹² exercise,¹³ and addition of salt to food.¹⁴ We calculated body mass index and collected data on prescribed antihypertensive drugs from the practice computer systems. Participants ranked 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.

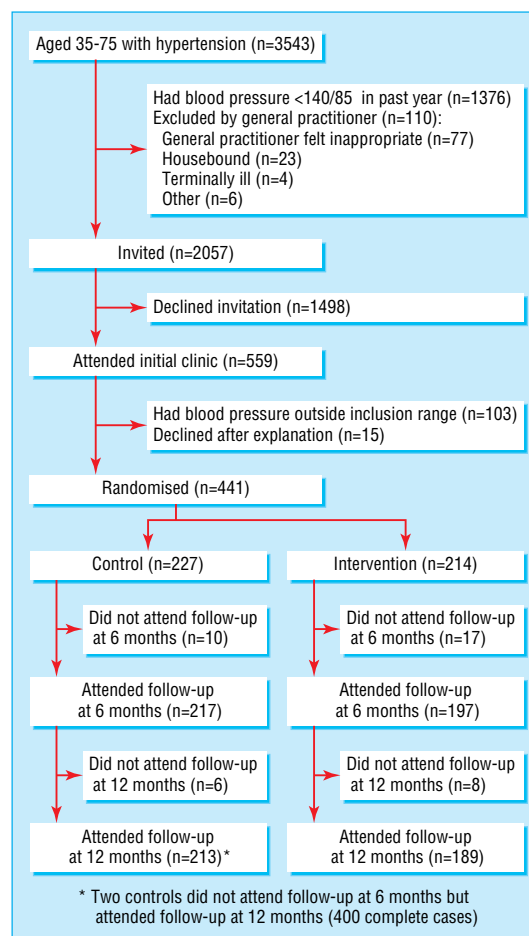
Analysis

The primary outcome was change in systolic blood pressure between baseline and the two follow-up sessions. We analysed the data on an “intention to treat” basis.¹⁵ We examined within subject differences in systolic blood pressure between baseline and the two follow-up sessions, with adjustment for practice (nested within intervention) and diabetic status and any baseline differences with potential effects on outcome.

We also analysed changes in diastolic blood pressure, anxiety, body mass index, and patients’ preferences. Changes over time between intervention and control with respect to exercise, alcohol, smoking, and addition of salt to food were assessed, with adjustment for practice, diabetic status, and sex.

Costing

We collected data on the number of consultations for hypertension, drug treatment, referrals for hypertension, and intervention costs (for equipment and training). We assumed that consultations had standard UK costs (£16 (\$28; €23) for a general practitioner and £8 for a practice nurse).¹⁶ We priced referrals at the rate for a general medical outpatient clinic (£104).¹⁷



Flow of participants through the trial

Results

In all, 441 people were randomised, of whom 400 (91%) attended follow-up at both six and 12 months. The figure shows flow through the trial.

Primary outcome (systolic blood pressure)

Taking into account intervention group, practice (nested within intervention), sex, and diabetic status, we found a significant difference in systolic blood pressure in the intervention group between baseline and six month follow-up (mean difference in change between the intervention and control groups, 4.3 mm Hg (95% confidence interval 0.8 mm Hg to 7.9 mm Hg); $F(1, 381) = 8.2$; $P = 0.004$) but not between six months and one year (-1.6 mm Hg (-5.3 mm Hg to 2.2 mm Hg); $P = 0.33$) (table 1). The intervention group experienced

Table 1 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.

a greater fall in blood pressure in the first six months, 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 ($P=0.91$) (table 1). The groups did not differ over time for anxiety, smoking, exercise, salt intake, or number of prescribed drugs (see tables 3 and 4 on bmj.com). Body mass index reduced significantly more over time in the intervention group than in the control group ($P=0.005$). Most of the reduction occurred in the first six months of the study, with the change between baseline and six months being significant ($P=0.001$) but not the change between six months and one year ($P=0.45$). 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).

Ranking of preferences for method of blood pressure measurement was significantly different between the intervention and control groups ($P<0.001$). Patients in the intervention group ranked home measurement highest, followed by self measurement in the surgery. Control patients ranked measurement by a doctor highest, followed by nurse measurement.

Cost effectiveness

Table 2 shows the cost and effectiveness results. The intervention group consulted less frequently than the control group, and the drug costs did not differ between the two groups. Intervention costs (£26.80 per patient) were dominated by the training of staff and patients (£25.40). The cost per additional 1 mm Hg reduction in blood pressure was £5.10.

Discussion

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. Costs of self monitoring were not significantly greater than usual care.

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

The study was unblinded, but 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 the intervention group might have led to a reduced "white coat" effect and an artefactually greater reduction in blood pressure.

The study used individual rather than cluster randomisation, presenting a possibility of "contamination" of the control group, in that blood pressure monitors were available in the waiting room. However, 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).

More frequent measurement of blood pressure than used in this study might lead 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.

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, so a patient's self measurement of blood pressure at a general practice on eight occasions annually would have a notional cost for each individual of £40.¹⁸

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.⁷ They 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 adequately powered study evaluated self monitoring over 12 months or more. Soghikian and colleagues studied 430 people with uncomplicated hypertension who monitored their own blood pressure at home for a year.⁸ They found that blood pressure control was similar for self monitoring and usual care, with similar costs too.

Little and colleagues evaluated the acceptability to patients of measuring their own blood pressure both at home and in a surgery setting.¹⁹ As in our study, the participants ranked home monitoring as more acceptable than other methods of blood pressure measurement. The control participants in our study, however, preferred measurement by a doctor or nurse, suggesting that experience of self monitoring influences patients' views. Given the relatively low proportion (27%) of subjects responding to the study invitation, success in recruiting individuals to self monitoring may require "taster" sessions.

Table 2 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 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. Self monitoring of blood pressure results in worthwhile 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, and is acceptable to patients. If the training associated with self monitoring were performed by non-medical or lay individuals then cost savings might be possible.

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.

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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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Corrections and clarifications

Short Cuts

Readers might have been confused by some inaccurate labelling of a figure in this section by Alison Tonks (*BMJ* 2005;331:13-4, 2 July). In preparing the figure to accompany the third item ("Antibiotics don't work for patients with cough"), we ill-advisedly labelled the y axis as "Cumulative percentage cured." We should have said, "Cumulative percentage feeling better."

The future of health care in Africa

We inadvertently omitted to say that Eric Buch, who cowrote this editorial with Lola Dare (*BMJ* 2005;331:1-2, 2 Jul), is also professor of health policy and management at the University of Pretoria, South Africa.

Editor's Choice

In Fiona Godlee's column in the issue of 16 July, she said that the *BMJ* had never failed to come out "in its 160 year history" (*BMJ* 2005;331). In fact, the *BMJ* has been around for slightly longer than that. It began life in 1833 as *Transactions of the Provincial Medical and Surgical Association*. In 1840 it became the *Provincial Medical Journal*, changing its name in 1845 to the *British Medical Journal*. Finally, in 1988, it became the *BMJ*. However, we consider the "official" start date of our journal to be 1840 as that is when we began our volume numbering system; some readers (and long serving staff) will remember that we celebrated our 150th birthday in 1990.