Randomised controlled factorial trial of dietary advice for patients with a single high blood pressure reading in primary care

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Abstract

Objective To assess the effect of brief interventions during the "watchful waiting" period for hypertension.
Design Factorial trial.
Setting General practice.
Methods 296 patients with blood pressure >160/90 mm Hg were randomised to eight groups defined by three factors: an information booklet; low sodium, high potassium salt; prompt sheets for high fruit, vegetable, fibre, and low fat.
Main outcome measures Blood pressure (primary outcome); secondary outcomes of diet, weight, and dietary biomarkers (urinary sodium:potassium (Na:K) ratio; carotenoid concentrations).
Results Blood pressure was not affected by the booklet (mean difference (diastolic blood pressure) at one month 0.2, 95% confidence interval 1.6 to 2.0), salt (0.13; 1.7 to 2.0), or prompts (0.52; 1.3 to 2.4). The salt decreased Na:K ratio (difference 0.32; 0.08 to 0.56, P = 0.01), and the prompts helped control weight (difference 0.39 (0.85 to 0.05) kg at one month, P = 0.085; 1.2 (0.1 to 2.25) kg at six months, P = 0.03). Among those with lower fruit and vegetable consumption (<300 g per day), prompts increased fruit and vegetable consumption and also carotenoid concentrations (difference 143 (16 to 269) mmol/l, P < 0.03) but did not decrease blood pressure.
Conclusion During watchful waiting, over and above the effect of brief advice and monitoring, an information booklet, lifestyle prompts, and low sodium salt do not reduce blood pressure. Secondary analysis suggests that brief interventions—particularly lifestyle prompts—can make useful changes in diet and help control weight, which previous research indicates are likely to reduce the long term risk of stroke.

Introduction

Patients with a single high reading of high blood pressure should be given "non-pharmacological" advice and their blood pressure monitored over several weeks or a few months.[1] Interventions supporting these guidelines and shown to be effective through systematic reviews include decreasing dietary sodium,[2] increasing dietary potassium,[3] reducing weight,[4 5] and increasing exercise.[6] Intensive multiple lifestyle interventions have also been shown to reduce blood pressure.[7] There is mixed evidence that increasing the intake of fibre and fruit and vegetables lowers blood pressure,[7 8] although a large US cohort study found that eating fruit and vegetables reduces the risk of ischaemic stroke.[9]

Most studies have been performed either in hypertensive patients in tightly controlled secondary care settings, or in general population groups, and their findings may not generalise to typical primary care settings. Several simple strategies have had little assessment in general practice: the use of booklets,[10 11] advice to use a low sodium, high potassium salt,[12] and the use of very simple healthy lifestyle prompts—a five-a-day fruit and vegetable prompt,[13] a food swap sheet for fatty foods,[14] and fibre prompts.[15]

We assessed whether a booklet, advice to use a low sodium, high potassium salt, and advice to use healthy lifestyle prompts are more effective in changing diet and blood pressure than brief verbal advice during the period of "watchful waiting" before definitive diagnosis of hypertension.

Methods

The study was carried out in nurse run hypertension clinics in six general practices in the Southampton area during 1999-2001.

Inclusion and exclusion—We included patients aged over 17 not taking hypertensive drugs who had a systolic blood pressure >160 mm Hg or diastolic blood pressure >90 mm Hg from a single reading. We excluded patients with established hypertension, renal impairment, regular non-steroidal anti-inflammatory drugs; patients who were very ill or less able to change diet; and patients with systolic blood pressure >200 mm Hg or diastolic blood pressure >120 mm Hg.

S*ample size*—We calculated that we required 99 patients for each arm (control; intervention) of a factor. Using 240 patients allowed for 20% loss to follow up.

P+ *Tables showing changes from baseline for all groups are on bmj.com*

ELPS *This is the abridged version of an article that was posted on bmj.com on 13 April 2004: http://bmj.com/cgi/doi/10.1136/bmj.38037.435972.EE*

Randomisation—In each practice subjects were individually randomised to one of eight groups defined by a 2×2×2 factorial design: no booklet or booklet; no advice to use "low salt" or advice to use low sodium salt; and no use of prompts or use of healthy lifestyle prompts.

Interventions—We used the British Hypertension Society's booklet *Understanding High Blood Pressure*; nurses highlighted the sections on advice to stop smoking, moderate alcohol intake, reduce weight as appropriate, exercise regularly, and avoid salty foods. Patients were given a pot of low sodium salt and asked to use it in cooking and on food instead of normal salt, and to get replacements from the supermarket. The fatty food swap sheet[14] lists, in one column, foods which subjects are asked to swap when shopping and eating with similar but lower fat foods from the other column. At baseline and four week interview, the nurse asked the patient to use fruit-vegetable-fibre daily prompt sheets.[13 15] Patients filled in their portions each day.

Instruction sheets—The core content of each consultation and group differentiation was controlled by an instruction sheet. All groups were given a very brief, structured statement about salt, alcohol, weight, and exercise.

Follow up—At four weeks and six months, the original interventions were reinforced.

Outcomes—Outcomes (measured at baseline, four weeks, and six months) were chosen, to mimic the assessment that nurses could provide in primary care, and thus minimise change in behaviour due to intensive measurements. The primary outcome, blood pressure, was measured by the nurse at one month, three times after the patient had been seated for five minutes. Home measurements were performed by patients, who had been trained by the nurse, after the six month appointment. We also measured several secondary outcomes: serum concentrations of carotenoids, urinary sodium:potassium (Na/K) ratio, lipids, food frequency (through a validated questionnaire[16]), and weight. The final assessment consisted of 14 home measurements of blood pressure, carried out in the patient's home; a validated seven day food diary, and a 24 hour urine collection to determine Na:K ratio. We measured anxiety with the hospital anxiety and depression scale.

Data entry and analysis—The primary outcome was blood pressure at one month, and change in biomarkers (urinary Na:K ratio and serum concentrations of carotenoids). All other outcomes were secondary. We assessed the estimates for the interactions between factors, and if no interaction was found the main effects were estimated. Changes of means from baseline were assessed for each variable with the *t* test.

Results

The mean age of the trial cohort was 55 (SD 10) years; 56% (16/294) of patients were male, and 31% (80/258) had higher education (beyond A level). The arms of each factor were well balanced (figure), but at the baseline appointment with the nurse the cohort's reported fruit and vegetable consumption was slightly higher than expected (see bmj.com).

No intervention altered blood pressure (table). Mean change in diastolic blood pressure with the booklet at one month was 0.2 (−1.6 to 2.0) mm Hg; salt 0.13 (−1.7 to 2.0) mm Hg; and prompts 0.52 (−1.3 to 2.4) mm Hg. The salt decreased Na:K ratio (−0.32; −0.08 to −0.56, P=0.01), and the prompts helped control weight (−0.39; (−0.85 to 0.05) kg, P=0.085 at one month; −1.2 (−2.25 to −0.1) kg, P=0.03 at six months). See bmj.com for table of results at six months.

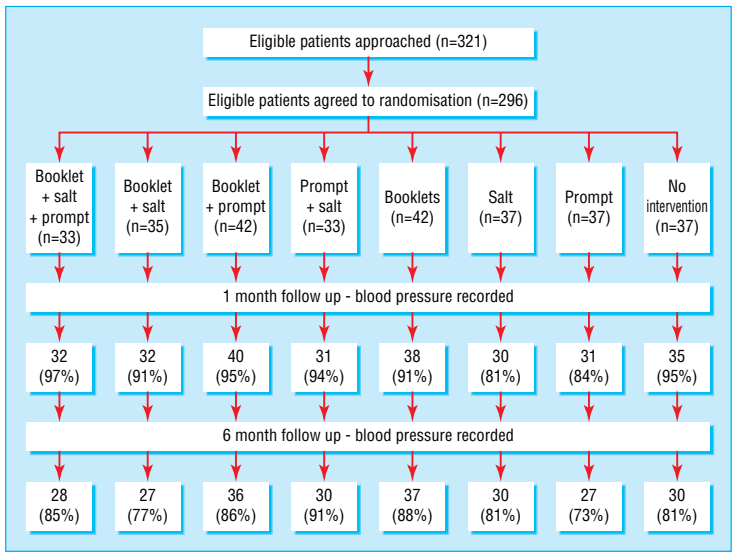
The control group, which only had brief advice and monitoring, had modest reductions in blood pressure and 10-20% change in biomarkers (see bmj.com).

Advice to use a low sodium, high potassium salt increased anxiety (table). None of the interventions had an effect on a 10 item knowledge score based on factual information in the booklet, nor a six item satisfaction score.

Interactions—Tests for interaction showed non-significant P values for patients' characteristics and for all the main factors except possibly the effect of the booklet and low sodium salt on the ratio of cholesterol to high density lipoprotein (interaction term 0.42 (0.07 to 0.78); P=0.02). Given the large number of tests, this finding may be due to chance. Patients' characteristics (age, sex, year of education) did not show an interaction for any intervention. We found a significantly smaller effect of prompts on carotinoids among those with lower baseline fruit and vegetable consumption (interaction term 252 (51 to 454) mmol; P<0.01). Thus in patients with lower fruit and vegetable consumption (<300 g per day) the prompts significantly increased both fruit and vegetable consumption (difference 158 (69 to 250) g; P<0.001) and carotenoids (143 (16 to 269) mmol; P<0.03) at one month. The estimates of effect of intervention on diastolic pressure were little different in just those patients with low fruit and vegetable intake (booklet 0.5 (−2.6 to 3.6) mm Hg; low sodium salt −0.4 (−3.5 to 2.7) mm Hg; prompts −0.5 (−3.6 to 2.6) mm Hg).

Discussion

Over and above brief advice and monitoring, simple interventions in the watchful waiting period do not modify blood pressure, but can make useful changes to diet which are likely to be important in the overall management of hypertension.



Intervention and measurements in trial

Effect of randomised interventions at one month follow up estimated by analysis of covariance*

Outcome	Booklet (n=152)		Low sodium salt (n=138)		Prompts (n=145)	
	Mean (95% CI)	P value	Mean (95% CI)	P value	Mean (95% CI)	P value
Blood pressure (mm Hg)*:						
Systolic (n=268)	0.31 (–2.5 to 3.1)	0.83	1.3 (–1.5 to 4.1)	0.37	2.4 (–0.5 to 5.2)	0.10
Diastolic (n=268)	0.2 (–1.6 to 2.0)	0.83	0.13 (–1.7 to 2.0)	0.89	0.52 (–1.3 to 2.4)	0.58
Carotenoid concentration (mmol/l) (n=235)	55 (–41 to 151)	0.26	–64 (–160 to 33)	0.19	10 (–86 to 107)	0.83
Na:K ratio (n=260)	0.13 (–0.11 to 0.37)	0.28	–0.32 (–0.56 to –0.08)	0.01	0.07 (–0.17 to 0.31)	0.57*
Weight (kg) (n=264)	0.39 (–0.07 to 0.84)	0.10	–0.10 (–0.56 to 0.35)	0.65	–0.39 (–0.85 to 0.05)	0.085
Cholesterol:HDL ratio (n=246)	0.10 (–0.07 to 0.27)	0.23	0.04 (–0.13 to 0.22)	0.61	–0.03 (–0.2 to 0.14)	0.70
Low density lipoprotein (mmol/l) (n=204)	0 (–0.14 to 0.14)	0.99	0.05 (–0.09 to 0.19)	0.50	–0.07 (–0.21 to 0.07)	0.34
Food frequency questionnaire:						
Total fat (g/day) (n=219)	–1.1 (–10.5 to 8.3)	0.82	–12.8 (–3.4 to –22)	0.008	–7.1 (–16.5 to 2.4)	0.14
% energy from fat (n=202)	–0.7 (–2.4 to 1.1)	0.47	–0.3 (–2.1 to 1.5)	0.73	–1.0 (–2.8 to 0.80)	0.28
Non-starch polysaccharides (g/day) (n=202)	1.3 (–0.6 to 3.3)	0.19	–1.9 (–3.9 to 0.1)	0.06	–1.2 (–3.1 to 0.8)	0.24
Fruit and vegetables (g/day) (n=219)	18.7 (–37 to 74)	0.51	–61 (–5 to –116)	0.03	106 (51 to 161)	0.001
Anxiety (hospital anxiety and depression scale) (n=219)	–0.06 (–0.40 to 0.28)	0.71	0.45 (0.11 to 0.80)	0.009	–0.24 (–0.59 to 0.11)	0.17

HLD=high density lipoprotein.
Numbers for outcomes vary due to missing values.
*Estimates for each intervention control for the effects of the other interventions and for baseline values.

Limitations

In our population, reported baseline fruit and vegetable intake (390 g) was slightly higher than in the national food survey of 2000 (360 g), which represents reporting bias, a slightly healthier population, or possibly changes in diet in the two or three weeks between referral and seeing the nurse. Although baseline intake did predict whether carotenoids increased in response to the prompts—which makes reporting bias an unlikely sole explanation—it did not predict change in blood pressure nor the effect of interventions on change in blood pressure, and thus has no major implications for the main results of the study.

A major limitation is the ability to make significant changes to patients' diets. The conditions of this study were those of routine practice, and changes in diet and biomarkers were significant, but these were not sufficient to change blood pressure.

Discussion of main findings

Brief advice and careful follow up resulted in 10-20% changes in diet and biomarkers compared with baseline in the whole cohort and in the control group at one month and was mostly maintained at six months. Which element of this basic intervention and assessment (assessment, brief advice, or both) is important, and how much is due to the Hawthorne effect, requires further research.

Effect of randomised interventions

No interventions modified blood pressure, which contrasts with previous studies of using low sodium salt, fruit and vegetable consumption, and intensive behavioural lifestyle interventions. Secondary analysis suggested the salt and the prompts changed both diet and biomarkers. These changes are unlikely to be chance findings since the effects were as expected and group specific.

Advice to use the low sodium, high potassium salt had adverse effects—a modest rise in anxiety at one month. This clearly could be a chance finding, and we report it cautiously as a secondary outcome. However, given that potassium is the major intracellular metal ion and responsible for repolarisation in nerve cells, and that other metal ions in the same group of the periodic table (such as lithium) affect both ion transport and psychological status,[17] it would be unwise to dismiss this as a chance finding without further research.

What is already known on this topic

Health professionals are advised to give non-pharmacological advice during the period of watchful waiting for hypertension—but it is unclear what dietary changes and blood pressure changes are possible within existing resources in primary care

Simple lifestyle prompts, low sodium salt, and leaflets show promise

What this study adds

During watchful waiting, over and above the effect of brief advice and monitoring, an information booklet, lifestyle prompts, and low sodium salt do not reduce blood pressure

Brief interventions—particularly lifestyle prompts—can help patients make useful changes in diet and control their weight, which previous research indicates are likely to reduce the long term risk of stroke

Conclusions

During watchful waiting, additional brief interventions do not change blood pressure. Secondary analysis indicates that brief interventions—particularly lifestyle prompt sheets—can make useful changes in diet and help control weight, factors that are likely to reduce the long term risk of stroke. The low sodium salt may have adverse effects in the short term.

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Do patients with unexplained physical symptoms pressurise general practitioners for somatic treatment? A qualitative study

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Abstract

Objectives To identify the ways in which patients with medically unexplained symptoms present their problems and needs to general practitioners and to identify the forms of presentation that might lead general practitioners to feel pressurised to deliver somatic interventions.

Design Qualitative analysis of audiorecorded consultations between patients and general practitioners.

Setting 7 general practices in Merseyside, England.

Participants 36 patients selected consecutively from 21 general practices, in whom doctors considered that patients' symptoms were medically unexplained.

Main outcome measures Inductive qualitative analysis of ways in which patients presented their symptoms to general practitioners.

Results Although 34 patients received somatic interventions (27 received drug prescriptions, 12 underwent investigations, and four were referred), only 10 requested them. However, patients presented in other ways that had the potential to pressurise general practitioners, including graphic and emotional language; complex patterns of symptoms that resisted explanation; description of emotional and social effects of symptoms; reference to other individuals as authority for the severity of symptoms; and biomedical explanations.

Conclusions Most patients with unexplained symptoms received somatic interventions from their general practitioners but had not requested them. Though such patients apparently seek to engage the general practitioner by conveying the reality of their suffering, general practitioners respond symptomatically.

Introduction

About a fifth of patients who consult their general practitioner present with physical symptoms that the general practitioner thinks are not explained by physical disease.[1] Nevertheless, these patients often receive extensive somatic investigation and treatment, which is largely ineffective and sometimes iatrogenic[2 3] and which is usually attributed to pressure from patients for somatic treatment and cure.[4 5] That general practitioners feel pressurised to offer somatic interventions helps to explain reports of their dissatisfaction with these consultations[6–9] and the widespread use of terms such as "difficult" and "heartsink"[10] to describe such patients.

In this study we identified types of presentation that had the potential to lead general practitioners to feel pressurised to give somatic interventions.

Method

Sample

We wrote to general practitioners from seven practices to ask them to take part. Of 30 contacted, 28 agreed (13 women and 15 men, with experience ranging from 5 to 42 years, mean 18.4 years). Three practices were urban, three were suburban, and one was rural. List sizes ranged from 2180 to 13 116 patients, and each practice had from one to 10 doctors. The Jarman deprivation indices for the study areas were −11 to 38

P+ *A table of symptoms presented by patients can be found on bmj.com*

ELPS *This is the abridged version of an article that was posted on bmj.com on 31 March 2004: http://bmj.com/cgi/doi/10.1136/bmj.38057.622639.EE*

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