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Primary care

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

Hypertension is one of the commonest conditions managed by general practitioners, and authorities advise that 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] A systematic review identifying 30 trials found that in people over the age of 44 a reduction of 100 mmol sodium reduced systolic blood pressure by 6 mm Hg, although this magnitude of change requires a substantial alteration in diet with intensive intervention.[2 3] A recent trial of the dietary approach to stop hypertension (DASH) diet confirms that intensive multiple lifestyle interventions can reduce blood pressure by 4 mm Hg.[4] Systematic reviews support increasing dietary potassium,[5] reducing weight,[6 7] and increasing exercise.[8] A large US cohort study found that eating fruit and vegetables reduces the risk of ischaemic stroke[9]—which highlights the importance of increased fruit and vegetable consumption in the overall management of hypertension. There is mixed evidence that increasing the intake of fibre and fruit and vegetables lowers blood pressure.[4 10] However, most of the studies addressing the efficacy of intervention have been performed either in hypertensive patients in tightly controlled secondary care settings, or in general population groups,[11 12] and their findings may not generalise to typical primary care settings. Most patients with hypertension in well organised practices do not recall having been given simple non-pharmacological advice on lifestyle.[13 14] In this context it is an urgent priority to assess simple strategies—which could be implemented during the mandatory "watchful waiting" period—which have minimal cost and fall within current resource limitations in the NHS. Several very simple strategies have had little assessment in general practice: the use of booklets,[15 16] which are effective in other conditions; advice to use a low sodium, high potassium salt,[17] which has been effective in a small trial in older subjects with mildly raised blood pressure; and the use of very simple healthy lifestyle prompts—a five-a-day fruit and vegetable prompt,[18] a food swap sheet for fatty foods,[19] and fibre prompt,[20] which have achieved national targets for percentage of energy from fat and for fruit and vegetable consumption.[18–20]

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 >90 mm Hg from a single reading. These patients should normally be given non-pharmacological advice in primary care during "watchful waiting" before definitive diagnosis of hypertension.[1] We excluded patients with established hypertension, renal impairment, regular non-steroidal anti-inflammatory drugs (which may lead to complications with low sodium salt); patients who were very ill or less able to change diet (for example, severe chronic illness, anorexia, bulimia, pregnancy, breast feeding); and patients with systolic

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

blood pressure >200 mm Hg or diastolic blood pressure >120 mm Hg, who it is unethical to observe over months.

S*ample size*—Sample size was determined for $\alpha = 0.05$, $\beta = 0.2$, and took account of guidelines for factorial studies.[21] Assuming a standard deviation of 10 mm Hg and that a "factor" changes diastolic blood pressure by 3-4 mm Hg (the "main effect"),[17] we required 99 patients for each arm (control; intervention) of a factor. Using 240 patients allowed for 20% loss to follow up.

Randomisation—Several weeks in advance opaque, sealed, numbered randomisation envelopes containing instruction sheets for one group were prepared at the study centre by using random number tables. In each practice, after written informed consent was obtained, 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*, which includes information about blood pressure and its treatment; 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 (LoSalt; Klinge Foods, East Kilbride) and asked to use it in cooking and on food instead of normal salt, and to get replacements from the supermarket (either the same brand or supermarket own brand). The fatty food swap sheet[19] 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. The nurse asked the patient to take the sheet when shopping, and keep it in a prominent position at home (fridge, cupboard door). At baseline and four week interview, the nurse asked the patient to use fruit-vegetable-fibre daily prompt sheets.[18 20] Each sheet gives options each day for eating fruit and vegetables (for example, an extra portion of fruit, salad, bowl of soup) and fibre (a bowl of cereal a day, or the equivalent in bread); and 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; each group was given its specific statements.

Training—Nurses were trained to use both the equipment and the prompt sheets during a training session.

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 for an effectiveness study—that is, to mimic the assessment that nurses could easily 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, using the Omron HEM-705CP blood pressure monitor.[22] Home measurements[22] 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 (biomarker for fruit and vegetable consumption) and urinary sodium:potassium (Na/K) ratio (for increased potassium and reduced sodium); lipids (cholesterol, high density lipoprotein, low density lipoprotein); food frequency (through a validated questionnaire[23]); weight (electronic Seca scales). The final assessment consisted of 14 home measurements of blood pressure, carried out in the patient's home, using the equipment as above; a validated seven day food diary, and a 24 hour urine collection to determine Na:K ratio, with para-aminobenzoic acid to establish completeness of urine collection.[23] We measured anxiety with the hospital anxiety and depression scale.

Data entry and analysis—Data were analysed with SPSS and Stata for Windows on an intention to treat basis, with no substitution of missing follow up data. The study was analysed as a factorial study by analysis of covariance for continuous outcomes. The primary outcome was blood pressure at one month, and also 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 by statistical models as above, and if no interaction was found the main effects were estimated (that is, the effect of each factor when the effect of other factors was controlled for). Changes of means from baseline were assessed for each variable with the *t* test.

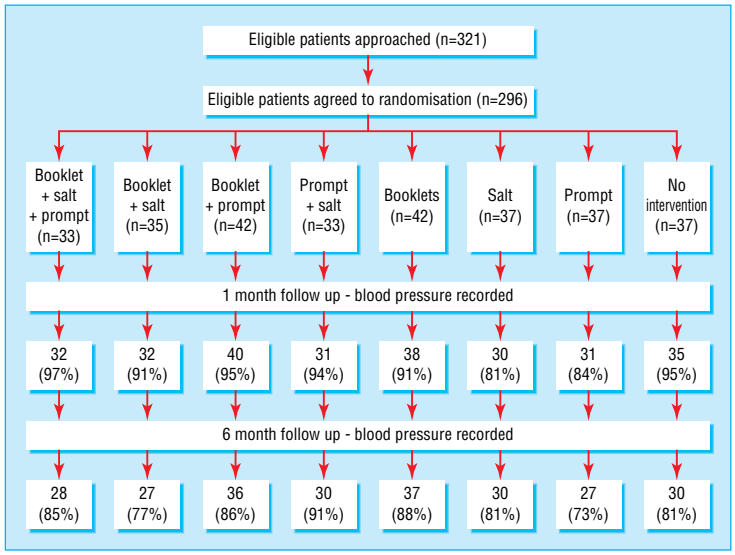
Results

The mean age of the trial cohort was 55 (SD 10) years; 56% (165/294) of patients were male, and 31% (80/258) had higher education (beyond A level). The arms of each factor were well balanced (figure; table 1), but at the baseline appointment with the nurse the cohort's reported fruit and vegetable consumption was slightly higher than expected, making it important to explore the effect of baseline fruit and vegetable intake on the effectiveness of interventions.

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).

The control group, which only had brief advice and monitoring, had modest reductions in blood pressure and 10-20% change in biomarkers (see table A on bmj.com). No intervention altered blood pressure (tables 2 and 3 and tables on bmj.com), although advice to use a low sodium, high potassium salt lowered urinary Na:K ratio and increased anxiety, and lifestyle prompts helped reduce weight in the longer term. None of the interventions had an effect on a 10 item knowledge score based on factual information in the booklet (difference for low sodium salt −0.11 (95% confidence interval −0.45 to 0.23); prompts 0; (−0.35 to 0.32); booklet 0.24 (−0.10 to 0.58)) nor a six item satisfaction score (difference for low sodium salt 0.08 (−0.27 to 0.42); booklet −0.07 (−0.41 to 0.28); prompts −0.19 (−0.53 to 0.15)).

Interactions—Tests for interaction showed non-significant P values 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, years of education) did not show a differential effect (that is, an interaction) for any intervention. Prompts had a significantly smaller effect on carotenoid concentrations when carotenoids were higher at baseline (interaction term −0.18 (−0.02 to −0.33) mmol; P < 0.03) and in patients with lower fruit and vegetable consumption at baseline (<300 g per day, the bottom 40%: interaction term 252 (51 to 454) mmol; P < 0.01). In patients with lower fruit and vegetable consumption (the only group in which an increase in fruit and vegetable consumption



Intervention and measurements in trial. In total 138 patients were given low sodium salt and 158 not; 145 patients were given prompts and 151 not; 152 were given the booklet and 144 not

might help) 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 estimate of the effect on carotenoids in this subgroup was similar at six months (138 mmol) but with the high variance and a smaller sample was not significant ($P=0.2$). However, high baseline fruit and vegetable intake did not modify the effect of the prompts nor of any other intervention on blood pressure change (that is, interactions were not clinically or statistically significant). Thus 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).

Adverse events—One patient (in the leaflet group) had a fatal myocardial infarction.

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.

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 may represent reporting bias, a slightly healthier population, or changes in diet in the two or three weeks between referral and seeing the nurse—that is, in response to the knowledge of having high blood pressure and being asked to document diet. 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 grounded in the type of resources available in routine practice, and changes in diet and biomarkers were significant, but these were not sufficient to change blood pressure. With additional resources in

Table 1 Mean (SD) values at baseline

	Booklet		Low sodium salt		Prompts	
Outcome	**Yes (n=152)**	**No (n=144)**	**Yes (n=138)**	**No (n=158)**	**Yes (n=145)**	**No (n=151)**
Blood pressure (mm Hg)*:						
Systolic (n=295)	152 (18)	154 (19)	154 (19)	152 (18)	150 (18)	156 (18)
Diastolic (n=295)	93 (10)	93 (10)	94 (10)	92 (10)	92 (10)	94 (11)
Weight (kg)(n=292)	82 (13)	81 (15)	82 (14)	81 (15)	82 (15)	81 (13)
Cholesterol:HDL ratio (n=283)	4.6 (1.5)	4.6 (1.5)	4.7 (1.5)	4.5 (1.5)	4.6 (1.4)	4.6 (1.5)
Low density lipoprotein (n=250)	3.6 (0.8)	3.7 (1.1)	3.7 (1.0)	3.6 (0.9)	3.7 (1.0)	3.7 (0.9)
Carotenoid concentration (mmol/l) (n=281)	902 (555)	918 (640)	903 (535)	916 (647)	902 (608)	919 (586)
Na:K ratio (n=287)	2.0 (1.2)	2.0 (1.4)	2.0 (1.2)	2.0 (1.4)	1.9 (1.2)	2.1 (1.4)
Food frequency questionnaire:						
Total fat (g/day) (n=219)	74 (42)	69 (35)	71 (38)	72 (40)	76 (41)	67 (37)
% energy from fat (n=202)	32 (7)	32 (7)	32 (7)	32 (7)	32 (7)	31 (7)
Non-starch polysaccharide (g/day) (n=202)	17 (7)	17 (8)	16 (8)	17 (7)	17 (7)	16 (8)
Fruit and vegetables (g/day) (n=219)	386 (233)	412 (240)	408 (255)	389 (219)	392 (226)	403 (247)

HLD=high density lipoprotein.
Numbers for outcomes vary due to missing values.
*Baseline appointment with the nurse (rather than measurement that lead to referral).

Table 2 Effect of randomised interventions at one month follow up estimated by analysis of covariance*

Outcome	Booklet (n=152) Mean (95% CI)	P value	Low sodium salt (n=138) Mean (95% CI)	P value	Prompts (n=145) 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 to8.3	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 (HAD anxiety 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.

primary care, more intensive intervention might result in larger changes in blood pressure,[4] although this remains to be proved.

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, previous studies of fruit and vegetable consumption, and intensive behavioural lifestyle interventions.[3 4] Because of the danger of type I error (that is, of the results being due to chance), care must be taken when assessing secondary analysis, but secondary analysis suggested the salt and the prompts did change both diet and biomarkers. These changes are unlikely to be chance findings since the effects were as expected and group specific—only the salt led to a

Table 3 Effect of the randomised interventions at six month follow up, assessed by analysis of covariance*

Outcome	Booklet (n=152) Mean (95% CI)	P value	Low sodium salt (n=138) Mean (95% CI)	P value	Prompts (n=145) Mean (95% CI)	P value
Blood pressure (mm Hg)*:						
Systolic (n=244)	5.76 (−6.8 to 18.3)	0.37	1.42 (−11.2 to 14.0)	0.82	1.62 (−11.1 to 14.3)	0.80
Diastolic (n=244)	1.4 (−2.3 to 5.2)	0.45	1.6 (−2.1 to 5.3)	0.41	0.51 (−3.2 to 4.2)	0.79
Home measurement, systolic (n=191)	−1.34 (−6.32 to 3.65)	0.60	1.82 (−3.18 to 6.82)	0.47	−2.75 (−7.72 to 2.21)	0.28
Home measurement, diastolic (n=191)	0.10 (−1.56 to 3.56)	0.44	1.47 (−1.10 to 4.04)	0.26	0.44 (−2.10 to 2.99)	0.73
Carotenoid concentration (mmol/l) (n=205)	36 (−96 to 167)	0.59	−52 (−183 to 79)	0.44	87 (−43 to 218)	0.19
Na:K ratio (n=223)	0.01 (−0.27 to 0.29)	0.95	−0.10 (−0.39 to 0.18)	0.46	0.21 (−0.07 to 0.50)	0.14
Weight (kg) (n=240)	0.37 (−0.71 to 1.44)	0.50	0.70 (−0.38 to 1.78)	0.20	−1.17 (−2.25 to −0.1)	0.03
Cholesterol:HDL ratio (n=221)	0.05 (−0.13 to 0.24)	0.55	0 (−0.18 to 0.18)	0.98	−0.11 (−0.29 to 0.07)	0.23
Low density lipoprotein (mmol/l) (n=175)	−0.13 (−0.29 to 0.03)	0.10	0.09 (−0.06 to 0.24)	0.23	−0.07 (−0.23 to 0.08)	0.35
Food frequency questionnaire:						
Total fat (g/day) (n=219)	−2.2 (−11.6 to 7.2)	0.65	−1.7 (−11.1 to 7.7)	0.72	−4.2 (−13.6 to 5.2)	0.38
% energy from fat (n=202)	0 (−1.9 to 1.9)	0.98	0 (1.9 to 1.9)	0.96	−1.0 (−2.9 to 0.9)	0.31
Non-starch polysaccharide (g/day) (n=202)	0.10 (−1.9 to 2.0)	0.92	−1.4 (−3.3 to 0.50)	0.15	1.5 (−0.4 to 3.3)	0.13
Fruit and vegetables (g/day) (n=219)	39 (−17 to 96)	0.17	−70 (−13 to −126)	0.015	48 (−8 to 104)	0.09
Anxiety (HAD anxiety scale) (n=202)	0.16 (−0.20 to 0.51)	0.38	0.05 (−0.30 to 0.41)	0.77	−0.14 (−0.49 to 0.22)	0.45

HLD=high density lipoprotein.
Numbers for outcomes vary due to missing values.
For cholesterol/HDL ratio there was a possible interaction between booklet and low sodium salt: interaction term 0.42 (0.07 to 0.78; P=0.02) low sodium salt −0.23 (−0.49 to 0.04; p=0.09) booklet −0.14 (−0.39 to 0.10; P=0.25) prompts −0.11 (−0.29 to 0.06; P=0.22). Given the number of interactions tested this may be a chance finding.
*Estimates for each intervention control for the effects of the other interventions and for baseline values.

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

change in urinary Na:K ratio, only the prompts led to a change in weight, and only the prompts led to a change in carotenoid concentrations among patients with low fruit and vegetable consumption.

Some evidence indicated that advice to use the low sodium, high potassium salt had adverse effects—a modest rise in anxiety at one month (see table 2). 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,[24] it would be unwise to simply dismiss this as a chance finding without further research.

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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Contributors: PL had the original idea for this research, which was developed by PL, BM, and DW. JB and MD managed patients, and with JK further developed the protocol and ran the study on a day to day basis. PL and BM analysed the data. All authors contributed to writing the paper. PL is guarantor.

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