

Primary care

Blood pressure control by home monitoring: meta-analysis of randomised trials

Francesco P Cappuccio, Sally M Kerry, Lindsay Forbes, Anna Donald

Abstract

Objective To determine the effect of home blood pressure monitoring on blood pressure levels and proportion of people with essential hypertension achieving targets.

Design Meta-analysis of 18 randomised controlled trials.

Participants 1359 people with essential hypertension allocated to home blood pressure monitoring and 1355 allocated to the "control" group seen in the healthcare system for 2-36 months.

Main outcome measures Differences in systolic (13 studies), diastolic (16 studies), or mean (3 studies) blood pressures, and proportion of patients achieving targets (6 studies), between intervention and control groups.

Results Systolic blood pressure was lower in people with hypertension who had home blood pressure monitoring than in those who had standard blood pressure monitoring in the healthcare system (standardised mean difference 4.2 (95% confidence interval 1.5 to 6.9) mm Hg), diastolic blood pressure was lower by 2.4 (1.2 to 3.5) mm Hg, and mean blood pressure was lower by 4.4 (2.0 to 6.8) mm Hg. The relative risk of blood pressure above predetermined targets was lower in people with home blood pressure monitoring (risk ratio 0.90, 0.80 to 1.00). When publication bias was allowed for, the differences were attenuated: 2.2 (-0.9 to 5.3) mm Hg for systolic blood pressure and 1.9 (0.6 to 3.2) mm Hg for diastolic blood pressure.

Conclusions Blood pressure control in people with hypertension (assessed in the clinic) and the proportion achieving targets are increased when home blood pressure monitoring is used rather than standard blood pressure monitoring in the healthcare system. The reasons for this are not clear. The difference in blood pressure control between the two methods is small but likely to contribute to an important reduction in vascular complications in the hypertensive population.

Introduction

High blood pressure is one of the most readily preventable causes of stroke and other cardiovascular complications.¹⁻⁴ It can be easily detected, and most cases have no underlying detectable cause; the most effective way to reduce the associated risk is to reduce the blood pressure. Unlike many other common, chronic conditions, we have very effective ways of treating high blood pressure and we have clear evidence of the benefits of such interventions.¹ However, despite a great deal of time and effort, hypertension is still underdiagnosed and undertreated.⁵ Furthermore, losses to follow up are high and are responsible for avoidable vascular deaths.⁶

Blood pressure is usually measured and monitored in the healthcare system by doctors or nurses in hospital outpatient departments and, increasingly, in primary care settings. New electronic devices have been introduced and validated in the clinical setting to replace the mercury sphygmomanometer and to overcome the large variations in measurement due to variability between observers. Ambulatory blood pressure monitoring is also being used more often to assess individuals' blood pressures outside the clinical setting.

Measuring blood pressure at home is becoming increasingly popular with both doctors and patients.^{7,8} Some national and international guidelines also recommend home monitoring in certain circumstances.⁹ A recent qualitative review of the role of home blood pressure measurement in managing hypertension concluded that no evidence exists as to whether home monitoring leads to better control of high blood pressure.¹⁰

We reviewed the literature on home blood pressure monitoring and did a meta-analysis of the effect of home monitoring on blood pressure levels and the control of hypertension in randomised trials that compared home or "self" blood pressure monitoring and usual blood pressure monitoring in the healthcare system.

Methods

Identification and selection of trials

To identify published trials that met the inclusion criteria we searched Medline (1966 to January 2003) and Embase (1980 to January 2003) for randomised controlled trials of home or self blood pressure monitoring in people with high blood pressure (see appendix A on bmj.com for strategy). We also searched the Cochrane Database of Systematic Reviews, the Database of Abstracts of Clinical Effectiveness, the Health Technology Assessment Database, the NHS Economic Evaluation Database, the TRIP database, and the websites of the Centre for Reviews and Dissemination and the Agency for Healthcare Research and Quality for reviews of blood pressure monitoring studies. Finally, we examined reference lists of the relevant reviews and all identified studies and reviewed the cited literature. We extended the search to all languages.

We included studies in which the intervention under test was at least one measurement of blood pressure at home by study participants or their family members, whether the result was recorded by the participant or transmitted to a healthcare provider.¹¹⁻³¹ We excluded studies that were not randomised con-



Appendices A-D are on bmj.com

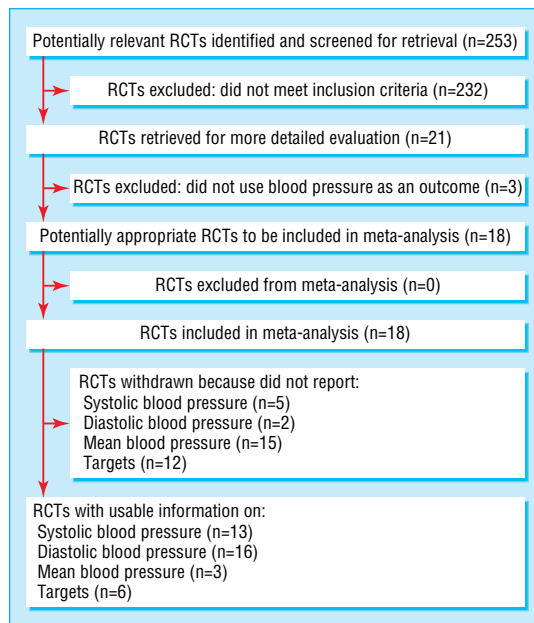


Fig 1 QUORUM statement flow diagram. RTC=randomised controlled trial

trolled trials and those that used “ambulatory” blood pressure monitoring rather than “home” or “self” blood pressure monitoring. When several publications reported aspects of the same study, we chose only one paper to represent the trial data on blood pressure control or on achievement of hypertension targets. Where endpoints were presented at different time points—for example, Earp et al and Stahl et al with endpoints at one and two years of follow up^{17 19}—we repeated analyses with the alternative time point.

We extracted data from text, tables, and graphs. Two reviewers (SMK and LF) independently examined the data. Differences about inclusion of studies and interpretation of data were resolved by arbitration (FPC), and consensus was reached after discussion. We found 253 references. Twenty one studies met the inclusion criteria.^{11–31} We excluded three of these studies because they did not use blood pressure as an outcome measure^{11–13} (fig 1).

Outcome measures

We assessed change in blood pressure (systolic, diastolic, and mean) between intervention and control arms as mean (SD) and change in the proportion of people with blood pressure above target (see appendix B on *bmj.com* for methods of assessment of outcome). We used target blood pressure as defined in each paper (see appendix C on *bmj.com* for targets used in each study); older studies used diastolic blood pressure only (90 or 95 mm Hg), and others used systolic pressure of 140 mm Hg and diastolic pressure of 90 mm Hg (see appendices D1–D3 on *bmj.com* for detailed blood pressure values and effects in each study).

Statistical analysis

We used a random effects model (StataCorp, College Station, TX, USA) for the meta-analysis of the difference in change in systolic blood pressure, diastolic blood pressure, or mean arterial pressure. Where standard deviation of the change was not reported or could not be calculated from the 95% confidence interval, we estimated it. As the standard deviation of the change was approximately the same as the standard deviations of the initial and follow up blood pressures in studies in which these

were reported, we estimated the standard deviation of the change as the average of the standard deviations of the initial and follow up pressures where only the standard deviation of the change was missing. If no standard deviations were reported then we used the average standard deviation for all the remaining studies. We used relative risk to estimate the effect of intervention on the percentage of patients with blood pressure above target at follow up.

We assessed potential publication bias by using a funnel plot and Egger’s test.³² Publication bias is due to small negative studies failing to be accepted for publication, which then causes the funnel plot to display asymmetry. We recalculated the combined estimate after estimating from the asymmetry of the funnel plot the number of “missing” studies and their effect sizes and standard errors, a method known as “trim and fill.”^{33 34} We assessed heterogeneity between trials by using the χ^2 test.

Results

We identified 18 randomised controlled trials that compared blood pressure control or the proportion of people with blood pressure above target. The table shows the characteristics of the analysed trials. Six were based in hospital outpatient clinics,^{14 19 21 22 25 31} eight in communities and general practices,^{16 18 23 24 26–29} and four in mixed settings.^{15 17 20 30} Treatment in the “control” group was mainly “usual” or “standard” care,^{15–19 21 22 24–29 31} but some trials had nurse clinics,^{14 30} educational interventions,²⁰ or flagged medical records.²⁵ Trials used different methods of home or self blood pressure monitoring. In total, 1359 people were randomised to home or self blood pressure monitoring and 1355 to a control group of blood pressure monitoring by health professionals in clinical settings. Two trials used a factorial design,^{16 18} four had more than two randomised groups,^{17 19 20 29} and one was randomised in clusters.²⁵ Only in eight trials was outcome assessment stated to have been blind,^{14–16 24 25 29 31} and only in nine was randomisation concealed.^{15–18 20 21 24 29 31} The duration of the intervention varied between two months³¹ and 36 months.¹⁹

Systolic blood pressure

Thirteen studies reported systolic blood pressure at follow up and baseline or the change from baseline (see appendix D1 on *bmj.com*), but only five of these studies reported full data on means and the standard deviation of the difference. For the remaining seven studies we estimated standard deviations. The overall effect of intervention was 4.2 (95% confidence interval 1.5 to 6.9) mm Hg, with highly significant heterogeneity between studies ($P < 0.001$) (fig 2, top panel). The funnel plot showed some asymmetry, and Egger’s test for publication bias was significant ($P = 0.038$) (fig 3, top panel). The trim and fill method estimated three missing studies and gave a revised estimate of 2.2 (–0.9 to 5.3) mm Hg.

Diastolic blood pressure

Sixteen studies reported diastolic blood pressure at follow up and baseline or the change from baseline (see appendix D2 on *bmj.com*), but only eight of these studies reported full data on means and the standard deviation of the difference. For the remaining eight studies we estimated standard deviations. One study had multiple endpoints.¹⁹ We included results from the one year endpoint. Use of the two year endpoint did not make an important difference to the results (2.2 (1.0 to 3.3) mm Hg). The overall effect of intervention was 2.4 (1.2 to 3.5) mm Hg, with significant heterogeneity between studies ($P = 0.014$) (fig 2, middle panel). The funnel plot showed some asymmetry (fig 3, bottom

Characteristics of trials included in meta-analysis of home or self blood pressure monitoring

Author and country	Setting	Age group (years)	Definition of hypertension	Length of intervention (months)	Intervention group	Control group
Carnahan 1975, USA ¹⁴	Hospital outpatient	Not stated	DBP >90 mm Hg	6	Home BP self recorded twice daily	Nurse clinic
Haynes 1976, Canada ¹⁵	Workplace	Not stated	DBP ≥90 mm Hg	6	Daily BP self recorded on chart	"Usual care"
Johnson 1978, Canada ¹⁶	Community	35-65	On BP treatment at baseline and DBP ≥95 mm Hg	6	Daily BP self recorded on chart	Home visits or "usual care"
Earp 1982 ¹⁷	Hospital outpatient and general practice	Not stated	Not stated	18	Daily or twice weekly BP by family member	Home visits
Pierce 1984, Australia ¹⁸	General practice	<70	SBP >160 mm Hg or DBP >95 mm Hg	6	Daily BP self recorded on chart	"Usual care" or health education programme
Stahl 1984, USA ¹⁹	Hospital outpatient	16-70	3xDBP ≥95 mm Hg if >30 years; DBP >90 mm Hg if 16-30 years; 2xDBP >100 mm Hg; DBP >120 mm Hg	36	Daily BP self recorded at home	"Standard care"
Binstock 1988, USA ²⁰	Not clear	Not stated	"Documented" hypertension on treatment	9	Home BP monitoring	Educational intervention
Midanik 1991, USA ²¹	Hospital outpatient	Not stated	SBP <180 mm Hg and DBP 90-99 mm Hg	12	Twice weekly BP self recorded at home	Standard care (not measuring BP at home)
Soghikian 1992, USA ²²	Hospital outpatient	Not stated	Not stated	12	Twice weekly BP self recorded at home	"Usual care"
Muhlhauser 1993, Germany ²³	General practice	30-60	2xBP >160 or >95 mm Hg	18	Twice daily BP self recorded at home	"Usual care" with flagged notes
Friedman 1996, USA ²⁴	Community	≥60	On BP treatment at baseline and SBP ≥160 or DBP ≥90 mm Hg	6	Weekly BP self recorded at home	Regular medical care
Zarnke 1997, Canada ²⁵	Hospital outpatient	18-80	Not stated	2	Twice daily BP self recorded at home	Standard office based care
Bailey 1999, Australia ²⁶	General practice	Not stated	Not stated	2	Twice daily BP self recorded at home	"Usual care"
Mehos 2000, USA ²⁷	General practice	≥35	SBP 140-179 mm Hg or DBP 90-109 mm Hg	6	Daily BP self recorded at home	No home monitoring
Vetter 2000, Switzerland ²⁸	General practice	18-85	SBP 160-200 and DBP 95-115 mm Hg and losartan	2	Twice daily BP self recorded at home before and 12 hours after treatment	Doctor's office
Artinian 2001, USA ²⁹	Community	Not stated	SBP ≥140 or DBP ≥90 mm Hg; if diabetes or myocardial infarction, SBP ≥130 or DBP ≥85 mm Hg	3	BP self recorded at home three times a week	"Usual care"
Broege 2001, USA ³⁰	Community and hospital outpatient	≥65	SBP >150 and DBP <90 (on treatment) or >90 mm Hg (not on treatment)	3	BP self recorded at home every other day (also monthly clinic visits)	Fortnightly nurse clinic
Rogers 2001, USA ³¹	Hospital outpatient	≥18	Between ≥130 or ≥85 mm Hg and ≥180 or ≥110 mm Hg, depending on complications	2-7	BP self recorded at home three times a week	Usual outpatient care

BP=blood pressure; DBP=diastolic blood pressure; SBP=systolic blood pressure.

panel) (Egger's test for publication bias, $P = 0.095$). The trim and fill method estimated two missing studies and gave a revised estimate of 1.9 (0.6 to 3.2) mm Hg.

Mean arterial pressure

Three studies reported mean arterial pressure, one of which did not report either systolic or diastolic blood pressure.²⁵ All studies reported change from baseline (see appendix D3 on bmj.com) with standard deviation of the difference. The overall effect was 4.4 (2.0 to 6.8) mm Hg, with no significant heterogeneity ($P = 0.319$) (fig 2, bottom panel).

Blood pressure above target

Six studies reported the number of patients whose blood pressure was controlled at follow up. Different definitions of blood pressure control were used (see appendix C on bmj.com). Two studies reported the outcome at more than one time point. The analysis reported here is for the one year outcome in both studies. The overall relative risk was 0.90 (0.80 to 1.00), with no significant heterogeneity between studies ($P = 0.34$) (fig 4). Inclusion of the two year outcomes for Earp¹⁷ and Stahl¹⁹ slightly reduced the effect—relative risk 0.92 (0.83 to 1.04).

Discussion

Main findings

The meta-analysis of 18 randomised controlled clinical trials found that "self" blood pressure monitoring at home results in better blood pressure control and greater achievement of blood pressure targets than "usual" blood pressure monitoring in the healthcare system. The size of the difference is rather small from the clinical viewpoint: 2.2/1.9 mm Hg (when allowing for publication bias), with 10% greater proportion on target. However, this may represent an adjunctive useful improvement in management of hypertension likely to contribute to a better outlook for cardiovascular events. The main inclusion criterion in the study was that participants had undertaken blood pressure monitoring at home either by themselves or with the aid of a family member. As this is the likely scenario for implementation in a population setting, the results of our meta-analysis could be applicable to the general population of people with mild to moderate essential hypertension.

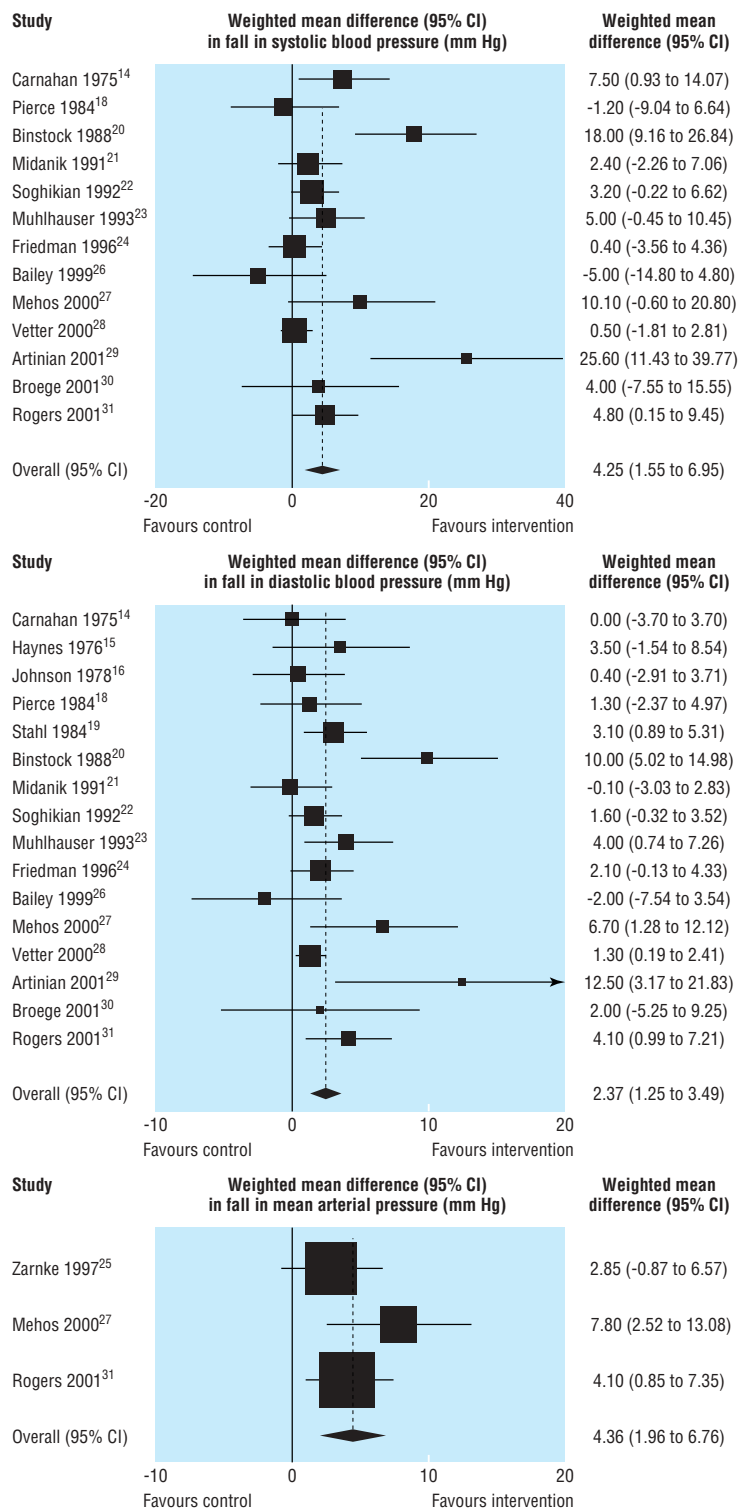


Fig 2 Standardised mean differences (95% confidence interval) in systolic (top), diastolic (middle), and mean (bottom) blood pressures achieved in people monitoring blood pressure at home compared with people whose blood pressure was monitored by health professionals in clinical settings

Limitations of the study

The studies included in the quantitative review were done in a variety of settings, with different methods, using different criteria and different comparative groups. Any potentially consistent effect might have been underestimated. Furthermore, despite our adjustments with statistical methods, the likelihood of publi-

cation bias cannot be excluded. The analysis of hypertension targets may not be easily extrapolated to today's recommended targets of national and international guidelines, because different thresholds were used in different studies.

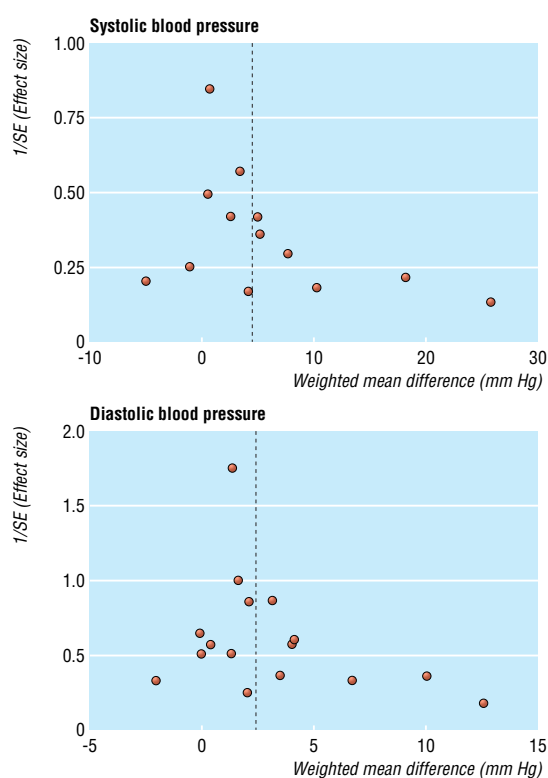


Fig 3 Funnel plots for systolic and diastolic blood pressure

Implications

Home blood pressure monitoring has been shown to be feasible; acceptable to patients, nurses, and doctors in general practice; and more suitable for the screening of “white coat” hypertension than ambulatory blood pressure monitoring.^{35 36} The white coat effect is important in the diagnosis and treatment of hypertension, even in a primary care setting, and is not a research artefact.³⁷ Either repeated measurements by health professionals or ambulatory or home measurements may substantially improve estimates of blood pressure and management and control of hypertension. Home blood pressure measurements are the most acceptable method to patients and are preferred to either readings in the surgery or ambulatory monitoring.^{38 39} They provide accurate blood pressure measurements in most patients, although some patients of low educational level may have poor reporting accuracy.³⁹ Finally, blood pressure monitoring at home might help to improve awareness and concordance, and thus overall effective management.

What is already known on this topic

Blood pressure is usually measured and monitored in the healthcare system by health professionals

With the introduction and validation of new electronic devices, self blood pressure monitoring at home is becoming increasingly popular

No evidence exists as to whether use of home monitoring is associated with better control of high blood pressure

What this study adds

Patients who monitor their blood pressure at home have a lower “clinic” blood pressure than those whose blood pressure is monitored in the healthcare system

A greater proportion of them also achieve blood pressure targets when assessed in the clinic

After we submitted our manuscript, a multicentre randomised trial was published that compared the use of blood pressure measurements taken in the physician’s office and at home and the potential impact on the management of hypertension.⁴⁰ After a year, home blood pressure levels were lower than office blood pressures. Adjustment of antihypertensive treatment on the basis of home blood pressure instead of office blood pressure led to less intensive drug treatment and lower costs. Less good blood pressure control as judged by office blood pressure targets was obviously recorded. At variance with this trial, our results indicate that the practice of monitoring blood pressure “at home” leads to a better control of blood pressure “in the clinic.” Nevertheless, the results of our systematic review and of the latest trial highlight the need for further evidence from prospective studies of outcome to inform potential modifications of treatment guidelines.

Conclusions

We conclude that blood pressure monitoring by patients at home is associated with better blood pressure values and improved control of hypertension than usual blood pressure monitoring in the healthcare system. As home blood pressure monitoring is now feasible, acceptable to patients, and reliable for most of them,⁴¹ it could be considered as a useful, though adjunctive, practice to involve patients more closely in the management of their own blood pressure and help to manage their hypertension more effectively.

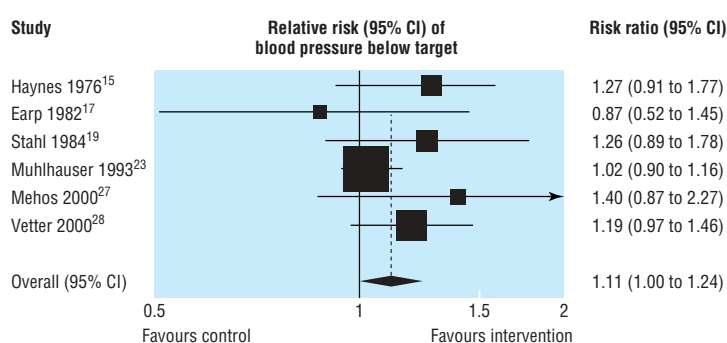


Fig 4 Standardised relative risk of blood pressure above target in people monitoring blood pressure at home compared with people whose blood pressure was monitored by health professionals in clinical settings

FPC is a member of the St George's Cardiovascular Research Group.

Contributors: FPC, LF, and AD conceived the idea, set the objectives, and contributed to design and interpretation. LF ran the searches. SMK and LF abstracted the data, consulting FPC when necessary. SMK did the statistical analysis. FPC drafted the paper, and all authors reviewed it. FPC is the guarantor.

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Ethical approval: Not needed.

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Department of Community Health Sciences, St George's Hospital Medical School, London SW17 0RE

Francesco P Cappuccio *professor of clinical epidemiology and primary care*
Sally M Kerry *senior lecturer in medical statistics*

Bazian Ltd, London N1 1QP
Lindsay Forbes *public health consultant*
Anna Donald *managing director*

Correspondence to: F P Cappuccio f.cappuccio@sghms.ac.uk