Telemonitoring based service redesign for the management of uncontrolled hypertension

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RESEARCH

Telemonitoring based service redesign for the management of uncontrolled hypertension: multicentre randomised controlled trial

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Abstract

Objective To determine if an intervention consisting of telemonitoring and supervision by usual primary care clinicians of home self measured blood pressure and optional patient decision support leads to clinically important reductions in daytime systolic and diastolic ambulatory blood pressure in patients with uncontrolled blood pressure.

Design Multicentre randomised controlled trial.

Setting 20 primary care practices in south east Scotland.

Participants 401 people aged 29-95 years with uncontrolled blood pressure (mean daytime ambulatory measurement ≥135/85 mm Hg but ≤210/135 mm Hg).

Intervention Self measurement and transmission of blood pressure readings to a secure website for review by the attending nurse or doctor and participant, with optional automated patient decision support by text or email for six months.

Main outcome measures Blinded assessment of mean daytime systolic ambulatory blood pressure six months after randomisation.

Results 200 participants were randomised to the intervention and 201 to usual care; primary outcome data were available for 90% of participants (182 and 177, respectively). The mean difference in daytime systolic ambulatory blood pressure adjusted for baseline and minimisation factors between intervention and usual care was 4.3 mm Hg (95% confidence interval 2.0 to 6.5; P=0.0002) and for daytime diastolic ambulatory blood pressure was 2.3 mm Hg (0.9 to 3.6; P=0.001), with higher values in the usual care group. The intervention was associated with a mean increase of one general practitioner (95% confidence interval 0.5 to 1.6; P=0.0002) and 0.6 (0.1 to 1.0; P=0.01) practice nurse consultations during the course of the study.

Conclusions Supported self monitoring by telemonitoring is an effective method for achieving clinically important reductions in blood pressure in patients with uncontrolled hypertension in primary care settings. However, it was associated with increase in use of National Health Service resources. Further research is required to determine if the reduction in blood pressure is maintained in the longer term and if the intervention is cost effective.

Trial registration Current Controlled Trials ISRCTN72614272.

Introduction

Raised blood pressure is one of the most important risk factors for ischaemic heart disease and stroke, and globally is estimated to contribute to 7.6 million premature deaths annually.[1] Despite the availability of effective drugs, the control of blood pressure typically remains poor in routine clinical settings.[2] The reasons for this include infrequent monitoring of blood pressure,[3] reluctance by doctors to intensify drug treatment,[4] and poor treatment adherence by patients.[5] Self monitoring is a potentially attractive way of tackling the first problem; however, several trials have shown that isolated patient self monitoring has, if any, a small effect on improving blood pressure.[6 7] Telemonitoring has been advocated as an enhancement to self monitoring, where readings taken by the patient are transmitted automatically, usually by mobile phone, to a website, enabling patients to share their readings with healthcare professionals in real time.[6] Patients and clinical staff have the advantage of access

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Details of the intervention

to multiple readings taken throughout the day both at home and at work. Systematic reviews[8 9] on the use of telemonitoring in the management of hypertension have identified a relatively small body of studies—some methodologically weak—that have been specifically targeted at people with high blood pressure. Other larger studies that have included telemonitoring to manage blood pressure have concerned additional interventions such as self management[10] or pharmacist intervention,[11] or included some people who did not have high blood pressure.[12 13] Few studies have used ambulatory blood pressure monitoring, the accepted ideal measure,[14] and as a result have included people with "white coat" hypertension or used unblinded outcome measures possibly leading to exaggerated treatment effects. These studies are therefore difficult to interpret, hence the systematic reviews have highlighted the need for further methodologically robust studies of low cost telemonitoring interventions undertaken in routine clinical care using blood pressure measured by ambulatory blood pressure monitoring as the main outcome.[6 9]

We determined whether using a six month intervention of telemonitored support of self monitoring in patients with uncontrolled blood pressure within the context of their usual primary care services, with optional patient decision support and appropriate supervision from primary care clinicians, could lead to clinically important reductions in blood pressure. We also determined the impact of such telemonitored support on use of health service resources.

Methods

During 2009-11 we conducted a pragmatic parallel group randomised controlled trial with blinded outcome assessment and analysis.

We identified potentially eligible participants from electronic searches of clinical record systems in 20 socioeconomically diverse general practices in south east Scotland, based on the Scottish index of multiple deprivation,[15] and recruited participants between February 2009 and October 2010. We invited those aged 18 or more with a diagnosis of hypertension whose last surgery blood pressure measurement was >145 mm Hg systolic or >85 mm Hg diastolic to attend for a screening assessment. Exclusion criteria were inability to consent, atrial fibrillation, being on the stroke or diabetes registers (as these participants would be invited to other trials in our portfolio of trials investigating the role of telemonitoring in the management of long term conditions), treatment for a cardiac event or other life threatening illness in the past six months, major surgery within the past three months, renal failure, or hypertension managed in secondary care.

Recruitment of participants and baseline assessment

Potentially eligible participants were invited to undertake daytime ambulatory blood pressure monitoring (90207 ABP Monitors; Spacelabs Healthcare, Washington).[16] Readings were taken every 20 minutes for 14 hours. As experience in our pilot work suggested that some participants might be unwilling to undergo a second ambulatory blood pressure monitoring at the end of the study, we also measured blood pressure electronically in the clinic on both arms, initially using the Stabil-O-Graph (IEM, Germany)[17] device with an appropriately sized cuff and after a five minute rest, and then twice more using the ambulatory blood pressure monitor. We then fitted the monitor on the non-dominant arm or, if there was a difference of >20/10 mm Hg between the two arms, the arm with the higher systolic reading. Participants were included if their mean daytime ambulatory blood pressure was ≥135/85 mm Hg but ≤210/135 mm Hg.

Outcome measures

The primary outcome was mean daytime ambulatory systolic blood pressure at six months post-randomisation.

Secondary outcomes were mean daytime ambulatory systolic and diastolic blood pressure (mean of the second two out of three office readings each). In addition we recorded details of antihypertensive drugs prescribed and use of National Health Service resources. Two further planned secondary outcome measures were not measured or reported: grip strength was not measured in the trial owing to problems with equipment, and a questionnaire on self reported frequency of exercise[18] was found to be too complex or deemed inappropriate by many participants and as a result was so poorly completed that it was not considered appropriate to report.

Randomisation and protection against bias

The Edinburgh Clinical Trials Unit independently randomised participants to intervention or usual care arms in a 1:1 ratio using a secure system. The computer generated allocation sequence was accessed via the internet and ensured allocation concealment. Minimisation was undertaken on the basis of age, sex, general practice, use of three or more antihypertensives, and current use of blood pressure self monitoring. Because simple minimisation within centres can lead to alternation of treatment allocation and potential loss of allocation concealment, we also incorporated a degree of random allocation. As the intervention comprised providing telemonitoring equipment, neither participants nor investigators could be masked to group assignment. The main outcome measure was machine derived, and research nurses blinded to allocation undertook the assessment of other outcomes, thereby minimising the risk of bias.

Trial procedures

Telemonitoring

Research nurses gave participants assigned to the intervention a 20 minute training session on how to use the telemonitoring equipment. Participants were asked to monitor their own blood pressure twice each morning and twice each evening for the first week and then at least weekly thereafter or as often as they wished. They used a validated automated sphygmomanometer (Stabil-O-Graph mobil; IEM, Stuttgart, Germany).[17] This was linked by a short range wireless connection to a mobile phone, which automatically transmitted readings to a central server managed by IEM. Participants and clinicians could log on to a website to see the data, and automated SMS texts or emails could be sent to participants with feedback on their blood pressure control (see the box for a fuller desription of the process). Participants could contact their clinicians if they were concerned about their blood pressure control and clinicians could contact the participants if needed to arrange modification of therapy. The target home monitored blood pressure was <135/85 mm Hg based on contemporaneous UK guidelines,[19] subsequently endorsed by the National Institute for Health and Clinical Excellence.[20]

Participants allocated to both the intervention and the usual care group were told that the ambulatory blood pressure showed that their blood pressure was uncontrolled. Participants allocated to the usual care group were advised that they should see their

Telemonitoring intervention (see supplemental file for illustrations)

The intervention

The practices and participants were asked to use a system that comprised a validated electronic home blood pressure monitor and mobile phone technology. The phone technology enabled the transfer of blood pressure readings via SMS to a secure website that was accessible to the users and their doctor or nurse, and also provided automated feedback to the patient. The blood pressure monitor linked to a mobile phone wirelessly, via Bluetooth. The intervention comprised several components:

Home blood pressure monitoring—participants were asked to record their blood pressure as agreed with the healthcare team, or more often as they wished. Guidance was initially to record blood pressure twice in the morning and twice in the evening for a week in line with the European guideline on blood pressure monitoring,[47] to build a baseline average. Thereafter they were asked to take weekly measurements, preferably at different times of day if their average blood pressure was within the recommended range. If, however, they had made any change to lifestyle or drugs that would impact on their blood pressure, they were asked to measure their blood pressure for a more intensive period of monitoring to allow the rolling average to change and more quickly assess the effect.

Transmission of data—this simply required the phone to be switched on and to have a signal when the blood pressure measurement was taken. Participants just had to apply the cuff and press a button on the blood pressure monitor. The reading and transmission occurred automatically. Mobile phone problems did not lead to loss of data because all readings were stored in the monitor and any readings that did not get transmitted were sent when the next reading was taken.

Feedback to patient participants (closed loop feedback)—in addition to optionally accessing their blood pressure record online, participants could also opt to receive reports via text message or email. These messages gave advice on the current status of the participants' blood pressure, based on the average of the last 10 readings, and whether they should contact their doctor or nurse. Reports were generated every 10 readings or weekly, whichever was sooner, with a reminder to check blood pressure if this had not been done. These reports could reassure participants that their average blood pressure was within target (≤135/85 mm Hg) or tell them that their blood pressure average was improved from the last report but not yet to target and to maintain current therapy, or that their blood pressure was not at target and that they should contact their clinician. If an individual blood pressure reading was high (>220/120 mm Hg), an immediate text or email report was generated, reinforcing the written advice in the patient information leaflet to rest for 30 minutes, check again, and contact the practice if blood pressure remained high.

Sharing readings with healthcare team—members of the healthcare team were able to access the records of their patients online via a secure login to a summary screen, which listed their patients, their average blood pressure over the last 10 readings, and the date of their last reading. Average blood pressures outside the recommended limits (set at 135/85 mm Hg for the study) were highlighted. Clicking on the name of individual patients led to lists or graphs of all their readings. Clinicians could then check their patients' electronic general practitioner record to see if there had been recent advice about drug or lifestyle change and, if not, could contact the patient to make a change. Clinicians were recommended to check the website weekly, but they could choose the frequency of log on.

Usual care

Participants allocated to the usual care group were asked to continue to attend the practice for blood pressure checks according to the usual routine of the practice. If they were already monitoring their blood pressure at home they were not discouraged.

All participants

The general practitioner or practice nurse was informed that the ambulatory monitoring used to screen for eligibility for the current trial had shown that their average blood pressure for all participants was above the target range, but they were not given the actual reading. All participants were given an information pack containing a range of publicly available leaflets on the management of hypertension and lifestyle modification.

doctor or practice nurse for further management. Subsequently they received standard care for hypertension from their doctor or nurse who were asked to aim for a target surgery blood pressure of <140/90 mm Hg based on the current UK guidelines for that period.[19]

Clinical care in both groups

All participating doctors and nurses were already using a local guideline for hypertension management derived from national hypertension guidelines[19] but were given additional guidance on timelines for escalating therapy. Participating practices were offered an educational session with a member of the research team (PLP) who specialises in the management of hypertension. All participants received written information outlining drug and non-drug interventions to reduce blood pressure. Members of the research team did not provide any ongoing monitoring or clinical care.

Data collection

Research nurses who had not been involved in recruitment undertook the end of study visit in the general practice surgery. Participants were asked by letter before the appointment not to reveal their allocation. Baseline measures were repeated. Those participants who were not prepared to undertake ambulatory blood pressure had three measures taken in the doctor's surgery and the average of the second two measures were recorded. From the electronic health record the research nurses obtained information on antihypertensives prescribed, attendances, and telephone contacts with doctors, practice nurses, district nurses, and hospital and out of hours contacts.

Sample size calculations

The sample size was based on the mean daytime systolic ambulatory blood pressure (142 mm Hg) and its standard deviation (14 mm Hg) measured in a similar group of participants at the end of our pilot work. The likely effect size was based on a systematic review of non-drug interventions to reduce hypertension in which there was an average reduction of 4.5 mm Hg in systolic blood pressure.[21] Such a reduction is considered clinically significant in that if it were to be sustained over 10 years it would be expected to lead to a greater than 15% reduction in risk of stroke and a greater than 10% reduction in risk of coronary heart disease.[22] To have 80% power to identify a difference between telemonitoring and usual care of 4.5 mm Hg in systolic ambulatory blood pressure in a two tailed test with α set at 0.05, we needed 155 participants in each arm. Allowing for a 20% dropout, we aimed to recruit a total of 400 participants.

Data analysis

We used analysis of covariance to analyse the primary and secondary outcomes, adjusting for the baseline value and the minimisation factors (age, sex, general practice, use of three or more hypertension drugs, history of self monitoring blood pressure). We analysed the participants' data on an intention to treat basis. In the primary analysis we excluded participants with missing outcome data. Adjusted analyses and analyses adjusted only for baseline are presented. We assessed all modelling assumptions that were deemed to be valid. Where relevant, we investigated the effect of excluding outlying data points and were unable to identify any important differences (data not shown).

We compared the change in hypertension drug status using a χ^2 test and the changes in defined daily doses[23] of blood pressure drugs using a χ^2 test for trend.

The predefined subgroups for the primary outcome were sex, age group, and socioeconomic status, defined using fifths of the national area based Scottish index of multiple deprivation score.[15] Subgroup analyses were performed by adding the interaction between the subgroup variable and randomised treatment into the analysis of covariance model.

We measured quality of life using index scores generated from standard algorithms for the EuroQol-5D (EQ-5D).[24] The EQ-5D index scores were tested using non-parametric bootstrap of differences in means between trial arms reporting confidence intervals and P values (two tailed) for each, with significance set at the 5% level.

As a secondary analysis we used multiple imputation by chained equations[25] to create 10 imputed datasets by imputing incomplete variables under fully conditional specification. This was based on age, sex, body mass index, blood pressure (systolic and diastolic), number of hypertension drugs, cholesterol level, exhaled percentage of carbon monoxide, HbA_{1c} level, EQ-5D responses, and all variables for use of healthcare resources.

Calculations were undertaken in STATA 12 using the user written "mi ice" command. We imputed normally distributed variables (including primary outcome data) using multiple regression by ordinary least squares, ordered categorical variables using ordinal logistic regression, and other non-normal variables using predictive mean matching. We then estimated model variables using the respective regression techniques described. These estimates and their standard errors were combined using Rubin's rules[26] within Stata's "mi" suit.

Economic evaluation

A full description of the analysis of resource use and costs are presented elsewhere[27]; however, we searched the general practitioner records to establish the use of NHS resources (telephone calls, surgery and home visits carried out by general practitioners, practice nurses, and district nurses, and attendance at out of hours service, accident and emergency, and hospital admission) and data on antihypertensive drug use. Unit costs were taken from recognised national sources.[28-32]

The health economic analysis was performed using SAS statistical software (version 9.2), Minitab statistical software (version 16), Stata 12, and Microsoft Excel 2003.

Qualitative process evaluation

A full description of the process analysis is presented elsewhere.[33] Participating patients, doctors, and nurses taking part in the study were approached and, using semistructured interviews, asked about their experience of taking part in the intervention. All interviews were recorded and transcribed. They were analysed thematically, with initial codes and themes identified inductively from the data. We used constant comparison[34] to ensure consistency in coding, and we sought negative cases for each coding category. Two researchers checked and iteratively refined the coding using paired analysis of transcripts and these were presented to a meeting of participant patients and clinicians to elicit their views on the analysis.

Results

Participants were recruited from practices representing a range of socioeconomic diversity, including practices with postcodes in the fifth most deprived and second most affluent areas in Lothian, Scotland. Four hundred and one participants from 20 general practices (range 5-45 participants per practice) were randomly assigned to the monitored (n=200) or usual care (n=201) group (fig 1⇓). Of these, 182 (91%) in the intervention group and 177 (88%) in the usual care group undertook daytime ambulatory blood pressure monitoring for the primary outcome. In total, 195 (98%) in the intervention group and 185 (93%) in the usual care group attended the follow-up visits at six months and provided some data. Of those not providing complete data, 11 participants in the intervention group and eight in the usual care group declined to have repeat ambulatory blood pressure monitoring; three for medical reasons and 16 because they felt the procedure too uncomfortable. Of the remainder, a further six participants in the intervention group and 14 in the usual care group were either lost to follow-up or withdrew consent, and one in the intervention group and two in the usual care group died before follow-up. Around half of the participants in the intervention group asked for text or email alerts at some point, although a small number subsequently asked for them to be switched off.

Baseline characteristics

Table 1⇓ shows the baseline characteristics of the 401 participants and the characteristics of those who did not provide primary outcome data. The trial arms were well balanced.

Primary outcome

The mean daytime systolic ambulatory blood pressure fell in both groups, from 146.0 mm Hg to 140.0 mm Hg in the telemonitoring arm and from 146.5 mm Hg to 144.3 mm Hg in the usual care arm (table 2⇓. The difference between the two arms at six months (that is, usual care minus intervention) was 4.3 mm Hg (95% confidence interval 2.0 to 6.5; P=0.0002), adjusted for baseline mean daytime systolic ambulatory blood pressure and minimisation factors. The treatment effect was similar for age, sex, and fifth of deprivation index (fig 2⇓).

In a sensitivity analysis using multiple imputation to allow for missing outcome data, the mean difference was 4.5 mm Hg (95% confidence interval 2.5 to 6.6; P<0.001). In addition we carried out a retrospective cluster analysis. The intraclass correlation coefficient was 0.02, and the point estimate after adjustment for clustering was 4.06 (95% confidence interval 1.43 to 6.68), P=0.0034. There was no evidence of between centre heterogeneity.

Secondary outcomes

The mean daytime diastolic ambulatory blood pressure also fell in both arms (table 2), from 87.4 mm Hg to 83.4 mm Hg in the telemonitoring arm and from 85.7 mm Hg to 84.3 mm Hg in the usual care arm. The difference in mean daytime diastolic ambulatory blood pressure at six months between the two arms (usual care minus telemonitored) was 2.3 mm Hg (95% confidence interval 0.9 to 3.6; P=0.001), adjusted for baseline mean daytime diastolic ambulatory blood pressure and minimisation factors.

The difference in mean surgery measured systolic blood pressure at six months between the two groups (usual care minus intervention) was 4.6 mm Hg (95% confidence interval 1.7 to 7.5; P=0.0017) and for surgery measured diastolic blood pressure was 2.8 mm Hg (1.0 to 4.6; P=0.0021), adjusted for baseline surgery blood pressure and minimisation factors (table 3⇓).

Intervention and usual care groups did not differ significantly in the secondary outcome measures of self reported adherence

to drugs, potential indicators of lifestyle adjustment (weight, spot sodium:creatinine ratio, cholesterol level, HbA_{1c} level), self assessed therapy adherence, anxiety, health related quality of life, or exercise tolerance (table 4⇓).

Number of drugs and defined daily dosage

At follow-up more participants were taking two or three antihypertensive drugs compared with at baseline (fig 3⇓ and table 5⇓). More participants in the telemonitoring arm than in the usual care arm had an increase in the number of drugs (P<0.001). There were increases in drug use across all the main drug groups, with calcium antagonists showing the biggest rise (table 6⇓).

In a retrospective comparison we found that the treatment intensity in the telemonitoring group also increased, with 76 (39%) of participants in the telemonitoring group increasing their defined daily dosage of antihypertensive drugs compared with 22 (12%) of participants in the usual care group (P=0.0003).

Resource use

A full description of NHS resource use is presented elsewhere.[27] After multiple imputation the mean NHS costs (excluding hospital admissions) per patient over the six month intervention period were significantly higher in the telemonitoring group than in the usual care group, by approximately £109.32 ($173.41; €130.24). The increase in costs was predominantly driven by the estimated intervention costs (£70.77), including monitor, mobile phone, and connection charges; server and web hosting; and the time it took nurses to check the website weekly. In addition significant increases in costs were associated with participants in the telemonitoring group using on average one additional general practitioner surgery consultation (£32.89), half of a practice nurse surgery consultation (£5.86), and half of a practice nurse telephone consultation (£2.57, table 7⇓).

Compliance with the intervention

Participants in the telemonitoring arm took a median of 76 blood pressure readings, and 178 (89%) completed more than 90% of the expected minimum number of readings during the trial. Five people requested to stop using the home monitor of whom three subsequently withdrew (with the other two continuing until the end of the trial).

Adverse events

In total, 43 adverse events were recorded. One death occurred in the intervention group and two in the usual care group, none of which were thought to be related to blood pressure. The other events included three people who reported anxiety as a result of self monitoring, one who had a fall, and two who fainted (which may have been related to blood pressure control), and six seen in hospital because of cardiovascular problems (two atrial fibrillation, two chest pain, two very high blood pressure). In addition, one patient had a rash thought to be due to antihypertensive drug therapy and one developed hyperkalaemia secondary to dehydration and a viral illness but that was possibly exacerbated by antihypertensive drug therapy. The remainder had hospital admissions thought to be unrelated to blood pressure or the intervention. Apart from the three who had become anxious as a result of self monitoring, adverse events were evenly distributed between the groups.

Qualitative process analysis

A full description of the process analysis is presented elsewhere.[33] Interviews were conducted with 11 nurses, nine doctors, and 25 patient participants, representing a maximum variation sample of patients based on age, sex, and deprivation status of the practice. Patients were generally positive about the intervention, although it was associated with anxiety in a small number of cases. Patient participants and clinicians admitted that before the intervention they were reluctant to increase drugs based on single blood pressure measurements taken in the surgery. Patient participants thought that the process improved access to clinicians and to reliable shared data, around which it was possible to have more equitable and informed discussions. Telemonitoring measurements based on multiple readings were perceived to be more accurate, be difficult to ignore, and lead to action. In some cases the alerts warning of inadequate blood pressure control were considered intrusive and irritating, especially when the blood pressure drug had recently been adjusted or the blood pressure was only 1 or 2 mm Hg above target, and some asked for these to be switched off, although others believed that they kept them engaged with the process. Clinicians noted a perceived increase in workload as a result of the intervention, partly due to lack of integration with main electronic health records and routine working processes, which also meant that the online blood pressure record was not easily accessed by all members of the healthcare team. Nurses reported that some patients did not respond to requests to attend the surgery, and accessing patients by phone was also sometimes problematical. On the few occasions when email was used for communication this was considered to work well. Both patient participants and clinicians thought that over the long term, with improved integration into normal practice systems the intervention would eventually reduce the need for visits to the surgery.

Discussion

In this pragmatic[35] community based trial we found that a relatively brief period of management of hypertension by home self measurement by patients with telemonitoring delivered by practice nurses and general practitioners was more effective in lowering daytime systolic and diastolic ambulatory blood pressure than was usual care. The average reduction in daytime systolic ambulatory blood pressure of 4.3 mm Hg over and above the improvements seen in the usual care group was impressive, particularly since the UK's Quality and Outcomes Framework[36] financially incentivises general practitioners to achieve strict blood pressure control targets. Most participants in this study had been selected from a cohort for whom—despite these incentives—this target had not been reached. This study was not powered to detect changes in cardiovascular outcomes; however, based on previous studies, if sustained, blood pressure reductions of the magnitude achieved in this study would be expected to lead to a greater than 15% reduction in risk of stroke and a greater than 10% reduction in risk of coronary heart disease.[22]

The total cost of the intervention over the six month period was £109.32 or approximately £25.56/mm Hg of systolic pressure lowered. This figure includes the costs of the equipment and training. However, there was a small increase in consultations with general practitioners and nurses. Some additional visits were inevitable—for example, to check renal function after starting treatment. Despite increased use of telephone management, duplication of effort which often happens in the introductory phase of new technologies may have played a part,[37]

and other similar studies have found no increased use of clinical services.[10 38] Patient participants and clinicians both thought that efficiencies in direct professional-patient contact time may, in time, be realised once these new ways of working are established and there is better integration of telehealth data within practice computer systems and the use of asynchronous methods of communication such as email or webmail become more prevalent. In addition, the costs, if blood pressure lowering were to be sustained, are likely to be mitigated by prevention of cardiovascular events in succeeding years. None the less, some caution should be applied when considering rolling out telemonitoring at scale based on these findings.

Strengths and limitations of this study

Unlike many other trials we applied no age limits (the oldest participant was 95) and we did not exclude on the basis of maximal treatment. We also recruited from practices caring for patients from a wide socioeconomic profile. There was no apparent impact on the effectiveness of the intervention in relation to age, sex, or social deprivation, although the study was not powered to detect subgroup effects. Our qualitative research shows that patients were generally positive about the intervention and complied with it well. Although a few people did stop because of anxiety, there was no overall increase in anxiety in the telemonitored group as measured by the hospital anxiety and depression scale.[39] Additionally, intensification of treatment in the telemonitoring group did not seem to lead to a reduction in quality of life. Improved quality of life, however, has been found in other similar studies.[38 40] We consider that our findings are robust. Unlike most previous studies we used the ideal method of ambulatory blood pressure monitoring at baseline and for measuring the primary outcome. Thirty per cent of participants whose last blood pressure reading in the surgery was >145/85 mm Hg were found on ambulatory blood pressure monitoring to have a blood pressure reading <135/85 mm Hg and were therefore not included. This therefore excluded those with "white coat hypertension" and minimised the effect that any possible "habituation" with self monitoring may have had on electronic measurements. Although participants could not be blinded to allocation, nurses involved in the follow-up were blinded. Although 94% of participants attended follow-up, the primary outcome was measured in 90% of participants as some refused a second ambulatory blood pressure monitoring. However, similar results were obtained for ambulatory blood pressure monitoring and surgery measured blood pressure. It is possible that those lost to follow-up affected the treatment effect estimate. We found no significant difference in the baseline values of those with and without primary outcome measurements; however, we accept that the failure to identify statistically significant differences may relate to the small numbers of people without an outcome measure. An analysis using multiple imputation of missing outcome data gave similar results to the primary analysis excluding missing data and, indeed, the primary analysis was the more conservative approach. Randomisation was at the level of the participant. Although this raises the possibility of clustering effects, the numbers of study participants within each practice constituted a tiny proportion of all such patients and the risk of significant contamination is therefore small. A retrospective cluster analysis showed a low intracluster correlation coefficient and did not alter the outcome, suggesting that clustering did not have a major effect. In this situation, a cluster randomised trial may have been more open to bias than a randomised trial at participant level.[41] Indeed, the highlighting of poor blood pressure control and treatment optimisation in the non-intervention group may have led to an underestimate of the intervention effect. Confidence intervals around the difference in blood pressure suggested the effect could be as low as 2.0 mm Hg or slightly lower if clustering is taken into account. However, pooled data from other trials and observational studies estimated that even blood pressure reductions as low as a 2-3 mm Hg difference can result in a reduction of the stroke rate by 6-12%.[42] Our intervention ran for six months. It is unclear whether a longer intervention may have shown similar, greater, or lesser effects or if the impact would be sustained. One study[10] showed a small increase in effect between six and 12 months and another study, in which blood pressure was telemonitored by a research nurse, found a sustained improvement at 18 months in a subgroup of participants with uncontrolled blood pressure at baseline.[13] Other studies have found worse control with self monitoring.[43 44] In these studies, however, participants reduced their drug dose in response to the lower blood pressure reading at home. In a complex intervention such as this that involved self monitoring, telemonitoring, and a degree of decision support through the feedback participants received, it is difficult to be sure to what extent each of these components contributed. A meta-analysis of studies exploring the use of self monitoring alone that have used ambulatory blood pressure as an outcome showed no significant improvement in systolic blood pressure.[7] None the less, further research directly comparing self monitoring alone with that supported by telemonitoring should be considered in future.

Strengths and weaknesses in relation to other studies

The major contribution of this study is to clearly establish that telemonitored supported self monitoring is an effective tool that can improve the management of objectively measured hypertension within a usual care context without the addition of extra services or new protocols. While there have been other studies of telemonitoring alone in people with uncontrolled blood pressure, whose primary endpoint was systolic blood pressure measured by ambulatory blood pressure monitoring, two were small single centre studies that ran for 12 weeks,[45 46] and another study that showed no difference between intervention and control at six months may have been underpowered.[38] A fourth trial, set in Italian primary care, showed a significant improvement in the numbers of participants achieving control of blood pressure but showed no overall reduction in daytime ambulatory systolic blood pressure.[40] Those using unblinded office results have been more positive, reporting reductions of 5.64/2.78 mm Hg.[8] Other, larger studies using ambulatory monitoring have focused on people with diabetes some of whom had normal blood pressure,[12] or included complex interventions of which telemonitoring was only a small component. One study[11] showed that a web based recording system combined with encouragement to contact a clinician if blood pressure was raised had a modest effect in controlling blood pressure; however, this was enhanced by the addition of an intensive pharmacist intervention. Another study[10] also showed that adding a drug self management plan to self monitoring, with a monthly summary of results collected by telemonitoring sent to the patient and the doctor by the research team produced similar reductions in blood pressure to our study. It is likely that the greater reduction in blood pressure in the telemonitored arm was largely achieved by increased prescribing. This has been found in other trials where telemonitoring has been an integral component.[8 9] Other possible contributing factors were the effect of self monitoring itself and the impact of perceived surveillance on adherence to drugs and

lifestyle advice. However, there was no evidence in this trial that the intervention had influenced self reported adherence, or measures indicative of behavioural change. Indeed, patients and clinicians taking part in the embedded accompanying linked qualitative study said that ready access to timely good quality data indicative of high blood pressure had some impact in overcoming what has been described as "therapeutic inertia."[4]

Conclusion and implications

A recent systematic review and meta-analysis of home blood pressure monitoring described the management of blood pressure generally to be "dismal."[6] The present trial, using rigorous endpoints, showed that the use of supported telemonitoring of home measured blood pressure in primary care produces clinically important reductions in both daytime systolic and diastolic ambulatory blood pressure in a group of patients with uncontrolled blood pressure. However, supported telemonitoring was associated with an increase in use of NHS resources. The intervention was viewed positively by both clinicians and patients and has the potential to be implemented in many healthcare settings, which may be facilitated by improved integration with existing primary care electronic health records. However, before advocating rolling out this intervention at scale, further research is required to determine if the reduction in blood pressure achieved over six months is maintained in the longer term and that it is cost effective.

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Contributors: BMcK, JH, SW, CP, and PP designed the trial. JH and BMcK led the research. MP was trial manager, SL planned and supervised the analysis. AK carried out the statistical analysis. ASt carried out the economic analysis. ASh provided advice throughout the trial. All authors were involved in writing the paper. All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. BMcK and JH are guarantors.

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Ethical approval: This study was approved by the Lothian research ethics committee (reference No 08/S1101/38). Written informed consent was obtained from all participants.

Data sharing: Deidentified data and additional data on patient acquired blood pressure are available on application to the corresponding author (brian.mckinstry@ed.ac.uk).

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What is already known on this topic

Mobile phones are a convenient method of receiving and transmitting data in healthcare

Some studies have shown that blood pressure can be successfully managed using telemonitoring

Few studies, however, have been managed within primary care or used rigorous daytime ambulatory blood pressure measurement as an endpoint

What this study adds

The use of telemonitoring by primary care staff of patient self monitored blood pressure can significantly reduce systolic and diastolic ambulatory blood pressure in those with previously uncontrolled hypertension, although it was associated with increased health service use

This effect seems to be mediated through increased prescribing of antihypertensives rather than to the intervention inducing other broader lifestyle changes

Patients and clinicians viewed telemonitoring positively

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Tables

Table 1| Baseline characteristics for full dataset and for participants not providing primary outcome data. Values are numbers (percentages) unless stated otherwise

	Primary outcome data provided		Primary outcome data not provided	
Variables	**Monitored group (n=200)**	**Usual care group (n=201)**	**Monitored group (n=18)**	**Usual care group (n-24)**
Mean (SD) age (years)	60.5 (11.8)	60.8 (10.7)	60.6 (11.5)	57.3 (12.8)
Men	117 (59)	120 (60)	9 (50)	12 (50)
History of blood pressure self monitoring:				
Never	128 (64)	126 (63)	13 (72)	16 (67)
Occasionally	56 (28)	56 (28)	4 (22)	5 (21)
Regularly	16 (8)	19 (9)	1 (6)	3 (13)
Mean (SD) body mass index (kg/m^2)	30.1 (5.7)	30.2 (6.2)	31.5 (5.6)	30.7 (7.0)
Smoker	23 (12)	20 (10)	2 (11)	3 (13)
Mean (SD) No of cigarettes/day	17.6 (9.2)	14.9 (10.4)	13.5 (9.2)	32.5 (10.6)
Non-smoker	177 (89)	181 (90)	16 (89)	21 (88)
Consumes alcohol	158 (79)	159 (79)	12 (67)	17 (71)
Median (interquartile range) units of alcohol (10 mL)/day	1.7 (0.9-2.9)	2.0 (0.7-4.0)	1.5 (0.8-2.5)	1.3 (0.6-3.4)
Does not consume alcohol	37 (19)	41 (20)	4 (22)	7 (29)
Missing data	5	1	2	1
Exhaled carbon monoxide category (parts per million):				
Non-smoker (1-6)	177 (89)	179 (89)	16 (89)	20 (83)
Light smoker (7-10)	0 (0)	3 (1)	0 (0)	0 (0)
Moderate smoker (11-20)	8 (4)	11 (5)	1 (6)	2 (8)
Heavy smoker (≥20)	15 (8)	8 (4)	1 (6)	2 (8)
Mean (SD) cholesterol level (mmol/L)	5.5 (1.0)	5.3 (1.0)	5.5 (0.7)	5.7 (1.3)
Missing data	5	8	0	1
Mean (SD) haemoglobin A_{1c} level (mmol/mol)	38.0 (6.3)	37.7 (5.1)	37.3 (4.9)	39.5 (9.2)
Missing data	7	9	0	1
Mean (SD) urinary sodium:creatinine ratio	9.7 (5.4)	10.9 (8.7)	10.7 (6.9)	9.1 (6.7)
Missing data	4	2	0	0
Mean (SD) surgery measured blood pressure (mm Hg):				
Systolic	152.9 (15.1)	152.4 (14.3)	153.8 (15.5)	152.9 (13.6)
Diastolic	92.1 (11.5)	89.9 (11.3)	89.7 (11.6)	89.5 (10.1)
Mean (SD) daytime ambulatory blood pressure (mm Hg):				
Systolic	146.2 (10.6)	146.2 (10.5)	147.8 (11.7)	144.4 (9.0)
Diastolic	87.1 (10.0)	85.4 (9.6)	83.6 (8.7)	83.5 (9.1)
Hospital anxiety and depression scale[32]:				
Mean (SD) anxiety score	5.0 (2.9)	5.1 (3.6)	5.7 (2.9)	6.1 (3.8)
Mean (SD) depression score	2.8 (2.4)	2.9 (2.5)	3.2 (2.6)	3.6 (2.6)
Missing data	2	2	0	0
Mean (SD) exercise tolerance score[48]	7.8 (2.9)	7.6 (3.0)		
Missing data	1	2		
Mean (SD) Stanford self efficacy questionnaire (short version)[49]	8.7 (1.4)	8.5 (1.4)		
Missing data	6	1		
Morisky medication adherence scale[50]:				
Sometimes forgets to take drugs	61 (31)	63 (31)		

Table 1 (continued)

Variables	Primary outcome data provided		Primary outcome data not provided	
	Monitored group (n=200)	Usual care group (n=201)	Monitored group (n=18)	Usual care group (n-24)
Does not forget to take drugs	132 (66)	132 (66)		
Missing data	6	7		
Sometimes careless about taking drugs	24 (12)	23 (11)		
Not careless about taking drugs	169 (85)	173 (86)		
Missing data	5	7		
Sometimes stops taking drugs when feeling better	11 (6)	15 (7)		
Does not stop taking drugs when feeling better	181 (91)	180 (90)		
Missing data	6	8		
Sometimes stops taking drugs when feeling worse	18 (9)	22 (11)		
Does not stop taking drugs when feeling worse	170 (85)	173 (86)		
Missing data	6	12		
Median (interquartile range) No of defined daily doses of hypertensive drugs	1.5 (1-3)	1.7 (1-3)		
Mean (SD) EuroQol-5D[22]	0.875 (0.177)	0.857 (0.220)		
Missing data	5	6		

Table 2| Daytime ambulatory systolic and diastolic blood pressures over course of study in 359 participants with complete primary outcome data

Blood pressure measurement	Mean (SD) blood pressure (mm Hg)		Adjusted difference* (usual care–monitored) (95% CI)	P value	Adjusted only for baseline difference (usual care–monitored) (95% CI)	P value
	Baseline	6 months				
Systolic:						
Monitored	146.0 (10.5)	140.0 (11.3)	4.27 (2.01 to 6.53)	0.0002	4.08 (1.77 to 6.39)	0.0006
Usual care	146.5 (10.7)	144.3 (13.4)				
Diastolic:						
Monitored	87.4 (10.1)	83.4 (9.1)	2.3 (0.92 to 3.61)	0.001	2.17 (0.79 to 3.56)	0.0022
Usual care	85.7 (9.6)	84.3 (10.4)				

*Adjusted difference between treatment groups for baseline blood pressure and minimisation factors.

Table 3| Mean of second and third surgery measured systolic and diastolic blood pressures over course of study in 374 participants with surgery measured blood pressure results

Blood pressure measurement	Mean (SD) blood pressure (mmHg)		Adjusted difference* (usual care–monitored) (95% CI)	P value	Adjusted only for baseline difference (usual care–monitored) (95% CI)	P value
	Baseline	6 months				
Systolic:						
Monitored	153.1 (15.2)	144.7 (16.1)	4.63 (1.74 to 7.51)	0.0017	4.31 (1.38 to 7.23)	0.004
Usual care	152.5 (14.5)	148.8 (14.7)				
Diastolic:						
Monitored	92.4 (11.6)	86.9 (11.8)	2.83 (1.03 to 4.63)	0.0021	2.82 (1.00 to 4.64)	0.0024
Usual care	90.1 (11.4)	88.3 (11.2)				

*Adjusted difference between treatment groups for baseline blood pressure and minimisation factors.

Table 4| **Results at six month follow-up. Values are numbers (percentages) unless stated otherwise**

Variables	Monitored group (n=200)	Usual care group (n=201)	Adjusted difference (95% CI)	P value
Mean (SD) body mass index (kg/m^2)	30.2 (5.9)	30.4 (6.2)	0.03 (–0.26 to 0.20)	0.791
Missing data	7	16		
Smoker	22 (11)	18 (9)	0	
Mean (SD) No of cigarettes/day	16.0 (8.4)	13.6 (8.7)	0	
Non-smoker	172 (86)	164 (82)	0	
Missing data	6	19	0	
Consumes alcohol	158 (79)	159 (79)	0	
Median (interquartile range) units of alcohol (10 mL)/day	1.7 (0.9-2.9)	2.0 (0.7-4.0)	0	
Does not consume alcohol	37 (19)	41 (20)	0	
Missing data	5	1		
Exhaled carbon monoxide category (parts per million):				
Non-smoker (1-6)	171 (86)	159 (79)	0	
Light smoker (7-10)	2 (1)	4 (2)	0	
Moderate smoker (11-20)	5 (3)	9 (4)	0	
Heavy smoker (≥20)	16 (8)	9 (4)	0	
Missing data	6	20		
Mean (SD) cholesterol level (mmol/L)	5.5 (1.2)	5.3 (1.0)	0.02 (–0.15 to 0.18)	0.855
Missing data	28	35		
Mean (SD) haemoglobin A_{1c} level (mmol/mol)	38.2 (6.6)	37.4 (5.1)	0.28 (–0.35 to 0.92)	0.386
Missing data	32	39		
Mean (SD) urinary sodium:creatinine ratio	9.5 (6.1)	10.6 (7.1)	0.82 (–0.51 to 2.15)	0.228
Missing data	27	24	0	
Hospital anxiety and depression scale[32]:				
Mean (SD) anxiety score	4.8 (3.4)	4.8 (3.8)	0	
Mean (SD) depression score	2.9 (2.8)	3.1 (2.9)	0	
Missing data	10	19	0	
Mean (SD) exercise tolerance score[48]	7.5 (3.0)	7.2 (3.0)	0	
Missing data	10	19	0	
Mean (SD) Stanford self efficacy questionnaire (short version)[49]	8.6 (1.5)	8.3 (1.8)	0	
Missing data	17	23	0	
Morisky medication adherence scale[50]:			0	
Sometimes forgets to take drugs	54 (27)	55 (27)	0	
Does not forget to take drugs	137 (69)	118 (59)	0	
Missing data	9	8	0	
Sometimes careless about taking drugs	16 (8)	17 (8)	0	
Not careless about taking drugs	175 (88)	156 (78)	0	
Missing data	9	28	0	
Sometimes stops taking drugs when feeling better	11 (6)	9 (4)	0	
Does not stop taking drugs when feeling better	179 (90)	163 (81)	0	
Missing data	10	29	0	
Sometimes stops taking drugs when feeling worse	11 (6)	15 (7)	0	
Does not stop taking drugs when feeling worse	181 (91)	180 (90)	0	
Missing data	8	6	0	
Median (interquartile range) No of defined daily doses of antihypertensive drugs	2.0 (1-3)	1.7 (1-3)	0	
Missing data	1	3	0	
Mean (SD) EuroQol-5D	0.864 (0.185)	0.824 (0.178)	0	
Missing data	11	23	0	

Table 5| **Change in hypertensive drug use at follow-up. Values are number (percentage) unless stated otherwise**

Change in hypertensive drug use from baseline	Monitored group (n=200)	Usual care (n=201)	P value
Decrease	11 (6)	11 (5)	<0.0001
None	108 (54)	149 (74)	
Increase	75 (38)	26 (13)	
Missing data	6 (3)	15 (7)	

Table 6| Patterns of antihypertensive drug group prescribing for patients with primary outcome data

	No (%) of patients prescribed drug category		No (%) of patients with change in DDD from baseline to follow-up		
Drug category	**Baseline**	**Follow-up**	**Decreased**	**Same**	**Increased**
Thiazides:					
Usual care	75 (42)	78 (44)	4 (2)	166 (94)	7 (4)
Monitored	71 (39)	85 (47)	4 (2)	160 (88)	18 (10)
β blockers:					
Usual care	29 (16)	31 (18)	2 (1)	171 (97)	4 (2)
Monitored	32 (18)	34 (19)	2 (1)	177 (97)	3 (2)
ACE inhibitors:					
Usual care	71 (40)	67 (38)	5 (3)	171 (97)	7 (4)
Monitored	81 (45)	98 (54)	4 (2)	156 (86)	12 (7)
Angiotensin receptor blockers:					
Usual care	31 (18)	37 (21)	1 (1)	169 (95)	7 (4)
Monitored	25 (14)	36 (20)	1 (1)	169 (93)	12 (7)
Calcium channel blockers:					
Usual care	58 (33)	64 (36)	2 (1)	167 (94)	8 (5)
Monitored	52 (29)	80 (44)	2 (1)	148 (81)	32 (18)
Diuretics:					
Usual care	3 (2)	2 (1)	1 (1)	176 (99)	0 (0)
Monitored	7 (4)	10 (5)	0 (0)	178 (98)	4 (2)
α blockers:					
Usual care	16 (9)	18 (10)	1 (1)	173 (98)	3 (2)
Monitored	7 (4)	13 (7)	1 (1)	175 (96)	6 (3)
Others:					
Usual care	4 (2)	4 (2)	0 (0)	177 (100)	0 (0)
Monitored	4 (2)	5 (3)	1 (1)	178 (98)	3 (2)

DDD=defined daily dose; ACE=angiotensin converting enzyme.

Data were missing for 24 of 201 (12%) in usual care group and 18 of 200 (9%) in monitored group.

Table 7| **Results from resource use survey**

Resources	Monitored group (n=177)	Usual care group (n=177)	Mean difference (95% CI*)	P value
General practitioner consultations				
In the surgery:				
Total No	648	460	0	0
No (%) with ≥1 consultations	163 (92)	140 (79)	0	0
Mean (SD)*	3.66 (2.67)	2.60 (2.52)	1.06 (0.53 to 1.61)	0.0002
Median (interquartile range)†	3 (2-5)	2 (1-4)	0	<0.0001
By telephone:				
Total No	87	77	0	0
No (%) with ≥1 consultations	51 (29)	43 (24)	0	0
Mean (SD)*	0.49 (0.96)	0.44 (1.02)	0.07 (–0.16 to 0.27)	0.5742
Median (interquartile range)†	0 (0-1)	0 (0-0)	0	0.3358
At home:				
Total No	10	13	0	0
No (%) with ≥1 consultations	7 (4)	7 (4)	0	0
Practice nurse consultations				
In the surgery:				
Total No	331	229	0	0
No (%) with ≥1 consultations	116 (66)	112 (63)	0	0
Mean (SD)*	1.87 (2.54)	1.29 (1.73)	0.58 (0.14 to 1.04)	0.0110
Median (interquartile range)†	1 (0-3)	1 (0-2)	0	0.0535
By telephone:				
Total No	112	17	0	0
No (%) with ≥1 consultations	54 (31)	13 (7)	0	0
Mean (SD)*	0.63 (1.17)	0.10 (0.38)	0.54 (0.36 to 0.72)	<0.0001
Median (interquartile range)†	0 (0-1)	0 (0-0)	0	<0.0001
At home:				
Total No	3	1	0	0
No (%) with ≥1 consultations	2 (1)	1 (1)	0	0
District nurse consultations				
Total No	1	28	0	0
No (%) with ≥1 consultations	1 (1)	3 (2)	0	0
NHS 24 consultations				
Total No	12	7	0	0
No (%) with ≥1 consultations	10 (6)	7 (4)	0	0
LUCS consultations				
Total No	8	5	0	0
No (%) with ≥1 consultations	8 (5)	4 (2)	0	0
Accident and emergency visits				
Total No	10	14	0	0
No (%) with ≥1 consultations	9 (5)	10 (6)	0	0
Hospital admissions				
Total No	21	15	0	0
No (%) with ≥1 consultations	13 (7)	11 (6)	0	0

LUCS=Lothian Unscheduled Care Service.

*Confidence interval and P value (two tailed) for difference in means estimated by bootstrap (10 000 replications).

†Wilcoxon rank sum test for difference in distribution.

Figures

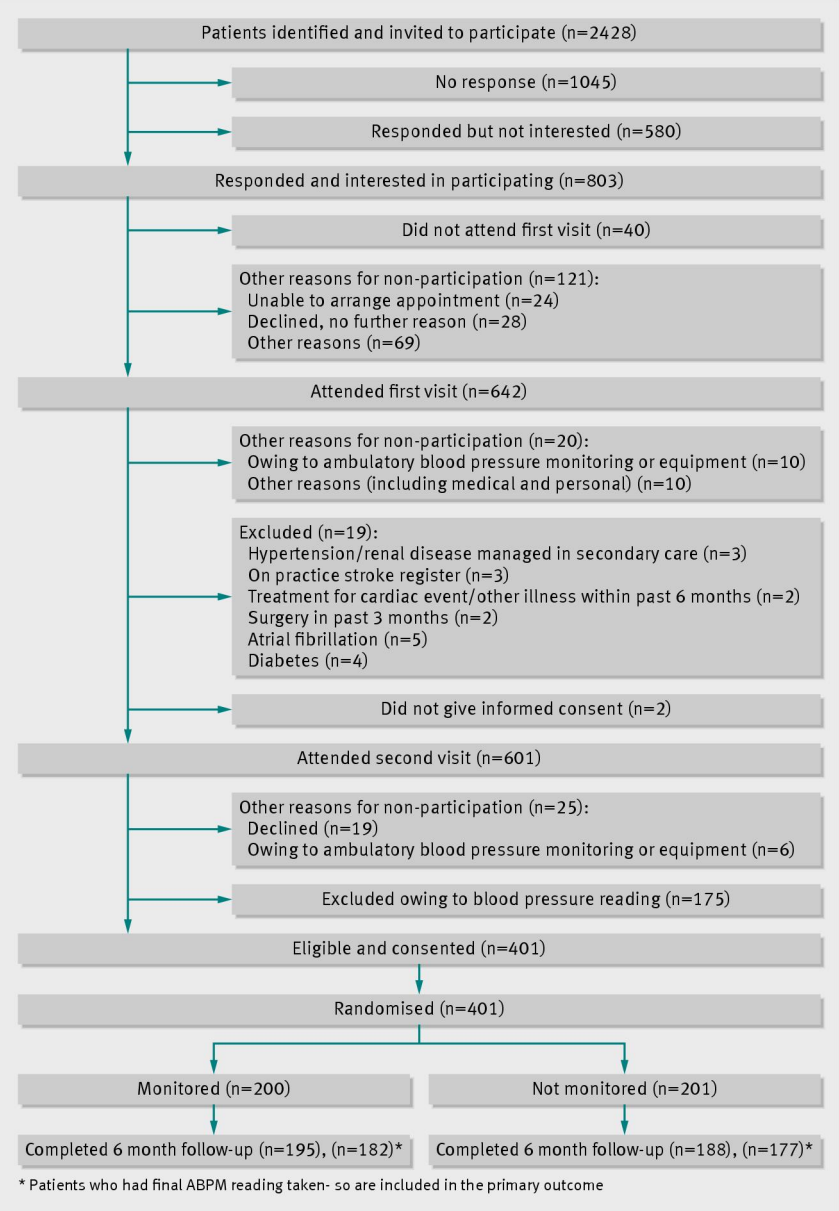


Fig 1 Flow of participants through trial. ABPM=ambulatory blood pressure monitoring

Subgroups	Mean (SE) telemonitored	Total	Mean (SE) control	Total	Mean difference (95% CI)	Mean difference (95% CI)	P value
Sex							
Men	141.37 (1.53)	108	146.17 (1.49)	108		4.80 (1.93 to 7.66)	0.537
Women	141.25 (2.39)	74	145.01 (2.63)	69		3.75 (-0.17 to 7.67)	
Age group (years)							
<70	139.41 (1.38)	140	143.77 (1.37)	134		4.36 (1.71 to 7.00)	0.884
≥70	140.42 (2.26)	42	143.68 (2.43)	43		3.26 (-1.31 to 7.83)	
Deprivation fifth							
1st (most deprived) and 2nd	145.19 (3.51)	34	147.65 (3.14)	35		2.46 (-5.30 to 10.22)	0.805
3rd	133.06 (4.73)	26	139.29 (3.66)	30		6.23 (-2.1 to 14.56)	
4th	142.93 (3.04)	36	147.12 (3.34)	35		4.19 (-1.69 to 10.06)	
5th (most affluent)	140.47 (1.81)	86	143.53 (2.02)	77		3.06 (-0.09 to 6.21)	

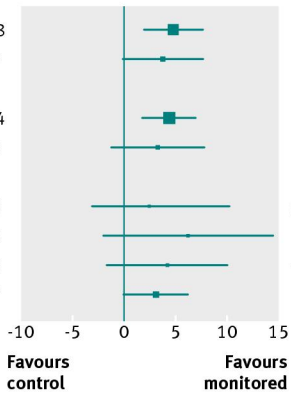
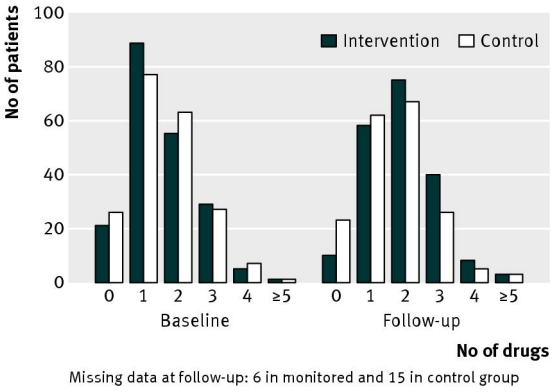


Fig 2 Subgroup analyses on primary outcome of average daytime ambulatory systolic blood pressure measured at six months



Missing data at follow-up: 6 in monitored and 15 in control group

Fig 3 Number of antihypertensive drugs by randomised group and follow-up point