**Home and Online Management and Evaluation of Blood Pressure using a digital intervention in poorly controlled hypertension (HOME BP): a randomised controlled trial**

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**What is already known**

* Previous trials of self-monitoring and self-management have shown effectiveness in reducing blood pressure but have often relied on relatively expensive technology and/or time-consuming training packages in order to realise these benefits.
* Short lived trials of digital interventions have shown potential for improvement of blood pressure control but have not provided sufficient evidence for widespread implementation.

**What this study adds**

* The HOME BP intervention for the self-management of high BP consisted of an integrated patient and healthcare practitioner online digital intervention, including online training, BP self-monitoring, health professional directed and supervised titration of anti-hypertensive medication and user-selected lifestyle modifications.
* HOME BP resulted in better control of systolic blood pressure after one year at low incremental cost and with similar adverse events compared to usual care.
* This was reflected in better blood pressure control, increased titration of antihypertensive medication and improved patient enablement.
* Digital interventions such as this have the potential to be implemented at scale in a cost-effective manner. However, people of lower socio-economic status and those with poor internet access were underrepresented in the trial hence implementation should include strategies to realise such benefits for the whole population.

**Print Abstract (300 words)**

**Study question:**

Can a digital intervention for management of hypertension in primary care combining self-monitoring of blood pressure with guided self-management lead to lower systolic blood pressure (BP) after a year in people with poorly controlled hypertension.

**Methods**

People with poorly controlled hypertension (blood pressure greater or equal to 140/90mmHg were randomised to the HOME BP intervention or usual care. The intervention consisted of an integrated patient and healthcare practitioner online digital intervention, including training, BP self-monitoring with study provided monitors, health professional directed titration of anti-hypertensive medication and user-selected lifestyle modifications. Usual care was routine hypertension care, with appointments and medication changes made at the GP’s discretion. The primary outcome was difference in office systolic BP after one year, adjusted for baseline BP, BP target, age and practice, with multiple imputation for missing values.

**Study Answer and limitations**

After one year, data were available from 552 participants (88.6%) with imputation for the remaining 70 (11.4%). Office BP dropped from 151.7/86.4mmHg to 138.4/80.2mmHg in the intervention group and 151.7/85.3mmHg to 141.8/79.8mmHg in the usual care group giving a mean difference in BP of -3.5 (95% confidence interval -6.2 to -0.9) / -0.6 (-1.9 to 0.8) mmHg. The major limitations were that the intervention required online access and self-monitoring equipment which may not be available to all members of society and that sub group analysis suggested a reduction in effect in older people.

**Funding, competing interests and data sharing**

The trial was funded by the National Institute for Health Research (NIHR) (RP-PG-1211-20001). Omron provided the monitors used in the HOME BP study at reduced cost. RJM has received BP monitors for research from Omron and is collaborating with them on development of a telemonitoring system. Anonymised trial data are available on reasonable request via the corresponding author.

**Trial registration**

ISRCTN 13790648.

**Abstract**

*Objective*

The HOME BP trial aimed to test a digital intervention for management of hypertension in primary care combining self-monitoring of blood pressure with guided self-management.

*Design*

Unmasked randomised controlled trial with automated ascertainment of primary end point.

*Setting*

76 UK General Practices.

*Participants*

622 people with treated but poorly controlled hypertension (>140/90mmHg) and access to the internet.

*Interventions*

Participants were randomised using a minimisation algorithm to either self-monitoring of blood pressure (BP) with a digital intervention (305 participants) or usual care using clinic BP (317 participants). The digital intervention provided feedback of BP results to patients and professionals with optional lifestyle advice and motivational support. Target BP for hypertension, diabetes and over 80’s followed UK national guidelines.

*Main Outcome Measures*

The primary outcome was difference in office systolic BP after one year, adjusted for baseline BP, BP target, age and practice, with multiple imputation for missing values.

*Results*

After one year, data were available from 552 participants (88.6%) with imputation for the remaining 70 (11.4%). Office BP dropped from 151.7/86.4mmHg to 138.4/80.2mmHg in the intervention group and 151.7/85.3mmHg to 141.8/79.8mmHg in the usual care group giving a mean difference in BP of -3.5 (95% confidence interval -6.2 to -0.9) / -0.6 (-1.9 to 0.8) mmHg. Results were comparable in the complete case analysis and adverse effects were similar between groups. Considering within trial costs, these showed an incremental cost effectiveness ratio of £11 (6 to 29) per mmHg reduction.

*Conclusions*

The HOME BP digital intervention for the management of hypertension, utilising self-monitored BP, led to significantly lower office BP than usual care at low incremental cost. Implementation in primary care will require integration into clinical workflows and consideration of those currently digitally disenfranchised.

*Trial Registration*: The HOME BP trial is registered at: ISRCTN13790648.

**Introduction**

Hypertension is the major risk factor for cardiovascular disease internationally and evidence from multiple randomised controlled trials shows that this risk can be reduced by lowering blood pressure (BP).1 2 In the UK, almost 30% of adults have raised BP (≥140/90mmHg), rising to more than half aged sixty five and over.3 Target BP levels are reached for fewer than half of this group and with an ageing population, novel interventions are required to improve BP control.3 4

Digital interventions (apps, programmes or software used in a health context) are one such intervention and have the potential to support individuals in self-management.4 5 A digital intervention facilitating lifestyle change in obese primary care patients developed by our group resulted in cost-effective weight loss.6 In hypertension however, evidence for digital interventions to date has been from small trials with relatively short follow-up and significant heterogeneity of results.7 Only one trial has lasted longer than ten months and did not reduce BP.8 We have previously shown that self-monitoring combined with self-titration of antihypertensive medication leads to significantly lower BP in both essential hypertension and higher risk individuals, is cost effective, but required extensive manual and paper recording making implementation difficult.9-12 Hence a digital intervention combining our previous knowledge of self-management of hypertension with digital support for self-management and lifestyle change might result in lower BP with associated changes in lifestyle including weight and be more easily integrated into clinical care by both patients and professionals. Such an intervention would also facilitate remote monitoring, an important consideration for those restricted to their homes by disability or to avoid exposure to infection where clinic monitoring is difficult or not possible.13

The HOME BP trial aimed to evaluate whether a digital intervention comprising self-monitoring of BP with reminders and predetermined medication changes combined with lifestyle change support resulted in lower systolic BP in individuals with poorly controlled treated hypertension and whether this was cost-effective.

**Methods**

The methods of the HOME BP trial have been previously described in detail.14 In brief it was an unmasked randomised controlled trial with automated ascertainment of outcome comparing a digital intervention for hypertension management combined with self-monitoring of BP with usual care, i.e. management based on clinic BP.

*Population*

Eligible participants were aged 18 or over, with treated hypertension, a mean baseline BP reading (calculated from the second and third BP readings) of >140/90 mmHg and taking no more than three antihypertensive medications. In order to use the digital intervention, they needed to be willing to self-monitor and have access to the internet (with support from a family member if needed).

Exclusions included BP >180/110 mm Hg, atrial fibrillation, hypertension not managed by their General Practitioner (GP), chronic kidney disease stage 4-5, postural hypotension (>20mmHg systolic drop), an acute cardiovascular event in the previous three months, terminal disease or other condition which in the opinion of their GP made participation inappropriate.

*Procedure*

Practices were recruited from the National Institute for Health Research Clinical Research Network (<https://www.nihr.ac.uk/explore-nihr/support/clinical-research-network.htm>). Eligible participants were identified from clinical codes within the electronic health records of collaborating general practices and invited to attend a baseline clinic to learn about the study, establish eligibility, take consent from individuals who wished to participate, and collect baseline clinical data. Individuals not wanting to take part could optionally complete a form detailing their reasons. Blood pressure was measured by a study nurse in a standardised manner after five minutes rest with a validated electronic automated sphygmomanometer (BP TRU BPM 200).15 Six BP readings were taken at intervals of one minute. Participant questionnaires were completed online by all participants.

Following informed consent and baseline data collection, eligible participants were randomised using an online system (<https://www.lifeguideonline.org>) in a 1:1 ratio to receive either usual care or the HOME BP intervention with optional nurse support. Minimisation factors were participants’ baseline systolic BP, age, diabetes status and practice. Practice staff were notified of patient group allocation by email.

Following randomisation, all patients received a BP medication review from either a GP or nurse prescriber (“prescribers”). For patients allocated to the intervention group, prescribers were asked to select and agree an individualised medication titration plan (including three potential medication changes should BP remain above target).10 Participating clinicians were given information regarding NICE guidance within the HOME BP intervention but were not asked to follow set algorithms for medication.

At 6- and 12-months after randomisation, participants attended a follow-up appointment with an independent research nurse where BP and weight (latter 12 months only) were recorded. Follow-up questionnaires were again completed online.

*Intervention*

The HOME BP intervention for the self-management of high BP consisted of an integrated patient and healthcare practitioner online digital intervention, BP self-monitoring, health professional directed and supervised titration of anti-hypertensive medication and user-selected lifestyle modifications. The intervention was developed using a theory-, evidence- and person-based approach16 which was designed to influence both participants’ and their clinicians’ behaviour; the development process has been fully described elsewhere but comprised an iterative process including “think aloud” interviews to provide detailed feedback on the HOME BP prototype.17-19

Participants were given online instruction in how to correctly undertake self-monitoring (using an Omron M3 monitor), with a demonstration video.20 Following this they were asked to rehearse self-monitoring for a minimum of seven days and enter these initial readings into HOME BP online before undertaking study procedures.

Participants were advised, with automated email reminders, to take two morning BP readings for seven days each month and in each case to enter online the second reading (as per the TASMINH2 and TASMIN-SR studies).21 22 Mean home BP was then calculated and feedback provided to the participants and the healthcare practitioners according to a traffic light system (developed from that used in previous medication titration procedures).21 22 Where mean home BP was above target for two consecutive months, the prescriber was asked by email to implement the pre-planned medication change.

Home blood pressure targets were set in line with the then current NICE hypertension guidelines,23 with adjustment by 5/5 mmHg for home readings24:

People under 80 without diabetes <135/85 mmHg,

People aged 80 and over without diabetes <145/85 mmHg,

People with diabetes <135/75 mmHg.

In the case of very high (>180/110mmHg) or very low home BP readings (systolic BP<100mmHg), patients were advised to call the GP Practice within three days and HOME BP healthcare practitioners were alerted by email. If mean home BP was controlled for three consecutive months (defined as 100-134/≤84 mmHg), patients were advised to reduce BP monitoring to once every eight weeks, reverting to monthly should mean BP subsequently rise above 135/85mmHg.

The HOME BP intervention included elements designed to motivate and support healthy behaviours. Information was presented regarding the health-related benefits of self-monitoring, of reducing BP through medication and aiming to address common patient concerns regarding medication side effects. Nine weeks after participants were allocated to the intervention (judged to be sufficient time for self-monitoring habits to have been implemented), an optional tool became available outlining user-selected evidence based lifestyle modifications targeting healthy eating, physical activity, losing weight (if appropriate), and salt and alcohol reduction.14 The health behaviours targeted were chosen with due regard to normalisation process theory and took the form of web pages and links 17

The HOME BP intervention also aimed to build healthcare practitioner motivation, knowledge and skills, to reduce clinical inertia.17 This was achieved through presenting evidence of efficacy and addressing concerns regarding patient titration acceptance, the reliability of home blood-pressure readings and study procedures.

Optional additional behavioural support for self-monitoring and lifestyle modifications was available to intervention participants via the practice nurses or healthcare assistants (‘supporters’) , using the CARE (Congratulate, Ask, Reassure, Encourage) approach.17 This comprised up to six brief face-to-face, telephone or email support contacts addressing difficulties associated with self-monitoring or lifestyle change, with additional monthly email support using pre-written templates.

*Usual Care*

Participants allocated to usual care were not provided with self-monitoring equipment or the HOME BP intervention but had online access (via the same system that delivered the online questionnaires), to the information provided in the BP UK patient leaflet for hypertension, which comprised definitions of hypertension, causes, and brief guidance on treatment including lifestyle change and medication. They received routine hypertension care typically using clinic blood pressure to titrate medications, with appointments and medication changes made at the GP’s discretion. They were not prevented from self-monitoring and data were collected at the end of the trial from patients and practitioners on self-monitoring practices.

In both intervention and control groups, decisions about patients’ medication remained at the prescriber’s discretion at all times.

*Outcomes*

The primary outcome of the trial was the difference in clinic systolic BP (mmHg, mean of 2nd/3rd readings) at 12-month follow-up between the intervention and control groups adjusting for baseline BP, practice, BP target levels and gender.

Secondary outcomes (also adjusted for baseline and covariates where appropriate) included: systolic and diastolic BP at six and twelve months using both 2nd/3rd and 2nd-6th BP readings, weight, modified patient enablement instrument (patients' feelings of confidence in relation to understanding of their illness and individual’s ability to manage understand and cope with their condition, and health problems following in general, after the healthcare they have received),25 26 medication adherence (MARS questionnaire),27 health-related quality of life measured using EQ-5D-5L,28 and side effects from the symptoms section of an adjusted Illness Perceptions Questionnaire.29 At the end of the trial a medical record review captured prescription of antihypertensive medication (including any changes) and within trial primary health care resource utilisation (both primary care and secondary care including outpatient and inpatient visits). In questions added following trial registration, participants and GPs were asked about use of self-monitoring in the control group. Additional outcomes which will be published elsewhere included long term economic modelling and a detailed process evaluation.

*Power Calculation and Analysis*

A sample size of 244 patients per group was required in order to have 90% power to detect a difference in systolic BP of 5 mmHg (SD 17 mmHg) between intervention and control groups, based on the findings from the TASMINH-2 study.22 Allowing for a 15% participant drop out, 287 participants were required per group, resulting in a total sample size of 574 participants. During the trial, it was decided to increase the sample size to 610 to allow for a 20% drop out rate due to concerns regarding higher than expected initial drop out (which later proved unfounded).

The principal analysis used both raw and adjusted data and was agreed in a statistical analysis plan before final data lock (see appendix). The primary analysis used general linear modelling to compare intervention and usual care systolic BP at follow-up adjusting for baseline BP, practice (as a random effect to take into account clustering), BP target levels, and gender. Analyses were on an intention to treat basis using 100 multiple imputations by chained equations for missing data. The imputation model included all outcome and stratification variables. Sensitivity analyses used complete cases and also a repeated measures technique. Planned sub-group analyses included: BP target groups, older vs younger (67 as threshold), males vs females, lower Index of Multiple Deprivation (IMD) scores versus higher IMD scores, and better controlled at baseline vs worse controlled at baseline (above/below median systolic BP). Secondary analyses used similar techniques to assess differences between groups. Post hoc it was decided to present antihypertensive medication in number of dose changes and medication changes rather than defined daily dose (which combines dose and number of medications) to show the specific type of changes more clearly.

A within trial economic analysis estimated cost per unit reduction in systolic BP, the primary outcome, using similar adjustments and multiple imputation for missing values as described in the statistical analysis section. National Health Service (NHS) resource use costs included those due to the intervention, as well as those due to changes in medication and use of other relevant NHS resources. The following items were costed [further details Appendix Table A6]:

* Antihypertensive drug (by dose along with any change in dose, and any new antihypertensive drug, all by number of days used) from NHS Drug Tariff 2018,30
* Primary care contact related to BP  (by type of staff (GP, practice nurse or health care assistant) and type of contact (face to face, telephone, email or text including clinical contacts from supporting the intervention),31
* Inpatient admission [by health resource use code], Outpatient visit, or Emergency Department attendance, related to hypertension. 32

Repeated (1000 times) bootstrapping was used to estimate the probability of the intervention being cost effective at different levels of willingness to pay per unit reduction in BP.

*Patient and Public Involvement*

Patient and public contributors were involved from the outline application stage (Samantha Hall and Mark Stafford-Watson). At full application stage they were joined by Keith Manship and Shelley Mason. Key aspects they contributed to included the development of the intervention, commenting on trial documentation, and taking part in the steering group meetings. Cathy Rice joined as a patient and public contributor during the trial and has remained significantly involved, including optimising many patient-facing documents and intervention training content, authorship of this paper and assisting in dissemination. We are immensely grateful for all of our public contributors’ input.

*Trial registration and approvals*

HOME BP is registered as ISRCTN13790648 <https://doi.org/10.1186/ISRCTN13790648>. The original registration was for the development and pilot phase which ran into the main trial without change. Other than an increase in sample size as documented above, no other substantive changes were made to the protocol following commencement of the trial. The trial registration did not specify which blood pressure measurements were to be used in the secondary outcomes, but these were clarified in the statistical analysis plan prior to data lock as both the mean of 2nd and 3rd measurements and mean of 2nd to 6th measurements. Post hoc analyses are stated. Ethical approval was granted from NRES Hampshire A, 19/03/2015, ref: 15/SC/0082 and research governance approval was gained from the relevant NHS bodies.

**Results**

Of 11399 invitation letters sent out, 1389 (12%) potential participants from 76 General Practices responded positively and were screened for eligibility. Those declining to take part could optionally give their reasons and responses were gained from 2426/10010 (24%). From those that gave a reason for declining, the mean age was 73 and the most commonly selected responses were: not having access to the internet (982, 41%), not wanting to be part of a research trial (617, 25%), not wanting to participate in an internet study (543, 22%) and not wanting to change medication (535, 22%)[Table A1].

Of the 1389 screened, 734 were ineligible and excluded [Figure 1]. A further 33 did not complete baseline measures and randomisation leaving 622 people who were randomised to the HOME BP intervention (305) or usual care (317) [proportions in line with the minimisation algorithm]. The main reasons for exclusion (denominator 734 in each case) were BP <140/90 mmHg (652, 89%), postural hypotension (31, 4%), not taking antihypertensive drugs (18, 2%), and BP too high (>180/110mmHg, 16, 2%). Fifteen people (2%) not fulfilling the inclusion criteria due to out of range BP were randomised in error (10 BP too high, 5 BP too low). After discussion with the sponsor and their GPs, it was decided to keep these individuals in the trial unless they wished to withdraw and they have been included in the intention to treat analysis.

The groups were well matched with a mean age of 66 years and mean baseline clinic BP of 151.7/85.3 mmHg and 151.7/86.4 mmHg (usual care and intervention respectively) [Table 1]. Most participants were White British (94%), just over half were male and time since diagnosis averaged around 11 years. The three most deprived deciles accounted for 63/622 (10%) with the three least deprived deciles accounting for 326/622 (52%).

After 12 months, primary end point data were available from 271 (89%) intervention participants and 282 (89%) controls [Figure 1]. Clinic blood pressure dropped from 151.7/86.4mmHg to 138.4/80.2mmHg in the intervention group after 12 months and from 151.7/85.3mmHg to 141.8/79.8mmHg in the usual care group giving a mean difference in systolic BP of -3.5 (-6.1 to -0.8)mmHg and of -0.5 (-1.9 to 0.9)mmHg diastolic. Results were similar in the complete case analysis and showed a smaller but still significant effect size when considering the mean of BP readings 2-6 [Table S2]. Similarly, consideringthe primary outcome data as repeated measures over the 12 months, controlling for baseline, there was still a significant difference between groups in favour of the HOME BP intervention: -2.9 (95% CI -4.8 to -1.1) for systolic BP and -0.6 (-1.6 to 0.5) for diastolic.

A post hoc analysis showed that BP dropped by at least 5 mmHg in 201/270 (74.4%) of intervention group participants compared with 170/282 (60.3%) of those receiving usual care: adjusted odds ratio for a 5mmHg drop: 1.9 (95% CI 1.3 to 2.8) [controlling for practice level clustering and stratification factors].

Exploratory sub-group analyses [Figure 2, Table S3] suggested that those in the older half of the age distribution (aged 67 or more) had a smaller effect size (-0.4 (95% CI -3.9 to 3.0) mmHg) compared to those in the younger half (-7.7 (-11.9 to -3.5) mmHg). Similarly, whilst the effect sizes in the standard and diabetes target groups ((-4.0 (-6.9 to -1.1) mmHg) and (-3.8 (-13.4 to 5.8) mmHg) respectively) were similar, those aged over 80 with a higher target of 145/85 mmHg showed little evidence of benefit (1.5 (-7.4 to 10.4) mmHg). Other sub-groups for sex, baseline BP, deprivation and previous history of self-monitoring were very similar between groups but it is possible that those with co-morbidities gained less from the intervention (systolic BP difference mmHg: no co-morbidity -5.1 (-8.4 to -1.8) vs one co-morbidity -0.6 (-5.8 to 4.5) vs multiple -2.0 (-11.1 to 7.2); controlled for age).

Information regarding possible adverse effects was derived from an extended version of the Illness Perceptions Questionnaire symptoms section and showed no differences between groups.29 [Table 3]. More participants in the intervention group reported weight loss (29/243 (11.9%) vs 57/251 (22.7%; p=0.002) but this was not borne out by the objective weight data (mean difference -0.36kg (-1.10 to 0.38) [Table A4]).

Those using the digital intervention were more likely to have their antihypertensive medication adjusted during the study: this included significantly more changes in dose (relative risk of a dose change, intervention vs usual care: 1.70 (95% CI 1.37 to 2.12)) and changes in medication (relative risk of any medication change, intervention vs usual care: 1.7 (95% CI 1.4 to 2.1)) [Table 4]. Self-reported adherence in both groups was high throughout (MARS questionnaire27 median baseline 24 (maximum possible 25, interquartile range 23 to 25) and at 12 months 24 (interquartile range 23 to25) in the control group and 24 (interquartile range 24 to 25) in the intervention group, p=0.97 for the difference).

Engagement with the digital intervention was high, with 281/305 (92%) of patients completing the two core training sessions, 268/305 (88%) completing a week of practice BP readings, and 243/305 (80%) completing at least three weeks of BP entries [Table A5]. Furthermore 214/305 (70%) were still monitoring in the last 3 of 12 months in the study. However, less than one third of patients chose to register on one of the optional lifestyle change modules. Of the sub-sample of 243 patients with a BMI over 25, 46 (19%) registered on the online weight loss programme.

The patient enablement score showed a reduction over time (ie increased enablement) in the self-management group which meant that by 12 months there was a statistically significant difference (0.4 (95% confidence intervals 0.2 to 0.5) between control and intervention [Table 5a].

After 12 months in a post hoc analysis, 112/234 (47%) of usual care patients reported monitoring their own BP at home at least once per month during the trial and of these 78/112 (70%) said that they took their readings to the GP. Of 56/79 (71%) GPs responding regarding usual care, 35/56 (63%) reported using home readings in their titration decisions.

The within trial analysis for quality of life (EQ5D-5L) showed no significant difference between the two groups [Table 5b]. The difference in mean cost per patient was £38 (95% confidence interval 27 to 47), which along with the decrease in systolic BP (see above) gave an incremental cost per mmHg BP reduction of £11, (6 to 29) [Table 5c]. Figure A1 shows the results of bootstrapping the incremental cost and BP gains which are summarised in the cost effectiveness acceptability (CEAC) curves [Figure A2] which show the intervention having high (90%) probability of being cost effective at willingness to pay above £20 per unit reduction. The probabilities of being cost-effective for the intervention against usual care were 87%, 93% and 97% at thresholds of £20, £30 and £50 respectively.

**Discussion**

*Main findings*

A digital intervention facilitating self-management of hypertension including self-monitoring, titration based on self-monitored BP, lifestyle advice and behavioural support for patients and professionals resulted in a significant reduction of systolic BP, achieved at very modest cost. This finding was robust in sensitivity analyses including complete case and also when the mean of 2-6th BP readings was used as the outcome. This was achieved through increased titration of antihypertensive medication with no increase in adverse effects, suggesting that the HOMEBP digital intervention reduces clinical inertia and leads to optimisation of therapy. The effect size observed from this intervention might be expected to result in a reduction of stroke by 10-15% and of coronary heart disease by 5-10%. Given the low marginal cost, such an effect could make a significant difference to the millions of people being treated for hypertension in the UK and worldwide.

*Strengths and weaknesses*

To our knowledge, this is the largest trial of a digital intervention in the field of hypertension and one of the longest in terms of follow-up. There was adequate power to detect a difference in BP, facilitated by over recruitment to ensure such an effect was not missed. By recruiting from a large number of general practices, we ensured generalisability in terms of professionals but there was some evidence of preferential recruitment of those with higher socio-economic status (SES) – although no evidence that SES mediated outcomes. Although white ethnicity (94%) appears over represented in comparison to the England and Wales population as a whole, this reflects differences in ethnicity by age: 95% of those aged 65-69 have white ethnicity.33

The mean age of those declining to take part was 73 and the commonest reason cited was lack of internet access, mirroring Ofcom’s latest data showing a reduction in computer access by SES as well as age.34 While online access is increasing year on year in all age groups and societal strata, suggesting this barrier may be reduced in the future, it will remain important to better understand barriers to uptake by those in more deprived areas.35 Investment in specific measures will be needed to enable the most vulnerable to engage with digital health initiatives and mitigate the risk that digital health contributes to a widening of health inequality, particularly as deprivation did not modify the effects of intervention.

The study used minimisation to reduce important baseline imbalance and this has the potential to reduce the effect of randomisation. However, we have not evidence that randomisation concealment was affected. Similarly imputation can influence results but here with high follow-up (89%) and similar complete case results this seems unlikely.

Whilst prescribing records suggested an increase in medication use, and the questionnaires suggested high rates of medication adherence, data were not available regarding filling of prescriptions nor validated adherence. The best measures of adherence use electronic systems which were without the resources available for this study and other work using such methods suggests that self-monitoring improves adherence.36 However, taken together, it appears likely that increased medication use drove lower blood pressure.

The effect size seen in this trial was slightly smaller than, but within the confidence intervals of, our trial assessing a similar paper based self-management intervention in a similar population and the upper confidence interval crosses our prespecified clinically important level of 5mmHg.9 As with our previous work, the results at 12 months showed greater divergence than at six months suggesting that the intervention might have ongoing impact. We know that just under half of patients in the control group reported self-monitoring BP during the trial and that these records were used by their GPs in making treatment decisions. This might be expected to reduce the effect size although self-monitoring outside of a more complex intervention such as HOME BP has similar efficacy to usual care.37 Engagement with the digital intervention was high (70% were still monitoring after 9 months) and equivalent to our previous work, but the home monitoring target was not as low as that in TASMINH2 (135 vs 130mmHg systolic) due to changes in national guidance and this may have reduced the effect size.9

The self-monitoring schedule used here was developed in our previous self-management work but is different to that recommended in subsequent international recommendations.9 10 38 39 However the requirement for 14 readings to be taken per week is in line with these recommendations and recording the second of two morning readings each day was originally chosen to simplify self-monitoring as morning readings are better correlated with stroke risk.40

Sub-group analysis suggested a differential effect by age which is important given that such interventions have been proposed as particularly relevant to the ageing population.4 Those in the younger half of the age distribution achieved twice the overall reduction in systolic BP and those in the older half gained no benefit. The effect did not seem to be due to the higher target for those people over 80. This has not previously been observed in other trials of self-monitoring but too few studies of digital interventions in hypertension have been published to assess whether it is a particular issue with the type of intervention.7 37 Furthermore, the ageing population also influences rising levels of multimorbidity, and so the suspicion that those with co-morbidities gained less from the intervention, also merits further investigation.41 42 Our process evaluation, which is published in detail elsewhere, has not found evidence of access or engagement problems, nor of explanatory characteristics in older people or their clinicians, but the results may have been confounded by the differential BP target for those over 80 (145mmHg).43 Given the inclusion criteria was 140mmHg systolic, older individuals would not have been prompted to change medication until their BP rose 10mmHg higher than the younger group. Furthermore, there was some evidence of increased uptake of physical activity in the younger group which might partly explain the findings [to be reported elsewhere].

*Relationship to the literature*

The observed increase in medication changes in the intervention group suggests that the HOME BP intervention led to reduced clinical inertia. This phenomenon has been shown to result in reduced action by clinicians in the face of evidence in this case of raised BP.44 45 Our previous self-monitoring/management work has also resulted in increased use of antihypertensive medication but the data captured here are more detailed than has been previously possible.9 10 46 The medication titration algorithm used gave clinicians the opportunity to develop individual treatment plans for their patients in line with national and international guidance.38 39

In tandem with reduced clinical inertia, self-management in the context of HOME BP improved patient enablement and this may also have mediated the effect. Behavioural aspects of the intervention were however less successful and only taken up by a minority of participants.

The major advantage of a digital intervention is the ability to be deployed at a small marginal cost and the within trial cost-effectiveness analysis supports this assumption. All training for the intervention was delivered online meaning implementation can also be cost effective. This is reflected in the cost of £11/mmHg reduction which compares well with £25.66 in the HITS trial in Scotland using a propriety telemonitoring system.47 One would expect this blood pressure reduction to lead to longer term impact on cardiovascular events. However, in order to properly assess this impact on cost-effectiveness in the longer term, additional modelling taking into account these effects with extrapolation to a longer time horizon is needed and we are in the process of such work. Previous self-monitoring interventions have proven to be cost-effective in the long term within standard parameters.11 12

Interestingly, the patient enablement instrument showed that patients were enabled to be more active in controlling their hypertension. Many chose to do this through medication only, whereas a minority chose to include behavioural or lifestyle modifications as part of management of blood pressure. The small proportions choosing behavioural support may seem counterintuitive, but as has been pointed out before, enabled patients do not always make the decisions that clinicians or public health physicians would like them to.48

Trials of self-monitoring blood pressure appear to work best with relatively intensive co-interventions (such as telemonitoring, educational advice or pharmacist input) and the current study fits with that literature.37 It is not possible in the context of the current trial to distinguish the relative importance of the different parts of the digital intervention. There have been relatively few studies combining self-monitoring with a digitally delivered co-intervention and none have shown a significant effect in an adequately powered trial over a year.7 The HOME BP trial provides evidence that a digitally delivered intervention for hypertension can be successful over 12 months with engagement from both clinicians and patients.

*Clinical implications*

Surveys suggest that most GPs are drawing on self-monitoring in their hypertension management and that at least one third of patients with hypertension are self-monitoring.49 50 Over and above the clinical benefit from the HOME BP digital intervention, the ability to manage BP remotely at scale has never been so important as during the current crisis.13 Therefore implementation of a cost-effective digital intervention which leads to lower BP would now seem to be appropriate. However such implementation will not be possible without some consideration of the factors influencing successful translation into daily practice.51 Some of these factors were successfully addressed in the development of HOME BP, which used extensive user feedback to ensure that both health professionals and patients had a shared, positive understanding of the aims and likely benefits of HOME BP and perceived it as easy and not onerous to use.16-19 Achieving clinician “buy in” is more likely to occur once evidence from trials such as this are incorporated into routine clinical practice guidelines. A key barrier to achieving such “buy in” and professional usability is likely to be the lack of integration of the HOME BP digital intervention into electronic health records. A system to allow deployment of proven digital interventions within the NHS and other health systems is now urgently needed. Examples of this are beginning to emerge, for example, GPs in Scotland can now get home BP readings sent to their Docman electronic record system (PCTI Solutions, UK) although the underlying telemonitoring is SMS-based hence lacking much of the fuctionality included in the HOME BP digital intervention.52 Further work might evaluate such implementation to ensure that predicted benefits are achieved and to allow further development of the intervention, particularly for older people and those from more disadvantaged backgrounds.

*Conclusions*

Overall, this digital intervention for the management of hypertension, utilising self-monitored BP and behavioural techniques, led to significantly lower BP than usual care using clinic BP. The HOME BP digital intervention, combined with self-monitoring, has the potential to provide cost-effective support for both patients and professionals in lowering BP. The next step is an implementation strategy to realise such benefits for the whole population.

**Statement of contributorship**

LY, together with PL and RJM, conceived and led the study, providing detailed supervision of all aspects throughout. JR, EM, CM, SM, FM, PS, AG and BW provided senior expertise and leadership, contributing to designing the study, securing funding and supervising the conduct of the study. BS carried out the statistical analysis and JR and SZ carried out the economic analysis. KM, KB, JZ and RB developed the intervention, supported its implementation, contributed to designing the study and carried out the process evaluation. JK led trial implementation along with EO and JA, with advice from JN, and CR was the key public contributor. All authors commented on drafts of this paper. RM will act as guarantor and affirms that the manuscript is an honest, accurate, transparent and full account of the HOME BP trial.

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**Competing Interests**

Omron provided the monitors used in the HOME BP study at reduced cost. All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) and declare: support from NIHR for the submitted work”); no financial relationships with any organisations that might have an interest in the submitted work in the previous three years apart from RJM has received BP monitors for research from Omron and is collaborating with them on development of a telemonitoring system as part of the NIHR Oxford and Thames Valley Applied Research Consortium. He receives occasional travel and accommodation reimbursement for talks. He does not personally receive any honoraria or consultancy payments.; no other relationships or activities that could appear to have influenced the submitted work.

**Ethical Approval**

Ethical approval was granted from NRES Hampshire A, 19/03/2015, ref: 15/SC/0082 and research governance approval was gained from the relevant NHS bodies.

**Data sharing**

The HOME BP trial is a member of the BP SMART consortium of randomised controlled trials of self-monitoring in hypertension and data will be included in future meta-analyses. Anonymised trial data from HOMEBP are available on reasonable request via the corresponding author.

**Transparency**

The lead author (RJM, the manuscript’s guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

**Dissemination Plans**

A lay summary of the results of the study will be shared with participating patients and their practices.

**Provenance and peer review**:

Provenance and peer review: Not commissioned; externally peer reviewed.

**Open Access**

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**Table 1:** Baseline characteristics

|  |  |  |
| --- | --- | --- |
|  | **Usual Care\***  **N=317** | **Intervention\***  **N = 305** |
| Age | 66.7 (10.2) | 65.2 (10.3) |
| Systolic blood pressure | 151.6 (11.1) | 151.7 (11.8) |
| Diastolic blood pressure | 85.3 (9.9) | 86.4 (9.6) |
| Female | 143/318 (45.0%) | 145/305 (47.5%) |
| Ethnicity |  |  |
| White | 299/317 (94.3%) | 285/304 (93.8%) |
| Black African | 3/317 (1.0%) | 5/304 (1.6%) |
| Black Carribbean | 1/317 (0.3%) | 0/304 (0.0%) |
| Indian | 0/317 (0.0%) | 3/304 (1.0%) |
| Pakistani | 3/317 (1.0%) | 1/304 (0.3%) |
| Other | 11/317 (3.5%) | 10/304 (3.3%) |
| Index of Multiple Deprivation |  |  |
| 1-3 (most deprived) | 27/318 (8.5%) | 36/304 (11.8%) |
| 4-7 | 125/318 (39.3%) | 108/304 (35.5%) |
| 8-10 (least deprived) | 166/318 (52.2%) | 160/304 (52.6%) |
| Marital status |  |  |
| Married/cohabiting | 244/318 (76.7%) | 240/302 (79.5%) |
| Single/divorced/widowed | 74/318 (23.3%) | 62/302 (20.5%) |
| Duration of hypertension | 10.9 (9.4) | 11.3 (9.8) |
| Past medical history |  |  |
| Diabetes  Of which: Type I | 32/291 (11.0%)  1/291 (0.3%) | 24/278 (8.6%)  1/278 (0.4%) |
| Chronic kidney disease | 26/291 (8.9%) | 22/279 (7.9%) |
| Stroke | 3/292 (1.0%) | 2/278 (0.7%) |
| Myocardial infarction | 4/291 (1.4%) | 7/278 (2.5%) |
| Coronary artery bypass graft, antioplasty or stent | 3/292 (1.0%) | 10/278 (3.6%) |
| Other comorbid condition | 67/288 (23.2%) | 70/273 (25.6%) |
| BMI | 29.6 (5.4) | 30.2 (6.6) |
| Median baseline number of antihypertensive mediations | 1  (interquartile range 1 to 2) | 1  (interquartile range 1 to 2) |

Number (%) or mean (SD) unless stated otherwise

**Table 2** Mean blood pressure at baseline, 6 months and 12 months using   
measurements 2-3

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Imputed (100 imputations) | | | Complete cases | |
|  | Baseline+ | 6 months+ | 12 months+ | Adjusted\* difference at 6 months | Adjusted\* difference at 12 months | Adjusted\* difference at 6 months | | Adjusted\* difference at 12 months |
| Systolic blood pressure$ |  |  |  |  |  |  | |  |
| Usual Care | 151.6 (11.1) | 140.9 (16.0) | 141.8 (16.8) |  |  |  | |  |
| Intervention | 151.7 (11.8) | 138.7 (17.0) | 138.4 (16.0) | -2.3  (-4.9 to 0.3) | -3.4  (-6.1 to -0.8) | -2.3  (-4.8 to 0.3) | | -3.5  (-6.2 to -0.9) |
| Diastolic blood pressure |  |  |  |  |  |  | |  |
| Usual Care | 85.3 (9.9) | 80.2 (10.3) | 79.8 (10.1) |  |  |  | |  |
| Intervention | 86.4 (9.6) | 79.9 (9.7) | 80.2 (10.1) | -1.0  (-2.4 to 0.4) | -0.51  (-1.89 to 0.87) | -1.0  (-2.4 to 0.3) | | -0.5  (-1.8 to 0.9) |

+ Mean (standard deviation)

\*Mean difference (95% confidence interval) controlling for baseline blood pressure, age, sex and BP target, with a random effect for practice

$ Systolic blood pressure at 12 months was the primary outcome

**Table 3** Participants who reported a hypertension medication-specific symptom or adverse effect at final follow-up.

|  |  |  |  |
| --- | --- | --- | --- |
| Reported symptom | Control | Intervention | p-value for difference |
| Stiff joints | 140/252 (55.6%) | 138/243 (56.8%) | 0.92 |
| Pain | 118/252 (46.8%) | 116/244 (47.5%) | 0.40 |
| Sleep difficulties | 129/252 (51.2%) | 111/243 (45.7%) | 0.54 |
| Fatigue | 109/252 (43.3%) | 112/242 (46.3%) | 0.15 |
| Cough | 94/251 (37.5%) | 85/246 (34.6%) | 0.75 |
| Loss of strength | 62/251 (24.7%) | 75/244 (30.7%) | 0.19 |
| Sore eyes | 62/251 (24.7%) | 71/244 (29.1%) | 0.86 |
| Pins and needles | 69/250 (27.6%) | 71/246 (28.9%) | 0.92 |
| Loss of libido | 59/249 (23.7%) | 63/238 (26.5%) | 0.55 |
| Headaches | 72/251 (28.7%) | 64/245 (26.1%) | 0.96 |
| Dry mouth | 64/250 (25.6%) | 63/244 (25.8%) | 0.95 |
| Breathlessness | 50/251 (19.9%) | 57/244 (23.4%) | 0.55 |
| Sore Throat | 44/250 (17.6%) | 51/243 (21.0%) | 0.20 |
| Fast heart rate | 40/251 (15.9%) | 41/243 (16.9%) | 0.52 |
| Mood change | 33/250 (13.2%) | 36/243 (14.8%) | 0.90 |
| Wheeziness | 32/251 (12.8%) | 32/245 (13.1%) | 0.77 |
| Nausea | 26/251 (10.4%) | 22/242 (9.1%) | 0.51 |
| Rash | 16/249 (6.4%) | 16/243 (6.6%) | 0.77 |
| Other | 43/240 (17.9%) | 35/229 (15.3%) | 0.23 |
|  |  |  |  |
| **Hypertension specific symptoms** |  |  |  |
| Swelling of legs/ankles | 59/251 (23.5%) | 65/247 (26.3%) | 0.26 |
| Feeling flushed | 40/250 (16.0%) | 47/243 (19.3%) | 0.23 |
| Upset stomach | 45/252 (17.9%) | 50/242 (20.7%) | 0.18 |
| Dizziness | 47/251 (18.7%) | 40/245 (16.3%) | 0.64 |
| Impotence | 37/248 (14.9%) | 36/234 (15.4%) | 0.87 |

**Table 4** Number of medication and dose changes

|  |  |  |  |
| --- | --- | --- | --- |
|  | Median  (interquartile range) | Mean (standard deviation) | Relative risk\* (95% confidence interval) |
| **Number of any type of medication change during the study period$** |  |  |  |
| Usual care(n=293) | 0 (0 to 1) | 0.9 (1.4) | 1.00 |
| Intervention (n=283) | 1 (0 to 2) | 1.5 (1.7) | 1.7  (1.4 to 2.1) |
|  |  |  |  |
| **Number of dose changes** |  |  |  |
| Usual care(n=293) | 0 (0 to 0) | 0.4 (0.7) | 1.00 |
| Intervention (n=283) | 0 (0 to 1) | 0.7 (1.1) | 2.0  (1.5 to 2.7) |
|  |  |  |  |
| **Number of medication changes** |  |  |  |
| Usual care (n=293) | 0 (0 to 1) | 0.5 (1.0) | 1.00 |
| Intervention (n=283) | 0 (0 to 1) | 0.8 (1.1) | 1.5  (1.1 to 1.9) |

\*the data follow a negative binomial distribution and the analysis controls for the same factors as the primary analysis, as well as the baseline number of medications

$ Either increase in dose or additional medication.

**Table 5** Patient Enablement, Quality of life and Costs

1. Modified Patient Enablement Instrument (PEI)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Group** | **Number with measures at both timepoints** | **Mean baseline PEI (standard deviation)** | **Mean 12m PEI (standard deviation)** | **Difference in PEI at 12 months (95% confidence intervals)\*** |
| Usual care | 246 | 3.0 (1.0) | 3.1 (1.1) | REF |
| Intervention | 252 | 3.1 (1.1) | 2.8 (1.0) | -0.4 (-0.5 to -0.2) |

\*model as per primary outcome but also controlling for baseline PEI

The modified patient enablement instrument is scored from 1-7 with lower scores implying higher enablement.26

1. EQ5D-5L

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  |  |  | **Imputed  (100 imputations)** | | **Complete cases** | |
|  | **Baseline** | **6 months** | **12 months** | **Difference in AUC at 6 months** | **Difference in AUC at 12 months** | **Difference in AUC at 6 months** | **Difference in AUC at 12 months** |
| Usual care | 0.90 (0.13) | 0.92 (0.10) | 0.90 (0.12) |  |  |  |  |
| Intervention | 0.89 (0.14) | 0.89 (0.15) | 0.90 (0.14) | -0.007  (-0.02 to 0.002) | 0.002  (-0.007 to 0.01) | -0.006  (-0.02 to 0.003) | 0.002  (-0.008 to 0.01) |

*Mean (standard deviation) or difference (95% confidence interval);* AUC: area under curve

1. Costs, systolic blood pressure reduction from the baseline, and incremental cost per blood pressure reduction using bootstrap methods based on imputed blood pressure data (mean, 95% confidence intervals)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Group** | **Cost (£s)** | **Incremental cost (£s)** | **Systolic Blood pressure reduction mmHg** | **Incremental systolic blood pressure reduction** | **ICER**  **(blood pressure reduction)** |
| Usual care | 92  (85 to 99) |  | 9.8  (8.2 to 11.5) |  |  |
| Intervention | 130  (122 to 137) | 38  (27 to 47) | 13.2  (11.7 to 14.8) | 3.5  (1.3 to 5.6) | 11  (6 to 29) |

**<Figure 1 here>**

**<Figure 2 here>**

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