SUMMARY

Background: While evidence from randomised controlled trials shows that telemonitoring for hypertension is associated with improved blood pressure (BP) control, health care systems have been slow to implement it, partly because of inadequate integration with existing clinical practices and electronic records. Neither is it clear if trial findings will be replicated in routine clinical practice at scale. We aimed to explore the feasibility and impact of implementing an integrated telemonitoring system for hypertension into routine primary care.

Methods and findings: This was a quasi-experimental implementation study with embedded qualitative process evaluation set in primary care in Lothian, Scotland. We described the overall uptake of telemonitoring and in a sub-group of representative practices, used routinely acquired data for a records based controlled before and after study; plus qualitative data from staff and patient interviews and practice observation. The main outcome measures were intervention uptake, change in BP, change in clinician appointment use, and participants’ views on features that facilitated or impeded uptake of the intervention.

Seventy-two primary care practices enrolled 3,200 patients with established hypertension. In an evaluation subgroup of eight practices (905 patients of whom 427 (47%) were female with median age of 64 (IQR 56 - 70, range 22 – 89), and median SIMD 2012 decile of 8 (IQR 6 – 10), mean systolic BP fell by 6.55mmHg (SD 15.17) and mean diastolic BP by 4.23mmHg (SD 8.68). Compared with the previous year, participating patients made 19% fewer face-to-face appointments compared
with 11% fewer in patients with hypertension who were not telemonitoring. Total consultation time for participants fell by 15.4 mins (SD 68.4) compared with 5.5 mins (SD 84.4) in non-telemonitored patients. The convenience of remote collection of BP readings and integrating these readings into routine clinical care was crucial to the success of the implementation. Limitations include the fact that practices and patient participants were self-selected, younger and more affluent than non-participating patients and the possibility that regression to the mean may have contributed to the reduction in BP. Routinely acquired data is limited in terms of completeness and accuracy.

Conclusions: Telemonitoring for hypertension can be implemented into routine primary care at scale with little impact on clinician workload and resulting in similar reductions in BP to large UK trials. Integrating the telemonitoring readings into routine data handling routines was crucial to the success of this initiative.

Keywords: Telemonitoring; hypertension; implementation research

Why was this study done?

- Although uncontrolled hypertension is the biggest remediable cause of stroke and myocardial infarction, and anti-hypertensive medications are effective, many patients have uncontrolled BP.
- Despite strong evidence that telemonitoring encourages medication use and is effective at lowering BP, clinicians have been slow to adopt it, in part due to poor integration with routine clinical processes.
- We wanted to see if an integrated telemonitoring system would be taken up by primary care clinicians at scale, what impact this would have on their workload and if changes in BP matched those of RCTs.
What did the researchers do and find?

- Based on our previous research with clinicians on the desirable attributes of a telemonitoring system, NHS Lothian developed an integrated system which provided regular summaries of patient home-monitored BP readings to their GP practice which were delivered alongside routine laboratory results.

- We observed the roll-out of this system, interviewing patients and clinicians about their attitudes to the innovations to determine what worked and did not in terms increasing uptake.

- In a group of eight practices we collected routinely acquired data on blood pressure, clinician appointments and other resource use and compared these to the previous year. Resource use was compared with patients in these practices with high BP who did not use telemonitoring.

- We found that the intervention was popular in many but not all practices. Patients who used the system took up fewer appointments in the year of the intervention compared with the previous year than those who did not. BP fell in the intervention group in line with findings of UK randomised controlled trials.

What do these findings mean?

- The findings suggest that introducing telemonitoring to routine practice at scale is feasible.

- Although not definitive, they provide some reassurance that the intervention did not increase practice workload and that in routine practice the improvements in BP control were similar to those in controlled trials.

- However, the people who took part were not entirely typical of practice populations as a whole, being younger and slightly more affluent.

- The findings support plans to introduce telemonitoring more generally, but within an evaluative framework.
INTRODUCTION

Hypertension is common among people over the age of fifty and an important risk factor for cardiovascular disease [1]. Although effective management greatly reduces the risk of cardiovascular events, blood pressure (BP) remains uncontrolled in many people [2]. This is in part due to poor adherence to medication [3], but also reluctance on the part of clinicians to intensify therapy [4] and patients to accept intensified therapy [5].

In the United Kingdom (UK), hypertension is managed in primary care mainly by practice nurses assisted by health care assistants with specific training in BP monitoring, supported by general practitioners (GPs). In Scotland (population 5.45 million), 1.2 million appointments were taken up every year solely for hypertension checks in 2018 [6] despite evidence that home-monitoring is a better predictor of long-term outcomes than office measurement [7]. Under the Scottish National Health Service all primary care attendances and medications are free at the point of contact, paid for from general taxation. However, primary care is currently under considerable stress with falling numbers of GPs [8] and rising workload [9] as populations age and the prevalence of hypertension increases. Technology has been promoted as a strategy for managing this workload [10, 11].

A number of trials have demonstrated that patient self-monitoring has a small, but statistically significant effect on improving BP control [12]. Telemonitoring, however, which engages clinicians in reviewing readings taken by patients and submitted over the Internet or Short
Message Service (SMS), results in much larger clinically significant reductions in BP [13] and is cost-effective [14, 15]. Telemonitoring is associated with an intensification of medication [16] and qualitative research has shown that this is because multiple, persistently raised BP readings convince both clinicians and patients that medication intensification and improved adherence is required thus overcoming ‘therapeutic inertia’ [5]. Supported self-monitoring enables patients to act on physiological measures rather than on (perceived) symptoms such as headache or fatigue [17].

Why then, given consistent findings from randomised controlled trials (RCTs), has telemonitoring not been more widely adopted? Implementing new models of care at scale is challenging [18, 19], particularly in the context of clinical teams already working at full stretch. Telehealth trials have tended to recruit relatively few, often highly selected individuals who have been followed-up for relatively short periods leaving unanswered questions about the day-to-day practicality of managing large numbers of patients [20]. In addition, the adoption, effectiveness and impact on resources of delivering BP telemonitoring as a routine approach to care is unknown and may differ from the experience in trials.

Following our earlier randomised controlled trial of telemonitoring for uncontrolled hypertension [16], we sought to investigate the acceptability and impact of introducing long-term telemonitoring across NHS Lothian in Southeast Scotland for people with previously diagnosed hypertension.
METHODS

This study is reported in accordance with the Standards for Reporting Implementation Studies (StaRI) [21]. We describe the deployment and uptake of telemonitoring generally and then the evaluation of the impact of the implementation in eight practices chosen to represent a range of size, deprivation and earlier and later adopter of the technology.

Setting

The study was carried out in Lothian, Scotland (population 858k). This region of Scotland, which contains Edinburgh the capital of Scotland, is mainly urban with a mix of small towns, suburban, inner city, and some rural areas. There are a range of levels of affluence and deprivation.

The Scale-Up BP telemonitoring system and deployment.

Logic model

The logic model for the Scale-Up BP deployment is illustrated in Figure 1, with primary (implementation and health) outcomes and process outcomes mapped to the mechanism by which the Scale-Up BP implementation strategy and telemonitoring was anticipated to work.
Figure 1. This logic pathway illustrates how the Scale-Up BP implementation strategy was expected to work. The primary outcomes are in white font on a blue (implementation outcomes) or green (health outcomes) backgrounds. The distinction is made between the evidence-based intervention (BP tele-monitoring) and the Scale-Up BP implementation strategies used to implement BP tele-monitoring in routine practice.

The telemonitoring intervention implemented is described in detail in the online supplement (Appendix S1 and figure S1). Participating people with hypertension were provided with an electronic, oscillometric sphygmomanometer and shown how to submit BP readings via a low-cost third-party text-based telemonitoring system (Florence) [22] using their own mobile phone. These readings were stored in a central server and made available to practices via an internet link. However, previous research had shown that a major barrier to adoption was the need for clinicians to log-on to third party web-sites during busy clinics [20] and so a novel element [23] was developed which automatically extracted patient-generated data from the third-party website. This displayed a mean BP and summarised BP values in graphical and tabular format, (Appendix S1, figure S2) and dispatched these summaries, at intervals chosen by the clinician, through the routinely used Primary Care data management system, Docman [24]. This obviated the need for third-party log-ons and, critically, systematically presented the telemonitoring results in manageable numbers on a daily basis with relatively infrequent, but data-rich reports integrated into the electronic medical record and seen alongside routine laboratory results and hospital communications. Between reports, patients were informed by automated text responses if submitted readings were low, normal, high or very high and advised to follow
a written action plan in respect of contacting their practice either routinely or urgently as appropriate.

The Scale-Up BP implementation project was launched in June 2015 and continues. The Scottish Government’s Technology Enabled Care (TEC) fund [25] financed the third-party telemonitoring service, the development of the software to link it with Primary Care systems using Docman, supported facilitators to visit/train practices and purchased sphygmomanometers for loan to patients.

**Recruitment of practices**

All 126 Lothian practices were invited to participate via a weekly newsletter. Practices expressing interest were followed up with information visits and training if they participated.

**The Scale-Up BP implementation strategy**

The implementation strategy was informed by barriers and facilitators identified in previous research as important to clinicians [20, 26] and utilised elements of ‘COM-B’ behaviour change [27] and diffusion of innovation theories [28]. Table S1 of the supplementary appendix lists how these barriers were addressed. In essence this comprised of: motivating clinicians and service planners by demonstrating how an evidence-based BP telemonitoring service could improve outcomes and potentially save time; enhancing capability by providing initial training and (importantly) retraining and ongoing support as required; and providing opportunity by supporting recruitment drives within individual practices. Local practitioner ‘champions’ were recruited to be early adopters in the expectation that they would demonstrate and promote the intervention to colleagues [29]. Practices were encouraged to adapt the system to suit their routines and priorities with flexibility in terms of the initial patient groups targeted (some focusing on uncontrolled BP). Clinicians were continuously involved in the development of the
implementation strategy, trialling different recruitment methods and in managing
telemonitoring data. Learning from practices was shared in regular newsletters.

Outcomes of interest

Our primary implementation outcome was the number of participating practices and the
overall number of patients recruited. In addition, in a group of eight practices, chosen to
represent a range of socio-economic status, list size, city centre/small town, and
fast/slow patient recruitment, we measured patient engagement and adherence,
resource and medication use, BP change over time, and gauged clinician and patient
acceptability of the implementation.

These practices agreed for data on BP, anti-hypertensive medication prescriptions,
practice workload (as recorded in the appointment system) for all patients with
hypertension including those not being managed by the Scale-Up BP system to be
extracted from their electronic health record (EHR), linked to data from the
telemonitoring system, de-identified and transferred to the local NHS safe haven (a
secure analysis server which does not permit any data to be taken away).
This allowed comparison of resource use between participating and non-participating
patients. Primary Care stored data were collected and transferred by a data extraction
service (Albasoft) through software already resident on the practice computers. Time to
action of very high (>160mmHg) and very low (<90 mmHg) average systolic BP readings
was obtained from manual searching of Docman reports and practice records. Change in
BP over time was derived from telemonitored data from Scale-Up BP patients only.

As the purpose of the study was primarily to determine uptake of the intervention a
formal power calculation was not deemed appropriate.

Assessment of attrition
Patients were considered to have discontinued monitoring if they did not record any readings for seven months during the observation period. This period was chosen because we did not want to exclude patients with good BP control some of whom were asked to submit readings only every six months.

A logistic mixed regression analysis was performed on the discontinuation outcome to help us identify the type and characteristics of patients who had discontinued. The variables: female gender, second systolic BP, Scottish Index of Multiple Deprivation (SIMD) ≥ 5 (more deprived), and Age were included in the model, and adjusting for GP practice as a random effect. The continuous variables systolic BP and age were initially fitted as continuous (linear), but this assumption was subsequently relaxed in sensitivity analysis whereby we used flexible natural B-spline functions to model the relationship between these variables and the probability of discontinuation. The modelled relationships were then displayed graphically in line plots.

**Practice workload and resource use**

We collected data on (i) the total number of appointments, (ii) total number of face-to-face appointments, (iii) total consultation time, and (iv) total consultation time in the surgery.

The practice appointment system was used to identify all interactions including face-to-face and planned telephone consultations, home visits or administration activities (for example, prescribing a requested repeat prescription). Face-to-face consultations could be reliably identified as they had different arrival and start times. We determined time spent in activities recorded in the appointment system in total and in face-to-face activities for all people with hypertension in the eight practices and could compare those taking part in the intervention with those who were not.

There was no automated extraction method that could determine time spent in
consultations which were not recorded in the appointment system such as ad-hoc phone calls or record checking.

Analysis of resource use outcomes was conducted by computing totals/averages across all patients and comparing before-and-after, and separately performing a patient-level analysis by computing sum totals/averages within patients. We only included patients with a full year of data before and after the start of telemonitoring. Regarding the consultation time analysis, the first analysis weighted patients with a greater number of appointments more heavily than in the second patient-level analysis, which is appropriate when simply trying to give an overall impression of resource use burden. On the other hand, the second analysis takes a within-patient approach to ascertain if consultation times have changed at the patient level, after properly taking into account clustering by patient. Both sets of analyses are complementary in allowing us to provide a full and clear presentation of the resource use data.

The telemonitored patients’ appointments data were compared against comparator patients (all patients with a diagnosis of hypertension, who did not use the telemonitoring system), from the same eight evaluation practices. For the comparator group we could not choose the start of telemonitoring as the “anchor point” to define the before and after groups, we therefore used a randomly chosen date for the anchor point within a date range consistent with the telemonitoring group (between October 2015 and June 2016). Outlier consultation durations (>30 minutes: three times the length of a typical primary consultation in the UK) were excluded from all analyses involving consultation time as these are very likely to be erroneous and so it was not appropriate to retain them in the analyses. These long consultation times are almost certainly because clinicians fail to close the electronic record, for example before taking breaks or other tasks. It would be very unlikely that a consultation related to BP management would be so long; including these would
lead to an overestimate of resource use.

Linear mixed effects models were then fitted to the resource outcomes to compare telemonitored patients with the comparator group, adjusting for female gender, SIMD ≥ 5 (less deprived), second surgery measured systolic BP (after Sept 2015), age (in years), and GP practice as a random effect. As for the attrition analysis, natural B- spline functions were used to model the effects of age and systolic BP on outcome.

**Change in BP over six-months and proportion controlled**

The difference between the second BP reading and the last BP reading occurring 6-12 months after the second reading was calculated for each patient (Second – Last). Because of the known disparity between home and office BP readings we used the second telemonitored reading as the first was sometimes taken in the GP practice as a demonstration of the system to the patient. Only patients with a full year’s follow-up were included. Summary statistics (mean, median, standard deviation, lower quartile, upper quartile, minimum, maximum) were calculated based on these BP differences, overall and stratified by age, gender, SIMD and starting systolic BP.

To assess the proportion of patients whose BP was uncontrolled as defined by National Institute of Health and Clinical Excellence Guidelines [31] (home systolic BP>135mmg) we categorised the BP data according to level of control of BP, and compared the proportions with uncontrolled BP at baseline with 6-12 months later. Patients were only included in this analysis if they had complete data at baseline and 6-12 months.

**Assessment of medication prescribed**

For each patient, we calculated the total number of anti-hypertensive medication prescriptions in the year before the patient first started telemonitoring and in the year after. To avoid bias, we only included patients with a full year of data before and after the start of telemonitoring. Summary statistics were then computed overall and stratified by
age, gender, SIMD and initial systolic BP. SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA) was used to analyse the data.

Mean defined daily doses (DDD) were calculated for the 6 months before and after date of first monitoring for all patients with at least 6 months follow-up, based on WHO DDD index values [32] and compared using a paired t-test (analysis undertaken in R version 3.5.3).

**Qualitative exploration of patient and professional perceptions**

In the eight practices, we undertook semi-structured face-to-face interviews with patients, GPs, practice nurses and health care assistants, to explore perceptions of the telemonitoring intervention in terms of ease of use, organisational adoption and adaptation, barriers, facilitators and potential improvements to the implementation of Scale-Up BP. See Appendix S2 for details of methodology.

**RESULTS**

**Progress of the implementation.**

Practice and patient recruitment.

The number of participating practices throughout Lothian grew steadily following the launch and by July 2019 (45 months after the start of the project) 75/126 practices in Lothian had participated. Patient recruitment accelerated as new practices were trained reaching a total of 3200 patients by July 2019 (see supplementary figure S3). Practices differed greatly in terms of the numbers of patients they recruited (range 6-400). Some required several training sessions before commencing recruitment. The most successful recruiting practices systematically invited all their patients with hypertension to register. Two practices had evening group meetings. Others, with highly motivated clinical staff, were very successful at recruiting patients during routine attendances. In some practices clinicians were selective about to whom they offered the intervention. For example, initially, when they had less experience with the system, they tended to offer it selectively
to more able patients. Some practices focused initially on uncomplicated patients with controlled BP while others chose less well controlled patients.

Patient population

In the eight evaluation practices, of the 905 patients signed up to use the telemonitoring system and providing BP data, 427 were female (47%) with median age of 64 (IQR 56 - 70, range 22 – 89), and median SIMD 2012 decile of 8 (IQR 6 – 10). The comparator group were older (median age 71, IQR 62-79, range 20-90), with a slightly higher percentage of females (54%) and slightly less affluent on average (median SIMD of 7). First systolic blood pressure reading was similar between groups (see Table 1). The median number of patients using the telemonitoring system per practice was 80 (IQR 44 to 153), compared to 450 (IQR 332 to 599) controls. Apart from being slightly more affluent, generally the practices were representative of practices in Lothian (see Table 2).

Patient engagement

We explored patient engagement during the period 2nd Sept 2015 to 7th Jan 2018 in the eight evaluation practices. Of 905 patients signed up to use the telemonitoring system and providing BP data, a median of 28 (IQR 14 to 76) BP readings were submitted in total per patient, although many of these patients were only recently recruited and had varying lengths of follow-up. Excluding patients with less than one year follow-up, the remaining 430 patients submitted a median of 42 readings in one year (IQR 22 to 94), with 359/430 patients (83%) submitting over 20 readings and 97/430 patients (23%) submitting over 100 readings (see supplementary figure S4).

Patient attrition

Of the 655 patients who had been registered for more than seven months, 49 (7%)
stopped texting readings. Gender, age or SIMD did not significantly predict discontinuing (see appendix Table S2). However, patients with higher systolic blood pressure were more likely on average to discontinue (odds ratio 1.03, 95% CI 1.01 to 1.05). Figures S7 and S8 show how the predicted probability of drop-out varies with systolic blood pressure and age when these variables are fitted using flexible spline functions and are not constrained to be linear in the statistical model.

Change in resource use over time recorded in the appointment system

There were 1260 appointments in total (671 face-to-face) in the year before the start of telemonitoring compared to 1158 appointments in total (569 face-to-face) in the year after. This corresponded to an observed 8% reduction in total appointments, and 15% reduction in the number of face-to-face appointments.

There was an observed increase in appointments just prior to the start of telemonitoring probably due to patients attending for training to measure BP and text results which might potentially exaggerate potential reductions in consultation numbers (see supplementary figure S5). In further analysis, in comparing changes in resource use with a comparator group of non-participating patients we therefore excluded consultations within two weeks of the anchor point which for telemonitoring patients may have involved appointments to set up the system. We also excluded 7% of consultations for which the appointment times were not recorded and an additional 3% of consultations which were recorded as being over 30 minutes in duration.

Both comparator group and telemonitoring group showed falls in numbers of all appointments and face-to-face appointments. Falls in the number of appointments were notably more pronounced in females, relatively more deprived (SIMD<5), and people whose BP was controlled in the telemonitored group than in the comparator group (see supplementary table S3).
Table 3 shows the number of consultations and consultation times per patient and comparator group before and after the intervention. A total of 118 telemonitoring patients were included who recorded at least one consultation before and/or after the intervention. As above, we excluded consultations within two weeks of the anchor point.

These 118 patients had a median age of 64 (IQR 54 to 69), 46 (39%) female, median SIMD of 9 (IQR 7 to 10, relatively less deprived), and mean first surgery systolic BP value of 139.4 (SD 16.0). The patient characteristics of the comparator group were as shown in Table 1. Therefore, the difference in demographics between telemonitoring and control were more pronounced than for the overall cohort, except average initial systolic BP values which were very similar between groups.

Mixed effects models were fitted to the outcomes to compare telemonitored patients with the comparator group, adjusting for SIMD category (<5 or 5+), age, gender, or initial systolic BP (see supplementary table S4). Time spent in all appointments in the year was significantly reduced in the telemonitoring group (adjusted mean difference 16.1 minutes, 95% CI 0.1 to 32.1 minutes, p=0.048). Although the reduction in time spent in face-to-face appointments did not achieve statistical significance, the observed reduction was clinically relevant (12.7 minutes (95% CI -0.5 to 25.9 minutes, p=0.059). Note that confidence intervals were wide due to the relatively small sample size in the telemonitoring group. There was no significant difference in total number of appointments (face-to-face or overall) in the adjusted analysis.

**Change in BP over time**

During the study period, there were 399 patients in the eight evaluation practices who had two telemonitored blood pressures at least six months apart, and with at least one year of follow-up. This group had similar first surgery systolic blood pressure reading compared to other hypertension patients in the practices who had not been telemonitored (who also had at least two readings six months apart). However, there was a lower percentage of
females in the telemonitoring group

compared to the comparator group, patients were younger on average, and with a higher
median SIMD decile (median 9 versus 7) indicating a more affluent population (see table
4).

The median difference between the second telemonitored systolic BP and the last was 6
mmHg (IQR -3 to 15) and for diastolic BP 4 mmHg (IQR -1 to 10). Falls in BP were greater
for those whose BP was initially uncontrolled (people whose systolic BP was >135mmHg
had a median fall in BP of 13mmHg (IQR 6 to 23) whereas people whose BP was <135 had
no change in the median BP (IQR -7 to 7). This reduction in systolic BP was consistent across
age, gender and deprivation (see supplementary table S5), and was reflected in the
proportion achieving control (see table 5).

Figure 2 shows how mean BP changed over time for 185 people who recorded at least one
blood pressure reading per month for 12 months after the start of telemonitoring. The
relative variability in the mean between groups and over time is represented in the plot by
vertical error bars (+/- 1 standard error). A similar plot based on the full n=399 is shown in
the supplementary file (Figure S6), which shows a very similar relationship over time. (Note
that the data is not completely paired in Figure S6: some patients did not record monthly
readings continuously and so the points are not joined together.)
Clinician responsiveness to high BP readings.

We searched the Docman reports in the eight practices for instances where BP control was poor and would normally result in management changes. We found 44 instances of average systolic BP >160mmHg and three instances of an average systolic <90mmHg in Docman reports.

The median number of days between first systolic BP >160mmHg or <90mmHg appearing in the medical record (transcribed from the Docman report) to clinical review and action (or not) was 13 (range 0-91 days). Actions recorded in the Primary Care records occurring in response to these reports are summarised in supplementary table S6.
Change in number of anti-hypertensive medications prescribed

For 622 patients taking part in Scale-Up BP for one year we calculated average defined daily doses (DDDs) of BP lowering medications in the 45 days before they started telemonitoring and, to allow for discovery of a raised BP and time to respond to it, for a similar period 4-6 months after they started telemonitoring. DDDs rose from 2.08 to 2.35 between those times, a rise of 12% (See appendix table S7). Additionally, there was a small increase in the total number of prescriptions issued for anti-hypertensive medications to patients over the whole year (1.06 SD 4.77 additional prescriptions). Prescription numbers increased more in people whose baseline BP was > 135mmHg and who were from more deprived areas. Similar changes were found in patients with raised BP not taking part in Scale-Up BP (see supplementary tables S8a and b).

Perceptions of the implementation

Details of the process evaluation including observation of the implementation process and interviews with clinicians and patients can be found in Appendix S3 and supplementary tables S9 and S10. In summary clinicians found that getting regular reports integrated with their usual data-handling practices was particularly helpful. Continued support from the implementation team, the involvement of local champions and patient enthusiasm for the service were all instrumental in building confidence in the process. Initially starting patients on the system was seen as time consuming but this improved with time and was perceived as balanced by subsequent time saving. Practice teams adapted aspects of the intervention, particularly data handling, to their own routines.

DISCUSSION

Summary of findings

This study shows that a telemonitoring system for BP monitoring using software to integrate it with normal Primary Care work patterns can be implemented at scale. BP
control improved in line with that found in RCTs of telemonitoring, probably mediated by
an intensification in therapy [16, 33-36]. This new model of care was associated with an
observed reduction in the number of face-to-face appointments and consulting time. The
well-recognised barriers to implementation of new technologies (lack of confidence in
technology, workload fears, lack of time to learn and introduce new things, and scepticism
that the implementation will improve patient care or efficiency) were overcome through
engaging frontline clinicians in the development of the system, particularly local
champions, and strong continuous support from a facilitator team. While it was relatively
straightforward to persuade practices of the likely benefits of the intervention and to
undertake training, they varied in translating that training into action. Some practices
required several training sessions before they started regular recruitment while some did
not get started usually citing lack of time. Others, however, recruited large numbers and
their success persuaded others to follow them. Patients liked the system and relatively
few discontinued, however, it is concerning that people with less well controlled BP were
over-represented in those that did and this requires further investigation.

**Strengths and limitations**

This intervention was implemented in typical primary care practices by clinical staff for
patients for routine care purposes rather than a research setting. Integration with practice
data management routines and the ability to adapt the intervention encouraged uptake
by practices and apart from initial training and remote technical support needed little
additional support. The use of routine data sources means that any evaluation can be
continued in future to determine the longer-term effects of the intervention.

The Scale-Up BP patients in the eight evaluation practices were self-selected or chosen
by clinical staff, were slightly less deprived and younger than others in their practices with
hypertension and may have been more able in terms of self-management or more
motivated. Nonetheless, older and more deprived participating patients benefitted
equally or more from the intervention than others. A component of the large reduction in blood pressure over time for patients who were initially uncontrolled (15mmHg) could be considered as regression to the mean, but this was a largely unselected group in terms of BP control and the reduction in overall mean is unlikely therefore to be a totally random effect. However, the purpose of our study was not to prove effectiveness (as this has already been established) [13] but to show that telemonitoring can be implemented at scale. It is reassuring that the fall in mean systolic BP was similar to or exceeded those of the intervention groups in UK RCTs with similar patient characteristics and which showed significant reductions in BP compared to a control group [16, 33-36] (see supplementary table S11).

Patients were texting in their results and this could have been a source of bias. However, our previous work [37] showed that end-digit and target preference by patients, if it occurred, was relatively trivial and considerably less than is found in office measurements [38]. Although overall contact time and face-to-face appointments fell both in absolute terms and in comparison with people with hypertension who were not participating, time spent dealing with abnormal reports in an ad hoc way that did not involve the appointment system was harder to capture. However, practices with large numbers of patients on the systems believed that it was saving them time. Additionally we did not capture the time spent by clinicians in the evening recruitment meeting. However, these lasted around 90 minutes involved two clinicians and typically around 70 patients were recruited so were very time efficient.

The sample size in relation to the number of telemonitoring patients with valid resource use data was quite small (N=118) in comparison to the N=430 patients signed up to telemonitoring with a full year of follow-up, perhaps reflecting difficulties in capturing resource use data. Caution is therefore needed when seeking to generalize the
descriptive data to a wider population. Our use of a control group was important in this situation so that we had a valid comparator whose data was collected under the same conditions.

**Discussion in relation to published literature**

Previous studies of telemonitoring have been in the context of RCTs with practices contributing relatively small numbers of patients that are relatively easy to manage. In this study some practices were recruiting hundreds of patients. Systematic reviews of telemonitoring of hypertension suggest that it is effective [15] in reducing BP, but that the effectiveness depends on the intensity of the intervention [13]. The most effective systems were similar to Scale-Up BP. Methods of assessing change in BP vary from study to study, but those using research nurse clinic measurements demonstrated similar or greater falls to Scale-Up BP for patients whose starting BP was uncontrolled in UK trials.

There have been no direct trials exploring the impact of telemonitoring on cardiovascular outcomes, but based on previous of anti-hypertensive agents, BP reductions of the magnitude achieved in this study, probably through intensification of anti-hypertensive therapy, if sustained, 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 [39].

**Implications for policy, practice and future research**

Telemonitoring of hypertension has been shown to be cost-effective [14, 15]. Sphygmomanometers have become less expensive in recent years and in Lothian will in future be provided by the Health Board. Low cost telemonitoring systems have become available potentially lowering costs further. We believe that the integrated system we tested will improve efficiency. The system has recently been adopted by the Scottish Government with plans to roll it out across the country. Further work is underway to determine the optimum strategies to enrol patients in the system and to get them to adhere to it. Further integration with the Primary Care medical record and making the
reports available to secondary care is planned, as is the development of an app based solution and improved asynchronous communication with patients. An economic evaluation will be the subject of a future paper.

CONCLUSION

Scale-Up BP has demonstrated that improvements in BP control similar to those found in RCTs of telemonitoring in hypertension can be achieved when implemented in routine practice and at scale and that this is accomplished with no increase in workload. The strategy of integrating the telemonitoring system with current data handling routines was critical in the adoption and is a model for managing other long-term conditions. Based on the findings from this implementation study, we conclude that Scale-up BP is ready for routine use across NHS Scotland and possibly also other parts of the UK.

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Contributors: BM, JH, HP, PP and MP initiated the study, VH collected and analysed the qualitative data aided by JH, BM and VH wrote the first and subsequent drafts of the paper aided by ASh. RP conducted the statistical analyses and takes responsibility for the integrity of the data and accuracy of the data analyses. AS t and HGP contributed to the analysis of medication use. All authors have approved the final version of this manuscript submitted for publication. BM and RP are guarantors.
The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Competing interests: Competing interests: BM and MP are supported by the Scottish Government in relation to their plans to scale up telemonitoring for hypertension across Scotland. BM and AS are in receipt of grants from the British Heart Foundation and Stroke Association in relation to a study exploring the use of telemonitoring of BP in stroke survivors. BM and HP have been in receipt of funding in the last 3 years from the European Union EIT Digital fund to develop an app for BP management. All other authors declare no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: This study was approved by East of England - Cambridge South Research Ethics Committee 16/EE/0058.
References


6. ISD Top 10 conditions seen in General Practice. doi: https://www.isdscotland.org/Health-Topics/General-Practice/GP-Consultations/.


Table 1: Patient characteristics in the telemonitoring and comparator groups

<table>
<thead>
<tr>
<th></th>
<th>Telemonitoring (n=905)</th>
<th>Comparator group (n=9,061)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female Gender</td>
<td>427/905 (47%)</td>
<td>4934/9061 (54%)</td>
</tr>
<tr>
<td>Age of patients in 2015</td>
<td>Median 64, (IQR 56 to 70, min 22, max 89, n=905)</td>
<td>Median 69, (IQR 60 to 79, min 19, max 90, n=8610)</td>
</tr>
<tr>
<td>SIMD 2012 decile</td>
<td>Median 8, (IQR 6 to 10, min 2, max 10 n=888)</td>
<td>Median 7 (IQR 5 to 10, min 1, max 10, n=8957)</td>
</tr>
<tr>
<td>First systolic blood pressure reading in the surgery (after Sept 2015)</td>
<td>Median 140, (IQR 130 to 150, min 90, max 200, n=877)</td>
<td>Median 138 (IQR 129 to 149, min 71, max 240, n=7694)</td>
</tr>
</tbody>
</table>
Table 2: Comparison of descriptive statistics for evaluation practices compared to non-evaluation practices in Lothian

<table>
<thead>
<tr>
<th></th>
<th>Non-evaluation practices in NHS Lothian (n=117)</th>
<th>Evaluation practices (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage Female</td>
<td>50.7% (50.0% to 51.5%)</td>
<td>51.0% (50.7 to 51.5%)</td>
</tr>
<tr>
<td>Percentage 25-44 years old</td>
<td>28.5% (25.3% to 36.1%)</td>
<td>27.1% (25.6% to 36.7%)</td>
</tr>
<tr>
<td>Percentage 45-64 years old</td>
<td>27.0% (24.2% to 28.6%)</td>
<td>27.6% (18.6% to 29.2%)</td>
</tr>
<tr>
<td>Percentage 65+ years old</td>
<td>16.0% (12.7% to 19.5%)</td>
<td>17.3% (10.6% to 20.6%)</td>
</tr>
<tr>
<td>Percentage SIMD &lt;5 (more deprived)</td>
<td>31.5% (12.2% to 50.7%)</td>
<td>22.9% (12.1% to 38.3%)</td>
</tr>
<tr>
<td>Modal Urban/Rural Classification</td>
<td>Large Urban Areas 68 (59%)</td>
<td>Large Urban Areas 5 (62%)</td>
</tr>
<tr>
<td></td>
<td>Other Urban Areas 23 (20%)</td>
<td>Other Urban Areas 2 (25%)</td>
</tr>
<tr>
<td></td>
<td>Accessible Small Towns 12 (10%)</td>
<td>Accessible Small Towns 1</td>
</tr>
<tr>
<td></td>
<td>Accessible Rural 8 (7%)</td>
<td>Accessible Rural 0 (0%)</td>
</tr>
<tr>
<td></td>
<td>Remote Small towns 5 (4%)</td>
<td>Remote Small towns 0 (0%)</td>
</tr>
</tbody>
</table>

Results are expressed as Median (Interquartile range), except modal urban/rural classification which is presented as frequency (percentage)
Table 3 Change in total and face-to-face appointment numbers and consultation length in people with hypertension participating and not participating in telemonitoring

<table>
<thead>
<tr>
<th>Variable</th>
<th>Telemonitoring (N=118)</th>
<th>Comparator (N=9061)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of appointment activities per patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>6.5</td>
<td>4</td>
</tr>
<tr>
<td>After</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Reduction (Before – After)</td>
<td>0</td>
<td>-3</td>
</tr>
<tr>
<td>Number of face-to-face consultations per patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>After</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Reduction (Before – After)</td>
<td>1</td>
<td>-2</td>
</tr>
<tr>
<td>Consultation time per patient all appointments (minutes)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>67.5</td>
<td>30</td>
</tr>
<tr>
<td>After</td>
<td>49.5</td>
<td>25</td>
</tr>
<tr>
<td>Reduction (Before – After)</td>
<td>14</td>
<td>-25</td>
</tr>
<tr>
<td>Face-to-face consultation time per patient (minutes)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>63</td>
<td>27</td>
</tr>
<tr>
<td>After</td>
<td>41</td>
<td>19</td>
</tr>
<tr>
<td>Reduction (Before – After)</td>
<td>15</td>
<td>-18</td>
</tr>
</tbody>
</table>
Table 4: Patient characteristics in the telemonitoring and control groups who had two telemonitored blood pressures at least six months apart, and with at least one year of follow-up

<table>
<thead>
<tr>
<th></th>
<th>Telemonitoring (n=399*)</th>
<th>Comparator group (n=3,484*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female gender</td>
<td>182/399 (46%)</td>
<td>1845/3484 (53%)</td>
</tr>
<tr>
<td>Age</td>
<td>Median 64 (IQR 56 to 70, min 29, max 89)</td>
<td>Median 71 (IQR 62 to 79, min 20, max 90)</td>
</tr>
<tr>
<td>SIMD 2012 decile</td>
<td>Median 9, IQR 6 to 10, min 2, max 10</td>
<td>Median 7, IQR 5 to 10, min 1, max 10</td>
</tr>
<tr>
<td>First systolic blood pressure reading in the surgery (after Sept 2015)</td>
<td>Median 138, IQR 128 to 150, min 100, max 188</td>
<td>Median 138, IQR 130 to 150, min 71, max 240</td>
</tr>
</tbody>
</table>

*SIMD decile and systolic blood pressure was based on n=392 in the telemonitoring arm. SIMD decile was based on n=3,436 in the comparator group

Table 5 Proportion with uncontrolled BP at baseline and follow-up

<table>
<thead>
<tr>
<th></th>
<th>Second telemonitored reading</th>
<th>Telemonitored reading 6 - 12 months later</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tele SBP ≥ 135</td>
<td>190/399 (48%)</td>
<td>94/399 (24%)</td>
</tr>
<tr>
<td>Tele SBP ≥ 140+</td>
<td>138/399 (35%)</td>
<td>51/399 (13%)</td>
</tr>
<tr>
<td>Tele SBP ≥ 145+</td>
<td>92/399 (23%)</td>
<td>37/399 (9%)</td>
</tr>
<tr>
<td>Tele SBP ≥ 150+</td>
<td>62/399 (16%)</td>
<td>20/399 (5%)</td>
</tr>
<tr>
<td>Tele DBP ≥ 85+</td>
<td>138/399 (35%)</td>
<td>66/399 (17%)</td>
</tr>
<tr>
<td>Tele DBP ≥ 90+</td>
<td>90/399 (23%)</td>
<td>23/399 (6%)</td>
</tr>
</tbody>
</table>