



RESEARCH ARTICLE

REVIEWED Ambulatory blood pressure monitoring using telemedicine: proof-of-concept cohort and failure modes and effects analyses [version 3; peer review: 2 approved]

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Abstract

Background: The COVID-19 pandemic has accelerated adoption of remote consulting in healthcare. Despite opportunities posed by telemedicine, most hypertension services in Europe have suspended ambulatory blood pressure monitoring (ABPM).

Methods: We examined the process and performance of remotely delivered ABPM using two methodologies: firstly, a Failure Modes and Effects Analysis (FMEA) and secondly, a quantitative analysis comparing ABPM data from a subgroup of 65 participants of the Screening for Hypertension in the Inpatient Environment (SHINE) diagnostic accuracy study. The FMEA was performed over seven sessions from February to March 2021, with a multidisciplinary team comprising a patient representative, a research coordinator with technical expertise and four research clinicians.

Results: The FMEA identified a single high-risk step in the remote ABPM process. This was cleaning of monitoring equipment in the context of the COVID-19 pandemic, unrelated to the remote setting. A total of 14 participants were scheduled for face-to-face ABPM appointments, before the UK March 2020 COVID-19 lockdown; 62 were scheduled for remote ABPM appointments since emergence of the COVID-19 pandemic between November 2020 and August 2021. A total of 65 (88%) participants completed ABPMs; all obtained sufficient successful measurements for interpretation. For the 10 participants who completed face-to-face ABPM, there were 402 attempted ABPM

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measurements and 361 (89%) were successful. For the 55 participants who completed remote ABPM, there were 2516 attempted measurements and 2214 (88%) were successful. There was no significant difference in the mean per-participant error rate between face-to-face (0.100, SD 0.009) and remote (0.143, SD 0.132) cohorts (95% CI for the difference -0.125 to 0.045 and two-tailed P-value 0.353).

Conclusions: We have demonstrated that ABPM can be safely and appropriately provided in the community remotely and without face-to-face contact, using video technology for remote fitting appointments, alongside courier services for delivery of equipment to participants.

Keywords

Hypertension, Telemedicine, Screening, Cardiovascular Disease, Blood Pressure Monitoring, Ambulatory Blood Pressure Monitoring

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REVISED Amendments from Version 2

In this latest revision we have responded to reviewer comments requesting further information regarding:

1. ABPM procedures including the scheduling, resources and costs; we have clarified when, after hospital discharge ABPM took place for the two (face-to-face and remote) cohorts and the time and financial requirements of ABPM for both cohorts.
2. Our assessment of the risk of surface contamination of ABPM monitors in the context of COVID-19, and current literature regarding the severity of this risk at the time informed our assessment of the severity of this risk.
3. Participant characteristics of the two cohorts.

Any further responses from the reviewers can be found at the end of the article

Introduction

The World Health Organization states “A good health system delivers quality services to all people, when and where they need them”¹. In 2020, the outbreak of the COVID-19 pandemic accelerated a move to remote consultations in UK healthcare². Whilst this ensured a number of services continued to be accessed by a proportion of the population when and where they needed them, this was not universal. Some services, such as ambulatory blood pressure monitoring (ABPM), became inaccessible to patients and participants in clinical and research settings³.

ABPM was first introduced to regular clinical use in the late 1980s⁴. Since then, 24-hour ABPM has become the gold standard method for assessing for hypertension in the UK and Europe⁵. However, the European Society of Hypertension Coronavirus Disease 19 Task Force reported that 57% of hypertension excellence centres in Europe ceased delivering 24-hour ABPM during the COVID-19 pandemic³. Where ABPM has continued, provision is often limited to selected clinical scenarios such as pregnancy or following a hypertensive emergency³. The major barrier to service continuation has been the face-to-face contact required between healthcare professional and patient. Standard practice traditionally requires face-to-face appointments to complete safety screening checks, fit the monitor, and remove it 24 hours later for data download with interpretation⁶. Whilst home blood pressure monitoring has been utilised for diagnostic and monitoring purposes during the COVID-19 pandemic, it is inferior to ABPM in that it does not provide information on a person's blood pressure during activities of daily living, sleep, or 24-hour variability in blood pressure⁷. Blood pressure measurements obtained from ABPM are also a better predictor of hypertension-mediated organ disease⁸. As the effects of the COVID-19 pandemic extend with time, new ways of delivering services, including ABPM, must be considered and evaluated to continue delivering gold-standard diagnostics, maintain standards of care, and offer resilient healthcare services accessible to patients when and where they are needed.

In 2019, we began recruiting NHS patients to the Screening for Hypertension in the INpatient Environment (SHINE) study at the Oxford University Hospitals NHS Foundation Trust,

UK⁹. In March 2020, all clinical research that was not essential to delivery of care or concerning COVID-19 was suspended. Upon resumption of recruitment in September 2020, we had amended the SHINE study protocol⁹ to minimise face-to-face contact between participants and clinical researchers, reducing risk of transmission of COVID-19. We designed a procedure for delivering ABPM remotely to participants, whilst still adhering to the British and Irish Hypertension Society Standard Operating Procedure (SOP) for the performance of ABPM⁶ and their resources for clinical services providing ABPM¹⁰.

We identified Failure Modes and Effects Analysis (FMEA) as an appropriate methodological approach for a detailed analysis of the potential risks and possibilities for failure that might arise from adapting ABPM to a remote service. FMEA provides a framework for the systematic, in-depth evaluation of a specific process, to identify where and how the process may fail and assess the potential effect of failures¹¹. Once potential failure points are identified, preventive measures are prioritised according to the likelihood of the failure, risks and effects¹². A recent systematic review highlighted the broad and increasing use of FMEA in healthcare, to evaluate a range of services including drug administration and delivery, blood transfusion, treatment of sepsis and surgical procedures¹³. The authors concluded that FMEA can proactively reduce errors in medicine and improve quality of care, particularly in the context of increasing sophistication and complexity of medical interventions, equipment and related processes¹³.

The objective of this study was to examine the process and performance of ABPM when delivered remotely, using FMEA and a quantitative analysis that compared ambulatory blood pressure data from participants receiving remote ABPM appointments, versus ambulatory blood pressure data from participants receiving face-to-face ABPM appointments.

Methods

Study registration

The SHINE Study protocol was registered with the ISCTRN Registry (Identification number ISRCTN80586284, date 20 August 2019).

Study design and setting

Firstly, we evaluated the process of remote ABPM, its potential risks, failure points and the impacts of these using FMEA. A multi-disciplinary FMEA panel was assembled comprising a patient and public representative, a research coordinator with technical expertise, a General Practitioner, a physiotherapist and two clinical research nurses. An initial training and introductory session in FMEA was conducted for the panel, followed by six weekly sessions between February and March 2021. During these six sessions we systematically worked through the process of an episode of ABPM, using an FMEA framework. First, the process of interest was identified (remote performance of ABPM), followed by the main steps (e.g. scheduling the 24-hour ABPM episode with the participant) and then sub-steps involved in the process (e.g. phoning the participant, confirming eligibility, agreeing a date for monitoring, configuring the monitor and scheduling courier delivery). These steps and sub-steps were identified using the participant and

researcher guides that were developed for the remote delivery of ABPM. These study guides were developed with reference to the British and Irish Hypertension Society's (BIHS) Standard Operating Procedure for ABPM⁶, the BIHS Clinic Checklist and Educational Resource Video for ABPM¹⁰, and the UK NICE Guidelines for diagnosing and managing hypertension⁵. The team identified the potential failure modes (ways in which a failure could occur), failure causes (what might lead to a failure occurring) and the failure effects (consequences) for each sub-step. Scores were then assigned to each of the failure modes as described further under the 'Measures' sub-heading below.

Secondly, we evaluated the performance of remote ABPM by analysing the proportion of successful 24-hour ABPM monitoring episodes prior to the onset of the UK COVID-19 epidemic (before which time the procedure was delivered by face-to-face appointments) and since the UK COVID-19 epidemic (since which time the procedure has been delivered using telemedicine). We also investigated the rate of successful ABPM measurements, per 24-hour period in the face-to-face versus remote ABPM groups.

Participants

Participants included in the analysis of the *performance* of remote ABPM were a subgroup of those enrolled on the SHINE diagnostic accuracy study who had, following discharge from hospital (index admission), worn a 24-hour blood pressure monitor in accordance with the SHINE study protocol⁹. All participants gave written informed consent for their participation in the study. The subgroup consisted of two cohorts, the first cohort being all participants who attended fitting and removal ABPM appointments face-to-face prior to the UK coronavirus epidemic in 2020, the second cohort being all participants who undertook fitting and removal of the ABPM through remote appointments using telemedicine, from November 2020 to August 2021. The full inclusion and exclusion criteria for the SHINE study have been published elsewhere⁹, but in short, included adult patients aged 18–80, admitted to Oxford University Hospitals NHS Foundation Trust, UK for a minimum of 24-hours and no previous or existing diagnosis of, or prescription for, hypertension or atrial fibrillation.

Intervention

The intervention evaluated in this study was the remote performance of 24-hour ABPM, using a courier service to deliver and retrieve the monitoring equipment, and telemedicine to complete fitting and removal appointments with participants. The comparator was 24-hour ABPM with traditional face-to-face consulting at a primary care health centre to complete fitting and removal of the ABPM. Participants in both the face-to-face and remote ABPM groups were provided with a Mobil-o-graph NG 24hr BP Monitor System (IEM Healthcare, Stolberg, Germany), serviced and calibrated according to the manufacturer's recommendations.

Both the face-to-face and remote 24-hour ABPM processes were based on the ABPM process outlined in the BIHS SOP for Ambulatory Blood Pressure Monitoring⁶, with close attention to maintaining standard safety checks for atrial fibrillation,

other contraindications for ABPM and severely elevated blood pressure. An overview of the process for performing remote ABPM is presented in Figure 1, and details regarding the safety checks are presented in Table 1. The process involved initial screening for eligibility and suitability at enrolment during the participant's index hospital admission as per the SHINE protocol⁹. Once participants were enrolled, their upper arms were measured to assign the correct-sized ABPM cuff to be dispatched with the ABPM for the fitting appointment. After discharge from hospital, participants were contacted by telephone to arrange the ABPM-fitting appointment, and to collect details about their sleep and wake patterns for tailored configuration of monitor settings. All ABPM fitting appointments were scheduled for between 1 and 6 months post-hospital discharge. For the remote cohort, the validated and calibrated monitor was then couriered to the participant, along with an AliveCor KardiaMobile ECG device (AliveCor Inc, Mountain View, CA), and a tablet computer with a SIM card installed for 4G internet connectivity. The tablet computer had the secure video-calling Nye Health App (Nye Health Ltd, Oxford, UK) and the ECG partner application Kardia pre-installed (both applications downloaded from the Google Play app store <https://play.google.com/store/apps> and regularly updated to the latest application versions throughout the study period). Video appointments for ABPM fittings were completed using the Nye Health App. During the appointment, the AliveCor KardiaMobile ECG device recorded data to the Kardia app on the tablet computer, with the app generating automated real-time ECG interpretation. This enabled clinical research staff to screen for atrial fibrillation, that would exclude participants from being eligible to proceed with ABPM. Following the ECG recording, the participant was walked through the checking of their blood pressure using the device in both arms, before being shown how to fit the monitor to the most appropriate arm and proceeding with the 24-hour monitoring. At least twenty-four hours following the fitting appointment, the participant was phoned to confirm removal of the monitor and complete removal and return procedures.

Measures

Failure modes and effects analysis. The failure modes assigned to each of the sub-steps identified were assigned three initial scores on a scale of 1–10, based on likelihood of failure (1 being very unlikely and 10 being very likely), likelihood the failure would go undetected (1 being very unlikely and 10 being very likely) and severity of the effects (1 being minor or only a slight annoyance with 10 being very severe and causing harm to a patient, researcher or the study). A key for the scoring is shown in Table 2. These three scores were then multiplied by one another to calculate risk priority numbers (RPN). Those sub-steps with the highest RPN were deemed to be priority steps for identifying remedial actions to be proactively addressed to prevent, detect and mitigate failure of the remote ABPM process.

Analysis of the performance of remote ambulatory blood pressure monitoring. We planned *a priori* to assess the proportion of successful 24-hour ABPM episodes and ABPM measurements within that 24-hour period, in each participant cohort. A 24-hour ABPM episode was deemed successful and suitable for diagnostic interpretation if ≥ 14 measurements were

Enrolment during hospital admission

- Screen for eligibility including ECG to screen for atrial fibrillation
- Upper arm measured for ABPM cuff fitting
- Contact details taken for ABPM booking post discharge.

ABPM booking call

- Further screen for eligibility; any change in circumstances
- Configure ABPM according to participant's usual sleep and wake times
- Clean and package equipment ready for dispatch
- Arrange courier delivery of ABPM.

Remote ABPM fitting appointment

- Further screen for eligibility including ECG to screen for atrial fibrillation using AliveCor KardiaMobile device and enclosed tablet computer
- Walk participant through appropriate fitting and placement of cuff
- If clinically appropriate, measure BP in both arms and review measurements for severely elevated BP or marked difference in BP between both arms
- Fit cuff to chosen arm, paying attention to dominant arm, or between arm differences
- Complete study questionnaires and orientate participant to ABPM diary
- Familiarise participant with their ABPM guide and instructions for the 24 hour period e.g. turning monitor off whilst driving, not to get device wet
- Arrange time for removal call.

24-hour monitoring period

- Participant wears monitor continuously for 24 hours
- Monitor to be removed for driving and washing
- Participant to avoid vigorous activity while wearing the monitor.

ABPM removal and return

- Guide participant to remove monitor and replace in packaging, affixing return courier label and closing and securing parcel
- Remind participant of courier collection details
- Upon receipt of equipment clean all equipment before data download
- Download data from BP device and tablet computer
- Charge and store monitoring equipment.

Figure 1. Summary of the remote ambulatory blood pressure monitoring (ABPM) process.

obtained during waking hours, as defined by the UK NICE Guidelines for the diagnosis and management of hypertension⁵. We also assessed the number of attempted BP measurements per participant during the period of monitor wear, and the number of failed BP measurements per participant during the same period (denoted by a time-stamped error message on the ABPM report; the list of error messages returned is detailed in Table 3). From these we calculated the error rate for each participant as the number of failed BP measurements divided by the number of attempted BP measurements. The mean error rate was then calculated for the face-to-face ABPM cohort and the remote ABPM cohort.

The sample size for the face-to-face ABPM cohort was not within our control, owing to the short time during which we were able to recruit and follow up participants prior to suspension of research activity during the first wave of the UK COVID-19 epidemic. Whilst the sample size was not powered to assess for a statistically significant difference, we performed a t-test (GraphPad Prism, San Diego, USA) to investigate for a significant difference between the mean error rate for the two participant cohorts.

Ethical review and participant consent

Ethical approval for the SHINE study has been provided by the National Health Service Health Research Authority South Central—Oxford B Research Ethics Committee (19/SC/0026).

All participants in this study gave written consent for their involvement in the study, and for the publication of non-identifiable reports of results and scientific manuscripts, available in the public domain.



Results

Failure modes and effects analysis

Identifying key steps in the process and potential failure modes.

The FMEA panel identified four key stages in the process for remote ABPM which were the remote fitting appointment, the 24-hour monitoring period, the remote removal appointment and equipment return and data download. Each stage was divided into a total of 14 steps and then 42 sub-steps. Potential failure modes, causes and effects were identified for each of these 42 sub-steps. Several of the sub-steps were

Table 1. Safety checks performed during remote configuration, fitting and removal of a 24-hour ABPM.

| Safety check  | Screen for severely elevated blood pressure | | | Screen for contraindications to ABPM on one or more limbs | | Screen for arrhythmias | | | |
|--|---|---|--|---|---|------------------------|----------|---|---|
| | Included | Procedure | Definition | Included | Procedure | Definition | Included | Procedure | Definition |
| Timepoint in study  | | | | | | | | | |
| At enrolment | Yes | <ul style="list-style-type: none">Average 24-hour blood pressure measured by screening algorithmandEnrolment blood pressure performed by clinical research nurse. | <ul style="list-style-type: none">Average 24-hour BP ≥ 180mmHg systolic or ≥ 120 mmHg diastolicEnrolment blood pressure ≥ 180 mmHg systolic or ≥ 120mmHg diastolic | Yes | <ul style="list-style-type: none">Review of hospital medical records and, if available, primary care summary care record.Verbal screening with participant | | Yes | <ul style="list-style-type: none">6-lead ECG using AliveCor KardiaMobile 6L ECG device with automated screening for AF and instant reportClinician review of ECG and automated report for accuracy | <ul style="list-style-type: none">Automated report showing atrial fibrillationAbsence of p waves and irregularly irregular QRS complex on clinician review |
| ABPM booking call | No | <ul style="list-style-type: none">n/a | <ul style="list-style-type: none">n/a | Yes | <ul style="list-style-type: none">Verbal screening with participant | | No | <ul style="list-style-type: none">n/a | |
| ABPM fitting appointment | Yes | <ul style="list-style-type: none">Blood pressure checked in both arms in accordance with British and Irish Hypertension Society SOP for ABPM fitting. | <ul style="list-style-type: none">Blood pressure measurement ≥ 180mmHg systolic or ≥ 110 mmHg diastolic*Between arm BP difference ≥ 20mmHg systolic or ≥ 10mmHg diastolic | Yes | <ul style="list-style-type: none">Verbal screening with participant | | Yes | <ul style="list-style-type: none">Single-lead ECG using AliveCor KardiaMobile ECG device with automated screening for AF and instant report | <ul style="list-style-type: none">Automated report showing atrial fibrillation |
| ABPM data download | Yes | <ul style="list-style-type: none">Review of mean daytime blood pressure | <ul style="list-style-type: none">Mean daytime blood pressure ≥ 160 mmHg systolic or ≥ 105 mmHg diastolic | n/a | n/a | | Yes | <ul style="list-style-type: none">Clinician review of ECG and automated report for accuracy | <ul style="list-style-type: none">Absence of p waves and irregularly irregular QRS complex |

*Denotes screen for significant inter-arm blood pressure difference.

n/a = not applicable, SOP = Standard Operating Procedure, AF = Atrial fibrillation, ECG = electrocardiogram

Table 2. Scoring key for the failure modes associated with each sub-step in the ABPM process^{11,14}.

| Rating | Likelihood of occurrence | Likelihood of detection | Severity of risk |
|--------|-------------------------------|---|---|
| 1 | Remote – no known recurrence | Certain – error will always be detected | Slight annoyance only – no injury to participant or research staff and no impact on study |
| 2 | Rare – yearly | Very high probability of detection | Slight danger – but with no injury to participant or research staff or slight impact on study |
| 3, 4 | Occasional – quarterly | High probability of detection | Low to moderate danger – very minor or no injury to the participant or research staff and minimal impact on study |
| 5, 6 | Moderately frequent – monthly | Moderate chance of detection | Moderate danger – minor or no injury to participant or research staff, moderate impact on study |
| 7, 8 | Very frequent – weekly | Low chance of detection | Dangerous – minor or moderate injury to the participant or research staff and/or marked impact on study. |
| 9 | Inevitable | Remote chance of detection | Very dangerous – may result in major injury to participant or research staff and/or major impact on study. |
| 10 | Certain – daily | No chance of detection | Extremely dangerous – may cause death to participant. |

Table 3. Error messages analysed during 24-hour ambulatory blood pressure monitoring.

| Measurement comments contributing to calculation of error rate in ABPM episodes | Measurement comments not regarded erroneous and therefore not included in calculation of error rate in ABPM episodes |
|---|--|
| Pressure increased during deflation. Movement? | Start of a manual measurement |
| Difference between the systolic and diastolic value is too small | Device was switched off |
| Movement artefact | Event button |
| The heart rate was outside the defined range | The day/night button was not pressed during the set time frame |
| Exceeded measurement limit | Restarted during a 24h profile |
| Measurement aborted by the user | |
| Difference between the systolic and diastolic value is too small | |
| Can not determine the blood pressure | |
| [Druck zu groß.] (translates to pressure too great) | |
| Cuff inflation was too fast. Is there a kink? | |
| Undefined error | |
| Pressure cannot be increased fast enough. Leakage? | |

potentially at risk of multiple failure modes but all of which would result in the same effects, and the same likelihood of detection and risk severity. We therefore assigned the scores for likelihood of occurrence, likelihood of detection and severity of risk to the groups of failure modes that belonged to each sub-step. Each sub-step was therefore assigned a RPN. Those with the highest ranking RPNs are reported in [Table 4](#).

Risk priority numbers. The total RPN across all 42 sub-steps and their associated failure modes was 248. The lowest score assigned to any sub-step and associated failure modes was 0 (with 16 sub-steps scoring 0) and the highest was 84. The majority of the sub-steps and associated failure modes were deemed very low risk and scored 10 or less (36, 86%). We identified 5 low-to-moderate risk sub-steps (12%) and one moderate-to-high risk sub-step. We prioritised these two groups for the proactive

Table 4. Failure Modes and Effects Analysis results for low-moderate and high-moderate risk sub-steps in remote ABPM.

| Step of remote ABPM | Sub-step | Failure mode | Failure cause | Failure effects | Likelihood of occurrence | Likelihood of detection | Severity | Risk priority number |
|--|---|---|---|--|--------------------------|-------------------------|----------|----------------------|
| Contact participant to book 24-hour ABPM, programme monitor and schedule courier delivery | Reconfirm eligibility at booking call | Patient proceeds to ABPM but would not have been eligible due to change in circumstance since hospital admission | Eligibility not checked during this phone call | Inappropriate use of study resources, inconvenience to the participant, inaccurate data if error not detected, non-usable/destroyed data if error detected. | 2 | 4 | 4 | 32 |
| | Configure the monitor to record the participant's blood pressure twice hourly in waking hours and once hourly in sleeping hours | Measurements performed at incorrect frequency | Incorrect sleep and wake times entered or incorrect frequency selected when configuring monitor | Insufficient waking time measurements to assess for the presence of daytime hypertension in keeping with UK guidance ⁵ . Sleep disturbance to participant. | 2 | 2 | 6 | 24 |
| | Arrange courier | ABPM and associated equipment do not arrive with participant | Incorrect address, change in participant schedule since booking phone call, too great a time between booking call and delivery date, courier error, theft of equipment. | Financial loss to study owing to loss of equipment. Human resource in rearranging and reordering equipment, delay in follow up and data collection for participant and if delay major then breach of follow up window permitted by protocol and participant withdrawal | 4 | 1 | 3 | 12 |
| Fit the ABPM to the chosen arm for the 24-hour monitoring | Explain to the participant where the ABPM tubing should lie | Tubing placed incorrectly | Participant confused by instructions, participant isn't instructed how to thread the tubing through clothing down the back | Multiple attempts at repeat measurements, by the automated BP device, multiple erroneous/failed measurements | 6 | 1 | 2 | 12 |
| Participant commences and completes 24-hour ABPM | Participant advised and aware not to exercise any more vigorously than brisk walking during the monitoring period | Participant may wear monitor during vigorous activity if ambiguity/subjectivity in its interpretation; participant may remove the monitor during brisk activity and forget to replace it or turn it back on after exercising. | Participant unable to avoid vigorous activity due to lifestyle, instruction regarding avoiding vigorous activity not given to participant | Potential for elevated or failed BP measurements if monitor attempts to take measurements during vigorous exercise; loss of a period of measurements if participant forgets to resume monitoring after exercise. | 2 | 2 | 3 | 12 |
| Clean equipment upon its return to the research centre, prior to data download | n/a | Equipment not cleaned after unpacking | Equipment is unpacked by someone unaware of cleaning protocol, lack of access to cleaning supplies | Risk of transmission of infection to the researcher [*] | 2 | 6 | 7 | 84 |

ABPM = ambulatory blood pressure monitoring, n/a = not applicable.

^{*}Risk was deemed only to be to the researcher as the equipment is quarantined for a minimum of 72 hours upon return, before dispatch to another study participant.

identification of risk-reduction strategies for mitigating failure of the remote ABPM process. Of note, there was only 1 sub-step (arranging courier delivery and return of the ABPM) that was unique to the remote setting of ABPM; this was identified low-to-moderate risk. All other sub-steps were inherent to the ABPM process itself, whether performed face-to-face or remotely. The sub-steps with failure modes that were scored as low-to-moderate risk (RPN 11–50) or moderate-to-high risk (RPN greater than 50) are reported in Table 3.

Strategies for risk reduction in the remote ABPM process.

The FMEA panel developed strategies for proactive risk reduction to prevent failure to the remote ABPM process. Examples include creating a checklist of eligibility criteria against which participants should be re-screened when booking their remote ABPM fitting appointment and a checklist for the information required from participants to accurately configure the monitor to their schedule. Other strategies included refining written instructions and photographs regarding how to position the monitor tubing for the 24-hour period of wear with the panel patient and public representative. For the highest scoring sub-step and failure mode (cleaning monitoring equipment on its return to the research centre), strategies developed

included ensuring the equipment was returned personally to those staff trained in the study procedures to avoid the parcel being opened by non-trained staff, adding cleaning instructions to the ABPM download instructions as the first step in this process, and a clear process for escalation in the event of diminishing or absent cleaning supplies.

Assessment of successful ambulatory blood pressure monitoring episodes

Between 17 January 2020 and 10 March 2020, prior to the first COVID-19 lockdown in the UK, 14 face-to-face ABPM appointments were arranged and 10 (71%) were completed; three (21%) participants did not attend their scheduled fitting appointment and one (7%) was not undertaken due to the detection of atrial fibrillation at their fitting appointment, warranting same-day medical referral (Figure 2). The average time from hospital discharge to the ABPM fitting appointment was 54 days for the face-to-face cohort. Following resumption of research activity with easing of COVID-19 restrictions, 61 remote-ABPM fitting appointments were arranged between 9 December 2020 and 16 August 2021 and 54 (89%) were completed. Two (3%) of these participants were not able to proceed to ABPM due to the detection of severe hypertension at their remote fitting appointments (warranting same-day medical

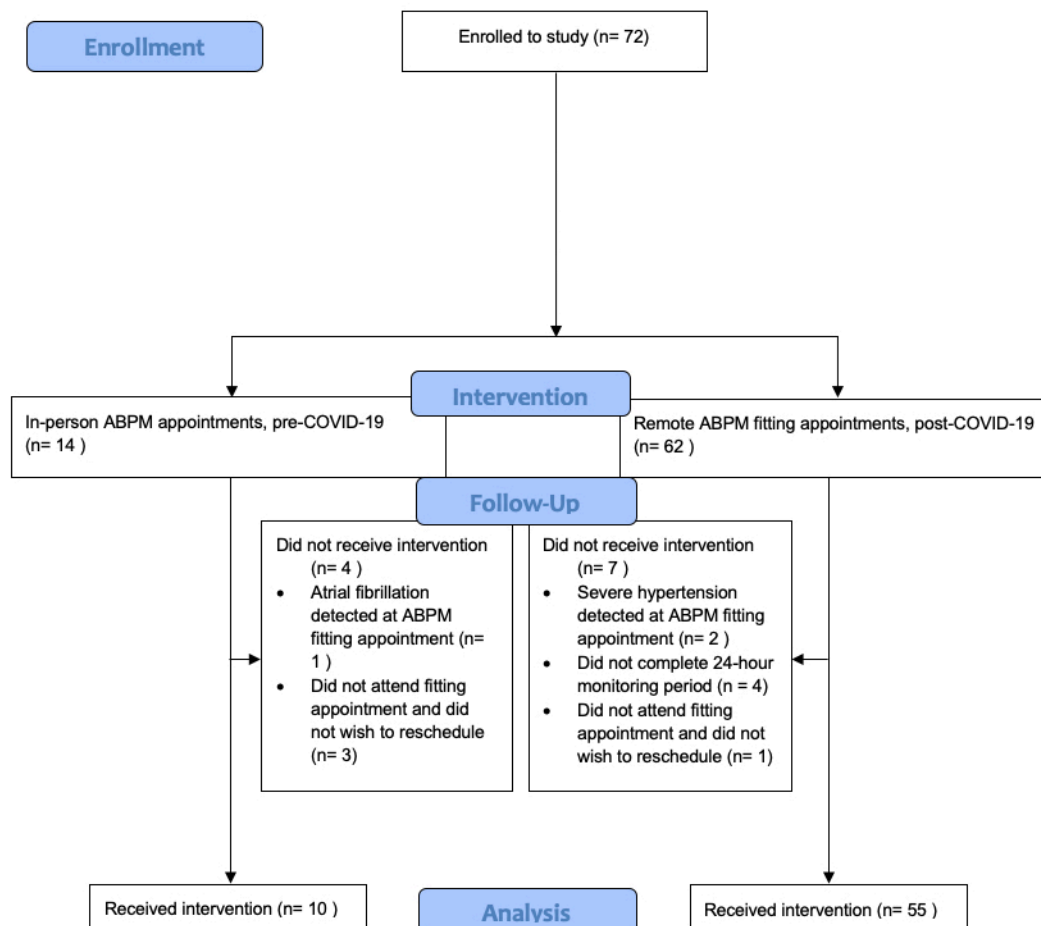


Figure 2. Participant flow diagram.

referral); one (2%) participant did not attend their remote fitting appointment and did not wish to reschedule and 4 (6%) participants did not complete their 24-hour monitoring period. Two (3%) participants switched their ABPM monitor off at night-time but complied with the day-time monitoring. Two (3%) fitting appointments required rescheduling due to issues with courier delivery of the monitors. All monitors were safely returned to the research centre after completion of ABPM with no loss of data. The average time from hospital discharge to the ABPM fitting appointment was 57 days for the remote cohort.

Of the 10 ABPM episodes performed via face-to-face fitting and removal, all were successful and obtained sufficient data (defined by the National Institute for Health and Care Excellence as ≥ 14 daytime measurements⁵) for diagnostic analysis. Mean age of these participants was 59 years and 80% were male. Similarly, of the 55 completed ABPMs performed with remote fitting, all were successful and obtained sufficient data for diagnostic analysis. Mean age of these participants was 50 years and 57% were male. [Table 5](#) provides further details of the participant characteristics for both groups.

For the 10 ABPM episodes with face-to-face fitting, there were 402 attempted blood pressure measurements, of which 361 (89%) were successful. Across the 55 participants who underwent remote fitting appointments, there were 2,516 attempted measurements, of which 2,214 (88%) were successful. There was no significant difference between the mean error rate per participant between the face-to-face and remote ABPM cohorts (mean error rates 0.100 [SD 0.009] and 0.143 [SD 0.132] respectively, 95% confidence interval for the difference being -0.125 to 0.045 and two-tailed P value 0.353).

Safety procedures

All ECGs were reviewed and manually interpreted by a GP on return of the tablet computers for any instances of atrial fibrillation missed by the automated interpretation of the ECG via the Kardia app; no missed instances of atrial fibrillation were detected. Similarly, all ABPM reports were

reviewed by two research clinicians (a research physiotherapist and a GP) for any instances of severely elevated blood pressure not detected at the fitting appointment and none were detected.

Discussion

Summary of results

We compared the performance of ABPM when delivered via face-to-face clinic appointments, versus when delivered remotely using telemedicine in a research study setting. We observed no statistically significant or clinically important difference in the performance of the monitoring between the two settings and demonstrated that monitors can be reliably and safely configured, fitted and removed for return using remote telemedicine consulting. Our safety procedures at the fitting appointments were effective at detecting one person with atrial fibrillation and two with severely elevated blood pressure. Non-attendance rates for ABPM were markedly higher in the face-to-face monitoring group (three participants, 21%) than the remote monitoring group (seven participants, 12%). Of the seven participants in the remote monitoring group who did not attend, six rearranged and attended a rescheduled appointment. We observed a greater number of blood pressure measurements per monitoring period in the remote ABPM group than the face-to-face group, likely owing to a greater flexibility in appointment times following the adoption of the remote process. When performing face-to-face ABPM appointments, appointment times were limited by the schedule of pre-booked clinic rooms, and to ensure adequate monitoring periods for all participants attending each clinic, we scheduled participants two appointments exactly 24 hours apart. Unfortunately the sheer pressure on clinic room space in General Practice meant we could not offer greater flexibility than this. However, with the move to remote monitoring, we were able to offer participants greater flexibility in appointment time. This provides a learning point which is translatable to the face-to-face setting, around the benefits of providing greater appointment flexibility to patients if clinic space and clinicians can both be made available.

We performed a Failure Modes and Effects Analysis of the process of remotely delivered ABPM and observed a single high-risk step, which related to the cleaning of equipment in the context of a global COVID-19 pandemic, and did not pertain to the remote nature of the process. Around the time of us performing the Failure Modes and Effects Analysis, there was debate in the literature regarding the significance of COVID-19 surface contamination and contact transmission. Based on available literature and individual perceptions of risk, others may not rate the risk posed by surface contamination of our monitoring equipment as highly as our multi-disciplinary team in this instance. It has been suggested however, that coronaviruses survive longer on plastic surfaces, such as an ABPM monitor, than metallic surfaces and that SARS-COV-2 virus specifically may survive on plastic surfaces for 3–4 days¹⁵.

Overall, we observed very low RPNs when performing the FMEA for remote ABPM. There are two potential contributing

Table 5.

| Participant characteristics | Face-to-face ABPM cohort | Remote ABPM cohort |
|--|--------------------------|--------------------|
| Male, n (%) | 8 (80) | 31 (57) |
| Age, mean (SD) | 59 (9.8) | 50 (13.3) |
| BMI, mean (SD) | 28 (3.8) | 28 (5.6) |
| Current smoker, n (%) | 1 (10) | 6 (11) |
| Diabetes, n (%) | 2 (3.7) | 1 (10) |
| History of cardiovascular disease, n (%) | 0 (0) | 0 (0) |
| History of serious mental illness, n (%) | 2 (20) | 4 (7.4) |

factors to these low-risk scores. Firstly, ABPM is a safe and non-invasive clinical test delivered routinely in clinical care and known to be associated with minimal risk. Secondly, the study processes had already been designed to minimise risk to participants and the study, such as careful screening for eligibility for study inclusion and suitability for ABPM at baseline enrolment, with further eligibility checks at the point of arranging and fitting the ABPM.

Strengths and limitations

We undertook a mixed-methods approach to evaluating the process and performance of remote ABPM. We performed a quantitative analysis of the ABPM data obtained through face-to-face ABPM fittings and remote ABPM fittings, using all data available from both groups at the time of performing the analysis. We performed an in-depth risk analysis of the remote ABPM process, using FMEA and with broad representation on the FMEA panel.

We were not able to calculate our sample size *a priori* to ensure it was powered to detect a significant difference in the proportion of successful episodes of ABPM or attempted measurements during each ABPM episode. This was due to the face-to-face cohort size being defined by the short time period in which we were able to recruit and follow up participants in a face-to-face setting before suspension of research activity due to the first wave of COVID-19 in the UK. Our comparative analysis of the mean error rate between the two cohorts is therefore vulnerable to a type II error. However, the width and magnitude of the calculated 95% confidence interval is small. We elected not to resume face-to-face ABPM appointments following the gradual lifting of COVID-19 restrictions in the UK, as we observed a number of benefits to the remote appointment offering, alongside the quality of remote ABPM appearing equivalent when compared to ABPM set up via face-to-face appointments. These observed benefits included greater patient interest in enrolling to the study, which translated to higher recruitment rates, lower rates of 'no shows' for booked ABPM appointments and removal of the barrier of travel and parking at healthcare centres for face-to-face appointments. Furthermore, pressures on primary care clinic room space in healthcare facilities are a major challenge in the UK at the present time and securing clinic space at times and locations convenient to participants was a major challenge¹⁶.

We primarily assessed the success of each ABPM episode against NICE Guidelines' recommendation of having at least 14 daytime measurements available from ABPM, due to the study setting being in the UK⁶. The NICE Guidelines for the diagnosis and management of hypertension do not make any recommendations for diagnosing blood pressure using night-time measurements. However, internationally, the full 24-hour period of monitoring is considered when making a diagnosis of hypertension^{7,17}. We therefore also assessed the rate of successful BP measurements within the 24-hour period of ABPM for both groups of participants. In the full analysis for the over-arching diagnostic accuracy study, from

which this data has been obtained, we have committed in our protocol, *a priori*, to assess the rate of nocturnal hypertension and 24-hour hypertension, using international guidelines¹.

The population in this study may not be representative of typical patients who are offered ABPM in the real-world clinical setting and further research evaluating this remote process in other settings is recommended.

Comparison with existing literature

We consider the approach to delivering and evaluating remote ABPM as described in this study to be novel. Our demonstration of the reliability and safety of remote ABPM may help primary care and hypertension clinicians and researchers consider whether existing services can be adapted to resume a resilient delivery of this important component of hypertension diagnostics and care.

Several other researchers have used FMEA to analyse the safety of healthcare environments that have been impacted by COVID-19^{18–20}. However, we have not identified any studies that have used FMEA to evaluate the adaptation of a specific medical procedure with the aim of reducing risk of transmission of COVID-19, such as this present study. We found FMEA a useful tool for this purpose; the systematic approach helped identify the risks associated with the specific adaptation of ABPM to a remote service.

Implications for research and clinical practice

In 2018, the WHO Regional Office for Europe launched a roadmap for the digitalisation of national health systems and in 2019, the NHS Long Term Plan for England outlined how digitally-enabled outpatient and primary care will become 'mainstream' throughout the NHS²¹. COVID-19 has necessitated an accelerated digitalisation of healthcare services and our findings support ABPM being one such service that may be digitally-enabled and offered remotely.

ABPM is a safe and routine procedure in every-day clinical care, and we have highlighted the key potential failure points that could occur when delivering this remotely which will likely be of interest to clinical and research services. However, researchers would need to consider the applicability of the risks assessed here to any other research and clinical settings in which remote ABPM is proposed.

The remote ABPM package in this study included a CE-marked and FDA approved mobile ECG device to screen for atrial fibrillation as part of our eligibility checks given we stated, *a priori*, that people with atrial fibrillation would be excluded from this study. This decision was made due to the overarching clinical study being one of diagnostic accuracy, and the reliability of automated blood pressure measurements in the context of atrial fibrillation has been debated²². It is possible however, that a clinical service offering remote ABPM may not require the inclusion of a mobile ECG device if an

ambulatory blood pressure monitor with proven reliability and validity in the context of atrial fibrillation could be deployed. A previous systematic review and meta-analysis investigating the reliability of automated blood pressure machines in the context of atrial fibrillation included six studies of four ambulatory blood pressure machines; this found that ambulatory measurements of systolic blood pressure performed with two specific devices were comparable to readings with mercury sphygmomanometers²³. Interestingly, the authors also found no evidence that ambulatory blood pressure monitors which are able to detect atrial fibrillation are any more accurate at blood pressure measurements in the context of atrial fibrillation than monitors without this function.

The costs of adapting services to offer remote ABPM need consideration in both research and clinical settings; associated costs with the remote delivery include the use of mobile ECG devices (each costing approximately £100 GBP at the time of purchase for this study) and courier usage which was £15 per remote ABPM appointment. We estimate that two hours of nursing and administration time were required per participant for the remote ABPM procedure, including contacting participants, arranging appointments, arranging the courier, configuring the monitor, completing fitting and removal appointments, packing and unpacking the couriered equipment, data download and interpretation. This was comparable to the face-to-face ABPM procedure for which 90–120 minutes was estimated to be required per participant. It should be noted that some of the time-consuming steps in this process included administrative tasks unique to a clinical study setting which would not transfer to an every-day clinical setting. A further consideration relating to technological costs concerns the study-owned tablet computers that we deployed for video calling and ECG interpretation, to promote inclusivity of participation and remove requirements on participants to download applications to their personal devices or indeed own such devices. As mobile device ownership and digital literacy become ubiquitous among the communities in need of this

service, provision of this equipment may become unnecessary. Similarly, as described above, if this remote method of ABPM measurement were to be implemented at scale in clinical care, outside of the context of a diagnostic accuracy study, provision of an ECG device for the screening of atrial fibrillation may not be required. The costs associated with remote delivery of ABPM may be offset by the costs of a clinic room and societal costs to patients and participants in travelling to face-to-face clinic appointments. However, a full economic evaluation would be required to understand this in greater detail and to inform decisions over adaptation of clinical services. Such an economic evaluation may also include home blood pressure monitoring as an additional comparator²⁴.

Conclusion

We have demonstrated that ABPM can be safely and appropriately provided in the community remotely and without face-to-face contact, using video technology for remote fitting appointments, alongside courier services for delivery of equipment to participants. This remote service has been instrumental in resuming research activity whilst mitigating the risk of COVID-19 transmission between participants and researchers. The COVID-19 pandemic has presented an opportunity for reconfiguring services, in this case to deliver a more accessible service for patients and one that is resilient to disruptions in usual care. Looking to the future, ABPM could be one service that is digitally enabled in both primary and secondary care.

Data availability

Oxford Research Archive for Data: Remote versus face-to-face ambulatory blood pressure monitoring: de-identified blood pressure data from 65 participants of the Screening for Hypertension in the Inpatient Environment (SHINE) study, <https://doi.org/10.5287/bodleian:qa9ZZmdOJ>.

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](#) (CC-BY 4.0).

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Reviewer Report 25 August 2022

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Christian Delles 

School of Cardiovascular and Metabolic Health, University of Glasgow, Glasgow, UK

Thank you for providing further information. I am happy with the changes that you made.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Cardiovascular diseases

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 2

Reviewer Report 19 July 2022

<https://doi.org/10.21956/wellcomeopenres.19705.r51412>

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Christian Delles 

School of Cardiovascular and Metabolic Health, University of Glasgow, Glasgow, UK

Laura Armitage and colleagues describe their experience with a remote setup for ambulatory blood pressure monitoring. They share their experience with others who may also have made adaptations to their hypertension service.

I enjoyed reading the paper, but it is not necessarily the most concise paper I have ever seen. For example, within just three columns spanning pages 3 and 4, the authors mention three times that they adhered to the BIHS protocol. The abstract is not a particularly easy read. Still, I appreciate that rounds of revisions don't always help to improve a paper and I will not request that the authors shorten their paper.

I have, however, a number of other comments.

1. First of all I should say that I fully agree with Dr Omboni's comment of definition of a valid ABPM. The introduction of the paper praises ABPM compared to HBPM, but then defining success based on daytime readings alone is counterintuitive – even if this is what NICE says. I note the authors' response but still wonder when we will see the night time data. Will you really get back to this small group in a future full paper and report the here missing data for this group?
2. I agree that the data are convincing in terms of feasibility and performance but I am not sure if the readings are accurate. I appreciate that even repeated ABPM in a face-to-face setting will never be exactly the same but just from the fact that there were successful readings once cannot conclude that the measurements were indeed precise. This would require further study.
3. I do not fully understand when (how many weeks/months later?) after discharge from hospital these ABPMs were done. Please specify this and provide data.
4. Please clarify data in Table 1. Is the definition of severity at download also " ≥ 160 or ≥ 105 " like in other rows or is it here " $\geq 160/105$ " in the sense of " ≥ 160 and ≥ 105 "?
5. I am really missing clinical data. The authors mention on page 11 that the "population in this study may not be representative of typical patients who are offered ABPM in the real-world clinical setting...". One way to help the reader comparing the present patients with their own patients would be to provide demographic and clinical characteristics including blood pressure readings and medication. I have seen a brief mention of age and gender but not any blood pressure readings or clinical characteristics. These would make a nice table.
6. I am a bit unsure how long the "telemedicine" sessions took. Could you specify this please? I appreciate that this is not the time for a detailed cost effectiveness analysis but could you provide very simple data that could help readers to speak to their own services if they want to do something similar? What were your courier costs? How much additional time did you need for packing/shipping/unpacking the equipment? How much time did remote sessions take (see above)?
7. I note that cleaning of the equipment was the single high-risk step in the FMEA. I appreciate this. But is this a real risk or is it a perceived risk? I am not aware that handling blood pressure equipment was a major driver of the COVID-19 pandemic. A critical discussion of this topic (with the benefit of hindsight) is missing. Did you use disposable cuffs? Or standard cuffs and washed them? Has cleaning of cuffs changed with onset of the pandemic compared to your previous practice? I would assume that you didn't send ABPM devices to patients how had COVID-19 or symptoms of COVID-19 and this was probably one of the screening questions? So the risk should be really low and I wonder why this was such a

concern.

8. Finally, I appreciate that the remote service offers greater flexibility but assume this is still within regular working hours? I was surprised to read that you offered F2F appointments only with an exact 24-hours interval. Surely it would be possible to switch a device off and return it later, e.g. after a weekend or in the evening? So maybe this study also offers us learning points to be taken into account for conventional services as well.

Minor issues:

1. On page 3, right column, it should read "British and Irish Hypertension (not: Heart) Society" like elsewhere in the text.
2. I can't follow the maths on page 9, right column. If one out of 14 was not undertaken due to AF that would be $1/14=0.07$, i.e. 7% rather than 2%?

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Partly

If applicable, is the statistical analysis and its interpretation appropriate?

Partly

Are all the source data underlying the results available to ensure full reproducibility?

No

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Cardiovascular diseases

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 18 Aug 2022

Laura Armitage, University of Oxford, Oxford, UK

Laura Armitage and colleagues describe their experience with a remote setup for ambulatory blood pressure monitoring. They share their experience with others who may also have made adaptations to their hypertension service.

I enjoyed reading the paper, but it is not necessarily the most concise paper I have ever seen. For example, within just three columns spanning pages 3 and 4, the authors mention three times that they adhered to the BIHS protocol. The abstract is not a particularly easy read. Still, I appreciate that rounds of revisions don't always help to improve a paper and I will not request that the authors shorten their paper.

I have, however, a number of other comments.

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Author response: Thank you for this comment. The night-time BP data are available with all data in the linked data repository. We have committed, a priori, in the SHINE study protocol to assess the rate of nocturnal hypertension and 24-hour hypertension using international guidelines and have added a statement about this commitment to the present article. We have another article in print at present, highlighting the importance of assessing night-time BP as we agree that the present NICE guidelines are limited. Recent evidence points to the need for 24-hour, including night-time, BP assessments, in line with hypertension diagnostic guidelines globally.

1. I agree that the data are convincing in terms of feasibility and performance but I am not sure if the readings are accurate. I appreciate that even repeated ABPM in a face-to-face setting will never be exactly the same but just from the fact that there were successful readings once cannot conclude that the measurements were indeed precise. This would require further study.

Author response: Thank you for this comment. Our conclusion is that ABPM can be delivered safely and appropriately in the community remotely and we have been careful around our use of language, not asserting any certainty over accuracy. We have previously discussed as a group, how level of accuracy could be determined, and this would be extremely difficult to study because, as you say, ABPM varies day-to-day and so it wouldn't be adequate to ask the same individuals to wear a monitor fitted remotely during one 24-hour period and then wear a monitor fitted face-to-face for another 24-hour period. The way around this could be for individuals to wear one monitor on each arm for the same 24-hour period, with one fitted remotely and one face-to-face, but problems with this could include additional discomfort and inconvenience to participants and difficulty going about every-day life whilst wearing the monitors, and possibly contamination between the two settings given participants would have the same instructions repeated at each appointment (remote and face-to-face) - so whichever came second may be optimised in terms of fitting and therefore accuracy.

1. I do not fully understand when (how many weeks/months later?) after discharge from hospital these ABPMs were done. Please specify this and provide data.

Author response: ABPMs were conducted between 1 and 6 months post-hospital discharge. The mean time between discharge and ABPM fitting was 54 days in the face-to-face ABPM cohort and 57 days in the remote ABPM cohort. This detail has been added in the results section under the sub-header 'Assessment of successful ambulatory blood pressure monitoring episodes'.

1. Please clarify data in Table 1. Is the definition of severity at download also “ ≥ 160 or ≥ 105 ” like in other rows or is it here “ $\geq 160/105$ ” in the sense of “ ≥ 160 and ≥ 105 ”?

Author response: Thank you, we have now clarified this.

1. I am really missing clinical data. The authors mention on page 11 that the “population in this study may not be representative of typical patients who are offered ABPM in the real-world clinical setting...”. One way to help the reader comparing the present patients with their own patients would be to provide demographic and clinical characteristics including blood pressure readings and medication. I have seen a brief mention of age and gender but not any blood pressure readings or clinical characteristics. These would make a nice table.

Author response: The blood pressure data are available in the linked data repository as required by Wellcome Open Research. The aim of this study was to establish proof-of-concept and feasibility of a remote ABPM procedure and so it is out-with the scope of this present manuscript to analyse the results of the blood pressure data. Once a full dataset for the SHINE study is achieved, we will fulfil all of the study objectives in the published protocol, which include an analysis of the diagnostic blood pressure data, including in the context of patient clinical characteristics. However, we have now provided some further participant characteristics in this paper in Table 5.

1. I am a bit unsure how long the “telemedicine” sessions took. Could you specify this please? I appreciate that this is not the time for a detailed cost effectiveness analysis but could you provide very simple data that could help readers to speak to their own services if they want to do something similar? What were your courier costs? How much additional time did you need for packing/shipping/unpacking the equipment? How much time did remote sessions take (see above)?

Author response: Thank you, we have added this detail to the Discussion under the 4th paragraph of the ‘Implications for research and clinical practice section’.

1. I note that cleaning of the equipment was the single high-risk step in the FMEA. I appreciate this. But is this a real risk or is it a perceived risk? I am not aware that handling blood pressure equipment was a major driver of the COVID-19 pandemic. A critical discussion of this topic (with the benefit of hindsight) is missing. Did you use disposable cuffs? Or standard cuffs and washed them? Has cleaning of cuffs changed with onset of the pandemic compared to your previous practice? I would assume that you didn’t send ABPM devices to patients who had COVID-19 or symptoms of COVID-19 and this was probably one of the screening questions? So the risk should be really low and I wonder why this was such a concern.

Author response: Thank you for your comments on this. We used standard cuffs and washed them. The cleaning of the cuffs did not change with the onset of the pandemic compared to previous practice, nor did the cleaning of the monitors; however, it was perceived that if cleaning was not adhered to the risk of infection transmission could be significant but as we have stated, this is irrespective of whether the ABPM appointments are conducted face-to-face or remotely. Around the time of carrying out the Failure Modes and Effects Analysis for this work, the significance of surface contamination and contact transmission was being debated within the literature and we have now added a critical discussion of this point to our article as you have suggested.

1. Finally, I appreciate that the remote service offers greater flexibility but assume this is still within regular working hours? I was surprised to read that you offered F2F appointments only with an exact 24-hours interval. Surely it would be possible to switch a device off and return it later, e.g. after a weekend or in the evening? So maybe this study also offers us learning points to be taken into account for conventional services as well.

Author response: Thank you for this comment. The majority of the time, the remote service was within regular working hours. Unfortunately it wasn't possible to offer such flexibility with face-to-face appointments with regard to return of the monitors due to severe constraints on clinic room availability in GP surgeries, which is a national issue; we therefore needed to block-book clinic appointments and the most effective way we found to do this, to suit the majority of participants, ensure room availability and manage the human resource required to travel to clinics was to block book a clinic room for a session on 2 consecutive days, and therefore book participants into two appointments 24-hours apart. We have briefly added some further discussion of this point.

Minor issues:

1. On page 3, right column, it should read "British and Irish Hypertension (not: Heart) Society" like elsewhere in the text.

Author response: Thank you, this is now amended.

1. I can't follow the maths on page 9, right column. If one out of 14 was not undertaken due to AF that would be $1/14=0.07$, i.e. 7% rather than 2%?

Author response: Thank you, this has been corrected

Competing Interests: No competing interests were disclosed.

Reviewer Report 07 April 2022

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The authors have thoroughly and adequately responded to the remarks I previously raised. I have no further comments.

Is the work clearly and accurately presented and does it cite the current literature?

Partly

Is the study design appropriate and is the work technically sound?

Partly

Are sufficient details of methods and analysis provided to allow replication by others?

Partly

If applicable, is the statistical analysis and its interpretation appropriate?

Partly

Are all the source data underlying the results available to ensure full reproducibility?

Partly

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: telemedicine; ambulatory blood pressure monitoring; hypertension

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 17 February 2022

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In this paper, the authors demonstrate that ABPM can be safely and appropriately provided in the community remotely and without face-to-face contact using telemedicine. The study is novel in its kind, interesting, and well presented, and it confirms what is documented in other studies in different settings (e.g., pharmacies).

The authors set to use the NICE criteria for evaluating the ABPM quality ("When using ABPM to confirm a diagnosis of hypertension, ensure that at least two measurements per hour are taken during the person's usual waking hours (for example, between 08:00 and 22:00). Use the average value of at least 14 measurements taken during the person's usual waking hours to confirm a diagnosis of hypertension."). However, these criteria are questionable because they are too loose

compared to International ones. The decision to perform a 24-hour ABPM and then limit the diagnosis to daytime hours is also questionable. Since a significant proportion of patients may have night-time hypertension (particularly older people and those treated with antihypertensive medication), including recordings deemed valid only for the waking hours, but potentially invalid for night-time hours and excluding the night-time period from the diagnostic assessment may be a significant source of diagnostic inaccuracy. The authors must discuss this aspect as a study limitation. In the future, I would recommend applying more strict quality criteria to ensure high diagnostic accuracy.

Did any patient have missing BP readings during the night-time? The author should indicate whether readings were available for the whole 24 hours for all recordings.

The use of a mobile ECG device shipped to the user and the ABPM monitor might be a complication in the routine workout of the service. Current ABP monitors can detect the occurrence of arrhythmias (also atrial fibrillation in some cases) as well as smartwatches that are available to many young people. The authors may discuss this aspect in the "Implications for research and clinical practice" section.

A significant limitation of this study is the small sample size of the face-to-face cohort. The authors discuss this aspect and acknowledge this limitation. Nevertheless, this is a significant limitation that would deserve a more thorough discussion. For instance, did authors resume face-to-face appointments after the lockdown? Were they able to recruit more patients in that cohort after the lockdown or isolation? This is not mentioned on page 9 ("Assessment of successful ambulatory blood pressure monitoring episodes")

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Yes

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: telemedicine; ambulatory blood pressure monitoring; hypertension

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 20 Mar 2022

Laura Armitage, University of Oxford, Oxford, UK

Outcome: Approved with reservations

Ambulatory blood pressure monitoring using telemedicine: proof-of-concept cohort and failure modes and effects analyses.

In this paper, the authors demonstrate that ABPM can be safely and appropriately provided in the community remotely and without face-to-face contact using telemedicine. The study is novel in its kind, interesting, and well presented, and it confirms what is documented in other studies in different settings (e.g., pharmacies).

Author response:

Thank you for this feedback

- *The authors set to use the NICE criteria for evaluating the ABPM quality ("When using ABPM to confirm a diagnosis of hypertension, ensure that at least two measurements per hour are taken during the person's usual waking hours (for example, between 08:00 and 22:00). Use the average value of at least 14 measurements taken during the person's usual waking hours to confirm a diagnosis of hypertension."). However, these criteria are questionable because they are too loose compared to International ones. The decision to perform a 24-hour ABPM and then limit the diagnosis to daytime hours is also questionable. Since a significant proportion of patients may have night-time hypertension (particularly older people and those treated with antihypertensive medication), including recordings deemed valid only for the waking hours, but potentially invalid for night-time hours and excluding the night-time period from the diagnostic assessment may be a significant source of diagnostic inaccuracy. The authors must discuss this aspect as a study limitation. In the future, I would recommend applying more strict quality criteria to ensure high diagnostic accuracy.*
- **Response:** Thank you very much for this feedback. We acknowledge your concerns regarding the NICE diagnostic criteria for hypertension and in our study protocol for the diagnostic accuracy study (<https://bmjopen.bmj.com/content/9/12/e033792.long>) we have planned, a priori, to perform additional analyses incorporating night-time measurements and using the European and American diagnostic thresholds for hypertension. We have added the following text regarding this to our discussion under the sub-header Strengths and limitations to the present manuscript: "We primarily assessed the success of each ABPM episode against NICE Guidelines' recommendation of having at least 14 daytime measurements available from ABPM, due to the study setting being in the UK.⁶ The NICE Guidelines for the diagnosis and management of hypertension do not make any recommendations for diagnosing blood pressure using night-time measurements. However, internationally, the full 24-hour period of monitoring is considered when making a diagnosis of hypertension.^{8,15}

We therefore also assessed the rate of successful BP measurements within the 24-hour period of ABPM for both groups of participants. In the full analysis for the overarching diagnostic accuracy study, from which this data has been obtained, we will also assess the rate of nocturnal hypertension and 24-hour hypertension, using international guidelines.¹ "

- *Did any patient have missing BP readings during the night-time? The author should indicate whether readings were available for the whole 24 hours for all recordings.*
- **Response:** Thank you for this comment. In the pre-COVID, face-to-face ABPM group, none of the participants switched off their monitor during the night-time. In the post-COVID, remote ABPM group, two participants switched off their monitor during the night-time. We have added this detail to the manuscript under the Results sub-header 'Assessment of successful ambulatory blood pressure monitoring episodes'. The error rate reported for both groups has been calculated using all blood pressure values measured during the full period of wear (both day-time and night-time values).
- *The use of a mobile ECG device shipped to the user and the ABPM monitor might be a complication in the routine workout of the service. Current ABP monitors can detect the occurrence of arrhythmias (also atrial fibrillation in some cases) as well as smartwatches that are available to many young people. The authors may discuss this aspect in the "Implications for research and clinical practice" section.*
- **Response:** Thank you, our reason for screening for atrial fibrillation using the ECG device was due to the debated reliability of automated blood pressure machines in the context of AF. The use of a monitor which has proven reliability and validity in the context of AF would be of most important to the diagnostic accuracy of the results. We note a recent review by Clark et al made an important distinction between ABPM monitors that can identify AF and those which are reliable in the context of AF. We have added some to the section 'Implications for research and clinical practice' as follows: "The remote ABPM package in this study included a CE-marked and FDA approved mobile ECG device to screen for atrial fibrillation as part of our eligibility checks given we stated, a priori, that people with atrial fibrillation would be excluded from this study. This decision was made due to the overarching clinical study being one of diagnostic accuracy, and the reliability of automated blood pressure measurements in the context of atrial fibrillation has been debated.²⁰ It is possible however, that a clinical service offering remote ABPM may not require the inclusion of a mobile ECG device if an ambulatory blood pressure monitor with proven reliability and validity in the context of atrial fibrillation could be deployed. A previous systematic review and meta-analysis investigating the reliability of automated blood pressure machines in the context of atrial fibrillation included six studies of four ambulatory blood pressure machines; this found that ambulatory measurements of systolic blood pressure performed with two specific devices were comparable to readings with mercury sphygmomanometers.¹⁸ Interestingly, the authors also found no evidence that ambulatory blood pressure monitors which are able to detect atrial fibrillation are any more accurate at blood pressure measurements in the context of atrial fibrillation than monitors without this function. "
- *A significant limitation of this study is the small sample size of the face-to-face cohort. The*

authors discuss this aspect and acknowledge this limitation. Nevertheless, this is a significant limitation that would deserve a more thorough discussion. For instance, did authors resume face-to-face appointments after the lockdown? Were they able to recruit more patients in that cohort after the lockdown or isolation? This is not mentioned on page 9 ("Assessment of successful ambulatory blood pressure monitoring episodes")

- **Response:** Thank you for this question. We did not resume face-to-face ABPM when COVID-19 restrictions started to lift in the UK. We have updated the manuscript with the following text under the Strengths and Limitations section: "We elected not to resume face-to-face ABPM appointments following the gradual lifting of COVID-19 restrictions in the UK, as we observed a number of benefits to the remote appointment offering, alongside the quality of remote ABPM appearing equitable when compared to ABPM when set up via face-to-face appointments. These observed benefits included greater patient interest in enrolling to the study, which translated to higher recruitment rates, lower rates of 'no shows' for booked ABPM appointments and removal of the barrier of travel and parking at healthcare centres for face-to-face appointments. Furthermore, pressures on primary care clinic room space in healthcare facilities are a major challenge in the UK at the present time and securing clinic space at times and locations convenient to participants was a major challenge. 14"

Competing Interests: None to declare