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Risk reduction intervention for raised blood pressure

Submission date
18/03/2022

Recruitment status
No longer recruiting

Registration date
08/04/2022

Overall study status
Completed

Last Edited
01/06/2023

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English Summary
Background and study aims
People with raised blood pressure (range 120-139/80-89 mmHg) are at increased risk of cardiovascular disease (CVD) related conditions as well as high blood pressure (hypertension) itself. Around 40% of adults have raised blood pressure. Raised blood pressure lies between normal (<120/80 mmHg) and high (≥140/90 mmHg) blood pressure. While raised blood pressure does not require drug intervention, discussions with patients, the public, and health care professionals (HCPs) have identified this as an area that merits investigation. Of importance is the identification of effective preventative initiatives to manage raised blood pressure to try to prevent the development of high blood pressure and CVD.
Currently there is little evidence available to: a) guide practice on how best to identify and alert people to raised blood pressure; b) show what types of interventions would be feasible and acceptable to both patients and healthcare providers; and c) highlight which interventions may be clinically effective. Self-monitoring of blood pressure could allow people to monitor and manage their risk and may allow individuals to modify lifestyle factors (e.g. diet, smoking, and physical activity).
The first purpose of this study is to find out whether people who have raised blood pressure, as well as health care providers, are willing to engage with the concept of raised blood pressure and also take part in a self-monitoring of blood pressure intervention. The researchers also want to know if the study and intervention processes are acceptable to participants to allow them to be used in any future study.

Who can participate?
Adults aged 18 years or over with raised blood pressure

What does the study involve?
The study will involve attending an initial research appointment, either online or in person, where the researchers may re-measure blood pressure, height and weight and will ask the participant to complete a questionnaire. Participants will be given a blood pressure monitor and training in how to use it. They will be asked to monitor their blood pressure at home for 6 months and send their readings to the research team. After the 6 months of home blood pressure monitoring, participants will attend a follow-up appointment where they will be asked to complete a second questionnaire. After 12 months participants will be emailed a third and

final questionnaire to complete.
Participants and healthcare providers may also be asked if they would be willing to take part in a follow-up interview or focus group to discuss their experiences of blood pressure self-monitoring and begin to design a lifestyle intervention, which will be tested alongside blood pressure self-monitoring in a future trial.

What are the possible benefits and risks of participating?
Participants will learn more about their blood pressure and how to take accurate blood pressure measurements, which may help them to keep their blood pressure within a healthy range. Participants will also be gifted a blood pressure machine so that they can use it after the study. During the study participants will be helping to gather information on whether self-monitoring blood pressure at home can be useful for people with raised blood pressure.
There are no anticipated risks with taking part in this study. However, although many studies have found self-monitoring of high blood pressure to be safe and effective, there are very few studies into self-monitoring of blood pressure in people with raised blood pressure, and therefore we will be monitoring any unexpected adverse events.

Where is the study run from?
University of Central Lancashire (UK)

When is the study starting and how long is it expected to run for?
October 2021 to March 2024

Who is funding the study?
National Institute for Health Research Research for Patient Benefit (UK)

Who is the main contact?
1. Dr Emma Bray, EBray@uclan.ac.uk
2. Lucy Hives, LHives1@uclan.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Emma Bray

ORCID ID
http://orcid.org/0000-0001-9882-3539

Contact details
Stroke Research Team
School of Nursing
Faculty of Health and Care
University of Central Lancashire
Brook Building, BB247
Preston
United Kingdom

PR1 2HE
+44 (0)1772 893883
EBray@uclan.ac.uk

Type(s)
Scientific

Contact name
Miss Lucy Hives

ORCID ID
http://orcid.org/0000-0003-4125-4034

Contact details
Research Facilitation and Delivery Unit
Applied Health Research Hub
University of Central Lancashire
Brook Building 406
Preston
United Kingdom
PR1 2HE
+44 (0)1772 893910
LHives1@uclan.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
282624

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 51123, IRAS 282624

Study information

Scientific Title
Risk reduction intervention for raised blood pressure (REVERSE): a feasibility study exploring the use of blood pressure self-monitoring

Acronym
REVERSE

Study hypothesis
The primary aim of REVERSE is to determine the feasibility and acceptability, to both healthcare professionals (HCPs) and individuals of using self-monitoring (SM) of blood pressure (BP) in

people with pre-hypertension (PHT). The results will determine the appropriateness, and design of any future multi-centre, randomised trial to investigate if SM helps in detecting and increasing awareness of PHT, as well as encouraging lifestyle changes to prevent ill health.

The primary objectives are:
1. Determine the willingness of people in PHT range and health service providers to take part in a self-monitoring intervention
2. Assess and evaluate the acceptability of the intervention and study processes to people in the PHT range and to health service providers.

The secondary objectives are:
1. Determine recruitment and attrition rates to inform a future trial
2. Determine the completeness of the data collected at each timepoint and the appropriateness of the data collection methods
3. Assess the adherence of participants to the SM intervention
4. Determine drop-out rates from the intervention and from the study overall
5. Assess the fidelity of the study processes
6. Determine the incidence and impact of any unintended negative consequences (UNCs), such as any adverse psychological, behavioural or healthcare utilisation outcomes (cost analysis)
7. Explore participants' willingness to pay regarding self-monitoring
8. Assess the extent SM encourages lifestyle modification
9. Explore with participants acceptable content and procedures of a future lifestyle intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/03/2022, London - Fulham Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8021; fulham.rec@hra.nhs.uk), ref: 22/PR/0108

Study design
Non-randomized; Interventional; Design type: Prevention, Education or Self-Management, Active Monitoring

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Condition
Pre-hypertension

Interventions
Design:
REVERSE is a non-randomised feasibility study to explore whether individuals with raised blood pressure and health care professionals (HCPs) will engage with a study on raised blood pressure (BP) (also known as pre-hypertension [PHT]) and whether self-monitoring of blood pressure could be used with people who have blood pressure in the pre-hypertension range. The researchers will recruit participants from GP practices, pharmacies and workplace health check providers based in Lancashire, that offer the NHS-commissioned health check.

Purpose and research questions:
The first purpose of this study is to find out whether people who have raised blood pressure, as well as health care providers, are willing to engage with the concept of pre-hypertension and also take part in a self-monitoring of blood pressure intervention. The researchers also want to know if the study and intervention processes are acceptable to participants to allow them to be used in any future study.

The researchers will also be interested in the following feasibility outcomes; recruitment and drop-out rates throughout the study, completeness and usefulness of data, participant adherence to the self-monitoring protocol, the fidelity of the study processes, and unintended negative consequences (UNCs e.g., anxiety, QoL, health resource use). Finally, they will collect data to help determine the content of a future lifestyle intervention, as well as data on willingness to pay (WTP), and mechanisms of action including lifestyle modification.

Methodology:
Study population:
The study population will comprise of people with BP in the PHT range as identified from electronic records in general practices, or from an NHS health check conducted in pharmacies or by workplace health check providers in workplace sites. Sites will be selected based on the Index of Multiple Deprivation (IMD) category (low, mid and high) to ensure a range of socio-economic variation.

Sample:
The researchers are aiming to have 90 individuals remaining in the study at the 6-month follow up. To allow for drop-outs they will recruit and consent 114 participants (38 per provider). They estimate this number can be recruited from three sites per provider (12 or 13 participants per site) but this will be monitored as part of the study aims.

Identification procedures:
Participants will be identified by three types of healthcare provider (general practices, pharmacies, workplace health check providers) who will act as Participant Identification Centres (PICs).

Pharmacies and workplace health check providers will identify potential participants from the BP check within the NHS health check they are commissioned to conduct. If an individual's BP during the health check is within the accepted PHT range (2nd reading between 120- 139 mmHg systolic and/or 80-89 mmHg diastolic), the individual will be handed a Participant Information Sheet (PIS) by the HCP doing the health check. Identification will continue until 38 people per provider are enrolled in the study.

In general practice, electronic registers will be searched, by the usual care team, on the following criteria; last recorded BP (within last 7 years) within 120-139 mmHg and/or 80-89 mmHg, age 18 or over, no diagnosis of hypertension, not on any anti-medication, not pregnant, no life-limiting illness, no past recorded stroke or MI. Of those identified, 50 will be randomly chosen and posted a PIS. Subsequent mail-outs, in batches of 50, will be done if required until 13 people per site have been enrolled into the study.

Interested individuals who have received a PIS will contact the research team directly via email or phone. Those receiving the letter from their GP will be invited to return a simple decline invitation slip giving their reasons should they not be interested. For those recruited via a health check, numbers declining the invitation will be recorded by the PIC.

Recruitment and consent:
For those interested individuals who contact the research team, the study will be fully explained, and any questions answered.

Pharmacy/workplace health check provider identified participants:
Participants identified via a pharmacy or workplace provider health check, if deciding they would like to take part, will have their eligibility checked on the initial phone call, by the research team. Eligibility criteria for participants will be aged 18+ with no upper age limit, a BP (taken at health check) between 120- 139 mmHg systolic and/or 80-89 mmHg diastolic, and no previous diagnosis of hypertension. Exclusion criteria will include prescribed anti-hypertensive medication, previous stroke or MI, pregnant, currently actively self-monitoring BP, and life-limiting illness. Once deemed eligible, the researcher will determine whether the participant would prefer a face-to-face or online baseline research appointment, and a date will be set for them to attend. If an on-line appointment is preferred, as delivery of a BP monitor will need to be arranged, consent to participant will be taken via an audio-recording.

General practice identified participants:
For participants identified via general practice eligibility and consent will not be possible during the initial phone contact, as the last recorded BP used to identify individuals is unlikely to be recent, and so BP will need to be taken to determine eligibility. Therefore, once queries/ questions have been answered the researcher will arrange a date for the individual to attend a face-to-face baseline research appointment.

Baseline research appointment:
GP identified participants:
For individuals identified through GPs, these face-to-face appointments will take place at the General Practice from which the individual was identified. At the appointment any remaining questions will be answered, eligibility confirmed using the criteria listed above, and consent will be taken using the paper consent form.
Once these stages are complete and the individual is enrolled in the study the researcher will support the participant in completing the online questionnaire. Each individual will then be provided with a home BP machine, and will receive training on how to monitor their BP at home.

Pharmacy/workplace health check provider identified participants:
Face-to-face:
For those participants who have opted for a face-to-face appointment, this will take place at the Pharmacy from which they were identified, or at the University. At the appointment the researcher will obtain consent using the paper consent form, then support participants in completing the online questionnaire. Each individual will then be provided with a home BP machine, and will receive training on how to monitor their BP at home.

Virtual online:
Appointments will take place using Microsoft Teams where possible or Zoom/Skype if not possible. At the start of the appointment consent will be re-confirmed (previously taken on phone), then the online questionnaire will be completed. Once completed each individual will receive training on how to monitor their BP at home.

Intervention:
Intervention training will be provided by the research team during the baseline research appointment and will be supplemented with an online training video that will be available to participants throughout the study. Should participants not have access to a computer then a paper training resource will be provided. The training session will cover how to self-measure BP, how to record and send the readings for the study, and what actions to take depending on the readings. Following the training session, participants will be asked to complete a practice week of readings to ensure competency. Following successful completion of the training, each participant will start the intervention at the beginning of the following month.

All participants will be asked to measure their own BP on the first 3 days of every month, for 6-months. If participants need to change the exact 3 days due to holidays, forgetting to take readings etc, this can be done by notifying the research team. Each individual can pick the time of day that they take their readings, but this must then be kept consistent throughout the 6-months of monitoring. Readings need to be taken no sooner than 30 minutes after food or exercise, and participants will need to make sure that the timing of medications in relation to the BP reading is always the same. Participants will be asked to take two BP readings per day, and write both of these on their BP record, along with the time each was taken. They will then colour code the 2nd of these readings as follows: Green for BPs in the normal range (SBP <115 mmHg AND DBP <75 mmHg), Amber for those in the PHT range (SBP 115-134 mmHg OR DBP 75-84 mmHg), and Red for those falling into the hypertensive range (SBP >135 mmHg OR DBP <85 mmHg). These targets are reduced for home readings by 5/5 mmHg as recommended in the literature. Alternative targets will be provided to those participants who require them, e.g., for those with diabetes targets will be 10/10mmHg lower than the normal targets. Each month, participants will consider the three days colour codes, and provide an overall colour code for the month as follows; if there have been any Red days the week should be classed as Red, if there were no Red days and more Amber than Green days, the week should be Amber and if there were no Red days and more Green than Amber days, the week should be classed as Green. Again, red, amber and green correspond to hypertensive, PHT and normal BP respectively.

Participants will then email/post/phone (depending on preference) their readings to the research team each month. The research team will check the colour coding and record fidelity to the protocol. Additionally, if participant's readings are categorised (as outlined above) as hypertensive over two consecutive months, or are higher than 180/95 mmHg on 2/3 measurement days in a given week, they will contact their GP providing their readings accompanied by a covering letter produced by the research team, which explains their participation in the study. Participants will also be asked to inform the research team and their GP (using a provided template letter) on these occasions.

Follow-up research appointments:
After month 6 of monitoring, all participants will be invited to attend a follow-up appointment. Invitations will be sent by the research team via the participant's preferred method of contact (email, letter or phone call). As with the baseline appointments, these will be either face-to-face at the site of recruitment, or via video call (depending on COVID-19 restrictions and personal preference). At this research appointment, as part of the fidelity assessment, the readings

stored on each participant's monitor will be compared to the paper record, and the researcher will check whether contact with the GP had been made in any cases where two consecutive RED months had been recorded. The BP machine will then be gifted to the participant. They will then be asked to complete a second online questionnaire with the researcher. Participants will also be asked if they would be interested in taking part in an in-depth semi-structured interview or a focus group (See qualitative section below). Separate times will be arranged for these elements to be conducted.

Participants will then be reminded that in a further 6-months' time, they will be emailed a link (or posted a paper version) to complete a final questionnaire. They will be told that there is no expectation, as part of the study, for them to continue to self-monitor their BP, but they can do so if they wish.

Following the 6-month appointment, with consent from participants, the research team will contact the relevant GP practices of any participant that had 2 consecutive RED months of readings, to evaluate whether the home readings had been received by the practice. A final data collection point will occur at 12-months. This will not involve any direct involvement with the researcher. Instead, participants will be emailed a link to the online questionnaire (or offered a paper version). However, a researcher will contact them using their preferred method of contact (email, letter or phone call) prior to the email being sent, to remind participants about this. It has been decided to conduct this final follow-up online, as it will allow data completeness to be compared with the “researcher supported” collection method.

Qualitative component:
The incorporation of qualitative methods makes an important contribution to feasibility studies. The researchers will conduct up to 35 (20 main study participants; 15 HCPs e.g. pharmacists, pharmacy assistants, GPs, practice nurses, and workplace provider practitioners) semi-structured interviews, via telephone/video call, and a focus group (either face-to-face or via video call depending on current COVID-19 situation) with 4-8 participants (mixture of main study participants and HCPs) to begin to co-develop the lifestyle component of any future study.

Recruitment:
HCPs:
Each PIC will be told on recruitment into the study that it will be a condition of taking part that staff members are involved in the interviews/focus groups. Sites will be asked to identify suitable and willing members of staff to take part and provide the research team with their contact details. Those identified will be sent a PIS by the research team and an appointment for the interview/focus group to take place will be arranged.

Participants:
Participants will be told about the interviews/focus group at their 6-month follow-up appointment. They will be handed a PIS and are asked to contact the research team if they are interested in taking part.

Interviews:
Interview questions will be theory-driven (Theoretical Domains Framework [TDF]) and the researchers will explore participant and staff experiences of blood pressure self-monitoring, covering benefits and barriers, and areas for improvement or change, and awareness and knowledge of PHT including any UNCs.

Focus group:
The purpose of the focus group is to begin to co-develop the lifestyle component of any future

trial. The researchers will ascertain from this information, in conjunction with the questionnaire data, any links between self-monitoring and lifestyle changes, what such an intervention should look like in terms of content and focus, and how this should be delivered and operationalised alongside the self-monitoring. They will use the COM-B model and the TDF to underpin this development process.

Health economic component:
The researchers will also undertake a cost analysis and a cost-benefit analysis (CBA). The cost analysis will look at the health resource use associated with the self-monitoring intervention including patient-reported information on consultations, medications and referrals, as well as information on human (i.e. training) resources used to set up the intervention. The CBA will be based on a willingness-to-pay (WTP) approach by exploring the value that participants place on the BP self-monitoring machine (and consequently on their risk of becoming hypertensive)and any association between the WTP and socio-demographic and clinical factors.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
1. Willingness to engage with the pre-hypertension concept and the self-monitoring intervention, assessed using the number and proportion of services and patients/people approached expressing an interest in taking part at the time of recruitment
2. Acceptability of the intervention and study processes, assessed using service provider and participant interviews after 6 month follow up, covering:
2.1. Opinions and experiences of the study, study processes, and the intervention
2.2. Barriers and facilitators to SM
2.3. Suggested changes and improvements
2.4. Ease of integration into current practice

Secondary outcome measures
1. Recruitment rates of participants and service providers:
1.1. Proportion of sites enrolled and actively recruiting
1.2. Time taken to recruit the target sample
1.3. Proportion of people who are eligible and proportion who consent to take part
Measured during the recruitment period
2. Attrition rates and completeness of data:
2.1. Proportion of people who attend each study timepoint
2.2. Number withdrawing definitively, and from just the intervention
2.3. Reasons for withdrawal
2.4. Proportion of missing data
Measured throughout the study
3. Protocol adherence:
3.1. Number, frequency and timing of self-monitored readings
3.2. Correct action taken each month
3.3. Accuracy of recorded readings

3.4. Reasons for non-adherence
Measured at 6 month follow up
4. Fidelity of the intervention:
4.1. Competency assessments for HCP recruitment process during the recruitment period
4.2. Competency assessments for research team training delivery during baseline sessions
4.3. Number of participants deemed as competent to self-monitor during baseline sessions
4.4. Proportion of appropriate home readings entered into GP clinical systems after 6 month follow up
5. Incidence and impact of any unexpected negative consequences (UNC):
5.1. Health anxiety assessed using the Health Anxiety Inventory (HAI) short version score at baseline, 6 and 12 months
5.2. Depression assessed using the Patient Health Questionnaire (PHQ) at baseline, 6 and 12 months
5.3. Health care utilisation including consultations, medications and referrals attributable to the intervention at baseline, 6 and 12 months
5.4. Quality of life assessed using the EQ5-D at baseline, 6 and 12 months
6. Willingness to pay regarding self-monitoring assessed using a self-developed willingness to pay questionnaire at 6 months
7. Extent SM encourages lifestyle modification assessed using:
7.1. Simple lifestyle Indicator Questionnaire (SLIQ) score at baseline, 6 and 12 months
7.2. Risk perception score assessed using an adapted questionnaire by Kaufman et al (2020) at baseline, 6 and 12 months
7.3. Determinants of Lifestyle Behaviour Questionnaire (DBLQ) score at baseline, 6 and 12 months
7.4. Illness perceptions assessed by score on the Illness perception Questionnaire - Brief at baseline, 6 and 12 months
7.5. Health locus of control assessed by score on the Multidimensional Health Locus of Control (MHLC) at baseline, 6 and 12 months
8. Acceptable content and procedures of a future lifestyle intervention assessed using a participant and service provider focus group to co-design a potential lifestyle intervention at post 12 month follow up

Overall study start date
01/10/2021

Overall study end date
31/03/2024

Eligibility

Participant inclusion criteria
1. Aged 18 years and over with no upper age limit
2. Blood pressure between 120-139 mmHg systolic and/or 80-89 mmHg diastolic
3. No previous diagnosis of hypertension

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 114; UK Sample Size: 114

Participant exclusion criteria
1. Prescribed anti-hypertensive medication
2. Previous stroke or myocardial infarction
3. Pregnancy
4. Currently actively self-monitoring blood pressure
5. Life-limiting illness

Recruitment start date
15/06/2022

Recruitment end date
24/01/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Central Lancashire
School of Nursing
Faculty of Health and Well-being
Preston
United Kingdom
PR1 2HE

Sponsor information

Organisation
University of Central Lancashire

Sponsor details
Prof St John Crean
Ethics and Integrity Unit

Room 033, Foster Building
Preston
England
United Kingdom
PR1 2HE
+44 (0)1772 895583
IRASSponsor@uclan.ac.uk

Sponsor type
University/education

Website
http://www.uclan.ac.uk/

ROR
https://ror.org/010jbqd54

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR201028

Results and Publications

Publication and dissemination plan
Planned publications in high impact peer-reviewed journals including a protocol paper by December 2022, an article in The Conversation by December 2022, and papers disseminating the main results of the study by 1 year after the overall trial end date (March 2025)

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository UCLan Data (http://uclandata.uclan.ac.uk/) and will also be available upon considered request from Dr Emma Bray (EBray@uclan.ac.uk). An anonymous research dataset will be shared including quantitative and qualitative data at the end of the project (March 2024) and available indefinitely. Data will be freely available for researchers at UCLan. Access by external organisations/ individuals may be allowed under a defined protocol, for secondary research purposes. This will be managed through a standard access request process. Consent from participants will be obtained. All data shared on UCLan Data will be anonymous. Data will not be shared for market research purposes.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		31/05/2023	01/06/2023	Yes	No
HRA research summary			28/06/2023	No	No