ISRCTN17647940 https://doi.org/10.1186/ISRCTN17647940

Comparing treatments for high blood pressure in older patients with more than one chronic illness

Submission date
24/11/2020

Recruitment status
No longer recruiting

Registration date
01/12/2020

Overall study status
Completed

Last Edited
31/01/2025

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
People are living longer and older adults often have several long-term health conditions or have to take many different types of medication as well as being treated for raised blood pressure. Currently doctors are unsure of the best way to control blood pressure in these patients, particularly in patients where blood pressure is not very high. There are a number of different types of medication available to lower blood pressure but is it better for a patient for doctors to more intensely manage blood pressure by prescribing additional types of medication or would prescribing fewer types of medication lead to fewer side effects and better health? In this pilot study the aim is to recruit 200 older adults and compare how these two options affect blood pressure and ensure that the safety of participants is not adversely affected by either option. Older people who do suffer from several long-term health conditions may be less likely to want to travel to research centres to take part in research trials so this study is also testing the feasibility of recruiting and managing participants remotely without the need to attend study centres. The study has been designed to enable participants to be recruited and monitored from home and this is made possible by a computer system designed specifically for the trial which participants are able to access at home from any device (smartphone, PC or tablet) which allows them to enter information and contact the research team.
The results from this pilot study will be used to plan a larger, multi-centre, international study with sufficient participant numbers to show if the changes made to blood pressure medications work.

Who can participate?
Adults living in the Thames Valley area, aged 64 and over who have three or more long-term health conditions OR are taking at least five different types of medication in addition to any being taken to reduce blood pressure.

What does the study involve?
Participants are identified in one of two ways. They may be customers of the online pharmacy Pharmacy 2U who consent to be contacted by the research team, or they may be identified as potentially eligible by NHS Digital. In both scenarios, the potential participant will receive an

invitation letter outlining the study and providing user details to allow them to complete a preliminary eligibility questionnaire online.
Participants who meet the initial eligibility criteria are offered the opportunity to participate in the study. After consent they enter a run-in period where the research team further checks their eligibility. This includes a visit to the home by a clinician who will collect a blood sample and collect any additional information required. Participants are provided with a blood pressure monitor, are given instructions on how to use it and are asked to record their blood pressure daily. These readings can then be entered on the specially designed computer system.
Information entered from home on the computer system is then available to the study team to review. The system also allows participants to enter other details about their health and medications on an ad-hoc basis and at timed intervals when specific health questionnaires will be provided to participants.
When a participant's eligibility is confirmed, the participant is randomly allocated to one of two groups. The first group will receive up to two extra types of blood pressure medication and the second group will receive up to two fewer types of blood pressure medication. The research team are responsible for managing the blood pressure medications of participants and they will increase or decrease the number of types of medications each participant is taking based on the treatment group they are allocated to and their medical history (including known intolerance to medications and possible interactions with other medications being taken). Participants are asked to continue to record their blood pressure at least weekly and report changes to their health and medications via the computer system. Additional blood samples may be required in which case, the clinician will visit the participant in their home to collect the sample(s). The research team will review their blood pressure medications every 4 weeks and adjust medications as required until the end of study participation which may vary by participant but is likely to be around 6 months.

What are the possible benefits and risks of participating?
It is not known if changing the number of medications prescribed to participants will result in a significant change in blood pressure, which is why the research is being done. There may not be any direct benefits to participants but there is the possibility that changes made to blood pressure medications during the study will help to improve overall health and wellbeing. There should be benefits to future patients as the study results will help to develop better ways to manage blood pressure in older people.
The main risks of taking part are changes in blood pressure which may lead to symptoms associated with low blood pressure such as dizziness and an increased risk of falling or high blood pressure, which could increase the risk of suffering a heart attack or stroke. Participants will provide regular blood pressure measurements from home which will allow the research team to closely monitor blood pressure and make changes to blood pressure medications if they are concerned about any adverse changes in blood pressure or reported symptoms.

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

When is the study starting and how long is it expected to run for?
April 2019 to August 2022

Who is funding the study?
National Institute of Health Research (NIHR) Oxford Biomedical Research Centre and Oxford Martin School (UK)

Who is the main contact?
Prof. Kazem Rahimi
kazem.rahimi@wrh.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Kazem Rahimi

ORCID ID
https://orcid.org/0000-0002-4807-4610

Contact details
Nuffield Department of Women's & Reproductive Health
University of Oxford
Level 3
Women's Centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 610297
kazem.rahimi@wrh.ox.ac.uk

Type(s)
Public

Contact name
Mrs Debbie Hedgecott

Contact details
Nuffield Department of Women's & Reproductive Health
University of Oxford
Level 3
Women's Centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 610297
debbie.hedgecott@wrh.ox.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
284172

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 284172

Study information

Scientific Title
Feasibility and efficacy of a home-based randomized intervention of up to two classes of anti-hypertensive medications versus up to two fewer classes of anti-hypertensive medications among older patients with multimorbidity or polypharmacy

Acronym
ATEMPT

Study objectives
An intervention that is designed to remotely change participants' medications and deliver them to their homes is feasible and leads to a 10-mmHg difference in systolic blood pressure among treatment groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/09/2020, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048127; gmsouth.rec@hra.nhs.uk), REC ref: 20/NW/0344

Study design
Single-centre interventional two-armed parallel-group partially blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Blood pressure treatment in older, multimorbid patients

Interventions
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NHS Digital as potentially eligible. In both scenarios, the potential participant will receive an invitation letter outlining the study and providing user details to allow them to complete a preliminary eligibility questionnaire online.

Participants who meet the initial eligibility criteria are offered the opportunity to participate in the study and after consent they enter a run-in period where their eligibility is further checked by the research team and this includes a visit to the home by a clinician who will collect a blood sample and collect any additional information required. Participants are provided with a blood pressure monitor, given instructions on how to use and asked to record their blood pressure daily, these readings can then be entered on the specially designed computer system. Information entered from home on the computer system is then available to the study team to review. The system also allows participants to enter other details about their health and medications on an ad-hoc basis and at timed intervals when specific health questionnaires will be provided to participants.

When a participants' eligibility is confirmed, the participant is randomly allocated to one of two groups. The first group will receive up to two extra types of blood pressure medication and the second group will receive up to two fewer types of blood pressure medication. The research team are responsible for managing the blood pressure medications of participants and they will increase or decrease the number of types of medications each participant is taking based on the treatment group they are allocated to and their medical history (including known intolerance to medications and possible interactions with other medications being taken). Participants are asked to continue to record their blood pressure at least weekly and report changes to their health and medications via the computer system. Additional blood samples may be required in which case, the clinician will visit the participant in their home to collect the sample(s). The research team will review their blood pressure medications every 4 weeks and adjust medications as required until the end of study participation which may vary by participant but is likely to be around 6 months.

Intervention Type
Other

Primary outcome(s)
Modelled difference in mean change in systolic blood pressure from baseline to end of study between treatment groups and cumulative time-weighted difference in systolic blood pressure between treatment groups, as measured by participants themselves at home using a blood pressure monitor on a weekly basis

Key secondary outcome(s))
1. Counts of each anti-hypertensive drug class for each participant and the average daily dose of all anti-hypertensive drugs for each participant, measured at monthly intervals throughout the study
2. Serious adverse events as measured by the incidence of serious adverse events and selected non-serious adverse events with information collated directly from participants and central databases throughout the study
3. Acceptability and tolerability of the intervention measured using participant completed health questionnaires (EQ-5D-5L), measures of frailty (PRISMA 7) and drug compliance and a researcher assessment of cognitive function (T-MoCA) completed every 3 months for the duration of the study

Completion date

31/08/2022

Eligibility

Key inclusion criteria
1. Age 65 years or more
2. Having at least three chronic diseases or taking at least five non-antihypertensive drugs
3. Baseline office systolic BP in the range of 115-165 mmHg (or home systolic BP of 110-160 mmHg)
4. Willingness to have anti-hypertensive medication modified (increased, decreased or left unchanged) by trial team for the duration of the trial
5. Willingness to register with the specified on-line pharmacy service to facilitate remote dispensing of anti-hypertensive medication and period sharing of participants prescription list
6. Willingness and ability to monitor BP at home
7. Participant is willing and able to give informed consent for participation in the trial
8. Participant's or carer's ability to understand English language is required to operate the IT-enabled (web-based) system

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Sex
All

Total final enrolment
230

Key exclusion criteria
1. Previous admission to hospital with primary diagnosis of heart failure or known systolic heart failure
2. Self-reported symptomatic orthostatic hypotension
3. Pre-existing anti-hypertensive treatment, or baseline BP prohibit the achievement of the minimum required change in anti-hypertensive drugs defined as:
3.1. Office systolic BP 155 to 165 mmHg and on three or more anti-hypertensive medications
3.2. Office systolic BP 115 to 124 mmHg and no anti-hypertensive medications
4. Routine use of a dosset box or NOMAD box to help manage medications
5. No reliable 4G mobile or WiFi network connectivity at home
6. Lack of uncertainty in the opinion of the Investigator for changing BP drug treatment (e.g., any other significant disease, which, in the opinion of the Investigator, may either put the

participant at risk because of participation in the trial, or the participant's ability to participate in the trial)
7. Current participation in any other research trial that investigates blood pressure management

Date of first enrolment
15/12/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Oxford
Nuffield Department of Women's & Reproductive Health
University of Oxford, Level 3
Women's Centre, John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
NIHR Oxford Biomedical Research Centre

Funder Name
Oxford Martin School, University of Oxford

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Kazem Rahimi (kazem.rahimi@wrh.ox.ac.uk) for academic research. Data will be made available after a proposal is shared and an assessment of scientific merit and work involved in making data available has been made.

IPD sharing plan summary
Available on request, Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2023	16/08/2023	Yes	No
Results article		01/03/2024	31/01/2025	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes