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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
24/11/2020		Protocol		
Registration date	Overall study status	Statistical analysis plan		
01/12/2020	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
31/01/2025	Circulatory System			

#### 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**

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#### Type(s)

Public

#### Contact name

Mrs Debbie Hedgecott

#### Contact details

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# 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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#### 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

# **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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes