ISRCTN12069204 https://doi.org/10.1186/ISRCTN12069204

Exploring why people with high blood pressure and other long-term conditions may not take their blood pressure medication and how to help them

Submission date
20/02/2025

Recruitment status
Not yet recruiting

Registration date
12/05/2025

Overall study status
Ongoing

Last Edited
04/07/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and aims
People who take medications to lower their blood pressure often struggle to take these medications regularly; this is called medication nonadherence. This can be due to a variety of reasons, including worries about side effects, forgetfulness or difficulties in managing conditions. This means that these people may be at higher risk for future heart problems. People with low medication adherence often struggle to talk to their doctor about it, and so the doctor is not aware. The aim of this study is to explore the use of a new test to investigate medication-taking behaviours and the feasibility of detecting medications in urine. By doing this we can support patients and make sure that they are receiving the best care possible.

Who can participate?
Adults aged 18 years or over, who have been diagnosed with high blood pressure and are receiving at least three prescribed medications for high blood pressure (including at least one for over a year), and have one other relevant long-term condition e.g., diabetes, heart disease. The researchers will also conduct a smaller interview-based study within this study, including both patients and healthcare professionals. The patient group will be adults aged 18 years or over, who have been diagnosed with high blood pressure and are receiving at least three prescribed medications for high blood pressure (including at least one for over a year). Healthcare professionals will be those involved in the management of patients with high blood pressure.

What does the study involve?
For the main study, a single visit will occur following attendance at a routine appointment. The data the researchers will collect includes:
1. Anthropometric data: height, weight, and Body Mass Index (BMI).
2. Demographic data: age, sex, ethnicity, postcode, smoking status, current medications and conditions, first spoken language, religion and highest educational status attained.
3. Biomedical data: blood pressure, cholesterol and lipids, glycated haemoglobin (a long-term

measure of blood sugar for those with diabetes), and measures of kidney function.
4. Medication data: all prescribed medications for high blood pressure and other conditions.
5. Questionnaires: three questionnaires to measure quality of life, levels of anxiety and depression, and medication adherence.
A urine sample will be taken to be sent for chemical adherence testing to detect the presence or absence of prescribed medications for high blood pressure.
For participants of the sub-study, the researchers will conduct one interview or focus group discussion to investigate attitudes and perceptions towards the use of chemical adherence testing, and anything relevant to its use in the future.

What are the possible benefits and risks of participating?
Taking part in this research study could potentially benefit other people with high blood pressure by providing information on how best to support them in taking their medications regularly. The results could lead to improved medical treatments and care in the future.

Where is the study run from?
The study is being run by the Leicester Diabetes Centre, at the University of Leicester, UK. Data collection for the main study will occur in participating GP practices, whilst the sub-study will be conducted either in person at the Leicester Diabetes Centre or virtually.

When is the study starting and how long is it expected to run for?
November 2024 to June 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Patrick Highton, ph204@le.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
350792

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 65050, Grant Code: NIHR303176

Study information

Scientific Title
Assessing patterns, barriers and facilitators of antihypertensive medication non-adherence in diverse populations with multiple long-term cardiometabolic conditions (CAT-BP)

Acronym
CAT-BP

Study objectives
The overall aim of this project will be to investigate the acceptance, uptake and outcomes of chemical adherence testing (CAT) for assessing adherence to antihypertensive medications in those from ethnically diverse populations and socioeconomically deprived areas.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2025, Yorkshire and the Humber – South Yorkshire REC (postal address: not available; +44 (0)207 104 8021, +44 (0)2071048075; southyorks.rec@hra.nhs.uk), ref: 25/YH/0036

Study design
Observational; Design type: Cross-sectional

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
GP practice

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Cardiometabolic conditions

Interventions
There will be two main elements to this study – a cross-sectional observational study conducted in primary care practices, and a qualitative study. This will allow both the collection of adherence rates, factors that are associated with adherence status and process measures (such as recruitment rates and barriers to recruitment) from the observational study element and data relating to perceptions and acceptability of CAT for testing adherence to antihypertensive medications in both patients and healthcare professionals and barriers and facilitators to medication adherence from the qualitative study. Combining these study elements and data sources will therefore give a strong evidence base on which to both support future equitable implementation of CAT and also the development of a new intervention and trial to investigate how to support increased medication adherence in these populations. Participation in the qualitative study will be open to both people who have already participated in the observational study and those who haven't, to explore if direct experience of the test influences perceptions. The inclusion of healthcare professionals in the qualitative study will allow the investigation of any system-level barriers and/or facilitators.

Participation in the observational study will require only a single visit completed after the attendance at a routine healthcare appointment and will involve:
1. Provision of informed consent
2. Provision of a urine sample for chemical adherence testing
3. Completion of three questionnaires, either on paper or online
4. Allowing the research team to access the electronic healthcare record to collect anthropometric, demographic, biomedical and medication data

Participation in the qualitative study will involve:
1. Provision of informed consent
2. Participation in a single semi-structured interview (~30 mins) or focus group discussion (~45-60 mins). Interviews can be completed online, over the phone or in person, whilst focus group discussions will be completed in person at the Leicester Diabetes Centre.

An estimated 114 participants from an estimated 6 primary care practices will be recruited to the observational study. An estimated 32-36 participants (20-24 patients, 12 healthcare professionals) will be recruited for the qualitative study. It is estimated that 10-12 participants in the qualitative study will be those who have already participated in the observational study.

Potential participants of the observational study will be approached opportunistically by members of the research team after their routine appointment having indicated interest in participating to their usual care team. They will also be given the option to consent to be contacted regarding participation in the qualitative study at this time.

Potential participants of the qualitative study who were not previous participants in the observational study will be recruited via a number of channels, including:
1. Recruitment from other GP practices not involved in the observational study
2. Study posters placed in community venues and researcher attendance at relevant community

and health events
3. Centre for Ethnic Health Research (CEHR): Staff from the CEHR will be asked to display posters in community and faith centres and to circulate them to their local networks and groups.
4. Research database: Participants of previous research studies delivered by the Leicester Diabetes Centre who have consented to be contacted for future research studies will be contacted. Social media posts, including the study poster, through various platforms including X (Twitter), Facebook and LinkedIn. Existing local patient and community social media groups will also be contacted via social media.
5. Snowball sampling: those contacted by the methods above will also be able to share the details of other eligible patients who are interested in taking part with the study team.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Medication adherence status to antihypertensive medications, identified using chemical adherence testing (CAT) at baseline

Secondary outcome measures
1. Blood pressure, measured in clinic using a sphygmomanometer at baseline
2. Blood lipids, obtained from electronic healthcare records at baseline
3. HbA1c (in people with diabetes), obtained from electronic healthcare records at baseline
4. eGFR, obtained from electronic healthcare records at baseline
5. Urine albumin-to-creatinine ratio (ACR), obtained from electronic healthcare records at baseline
6. Quality of life, assessed using the EQ-5D-5L at baseline
7. Depression and anxiety, assessed using the Hospital Anxiety and Depression Scale (HADS) at baseline
8. Self-reported antihypertensive medication adherence, assessed using the Hill Bone Compliance to High Blood Pressure Therapy Scale at baseline
9. Weight, height and body mass index (BMI), measured directly at baseline
10. Demographics and equality data, asked directly to the participant at baseline: age, sex, ethnicity, index of multiple deprivation, smoking status, first spoken language, religion, highest education attained, home blood pressure monitoring status
11. Prescribed antihypertensive medications, assessed using electronic healthcare records at baseline
12. Total number of current repeat prescriptions, obtained from electronic healthcare records at baseline
13. Diagnosis of other conditions, including CKD, CVD, diabetes, heart failure and depression, obtained from electronic healthcare records at baseline
14. Previous number of ‘Did Not Attend’ instances, obtained from electronic healthcare records at baseline
15. Recruitment rates, key demographic factors of those recruited vs not recruited, identification of any barriers to recruitment assessed via study documents
16. Barriers, facilitators and attitudes towards antihypertensive medication adherence and chemical adherence testing assessed using either 1:1 semi-structured interviews or focus groups at a follow-up visit

Overall study start date
15/11/2024

Completion date
30/06/2027

Eligibility

Key inclusion criteria
Inclusion criteria for observational study:
1. Adults (aged >=18 years)
2. Receiving a prescription for >=3 antihypertensive medications, at least one of which has been prescribed for over a year
3. Displaying signs of uncontrolled hypertension (BP >140/90 mmHg), an indicator of medication nonadherence
4. With cardiometabolic MLTCs (hypertension plus at least one of diabetes, chronic kidney disease (CKD – stage G3A1 and above), CVD or heart failure)
5. Willing and able to consent to participate in the study

Inclusion criteria for qualitative study:
For the qualitative study, inclusion criteria for patients will be:
1. Adults (aged >=18 years)
2. Receiving a prescription for >=3 antihypertensive medications, at least one of which has been prescribed for over a year
3. Willing and able to consent to participate in the study
4. Access to information technology (if required to participate in remote interviews)
5. Ability to understand English (for focus group attendance only)

For HCPs participating in the qualitative study, the inclusion criteria will be:
1. Nurses, doctors, pharmacists and other HCPs from primary care involved in the management of patients with hypertension
2. Participant is willing and able to give informed consent to participate in the study
3. Participant is able (in the Investigators opinion) and willing to fulfil all the study requirements
4. Access to information technology (if required to participate in remote interviews)

Participant type(s)
Patient, Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150 (114 in observational study, 36 in qualitative study)

Key exclusion criteria
Exclusion criteria for observational study:
1. Coded as terminally ill, housebound or in residential care
2. Unable to understand a language in which it is possible to provide the study material or support understanding of the study through the assistance of an interpreter

Exclusion criteria for qualitative study:
For the qualitative study, the exclusion criteria for patients will be:
1. Coded as terminally ill, housebound or in residential care
2. No access to information technology (if required to participate in remote interviews)
3. Unable to understand English (for focus group attendance only)

For HCPs participating in the qualitative study, the exclusion criteria will be:
1. Not involved in the care or management of patients with hypertension
2. No access to information technology (if required to participate in remote interviews)

Date of first enrolment
15/08/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leicester
Leicester Diabetes Centre
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
East Midlands RRDN
Leicester Royal Infirmary
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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name
NIHR Academy

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2028

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date