ISRCTN56336493 https://doi.org/10.1186/ISRCTN56336493

Home monitoring and self-management of blood pressure in chronic kidney disease

Submission date
04/05/2023

Recruitment status
No longer recruiting

Registration date
09/05/2023

Overall study status
Ongoing

Last Edited
10/05/2024

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Chronic kidney disease (CKD) is a long-term disease resulting in the kidneys not functioning properly. Kidneys filter the blood, removing toxins and waste products, to keep us healthy. Most people do not develop symptoms until kidney function is very low – this is called end-stage kidney disease (ESKD) and requires dialysis treatment or a kidney transplant. Any drop in function (assessed by blood and urine tests) is associated with an increased risk of heart disease, strokes, ESKD and early death. One of the most important ways to reduce this risk is by measuring people's blood pressure (BP) regularly and lowering high BP (often associated with CKD) to the optimal level with tablets. Achieving this in practice may be difficult because people with CKD usually require more tablets than others. Research has shown that BP in people with CKD is often above the recommended level. New international CKD guidelines recommending a lower BP target of less than 120 mmHg (based on research including main people with mild CKD) make this more challenging. It is unclear whether this is achievable in people with more severe CKD and whether it will be associated with negative effects, including excessively low BP, falls or reduced kidney function. This study aims to establish whether people measuring BP at home, supported to increase BP tablets themselves, is achievable without negative effects in people with CKD looked after in hospital clinics; establish whether a questionnaire to measure the way people view and understand their CKD works as part of the study; and, to use interviews with participants to obtain feedback on the intervention study.

Who can participate?
Adults aged 18 years old and over with CKD looked after in a hospital kidney clinic in Derby who have a BP of greater than 120mmHg (the top number in BP) or 130mmHg if diabetic

What does the study involve?
The study starts with an eligibility assessment involving a standardised BP measurement where an average of 3 readings are taken to establish if BP is not too low to be included in the trial. After informed consent, participants will be randomly assigned to either start measuring their BP at home and kidney clinic care or to just continue with normal kidney clinic care.

Study:
If assigned to the self-management group, participants will discuss with a doctor from the

research team and decide on a BP target (120 or 130mmHg “top number”) and be shown how to use the home BP monitor that they will keep. Together a plan will be agreed plan for participants to increase the doses of or add additional BP medications if their BP is over the agreed target for two consecutive months (one week of readings each month) using a colour-coded guide.

All participants will be followed up for one year with research visits at recruitment, 6 and 12 months. Blood and urine tests, a BP check and a questionnaire will be completed at each visit for all participants. Participants in the self-management group will also have a follow-up phone call at 2 months and support from the study team will be available throughout.

After six months ten to fifteen people who have self-managed their BP in this study (intervention group) will be invited to be interviewed about their experience of the study.

What are the possible risks and benefits of participating?
This study aims to find a sustainable way to reduce BP for patients with CKD. We know from previously published research that lower BP has benefits for heart disease, strokes and reducing the risk of kidney function getting worse. The data we obtain from the study may help us gain a greater understanding of how home BP monitoring can be used for patients with kidney disease, and could potentially help us monitor patients better or improve treatments for other patients in the future.

The risks of taking part in the study are mainly related to symptoms from your BP becoming too low. Low BP can make people feel dizzy, and in serious cases, this may make people fall. Some medications that we use for BP can affect the salts (electrolytes) in your blood and we would routinely recheck blood tests after increasing some medications. In medication plans, we will arrange blood tests if these are required. The main risk is an increase in a salt called potassium, if this is high participants may need to attend the hospital for a repeat blood test or even admission. Any potential side effects will be recorded by the study team and also any hospital admissions.

Where is the study run from?
The Centre for Kidney Research and Innovation (CKRi) research team at Royal Derby Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2021 to December 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR), as part of Dr Bethany Lucas’ NIHR Doctoral fellowship (NIHR 302626) (UK)

Who is the main contact?
Dr Bethany Lucas, Bethany.lucas1@nottingham.ac.uk

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
321439

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55643, IRAS 321439

Study information

Scientific Title
Self-Management and Realisation of Target Blood Pressure in Chronic Kidney Disease (SMaRT BP CKD)

Acronym
SMaRT BP CKD

Study objectives
An intervention based on home monitoring and self-titration of medication previously evaluated in primary care with the addition of the Revised Illness Perception Questionnaire (IPQ-R) at study visits can be adopted in participants with chronic kidney disease (CKD) in secondary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/04/2023 (East Midlands - Nottingham 2 Research Ethics Committee, Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8169, (0)2071048035, (0)20 71048016; nottingham2.rec@hra.nhs.uk), ref: 23/EM/0076

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital, Internet/virtual, Telephone

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Renal and urogenital

Interventions
Recruitment
•Potentially eligible participants will be identified using medical records (Vital Data renal system) and nephrology outpatient clinic lists. Potential participants will be posted a cover letter and PIS detailing the study. They will be advised to either contact the research team or be contacted 2 days after receipt of the information to assess interest.
•If interest is expressed an eligibility assessment and potential baseline visit will be arranged. In line with PPIE group feedback, the research team will endeavour to align this with existing outpatient appointments to minimise travel and disruption.

Eligibility assessment
•To establish if standardised blood pressure is over the target – which although recommended, is not routinely measured in outpatient clinics, potential participants will be asked to verbally consent to a standardised blood pressure reading.
•Standardised blood pressure will be taken in line with European Society of Cardiology (ESC) guidelines (>5 minutes of rest, caffeine, exercise and smoking avoided 30 minutes prior to measurement and an average of 3 readings taken.)
•If standardised BP is over the target (120mmHg or 130mmHg systolic) for higher-risk or diabetic participants they will be invited to take part.
Informed written consent will then be taken in line with GCP guidance.

Randomisation
•Participants will be randomised using web-based software provided by Debry CTSU to either the usual care or self-management (intervention) arm in a 1:1 distribution.

Self-monitoring arm
Baseline visit:
Demographic data recorded
Past medical history
Medication history
Standardised BP
Lying and standing BP
Blood and urine tests
Revised Illness Perception Questionnaire (IPQ-R)
Demonstration of home blood pressure machine and record
Agreement on titration plan and blood pressure target

Month 1
Participants record blood pressure at home twice a day for a week and record blood pressure readings

Month 2
Participants record blood pressure at home twice a day for a week and record blood pressure readings.
Investigator team to call participants when they are due to titrating medications to offer

additional support if required
Every 2 months participants increase/change medication as per the pre-agreed plan if ≥4 home blood pressure readings are >120mmHg systolic or >130mmHg depending on the set target. This continues until the 12-month follow up

Month 6 - follow up visit
Demographic data recorded
Past medical history
Medication review
Standardised BP
Review and record home BP readings
Lying and standing BP
Blood and urine tests
IPQ-R
Review of titration plan and medication changes
Invitation to participate in a semi-structured interview (n=15) and separate PIS and consent form

Month 6-12
Semi-structured interviews for those who have consented

Month 12 - follow up visit
Demographic data recorded
Past medical history
Medication review
Standardised BP
Review and record home BP readings
Lying and standing BP
Blood and urine tests
IPQ-R
End of study

Standard care arm
Baseline visit
Demographic data recorded
Past medical history
Medication history
Standardised BP
Lying and standing BP
Agreement of blood pressure target recorded
Blood and urine tests
IPQ-R
Continued clinical OP CKD care

Month 6
Demographic data recorded
Past medical history
Medication review
Standardised BP
Lying and standing BP
Blood and urine tests
IPQ-R

Month 12
Demographic data recorded
Past medical history
Medication review
Standardised BP
Lying and standing BP
Blood and urine tests
IPQ-R
End of study

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Feasibility outcomes:
Adherence to the intervention will be measured at 6 months and 12 months using patient/study medical notes:
1. Number of escalations of treatment (dose increase or additional agent) in 12 months
2. The proportion of participants who have any escalation in their antihypertensive therapy
3. Number of home blood pressure readings taken by participants in the intervention arm
4. Study visit completion rates
5. Response rates to the Revised Illness Perception Questionnaire (IPQ-R)
6. Proportion of eligible participants willing to be randomised – measured using screening log

Secondary outcome measures
Clinical outcomes measured using patient/study medical notes:
1. Change in standardised office systolic BP between baseline, 6 and 12 months
2. Proportion of participants who achieve KIDGO systolic BP target <120mmHg
3. Change in IPQ-R scores over 12 months in participants (measured at baseline, 6 months and 12 months)

Safety outcomes:
Incidence of adverse events such as symptomatic hypotension, syncope, falls, AKI, electrolyte abnormalities, changes in eGFR or albuminuria – through CRF hospital admissions, self-reported AEs and blood and urine tests measured at 6 and 12 months.

Overall study start date
04/10/2021

Completion date
01/12/2025

Eligibility

Key inclusion criteria

1. Capable of giving informed consent
2. >=18 years
3. Chronic kidney disease stages 1-4 looked after in secondary care nephrology
4. Standardised office systolic BP >120 mmHg or >130 mmHg with diabetes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment
58

Key exclusion criteria
1. Evidence of postural hypotension defined as standing BP < 110mmHg, significant postural drop in BP (> 20mmHg) or patient reported symptoms
2. Currently taking > = 4 antihypertensive medications – due to limited scope to up titrate medication.
3. Memory impairment or dementia – such that would prevent the ability to self- monitor and manage medication safely.
4. Pregnancy or breastfeeding or intending pregnancy in trial period – due to different BP targets and medication used in hypertension during pregnancy and limitations on drugs used.
5. Estimated date of requiring dialysis (EDD) within the next 6 months – this is due to the increased risk of side effects and electrolyte abnormalities in titrating medication in this group and the likelihood of completing the 12 month follow up period (most anti-hypertensives are stopped once participants commence dialysis).
6. Renal transplant recipients

Date of first enrolment
14/06/2023

Date of final enrolment
10/05/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
University Hospitals of Derby and Burton NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.uhdb.nhs.uk/

ROR
https://ror.org/04w8sxm43

Funder(s)

Funder type
Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal and dissemination in national and international nephrology conferences by one year after trial completion. Results from the study will also form part of Bethany Lucas' PhD thesis.

Intention to publish date
01/12/2026

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. The final dataset will be limited to the Chief Investigator and co-investigators as well as authorised sponsor personnel and statisticians from the University of Nottingham Digital Research service. External investigators will be required to submit a formal request to the sponsor for access to data at uhdb.sponsor@nhs.net.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	12/04/2023	09/05/2023	No	Yes
Participant information sheet	version 1.1	12/04/2023	09/05/2023	No	Yes