ISRCTN11042045 https://doi.org/10.1186/ISRCTN11042045

Self-management of blood pressure following a hypertensive pregnancy

Submission date
17/05/2024

Recruitment status
Recruiting

Registration date
11/06/2024

Overall study status
Ongoing

Last Edited
11/06/2024

Condition category
Circulatory System

[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
High blood pressure (BP) (hypertension) during and following pregnancy affects around 80,000 women each year in the UK, and can lead to very serious problems such as pre-eclampsia or stroke. In the longer term, women who had high BP during pregnancy have an increased risk of heart attack and stroke, and this seems to be linked to their blood pressure in the early weeks following birth.
After birth, women's BP can remain elevated, but in most cases it returns to normal over 2–12 weeks. During this time, blood pressure medication needs to be adjusted to achieve the correct control. Previous research suggests that better BP control during this time is associated with improved long-term health outcomes. This trial aims to test whether women with high BP, can achieve lower blood pressure than is usual in the weeks and months following birth, through self-monitoring and adjusting their own medication.

Who can participate?
Women aged 18 years or over in the postnatal period who have had a hypertensive pregnancy

What does the study involve?
Women recruited to the study will be randomly assigned to one of two groups: either monitoring their own blood pressure and using this to manage their blood pressure medication, or receiving the standard care that they would otherwise have. Participants allocated to 'usual care' will have their BP monitored and medication adjusted by their obstetrician, GP and midwife as normal. Participants allocated to the 'self-management' group will use a home BP monitor daily following discharge from hospital after birth until their blood pressure has settled, and then once a week. They will be provided with an individualised schedule (via a specially designed app) for gradually adjusting their medication(s) in line with their BP readings, overseen by their obstetrician, GP and midwife.

What are the possible benefits and risks of participating?
Taking part in the study may give participants better information and understanding about their blood pressure. If possible, it is hoped that achieving better blood pressure control in the period after birth may contribute to better long-term health outcomes. However, the study is being conducted as it is not clear if medication adjustments (facilitated by the app and directed by

clinicians' review) can achieve better blood pressure control than standard care.
It is hoped that information from this work will improve the care of women with raised blood pressure after birth in the future. The researchers think there is very little risk of harm in taking part.
All women will still receive their usual care while in this study. The only disadvantage is the extra time taken to measure blood pressure for women allocated to the self-management group and the additional time spent with the study team at the follow-up visits. Other than the time taken to undertake the study, we do not anticipate any other disadvantage from taking part.

Where is the study run from?
University of Oxford - Primary Care Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
July 2023 to December 2026

Who is funding the study?
NIHR - Programme Grants for Applied Research (UK)

Who is the main contact?
SNAP2 Trial Manager, snap2trial@phc.ox.ac.uk

Study website
https://www.phctrials.ox.ac.uk/studies/snap2

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof RIchard McManus

ORCID ID
http://orcid.org/0000-0003-3638-028X

Contact details
Nuffield Dept Primary Care Health Sciences
RPC Building
Woodstock Road
Oxford
United Kingdom
OX2 6GG
+44 (0)1865 617852
snap2trial@phc.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
332333

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 59560, IRAS 332333

Study information

Scientific Title
Randomised controlled trial of self-management of postnatal antihypertensive treatment

Acronym
SNAP2

Study objectives
Self-management of blood pressure reduces diastolic blood pressure following a hypertensive pregnancy

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/05/2024, South Central - Oxford B Research Ethics Committee (Bristol Research Ethics Committee Centre, Whitefriars Level 3, Block B Lewin's Mead, Bristol, BS1 2NT, United Kingdom; +44 (0)207 104 8178; oxfordb.rec@hra.nhs.uk), ref: 24/SC/0071

Study design
Multicentre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital

Study type(s)
Efficacy

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

Health condition(s) or problem(s) studied
Monitoring of hypertension in women following hypertensive pregnancy

Interventions
Women recruited to the study will be randomly assigned to one of two groups: either monitoring their own blood pressure and using this to manage their blood pressure medication, or receiving the standard care that they would otherwise have.

Participants allocated to the 'self-management' group will use a validated monitor and titration of antihypertensive therapy guided by a specially developed digital intervention (a smartphone app), daily following discharge from hospital after birth until their blood pressure has settled, and then once a week. They will be provided with an individualised schedule via the app for gradually adjusting their medication(s) in line with their BP readings. This will be overseen, with any change approved by their own health care professionals who review the uploaded readings and respond to tele-monitored abnormal readings in a timely fashion. All intervention participants will in addition receive usual NHS care.

Participants allocated to 'usual care' will have their BP monitored and medication adjusted by their obstetrician, GP and midwife as normal.

Randomisation will be completed by site staff on randomising software Sortition.

Intervention Type
Other

Primary outcome measure
Mean daytime ambulatory diastolic blood pressure measured using an ambulatory blood pressure monitor at 26 weeks.

Secondary outcome measures
1. Mean daytime ambulatory systolic blood pressure measured using an ambulatory blood pressure monitor at 26 weeks
2. Mean 24-hour and nocturnal ambulatory blood pressure measured using an ambulatory blood pressure monitor at 26 weeks
3. Systolic and diastolic blood pressure at follow-up (mean of 2nd/3rd readings and mean of 2nd – 6th readings) measured in clinic or at home at baseline, 6 weeks, 12 weeks, 26 weeks and 52 weeks
4. Maternal health-related quality of life measured using EQ-5D-5L health questionnaire results at baseline, 6 weeks, 12 weeks, 26 weeks and 52 weeks
5. Anxiety associated with self-management of BP measured using the short-form anxiety inventory questionnaire at baseline, 12 weeks and 52 weeks
6. Medication adherence measured by the presence of urinary antihypertensive metabolites at 6 weeks and the Medication Adherence Rating Scale (MARS) at baseline and 6 weeks
7. Postnatal readmissions measured using all-cause admissions, pregnancy hypertension admissions and cardiovascular events at records review
8. Healthcare resource use and cost analysis of key cost drivers between study arms measured using participant resource use data collection at baseline, 12 weeks, 26 weeks and 52 weeks
9. Cost-consequence analysis presenting costs and key outcomes in a disaggregated manner measured over the trial period
10. Long-term modelled cost-utility analysis using quality-adjusted life years (QALYs) measured using Modelled lifetime horizon and Sensitivity analysis to judge time to benefit/harm
11. Qualitative process evaluation measured using in-depth semi-structured interviews over the trial period

Overall study start date
01/07/2023

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. People who have recently given birth within the last 7 days
3. Aged 18 years or above
4. Participant with pregnancy hypertension including: chronic/essential hypertension (predating current pregnancy or requiring treatment before 20/40), or gestational hypertension (new-onset hypertension from 20/40 of index pregnancy) or pre-eclampsia (hypertension (GH or with proteinuria or metabolic changes), prior to their discharge from hospital post-delivery.
5. Participant still requiring antihypertensive medication at randomisation following delivery
6. Able and willing to comply with trial requirements
7. Willing to allow their primary and secondary healthcare teams, if appropriate, to be notified of participation in the trial
8. Access to a smartphone compatible with the app

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Target number of participants
628

Key exclusion criteria
1. Participant does not wish to self-monitor/self-manage their blood pressure
2. Participant already taking part in another trial that might affect their anti-hypertensive prescription

Date of first enrolment
24/06/2024

Date of final enrolment
01/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
NIHR Guy's and St Thomas' Clinical Research Facility
16th floor Tower Wing
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield
United Kingdom
S10 2JF

Study participating centre

Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Governance, Ethics and Assurance
Boundary Brook House
Churchill Drive
Headington
Oxford
England
United Kingdom
OX3 7GB
+44 (0)1865616497
RGEA.Sponsor@admin.ox.ac.uk

Sponsor type
University/education

Website
https://researchsupport.admin.ox.ac.uk/contacts/rgea#collapse3089471

ROR
https://ror.org/052gg0110

Funder(s)

Funder type

Government

Funder Name
Programme Grants for Applied Research

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal and scientific conferences
2. Dissemination via dedicated events and social media platforms
3. Dissemination to participating sites

Intention to publish date
01/10/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the chief investigator Prof. Richard McManus (richard.mcmanus@phc.ox.ac.uk)

IPD sharing plan summary
Available on request