Self-management of blood pressure following a hypertensive pregnancy

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
17/05/2024		<pre>Protocol</pre>		
Registration date	Overall study status Ongoing	Statistical analysis plan		
11/06/2024		Results		
Last Edited	Condition category Circulatory System	Individual participant data		
22/10/2025		[X] 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 January 2027

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

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Prof Richard McManus

ORCID ID

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

THERMOWN

Integrated Research Application System (IRAS)

332333

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Efficacy

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(s)

Current primary outcome measures as of 22/10/2025:

Mean daytime ambulatory diastolic blood pressure measured using an ambulatory blood pressure monitor at 26-39 weeks.

Previous primary outcome measures:

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

Key secondary outcome(s))

Current secondary outcome measures as of 22/10/2025:

- 1. Mean daytime ambulatory systolic blood pressure measured using an ambulatory blood pressure monitor at 26-39 weeks
- 2. Mean 24-hour and nocturnal ambulatory blood pressure measured using an ambulatory blood pressure monitor at 26-39 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, 26-39 weeks and 48-60 weeks
- 4. Maternal health-related quality of life measured using EQ-5D-5L health questionnaire results at baseline, 6 weeks, 12 weeks, 26-39 weeks and 48-60 weeks
- 5. Anxiety associated with self-management of BP measured using the short-form anxiety inventory questionnaire at baseline, 12 weeks and 48-60 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, 26-39 weeks and 48-60 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

Previous 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
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Completion date

31/01/2027

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

50 years

Sex

Female

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

30/11/2025

Locations

Countries of recruitment

United Kingdom

England

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

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

Study participating centre Airedale NHS Foundation Trust

Airedale General Hospital Skipton Road Steeton Keighley United Kingdom BD20 6TD

Study participating centre Blackpool Teaching Hospitals NHS Foundation Trust Victoria Hospital Whinney Heys Road

Blackpool United Kingdom FY3 8NR

Study participating centre Chesterfield Royal Hospital NHS Foundation Trust

Chesterfield Road Calow Chesterfield United Kingdom S44 5BL

Study participating centre University Hospitals Dorset NHS Foundation Trust

Management Offices Poole Hospital Longfleet Road Poole United Kingdom BH15 2JB

Study participating centre East Lancashire Hospitals NHS Trust

Royal Blackburn Hospital Haslingden Road Blackburn United Kingdom BB2 3HH

Study participating centre

East Suffolk and North Essex NHS Foundation Trust

Colchester Dist General Hospital Turner Road Colchester United Kingdom CO4 5JL

Study participating centre Imperial College Healthcare NHS Trust

The Bays St Marys Hospital South Wharf Road London United Kingdom W2 1BL

Study participating centre Kingston and Richmond NHS Foundation Trust

Galsworthy Road Kingston upon Thames United Kingdom KT2 7QB

Study participating centre Lewisham and Greenwich NHS Trust

University Hospital Lewisham Lewisham High Street London United Kingdom SE13 6LH

Study participating centre Mid and South Essex NHS Foundation Trust

Prittlewell Chase Westcliff-on-sea United Kingdom SSO ORY

Study participating centre Royal Berkshire NHS Foundation Trust

Royal Berkshire Hospital London Road Reading United Kingdom RG1 5AN

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road

Worthing United Kingdom BN11 2DH

Study participating centre West Hertfordshire Teaching Hospitals NHS Trust

Trust Offices
Watford General Hospital
Vicarage Road
Watford
United Kingdom
WD18 0HB

Study participating centre Frimley Health NHS Foundation Trust

Portsmouth Road Frimley Camberley United Kingdom GU16 7UJ

Study participating centre Whittington Health NHS Trust

The Whittington Hospital Magdala Avenue London United Kingdom N19 5NF

Study participating centre Buckinghamshire Healthcare NHS Trust

Amersham Hospital Whielden Street Amersham United Kingdom HP7 0JD

Sponsor information

Organisation

University of Oxford

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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