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Blood pressure monitoring in pregnancy

Submission date
18/04/2024

Recruitment status
No longer recruiting

Registration date
14/05/2024

Overall study status
Completed

Last Edited
22/05/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Currently, 1 out of 10 pregnancies are affected by high blood pressure (BP). If this is not kept within safe levels there is the potential of complications to both mother and baby, including pre-eclampsia. Pre-eclampsia is a serious condition which is diagnosed by rising BP and protein in the urine in the second half of pregnancy. Currently, pregnant women with hypertension have frequent clinic appointments for monitoring, and to make any changes needed to their BP medications. Early detection of rising BP and/or protein in the urine is highly important to reduce the risk of future issues for mother and baby. There have been recent trials investigating the use of self-monitoring of BP in pregnancy, where women check their BP readings daily at home, and use these to guide their management. These have shown self-monitoring to be safe, cost-effective and well-received by participants, but more research is needed into how to use it to improve outcomes.

Who can participate?
Pregnant women aged 18 to 60 years old with hypertension from the 20th week of pregnancy

What does the study involve?
This study will ask participants to self-monitor their blood pressure daily, test their urine weekly for protein, and submit these readings into a mobile phone app. Via the app, their healthcare team will be able to recommend if an increase in their medication is needed based on their readings, or if a clinical review is required, with the aim that earlier detection of changes will improve outcomes. This study will assess the feasibility of this process, before the development of larger-scale clinical trials to investigate the impact on outcomes.

What are the possible benefits and risks of participating?
Potential benefits for individuals taking part include better information about their BP and the possibility that worsening hypertension or pre-eclampsia could be recognised earlier than it would have been with standard care alone. Trial results will provide information about the diagnosis of hypertension during pregnancy to inform future antenatal care.

During this study, participants will continue to receive usual care regardless of the randomisation group, therefore the potential risks are anticipated to be low. Particular issues include a participant obtaining an excessively high or low self-monitored BP reading, and not appropriately escalating this to a healthcare professional. Even if these readings are assessed

suitably, they could lead to increased maternal anxiety due to the study. Training of participants will cover repeating measurements in the case of unusually high or low readings, as well as how and when to seek medical support should they occur. The participant instruction booklet will provide information about BP and proteinuria testing and give clear advice to women to contact the antenatal care team or other healthcare professional (e.g. General Practitioner (GP)) in the case of maintained high or low BP readings or a positive proteinuria result. The app system will automatically re-state this advice when high or low readings are sent in. Women will continue to be seen as per standard care by their clinical teams (midwives/GPs/obstetricians) throughout regardless of randomisation group

Where is the study run from?
Nuffield Department of Primary Care Health Sciences, University of Oxford

When is the study starting and how long is it expected to run for?
May 2023 to December 2025

Who is funding the study?
The National Institute of Health and Care Research (NIHR) Applied Research Collaboration Oxford and the Thames Valley (ARC-OxTV)

Who is the main contact?
Dr Katherine Tucker, katherine.tucker@phc.ox.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
333984

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 333984, CPMS 59682

Study information

Scientific Title
Combined monitoring for hypertensive pregnancy: a feasibility trial

Acronym
My Pregnancy Care

Study objectives
This study aims to assess the feasibility of self-monitoring of blood pressure, self-testing of urine for proteinuria and remote titration of antihypertensive medication via an app for those with hypertension at 20 weeks pregnant or greater. This is to evaluate if it has the potential to be a successful strategy in the management of hypertensive disorders of pregnancy and earlier detection of pre-eclampsia.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/03/2024, East of England - Cambridge South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)2071048194; cambridgesouth.rec@hra.nhs.uk), ref: 24/EE/0045

Study design
Multi-centre randomized controlled feasibility trial

Primary study design
Interventional

Study type(s)
Diagnostic, Prevention

Health condition(s) or problem(s) studied
Hypertension in pregnancy

Interventions
The intervention is daily self-monitoring of blood pressure with weekly urine protein testing, recorded using a multi-component app. Depending on self-monitoring blood pressure readings a 1-step titration in antihypertensive medication may be advised by a clinician and communicated to the participant via the app.

Randomisation is completed electronically using the web-based Sortition database. Following informed consent and baseline assessment, participants will be randomised using a validated web-based randomisation programme (Sortition) provided by the Oxford Primary Care Clinical

Trials Unit (PC-CTU). Women will be allocated to one of the two study groups: self-monitoring or usual care on a 2:1 basis respectively with allocation stratified for recruitment site and parity (0, 1+).

Self-monitoring of blood pressure:
Participants in the intervention arm will be provided with a validated monitor for use in pregnancy and pre-eclampsia with instructions. Participants will be asked to measure blood pressure in a seated position with the arm supported on a table or similar so that the cuff is at the level of the heart. They will be asked to measure their BP once daily by taking two readings separated by at least one minute. The second reading should be recorded on the app. Depending on this value, further readings may be requested from the participant.

Training of participants will cover repeating measurements in the case of unusually high or low readings, as well as how and when to seek medical support should they occur. The participant guideline/booklet will provide information about BP and proteinuria testing and give clear advice to women to contact the antenatal care team or other healthcare professional (e.g. General Practitioner (GP)) in the case of maintained high or low BP readings or a positive proteinuria result. The app system will automatically re-state this advice when high or low readings are sent in. Women will continue to be seen as per standard care by their clinical teams (midwives/GPs/obstetricians) throughout regardless of the randomisation group. Those obtaining very high (or very low) BP readings will be given advice to contact their maternity assessment unit within 4 hours. Women not sending BP measurements will receive reminder app messages. Within the study information, it will be made clear that any participant who experiences any symptoms consistent with pre-eclampsia will be advised to contact their maternity assessment unit regardless of their BP reading.

Self-management of anti-hypertensive medication:
Raised BP readings with no proteinuria will be reviewed via the app by a suitable healthcare professional. An increase in the dose of the participant's usual antihypertensive medication may be recommended by the clinical team, if appropriate, and communicated back to the participant via the app as a message, and by a duplicate SMS. The participants will be asked to confirm the medication they are taking 24 hours after a medication change. Low BP readings will be reviewed in the same way and may lead to a recommendation for a reduction in the dose of antihypertensive medication. In general, only one remote titration of anti-hypertensive medication can be made between antenatal appointments and assessment by a clinician. If a further titration of antihypertensives is required between antenatal assessments then an in-person clinical review will be organised.

Self-Proteinuria Testing:
Participants in the intervention group will be asked to self-test their own urine weekly. If they have raised BP readings they will then be asked to test their urine more frequently. They will be provided with the necessary kit and guidance on how to do this. If their BP is raised and they have a reading of 1+ or more of urinary protein, then they will be advised to contact their maternity assessment unit. If they have normal BP, but protein in their urine, they may be asked to either repeat the urine test in 24 hours or contact their maternity assessment unit, depending on the amount of protein detected.

The My Pregnancy Care App:
The app has been developed by the study team at the University of Oxford and the backend servers will be hosted by NHS servers, located on the OUH site in Oxford. The developers are researchers from the University and will have access to the anonymised data sets. A limited number of researchers with NHS contracts (Dr Cristian Roman) will also access the non-

anonymised datasets on the NHS servers. For participating women randomised to the intervention the app will hold information about them including; their name, age and gestation of pregnancy, blood pressure readings, urine testing results, and current medication. Participants will be notified of dose titrations by a message through the app (and by a duplicate SMS) or by a telephone call from their clinical team. The participants will be asked to confirm the medication they are taking 24 hours after a medication change. A participant's phone number is needed to send the duplicate blood pressure medication changes message and also the 'password forgot' requests (which occur regularly - participants change phones or delete the App to save space). The database is linked to the NHS server but no identifiable information (first name, last name, phone number) is allowed to be exported from the database. Records are exported and further accessible for research analysis only in a pseudo-anonymised format (with the study ID). SMS will be used only during registration (to send credentials) and to send new medication plans (or changes).

Outcome measures:
The primary outcome measures will examine the feasibility of self-monitoring of hypertension, self-testing for proteinuria, and remote titration of medication in a group of pregnant women with hypertension. The secondary outcome measures assess whether the use of self-monitored BP readings with self-titration improves BP control during pregnancy in women with hypertension and whether the self-monitoring, self-testing and self-management intervention is safe in this context.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MyPregnancyCare app

Primary outcome(s)
The following primary outcome measures will be assessed:
1. The recruitment rate per site (number approach versus number recruited) measured using data recorded in the My Pregnancy Care app at the end of the recruitment period
2. Adherence and persistence to the self-monitoring protocol (number of readings submitted versus the number of readings that the protocol requests) measured using data recorded in the My Pregnancy Care app at the time point of delivery of the baby
3. Adherence and persistence to self-testing for proteinuria (number of readings submitted versus the number of readings that the protocol requests) measured using data recorded in the My Pregnancy Care app at the time point of delivery of the baby
4. Loss to follow-up measured using data recorded in My Pregnancy Care at the end of the study

Key secondary outcome(s))
1. Systolic blood pressure between groups measured using a sphygmomanometer device at the end of the study
2. Serious adverse events and side effects and the number of adverse events measured using data collected in the study records at the end of the study

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Pregnant women aged 18 years to 60 years
3. Diagnosis of hypertension (blood pressure previously sustained at ≥140/90mmHg)
4. From 20 weeks (+/-4 weeks) gestation, up to 34 weeks gestation
5. Currently prescribed one antihypertensive medication
6. Currently negative protein on urine dipstick testing

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
Female

Key exclusion criteria
1. Women whom the midwife or obstetrician feels that it would be inappropriate to approach, for example, those acutely unwell
2. Participant does not wish to self-monitor / self-manage their blood pressure
3. Abnormal uterine artery Doppler results in this pregnancy
4. Early onset (<34 weeks gestation) pre-eclampsia in a previous pregnancy
5. Imminent delivery

Date of first enrolment
11/06/2024

Date of final enrolment
30/06/2025

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

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research Applied Research Collaboration Oxford and Thames Valley

Alternative Name(s)
NIHR ARC Oxford and Thames Valley, NIHR Applied Research Collaboration Oxford and Thames Valley, Oxford and Thames Valley NIHR Applied Research Collaboration, NIHR Oxford and Thames Valley Applied Research Collaborative, National Institute for Health and Care Research (NIHR) Oxford and Thames Valley Applied Research Collaboration, NIHR Applied Research. Collaboration (ARC) for Oxford and the Thames Valley, ARC OTV, OTV ARC, NIHR ARC OTV, NIHR ARC-OxTV, ARC OxTV

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 study will be available upon request from the chief investigator, Dr Katherine Tucker, katherine.tucker@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	version 1	15/09/2023	29/04/2024	No	Yes
Protocol file	version 1	15/09/2023	07/06/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes