

Pre-eclampsia prevention resource acceptability and feasibility study

Submission date 19/07/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/10/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Pre-eclampsia is a serious pregnancy complication that can hurt both the mother and the baby. Some women are more likely to have it. This could be because they had high blood pressure in their past pregnancies, have a family history of the disease, or have an underlying health condition. Taking a small amount of aspirin every day can help lower the chance of getting pre-eclampsia for these women. But sadly, many women who are at risk don't get enough information and support. That's why this study wants to see if a new package of care, which includes giving more information and support, is helpful. The study also wants to check if it's possible to give this care easily in the NHS context, so bigger studies can be done in the future. The new package of care (also called an intervention) was co-produced with two national charities and members of the public and consists of multiple components, including giving information to improve knowledge and skills, enabling informed decision making and facilitating discussions between healthcare professionals and women; an active offer of support during regular appointments with healthcare professionals; and, a supply of aspirin at the point of contact to ensure access to medicine.

Who can participate?

Women aged 18 years old and over between 11+2 and 14+1 weeks gestation at increased risk of pre-eclampsia as defined by NICE will be invited to participate. The study will be delivered during regular appointments with community midwives, sonographers, and obstetricians. This means there won't be any extra appointments needed. The study will enrol 30 women, their partners (or supporters), and 10 healthcare professionals involved in the delivery of the intervention.

What does the study involve?

Women will be asked to complete three simple surveys: one at the start and two at the end of the study. Women and healthcare professionals will be invited to take part in individual interviews to discuss their experiences with the intervention. Partners or supporters will be asked to join focus groups, which are group discussions, to talk about how involved they felt with the intervention and its impact. The study will collect information on how many people are recruited and how many stay involved throughout the study. It will also collect data on our ability to collect data such as the number of aspirin pills returned, completion of the questionnaire and data of clinical significance. Further, the study will keep track of how many

women choose not to take part and the reasons they give for not participating, if they provide any.

What are the possible benefits and risks of participating?

This study's results will help improve the intervention and prepare for a bigger study to see if it works. By listening to what people who engaged with the intervention have to say and making changes based on their feedback, we can make sure the intervention does what it's supposed to do. All participants in the interview will receive £25 thank you vouchers for their time.

A steering group will closely supervise this study made up of key stakeholders (women who have experienced pre-eclampsia in their pregnancies, professionals who work with pregnant women, representatives from national charities, clinicians, and academics).

This is a low-risk study. During the intervention development stages, care was taken to derisk the intervention. Women will receive additional resources and be provided with further opportunities to discuss their medication-taking routine. Access to aspirin will be simplified.

Where is the study run from?

Newcastle upon Tyne Hospitals NHS Foundation Trust

When is the study starting and how long is it expected to run for?

September 2023 to December 2025

Who is funding the study?

Newcastle upon Tyne NHS Hospitals Foundation Trust Researcher Development Institute

Who is the main contact?

Raya Vinogradov, raya.vinogradov@ncl.ac.uk

Study website

<https://northernlms.org/research/pre-eclampsia-prevention-resources/>

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Mrs Raisa Vinogradov

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

343708

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

R&D 10864, IRAS 343708

Study information

Scientific Title

Pre-eclampsia prevention resource acceptability and feasibility study

Acronym

PEPA

Study objectives

To assess feasibility of delivery of the intervention programme and to evaluate delivery, receipt, and alternation to the programmes via process evaluation.

Ethics approval required

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Ethics approval(s)

Approved 01/10/2024, London - Brighton and Sussex Research Ethics Committee Health Research Authority (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8202; brightonandsussex.rec@hra.nhs.uk), ref: 24/LO/0662

Study design

Non-randomized feasibility study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community, Hospital

Study type(s)

Prevention

Participant information sheet

Patient information material can be found at <https://northernlms.org/research/pre-eclampsia-prevention-resources/>

Health condition(s) or problem(s) studied

Improving adherence to aspirin treatment to prevent pre-eclampsia

Interventions

Previous interventions as of 08/10/2024:

This study involves a behavioural change intervention generally consisting of:

1. Pre-eclampsia resources (delivered as a hard copy, web content and bite-size sections via an electronic maternity record) to build knowledge, support the decision-making process and develop a medicine-taking routine.
2. Supply of medicine (aspirin) at the point of contact
3. Practical social support (Health Care Professional)
4. Indirect activation of unspecified social support (partners/supporters)

This study has only one arm that tests the feasibility and acceptability of an intervention.

Randomisation procedures are not applicable.

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The intervention consists of multiple components: provision of information to improve knowledge and skills, enablement of informed decision making, facilitated discussions between healthcare professionals and women; an active offer of support during regular appointments with healthcare professionals, supply of aspirin at the point of contact to ensure access to medicine. The intervention will use several resources to deliver the components: policy change with the introduction of supply of medicine under the Patient Group Directive (PGD), scripts to lead conversations with pregnant people at risk of pre-eclampsia, information provided in 3 formats (brochure, leaflets in e-records, web-content).

Intervention Type

Behavioural

Primary outcome measure

To assess the feasibility of delivery of the intervention programme and to evaluate delivery, receipt, and alternation to the programmes via process evaluation

Fidelity of intervention delivery

Barriers to implementation of the intervention

Alternations

Accessibility of the materials (physical and cognitive)

Acceptability of the materials (cultural and emotional)

Acceptability of intervention delivery schedule

Engagement with the intervention

Usefulness of the content

Accessibility of medicine and it's storage at home

Ethicality (potential for negative effects)

Engagement of partners/supporters in the intervention.

Secondary outcome measures

Feasibility of recruitment and data collection for future evaluative trial.

Feasibility of recruitment and data collection for future evaluation trial:

Proportion of eligible patients

Recruitment rate

Retention rate

Adherence rate

Rate of completion of questionnaires

Feasibility of collection of clinical outcomes

Feasibility of collection of health economic outcomes

Feasibility of using existent questionnaires to elicit change in key targeted domains: knowledge, necessity, and concerns.

Address uncertainties identified through public consultations:

Acceptability of use of the NHS app and adherence to data sharing with NHS.

Involvement and interaction with wider family/friends using intervention materials.

Risk perception of vaginal bleeding and significance of bleeding for parents.

Significance of potential for stopping aspirin early considering bleeding risk.

Overall study start date

01/09/2023

Completion date

31/12/2025

Eligibility

Key inclusion criteria

1. Women at increased risk of PE as per NICE recommendation
2. Aged 18 years old and over
3. Able to provide informed consent
4. Able to understand written English and complete the questionnaires

Participant type(s)

Healthy volunteer, Patient, Health professional

Age group

Mixed

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

up to 70

Key exclusion criteria

Contraindications to aspirin use in pregnancy as described in the national Patient Group Directive (PGS) for supply of aspirin in pregnancy

Date of first enrolment

31/10/2024

Date of final enrolment

31/07/2025

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Newcastle upon Tyne Hospitals NHS Foundation Trust

Research midwives office, Level 6, Leazes Wing, The Royal Victoria Infirmary, Victoria Road

Newcastle Upon Tyne

United Kingdom

NE1 4LP

Sponsor information**Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details

Level 1, Regent Point
Regent Farm Road
Gosforth
Newcastle Upon Tyne
England
United Kingdom
NE3 3HD
+44 (0)191 28 24510
nuth.nuthsponsorship@nhs.net

Sponsor type

Hospital/treatment centre

Website

<https://www.newcastle-hospitals.org.uk/>

ROR

<https://ror.org/05p40t847>

Funder(s)**Funder type**

Research organisation

Funder Name

Newcastle upon Tyne NHS Hospitals Foundation Trust Researcher Development Institute

Results and Publications**Publication and dissemination plan**

Multiple routes will be used to disseminate the results of the project:

- Lay summary of the results in accessible formats will be disseminated to the public through relevant charities and available on the study web pages to public and professionals to view.
- Scientific abstracts will be disseminated to relevant conferences such as international society for medication adherence (ESPACOMP), European Health Psychology Society (EHPS), Annual Royal College of obstetricians and Gynaecologists Scientific meeting (RCOG), British Maternal & Fetal Medicine Society (BMFMS), Action on Pre-Eclampsia (APEC) annual expert meeting.
- Scientific output will be published in peer-reviewed journals.

Intention to publish date

01/01/2027

Individual participant data (IPD) sharing plan

The data set generated during this study will be available upon request from Raya Vinogradov, raya.vinogradov@ncl.ac.uk.

Only anonymised data will be shared. PEPA dataset will contain clinical risk factors related to pre-eclampsia, adherence data, pregnancy outcomes and bleeding complications. Data will only be available once the results of the study are published. Consent from participants was required and obtained. All data held will be fully anonymised. REC approvals are pending, however, we do not expect any restrictions once the study results are published.

IPD sharing plan summary

Available on request