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Pre-eclampsiaprevention resourceacceptability and feasibility study

Submission date
19/07/2024

Recruitment status
No longer recruiting

Registration date
19/08/2024

Overall study status
Completed

Last Edited
08/10/2024

Condition category
Pregnancy and Childbirth

[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
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

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)
343708

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
R&D 10864, IRAS 343708

Study information

Scientific Title
Pre-eclampsiaprevention resourceacceptability 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
Ethics approval required

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

Study type(s)
Prevention

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.
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.

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This study has only one arm that tests the feasibility and acceptability of an intervention. Randomisation procedures are not applicable.
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), scrips 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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

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
United Kingdom

England

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

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

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

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