PEPA Study Summary

PEPA study will form part of a PhD. PEPA study is testing a new package of care that aims at supporting pregnant women and people who were told that they could be at increased risk of pre-eclampsia (a serious pregnancy complication that can harm both the mother and the baby). The care package will be delivered to you during your routine care appointments. We will be asking you about your experience with the bundle in a short conversation at around 28 weeks gestation. You also will be sent three online questionnaires to complete at your leisure.

We would also like to invite your partner or anyone who is taking an active role in supporting you through your pregnancy journey to participate in a conversation with other partners/supporters about the role they play in assisting you through your pregnancy. You partner/supporter's participation is optional.

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details. Only professionals from the direct research team, the Sponsor's organisation (The Newcastle upon Tyne Hospitals), or regulatory authorities may have access to your name and contact details.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data for a short duration in case we need to check it. Only non-identifiable data will remain available for analysis and for future research. We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

Pre-Eclampsia Prevention Resource Acceptability and Feasibility study PEPA:

Pregnant Participant Information Sheet

Research Centre: The Newcastle Upon Tyne Hospitals NHS Foundation Trust

Chief / Principal Investigator: Raya Vinogradov, Newcastle upon Tyne NHS Foundation Trust, Reproductive Health Research Team, The Royal Victoria Infirmary (RVI), 0191 2820362, raya.vinogradov@newcastle.ac.uk or nuth.rhnresearch@nhs.net

Study sponsor: Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH)

We would like to invite you to take part in a research study.

Before you decide if you want to take part it is important that you understand what it will involve. Please take time to read this information sheet and discuss it with other people if you wish. You can also watch a video introduction to the research here Pre-eclampsia prevention resources - Local Maternity Systems Northern England Local Maternity Systems Northern England (northernlms.org) also available via QR link at the bottom of this page.

You will have the opportunity to discuss the research with a member of the team at your 12-week scan appointment. If you have received this information sheet before your scan appointment, you can contact us directly if you would like to discuss anything in advance.

Part one of this information sheet tells you about the purpose of the study and what would happen if you decided to take part.

Part two is about extra parts of this research that you can choose to take part in.

Part three gives more details about the conduct of the research.

Contact details are on the last page of this document.

Part One

Why do we conduct this research?

Pre-eclampsia is a serious pregnancy complication that can harm both the mother and the baby. Some women are more likely to develop it than others: taking a small amount of aspirin every day can help lower the chance of getting pre-eclampsia.

Unfortunately, many women who are at risk don't get enough information and support. To better support the women who are at an increased risk of this disease, a new package of care was created together with two national charities (APEC and SANDS), women, clinicians and academics. This study wants to see if the new package of care, which gives more information and support, is helpful. It will also assess whether it's possible to give this care easily within the NHS, so bigger studies can take place in the future to improve maternity services across the country.

Why have I been invited to take part?

The study is being carried out at the RVI. We are inviting pregnant women who have been identified by their midwives at an increased risk of pre-eclampsia and will benefit from taking small dose of aspirin.

We aim to include 30 pregnant women in this study, partners (or people who support pregnant mothers through their pregnancy).

What will happen to me if I take part?

Consent: A member of the research team will discuss the research with you at your dating scan appointment. If you decide to take part, you will be asked to sign a consent form.

Personal Risk Information: A member of the study team will take an additional blood pressure measurement and use an ultrasound machine to listen to your blood flow through your abdomen, providing you with personalized information about your risk of pre-eclampsia. This will take only couple of minutes and will not cause you any unusual discomfort. **Information pack**: We will provide you with verbal, printed information, access to the web pages and information on the electronic system (Badger app).

Supply of aspirin: In line with the national recommendation, we will supply you with aspirin at the time of the appointment, this will save you time going to the pharmacy to obtain your aspirin.

Tailored support: You also will be offered extra support from your health care team.

Questionnaires: You will be asked to fill in a short questionnaire to get some extra information about you at your first appointment, and three more questionnaires about your routines and beliefs around taking aspirin. You will be asked to complete last three questionnaires independently online via secure system called REDcap.

Interview: We will invite you to take part in an online conversation about your experience of the new care package (interview) at around 28 weeks of pregnancy. The interview will be conducted using an online platform of choice, at convenient time.

During the interview you will be asked a series of questions about your experience of the care package. There are no right or wrong answers, we are interested in hearing a range of perspectives. It will last for about one hour, but this may vary slightly depending on how much you have to say. We will ask your permission to record and transcribe the discussion and we will send you transcripts to check for accuracy and to clarify or remove information. **Pregnancy outcome data collection**: We will review your routine maternity records after you have had your baby for information such as, how you delivered your baby and whether you had any pregnancy complications.

GP letters: We will inform your GP about your participation in the PEPA study.

We will need to use information from you for this research project. This information will include: name, NHS number, date of birth, your post code, email, and phone.

People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure.

What will happen to the results of the research study?

The results of this study will help to improve the care package and will help to shape larger study to test whether the intervention really works. By listening to feedback, we can make sure the new care package does what it's supposed to do.

The results will be available on the study website, and they will be published in a scientific journal so that other researchers and health professionals can learn from this research. Direct quotations from the interview may be used in publications, but you will not be identified in any results we present or publish.

If you would like to receive a summary of results, we can share these with you.

What are the possible benefits and disadvantages of taking part?

Your 12 week' ultrasound scan appointment will be about 20 minutes longer.

We will give you your full supply of aspirin at the time of your 12 and 20 weeks' appointments to avoid repeat trips to pharmacy.

Benefits of participation in this study are unclear as we yet need to establish effectiveness of this care package.

As a thank you for taking part you will receive free printed pictures of your baby from your 12 week and 20-week scans and a £25 gift voucher after the interview.

Do I have to take part?

No, your participation is voluntary, and it is up to you to decide if you want to participate in the study. If you do not want to take part, you do not have to give a reason and your care will not be affected in any way.

However, we would appreciate knowing more about the reason people not taking part in research, so we can improve our services in the future.

If you have received this information sheet before your scan and you decide that you don't want to take part, you can let us know before your appointment or turn up and let us know on the day. Your scan will go ahead as planned whether you decide to take part in this research or not.

What if I change my mind?

You are free to withdraw from the study at any time, without giving a reason. If you change your mind, your care will not be affected in any way. If you want to withdraw from the study, please use the contact details on page 2 of this document.

If you withdraw from the study, we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Part Two: Optional
Focus groups with partners/supporters

We would like to invite your partner or a person who supports you during pregnancy to have a group discussion about ways they are involved in the pregnancy and whether the new care package was helpful to them. This will happen late in pregnancy.

You can still take part in the research without your partner/supporter agreeing to participate.

Focus group discussions

A partner or supporter forms an important part of the support system for women in pregnancy. We will be asking your partner/supporter to share their contact details with the research team, so we can get in touch with them later in pregnancy to arrange a group discussion about their role in supporting you in this pregnancy.

The group discussion will be conducted in small groups with up to 10 people using videoconferencing facility. It will last about an hour. We will have a few questions and we will encourage an open discussion amongst participants.

All partners/supporters will be given a £25 gift voucher as a thank you. The research team will provide more information to your partner/supporter once you reach 28 weeks of pregnancy.

If you partner/supporter doesn't want to take part, they do not have to give a reason and your care or participation in this study won't be affected in any way.

Part three

How will we use information about you?

The information we collect during the study will be analysed to enable us to understand whether the new care package works, is acceptable and feasible to deliver and what can be changed to improve it.

We will need to use information from you and from your medical records for this research project.

This information will include your: NHS number, name, date of birth and contact details. People will use this information to do the research or to check your records to make sure that the research is

being done properly. People who do not need to know who you are will not be able to see your NHS number, name, date of birth and contact details. Your data will have a code number instead. We will keep all information about you safe and secure on the REDcap database.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) is the sponsor for this study and will act as the data controller. They are responsible for looking after your information and using it properly. NuTH will keep identifiable information about you for 5 years after the study has finished.

NuTH will collect information from you and/or your medical records for this research study in accordance with our instructions. Only trained clinical-research team members will have access to your information.

Your rights to access, change, or move your information is limited, as we need to manage your information in specific ways for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personal identifiable information possible.

Individuals from NuTH and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The research team will pass these details to individuals at NuTH along with the information collected from you and/or your medical records upon request for audit purposes. The only people in NuTH who will have access to information that identifies you will be people who need to contact you to discuss this study or audit the data collection process. People outside NuTH will have no access to your identifiable information and will not be able to access your medical notes, find out your name, NHS number or contact details.

If you give consent to participate in the study, we will use non-identifiable personal information (a study ID number) to analyse the data and report the findings. Any paper documents will be stored in a locked fire-resistant cupboard at the RVI. To allow us to analyse the anonymised data it will be transferred to a secure server on the Newcastle University system and stored in accordance with the regulations of the Data Protection Act 2018 and the Newcastle upon Tyne Hospitals NHS Foundation Trust Caldicott guidelines.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from https://newcastlejro.com/research/new-study/data-security
- by asking one of the research team
- by sending an email to nuth.dpo@nhs.net
- by ringing us on 0191 282 0362

Who is organising and funding the research?

This project is funded by the Researcher Development Institute, Newcastle Hospitals Charity, Newcastle upon Tyne Hospitals NHS Foundation Trust. It is being led by Raya Vinogradov, who is a radiographer in Newcastle Hospitals and a PhD student in Newcastle University.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by London - Brighton & Sussex Research Ethics Committee (ref 24/LO/0662).

The study design has been reviewed by Sponsor (Newcastle Joint Research Office). Members of charities and the public were closely involved in development of the care package, this study design and will be involved in the analysis of anonymised data collected during this study.

What if there is a problem?

If you are not satisfied with any aspect of the way you have been approached or treated during this study, you can speak to the research team (please see contact details on page 2), who will do their best to answer any questions. If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advice and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, you can make a formal complaint by contacting the Patient Relations Department, Tel: 0191 2231382 or 0191 2231454, Email: nuth.patient.relations@nhs.net Address: Patient Relations Department, Newcastle upon Tyne Hospitals NHS Foundation Trust.

Insurance and Indemnity Information.

Insurance for the design, conduct, and management of this study is covered by the NHS scheme.

Extra Contact Details

Where can I get further information about the study?

If you have any questions or concerns about taking part in the study, please contact the Chief /Principle Investigator for this research at the RVI (Raya Vinogradov, 0191 2820362 raya.vinogradov@ncl.ac.uk) or by contacting the research team at nuth.rhnresearch@nhs.net

Thank you for taking the time to read this participant information sheet.