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. The aim of this part of the study is to assess whether it's possible to give this care package easily within the NHS settings and if this can be improved before bigger studies can take place in the future to improve maternity services across the country.

We are contacting you because you have experience of delivery of some aspects of this package of care.

Involvement in this part of the project consists of one online conversation (interview).

In this research study we will only use information provided by you. 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:

Health Care Professionals 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 document and discuss it with others if you wish. You will have the opportunity to discuss the research with a member of the team at your convenience and we encourage you to do this if there is anything you are unsure of.

Part one of this document tells you about the purpose of the study and what would happen if you decided to take part. Part two gives more details about the conduct of the research. Further contact details are on the last page of this document.

Part One

What is the purpose of the research?

NICE recommends low-dose aspirin for pre-eclampsia prevention amongst women at increased risk of the disease. Research shows that women face multiple barriers to this treatment. This results in women not taking aspirin regularly or not taking aspirin at all, diminishing the effectiveness of the treatment. Further research demonstrated that midwives are lacking resources that would help to facilitate discussion with women about pre-eclampsia prevention. To support women at 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 a new package of care, which gives more information and support, is helpful. The study also wants to assess whether it's possible to give this care package easily within the NHS settings and if this can be improved before bigger studies can take place in the future to improve maternity services across the country.

Why have I been invited?

The study is being carried out at the RVI. We are inviting all health care professionals involved in delivering this study to participate in one-to-one interviews. We aim to include at least 10 health care professionals.

What will happen to me if I take part?

A member of the research team will discuss the research with you once the intervention delivery is complete. If you decide to take part, we will agree with you a date and time for the interview at your convenience and will ask you to sign a consent form.

During the interview you will be asked a series of questions about your experience of delivering the care package as part of the PEPA study. There are no right, or wrong answers and we are interested in hearing a range of perspectives. The interview will last approximately one hour, but this may vary depending on how much you have to say.

We will ask your permission for the interview to be recorded and later transcribed. We will send you transcripts to check for accuracy, to clarify or remove information.

What will happen to the results of the research study?

The results of this study will help make the intervention better and get ready for a larger study to see if it really 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 will be delivered as intended and does what it's supposed to do. The results will be available to public on the study and charities' websites and 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 from the study, then we can share these with you.

We will need to use information from you for this research project. This information will include: name, date of birth, professional background, 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 are the possible benefits and disadvantages of taking part?

Benefits of participation in this study are unclear as we yet need to establish effectiveness of this care package.. The study team will also provide you with a certificate of research participation.

Do I have to take part?

No, 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, however, we would appreciate you sharing with us the reason for declining participation, so we can improve approaches to research participation in the future.

What if I change my mind?

You are free to withdraw from the study at any time, without giving a reason. 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

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 helps to engage partners/supporters.

We will only need to use information provided by you for this research project.

This information will include your: name and contact details. People will use this information to do the research or 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 name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

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, based in the United Kingdom, is the sponsor for this study and will act as the data controller for it. This means they are responsible for looking after your information and using it properly. Newcastle upon Tyne Hospitals NHS Foundation Trust will keep identifiable information about you for 5 years after the study has finished. Newcastle upon Tyne Hospitals NHS Foundation Trust 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 in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personal identifiable information possible.

Individuals from Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) and regulatory organisations may look at the documents associated with this research 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 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 the NuTH will have no access to your identifiable information and will not be able to access your medical notes, find out your name, or contact details.

If you give consent to participate in the study, we would use non-identifiable personal information (through allocating 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:

- 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

What will happen to information collected about me for the research study?

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

Who is organising and funding the research?

This project is funded by 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 (NuTH). Members of charities and the public were closely involved in development of the care package, this study design and will be involved in 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 the course of this study, you should first speak to the research team (please see contact details on page 2, who will do their best to answer your questions. If you remain unhappy and wish to complain formally, the normal National Health Service complaints mechanisms are available to you (Datix).

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 participating 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.