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).

In this part of our research, we would like to find out if new package of care helps to engage partners/supporters.

We are contacting you because you gave us a permission to get in touch about this part of the project.

Involvement in this part of the project is optional and consists of one meeting with other partners/supporters like you, so it can be discussed in an online group.

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 your contact data for a short duration in case we need to check for accuracy of the research records. 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:

Partner/Supporter 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 others if you wish. You will have the opportunity to discuss the research with a member of the team if there is anything you are unsure of.

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

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

Contact details are on the last page.

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: for these women 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 and if it helps to engage partners/supporters.

The study also wants to 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 the partners/supporters of participants in the PEPA study. We aim to include up to 30 partners/supporters to match the number of pregnant participants.

What will happen to me if I take part?

A member of the research team will discuss the study with you when pregnant participant is around 28 weeks pregnant. If you decide to take part, we will agree on a date and time for a group discussion and will ask you to sign a consent form.

During the group discussion you will be asked a series of questions to prompt a discussion about your experience of supporting a pregnant participant and your engagement with the care package. There are no right or wrong answers, and we are interested in hearing

a range of perspectives. The group discussion will take place with 1-5 people and 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.

We will need to use information from you for this research project. This information will include: name, 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 package of care does what it's supposed to do.

The results will be available on the study and charities' website, and will be published in a scientific journal so other researchers and health professionals can learn from this research. Direct quotations from the focus group discussions may be used in the 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?

Benefits of participation in this study are unclear as we yet need to establish effectiveness of this care package. You will be provided with £25 thank you voucher upon completion of 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, however we would appreciate knowing why you decides not to participate, 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 information sheet.

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 (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 such as name and contact details needed for contacting you about your participation. 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.

Professionals from 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 NuTH will have no access to your identifiable information and your name 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 identifying you, such as a consent form, 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 (NuTH). 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 takin 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.