Participant Information Sheet

Project Title: Acceptability of a digital health intervention to empower and inform women about postpartum contraception and facilitate access: a pilot study

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and contact us if you need further information before deciding whether or not you wish to participate.

What is the purpose of the study?

This research is to evaluate a new way of providing information to pregnant women about contraception after childbirth. This is an important part of pregnancy care as many women experience an unplanned pregnancy in the months after childbirth and a short gap between pregnancies can also lead to complications for mothers and babies. We also know that it can be difficult to access reliable information about your contraceptive options in a convenient way, and that making and attending appointments to start contraception can be more difficult when looking after a new baby. We are therefore looking at ways that might make this easier.

At present, most contraceptive discussions takes place with a midwife or doctor during an antenatal clinic visit. As part of this study, we will evaluate adding in a short audio-visual animation and package of text messages alerts/links. Previous research has shown that women like to receive health information this way and it helps them to remember key facts. It can also be easily subtitled and translated into different languages making it more accessible to more patients.

By providing clear, consistent and accurate information about fertility and contraception after childbirth, as well as signposting to other reliable sources, we hope to empower and inform women about their choices and simplify the process of starting contraception after having a baby. We are keen to understand more about the views and experiences of pregnant women receiving this new intervention to help us develop this service further as a routine part of antenatal care.

Why have I been asked to take part?

You have been asked to part because you are at a stage of pregnancy when contraception would usually be discussed with you. We are interested in finding out what women who decide to opt in to receive the new information package have to say about it, and how it affects their contraceptive decision-making. We also want to compare this to women who receive this information in the usual way (by discussion with midwife or doctor and/or receiving an information leaflet).

Do I have to take part?

No, it is entirely up to you as participation is voluntary. If you do decide to take part you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time, and without giving a reason. Deciding not to take part, or changing your mind at a later stage will not affect the healthcare that you receive.

What will happen if I take part?

If you choose take part, you will be randomly allocated to one of two groups. You will either receive routine care (discussion with midwife/doctor and information leaflet) OR you will be part of the 'intervention' group receiving the new information package.

1) Routine care

If you are part of the routine care group, you will be asked to complete a short survey with a member of the research team after your routine antenatal clinic visit. This will include questions about your future contraceptive plans and experience and recall of facts from the consultation with your midwife or doctor, specifically about the information you received in relation to contraception after childbirth. This survey will be anonymous and will not affect your routine care during the rest of your pregnancy in any way.

Around 6 weeks after your baby is born, a research midwife will contact you to complete a further short survey by either telephone or text (as per your preference). This will include questions about your final contraceptive method choice and overall experience of receiving contraceptive information and/or supplies during and after pregnancy. If you complete all parts of the study, you will receive a gift voucher (£15) as a token of thanks for taking part.

2) Intervention group

If you are part of the intervention group, you will be asked to watch a short video (or a mobile device or laptop) **in addition** to your routine consultation with the doctor/midwife. After your consultation, you will also be asked to complete a short survey with a member of the research team. This will include questions about your future contraceptive plans and your experience and recall of facts from watching the animation. You will also be asked to opt in to receive text message alerts at specific points during the rest of your pregnancy and in the first few weeks after your baby is born. These will be delivered to you no more than once per month. The texts will include brief educational messages and reminders about contraception and fertility, as well as optional links to other current NHS Scotland/Lothian websites for further information and/or to access services such as for contraceptive device (coil or implant) insertion.

Around 6 weeks after your baby is born, a research midwife will contact you to complete a further short survey by either telephone or text (as per your preference). This will include questions about your final contraceptive method choice and overall experience of receiving contraceptive information and/or supplies during and after pregnancy. You will be asked for your feedback on the number and content of the text messages and whether or not you found these helpful, informative and understandable. If you complete all parts of the study, you will receive a gift voucher (£15) as a token of thanks for taking part.

If you are part of the intervention group you will also be asked if you would like to part in a further **optional** interview with the researcher. This will allow us to discuss your experience and views about watching the animation and receiving the texts in more detail, and how you feel these could be improved. This may help us develop these resources for future use as part of routine pregnancy care.

If you agree to take part in an interview the researcher will call or email you to arrange it. The interview will take place by telephone at a day and time that is suitable for you. Alternatively, you can choose to attend a community clinic (Chalmers Centre) or your local hospital (St Johns Hospital or Royal Infirmary of Edinburgh). This option will depend on COVID-19 regulations at the time. We expect

the interview to last around 30 minutes, although actual times may vary slightly. You may choose not to answer any question during the interview without giving a reason. The interview will be recorded, and later transcribed by a third party service (First Class Secretarial). . Any travel costs incurred in attending an interview will be reimbursed and you will receive an additional gift voucher (£15) as a token of thanks for taking part.

What are the possible benefits or disadvantages of taking part?

Results from the study may help us to develop services further to best meet the contraceptive needs of women in the future. If you are in the group receiving the text messages, it is possible you might find these an inconvenience. You can choose to opt out of receiving these at any time. This is one of the questions we hope to answer by doing this research and so your feedback about this important to us. You can also choose to opt out of receiving these at any time. It is not thought that there are many disadvantages; however, you will contribute some of your personal time to take part.

What if there is a problem?

If you have questions or concerns about the research project at any stage, please contact the research team (details below) who will do their best to assist you.

The research team are not able to give advice about health concerns during pregnancy, and you should speak to your midwife, GP or obstetric doctor. If you have concerns about your personal safety during pregnancy, or feel you are at risk of harm, then our research team can signpost you to sources of support.

What will happen if I don't want to carry on with the study?

You can stop being part of the study at any time and without giving a reason. You can do so by contacting the research team. This will mean you will no longer take any further part in the research, such as receiving text message alerts or follow-up calls from the research team. This will not affect your ongoing pregnancy care, contraceptive options, or plan.

What happens when the study is finished?

After the study if finished, the data will be looked at in detail by the research team. The recorded interviews will be transcribed by an external professional service (1st Class Secretarial). Data will not be sent to any other third party. Original interview recordings will be destroyed after they are transcribed. Any personal data collected about you as part of the study will be destroyed safely once the study is completed.

Will my taking part in the study be kept confidential?

All the information we collect during the research will be kept confidential and there are strict laws with safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you for this research project. This information will include your:

- Name
- CHI number
- Contact details

- Ethnicity
- 1st half of postcode

People will use this information to do the research or to check your records to make sure 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.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

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

You can find out more about how we use your information at: www.hra.nhs.uk/information-about-patients or by asking one of the research team using the contact at the end of this leaflet.

What will happen to the results of the study?

In time, we aim to present the results in a medical journal and at national and international conferences. You will not be identifiable in any published results, but are very welcome to receive a copy of these results if you wish (by contacting the research team). A summary of the results will also be made available the Lothian Sexual Health website.

Who is organising this research and why?

The study is being funded by the Edinburgh Family Planning Trust, a local charity dedicated to improving women's health. The study is led by research doctors who work in women's health within the NHS. The study is being sponsored by University of Edinburgh and NHS Lothian.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee in order to protect the safety, rights and well-being of those taking part. A favourable ethical opinion has been obtained from <insert REC name>. NHS Management Approval has also been given.

Study contact details

If you have any further questions about the study, please contact:

Karen McCabe (Research Midwife)

k.mccabe@ed.ac.uk

<insert phone>

Independent contact details

If you would like to discuss this study with someone independent of the study, please contact:

Claire Nicol (Midwife/Advanced Nurse Practitioner)

Claire.Nicol@nhslothian.scot.nhs.uk

<insert phone>

Complaints

If you wish to make a complaint about the study, please contact:

NHS Lothian Patient Experience Team

2-4 Waterloo Place, Edinburgh, EH1 3EG

feedback@nhslothian.scot.nhs.uk

0131 536 3370