Participant Information Sheet

You are invited to take part in our research study

Before you decide whether to get involved, it is important you understand why the study is being carried out and what it will involve for you if you decide to take part. Please take time to read this information and ask us if there is anything that is unclear or you would like more information about.

1. What is the purpose of the research?

The contraceptive implant is the most effective form of hormonal contraception which means that people who use it have the smallest chance of becoming pregnant when they don't want to be, a risk of less than one in a thousand. Some people may choose to have their implant removed and switch to contraception that doesn't contain hormones, or which has a higher risk of pregnancy. There haven't been any studies about this yet in the UK, so this research will help us to know how and why people make decisions about having their implant removed and what matters to them when choosing a different type of contraception. We want to get better at helping people with their contraception so that less people become pregnant when they don't want to be, and the information we discover in this study may help us to do that.

2. How we will do this

- In this part of the study, we want to interview up to 20 people about their decisions and beliefs regarding hormonal contraception and their experience of using the implant.
- We will compare all the findings to see if there are any patterns or similarities than can help us discover new or useful information.

3. How we will use this information

- We will write a report on what we've discovered and share it.
- We can use what we have learnt in a future study to help us develop new ways of giving people information about contraception that includes issues that are important to them.

4. Why have you been invited to take part?

You have been invited to take part in this study because you have had an implant removed. We would like to know more about this decision and your experience of using the implant, what you chose to use for contraception after your implant was removed and what is important to you when choosing contraception.

Inclusivity

We aim to be inclusive and sensitive to the needs of individuals whose gender identity does not align with the sex they were assigned at birth. Use of the terms 'woman' and 'women' are not intended to discriminate against or exclude anyone. We welcome participation from trans men and non-binary and intersex people whose experiences and opinions are important to us.

5. Do you have to take part?

No, it is entirely your choice whether to take part in the study or not. Even if you agree now, you are free to withdraw at any time if you wish. We will talk to you about the study and answer any questions you may have. If you agree to take part, we will ask you to sign a consent form before we interview you. If you choose not to take part, this will not affect your future contraception or healthcare services in any way.

6. What would taking part involve?

If you agree to take part, you will be asked to complete a questionnaire and provide your contact details. The research team will then contact you to let you know if we would like to interview you and if so, to arrange a date, time and location that is convenient for you. The interview can be done in person or by video call on MS Teams and will last up to 1 hour. It will be a one-to-one interview with you and a member of the research team. You do not have to have your camera switched on if you choose a video call.

We will ask you about your experience of using contraception and what's important to you when deciding which method to use. You can stop the interview at any time if you wish. We will make an audio recording of the interview and transcribe it into a written document. We can send you a copy of the transcription so that you can check that it is accurate.

7. What are the possible benefits of taking part?

Taking part in the trial may not directly benefit you, but your contribution may help us gain a better understanding of what's important to contraception users and improve future care. You will receive a £25 voucher when you have completed the interview as a thank you for your time.

8. What are the possible disadvantages of taking part?

You will be giving up some of your time (up to one hour) to participate but can withdraw at any time.

9. 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
- 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 name or contact details. Your data will have a code number instead.

The University of Nottingham health Service (UNHS) is the sponsor of this research. UNHS is responsible for looking after your information. Information about you related to this research project may be looked at by authorised individuals from:

- the sponsor organisation (UNHS)
- the funding organisations (Wellbeing of Women and the College of Sexual & Reproductive Healthcare)
- the study research group
- regulatory authorities

We will keep all information about you safe and secure by:

- following and adhering to the laws relating to General Data Protection Regulation (GDPR)
- deleting your personal data when it is no longer required
- keeping your personal details separate from the recording and transcription of your interview.
- ensuring all documents and audio recordings are stored safely and securely in confidential conditions only accessible to the research team
- storing digital information on a password protected computer only accessible to the study team and storing hard copy files in a locked room on the UNHS premises.

International transfers - your data will not be shared outside the UK.

10. How will we use information about you after the study ends?

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.
We will keep your study data for a maximum of 5 years. The study data will then be fully anonymised and securely archived or destroyed.

11. 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. You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

12. 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/patientdataandresearch
- by contacting Daniel Hammersley, the UNHS Data Protection Officer, at:

University of Nottingham Health Service, Cripps Health Centre, University Park, Nottingham NG7 2QW Tel: +44 (0)115 822 7979 Email: nnicb-nn.rrisck1@nhs.net

13. What will happen if you don't want to carry on with the study?

You are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw, or are withdrawn from the study for any reason, your personal

details will be erased. If you would like to withdraw, please contact the Research team (see the **How to Contact Us** section on the last page).

14. What if there is a problem?

If you have any questions or concerns, you can contact the study team (see the **How to Contact Us** section on the last page).

If you remain unhappy and wish to complain formally, you can do this through the National Health Service (NHS) Complaints Procedure via your local Patient Advisory and Liaison Service (PALS): Tel: +44 (0) 20 8725 2453, Email: england.contactus@nhs.net

15. Who is organising and funding this study? How has it been reviewed and approved?

The study is being organised by the UNHS. A research scholarship grant awarded by the College of Sexual & Reproductive Healthcare (CoSRH) and Wellbeing of Women (WoW) is funding the study.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by a Research Ethics Committee.

This study has been designed by clinician who regularly sees patients regarding their contraception and listens to their experiences and concerns regarding hormonal birth control. Patients' representatives are also involved in the design of the study to ensure we consider the needs of our patients and participants.

16. What happens at the end of the study?

At the end of the study the report will be published in scientific medical journals and presented at conferences. You will not be identified in any publication. We will send you a newsletter with a summary of the study reports, unless you ask us not to.

17. How to contact us

If you want to participate, would like any further information or wish to report a problem, please contact the study team:

Tel: +44 (0)115 822 7979 Email: nnicb-nn.rrisck1@nhs.net

Registration form: RRISCK1 study interview registration form – Fill out form

Address: Research Team, University of Nottingham Health Service,
Cripps Health Centre, University Park, Nottingham, NG7 2QW

Thank you