



Centre for
Trials Research
Canolfan
Ymchwil Treialon



School of
Healthcare Sciences
Ysgol y Gwyddorau
Gofal Iechyd

THE PLAN-IT STUDY

THE ACCEPTABILITY AND FEASIBILITY OF A PLANNED PRE-PREGNANCY WEIGHT LOSS INTERVENTION.

Information Sheet: Interviews with practitioners who remove long acting reversible contraceptives (intrauterine devices and/or subdermal implants)

Thank you for completing the Plan-it Study survey, which asked questions about your experiences of conversations with patients regarding weight management and whether it would be possible to do a research study that asks people who are overweight to delay removal of their contraceptive coil/implant/rod (also known as Long Acting Reversible Contraception, or LARC) to take part in a weight loss programme prior to trying to get pregnant.

You are being invited to take part in a short interview as part of the **Plan-it** study. Before deciding if you want to take part, it is important that you understand why the research is being done and what it will involve. Please take the time to read this information sheet carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you feel you need more information.

What is the aim of this study?

The overall aim of the **Plan-it** study is to establish if it is acceptable and feasible to conduct a study that asks women who are overweight/ obese to delay removal of a long-acting reversible contraception e.g. coil/ contraceptive implant, also known as LARC, to participate in a targeted pre-pregnancy weight loss intervention.

We have developed ideas regarding a potential intervention from a review of the current evidence and from the surveys we have done with women and healthcare staff. We would now like to gather your views in relation to the proposed intervention.

Why have I been invited to take part?

You previously provided your contact details for us to contact you again about the study.

What will happen if I take part?

If you decide to take part you will be asked to participate in an interview with a researcher from Cardiff University. Interviews will take place over the telephone or via ZOOM. The researcher will arrange a convenient time for the interview, which will take around 30 minutes. During the interview you will be asked about your views in relation to the proposed study. The researcher will ask for your agreement to audio record the interview for subsequent transcription and analysis.

What will happen to the results of the study?

The results of the interviews will be included in the **Plan-it** study findings which will be reported in academic journal articles and publicised through conference presentations and articles in the press. We will not publish any personal details about an individual who has taken part in the study, or anything that could allow them to be identified.

What are the possible disadvantages and advantages of taking part?

There are no specific risks or disadvantages of taking part. If you do become uncomfortable during the interview, it can be stopped at any time, and you do not have to answer any questions you do not want to. By sharing your experiences and views, you will help us understand which factors are important for practitioners and women in considering the potential study of delaying LARC removal for a pre-conception weight-loss intervention.

Will my taking part be kept confidential?

Yes. All personal information will be kept completely confidential. Your role or profession may be identified, but any information which could identify you or your workplace will be removed following data collection, and in the reporting of findings. Quotes of what is said in the interview may be used in reports of the research, but you will not be identified.

How will my data be used?

This study is being led by Cardiff University in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller and data processor for this study. This means that we are responsible for looking after your information and using it properly. Cardiff University will keep identifiable information about you from this study for a minimum of 12 months after the study has finished. The research data generated by this study will be kept for 15 years. All data will be used in accordance with the General Data Protection Regulation 2018 and the UK Data Protection legislation 2018.

Cardiff University will use your email address or telephone number to contact you about the research study and to oversee the quality of the study. Individuals from Cardiff University and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in Cardiff University who will have access to information that identifies you will be people who need to contact you in relation to your participation in the study or audit the data collection process.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by visiting <https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection>

What if I do not want to carry on being part of the study?

You can decide to stop taking part in the interview at any time, without giving a reason. Your contribution to the interview up until that point will be included in our analysis of findings, and quotes of what you have said in the interview may be used in reports of the research, but you will not be identified.

Has the study undergone ethical review?

Yes - the study was reviewed and approved by Cardiff University School of Medicine Research Ethics Committee.

Who has funded the study?

The study is funded by the National Institute for Health Research Health Technology Assessment Programme.

Who has organised the research and who will be supervising it?

The study is being organised by the Centre for Trials Research and Cardiff University is the responsible organisation.

What if there is a problem?

If at any point you are unhappy with any aspect of the study, please advise the research team at the Centre for Trials Research, Cardiff University (contact details below). You also have the right to lodge a complaint with the ICO (Information Commissioners Office).

If you have any questions about the study or would like more information you can email the study team:

Plan-it@cardiff.ac.uk

Study Manager: Elinor Coulman/ john1@cardiff.ac.uk/ 02920687624