



Pre-conception care for women with pre-existing diabetes

PARTICIPANT INFORMATION SHEET

We would like to invite you to participate in this original research study

- You should only participate if you want to; choosing not to take part will not disadvantage you in any way.
- Regardless of your decision, your treatment and care will not be affected.
- Before you decide whether you want to take part in the research, it is important for you to understand why the research is being done and what your participation would involve.
- Please take time to read the information carefully and discuss it with family and friends if you wish.

What is the study about?

- The study aims to understand why women with pre-existing type 1 or type 2 diabetes of childbearing age, do, or do not, access pre-conception care.
- We want to hear about your views, your experience and your recommendations
- The study also aims to investigate the views of staff and other stakeholders with a view to exploring existing and future provision of pre-conception care services.

What would taking part involve?

- This will involve an interview at your home, or at another location if you prefer, and at a convenient time for you.
- The researcher will interview you for up to one hour and 15 minutes. All of the interviews will be audio recorded with your permission.
- You will be asked to answer questions about your experience of diabetes and your views on, or experiences of, pregnancy and pre-conception care.
- You will also be invited to participate in the next phase of the study (a focus group) but can choose not to, even if you agree to participate now.

Why are we doing this research?

- We are interested in this research because diabetes is the most common medical complication in pregnancy and rates of diabetes are increasing.
- Diabetes in pregnancy can be harmful to health if not managed correctly and this research project aims to find out how pregnancy planning could improve the health of women and babies.
- All members of the research team have a strong track record in carrying out health research and have experience of research in diabetes and reproductive care.

How many will be involved in the study?

- In this phase of the study we are hoping to recruit 24 White women and 24 Pakistani women who have either type 1 or type 2 diabetes and who have either accessed or not accessed pre-conception care.

Why have I been invited?

- You have been invited to participate because you receive care at either Heartlands Hospital or have registered with a GP in Sandwell and West Birmingham area.; we are using different sites because different settings for care may influence women's experiences of their care and their access to it.
- You have been identified as eligible for the study by a member of your healthcare team.
- To participate you must be between 18 and 45 years of age and will be of white British origin, or Pakistani origin whose preferred language is not English.
- Rates of diabetes are increasing amongst White British and Pakistani women and Pakistani women have a particularly high risk of developing diabetes.
- There are high numbers of White British and Pakistani women who access pre-pregnancy and ante-natal care in Birmingham.

Who are we excluding from the study?

- Women under the age of 18 and over the age of 45.
- Unfortunately, we ask you *not* to participate if you have been diagnosed with a mental health problem.

Who is organising and funding this research?

- The study is being organised by a team of researchers at the Open University, The University of Birmingham and Heart of England NHS Trust.
- The Principle Investigator is Dr Sarah Earle, based at The Open University.
- The study is funded by the National Institute for Health Research (NIHR).

Expenses and payments

- Unfortunately we are unable to compensate you for your time in this study.
- We will travel to your choice of venue for the interview.

What to expect during the consent process?

- If you do decide to take part you will be asked to sign a consent form.
- The Research Associate (Dr [Anisah Tariq](#)) will take you through this form and answer any questions you have.
- Your participation in this study will not be affected should you choose not to be contacted again in the future.

What are the advantages of taking part in the study?

- You may enjoy taking part. You can also find useful information about diabetes and pre-conception care on the study website and you may want to contribute to the research blog.
- At the conclusion of the study, we will send you a newsletter describing the major findings and alerting you to any publications we have generated from the project.

What if something goes wrong?

- The risks involved in participating are minimal.
- If there are questions that you find upsetting or intrusive in any way, you are free to not answer them or to withdraw from participating, without giving a reason.

How will we maintain your privacy and confidentiality?

- Everything you tell us will remain completely confidential within the limits of the law.
- We will give you a pseudonym and replace any information we have about you that could identify you.
- Your information will be stored on secure computers in locked offices and in locked filing cabinets.
- At the conclusion of the study, these data may be made available in totally anonymous form to other researchers outside of the project team. This means that, with your permission, the information you give us will be available to other researchers in the future. However, they will have no means of identifying you.
- The data generated from the project will be kept for ten years after which it will be destroyed securely.

Involvement of General Practitioner (GP)

- If you agree to participate we will inform your GP.

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

- It is up to you to decide whether to take part in the study or not.
- If you decide to take part you are still free to withdraw at any time and without giving a reason.

Further information and contact details

Ask us if anything is unclear or you would like more information.

If this study has harmed you in any way you can contact The Open for further advice and information:

Thank you for reading this participant information sheet