"Exploring The Long-Term Outcomes Following a Pregnancy with Gestational Diabetes Mellitus (ELOPE- GDM)"

Participant Information Sheet (PIS)

You are being invited to take part in a research study investigating women's experiences of gestational diabetes. Gestational diabetes is high blood sugar (glucose) that develops during pregnancy and usually disappears after giving birth.

Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

Summary

What's the study about?

- We are exploring the experiences of women about being tested for and living with Gestational Diabetes Mellitus (GDM).

Who is doing the study?

- The study is being conducted by researchers from University College London. The study will run from 01.10.2021 until 30.09.2023

Why have I been selected?

- You have been selected because we believe you may have been diagnosed with GDM in the last two years.

What's involved?

- Participation in the research will involve taking part in an interview about your experiences with GDM and completing a brief questionnaire about you, your healthcare and health.

Next steps?

- If after reading the information on this sheet you have any questions or would like to get involved in the research please contact the research team *(details to be confirmed)*

Further details

About the research

- **Who will conduct the research?**

This research is being led by the Department of Primary Care and Population Health at University College London. The researchers carrying out this research are Dr Shoba Poduval and Dr Jamie Ross

What is the purpose of the research?

Diabetes is a group of diseases linked with high blood sugar levels. The number of people affected by diabetes is increasing. Gestational diabetes (GDM) only affects pregnant women. GDM doesn't usually cause symptoms, so a woman might not know she has GDM unless she has a test. We know that GDM causes problems during pregnancy and delivery. But recent research also shows GDM can cause health problems for women later in life. Women who get GDM are at increased risk of developing type 2 diabetes, high blood pressure and heart attack than women who don't get GDM. But the full extent of the longer term impact of GDM beyond these diseases is not clear.

Using interviews we will explore the experiences of women about being tested for, and living with GDM. You have been selected because you have been diagnosed with GDM in the last two years.

- **Will the outcomes of the research be published?**

We will study the interviews of all the people we talk to about gestational diabetes and will develop a set of 'themes' that describe overall views and experiences of the participants. These findings will be written up as articles for publication in scientific journals and as a report for the funder of the research. The findings will also be presented at scientific conferences, and might be summarised as an online blog article. A report of the findings will be sent to study participants who wish to receive them and who agree to this on the consent form.

- **Who is eligible to take part?**

Eligible participants include women who have been diagnosed with gestational diabetes in the last 24 months. We intend to interview up to 30 people in total. Recruitment will close once we reach our target.

We may be able to provide translation and interpretation assistance if you would like to take part but are not proficient in English.

- **Who has reviewed the research project?**

This study has been reviewed and approved by the Yorkshire & The Humber - Sheffield Research Ethics Committee (ref. 22/YH/0124).

- **Who is funding the research project?**

The study is funded by the National Institute for Health Research's School for Primary Care Research.

- **How long is the study for?**

The study is for 24 months from the 01.10.2021.

What would my involvement be?

- **What would I be asked to do if I took part?**

If you agree to take part a researcher will interview you about your views and experiences of gestational diabetes.

The interview will be carried out over video call (such as Zoom, Teams or Skype), or over the telephone. If deemed safe under current Covid-19 restrictions, interviews may also take place in person, at a place convenient for you (e.g. at your GP practice or the researcher's university building).The interview will be audio-recorded and will last up to one hour.

Before the interview starts the researcher will check whether you have any final questions and ask for your signed consent (or verbal consent if taking part over the phone or video call) for recording the interview and using the recording as described in this information sheet. The interviewer will also ask you to fill out a short questionnaire about your background and health.

The interview will include questions about your experiences of gestational diabetes, including your views and experiences of testing for gestational diabetes and lifestyle modifications.

- **Will I benefit from taking part?**

It is hoped that this work will contribute to better support for gestational diabetes and provide information about how to deliver better treatments and prevention strategies.

If you need support for childcare to get involved in this research any reasonable expenses you incur will be reimbursed.

- **Are there any risks?**

We believe this to be a very low risk study. However, some people may be upset and discussing their health and potential future problems. If so, we encourage you to talk about any worries or anxieties you have with your doctor or nurse.

The research procedures are also very low risk. You will be asked to take part in an interview about your experiences with GDM.

In the unlikely eventuality of distress, if you should wish for further advice or support we will signpost you to relevant resources.

- **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. If you would like to take part you can contact the researcher, [Name tbc], using the contact details at the end of this information sheet. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form or to provide verbal consent if taking part by telephone or video call.

If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised and analysed as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further. As the interviews need to be audio-recorded for use in the study, it is not possible to take part without the interview being recorded. However, if you become uncomfortable with the recording process you are free to stop the interview and the recording at any time.

Reimbursement

As a thank you for taking part you will be offered £20 for participating in the interview. This will be offered as a high street shopping voucher.

Data Protection and Confidentiality

- **What information will you collect about me?**

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect:

- Your name, contact details and postal address (e.g. to arrange the interview, to send you a report of the findings, and to contact you about future research)
- An audio-recording of your voice and any identifiable names/places mentioned in the interview

We will also ask to complete a brief questionnaire containing questions about you (including your ethnic origin) and your health. This will allow us to describe the people who take part in this study. *This data will be identified only by an ID number.*

All information collected about you during the research will be kept strictly confidential. You will be assigned an ID number. This pseudo-anonymised (key-coded) information will be collected, stored, handled and processed by the research team at University College London. You will not be able to be identified in any ensuing reports, publications, lectures or presentations.

The audio recording of the interview will be transcribed by a transcription company (Transcription Divas) which is a UCL preferred supplier, and deleted following transcription.

If you agree, anonymised data you provide may be used by other researchers.

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

- **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings.
If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our data protection notices: https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies

- **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, University College London is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

Participants' confidentiality will be respected at all times, unless there are compelling and legitimate reasons for this to be breached. We have a duty of care to report to the relevant authorities any possible harm or danger to participants or others.

What if I have a complaint?

If you have a complaint that you wish to direct to members of the research team, please contact the UCL Principal Investigators Dr Shoba Poduval s.poduval@ucl.ac.uk, 020 3108 1207.

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher:

Dr Shoba Poduval s.poduval@ucl.ac.uk, 020 3108 1207.