# Participant Information Sheet

**Title:** SPROUT: **S**tudy of **P**sychological **O**utcomes in Women with and Witho**UT** Gestational Diabetes Mellitus: a mixed-methods prospective cohort design.
**IRAS Number:** 332747
**Chief Investigator:** Prof Khalida Ismail
**Version 1.1 Date 03.03.2024**

**About the research**
We would like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide, we would like you to understand why the research is being done and what it would involve for you.

One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. This should take about 5-7 minutes. Please feel free to talk to others about the study if you wish.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part.

The second part will give you more detailed information about the conduct of the study. Please ask if anything is unclear.

**What is the purpose of the study?**
Everyone experiences pregnancy in different ways. The purpose of the study is to understand if and how psychological, biological, and social aspects of pregnancy and postnatal differ for women with and without gestational diabetes mellitus (GDM). The study involves surveys and interviews which include questions about you, your mental health, and your relationship with your baby. The overall aim of the study is to improve health care services for women and their infants. Understanding your experiences during pregnancy and after birth is very important for the research team to achieve this.

**Why have I been invited?**
You are being invited to participate in this study because you are attending screening for GDM at King's College Hospital NHS Foundation Trust.

**Do I have to take part?**
No, you do not have to take part. We will describe the study and go through this information sheet, which we will then give to you. You will be able to keep this information sheet and think about taking

part. You are free to discuss the information with anyone you wish including your family and friends. If you agree, we will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time during completion of the survey and up to 4 weeks after completion of the interviews, without giving a reason. This will not affect the standard of care you receive.

**What will happen to me if I take part?**

*Surveys:*

If you choose to take part in this study, you will be asked to participate in four surveys at different time points either online or on paper, depending on your preference. The time points for the survey are:

1. At the time of your GDM screening results;
2. 35 weeks pregnant;
3. 3 months postpartum, and;
4. 12 months postpartum.

Each survey lasts approximately 5-10 minutes and will ask general questions such as your date of birth, ethnicity, as well as questions related to your mental health. There are questions that screen for depression, anxiety, eating disorders, perceived social support and stigma. When you are pregnant, we will ask you about your pregnancy experiences, breastfeeding intentions, and antenatal mother-infant bonding. After birth, we will ask you about your birth experiences, breastfeeding experiences (if you are breastfeeding), and postnatal mother-infant bonding.

If you choose to complete the survey online, it will be on Qualtrics XM. As you progress through the online survey, your data will be automatically saved. Alternatively, if you would like to complete the survey on paper we will provide you with a return paid envelope.

Any personally identifiable knowledge such as your date of birth will be stored at a safe and secure university database that only King's College London researchers have access to.

*Optional components of the research*

There are two optional parts of the project. You do not have to take part in either and can just complete the survey section (outlined above).

1. *A video of you and your baby:*

If you would like to take in this additional component, we will ask you at 3 months postpartum to take a 3-minute video of you and your baby interacting. This involves recording a video of you and your baby for around 3 minutes playing or being together so the research team can understand different types of mother-baby relationships. If you would like to take part we may contact you with additional information, including how to safely send the video to us. We will keep the video in a safe university database which only the King's College London researchers have access to.

*2. Individual interviews:*

If you are diagnosed with GDM and wish to take part in this section of the project, we may ask you to take part in an interview with a senior researcher to talk about your pregnancy and

postnatal experiences. This can be in-person or online depending on your preferences. The time points for the interview are:

1. 35 weeks pregnant;
2. 3 months postpartum, and;
3. 12 months postpartum.

If you do agree to taking part, each interview will last for approximately 60 minutes. You will be provided with a £20 voucher per interview as a thank you. If you consent to being contacted about the interview, we will invite a subset of women and provide more detailed information about this aspect of the research.

**What are the possible benefits of taking part?**

The findings from this study may not benefit you directly but will help improve mental health outcomes for women with GDM.

**What are the possible disadvantages and risks of taking part?**

If you do agree to take part, it is possible you may experience some inconvenience as the survey is 5-10 minutes long. Reflecting on your experiences of pregnancy could bring up distressing memories or feelings, especially if you found this to be a difficult time. If you do feel distressed, then you may get into contact with the team we provide at the end of the survey for mental health support.

While you are completing the survey you can take breaks or end the survey if you would like. If you require mental health support, we suggest you contact your own GP, NHS emergency, or Samaritans.

**Who is organising and funding this study?**

The researcher in charge of this study is Professor Khalida Ismail. The study is funded by Applied Research Collaborations (ARC) at the National Institute for Health and Care Research and is being sponsored by King's College London and King's College Hospital NHS Foundation Trust. There are no conflicts of interest for this study.

Name of Co-Sponsor Organisation/s: King's College London and King's College Hospital NHS Foundation Trust.

**How have patients and the public been involved in this study?**

We have an established a Patient and Public Involvement (PPI) group comprising six women who contribute to GDM projects the team is conducting. This PPIE group has contributed to varying aspects of work, including informing survey questions and survey timepoints.

**Who has reviewed this 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 Research Ethics Committee. It has also been approved by the Health Research Authority and each local hospital will also give confirmation that the study can go ahead.

**Expenses and Payments**
There are no funds available for payments to those participating in this study.

**What will happen if I don't want to carry on with the study?**
You are free to withdraw from the study at any time during completion of the survey and up to 4 weeks after completion.

If you choose to withdraw your responses after completing the survey, we will destroy any information we have collected about you through the survey and consent form. We will also not contact you for future studies.

If you choose to withdraw from both the survey and interview, please contact us:

Name: Dr Madeleine Benton
Email: madeleine.benton@kcl.ac.uk

Your decision to withdraw from the study will not affect the care you receive.

**What if there is a problem?**
If you have a concern about any aspect of this study, you should ask to speak to your study doctor who will do their best to answer your questions.

Name: Dr Madeleine Benton
Email: madeleine.benton@kcl.ac.uk

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints procedure by contacting your local Patient Advice Liaison Service (PALS) office.

Details of your local office can be obtained by asking your study doctor, GP, telephoning your local hospital or looking on the NHS website. https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/

Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available.

In the event that something does go wrong, and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against King's College Hospital NHS Foundation Trust but you may have to pay your legal costs.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the study, the normal NHS complaints mechanisms are available to you. Please ask your study doctor if you would like more information on this.

**Will my taking part be kept confidential?**
If you consent to take part in the research, any of the information collected about you may be inspected by the sponsor (including representatives of the sponsor). These inspections are solely for the purposes of the research and analysing the results. Your records may also be looked at by the regulatory authorities or ethics committees to check that the study is being carried out correctly.

The organisations listed above will keep information about you confidential and secure. Your name will not be used in any reports about the study and all data is stored in accordance with the principle of the Data Protection Act 2018. However, your hospital doctor may tell your GP about your participation if you agree to enter the study.

Your data will be added to an electronic data file, in SPSS. Data will be handled, computerised and stored in secure password-protected computer systems ensuring compliance with the General Data Protection Regulation (2018) in accordance with the Data Protection Act (2018). All study data will be stored on secure KCL computer systems and only KCL researchers will have access to this data. All data will be held for a minimum of 5 years. Your personally identifiable data such as your date of birth, postcode and your email address – should you choose to provide this, will be stored for up to 3 years after the study has ended for the purpose of disseminating study findings.

You can find out more about how we use your information at this link:
https://www.kcl.ac.uk/research/research-environment/rgei/research-ethics/use-of-personal-data-in-research

The data controller for this project will be King's College London (KCL). Only KCL researchers will have access to the data. The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under General Data Protection Regulation is a 'task in the public interest'. You can provide your consent for the use of your personal data in this study by completing the consent form that will be provided to you. You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the King's College London Data Protection Officer Mr Albert Chan info-compliance@kcl.ac.uk. If you wish to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk

**What will happen to the results of the research study?**
The results of the project will be summarised in publications including peer-reviewed scientific journals, and presented at conferences and/or to interested organisations. You won't be identifiable in any outputs from the study.
If you would like a copy of the findings, people contact us at:
Name: Dr Madeleine Benton
Email: madeleine.benton@kcl.ac.uk
Phone: 07832 158429

**How we will use your data**

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

- Name
- Date of birth
- Psychiatric diagnoses
- Physical comorbidities
- HbA1c & CGM mean glucose, GMI, frequency & duration of glycaemic excursions
- Hypertensive disorders
- Gestational weight gain
- Diabetes treatment [if applicable]
- Hospital admissions and duration of stay
- Occurrence of severe hypoglycaemia and diabetic ketoacidosis episodes
- BMI
- Pre-pregnancy BMI
- Date of delivery
- Mode of delivery
- Occurrence of adverse events
- Feeding at hospital discharge
- Length of hospital stay

And your baby's:

- Gestational age at birth
- Birth weight
- Occurrence of birth injury

We 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.

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.

- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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

If you consent to take part, we will use your data to deliver this project as described in the Patient Information Sheet. You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available entitled 'How we use your data' which you can request from the study team
- by asking one of the research team
- by contacting our DPO at: info-compliance@kcl.ac.uk
- by visiting our webpage King's College London Statement on Use of Personal Data in Research - King's College London (kcl.ac.uk)

**Thank you**

Thank you for considering taking part and taking the time to read this information sheet.
If you decide to take part in the study, we will give you a copy of the information sheet and a signed consent form to keep.

**Further information and contact details**

Chief Investigator of the study:
Professor Khalida Ismail
Email: Khalida.2.ismail@kcl.ac.uk
Tel: (0)20 7848 5131

If you experience any distress, we have provided the contacts details of Samaritans who can provide 24-hour support**.**
Name: Samaritans
Phone: 116 123

If you are experiencing significant distress, please go to your nearby **local hospital** if you feel you are unable to keep yourself or your child safe or call the **emergency services** on 999.