 

**Diet, Activity and Screening after gestational diabetes: an Interview Study**

Participant information sheet

## Invitation

We would like to invite you to take part in an interview to discuss your experience of gestational diabetes. We would like to find better ways of helping women reduce their chances of developing diabetes in the future.

Joining the study is entirely up to you, and before you decide we would like you to understand why the research is being done and what it would involve. This Participant Information Sheet tells you the purpose of the study and what will happen if you take part. Please feel free to talk to the study team or others about the study if you wish. We will do our best to answer any questions you may have.

## What’s involved?

### Why are we doing this study?

As your clinical team will have explained to you, women who have had gestational diabetes are more likely to develop type 2 diabetes in the future compared to other women of the same age. We are researching how to help women to reduce their risk of developing diabetes after having had a pregnancy affected by gestational diabetes. In particular, we are interested in hearing your views and experiences of diet, physical activity and about blood glucose testing (diabetes screening) after your pregnancy, and any suggestions that you have. This will help us to develop and improve approaches to best support mothers.

### Why am I being asked to think about taking part in this study?

We are looking for women who have recently had a pregnancy affected by gestational diabetes to take part in this study. We hope to recruit about 25 women with different experiences and from different backgrounds, so we may not be able to include everyone who would like to take part.

### What would taking part involve?

If you agree to take part in this study, we will
arrange an interview with a member of the study team. This can take place at a time and in a private location that is most suitable for you, and you’re welcome to have your child or children with you. The interview is likely to take between 30 minutes and an hour. You will be able to stop the interview at any time or to choose to not answer specific questions. With your permission we will audio-record the interview so that we can transcribe it and keep a written record of what was said. This record will not include identifying information.

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

There will not be any direct benefits to your health from taking part and your healthcare will not be affected in any way. However, it is an opportunity to share your views and suggestions, which we will consider carefully, and you will be contributing to research that aims to support and improve care for people like you.

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

We do not expect there to be any risks of taking part, although talking about diabetes and your diet or exercise can be sensitive issues. You can choose which parts of your experience you tell us about and will be free to pause or end the interview at any time. If the questions raise issues you would like support with, we can direct you to some useful services.

### Will I receive any payment for taking part?

You will receive no payment or compensation for your time but we can reimburse reasonable travel costs if you need to travel to the interview venue.

### What do I do if I want to take part?

It is entirely up to you whether or not to take part. Taking part in the study is completely voluntary and you can withdraw from the study at any time.

If you would like to take part, please reply using the contact details supplied on the invitation letter. The hospital team will pass your details on the researchers who will contact you to arrange an interview. You can also contact the hospital team to ask any questions before you decide whether to take part.

## Other information

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

You can choose to withdraw from the interview any time before or during the interview. If you choose to withdraw after the interview has been completed, we will ask you if the interview data we have obtained may be kept and used to contribute to the study results. However, should you request that your interview data be destroyed, we will ensure that this takes place.

### What if something goes wrong?

If you have any questions about the research or any concerns about the way you have been approached or treated, please contact Dr Claire Meek, the Chief Investigator, by emailing claire.meek@nhs.net.

### How will my information be kept confidential?

The University of Cambridge and Cambridge University Hospitals NHS Foundation Trust are the sponsors for this study based in the United Kingdom. They will be using information from you in order to undertake this study and will act as the data controller for this study. This means that they are responsible for looking after your information and using it properly. The sponsor organisations will keep identifiable information about you for 12 months after the study has finished to ensure your safety and allow the study to be reviewed by the authorities after it is finished.

Your rights to access, change or move your information are limited, as the sponsor organisations need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how the sponsors use your information using the information below:

* For CUH NHS Foundation Trust, please visit: www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information, or email the Data Protection Officer at: gdpr.enquiries@addenbrookes.nhs.uk
* For University of Cambridge, please visit: www.medschl.cam.ac.uk/research/information-governance, or email the Information Governance team at: researchgovernance@ medschl.cam.ac.uk.

### What will happen to the results of this study?

When the study is completed, the results will be presented at scientific meetings and published in scientific journals. They will also make up part of a PhD thesis. Your identity and personal details will be kept confidential: no information that could identify you, like your name, will be published in any report about this study. We can share these publications and a summary with you.

### Who is organising and funding this study?

The study is being organised by the University of Cambridge and funded by the School of Primary Care Research.

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

Patients and the public have helped with the design of the research, and will be involved all the way through the research process. This includes managing the study, looking carefully at the results and sharing the findings.

### Who has reviewed this study?

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| Research team |
|  | http://www.mrl.ims.cam.ac.uk/wp-content/uploads/2018/05/Meek-Claire-FG.jpg |
| Mrs Becky Dennison, PhD Student (Study Researcher) | Dr Claire Meek,Senior Clinical Research Fellow and Consultant Diabetes Physician (Chief Investigator) |
|  With Prof Simon Griffin, Dr Juliet Usher-Smith and Dr Catherine Aiken. |

All research in the NHS is looked at carefully by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the London – West London & GTAC Research Ethics Committee.