



PARTICIPANT INFORMATION SHEET

Full study title: Prevention of progression to type 2 diabetes in women with gestational diabetes: A feasibility study for a randomised trial on a Mediterranean diet.

REC reference number: 19/SC/0064
IRAS project ID: 255208



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We are inviting you to take part in the MERIT study. This leaflet will tell you why you have been invited, why the research is being done, and what it will involve if you decide to take part.

Why have I been invited, and do I have to take part?

You have been invited as you have been diagnosed with gestational diabetes, a condition where diabetes is diagnosed for the first time in pregnancy, and for which you are being treated with metformin and/or insulin.

It is your choice to take part or not. Whether you decide to take part or not, your medical care will not be affected in any way.

What is the purpose of the study?

About 4 out of 10 women with gestational diabetes develop type 2 diabetes within 5 years after childbirth. In the long term, type 2 diabetes can cause serious health complications.

We think that following a Mediterranean diet after your pregnancy may prevent type 2 diabetes from developing in the future. A Mediterranean diet does not restrict the amount of calories you eat – it suggests certain kinds of food that are better for you. These foods can have a positive

effect on blood sugar levels and have the potential to prevent diabetes.

Before we undertake a large trial to test this, we want to run a small-scale study. This study will assess the experiences of mothers and researchers involved, and provide the necessary information to conduct the large-scale trial successfully. A total of about 65 women will be offered the intervention at different hospitals within Barts Health NHS Trust.

What will happen if I choose to take part?

A member of the research team will meet with you and answer any questions you may have about the study. If you decide to take part, you will be asked to sign a consent form; you will get to keep a copy of the consent form and this leaflet. We would then also collect some basic information about your health and your gestational diabetes.

If you do decide to take part, we will invite you to follow a Mediterranean diet after you've had your baby, starting from your routine check-up visit after the birth, until 1 year after childbirth.





This will involve the following:

- You will have a one-to-one session with a health **coach** (a qualified member of your hospital research team) to introduce the principles of the diet to you. This will happen at your routine check-up, about 6 to 13 weeks after you've had your baby.



- You will receive a free **mobile app** to download onto your smartphone. Through this mobile app, the health coach will communicate with you on a regular basis (every one or two weeks, on an agreed day). The coach will give you advice and send you ideas, documents and videos to support you through your diet. The app will also allow you to log how you get on with your diet goals, and you can send messages, videos and photos to the coach. And finally, the app contains a forum that allows you to chat with other mothers who take part in the MERIT study. During the study, we will ask you to log into your app at least once a week.

- You will receive **supplies** of olive oil and a variety of nuts, which are part of the Mediterranean diet plan, for the duration of the study.

Please note that giving consent will not guarantee that you will be included in the study, as your health status may change or the planned number of participants may already have been included by the time you give birth.

Are there any visits I should attend?

Yes, we will ask you to come back to the hospital for 3 visits after you've had your baby:

- At 6-13 weeks after childbirth – that's your routine check-up, and the point at which we would like you to get started on the new diet and the app;
- At 6 months after childbirth;
- At 12 months after childbirth – that's when all mothers who had diabetes in pregnancy are meant to have a blood test to check blood sugar levels. This would be your final study visit.

At these 3 visits, we would like to collect some basic data about your health, we will ask you to complete a short questionnaire about your diet, and there will be a blood test to check your blood sugar levels

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(which will be like the blood tests you have during pregnancy).

At the first and last visit, we will also ask you to come in fasting for the blood test, and we will give you an additional questionnaire about your general health and wellbeing.

In between the visits, a member of the research team may also be in touch with you over the phone see how you are getting on with the study and to remind you of upcoming visits. This will be every 2 to 4 weeks. In addition to the messages through the app, the health coach may also contact you by phone once or twice to discuss the diet with you.

What will happen to my blood samples?

Your samples will be analysed by laboratories based at Barts Health NHS Trust. We will communicate the results of any routine tests to your GP. If you are diagnosed with type 2 diabetes, we will transfer your care to your GP; you would then no longer be part of the study and will not receive further dietary advice or supplies through the study. Your blood samples will be discarded after the tests have been done.

Your views and experiences

Another part of this study is to understand how we can improve the involvement of women in the

future large study. To do this, we may invite you to take part in one or two **1 hour interviews** with an independent researcher. Interviews will take place in a location convenient for you. You will receive a £10 voucher for your time if you participate in an interview.

If you do not wish to take part in these interviews, you can still participate in the study.

What are the possible disadvantages and risks of taking part?

There are no anticipated side effects or risks in taking part in this study. If you or a member of your household has a nut allergy, you will not be able to take part in the study.

What are the possible benefits of taking part?

The intervention in this study may or may not benefit you personally. The information we get from this study will help us improve and develop future studies. It may also help us to improve the treatment of women who have gestational diabetes in the future.

What if new information becomes available?

If important new information becomes available during the MERIT study, you will be informed and asked if you wish to continue taking part.



What if I change my mind?

You can withdraw from the study at any time without giving a reason. Of course we hope you will want to stick with the diet for the duration of the study, but you can always change your mind.

What if there is a problem?

If you wish to discuss anything about the study or have a complaint, you can speak to the research team (contact details at the end of this booklet) who will do their best to answer your questions. You can also contact the Independent Patient Advice and Liaison Service (PALS) at your hospital (details below).

We do not believe that any harm will come to you through taking part in this trial. The organisers of the study do however have insurance in place for any injury caused as a direct result of the intervention or procedures you received during the course of the study.

Will my taking part in this study be kept confidential?

Your hospital will collect information from you and your medical records for this research study. Your hospital will keep your name, date of birth, NHS number and contact details confidential and will not pass this information to the study organisers. Your hospital will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from the study organisers and regulatory organisations may look at your medical and research records to check the accuracy of the research study. All information which is collected about you during the course of the research will be kept strictly confidential and will be stored securely. The study organiser (Queen Mary University of London) will receive data about you that contains no identifying information (no names,



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dates of birth or NHS number), only a unique study number. If shared with other researchers, your data will be completely anonymised. All data will be kept for 20 years, but no data that is kept by the study organisers will identify you. Queen Mary University of London will be using information from you and your medical records 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.

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. You can find out more about how we use your information at www.barc-research.org/data. Your GP and other doctors involved in your clinical care will be informed that you are taking part in this study.

How is the data from the mobile app used?

The app we are using for this study is called Liva. It's already being used in the NHS for diabetes prevention. To register with the mobile app, you will be asked to enter your name and email address. You can choose a nickname and a profile picture if you wish. The providers of the app, Liva Healthcare UK, will keep your personal information (your contact details and any health information you enter or data you upload) confidential and





secure, for up to 10 years after you have finished the study. None of your personal health information, private messages and information that you share with your health coach will be shared with other users or with the central study team. Any discussions you have on the app forum will only be seen by your coach and by the other mothers who take part in the MERIT study. These other app users will see the nickname and the profile picture that you select, along with any messages you post on the forum.

To learn how the app is used, the central research team may receive usage data from Liva; this data will not identify you. At the end of the study, the central research team may receive a completely anonymised transcript of the forum discussions; all names, pictures and other identifying information will be removed. This information will help us learn about how mothers use such an app and how interacting with others may help with a dietary intervention.

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

Members of our patient and public group called Katie's Team have provided input into the research proposal and patient documents, and will continue to support the progress of this study. We have

also conducted surveys among pregnant women on using an app for health and diet, to find how women might want to use such an app.

What will happen with the results of the research study?

The results of the study will be published in medical journals and the results circulated to medical staff and the local communities. You will not be identified in any report or publication.

Who is organising and funding the research?

This study is organised by the Barts Research Centre for Women's Health (BARC) at Queen Mary University of London and is funded by Barts Charity.

Who has reviewed the study?

The study has been reviewed and approved by a Research Ethics Committee (REC) and the Health Research Authority (HRA). These groups ensure that the research is ethically appropriate, safe and protects your interests. This study has been reviewed and given favourable opinion by the South Central – Berkshire Committee (Reference Number 19/SC/0064).



Further Information and contact details

If you have any questions please feel free to ask a member of the research team. Please keep this copy of the MERIT study participant information sheet.

You can contact the Research Midwife on:

Hospital doctor in charge of the study:

Patient Advice and Liaison Service (PALS):

Thank you for taking time to read
this information sheet.

