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**Participant Information Leaflet - DiGest study**

**Full Title: Dietary Intervention in Gestational Diabetes**

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

**Part 1** tells you the purpose of this study and what will happen to you if you take part.

**Part 2** gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

**PART 1**

**What is the purpose of this study?** The overall aim of our research is to work towards healthier mothers and healthier babies by improving care for women with diabetes in pregnancy (gestational diabetes). This is a type of diabetes which comes on during pregnancy and usually resolves after the delivery. However, gestational diabetes is also associated with complications during pregnancy which affect both mums and babies – for example, mothers can have more complicated deliveries and babies can grow particularly large. Women with gestational diabetes are often asked to follow a strict diet and may have to take tablets or insulin in order to keep blood sugar levels under control. Although most women with gestational diabetes will have to change their diet, there is very little information available about exactly which foods are most beneficial, and what the total calorie content should be.

We have recently completed a research study which showed that women who control their weight gain after a diagnosis of gestational diabetes may have better pregnancy outcomes. Our study showed that women who gained only small amounts of weight in late pregnancy had healthier pregnancies and easier deliveries compared to women who gained large amounts of weight in late pregnancy. For example, women with smaller amounts of weight gain were much less likely to need medical interventions during labour and were much more likely to have a healthy normal delivery. They also needed less medication to control their blood sugar levels and their babies were a healthier size.

However, it is still unclear what targets for weight change women should be aiming for in late pregnancy. It is also unclear what the daily calorie intake should be to help women with gestational diabetes achieve the best pregnancy outcomes. The overall aim of the study is to test two special diets for gestational diabetes to identify which one has the best outcomes for mums and babies.

**Why have I been invited?** You have been invited because you have had a recent diagnosis of gestational diabetes. We are looking for around 500 volunteers to help us carry out this research project.

**Do I have to take part?** You are under no obligation to take part in this study. If you have expressed interest, we will describe the study, give you this information sheet and answer any questions you might have. If you decide to take part in the study, we will then ask you to sign a consent form to show you have agreed to take part. Even after you sign the consent form, you are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

**Will my normal medical or antenatal care be affected by this study?** Your normal medical and antenatal care will not be affected by this study.

**What do I have to do?** You have been invited to take part in this study because you have been diagnosed with high blood sugar levels in pregnancy (gestational diabetes). If you would like to take part in this study, we will arrange a study visit, shortly after your diagnosis (Visit 1). This study requires 4 visits in total. We will try to arrange the visits to coincide with your antenatal appointments where possible.

Visit 1 will last around 2 hours. At visit 1, we will ask you to:

1: Have blood tests to assess your levels of sugar and hormones such as insulin. We will ask you to fast before this visit and will take 30ml of blood (6 teaspoons).

2: Place a sensor on your skin to enable us to monitor your blood sugar levels for 2 weeks. This is called continuous glucose monitoring (CGM). Although there is a tiny needle in the sensor, most people find this very comfortable to wear. The sensor can be worn in the shower and should not affect your day-to-day activities.

3: Complete some questionnaires, for example, about your medical history, eating behaviour and your quality of life during pregnancy. We will also ask you about your food intake, food preferences and any food allergies or intolerances you have. We will also show you how to order the dietboxes and help you to place the first order.

4: Measure your weight, height, some skinfolds and blood pressure.

5: We will also give you a set of scales and will ask you to weigh yourself at home 1-2 times per week during the study and let us know if you lose weight. We will ask you to return the scales at the end of the study.

1-2 weeks after Visit 1, we will arrange for you to start the specialised diet. This will be provided in the form of a dietbox, which will be delivered to your home. This dietbox will contain all your weekly food and is nutritionally-balanced and specially designed to be suitable for pregnant women with gestational diabetes. You should eat all the food in your dietbox, and it should not be shared with other family members. If you are too full to finish all the food in your dietbox, then you can stop eating – there is no need to overeat in order to finish everything. Whether you are hungry of full after eating your dietbox, you should not eat anything else. You can have sugar-free and calorie-free drinks such as water, tea or coffee with a teaspoon of milk, or calorie-free fizzy drinks such as Coke Zero or Diet Coke.

The food in the dietbox will be easy and quick to cook, using a microwave, hob or oven. The food will be freshly prepared with no artificial additives by our dietbox suppliers. They will take into account your special dietary requirements and food preferences when they design the dietbox for you. You will also be able to choose your dietbox meals for future deliveries. The food will be delivered mainly frozen and come with full instructions on storage, use and cooking instructions for microwave and oven.

Some women may find it difficult to keep to a diet during pregnancy which might be different to the meals that other family members are eating. However, this food has been specially designed to help treat your gestational diabetes. Following this diet carefully will help you and your baby have a safe and healthy pregnancy and may help you avoid medication. We would encourage you to discuss the study with your partner and other family members. Your partner or a family member could also join you for the first study visit, so that they can hear more about the study.

After the dietboxes commence, our study team will be in regular contact with you. We will ask about your satisfaction with the dietboxes and will help you to adjust future deliveries in line with your food preferences. You will continue to attend your routine antenatal appointments and scans during this time for monitoring of the baby’s growth. If you have any concerns during this time, or if you gain or lose substantial amounts of weight, we will arrange additional study visits.

Visit 2 will be arranged at 32 weeks of pregnancy and will last up to 40 minutes. At this visit we will:

1: 2: Start a new 2-week period of continuous glucose monitoring

3: Repeat your weight, height and blood pressure

4: Ask you to complete another questionnaire about your food intake and satisfaction with the dietboxes.

Visit 3 will be arranged at 36 weeks of pregnancy and will last around 45 minutes.

At the 36 week visit we will:

1: Repeat the fasting blood tests - another 30ml of blood will be taken (6 teaspoons). If any abnormalities are found on these blood tests, we may take a further sample at 38 weeks. This would allow us to identify and treat any issues such as anaemia before you have your baby.

2: Start a new 2-week period of continuous glucose monitoring and activity monitoring

3: Repeat your weight, height, some skinfolds and blood pressure

4: Ask you to complete more questionnaires for example, about your food intake, quality of life and satisfaction with the dietboxes.

Delivery

We will gain information on the hospital computer systems to record how you delivered your baby and some information about your health and the baby’s health after you gave birth. This includes information about the baby’s birthweight and health, for example, whether the baby needed a prolonged admission for any reason. Depending upon the time of day that you give birth and your health and the health of your baby, we may ask you if we can take a sample of placenta, amniotic fluid or blood or tissue from the umbilical cord. Amniotic fluid is collected during labour or delivery when the membranes are ruptured. The placenta and cord tissue/blood sampling would be performed after the baby is disconnected from the cord and placenta, and so does not cause any pain or discomfort to you or your child. If you are willing, we may perform a short examination of your baby, and ask if you would be willing to have your child’s body composition measured. This involves placing the baby in a special cocoon called a Peapod in order to measure the amount of fat and non-fat tissue the baby has at birth. This is entirely voluntary and we understand that there may be circumstances where this will not be possible. The Peapod is specially designed for babies and involves no needles or radiation. The facilities for sampling of placenta, amniotic fluid, cord blood and the Peapod device may not be available at all study centres. The location and timing of the birth may also affect whether or not these procedures can be performed.

The dietboxes will stop when you deliver your baby. As gestational diabetes usually resolves after the birth, you can then return to your normal diet. We will arrange a fourth visit around 6 weeks’ after the birth.

Visit 4 – at 6 weeks after the birth (postpartum). This visit will take 2 hours but will replace your standard postpartum visit for glucose (sugar) testing. At this visit we will:

1: Ask you to do an oral glucose tolerance test (OGTT) to check if your gestational diabetes has resolved. This is a similar test to the one you would have when you were diagnosed with gestational diabetes. 35 ml of blood will be taken as part of this test (7 teaspoons).

2: Start another 2 week period of glucose monitoring and activity monitoring

3: Take your weight, height and blood pressure and some skinfold measurements. We will also ask for a urine sample.

4: Ask you to complete questionnaires, for example, about your food intake, eating behaviour and infant feeding choices.

5: Ask you to have a DXA scan – this scan looks at bone strength and the proportion of fat and non-fat tissue you have in your body. This provides an extremely low dose of radiation and takes around 20 minutes. This is voluntary and can be done during the OGTT to avoid prolonging your visit. This test helps us to identify if your diet in pregnancy affects the proportion of fat in your body after pregnancy – this is important as a diet which reduces the proportion of fat in your body could offer you long-term health benefits. DXA scanning is not available at all study sites.

6: Perform a short examination of your baby including skinfold measurements.

7: Discussion about your possible interest in participating in a follow-up study.

**What will the dietboxes contain?**

The dietboxes will contain your food for a whole week. This will include three meals and three snacks per day. You will be able to choose which meal options you would like to receive. Examples of the food which will be provided are as follows:

Breakfast:

* Porridge with nuts (V)
* Breakfast Roll
* Cheese and Ham Omelette, with Rosti
* Cheese and Mushroom Omelette, with Rosti (V)
* Spiced Omelette with Sag Aloo (V)
* Granola (V)

Lunch & Dinner

* Mushroom Stroganoff with rice (V)
* Roasted Vegetable Lasagne (V)
* Seafood Lasagne (V)
* Lemon Salmon on Puy lentils (V)
* Vegetarian Chilli Rice/Quinoa (V)
* Spanish Bean Stew with Vegetarian meatballs (V)
* Chilli Bean Wrap (V)
* Edamame and Feta Wrap (V)
* Spiced Moroccan Chicken Wrap (V)
* Vegetable casserole with Cobbler (V)
* Egg Curry (V)
* Goujon, minted peas & wedges
* Beef Madras with Rice
* Tandoori Chilli Chicken
* Sausage and Pasta Bake
* Chicken Schnitzel, green beans, garlic butter & wedges
* Chilli Con Carne
* Thai Red Chicken Curry, Courgette, Carrot and Rice
* Beef In Black bean Sauce
* Venison Sausage, Red Wine Jus, Dauphinoise, Brussels Sprouts
* Pork Dijon
* Beef in Green Peppercorn Sauce
* Ham Hock Cassoulet
* Chermoula Chicken and Bulgar Wheat
* Jambalaya
* Teryiaki Chicken, Coconut Rice, Cabbage
* Beef and Red Wine Casserole

Snack packs contain a range of options including

* Nuts
* Fruit including banana and apples
* Cream cheese dip
* Eggs
* Sausage bites

**What are the possible disadvantages or risks of taking part?** The risks of taking part in this study are low. The dietboxes are specially formulated to be suitable for pregnant women with gestational diabetes and we hope these will improve your health and that of your baby during this pregnancy.

We don’t know exactly how much food women with gestational diabetes need during pregnancy. There is therefore a risk that you will be hungry on the diet or you may feel very full. Some women may gain weight (as expected in late pregnancy), while other women may have a stable weight or small weight loss during the study. In the past, weight loss in pregnancy has not been recommended, but there is now good scientific evidence that in women with gestational diabetes, weight loss can be safe and even beneficial to both mum and baby. We will monitor your weight carefully at your study visits and antenatal appointments. If you gain or lose substantial amounts of weight, we will make extra appointments and arrange extra ultrasound scans if needed. Gaining excessive weight in pregnancy has been linked to having a high birth-weight baby (large-for-gestational age is the technical term for this). Substantial weight loss can cause babies to be born smaller than usual (small-for-gestational-age). If you, or the study team, or your doctors and midwifes are concerned about your weight gain or weight loss, or your baby’s weight gain, we would discuss the matter with you. If you experienced extreme weight loss or weight gain during the study, we would stop the dietboxes and increase the number of visits or scans.

Blood testing will cause a small amount of discomfort to you. The small volume of extra blood taken will not pose a risk to you or your baby. Wearing a sensor for glucose (sugar) could be inconvenient for some women but most people do not find this troublesome.

If you choose to have the DXA scan at the final visit, 6 week after the birth, there is a very small dose of radiation given. The dose of radiation received during a DXA scan is equivalent to the amount of radiation we receive naturally through the atmosphere in a few hours. This does not pose any substantial risk to you.

**Are any devices or drugs involved?** There are no drugs involved in the study. We will use devices in this study to measure glucose levels (continuous glucose monitoring). These devices have been used in pregnant women before.

**What are the possible benefits of taking part?** We cannot promise the study will help you, but the information we obtain from our research may help us improve care for pregnant women with gestational diabetes in the future.

However, participating in this study offers some advantages to you and your baby. We will be using the latest evidence to improve your care during pregnancy and to help you and your baby have good pregnancy outcomes. Receiving the dietboxes allows you to relax in the knowledge that you are receiving the best possible diet for women with gestational diabetes while requiring minimal time in preparation or cooking. In addition, the provision of 8-10 weeks of free food could allow you to save some money, allowing you to treat yourself in other ways or to prepare for the arrival of your baby.

There is also a possibility that while analysing your blood tests, we will detect abnormalities which you were not aware of before. This might include evidence of high cholesterol or about your long-term risk of diabetes, after this pregnancy. If we find out information relevant to your future health, we will send you a letter and can discuss the matter with you in confidence. We would also inform your GP. This offers you the possibility of having important conditions diagnosed early, which may be of benefit to your long-term health. The chief investigator and local principal investigators will be responsible for informing you and your GP about any unexpected findings.

**Will I be paid for my participation in the study?** Volunteers will not be paid for their participation. However, we will be supplying 8-10 weeks of free food which should allow you to save money on your grocery bills. If the study requires you to make extra visits to your hospital or clinic, we will reimburse your travel costs and contribute towards your parking costs. Your research midwife can give you further details about these reimbursements and can help you apply.

**What happens when the research study stops?** The blood and other samples taken for analysis will be stored and discarded 12 months after the end of the research study, or used in future ethically-approved studies. If you wish, after the study has been completed (~2022), the investigators will send you a report explaining the results of the research. If you would like to receive this report, please tick the appropriate box on the consent form.

**What if there is a problem?** Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information of this is given in part 2.

**Will my taking part in the study be kept confidential?** Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If the information has interested you and you are considering participating, please read the additional information in Part 2 before making any decision.

**PART 2**

**What if new information becomes available?** We continuously review the latest scientific reports in order to plan useful and worthwhile experiments. If new evidence came to light, we might consider amending our study design. However, if this occurred, we would explain the changes to you and give you the opportunity to withdraw if you wish.

**Will video/audio tapes be used?** No

**What if there is a problem?** If you have a concern about any aspect of this study you should ask to speak to the researchers who will do their best to answer your questions (see contact details below). The patient advice and liaison service (PALS) can be approached for independent advice (for each institution: <insert contact details>). If you remain unhappy and wish to complain formally you can do this through the NHS Complaints Procedure, details of which can be obtained from your hospital.

**Are there any compensation arrangements if something goes wrong?** If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism may be available to you. In the event that something does go wrong and you are harmed during the research and that is due to someone’s negligence then you may also have grounds for legal action for compensation against the University of Cambridge or Cambridge University Hospitals NHS Foundation Trust, but you may have to pay your legal costs.

**Will my taking part in this study be kept confidential?** We believe that the confidentiality of your personal data is vital. The study will meet all relevant data protection requirements and will adhere to the NHS Code of Confidentiality. All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed (anonymised) so that you cannot be recognised.

Dr Claire Meek and the study team will have access to your personal data. These healthcare professionals have either full NHS hospital contracts or honorary hospital contracts which have the appropriate confidentially clauses inserted. We sometimes supervise students in healthcare disciplines who need to learn about clinical research, who also have strict obligations to maintain confidentiality. It is also possible that representatives of the University of Cambridge or Cambridge University Hospitals NHS Foundation Trust may ask to see the study files, to confirm that the research is being performed to the required high standards. All staff are aware of the requirement for strict confidentiality and work to appropriate confidentiality standards.

We will delete your personal details 12 months after the study is completed or store them securely for use in future ethically approved studies, such as a follow-up study after the current study is completed. For example, we may run a future study to assess if weight changes in late pregnancy affect the risk of high blood pressure or diabetes in women after gestational diabetes. Further details of the data protection arrangements and the use of your personal data during the study are given below.

**How will my personal data be used in the DiGest Study?**

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge are the joint sponsors for this study based in the United Kingdom. We 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 we are responsible for looking after your information and using it properly. Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge will keep identifiable information about you from this study for 1 year after the study has finished unless there is new ethical approval for the use of your data in a new study.

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. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the research team or Dr Claire Meek, the chief investigator <insert contact details>.

How we collect and use your personal data

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge will collect information from you and your medical records for this research study in accordance with our instructions.

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge will use your name, NHS number, date of birth and contact details 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. Individuals from Cambridge University Hospitals NHS Foundation Trust, University of Cambridge and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Each study site will pass these details to Cambridge University Hospitals NHS Foundation Trust and University of Cambridge along with the information collected from you and your medical records.

The only people in Cambridge University Hospitals NHS Foundation Trust and University of Cambridge who will have access to information that identifies you will be people who need to contact you to arrange deliveries of dietboxes, to check you are satisfied with the dietboxes, to respond to any queries or concerns you have or to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number, date of birth or contact details.

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge will keep identifiable information about you from this study for 1 year after the study has finished unless there is new ethical approval for the use of your data in a new study.

Use of data in future research

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

In this study, we will hold your personal identifiable information separately to the main research data.

**What will happen to the samples I give?** Once the samples have been obtained by the researchers, they will be coded for identification and storage (this is called linked anonymised storage). The investigator and research team will have access to the code to enable us to identify your samples. Most of the laboratory analysis will be performed in the UK, but occasionally we send samples to other laboratories across the world for specialist testing. All samples which leave the UK will be anonymised to keep your personal data safe and the samples will be returned to us. Once 12 months has passed after the end of the study, the samples will be disposed of in accordance with the best practice for research samples as defined by the Human Tissue Act (2004), or used in future ethically-approved studies.

**Will any genetic tests be done?** A sample will be taken from you for genetic analysis. We may also use genetic testing on samples from the placenta, umbilical cord and cord blood, which give information about your baby’s genes. If we find evidence of different patterns of blood sugar levels, different pregnancy complications or different responses to the diet, we will perform genetic testing to identify if these features are likely to be inherited. However, as our understanding of these genes is still very limited, we would not normally share this information with you as it is unlikely to provide clear information about your future health.

**What will happen to the results of the research study?** We plan to write scientific papers in medical journals explaining to others what we have learnt from doing these studies. Personal identities will not be revealed in any publications.

**Withdrawal clause.** You will be free to withdraw from this study at any stage without explanation and without affecting your current or future treatment. Any samples taken up to the time of withdrawal will be kept and used in the study for the purposes they were taken for, unless you specifically request otherwise.

**Who is organising and funding the research?** The study is jointly sponsored by the University of Cambridge and Cambridge University Hospitals NHS Foundation Trust.This study is funded by Diabetes UK. The doctors conducting the research do not receive any personal financial gain from including patients in the study.

**Who has reviewed the study?** All research in the NHS is looked at 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 given a favourable opinion by the Black Country Research Ethics Committee and the Cambridge Patient participation & involvement panel.

**Local contact for information.** Should you wish to discuss any issues related to this study, please contact the study team using the details below. Thank you for reading this leaflet.

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