NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES
UNIVERSITY OF OXFORD

RECORD
Reduced-carbohydrate intervention to prevent gestational diabetes

Chief Investigator:
Dr Nerys Astbury
DPhil Student:
Moscho Michalopoulou
Tel: 01865 617 857
Email: record@phc.ox.ac.uk

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PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in this research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If anything is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

This study is a PhD educational project, aiming to test if it is possible to deliver a dietary programme designed to reduce the risk that women who are pregnant will develop gestational diabetes (GDM). GDM is a condition that develops usually during the second or third trimester of pregnancy, in which women's blood glucose levels are high. It can lead to health complications for the mother and the baby during pregnancy and later in life. Carrying or gaining too much weight during pregnancy, increases the chances of developing GDM. Effective ways to help women who are at increased risk of GDM to control their weight and blood glucose levels early in pregnancy are needed.

What we eat affects our weight and blood glucose levels. Carbohydrates are the main source of energy (calories) and eating carbohydrates leads to rise in blood glucose. We therefore developed a new dietary programme to help you moderately reduce, but not cut out, the amount of carbohydrate that you eat, while maintaining a balanced diet.

This small study will test if it is possible to deliver the new programme alongside routine appointments and how well women can follow this advice for approximately 6 months. We will monitor the impact of the programme on some markers in the blood, and explore its effect on weight gain and other health outcomes throughout pregnancy. If the programme is feasible and well-liked, we will run a bigger study aiming to help prevent GDM.

Why have I been invited?

We are looking for 60 women who are at increased risk of developing GDM. Your most recent weight and height measurements suggest that you may have a raised Body Mass Index, which is a risk factor for GDM.

Do I have to take part?

No, you don't have to take part. Taking part is voluntary. If you decide not to take part, this will not affect the care you receive during pregnancy and delivery. If you decide to take part but then change your mind, you can withdraw at any time without giving us a reason. This will not affect the care that you receive.

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

If you decide to take part, you will be asked to attend two research study visits at the hospital with the study team. One visit will happen before you are 20 weeks pregnant, and the other visit will happen around 24-28 weeks of pregnancy. This second visit replaces a visit that you would be required to attend even if you were not taking part in the study. Each visit will be scheduled in the morning and will last for approximately 2 hours.

Preparation for study visits: You will be asked to arrive to these appointments after an overnight fast. This means you should not eat or drink anything (apart from water) from the night before the visit. You should also avoid smoking, vaping, using nicotine replacement therapy and chewing sugar gum since the previous night.

First study visit: At the first study visit (before 20 weeks of pregnancy), the researcher will go through this information sheet with you and you will have the opportunity to ask any questions about the study. If you are happy to take part, you will be asked to sign a consent form and you will be given a copy to keep. With your consent, we will complete the following procedures:

- **Oral Glucose Tolerance Test (OGTT):** We will collect a small blood sample and then ask you to drink a special sugar drink. We will collect further small blood samples after 1 and 2 hours. The OGTT tests how well your body handles the ingestion of sugar.
- **Study assessments:** Whilst you are waiting, we will measure your height, weight and blood pressure, and ask you to fill in questionnaires about yourself, including your usual diet and quality of life.

You will also be allocated to one of the study groups. Two-thirds of participants will be assigned to the RECORD diet group, who will be guided to moderately reduce their carbohydrate intake, whilst the other participants will be assigned to the control group, who will continue to receive the usual care and support given to women who are pregnant. Having a control group helps us test if our intervention is more beneficial compared to the usual dietary advice. Group allocation is entirely down to chance and will be decided by a computer programme. You cannot choose which group you are in and you won't be able to change group allocation once you have been allocated.

Two groups:

- **Intervention group:** If you are assigned to the RECORD diet group, we ask that you follow the dietary advice and recommendations to the best of your ability until the delivery of your baby. During the first study visit, you will be advised to moderately reduce, but not cut out, the amount of carbohydrate in your diet. You will receive a booklet, meal and recipe ideas and other materials to help you follow the dietary advice. We will arrange another six brief sessions to support you through the diet plan, at a convenient time, when you are around 16, 18, 20, 24-28, 30 and 34 weeks pregnant. These sessions will be by telephone, except the one at 24-28 weeks, which is on the same day as your second study visit and can be either on the telephone or face-to-face. All support sessions will take a maximum of 15 minutes. We will ask your permission to audio-record the face-to-face and telephone sessions. You will also be asked to monitor your weight once a week and send the measurements to the study team. We can lend you weighing scales if you don't own a set.
- **Control group:** If you're assigned to the control group, you will continue to receive any dietary advice that is given as part of the routine pregnancy care.

Blood glucose and ketone monitoring: Everyone taking part will be asked to measure their blood glucose and ketone levels at home twice a week for the duration of the study, using a monitor we will provide. You can log your measurements into a mobile phone/tablet/iPad application or text them to the study team. The study team and members of the clinical care team will have access to these readings. Taking part in this study will not affect any other treatment you may be receiving.

Follow-up study visit: During the follow-up appointment at 24-28 weeks of pregnancy, we will repeat the procedures conducted at the first study visit. The OGTT conducted at this visit will determine whether you have developed GDM. You would usually have this same test at this time at the hospital or your GP practice, even if you were not taking part in the study. To avoid having the same test twice, our test will replace the test you would usually have and we will share the results with your clinical care team.

Diagnosis of GDM: If the results of this second OGTT indicate that you have developed GDM, you will have the same access to medical care and any necessary medications, regardless of your study group allocation. Everyone will be offered routine care dietary advice for GDM, which is similar to that we are testing in this study. Therefore, if you are in the intervention group, you can continue following the RECORD moderately reduced-carbohydrate programme, and weigh yourself weekly until delivery.

Optional discussion: After the follow-up visit, if you are in the RECORD diet group, we may ask if you would be willing to have an in-depth discussion on the phone with a member of the study team about your experiences of the intervention. This is entirely optional. We will provide you with more details during your follow-up visit.

End of study-health outcomes: With your consent, we will access your medical records after the delivery of your baby. This will enable us to compare health outcomes of the mothers and new-borns between the two study groups.

What should I consider?

You may not be able to take part if you have certain medical conditions or taking medication that might make the dietary advice we are giving unsuitable for you. These include: taking metformin, being diagnosed with GDM at the first study visit, having diabetes before pregnancy, a serious medical condition (e.g. heart failure, serious liver or kidney disease, or disease of the nervous system), serious mental health problems requiring hospital stays, current or previous eating disorders affecting your physical and mental health, or very bad nausea or vomiting. To be able to take part, we also need to confirm that you are not carrying a baby with a serious medical condition identified during scans, that you have not had an organ transplant or weight loss surgery, that you are able to understand spoken and written English, and that you are not taking part in other intervention research studies that may affect your weight, health behaviours or blood glucose control. If you are eligible and decide to take part, you can continue to take your regular prescribed or over-the-counter medication during the study.

Are there any possible disadvantages or risks from taking part?

Severely restricting carbohydrate intake may lead to increased ketone levels, compounds that are produced when glucose – which mainly comes from carbohydrate foods – is not available to the body. It is not expected that the RECORD programme will lead to increased ketones because it has been designed to ensure you get adequate amount of carbohydrate which is the same as advised in routine care if women are diagnosed with GDM. The only difference is that we ask you to follow this advice earlier in pregnancy and in a more structured way. In addition, no evidence is available to determine any effect of the diet on the unborn child. We will provide you with a device to monitor both your blood glucose and ketone levels as an extra check. We will also ask you to measure your blood glucose and ketones if you are unwell and contact your clinical care team for advice if required.

You will be asked to fast overnight before each study visit. Some people can feel lightheaded or unwell if they don't eat for long periods of time. Once we have finished the tests, we will provide you with a light breakfast before you leave the hospital. You will be asked to provide small blood samples and as with any blood sample, there is possibility of stinging and a risk that you develop some bruising around the area, which should go away in a few days. Some people may feel faint while the sample is taken, but all blood samples will be taken by health care professionals who are trained and experienced in these procedures. Finally, all measures against coronavirus will be taken during the study visits as per Government guidance.

What are the possible benefits of taking part?

If you are randomised to the RECORD diet group you will receive detailed advice, support and guidance on your diet early in pregnancy. In addition, the knowledge gained in this study may help to plan a bigger study which may help in the future other women who are pregnant, to control their weight gain and blood glucose levels with diet alone, and to possibly reduce their risk of developing GDM.

Will my General Practitioner/family doctor (GP) be informed of my participation?

With your consent, we will notify your GP of your participation in this study and we will share with them the results of any relevant blood tests.

Will my taking part in the study be kept confidential?

Any data that we collect about you during this study will be kept strictly confidential. You will be assigned a unique study code to avoid identification with your name. Responsible members of the University of Oxford and the Oxford University Hospitals NHS Foundation Trust, may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

You will be offered £30 at each study visit (£60 in total) in the form of gift cards or bank transfer according to your preference, to compensate you for the time, inconvenience and expenses such as parking costs, associated with attending the study visits. If you prefer a bank transfer, we will ask your permission to collect your bank details.

What will happen to the samples I give?

Your blood samples will be analysed to measure blood glucose, HbA1c (average blood glucose levels of the past 2-3 months), insulin, and to estimate a measure of insulin resistance. The samples will then be destroyed and will not be used for other purposes.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records, in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for a year after the study has finished (e.g. contact details), in order to prepare and send you a summary of the study results. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study. Audio-recordings from the intervention sessions will be encrypted and kept securely in a password protected computer at the University of Oxford. Members of the study team will listen to these audio-recordings to assess how well the intervention is delivered. The audio files will then be deleted. The Oxford University Hospitals NHS Foundation Trust will use your name, home address and

contact details, to contact you about the research study, and to oversee the quality of the study. They will keep identifiable information about you from this study in keeping with local policies for retention of medical records. Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights .To find out more about how we use your information contact us on 01865 617 857 or record@phc.ox.ac.uk .

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

If you decide now that you want to take part, but change your mind later, you can withdraw from the study at any point and without giving us a reason. If you decide to withdraw we will use any data, including blood samples, which we have collected from you up to the point at which you decide to withdraw, unless you explicitly request us to delete/destroy them.

What will happen to the results of this study?

The results of this study will help us design future studies with the aim of helping women who are pregnant to reduce their risk of developing GDM. These studies may help to change guidelines about ways to prevent GDM. The overall study results may be presented at scientific conferences or published in scientific journals. This research will also contribute to the fulfilment of a doctoral thesis and educational qualification (Doctor of Philosophy) at the University of Oxford. On successful submission of the thesis, it will be deposited in the University archives, and will be available to the public. All results will be presented or published in a form that does not identify you. We will send you a summary of the study results once the study has finished and data has been analysed (from late 2022 onward).

What if we find something unexpected?

We will share any relevant blood test results with your direct clinical care team and GP. They will be in touch if anything unexpected is found.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided. If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Dr Nerys Astbury or Moscho Michalopoulou on 01865 617 857 or record@phc.ox.ac.uk ; or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email: ctrg@admin.ox.ac.uk .The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact 01865 221473 or PALS@ouh.nhs.uk .

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

We have discussed this research with women affected by GDM. They helped to shape the ideas for this research and to determine the questions we are trying to answer. In designing this study, we have taken into account their opinions on what information women who are pregnant would like to have available to help them change their diet in order to control their weight and blood glucose levels. A patient representative has provided feedback on the intervention materials and will continue to be involved throughout the study.

Who is organising and funding the study?

The study is sponsored by the University of Oxford. The research is funded by the Oxford-Medical Research Council Doctoral Training Partnership and the National Institute for Health Research Oxford Biomedical Research Centre.

Who has reviewed the study?

Research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. The South-Central Oxford B Research Ethics Committee has approved the ethics of this study.

Further information and contact details

Please contact Dr Nerys Astbury or Moscho Michalopoulou on 01865 617 857 or record@phc.ox.ac.uk .

Thank you for considering taking part in this study.