NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES
UNIVERSITY OF OXFORD

RECORD
Reduced-carbohydrate intervention to prevent gestational diabetes

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RECORD

Reduced-carbohydrate intervention to prevent gestational diabetes-Qualitative Interviews

PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in an informal interview about your experiences of the RECORD study. Before you decide, it is important that you understand why this interview 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 there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the informal interview?

We would like to know how participants feel about the RECORD intervention. We will discuss with you to understand your experiences of the dietary programme and use the feedback to refine the intervention.

Why have I been invited?

We are looking for up to 30 women from the main RECORD study so that we can explore their views about the RECORD diet advice. You have been invited to take part because you have been allocated to the RECORD diet intervention group.

Do I have to take part?

No, taking part in the interview is entirely voluntary. You may decide not to take part in the interview and this will not affect your participation in the main RECORD study or the clinical care you receive. If you decide now to take part, but at a later time decide that you no longer wish to participate, you can withdraw from the study. If you decide to withdraw for any reason, we will keep any information already collected about you.

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

We will invite you to talk about your experience of the RECORD intervention and provide feedback, on a day and time that is convenient for you. This will involve discussing with the researcher over the phone for approximately 30 minutes. We will audio-record this discussion.

What should I consider?

We would expect you to talk about your experiences of attempting to follow the RECORD intervention, of taking part in the study, and of monitoring your weight, blood glucose and ketone levels. The discussion will be audio-recorded.

Are there any possible disadvantages or risks from taking part?

The risks of taking part in this interview are extremely minimal. However, it is possible that some of the questions asked during the interview may cause you embarrassment or distress. The questions will focus on exploring your experiences of the dietary advice you were given and of taking part in the main RECORD study. If you feel uncomfortable about answering any of the questions, you can decline to answer any question and the interviewer will move on to the next question.

What are the possible benefits of taking part?

Although there are no direct benefits to you from taking part, your participation may help researchers understand which components of the dietary intervention work well and which don't work so well. This may help future decisions with respect to making consistent dietary advice routinely available during antenatal care in the NHS.

Will my taking part in the informal interview be kept confidential?

Any information that we collect about you during this discussion will be kept strictly confidential. We will not disclose your participation in these interviews to your GP. We will use 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 compensated for your time with £20 for taking part in the interview in the form of a gift card or bank transfer, according to your preference. This is in addition to any compensation you may receive from taking part in the main RECORD study. If you prefer a bank transfer, we will ask your permission to collect your bank details (if not already done so).

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 use your contact details to arrange the interview and will use the minimum personally-identifiable information possible. We will keep identifiable information for a year after the main study has finished (e.g. contact details), in order to prepare and send you a summary of the study results. We will ask you to verbally consent on the telephone to take part in the interviews and will record your consent on a consent form. We will send a signed copy of the consent form to you in the post. The interviews will be audio-recorded. The audio-recording will be encrypted and stored securely on a password protected server separately from any personal information held about you. The audio-recording will then be typed-out by an approved transcriber service. The recording passed to the transcriber will be identified by a study code number, rather than any of your personal details. The transcriber will not retain the recording after they have been typed out and returned to the research team. This processing of data will be formalised in a written agreement to ensure it is undertaken confidentially and securely. The original audio-recording will then be deleted. The original consent form with your recorded verbal consent will be held securely at the University of Oxford for 5 years after the end of the main RECORD study and will then be destroyed. The pseudonymised transcription from your audio-recorded interview will be stored securely on an encrypted and password-protected server for 3 years after the end of the main study and will then be deleted.

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 .You can find out more about how we use your information by contacting us on 01865 617 857 or record@phc.ox.ac.uk .

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

Participation is voluntary and participants may change their minds at a later stage. If you decide to withdraw from this interview, it will not affect the care you receive from any relevant service. If you decide to withdraw from this interview, you will remain in the main RECORD study, unless you notify us otherwise. If you withdraw from this interview after we have already started the discussion, unless you state otherwise, any data already collected will be used as detailed in this participant information sheet.

What will happen to the results of this study?

The transcriptions of the interviews will be coded and all these coded interviews will be analysed to determine whether there are similar themes identified. We plan to publish the findings in scientific journals and present the results at conferences. Please be reassured that you will not be identified in these outputs. If your quotes are used

they will be identified by an anonymous pseudonym. When these publications or reports become available (from late 2022 onward), we will send you a copy of the results. Some of the research being undertaken will also contribute to the fulfilment of a doctoral thesis and educational qualification (Doctor of Philosophy) at the University of Oxford.

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 interview. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the Chief Investigator Dr Nerys Astbury, or the DPhil Student and main researcher, Moscho Michalopoulou, on 01865 617 857 or record@phc.ox.ac.uk . Alternatively, you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or ctrg@admin.ox.ac.uk .

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

Potential participants have been actively involved in developing the questions asked during the interviews.

Who is organising and funding the study?

The RECORD study, including the informal interviews, is sponsored by the University of Oxford. The research is funded by the Oxford-Medical Research Council (MRC) Doctoral Training Partnership and the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre.

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 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 reading this information.