

**G**estati**o**nal **D**iabetes future **D**iab**E**te**S** prevention **S**tudy (GODDESS)

**Participant Information Sheet**

**Invitation to take part in a research study**

We would like to invite you to take part in a research study to find out if providing extra lifestyle support to women with gestational diabetes during and after pregnancy helps women to stay healthy and lose weight after birth. This information leaflet explains why this study is being done and what we would like you to do if you wish to take part. We will be happy to answer any questions you may have. Taking part is completely voluntary and you can decide to withdraw at any time. This study is being conducted by King’s College London in collaboration with Guy's and St Thomas' NHS Foundation Trust and King’s College Hospital.

**Funding and Sponsorship**

The study is Sponsored by King’s College London and Co-Sponsored by King’s College Hospital NHS Foundation Trust. The study is part of an educational project and funded by the National Institute for Health Research (NIHR) as part of a doctoral fellowship.

**Purpose of the study**

Women who develop diabetes during pregnancy (called gestational diabetes) have a higher chance than other women of developing type 2 diabetes later on. They also have a higher chance of having gestational diabetes in future pregnancies. Type 2 diabetes can cause health complications, but it can be delayed or prevented through eating healthily, being physically active and losing weight.

However, little research has been done to find out how women with gestational diabetes can be supported to reduce their risk of developing type 2 diabetes. We know that after having a baby it is often difficult for women to focus on their own health. Therefore, we want to try out some extra lifestyle (diet, physical activity and breastfeeding) support for women who have gestational diabetes that we hope will help them to stay healthy and lose weight after birth.

**Why have I been invited?**

You have been invited to take part in this study because you have recently been diagnosed with gestational diabetes. We are looking for 60 women to take part in our study.

**Do I have to take part?**

It is up to you if you want to take part in this study. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of any care you would receive at the hospital. If you decide to withdraw, data already collected will be used in the data analysis, unless you request otherwise.

**What will happen to me if I want to take part?**

With your agreement, a researcher will contact you by telephone and arrange to meet with you to discuss the study. If you agree to take part you will be asked to sign a consent form. We will ask your permission to access some of your medical records to find out information about your pregnancy, and arrange an appointment with you to collect some more information about you. You will then be randomly assigned to receive either (1) the extra lifestyle support or (2) just your usual appointments. If you receive the extra lifestyle support you will still receive your usual appointments as well. At the end of the study we will compare the women who received the extra support with those women who didn’t receive it in order to see if the support has made any difference.

If you do receive the extra support you will have:

* Five one-to-one sessions with a diabetes nurse.
* A pedometer or FitBit
* The opportunity to join a WhatsApp group with other women with gestational diabetes. This can be done on a smart phone, a tablet or a computer. The WhatsApp group will be facilitated by a moderator who will be able to direct you to information or support in relation to your gestational diabetes. The group will also enable you to have discussions with other women who have gestational diabetes.
* Access to a website with information on gestational diabetes

If you are not assigned to receive the extra support you will receive your usual appointments.

All 60 participants (both those receiving the extra support and those not) will visit the hospital three times for us to collect some information and carry out some checks.

The data collection will involve collecting the following information from you (not all of the checks will be carried out at all three visits): weight, height, waist circumference; blood pressure; glucose tolerance test; blood test; general information about you (age, ethnicity etc.); diet and physical activity; your attitudes about diabetes risk; your attitudes towards your body; eating behaviour; motivation to change; quality of life and depression; sleep; feeding your baby; your feedback on the study.

The study will last for around a year – up until your baby is 9 months old. At the end of the study all of the participants will be given a questionnaire to complete about their feedback on the study, and some of the participants will be interviewed. Those participants who have not received the extra support will be given some information and directed to where they can get support at the end of the study.

The diagram below shows what will happen at each visit.

|  |  |  |
| --- | --- | --- |
| Gestational diabetes diagnosis | **Participants who receive extra support**  Telephone call from researcher  Information and consent visit  (20-30mins)  Information collection visit (1hr)  One-to-one session (1hr)  Information collection visit (1hr)  One-to-one session (1hr)  Information collection visit (1hr)  One-to-one session (1hr)  Information collection visit (1hr)  One-to-one session (1hr)  Information collection visit (1hr)  Information collection visit (1hr)  One-to-one session (1hr)  Interview (some participants only)  Feedback questionnaire (30 mins)  Receive information about the research (5min) | **Participants who don’t receive extra support** |
| Soon after diagnosis |  |  |
| Soon after diagnosis |  |  |
| Soon after diagnosis |  |  |
| Third trimester of pregnancy |  |  |
| 3 month after birth |  |  |
| 6 months after birth |  |  |
| 9 months after birth |  |  |
| 9 months + after birth |  |  |

**How will participation in the research affect my usual appointments?**

As well as the extra appointments, you will get exactly the same appointments as you would get if you don’t take part in the research.

**What will happen to my blood sample and data?**

Blood samples collected for the purposes of the research will be used immediately. At the end of the study the samples will be disposed of in accordance with Human Tissue Authority (HTA) policies.

The data from the study will be stored in a research office in King’s College London in a locked filing cabinet or on a password-protected computer. It will not contain any participant identifiable data. Data will only be accessible to the research team and after five years the data will be destroyed.

We will audio-record the final interview for the purposes of our own analysis. No one else other than the researchers will listen to the recordings for any reason. Recordings will be transcribed, de-identified and destroyed as soon as possible. Any publications of direct quotes will not be identifiable.

**Will my taking part in the study be kept confidential?**

All data will be kept confidential and used anonymously. Information will be stored securely and only the research team will have access to it. The healthcare staff providing your usual appointments will not have access to the research data.

**Benefits of taking part**

Benefits for those participants receiving the extra support could include: decreased risk of type 2 diabetes, improved diet, increased physical activity, improved physical and mental wellbeing, better understanding about diabetes. Benefits for all participants include the opportunity to be screened and tested for diabetes risk. In addition, the participants who do not receive the extra support will receive some information at the end of the study. Finally, although not a direct benefit, participating in the study provides an opportunity to help improve care for future women who have gestational diabetes.

**Risks and disadvantages of taking part**

There are no known risk associated with this study. The biggest disadvantage of taking part will be the time commitment involved with coming to the hospital for us to collect information and you to have your one-to-one sessions.

**What if there is a problem?**

If you have any concerns during the study you can contact the research team on the telephone numbers provided. If you have concerns regarding the study or are unhappy in anyway, you can do this by contacting the Patients Advice and Liaison Service (PALS): phone: 020 7188 8801, email: pals@gstt.nhs.uk. The PALS team is based in the main entrance on the ground floor at St Thomas’ Hospital and on the ground floor at Guy’s Hospital in the Tower Wing.

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against Guy’s and St Thomas’ NHS Foundation Trust and/or King’s College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (*If appropriate*).

**Involvement of the general practitioner/ doctor**

Your GP will be informed, with your consent, that you are taking part in the study.

**What will happen to the results of the research study?**

The results of the study will be disseminated locally, nationally and internationally in meetings for healthcare professionals and via diabetes related support groups. Papers will be published in health journals associated with diabetes and newsletters for people with diabetes. We hope that the results of the study can help improve care for women with gestational diabetes. We will also provide a summary of the results for participants, should they wish to receive them.

**Research Ethics review**

This study has been reviewed and given favourable opinion by ……. Research Ethics Committee

**Participation in future research**

The researchers will request permission to contact you again for future investigation. This is an optional request and if you do not wish to give consent to be contacted for future investigations, it will not impact your participation in this study nor will it impact your clinical care.

**Further information and contact details**

Thank you for reading this participant information leaflet. If you have any questions, or would like to find out more about the study please contact the researcher who will be happy to discuss this study with you:

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