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**PARTICIPANT INFORMATION LEAFLET**

**The BABY STEPS study**

**Chief Investigator:** Professor Kamlesh Khunti (Diabetes Research Centre, University of Leicester)

**Full Study Title:** *A randomised controlled trial to investigate the effect of a structured education programme on women who have had gestational diabetes and are at risk of developing type 2 diabetes.*

We would like to invite you to take part in what we think is a very important research study. Before you decide whether or not to take part, it is important for you to understand why the study is being done and what it will involve, so that you can make an informed decision. If there is anything you do not understand or want more information, please contact the research team (details at the end of the leaflet) and we will be happy to speak to you.

**What is the purpose of the study?**

Research has shown there is an increased risk of developing type 2 diabetes within 10 years of having diabetes during pregnancy. Type 2 diabetes is a serious condition that occurs when people have too much sugar in their blood for too long. This can lead to lots of health problems, including problems with the heart, kidneys, eyes and feet.

We know that certain characteristics and lifestyle choices such as exercise and a healthy diet can reduce the risk of developing type 2 diabetes. This study aims to develop and evaluate an education programme that aims to reduce the risks of developing type 2 diabetes for women who had diabetes during pregnancy. The education programme will cover risks of diabetes, increasing physical activity, diet and goal setting.

**Why have I been invited?**

We are inviting you to take part because you had diabetes during your last pregnancy. We are looking for women aged 18 years and older who have had diabetes in their most recent pregnancy and gave birth up to thirty-six months ago and can speak and read English.

**Do I have to take part?**

No, it is entirely your own decision whether or not you take part in the study. If you do decide to take part, you are free to withdraw at any time without giving a reason and this will not affect the standard of health care that you receive. All you have to do is contact the study team and let them know (contact details are at the end of the leaflet). Please note that the researcher may withdraw you from the study for the following reasons: you become ineligible to take part, an illness that affects your participation, we cannot contact you and if you lose capacity to make decisions. If this occurs the study team will let you know.

**If I choose to take part, what will I have to do?**

Please return the attached reply slip to the **(Enter local site)** using the stamped addressed envelope. A member of the research team will contact you via telephone to arrange an appointment and will go through a provisional screening to check if you can take part in the study. This does not mean that you are obliged to take part in the study. At the first visit you will have time to ask any questions. Once you are happy and want to take part, you will be asked to sign a consent form. You will be given a copy of your signed form to keep for your own information. If you give us permission, we will let your GP know you are taking part in this study.

The next section will outline the study procedures and what the study involves.

**The Study Procedure**

**Visit 1**

Visit 1 is known as the consent and baseline assessment and will take up to 2 hours. You will be involved in the study for 12 months and this is when you will attend your second assessment visit. On visit 1 you will meet a member of the research team who will go through this information leaflet and take your consent. Once you have agreed to take part in the study, the baseline assessment measures will be taken. These are outlined below:

* ***Personal and Demographic data*:** Ethnicity, age, smoking and alcohol status, history of gestational, medical history, current medication and family medical history.
* ***Body measures*:** Height, weight, waist circumference, and hip circumference will be measured using scales and a tape measure.
* ***Cardiovascular measures*:** Blood pressure and resting heart rate will be measured using an upper arm monitor.
* ***Blood tests****:* We will take a blood sample to measure blood sugar and blood fats. These samples will be process in the same way as those that are taken as part of your routine care, in an accredited NHS laboratory. After processing, the samples will be destroyed.
* In addition to this we would like to take further samples of blood from you at baseline and 12 month clinic visit. These samples are ***optional*** and will be stored in line with all regulatory requirements. They may be stored indefinitely for future research and a new research application will be processed for blood analysis if there are further novel interventions or findings. All samples will be stored in an anonymous form so that those working with them will not know who they have come from. We take your privacy and confidentiality very seriously. During the study they will be stored in a research laboratory at the Leicester Diabetes Centre or the George Eliot hospital. Once the study has finished, these samples will be stored in a Human Tissue Accredited Laboratory in Leicester.
* ***Questionnaires:*** There will be a range of questionnaires to complete. These will cover health, fitness and general well-being. These will be analysed and used as data for the study.
* ***Daily activity:*** You will also be asked to wear an activity monitor for eight days from your assessment. This will involve wearing a wrist monitor similar to a watch which will measure your physical activity. If you do need to remove the monitor for any reason a log book will be provided so you can write this information down. We will provide you with full instructions and an activity log along with a stamped addressed envelope for you to return the monitor and log book after the eight days.

After the first visit you will be randomly assigned to **one** of two groups (these are listed below). A computerised system will do this; therefore, you or the researcher cannot choose which group you are allocated into.

**Group 1: Intervention group**

If you are randomly allocated to the education group, you will be given a leaflet addressing the risks of developing type 2 diabetes and asked to attend two education sessions focusing on type 2 diabetes and physical activity. The education sessions will be two weeks apart and approximately three hours long in a group based style. The education sessions will take place in various local venues within **(enter locality)** and they will vary with time: morning, afternoon and evening sessions will be available. You will also have access to an interactive website and be given a wrist-worn monitor for your own use to see your progress. You will receive a 6 month interim postal follow up which will include the activity monitor to measure physical activity and questionnaires. These will be sent to you with full instructions and a stamped addressed envelope for you to return the monitor and questionnaires. You will then be asked to return 12 months after your baseline assessment so we can repeat all the measurements taken at your first visit.

**Group 2: Control group**

If you are randomly selected to the control group, you will be given a leaflet addressing the risks of developing type 2 diabetes. You will receive a 6 month interim postal follow up which will include an activity monitor to measure physical activity and questionnaires. These will be sent to you with full instructions and a stamped addressed envelope for you to return the monitor and questionnaires. We will invite you to return 12 months after you baseline visit to repeat the measurements taken measurements taken at your first visit.

Please note we will also send you a letter with your results of the baseline and 12 month assessments. If you have given us permission, a copy of this will also be sent to your GP so they have the information.

**What are the possible benefits of taking part?**

Your contribution to the study will enable us to evaluate the education programme and contribute towards future care for women who have had diabetes during pregnancy. You will all (control & intervention group) benefit from a free health assessment and physical activity advice. You will also receive information on your general fitness levels.

**What are the possible disadvantages and risks of taking part?**

There may be potential risks associated with increasing physical activity although we presume these will be minimal as the education sessions focus on increasing day to day activity rather than vigorous physical activity. All measurements are carried out by qualified professionals. Some people experience minor discomfort and slight bruising from blood tests. A fully qualified research team member will carry out the blood test to ensure any pain is kept to a minimum.

**What if I am harmed by the study?**

It is very unlikely that you would be harmed by taking part in this type of research study.

However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you should ask to speak to study team in the first instance and the details are provided at the end of this leaflet. They will do their best to answer your questions.

In the event that something does go wrong and you are harmed during the research and this is due to someone’s negligence then you may have grounds for a legal action for compensation against University of Leicester but you may have to pay your legal costs as there are no special compensation arrangements for this study. The normal National Health Service complaints mechanisms will still be available to you. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Patient Information and Liaison Service at:

***(Enter local PILLS contact details)***

**Will it cost me anything to take part?**

We want to make it as easy as possible for you to take part and parking charges and public transport expenses can be claimed for every visit associated with the study (maximum of £10 per visit). We will attempt to hold the clinics and education sessions in venues which provide childcare services and there will be no charge if you use these services. If a venue does not have childcare services or you do not wish to use them, we will provide you with a £15 love2shop gift voucher for each clinic and education session you attend. This will be to acknowledge any inconveniences that attending the session may have caused you. If you would like further information or have any questions please contact the study team (details are at the end of the leaflet).

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

Yes. We will follow ethical and legal practice in accordance with the Data Protection Act (1998). All information about you will be handled in confidence unless you disclose that you, or someone else, are in immediate danger of serious harm. Access to identifiable data (name, address etc.) will be limited to selected members of the research team and to auditors for the purpose of monitoring the quality of the research. This information and other personal details will not be included in analysis, or in publications or reports. All information collected during the study will be identified by a unique code so that you cannot be identified from it. All data will be kept on secure computer systems and in locked filing cabinets, archiving rooms at the **(enter local site)** or our secure off-site storage provider.

Your medical notes may be accessed by the Sponsor, host NHS institution and regulatory authorities for monitoring and auditing purposes. Also, we will keep your personal details until we are in a position to send you a newsletter reporting the study results at the end of the study.

**Who is organising and funding the research?**

The study is funded by the Collaboration for Leadership in Applied Research and Care East Midlands (CLAHRC-EM), Collaboration for Leadership in Applied Research and Care West Midlands (CLAHRC-WM) and Academic Health Science Network (AHSN). It is being run by a research team based at the Leicester Diabetes Research centre, University Hospitals of Leicester and George Elliot Hospital.

**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 interests. This study has been reviewed and given favourable opinion by **[insert name of ethics committee].** This has also been reviewed by the University of Leicester as sponsor of the study.

**What happens when the research study stops?**

When the research study stops you will be advised to continue your activity. You will receive a short summary report of the study once it has been completed.

**What do I do now if I want to take part?**

We are pleased that you are considering taking part in this study. For the next step, please complete the enclosed reply slip and post it to the BABY STEPS study team using the pre-paid envelope provided. A member of the research team will then contact you to set up a suitable date and time for your appointment. Alternatively, please contact the research team on the number or email below and a member of the research team will arrange this for you.

Just because you agree to attend the appointment, it does not mean you are agreeing to take part in the study. At the visit we will answer any questions you may have, and only when you are happy with everything will we ask you to sign a consent form to say you agree to take part. We will give you a copy if this form for your records. Remember, even after you have signed the consent form you are still free to withdraw at any time with no reason. Once again, thank you for taking the time to consider taking part in our study. We really look forward to having you on board.

**How do I get further information?**

If you would like any further information please contact the BABY STEPS study team using the details below:

**The BABY STEPS study team**

**(Enter study contact details)**

Thank you for taking the time to read this leaflet.

The BABY STEPS Study Team