

**Insert Local Trust Logo**

**Front cover**

* 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. (The Baby Steps Study)
* **Study logo, UoL logo**

**Did you have diabetes during your pregnancy?**

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* Have you had a baby within the last 3 years?
* Were you diagnosed with gestational diabetes in your most recent pregnancy?

If your answer to the above is ‘yes’, we would like to hear from you. We are a multi-disciplinary team of clinicians and researchers at the University Hospitals of Leicester trust and George Eliot hospital trust, with a specific interest in lifestyle, diet and exercise.

We know that certain characteristics and lifestyle choices such as exercise and eating healthier food can reduce the risk of developing type 2 diabetes. This study aims to develop and evaluate an education programme that focuses on reducing the risks of developing type 2 diabetes after having diabetes during 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.

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**What will the study involve?**

The study will involve attending a baseline clinic visit where a member of the research team will go through the study with you, give you further opportunities to ask any questions and once you are happy to take part, written consent will be taken. Please remember, you can withdraw from the study at any point should you wish to, without affecting your routine care. Once you have agreed to take part some assessment measures will be taken. This includes personal and demographic data, body measures such as height, weight etc., blood tests and questionnaires. You will also be given an activity monitor to wear for 8 days and return.

After this visit you will be put in to two groups:

**Intervention group**

The intervention group will be invited to attend two education sessions that last up to 3 hours each and other support (interactive website and wrist-worn monitor). You will have a 6 month postal follow-up to wear the activity monitor for eight days and some questionnaires. You will then be asked to return 12 months after your education to repeat the measurements taken at the baseline visit which has been discussed above.

**Control group**

The control group will be given a leaflet on being at an increased risk of developing type 2 diabetes. You will have a 6 month postal follow-up to wear the activity monitor for eight days and some questionnaires. You will then be asked to return 12 months after your education to repeat the measurements taken at the baseline visit which has been discussed above.

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

Your contribution to the study will enable us to evaluate the education and contribute towards future care for people 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.

**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. We will discuss what arrangements you require over the phone, when booking in your baseline clinic visit**.** After this, we will send you a confirmation letter of the visit and we will provide further details of the childcare that has been arranged with you.

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**I am interested and would like to know more.**

We are pleased that you are considering taking part in this study. For more information please contact the BABY STEPS study team:

**The BABY STEPS study team**

**Insert Local site contact details (address, tel. and email)**

Alternatively you can complete the attached reply slip and send it back to us. A member of the research team will then contact you to discuss this further.

Thank you for taking the time to read this leaflet.