

Participant Information sheet for Use of Wearable Technology in Pregnancy by Women with Type One Diabetes – mTech4U

As a pregnant woman with Type One diabetes, you are invited to participate in a research project investigating the use of the FreeStyle Libre glucose monitor and a fitness tracker. Before you decide whether or not to take part, it is important that you understand what the research is for and what you will be asked to do. Please read the following information and ask questions about anything that might not be clear to you.

Project title

Use of Wearable Technology in Pregnancy by Women with Type One Diabetes.

What is the purpose of this study?

We would like to know more about the link between activity levels, heart rate patterns, carbohydrate intake, insulin and glucose levels during pregnancy. We will also look at the length of your pregnancy, the birthweight of your baby and their risk of hypoglycaemia after they are born.

Why have I been asked to take part?

You are being invited to take part in this research as you:

- are aged 18 years or older
- have had Type one diabetes for more than 1 year
- have had additional training around managing your condition, i.e. DAFNE or similar
- are using multiple daily injections of insulin
- have no health complications.

What will I be asked to do if I decide to take part?

We will ask you to wear the following devices for a period of two weeks between 7-12 weeks, 18-24 weeks and 30-38 weeks

- a fitness tracker, which will be provided by the research team, to monitor your heart rate, active minutes and number of steps taken each day.
- FreeStyle Libre glucose monitor to record glucose levels, carbohydrate intake & insulin doses taken and any notes e.g. activity, illness etc. We will ask you to email information from your FreeStyle Libre to provide the team with information collected.

We would also like you to photograph the food you eat each day over the two-week period. You can email or WhatsApp these photos to us. Information from the Libre and wearable fitness tracker will be collected at the end of each fortnight's use for analysis. The information may help us to better understand blood glucose changes. We would also like you to keep a diary to write about how you feel about taking part in this study.

Do I have to take part?

You do not have to take part in this study, your participation is entirely voluntary. You can choose to stop taking part in the study at any time, but we will use data we have already collected from you for analysis.

Are there any risks to taking part?

No additional risks have been identified. If you have any worries about your blood glucose, you are advised to contact your Diabetes Specialist Nurse. If you have concerns, about your baby or the pregnancy in general, you should contact the Maternity Admissions and Assessment Unit for further advice. The hospital team are responsible for the care of you and your baby. Your agreement to take part in this research will not affect the you or your baby receive.

Benefits

Benefits of this research include increased monitoring during your pregnancy. The results may help women with Type One diabetes and their babies in the future.

What if something goes wrong?

This study has been carefully planned, approved and reviewed by Ulster University and Southern Health and Social Care Trust. This study is primarily about the information from your Libre, food eaten, insulin taken and the wearable fitness tracker records, no additional risks have been identified.

Information about blood pressure, your HbA1c and weight will also be collected but this is for analysis purposes only.

Will my details be kept confidential?

If you agree to take part in this research your details will be kept confidential. All information collected will be securely stored within Ulster University. It will only be available to the research team. None of your personal details will be available to anyone outside the research team.

What will happen to the results from this study?

The knowledge we gain from this research will be made publicly available through research papers and information posters. No information which could identify you will be available.

Who is organising the study?

This study has been organised by Ulster University in conjunction with the Southern Health and Social Care Trust. It is funded by The Department for the Economy leading to a PhD qualification.

Who can I contact about this study?

If you would like to take part in the study or you would like to speak to someone about this research project, please contact:

Dawn Adams, PhD Researcher

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Additional contacts

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What if I wish to make a complaint about the study?

If you want to make a complaint about this study, or the way it is completed, you can do so using the complaints procedure of Ulster University, which is available here:

https://www.ulster.ac.uk/_data/assets/pdf_file/0011/75638/Complaints.pdf

If you want to know more about the Research Governance process, please contact:

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