The GILD Study

Participant Information Sheet

You are invited to take part in our research study

- Gestational diabetes is high blood sugars during pregnancy, which usually disappears after birth.
- The GILD study is looking at how blood sugars are monitored during labour in women and birthing people with gestational diabetes.
- We want to find out if a 'more relaxed' approach to monitoring blood sugars is just as good as 'tight' (more frequent) monitoring.
- This information sheet is to help you understand why the research is being carried out and what it will involve for you if you decide to take part.

Please take time to read this information and ask us if there is anything that is unclear or you would like more information.

- Only you can decide if you'd like to take part. But you can discuss this with others if this helps.
- If you agree to take part, you are free to withdraw at any time without giving a reason.
- If you choose not to take part, your care will continue in the usual way.

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In this booklet:

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What is the GILD study?

A summary of the GILD study

Gestational diabetes (GDM) is high blood sugars during pregnancy that usually disappears after giving birth. GDM currently affects 8 in 100 (8%) women/birthing people during pregnancy. Women/birthing people with GDM are tightly monitored and given insulin, when it's needed, in labour or before a planned caesarean birth, to keep their blood sugars at a safe level for them and their baby. This is known as 'tight' monitoring, which means checking blood sugars every hour and keeping them in a range of between 4 and 7 mmol/L. Many women/birthing people find 'tight' blood sugar monitoring during labour intrusive.

More recent research suggests 'tight' monitoring of blood sugars during labour may not be as important for preventing problems in the baby as previously thought. In this study, we will compare 'tight' monitoring of blood sugars with a 'more relaxed' approach to see if this impacts the woman/birthing person's labour, birth outcomes and experience, and their baby's blood sugar levels, health and need to be admitted to a baby unit for special care (neonatal unit).

Some experts are now recommending 'more relaxed' monitoring in labour. This means checking blood sugars every 2 to 4 hours and keeping them in a range of between 4 and 10 mmol/L. There have been no studies to look at which is the best way to monitor blood sugars during labour. If you decide to take part in the study, you could receive 'tight' or 'more relaxed' monitoring when you come to hospital to have your baby. Taking part in the study will not change how your blood sugars are managed before or after labour, only during.

We will compare the rates of low blood sugars in babies born in each of the groups to see if 'more relaxed' control is just as good as 'tight' control. We will ask women/birthing people what they think about the blood sugar monitoring plan and their birth experience. We will also compare costs and outcomes of the two monitoring strategies used in the study to see if one is better value for money for the NHS.

Tight monitoring

- Finger prick blood tests are taken every 1 hour
- Blood sugars are kept between 4 - 7 mmol/L

or

More relaxed monitoring

- Finger prick blood tests are taken every 2 - 4 hours
- Blood sugars are kept between 4 - 10 mmol/L

The rest of yours and your baby's care will continue as normal.

What is the purpose of the study?

- We are conducting this study because we do not know whether ‘more relaxed’ monitoring is as good as ‘tight’ monitoring during labour for women/birthing people with GDM, their babies, and the NHS. The study is needed so that we can find out if ‘more relaxed’ monitoring is as good as ‘tight’ monitoring at reducing the risk of low blood sugars in babies and admission to the neonatal unit.
- We will also be able to see whether the different blood sugar monitoring strategies lead to different experiences for the woman/birthing person, and different health outcomes for the woman/birthing person and their baby.

Why have I been invited to take part?

You have been invited to take part in this study as you have gestational diabetes. We are looking for 1630 women/birthing people with gestational diabetes in the UK to join the study.

Do I have to take part?

No, it is up to you whether or not you take part in the study. Even if you agree now, you are free to withdraw later if you wish.

We will talk to you about the study and answer any questions you may have. If you agree to take part, we will ask you to sign a consent form.

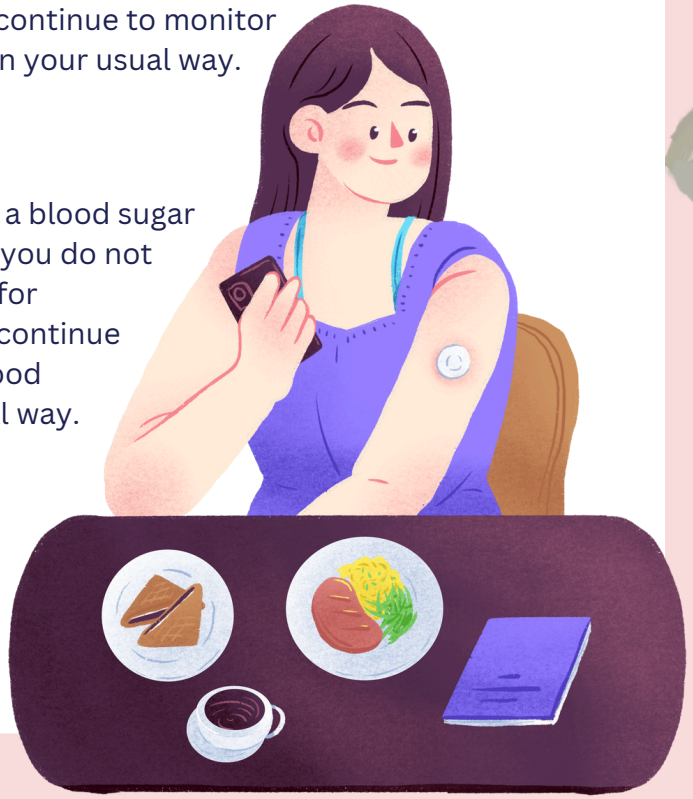
Do I get to choose whether I will have ‘tight’ or ‘more relaxed’ monitoring during my labour?

- As nobody knows if ‘more relaxed’ monitoring is as good as ‘tight’ monitoring, the type of monitoring you receive in hospital will be allocated using a process called ‘randomisation’.
- This means you will have an equal chance of having ’tight‘ or ’more relaxed‘ monitoring.
- Randomisation is used as it creates groups of patients that are similar except for the treatment received.
- This will enable a fair comparison of the different monitoring methods so we can assess at the end of the study which one is best for future patients.
- Neither you, the doctors or the research team can choose which group you will go in, as this could result in the groups being unequal and the findings unreliable.

What would taking part involve?

Blood sugar monitoring device

- If you take part, you will have a continuous glucose monitor (CGM) applied to the back of your upper arm when you are more than 37 weeks pregnant. This is a device that automatically measures blood sugars so we can check whether the hospital is monitoring your blood sugar levels as planned. The CGM will be removed after you have given birth.
- You and the health care professionals caring for you will not be able to see the blood sugar readings from this device, the results will only be seen by the research team.
- You will be able to continue to monitor your blood sugars in your usual way.
- If you already wear a blood sugar monitoring device, you do not need a new device for the study. You will continue to monitor your blood sugars in your usual way.



Questionnaires

- Once you have had your baby, but before you leave the hospital, you will be asked to complete a questionnaire about your quality of life.
- We will also send you a questionnaire by email (or in the post if you prefer) when your baby is 6 weeks old, asking about breastfeeding, how satisfied you felt about blood sugar monitoring strategies, your birth experience, and postnatal depression.

Shopping voucher

You will receive a £10 shopping voucher as a token of appreciation for taking part in the study.

Optional discussions

- 6-12 weeks after you have had your baby you may be contacted to share your thoughts on the acceptability of blood sugar monitoring approaches
- You will be invited to share your views during a telephone or video call which may last up to an hour, and if you agree, it will be audio-recorded on an encrypted device.
- Talking to us is optional and if you agree, we will organise a time that suits you
- If you choose to speak with us about blood sugar monitoring approaches, you will receive a further £25 shopping voucher as a small thank you

Consent

- You will be asked to sign a consent form to agree to take part in the study.
- You will be asked to sign a separate consent form if you agree to a optional discussion.
- You can also indicate on the consent form if you are happy to be contacted in the future about taking part in further research studies.
- With your consent, your name and telephone number will be shared with Esendex, our text messaging provider and their sub-processors, and will be used to send you text message reminders about the study and questionnaires whilst you are participating in the study.
- With your consent, we will inform your General Practitioner (GP) about your participation in this study.

Notes

What are the risks and benefits of taking part?

What are the possible benefits of taking part?

Taking part in the study may not directly benefit you, but the information we collect from this study may help us to understand more about the best way to monitor blood sugars during labour in people with gestational diabetes, this may be of benefit to you in a future pregnancy and may help all women/birthing people with GDM in the future.

What are the possible disadvantages and risks of taking part?

- Whilst recent research suggests tight monitoring of blood sugars may not be as important for preventing problems in the baby as once thought, we do not know which one is better for women/birthing people and their babies. That is why we are doing this study. When women's blood sugars are monitored in labour 'tightly', about 10 in every 100 babies (i.e., 10%) have low blood sugars after birth, which could mean the baby is admitted to the neonatal unit, away from their Mum, for treatment. If a woman/birthing person's blood sugars are monitored labour in a 'more relaxed' approach, we think about 15 in 100 babies (i.e., 15%) might have low blood sugars after birth, but we don't know – it might be slightly less, it might be slightly more.
- Some people may be sensitive to the adhesive that keeps the continuous glucose monitor in place and may experience some skin irritation. If this occurs, the device will be removed but you can continue in study.
- There are no physical risks from completing the questionnaires or if you take part in the optional discussions. It is possible that thinking and talking about your feelings and other issues related to your gestational diabetes and birth experience may cause anxiety. Please be aware that you are able to pause or finish questionnaires and the optional discussion with the researcher at any time.

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

You are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you would like to withdraw, contact your local researchers and they can organise this for you. Their contact details are at the end of this information sheet. If you withdraw, the information collected will not be erased and this information may still be used in the project analysis.

How will we use information about you and your baby?

We will need to use information from you, your medical records, and your baby's medical records for this research project. This may include information held and maintained by your GP, NHS England Digital, and other central NHS organisations.

This information will include your initials, NHS number, name, contact details and a copy of your consent form. People will use this information to do the research or to check your records to make sure that the research is being done properly.

A copy of your consent form will be sent to the University of Nottingham.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Nottingham is the sponsor of this research. The University of Nottingham is responsible for looking after your information. "We" (meaning the sponsor) will keep all information about you safe and secure by:

- Following and adhering to the laws relating to General Data Protection Regulation (GDPR)
- Having strict access controls on our electronic systems
- Deleting your personal data (as outlined in this information sheet) when it is no longer required
- Keeping the details we have to contact you separate from the study data

Your data will not be shared outside the UK.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 7 years.

The study data will then be fully anonymised and securely archived or destroyed.

Notes

What are my choices about how my information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you and your baby that we already have.
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of this study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we can't do this.

Where can I find out more about how my information is used?

You can find out more about how we use your information:

by asking a member of your local maternity research team

by sending an email to GILD@nottingham.ac.uk

by calling the Nottingham Clinical Trials Unit on 0115 748 5883

Or by visiting the following websites:

- www.hra.nhs.uk/patientdataandresearch
- www.nottingham.ac.uk/utilities/privacy/privacy-information-for-research-participants.aspx
- http://www.nctu.ac.uk/data-protection/data-protection.aspx

What happens at the end of the study?

When the study ends, yours and your baby's healthcare will continue as normal. If you withdraw from the trial, we will need to keep and use the data collected up to your withdrawal. At the end of the study the results will be published in scientific medical journals and presented at conferences. You will not be identified in any publication. We will send you a newsletter with a summary of the study findings, unless you ask us not to.

Subject to receiving additional funding, we might like to see how you and your baby are doing in a few years' time. If we do, we will contact you at that time and you will be able to decide then whether or not you would like to take part.

After 7 years yours and your baby's data collected during the study will be disposed of securely. If you give us your permission, we may keep your contact details so we can get in touch if there is any relevant future research to do with gestational diabetes that you may be interested in taking part in. You will also have the option to take part in future research using your data saved from this study. If you do not wish for your contact details to be kept for a copy of the study results to be sent to you or to be contacted about future research, your details will be disposed of securely a year after the end of the trial has been declared.

What if relevant new information becomes available?

Sometimes we get new information about gestational diabetes during the study. If this happens your research doctor will tell you about this new information and discuss whether you should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue as normal. If you decide to continue in the study they may ask you to sign a new Informed Consent Form.

Notes

Study organisation

Who is organising and funding this trial?

The study is being organised by the University of Nottingham (the Sponsor) and coordinated by the Nottingham Clinical Trials Unit (NCTU). The funding for the study is provided by the National Institute of Health and care Research, which is the research part of the NHS (ref: NIHR159223).

How has it been reviewed and approved?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect you. This study has been reviewed and approved by The Cambridge East Research Ethics Committee.

Who has helped design this study?

Patients who have previously experienced gestational diabetes have helped us plan and design this study. Patients' representatives are also involved in the teams that oversee the running of the study.

Representatives from the South Asian Health Action charity, a charity focusing on good health for people of South Asian heritage, and the haPPIE research group, an organisation focused on diversity in maternity services and research, are also collaborating with us on this study to help us include people from different backgrounds who have not traditionally been included in research studies.

Contact details

Contact details of your local care team who will be your main point of contact for the duration of the study:

<contact details.
<contact details>
<contact details>

What if there is a problem?

If you have concerns or questions about any aspect of this study, you should ask to speak to the local researchers. Their contact details are above.

If any questions remain you can contact the study coordinating centre:

Tel: 0115 748 5883
Email: GILD@nottingham.ac.uk.

If you remain unhappy and wish to complain formally, you can do this through the National Health Service (NHS) Complaints Procedure via your local Patient Advisory and Liaison Service (PALS)
<insert Local PALS details>
<insert Local PALS details>

The University has in force the relevant insurance policies which apply to this study. In the event that something does go wrong and you are harmed during the research then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Notes