Participant Information Sheet

MyGDM Scotland Home HbA1c Testing Pilot

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Gestational diabetes mellitus (GDM) is the name for diabetes that develops in pregnancy. It means that you have high blood sugars and may need to start treatments to control this during pregnancy. If you are treated with metformin or insulin these will be stopped after you give birth and for most women blood sugar levels will return to normal.

It is recommended that all women with GDM have a follow-up blood test after delivery to check that their blood sugars are normal. This blood test is called an 'HbA1c' and it is normally taken around 13 weeks after your baby is born, just to make sure that your blood sugars are normal. This is important as a small number of women will have high blood sugars which may indicate that they have type 2 diabetes or are at high risk of developing this in the near future.

People who have GDM, are ten times more likely to go on to develop type 2 diabetes at some point in their lives. For this reason it is also recommended that people with a history of GDM have their HbA1c level taken once a year.

At the moment women with GDM are invited to attend a clinic to have this blood test done after having their baby. Although this is the correct test to screen for type 2 diabetes, we know that some women struggle to attend these appointments and therefore do not have their blood level checked. This study is trialling a HbA1c blood test which is taken **at home**, to see if it improves the number of people who have HbA1c testing after a pregnancy affected by GDM. We also hope to gain an understanding of how people feel about doing an at-home test, rather than visiting a clinic for one, in order assess whether at home tests might provide an alternative to in-clinic testing for NHS patients in the future.

We are hoping to recruit around 30 people to take part in the study. Results from this small pilot study will help to shape the design of a larger clinical study into home HbA1c testing.

Why have I been invited to take part?

You have been asked to take part as you have been diagnosed with Gestational Diabetes (diabetes in pregnancy) and are having your antenatal care within NHS Lothian.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

You will be invited to join the study between 28 weeks pregnant and 2 weeks after having your baby. You will be given this Participant Information Sheet at a hospital doctor's appointment to monitor your diabetes in pregnancy. A member of your care team will check that you meet the criteria to allow you to join the study.

You should take your time to read this Participant Information Sheet and understand it. You will also be given the chance to speak to a member of the research team, in case you have any questions.

If you decide to take part, you will be asked to sign the Consent Form at the end of this Participant Information Sheet. You can also sign this Consent Form online, if this is easier for you (scan this QR code with your phone or click the link):

https://app.onlinesurveys.jisc.ac.uk/s/edinburgh/home-hba1c-pilot-consent

You do not have to sign the Consent Form at the back of this Participant Information Sheet on the same day that you receive it. A member of the research team can meet you at a subsequent maternity care appointment to do so, at your convenience. This consenting procedure will happen at your standard clinic appointment but will require you to stay approximately 15 minutes longer than usual. You will be given a copy of your Consent Form for your maternity notes, and one for your own records.

What do I have to do in the study?

Around 13 weeks after you deliver your baby the research team will send you a HbA1c blood testing kit in the post to do at home. This kit will need to be returned via a post box (the postage will be pre-paid for you). We will send you one reminder to carry out the blood test, if you have not done so, at around 15 weeks postpartum. As the home test replaces the in-person test usually taken in clinic should you not return the home blood test by 16

weeks postnatal you will be sent an appointment to attend clinic to have it performed. The total time you will be involved in the study is about 7 months (from around 28 weeks antenatal until 16 weeks after you have your baby).

The home blood test involves using a very small handheld needle device to prick your finger (the same as those used to measure your blood sugars during pregnancy). You then collect around 5-6 drops of blood in a small bottle. You will be provided with clear instructions in the kit as to how to do this. There is a laboratory form in the kit which you will need to complete (name, gender, month and year of birth) to allow the laboratory and research team to identify your sample and result. After taking the blood, the kit instructions will tell you how to label it and send it and the form by tracked post back to the laboratory who will analyse it.

The home blood test kit is not provided and analysed by the NHS. It is provided by a third party company (Forth, a trading name of Humankind Ventures Ltd, www.forthwithlife.co.uk). This company and labs analysing the samples meet all the necessary standards to process your sample accurately and securely. Your blood sample will be analysed shortly after arriving at the laboratory by post. Samples are then disposed after 4 days. The laboratory form will be kept for 14 days in case there are any queries after the sample has been analysed. To ensure confidentiality, forms are then disposed of in the confidential waste.

If you choose to do the home blood test, the result will be sent to you by the research team in the post.

At the same time as you receive your test result in the post, you will be asked to complete an online survey to help the team understand your experience of the home testing kit. The survey will take around 5 minutes to complete. Your test result will also be sent to your GP. If out with normal range the result will be shared with your usual NHS Lothian diabetes team, and they will be in touch to arrange a follow-up appointment.

What happens if I decide not to do the home blood test?

If you choose not to return the home test kit, the research team will contact you after 16 weeks have passed since birth. You will be asked to complete an online survey to help the team understand your experience of the home testing kit. The team will still want to know your thoughts, even if you do not return the test.

Your details will be passed to your GP as well as your usual NHS Lothian diabetes team. You will then be invited to attend a clinic in person to take the HbA1c test, as part of the standard NHS care after having diabetes in pregnancy. If you attend clinic there is no need to also return the home HbA1c test.

What happens if there are any issues with the home blood test?

If there are any issues with the home blood test (for example, the blood test cannot be processed by the lab), the research team will contact you to offer you the opportunity to repeat the home test or be referred for the standard in clinic test.

How does the study finish?

If you complete the online survey, you will be contacted with a £15 shopping voucher to thank you for your time.

Is there anything I need to do or avoid?

You do not need to do anything different or avoid doing anything whilst in the study.

What are the possible benefits of taking part?

You may or may not find it more convenient to take your postnatal HbA1c test at home.

There are otherwise no direct benefits to you taking part in this study, but the results from this study might help to improve the healthcare of patients in the future.

What are the possible disadvantages of taking part?

You may find it more inconvenient to post your home HbA1c blood test kit, rather than to attend for an in-person clinic blood test. Your blood sample and associated personal identifying data (name, gender, year and month of birth) could get lost in the post, but the postage is tracked to help avoid this.

Apart from the consenting appointment, there are no extra appointments involved with this study. You will be asked to take time to complete the survey about your experience in the study.

Taking a finger-prick blood sample can be slightly painful. It should not be any more painful that the finger prick tests you are asked to perform for management of your GDM.

What if there are any problems?

If you have a concern about any aspect of this study please contact the research team on loth.researchmidwives@nhs.scot who will do their best to answer your questions.

In the unlikely event that something goes 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 NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

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

If you decide not to continue taking part in the study at any point, you can contact the study team using the details given below:

loth.researchmidwives@nhs.scot
0131 242 2480

You will be provided the link to an online withdrawal form by email or other preferred contact method. If required, the research team can support you to complete this form.

The withdrawal form allows you to choose between three options:

(1) Withdrawal from all aspects of the study but continued use of data and sample collected up to that point.
(2) Withdrawal from all aspects of the study but continued use of data and sample collected up to that point and routine data collection from the electronic health care record. The minimum personally-identifiable information possible will be collected.
(3) Withdrawal from all aspects of the study and all data and sample collected up to the point will be withdrawn and we will not collect any further data.

If you choose to withdraw from the study, the research team will inform your GP and usual diabetic team, to ensure you continue to receive any relevant care. You will not receive the 'thank you' shopping voucher unless the experience survey is completed. Receiving the voucher is not affected by whether you return the home blood test.

What happens when the study is finished

Once the study is finished, some personal identifying data (participant name and date of birth) will be retained by the research team for 5 years. This will always be stored securely in a locked environment, and kept separate to any anonymised study data.

Anonymised study data will be archived after the end of the study and made available in de-identified format to satisfy data sharing requirements at the end of the study.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you and your medical records for this research project.

We will collect your Community Health Index (CHI) number. Note that the CHI is a population register, used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index and contains personal identifiable information. Your CHI number or NHS number is being collected to allow us to identify the following information:

Other personal identifiable information collected will include your:

- Full name and initials;
- Date of birth;
- Postal address / Email address / Telephone number (and preferred contact method);
- Parity (how many children you have given birth to);
- Age;
- Ethnicity;
- Interpreter requirements and preferred language;

- The treatment used to manage your Gestational Diabetes (dietary modification, metformin and/or insulin).

People will use this information to do the research or to check your records to make sure that the research is being done properly.

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 unique code number assigned instead.

We will keep all information about you safe in a secure locked environment administered by the University of Edinburgh.

Your data will not be shared out with the UK.

We will keep your study data for a maximum of 5 years. The study data will then be fully anonymised and securely archived or destroyed.

By completing and returning the home blood test kit, some of your information (see below) will be sent to a third-party company (Forth, a trading name of Humankind Ventures Ltd, www.forthwithlife.co.uk). This is to allow storage, analysis and disposal of the sample safely and according to laboratory protocols:

- Name;
- Gender;
- Month and year of birth;
- Date and time blood sample taken.

What are your choices about how your 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 that we already have.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to , loth.researchmidwives@nhs.scot
- by ringing us on 0131 242 2480

- by contacting a Data Protection Officer.

University of Edinburgh
Data Protection Officer
Governance and Strategic Planning
University of Edinburgh
Old College
Edinburgh EH8 9YL
Tel: 0131 651 4114
dpo@ed.ac.uk

NHS Lothian
Data Protection Officer
NHS Lothian Waverley Gate
2-4 Waterloo Place
Edinburgh EH1 3EG
Tel: 0131 465 5444
Lothian.DPO@nhs.net

What will happen to the results of the study?

This study will be written up as a conference presentation or written publication. As one of the University of Edinburgh PhD students is involved in organising the study it may be included in their PhD thesis.

You will not be identifiable in any published results.

The results of the study are to be made available to the participants via this website, https://edinburgh-pregnancy-research.ed.ac.uk/.

Who is organising and funding the research?

This study has been organised by The Edinburgh Pregnancy Research Team at the University of Edinburgh and Sponsored by The University of Edinburgh and NHS Lothian.

This study forms part of a PhD project supervised by Professor Reynolds.

The study is being funded by the Chief Scientist Office.

Who has reviewed the study?

The study proposal has been reviewed by peer reviewers and the research funding panel.

Two online patient/public involvement sessions with those affected by gestational diabetes were held in 2024 to guide the development of this study.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from the South Central - Berkshire B Research Ethics Committee. NHS Management Approval has also been given.

Researcher Contact Details

If you have any further questions about the study please contact the study team on 0131 242 2480 or email on: loth.researchmidwives@nhs.scot

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact Dr Sarah Murray (sarah.murray@ed.ac.uk).

Complaints

If you wish to make a complaint about the study please contact:

Patient Experience Team, 2 – 4 Waterloo Place, Edinburgh, EH1 3EG
feedback@nhslothian.scot.nhs.uk
0131 536 3370