NORWICH CTU

SITE LOGO

PROTECT

PRegnancy **O**utcomes using continuous glucose monitoring **TEC**hnology in pregnant women with early-onset **T**ype 2 diabetes

PARTICIPANT INFORMATION SHEET

Before you decide whether to take part in the PROTECT study, it is important that you understand why the study is being done and what it will involve. Full details are given in the digital Participant Information Tool, or in this information sheet.

Please ask us if there is anything that is not clear. You can take time to decide whether or not you wish to take part.

What is this study about and why is it needed?

We want to find out if a newer way of monitoring glucose levels during pregnancy can help women with **type 2 diabetes**, and their babies. We know that the best way to protect your baby is to manage your glucose levels. Until recently, the only way of checking your glucose levels was by doing repeated **finger-prick blood glucose checks**, 4-7 times every day.

A newer way of measuring glucose called '**continuous glucose monitoring**' (CGM), might help. It gives you a lot more detail about what is happening with your glucose levels, and whether they are on target, too high or too low.

We know that using CGM improves the mother's glucose and reduces baby admissions to hospital in type 1 diabetes. The purpose of this study is to examine **whether using CGM leads to improved glucose levels and better baby outcomes in pregnant women with type 2 diabetes.**

We will also look at whether using CGM affects women's wellbeing, their diabetes treatments, and whether it is affordable for the NHS.

What is continuous glucose monitoring?

Continuous glucose monitors (CGMs) measure glucose levels, every minute, so you can check without having to prick your fingers. CGMs are already used by millions of people worldwide.

You wear a small sensor on the back of your arm day and night, which lets you view your glucose levels on your mobile phone, or other device.

You can set an alarm to sound if your glucose levels go too high or too low. If someone helps you look after your diabetes, their mobile can be linked up too.

Why have I been invited?

We would like 422 pregnant women with type 2 diabetes, from all over the UK, to help us with this study. We will ask half the women who take part in the study to use CGM, and half to use finger-prick monitoring. We'll compare the two groups to see if CGM is better. If it is better, then the NHS may offer this to all pregnant women with type 2 diabetes in the future.

You do not have to take part - it is up to you. If you decide not to take part, that won't affect the care you get from health professionals.

What would taking part involve?

You will be asked to:

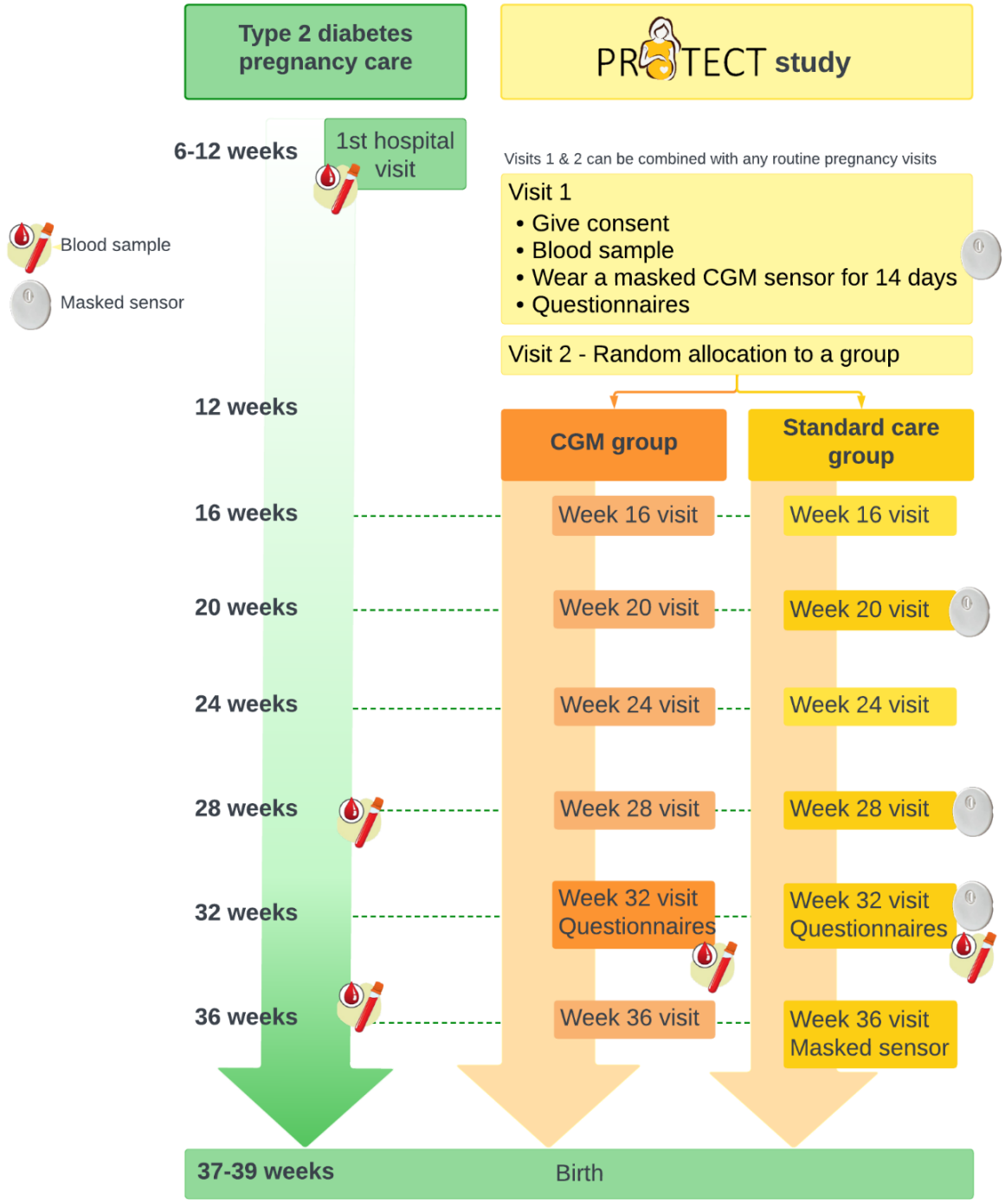
- Wear a masked CGM sensor for up to 14 days (without seeing the glucose levels). You will monitor your glucose by finger-prick testing during this time.
- Give a blood sample.
- Answer some questions in questionnaires (takes 10-15 minutes).
- Agree to be put into the CGM group or the standard care (finger-prick testing) group.
- If you are in the CGM group, you will wear a CGM sensor for the rest of your pregnancy so that you and your hospital team can see your glucose measurements.
- If you are in the standard care group, you will wear a masked CGM sensor for up to 14 days four more times at 20, 28, 32 and 36 weeks (without seeing your glucose levels).

You may also be invited to take part in an interview (about 30 minutes), but this is optional.

You will be seen by the hospital research team (e.g., nurse, midwife or doctor) at your normal hospital pregnancy appointments. Some visits may be offered virtually (by video or telephone calls), if this is convenient for you.

Nothing else about your pregnancy care will change and your clinical team will continue to look after as normal.

Here are the study visits which would tie in with your routine pregnancy visits:



Visit 1 – Recruitment visit

Your team will talk through the study details with you, and show you the CGM sensor. They will answer any questions you have and make sure taking part is suitable for you.

If you decide to take part, you will be asked to sign the consent form which we will keep in your hospital records, and we will let your GP know.

We will ask for a blood sample to measure your average blood glucose (called HbA1c) if you haven't already had it done. At the same time, we will take a little extra, around 10 mL, or two teaspoonfuls of blood, to help us understand the different subtypes of type 2 diabetes.

The team will apply a CGM sensor, which is about the size of a pound coin, to the back of your upper arm. The sensor has a tiny filament which goes just under the skin. It doesn't hurt. We will ask you to keep the sensor in place for up to 14 days. You will not be able to see any data about your sugar levels from the sensor applied at this visit, this is what's known as a 'masked' sensor.

You will be given some questionnaires to complete at home, or emailed a link to complete them online. They should take about 10-15 minutes to complete.

Visit 2 – Randomisation visit

The team will check that enough glucose information has been collected by the CGM and that the questionnaires are completed. If there is not enough CGM information you might be asked to wear a second sensor before going forward.

Randomisation means you will have equal chance of being allocated to each of the two study groups.

Using a computer, we will randomly allocate you to receive either the study CGM, or to continue with finger-prick monitoring (standard care).

If you are in the CGM group

You will be shown how to use the study CGM, FreeStyle Libre 3. You will need to re-apply a new sensor every 14 days. You will be asked to download the mobile phone apps where you can view and share all your glucose information. If you don't have a compatible phone, you will be given a device to view your CGM glucose information.

Your team will teach you how to understand and use the CGM glucose information, to help you decide about your food, activity, and insulin doses (if you use insulin).

Written information and instructions will also be provided so that you can become confident using the CGM system.

If you are in the standard care group

You will continue with finger-prick glucose monitoring.

You will be asked to wear a study CGM sensor for 14 days at 20, 28, 32 and 36 weeks into your pregnancy. Neither you or your team will be able to see the glucose information from these sensors. This is so that we can truly compare your glucose results to those in the CGM group.

If, as part of standard care, you go on to use a non-study glucose monitoring system, we would like your permission to collect the glucose information from this. This will help us to understand more about how glucose levels change during type 2 diabetes pregnancy.

During pregnancy

We will ask you to continue using the glucose monitoring method to which you have been allocated.

We will see (or speak with) you and collect information from you, your CGM or other glucose monitoring system, and your hospital notes, every 4 weeks until the end of pregnancy.

We will re-check your HbA1c levels at 28, 32 and 36 weeks, and ask you to repeat the questionnaires at around 32 weeks into your pregnancy.

What will happen after pregnancy?

Before you leave hospital, we will collect information from you, your CGM or other glucose monitoring system, and hospital notes (details about the birth, baby's weight, any admission to the neonatal care unit including any re-admissions for the baby in the first 7 days after birth, and how you are feeding your baby). We would also collect details in the event of pregnancy loss.

Optional interview study

If you have given your permission for interviews and are one of the 25 women in the CGM group who are invited to take part, you will be asked to speak with a researcher from King's College London. This would usually be towards the end of your pregnancy, but may be after birth if preferred.. You can choose to say yes or no to this. The interviews are to find out

what you think about CGM: what could make CGM hard or easy to use for pregnant women.

The interview would take place at a time convenient to you over the phone or in person, and would last about 30 minutes. The interview will be audio-recorded and then transcribed (written down), with anything that could identify you taken out. We may use anonymised quotes from the interview if you are happy for us to do so. If you have a face-to-face interview then travel expenses will be reimbursed. You will receive a £20 voucher as a thank you for taking part in the interviews.

What will happen after the study?

If you are in the CGM group you may continue to use any CGM sensors that you have left over. Your clinical care team will discuss options for continuing care with you.

With your permission we would like the option of contacting you in the future to follow up with you and your baby up longer-term.

What are the possible risks of taking part?

The most common risk is a minor skin reaction to the adhesives used on the CGM sensor to keep it in place. There might be itchiness, redness, bleeding, and bruising at the CGM insertion sites. Tell your hospital team if you have any skin problems.

If you are allocated to CGM, the CGM system will alert you to problems. If there are any technical problems which cannot be fixed, you would go back to the usual method of finger prick glucose monitoring until the problem had been fixed.

What are the possible benefits of taking part?

We cannot guarantee any personal benefits for you. Taking part in this study will help us to understand whether or not using CGM affects mothers' glucose and babies' health outcomes. We hope this this will help pregnant women with type 2 diabetes in the future – maybe including you if you are pregnant again.

If you are in the CGM group

You may prefer using technology instead of finger-pricking to measure your glucose. It will also give you real-time information about your glucose levels.

If you are in the standard care group

There are known benefits of taking part in a study, and being cared for by a research team.

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

If you decide not to carry on, it will not affect your care in any way. You are free to stop at any time without explanation. All you need to do is tell the research team.

What if something goes wrong?

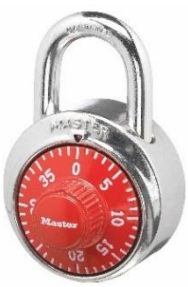
The CGM system used in the study is already used by millions of people worldwide. The risk of anyone being harmed as a result of taking part is minimal. However, during the study, any harm caused by clinical negligence will be covered by NHS insurance. As the Sponsor, the University of East Anglia (UEA) is liable for harm caused by negligence which may occur to participants due to the management or design of the research. If you are unhappy about any part of the study, you can discuss this with the hospital team or with the Patient Assistance and Liaison Services (PALS) at your local hospital (contact details at the end of this information sheet). Normal legal processes are also open to you.

What will happen to my blood samples?

Blood samples to measure HbA1c at the local laboratory will be looked at by your hospital team, as is normal in type 2 diabetes pregnancy.

We will ask for your consent to retain your samples for future research and to analyse your DNA. You do not have to agree to this to take part in the study. A blood sample usually taken at Visit 1 will be linked with your unique study number and stored at your hospital before being sent to the Norwich Research Park Biorepository. Researchers will look at how your pancreas works, as well as antibodies and genes associated with diabetes. This will help researchers to better understand how the different subtypes of diabetes affect mother's glucose levels and pregnancy risks. Samples may be further analysed in future ethically-approved research. Your sample (including DNA) will be treated as a gift from you and will be used for research purposes only.

The results from these tests will not be given to you or your hospital as they will not affect your care. Only researchers directly involved in the study will have access to the samples, and once the samples have been analysed they will be destroyed.



How will we use information about you?

We will need to use information from you and your medical records for this study. This information will include your initials, name, contact details (email and postal address), month and year of birth. 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 code number instead. Data leaving the hospital will normally be labelled with your code (study) number, month and year of birth, and initials.

We will keep all information about you safe and secure.

Some data, such as safety data, will be sent from your local hospital to Norwich Clinical Trials Unit, usually via email or sometimes via standard post. A copy of the consent form with your name and signature will also be sent to Norwich Clinical Trials Unit. The consent form will be checked to ensure that it has been correctly completed and then destroyed.

Study data which leaves the NHS Trust where you are being treated, and your answers to questionnaires, will be held securely in a database, managed by the Norwich Clinical Trials Unit.

All information you give us will be kept confidential, unless something you disclose suggests you might be in danger of harm, or needs following-up. In this case, we will notify your hospital team, who will take any further action they see necessary.

The research team will hold your contact details (i.e., email address) to send the questionnaires, and so that we are able to contact you during and after the study if needed, including sharing information about the study results. The research team may also request your address, if needed for sending study supplies.

If you are in the CGM group

Your CGM information will be recorded by the same diabetes management software that is widely used outside of the study: The apps currently used are FreeStyle Libre 3, LibreView, and LibreLinkUp.

Whilst you are using the study CGM, the information can be seen by your clinical care team and the study research teams.

If you are in the standard care group

Your masked CGM information will be recorded by Freestyle Libre diabetes management software, and used by the research team.

We will ask for your permission to access data from any non-study glucose monitoring system that you may use during the course of the study.

Your used masked sensors will be collected and sent to Abbott Diabetes Care (Witney, UK) to extract the data. No identifying details will be shared, only the sensor serial number will let the research team link to your data.

All CGM data, and some clinical data, will be shared with the Jaeb Center for Health Research in the USA who specialise in CGM research and will be analysing the data for us. This will include only linked anonymised study data, and will not have your name or any other identifying details on it. However you should be aware that the USA data protection laws differ from those in the EU.If you join the study, the data collected for the study, together with any relevant medical records, may be looked at by authorised persons from Norwich Medical School, the Research and Development Department of your local hospital

and the Regulatory Authorities to check that the study is being carried out correctly. They all have a duty of confidentiality to you as a research participant.

Other third party researchers (e.g. universities, NHS organisations or companies involved in health and care research) may wish to access anonymised data from this study in the future (anonymised data do not include names, addresses or dates of birth, and it is not possible to identify individual participants from anonymised data). If this is the case, the Chief Investigator will ensure that the other researchers comply with legal, data protection and ethical guidelines. This may include research outside of the UK and EU and/or research that is commercial in nature. Your data will be stored securely for a period of 10 years after the end of the study before being destroyed.

If you choose to stop using the study CGM, we would still like to collect follow up information if you are willing for us to do so, and digital data from any non-study glucose monitoring systems that you may use during your pregnancy.

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. Samples already collected may be retained and analysed for the study.
- If you transfer to another hospital before the end of your pregnancy, we would like to continue collecting information from your new care team. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

The Sponsor for this study is the University of East Anglia (UEA). Norwich Clinical Trials Unit is also a part of UEA, and as such, UEA is the Data Controller for this study. This means that we are responsible for looking after your information and using it properly. UEA, King's College London, Abbott Diabetes Care (UK), and Jaeb Center for Health Research (USA) are Data Processors for this study. The lawful basis for processing personal data collected in this study is that it is a task in the public interest. You can find out more about how we use your information

- at www.hra.nhs.uk/patientdataandresearch
- at https://norwichctu.uea.ac.uk/personal-data

- by contacting UEA's Data Protection Officer (email: dataprotection@uea.ac.uk, or telephone 01603 59 2431).

Further information

What will happen with the study results?

Once we have finished the study, we will keep 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.

The study results may be presented at meetings or published in scientific journals. After the study has ended, we will send the study results to your hospital team, which they will be able to share with you.

Who is organising and funding the research?

The research study has been funded by the National Institute of Health Research and is being sponsored by the UEA. The Chief Investigators for the study are Professor Helen Murphy from the University of East Anglia and Professor Eleanor Scott from the University of Leeds. The study will be coordinated by the Norwich Clinical Trials Unit.

Who has reviewed the study?

Before any research goes ahead it has to be checked by an Ethics Committee. This study has been reviewed by South Central - Berkshire B Research Ethics Committee.

Is there anything else I should know?

Travel and parking expenses can be claimed for up to 2 visits to help you with taking part in the study. Speak to your team if you wish to claim.

Contacts for more information

Hospital team

Name of local PI
Address of local PI
Contact information for local trial team

Local Patient Assistance and Liaison Services (PALS)

<contact details>

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Coordinating centre

Email: **PROTECT.trial@uea.ac.uk**
Postal address: PROTECT trial team, Norwich Clinical Trials Unit, University of East Anglia, Norwich. NR4 7TJ