Participant Information Sheet

Continuous Glucose Monitoring for Pregnant People with Type 2 Diabetes - a Feasibility Study

Sponsor: The University of Auckland

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Study Site: Te Whatu Ora Counties Manukau

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Ethics committee ref.: *2025 FULL 22206*

You are invited to take part in a study on the use of Continuous Glucose Monitoring (CGM) for pregnant people with Type 2 Diabetes.

Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what taking part would involve, what the benefits and risks to you might be, and what would happen after the study ends.

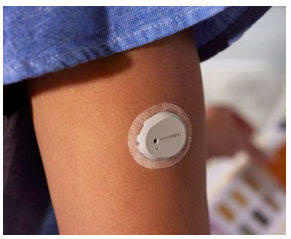
We will go through this information with you and answer any questions you may have. You do not have to decide today whether you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep. This document is 10 pages long including the consent forms. Please make sure you have read and understood all the pages.

Voluntary Participation and Withdrawal From This Study

Taking part in this study is entirely your choice. If you choose not to take part, your treatment and care will not be affected in any way. If you consent to take part, you are free to stop being in the study at any time without giving a reason. You can let the study team know you want to stop being part of the study by contacting them on the phone number or email address given above or provided to you at the time you enrol.

What is the purpose of the study?



A Continuous Glucose Monitor (CGM) is a small patch worn on your skin that monitors your blood glucose. It is another way of testing your glucose levels, and can be an alternative to finger-prick testing. We know that for people with Type 1 diabetes, using a CGM to guide diabetes treatment can result in less pregnancy complications than finger-prick testing.

CGM is not currently funded for people with type 2 diabetes in New Zealand. We do not know whether using CGM to monitor blood glucose when mothers have Type 2 diabetes is better than monitoring by finger-prick testing in pregnancy. To be able to find this out, we need to carry out a large research study. To get ready for this large study, we are conducting this study (a feasibility study).

In this study we will see whether pregnant people with type 2 diabetes consent to use a CGM as part of research, whether the device is easy for you to use, if it is possible to get continuous recordings from CGM for the whole study period, and how we can make taking part in a study like this easiest and best for you. The results of this study will help us plan a large study of CGM use in pregnancies where the mother has type 2 diabetes, to see if CGM to guide diabetes treatment during pregnancy reduces health risks for both parents and babies.

How is the study designed?

This study will take place at Te Whatu Ora Counties Manukau Health in South Auckland. We will enroll 30 people who are pregnant with Type 2 diabetes to wear a Dexcom One+ CGM device for 20 days (or until they give birth if this is sooner). All people in the study will be asked to keep testing their glucose levels by finger-prick, like you normally do. Half of the people in the study will be able to see the results of the CGM in real time. The other people in the study will not be able to see their glucose results until after the study is finished (masked group). You or the research team do not get to choose what group you are in, this will be decided by chance (randomly). Each person in the study has a 1 in 2 chance of being in either group.

If you are in the group where you cannot see the CGM results in real time, you have the option of looking at your results at the end of the study.

Who can take part in the study?

You are being invited to take part in this study because you are currently pregnant and have Type 2 diabetes.

To take part in this study, you must:

- be 34 weeks' pregnant or more at the time of enrolling - have a single baby with no known major health concerns.

- be diagnosed with type 2 diabetes before pregnancy, *or* your blood tests early in pregnancy showed a HbA1c of more than 49 mmol/mol.
- be taking diabetes medication (such as metformin or insulin) to help manage your blood sugar levels.

You will not be able to take part in this study if you

- are planned to have your baby within 14 days of enrolling
- have had a steroid injection (e.g. to help your baby's lungs develop) within 7 days of planned enrollment
- cannot speak or understand English. We do not currently have the study resources translated into other languages, or researchers fluent in other languages for this initial study
- are not able to wear a CGM for any reason

There are no specific medication or lifestyle restrictions during the study, but you will be asked to continue your usual diabetes management, including regular finger-prick blood sugar tests, and attending your clinic visits.

What will my participation in the study involve?

Wearing a CGM

A member of the study team / researcher will meet you to show you how to use the CGM, including how to place the sensor. You will need to create a login for the Dexcom website, which involves entering your name, and contact details. We can show you how to do this at the meeting. You will also need to read and agree to the Dexcom privacy policy and agree to sharing your CGM data with the research team.

If you are in the group where you can see your CGM readings in real time, the researcher will show you how to do this using either a cellphone app, and /or a web-based app. If you choose to use a cellphone app, the researcher can help you install this on your phone. If you do not wish to use your phone to view glucose readings, you will be provided with a receiver. This is a small cellphone sized device that can display and store glucose readings. The receiver will be collected by the researchers at the end of the study.

If you are in the group who does not see your CGM readings (masked group) the researcher will show you how to work the receiver. However, the receiver will be in "blind" mode, so you will not be able to view your glucose levels on it. You will have the option of seeing your glucose levels for 20 days in the study *after* finishing wearing the CGM. The receiver will be collected by the researchers at the end of the study, because your data will be wiped from them, and they will be reused.

Both groups are asked to wear a CGM device for a total of 20 days, changing it once after 10 days. **The CGM readings will not alter your treatment decisions. You will continue regular self-testing with finger-prick tests and usual diabetes care.** A second CGM will be provided to replace the first one after 10 days. If the device falls off or stops working earlier you can contact the study team for a replacement and support. Both the sensor and the applicator can be disposed of in standard rubbish after use.

Completing Questionnaires
You will be asked to fill out short questionnaires about your health and diabetes, and how diabetes affects your life (the Diabetes Distress Scale or DDS17) at the start and end of the study.

Contact by the study team
The study team will call you three times:

- 1-2 days after you start using the CGM to check for any issues
- On day 11 to remind you to change the CGM sensor
- On day 21 to remind you to remove the CGM and arrange the final steps.

Taking part in an interview (your experience of being in the study and wearing a CGM) We ask you to take part in a short interview (up to 30 minutes in length), which you can choose to do in person or by phone. During the interview you will be free to stop at any time without giving a reason. You are free to not answer questions you feel uncomfortable with. The interview will be audio recorded, typed out in full, with any details that could identify you removed from the typed out copies. You will be given the option of reading your typed out interview and making any changes to it, however you need to do this within 2 weeks of it being sent (emailed or couriered) to you.
The interviews are analysed to help the study team understand your experience of being in the study and using the CGM device.

Specialised baby measurements (after birth)
There is an option for your baby to have their body composition measured using a small (handheld) ultrasound, and a specialised scale called a PeaPOD. This provides extra information about your baby's growth and fat stores. If you consent to this part of the study, after birth while you and baby are in the hospital, a research midwife can do these measures for your baby. The measures are performed at Middlemore hospital, in an area close to the maternity ward and delivery suite. You or a family member are welcome to accompany the baby while they are having these measurements taken.

Summary of Study Participation

Timepoint	Your involvement with study	How long it takes
Day 0	Consent, questionnaire, CGM set up	Up to 1 hour
Days 1-20	Wear CGM, remove and replace on day 10	5 minutes on day 10
Day 1-2	Phone call from study team	Up to 10 minutes.
Day 11	Phone call reminder to replace CGM	5 minutes.
Day 21+	Final questionnaire & interview (by phone or in person)	Up to 30 minutes.
After birth	Baby ultrasound and PeaPOD (optional)	Up to 30 minutes

What are the possible risks of this study?

When the CGM is applied, there may be risk of infection or the sensor not sticking well especially if the insertion site is not clean and dry. The study researcher will show you how to clean the insertion site with alcohol wipes to prevent infection. Applying the sensor may be slightly uncomfortable, but there should be no ongoing discomfort when the device is applied correctly. We will help you when attaching the CGM for the first time to keep these risks low.

There is a small risk of sensor insertion issues, where the sensor can cause infection, bleeding, pain or skin irritation. There have been no cases in clinical studies of the sensor wire detaching. However, in theory, the sterile sensor wire could break or detach and remain under the skin. Sterile detached sensor wires usually don't pose a significant medical risk. If a sensor wire breaks off or detaches, remains under your skin, contact a member of the study team and a healthcare provider for advice.

When using the CGM in this study, you must continue with your regular diabetes management and finger prick testing. The CGM should not be used to make decisions about treatment when how you feel doesn't match the sensor reading. If you feel that your glucose levels are very low or high, you must check them by finger-prick test, as there is a chance that the CGM may not be reading accurately.

You must not wear the CGM while undergoing magnetic resonance imaging (MRI) or high-frequency electrical heat (diathermy) treatment - as this may damage the CGM device.

What are the possible benefits of this study?

You will receive two Dexcom ONE+ sensors for free and regular support and contact from the study team. You will have access to more information on your blood sugar levels in real time, or at the end of the study (masked group). This may help you better understand how your daily habits, meals, and medications affect your diabetes. The study team will support you in learning how to use the CGM device.

Taking part will help improve the design of larger studies in the future, which could lead to better diabetes care for pregnant people and their babies. The findings may contribute to long-term improvements in diabetes care during pregnancy, potentially leading to healthier outcomes for mothers and babies.

After completing the exit interview, you will receive a $100 supermarket voucher to thank you for your time and contribution to this study.

What are the alternatives to taking part?

You will receive your regular diabetes management and self-test with finger pricks regardless of whether you participate or do not participate in the study.

Will any costs be reimbursed?

Participants will not incur any costs for taking part in the study. After completing the interview, you will receive a $100 supermarket or MTA (petrol station) voucher in recognition of participation in the study.

What if something goes wrong?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

What will happen to my information?

CGM data during the study

The researchers will be able to see and download your CGM readings through a web-based computer program (Clarity) that is password protected. We have created a research account for this study that is only used by researchers on this study. This account will store readings while you are in the study. When you have finished using the CGM, the researchers will download your readings and delete your profile from the research account. However *you* will still be able to view *your* CGM readings using your own Dexcom account.

Unmasked group: you can show your readings to your doctor, midwife or healthcare team any time using your app/reader, or a member of the study team can send this information to your healthcare provider if you ask. You will be able to continue to view your CGM data collected during the study via your app as long as this is installed.

Masked group: a doctor will review your CGM readings at the end of the study, to make sure there are no unexpected results. Any unexpected results will be discussed with you and recorded in your medical record. At the end of the study you will be asked if you would like a copy of the CGM results and these can be provided to you.

Research data

During this study the researchers will record information about you and your study participation. This includes information about you (e.g. your age, your pregnancy due date), your baby (weight and measures at birth), data from the CGM device (your blood glucose readings), questionnaires answered, and audio records and transcripts of interview(s). Basic health information from your hospital records will also be collected. You cannot take part in this study if you do not consent to the collection of this information.

To make sure your personal information is kept confidential, information that identifies you will not be included in any report or results generated by the research team.

During the study, information about you is collected and stored as:

Identifiable Information: any data that could identify you (e.g. your name, date of birth, or address). Only the research team will have access to your identifiable information.
De-identified (Coded) Information: Your information will be stored next to a code. The research team will keep a list linking your code with your name, so that you can be identified by your coded data if needed. Only the research team will have access to your de-identified information.

Security and Storage of Your Information

Your information is held on servers licensed to the University of Auckland during the study. After the study it is transferred to a secure archiving site and stored for 10 years then erased. All storage will comply with local and/or international data security guidelines.

Use of Clarity software and CGM One+ device.

Use of the Dexcom ONE+ CGM device and Dexcom Clarity Software is needed for you to take part in this study. To view CGM readings on your phone, you will need to sign up for a Dexcom account. This involves entering a name (you don't have to use your real name, but you will have to inform the study team of the name you are using), country, and contact email address.

Dexcom will hold a copy of any information you enter into your account. Dexom operates in various countries throughout the world, and personal data collected by Dexcom may be transferred and maintained outside of New Zealand. Dexcom, provides a privacy notice that explains how they collect, store, use, share, transfer, delete and otherwise process information collection from or known about you. You will be asked to accept this when you first sign in for an account. A copy is available:

https://www.dexcom.com/en-NZ/legal/privacy-policy#_Personal_Data_Collected

As an international company, Dexcom has multiple legal entities in different countries that may be responsible for the personal data processed, and Decom processes personal data in accordance with these laws.

Options for limiting information Dexcom holds about you

If you want to take part in the study, but limit the information Dexcom will have about you, you can ask the study team to help you set up a Dexcom account using a different name and date of birth (you will still need to supply your email or cell phone number), OR you can ask the study team to use a receiver instead of your phone.

What happens after the study or if I change my mind?

You may withdraw your consent for the collection and use of your information at any time, by informing any member of the study team. Details are on this form and are given to you when you enrol in the study.

If you withdraw your consent, you will be asked if you will still take part in an interview. This is because it is important for us to understand the reasons why people no longer want to take part, so we can try and improve the way the study is run.

You will also be asked if the information collected up until your withdrawal can still be used in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

If you have used a receiver, a study member will contact you to arrange for this to be collected.

Can I find out the results of the study?

Yes. We can provide you with a summary of the study findings by post or email. This is expected by September 2026. Please leave your preferred contact address on the signed consent form. The study is registered with the Australian New Zealand Clinical trials registry

https://www.anzctr.org.au

Who is funding the study?

The study is investigator-led and is funded by a grant from the Faculty Research Development Fund, University of Auckland awarded to Charlotte Oyston.

Who Has Approved the study?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The [Northern A committee has approved this study.

Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:
Name: Charlotte Oyston
Position: Principal investigator, obstetrician
Phone 021 076 6220
Email c.oyston@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:
Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

Or, the Ministry of Health for general enquires
Phone: 0800 855 066.

For Māori health support please contact:
Te Kaahui Ora Māori, Health Service (Middlemore)
Phone: 09 276 0044 extn 5995
Email: tekahuiora@middlemore.co.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:
Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz

Consent form

Continuous Glucose Monitoring for Pregnant People with Type 2 Diabetes - a feasibility study

- I have read, or have had read to me, and I understand the Participant Information Sheet.
- I have been given enough time to consider whether or not to participate in this study.
- I have had the opportunity to have whānau/ family support or a friend to help me ask questions and understand the study.
- I am satisfied with the answers given about the study and have a copy of the information sheet.
- I know who to contact if I have any questions about the study in general.
- I understand that taking part in this study is my choice and that I may withdraw from the study at any time without this affecting my medical care.
- I understand that my participation in this study is confidential and that no material which could identify me personally, will be used in any reports on this study.
- I consent to the research staff collecting and processing my information and my baby's information including information about my/ their health.
- If I decide to withdraw from the study, I agree that the information collected up to the point when I withdraw may continue to be processed, including information on my reasons for withdrawing.
- I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study.
- I consent to my maternity care provider being informed about my participation in the study.

	Yes	No
I consent to de-identified (coded) data collected as part of this study being used for future related teaching or research purposes.		
I wish to have a copy of my interview sent to me to check/edit. I am aware I have 2 weeks to return the edited version for changes to be included.		
I wish to get a summary of findings		
If you have answered yes to interviews or summary of findings being sent, please write your preferred address (email or post) here:		

Declaration by participant: I hereby consent to take part in this study

Participants name:

Signature: Date:

Declaration by a member of the research team:
I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it. I believe that the participant understands the study and has given informed consent to participate.

Researcher's name

Signature: Date:

Consent form

Continuous Glucose Monitoring for Pregnant People with Type 2 Diabetes - a feasibility study

Consent for baby to have ultrasound and PEAPod measures

(to be completed after baby's birth)

- I have read, or have had read to me, and I understand the Participant Information Sheet.
- I understand the procedures (ultrasound and PeaPod), their purpose and risks.
- I confirm I have had the opportunity to discuss any questions with the study team and I have had my questions answered to my satisfaction.
- I agree for my child to take part in this project as described, and I understand I am free to withdraw my child at any time without it affecting the future healthcare of my child.
- I confirm my consent for my baby to have ultrasound and PeaPod measurements.

Declaration by participant: I hereby consent for my child to take part in this study.

Participants name:

_____

Signature: Date:

_____

Declaration by a member of the research team:
I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it. I believe that the participant understands the study and has given informed consent to participate.

Researcher's name

_____

Signature: Date:

_____

PIS/CF version no.: 2 31/3/2025
Provisionally approved by the Northern A Health and Disability Ethics committee on 28/03/2025 for a period of 3 years (FULL 22206)
Dated: 6/2/2025