Participant Information Sheet

Study title:	Glycaemic outcomes in people with type 2 diabetes initiating continuous glucose monitoring: The 2GO-CGM study
Locality:	Southern District Health Board
Lead investigator:	Dr Martin de Bock
Local investigator:	A/Prof Ben Wheeler
Ethics committee ref:	21/CEN/75

You are invited to take part in a study on a continuous glucose monitoring (CGM) system, using the Dexcom G6 CGM device. The features of this system are explained further in this information sheet.

This Participant Information Sheet will help you decide if you would like to take part. It sets out why we are doing the study, what your participation 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, we will ask you to sign and date the Consent Form on the last page of this document. You will get a copy of both the Participant Information Sheet and the Consent Form to keep. This document is 13 pages long, including the Consent Forms. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Whether or not you take part in this study is your choice. There is no cost to you for participating in this study. If you do not want to take part, you do not have to give a reason, and it will not affect future care you receive or the relationship with your health care specialist. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

WHAT IS THE PURPOSE OF THE STUDY?

Continuous glucose monitoring (CGM) has been successfully used in type 1 diabetes for improving health outcomes and reducing the risk of hypoglycaemia for over a decade. New modern CGM systems are more accurate and no longer require finger prick glucose calibration. Therefore, modern real-time CGM has an even greater potential to be used by people with diabetes to improve glucose levels. However, the use of this system has not yet been well studied in people with type 2 diabetes. The purpose of our study is to find out whether using CGM helps people with type 2 diabetes to keep glucose levels in a healthy range and to improve other outcomes, such as quality of life.

The CGM system used in this study is the Dexcom G6 continuous glucose monitor (manufactured by Dexcom Inc.), which is worn as a small sensor in your skin. This device measures interstitial glucose levels (glucose levels within the tissues), which are similar to blood glucose levels apart from a delay of about 5-10 minutes when glucose levels are

rapidly changing. You can easily insert a new sensor every 10 days. Every 5 minutes, glucose readings are sent wirelessly (via blue tooth) from the sensor to a smartphone app. If you wish, you can invite other people to 'follow' your glucose levels on their own smartphones. You can set individualised alerts for low or high glucose levels and for rapidly changing glucose levels. You may still need to check your blood glucose via finger pricks if the way you feel does not match the Dexcom G6 sensor readings.

Figure 1: The Dexcom G6 CGM sensor

Figure 2: Scanning the Dexcom G6 sensor with your smartphone

HOW IS THE STUDY DESIGNED?

80 volunteers aged 16-65 years with type 2 diabetes will take part in the study. After baseline assessments and a run-in period of 14 days, participants will be randomised into one of two groups, with a 50% chance to be included in either group: the control group will continue to use finger pricks to measure their glucose levels, and the intervention group will receive a Dexcom G6 for 3 months. All participants will receive frequent instructions on how to manage their diabetes control by a member of the study team during this period. This first study period is followed by a 3-month continuation period during which all participants will use the Dexcom G6 system. The study will conclude after 6 months. The study is divided into 3 parts:

1. Baseline Assessments – Blinded continuous glucose monitoring (CGM) (2 weeks)

   You will use a 'blinded' Dexcom G6 sensor for 2 weeks. You will not be able to see the glucose readings, but we will use them to assess your usual glycaemic control before the start of the study.

2. Randomisation and Treatment Period 1 (12 weeks)

   You will be randomised into the control or intervention group and measure your glucose levels according to your group's requirements for 12 weeks. You will also receive a schedule on how to manage your diabetes needs during this time. If you are in the control group, you will receive a second 'blinded' Dexcom G6 sensor during the last two weeks of this study period (weeks 10-12).

3. Continuation Study – Treatment Period 2 (12 weeks)

   If you are in the control group, you will now receive a Dexcom G6. All participants will use the Dexcom G6 system for a further 12 weeks.

During the study, research staff will record information about you and your study participation. You will undergo Hba1c tests to assess your diabetes control as well as undergo medical reviews before the beginning of the study and then at 3 and 6 months during the study. In addition, we will monitor your height and weight.

The results of the study will help to improve CGM systems and their application. We hope this may improve treatment for people with diabetes.

QUALITATIVE INTERVIEW – OPTIONAL SUB-STUDY

We are interested in learning how new technologies that we investigate in this study can help people with type 2 diabetes to improve their diabetes management and the effects on their daily lives. We will invite some participants (approximately 15 in total) to be interviewed about their experiences using the Dexcom G6 system. Taking part in these interviews is voluntary. If you agree to take part in this optional sub-study, we may ask you questions about your experiences with the system. This one-to-one interview with a trained member of the study team will occur after 6 months of using the Dexcom G6 CGM system. The interview will take place in your home, a private clinic room, or over Zoom in a password-protected private meeting. The interview will last approximately 30 to 60 minutes and will be digitally recorded. We will later write the recorded interview out in full and look for similarities and differences between your responses and other participants' responses. If you wish, you can read the transcript of your interview before we use it for the study. Some information collected about you at the start of the main study (age, gender, ethnicity, HbA1c, duration of diabetes) will be used to help describe participants in this optional sub-study. Participants will receive a $20 gift voucher after the interview.

WHO CAN TAKE PART IN THE STUDY?

You have been invited to take part in this study because:

- you are aged 16 years and over,
- you have type 2 diabetes,
- your current HbA1c level is ≥8.0% (≥64mmol/mol).

To be eligible to take part in this study, it is also necessary that you:

- receive at least one injection of insulin per day,
- pass all the screening assessments,
- have no history of any other types of diabetes,
- have not been admitted to hospital for hyperglycaemia within the last 6 months,
- have not had severe heart disease or major surgery within the last 3 months,
- have no history of recurrent or chronic systemic infections that would impact on your glucose levels,
- have no previous or planned bariatric surgery,
- do not have active cancer requiring ongoing treatment,
- are not currently pregnant or plan to become pregnant during the study,
- do not take oral steroid medication (Prednisone or other),
- are willing and able to adhere to the study protocol.

Members of the research team will check that you are eligible to take part in the study. The first visit to the recruitment site will be your screening and baseline visit. Before we do any screening procedures, you can ask any questions you may have regarding the study and you will sign and date this consent form. At your screening visit, you will have several assessments, which are described in detail below. If you do not want any of the tests done, you should not take part in this study. Study staff will also contact your GP and/or diabetes specialist about your study participation. We may need to discuss health issues or parts of your medical history that could affect you taking part in the study. During screening or the study, tests may give an unexpected result that could be important in terms of your health. If this happens, we will discuss these results with you and your GP/diabetes specialist, and arrange appropriate follow-up through your usual doctor. We will tell you if you can take part

when all your screening tests have been checked.

You will get a card stating that you are taking part in a clinical trial. You should present this card at the time of any medical treatment you receive during the study.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You will be in this study for up to 6.5 months. This includes at least 4 visits at the study site. If you become unwell, or the study doctor is concerned about any of your assessments, we may ask you to schedule extra visits. The overall study will last about 12 months (from when the first participant is screened until the final participant has completed his or her last visit of the 12-week continuation study). The assessments during the study visits are explained below. For an overview of the study visits, see the table below.

Visit 1: Study staff will obtain an original signed consent form. We will collect data about your demographics, height, weight, HbA1c and details about your diabetes, medical history and lifestyle. A laboratory blood test will be done to check your current health. We will train you on how to insert and change sensors. You will then receive a blinded CGM device from a member of the study team. You will wear this device for 14 days.

Visit 2: During the next visit (2 weeks after visit 1), your blinded sensor/s will be collected. You will be randomised to either the control or the intervention group. If randomised to the control group, you will continue finger pricks to test your glucose levels. You will have to test your glucose levels with finger pricks at least 4 times per day. If randomised to the intervention group, we will train you on how to use the Dexcom G6 CGM system and you will receive your device, which you will use for the next 12 weeks. Independent of what group you are randomised to, you will receive training on a personalised diabetes management protocol, which will be used to manage your insulin regimen. During this study phase, you will be in frequent contact with a nurse, who is a member of the study team, and who will provide ongoing support to adjust your insulin doses based on your glucose levels ('Remote/Electronic review').

Visit 3: If you are in the control group, you will visit the study site again 10 weeks after visit 2. You will receive another blinded CGM device that you will wear for 14 days.

Visit 4: At the end of the main study period (12 weeks after visit 2), you will visit the study site for collection of your height, weight and HbA1c. A laboratory blood test will be done to check your current health. If you agree to do the Qualitative interview, we may invite you to take part in the interview during this visit. If you are in the control group, we will now train you in the use of the Dexcom G6 CGM system and receive your device. All participants will use the Dexcom G6 system and continue following the nurse-led diabetes management protocol for the next 12 weeks. You will be in regular contact with members of the study team, who will provide ongoing support to adjust your insulin doses based on your glucose levels ('Remote/Electronic review').

Visit 5: During your last visit (12 weeks after visit 4), we will record your height, weight and HbA1c. A laboratory blood test will be done to check your current health. The study will end after this visit.

After the study ends: At the end of the current study, all participants will be invited to take part in a 12-month extension study, where everyone will wear the Dexcom G6 system for further 12 months. The study team will give you more information about the extension study at the end of the current study and, if you are interested, collect your consent.

	BASELINE	RUN-IN PERIOD	TREATMENT PERIOD Week 1 – 12				Continuation PERIOD Week 12 – 24		EXTENSION PERIOD Week 25 - 77	
	Visit 1	14 days	**Visit 2** Study Day 1	Remote review Week 2, 8	**Visit 3** (Control group) Week 10	**Visit 4** End of Main Study Week 12	Remote review Week 14, 20	**Visit 5** End of Continuation Study Week 24	Clinic Visit Week 51	End of Extension Study Week 77
Informed consent	X								X	
Demographics	X									
HbA1c, height, weight, BMI	X		X			X		X	X	X
Medical review	X					X		X	X	X
Blood pressure	X					X		X	X	X
Urine pregnancy test	X								X	
Laboratory blood tests	X					X		X	X	X
Blinded CGM (14 days)		X			X					
CGM training			X (Intervention group)			X (Control group)				
Electronic review				X			X			
Retinal scan results	X									X
Personalised diabetes management protocol			←---------- Ongoing ----------→							

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

It may take some time to get used to the new sensor. We will give you training and support throughout the study, including direct phone access to our study staff in case you need it. This support will be available 24 hours a day.

You may not have worn a glucose sensor. Risks related to sensor use include (including those sensors currently funded in New Zealand):

- Skin irritation or other reactions, redness or rash, residual redness associated with adhesive or tape or both, discomfort, pain, soreness, raised bump, appearance of small 'freckle-like' dot where needle was inserted (very common)
- Bruising or bleeding, swelling at insertion site, minor scarring (common)
- Infection, sensor breakage or damage, fainting secondary to anxiety or fear of needle insertion, minimal bleeding associated with sensor needle removal (uncommon)
- Severe allergic reaction (very rare)

Reproductive risks for sexually active participants of child-bearing potential

You cannot take part in the study if you are pregnant or planning to become pregnant during the study. If you are sexually active and of child-bearing potential (able to become pregnant), it is very important that you do not become pregnant during this study. The device does not have approval for use during pregnancy. Therefore, use of this device in pregnancy is excluded and we advise use of contraception in women of child-bearing potential (see below). **In the event of an unplanned pregnancy during the duration of this study, you will need to contact the research team immediately.**

We recommend the use of one of the following methods of contraception:

Highly effective methods (<1 pregnancy per 100 women using the method for one year) e.g.:

- Implant contraceptive (e.g. Jadelle®)
- Intra-uterine device (IUD) containing either copper or levonorgestrel (e.g. Mirena®)
- Male sterilization (vasectomy)
- Female sterilization (e.g. bilateral tubal ligation ('clipping or tying tubes') or hysterectomy)

Effective methods (5-10 pregnancies per 100 women using the method for one year) e.g.:

- Injectable contraceptive (e.g. Depo Provera)
- Oral Contraceptive Pill (combined hormonal contraceptive pill or progestogen-only 'mini-pill')
- Vaginal contraceptive ring (e.g. NuvaRing®)

Are there any other risks?

No further risks involved with participating in this study are currently known. If any new information is discovered that might affect your decision to continue with the study, you will be told by a member of the study team. **Please tell the study doctor or study staff if you feel unwell at any time during the study (whether you think it is related to the study or not). You will be monitored throughout the study in order to minimize risks.**

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

This study may have the potential to reduce your daily diabetes management burden and improve your glycaemic control and health outcomes. You may also learn more about how different diabetes technology works, and about your own management of your blood glucose levels. Information from this study will be used to further develop and improve the CGM

platform, and potentially make CGM a new gold standard treatment in people with type 2 diabetes.

WILL ANY COSTS BE REIMBURSED?

Study personnel will arrange for taxis or petrol vouchers to assist with transport to and from the unit if you live far from the study centre. If you live outside this area, we will discuss your travel costs individually. You will not otherwise be paid for your study participation.

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. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the study doctors, nurses and other study staff will record information about you, your health and your participation in the study. You will not be able to take part in this study if you do not consent to the collection of this information about you.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). The following groups may have access to your identifiable information:

- Study staff (to complete study assessments)
- Representatives from ethics committees or government agencies from New Zealand, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.
- Your usual doctor, if a study test gives an unexpected result that could be important for your health. This allows appropriate follow-up to be arranged.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report that will leave the study site or any study information sent to Dexcom Inc., the device manufacturer. Instead, you will be identified by a code. Only study staff will keep a list linking your study code with your name, so that you can be identified by your coded data if needed. The following groups may have access to your coded information, which may be sent and stored overseas:

- Dexcom Inc., for the purposes of this study.
- People and companies working with or for the sponsor, for the purposes of this study.
- Regulatory or other governmental agencies worldwide.
- The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.
- A description of this clinical trial will be available on the public clinical trial registry http://www.anzctr.org.au/. This website will not include any information (identified or de-identified) that can identify you. At most, it will include a summary of the study results. You can search this website at any time.

Security and Storage of Your Information

Your identifiable information is held at secure servers of the University of Otago during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Coded glucose information will be kept by the manufacturer in secure, cloud-based storage indefinitely (see below – under "Use of CareLink®"). All storage will comply with local and/or international data security guidelines.

Rights to Access Your Information

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected. Please ask if you would like to access the results of your screening during the study. If you have any questions about the collection and use of information about you, you should ask the study doctor.

Use of Dexcom CLARITY

The Dexcom G6 app is a mandatory feature of study participation. Your glucose readings will be continuously sent from the sensor transmitter to the app and from there this information will be sent to the cloud. All data is encrypted when transmitted. Glucose data will remain with Dexcom and can be shared with designated recipients (researchers, your invited 'followers'). This is standard policy and no different from using Dexcom G6 outside of the research study. Research staff will access your uploaded glucose data from a password-protected website (Dexcom CLARITY). The Dexcom CLARITY system is a cloud-based de-identified data platform that allows your device to send information over the internet using a telecommunication network (such as a cellular network, wireless network, etc.). Dexcom will receive your coded (de-identified) device data from Dexcom CLARITY (your identifiable information is not included, only your de-identified study code). The software we use to access your data will record no identifiable information. Dexcom takes steps to protect the privacy of the health information sent to the Dexcom CLARITY network over the internet. However, Dexcom cannot guarantee the health information is protected against unauthorized interception. Your glucose data may be stored in any country where Dexcom has facilities or where Dexcom Service Providers are located, including, but not limited to, the US, Canada, countries located in the EU, Australia, Japan, South Korea, and the Philippines.

Risks

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information. Your coded information (glucose data) is being sent overseas (for more details see above – under "De-identified [Coded] Information"). Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations, which make decisions about the use of your information. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders.

WHAT HAPPENS IF I CHANGE MY MIND?

You are free to withdraw from this study at any time without having to give a reason. Information collected up until your withdrawal will continue to be used and the results of these assessments will be included in the study. This is to protect the quality of the study, and to make sure the safety of the CGM system is accurately assessed. If you do not wish your information to be used if you withdraw, you should not take part in this study. You may

also be withdrawn from the study even if you want to continue, for example:

- The investigators believe it is in your best interest for you to stop taking part, or
- You do not follow study instructions, or
- The study is stopped early for any reason by the investigator, sponsor, or device manufacturer (e.g. for safety reasons, or problems with study conduct or the quality of collected information).

If this happens, we will tell you and explain the reasons to you. If you wish to leave the study early, tell a member of the study staff. We will ask you questions about your experience while you were in the study.

WHAT HAPPENS AFTER THE STUDY?

You may keep your transmitter and any remaining sensors at the end of the study. However, once these devices expire, the study team will not provide any further new sensors or transmitters. You may choose to purchase the Dexcom G6 CGM system yourself after the study. The system is currently not subsidised and costs approximately $4,554 per year. You may be eligible to apply for partial funding through WINZ.

CAN I FIND OUT THE RESULTS OF THE STUDY?

You can request a letter telling you about the results of this study. The letter will be sent to you once the final study report is available (this can take 1 – 2 years).

WHO IS FUNDING THE STUDY?

This study is an investigator (Drs de Bock, Wheeler and Paul) initiated study funded by Dexcom Inc., the device manufacturer. Drs de Bock, Wheeler and Paul are in charge of overseeing and running the trial.

WHO HAS APPROVED THE STUDY?

An independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards, 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:

Associate Professor Ben Wheeler
Email: ben.wheeler@otago.ac.nz
Phone: 027 470 1980

If you want to talk to someone who is not 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@hdc.org.nz
Website:	https://www.advocacy.org.nz/

To ensure ongoing cultural safety, the Southern District Health Board encourage those who identify as Māori, and who are participating in health research or clinical trials, to seek cultural support and advice from their own Kaumātua in the first instance, or please contact:

Wendi Raumati
Te Ara Hauora
Māori Health Unit
Southern District Health Board
Dunedin
Phone 03 373 0999 ext 58649

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC
Email: hdecs@moh.govt.nz

Consent Form

Study title:	Glycaemic outcomes in people with type 2 diabetes initiating continuous glucose monitoring: The 2GO-CGM study
Locality:	Southern District Health Board
Lead investigator:	Dr Martin de Bock
Local investigator:	A/Prof Ben Wheeler
Ethics committee ref:	21/CEN/75

Please tick to indicate you consent to the following

I have read and I understand the Participant Information Sheet.
I have been given sufficient time to consider whether or not to participate in this study.
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
I consent to the research staff collecting and processing my information, including information about my health.
I consent to my information being sent overseas.
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
I agree that my current health care provider will be informed about my participation in the study and of any significant abnormal results obtained during the study, and that my health care provider may disclose relevant health information to the study doctor.
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
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 understand the compensation provisions in case of injury during the study.

I know whom to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		
I wish to receive a summary of the results from the study.	Yes ☐	No ☐
I consent to being contacted about participation in future diabetes research.	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of 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
For Participation in the Qualitative Interview

Study title:	Glycaemic outcomes in people with type 2 diabetes initiating continuous glucose monitoring: The 2GO-CGM study
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Please tick to indicate you consent to the following

I agree to take part in the **optional** interview sub-study about my experiences with the advanced insulin delivery system	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in the sub-study of this research study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the sub-study of this research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the sub-study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____