Participant Information Sheet

Early AID Study

Formal Study title:	Early Automated Insulin Delivery to improve equity in type 1 diabetes.
Sponsor:	University of Otago, Christchurch
Lead Study Doctor:	Associate Prof Martin de Bock
Study Site:	Te Whatu Ora – Waitaha Canterbury
Contact phone number:	021 195 6579
Ethics committee ref.:	2024 FULL 21236

Kia Ora, Kia Orana, Talofa, Malo e lelei, and Hello!

You are invited to take part in a study on early use of an automated insulin delivery system. 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 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, 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 12 pages long, including the Consent Form. 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 don't want to take part, you don't have to give a reason, and it won't 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?

Automated insulin delivery (AID) systems consist of an insulin pump, a continuous glucose monitoring (CGM) sensor, and a computer program (algorithm). The program uses sensor glucose levels to decide how much insulin should be delivered by the pump. We want to

assess th  i and their whānau, I a view to increasing ypsoPump compatible martphone (Figure 1) ystem will deliver va d glucose levels stat he burden of diabetes management compared to multiple daily injections.

FIGURE 1: CGM, smartphone and YpsoPump

HOW IS THE STUDY DESIGNED?

Up to 20 participants aged under 25 years and who identify as a person of Māori and/or Pacific descent ethnicity, newly diagnosed with type 1 diabetes, will take part in the study. You will be in this study for about 12 months. This includes at least 6 visits at the study site (also see Visit Table below). If you become unwell, or the study doctor is concerned about any of your assessments, you may be asked to schedule extra visits. What exactly happens during the study visits is explained below. All procedures described here will be carried out by trained members of the study team.

Visit 1: Before any tests are done, you can ask the study team any questions you have about the study, and your consent will be collected. Then, your height, weight, blood pressure, HbA1c and details about your medical history will be collected. You will receive a CGM sensor which is worn on your body. You may be asked to be involved with 3 qualitative interviews to explore the experiences of whānau during their diabetes journey. If you are asked to do the qualitative interviews, you will take part in the first interview within 14 days of your type 1 diabetes diagnosis.

Visit 2: You will return to the clinic within 3 months of diagnosis to begin using the AID system. Your height, weight and HbA1c will be collected. You will be trained in the use of the YpsoMed insulin pump. You will start to use the AID system and will receive ongoing help and support from the study team. Insulin pump settings will be reviewed regularly by study staff, and adjustments made as required. If you are asked to do the qualitative interviews, you will take part in the second interview within 14 days of starting AID.

Visits 3, 4 and 5: You will visit the study site 3-, 6- and 9 months after starting the AID system. Your height, weight and HbA1c will be recorded on each of these visits. The

device data will be reviewed, and pump settings will be adjusted if needed as part of your routine clinical care.

Visit 6: During your last visit (12 months after starting the AID system), your height, weight, blood pressure and HbA1c will be recorded. You will return your study Ypso pump. You will have the option to continue using the AID system with a prescribed Ypso pump and CGM. You may also retain your study smartphone with the installed app if you choose to continue using this AID system. You will receive clinical support with the diabetes management system you choose to use following the study, and CGM and pump consumables can be prescribed. If you are asked to do the qualitative interviews, you will take part in the final interview. The study ends after this visit.

Visit Table

	BASELINE	**AID INITIATION**	**AID PERIOD** 12 months			
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
	Around the time of diagnosis	Within 3 months of diagnosis	3 months after AID start	6 months after AID start	9 months after AID start	12 months after AID start
Informed consent	X					
HbA1c, height, weight	X	X	X	X	X	X
Blood pressure	X					X
Medical review	X	X	X	X	X	X
Pump training and initiation		X				
Qualitative interview	X[a]	X[b]				X[c]

[a] the first Qualitative interview takes place within 14 days of diagnosis

[b] the second Qualitative interview takes place within 14 days of starting the AID system

[c] the third Qualitative interview takes place within 14 days of completing the study

QUALITATIVE INTERVIEWS

We are interested in learning more about the experiences of whānau as they progress through their type 1 diabetes journey. Some participants (and their whānau) will be asked to be interviewed about their experiences following diagnosis until the end of the study. If you do not want to be interviewed, you should not take part in this study.

If you are asked to take part in the interviews, you will be asked questions about your experiences since your diagnosis. These interviews with a trained member of the study team, using a kaupapa Māori approach, will involve meeting with whānau 3 times. The location, time and people present at these interviews will be decided by whānau. The interviews will take about 30-60 minutes and will be recorded. Your interview will be transcribed to look for similarities and differences between your responses and other participants' responses. If you wish, you can read the transcript of your interview before it is used for the study. Your interview transcript will only be able to be viewed by members of the study team. If we publish reports or give talks about this research, we will not use your

name or any other personal information that would identify you. Participants will receive a $20 gift voucher after each interview.

Interview 1: Takes place within 2 weeks of diagnosis and involves answering questions that explore the experiences of whānau since the diagnosis of type 1 diabetes. At the end of the interview, you will be asked to take about 5 photos that you feel reflect your experiences at the beginning of your diabetes journey.

Interview 2: Takes place within 2 weeks of starting to use the AID system. You will be asked to share and discuss the photos that you have taken.

Interview 3: Takes place within 2 weeks of completing the study (approximately 12 months of using the AID system). During this interview, tamariki and rangatahi will be able to draw what they have learned about diabetes over their journey so far.

WHO CAN TAKE PART IN THE STUDY?

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

- You are aged under 25 years.
- You identify as a person of Māori and/or Pacific descent.
- You are newly diagnosed with type 1 diabetes.

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

- Adhere to the instructions by the study team.
- Agree to take part in the Qualitative Interviews.

Members of the research team will check that you are eligible to take part in the study. The first visit will be your screening and baseline visit. Before any screening procedures are done, you will be given a chance to ask any questions you may have regarding the study, and you will sign and date this consent form. You will be told if you can take part when all your screening tests have been checked. At your screening visit you will have several assessments, as explained 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, these results will be discussed with you and your GP/diabetes specialist, and appropriate follow-up will be arranged through your usual doctor.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Your participation in the study will involve at least 6 visits at the study site (see visit table above).

Visit 1: Your consent will be collected to participate in the study. Your height, weight, blood pressure, HbA1c and details about your medical history will be collected. A CGM sensor will be placed on your body. This visit will take up to 90 minutes.

Visit 2: Your height, weight and HbA1c will be collected. You will receive insulin pump training, and you will start using the AID system. This visit will take up to 6 hours. Support will be provided by the study team as you learn to use the system.

Visits 3, 4 and 5: Your height, weight and HbA1c will be collected. Device data will be reviewed, and insulin pump settings will be adjusted if required, as part of your usual clinical care. These visits will take up to 60 minutes.

Visit 6: Your height, weight, blood pressure and HbA1c will be collected. This visit will take up to 60 minutes. The study ends after this visit, and you will receive support from your local diabetes clinical care team going forward.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The new pump and sensor may take some time to get used to. 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 during office hours. After hours, your diabetes team will provide you with local contacts for emergencies. Currently funded insulin pumps have risks that come with using them as outlined below (yearly risks noted here in brackets).

Risks related to insulin pump infusion sets:

General risks related to insulin pump infusion sets may include:

- Skin irritation or redness, bruising, discomfort or pain, irritation, rash (very common)
- Bleeding (common)
- Localized infection (uncommon)
- Blockages that can prevent insulin delivery and lead to high glucose or diabetic ketoacidosis (uncommon)

Diabetic ketoacidosis happens when there is not enough insulin, and the body cannot use glucose as a fuel source. Therefore, fat is used for fuel instead. When fat breaks down, it produces ketones and those can build up in the body.

Risks related to insulin administration and pump use:

Due to the use of insulin, there is risk related to the infusion of insulin and the potential interruptions of insulin delivery. These general risks may include:

- Hypoglycaemia, hyperglycaemia (very common)
- Diabetic ketoacidosis (uncommon)
- Seizure (rare)
- Coma, death (very rare)

Risks related to CGM sensor use include:

- 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 blood splatter associated with sensor needle removal (uncommon)
- Severe allergic reaction (very rare)

Are there any other risks?

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 that of your whānau 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. If you decide not to be in this study, there is other care available to you, as you already receive with your health care professional team. You may be treated in other ways, for example, other infusion pump therapy or multiple daily injections. You should discuss other treatments and their possible risks and benefits with your doctor.

WILL ANY COSTS BE REIMBURSED?

You will not have to pay to participate in the study. All study devices and consumables will be provided or prescribed. Study personnel will arrange for vouchers to assist with transport for study visits if required.

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 won't 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).
- Your diabetes clinical team at the hospital will have access to your pump upload data (reviewed in Glooko) as required for usual clinical care post-diagnosis.
- 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 or well-being. 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. Instead, you will be identified

by a code. Only study staff will keep a list linking your 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 (including e.g. glucose data), which may be sent and stored overseas:

- 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.

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 after the youngest study participant turns 16 years of age, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

Use of Glooko

The mylife CamAPS FX app will be installed on your study phone and connected to your pump. The app receives data from the pump and automatically sends the data to your connected Glooko account. The Glooko system is a cloud-based data platform that allows your device to send information over the internet using a telecommunication network (such as a cellular network, wireless network, etc.). The information available from the Glooko system is identifiable and is the same information the study team or your diabetes clinical team at the hospital would usually collect from your device during an in-person visit. The pump and CGM manufacturers will not have access to this data. You will have the option to use the mylife CamAPS FX app, to share your pump data with designated others, such as family members or friends.

In order to view your pump data on your phone, no internet is required, as the devices are connected via Bluetooth. Data or a Wi-Fi connection is required in order for others to “follow” you, and for the automatic pump data uploads to the cloud, which are required by the study team for remote monitoring. If you would like to use the “follow” feature the study team will provide data on the study phone to enable this.

Risks

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised 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.

This research includes basic information such as your ethnic group, geographic region, age range, and sex. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

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.

If you have any questions about the collection and use of information about you, you should ask the study doctor.

Rights to Withdraw Your Information

You may withdraw your consent for the collection and use of your information at any time, by informing your Study Doctor.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

Māori Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

- We have consulted with Dr George Haremate about the collection, ownership, and use of study data.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

The study pumps must be returned at the end of the study, or when you decide to withdraw from the study. You will have the option to continue using the AID system, with a prescribed Ypso pump and CGM, and to retain the study issued smartphone with the installed app if you do continue.

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. 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 you will be told, and the reasons will be explained to you. If you wish to leave the study early, tell a member of the study staff. You will be asked questions about your experience while you were in the study.

You will receive clinical support with the diabetes management system you choose to use following the study. The study team will tell you more about your options at the end of the study.

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 (Dr de Bock, Christchurch) initiated study funded by Cure Kids and the University of Otago. YpsoMed is providing the insulin pumps and smartphones with the CamAPS FX algorithm installed. The CGM will be prescribed for you and Dr de Bock is in charge of overseeing and running the trial.

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 B HDEC 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 Martin de Bock
Phone: 0211956579
Email: martin.debock@otago.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/

To ensure ongoing cultural safety, Te Whatu Ora – Waitaha Canterbury 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 or Kuia in the first instance, or please contact :

Kelly Tikao
Senior Lecturer
Phone : +64 27 482 6324
Email : kelly.tikao@otago.ac.nz

To ensure ongoing cultural safety, Te Whatu Ora – Waitaha Canterbury encourage those who identify as Pacific Peoples, and who are participating in health research or clinical trials, to seek cultural support by contacting:

Dr Soana Muimuiheata
Registered Dietitian
Phone : +64 27 2555513
Email : soana.totalwellbeing@xtra.co.nz

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

Email: hdecs@health.govt.nz
Phone: 0800 400 569 (Ministry of Health general enquiries)

Consent Form

Early AID Study

An interpreter is available upon request if required.

Please tick to indicate you consent to the following

I have read the Participant Information Sheet or have had it read to me in a language I understand, and I fully comprehend what it says.
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 agree to take part in the interviews about my experiences following diagnosis with type 1 diabetes.
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 consent to my current health care provider being informed about my participation in the study and of any significant abnormal results obtained during the study.
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 who 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 ☐

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: