Participant Information Sheet

Study title:	Optimising self-management in youth with type 1 diabetes: OPTIMISE Study		
Locality:	Southern District Health Board	Ethics committee ref.:	20/NTA/127
Lead investigator:	Dr Sara Styles	Contact phone number:	03 479 7946

Kia ora! You are invited to take part in a study on type 1 diabetes. This Participant Information Sheet will help you decide if you'd like to take part. It tells you why we are doing the study, what we'd like from you, what the benefits and risks to you might be, and what will 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 or not 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, kaumatua 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 11 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Getting enough sleep, snacking as part of a routine meal plan, coping with diabetes, and frequent glucose level checks are important for rangatahi (young people) with type 1 diabetes. These behaviours haven't been studied together in young people with type 1 diabetes and above recommended HbA1c (an indication of longer-term blood glucose control). The purpose of this study is to find out if combining our brief interventions targeting these behaviours helps glucose levels stay in a healthy range over a short period of time. If this study finds a benefit to day-to-day glucose levels then we will repeat the study to see if there is a benefit to HbA1c and other outcomes such as quality of life. We hope that our research will improve care for young people with type 1 diabetes.

The study is conducted by a team of researchers affiliated with Southern, Capital and Coast, Canterbury and MidCentral District Health Boards, the University of Otago, The University of Auckland, Ngāti Tūwharetoa and Ngāti Raukawa (ki Horowhenua) and in consultation with Ngāi Tahu. If you have any questions about

this study, please contact Dr Sara Styles, lead investigator (phone: 03 479 7946 or sara.styles@otago.ac.nz).

This study has been approved by the Health and Disability Ethics Committee (REF**:** 20/NTA/127).

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been invited to participate in this study because:

- You have had type 1 diabetes for at least 6 months
- You are at least 13 years old and you are no more than 20 years old, inclusive
- Your glycaemic control (HbA1c; an indicator of your usual blood glucose levels) has been ≥58 mmol/mol (above recommended) in the past 6 months

To be eligible to participate in the study, you also must spend no more than 10 hours a night in bed (on a typical night) and be willing to:

- wear an activity monitor (a wrist-worn device) continuously for 7 days and 8 nights during the first and final weeks of the study period;
- wear an interstitial glucose sensor for up to 6 weeks; and
- discuss barriers to self-management with a member of research staff who is not involved with your diabetes care.

You will be ineligible to participate in the study if you:

- have any conditions that would interfere with study participation
- currently use a continuous glucose monitoring system (Dexcom) (other than occasional hospital/clinic use in the past 3 months)
- use sleep medication
- work any night shifts

We will consult a clinical psychologist to confirm your eligibility if your mental health screening questionnaire responses indicate you are experiencing severe depression.

Study visits

There are 4 study visits over 6 weeks (see below). Study visits will take place either in a private clinic room or at your whare (home) with someone who is not

involved with your diabetes care. You can bring a family member or friend if you wish.

VISIT 1, 30-60 minutes, start of study

- We'll make sure you are eligible to be part of the study
- If eligible, you'll begin continuously wearing a glucose sensor for 2 weeks and an activity monitor for 1 week
- You won't need to do anything else to the sensor as you wear it.
- The sensor will not show your glucose levels.
- The activity monitor is worn on your wrist like a watch.
- You'll tell us about nights when your sleep was disturbed or unusual in a sleep diary (only during the week you wear the activity monitor)
- We will let your diabetes care provider know if you join the study. We will ask them for information about your diabetes (diabetes date of diagnosis, HbA1cs in the past 6 months, episodes of severe 'lows' needing medical treatment and episodes of DKA (diabetic ketoacidosis)).

2 weeks later - VISIT 2, 1-2 hours

- Complete questionnaires about your sleep, eating habits, coping with diabetes, diabetes self-care
- Find out your study group for **the next 4 weeks (28 days)**
- You might receive information about snacking or sleep
- You might start using a new continuous glucose monitoring system
- You might be scheduled to talk with someone about making a change that will help you take care of your diabetes when it gets in the way of things you like to do.
- This depends on what study group you are randomly (by chance) assigned to.

2 weeks later - VISIT 3, about 1 hour

- Complete questionnaires about you and your diabetes
- Begin wearing glucose sensor and activity monitor, just like at the start of the study; you'll tell us if your sleep is disturbed/unusual while you wear the activity monitor

2 weeks later - VISIT 4, 1-2 hours, end of study

- Complete questionnaires about you and your diabetes
- Tell us what you liked or didn't like about being in the study

- Receive a handout of free mental health and diabetes support
- Receive a $20 gift voucher as a token of 'thanks' for being in the study

You will be randomly (by chance) assigned to a study group. You may be assigned to as many as four interventions (see below) for 4 weeks (28 days). The aim of all interventions is to help your glucose levels be in the recommended range (3.9-10.0 mmol/L) more often.

Continuous Glucose Monitoring (CGM)

- A glucose level sensor is worn just beneath the skin on the abdomen or arm.
- Sensors are changed every 10 days for 4 weeks.
- Glucose levels are sent to a smartphone app on your phone. Other people can 'follow' your levels on their phone if you want them to.
- The app shows the current glucose level, past levels and where levels are heading.
- High and low glucose alerts mean action is needed to bring glucose levels in a healthy range (3.9-10.0).
- Finger pricks are needed if the way you feel does not match readings on the app.

Healthful snacking

- Receive education on healthier snack choices, reducing 'grazing' and having planned snacks as part of normal eating plan.
- A healthier snacking goal will be set to complete over 4 weeks.

Sleep extension

- A bedtime recommendation will be provided.
- The bedtime will be an hour earlier than your usual bedtime.
- Tips to help go to bed earlier will be provided.

Values-guided self-management

- Meet someone from our research team to talk about:
  - what is important to you (things you enjoy)
  - how diabetes gets in the way of what's important to you
  - one small diabetes-specific change that would help you get more of what matters to you
- The meeting will be face-to-face for about 30 minutes either in person or via Zoom (similar to Skype or Facebook video chatting)

No intervention

- Wait 4 weeks before receiving information about:

    - glucose levels collected from the continuous glucose monitoring sensors worn at the start and end of the study
    - information about healthful snacking
    - free mental health and diabetes support
- Everyone will receive tips for sleeping well at Visit 2 and a handout of free mental health and diabetes support resources at Visit 4 (the final study visit).
- Everyone who is NOT in the CGM group will receive a report of their glucose levels collected from the CGM worn at the start and end of the study at Visit 4.
- Everyone who is NOT in the healthful snacking group will receive snacking tips at Visit 4.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Participating in this study may directly benefit you. You will receive information about snacking, sleep and your day-to-day glucose levels, which may be useful to you. You will receive a handout of free diabetes and mental health resources at the end of the study.

Wearing a glucose sensor may cause skin problems such rash, redness, or discomfort. The study will provide medical advice and treatment if needed. You may experience lower glucose levels from changing your diabetes self-care during the study. It is recommended that you check your glucose levels frequently to identify low blood glucose. Being part of this study might bring up uncomfortable or difficult thoughts or feelings about having diabetes. Contact your usual diabetes care provider for all medical advice and concerns about your diabetes.

WHO PAYS FOR THE STUDY?

It is free to participate in this study. At the end of the study you will be provided a $20 gift voucher in recognition of your participation and as a contribution towards your travel costs. You will be reimbursed for travel costs (in the form of a gift voucher) if you incur more than $20 of travel costs to participate in this study.

This research is funded by Lottery Health Research (grant reference: LHR-2020-128791).

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 ARE MY RIGHTS?

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 and don't have to give a reason.

You will be told of any new information related to the study that may benefit or harm your health.

The information about you collected as part of the study is confidential. Your medical information would only be shared with your health care provider with your permission. You have the right to access information about you collected as part of the study. All information about you will be linked to an uninformative study identification number. Your unidentifiable information will be stored electronically for 10 years after the study ends and then it will be destroyed. This information may be used for other diabetes research.

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

The results of the study may be shared at scientific meetings and in scientific journals. A summary of key results will be sent to local rūnanga.

You'll receive a summary of key results at the email address you provide. These results will be available approximately 1 year after the study finishes (estimated June 2022).

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the research staff will record information about you and your study participation. This includes the results of any study assessments and information about your diabetes from your medical records. You cannot take part in this study if you do not consent to the collection of this information.

IDENTIFIABLE INFORMATION

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only research staff will have access to your identifiable information.

DE-IDENTIFIED (CODED) INFORMATION

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the study. Instead, you will be identified by a code. The study will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

FUTURE RESEARCH USING YOUR INFORMATION

If you agree, your coded information may be used for future research related to diabetes, sleep, eating habits or mental health.

This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers. Your information may also be added to information from other studies, to form much larger sets of data.

You will not get a summary of findings from future research that is done using your information.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

SECURITY AND STORAGE OF YOUR INFORMATION

Your identifiable information is held at 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 participant turns 16, then destroyed. All storage will comply with local and/or international data security guidelines.

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.

USE OF DEXCOM G6 APP

The Dexcom G6 app will be a mandatory component of study participation for participants allocated to this intervention.

Your glucose readings and trends will be continuously sent from a transmitter worn on the sensor to the app and this information is sent to the cloud. All data is encrypted when transmitted. Glucose readings and trends will remain with Dexcom to store and share glucose data with designated recipients (Researchers, “Followers”). This is no different than using Dexcom G6 outside of the study (i.e., as part of your usual diabetes management). Researchers will access your glucose information (linked to your study identification number) in the cloud from a password protected website (Dexcom Clarity).

No identifiable information will be collected by the app or the website we use to access your glucose data. Your glucose data may be stored or processed in any country where Dexcom has facilities or in countries where Dexcom Service Providers are located including, but not limited to, the US, Canada, countries located in the European Union and European Economic Area, Australia, Japan, South Korea, and the Philippines.

After the study ends, you may choose to purchase the Dexcom G6 continuous glucose monitoring system. This system includes sensors, transmitters, and delivery.

It costs $4,554 per year and is not subsidized. You may be eligible to apply for some funding through WINZ.

OPTIONAL QUALITATIVE SUB STUDY

We are interested in learning what helps young people to gain the most benefit from the interventions being investigated in this research. This knowledge will help us develop better ways to support young people with type 1 diabetes. If you agree to participate in this optional qualitative sub study then you will be asked questions about your experience with the intervention/s in an interview with a researcher who is not directly involved with your diabetes care. The interview will take place in your whare (home), a private clinic room, or over Zoom in a password protected meeting room within 4 weeks of your final OPTIMISE Study visit. The interview will last approximately 30 to 60 minutes. We will record the interview to write it out in full later and then look for similarities and difference between your responses and other participants' responses. You are welcome to read the transcript of your interview before we use it for the study. With your permission, we will use information collected about you (age, gender, ethnicity, duration of diabetes, insulin therapy type, HbA1c) during the OPTIMISE Study to help describe participants in this sub 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:

Dr Sara Styles, Lecturer
03 479 7946
sara.styles@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, 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 or Whaea in the first instance, or please contact Te Ara Hauora Māori Liaison Service in the Southern DHB:

Wendi Raumati
Kaiāwhina
Te Ara Hauora - Māori Health Liaison Service
Dunedin Hospital
Phone 4740 999 ext 58649

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

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

Consent Form

Please tick to indicate you consent to the following

I have read, or have had read to me, and I understand the Participant Information Sheet.	Yes ☐	
I have been given sufficient time to consider whether or not to participate in this study.	Yes ☐	
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.	Yes ☐	
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.	Yes ☐	
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.	Yes ☐	
I consent to the research staff collecting and processing my information, including information about my health from my diabetes care provider.	Yes ☐	
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.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic 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.	Yes ☐	
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.	Yes ☐	
I understand the compensation provisions in case of injury during the study.	Yes ☐	

I know who to contact if I have any questions about the study in general.	Yes ☐	
I understand my responsibilities as a study participant.	Yes ☐	
I agree to participate in the optional qualitative sub study.	Yes ☐	No ☐
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: _____