Participant Information Sheet

Study title:	**Whole grains for Health** **He pata tikitū, he kai hauora** **Wholegrain structure in the blood glucose management of adults with type 2 diabetes**	
Locality:	Dunedin, Otago	Ethics committee ref: 21/STH/229
Lead investigator:	Dr Andrew Reynolds	Contact phone number: 020 4100 9343

You are invited to take part in a wholegrain and blood glucose control study that goes for twelve weeks. 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 will happen after the study ends. 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, or healthcare providers.

If you agree to take part in this study, you will be asked to sign an online consent form. A copy of this Participant Information Sheet and the Consent Forms are always available to you. Please make sure you have read and understood all the pages of this form and take the time to think about whether joining the study is for you.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to find out if eating unmilled wholegrains foods that are less processed improves blood glucose control more than eating whole grains that are finely milled. Findings from this study will be useful to patients and health professionals. The main aim of the study is to see if glycated haemoglobin (HbA1c) and other markers of health improve after the 12 weeks of whole grains. People who decide to join the study will be randomly put into one of two groups. One group will receive a delivery each fortnight of finely milled wholegrain foods for twelve weeks. The other group will receive a delivery each fortnight of unmilled wholegrain foods that are less processed, and more intact, for twelve weeks. All foods are provided for free and are the types of foods you can find at a supermarket or health store. Participants will have no say in which group they will be placed into, it is random.

We don't yet know if providing these wholegrain foods will provide the same health benefits, or if one will be better than the other. However this trial has been designed to answer this question. We will mainly use information from your blood samples, but we will also need to ask participants what they have been eating. Recording what you eat can take some time, but it is very important to us that this is done correctly. If you don't enjoy filling out details on what food you have eaten, this study may not be for you. There are also several other research aims of this study. We would like to know how hungry or full you feel during the study. We will

ask you during the 12 weeks about your general health, and your bowel health. We will also test if we can measure markers of the foods you eat from your dried blood samples.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

We are looking for participants aged between 18-80 years old who have type 2 diabetes. We will be recruiting participants from Otago, Southland, and Canterbury. Participants will have not changed medicines that might affect their blood sugar levels in the last three months. Participants must be willing to replace the grain foods they usually eat with the provided wholegrain foods. People with coeliac disease or who have a grain allergy should not participate in this study.

You will receive a delivery of wholegrain foods, once a fortnight for 12 weeks. Please replace the grain foods you normally eat, with the wholegrain foods provided by the study. Please don't eat more or less food than usual. There will be enough wholegrain foods provided to share with the household, but you will still need to buy other groceries during these 12 weeks. The foods provided will be wholegrain food basics that you can eat in any way you like. We do not provide a meal plan, or specific recipes for each meal, but suggest you find ways that you enjoy incorporating the food into your diet. The whole grains we provide will either be ready to eat (bread) or need to be boiled in water for up to 15 minutes before eating. You must, in general, be willing to eat the wholegrain foods provided. But if there are certain foods you do not like, that is fine, you can give those foods away.

As much as possible, we will run this study remotely. The wholegrain foods will be delivered to your door fortnightly for 12 weeks. During increased public health alert levels the couriers do contactless delivery while wearing masks. This is to reduce your risk of infectious diseases. Participants do not meet the researchers in person, instead we are available by email, Zoom, and phone. Using online surveys, we will ask you many questions about things like your ethnicity and what other health conditions you may have. We don't think any of these questions will embarrass you, instead they are used to describe who participates in the study. Answering these questions during the study will require you being comfortable with spending time in front of a computer.

We will also ask you about what food you normally eat before, during, and after the study. This is done online with a smart phone, tablet or computer. We are unable to provide you with one of these devices if you do not have one.

At the start and end of the twelve weeks, you will visit a participating Southern Community Laboratory to get a blood test and measure your body weight and body fat percentage. This is done by stepping on a scale. These services can operate in the most stringent of the increased public health alert levels if required. On the day of your blood test we will also ask you to do a finger prick 'dried blood spot test' at home. This takes the same time and effort as it does to test your blood sugar at home.

The 'dried blood spot test' will be sent to the University of Otago and stored until we have collected all samples from participants. They will be stored with an ID number only and not any information that may be able to identify you. These dried blood spots will be analysed to see if we can measure markers of the foods you eat. All blood samples are destroyed when they are processed. A karakia cannot be performed at this time. As part of gaining our

ethical approval, we have consulted with the Ngāi Tahu Research Consultation Committee about our research and blood samples.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

We don't think there are any large risks in participating in this study. The wholegrain foods we send you are normal foods that are widely available from supermarkets. We aim to give you a decent amount of foods, so that if you live with a partner or other people, these foods can be shared or incorporated into meals, rather than just be consumed by you. We will however provide the exact same foods each fortnight, which some people may find repetitive.

We think it is unlikely you will have any negative health effects from this study. However, we will check-in with you every 2 weeks to ask if you have any concerns about your health. You should continue to see your usual health care professionals about any immediate health concerns you may have.

Your arm may be slightly sensitive after the blood test, however this quickly fades. We do not think this study introduces any risk to your health, or the health of your family members. We will use fully trained staff to undertake the testing in a standardised manner, enabling us to provide you with the appropriate level of support. While participating in this study you are expected to continue attending your health care services as normal.

WHO PAYS FOR THE STUDY?

There is no cost to participate in this study. This study is largely funded by a Lottery Health Grant, and a Heart Foundation of New Zealand Fellowship.

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.

In the very unlikely event, that ACC determines that their cover did not apply to your injury, then the University of Otago's clinical trial insurance would apply. This cover would provide you with compensation equivalent to that you would otherwise have been entitled to under the Accident Compensation Act 2001. By signing the Consent Form for this study, should ACC decline cover, you are explicitly agreeing that compensation for any injury will be as per the terms of University's then current clinical trials insurance cover, the full terms and conditions of which are freely available on request. 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?

Participation in this study is voluntary. You are free to withdraw from the study at any time without experiencing any disadvantage. You have the right to access information about yourself collected as part of this study. You also have the right to correct any information you disagree with. Should any new information arise during the study about adverse or beneficial effects of participation that may impact your health, we will notify you as soon as is practical

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

You can change your mind about being a part of the study at any time. There is no disadvantage to you if you chose not to start the study, or if you chose not to continue with the study. We are unable to provide you with free wholegrain foods after the study. After you complete the study we will provide you with a summary of your blood test, body fat percentage and weight results.

Data collected during this study will be stored securely for a minimum 10 years. With your permission we may contact you after the study to see if you are interested in further research. You may decide not to be contacted about future research, and there is no disadvantage to you if you decide not to participate in future research.

WHO HAS ACCESS TO MY INFORMATION?

During this study the research staff will record information about you and your study participation. After you complete the study we will provide you with your personal blood test results, weight and bodyfat percentage. If you wish, after all the participants have completed the study, we can also provide you with a summary of the results of the study in general. No material that could personally identify you will be used in any published reports from this study.

The following people will have access to some of your identifiable information, such as your name, date of birth and address.

- Research staff directly involved in the project.
- The grocery delivery organisation will be provided with your name, delivery address and phone number.
- We will let your GP know you are part of this study, and the results of your blood test and weight. This allows appropriate follow-up to be arranged.

Apart from this, no identifiable information will be released to others who are not involved in the study. To help us keep your information private, all samples collected during this study will be labelled with a unique study identifier, not any of your identifiable information,

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.

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:

Lead Investigator
Dr Andrew Reynolds

Research Fellow within the Department of Medicine
University of Otago
020 4100 9343
grainstudy@otago.ac.nz

For Independent Health and Disability advocate:
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
Email: advocacy@advocacy.org.nz

For Cultural Support:
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 Kuia in the first instance, or please contact:

Wendi Raumati & Eleanor Russell
Kaiāwhina
Te Ara Hauora - Māori Health Unit
Dunedin Hospital
Phone (03) 4740 999 ext 58649

Andrea Jerry
Kaiāwhina
Te Huinga Tahi Māori Health Cultural Support
Southland Hospital
Phone: (03) 2181 949 ext 48509

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

Whole grains for health
He pata tikitū, he kai hauora

Wholegrain structure in the blood glucose management of adults with type 2 diabetes

I have read, or have had read to me in my first language, 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, whanau/ 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 (emailed to you).
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 accessing information about my health.
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.
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 understand my responsibilities as a study participant.
I know who to contact if I have any questions about the study in general. (grainstudy@otago.ac.nz)
I have read the 'What if Something Goes Wrong' section in the Participant Information Sheet. I agree that in the unlikely event that ACC declines cover for any injury to me arising from this study, the compensation available will be as per the terms of University's then current clinical trials insurance cover.
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 GP or current provider being informed about my participation in the study and of clinically relevant results obtained during the study.
Yes I confirm the statements listed above ☐

I wish to receive a summary of the results from the study.	Yes ☐	No ☐
I wish to be contacted about participation in future studies.	Yes ☐	No ☐

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

Participant's name	Date: