University of Otago
ŌTĀKOU WHAKAIHU WAKA

Participant Information Sheet

Study title:	Dietary fibre and its potential role in mitigating the health effects of dietary intakes high in processed foods.	
Principal investigator:	**Sheila Skeaff** **Department of Human Nutrition** **Position: Professor**	Contact phone number: +64 3 479 7944

Introduction

Thank you for your interest in this study. Please read this information sheet carefully before deciding whether you would like to take part. You may also wish to talk about it with your family, whānau, or friends.

Taking part in this study is your choice. If you decide to take part, we thank you. If you decide not to take part, that is completely okay and there will be no disadvantage to you.

Why are we doing this study?

Many people eat processed foods as part of their usual diet. These foods can be convenient and commonly available, but they may contain more salt, sugar, and saturated fat, and less fibre, than less processed foods.

Fibre is important for health. It may help support blood sugar control after meals, cholesterol levels, blood pressure, and body weight.

This study is being done to find out whether taking a fibre supplement can help reduce short-term changes in health markers when healthy young adults eat more processed foods than usual for a short time.

We are mainly interested in how blood sugar levels change after meals over a two-hour period. We will also look at blood pressure, body weight, cholesterol, lifestyle habits, and some markers measured in blood samples.

Who is funding this project?

This project is funded by the Riddet Institute, Centre of Research Excellence.

Who can take part in this study?

We are looking for healthy adults aged 20–29 years who live in Dunedin during the study, and usually consume a healthy diet. A healthy diet will be assessed using a dietary questionnaire. You must also usually eat three main meals per day or be willing to follow a three-main-meal eating pattern during the study.

You will be able to take part if you are willing to provide blood samples, wear a continuous glucose monitor, eat the study foods, take a fibre supplement or placebo, and complete online questionnaires and food diaries.

You will need to complete a screening questionnaire and blood test to check whether the study is suitable for you. To take part, your LDL cholesterol level must be below 3.0 mmol/L.

You may not be able to take part if you have certain health conditions, use medications that could affect the study, are pregnant or breastfeeding, regularly use fibre supplements or tobacco products, have dietary requirements that do not fit the study foods. You may also be unable to take part if you have limited control over your usual food intake, such as living in catered accommodation, do not have access to the internet and a suitable device, or do not have sufficient English proficiency or literacy to complete the study questionnaires and food diary.

What will you need to do if you take part?

Before starting, you will complete a screening questionnaire and attend a screening visit (visit 1) to check whether the study is suitable for you. The study team will explain the study and ask you to sign a consent form before any study procedures begin.

If you take part, you will be asked to attend five in-person study visits, requiring approximately two hours in total, complete study-related blood tests at Awanui Labs at Dunedin Hospital, and complete some study tasks online.

You will take part in two 2-week study periods, with a 3-6 week break between them. In one study period, you will take a fibre supplement. In the other study period, you will take a placebo. You will not know which one you are taking at the time. During each intervention period, you will be asked to mix one teaspoon of the study product with one cup of water and consume it three times per day, preferably with your main meals. You should maintain an adequate fluid intake while taking the study product.

You may choose either to collect the study-provided foods yourself from the supermarket or to have delivery arranged. If you choose to collect the foods yourself, you will be responsible for transporting and storing them safely after collection, including following any refrigeration or freezing instructions on the food packaging.

During the run-in period and each of the two intervention periods, you will be asked to wear a continuous glucose monitor and complete a four-day food diary. During each intervention period, you will also take the study product three times each day and eat selected study-

provided foods in place of some of your usual foods. Throughout the study, you will complete questionnaires, provide fasting blood samples, and have measurements taken, including body weight, body composition and blood pressure.

Your total involvement in the study will last at least 17 weeks. This includes screening and a run-in period, two 2-week intervention periods separated by a 3–6 week break, and an online follow-up session approximately eight weeks after the second intervention period.

At the end of each intervention period, you will be invited to take part in a short individual interview lasting approximately 15 minutes. The interview will ask about your experience of the study-provided foods, the study product and the study procedures. With your consent the interview will be audio-recorded and transcribed using Microsoft Word Transcribe through the University of Otago's Microsoft 365 Copilot licence. The recording will be uploaded to Microsoft OneDrive and may be processed outside New Zealand by Microsoft a third-party provider and its authorised subprocessors. Only the research team will have access to the recording and transcript. A researcher will check the transcript for accuracy and the recording will be deleted once the transcript is finalised.

You will not incur any study-related costs. To reimburse travel-related expenses, including petrol and parking associated with attending study visits, you will receive a NZD $100 supermarket voucher after completing each 2-week intervention period, for a total of NZD $200 if you complete both intervention periods. If you withdraw during an intervention period, you will still receive the NZD $100 supermarket voucher for that intervention period. If you complete the screening blood test but are subsequently found to be ineligible for the study, you will receive a NZD $40 supermarket voucher in recognition of the time and travel involved in attending the screening visit.

You will receive your individual blood test results after the second intervention is completed, and a summary of the overall study findings once the study is finished. If a clinically significant result is identified during screening or the study, an investigator will inform you promptly and arrange or recommend appropriate follow-up where necessary.

Are there any risks or possible discomforts?

This study is expected to involve minimal risk.

Some people may have mild stomach or bowel symptoms from the fibre supplement. These symptoms are usually mild and temporary.

Blood samples may cause brief pain, bruising, bleeding, or minor irritation where the needle was inserted. Approximately 14 mL of blood (just under a tablespoon) will be collected at each of four blood collection visits, giving a total of approximately 56 mL over the study.

The continuous glucose monitor may cause mild discomfort, redness, bruising, or skin irritation where it is placed.

Some interview questions may cause mild discomfort when discussing your experiences of eating, appetite or food cravings. You do not have to answer any question you do not wish to answer, and you may stop the interview at any time.

The study foods are common supermarket foods. They may be higher in salt, sugar, or saturated fat than less processed foods, but you will only be asked to consume them for two weeks at a time.

However, regularly eating large amounts of these foods over a long period (years to decades) may increase the risk of weight gain, high blood pressure, high cholesterol, type 2 diabetes, and heart disease. To reduce these risks, we will check your health before the study, monitor you during the study, and include a break between the two study periods. About eight weeks after the second study period ends, you will attend an online follow-up session with a member of the study team to check that your eating pattern has returned to normal. If you are having difficulty returning to your usual diet, we can arrange dietetic counselling at no cost to you.

The study team may stop your participation if they think it is no longer safe or suitable for you to continue. You may also withdraw at any time.

What information and samples will be collected?

We will collect information and samples needed for this study. This may include:

- your screening and consent information;
- your questionnaire answers, such as information about your diet, health, physical activity, medication use, alcohol intake, smoking status, and study experience;
- measurements such as height, body weight, body composition, and blood pressure;
- your food diary information;
- information from the continuous glucose monitor;
- fasting blood samples; and
- audio recordings and written transcripts of the study interviews.

Your blood samples will be used to measure cholesterol, and biomarkers related to diet, health, and physiological function. Blood samples will only be used for this study unless you give separate consent for future use.

Any remaining blood samples will be stored securely for up to 10 years and then disposed of according to University of Otago procedures. You may ask for disposal to include a karakia.

Your information and samples will be labelled with a study code instead of your name. A separate list linking your name to your study code will be kept securely on a password-protected University of Otago server. Only authorised members of the research team will be able to access this list.

Paper records will be kept in locked filing cabinets. Electronic data will be stored on password-protected computers and secure University of Otago servers. Study records will be stored for at least 10 years.

What about privacy and confidentiality?

All information collected during this study will be kept confidential. Your study information and research samples will usually be labelled with a study code instead of your name.

Awanui Labs will collect and analyse some of your blood samples. To make sure that the samples are matched to the correct person, Awanui Labs will receive identifying information, including your name and date of birth. This information will only be used to identify your samples, complete the requested blood tests, and report the results.

Only authorised members of the research team and relevant Awanui Labs staff will have access to information that can identify you.

Other laboratories involved in research analyses will receive coded samples or data and will not receive your name.

The study results may be published in a journal, presented at conferences, or included in student theses or reports. You will not be identified in any publication or presentation. Results will usually be reported as grouped or summarised findings.

Can you withdraw from the study later?

Yes. You can withdraw from the study at any time without giving a reason. There will be no penalty or disadvantage if you decide to withdraw.

If you withdraw, the study team may ask whether you are willing to tell us why, but you do not have to give a reason.

If you withdraw, the study team will discuss with you whether information or samples already collected from you can still be used. In some cases, it may not be possible to remove information that has already been de-identified, analysed, or combined with other study data.

Any questions?

If you have any questions now or in the future, please feel free to contact any of the following:

Name Sheila Skeaff **Position Professor** **Department of Human Nutrition**	Contact phone number: +64 3 479 7944 **sheila.skeaff@otago.ac.nz**
Name Andrew Reynolds **Position Associate Professor** **Department of Medicine**	Contact phone number: +64 27 956 5826 **andrew.reynolds@otago.ac.nz**
Name Aaron Hao **Position** **Department of Human Nutrition**	Contact phone number: +64 28 8518 4352 **haozi277@student.otago.ac.nz**

This study has been approved by the University of Otago Human Ethics Committee (Health) - Te Pae Matatika Tangata (Hauora), Ōtākou Whakaihu Waka . If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email humanethics@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.