Study title:	**Healthy Foods For Your Heart**	Ethics committee ref: 20/NTB/121
Locality:	Dunedin, Otago	Phone: 022 674 1431
Lead investigator:	Dr Andrew Reynolds	healthy_heart@otago.ac.nz

You are invited to take part in a study on grocery deliveries after an acute coronary event. 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 online Consent Forms. 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 the delivery of free healthy groceries for 12 weeks following an acute coronary event (such as a heart attack) improves health more than the usual care provided in Aotearoa New Zealand. Findings from this study will be useful to patients and health professionals. The main aim of the study is to see if cholesterol levels and other markers of health in blood samples improve due to the delivery of healthy groceries. People who decide to join the study will be randomly put into one of three groups. One third of participants will receive usual care and no groceries delivered. This is the control group. One third of participants will receive usual care and have a weekly delivery of high-fibre foods, such as vegetables, beans, whole fruit, and whole grains. Another third of participants will receive usual care and have a weekly delivery of foods high in health fats, such as tinned fish, nuts and seeds, vegetables oils, and avocado. Participants will have no say in which group they will be placed into, and therefore will need to be okay with being in any of the three groups.

We don't yet know if providing the groceries will help reduce risk of another heart attack or not. We also don't know if one of these food groups will improve health more than the other. However this trial has been designed to answer such questions. We will mainly use information from your blood samples, but we will also need to regularly 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 you used the groceries during the 12 weeks. We will test if your gut bacteria changed during the 12 weeks. We will test if we can measure markers of the foods you eat from your blood samples. We will test if your overall dietary quality predicts any change in your health over the 12 weeks. We will consider if the cost of paying for healthy groceries is worthwhile in the management of heart disease. Please carefully read the consent form, as it asks your permission to use your data to answer these other research questions.

This main research question to be answered is funded by the Riddet Institute, a Centre of Research Excellence. Additional funding and support for this study come from the Edgar Diabetes and Obesity Research Centre, the Department of Medicine at the University of Otago, Healthier Lives the National Science Challenge, and The National Heart Foundation of New Zealand. This study has ethics approval from the HDEC committee (20/NTB/121). Lead investigator (Dr Reynolds) can be contacted on andrew.reynolds@otago.ac.nz.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

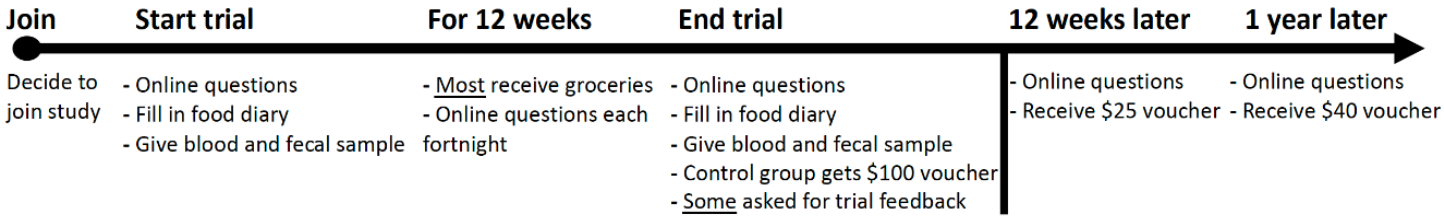
We are looking for participants aged between 18-80 years old who have had an acute coronary event. Potential participants must be willing to be randomly allocated into the group that receives no groceries, the group that receives high-fibre food, or the group that receives food high in healthy-fats. People allergic to such foods, or who do not like to eat such foods, may not wish to participate in this study. We will be working with cardiovascular risk clinics run from hospitals to identify potential participants.

As much as possible, we will run this study remotely. Participants will need to enter their details in our online portal. 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. Blood samples will be drawn from your arm like normal at hospitals, and then sent to us. For those participants receiving groceries, they will be delivered to your door each week for 12 weeks. One of the reasons to conduct this study this way is to so to reduce the risk of transmitting infectious diseases between participants and staff helping to run this study.

If you decide to join the study, we will ask you to give a fasted (morning) blood sample up to four times. Once, maybe twice, at the start of the study, and then once, maybe twice, after the 12 weeks. Staff who draw your blood at a Southern Community Laboratory facility will also be asked to measure your body weight and blood pressure each time. We will ask some of you to provide a faecal sample at the start and end of the 12 week period. This is not as troublesome as you may think. It is done by wiping your used toilet paper with a small cotton bud sized collector that we provide, popping the collector in a sealed container, and mailing it

away. These samples are attached to your study ID number only, and are sent away to be assessed in Australia. These samples are completely destroyed in the process.

We will also ask you about what food your normally eat before, during, and after the study. We will do this online where possible, or we will post you a paper-based food diary to fill out exactly what you eat over two four-day periods. After completion of the 12 week trial, we will contact all participants again three months and one year later to find out what you are eating and how you are feeling, to see if the trial provided any long-term benefits. Participants who respond to the three month questionnaire will receive a $25 grocery voucher for their time participants who respond to the one year questionnaire will received a $40 grocery voucher for their time. Here is a visual of what participation will involve:



WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

We don't think there are any large risks in participating in this study. For the participants receiving delivered groceries, we will send you 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.

Your arm may be slightly sensitive after each 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. We will provide you with your personal results once you finish your participation in the study, and then the overall study findings. We will never release your individual information to anyone but you. 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 funded primarily by the Riddet Institute, a Centre of Research Excellence. Participants who are randomised into our control group will not receive a delivery of free groceries over the 12 weeks. Instead, to thank them for their time we will send a supermarket voucher of $100 after the completion of the 12 week study period. If participants in the control group decide to stop participating during the 12 week period, we will still offer you the supermarket voucher.

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. 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. Data collected from you during the study will be de-identified to protect your privacy. No data relating to any one participant will be released in a way that could possibly identify them.

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. If you wish to continue eating the provided foods after the trial, they will be available in the supermarket. We are unable to pay for these foods after the 12-week period of the study. After you complete the study we will provide you with a summary of all your information. If you wish, we can also provide you with the average results of all participants from the study.

Data collected during this study will be stored securely for a minimum 10 years for future possible use. 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 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
022 674 1431
healthy_heart@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
Email: advocacy@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 ETHIC
Email: hdecs@health.govt.nz

Consent form

Study: Healthy Foods For Your Heart

Please tick to indicate you consent to the following when appropriate

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, 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 (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. (healthy_heart@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.

Yes I confirm the statements listed above ☐

We want to know if eating healthy foods improves heart health. To do this we need participants who receive groceries to eat them regularly for 3 months. If you don't think you can eat the study foods, this study may not be for you. You will still need to buy other groceries during the 12 weeks, but we need participants who can base their meals on the foods we deliver.	Yes I can do this ☐

If I decide to stop being part of the study, I agree that the information collected about me up to the point when I stop 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 ☐
GP Name:_____ Medical Centre:_____		
If requested, I agree to taking a faecal sample from a piece of my used tissue paper before and after the study, knowing that this sample will be sent to Australia for analysis. This sample will be destroyed during analysis.	Yes ☐	No ☐
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:

Signature: Date: