Participant Information Sheet

Beating Prediabetes Study

Formal Study title: **A study to assess the effects of beetroot and blackcurrant juices on glycaemic (blood sugar) responses in prediabetes**

Lead Researcher: Cameron Haswell

Study Site: Massey University Sports Lab

Ethics committee ref: 2022 EXP 11682

Researcher Introduction and invitation to take part

My name is Cameron Haswell, and I am a PhD student at Massey University, School of Health Sciences. My supervisors are A/Prof Kay Rutherfurd-Markwick, Prof Ajmol Ali, A/Prof Rachel Page and Dr Roger Hurst.

You are invited to take part in a study to assess the effects of beetroot and blackcurrant compounds on glucose (blood sugar) control in people with prediabetes.

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 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. 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.

Voluntary Participation and Withdrawal From This Study

Participating in this study is completely voluntary and you are free to decline to participate, decline to answer any particular question, or to withdraw from the research at any practicable time. Should you withdraw, you will still receive a koha for your participation up until the point of withdrawal.

What is the purpose of the study?

Obesity and diabetes are epidemic in New Zealand (and in other Western countries), and many individuals now have problems maintaining their blood sugar levels within normal levels.

Certain foods and drinks, including berries, teas and some vegetables have been shown to reduce blood sugar levels. This may be due to the high levels of antioxidants that are present in these foods, though other substances such as inorganic nitrate may also be involved. The effects of New Zealand beetroot and blackcurrant juices on blood sugar control have not been studied, thus, this study aims to determine whether blood sugar levels in prediabetes can be improved following daily consumption of a beetroot or blackcurrant beverage.

HOW IS THE STUDY DESIGNED?

The study will take place in NZ and will include a total of 160 participants. You will be enrolled in the study for a total of 12 weeks and will be required to come to the lab on 2 separate occasions at the start and end of the study period.

There are 4 groups in the study, and you will be randomly assigned to either beetroot, blackcurrant, a beetroot/blackcurrant mix or placebo and will consume a beverage each morning for 12 weeks. There is a 25% chance that you will be in any given group.

You will be asked to provide a finger prick blood samples during both study visits where we will measure HbA1c, lipid profile and fasting glucose. These visits will also involve measures of body composition and a food frequency questionnaire (FFQ).

During the 12-week study intervention, you will be asked to measure your fasting glucose weekly and complete weekly compliance diaries. These diaries and questionnaires will be used to check the appropriateness of the intervention and to ensure there are no adverse effects of the intervention drink.

WHO CAN TAKE PART IN THE STUDY?

You have been chosen to participate in the study because you have met the criteria to be included in the study. The criteria include:

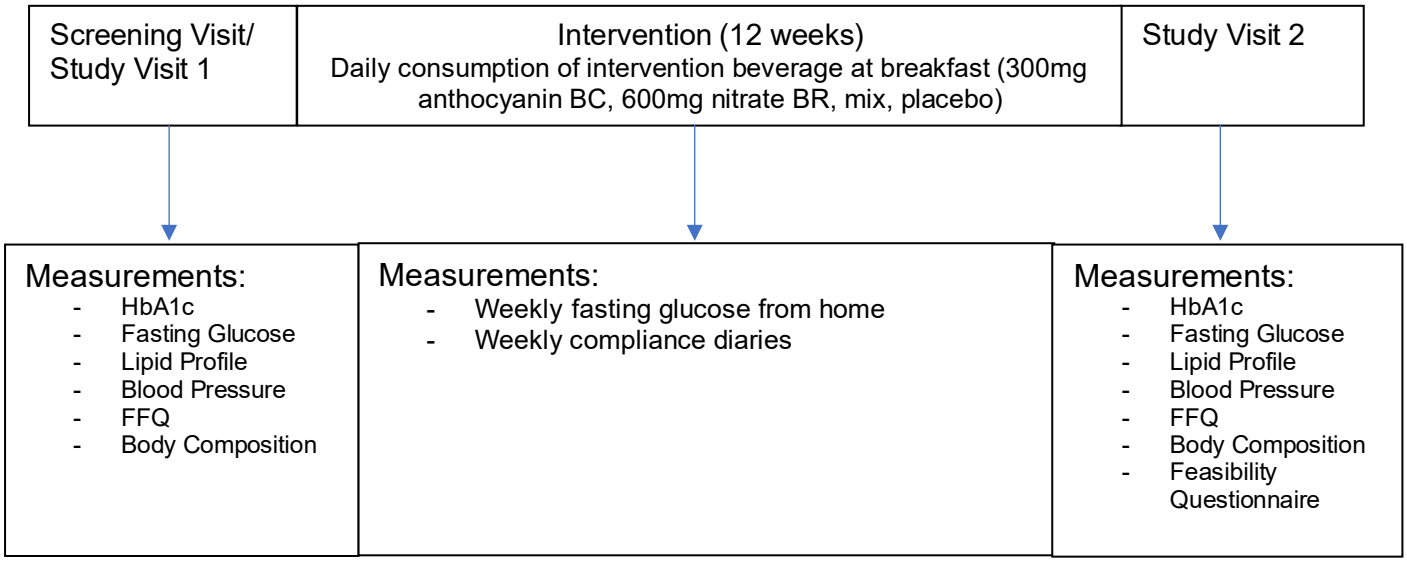
- 30-75 years of age
- BMI 18.5 - 40.0 kg/ m^2
- HbA1c 41-49 mmol/ mol
- Fasting glucose > 5.6 mmol/ L
- Not pregnant or breastfeeding
- Not allergic to beetroot or blackcurrant
- Non-smoker
- Able to communicate well in English

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

The study will involve you coming to the Massey University Sports Lab, located at the Albany campus. If you are eligible after an initial screening questionnaire, you will need to be available for TWO in-person morning visits separated by a 12-week intervention period. Each of these

visits will take place in the morning and will last approximately 1 hour. Each session, including the screening visit, will require you to fast overnight (i.e. no food or drink except water) for at least 10 hours before coming to the research facility.

Whole Study at a Glance



Screening visit (Visit 1)

During your screening and first study visit, we will assess whether you meet the study inclusion criteria. You will be required to arrive at the Massey University Human Nutrition Research Unit ONE morning to have a screening fasted blood sample collected. The session should take approximately one hour. A qualified phlebotomist will measure your fasting blood sugar, lipid profile and HbA1c levels through a finger prick blood sample. You will be invited to participate in the study visits if screening indicates you are eligible for the study.

In addition, trained researchers will determine your body mass index (BMI) by measuring your weight and height. They will also be measuring your waist and hip circumference, and your body composition (using a bioelectrical impedance scale). This can be done privately, and you do not need to undress, however you will need to remove socks and shoes. Blood pressure and heart rate will also be measured. You will also be asked about your relevant medical history, and any medication use. Finally, you will complete a food frequency questionnaire online which will provide us information on your eating habits over the previous 30 days.

If eligible to participate in the study, you will be issued with a handheld glucometer and all materials required to test your fasting blood glucose at weekly intervals for 12 weeks. A trained researcher will also show you how to do this safely at home. If you already own and use a handheld glucometer, you may use your own device.

Study Interval (12 weeks)

Between study visits 1 and 2 there will be a 12-week interval during which time you will be asked to consume a beverage daily. This beverage will be either placebo, blackcurrant, beetroot or a blackcurrant/beetroot mix. During this time, you will be asked to complete a

weekly fasting glucose measurement using the handheld glucometer issued to you during your first visit (or your own).

You will be asked to complete a compliance diary each week including questions about how you are feeling and how you are finding the intervention drink. This should take no longer than 5 minutes to complete.

Study Visit 2

Study visit 2 will be identical to study visit 1. You are required to come to the lab fasted and the same measurements that were taken at visit 1, will be taken by the researcher, to determine if the intervention has influenced any of the measures stated above. You will also complete a feasibility questionnaire to assess the long-term viability of the intervention drink. You will then be thanked for your time and receive a *koha* for you participation.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

It is highly unlikely that you will be injured during this study. Finger prick blood sampling is a safe and routinely used practice. A trained phlebotomist and first aider will be available during each study session and will assess for adverse events (i.e. feeling nauseous, dehydrated or faint) during each finger prick sample collection.

You may also find that the study intervention drink is not to your taste but there is no risk to you in consuming the beverages, apart from allergic reactions to either blackcurrant or beetroot, which is extremely rare.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

By participating in the study, you will obtain information about your general health status, HbA1c value, body composition and blood pressure measurement entirely at no cost to you. These results are not diagnostic, and should you be concerned about any of the results obtained, we would ask that you refer to your normal healthcare provider to seek further information.

In addition, there will be a $50 voucher as a *koha* for involvement in the study.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

Other treatments for prediabetes are available and you should consult with your general practitioner for more information.

WILL ANY COSTS BE REIMBURSED?

There will be a $50 *koha* to thank you and reimburse your travel costs for the study.

WHAT IF SOMETHING GOES WRONG?

If physical injury results from your participation in this study, you should visit a treatment provider to make a claim to ACC as soon as possible. ACC cover and entitlements are not automatic, and your claim will be assessed by ACC in accordance with the Accident Compensation Act 2001. If your claim is accepted, ACC must inform you of your entitlements, and must help you access those entitlements. Entitlements may include, but not be limited to, treatment costs, travel costs for rehabilitation, loss of earnings, and/or lump sum for permanent impairment. Compensation for mental trauma may also be included, but only if this is incurred as a result of physical injury.

If your ACC claim is not accepted, you should immediately contact the researcher. The researcher will initiate processes to ensure you receive compensation equivalent to that to which you would have been entitled had ACC accepted your claim.

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 researchers, and other staff will record information about you and your study participation. This includes the results of measurements mentioned in the protocol. You cannot take part in this study if you do not consent to the collection of this 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 researchers. Instead, you will be identified by a code. The researchers will keep a list linking your code with your name, so that you can be identified by your coded data if needed. Only the research group will have access to your coded information.

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 Massey University during the study. After the study, it will be transferred to a secure archiving site and stored for at least 10 years as per standard regulations, then destroyed. Your coded information will be entered into electronic case report forms. All storage will comply with local and/or international data security guidelines.

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.

Please ask if you would like to access the results of your screening and safety tests during the study.

If you have any questions about the collection and use of information about you, you should ask the primary researcher, Cameron Haswell.

Rights to Withdraw Your Information.

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

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

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to The Beverage Lab. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

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

You can withdraw from the study at any time and will be compensated according to the number of visits made. Furthermore, you are welcome to discuss any concerns you have with the research team at any time, and you have free access to your data. If you withdraw from the study all of the data that was related to you will be shredded.

The treatment intervention (beetroot and blackcurrant juices) will not be available to any participant after the study.

The study data will be stored at a secure location at Massey University Albany Campus. Electronic data and records will be the responsibility of the Principal investigator. All data will be kept for 10 years, at which point it will be destroyed using University Security methods for removal of confidential material.

It is very likely that the results of this study will be written up for publication in a peer-reviewed journal and/or presentation and a scientific conference within 12 months of completing the study. If this happens no participant identification information will be included.

CAN I FIND OUT THE RESULTS OF THE STUDY?

Participants are welcome to discuss the findings of this study with the researchers at any time. You will also be provided with a full copy of the final study report, if requested, as well as a lay summary of the results at the end of the study duration.

The study details are available on the ANZCTR under number ACTRN12622001108707.

WHO IS FUNDING THE STUDY?

The study is being funded by Massey University, School of Health Sciences. The blackcurrant juice used in the study has been provided by The Blackcurrant Cooperative.

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 HDEC committee 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 the following researchers involved in the study:

Cameron Haswell: PhD student, School of Health Sciences, Massey University, Albany
Phone: +204 175 2779
Email: c.haswell@massey.ac.nz

A/Prof Kay Rutherfurd-Markwick: Associate Professor, School of Health Sciences, Massey University, Albany
Ph: 09 414 0800 ext. 43646
Email: k.j.rutherfurd@massey.ac.nz

A/Prof Rachel Page: Head of School of Health Sciences, Massey University, Wellington
Phone: 04 801 5799 ext. 63462
Email: R.A.Page@massey.ac.nz

Prof Ajmol Ali: Associate Professor, School of Sport, Exercise and Nutrition, Massey University, Albany
Phone: 09 213 6414
Email: A.Ali@massey.ac.nz

Dr Roger Hurst: Principal Scientist, Food Innovation Portfolio, Plant & Food Research Ltd
Phone: 06 953 7677 Mobile - 021 2452310,
Email: Roger.Hurst@plantandfood.co.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 (085 00 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Māori health support, please contact:

Dr Bevan Erueti: Senior Lecturer - Health Promotion/Associate Dean – Māori, School of Health Sciences, Massey University, Wellington
Phone: 04 695 16087
Email: B.Erueti@massey.ac.nz

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