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The NZ Food and Beverage Study:
The Effect of Different New Zealand Foods and Beverages on Energy Expenditure, Blood Sugar and Appetite After Eating

Jack Penhaligan, Jia Jiet Lim, Ivana Sequeira, Shakeela Jayasinghe, Jennifer Miles-Chan

Formal Study Title

SYNERGY Acute Single-Product Sub-Study:
The Utility of NZ Origin Food and Beverage Products for the Acute Enhancement of Postprandial Thermogenesis (Energy Expenditure), Glycaemia (Blood Sugar) and Appetite

Participant Information Sheet/Informed Consent Form

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Participant Information Sheet

You are invited to take part in a research study which will investigate the effect of multiple New Zealand origin food and beverage products on metabolism in the hours after eating. Specifically, this study will be assessing how different food or beverage products change your metabolic rate, blood sugar levels and appetite.

This Participant Information Sheet (PIS) will help you decide if you would 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 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. Please feel free to do this. 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. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

If you agree to take part in this study, you will be asked to sign the Informed Consent Form on the last page. You will be given a copy of this Participant Information Sheet/Informed Consent Form to keep.

This document is 23 pages long, including the Informed Consent Form.

Please make sure you have read and understood all the pages.

1. Voluntary participation and withdrawal from this study

Your participation in this study is entirely voluntary. You are completely free to decline to participate, or withdraw from the present study at any time. In the event of doing so, you will not experience any disadvantage.

2. What is the purpose of the study?

It is well known that what we eat affects our health. It is now also well recognised that some products contain additional properties, such as high protein content, that can provide health benefit above a food's nutritional value.

Firstly, it has been suggested that such 'functional' foods could increase the amount of energy (calories) burned in the hours after eating. Secondly, these products may be able to promote the breakdown of fat after a meal has been eaten. Thirdly, 'functional' foods and beverages may help to regulate blood sugar response. Finally, eating certain food and beverage products could help us to feel fuller for longer.

Some examples of food and beverage components that may contribute to the desirable effects described above include polyphenols, complex carbohydrates or protein. So the test foods that will be provided in this study have been specifically selected to fulfil these criteria.

This study will be composed of four individual trials, with a different test food or beverage product will be provided in each. It is up to you whether you choose to participate in just one, two, three or all four of the different trials. Each of the four trials will be independent and self-standing. By agreeing to participate in one of the trials, there is absolutely no obligation to participate in any additional trials. However, if you do wish, you may volunteer for a second, third or fourth trial. However, you will not choose which of the individual trials you join. The specific trial and test food or beverage product that you will receive will be assigned by the researcher. In each trial, you will receive any one of the following food or beverage products highlighted in Figure 1.

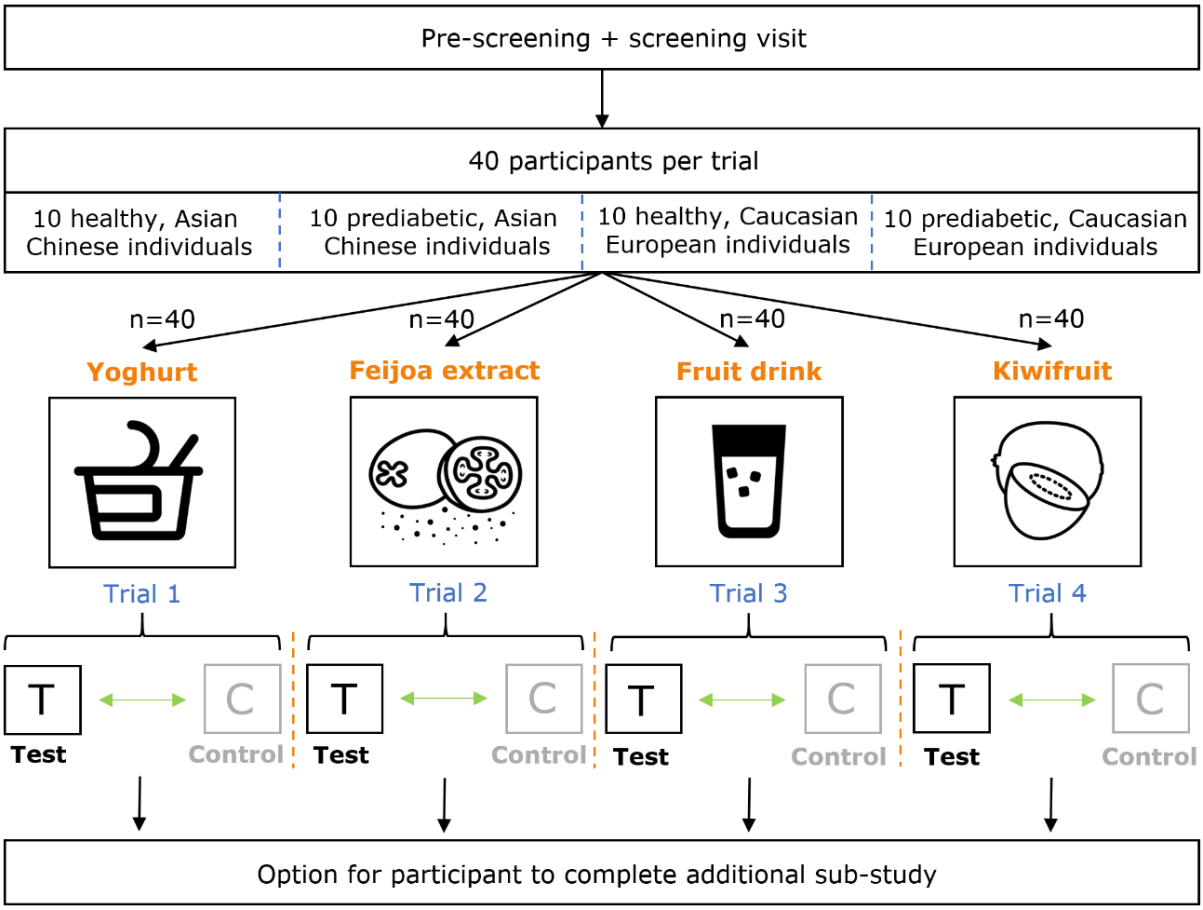

Figure 1. A study flowchart highlighting the study design and test products of the four different trials; T=Test product, C=Control product

For each of the trials, you will consume 2 food or beverage items: (1) test food or beverage item; (2) control food or beverage. You will consume the test product and the matched control separately in two study visits in a randomised order.

This study will investigate how different New Zealand origin food and beverage products change your short-term metabolism after eating. It will also explore whether healthy individuals and those at an increased risk of diabetes (individuals with prediabetes), and European Caucasian and Asian Chinese individuals respond differently to the same food or beverage.

The results from this study will increase our knowledge of how specific components of common foods (i.e. polyphenols, complex carbohydrates and protein) affect both the energy that we burn and how we process foods after eating. Learning how these mechanisms work could inform future dietary guidelines which may help people to avoid weight gain and poor metabolic health outcomes (e.g. type 2 diabetes).

3. How is the study designed?

This study is designed by research staff at the School of Biological Sciences (SBS) and the Human Nutrition Unit (HNU), University of Auckland.

We would like to enrol 40 adults for each of the four trials. The 40 adults comprising each group will consist of:

- **10** European Caucasian individuals with normal blood sugar
- **10** European Caucasian individuals with raised blood sugar (prediabetic)
- **10** Asian Chinese individuals with normal blood sugar
- **10** Asian Chinese individuals with raised blood sugar (prediabetic)

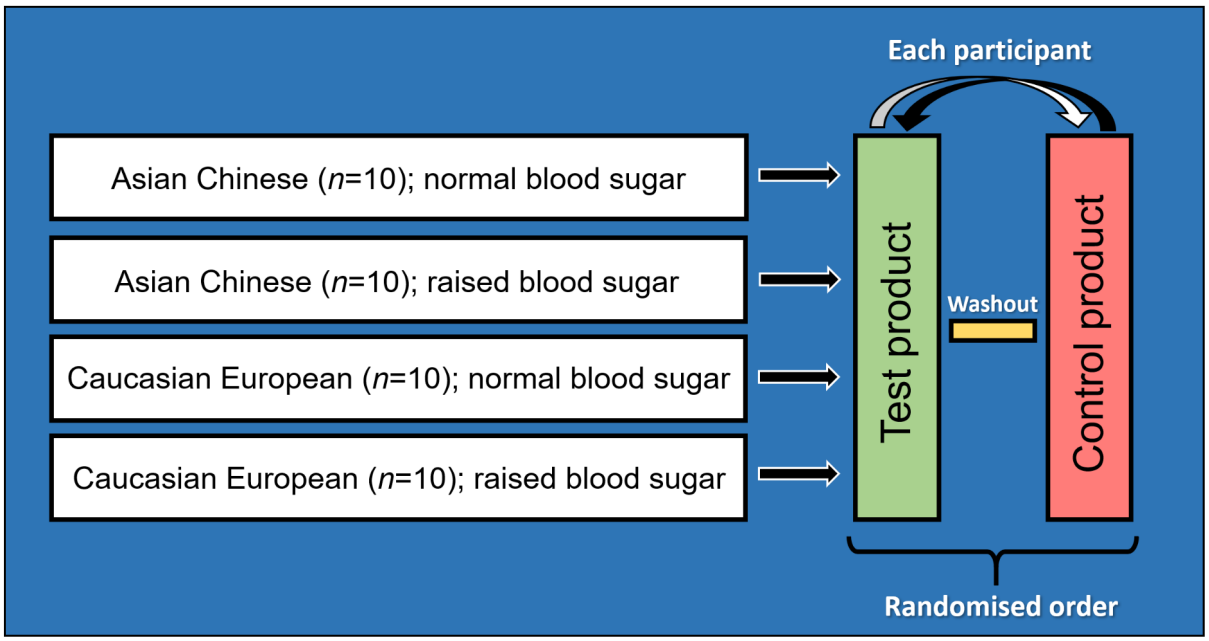

Figure 2. A diagram to highlight the participants that will be recruited into this crossover study

4. Who can take part in this study?

If you fit the following criteria, you may be eligible to take part in this study:

- European Caucasian, with both mother and father of Caucasian origin OR Asian Chinese, with both mother and father of Asian Chinese origin (more widely, individuals from mainland China, Singapore, Malaysia, Hong Kong, Taiwan, and South Korea may also be eligible)
- Between 18-60 years

- Overweight or obesity (BMI 24-40 kg/m2)
- Healthy or at an increased risk of diabetes (but not yet diabetic), based on a fasting blood sugar test

5. What will my participation in the study involve?

You are invited to take part in this study because you meet the initial inclusion and exclusion criteria for this study (summarised above). If you decide you wish to take part in this study, you will first need to attend a 'screening visit' to confirm that you are eligible. After the 'screening visit', if you meet the inclusion criteria, you will be invited to attend two further 'study visits' (as shown in *Figure 2*).

Screening Visit

If you are interested in being a participant in this current study, a member of the research team from the Human Nutrition Unit will contact you via telephone or email to confirm your age, height, body weight and medical history. These questions are important for us to understand whether you might be eligible for the study.

After assessing your responses, if you appear to be eligible for the study, the researchers will invite you to come to the Human Nutrition Unit in Mount Eden for a screening visit of a morning. This screening visit will take approximately 1-2 hours.

During the screening visit, we will explain the study in more detail, and you will have the opportunity to ask any questions that you might have up to this point. Once you are well informed about the study, we will give you enough time to decide if you want to participate or not. If you decide to take part in the study, we will ask you to sign a form stating that you agree to participate in the study. This is called an 'informed consent form (ICF)' - by signing it, you consent to take part in the study. Please note that you remain free to withdraw from the study at any time without any consequence even after signing the consent form.

If you decide you would like to take part in the study, we will proceed with a clinical assessment of your health which will be very similar to a visit to your family doctor/general practitioner (GP). We will ask you some personal questions (e.g. about where you live, your medical/medication history etc.). To facilitate this part, we ask that you bring any prescriptions/medication/supplements that you may have or any other information that you think may be important for us to know so that we can record your health information accurately. Please note that you do not have

to answer all of the questions and that you may stop the visit at any time. Do not worry if you are unsure of any of your personal details, we can also contact your GP for further information given your written consent.

We will also do some body measurements (height, body weight, body mass index/BMI, waist & hip circumference, blood pressure) at the screening visit.

Finally, we will take a blood sample to check your blood glucose (sugar) levels to confirm that you do not currently have diabetes. As your blood glucose levels will need to be examined in an overnight fasted state, we will require that you do not eat or drink anything (other than water) on the morning of your screening (or study) visit. If you have had a blood test anytime in the previous 4 weeks, we will be happy to repeat this to confirm whether you can be enrolled based on your blood glucose levels.

Between your screening visit and first study visit, we will also ask you to attend a "Body Composition Assessment" at the University of Auckland's Grafton campus (Clinical Research Centre). Specifically, this body composition visit involves a DeXA (Dual-energy X-ray Absorptiometry) scan. This is a whole-body scanning machine which will assess how your muscle and fat is distributed across your body. (See more in *Section 7*).

Study Visits

Following your screening visit, one of the researchers from the Human Nutrition Unit will be in contact to confirm whether you are eligible for the study. If your eligibility is confirmed, you will subsequently be invited to return to the Human Nutrition Unit on two further occasions for the (two) study visits which make up each individual trial.

If you are interested in completing more than one trial, you will simply return to the Human Nutrition Unit for up to two further study visits for each trial. Participation in any additional trials is not mandatory and you can freely choose to simply partake in one, two, three or four of the individual trials.

Each of the study visit will follow the same procedure. For each pair of trial visits, you will receive one of the four test products (i.e. yoghurt, whole fruit powder, fruit drink or kiwifruit) and the matched control, in a randomised order.

For all study visits you will be asked to arrive at the Human Nutrition Unit (HNU) in Mount Eden at 7:45 am after an overnight fast (no food or drink after the provided evening meal, except water). You will then remain at our research facility for 5-6 hours whilst we first conduct baseline measurements and subsequently assess your metabolism after you've consumed the individual food products. We ask that you please travel to

the HNU by car, bus or train as we don't want you to do more than minimal physical activity on the morning of your study visits. We also ask that you abstain from intense exercise, alcohol and excessive caffeine for 24 hours before each visit.

When you arrive, you will be given a glass of water and we will record your body weight. After this, our Research Nurse will insert a cannula (small plastic tube) into your arm. This will allow us to collect blood samples throughout the study visit without having to repeatedly prick with a needle. This technique is commonly used in hospitals, and once the cannula is in place it does not usually cause any discomfort. Nonetheless, you will be monitored by Research Staff over the 5-6 hour study period.

Once the cannula is inserted, we will collect a blood sample and measure your heart rate, blood pressure and body temperature. For the measurement of heart rate and body temperature, we will require you to wear a chest strap (which sits underneath your top) and a small battery-sized sensor (which sits on the tip of your finger), respectively. You will then wear both of these monitors whilst we continue to non-invasively assess your heart rate and body temperature for the duration of the morning visit.

We will also ask you to complete a short questionnaire about your appetite/wellness repeatedly throughout the morning using a visual analogue scale (VAS). An example of this type of measurement is shown below in the image (see *Figure 3*). You are required to mark a point along a continuous scale between two extreme limits to indicate how you feel.

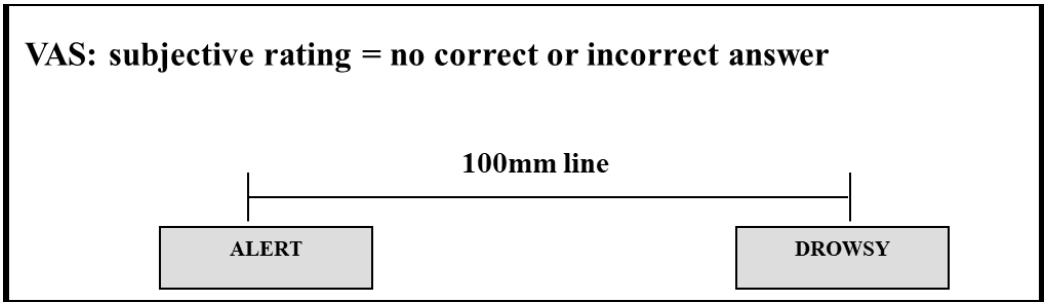

Figure 3. An example of a single visual analogue scale (VAS) question.

Another key feature of the study visits will be an assessment of energy expenditure (the amount of calories your body is burning) using the method of indirect calorimetry. A picture to help you understand what this procedure entails and what you expect is shown overleaf. For these measurements, we will ask you to sit in a comfortable chair whilst we place a canopy (a transparent head covering) over your head.

This system allows us to measure the air that you are breathing in and out which we can subsequently use to calculate your metabolic rate (rate at which you are burning energy at rest). You will remain seated in this chair (apart from a short break) with the canopy hood over your head from around 8.00 am until 12:00 pm. There is an opening at the top of the canopy for fresh air to enter and circulate the system.

Moreover, during your time under the hood, you will be able to watch a calm movie, documentary or TV show on our clinic room TVs. However, it is important that you do not fall to sleep or fidget excessively (e.g. use a laptop/mobile phone) during these measurements.

The first indirect calorimetry measurement will be completed whilst you are still in a fasted state and will last approximately 30-45 mins. After this initial baseline measurement, we will remove the hood and provide you with the food or beverage product from whichever trial you are participating in. The four food and beverage items (yoghurt, whole fruit powder, fruit drink and kiwifruit; or matched comparator) may be provided either as a standalone meal or incorporated into a more complete mixed-meal.

After giving you 5-10 minutes to consume the provided food or beverage, we will place the canopy hood back over your head and continue taking measurements for a further 3-3.5 hr. Trial 4 (the kiwifruit trial) will be of a slightly different design. For this specific trial, the canopy will again be removed after another 30 minutes and you will be provided with an additional mixed-meal.

During the indirect calorimetry session, we will also be conducting frequent blood samples from the inserted cannula (no additional needles), collecting subjective assessments of appetite/wellness using VAS, and taking multiple measurements of blood pressure.

It is important that you are relaxed throughout the indirect calorimetry procedure so please tell the researcher if you are uncomfortable or if there is something you need. During all of the measurements it is important that you avoid large movements, but if you need to readjust your position, use the bathroom, or itch in order to be more comfortable, of course you may do so.

At 12:15-12:30 pm we will have finished the above measurements and the canopy hood will be removed. We will then serve you a lunch meal (beef and tomato pasta) in the dining room and you will be asked to eat as much as you like until you are comfortably full. After lunch we will do a final appetite questionnaire measurement. You will be finished with the study visit at around 1:00 pm and will be able to leave the HNU after we have removed the cannula. A scheduled timeline of the tests which will be conducted throughout the course of a study visit morning is displayed below.

Study visit schedule

0745h – Approximate arrival at HNU (fasted)

0800h – Cannulation by registered nurse

0815h - Commencement of cardiometabolic monitoring (indirect calorimetry, heart rate, body temperature), visual analogue scale (VAS), and baseline blood sample (t=-45)

0845h-0854h - Indirect calorimetry measurement paused (canopy removed), VAS, blood pressure and baseline blood sample (t=-15 – t=-5)

0855h - Product ingestion (test or matched control) (t=-5)

0900h – Canopy replaced, and indirect calorimetry measurement restarted (t=0)

0915h – VAS and blood sample (t=15)

0930h – VAS, blood sample (t=30), and blood pressure

0945h – VAS, and blood sample (t=45)

1000h – VAS, and blood sample (t=60)

1015h – VAS (t=75)

1030h – VAS, blood sample (t=90), and blood pressure

1100h – VAS, blood sample (t=120), and toilet break

1130h – VAS, blood sample (t=150), and blood pressure

1200h – VAS, blood sample (t=180), blood pressure, **cardiometabolic monitoring stopped and lunch meal provided**

1300h – End of lunch, VAS, participant discharged

The tests will provide an insight into how the body's metabolism is altered by different New Zealand origin food and beverage products. The blood samples will allow the researchers to determine how the meals impact markers of metabolic health, such as blood sugar, insulin, cholesterol and immune markers in the blood.

In total, approximately 159 ml of blood will be collected for each pair of study visits that you wish to attend (79.5 ml/visit). In addition, 4 ml will be collected at the screening visit, bringing the total amount of blood collection for each trial to 163 ml (see *Table 1* for a breakdown of the amount of blood that will be sampled at each timepoint during the screening visit and each study visit). For reference, it should be noted that the overall amount of blood taken during each trial is only just over a third of the amount of blood typically collected during a standard blood donation (~470 ml).

Table 1. Blood sample amount (ml) at each timepoint (t, min) during the screening visit and each study visit.

Baseline (fasting) samples (ml)			Postprandial (after eating) samples (ml)								
Screening	t= -45	t= -5	t= 15	t= 30	t= 45	t= 60	t= 90	t= 120	t= 150	t= 180	
4.0	13.5	14.0	4.0	14.0	4.0	4.0	4.0	4.0	4.0	14.0	**83.5**

The use of indirect calorimetry with the ventilated hood will allow the researchers to measure the rate at which oxygen is used and carbon dioxide is produced by the body. These values will then be used to determine roughly how much energy (calories) you are expending (i.e. metabolic rate) and the source of this energy (i.e. fats or carbohydrates). Heart rate and blood pressure are also measured throughout the trial to help understand your cardiovascular response to each meal. Finally, appetite questionnaires will be issued several times during each study visit to compare how hungry/full you feel following the different food products.

6. What will happen to my blood samples?

With regards to the fate of your blood samples, these will be securely stored for up to four years. These samples will only be stored in New Zealand and used only for the purpose of this research. Once your blood has been collected, it will be sent for storage and then analysed as a group with all other participants' blood samples. Any leftover samples will be destroyed by incineration according to University policy at the end of the study.

7. What are the possible risks of this study?

There is very low risk associated with taking part in this research study.

Nonetheless, you may experience discomfort during cannulation, however this is uncommon. Research staff will be present to monitor you during all assessments. The research will be stopped should any harmful effects appear or if research staff feel that it is not in your best interest to continue. You should promptly inform the research staff if you feel uncomfortable or unwell at any stage.

DeXA is a scanning method, to measure body composition (bone, fat, muscle). The scanning process takes about 15 minutes and is not unpleasant. We will ask you to wear gym-style clothing and to remove any metal from your person for the scan. You will need to lie quietly, without moving, on an open bed whilst a scanning arm passes quickly over the top of you. As the scanning arm passes over you it emits two types of very low dose X-ray, similar to the radiation dose that you would be exposed to on a 1-hour flight – e.g. between Auckland and Wellington. If you participate in multiple trials as part of this study, you will only need to have one DeXA scan to minimise any additional exposure to radiation, unless more than 3 months has passed between your previous DeXA scan and your participation in another sub-study trial. At the end of the scan we will print a picture of you showing an image of the bone, fat and lean tissue in your body for you to take home with you.

8. What are the possible benefits of this study?

There will be no benefits from participating in this project other than obtaining valuable information pertaining to your health. You will also

importantly be contributing to scientific knowledge in the field of nutrition and health.

9. Will I be compensated for my participation?

Firstly, you will not incur any costs at all throughout the course of the study.

In fact, in recognition of your participation, you will be appropriately compensated for your time and travel. The compensation for each individual trial will total $170 in vouchers ($20 voucher after the completion of the screening visit, $50 after the completion of the DeXA body composition visit and $50 after the completion of each study visit). Hence, if you were to complete one, two, three or four trials, you would receive a total compensation of $170, $340, $510 or $680 in vouchers, respectively.

Aside from this, you will also have access to your results from this study. At the end of the study you will receive results from your blood tests such as your glucose, insulin, and lipid profile. It may take a while before you receive these blood results as we will need to wait until all participants have completed their visits to analyse all the collected blood samples together. You will also receive your whole-body DeXA scan results.

10. What if something goes wrong?

If you were injured in this study, which is unlikely, 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.

11. What will happen to my information?

During this study the researchers, nurses and other site staff will record information about you and your study participation. This includes the results of any study assessments. If needed, information from your hospital

records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

If there are any results from either the DeXA scan or the blood tests that are outside the reference ranges we will first discuss this with you. However, it will subsequently be mandatory for us to share any potentially important health information with your primary health care provider (i.e. your GP).

12. Identifiable information

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

13. Data confidentiality

To protect your privacy and confidentiality of your identity during and after your participation in the study, you will be allocated a unique study ID number upon your enrolment. This ID number will be used to label your samples, any data collected and your results throughout the study. Research files and all other information that you provide will remain de-identified and strictly confidential. No material that could personally identify you will be used in any reports throughout the course of this research project. Moreover, all computer records will be password protected throughout. The researcher will keep a password-protected list linking your code with your name, so that you can be identified by your coded data if needed.

14. Future research using your information

If you agree, your coded (de-identified) information may be used for future research related to studies investigating metabolism and general 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.

However, we will not share any identifiable information with anyone else other than the HNU research team.

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 already been shared for future research.

15. Security and storage of your information

Your identifiable information will be held at the HNU during the study and will be accessible only to members of the HNU research team. After the study is completed it will be transferred to a secure archiving site and stored for at least 10 years, then destroyed.

16. Risks associated with data

Although robust 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.

17. Rights to access your information

As a participant in the present study, you preserve all rights to access information about yourself as collected for the study. Upon request, this information will be disseminated as soon as possible, such as described with the blood test data in Section 5. You also have the right to request that any information you disagree with is corrected.

Given your consent, you will be informed of any new information which arises regarding adverse or beneficial effects related to the study which could have an impact on your health (i.e. that which becomes available during the study). If you have any questions about the collection and use

of information about you, you should ask Dr Jia Jiet Lim, the study coordinator.

18. Rights to withdraw information

You may withdraw your consent for the collection and use of your information at any time, by informing someone on the study team.

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 already been undertaken.

19. What happens after the study?

On completion of the study, it is planned that the findings will be communicated via a journal publication.

20. Can I find out the results of this study?

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

You can request a letter telling you about the study results. The letter will be sent to you once the final study report is available (this can take 1–2 years). A description of this trial will also be available on the Australian New Zealand Clinical Trials Registry (ANZCTR) website (https://www.anzctr.org.au/). This website will not include information that can identify you. At most, it will include a summary of study results.

Please ask if you would like to access the results of your screening and safety tests during the study. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study's scientific integrity.

21. Who is funding the study?

The present study will be funded by the MBIE National Science Challenge High Value Nutrition Programme, the Sir Charles Hercus fellowship of Dr Jennifer Miles-Chan and the University of Auckland Doctoral Scholarship of Jack Penhaligan. Dr Jennifer Miles-Chan, Jack Penhaligan, Dr Jia Jiet Lim and the other principal investigators for this study are all individuals working in affiliation with the University of Auckland.

22. 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.

23. 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 Jia Jiet Lim (Primary contact for participants)
Research Fellow & Study Co-ordinator

Human Nutrition Unit,
University of Auckland,
18 Carrick Place,
Mount Eden,
Auckland

Email: hnu_synergy@auckland.ac.nz
Contact number: 09 6301162

If you have further *unresolved* questions, concerns or complaints about the study at any stage, you can contact:

Dr Jennifer Miles-Chan

HNU Director, Senior Lecturer & Sir Charles Hercus Health Research Fellow

Human Nutrition Unit and School of Biological Sciences,
University of Auckland,
Auckland

Email: j.miles-chan@auckland.ac.nz
Contact number:09 923 4322

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/

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

Thank you for considering to take part in this study.

Informed Consent Form (ICF)

The Effect of Different New Zealand Foods and Beverages on Energy Expenditure, Blood Sugar and Appetite After Eating

I wish to have an interpreter to translate the study requirements from English into my preferred language.	Yes ☐ No ☐
I have read, or have had read to me, 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.	
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 information about my health.	
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 any significant abnormal results obtained during the study.	
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics 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 the compensation provisions in case of any injury during the study.	

I consent to my coded information being used for future research. This is completely optional and will not determine your eligibility for the current study.	Yes ☐ No ☐
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 know who to contact if I have any questions about the study in general.	
I understand my responsibilities as a study participant.	
I wish to receive a summary of the results from the study.	Yes ☐ No ☐
I consent for research staff at the HNU to contact me at a later date if there are future studies for which I am eligible	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:

A copy of this consent form is to be given to the participant and a copy to be kept in a research file by the investigator.