

# Higher-protein vs lower-carbohydrate diets for weight loss.

## PARTICIPANT INFORMATION SHEET

We invite you to participate in a clinical study where we aim to compare the effects of higher-protein and lower-carbohydrate diets on eating behaviour, weight loss and body composition.

Your participation in the study is entirely voluntary (your choice). If you do agree to take part, you are free to withdraw from the study at any time, without having to give a reason. You may take as much time as you need to consider whether or not you would like to participate.

### Who can take part?

We will invite 140 female participants to participate in this study. You can participate if you are female, between 18 - 65 years of age, have a Body Mass Index (BMI = weight / height<sup>2</sup>) between 30-45kg/m<sup>2</sup>, body weight no more than 130kg, and are healthy. You should not have any significant diseases (such as liver or kidney disease, diabetes, cardiovascular disease, cancer, digestive disease, etc.), should not be a smoker or have given up smoking for less than 6 months, and have not undergone bariatric surgery for weight loss.

You must be available to attend a **screening visit** at the University of Auckland Human Nutrition Unit (HNU) in Mt Eden, Auckland, which will take approximately one hour, to assess whether you are suitable to participate in this study. After that, you must be able to adhere to an assigned **weight-loss diet for 8 weeks**, during which time you will come to HNU on 6 occasions to meet with our Research Nurse and dietary counsellors. This will comprise **three morning study visits** (Week 0, Week 4 and Week 8) where we will collect your blood samples and other information. Additionally, you will also attend four **evening/weekend group counselling meetings** (Week 0, Week 2, Week 4, and Week 6) where you will receive the dietary support you need to stay on this weight-loss program.

## **Background to the study**

Maintaining a healthy body weight is important as obesity is linked to diseases such as diabetes, heart disease, kidney disease, liver disease, and some cancers. In theory, you can lose weight by simply reducing food intake and increasing exercise. In reality, many people struggle to lose weight and maintain a healthy body weight. Many people find following a weight-loss regime to be very difficult in the long term when feelings of hunger and the desire to eat increase during periods of dieting. While there are plenty of weight-loss diets being advertised, there are two which are particularly popular with the general public: (i) the 'high-protein diet' and (ii) the 'low-carbohydrate diet'. A high-protein weight-loss diet has been claimed to reduce hunger, increase energy expenditure, and retain muscle mass while helping to lose body fat. However, pushing up the protein content of your diet, means that you have to decrease either the carbohydrate or fat content, otherwise you will start to overeat, and possibly even gain weight. While the success of the 'high-protein diet' has been well documented in scientific articles, it has puzzled many researchers as to whether it is increasing to high-protein or decreasing to low-carbohydrate/low-fat that actually promotes the weight loss. Therefore, this study is designed to compare whether better weight loss can be achieved if you follow a 'high-protein' or if you follow a 'low-carbohydrate' diet.

## **Who designed the study?**

The research staff at the Human Nutrition Unit, University of Auckland designed this study. This study is supported by the Riddet Institute, a New Zealand Centre of Research Excellence, funded by the Tertiary Education Commission. Data from this study will contribute to the PhD research program of Jia Jiet Lim. You can find out more information about the HNU by visiting our website [www.hnu.auckland.ac.nz](http://www.hnu.auckland.ac.nz).

## **What is the aim of the study?**

The aim of this study is to compare the effects of an 8-week higher-protein vs. lower-carbohydrate weight-loss diet on:

- (i) Change in body weight
- (ii) Change in subjective feelings of hunger and fullness
- (iii) Change in body composition, i.e. fat tissue, muscle tissue

## What happens if you decide to take part?

You will need to attend a Screening Visit at the Human Nutrition Unit (HNU) in Mt Eden, Auckland to assess your eligibility. If you are eligible, we will enrol you in our 8-week weight-loss study. Then, we will invite you to attend HNU on 7 occasions (3 morning study visits and 4 evening/weekend group meetings) during your 8-week weight-loss period.

Table 1. The visits at HNU.

	<b>Week 0</b> <b>Study Visit 1</b> (5 hours)	<b>Week 2</b>	<b>Week 4</b> <b>Study Visit 2</b> (30 minutes)	<b>Week 6</b>	<b>Week 8</b> <b>Study Visit 3</b> (5 hours)
Morning study visits	Blood test		Blood test		Blood test
	Hand in 24-h urine sample and food diary		Hand in 24-h urine sample and food diary		Hand in 24-h urine sample and food diary
	Appetite assessment				Appetite assessment
	Body composition assessment <sup>1</sup>				Body composition assessment <sup>1</sup>
Evening/ Weekend group meeting  (1 hour)	Group meeting/diet consultation <sup>2</sup>	Group meeting/diet consultation	Group meeting/diet consultation <sup>2</sup>	Group meeting/diet consultation	

<sup>1</sup>We will assess your body composition at Auckland City Hospital using a Dual-energy X-ray Absorptiometry (DXA) scanner. We will provide transport to the hospital and return to HNU.

<sup>2</sup>This evening/weekend group meeting will be carried out separately from the morning study visit, which means you will need to attend HNU on 2 separate occasions in both Week 0 and Week 4.

### A. Screening

During your Screening Visit at HNU, we will explain the study in detail and you will have a chance to ask us any questions you may have. If you would like to participate, we will then ask you to sign an Informed Consent Form (ICF) saying that you agree to participate in the study. By signing the ICF, you will be giving permission for the researchers to enrol you in the study and conduct the various measurements described below. We will gather your personal information such as contact details, demographic (age, gender, ethnicity) and anthropometric data (height, weight, waist and hip circumference, and blood pressure). We will also ask you for your GP (family doctor) details and contact them with details of the study, so they know that you will undertake an 8-week weight-loss study. We will also collect a small blood sample to check your

plasma glucose concentration on site to screen for diabetes. You cannot join the study if you have diabetes. You may stop the interview at any time if you are not comfortable answering the questions.

Once you are eligible to participate, we will schedule you to attend the HNU for your morning Study Visits. We will also provide you with a urine bottle to collect your urine sample and a food diary to record the food that you eat over 4 consecutive days (3 weekdays and 1 weekend). You will need to hand in your urine sample and food diary to us during Study Visit 1 (just before the weight-loss diet starts).

### B. Weight-loss diets

Your diet plan will provide you with approximately 40% (i.e. less than half) of your usual energy requirement for a whole day. Eating a diet that is very low in energy (calories) is what will cause you to lose weight. You will be assigned to 1 of the 4 study diets, which each differ in protein and carbohydrate content (Figure 1). Your diet will have either **higher or normal PROTEIN** (examples of high-protein foods are meat, fish and dairy), in combination with either **normal or lower CARBOHYDRATE** (examples of high-carbohydrate foods are bread, pasta and rice). The diet that you are going to receive will be allocated just by chance (you cannot choose, and we cannot choose for you).

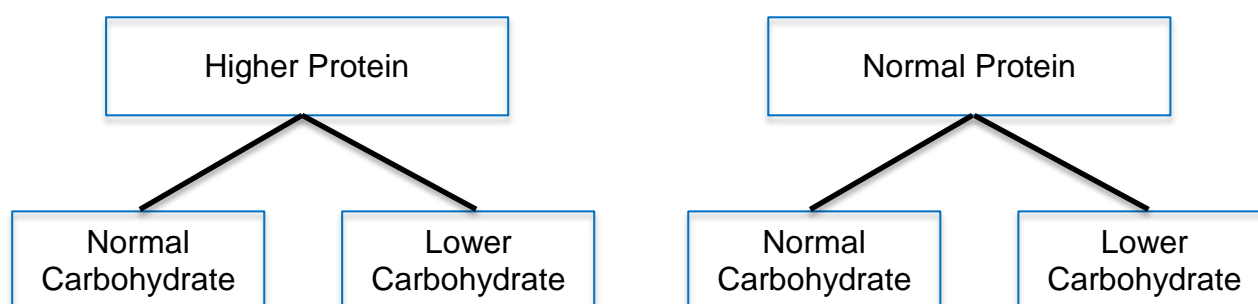


Figure 1. The 4 diets that you may receive, i.e. (i) Higher-Protein Normal-Carbohydrate, (ii) Higher-Protein Lower-Carbohydrate, (iii) Normal-Protein Normal-Carbohydrate, or (iv) Normal-Protein Lower-Carbohydrate.

We will provide you with Cambridge Low Energy Diet (LED) meal replacements (Cambridge Weight Plan™ Ltd) as part of your daily diet at no cost. The LED meal replacements come in the form of either a meal sachet or a bar. Each sachet or bar provides you with an exact serving to replace your regular meal. Therefore, when you consume the meal replacement instead of your regular meal, you consume less energy (calories) than usual, and cause you to lose weight in the longer term. Many health professionals and clinical trials recommend this Cambridge LED meal replacement as it has delivered promising weight loss to many people who have used it. If you stick to the diet for the full 8 weeks you can expect to lose approximately 8% of your body weight. For example, if you weigh 100kg now, then after the 8 weeks diet you can expect to have lost 7-8kg.

For more information about Cambridge LED meal replacements, please visit: <https://www.cambridgeweightplan.co.nz/>.

During the 8-week weight-loss period, we will recommend that you have a total of 4 eating occasions (breakfast, lunch, afternoon tea and dinner) in a day. Your breakfast, lunch and afternoon tea are known as ‘fixed meals’. These are known as ‘fixed meals’ because you must completely consume the meals recommended and nothing else. We will recommend you to consume an oat meal as your daily breakfast. For lunch and afternoon tea, we will recommend you to consume a serving (a sachet or a bar) of the Cambridge LED meal replacements.

In contrast, your dinner is called ‘variable home meal’, which means you will prepare your own meal based on our dietary recommendation. During the ‘variable home meal’, if you feel less hungry, you do not have to finish the meal; if you feel more hungry you can eat a little more. Therefore, if you feel less hungry and able to eat less during the ‘variable home meal’, we expect you may lose more weight. You will have to do your own shopping to buy the food ingredients to prepare your breakfast and dinner.

Table 2. Recommended eating occasions and meal format in a day.

Eating occasions	Meal format	Comment
Breakfast	Fixed – oat meal	You must completely consume one serving.
Lunch	Fixed – meal replacement	
Afternoon Tea	Fixed – meal replacement	
Dinner	Variable – home prepared meal	You prepare your own meal based on our dietary guidelines and have the choice to eat less or more if needed.

You should have 9 glasses of water every day and avoid all energy-containing beverages (e.g. alcohol, sugar-sweetened beverages, tea or coffee with milk & sugar). We will give you a diet plan booklet that consists of the dietary guidelines. This diet plan booklet will show you the types of food and the portion sizes you should consume to achieve your dietary targets (i.e. higher/normal protein and normal/lower carbohydrate).

You will aim to lose weight by following our dietary guidelines without changing your daily levels of physical activity. In other words, **you will achieve your weight-loss through dieting only, and not through an increase in exercise.**

### C. Morning Study Visits

For all study visits, we need you to arrive at HNU after an overnight fast of approximately 10 hours (nothing to eat or drink, except tap water), following the last evening meal.

Study Visit 1 (Week 0) may take approximately 5 hours. You will need to arrive at HNU at 8:00am for a ‘meal challenge’ to assess your appetite (see ‘what is a meal challenge?’ section). You will need to bring your 24-h urine sample and completed food diary along with you to the HNU (see ‘how to collect a 24-h urine sample; how to record your food diary’ section). First, we will give you a glass of water (250mL) to drink upon

your arrival. Then, we will measure your body weight, height, waist-hip circumference and blood pressure. After that, a Research Nurse will collect a small fasting blood sample (10mL) as part of the meal challenge. After the meal challenge, you will complete some simple questionnaires regarding your lifestyle. Then, we will provide you with both verbal and written guidance on how to achieve your dietary targets. Finally, we will invite you to Auckland City Hospital at Grafton to perform a body composition scan using DXA (see “What is a DXA?” section). You will begin your 8-week weight-loss diet immediately after attending Study Visit 1. You will receive another urine bottle and food diary to take home for you to collect your 24-h urine sample and record any food that you eat over 4 consecutive days (3 weekdays and 1 weekend).

Study Visit 2 (Week 4) is a shorter visit, which may take approximately 30 minutes. We need you to arrive at HNU in the morning between 8:00am and 10:00am, and bring along your 24-h urine sample and completed food diary. We will again measure your body weight, height, waist-hip circumference and blood pressure. Then, a Research Nurse will collect a small fasting blood sample (7mL). The purpose of this visit is to record your weight-loss progress and to review your diet diary. You will again receive another urine bottle and food diary to take home for you to collect your 24-h urine sample and record any food that you eat over 4 consecutive days (3 weekdays and 1 weekend).

Study Visit 3 (Week 8) is the last visit, which follows the same schedule as Visit 1. This marks the end of your weight loss diet period.

#### D. Evening/Weekend Group Meetings

The group meetings will be held at HNU at Week 0, Week 2, Week 4 and Week 6. A trained healthcare professional will provide dietary advice to you along with the knowledge you require to overcome any difficulties you face during your weight-loss period. During this meeting, you will have the opportunity to meet with some other participants that follow the same diet as you. Each group meeting will last one to two hours.

Additionally, between each visit at HNU, you are free to contact us if you face any difficulties in adhering to the diet.

#### **What is a meal challenge?**

A meal challenge is a method that we use to assess your appetite – how hungry and how full you feel. You will eat a standardised breakfast meal at HNU, and then we will assess your appetite using a series of questionnaires about your hunger over the next 3.5 hours. There will be a meal challenge during Study Visit 1 (Week 0, baseline) and Study Visit 3 (Week 8, end of study). Everybody must eat the breakfast meal and (A) complete the questionnaires but you may also choose to take part in (B) collection of blood samples throughout the morning, You will be compensated if you choose (B) collection of blood samples.

## A. Questionnaires

At the beginning of the meal challenge, we will ask you to complete a questionnaire that asks your subjective feeling of appetite (e.g. How hungry you do you feel?) using a Visual Analog Scale (VAS). You mark a vertical line on the 100mm scale that best represents how you feel. There is no correct or incorrect answer, it is just your personal opinion.

An example of the questionnaire is shown below:

The diagram shows a horizontal line representing a 100mm scale. Above the line, the text reads "100mm line". Below the line, on the left side, is the text "I am not hungry at all". On the right side, is the text "I am as hungry as I've ever been". The entire scale is enclosed in a rectangular box with a grey background. At the top of the box, the text reads "VAS: subjective rating = no correct or incorrect answer".

At the same time, a Research Nurse will collect a small blood sample (10mL).

At 9:00am, we will present you with a standardised breakfast (the Cambridge LED soup along with peanut butter toast and egg). You will have 15 minutes to finish the meal completely. To avoid any distraction, you will consume the meal in an individual dining booth and cannot bring anything with you (e.g. laptops, tablets, smart phones) into the booth. You will also be required to complete a questionnaire that asks the palatability of the breakfast meal (e.g. How pleasant was the meal?) using VAS.

After you finish the breakfast meal, you will then complete VAS questionnaires throughout the morning. We will provide you with a glass of water (250mL) at 11:05am. You cannot consume any other food or drinks (including water). The meal challenge will be completed at 12:30pm.

## B. Repeated blood samples

Since we are interested in blood markers that may control your hunger and fullness, we would like to collect blood samples throughout the morning for a sub-set of our participants. In addition to the VAS questionnaires, we will also take a small blood sample at the same time as the appetite questionnaires (see Table 2). To do this, a Research Nurse will insert a cannula (small plastic tube) into your forearm vein before the collection of your fasting blood sample. This is to enable blood collection throughout the meal challenge session, yet you will only feel the needle prick just once. Cannulas are often used in hospitals, and once inserted do not usually cause more than a little discomfort. We will collect 7mL of blood at each time point. As a result, we will collect a total of 66mL blood on each of the 2 meal challenge days. This additional procedure is

important for us to know how your blood biomarkers (e.g. the ‘satiety hormones’) change with your feelings of appetite.

Table 2: Summary of meal challenge procedure. Everybody must complete (A) Questionnaires, but you may also choose to take part in (B) collection of Repeated Blood Samples in addition to completing (A) Questionnaires.

Time	(A) Questionnaires	(B) Repeated Blood Samples
0830h		Cannulation – insert small blood collection tube into forearm
0850h	Appetite questionnaire Fasting blood sample (10mL)	
0900h	Breakfast meal – LED sachet Palatability questionnaire	
0915h	Appetite questionnaire	Blood sample (7mL)
0930h	Appetite questionnaire	Blood sample (7mL)
1000h	Appetite questionnaire	Blood sample (7mL)
1030h	Appetite questionnaire	Blood sample (7mL)
1100h	Appetite questionnaire	Blood sample (7mL)
1105h	250mL water to drink	
1130h	Appetite questionnaire	Blood sample (7mL)
1200h	Appetite questionnaire	Blood sample (7mL)
1230h	Appetite questionnaire	Blood sample (7mL), cannula removal

### What will my blood samples be collected for?

Your fasting blood samples will be tested for biomarkers of metabolic health, including Hb<sub>A1c</sub>, glucose, lipids, insulin and liver function, etc. We will also measure appetite-related biomarkers, such as amino acids and gut peptides (sometimes referred to as the ‘satiety hormones’). The additional blood collected during the meal challenge will be tested for appetite-related biomarkers. **If we find any abnormal results from your blood tests, we will issue you a letter for you to give it to your GP for follow-up testing.**

As this study is part of a long PhD program we may store the blood samples for up to 4 years. Samples will only be stored in NZ and used for the purpose of this research. Any leftover samples will be destroyed following standard methods according to University policy (all biological waste is placed in yellow biohazard bags and is disposed of by incineration by a commercial company, Interwaste).

We may send some of your blood samples to The University of Adelaide, Australia to analyse for appetite-related biomarkers. All analysis results generated from The University of Adelaide will be contributed to this study only. The University of Adelaide will not withhold any information or data generated from this study. Leftover blood



samples at The University of Adelaide will be destroyed following the standard methods according to the university policy.

If you would like to perform a karakia (blessing) at the time of blood collection, you are encouraged to do so. Once your blood has been collected, it will be sent for storage and then analysed as a group with all other participants. Any remaining samples will be destroyed at the end of the study. If you would like to request a specific tikanga (Māori custom) process, please feel free to talk with the research team.

You may hold beliefs about a sacred and shared value of any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose. You may also to talk to our Faculty of Science kaiārahi (Mr Michael Steedman) if you wish to.

**How to collect a 24-hour urine sample?**

Your urine samples will be collected to analyse 24-hour urine nitrogen content, which is a way to estimate your daily dietary protein intake.

When you wake up in the morning of the day of urine collection, you flush away your first urine into the toilet as you would normally do. Please record the time (e.g. 7am) when you flush your first urine in the morning because this marks the start time of the 24-hour period. Then, collect all your subsequent urine into urine bottles that we provide until the following morning. It is very important for you to collect **all urine for a whole day and night (i.e. 24 hours)**. It is best to store your samples in a cool place if you can, e.g. cool garage, to keep the samples fresh and to prevent bacteria growth. On the following morning, collect your last urine at about the same time when you started the previous day (e.g. 7am), this will mark the end time of your 24-hour period (Figure 2).

Flush away the 1 <sup>st</sup> urine of the day (7am)	Collect <u>all</u> urine <u>all</u> day	And overnight	And 1 <sup>st</sup> urine next morning (7am)
			

Figure 2. Summary of 24-hour urine collection.

### **How to record your food diary?**

You have to record everything that you eat and drink (all your meals and snacks) over 4 consecutive days, which must include 3 weekdays and 1 weekend. In other words, you will record your food diary either from Wednesday to Saturday or from Sunday to Wednesday.

You are encouraged to weigh all the food and drinks using an electronic scale (if you have one at home), otherwise you will record the amount of food that you eat using common household measures, such as a teaspoon, a tablespoon, a fist, a palm, etc. You must record the food as you eat it, do not wait until later as you may forget some important details. If there are any leftovers, please do record that in the diary too. We need you to give us detailed information regarding the foods/drinks, including the brand name (e.g. Heinz Watties, Anchor) , cooking method (e.g. steamed, baked, fried), packaging (e.g. fresh, frozen, tinned), and if there is anything added to the food (e.g. type of condiment, sugar, salt). You will be taught to keep a good food diary during the first group meeting session before you start your diet.

### **What is Dual-energy X-ray Absorptiometry (DXA)?**

DXA is a scanning method used to measure body composition (bone, fat, muscle). Many older people have a DXA scan at the hospital when checking their bone health. The scan takes about 10 minutes and is not unpleasant. You will need to lie quietly, without moving, on an open bed and a scanning arm passes quickly over the top of you. As the scanning arm passes over you it emits 2 types of very low dose X-ray, similar to the radiation dose that you would receive if you take a 1-hour flight – perhaps between Auckland and Wellington. The DXA then measures the density of the different tissues in your body. Bone is very dense so it appears bright white on the scan. Muscle is less dense and so it is less white, and fat even less dense and so it is the least white of all. At the end of the 10-minute scan, we will print a copy of your results showing an image of the bones, fat and lean tissues in your body for you to take home. (Please note that this is not a medical diagnostic scan, but you are very welcome to take this to show your family doctor and discuss the findings when you next visit them).

### **The risks and benefits of the research**

There are no significant risks associated with taking part in this research. Some people may be concerned about the 'high-protein diet' in regards to liver and kidney health. However, the higher-protein weight-loss diet in this study is only high in terms of percentage of total energy, but not higher than the upper level recommended by the Australian and New Zealand Nutrient Reference Values (NRV) in terms of grams. You will find that you may not have to increase protein intake by a large amount as compared to your usual diet in order to reach our target protein intake. However, it is very important to let us know if you have any liver or kidney problems, along with other medical records, as these are exclusions for the study. Healthy individuals will be able to consume the higher-protein weight-loss diet without adverse side effect.

You may feel headaches, dizziness, constipation or stomach cramps, tiredness and bloating in the first few days of your weight-loss diet. This is because you consume less

energy (calories) than your body would normally require. It is also a very low fibre diet. Please do talk to us if you experience any of these symptoms or you experience any other discomfort, so that our study clinician can review your symptoms and provide you with professional advice.

The dose of X-ray involved in the DXA scan is similar to the radiation exposure on a flight from Auckland to Wellington. Therefore the exposure represents a very low risk. However, it is very important to inform us if you have any metal implants such as cardiac pacemakers.

Some individuals may experience discomfort during insertion of the cannulation for collection of blood samples through the morning during the Meal Challenge. Research staff will monitor you during the procedure. 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 any condition arises during the study visits.

The benefits of this study are that you will be joining a weight loss program which (if you follow the diet instructions) will lead to weight loss, and also that you will receive all dietary LED products free of charge. You will get to know your weight, BMI, blood pressure and DXA scan at your study visits. At the end of the study, you will receive a copy of your personal results from blood tests as well as your appetite response. In the latter, we will explain to you whether your metabolic health has improved and whether your appetite has changed after the diet. It is important to understand that there may be a delay in receiving your results, as we must wait until all participants have completed the study, and the blood samples have all been analysed. You will not have continued access to the LED meal replacements and dietary consultation via the study. However, these commercial meal replacements are available to be purchased in the market place if you do wish to continue the diet yourself. We recommend that you talk with your family doctor if you do decide to continue with the diet on your own.

We expect that everybody who follows the diet will be able to lose some weight as shown by many previous studies, either conducted at HNU previously or internationally. We expect the weight loss will improve your metabolic risk biomarkers, such as the reduction of your blood glucose level which in turn may reduce your later risk of developing diabetes.

### **Dissemination of information**

All data generated from this study will eventually be published on scientific peer-reviewed journal and presented in scientific conferences. Other than that, we may also contribute our study outcomes to the Whānau Ora programmes through our Faculty of Science kaiārahi (Mr Michael Steedman).

### **Compensation**

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.

### **Confidentiality**

All data will be de-identified using a unique study ID. Research files and all other information that you provide will remain strictly confidential. No material that could personally identify you will be used in any reports on this research. Upon completion of the research, your records will be stored for **10 years** at HNU. All computer records will be password protected.

### **Trial Payments**

You will receive a \$20 voucher after the completion of Screening Visit to cover travel expenses. You will also receive a \$20 voucher after the completion of each Study Visit as travel expenses. Therefore, you will be compensated a total of \$80 for the entire study (1 Screening Visit and 3 Study Visits). If you consent and are selected to complete the additional procedure (repeated blood sampling) for the appetite study you will receive an additional \$50 voucher at the end of the 8-week study.

### **Finally**

Thank you for considering taking part in this study.

For more information, please contact:

#### **Jia Jiet Lim, BSc (Hons)**

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This research has received Ethical Approval from The Auckland Northern A Health and Disabilities Ethics Committee (HDEC); ref:

### **The principal investigators of the research are:**

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**The supervising dietitian for this study is:**

**Amy Liu, MSc**

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Practice Supervisor Diabetes Dietitian and Community Adults,  
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**The consulting physician for this study is:**

**Dr Manish Khanolkar, MBChB**

Diabetes Consultant  
Auckland District Health Board.

Department of Medicine,  
University of Auckland.  
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***Please keep this information sheet for your records.***

## Higher-protein vs lower-carbohydrate diets for weight loss.

### CONSENT FORM

I have read and I understand the Patient Information Sheet dated 5<sup>th</sup> February 2019 and wish to take part in the research entitled “**Higher-protein vs lower-carbohydrate energy-restricted diets: effects on eating behaviour, weight loss and body composition**”.

I have had the opportunity to discuss this research with the investigator. I am satisfied with the answers I have been given.

1. I have had the opportunity to use support from a family (whanau) member or a friend to help me ask questions and understand the research.
2. I understand that taking part in this research is voluntary (my choice), and that I may withdraw from the research at any time and this will in no way affect my future or continuing health care.
3. I understand that my participation in this research is confidential and that no material which could identify me will be used in any reports on this research. I understand that the sponsor of the research, others working on the sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current research and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.
4. I agree for my blood samples to be processed and analysed for appetite-related biomarkers at The University of Adelaide, Australia.
5. I understand that if I consent to such analysis, no rights will be created for the researcher to get my genetic information.
6. I understand that the treatment, or investigation, will be stopped if it should appear harmful to myself.
7. I understand the compensation provisions for this research.
8. I have had time to consider whether to take part.
9. I know whom to contact if I have any side effects from the research.
10. I know whom to contact if I have any questions about the research.
11. I agree not to restrict the use of any data or results that arise from this research provided such a use is only for scientific purposes.

<b>Participant to complete:</b> Please circle as appropriate			Participant Signature:
I consent to participate in this study.	Yes	No	
I consent to having blood samples sent to The University of Adelaide, Australia for the analysis of appetite-related biomarkers.	Yes	No	
I consent to having a DXA scan.	Yes	No	
I consent to participate in the Meal Challenge, with cannulation and repeated blood sampling.	Yes	No	

I wish to receive a copy of the results, when published. I understand that there may be a delay between data collection and the publication of the research results.	Yes	No	
I consent for the research staff at HNU to contact my GP.	Yes	No	
I consent for research staff at HNU to contact me later if there are future studies for which I am eligible.	Yes	No	

**INFORMED CONSENT FORM**

***Participant to complete:***

I \_\_\_\_\_ Print full name

of \_\_\_\_\_ Print address

\_\_\_\_\_

\_\_\_\_\_

hereby consent to take part in this research which is designed to investigate the effect of protein vs carbohydrate on weight-loss.

\_\_\_\_\_ Signature of Participant

\_\_\_\_\_ Date

***Research Personnel to complete:***

\_\_\_\_\_ Project explained by

(on behalf of the Principal Investigator)

\_\_\_\_\_ Signature

\_\_\_\_\_ Project Role

\_\_\_\_\_ Date

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