**NEW ZEALAND DIETS FOR DIABETES PREVENTION**

**(SYNERGY STUDY): a residential nutrition intervention**

**PARTICIPANT INFORMATION SHEET**

You are invited to take part in the NEW ZEALAND DIETS FOR DIABETES PREVENTION (NZ SYNERGY STUDY) Study in the Peak Nutrition for Metabolic Health (PANaMAH) Platform, within the National Science Challenge High Value Nutrition (NSC-HVN) Programme. Whether or not you take part is your choice. If you do not want to take part, you do not 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.

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 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 and also another Consent Form to ask if you agree for us to store your samples for future unspecified use within the (NSC-HVN) Program. You will be given a copy of both the Participant Information Sheet and the Consent Forms to keep.

This document is 15 pages long, including the Consent Form. **Please make sure you have read and understood all of the pages.**

This is a**2-week nutrition study where you will live at the University of Auckland Human Nutrition Unit in Mt Eden (*you may attend daily work or classes at University and can undertake light exercise*). Every day you will be provided with ALL your meals and snacks.**This study will investigate whether the foods that you eat (your diet) alter circulating blood markers that we have recently found to be associated with risk of type 2 diabetes.

**Who can take part?**

Any man or woman in the Auckland area, who:

• is Asian Chinese, with both mother and father of Asian Chinese origin (including mainland China, Singapore, Malaysia, Hong Kong, Taiwan and Korea)

• or European Caucasian, with both mother and father of Caucasian origin

• between 18-60 years

• is overweight (BMI 24-40 kg/m2)

• is at increased risk of diabetes, based on a blood glucose test

• is happy to participate in a 2 week residential study

• is happy to eat a wide range of foods (you cannot be vegetarian or vegan)

**We would like to enrol 30 people into our study: 20 Asian Chinese, 10 European Caucasian**

**IMPORTANT: You cannot be in the study if you have ALREADY been diagnosed with diabetes.**

**Who designed the study**

This study was designed by the research staff at the Human Nutrition Unit, University of Auckland, AgResearch Metabolomics Unit, the Malaghan Institute of Medical Research Immunology Group and the Plant and Food Research Consumer Insights Group, as part of the New Zealand National Science Challenge – High Value Nutrition (NSC-HVN) Programme, funded by the New Zealand Ministry of Business, Innovation and Enterprise (MBIE).

**What is the purpose of the study?**

Researchers from the NSC-HVN Programme aim to identify blood, urine and faecal markers of type 2 diabetes (T2D) risk that differ between ethnicities; and also to undertake nutritional interventions that target these biomarkers.

Our previous HVN study showed that Asian Chinese men and women had worse blood glucose (blood sugar) and lipids (blood fats) when they were still younger and outwardly-leaner than their matched European Caucasian counterparts. *We also discovered some novel (new) blood biomarkers of diabetes risk, using a method called ‘metabolomics’. These markers were completely different between the 2 ethnicities. The Asian Chinese group had a unique ‘fingerprint’ of markers.*

The reason for this difference is not known, and so in this current study we will try to find out what causes the difference. One possibility is that the markers are not due to different genetics of the 2 groups, but are a result of a completely different home diet. The foods that you eat have been shown to appear in the ‘metabolomics’ blood sample.

Therefore, we will test whether differences in the novel ‘metabolomics’ blood markers are completely due to diet and also assess whether diet with additional nutrients may together (synergistically) be beneficial in changing the profile of these novel blood markers.

In order to do so we will design two healthy diets based on the New Zealand and the Chinese dietary guidelines for improving metabolic health. The two diet arms will be:

1. HEALTHY DIET (‘control’ diet): which adheres to NZ and Chinese national dietary guidelines for good metabolic health
2. HEALTHY DIET + added nutrients\*\* (‘Synergy’ diet): which adheres to NZ and Chinese national dietary guidelines for good metabolic health and includes some additional nutrients hypothesised to have further improve metabolic health.

\*\* Examples are whole foods such as omega-3 rich fish, more fibre, nuts and seeds, meat with less saturated fats. Please note both diets are **healthy** and **matched with each other for energy content, so that you maintain your body weight throughout the two-week study**. *Both diet arms are known to be healthy diets.*

All Caucasian participants will be enrolled in the Healthy ‘control’ diet arm while the Chinese participants will be allocated by chance to either the Healthy ‘control’ diet or the Healthy Synergy diet arms (diagram below), so that we can test the response and differences in the diabetes biomarker profile.

**Assess the benefit of added nutrients on novel markers**

**Healthy diet**: Asian Chinese (10 participants)

**(Control Diet)**

**Assess differences in response of novel markers between ethnicity**

**Healthy diet + nutrients:** Asian Chinese (10 participants)

**(NZ Synergy Diet)**

**Healthy diet**: Caucasian European (10 participants)

**(Control Diet)**

* 2 week intervention, residential intervention, full diet control
* *Both diet arms are known to be healthy diets and optimise positive effects on metabolic health*

For this study we ask participants to be resident at the Human Nutrition Unit study facility in Mt Eden, Auckland. The study team will cook all of your food (and drinks). Only the foods from HNU can be consumed during the 2 weeks. You must not eat other foods or these will appear in the metabolomics blood sample, and affect results. Your compliance to the diet will be therefore also be determined during the study.

It is possible that differences in ‘metabolomics’ blood markers can be caused by differences in your body composition – how much muscle, fat, bone you have - so at the beginning of the study we will also ask you to have 2 body scans at Auckland Hospital.

**What are the aims of the study?**

We aim to:

1. **measure body composition** at baseline (before the study starts) using dual x-ray absorptiometry (DeXA) and magnetic resonance imaging (MRI).
* DeXA tells us how much fat and muscle is in the body
* MRI tells us whether any of this fat is in the liver and pancreas (high organ fat often means high risk of diabetes)
1. **measure common clinical markers of diabetes risk**, e.g. glucose and insulin, immune markers and **also novel ‘metabolomics’ markers of diabetes risk** at baseline (before the study starts)
2. then **measure how the blood clinical, immune and ‘metabolomics’ markers change during the 2-week study**, where diet is carefully controlled:
* between the Caucasian (n=10) and Asian Chinese (n=10) to determine the differential ethnic specific change in these markers
* and also between the Asian Chinese (n=20) to determine any benefit of added nutrients to the healthy diet

**What happens if I decide to take part?**

If you are interested in being a study participant, a member of the research team from the Human Nutrition Unit will speak to you over the telephone or by email to ask you some questions about your age, height, bodyweight as well as about your family and medical history. The questionnaire is important to understand whether you might be eligible for the study.

After assessing this questionnaire and if you appear to be eligible for the study, researchers will invite you to come to the Human Nutrition Unit in Mt Eden for a morning screening visit. The visit will take approximately 4 hours. During the screening visit we will talk to you, explaining the study in more detail and you will have the opportunity to ask questions. 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 do agree to be a participant in the study. This is called an ‘informed consent form’ or ICF – by signing it, you consent to take part in the study. Please note that you may always withdraw from the study at any time. We will also respectfully ask that you agree to NOT upload any photographs, messages, opinions etc. from the study (including the study diets) onto any social media platform which in any way refers to or reflects your participation in this study. Maintaining this confidentiality is very important. We ask this because we have other participants joining the study after you and we want to avoid biasing their response to the intervention in any way. Introducing any bias may undermine our research programme. Your written agreement to maintaining this confidentiality is very much appreciated.

If you would like to take part we will then carry out a clinical assessment of your health, which is very similar to a visit your family doctor/general practitioner (GP). We will ask you again about your medical and medication history, and we will ask some other personal questions (e.g. about where you live and what is your job, if you have one). We will request you to bring any GP prescriptions you may have or any other information that is important so that we can record your health information accurately. Were you to be unsure of these details then please do let us know as once you have provided written consent for us to contact your GP we could confirm the information you have provided with them. We will also do some body measurements (height, body weight, body mass index/BMI, waist & hip circumference, blood pressure). You do not have to answer all of the questions and you may stop the interview and measurements at any time.

During your screening assessment we will take a blood sample to check your blood glucose (sugar) levels to assess how likely you are to have a high risk of diabetes. If you have had a diabetes blood test anytime in the previous 4 weeks, and have been shown to be at high risk of diabetes, we will be happy to repeat this to confirm whether you can be enrolled.

**What happens once I am enrolled into the study?**

If you are eligible for the study we will give you an ID number, which will be used throughout the study to keep all of your personal and medical details confidential (de-identified). We will use this ID throughout the study and the samples you will provide during the study will only contain this de-identified number. When the data is collated for presentation at Conferences, or publication in an International Journal your data will not be able to be identified.

We will then arrange with you the dates for your study, and plan your diet. The amount of food that we prepare for you every day will be individualised to your height, weight, body composition and age. All participants in the same diet group will consume the same meals (foods that appeal to both Asian and Caucasian participants) but in different quantities (e.g. small, medium or large portions). This is not a weight loss study, so we will ensure that your body weight does not change whilst you are following this controlled diet. You cannot be vegetarian and vegan and participate in this study.

**Diet Group**

If you are Caucasian you will be in the Healthy Diet (Control Diet) and if you are Chinese you will be allocated to either (i) a Healthy Diet (Control Diet) or (ii) a Healthy + added Nutrients Diet (Synergy Diet). You will not be told which diet you have been allocated to until the end of the study. Both diets are known to be healthy diets and both follow all New Zealand Ministry of Health and Chinese National guidelines. We hypothesise that both will improve your diabetes risk over the 2 week study, however the Synergy Diet MAY show a bigger improvement.

**Baseline measures**: In the week before you begin the 2 weeks living at HNU we will conduct some baseline measurements, including a simple questionnaire that uses a visual analogue scale to measure your mood, and body scans.

Mood Questionnaire: At the beginning, also mid way (Day 7) and end of the study (morning of Day 15), we will ask you to complete a quick questionnaire that asks your subjective feelings using a Visual Analog Scale (VAS) e.g. Please indicate how alert or drowsy you feel at this time? 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. This will take no longer than 5-10 minutes of your time.

An example from the questionnaire is shown below:

*Please indicate how you feel at this time by placing a mark on each line below:*

****

We will measure your body composition (how much muscle and fat that you have) using a body scanner DeXA machine which is located at the Clinical Research Centre, University of Auckland (please see the section below for the full description of the measurement. It takes about 15 mins for the scan).

We will also measure how much ‘risky’ fat you have stored in your body. Storing a lot of fat around your stomach (‘belly’ fat) or inside important organs can increase your risk of diabetes. We don’t yet understand why some people store fat in these risky sites and yet other people don’t. We will measure the fat in your abdomen (stomach area), in your liver and in your pancreas; using a Magnetic Resonance Imaging (MRI) scanner which is also located at Auckland City Hospital (please see the section below for the full description of the measurement. It takes about 30 to 45 mins for the scan).

**Also at the start and end of the study:** you will also under go the following assessments:

Firstly we will measure your basal metabolic rate (BMR) using ***Indirect Calorimetry*** which willtake *approx. half an hour* to complete. BMR is also called resting metabolic rate (RMR) and is the minimum amount of energy needed to keep your body functioning. For example breathing and heart beat. This will be conducted non-invasively using an open-circuit ventilated hood/canopy system (Quark, Cosmed srl, Rome, Italy). We will ask you to sit in a comfortable chair to which a canopy is attached (like in the image), with fresh air coming into the canopy through the opening at the top. We will measure the amount of oxygen you consume and the amount of carbon dioxide you produce in your breath to calculate your metabolic rate. Also usual measurements of blood pressure and heart rate will be recorded. This is a relatively easy process however during all of the measurements it is important that you relax and avoid large movements, but if you need to readjust your position, use the bathroom, or you need to itch or scratch in order to be more comfortable, of course you may do so. The same procedure will also be applied after you consume the standardised glucose drink, described next, but this will be a longer assessment over 2 hours.

Secondly, we will remove the canopy and carry out an ***‘Oral Glucose Tolerance Test’*** (OGTT), where we ask you to drink a sugary drink and have some more blood tests. This is a test that is generally carried out by your family doctor for anyone who is thought to be at risk of diabetes. The test takes 2 hours, and you must be fasted (no breakfast on the day of the test). To summarise the test: (i) we will take a small (5mL) blood sample from a vein in your arm, then (ii) we ask you to drink a sugary drink, and finally (iii) 1 hour and then 2 hours later we will take 2 more small blood samples from you. This blood test will measure what happens to your blood glucose (sugar) levels when you consume a high sugar food item (= sugary drink). Whilst you are relaxing in the chair during the OGTT, we will continue with the Indirect Calorimetry measurements under the canopy. Although you cannot use your phone or a laptop during this measurement (as we need to you to relax, and stay quite still – although don’t fall asleep!) we will set up an Ipad for you to watch some films or TV series, so that you are not too bored during the measurement.

**What will I do while living at the Human Nutrition Unit?**

Once baseline measures are completed we will then invite you to stay at the Human Nutrition Unit in Mt Eden for 2 weeks. We ask that you arrive the day before (in the evening) so that you are relaxed, have a good nights rest and can start early the next morning at 6.30am with the measurements followed by the breakfast meal at 10am. We will collect a small blood sample the day you arrive at HNU. Each participant has a small study/bedroom of their own where they are free to relax during the day. Each day will be spent either going to (i) work or classes at University or (ii) quietly at the Unit, either within the building or if you choose you may spend some time in the garden. It is very important for the study that you are happy to follow the diet that we provide, and eat all of the meals. You will eat all of your meals in the HNU communal dining room. We will ask you **not to bring any other food into the Unit** with you – this is a very important rule. This is not a weight loss study, so your meals and snacks will be enough to make sure your weight doesn’t change during the 2 week study.

We will ask you to get up in the morning at around 6.30am (*except on first and last day of the study, due to measurements*), and to go to bed at around 10pm.

*Below is a Table to show you what the typical first day (ONLY) of your stay at HNU will involve:*

|  |  |  |
| --- | --- | --- |
| **Day** | **Time** | **Example Protocol of Day -1 (day before study begins) and Day 1 (start of study)** |
| **-1** | **Arrival at HNU** |  **faecal sample, diet questionnaire + blood sample collection + mood questionnaire** |
| **1**  | **6:30 am** | bodyweight, spot urine sample; cannulation + baseline blood sample (time = - 60minutes) |
|  | **6:45 am** | body temperature & blood pressure, start indirect calorimetry (30 min BMR, fasted) |
|  | **7:30 am** | indirect calorimetry stopped (canopy removed), body temperature & blood pressure |
|  | **7:40 am** | Collect baseline blood sample (time-5) |
|  | **7:42 -7.45am** | Consume 75g OGTT glucose drink, time = 0 minutes, 2-h OGTT indirect calorimetry (re-start) |
|  | **8-9.30 am** | blood sample every 15 minutes, time = 15 minutes to time = 90 minutes |
|  | **9.45am** | final blood sample time = 120 minutes, cannula removed, indirect calorimetry stopped (canopy removed), body temperature & blood pressure |
|  | **10.00am** | Breakfast |
|  | **1.00 pm** | Lunch |
|  | **3-4.00 pm** | Mid-afternoon snacks |
|  | **6.30 pm** | Dinner |
|  | **10.00 pm** | Bedtime |

Your diet will be fully monitored during your 2 week stay at HNU. On Day 2 until Day 14 you will be provided with breakfast at 7.00am, mid-morning snack at 10am, lunch at 1pm, mid-afternoon snack at 4pm and dinner at 7pm.

*On the morning of Day 15 you will end the study. Below is a Table to show you what the typical last day of your stay at HNU will involve:*

|  |  |  |
| --- | --- | --- |
| **Day** | **Time** | **Example Protocol of Day -1 (day before study begins) and Day 1 (start of study)** |
| **15** | **6:30 am** | bodyweight, spot urine sample; cannulation + baseline blood sample (time = - 60minutes) |
|  | **6:45 am** | body temperature & blood pressure, start indirect calorimetry (30 min BMR, fasted) |
|  | **7:30 am** | indirect calorimetry stopped (canopy removed), body temperature & blood pressure |
|  | **7:40 am** | Collect baseline blood sample (time-5) |
|  | **7:42 -7.45am** | Consume 75g OGTT glucose drink, time = 0 minutes, 2-h OGTT indirect calorimetry (re-start) |
|  | **8-9.30 am** | blood sample every 15 minutes, time = 15 minutes to time = 90 minutes |
|  | **9.45am** | final blood sample time = 120 minutes, cannula removed, indirect calorimetry stopped (canopy removed), body temperature & blood pressure |
|  | **10.00am** | Breakfast |
|  |  | END OF STUDY  |

You are welcome to bring any personal items with you that you would like to. Many people bring laptop computers or tablets, which you can connect to the free Wi-Fi broadband at HNU. If you have work to do there will be lots of time to sit quietly and do that. You can go for a walk around the suburb of Mt Eden, perhaps even (gently) climb the Maungawhau volcano if you would like to! It is very close by. Eden Park is also very close to HNU if you want to visit. We do however ask that you do not undertake any vigorous exercise during the 2 weeks of the study (e.g. power walking, running, cycling). Additionally, were you to have visitors (family, friends) at the HNU during the 2-week residential study we ask that they do not bring any food along with them.

While we ask that you eat your breakfast and dinner at HNU, under the supervision of the research team. If you attend work or University during the day, whilst you may go about your daily work habits please do refrain from social events that are related to foods (e.g. going out for a coffee, catching up at a café etc.) outside of HNU. We will pack up your lunch & afternoon snacks for you to take with you on those days, but of course ask that you eat no other foods whilst away from the Unit. Your compliance to the diet and adherence to the study protocol will be monitored from the analyses of a 24 hour urine sample that we will be collecting from you during the 2-week study.

Also, during your stay, a survey and an interview will be conducted by Research Staff from Plant and Food Research, so that we may understand your thoughts about food and your health, as well as your thoughts on this clinical trial. This will help provide information regarding formulation and feasibility of diets designed for prevention of type 2 diabetes. The survey will be administered in the form of an anonymous questionnaire consisting of 6 open-ended questions, during the study. The interview will be conducted with fellow participants resident at HNU as a Focus Group interview, in the HNU dining room or lounge. Participation is entirely voluntary and you may choose to take part in either the survey or the focus group interview, or both. The Focus Group will last approximately one hour, conducted on a single day (e.g. mid stay, Day 7) and will be audio recorded by the Researcher and later transcribed. If you agree to participate in the survey and/or the Focus Group you do not have to answer any question you are uncomfortable answering or contribute to any discussion you do not wish to. Once you complete the survey you can seal it in an anonymous envelope and hand it over to the researchers at any time. Please be assured that all names or other identifying information will be removed and the data will be de-identified and only be used for research purposes. Your individual thoughts will not be reported, just collective one’s, and only after the trial has finished. No names will be associated with anything reported.

**What will my diet be?**

You will be allocated to either of the healthy diet arms: the control heathy diet arm or the synergy heathy diet arm (with added nutrient). To help conduct the study according to best clinical practice guidelines, you will be not be told which of the diet arms you are allocated to. We will provide you with all of your foods, both meals and snacks. The menu will be a 5-day rotating diet, which means that you will have different meals every day for 5 days, and then this will be repeated for the next 5 days and then again until the end of the study. The diet will include animal and plant products, so you cannot be vegetarian or vegan for this study. Every day three meals will be served (breakfast, lunch, dinner) and two snacks (mid-morning, mid-afternoon), plus tea. As the amount of food that we prepare for you every day is individualised to your height, weight, body composition and age; we will ask you to eat all food items from every meal and snack every day; and not to eat any other foods. No outside foods are allowed at the Human Nutrition Unit.

***5 day rotating diet***: The diet will comprise a 5 day rotating menu, which will repeat throughout the 14 days study:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Monday  | Tuesday | Weds | Thurs | Friday | Sat | Sun |
| Week 1 | Menu 1 | Menu 2 | Menu 3 | Menu 4 | Menu 5 | Menu 1 | Menu 2 |
| Week 2 | Menu 3 | Menu 4 | Menu 5 | Menu 1 | Menu 2 | Menu 3 | Menu 4 |

**What blood and urine tests will I have?**

You will have a blood test at your screening visit to confirm that you are at high risk of type 2 diabetes and to assess your blood iron status; and then also an oral glucose tolerance test (OGTT) during the Baseline phase just before you start the 2 week intervention. You cannot take part in the study if any of these tests show you to either have normal healthy glucose levels or to have diabetes; and/or have low serum iron and ferritin levels.

During the 2 week residential study you will have a blood sample collected from your vein on 5 occasions. The samples will be collected in the early morning when you are fasted (before breakfast) on Day 1, Day 2, Day 7, Day 14 and Day 15. In addition, we will collect a small blood sample on the Day -1 (day before, when you come to HNU). The samples will be collected by our research team at the HNU under the supervision of our Research Nurse. We will also ask you to collect a urine sample on these 5 mornings (except Day -1).

**What measurements will I have?**

* **Height,** measured at the Human Nutrition Unit at baseline (before the start of the study).
* **Bodyweight**, measured at the Human Nutrition Unit every morning during the 2 week study. This will let us check that you are not losing (or gaining) and body weight during the study.
* **Waist and hip circumference**, measured using a simple plastic measuring tape.
* **30 minute basal metabolic rate and metabolic rate during the 2-h OGTT**, measured using Indirect Calorimetry at the Human Nutrition Unit, at the start and again at the end of the study.
* **Body composition using Dual X-ray Absorptiometry (DeXA),** measured at Auckland City Hospital. DeXA is a scanning method, to measure quantity of bone, fat and muscle in the body. The scan takes about 10 minutes. You lie quietly on an open bed and a scanning arm passes quickly over the top of you. You have to lie quietly without moving, but it is not an unpleasant measurement. 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 took a short flight – perhaps between Auckland and Wellington. The DeXA 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 picture of you showing an image of the bone, fat and lean tissue in your body for you to take away with you.
* **Magnetic Resonance Imaging (MRI),** measured at the Centre for Advanced MRI(CAMRI), Auckland Medical School, Grafton Campus. MRI is a body scanning method that has been used in hospitals worldwide for many years. It uses a magnetic field and radio frequency pulse to obtain detailed images of your organs. It does not involve radiation. It will scan your abdomen (stomach area) and identify if any fat has been stored in your liver or pancreas. You will be asked to lie down in a relaxed state, without movement if possible, within the chamber of the machine whilst it scans your abdomen and legs. **The scan will take around 30 to 45 minutes and it will be done only on ONE occasion at the beginning of the study**. Some people may feel a little claustrophobic while having an MRI. Please let us know if this is the case for you.
* **Blood pressure and heart rate,** measured at the Human Nutrition Unit using an automated machine, whilst you are sitting quietly in a chair
* **Fasting blood samples** (no more than 50ml of blood, which is 10x less than you would give if you were a blood donor) - to measure factors in your blood that are related to diabetes and heart disease; including glucose, insulin, HbA1c, lipids, CRP, liver enzymes, markers of inflammation, cytokines, immune cells, peptides and also novel metabolomic markers.
* **A sample of blood might also be collected for genetic** (DNA, SNPs and miRNA) analysis of your risk of diabetes (no other genetic tests) – only if you agree to it. We will not assess genetic diseases or any information on heritage. We are only interested in your risk of diabetes.
* **Oral Glucose Tolerance Test (OGTT)** – 2hr test following a sugary drink.
* **Microbiome, faecal sample** – We will ask you to collect a small faecal sample to analyse your intestinal bacteria (gut bugs), which recent research has shown to possibly be associated with good or poor health. The test can be done on a very small stool sample which we would ask you to collect on 2 occasions: (i) before the study at home and bring to the Human Nutrition Unit with you when you start the study, and (ii) at the end of the study (Day 15). If you do not wish to collect your faecal samples, you can still be part of the study.

**Will there be genetic testing?**

Dietary intake have been shown to regulate the activity of genes without modifying DNA by using specific signalling molecules called small or microRNA (miRNA) that play an important role in a range of biological processes. We will measure your genetic profile (your genes) to see if you may have any ‘risky’ diabetes genes, which may be more common in people who gain weight and develop diabetes. At the moment there are no known ‘gene therapies’ but in the future better understanding of genes may help us to treat or prevent diabetes. Although we will be able to see some of your unique DNA, we will only be looking at the genes that relate to weight gain and diabetes. There is no one gene that makes us all fat, but a number of small changes in your genes may make diabetes more likely. **We will NOT be testing other genetic diseases that you could be carrying.**

We are also interested in things that control how your genes work. These are the proteins that your genes produce, and the way that they are controlled is called ‘epigenetics’. Changes that you make in your life, such as the food that you eat or how much exercise you take, alters the way that your genes work and you make different proteins. Often we just need to know the type of proteins the genes are making and what chemicals are working on keeping your blood sugars normal.

Additionally, we will run analyses on your DNA, as small variations in the genetic code may explain the variability in T2D risk across a population. These are commonly called single nucleotide polymorphisms or SNPs. We aim to identify SNPs that are associated with differing levels of fat stored in the body, especially that surrounding the organs, such as pancreas and liver. None of the SNPs that we will measure in your blood are associated with any known hereditary diseases or health outcomes. Importantly, there is no one gene that determines health. **Importantly, the testing will NOT provide any information on heritage.** You will not be informed of the results of the SNP and small/micro (mi)RNA analyses. You are free to decline having your blood samples be analysed for SNP and miRNA, your decision to withdraw consent for these analyses will not affect your participation in the study.

**How will my samples and data be stored?**

Your eligibility will be assessed and you will need to provide written consent to participate. Following this, at the screen visit (and clinical days) we will always store a small sample of the blood that has been collected from you, to be further analysed for markers of diabetes and metabolic disease. The screening blood sample will allow us to correlate markers of diabetes in the general population with bodyweight, for example, at a given time point. On the other hand, the blood samples collected during the visits will allow us to see differences in the marker of diabetes following a nutritional intervention.

All of your data will be securely stored at the Human Nutrition Unit, in Auckland and at AgResearch, Palmerston North (metabolomics) and the Malaghan Institute of Medical Research (immune cell profiling). Data will be both written and also on computer files which can be accessed only by the study staff, using security codes. No one else at the University or outside the University will have access to your information. If you drop out of the study at any time (perhaps you become too busy), we ask that all of the data that we have collected can remain in the database in Auckland – we respect your right to withdraw from the study. All data collected from you to that point will remain in our database and be analysed as part of the study however, we will collect no other samples and data from you from that point onwards. The research team will need data from all study participants in order to report to regulatory authorities and also to publish the findings from the study.

**What if the researcher discovers incidental/unexpected findings?**

It is possible that you may be diagnosed with abnormal blood results, such as prediabetes or diabetes or liver enzymes, during the study. If so you will be informed, provided with the results, and advised to contact your GP directly. Our research staff will discuss with you the significance of any abnormal result and will suggest that you contact your GP or specialist to ensure adequate follow-up is in place, since these disorders can have significant impact on your health. If you were to request that we discuss the results with your GP then we could do so.

In the longer term study, MRI scans may also pick up incidental findings that could result in a new diagnosis or require further investigation. Again our research staff will develop a report and discuss with you the significance of the results. We will also suggest that you take the report to your GP or specialist to ensure adequate follow-up is in place. However, follow-up investigations would not be paid for by the researchers. You are the owner of your health information, hence, it is up to you whether you want to share the information with your doctor or not. We do not contact your Doctor, neither will we send any of your health information directly to them.

**Will I get my test results?**

You will get results of certain body measurements including weight, BMI, blood pressure, basal metabolic rate and DeXA scan, every time that you visit the research unit, if you agree to it. At the end of the study, we will also give your own information on blood tests such as blood sugar, HbA1c (diabetes test), and cholesterol. If you are interested in receiving a report about the findings from the Focus Group Interview we would be very happy to send one to you at the end of our study.

For the longer term study, DNA and other tests will be performed in a research laboratory and the results will not routinely be made available to you. This is to safeguard you from Insurance companies who demand, and in New Zealand, are allowed to know ANYTHING you know about your health. While gene variations may give information about how you might respond to different diets, they will not provide information that is useful to your own health or wellbeing, or could be used for medical treatment in any way. It is for this reason that no data about your DNA will be included in your medical files. However, you have a right to specify on your consent form if you want to receive information about genetic markers or findings that may indicate potential or actual risk to health.

If the research centre or laboratories hired by the research centre or research partners become aware of any such results, they will notify the research centre. Steps will be taken to inform you, and you will be offered counselling.

**What are my rights?**

You are free to decline to participate, or to withdraw from the research at any practicable time, without experiencing any disadvantage. You have the right to access information about you collected as part of the study. We will provide you with a report of all of your results at the end of the study (there may be a delay between you completing the study and receiving these results, as researchers have to wait until everybody has completed the study before reporting on the outcomes). You will be told of any new information about adverse or beneficial effects related to the study that becomes available during the study that may have an impact on your health.

**What are the possible benefits and risks of this study?**

Overall there is a low risk associated with taking part in this research study. The main risk is due to the dose of x-rays involved in the DeXA scan, which is similar to the radiation exposure on a 1 hour flight from Auckland to Wellington. It is also important to explain to the Research Nurse if you feel any discomfort during the blood sampling. Research personnel will monitor you during the trial. The research will be stopped should any harmful effects appear or if research investigators feel that it is not in your best interest to continue.

Incidental findings might be discovered during the MRI scan (e.g. fatty liver). In the large majority of the cases, these findings have no relevant health significance and you can continue in the study without follow up. However, all incidental findings are reviewed by a clinician at CAMRI and if he/she suspects that there could be some relevant health issue, you will be asked to contact your GP with these results. **If you decline to contact your GP after being advised of an incidental finding we must exclude you from the study for safety reasons. All incidental findings will be reported to you.**

There will be some benefits for your participation: You will be provided with a diet that meets healthy guideline recommendations during the 2 week residential stay at the HNU. We may see improvements in your blood sugar levels, cholesterol and other markers of disease but we cannot guarantee that this will happen as 2 weeks is quite a short timeframe for changes. You will also be contributing to important science knowledge in the field of nutrition and health.

**Will I be compensated for my participation?**

You will not incur any costs. In addition you will receive a **$20 voucher** wheneveryou come to the research unit, e.g. for your screening visit/clinical appointment. This is to cover your travel expenses. You will also be compensated with a **$50 voucher** for each of the whole body scans (DeXA and MRI). This is a gratuity and also to cover your travel expenses when you visit Auckland Hospital. At the end of the 2 week residential study you will also be compensated for your time with a **$30 voucher** for each day of the study. This is a gratuity and also to cover your travel expenses travelling to and from HNU.

**What if something goes wrong?**

The University of Auckland is sponsoring this study. 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. 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.

**Confidentiality**

Study files, including conversation recordings at the Focus Group interview, your answers to the anonymous survey questionnaire, and all other information that you give will be strictly confidential. Nothing that could identify you will be used in any reports on this study. On enrolling in the study you will be given a ***de-identified*** ***study number,*** e.g. PR37025, and all forms and other types of data collection will use only this study number. Your name will never be linked with any data at any time either during or after the study. If an unusual blood result is found, the lab would let us know which ***de-identified study number it is linked to*** and thenthe clinical researchers would be able to access your confidential file, and talk to you about the result. At the end of the study your records will be stored for 10 years in a secure place at the research units in Auckland, Palmerston North and Wellington. All computer records will be password protected. Study data will be under the care of the main study investigators*.* All future use of the information collected will be strictly controlled in accordance with national regulations.

The biological specimens collected during this research will not be destroyed at its conclusion but will be stored long-term at the School of Biological Sciences, University of Auckland as part of the National Science Challenge High Value Nutrition (NSC-HVN) biological samples biobank; and may be used for future analyses by the HVN researchers. We will need your written consent in order to do this, and will provide you with a separate consent form for this purpose only. Only following your written consent will we store your samples for any future unspecified research and you will be informed of any additional future analyses conducted.

A copy of your results will be sent to you at the end of the study, if you would like to have them. Please note that there will be a delay between conducting the study, analysing the blood samples and telling you the results. This will be done at the very end of the study, when all participants have completed.

**Who do I contact for more information or if I have concerns?**

If you would like some more information about the study please feel free to contact the study investigators: Dr Louise Lu or Dr Ivana Sequeira at the Human Nutrition Unit, University of Auckland on telephone (09) 630 1162.

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent Health & Disability Advocate:

Northern Area 0800 555 050

Free fax 0800 2787 7678 (0800 2 SUPPORT)

Email: advocacy@hdc.org.nz

This study has received Ethical Approval from the Southern Health and Disability Ethics Committee (**20/STH/51**).

|  |
| --- |
|  |

**The principal investigators of this research are:**

**Dr. Jennifer Miles-Chan**

Co-Director, Human Nutrition Unit

School of Biological Sciences

University of Auckland

Telephone: 09 6305160

Email: j.miles-chan@auckland.ac.nz

**Dr. Ivana Sequeira PhD Dr. Louise Lu PhD**

Research Fellow, Human Nutrition Unit Research Fellow, Human Nutrition Unit School of Biological Sciences School of Biological Sciences

University of Auckland University of Auckland

Telephone: 09 6301162 Telephone: 09 6301162

Email: ivana.sequeira@auckland.ac.nz Email: louise.lu@auckland.ac.nz

**Associate Investigator/Research Student**

**Mr. William Zhu**

Research Nurse

Human Nutrition Unit, University of Auckland,

Telephone: 09 6301162

**Mr Leiu Kok Hong BSc, MSc**

PhD Student

Human Nutrition Unit, University of Auckland,

Telephone: 09 6301162

**Mr Jack Penhaligan BSc, MRes**

PhD Student

Human Nutrition Unit, University of Auckland,

Telephone: 09 6301162

**Dr Ivy Gan, PhD**

Scientist, Stakeholder & Consumer Intelligence

Plant and Food Research, Auckland

Telephone: 09 925 7153

***Please keep this information sheet for your records***

**NEW ZEALAND DIETS FOR DIABETES PREVENTION**

**(SYNERGY STUDY): a residential nutrition intervention**

# Consent Form

*Please circle as appropriate:*

|  |  |  |  |
| --- | --- | --- | --- |
| English | I wish to have an interpreter. | Yes | No |

I have read and I understand the Patient Information Sheet (dated \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) for volunteers taking part in the NZ SYNERGY Study

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

|  |
| --- |
| 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, 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 NOT uploading photographs, messages, opinions on this dietary study onto any social media platform until the trial is completed.  |
| I consent to the research staff collecting and processing my information, including the VAS questionnaire and information about my health. |
| I am aware that the Focus Group interview will be audio-recorded and transcribed, and my answers to the anonymous survey questionnaire will be transcribed; with information kept securely by Researchers at Plant & Food Research, Auckland.  |
| I understand that as part of the reporting process, quotes from my answers to the anonymous survey questionnaire, and quotes from the Focus Group interview may be used but that no information that personally identifies me will be used. |
| 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 consent to having an Indirect Calorimetry measurement, OGTT, MRI/S and DeXA scans and faecal microbiome tests  |
| I also agree for my blood samples to be processed for small RNA (called miRNA) and DNA sequencing. I understand that no information that may identify me personally will be provided. |
| I also agree for my blood samples to be processed for novel risk markers, i.e. for metabolomics at AgResearch, Palmerston North and for immune profiling at the Malaghan Institute of Medical Research. I understand that no information that may identify me personally will be provided. |
| I wish to receive a copy of the results. This will not include the results from the miRNA and SNP analyses. I understand that there may be a specific delay between data collection and the publication of the research results. |
| I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy. |
| 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 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 that the Researchers may use my de-identified study data for future research  |
| I understand the compensation provisions in case of injury during the study. |
| I know who to contact if I have any questions about the study in general. |
| I understand my responsibilities as a study participant. |

|  |
| --- |
| ***Participants to Complete (****Please circle as appropriate)* |
| I wish to receive a summary of the results from the study. | Yes | No |
| I consent for research staff at HNU 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 their research file by the Investigator at HNU.***