

PREVIEW:NZ – PREVention of diabetes through lifestyle Intervention in NEW Zealand, Australia, and Europe

A 3 year weight loss study for overweight adults with a high risk of diabetes

PARTICIPANT INFORMATION SHEET

Principal Investigator: Professor Sally Poppitt PhD, Director, Human Nutrition Unit
Co-Investigators: Dr Marta Silvestre PhD, Research Fellow, Human Nutrition Unit
Dr Anne-Thea McGill MBChB PhD, Research Clinician, HNU
Associate Professor Lindsay Plank PhD, Department of Surgery
Dr Nicholas Gant PhD, Department of Exercise Science
Dr Lisa Te Morenga, Department of Human Nutrition, University of Otago

You are invited to join a 3 year weight loss and diabetes prevention program, called PREVIEW. This study will investigate whether you can lose weight by following advice on diet and exercise, which in turn may help you to prevent type 2 diabetes. Your being in the study is entirely voluntary (your choice). If you do agree to take part, you are free to leave the study at any time, without having to give a reason. You may take as much time as you like to consider whether or not to take part in the study.

Who designed the study?

This is a study designed by the research staff at the Human Nutrition Unit at the Universities of Auckland and Otago together with an International Research Team from Sydney, Australia and 6 European countries. The European countries are the UK, The Netherlands, Denmark, Finland, Spain and Bulgaria.

Why investigate *the effect of diet and exercise on weight loss and diabetes prevention?*

Type 2 diabetes is one of the fastest growing long-term diseases both within New Zealand and worldwide. This has been caused mainly by more people being overweight (and obese which means so overweight that people become unwell sick). Our most recent national nutrition survey, which was done in 2008/9, showed us that 2 of every 3 New Zealanders are either overweight or obese. Many of these people will be pre-diabetic, and may be expected to develop full blown diabetes within the next 3-5 years. It is well known that diabetes increases the risk of many other health problems such as heart failure, kidney failure, failure of eyesight, and amputation of lower limbs, and so it is important to stop it before it gets worse. Diabetes can be turned around in most people by losing weight and keeping the weight off longterm **AND it can also be prevented.**

Most people can lose weight by following a strict diet for several weeks, but very few people can keep the weight off longterm. The PREVIEW diabetes prevention study has been

developed to find the best diet and physical activity (exercise) program for longterm weight loss and to prevent diabetes, in a group of people who are overweight and therefore at high risk of developing the disease.

The best way to prevent diabetes is to lose weight, and to make sure that the weight is not put back on: this = **longterm weight loss maintenance**. In PREVIEW we will help you to lose weight, and then test 2 different diets to find which is the best for longterm weight loss maintenance (how to keep the weight off longterm) and which, in turn, is best for the prevention of diabetes.

The 2 diets that we are testing are the **KAKAPO diet** and the **PUKEKO diet**:

- **THE KAKAPO DIET:** Based on a longterm 4 year study called the '*Finnish Diabetes Prevention Study*' from 2004, which was conducted in the Northern European country of Finland in people at high risk of diabetes. This study showed that diabetes cases could be dropped by 60% through longterm weight loss maintenance by following a low fat, moderate protein, **higher carbohydrate** diet.
- **THE PUKEKO DIET:** Based on a more recent 6 month study called '*DIOGENES*' (Diet, Obesity, Genes) (2010), which was run across 6 different European countries, showed that a low fat, **higher protein**, lower carbohydrate (starch and sugar) diet was also very good for maintaining weight loss: It is thought that PUKEKO may be as good or better for long-term diabetes prevention, but this has never been tested.

In PREVIEW we will investigate whether the KAKAPO diet or the PUKEKO diet are best for longterm weight loss maintenance and prevention of diabetes.

Increasing your activity has also long been shown to improve weight loss, weight loss maintenance, and help to prevent diabetes. What we do not know is **how much** exercise is required to have the best effect. If you just increase your exercise by a small amount each week is this enough or must you really be very active in order for it to have an additional protection?

What are the aims of the study?

The aim of PREVIEW:NZ is to test whether the KAKAPO diet or the PUKEKO diet in combination with some exercise is better for:

- (i) long-term weight loss maintenance, *and*
- (ii) prevention of diabetes

in a group of 305 New Zealand adults. This will be done by conducting a 3 year 'diet and exercise' study in people who are more likely or at risk of getting diabetes (pre-diabetes = overweight with body mass index, BMI > 25 kg/m² or overweight and with other diabetes risk factors), and who want to be in a longterm diet and exercise program.

Who can take part?

Any man or woman in the Auckland area:

- who is between 25-45 or 55-70 years
- who is overweight
- who is at increased risk of diabetes, *and*
- who wants to change their diet and lifestyle long-term. This is a 3 year study.

You can't be in the study if you have ALREADY been diagnosed with diabetes.

We would like to enrol 305 male and female people in our New Zealand study. In total 2,500 adults and children will participate across all of the 8 countries who are taking part – from New Zealand, Australia and Europe.

What happens if I decide to take part?

If you are interested in being in the study, a member of the research team from the Human Nutrition Unit will speak to you over the telephone to ask you some questions about whether you are male or female, age, height, weight and family history to work out whether you might be eligible for the study.

Then, to enrol in this study, we ask you to come to the Human Nutrition Unit in Mt Eden, Auckland for a morning visit (screening visit) where we chat to you about the study, and you will have chance to ask more questions. If you would like to take part we will ask you to sign a form saying that you do agree to be in the study (this is called a 'consent' form. You consent to take part). After that we will ask you about your medical and weight loss history. We will also ask for some personal information about where you live and what sort of work you do. We will also do some body measurements (height, weight, body mass index/BMI, waist & hip circumference, blood pressure, & ECG which checks that the beating pattern of your heart is normal). You do not have to answer all of the questions and you may stop the interview and measurement-taking at any time.

If the results of your screening assessment show that you are likely to have a high risk of diabetes, then we will need to carry out an '**Oral Glucose Tolerance Test**' or OGTT, to confirm this. This is a test that is carried out every day at your family doctor's surgery 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). We will take a small (5mL) blood sample from a vein in your arm, then ask you to drink a sugary drink, and then 2 hours later take another small blood sample from your arm. This blood test will measure your blood glucose (sugar), and will also check that you have healthy liver and kidney function.

If you have had an OGTT test anytime in the previous 4 weeks, and have been shown to be at high risk of diabetes, then we will be happy to repeat your OGTT to confirm whether you can be enrolled.

What happens once I am enrolled into the study?

The PREVIEW study is in 2 parts:

- **PART 1 - an 8 week weight loss program**
- **PART 2 - a 3 year weight loss maintenance and diabetes prevention program.**

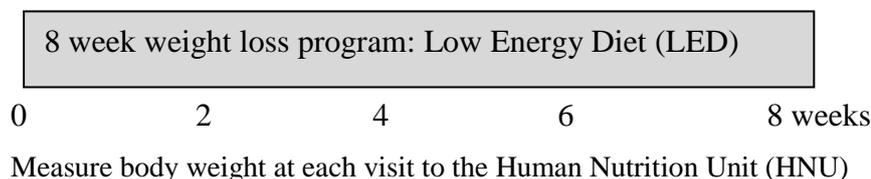
In order to enter PART 2 you must have lost at least 8% of your body weight (eg. 8kg if you weigh 100kg) in the 8 week weight loss program

8 week weight loss program (>8% wt loss)	3 year weight loss maintenance and diabetes prevention KAKAPO diet/PUKEKO diet: plus increased physical activity
--	---

PART 1: 8 week weight loss program

The aim of this program is to lose 8% of your body weight in 8 weeks (eg. 8kg if you weigh 100kg = approx. 2kg every 2 weeks). To make sure that you can get to this weight loss target we will provide for you a LOW ENERGY DIET (LED). This is provided for free. This has been designed carefully and is a diet used by many doctors and also sold as a commercial diet. It contains ~1000kcal or ~4MJ/day. We will discuss this diet with you, and explain the

program that you must follow. You must carefully do exactly as told with the LED for the whole 8 weeks. We will weigh you at the HNU clinic at the start of the 8 weeks, and then every 2 weeks until the end of the LED: week 0, week 2, week 4, week 8. We will be able to advise you about your rate of weight loss all the way through the program. We already know that people who do stick to the LED diet for the full 8 weeks will definitely lose the 8% body weight that you need to, which means you can go on to the next part of the study.

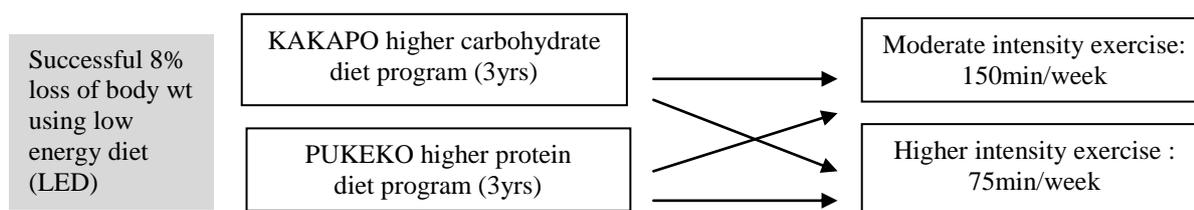


It can be quite hard to follow a low energy diet for weight loss. The diet contains all the nutrients (mineral and vitamins) the body needs, but with very little energy. This means you have to use up or burn your own fat stores over this time, and so you lose weight. During the LED you may get headaches, dizziness, constipation (hard or not much bowel motion) or stomach cramps, some tiredness and bloating particularly in the first few days. This is due to the reduced ‘food’ and particularly the low fibre in the LED diet. All these possible effects are normal and should disappear in a few days. You could be advised to take some fibre gel like Metamucil.

PART 2: 3 year weight loss maintenance

If you successfully lose at least 8% of your body weight by the end of the 8 week LED, you will then be asked to start the long-term weight loss maintenance program. This is a group program where you will be told how to maintain your weight loss, or even lose even more weight over the next 3 years, following a long-term lifestyle program with regular counselling sessions.

There are 4 groups in the PREVIEW study. You will be enrolled by chance (randomised) into either (i) the KAKAPO diet program with moderate exercise; (ii) the KAKAPO diet program with higher exercise; (iii) the PUKEKO diet program with moderate exercise; or (iv) the PUKEKO diet program with higher exercise



You will stay in your same diet and exercise group throughout the whole 3 year study.

This program needs a lot of commitment from you, especially in the first year when you will attend counselling sessions on a regular basis, every 2 or 4 weeks. During years 2 and 3 you will attend fewer sessions – by which time you will have been taught the skills/techniques/dietary and exercise habits that will help you to maintain your weight loss at home, on your own and with the support of family and whanau.

Which diet will I follow?

As this is a research study, you will be randomly (by chance) assigned to either the KAKAPO diet or the PUKEKO diet, and also to either a moderate or a higher intensity exercise program. **We expect**

BOTH diets to be successful – and that if you follow the diet and exercise programs you will successfully maintain your weight loss and decrease your risk of developing diabetes. What we won't know until the end of the 3 years is which of the 2 diets is the BEST diet.

	PUKEKO DIET	KAKAPO DIET
	Protein intake higher, Carbohydrate intake lower	Protein intake lower, Carbohydrate intake higher
Eat more of these foods	<ul style="list-style-type: none"> ▪ Whole-grain cereals with low GI • Pasta • Low-fat milk products • Chicken • Fish • Green peas, beans • Fruit and vegetables • Legumes 	<ul style="list-style-type: none"> ▪ Whole-grain cereals with moderate GI, e.g. bread • Potatoes, sweet potato • Rice • Couscous • Fruit and vegetables
Eat less of these foods	<ul style="list-style-type: none"> • Vegetable oils, margarine, butter • Red meat (e.g. beef, pork, lamb) • Sugar-sweetened beverages • Cakes and biscuits 	

Protein: is in many foods and is mainly for building up the body, for example building muscle, but we do also use it for energy.

Carbohydrate: is also in many foods and comes in 3 main forms - starch, sugar and fibre. After eating high-calorie starchy, sugary foods blood sugars go up quickly and to high levels, which makes diabetes more likely. These are high glycaemic index (GI) foods.

Glycaemic Index (GI): High GI foods raise your blood sugar levels. Low GI foods, that slow sudden rises in blood sugar, are high-fibre carbohydrates, or foods that also contain some protein or fat.

Which activity program will I follow?

As this is a research study, you will be randomly (by chance) assigned to either moderate or higher intensity exercise. **We expect BOTH programs to be successful**, but what we won't know until the end of the 3 years is which of the 2 programs is the BEST physical exercise regime.

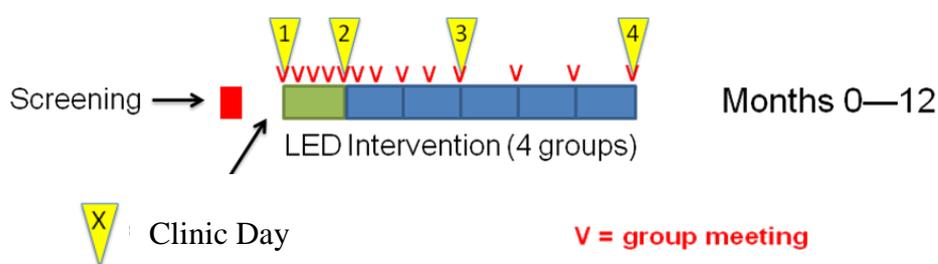
	Higher intensity activities	Moderate intensity activities
Weekly duration (in total)	75 minutes	150 minutes
Examples of activities (these may vary, since the activities will be adjusted according to your personal physical fitness)	<ul style="list-style-type: none"> • Power walking (>6km/h) • Running • Vigorous ball games • Aerobics, vigorous effort • Cycling > 20 km/h • Swimming, fast 	<ul style="list-style-type: none"> • Brisk walking (4-6 km/h) • Leisurely ball games • Most conditioning exercises (aerobics, power yoga, etc.) • Cycling 15-20 km/h • Swimming, recreational
Weekly frequency	2-3 times	3-5 times
Daily duration (guideline)	25-40 min	30-50 min (may be shorter sessions)

What happens at the group counselling visits?

Small group counselling sessions comprising 8-12 participants will be held during the 8 week LED weight loss program, and throughout the 3 year weight-maintenance period. These will help to provide you with all of your diet and exercise information, increase your motivation through discussions with the counsellors (and other study participants if you wish), and help you to achieve your weight loss goals. Gradually you have fewer meetings towards the end of the study: there are 5 meetings during the LED weight loss, then 8 meetings during the first year of weight-maintenance (study months 2—12), 3 meetings during the second study year, and 2 meetings during the last study year. All meetings have counselling by a dietitian and exercise trainer, or other similar health-care professional.

How often do I come to the counselling and clinic sessions during the 3 year study?

YEAR 1: In the first year of the study, there are 13 group counselling visits (approximately 1 per month), and at each session (shown in the figure by a 'v'= visit) you will be counselled about your diet and exercise by the study dietitian and an exercise trainer. These will be group sessions, and will last for ~2 hours in the evening or at the weekend. This will take place at the University of Auckland Tamaki Campus.



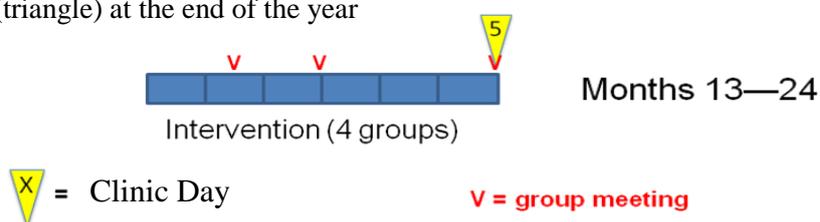
Four (4) of the visits in Year 1 are also Clinic Days (shown as triangles in the figure), when we will measure height and weight, body composition, blood pressure, and also carry out blood tests to check for diabetes. You must come to the Clinic Days in the morning before breakfast. The visit will take the whole morning.

13 group counselling visits in Year 1, including 4 clinic days:

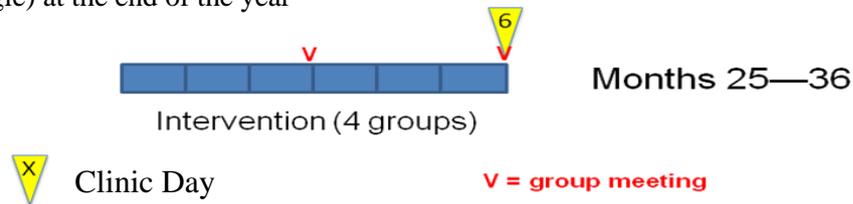
1	2	3	4	5	6	7	8	9	10	11	12	13
wk 0	wk 2	wk 4	wk 6	wk 8	wk 10	mth 3	mth 4	mth 5	mth 6	mth 8	mth 10	mth 12
LED	LED	LED	LED	LED								
Clinic				Clinic					clinic			clinic
weight	weight	weight	weight	Weight	weight	weight	weight	weight	weight	weight	weight	weight
OGTT				No test					OGTT			OGTT

Low Energy Diet (LED) for 8 wks weight loss; OGTT – oral (by mouth) glucose tolerance test = sugary drink and blood sugar tests over 2 hours.

YEAR 2: In the second year of the study, there are 3 group counselling visits ('v'), including 1 visit to the clinic (triangle) at the end of the year



YEAR 3: In the third year of the study there are 2 group counselling visits ('v'), including 1 visit to the clinic (triangle) at the end of the year



YEARS 4-6: We would like to measure your body weight for a further 3 years after the end of PREVIEW, if you agree to us contacting you and if we obtain sufficient funding to continue the study.

What measurements will I have?

We will measure your weight at every dietary counselling session and clinic day, and ask you about your health, and check your current medications.

Other measures and blood tests will occur only on the clinic days (Month 0, Month 2, Month 6, Month 12, Month 18, Month 24, Month 36), and these will be:

- Circumference of your waist, hip and thigh – using a measuring tape
- Body composition using a Dual X-ray Absorptiometry (DXA) scanner – this will tell us how much fat and lean (non fat tissue = muscle, bone and all the rest) tissue you have in your body, and takes approximately 10 minutes, lying on a bed; and bioelectrical impedance analysis (BIA) which is another simple way to measure your body composition. Small sticky electrodes are placed on your hands and feet and the speed that it takes a very low electrical current (the same as your beating heart) to pass through your body is an estimate of your body composition.
- Blood pressure and heart rate
- Fasting blood samples - to measure factors in your blood that are related to diabetes and heart disease; including glucose, insulin, HbA1c, lipids, C-RP, liver enzymes, markers of inflammation, adipocytokines and a sample of blood would be collected for genetic (DNA and RNA) analysis of your risk of diabetes only (no other genetic tests). We will collect less than 50mL of blood each time.
- Oral Glucose Tolerance Test (OGTT) – 2hr test following a sugary drink, where blood samples are collected every 30 minutes (we tape a butterfly needle or cannula into your vein, so only 1 needle jab).

Other measurements that we need to collect during the study are related to your diet and exercise, which we hope will gradually change once you join the program's counselling sessions:

- 4 day food record – you note down all of the foods that you eat every day for 4 days, to see if your diet is changing during the study (we give you a guide to do this)

- 24 hour urine collection – nitrogen in the urine sample is measured and from that we can check how much protein you have been eating (you have a big bottle at home and take smaller ones to work to collect urine)
- Exercise measurement using an accelerometer (similar to a step counter) and an exercise log – to check how much exercise you are taking and whether it changes during the study
- We will also ask 100 people in Auckland if they will collect a faecal (bowel motion) sample over 3 days at the beginning of the study (Month 0), at the end of Year 1 (Month 12) , and at the end of Year 3 (Month 36) – this is a new method to measure markers of colon cancer and other associated diseases, and how they change over the study

Will there be genetic testing?

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.

How will my samples and data be stored?

We will analyse some of your blood samples in Auckland, including the screening blood samples where we will measure blood sugar levels, but on each occasion a sample (with your Study number but NOT your name) will also be sent to the University of Helsinki in Finland where it will be safely stored until all the samples are analysed together at the same time (called batching the samples), alongside all of the other 2,500 participants in the PREVIEW study. The results will be sent back to us in Auckland, and we can give these results to you at the end of the study. The blood samples will be destroyed once they are analysed.

All of your data from the PREVIEW study will be securely stored at the Human Nutrition Unit and the Tamaki Campus in Auckland. Data will be both written, and also on computer files which can be accessed only by the PREVIEW staff using security codes. No one else at the University has access to your information. The data for all 2,500 PREVIEW participants will then be collected together in Copenhagen, Denmark where all of the group analyses will be done. Again, your data will only be identified by Study Number and not your name; and only PREVIEW research staff will have access to the data.

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 PREVIEW database in Copenhagen. The research

team will need data from all 2,500 study members in order to report to regulatory authorities in Europe and also to publish the findings from the study.

Will I get my test results?

You will get results of certain body measurements including weight, BMI, blood pressure, and DEXA scan, every time that you visit the HNU Clinic. At the end of the study, we will also give your own information on the most important blood tests such as blood sugar and insulin, HbA1c, HDL (good)- and LDL-(bad) cholesterol.

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 well-being, 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, if you have specified this on your consent form, and you will be offered counselling.

What happens if I don't want to continue in the study?

You are free to drop out of the study at any time. Being in the study is entirely your own choice. If you do choose to leave the study, we would like to ask if we can continue to measure your body weight until the end of the 3 years, even if you are no longer following the diet program.

The risk and benefits of the study

None of the procedures or tests in this study is dangerous. However, you could be a bit uncomfortable during the 8 weeks of the LED diet. You should keep in mind that there are some small risks in doing the exercise program. The most likely risks are related to injuries, such as pulling a muscle. You may also feel a bit stiff and tired, especially at the start of exercise program. We will try and make the exercise programs more comfortable for you by the following:

- you choose your favourite activities
- We will have a 'start low, go slow' period for 3 months so that you will build up slowly over this time to get the target amount of exercise
- how you are finding the exercises will be noted and discussed with trained staff-members at regular group meetings
- you will be given information on warm up and warm down exercises to help prevent injuries You are welcome to bring a friend or family (whanau) member with you to your screen or other appointments to help you understand the study and ask any questions.

Study staff will keep an eye on you for any side effects throughout the study. You can talk to Dr McGill, the study doctor, about any health problems that are to do with the study. Dr McGill will take you out of the study if she feels it is not right for you or it is causing you problems. Any health problems you have will be noted down as part of the trial and will be checked by an independent Medical Monitor. As this is a nutritional study it is unlikely anything harmful will occur. If we detect any medical abnormalities during the study we will recommend you speak with Dr McGill, who could advise you to see your own family doctor.

We will ask you who your family doctor (GP) is, but Dr McGill will only contact him or her in an emergency, or if you want her to.

Compensation

If you got some sort of injury because of the study, and this is not likely, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover does not always happen, and your case will need to be assessed by ACC. Even if your claim is accepted by ACC, you still might not get any compensation. This depends on whether you are an earner or non-earner. ACC usually pays some of the costs and expenses. These days there is usually no lump sum payout. There is no compensation for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your rights to sue the study staff (investigators). If you have any questions about ACC, you can contact the nearest ACC office or the investigators.

Confidentiality

Study files 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 an *anonymous study number*, eg. 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 then the lab would let us know which *anonymous study number it is linked to* and then Dr McGill the study doctor 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 5 years in a secure place at the HNU. All computer records will be password protected. Study data will be kept for 10 years and will be under the care of the main PREVIEW investigators. All future use of the information collected will be strictly controlled in accordance with the Privacy Act.

A copy of your results will be sent to you at the end of the study. As this is a 3 year study, there will be a delay between getting the data, analysing it and telling you the results, and publishing scientific articles.

Finally

If you would like some more information about the study please feel free to contact the Study Manager Dr Marta Silvestre at the Human Nutrition Unit on telephone (09) 630 3744.

- 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 Northern X Regional Ethics Committee (13/NTB/41).

Please keep this information sheet for your records.

**PREVIEW:NZ – PREVention of diabetes through lifestyle Intervention in
NEW Zealand, Australia, and Europe**

A 3 year diet and exercise study for overweight adults with a high risk of diabetes

CONSENT FORM

Please circle as appropriate:

English	I wish to have an interpreter.	Yes	No
Maori	E hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhaka pakeha korero.	Ae	Kao
Samoan	Ou te mana'o ia i ai se fa'amatala upu.	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea.	Io	Ikai
Cook Island	Ka inangaro au i tetai tangata uri reo.	Ae	Kare
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu.	E	Nakai

I have read and I understand the Patient Information Sheet dated 16 August 2013 for volunteers taking part in the PREVIEW:NZ 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 had the opportunity to use family (whanau) support or a friend to help me ask questions and understand the study.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my future or my continuing health care.
- I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study.
- I understand that the investigation, will be stopped if it should appear harmful to me.
- I understand the health compensations for this study.
- I have had time to consider whether to take part.
- I know whom to contact if I have any side effects of the study.
- I know whom to contact if I have any questions about the study.

Participants to Complete: Please circle as appropriate

I consent to participate in the 3 year PREVIEW diabetes prevention study	Yes	No
I wish to receive a copy of the results. I understand that there may be a long delay between data collection and the publication of the study results.	Yes	No

Participant to complete:

I _____ Print full name

of _____ Print address

hereby consent to take part in this study which is designed to investigate the effect of diet, exercise and weight loss on the prevention of diabetes

_____ Signature of participant

_____ Date

Participant to complete:

I also consent to the following:

(i) for my blood samples to be sent for analysis at the central laboratory in Denmark Y/N

(ii) for genetic material (genes) in my blood related to overweight and diabetes to be analysed Y/N

(iii) if genetic markers or findings that may indicate potential or actual risk to my health are found, I would like to be notified Y/N

_____ Signature of participant

_____ Date

Researcher to complete:

_____ Project explained by (name)

_____ Project role

_____ Signature of researcher

_____ Contact telephone number for researcher

_____ Date

A copy of this consent form is to be given to the participant to take home, and a copy is to be kept in their confidential study file at HNU