

Subject Name: _____ Date of Birth: ___/___/_____

“The OptiMuM Study”
Optimal Nutrition in the Elderly: High Protein Diets for
Muscular, Metabolic, and Microbiome Health

PARTICIPANT INFORMATION SHEET

We invite you to participate in a clinical trial on the effects of high protein diets on your muscle maintenance and metabolic and gut microbiota health. Your participation in the research is entirely voluntary (your choice). If you do agree to take part, you are free to withdraw from the research at any time, without having to give a reason.

Who can take part?

You can take part if you are a male, aged 70 years of age or older, and are reasonably healthy. You must be able to eat meat and dairy products to take part in this study. You must be available to participate in a 10 week study which includes 5 visits over 70 days which will take place at the University of Auckland, Liggins Institute (Grafton).

The study will involve the collection and analysis of muscle and blood samples. Many iwi, hapu, and whānau disagree with gene testing of blood samples due to issues with the loss of rights to your whakapapa. However, it is acknowledged that individuals have the right to choose. We encourage you to consult with your friends, family or whānau, especially around the gene testing process and the collection of your muscle tissue before agreeing to participate. If you have any cultural requirements or questions that relate to your potential participation in this project, please ask the research team before signing this document. It is the role of investigators to ensure that you understand all procedures and risks: please feel free to ask any questions you may have.

Who designed the trial?

This trial was designed by research staff at the University of Auckland. The research staff conducting this trial are interested in the maintenance of muscle function as well as metabolic health and the influence of diet on the gut microbiota (the bacteria in the gut). This study is funded by a grant from the Ministry of Business, Innovation and Employment.

Why might high protein diets have effects on muscle and health?

Maintaining muscle mass requires an adequate supply of protein in the diet. These dietary proteins are able to activate muscle protein synthesis (muscle building) for several hours. It is thought that regular intake of protein is important to help maintain muscle mass, muscle strength and muscle function as you age. Similarly, the types of food that we eat can have an impact on metabolic health (the way your body uses nutrients) and also the gut microbiota. Your metabolic health and the gut microbiota

are important for influencing risks associated with developing diabetes or cardiovascular disease.

What is the aim of the research?

The aim of the research is to assess the effects of a high protein or high carbohydrate diet on muscle strength and function, metabolism, and microbiota over 10 weeks. In this research, at the start of the trial each participant will be randomly assigned to a high protein diet (test) or a high carbohydrate diet also with adequate protein (control) which you will eat every day for ten weeks.

What happens if I decide to take part?

This research requires **Five** visits.

Visit one (screening 30 mins)

This will take place in person at the Liggins Institute at 85 Park Road, Grafton. We will discuss this participant information sheet with you and if you wish to participate you will be asked to sign an informed consent form to participate in this trial. You will be asked some questions about your health, and your height and weight. We will also ask you some simple questions and ask to you follow some simple instructions to make sure that you are able to participate. We will provide you with a faecal collection container and you will be asked to collect a sample prior to your next visit.

Visits two and four (4 hours each)

You will arrive at the Liggins Institute and will have your blood pressure measured. You will also have a pqCT scan of one of your legs to determine muscle size and bone strength. The pqCT scan will expose you to a small amount of radiation however the total exposure will be less than an international airplane flight. You will then give a blood sample. After this you will undergo a number of tests of your muscle strength and mobility. These will include having you push as hard as you can against a special machine, testing your balance and how fast you can get up from a chair 5 times.

Visits three and five (4 hours each)

These visits will take place 48 hours after visits two and four at the Liggins Institute. We ask that you do not eat anything after 10 pm the night before. You will have your blood pressure measured, and your waist circumference measured. You will also have a breath sample collected by blowing into a collection bag. A muscle biopsy will be taken from your thigh muscle. You will be given local anaesthetic to prevent you from feeling pain and a small 5mm incision will be made then a muscle sample the size of a small pea will be collected; you may still feel a deep pressure sensation. Your leg might be sore for a few days after the procedure. There will be a total of **TWO MUSCLE BIOPSIES** over the course of the study: one at the beginning and one at the end of the ten weeks of diet control.

After this, a small needle will be placed into your arm vein. This is slightly painful and can cause discomfort. This needle has a plastic cannula that will be left in your arm vein. This too is a little uncomfortable and you will not be able to fully bend your arm. The researcher will then take 30mls of blood (4 tablespoons) and this will be used to measure your resting blood glucose, insulin, hormones, and metabolites. Another blood sample of just 3ml (1 teaspoon) will be collected twice more, 15 minutes apart.

You will then be given a drink containing 75g of glucose (sugar). Another blood sample will be taken 30 minutes after you eat. This will be repeated every 30 minutes for 2 hours. These blood samples will be used to measure your metabolic responses to the meal. After the 2 hours the cannula will be removed; this may cause mild discomfort.

During the 2 hours, you will also undergo a DXA scan which will give you information about your bone, fat and muscle mass. We will ask you to lie still on table for 5-10 min while the scan takes place. Like the pQCT, DXA scans will expose you to a small amount of radiation (see above). After the 2 hours you will be given a light snack.

Diet

Because we are investigating the effects of a dietary regimen it is important that your diet be controlled. We will provide you with breakfast, lunch, dinner, and all beverages every day for the 70 days (10 weeks) of the study. These meals will be prepared by a professional chef and will make up all of the food you will need to eat in a day. You will also be allowed to consume water, tea, or coffee as you like, without adding milk or sweeteners. Meals will be delivered to you every few days, some will be frozen and need to be kept in the freezer and some will be fresh and need to be kept in the fridge. We will provide you with a sample menu along with this document.

Physical activity

Physical activity is very important in determining how big your muscles are and how they work. For the first and last week of the study we will ask you to wear an armband and pedometer which will track how many steps you take, so that we can determine if your regular physical activity may have impacted your muscle strength and function. We will ask you to continue to do the usual amount of physical activity you are used to.

Faecal samples

Before visits 2 and 4 of the study you will be asked to collect a small faecal sample. We will provide you with a container and instructions and ask you to inform us once you have collected the sample so we can arrange to send it to the Liggins Institute within 5 hours.

Urine samples

Before visits 2 and 4 of the study you will be asked to collect all your urine for a full day (24 hours, both day and night). We will provide you with a container and instructions and ask you to bring the container to the study visit the next day. This will allow us to calculate how much protein you ate the previous day.

Follow-up care

Research personnel will contact you after the final study visit to check how you are feeling. The muscle biopsy site may take several days to fully heal, if you experience any symptoms such as bruising or pain contact the research personnel via telephone.

How many and what type of people will be in the research?

There will be 30 males aged 70 years old or older in this research.

The risk and benefits of the research

Overall there are no major risks associated with taking part in this research. There is low risk associated with the DEXA. We are exposed to very low amounts of radiation all the time from the sun and other sources in our everyday lives. The DEXA scan involves exposure to a similar amount of radiation as a flight from Auckland to Wellington. The pqCT muscle scan involves a higher dose of radiation similar to an international flight.

There are minor risks involved in muscle biopsy, including bleeding, bruising, muscle soreness or infection. Our research staff will explain all of this to you in detail, and you will be welcome to ask questions. You may feel some discomfort from the biopsies on the day after the study. Again, staff will be available to answer any questions and advise you about any problems that you may experience.

The diets given in this study have both been designed to meet your daily requirements for protein and fruits and vegetables. The possible benefits of the research are that you will be contributing to the advancement of science in the area of healthy aging. In addition, you will be compensated for your time.

Dr. Paul Hoffman and research nurses will monitor you during the trial for any side effects of the diet or procedures. 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. Any symptoms that you may experience will be recorded as part of the trial. If any new information becomes available during the course of the research about the diets it will be shared by your investigator with you.

Will there be genetic testing?

We will measure the amount of some of your genes, proteins and metabolites because they can change after a meal or after a period of diet change and may provide a biomarker of muscle function during aging. There is no one gene, protein or metabolite that makes muscles strong or weak, but a number of small changes which contribute to muscle function. We will NOT be testing other genetic diseases that you could be carrying.

What will happen with my blood and muscle samples?

We will analyse your blood samples in Auckland for amino acids, hormone, gene and metabolite levels. Your breath samples will be sent to a specialist laboratory for breath metabolite analysis (Dr. Nicole Roy, Agresearch Ltd, Palmerston North). Blood and muscle samples will be stored in secure freezers in an access restricted area at the University of Auckland, until analysis is completed. Samples will be stored in the same facility as animal tissue. There will be no future unspecified research made on your samples without your prior approval. After these analyses have been performed on

your blood samples, it will not be possible to return any unused samples to you, although you are welcome to request their return prior to any analysis.

Some blood markers analysed in this research can be early indicators of diseases such as diabetes and heart disease. Any blood results outside of the normal healthy range will be provided to you, together with a letter that you can take to your doctor. If you do not wish to be informed of any blood results indicating a possible medical concern, you cannot participate in this study.

Your samples will be kept until the end of the analysis for a total of 10 years. At the end of this time a medical waste contactor will dispose of your tissue. If you would like a karakia performed at this time, please indicate so in the consent portion of this form. Any samples for disposal by karakia will be clearly marked.

Compensation

In the event of an injury during the study you have a right to ACC equivalent compensation. In case of any adverse event which is found to be related to the administration of the diet or trial procedures resulting in hospitalisation, the charges for treatment will be reimbursed to you by Auckland UniServices Ltd. who have indemnity insurance. If you have an accident while at the research site, not related to the treatment or trial procedures you will be covered by ACC. Auckland UniServices Ltd. provides indemnity insurance for any claims against the PI or research personnel due to personal injury or negligence.

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

Research files and all other information that you provide will remain strictly confidential. When the analysis is completed the researchers will analyse the whole group's data and report on averages. This data will be used for scientific publication and presentations. 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 in a secure place. All computer records will be password protected. Results from gene tests and other analysis performed in a research laboratory will not routinely be made available to you. However, a copy of your results will be given to you upon completion of the research at your request.

Trial Payments

There will be no financial cost to you for taking part in the trial. A gratuity of \$500 will be given in the form of Westfield vouchers. A \$100 voucher will be given after visits 2, 3 and 4, \$200 will be given after visit 5. You will also be provided all meals prepared by a professional chef for the duration of the trial. Parking or public transportation costs will be covered for all study visits.

Finally

Thank you for considering your participation in this study

Ngā Tāngata hei whakapānga atu - For more information please contact:

Cameron Mitchell, Liggins Institute, University of Auckland, 85 Park Rd. Grafton
Telephone: 099236606 Email: cameron.mitchell@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

This research has received Ethical Approval from the Southern Health and Disability Ethics Committee

The principal investigators of the research are:

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Please keep this information sheet for your records.

Subject Name: _____ Date of Birth: ___/___/___

Optimal Nutrition In the Elderly: High Protein Diets for, Muscular, Metabolic and Microbiome Health

CONSENT FORM

I have read and I understand the Patient Information Sheet dated 9th February, 2016 and wish to take part in the research entitled “Optimal Nutrition in the Elderly: High Protein Diets for Muscular, Metabolic, and Microbiome Health” which is designed to investigate the effects of high protein diets on muscle maintenance, metabolism, and gut health.

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 understand that blood and muscle samples will be collected and sent overseas for analysis, and will not be able to be returned to me.
5. I understand that any blood results found to be outside the normal healthy range will be conveyed to me and that if I do not wish to be informed, I cannot participate in this study.
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 and I will receive ACC equivalent compensation in the case of an adverse event resulting from the treatment or trial procedures.
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 purpose(s)

Participant to complete: Please circle as appropriate		
I consent to participate in the “Optimal Nutrition in the Elderly: High Protein Diets for, Muscular, Metabolic, and Microbiome Health” study	Yes	No
I wish for a karakia to be said at the time of my tissue disposal	Yes	No
I wish to receive a copy of the results. I understand that there may be a specific delay between data collection and the publication of the research results	Yes	No

Optimal Nutrition in the Elderly: High Protein Diets for, Muscular, Metabolic, and Microbiome Health

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 effects of high protein diets on muscle, metabolism, and microbiome.

_____ Signature of Participant

_____ Date

Research Personnel to complete:

_____ Full name of Principal Investigator

_____ Signature of Principal Investigator

_____ Contact telephone number for PI

Research Personnel to complete:

_____ Project explained by

_____ Project role

_____ Signature

_____ Date

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

APPROVED BY THE HEALTH AND DISABILITY ETHICS COMMITTEE
Reference Number 15/STH/236