

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

Post exercise effects of dairy products PARTICIPANT INFORMATION SHEET

We invite you to participate in a clinical trial on the effects of milk protein on your muscle after resistance exercise. 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 between 18-35 years of age, are reasonably healthy and do not perform regular resistance training for your lower body. You must not be allergic to dairy products to take part in this study. Men with a bleeding disorder are not eligible to participate. You must be available for two visits which will take place at the Liggins Institute (85 Park rd Grafton).

Who designed the trial?

This trial was designed by research staff at the University of Auckland and Fonterra Co-operative Group Ltd.

Why might dairy products have after exercise?

Dairy products such as milk provide a rich source of high-quality proteins including whey and casein, which provide the building blocks of protein (amino acids) necessary for growth and repair of different body tissues. It is known that milk proteins promote favourable changes in how your body works and in particular how your muscles work. After drinking a milk protein drink, amino acids are released into the blood and muscle building (protein synthesis) is activated for several hours. It is thought that regular intake of protein in conjunction with resistance training increases muscle mass, muscle strength and muscle function.

What is the aim of the research?

The aim of the research is to assess the effects of three different proteins on muscle protein synthesis after resistance exercise. In this research, you will be randomly assigned to one of three protein drinks: whey protein, casein protein or a new milk protein concentrate. We will not be able to tell you which beverage we gave you until several months after the end of the research.

What is the nutritional supplement being tested in the research?

Whey protein makes up 20% of the protein in cow's milk and is digested rapidly. Casein protein makes up 80% of the protein in cow's milk and is digested more slowly than whey. The new milk protein contains both whey and casein but has been treated to be digested similarly to whey. The drinks will be administered as a 350ml beverage with vanilla flavouring.

What happens if I decide to take part?

This research requires two visits. For both visits, you need to come to the Liggins Institute, 85 Park Road, Grafton.

You may stop the interviews/visits at any time and decide not to participate further in the study with no consequences.

Visit 1 – Baseline (2 hours)

You need to come to the Clinical Research Unit (CRU) at the Liggins Institute. 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. You will be asked some questions about your health, and your height and weight will be measured. You will need to wear some comfortable loose fitting clothes, and shorts. We want to assess the composition of your muscles, and to do this we need to do some scans (pqCT and DXA) using two different machines. The DXA scan will give you information about your body composition, total body fat, and lean mass. We will ask you to lie still on table for 5-10 min while the scan takes place. You will also have a pqCT scan of one of your legs to determine muscle size and bone strength. Three scans will be performed to determine the cross-sectional area of your thigh and calf muscles. Both DXA and pqCT scans will expose you to a small amount of radiation however the total exposure will be less than an international air plane flight.

We will assess your muscle function in your both legs at two speeds (slow and fast) on an isokinetic dynamometer, commonly used by physiotherapists and in sports clubs. After a short warm-up on a stationary bike, you will be asked to perform several practice tests on the dynamometer, which simply involves sitting in a chair and kicking one-leg to get used to the machine. Then you will be asked to do five maximal strength tests on the dynamometer at different speeds, which in involves kicking one-leg as hard and as fast as you can. Afterwards, we will do the same procedure on your other leg.

You will also need to complete an estimated one repetition maximum (1RM) test on the leg press and leg extension exercises. 80% of the 1RM load will be used for the exercise scheduled during the second visit.

Visit 2 – Meal Study (8 hours)

In preparation, you will need to avoid exercise and vigorous physical activity the day before. We will give you a standardised meal (60% carbohydrate, 20% protein and 20% fat) to consume the evening before. Then you must fast overnight and come in a fasted state. You need to come to the CRU at the Liggins Institute by car or taxi. Research personnel will take care of you during your visit. A muscle biopsy will be collected from a quadriceps muscle in a random leg. Local anaesthetic will be used and a small incision (~5mm) made in your leg before the muscle biopsy so you will not feel any pain but may feel a deep pressure sensation. A small cannula (a small plastic tube from which we can collect blood through the day without having to use lots of needles; these are often used when you have a drip in the hospital) will be introduced into your arm vein, and a blood sample taken. Then a continuous intravenous -infusion of phenylalanine which is labelled with a stable isotope (an isotope which is not

radioactive, and poses no danger to your health) will be run for seven hours using a second cannula. The infusion contains a small amount of labelled amino acids so we can track changes in muscle protein synthesis. After three hours, a second muscle biopsy will be collected from a quadriceps muscle in your other. You will then be directed to complete three sets of leg press and extension at 80% of the heaviest weight you can lift. After the exercise, you will be given one of the test protein dissolved in water to drink, and neither you nor the research personnel will know which treatment it is. You must drink the entire beverage. Venous blood samples will be taken again at 15, 30, 45, 60, 75, 90, 120, 150, 180 and 240min post ingestion, using the cannula in your arm so no more needles will be used. Muscle biopsies will be collected again at 120 min and 240 minutes post ingestion, firstly from your other leg and then again from your starting leg. Again we will use local anaesthetic before each muscle biopsy to minimise any discomfort. We will stop the study at any time should you find the procedures uncomfortable.

You will undergo a total of **four muscle biopsies** during this visit.

Follow-up care

Research personnel will contact you three days 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 healthy males aged 18-35 years old in this research.

Summary of what you have to do

- On visit 1 meet us at the CRU in the Liggins Institute, 85 Park Road, Grafton. We will do a full body scan, several muscle scans and strength tests.
- Before visit 2, avoid any vigorous physical activity the day before. Eat only the standardised meal we give you for your evening meal the day before. Don't eat breakfast the next morning and come to the CRU in the Liggins Institute after an overnight fast, by car or taxi.
- During visit 2, a small cannula will be placed in your arm. A continuous infusion will be administered over seven hours. You will then drink a 350ml treatment beverage; and over the course of the morning, twelve blood samples will be taken via the cannula and **four muscle biopsies** will be taken from your thigh muscle using local anaesthetic to minimise any discomfort.

The risk and benefits of the research

Overall there are no major risks associated with taking part in this research. During visit 1 there is low risk associated with the DXA and pqCT muscle scan due to the exposure to ionizing radiation. We are exposed to very low amounts of radiation all the time from the sun and other sources in our everyday lives. The DXA scan involves

exposure to a similar amount of radiation less than an international air plane flight. The pqCT muscle scan involves a similar dose of radiation.

During visit 2 there are minor risks involved in muscle biopsy, including bleeding, bruising, or infection. We 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. We recommend that you do not plan to take part in any active sporting events on the day after the biopsies. Again, we will be available to answer any questions and advise you about any problems that you may experience.

The IV infusion which will be given during visit 2 contains a stable isotope, which is not radioactive, and poses no danger to your health. The IV infusion will be supervised by a medical staff, and you may feel a slightly cool sensation as the infusion starts.

There are very small risks associated with the cannulas which will be used for the blood sampling and IV infusion. These include bruising, nerve damage and infection.

The treatment beverage given in this study is natural and comes from cow's milk. The product is made in New Zealand or Europe. The possible benefits of the research are a contribution to the advancement of science in the area of muscle health. In addition, you will be compensated for your time.

Research personnel will monitor you during the trial for any side effects of the treatment. 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 treatment it will be shared by your investigator with you.

Will there be genetic testing?

There will be no genetic testing of your DNA. We will be measuring changes in the amounts of some of your genes (RNA), proteins and metabolites because they can change rapidly after exercise or consuming protein and may provide a biomarker of muscle function. 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 for genetic diseases that you could be carrying.

How will my samples be stored?

We will analyze your blood samples at the Liggins Institute for amino acids, hormone, gene and metabolite levels. We need to send some of your muscle samples to a specialist laboratory overseas to determine protein synthesis rates (Dr David Wagner, New Hampshire, USA). Blood and muscle samples will be stored in secure freezers in an access restricted area at the University of Auckland, until analysis is completed. There will be no future unspecified research use of your samples. Any remaining human tissue following analysis will be destroyed. You have the option to have karakia said at this time.

We acknowledge that tissue removed from your body is considered as sacred by

some cultures. We have a strong desire to handle the samples you gift to us with care and respect. If you have any cultural concerns about the removal, storage and final destruction of the samples you supply, please talk to one of the research team

Compensation

In the event of an injury during the study you have a right to ACC equivalent compensation which would be paid for by Auckland Uniservices Ltd through their insurer. In case of any adverse event which is found to be related to the administration of the treatment resulting in the need for medical care or hospitalization, the charges for treatment will be reimbursed to you by Fonterra Co-operative Group Ltd who has indemnity insurance. If you have an accident while at the research site, not related to the treatment or trial procedures you may 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.

Confidentiality

Research files and all other information that you provide will remain strictly confidential. No material that could personally identify you will be used in any reports on this research. Upon completion of the research your records will be stored for 5 years in a secure place under the responsibility of Fonterra Co-operative Group Ltd, New Zealand. 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 at the end of the study in the form of vouchers which can be spent at any Westfield location. You must arrive at the laboratory via motorized transport will be reimbursed parking experiences.

Finally

Thank you for considering your participation in this study

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

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This research has received Ethical Approval from Central Health and Disability Ethics Committee, reference: 16/CEN/206

The principal investigators of the research are:

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Please keep this information sheet for your records.

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

Effects of dairy protein at rest and after exercise

CONSENT FORM

I have read and I understand the Patient Information Sheet dated 15th *November 2016* and wish to take part in the research entitled “Effects of dairy protein at rest and after exercise” which is designed to investigate the post-prandial effects of dairy products on metabolism.

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 the treatment, or investigation, will be stopped if it should appear harmful to myself.
4. I understand the compensation provisions for this research.
5. I have had time to consider whether to take part.
6. I know whom to contact if I have any side effects from the research.
7. I know whom to contact if I have any questions about the research.
8. 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)

<i>Participant to complete: Please circle as appropriate</i>			Participant Signature:
I consent to participate in the “Effects of dairy protein at rest and after exercise” study	Yes	No	
Your tissue will be disposed of at the end of the study. Would you like a karakia said at this time?	Yes	No	

Effects of dairy protein at rest and after exercise

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 post-prandial effects of dairy products on metabolism.

_____ 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.***