



THE UNIVERSITY OF AUCKLAND
NEW ZEALAND

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PARTICIPANT INFORMATION SHEET

Project title: **The acute effects of triacylglycerol structure of palmitic acid rich fats on chylomicron composition in lean subjects and those with the Metabolic Syndrome**

Names of Researcher: **Amber Milan**

Principal Investigator: **Professor David Cameron-Smith**

Co-investigators:

Professor Sally Poppitt (Human Nutrition Unit, University of Auckland)

Adjunct Professor Kaisa Linderborg (Department of Biochemistry, University of Turku)

Dr. James Markworth (Liggins Institute, University of Auckland)

Amber Milan, PhD Student (Liggins Institute, University of Auckland)

Researcher introduction

Much of a person's day is spent in a post-meal (postprandial) state and the composition of the diet can impact how the body responds. Postprandial inflammation has been linked to cardiovascular disease (CVD) risk, suggesting that the short term effects of a single meal can have long-term consequences. High-fat meals cause an inflammatory response, which depends on the type of fat and its chemical structure which determines how the body breaks it down. Additionally, different metabolic states (e.g. diabetes, obesity) affect the extent of a person's response to a meal.

Palm olein is widely used in food products and does not cause a heightened post-meal response compared to other fats. When its chemical orientation is changed during food processing to become interesterified palm olein it has a reduced effect on the post-meal response in healthy individuals. Therefore, it is important to know how this type of dietary fat affects the post-meal response in individuals who may already be at an increased risk of CVD. As a Professor in Nutrition, my research is how the body digests and responds to food and this research is to measure digestion and the immune responses of the body. Student researcher, Amber Milan, will be conducting this study as part of her Doctoral thesis.

Project description and invitation

The aims of this project are to compare the response of your body to four different breakfasts of different fat structures in relation to healthy lean adults and adults with the Metabolic Syndrome. Over four mornings, each one week apart, you will be asked to eat a breakfast of a high-fat muffin and milkshake. Measurement in your blood will be made of chylomicrons (the carriers of fats in the blood), lipids (the digested products of fats), hormones (such as insulin), and stress responses (inflammatory gene expression markers expressed in white blood cells that indicate how much the gene is turned on or off in response to stress and mild infection).

Project Procedures

There will be 5 study visits in total. At the first visit we will explain the study in details and answer any questions you may have ask about participation. If you are satisfied with everything and agree to take part we will ask you to sign the consent form (below). We will then take a small blood sample and do a Dual-Energy X-ray Absorptiometry scan (DXA) to assess body composition which involves a very low dose of x-ray exposure. We will also perform some tests to assess your eligibility for the study. This visit will take less than one hour.

There are 4 more visits (test days) remaining separated by at least 2 weeks. Before coming in for these visits you will be required to keep a 3 day food record of your diet. You will be provided with a low fat dinner to eat the night before each test day, and are not to eat after 10pm as this will affect your digestion in the morning. Except for water, you are to fast overnight and come to the Human Nutrition Unit. You will be asked to rest on a bed for 20 minutes before 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 15mls of blood (2 tablespoons) and this will be used to measure your resting lipids, amino acids, hormones and stress factors. You will then be given a test breakfast of a muffin and a milkshake. The breakfast will contain one of four different fats: palm olein, interesterified palm olein, lard, or sunflower oil. You will need to eat this within 10 minutes. Another 15ml blood sample will be taken one hour after you eat. This will be repeated for 5 hours. These blood samples will be used to measure your digestion, hormone and stress responses.

After the 5 hours the cannula will be removed; this may cause mild discomfort. You will be offered lunch and you are free to go. Before departing we will invite you to make an appointment for the next sessions to eat the other breakfasts.

We appreciate that this takes at least 33 hours of your time and we would like to offer all participants a \$200 gift voucher to reimburse you for your time and efforts.

Your Blood

Your blood will be used in the analysis of chylomicrons, lipids, hormones and immune responses that will provide vital insights into whether the Metabolic Syndrome impacts how you digest and respond to differences in chemical orientation of palm oil. As part of the immune response analysis, we will need to measure the level that your white blood cells express certain genes (turning these genes on or off) responsible for an immune response to infection; these analyses will be done on all participants' samples. These analysis techniques will take place in the laboratories of the Liggins Institute (University of Auckland) and each sample will be given a unique code. Since it will not be possible to complete the analysis of lipid responses at the University of Auckland, your samples will also be sent overseas to the laboratory of Adjunct Professor Kaisa Linderborg (University of Turku, Finland). 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 6 years. At the end of this time a medical waste contactor will dispose them.

Many iwi, hapu, and whānau disagree with overseas transport **or** genetic analysis of blood samples due to issues with the loss of rights to your whakapapa or DNA. However, it is acknowledged that individuals have the right to choose. These concerns may also apply to non-Māori. We encourage you to consult with your family or whānau before agreeing to participate, if you think this might apply to you.

What if something goes wrong?

If you were injured as a result of treatment given as part of this study, which is unlikely, you **won't** be eligible for compensation from ACC. However, compensation would be available from the study's sponsor, Auckland UniServices Ltd., in line with industry guidelines. We can give you a copy of these guidelines if you wish. You would be able to take action through the courts if you disagreed with the amount of compensation provided.

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

You may have your friend, family, or whānau support help you understand the risks and/or benefits of this study or any other

explanation you require. You are also welcome to have a friend, family, or whānau support with you during every session.

Right to Withdraw from Participation

You have the right to withdraw from this study at any time. Your contribution is entirely voluntary and if you chose to withdraw all your samples and data will be destroyed and excluded from all analysis. You are even able to withdraw up to 3 months after the study has been completed. Your samples will be destroyed and your records removed from all files.

Anonymity and Confidentiality

All samples and the measurements will be coded and recorded against this code to keep your identity confidential. Coding will be numerical and you will not be identifiable by this code. The only person able to link the code with your name is Professor Cameron-Smith who will keep the coding list in a locked filing cabinet in his office. When the analysis is completed Professor Cameron-Smith will analyse the whole group's data and report on averages. This data will be used for scientific publication and presentations. No person will be identifiable from the analysis.

Contact Details

Should you have further enquires or wish to have your blood samples removed from the study you can contact student researcher Amber Milan at any stage. Her mailing address is Liggins Institute, The University of Auckland, Private Bag 92019, Auckland Mail Centre, Auckland 1142, New Zealand. She can be contacted also by telephone (09-923 3439) or by email: a.milan@auckland.ac.nz, or PALMStrial@auckland.ac.nz.

APPROVED BY THE SOUTHERN HEALTH AND DISABILITY ETHICS COMMITTEE ON 21/01/2015 Reference Number 14/STH/184



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CONSENT FORM
THIS FORM WILL BE HELD FOR A PERIOD OF 10 YEARS

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Name of Researcher: Amber Milan

Principal Investigator: Professor David Cameron-Smith

Co-Investigators: Adjunct Professor Kaisa Linderborg
Professor Sally Poppitt
Dr. James Markworth

I have read the Participant Information Sheet, have understood the nature of the research and why I have been selected. I have had the opportunity to ask questions and have them answered to my satisfaction.

- I agree to take part in this research.
- I understand that I am free to withdraw participation at any time, and to withdraw any data traceable to me up to 3 months following the completion of the last breakfast meal.
- I understand that my blood samples will be sent overseas and will be tested for white blood cell gene expression.
- 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.
- I wish / do not (please circle) wish to receive the summary of findings.
- I understand that the results from this study will be used for scientific publication and presentations.
- I understand that data will be kept for 10 years, after which they will be destroyed.

Name _____

Signature _____ Date _____

Researcher's Signature _____ Date _____

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