**PARTICIPANT INFORMATION SHEET**

Project title: **Multivitamin and Mineral Supplement**

**Bioavailability and Metabolic Effects in Ageing: VIOME Study**

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| Name of Researcher: | **Dr Amber Milan (Research Fellow, Liggins Institute)** |
| Principal Investigator: | **Professor David Cameron-Smith (Professor of Nutrition, Liggins Institute)**  |
| Co-investigators: | **Pankaja Sharma (PhD Student) and Soo Min Han (Master’s Student)** |

**Researcher introduction**

Multivitamin and mineral supplements are the most widely used type of dietary supplements. Their purpose is to ensure micronutrient sufficiency for consumers and to prevent deficiency. These are made up of combinations of vitamins and minerals formulated to deliver a large percentage (typically 50-100%) of the daily recommended dietary intake (RDI).

Older adults are at a higher risk for nutritional deficiencies. In the 2008/09 New Zealand Adult Nutrition Survey, calcium, zinc, selenium, riboflavin and vitamin B6 intakes by adults aged 70 years or more were found to be inadequate. Factors such as changes in digestion, metabolism, and absorption, limited food choices due to weakened teeth and restricted physical movement. Yet, the clear difference in bioavailability of micronutrients between young and older adults have not been established.

This study aims to identify bioavailability of vitamins and minerals following consumption of commercially available multivitamin and mineral supplement (Centrum Advance). We are examining differences in bioavailability between young and older adults as well as other changes in metabolic profiles.

**Project description and invitation**

The aim of this study is to evaluate bioavailability of micronutrients from a commercially available multivitamin and mineral supplement and its effects on other metabolites in healthy adults. You have been invited to participate because you have identified that you have not been using any dietary supplements and you do not have any major medical conditions. This study will assess changes in metabolites in your body in response to ingestion of multivitamin and mineral supplements.

**Project Procedures**

If you choose to participate in this study, there will be 2 study visits in total, including 1 screening visit and 1 study visit. At the screening visit, we will explain the study in detail and answer any questions you may have about participation. If you are satisfied with everything and agree to take part we will ask you to sign the consent form (below). This visit will take less than one hour.

There is 1 more visit remaining. On your study visit, we will measure your height, weight and waist circumference. You will be provided with a multivitamin and mineral tablet along with a standard breakfast. Blood and urine samples will be collected over the course of 4 hours. You are asked to record your diet for 3 days prior to your visit.

Except for water, you are to fast overnight and come to the Nutrition and Mobility Clinic of the Liggins Institute. First, your resting blood pressure will be measured. Then, you will be asked to rest on a bed and a small needle will be placed into your arm vein. This can be slightly painful and can cause discomfort. The needle has a plastic cannula (thin tube) 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. You will then eat a standard breakfast and take the multivitamin and mineral tablet. Also, you will wear a Fitbit watch to count the number of your steps during the study. Blood samples will be repeated every 1 hour for 4 hours. These blood samples will assess metabolic changes by measuring:

* Vitamins and minerals (micronutrients) including vitamin B12 folate, calcium, iron, magnesium, phosphorus, chloride, potassium, sodium, serum ferritin and transferrin
* Metabolites (digested products of the supplement and markers of your body’s metabolic process) including lipids (the digested products of fats), amino acids (the digested products of proteins), sugars such as glucose (digestion products of carbohydrates), and hormones involved in digestion such as insulin.

We will collect fasting and continuous urine samples during the test to analyse the excreted metabolites including vitamins and minerals.

After the 4 hours the cannula will be removed; this may cause mild discomfort. You will be offered lunch and you are free to go.

We appreciate that this takes at least 2 visits to our research centre and 5 hours of your time and we would like to offer all participants a $50 gift voucher on the trial day to reimburse you for your time and efforts.

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| **Timeline** | **What will happen** | **Duration** |
| Screening Visit | Description & consent | < 1hr |
| Intervention Visit | Height, weight & waist circumferenceResting blood pressure Blood & Urine samples | 4 hrs |

***Figure 1.*** *Timeline of the intervention*

**Your Blood**

Your blood will be used in the analysis of vitamins, minerals, and metabolites; lipids, glucose and insulin. These will provide vital insights into bioavailability of vitamins and minerals in the supplement and if there are changes to other metabolites. Some analysis techniques will take place in the laboratories of the Liggins Institute (University of Auckland). Your samples will also be sent to AgResearch Limited (Palmerston North, New Zealand; metabolites), Otago University (Dunedin, New Zealand; minerals), and Nova Southeastern University (Fort Lauderdale, Florida, USA, B12 and metabolites) for analysis of things that we are unable to do in Auckland.

After these analyses have been performed, it will not be possible to return any unused samples to you. You can request the return of your blood prior to any analysis; this would mean we would not use your information in the study.

The information collected in this study will be kept for a total of 6 years. Electronic data will be password protected on secure servers accessible only to the research team. Hard copies will be secured in locked filing cabinets. Your samples will be kept until the end of the analysis. At the end of this time a medical waste contactor will dispose of your tissue. If you would like a karakia said at this time, please discuss this with a member of the research team.

Many iwi, hapu, and whānau disagree with overseas transport 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. 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.

**Detection of Abnormalities**

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, along with a letter to provide 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.

**What if Something Goes Wrong?**

If you were injured in this study, which is unlikely, 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.

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, without giving a reason. Your contribution is entirely voluntary and if you chose to withdraw without giving a reason, any remaining samples and data will be destroyed at that point, but data or samples that have already been collected and processed will continue to be used.

**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 the researchers 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 enquiries or wish to have your blood samples removed from the study you can contact researcher Dr Amber Milan, PhD Student Pankaja Sharma or Master’s Student Soo Min Han at any stage. Dr Milan’s mailing address is Liggins Institute, The University of Auckland, Private Bag 92019, Auckland Mail Centre 1142, New Zealand. Dr Milan can be contacted also by telephone (09-923-1151) or by email: nutrition.mobility@auckland.ac.nz

For any concerns regarding ethical issues you may contact the Chair, the University of Auckland Human Participants Ethics Committee, at the University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 ext. 83711. Email: ro-ethics@auckland.ac.nz

**APPROVED BY UNIVERISTY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON 20/06/2017 FOR 3 YEARS. Reference Number 019392**

**CONSENT FORM**

**THIS FORM WILL BE HELD FOR A PERIOD OF 6 YEARS**

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Name of Researcher: Dr Amber Milan

Principal Investigator: Professor David Cameron-Smith

Co-Investigators: Panjaka Sharma and Soo Min Han

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| * 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.
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| * I agree to take part in this research.
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| * I have had the opportunity to use support from a family (whānau) member or a friend to help me ask questions and understand the research.
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| * I understand that I am free to withdraw participation at any time, without giving reason, and to withdraw any data yet to be analysed traceable to me.
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| * I understand that blood and urine samples will be collected. I consent to the use of these samples for this research, and to my samples being sent outside New Zealand for analysis
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| * 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.
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| * I wish to receive the summary of findings. I understand that there may be a delay between data collection and the publication and availability of the research results.
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| * I understand that the results from this study will be used for scientific publication and presentations.
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| * 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 purposes.
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Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Researcher’s Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_

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