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

The effect of high intensity exercise training on gut microbiota in humans

PARTICIPANT INFORMATION SHEET

We invite you to participate in an intervention study aimed at identifying the effect of exercise on gut microbiota. The term gut microbiota refers to the large number of micro-organisms that exist in the human intestine of all individuals and may influence your metabolism. Your participation in the research is entirely voluntary (your choice). If you do agree to take part, you may contact the investigators to withdraw from the research at any time, without having to give a reason. You can also request that any samples or data you provide for this research be withdrawn prior to their analysis.

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY – THANK YOU

Who can take part?

You can take part if you are a male, aged 18-50 years of age, and are healthy. You must be willing to exercise vigorously and visit the University of Auckland (Grafton) 2 times, 4 weeks apart. The duration of these visits will be 1.5 hr. In addition, you must be willing to attend 9 supervised exercise training sessions over 3 weeks at the University of Auckland (St. John's, Tamaki campus, or Grafton campus). The duration of each exercise training session will be less than 40 mins.

The study will involve the collection and analysis of stool, blood, and oral swab samples. The study investigators understand that in Māori worldview, the body is considered tapu and therefore such sampling should be treated with special consideration and respect. Whilst individuals have the right to choose whether or not to participate in this study, we encourage you to discuss this project with your whanau and friends, especially with regards to the collection of your samples 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 the investigators to ensure that you understand all procedures and risks: please feel free to ask any questions.

Who designed the trial?

This trial was designed by research staff at the University of Auckland. The researchers conducting this trial are interested in understanding the effect of exercise on gut microbiota as a means of improving health.

Background

It is not clear how exercise improves health. It has recently been found that exercise may affect the composition of gut microbiota and it has been suggested that these changes in the gut microbiota may contribute to reducing the likelihood of obesity and development of metabolic disease. Here we will test the composition of the gut microbiota to examine if there are any differences before and after a series of exercise training sessions. In addition, we will also test blood and oral swab samples to examine if these show any changes which are connected with an improvement in health status.

What is the aim of the research?

The aim of the research is to assess the effects of high intensity exercise training on the composition of the gut microbiota.

What happens if I decide to take part?

This research requires **11** visits.

You will be asked to abstain from caffeine in the 12 hours prior, and from alcohol and vigorous activity in the 24 hours prior to visits 1 and visit 11 only.

Visit one (screening 1.5 - 2 hr)

This will take place in person at the University of Auckland Grafton campus. We ask that you do not eat anything after 10 pm the night before, and arrive at the laboratory in the morning having only consumed water (not coffee, tea or juice). 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. A sample of your blood sample will be taken from a vein in your arm by a trained phlebotomist and an oral (mouth) swab sample will also be taken. You will be asked some questions about your health, your height and weight, your usual exercise and dietary habits.

You will then be asked to perform an aerobic fitness test to determine your maximal exercise capacity. You will cycle continuously on a stationary bike with incrementally increasing workloads until exhaustion (<20 minutes) and your expired breath will be collected through a mouthpiece. You will be weighed and your height measured prior to undergoing a 'DEXA' scan which will give you information about your bone, fat and muscle mass. DEXA scans will expose you to a small amount of radiation, but this is no more than you would be exposed to as background in a normal day. This will take approximately 15 minutes.

Finally, you will be provided with collection tubes with which to supply your stool samples prior to visits 2 and 11. You will be advised to provide al least 2 stool samples, taken at least 36 hours apart and a minimum of 48 hours after fitness/exercise testing and/or any vigorous exercise. You will be given instructions on how to collect your sample. Your samples will be picked up from your location by a study investigator.

Visits two - ten (<40 min each)

These will be exercise-training visits and there will be nine visits over a period of 3 weeks with each visit being separated by at least 1 day of rest. These visits will take place at the University of Auckland (St. John's, Tamaki or Grafton campus). During these visits, after a short warm up you will be asked to complete 8-12 repetitions of 60 seconds high intensity stationary bike cycling with 75 seconds rest between each repetition. You may feel faint and/or nauseous following this high intensity exercise but this will pass quickly.

Visit eleven (1 – 1.5 hr)

This will take place in person at the University of Auckland Grafton campus. We also ask that you do not eat anything after 10 pm the night before, and arrive at the laboratory in the morning having only consumed water (not coffee, tea or juice). A sample of your blood sample will be taken by a trained phlebotomist and an oral (mouth) swab sample will also be taken. As per visit 1, you will be asked to perform an aerobic fitness test, weighed and your height measured prior to undergoing a DEXA scan.

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 you normally experience in one day.

While there is a risk of injury (such as muscle strain) or feeling faint/nausea associated with high intensity exercise, in healthy individual undertaking stationary cycle riding we believe this to be negligible.

There are slight risks associated with blood sampling. These are minimised by having all procedures undertaken by a qualified phlebotomist using accepted antiseptic technique. There is a small chance of minor bruising as a result of insertion of the venipuncture needle. Very occasionally, however, there can be infections. We consider the risk extremely low given the aseptic techniques used.

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 and you are be encouraged to inform the investigator of these as soon as possible.

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator. You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.

Will there be genetic testing?

We will analyse the microbiota contained in your stool and mouth swab sample using genetic testing to identify its composition. These are NOT your genes, but the genes of the bacteria which inhabit your gut/mouth. We will NOT be testing for any genetic diseases that you could be carrying. Our genetic testing will NOT provide any information on family history.

What will happen with my blood, stool and oral swab samples?

We will analyse your blood samples for metabolites, hormones, peptide levels, biomarkers of metabolism and exercise response, and stool and oral swab samples for composition, energy content, metabolism biomarkers and microbiota composition and activity levels. Blood, stool and mouth swab 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 (freezer) as animal tissue. Samples, molecules from them or DNA from bacteria may be sent overseas for expert analysis. There will be no future unspecified research made on your samples without your prior approval. After completion of the study, we will keep your contact details for 10 years but you will only be contacted in the unlikely event that we would like to

perform further unspecified analysis. If we cannot contact you at this time we will not perform this analysis. After analyses have been performed on your 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.

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 samples. If you would like a karakia performed at this time, please indicate so in the consent portion of this form. Any samples for disposal following karakia will be clearly marked. It is possible that the entire sample may be used for analysis, in that case there will be no need for disposal and a karakia is not possible.

What will happen if the research finds any results which could impact my health?

If any of the testing procedures or analysis of any samples produces findings which could have an adverse impact on your health status (such as blood glucose levels outside the normal range) the principal investigator will discuss with clinicians at the university. Potentially clinically actionable findings are reviewed by appropriate clinicians in the department and followed up with the participant, and if permission is given, their GP at appropriate intervals to determine if the health abnormality is being managed. However, we acknowledge that it is the participant's decision as to how and if they wish treat any health abnormality revealed by this study.

Confidentiality

Research files, data 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, however it is a requirement that individual data be reported in a public data-base. You will not be able to be identified from this data and 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. All computer records will be password protected. Upon completion of the research your records will be stored for 10 years in a secure place, before being destroyed by the principle investigator or co-investigators. If this is not possible for any reason the head of the principle investigators department or otherwise designated research will take responsibility for this process. 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. In addition to 9 supervised exercise training sessions, a comprehensive fitness assessment and body composition analysis you will receive a gratuity of $100 in the form of MTA fuel vouchers.

Finally

Thank you for considering your participation in this study

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

Troy Merry, Department of Molecular Medicine and Pathology, The University of Auckland, 85 Park Rd. Grafton
Telephone: 09 923 9008 Email: t.merry@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 Health and Disability Ethics Committee, approval number 17/STH/42

The investigators of the research are:

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Please keep this information sheet for your records

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

The effect of high intensity exercise training on gut microbiota in humans

CONSENT FORM

I have read and I understand the Participant Information Sheet and wish to take part in the research entitled "The effect of high intensity exercise training on gut microbiota in humans" which is designed to investigate the effects of exercise on the composition of the gut microbiota.

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 family (whānau) 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 blood, stool and oral swab samples will be collected and analysed, and will not be able to be returned to me unless request to be returned prior to analysis.
4. I understand that the treatment, or investigation, will be stopped if it should appear harmful to myself.
5. I understand the risks associated with partaking in this research.
6. I have had time to consider whether to take part.
7. I know whom to contact if I have any side effects from the research.
8. I know whom to contact if I have any questions about the research.
9. 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)
10. I understand that my donated samples, or molecules from them may be sent overseas for analysis.
11. I understand that my blood, stool and oral swab samples may be stored for up to 10 y.

Participant to complete: *Please circle as appropriate*		
I consent to participate in the "The effect of high intensity exercise training on gut microbiota in humans" study	Yes	No
I wish for a karakia to be said at the time of my sample 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

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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 intensity exercise training on gut microbiota.

_____ 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 17/STH/42