

PARTICIPANT INFORMATION SHEET



THE UNIVERSITY
OF AUCKLAND
NEW ZEALAND
Te Whare Wānanga o Tāmaki Makaurau

Study title: *How accurate are quick and portable methods for measuring body composition?*

Locality: Body Composition Unit,
University of Auckland

Ethics committee ref.: **19/NTA/76**

Lead investigator: Dr Jennifer Miles-Chan

Contact phone number: +64 9 630 1162

You are invited to take part in a study comparing different ways of measuring body composition. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 7 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

The accurate assessment of body composition is of considerable importance across a wide range of health-related areas, and is essential in monitoring response to physical therapy, exercise, and nutritional interventions. However current methods for measuring body composition involve the use of expensive, largely immovable devices, are often time-consuming or difficult to conduct, and/or require rigid control of environmental conditions which make them impractical (if not impossible) to use outside of a controlled environment.

This study aims to evaluate some quick, portable methods, which when combined would provide accurate body composition measurement while overcoming the current limitations. In a multi-ethnic group of young adults of varying body size, we will compare body composition measurements made using state-of-the-art 3-dimensional photonic body surface scanning coupled with bioimpedance spectrometry. These results will be compared to those obtained by the dual xray absorptiometry reference technique. This evaluation will be conducted in both men and women, and in people of different body sizes (i.e., normal-weight, overweight and obese). The results of this study will be of importance to a number of

different areas relevant to the New Zealand population and will help us better design studies measuring body composition in the future.

This study will be conducted by researchers from the Human Nutrition and Body Composition Units at the University of Auckland in cooperation with researchers from the Defence Technology Agency of the New Zealand Defence Force. It has received Ethical Approval from the Northern A Health and Disability Committee (Ethics reference: 19/NTA/76)

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You can participate in this research if you are aged between 18 and 30 years of age, and have a body mass index (BMI) of between 18.5 and 40.0. You should not have any implant (for example: implanted cardioverter-defibrillator (ICD), prostheses or metal implants, a pace-maker, cochlear implant) or amputation, a disorder of fluid balance (for example: oedema, dehydration), kidney disease, or heart failure. Pregnant women cannot participate in this study.

Participating in this study will involve a single visit to the Body Composition Unit at the Auckland City Hospital. During this visit we will measure your body composition. To do this we will first measure your height and weight. You will then undergo three different types of scan, all of which are painless and non-invasive. When your visit is scheduled, you will be able to specify if you prefer a) to be measured by a researcher of the same gender as you, and/or b) to attend a “single-gender” clinic session (i.e., where only researchers of the same gender as yourself are present). Each of the scanning techniques are described below:

1. Dual energy x-ray absorptiometry (DXA) scan

DXA is a scanning method to measure body composition (bone, fat, muscle). The scan process takes about 15 minutes. It involves lying flat, without moving, on an open bed and a scanning arm passes quickly over the length of your body. As the scanning arm passes over you it emits 2 types of very low dose X-ray, similar to the radiation dose that you would receive if you took a 1 hour flight between Auckland and Wellington. The DXA then measures the density of the different tissues in your body. Bone is very dense so it appears bright white on the scan. Muscle is less dense and so it is less white, and fat is even less dense and so it is the least white of all. Here is a picture of the device:



2. Bioimpedance spectroscopy

Bioelectrical impedance analysis is a very common method of estimating body composition. These days, simple bioimpedance bathroom scales can be bought from most homeware shops. This technique involves sending a very weak electrical current through the body and measuring the body's resistance (impedance) to it. You will not feel this current. We will use

two different machines to conduct these measurements. The first machine will be used while you are lying down and will involve two small electrodes (stickers) being placed on your hand, and two on your foot. The second machine will measure while you are standing on it, with your bare feet and hands each being placed onto metal plates. Below are pictures of these two devices:



3. 3D photonic scan

3D photonic surface scans are a rapid method of assessing body size and shape. For this scan you will stand inside a private cubicle in the position shown below and in 12-15 seconds the scanner will create a 3D image of you. The hundreds of measurements associated with the scan can be used to predict percentage body fat.

In order to make the measurements as accurate as possible, we ask you to wear form-fitting clothes during the scan – for example a speedos, crop top and bike shorts, or close fitting underwear. The scanner is surrounded by a blackout curtain so no one can see you while the scan takes place, and you can use this space to remove/replace outer (non form-fitting) layers of clothing. A skull cap will be provided to wear during the 3D body scan.

As outlined in the section “*What are my rights ?*” confidentiality will be maintained, and the 3D images obtained will be securely stored for analysis according to your unique study ID number, rather than linked to identifying information, and will be viewable only by the research team.



Finally we will measure the thickness of skinfolds at four different sites on your body – bicep (front of upper arm), tricep (back of upper arm), subscapular (below your shoulder blade),

and supraspinale (above your hip bone). These measurements will be conducted by a member of the research team within a curtained-off area.

We will ask you to wear gym-style clothing to the visit and avoid wearing any jewellery, as all metal and accessories will need to be removed from your person for the scans, and we cannot take responsibility if anything is lost.

This visit should last no more than 1 hour (likely between 30 and 45 minutes).

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

There will be no benefits from participating in this project other than obtaining some information about your body composition.

There is very low risk associated with taking part in this research study. The dose of X-ray involved in the DXA scan is similar to the radiation exposure on a flight from Auckland to Wellington.

WHO PAYS FOR THE STUDY?

There will be no cost to you for participating in this study. This study is funded by the University of Auckland, with the additional equipment (3D scanner) loaned, and operated, by the New Zealand Defence Force.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, 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 coverage.

WHAT ARE MY RIGHTS?

Your participation in this study is entirely voluntary, and you are free to decline to participate, or to withdraw from the research at any time, without experiencing any disadvantage. You have the right to access information about yourself collected as part of the study.

To protect the confidentiality of your identity during and after your participation in the study, you will be allocated a unique study ID number. This number will be used to label the data collected and results. This data 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 10 years at the Human Nutrition Unit, University of Auckland after the study ends and will be accessible only to members of the research team. All computer records will be password protected.

Furthermore, in recognition of Tikanga Māori, the research teams commits to the following:

- To recognise and acknowledge the importance of whānau support and encourage the involvement and presence of family and whānau in the study;
- To acknowledge the concept of manaakitanga, respecting the participant's inherent dignity and acting in a caring manner;
- To perform research in a safe, sensitive and ethical manner (aroha & māhaki), including the opportunity for a karakia to be undertaken by the participant (or support whanau) if they wish;
- To provide participants with all of the critical information regarding the study in a clear way, so participants can make informed decisions (whakapono);
- Acknowledging the tapu (sacred) nature of the human body, including the safe, secure storage of biometric data.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Upon completion of the research, your records will be stored for 10 years at the Human Nutrition Unit, University of Auckland after the study ends and be accessible only to members of the research team. All computer records will be password protected. At the end of the storage period, all records will be securely destroyed.

Following your study visit, you will receive a copy of your body composition results by email. This will likely occur within one month of your visit.

De-identified (i.e. anonymous) data from all study participants will be put together, analysed, and published in a scientific journal and presented at research conferences. If you wish to receive a summary of the results from the study please indicate on the consent form below.

Taking part in this study is entirely voluntary (your choice). If you change your mind and decide that you do not wish to participate in the study, you are entirely free to withdraw at any time without giving a reason.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Jennifer Miles-Chan

Senior Lecturer & Sir Charles Hercus Health Research Fellow

Human Nutrition Unit and School of Biological Sciences

University of Auckland, Auckland, New Zealand

Telephone: 09 923 4322

Email: j.miles-chan@auckland.ac.nz

Mr Jason Tutara (Ngāti Whātua o Ōrākei, Ngāti Tūwharetoa)

Kaiārahi Science/Maori Support Faculty of Science

University of Auckland, Auckland, New Zealand

Telephone: 027 2982 319

Email: j.tutara@auckland.ac.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

CONSENT FORM

Please tick to indicate you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.

I have been given sufficient time to consider whether or not to participate in this study.

I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.

I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time.

I consent to the research staff collecting and processing my information, including information about my health.

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. Yes No

I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.

I understand the compensation provisions in case of injury during the study.

I know who to contact if I have any questions about the study in general.

I understand my responsibilities as a study participant.

I wish to receive a summary of the results from the study. Yes No

Declaration by participant:

I hereby consent to take part in this study.

Participant's name: _____

Signature: _____

Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____

Date: _____