You are invited to take part in a study on the effect of exercise training on breathing, blood pressure and brain blood flow regulation. 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 11 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY**

Your participation in this study is voluntary. You are free to decline to participate or to withdraw from the research at any practicable time, without experiencing any disadvantage.

**WHAT IS THE PURPOSE OF THE STUDY?**

There is emerging evidence that specialised receptors in the body that respond to changes in blood gas levels (i.e., chemoreceptors) are over-active in chronic diseases such as high blood pressure and heart failure. This leads to worsening symptoms, reduced quality of life and poor outcomes. Despite the potential clinical benefit of developing therapies to target these receptors, there are currently no treatments available that are non-invasive and free from harsh side effects. Exercise training is well known to benefit both mental and physical health and is also linked to better brain health outcomes. The purpose of this investigation is to understand whether a period of exercise training is able to reduce the overactivation of chemoreceptors.
In this study, we are particularly interested in the effect of a community-based exercise training programme (GoldFit, YMCA) on chemoreflex function in older adults. We hope that this information will help us to understand some of the mechanisms behind the observed benefits of exercise training (e.g., reduced blood pressure).

This study is being conducted by Thalia Babbage (Doctoral Candidate, University of Auckland), Dr James P Fisher (Principal Supervisor, University of Auckland), Prof Julian Paton (Co-supervisor, University of Auckland), Dr Ana Luiza Carrari Sayegh (Postdoctoral Research Fellow, University of Auckland), and Dr Mickey Fan (Postdoctoral Research Fellow, University of Auckland).

For further information please contact Thalia Babbage, Principal Investigator (Email, thalia.babbage@auckland.ac.nz).

Ethical aspects of this study have been reviewed and approved by Health and Disability Ethics Committee Protocol number [2021 EXP 11418].

**HOW IS THE STUDY DESIGNED?**

This study is looking at a cross-section of people who are currently attending the GoldFit YMCA exercise programme three or more times/week and have been doing so for longer than 12 months, and people who are not doing any regular exercise. For those who are currently attending the GoldFit YMCA exercise programme, this study is open to participants at any of the eight participating YMCA locations across Auckland. The research team will recruit 15 people who are regularly exercising, and 15 people who are not regularly exercising to be involved in this study. All study visits will take place at the Human Physiology Laboratory at Auckland City Hospital.

You will be required to attend the lab on two separate occasions, scheduled ~2-7 days apart. The first visit will be a familiarisation visit, where an investigator will discuss any questions you may have regarding the study, and ask you to fill in forms for participation, including the Consent Form below. You will also be fitted with equipment to measure your heart rate, oxygen level, breathing and blood pressure.

At the second visit, a blood sample will be taken, and you will be fitted with the same equipment for measuring heart rate, oxygen level, breathing and blood pressure, as well as equipment to measure brain blood flow. Your blood pressure, breathing and brain blood flow responses to three different gas mixtures will then be assessed.

**WHO CAN TAKE PART IN THE STUDY?**

We are inviting 2 groups of people to participate:

- People who are currently enrolled in the YMCA GoldFit exercise training programme and have been regularly exercising (3 or more sessions/week) for >12 months, aged >60 years old
- People who have not been regularly exercising for >12 months, aged >60 years old

You have been invited to participate because you potentially fit into one of these 2 groups of people.

For safety and scientific reasons, you are ineligible to participate in this study if you are: younger than 60 years old, are a smoker, have a body mass index of <18 (weight in
kilograms divided by height in metres squared), or have a significant medical condition (e.g., heart failure, lung disease).

**WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?**

Participation involves one familiarisation visit (~60 min) and one experimental visit (~2 hours) where you will come to the Human Physiology Laboratory, Auckland City Hospital. The general procedure of participating is as follows:

Once you have read this form, an investigator will contact you to make sure that your questions have been answered and check that you understand what is involved. They will then schedule a familiarisation visit with you.

**Familiarisation / screening visit**

At the familiarisation visit (~60 min) an investigator will further explain the nature of the procedures, answer any remaining questions and ask you to complete the Consent Form below. You will be asked to complete a General Health Questionnaire and 7-day physical activity recall questionnaire. Then, providing you meet the study inclusion/exclusion criteria, you will be enrolled into the study. Body weight and height will be measured, and then you will be familiarised with the study procedures. To do this, you will be fitted with equipment for measuring heart rate, oxygen level, breathing and blood pressure (detailed below) and exposed to a brief low-oxygen gas mixture to understand the sensations that may be felt during gas challenges.

**Experimental visit**

You will attend a single experimental visit that will last ~2 hours. This will be conducted at the Human Physiology Laboratory.

Prior to the study visit the following pre-study stipulations apply:

- No food intake for 2 hours prior to the study.
- No caffeine (e.g., coffee, coke, red bull) for 12 hours before the study.
- No alcohol on the day before the study and the day of the study.
- No exercise after 8:00pm the evening before the study and no exercise on the day of the study.
- No ‘over the counter’ (e.g., paracetamol) or cardioactive medications (beta-blocker, ACE inhibitor, angiotensin receptor blockers, calcium antagonists, diuretics, alpha blockers) on the morning of the study. This can be discussed with a study investigator prior to your appointment. Please bring these medications [if you need to] to your study appointment so you can take your usual medication immediately after the research tests (by late morning).

The following procedures will be conducted while you rest on a comfortable bed.

**Experimental Protocol**

You will be asked to sit in a comfortable chair for the duration of the test. After a resting baseline period of ~15 minutes, we will assess your “peripheral” and “central” chemoreceptor tonicity and sensitivity using three short (~5-10 minute) gas mixture trials. One gas mixture will contain low oxygen to target the stimulation of your peripheral chemoreceptors, and one gas mixture will contain high oxygen to suppress the activity of your peripheral chemoreceptors. The other gas mixture will contain high carbon dioxide and...
high oxygen to target stimulation of your central chemoreceptors. After each trial you will be asked to rate your breathing sensation using a simple 0-10 scale.

**Measured Variables**

Throughout the experimental procedures described in the paragraph above we will continuously monitor your breathing and cardiovascular system. Breathing will be monitored with a lightweight mask covering your mouth and nose, or a mouthpiece with a nose clip. Your heart rate will be measured using a 3-lead electrocardiogram by placing sticky electrode patches on your chest. Your blood pressure will be monitored by a small blood pressure cuff around the finger, and another around your upper arm. A lightly placed finger-clip will monitor your blood oxygen saturation. Blood flow of the large arteries in your brain will be measured using two probes placed lightly on your temples with the help of an adjustable headband and gel.

Pictures of the study set-up are shown below:

![Study Set-Up Images]

**WHAT WILL HAPPEN TO MY BLOOD SAMPLES?**

Your donated blood sample will be processed and stored by LabPLUS at Auckland City Hospital. The sample will be measured for standard biochemistry measures (e.g., glucose, cholesterol) and inflammatory markers. There may be a small amount of these left over after this study has ended that can be destroyed using standard LabPLUS approved procedures.

We understand that many Māori consider their blood to be tapu and that participation in this type of study requires careful consideration. It may be appropriate to discuss participation with whānau / family members. We have included an optional section on the consent form for a whānau / family member to sign to indicate their support. The contact details for the administrator for He Kamaka Waiora (Māori Health Team) are provided below should their guidance be required.

**WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?**

The risks associated with this study are low. The research team are experienced with all the procedures used. To further minimise the risk associated with this investigation studies will
be undertaken in a clinical research laboratory at Auckland City Hospital. Medically trained personnel will be in close proximity, along with crash cart facilities, in the unlikely event that they are required. In addition, your heart rate, blood pressure, breathing, and oxygen levels will be carefully monitored throughout the study. The experiment will be stopped if untoward symptoms develop or at your request.

With-holding morning medications. Cardiovascular medicines are given to provide protection over years/decades and therefore the delay in medicines in this study (of 3-4 hours) will be extremely unlikely to cause harm over that time frame. As stated above, please bring your usual medications to your study appointment so you can take them immediately after the research tests (by late morning).

Hypoxia, hyperoxia and hypercapnia are used to stimulate the peripheral and central chemoreceptors, and may produce feelings of breathlessness, light-headedness or dizziness. The risk of this is low, and further minimised by being applied for a short period of time (5-10 minutes), but if this does occur symptoms rapidly reverse (in a few seconds) by breathing normal room air again. You will be seated so there is no risk of falling. Before the test begins, you will receive instructions to remove the mouthpiece if symptoms develop. You will also be carefully monitored by an investigator, who can also quickly switch you to room air breathing if required. In the unlikely event that it is needed, oxygen can be administered.

You have the right to access information collected about you as part of the study. You will be informed of any new information related to the study that becomes available during the study that may have an impact on your health. Your identity will be kept strictly confidential, and you will not be identified in the publication of the research findings.

COVID-19: The study will proceed in accordance with guidance from the University of Auckland regarding practices to minimise the risk of COVID-19 transmission. This will include the researchers wearing personal protective equipment and maintaining appropriate physical distance when able. Equipment is always sterilised between participants, and surfaces disinfected. If you feel unwell on the day of your scheduled testing, have been in close contact with a confirmed or probable case of COVID-19, please do not come in for assessment.

**WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?**

It is unlikely that there will be a direct benefit to you from participating in this study. However, we will be happy to talk to you about the data collected (e.g., your heart rate, blood pressure). The information we will gather from all the people taking part in this study will help us to understand the effect of exercise training on peripheral and central chemoreflex sensitivity in older adults.

**WILL ANY COSTS BE REIMBURSED?**

As a participant in this study, you will not incur any costs. A $50 voucher will be provided for each experimental session attended, in recognition of your participation. Parking costs will also be covered.

**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 cover.

**WHAT WILL HAPPEN TO MY INFORMATION?**

During this study the researchers will record information about you and your study participation. This includes the results of any study assessments. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

**Identifiable Information**

Identifiable information is any data that could identify you (e.g., your name, date of birth, or address). The following groups may have access to your identifiable:

- Research team (to complete study assessments)
- Laboratory staff, to process and report your blood sample test
- Sponsor study monitors, to make sure the study is being run properly and that the data collected is accurate.
- The sponsor and its representatives, if you make a compensation claim for study-related injury. Identifiable information is required in order to assess your claim.
- The sponsor, ethics committees, or government agencies from New Zealand or overseas, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.
- Your usual doctor, if a study test gives an unexpected result that could be important for your health. This allows appropriate follow-up to be arranged.

**De-identified (Coded) Information**

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the research team or any study information sent to the sponsor. Instead, you will be identified by a code. The research team will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information:

- The sponsor, for the purposes of this study.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

**Security and Storage of Your Information.**

Your identifiable information is held at the University of Auckland and/or Auckland DHB in a locked filing cabinet in a department with security-limited access, along with all paper records (e.g., health history forms) during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded information will be entered into electronic case report forms stored in secure and password protected University of Auckland servers. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.
Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study.

If you have any questions about the collection and use of information about you, you should ask the research team.

The full results of the studies being conducted will not be known until after the last participant has been tested and the data analysed (up to three years). The results will be reported in professional publications and meetings but will not be published in a form that identifies individual participants. If you are interested in receiving a summary of the results, please indicate as appropriate on the consent form below.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing the research team.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw unless you withdraw after the study analyses have been undertaken.

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

Confidentiality: All information collected about you during the course of the research will be secure. Your name will appear on the attached Consent Form, which will then be coded with a Participant Identification Number. Other study data will then be stored using this Participant Identification Number and not your name. The de-identified study data will be shared with other researchers on the project. Your de-identified data may be used in future studies by other researchers only with the permission of the Lead Investigator, Thalia Babbage.

Data storage, retention, destruction and future use: Electronic data will be stored on a password protected University of Auckland server. Primary research data will be preserved and accessible for ten years, in confidence to appropriate individuals.

HDEC Auditing: an approved auditor appointed by New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative may review your medical records for the sole purpose of checking the accuracy of information recorded for the study, for auditing purposes.

Withdrawing from the study: if you wish to withdraw from the study, please notify the lead investigator Thalia Babbage (thalia.babbage@auckland.ac.nz).
**CAN I FIND OUT THE RESULTS OF THE STUDY?**

The full results of the studies being conducted will not be known until after the last participant has been tested and the data analysed (up to three years). The results will be reported in professional publications and meetings but will not be published in a form that identifies individual participants. If you are interested in receiving a summary of the results, please indicate as appropriate on the consent form below.

The study is registered with Australian New Zealand Clinical Trials Registry (ACTRN12622000046707).

**WHO IS FUNDING THE STUDY?**

The study is sponsored by the University of Auckland and Lottery Health Research. All the researchers are affiliated with the University of Auckland.

**WHO HAS APPROVED THE STUDY?**

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The HDEC Extra Meeting Subcommittee has approved this study.

**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:

*Name, position:* Thalia Babbage, PhD candidate (lead investigator)

*Email:* thalia.babbage@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@advocacy.org.nz

If you require Māori cultural support, talk to your whānau, iwi, hapu or kaumatua in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext. 2324.

If you have any questions or complaints about the study, you may contact the Auckland and Waitakere District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext. 3204.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

*Phone:* 0800 4 ETHIC
*Email:* hdecs@health.govt.nz
## Consent Form

**Physical activity and health: the effect of GoldFit YMCA participation on the brain, breathing and blood pressure regulation**

**Please tick to indicate you consent to the following**

<table>
<thead>
<tr>
<th>Statement</th>
<th>Yes</th>
<th>No</th>
</tr>
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<tbody>
<tr>
<td>I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.</td>
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<tr>
<td>I have been given sufficient time to consider whether or not to participate in this study.</td>
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<tr>
<td>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.</td>
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<tr>
<td>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.</td>
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<tr>
<td>I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.</td>
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<tr>
<td>I consent to the research staff collecting and processing my information, including information about my health.</td>
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<tr>
<td>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.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics 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.</td>
<td></td>
<td></td>
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<tr>
<td>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.</td>
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<td>I understand the compensation provisions in case of injury during the study.</td>
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<td>I know who to contact if I have any questions about the study in general.</td>
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<tr>
<td>I understand my responsibilities as a study participant.</td>
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<tr>
<td>I wish to receive a summary of the results from the study.</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
**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: __________________________

This study has been reviewed and approved by the Health and Disability Ethics Committee [2021 EXP 11418] on [9/12/21] for [3] years.