Participant Information Sheet

Investigating a physical exertion testing protocol in the assessment of balance and visual function following sport-related mild traumatic brain injury (SR-mTBI).

Lead Researcher: Katherine Forch

Research team: Dr Mangor Pedersen, Professor Duncan Reid, Joe Royal, Oka Sanerivi, Dr Imran Niazi, Dr Sharon Olsen

Study Site: North Shore / St Johns / Pukekohe

Contact phone number: 027 445 0595

Ethics committee ref.: HDEC 19505

Kia ora, Talofa lava, and Hello. My name is Katherine Forch and I am a PhD student at Auckland University of Technology.

You are invited to take part in a study that is investigating using physical exertion as part of assessing recovery after sport-related concussion.

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, a legal representative,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 10 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Participating in this research is completely voluntary. 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 are being provided with this information, it means the doctor you have been seeing for your concussion will have indicated you are a candidate for the study, and safe to participate. Your doctor will not be informed if you choose not to participate. The research will be conducted separately to your clinical care, and the research team will not provide diagnosis or clinical advice. This study will not replace your usual clinical care, and if you

have any concerns or questions about your recovery you should continue to consult your usual doctor. However, any study results of concern will be passed on to your treating doctor with your permission.

WHAT IS THE PURPOSE OF THE STUDY?

Concussion is a complicated injury, and sometimes it is difficult to tell when we are fully recovered. Resolution of symptoms (or feeling better) is not a reliable indication that someone is fully recovered. Currently, someone returning to sport after a sport-related concussion has double the risk of another injury. This risk can persist for a year or more. We are trying to improve the testing process, so that we can pick up on subtle impairments (problems) someone might be still experiencing after a concussion that may be responsible for this increased risk. We are interested in how some assessments change after exertion, because exertion has been shown to help highlight ongoing problems after a concussion. Identifying these problems means athletes can continue to rehabilitate these problems (such as reduced balance) prior to returning to sport. This will aim to keep sports people returning to sport safer, by reducing the risk of repeated injury.

HOW IS THE STUDY DESIGNED?

This study will involve two groups, approximately 15 people who are recently recovered from a sport-related concussion, like yourself, and are close to returning to sport, and approximately 15 active people who play sport but have not had a concussion in the last year. Both groups will follow the same process.

WHO CAN TAKE PART IN THE STUDY?

You will be aged 18-40, normally playing a team sport and/or normally participating in at least 150 minutes of exercise per week.

You have been invited to participate in the study because you have experienced a sport-related concussion within the last 6 months and are at a point in your recovery where you are close to returning to play. You will not have another musculoskeletal or medical issue (aside from your concussion) that limit balance, the ability to participate in exercise, and/or could impact the measures we are investigating.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You will first be screened for study eligibility with some questions. If you are not eligible, you will be thanked for your time and your screening information sheet will be destroyed. The only thing recorded will be your reason for ineligibility (e.g. age over 40 years).
If eligible to participate, you will be asked to attend two testing sessions, approximately a week apart. These could be at one of several locations. AUT North Campus, Axis North Shore, Axis St Johns, or J2 Performance, Pukekohe. Whatever is easiest for you. These sessions will take approximately 1 ½ to 2 hours. You are welcome to bring whānau or a support person with you if you like, and can attend testing with another eligible participant if

you would prefer to be tested in a pair. You are also welcome to come and meet the research team, and see the study environment prior to your first testing session.

At the first session, you would be randomly allocated to either the exercise 'exposure' at the first session, or rest 'exposure'. The exercises will take approximately 25 minutes to complete and is based on the Gapski-Goodman test, used around the world with athletes after a concussion. You will start on an exercycle and do a warmup. This will be followed by some high intensity intervals where you will pedal hard for between 10 and 30 seconds and then rest. Following the bike, you will do some plyometrics exercises such as small hurdle step-overs or hops, burpees, box jumps or step-ups, and jump and turns. If you have been randomised to rest at your first session, you will just relax for 25 minutes.

You would have a series of repeated pre- and post- 'exposure' measurements. They involve some simple balance tests, and walking in a straight line, while wearing a smartphone attached with a strap to your lower back. You will also be reading some strings of letters on a grid stuck on the wall, with variations like reading between two grids, or reading while moving your head.

You can also 'opt in' to an additional measure, where a headband is used to record the blood flow in your brain. This may help researchers understand the changes that happen to this blood flow with exercise. This is called Functional Near InfraRed Spectroscopy (FNIRS). It is not painful. You would wear a head piece for 2-3 minutes at the timepoints 2) 4) and 5) above. This use of this additional measure would add approximately 15 minutes to your testing session, but is completely optional.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

You would be participating in moderate-vigorous intensity exercise. There is the possibility you could get injured, for example rolling your ankle. We will attempt to reduce this risk by having a warm-up as part of the exercise protocol. The lead investigator for the study is a registered physiotherapist and will be present for the entire session.

The aims of the study require us to take repeated measures over time. Unfortunately, this could be repetitive, and/or boring for participants. The study team will ensure that they are as efficient as possible, to minimise this.

When you are completing the rest 'exposure' (i.e. the session that you are not exercising), we would ask you to not use your phone or a device during the 25 min 'exposure'. This may be inconvenient for you. We welcome you to listen to music, rest, or chat with your support people. Your lead investigator will also be available at this time if you have any questions.

It is possible that participating in the exercise or the tests may provoke your concussion symptoms. This could indicate that your concussion is not completely resolved. In this case, the research team will provide a summary of your testing results to your treating doctor. This may form part of the information they use to decide whether to provide medical clearance for you to return to sport.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

If impairments are identified during the testing process that have not been uncovered during your usual return to play testing, this represents an opportunity for you to work on these issues and reduce your potential risk of repeated injury. As an appreciation for your time the lead investigator will offer to provide you with some resources with ideas for how you could do this.

The main possible indirect benefits of this study to you as a sports-person is that if you suffer a concussion in the future, the results of this work may improve your standard of care.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

The alternative to taking part is to continue with standard care.

WILL ANY COSTS BE REIMBURSED?

You should not incur any costs to participate. Free parking is provided by arrangement at each testing site. You will have the opportunity to request a personalised exercise plan and resources based on your testing findings. Each participant will be provided with $50 in their choice of petrol or supermarket vouchers upon completion of each study session in appreciation of their time and effort.

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 study team will record information about you and your study participation. This includes the results of any study assessments. Information from your clinical records held be Axis Sports Medicine Specialists may also be collected, such as your symptom scores, clinical outcomes, medical history, and recovery timeframes. You cannot take part in this study if you do not consent to the collection of this information.

Security and Storage of Your Information.

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 is currently very small, but may increase in the future as people find new ways of tracing information.

This research includes basic information such as your ethnic group, geographic region, age range, and sex. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you. This is unlikely considering the nature of the data collected.

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 information:

- Research staff (to complete study assessments and analysis), including the lead investigator Katherine Forch and her supervision team.
- The ethics committees, or government agencies from New Zealand 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 GP (with your permission), if a study test gives an unexpected result that could be important for your health or well-being. This allows appropriate follow-up to be arranged.

Your identifiable information is held at AUT North Campus during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed.

To make sure your personal information is kept confidential, information that identifies you will not be included in any report or publication generated by the research team.

De-identified (Coded) Information

All other information that we collect about you, such as your health information and test results, will be identified by a code. Katherine Forch will keep a list linking your code with your name, so that you can be identified by your coded data if needed. Your coded information will be stored in written form or on computer software. Written information will be stored in a locked cabinet only accessible to the research team. Electronic data will be stored on a hard drive on one laptop, and an external hard drive as back up, and not shared in a cloud-based system. The laptop and external hard drive will have dual-layer protection and be only accessible to the research team.

Future Research Using Your Information.

If you agree, your anonymised (this means your identifying code is removed) information may be used for future research related to assessment of sports-related concussion and/or other medical and/or scientific research that is unrelated to the current study. This is completely optional. If you do not consent to this, you can still participate in the study.

Your anonymised information could be shared with other researchers or companies or combined with data from other studies. If you agree, your data could be shared overseas. Once shared, because it is anonymised, it is extremely difficult or impossible to withdraw consent for its use.

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 a summary of the results of your tests during the study.

If you have any questions about the collection and use of information about you, you should ask the lead investigator, Katherine Forch.

Rights to Withdraw Your Information.

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

Use of New Technologies

The “Gait and Balance” app is used as one of the measures. This will involve data collection during your two testing sessions, using the research team’s smartphone. This app was developed by researchers at AUT to provide information about how your body sways during balance positions or walking. None of your identifiable information will be entered into this app. This app is not ‘cloud-based’. The app data will be downloaded after each session and stored on a secure laptop as per the other electronic information, after this it will be deleted from the app.

Balance data will also be collected using VALD ForceDecks. These force plates collect data through the “VALD hub” app. This app does store information on the cloud. None of your identifiable information will be entered into this app, and access to your information will be limited to a log in linked to Katherine Forch. Your data will be exported from the VALD Hub and deleted from the cloud within 48 hours of testing.

The “EliteHRV” app will be used to collect physiological data. This will be anonymised by the profile being set up as Katherine Forch’s demographic details, and participant data tagged with their anonymised code. This app does store information on the cloud. Your data will be exported from the EliteHRV dashboard into an excel spreadsheet, and stored on a secure hard drive. After exporting the data will be deleted from EliteHRV and the cloud.

Māori Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study and we will treat it with respect. To help protect this taonga:

- We have consulted with AUT’s Mātauranga Māori Committee about the collection, ownership, and use of study data.

- We will allow Māori organisations to access de-identified study data, for uses that may benefit Māori if participants have given consent.
- We acknowledge that Māori participants may prefer to keep their data in NZ, and therefore overseas data sharing is completely optional.
- We will ensure that results are disseminated in a way that is accessible to Māori

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

If you decide you wish to withdraw from the study you should contact the lead investigator as soon as possible. If you wish to withdraw your data, it can be deleted prior to analysis.

CAN I FIND OUT THE RESULTS OF THE STUDY?

Participants will be provided with a plain English summary of study results if requested. This will be available upon completion of data collection and after preliminary analysis, so may take 1-2 years.
Information about the trial can be accessed on the Australian New Zealand Clinical Trials Registry (ANZCTR) found at https://www.anzctr.org.au/ (Reference: 387390)

WHO IS FUNDING THE STUDY?

Katherine Forch (the lead investigator) is supported by a Clinical Research Training Fellowship from the Health Council of NZ. The research team are based at Auckland University of Technology.

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 has approved this study.

WHAT OPPORTUNITY DO I HAVE TO CONSIDER THIS INVITATION?

You are encouraged to take time to consider this invitation and to discuss it with family/whanau. If you have any questions, please feel free to contact Katherine, listed below. We can arrange a face-to-face meeting or a zoom call to get to know each other and discuss the study if that would be helpful for you. If you would like to be considered for the study, please respond to this invitation within two weeks.

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:

Katherine Forch, lead investigator
027 445 0595
katherine.forch@aut.ac.nz

Sharon Olsen - Primary supervisor
Sharon.olsen@aut.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
Website: https://www.advocacy.org.nz/

For Māori cultural support relating to this study please contact:

Joe Royal, Relationships Officer, Ngāti Whātua Ōrakei
021 129 1867

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

Email: hdecs@health.govt.nz
Phone: 0800 400 569 (Ministry of Health general enquiries)

Consent Form

Investigating exertion to assess dysfunction after mTBI

An interpreter is available on request for Te Reo Māori and Samoan

Please tick to indicate you consent to the following:

I have read the Participant Information Sheet, or have had it read to me in a language I understand, and I fully comprehend what it says.	Yes ☐	
I have been given sufficient time to consider whether or not to participate in this study.	Yes ☐	
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.	Yes ☐	
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.	Yes ☐	
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.	Yes ☐	
I consent to the research staff collecting and processing my information, including information about my current concussion from my clinical notes held with Axis Sports Medicine.	Yes ☐	
I understand that some of the measures will involve my anonymised data being temporarily stored on an overseas cloud-based system.	Yes ☐	
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.	Yes ☐	Name of doctor
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 consent to Māori organisations accessing my de-identified study data	Yes ☐	No ☐
I consent to my anonymised information being used for future research related to assessment of sports-related concussion	Yes ☐	No ☐
I consent to my anonymised information being used for other medical and/or scientific research that is <u>unrelated</u> to the current study	Yes ☐	No ☐

I consent to my anonymised data being shared overseas, and am aware that I will not be notified of this, and will be unable to withdraw my data after this has occurred	Yes ☐	No ☐
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.	Yes ☐	
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.	Yes ☐	
I understand the compensation provisions in case of injury during the study.	Yes ☐	
I know who to contact if I have any questions about the study in general.	Yes ☐	
I understand my responsibilities as a study participant.	Yes ☐	
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: