Participant Information Sheet (concussion participants)

Study title:	A streamlined approach to identifying adults suited to orthopedic musculoskeletal physiotherapy management acutely following concussion: a feasibility study.	
Principal Investigator:	Name: Dr Olivia Galea Department: of Physiotherapy Position: Lecturer	Contact phone number: +64 03 4797222

Introduction

Thank you for showing an interest in this project. Please read this information sheet carefully. Take time to consider and, if you wish, talk with relatives or friends, before deciding whether or not to participate.

If you decide to participate, we thank you. If you decide not to take part, there will be no disadvantage to you, and we thank you for considering our request.

What is the aim of this research project?

This aim of this research study is to determine whether using a screening tool (series of physical tests) to identify adults suited to musculoskeletal physiotherapy treatment following a medically diagnosed concussion is feasible (can it reasonably be done). Another aim is to determine whether using the screening tool is beneficial for those following concussion (does it help reduce symptoms and improve performance on certain physical tests).

Who is funding this project?

A Stanley Paris Research Fellowship, which is a University of Otago internal funding body, is funding costs related to the study including study materials and study running costs, the study co-ordinators salaries. The primary investigator and remaining researchers' salaries are covered by their respective Universities or regular workplaces.

Who are we seeking to participate in the project?

We are seeking male and female volunteers aged 18-60 who have experienced a medically diagnosed concussion (confirmed by a medical doctor) within the last 14 days. It is important that participants are acutely concussed since the study aims to determine whether the screening tool is useful in treatment selection in the early stages post-injury. We expect that from screening 160 participants we will find 30 individuals who are eligible and willing to participate in the treatment arm of our study.

You will not be eligible to participate if you meet any of the following criteria:

- Moderate to severe TBI
- Diagnosed concussion with associated brain bleeding (e.g., subarachnoid, or focal hemorrhage) evident on imaging (computed tomography or magnetic imaging), or cervical spine fracture
- Diagnosed concussion due to assault
- Neck pain unrelated to concussion injury(/ies) (requiring treatment)
- Headache disorders (including cervicogenic, migraine (chronic), and tensions type headaches)
- Vestibular (balance), oculomotor (eye motion), neurological disorders
- Major psychiatric disorders currently being actively treated (requiring the use of medication)
- Physical injury that would prevent completion of the screening session

The reason for these exclusion criteria is that often these conditions require additional treatments or prevent the screening tool we are using to accurately identify adults who are suited to musculoskeletal physiotherapy following concussion.

If you participate, what will you be asked to do?

Part 1 a: The Physiotherapy Screening Session

If you decide to participate you will be asked to do the following:

- Complete a series of baseline questionnaires online at least 1 day before you come to the laboratories for the screening session. These questionnaires relate to you as an individual (for e.g., your age and biological sex), your current level of concussion symptoms (these will include questions about neck pain, dizziness, and fatigue), your activity levels, general health, and health related quality of life and will take about 15 minutes for you to complete. You will be asked to provide consent prior to being able to complete these questionnaires.
- Complete a screening session (physical examination) at the University of Otago research laboratories (Dunedin) to determine whether you meet criteria to be included in the treatment arm of the study. The physical examination will take about an hour and will include use of standard assessments of your neck and balance system that your physiotherapist would ordinarily perform.

  These assessments will require you to do the following:
  - wear virtual reality goggles while you move your head and neck.
  - wear a pair of goggles with infra-red cameras in the frame that will record your eye movements.
  - perform a neck endurance test that requires you to lift your head off the treatment table while you are lying on your back and hold this position for as long as you can.
  - lie face down on the treatment table while the physiotherapist feels your neck to assess areas of tenderness or stiffness.
  - while sitting on a chair wear a low energy laser on your head while you move your head with your eyes closed.
  - perform other movements of your eyes and head consistent with usual physiotherapy assessment.

  Before you complete the screening session you will have an opportunity to discuss any questions about the study with the study coordinator. If you decide not to take part in the screening session, you will be able to withdraw, and your questionnaires will be destroyed and not used any further.

- Based on results of the screening session it will be determined if you are eligible to be included in the treatment arm. This will be based on you being identified as “suited to orthopedic musculoskeletal physiotherapy” following your recent concussion.
- If you do not meet the criteria, you will be provided with standard advice recommended in the literature for adults recovering from concussion.

Part 1 b: The Physiotherapy Screening Session: Objective Vestibular Oculomotor Screen validation.

If you decide to participate in this additional portion of the study, you will be asked to do the following:

- In addition to the oculomotor screen using the infrared eye goggles to measure your eye movements, you will repeat similar eye movements (although not the same) without the eye goggles on. This will take an additional 10-15 minutes. You will not receive any additional reimbursement for travel related expenses if you decide to complete this part of the assessment.

Part 2: Physiotherapy treatment sessions

- Those identified as “suited to orthopedic musculoskeletal physiotherapy” will be offered up to 8 sessions of physiotherapy over 4 weeks with the study physiotherapists. You will liaise with the physiotherapist regarding appointment times and your treatment. Your first treatment will be scheduled no later than 2 weeks following the screening session. Treatment will include performance of an exercise test (low intensity treadmill walking test) to determine the most suitable heart rate for you to safely exercise at. This will take place in the first treatment session.
- Those identified as “suited to orthopedic musculoskeletal physiotherapy” who accept the offer of treatment will be asked to wear activity monitors for the following 7 days after the screening session. These are worn on the wrist and waist and operate like a standard activity monitoring device such as a fitbit. You will also be asked to complete a sleep diary each morning for the 7 days you wear the activity monitors.
- While attending treatment sessions you will be asked to complete a diary of your exercises and physical activities.
- Following completion of your treatment sessions you will be asked to attend the laboratories for 2 further follow up sessions where you will complete the same assessment as you underwent prior to attending treatment.
- If you chose not to take part in the treatment arm of the study after completing the screening session and being identified as eligible to enter the treatment arm, you will be referred back to the health care provider who originally referred you to the study.
- If you complete the screening session and are identified to be ineligible to enter the treatment arm of the study, you will be referred back to the health care provider who originally alerted you to the study.

How will I benefit from participating?

Direct benefits of taking part are that you will receive physiotherapy care (assessment and as a minimum advice) to help recover from your concussion. If you are eligible to enter the treatment arm of the study, you will receive physiotherapy treatment provided at no cost to you.

If you choose to participate you will also be reimbursed with vouchers ($40 value) for reasonable costs associated with attending study assessment sessions (1 voucher per assessment) at the School of Physiotherapy research laboratories. Physiotherapy treatment costs associated with participating in the study will also be covered in full. Should you choose to continue with treatment beyond the 4-week treatment period of the study, you will be responsible for your ongoing treatment costs.

Is there any risk of discomfort or harm from participation?

Some of the tests and treatments (where applicable) being performed may cause some of your symptoms to temporarily worsen. This might include increases in neck pain, dizziness, and nausea. We expect the risk of symptom increase to be low and no greater than what you might experience when seeking treatment for your concussion usually. If you do experience symptom reproduction while attending the screening or treatment sessions, you will be able to stop to allow your symptoms to resolve. Alternately you can choose not to proceed further with testing or treatment.

If you are injured in this study, you will 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 data or information will be collected, and how will they be used?

During this study the researchers and physiotherapists will record information about you and your study participation. This includes the results of the online questionnaires, the screening and treatment sessions (if applicable). Some of this data will include video recordings of your eyes. You will not be identifiable as only your right eye is recorded. The physiotherapist will record the clinical assessment and treatments, as required, on their usual practice management systems. The researchers will have access to those clinical notes. You cannot take part in this study if you do not consent to the collection of this information.

<u>Identifiable Information</u>

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:

- Physiotherapy clinics staff (will be provided with a summary report of your screening session and will record the physiotherapy assessment and treatments).
- Members of the University of Otago, 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 GP may be notified of your participation in this study and results of the screening session, with your consent, additionally, if a study test gives an unexpected result that could be important for your health or well-being.

<u>De-identified (Coded) Information</u>

To make sure your personal information is kept confidential, information that identifies you will not be included in any research report generated by the researchers. Instead, you will be identified by a code.

The principal researcher (Olivia Galea) and the study coordinator (also an experienced physiotherapist) will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

Only the research group may have access to your coded information, which will be stored on the principal researcher's password protected laptop, and may be sent and stored overseas. If this feasibility study proceeds to a pilot study, your data may be included in that pilot study. Your de-identified data may also be combined with data from other research centres (including those that may be overseas) as part of a larger analysis. The results of such studies will not be shared with you. Sometimes when we publish research we are also asked to allow access to this anonymous data for other researchers to access.

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 School of Physiotherapy Clinics and other physiotherapy clinics participating in the study. It is also held with the researchers at the University of Otago during the study. After the study, it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Coded study information may be kept by the University of Otago in secure, cloud-based storage indefinitely. All storage will comply with NZ l 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.

Your coded information may be sent overseas to members of the research team. Other countries may have lower levels of data protection than New Zealand.

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 principal researcher, Gisela Sole.

Māori Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognize the taonga of the data collected for this study. To help protect this taonga we have consulted with the University of Otago Ngāi Tahu Research Committee about the collection, ownership, and use of study data.

If you agree to participate, can you withdraw later?

Taking part in this study is voluntary (your choice). You can withdraw your consent to participate in the study at any stage without penalty or any disadvantage to yourself by informing the Principal Investigator Olivia Galea. If you withdraw your consent at any stage, your study participation will end, and the study team will stop collecting information from you. Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

You may withdraw your consent for the collection and use of your information until the 31/05/2024, by informing the Principal Investigator, Olivia Galea, or your Physiotherapist. The reason for this date is that it is likely that by that time your de-identified data will be included in analyses of group data already submitted for publication.

Any questions?

If you have any questions now or in the future, please feel free to contact either:

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Name: Professor Gisela Sole **Position: Professor** **Department: School of Physiotherapy**	Contact phone number: 03-4797936 Email: gisela.sole@otago.ac.nz
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This study has been approved by the University of Otago Human Ethics Committee (Health). If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.