



Participant Information Sheet for people with post-concussion syndrome

Study title:	REMOTE – Remote Evaluation of Mobility via Telehealth for people with post-concussion syndrome	
Principal investigator	Name: Leigh Hale Department: School of Physiotherapy Position: Professor and Dean	Contact phone number: 03 479 5425

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, friends or whānau 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?

The aim of this project is to generate reliable, feasible and safe mobility tests which could be done remotely using videoconference (e.g. Zoom, Skype) with people with post-concussion syndrome who exhibit mild to moderate impairments.

Developing tools to test individuals' mobility remotely will help us to assist people with post-concussion syndrome who exhibit mild to moderate impairments who live in remote areas and/or in isolation. This project will also help us to conduct future projects that aim to deliver home-based physical activity programmes remotely (via videoconference) to increase mobility and to reduce the risk of falls in people with post-concussion syndrome. The first step towards this goal is to develop balance and walking tests that can be used remotely, via videoconference.

Who is funding this project?

This project is funded by the University of Otago Division of Health Sciences and School of Physiotherapy and Brain Research New Zealand.

Who are we seeking to participate in the project?

We are seeking 40 men and women diagnosed with post-concussion syndrome who are aged over 18 years. Volunteers should:

- be independently mobile (with or without walking aid)
- be able to understand the test instructions
- have a mobile device (e.g. smartphone, iPad)
- be familiar with mobile technology (or have support of someone who is familiar with this type of technology)

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

If you agree to participate in this study, we will ask you to do four things:

1. Answer some questions online (a web link will be sent to your e-mail). These questions will ask you about your general, physical, and mental health. This will take up to 1 hour to complete. You can complete these questions in more than one session. But it is important these questions are completed before your first assessment.
2. Have your balance and walking tested in the School of Physiotherapy Balance Clinic with a series of different tests. This will take up to 2 hours and 45 minutes, including refreshment and breaks if necessary.
3. Have your balance and walking tested remotely at home, using videoconference, 7 to 14 days after your visit to the School of Physiotherapy Balance Clinic. The balance and walking tests will be the same ones used in the testing at the School of Physiotherapy. We will instruct you how to set things up for the remote assessment. This will remote assessment will take up to 2 hours and 15 minutes, including refreshment and breaks if necessary.
4. Complete a falls calendar. After your visit to the School of Physiotherapy, we will give you a printed calendar (or e-mail it to you, if you prefer) in which you will have to write down whether you had any falls. We will contact you monthly to collect details about any falls you have had for approximately three months after your home videoconference assessment.

The health, balance and walking tests you will be asked to complete are:

1. Montreal cognitive test: this test evaluates your global cognition. This will be tested only at the School of Physiotherapy visit.

2. Physiological Profile Assessment: this test assesses common falls risk factors such as vision, sensation, reaction time, muscle strength and balance. This will be tested only at the School of Physiotherapy visit.
3. Balance tests: these are physical tests of balance, such as standing on one leg, reaching forwards or to the floor, or timing how fast you can stand up and sit down. These will be tested first at the School of Physiotherapy visit and then via videoconference at home.
4. Walking tests: these are physical tests of walking, such as seeing how fast you can walk a short distance or turn around. These will be tested first at the School of Physiotherapy visit and then via videoconference at home.

We will provide you with a \$20 grocery voucher to help reimbursing your travel and/or parking costs.

Is there any risk of discomfort or harm from participation?

There should be no discomfort caused by any of the balance and walking tests. The main risk of taking part in this study is during the balance and walking testing when there is a slight risk of losing balance while you are completing the tests. We will minimise this risk by: (i) ensuring the researchers testing you are trained in the safety requirements of the tests; (ii) asking you not to repeat any test at home that may be uncomfortable or too difficult for you to perform. If you feel unsure about attempting any test you can say you do not wish to complete that particular test.

If our balance, walking or any other tests shows that you are at risk of falling, we will advise you to see your General Practitioner and we will give you a report to take with you.

What information will be collected, and how will they be used?

The information from the balance and walking tests will help us to generate a mobility assessment tool to be used remotely for people with post-concussion syndrome. Using the falls calendar will allow us to see whether your performance in the balance and walking tests reflects your risk of falling. The information from this study will help us to plan appropriate exercise programmes to assist in the reduction of falls risk in people with post-concussion syndrome.

What about anonymity and confidentiality?

All information obtained from this study will be kept private and confidential. To make sure of this, you will be given a unique identifier. Information used for any publication will be kept anonymous. The researchers and staff working on this project may have access to the data, but the data collected will be securely stored in such a way that only these people will be able to

gain access to it. At the end of the project, any personal information will be destroyed immediately except that, as required by the University's research policy, any raw data on which the results of the project depend will be kept in secure storage for ten years, after which it will be destroyed.

Reasonable precautions will be taken to protect and destroy data collected by email. However, the security of electronically transmitted information cannot be guaranteed. Caution is advised in the electronic transmission of sensitive material.

If you agree to participate, can you withdraw later?

Participation in this study is entirely voluntary. You may withdraw from the project at any time and without any disadvantage to yourself.

Any questions?

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

Name: Paulo Henrique Silva Pelicioni Position: Postdoctoral Research Fellow Department: School of Physiotherapy	Contact phone number: (03) 479 7130
Name: Leigh Hale Position: Professor and Dean Department: School of Physiotherapy	Contact phone number: (03) 479 5422

This study has been approved by the University of Otago Human Ethics Committee (Health, approval number: H20/158). 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.