



Participant Information Sheet

Study title:	The initial effect of high-volume mobilization with movement on shoulder range of motion and pain in patients with rotator cuff-related shoulder pain: a randomized controlled trial (Evolution trial)	
Principal investigator:	Name Daniel Cury Ribeiro Department School of Physiotherapy Position Associate Professor	Contact phone number: 03 479 7455

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 study aims to explore whether: (1) whether shoulder movement is associated with shoulder pain; and (2) a gentle shoulder mobilization technique improves shoulder movement and shoulder pain in patients with shoulder pain.

Who is funding this project?

This project is supported by both School of Physiotherapy and Dunedin School of Medicine Research Student Support Committee.

Who are we seeking to participate in the project?

Sixty patients with pain-limited shoulder elevation, aged from 18 to 75 years old and fully vaccinated against COVID-19. If you had previous surgery on this shoulder or neck in the past 6 months or had previous corticosteroid injection in the past 6 weeks, you will not be able to be part of the study. Our aim is to recruit a total of 60 participants. Upon completion of this study, all participants will be offered a \$20 supermarket voucher as a thank you for your participation.

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

Should you agree to take part in this project, you will be asked to attend two sessions, at least two days apart and within one week. In the first visit, you will be assessed to confirm whether you meet the inclusion criteria for participating in Parts 1 and 2 of this study. If you meet the inclusion criteria for Part 1, your shoulder pain and shoulder movements will be assessed and you will be asked to complete a questionnaire. If you meet the inclusion criteria for Part 2 as well, you will be invited to come back for a second visit, and you will be randomised to receive the gentle shoulder mobilization or a sham gentle mobilization. In that second visit, you will be asked to complete a short questionnaire. It is likely that data collection will last for: approximately 90 minutes (first visit) and 45 minutes (second visit). After attending these two sessions, you will be asked to answer a questionnaire 4 times (at 1, 3, 5 and 7 days after the 2nd visit) about your shoulder pain (this can be done through computer/phone from your home). It should take less than five minutes to complete this short questionnaire.

Is there any risk of discomfort or harm from participation?

This is a very unlikely event, and every attempt will be made to avoid it. There is no potential harm when performing the shoulder MWM or sham MWM. Please be aware that you may decide not to take part in the project without any disadvantage to yourself of any kind.

What specimens, data or information will be collected, and how will they be used?

Anthropometric data (i.e., age, height and weight) will be recorded. Shoulder range of motion will be measured through a digital inclinometer and shoulder pain will be measured with an algometer and temporal summation. Pain-related questionnaires (i.e., pain catastrophizing scale, fear-avoidance beliefs questionnaire) and patient' expectation of treatment change will be collected. Only the mean values will be included in the final report and used for publication purposes.

The results of the project may be published and will be available in the University of Otago Library (Dunedin, New Zealand) but every attempt will be made to preserve your anonymity. Your personal data may be provided to you upon request.

The data collected will be securely stored in such a way that only those mentioned below will be able to gain access to it. Data obtained as a result of the research will be retained for at least 10 years in secure storage. Any personal information held on the participants may be destroyed at the completion of the

research even though the data derived from the research will, in most cases, be kept for much longer or possibly indefinitely.

What about anonymity and confidentiality?

The results of the project may be published and will be available in the University of Otago Library (Dunedin, New Zealand). Only group values will be included in the final report. This will be made to preserve your anonymity.

If you agree to participate, can you withdraw later?

You may withdraw from participation in 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 Tim Wang Position PhD student School of Physiotherapy	Contact phone number: 028 462 1473
Name Daniel Cury Ribeiro Position Associate Professor School of Physiotherapy	Contact phone number: 03 479 7455

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.