Participant Information Sheet

Physiotherapy for people with persistent shoulder pain: the Otago Shoulder Health Study

Formal Study title	**The effectiveness of manual therapy with pragmatic multi-modal physiotherapy for rotator cuff related shoulder pain: a pilot randomized non-inferiority controlled trial**
Lead Researcher	Professor Gisela Sole
Study Site	School of Physiotherapy Clinics, Dunedin and Christchurch
Contact phone number:	03-4797466
Ethics committee ref.:	2022 FULL 13022

We invite you to take part in a study exploring physiotherapy care for people with persistent shoulder pain. 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 9 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Voluntary Participation and Withdrawal From This Study

Taking part in this study is voluntary (your choice). You may withdraw from the study at any time without any disadvantage to yourself. If you decide to withdraw from the study, the information collected about you up to the point when you withdraw may continue to be included in the results.

WHAT IS THE PURPOSE OF THE STUDY?

Research suggests that the best physiotherapy care for shoulder pain is encouraging exercise and physical activity and providing support and advice for self-managing the pain. Manual therapy (using hands on your shoulder and spine) may be added. Currently, we do not know whether adding manual therapy to exercise prescription and information is of additional benefit for people with shoulder pain. The main purpose of this study is to compare rehabilitation consisting of exercise and provision of information to exercise, information and manual therapy. As a pilot study, we want to see how many individuals will be interested to participate, how many complete the program, what the initial results of the program are, the cost of the individual treatment and other treatments that participants might seek, and how useful participants and the physiotherapists find the program.

HOW IS THE STUDY DESIGNED?

This is a pilot randomized clinical trial in which people will be allocated to one of two groups, the 'Manual therapy' group and the 'No Manual therapy' group. Both groups will receive physiotherapy care that is based on the best evidence.

We are seeking 60 men and women in Dunedin and Christchurch. You will be asked to attend a screening assessment and, if your shoulder injury is suitable, be offered up to 8 face-to-face physiotherapy sessions over a three-month period. The sessions will last ½ to 1 hour each. The treatment sessions will be located at that School of Physiotherapy Clinics: in Dunedin, at 325 Great King str, and in Christchurch at 32 Oxford Terrace, Central Christchurch.

All participants will receive individualized information about their shoulder pain, why they feel pain, and what they can do about the pain and to remain physically active. The information provided by the physiotherapist will be complemented with a website that you will be able to access in between the sessions. You will be prescribed exercises for the shoulder and for the whole body. The physiotherapist will consult with you to find out what type of exercise you prefer, is suitable for your shoulder and your general health and well-being.

One group of participants will also receive manual therapy to their shoulder and/or neck/upper back for at least 4 of the 8 sessions.

The physiotherapist will consult with you (and your whānau) when you are ready to be discharged from physiotherapy. At that stage, up to 18 participants will be invited to be interviewed by one of the research team members (A/Prof Nicola Swain). She will ask questions about how you feel you have benefitted from the physiotherapy programme, and what your challenges were (if any). She will also ask how you experienced being part of a research study. We will provide you with another information sheet about those interviews when you are discharged from the physiotherapy care. You will be able to let us know at that stage whether or not you wish to be interviewed.

WHO CAN TAKE PART IN THE STUDY?

We are seeking men and women, aged 35 years or older, who meet the following criteria:

- Have had shoulder pain for more than 3 months for which they have not yet had physiotherapy care
- Have not had any shoulder surgery
- Have not had a shoulder dislocation, or fracture (broken bone) of the upper arm.

You may have consulted a GP for the shoulder pain prior to the study and will be able to seek help from the GP for any shoulder pain during the course of the study. In that case you will be asked to note that in your diary and to inform the physiotherapist. You will be asked not to attend other physiotherapy or osteopathic care for your shoulder pain while being part of this study.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Participating in the study will require the following:

- You will have a brief phone call with an assistant research fellow, Christina Douglas, to answer any questions you may have about the study, and to find out if you are eligible to take part (telephone screen).
- If the telephone screen suggests that you may be eligible, you will be offered an appointment for the second part of the screen. You would need to attend the physiotherapy clinic (Dunedin or Christchurch) for about ½ hour.
    - If you do meet the criteria and agree to take part, you will be asked to provide written informed consent and complete a baseline questionnaire.
    - The assistant research fellow will perform physical assessments to determine if you have 'rotator cuff related shoulder pain'. That will entail moving your arm in various directions, and moving your neck and upper back, reporting any pain to the assistant.
    - If you then do not meet the criteria to take part, you may discuss with the research fellow where you could seek care for your shoulder.
    - The research fellow will then book you in with the physiotherapist for the first session.
- You will then be offered up to 8 sessions with the physiotherapist. You will liaise with the physiotherapist how frequently you will attend, and what the physiotherapy care will entail.
- You will be asked to complete a diary of your exercise and physical activities, pain medication (if any), and patterns of your pain.
- You will be asked to complete the online questionnaire again at 3 and at 6 months after starting physiotherapy, from your home. A link to the questionnaire will be sent to you via email.
- You will be invited to attend an interview about your experiences about the physiotherapy care you have received and of being a participant in the research study.

WHAT KIND OF QUESTIONS WILL I BE ASKED?

We want to find out about how your shoulder pain affects your day-to-day life, recreation, sports and work.

The online surveys will ask you about the following:

- how active you usually are
- your ability to do everyday activities
- your general health
- your beliefs about your pain
- your expectations about your physiotherapy treatment

The questions will be structured to give you a range of answers to choose from. If there are questions you would prefer not to answer, you do not have to.

. WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

Taking part of this study will have similar risks to attending regular physiotherapy care for shoulder pain. You may experience slight discomfort or some pain during the treatment and exercises, but these should be mild and pass within a few minutes. You may experience muscle stiffness following some exercises. In that case, you would be able to report those to the physiotherapist at the next session. We can adjust the treatment and exercises if you experience increased pain or have other concerns.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Direct benefits of taking part are that you will receive physiotherapy care to help recover from your shoulder pain, be provided information to understand why you have shoulder pain and what you can do about it, and undertake exercises that benefit shoulder movement as well as whole body health. This will be provided at no cost to you.

Indirect benefits relate to positive effects of exercise and physical activity on your health and well-being.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

The alternative of taking part in the study is to arrange your own physiotherapy care or to consult with your GP about that best care for your shoulder pain.

WILL ANY COSTS BE REIMBURSED?

You will **not** be reimbursed for transport/parking or for taking time off from work, should that be necessary to attend the screening or the physiotherapy sessions.

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 and physiotherapists will record information about you and your study participation. This includes the results of the screening assessment and the online questionnaires. 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.

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:

- Physiotherapy clinics staff (to 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 with your consent, additionally, if a study test gives an unexpected result that could be important for your health or well-being.

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 researchers. Instead, you will be identified by a code. The principal researcher (Gisela Sole) and the assistant research fellow 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 may be sent and stored overseas. If this pilot study proceeds to a full study, your data may be included in that full 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 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.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing the principal researcher, Gisela Sole, or your Physiotherapist.

If you withdraw your consent, 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.

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.

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

You may withdraw from the study at any stage by informing the principal researcher, Gisela Sole, or your physiotherapist.

In the final session, the physiotherapist will discuss your future management with you and what options you may want to consider. If needed, we may refer you to your GP or for continued physiotherapy treatment.

CAN I FIND OUT THE RESULTS OF THE STUDY?

We will send you a summary of the results, should you be interested in these, via email or by post.

The study is registered with the Australia New Zealand Clinical Trials registry (Registration number ACTRN12623000034639). You will be able to access that registry here: https://bit.ly/3IDAi10

WHO IS FUNDING THE STUDY?

A Stanley Paris Fellowship, which is a NZ Physiotherapy funding body, is funding all costs related to the study, including the physiotherapy sessions, the salaries of Associate Professor Nicola Swain, the assistant research fellow and research fellows. The remaining researchers' salaries are covered by their respective Universities or regular workplaces.

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 Health & Disability Ethics Committees have 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:

Prof Gisela Sole, Principal Investigator
Tel: 03-4797466
Email: Gisela.sole@otago.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 please contact:
Dr Ricky Bell, co-investigator
Telephone number
Email: bodyhealthnz@xtra.co.nz

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

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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.		
I have been given sufficient time to consider whether or not to participate in this study.		
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.		
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.		
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.		
I consent to the research staff collecting and processing my information, including information about my health.		
I consent to my information being sent overseas.		
I consent that de-identified data may be made available to other researchers in future studies related to the study question or to the condition under study (shoulder pain).		
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.		
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. GP name:	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.		
I understand the compensation provisions in case of injury during the study.		
I know who to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		

I wish to receive a summary of the results from the study. Yes ☐ No ☐

Email address:

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: