Participant Information Sheet

Stepped care and Physiotherapy for Shoulder pain in New Zealand (StePS-NZ)

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Study sites:	School of Physiotherapy Clinic Dunedin Christchurch Physiotherapy and Sports Clinic Focused Physiotherapy, Ōtorohanga, Waikato Auckland Shoulder Clinic, Auckland Central Business District
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Ethics committee ref.:	2023 FULL 18871

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. If you sign the electronic consent form, you will be able to download a copy.

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

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?

Shoulder pain is common in Aotearoa New Zealand, and physiotherapy is the primary treatment. However, many people with shoulder pain are not eligible for ACC cover. This means they must seek private physiotherapy or at hospital out-patient clinics with long waiting lists.

Physiotherapy for shoulder pain usually includes encouraging exercise, general physical activity and providing support and advice for self-managing pain. Some patients may also receive hands-on treatment. The main purpose of this study is to compare two different approaches for physiotherapy care for people with shoulder pain. We will also be looking at the costs of the two approaches, to the patient (if they were to cover the costs) and the health care system.

Findings of this study may improve equity and accessibility to physiotherapy for people with shoulder pain, providing treatment at the 'right time', and providing more care to those who really need it.

HOW IS THE STUDY DESIGNED?

This is a randomised clinical trial in which people will be allocated to one of two groups. Both groups will receive physiotherapy care that is based on the best research evidence and current guidelines for persistent pain.

We are seeking 200 people to take part in this study across four centers – Ōtepōti Dunedin, Ōtautahi Christchurch, Ōtorohanga (Waikato) and Tāmaki Makaurau Auckland, Central Business District.

You will be asked to attend a screening appointment, and if your shoulder is suitable, you will be randomly allocated to either of the two groups.

Participants in each group will receive an individualised physiotherapy assessment, information about their shoulder pain, appropriate exercises, how to maintain or increase their physical activity levels and other self-management strategies. Follow-up physiotherapy for both groups will be tailored to the participants needs and may include ongoing physiotherapy visits for up to 3 months. The number of sessions will vary from weekly, fortnightly to monthly. The physiotherapist will clarify this with you at the first session.

On completion of the physiotherapy sessions, we will invite up to 21 participants to be interviewed by one of the research team members (A/Prof Nicola Swain). This may be either in-person or via Zoom. Nicola will ask questions about whether you feel you have benefitted from the physiotherapy programme, what you thought of the resources you were given, 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 your physiotherapy care is completed. You will be able to let us know at that stage whether you wish to be interviewed.

WHO CAN TAKE PART IN THE STUDY?

We are seeking men and women, aged 18 years or older, who meet the following criteria:

- Have had shoulder pain for more than 3 months
- Have not had any shoulder surgery
- Do not have a 'frozen shoulder'
- Have not had a shoulder dislocation or fracture (broken bone)
- Have not got an underlying condition which affects their joints, such as rheumatoid arthritis
- Have not had a steroid injection in their shoulder joint during the previous 3 months.

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 you do meet the criteria after the telephone screen, and agree to take part:

- You will be asked to provide written informed consent or complete an online consent form (e-consent).
- You will be offered an appointment for the second part of the screen. You would need to attend the physiotherapy clinic (Dunedin, Christchurch, Ōtorohanga or Auckland) for about ½ hour. The screening appointment will be held at the physiotherapy clinic in your area which is part of our study.
- At this appointment, a physiotherapist will assess you 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 or discomfort to the physiotherapist.

If you do meet the criteria after the in-person screening, and you agree to take part, the physiotherapist will ask you to complete some questionnaires on a tablet. The questionnaires will ask you about the following:

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

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.

If you agree to take part in the study after you have been screened, you will be randomly assigned to one of two groups. You won't be told which group you are in. You will then be booked in for your first physiotherapy appointment.

If you do not meet the criteria after the in-person screening, you may discuss with the physiotherapist where you could seek care for your shoulder.

Participants in both groups will have an one-hour session with the physiotherapist, followed by ½-hour sessions. The content of the sessions will vary, whereby participants of one group will first be provided information about their shoulder pain and how to self-manage it. For the other group, that information will be spread over more sessions, integrated with usual physiotherapy. Regardless of what group you are allocated, the physiotherapist will share information with you about taking care of your shoulder and lifestyle, and being physically active. You will have access to a website developed by members of the research team that includes additional videos and information.

The treatment received and the number of sessions with the physiotherapist will be adapted to your progress and preference during the study period.

PARTICIPANT'S RESPONSIBILITIES

During the course of the physiotherapy sessions:

- Participants **can** continue to seek treatment for their shoulder with the GP or Rongoa Māori. If you consult with a GP or other practitioners for your shoulder pain, you will be asked to inform the physiotherapist, to be recorded in your clinical notes, as is usual practice.

- Participants are asked **not** to seek care from another physiotherapist, an osteopath or chiropractor for the shoulder while receiving care from the study physiotherapist.

You will be asked to:

- **Report any increases of pain or discomfort you experience**, or other concerns you may have, during the study period to the physiotherapist. They will note those symptoms or concerns in the clinical notes as per usual practice, and will work with you to find out how the treatment or exercises need to be modified.

- **Complete a diary**. This is to record your goals, exercises and physical activity as well as any medication or other appointments (GP visits etc.) you may have needed for your shoulder during the study period. You will get weekly prompts via text or email to complete the diaries for the 3-month period.

- **Complete questionnaires** at five timepoints: following the screening assessment on the Clinic's tablet, and 6 weeks, 3 months, 6 months and 1 year after the first assessment. Except for the first one, you will receive a link via your email address to complete the questionnaire online. If you prefer, they will be posted to you with a return envelope.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

Taking part in 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. They will work with you to find out how much exercise you can tolerate without flaring the pain up unnecessary. All advice that the physiotherapist provides will be tailored to your needs.

Participating in the study will not affect any additional care you may need for your shoulder, such as seeing a specialist or being referred for an ultrasound scan or X-rays. The physiotherapist will guide you and your whānau for those decisions, and make the required referrals, if necessary. They will also guide you as to whether an ACC claim is necessary. If the ACC claim is accepted, costs for referrals to the GP, X-rays and ultrasounds may be covered.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Direct benefits of taking part are:

- you will receive physiotherapy care to help recover from your shoulder pain
- you will be provided information to understand why you have shoulder pain and what you can do about it
- you will undertake exercises for the shoulder movement as well as whole body health
- there is no cost to you in attending physiotherapy care as part of this study.

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 be offered a petrol or a food voucher of $30 for the initial screening appointment (to find out if you can take part in the study) to cover transport costs.

You will **not** be reimbursed for transport/parking or for taking time off from work, should that be necessary, to attend 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, and would be informed should there be any unexpected findings of your health that arise during the course of the physiotherapy sessions.

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. 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 will be held at the respective clinic 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 I 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 different 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. 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 and a Māori researcher (Kairangahau Māori) about the collection, ownership, and use of study data.

CAN I FIND OUT ABOUT THE RESULTS OF THIS 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 ACTRN12624000163505). You will be able to access that registry here: https://www.anzctr.org.au/

WHO IS FUNDING THE STUDY?

A Health Research Council (HRC) grant is funding all costs related to this study, including the physiotherapy sessions and the salaries of the New Zealand researchers.

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 Central Health and Disability Ethics Committee (NZ) has 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:

Dr. Gisela Sole Professor School of Physiotherapy	Contact phone number: 4797466 Email: gisela.sole@otago.ac.nz
Christina Douglas Assistant Research Fellow School of Physiotherapy	Contact phone number: 021 279 0668 Email: christina.douglas@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
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Māori cultural support please contact:

Name: Dr. Ricky Bell
Phone: 0212 545 422
Email: bodyhealthnz@xtra.co.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 0800 555 050
Email: hdecs@health.govt.nz

Consent Form

Stepped care and Physiotherapy for Shoulder pain in New Zealand (StePS-NZ)

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	
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	
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	
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 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's name: _____	Yes/No
I wish to receive a summary of the results from the study. Email address: _____	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: