EXPLANATORY STATEMENT

Project ID: 30397
Project title: The Shoulder HD Pilot Trial: The efficacy of high load-volume exercise versus low load-volume exercise for rotator cuff tendinopathy.

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You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

Why were you chosen for this research?
Thank you for contacting us about this study. You have been chosen for this research because you have responded to our advertisement seeking adults with shoulder pain. After the initial online and telehealth screening you have been chosen because you are over 18 years old and have shoulder pain (rotator cuff tendinopathy).

What does the research involve?
This research will investigate the effects of exercise for people with rotator cuff tendinopathy. Rotator cuff tendinopathy is the most common reason for pain among people experiencing shoulder pain. It is characterised by pain at the front or side of the shoulder and may radiate into the upper arm. Pain is typically worse when lifting the arm, completing overhead activities or generally with increased shoulder activity. The primary aim of this research is to compare the feasibility of two different exercise interventions for rotator cuff tendinopathy.

Participating in this research involves completing a 12 week exercise program. Once enrolled in the study, you will be randomised to one of two different exercise programs. Your exercise program will be guided by an experienced physiotherapist. Over the 12 weeks of your exercise program, you will attend seven supervised physiotherapy exercise sessions. This will be a combination of face to face and telehealth sessions. Prior to your first exercise session, you will attend an initial assessment to measure your baseline function and strength. This session is expected to take approximately 40-60 minutes and will be repeated at 6, 12 and 26 weeks. The strength tests within this session may be video recorded with your consent to allow accurate analysis of this test. You will be asked to complete a series of online questionnaires both at the beginning of the study, at the end of your 12 week program and 6 months from your first session. These questionnaires will detail your functional ability, pain, perceived improvement, health related quality of life, physical activity levels, sleep and any other treatment. Throughout the 12 week exercise program you will be required to log your completed exercises via a simple webform, including your fatigue and worst pain each week. We also ask that you continuously wear an activity tracker device one week at a time for up to 6 weeks of the 12 week period. Remote support will be provided to ensure the device is charged and reconfigured for your convenience. Alternatively, you will be provided with reply paid envelopes to mail the device to the lead investigator, which will then be returned to you as required.

As part of this study we are seeking to understand more about the individual experiences of the participants and clinicians involved in this study. If you agree, you may be contacted by the researchers to complete a semi-structured interview. Participating in this component of the study involves taking part in a recorded interview. The interview is expected to be approximately 30-45 minutes and will be audio recorded, then later transcribed. Prior to analysis of the interview, you will be given a copy of the completed transcript and asked to verify the content and consent to its inclusion in the analysis.

Checking intervention delivery
In order for the research team to ensure the intervention is delivered in accordance with the trial protocol, a small number of randomly selected treatment sessions will be recorded (audio and / or video). The recording will only be made available to the research team members responsible for checking the intervention delivery. You will be required to give your consent to be involved in this process. If you do not give your consent your session will not be recorded.

Consenting to participate in the project and withdrawing from the research

You will be provided with a consent form attached to this information sheet. We request that after reading this information sheet you sign and return the consent form to the lead investigator. Participation is completely voluntary. You are free to withdraw your consent at any time. There will be no adverse consequences if you choose to withdraw. All data will remain anonymous and any data collected prior to your withdrawal may still be used in the analysis. If you withdraw, you will not receive any further treatment or exercise advice but we will be able to provide you with a list of local clinics that treat shoulder pain.

Possible benefits and risks to participants

Participants of this study will receive a free 12 week exercise program, including online web based instructions and seven supervised physiotherapy exercise sessions. You will also be provided with basic exercise equipment if this is required as part of your program. At the completion of the 6 month questionnaires you will receive a $100 gift voucher for your time and any incurred expenses (e.g. travel).

Participating in this study and exercise program may help to improve your pain. From time to time, completing an exercise program may result in short term aggravation of your shoulder pain. Most people who experience any aggravation of their pain find that it resolves over 24-48 hours. We encourage you to record and report any worsening of your symptoms to the research team. We will then be able to provide you with advice about how to manage the pain and the appropriate steps to take.

All precautions will be taken to ensure that the exercise program is appropriate for you and is delivered in a safe and effective manner. All healthcare providers involved in this study will be required to follow current safe health care practices to minimise any potential risk of infectious diseases. You may be required to complete your supervised exercise session via telehealth in order to comply with the current government recommendations and guidelines at the time of your session.

Participating in the interview component of this study will focus on your experience of the intervention. There are no foreseeable adverse events or risks other than inconvenience.

Confidentiality
We intend to protect your anonymity, the confidentiality of your personal information and responses to questionnaires, subject to any legal requirements. Data will be managed and stored securely, only accessible to the research team. You will not be identified in any publications arising from this research as data will be processed by allocated ID number only. Your demographic data such as age and sex, with no links to your name will be reported in the study results if relevant to the outcomes of the project.

Storage of data

The data will be kept securely in a password protected computer of one of the researchers or on REDCap, a server that is password protected and only accessible by named researchers. Data will be kept for five years from the date of completion of the research, before being destroyed when no longer required. Data from the study may be submitted to a data repository that is owned by a scientific journal. This means that other researchers may be able to access this data. No data that could identify you will be submitted to a repository.

Who is funding this trial?
We have obtained funding from the Arthritis Australia Foundation to conduct this trial. The contact details for the lead investigators of this study are found at the top of this information sheet. The Trial Sponsor is Monash University.

Results

The research findings will be collated into a written report and submitted for publication in peer reviewed journals and/or presentations at conferences. Participants will not be identified in the final report. Raw data may be available to researchers on request, but participants will not be identifiable in this data. At the completion of the trial, you may request a copy of your results, including findings from the completed questionnaires. You may also request a written lay statement of the study results which can be emailed to you.

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
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Thank you,

Associate Professor Peter Malliaras
Chief Investigator

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