

Appendix 1. Overview of the physiotherapy intervention: Template for intervention description and replication

TIDier Item	Intervention
Name	Manual therapy plus usual physiotherapy for rotator cuff related shoulder pain (RCRSP)
Why.	There is a need to establish the benefits of manual therapy when added to a holistic, multi-modal approach to physiotherapy for RCRSP. This pilot randomised clinical trial (RCT) explored the feasibility, adherence, treatment fidelity and safety for a full RCT evaluating whether a multi-modal physiotherapy intervention without manual therapy (No Manual therapy group) is as effective as multi-modal physiotherapy interventions with manual therapy (Manual therapy group) for people with persistent RCRSP.
What (materials).	<p>Both groups received pragmatic physiotherapy care including participant education and supported self-management, exercise and physical activity prescription.</p> <p>Participant education: Delivered as part of the face-to-face sessions, supported by online resources (https://shoulderpain.org.nz/). Participants worked through the resource and watched the online videos at home and were asked to define the relevance of that information for their own lives.</p> <p>Exercise prescription: PhysiTrack; Strength training equipment such as free weights and resistance bands.</p> <p>Participant diaries to document goals; progress; physical activity and exercise; pain medication; visits to other health professionals; direct and indirect treatment costs.</p>
What (procedures).	<p>Manual Therapy and No Manual Therapy Groups</p> <p>Goal-setting. Instead of a didactic 'education' approach, the physiotherapist should use a person-centred approach, using empathetic curiosity and a culturally responsive approach to explore the participant's pain experience, goals and devise a rehabilitation plan (1-4). This approach incorporated principles of motivational interviewing and reflective listening (5). Essentially, a 3-stage process will be used where the participants are given choices, asked about their goals and there will be a focus on self-efficacy (based on Bandura's social learning theory) (6).</p> <p>Participant education. Guided conversations between the physiotherapist and participant (7).</p> <p>Anatomy of the shoulder. Surface anatomy of trapezius, deltoid, biceps, and triceps muscles; rotator cuff musculotendinous unit; tendinopathy, partial and full tears; common age-related changes of the rotator cuff; supported by a video on the website.</p> <p>Pain neuroscience. Basic neuroscience knowledge to highlight why the participant might feel pain, factors that influence pain (sensitivity and thresholds) and how to self-manage pain. Supported by a publicly-available video, 'Taming the Beast' by Prof Lorimer Mosely, linked on the website.</p> <p>General physical activity. Influence on persistent pain on body systems (stress levels, autonomic nervous system, sleep, digestion) and importance of</p>

general physical activity to build physical, mental and emotional resilience and well-being.

Whole body health (lifestyle factors). Possible lifestyle factors that the participant could consider. In our previous feasibility study, more than 50% of the participants self-reported two or more comorbidities (7). That highlights the importance of including 'whole body health' into the clinical conversations. This was supported by the metaphor of the 'whole body whānau':

<https://shoulderpain.org.nz/your-shoulder/whole-body-health>

Pain self-management. Identifying what factors are likely to influence participants' pain or risk for flare-ups, for example stress, nutrition, sleep disturbance and exploring individualised strategies to control/manage pain and recurrences thereof. An action plan for recurrences (relapses) were defined. These may have included changes in posture based on symptom-modifying strategies, stress management, sleep hygiene, pacing and chunking of physical activity; <https://shoulderpain.org.nz/faq-s>.

Exercise prescription. Prescription of exercise based on the physiotherapist's assessment, clinical decision making and participant preferences, following a phased approach (8).

- **Early rehabilitation.** Low intensity, slow, controlled movements, including thoracic, glenohumeral and scapular control. Motor control exercises and movement focused on quality.
- **Eccentric and heavy slow resistance.** Progressive isometric, eccentric exercises, and eccentric-concentric exercises. Gradually increasing range, load (weight), frequency and speed.
- **Functional programme.** Trunk and lower limb strength exercises and physical activity with the aim of progressively returning to function in terms of work, sports, daily activities, and recreation. This stage overlaps with 1 and 2 and progresses alongside the shoulder specific exercises.

General Physical Activity. Individualised paced physical activity relevant to the participant. Examples could include walking, cycling, running, yoga, Pilates, Māori rakau, waka ama, rowing, gym.

Manual Therapy Group only: Individualised symptom-modifying processes, focusing on pain and/or stiffness reduction using manual therapy, not restricted to a specific manual therapy concept (9-11). We defined manual therapy as a clinical procedure that involves the application of an external force applied to the participant, by a part of the clinician's body such as their hand, forearm or elbow. It may also be applied with equipment such as a belt, used for applying pressure. The pressure may be sustained, or oscillatory, and may be applied while the participant remains still, or moves a relevant body part. Combinations of applying pressure may also be used. A positive response is an immediate improvement in symptoms, which may manifest as less pain, improved movement, reduced kinesiophobia, and / or a feeling more stable during movement.

- Passive joint mobilizations (12)
- Mobilizations-with-movement (10)
- The symptom-modification approaches (8)
- Thoracic manipulations, following appropriate screening of the participant (13).
- Soft tissue techniques of the cervical spine, axioscapular and glenohumeral muscles.

Who

Physiotherapists and participant-directed home exercises

How	Individual face-to-face treatment sessions, independent exercise sessions, and use of participant resources at home.
Where	University of Otago Physiotherapy Clinics (Dunedin and Christchurch) or Christchurch Physiotherapy & Sports Clinic plus home-based programme.
When	A maximal 3-month treatment period, followed by 3-month follow-up period.
How much	<p>Up to eight physiotherapy sessions. Up to two sessions could have been a duration of 1 hour, with the remaining sessions being 30 min. At least 4 of the treatments sessions should include manual therapy for the Manual Therapy Group, for a minimum total of 10 minutes, including relevant reassessment.</p> <p>The frequency of sessions and discharge were based on collaborative decision-making between the physiotherapist and the participant. The participants had unlimited access to the participant resources up to the end of the 6-month follow-up assessment.</p>
Tailoring	The symptom-modifications, exercise prescription and physical activity were tailored to the participant's specific impairments, functional limitations, and participation requirements, as appropriate for their activities of daily living, work, and recreational/sports demands. The sequence of the educational topics could be varied based on the physiotherapists' judgement and their conversations with the participant.
How well	Participants recorded their activities in hard-copy diaries and physiotherapists recorded assessments and interventions as per clinical requirements. The diaries and participant documentation were audited and summarised qualitatively.

Appendix 2. Detailed patient reported descriptors and outcomes measures

Variable	Description and relevant psychometric properties
Descriptor variable	
Musculoskeletal Outcome Data Evaluation Management System - Patient Expectation Survey (MODEM-E) (14, 15)	The MODEM-E assesses patient expectation that treatment will modify symptoms for five domains: everyday life, sleep, job, exercise and disability. It uses a 5-point Likert scale, and a mean across the 5 domains is calculated where a mean score of '5' indicates high expectations of positive outcomes and '1' indicating very poor expectations of positive outcomes.
Outcome Measures	
Shortened Disabilities of the Arm, Shoulder, and Hand Questionnaire (QuickDASH) (16, 17)	The 11-item QuickDASH assesses disability and symptoms in people with upper extremity musculoskeletal disorders. It assesses the impact of these disorders on daily activities, social functioning, and pain. It uses a 5-point Likert scale to rate the difficulty of performing various tasks due to arm, shoulder, or hand problem. The score ranges from 0 (no disability/symptoms) to 100 (most severe disability/symptoms). A minimal clinically important difference (MCID) ranges between 12 and 15 (16). A non-inferiority margin (NIM) of 11 was selected <i>a priori</i> for analysis of our data.
International Physical Activity Questionnaire – short form (IPAQ-sf) (18)	The IPAQ-sf is an instrument to obtain estimates of physical activity. Participants were asked to enter the number of days and average time (hours or minutes) per week into their hard copy diary. These were provided for walking, moderate-intensity activities and vigorous activities. IPAQ guidelines were used to calculate total metabolic units, categorised as following: Category 1 Inactive (no activity reported or < 600 MET-minutes per week), Category 2 Minimally active (600 to <3,000 MET-minutes per week), or Category 3 Active, meeting World Health Organisation's guidelines (\geq 3,000 MET-minutes per week) (19). Data were extracted from the diaries and entered in a Microsoft® Excel spreadsheet for analysis.
Fear Avoidance Behaviour Questionnaire (FABQ) (20, 21)	The FABQ measures patient's pain-associated fear avoidance beliefs about physical activity and work. It consists of 16 items with a 7-point Likert scale where "0" is "completely disagree" and "6" is "completely agree". The total maximum score is 96, 24 for the subscale Physical Activity, and 42 for Work. A meaningful difference was defined as 8 for Physical Activity and 13 for Work. Cut-off values to indicate "high" scores for patients with shoulder pain have not been established, to our knowledge. In this study we consider scores to be "high" for fear avoidance beliefs for Physical Activity \geq 13/24 and for Work \geq 29/42, based on findings for patients with low back pain (20, 22).
Pain Self-Efficacy Scale (PSEQ) (23, 24)	The PSEQ assesses pain-related self-efficacy in people with chronic pain. It consists of 10 statements and respondents are asked to rate how confident they are with those scenarios/tasks despite the pain. Each statement is rated on a 7-point Likert scale where "0" is "not at all confident" and "6" is "completely confident". A higher score indicates higher self-efficacy beliefs. It has excellent validity, reliability and responsiveness for individuals with musculoskeletal disorders (25). Minimal clinically important difference range from 5.5 to 8.5 for patients with chronic low back pain (25). The minimal detectable change (MDC) over a period of 12 weeks is 11.5 of 60 PSEQ points (25). We considered a score of \geq 48/60 to indicate "high" self-efficacy (26).

Patient Acceptable Symptom State (PASS) (27)

PASS is the highest level of symptom beyond which patients consider themselves well, and has been used to determine to minimally important change for various patient reported outcome measures (28). It is used in adapted version in this study with the question “If you had to live the rest of your life with the symptoms you have now, how would you feel?” (29). Patients were asked to rate their satisfaction on a 4-point Likert scale ranging from “1” (very dissatisfied) to “4” (very satisfied).

Patient satisfaction with the intervention

Patient overall satisfaction with treatment, with frequency and with duration of treatments, and with time spent with the physiotherapists were assessed on a 3-point Likert scale, specific for each domain, for example, ‘not satisfied’, ‘satisfied’ and ‘very much satisfied’ (30)

Appendix 3. Healthcare referrals documented on clinical notes. Grey cells indicate referrals.

Manual Therapy Group				No Manual Therapy Group			
ID	Radiology	General Practitioner	Orthopaedic Surgeon	ID	Radiology	General Practitioner	Orthopaedic Surgeon
16				33			
24				89			
25				93			
47				110			
106				120			
121				131			
137							
147							
150							
Count	7	3	1		2	4	3
X-rays, Ultrasound or Magnetic resonance imaging							

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