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Initial effect of high-volume mobilisation with movement on shoulder range of motion and pain in patients with rotator cuff-related shoulder pain: protocol for a randomised controlled trial (Evolution Trial)

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ABSTRACT

Introduction Mobilisation with movement (MWM) is commonly used for treating patients with rotator cuff-related shoulder pain (RCRSP). However, the evidence supporting MWM efficacy for improving shoulder range of motion (ROM) and pain in patients with RCRSP is limited. It is also unclear whether higher volume MWM leads to better clinical outcomes compared with lower volume MWM in patients with RCRSP. The primary aim of this study is to assess the effect of MWM on the angular onset of pain during shoulder abduction in patients with RCRSP.

Methods and analysis Sixty participants with RCRSP will be randomised to receive either MWM or sham MWM intervention. The primary outcome is the angular onset of pain during shoulder abduction, and secondary outcomes are pain intensity at the angular onset of pain during shoulder abduction, maximum shoulder ROM, pain intensity during maximum shoulder abduction, pressure pain threshold, mechanical temporal summation, global rating of change scale (GROC) and Brief Pain Inventory-Short Form (BPI-SF). The angular onset of pain and the pain intensity at that range will be assessed at baseline, after 1 set and 3 sets of 10 repetitions of MWM or sham MWM. The GROC will be measured immediately after receiving 3 sets of interventions and on day 3 after interventions. The BPI-SF will be measured on days 1, 3, 5 and 7 after interventions. Other secondary outcomes will be assessed at baseline and after 3 sets of interventions. A linear mixed effects model with a random intercept will be used to compare changes in the outcome measures between MWM and sham MWM interventions.

Ethics and dissemination This study has been approved by the University of Otago Ethics Committee (Ref. H21/117). Findings from this study will be disseminated through presentations at international and national conferences and will be submitted for publication in a peer-reviewed journal.

Trial registration number ACTRN 12621001723875.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will determine whether mobilisation with movement (MWM) improves the angular onset of pain in patients with rotator cuff-related shoulder pain (RCRSP) using a robust study design, such as an appropriate sample size, double-blinded, randomised sham-controlled trial.
⇒ This study will be the first study to compare the initial effect of high-volume MWM with low-volume MWM on the angular onset of pain and movement-evoked pain (MEP) measures in patients with RCRSP.
⇒ This study will explore potential mechanisms of action using MEP measures, pressure pain threshold and mechanical temporal summation to explain the effects of MWM on patients with RCRSP.
⇒ A limitation of this study is that we will only assess the immediate and short-term effects of MWM on clinical outcomes in patients with RCRSP.

INTRODUCTION

Shoulder pain is the third most common musculoskeletal complaint in primary care, with a point prevalence and lifetime prevalence reaching up to 26% and 67%, respectively.[1] Recovery from shoulder pain can be slow and long-lasting. Approximately 50% of patients with new episodes of shoulder pain report full recovery within 6 months,[2 3] but 40%–50% of patients with shoulder pain still report persistent pain 6–12 months after consulting their primary care clinician.[3] Approximately 50% of all patients with shoulder pain are diagnosed with rotator cuff-related shoulder pain (RCRSP).[4] Those patients usually present restricted arm

movement and symptoms are exaggerated by overhead activity.[5 6]

Mobilisation with movement (MWM) is a manual therapy technique that aims to restore full range of pain-free movement and is commonly used for treating patients with RCRSP.[7 8] Evidence supporting the use of MWM on those patients is limited due to high levels of heterogeneity between trials and high risk of bias within included studies.[9 10] Together, findings from two reviews highlight the need for high-quality, low risk of bias trials assessing the effectiveness of MWM on peripheral joints (including the shoulder).[9 10] There is a clear need for high-quality trials to assess the short and long-term effects of MWM interventions.[10]

The volume of MWM within a treatment session can be defined as the product of sets and repetitions (sets×repetitions) of MWM performed.[8] The majority of studies treating patients with RCRSP have used a volume of 3 sets of 10 repetitions.[11–19] However, there are variations in the literature, and possibly in clinical practice, regarding sets and repetitions of MWM, particularly during the first session of treatment.[7 8 20] No studies have explored the initial effect of high-volume MWM (3 sets×10 repetitions) compared with low-volume MWM (1 set×10 repetitions) on the angular onset of pain and pain intensity in patients with RCRSP.

A recent meta-analysis found that manual therapy can immediately modulate pain sensitisation in patients with shoulder pain.[21] However, findings are inconsistent between trials[19 22] and are likely influenced by small sample sizes of previous trials, heterogeneity of MWM interventions tested and the use of different types of quantitative sensory testing.[19 22]

To advance our knowledge of the effect of MWM on clinical outcomes and to investigate the effect of dosage, we will explore the following objectives.

Primary objective

Objective 1: To assess the initial treatment effects of MWM in people with RCRSP. We will compare the improvements in the angular onset of pain during active shoulder abduction between the MWM treatment group and the sham MWM treatment group after receiving 1 set of 10 repetitions of treatment and 3 sets of 10 repetitions of treatments, respectively.

Secondary objectives

Objective 2: To assess the effects of MWM treatments on pain intensity during active shoulder abduction at the angular onset of pain, maximum range of motion (ROM) and pain intensity during active shoulder abduction, pressure pain threshold (PPT), mechanical temporal summation (MTS) scores and global rating of change scale (GROC) in people with RCRSP. We will compare the immediate changes in these secondary outcome measures after receiving 3 sets of 10 repetitions of treatments between the MWM treatment group and the sham MWM treatment group.

Objective 3: To assess the incremental effect of receiving additional 2 sets of 10 repetitions of the MWM treatment, after receiving 1 single set of 10 repetitions of treatment. We will examine the changes in the outcome measures after receiving additional 2 sets among those who receive MWM treatment.

Objective 4: To explore the changes in pain intensity and interference measured using Brief Pain Inventory-Short Form (BPI-SF) after receiving 3 sets of 10 repetitions of treatment. We will compare changes between MWM and sham MWM in pain intensity and pain interference over time (days 1, 3, 5 and 7) after receiving the intervention.

METHODS

Patient and public involvement

Patients were not involved in the development of the research question or study design.

Study design

This is a participant-blinded and assessor-blinded randomised sham-controlled trial. Participants will be randomised to either MWM or sham MWM group (figure 1). We followed the Standard Protocol Items: Recommendations for Interventional Trials statement.[23] The study will be reported as per the Consolidated Standards of Reporting Trials.[24] WHO trial registration data set information is described in table 1.

Study setting

The study will be conducted at the Centre for Health, Activity and Rehabilitation Research (CHARR), School of Physiotherapy, University of Otago, New Zealand.

Participants

We will recruit 60 participants with RCRSP from the local community. For the purposes of this trial, RCRSP is an overarching term and is defined as the presentation of pain and dysfunction during shoulder elevation and external rotation, for which other conditions have been excluded.[25] We will screen participants following the British Elbow and Shoulder Society (BESS) guidelines.[6] We widened the criteria proposed by the BESS guidelines and added resisted lateral rotation and resisted shoulder abduction tests due to the challenges in diagnosing patients with shoulder pain and the low sensitivity of most clinical tests for the RCRSP.[26 27] The BESS guidelines will be used to exclude other shoulder conditions and identify if a patient presents with RCRSP. All participants will review the study information sheet and will provide informed written consent before study participation.

Inclusion criteria

Participants must meet all the following criteria:

1. 18–75 years of age.[28]
2. Fully vaccinated against COVID-19.
3. Able to provide written informed consent.

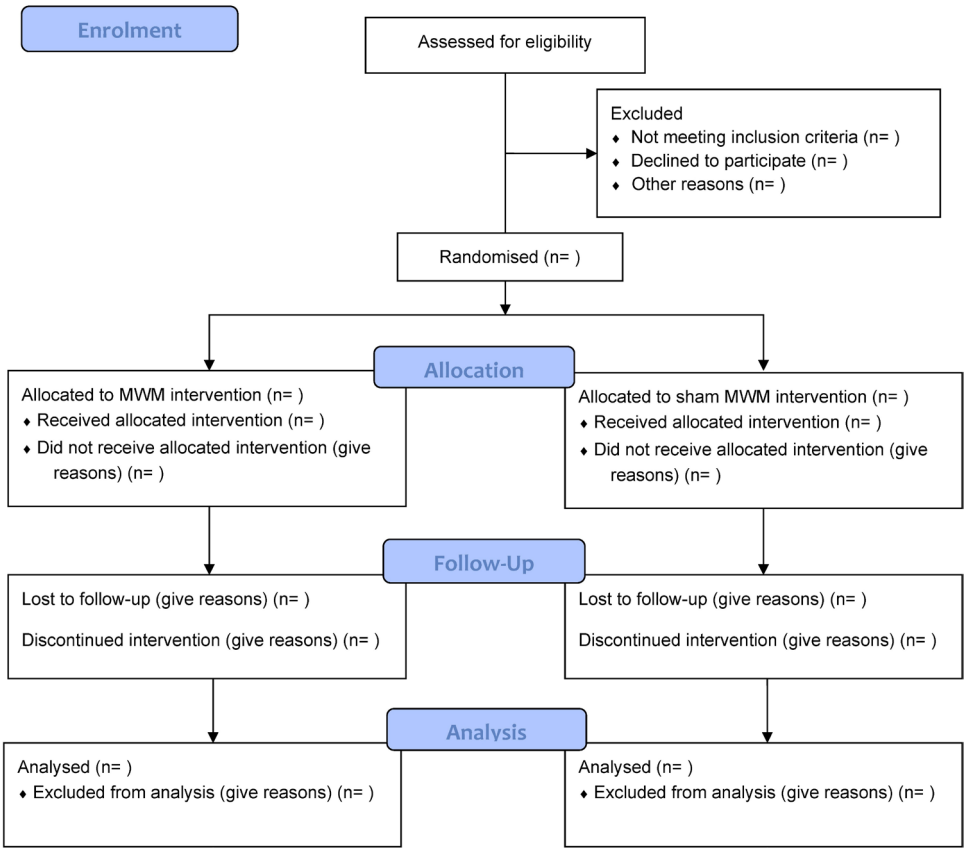

Figure 1 Study flow diagram for the Evolution Trial. MWM, mobilisation with movement.

4. Present with painful arc of movement during shoulder abduction; or pain on resisted lateral rotation or abduction; or positive Jobe's test.[6]
5. Respond positively to the application of the shoulder MWM using sustained posterolateral glide at the initial screening.[7 8] A positive response to MWM was defined as immediate improvement in shoulder pain or movement during application of MWM.[7 8] There are no standard criteria to confirm a positive response to MWM. For the purpose of this study, all participants will be asked during the application of MWM 'Regarding your shoulder pain, how would you describe your arm movement during gentle shoulder mobilisation compared with before receiving the gentle shoulder mobilisation?' Based on the clinical experience by some of our research team members, a positive response to MWM will be defined as an immediate improvement in pain or shoulder movement of at least one point on an 11-point Likert scale. The following scoring system was adopted for that scale: –5 (very much worse) through 0 (unchanged) to +5 (completely recovered).[29] A physiotherapist will apply a posterolateral glide MWM on the participant's glenohumeral joint and subtle changes in glide direction will be required to elicit a positive response to MWM during screening. If the physiotherapist fails to elicit a positive response after a maximum of four attempts of application of MWM, the participant will be excluded.

Exclusion criteria

Participants with any of the following conditions will be excluded:

1. Present signs or symptoms suggesting: acute rotator cuff tear or massive rotator cuff tears (defined by gross shoulder muscle weakness in the absence of pain).[30]
2. History of shoulder or cervical surgery in the past 6 months.[31–33]
3. History of corticosteroid injection on the affected shoulder in the last 6 weeks.[28]
4. History of shoulder subluxation or dislocation.
5. Other shoulder disorders (ie, glenohumeral arthritis, adhesive capsulitis, acromioclavicular joint pain and hemiplegic shoulder pain).[6] We will exclude participants with glenohumeral arthritis or adhesive capsulitis if they present with reduced passive external rotation, as recommended by the BESS guidelines.[6]
6. Symptoms of paraesthesia in the upper extremity.
7. Neurological disease affecting shoulder pain and/or function.
8. Systemic inflammation or disease, or tumour.

Table 1 WHO trial registration data set

Data category	Information
Primary registry and trial identifying number	ACTRN 12621001723875
Date of registration in primary registry	16 December 2021
Secondary identifying numbers	None
Source(s) of monetary or material support	None
Primary sponsor	University of Otago
Secondary sponsor(s)	None
Contact for public queries	daniel.ribeiro@otago.ac.nz
Contact for scientific queries	Dr Daniel Cury Ribeiro, School of Physiotherapy, University of Otago
Public title	The effect of high-volume mobilisation with movement on shoulder range of motion and pain in patients with shoulder pain
Scientific title	The initial effect of high-volume mobilisation with movement on shoulder range of motion and pain in patients with shoulder pain: a randomised controlled trial
Countries of recruitment	New Zealand
Health condition or problem studied	Rotator cuff-related shoulder pain
Intervention(s)	Experimental group: mobilisation with movement Control group: sham mobilisation with movement
Key inclusion and exclusion criteria	Inclusion criteria: Adult participants (from 18 to 75 years old) with rotator cuff-related shoulder pain
Study type	Type: interventional Allocation: randomised Masking: double-blind (participant and outcome assessor) Assignment: parallel Purpose: to (1) determine whether MWM works or not and further (2) explore whether the high-volume MWM leads to better clinical outcomes when compared with low-volume MWM in patients with subacromial shoulder pain
Date of first enrolment	29 March 2022
Target sample size	60
Recruitment status	Recruiting
Primary outcome(s)	Angular onset of pain
Key secondary outcomes	(1) maximum shoulder abduction range of motion, (2) pain at rest, (3) movement evoked pain, (4) pressure pain threshold, (5) mechanical temporal summation, (6) global rating of change scale and (7) adverse event
Ethics review	Approved Date of approval: 17 November 2021 Name and contact details of Ethics committee(s): University of Otago Human Ethics Committee (Ref: H21/117)
Completion date	15 December 2023
Summary results	Not applicable
IPD sharing statement	No

IPD, Individual Participant Data; MWM, mobilisation with movement.

Recruitment

Participants presenting with RCRSP will be recruited by means of periodic advertisement on local newspapers, social media (eg, Facebook), posters, adverts at general practitioner clinics, physiotherapy clinics, announcements through email within the University of Otago.

Baseline assessment

We will collect demographic information from participants (online supplemental file 1). Pain severity and interference in the past 24 hours, shoulder-related function, shoulder pain and disability, and psychological factors (depression, anxiety and stress, dispositional pain

Table 2 Patient-reported outcome measures

Baseline assessment	Questionnaire	Description
Pain severity and interference in the past 24 hours	Brief Pain Inventory-Short Form (BPI-SF)	The BPI-SF is a reliable and valid questionnaire to assess the intensity of pain and the impact of pain on daily activities.[56 57] BPI-SF includes four pain severity items (ie, worst pain, least pain, average pain and current pain) and seven interference items (ie, how pain interferes with general activity, mood, walking ability, normal work, relations with others, enjoyment of life and sleep) rated on an 11-point Numeric Rating Scale (NRS) ranging from 0 (no pain/does not interfere) to 10 (pain as bad as you can imagine/completely interferes). The overall pain intensity score will be calculated by averaging the four severity items, and the overall pain interference score will be calculated by averaging the interference items.[58]
Shoulder-related function	Patient-Specific Functional Scale (PSFS)	The PSFS is a valid and reliable tool for assessing shoulder-related disability and its minimum clinically important difference (MCID) is 1.3 (small change), 2.3 (medium change) and 2.7 (large change).[59] All participants will be asked to name up to three important activities that they cannot perform or are having difficulty performing due to shoulder problems. The participant will be asked to rate the level of difficulty when performing that activity on an 11-point NRS ranging from 0 (unable to perform the activity) to 10 (able to perform the activity at the same level as before injury or problem). An average PSFS score will be calculated by summing the ratings of the nominated activities and dividing by the number of named activities (up to 3).
Shoulder pain and disability	Shoulder Pain and Disability Index (SPADI)	The SPADI is a valid and reliable tool for assessing shoulder pain and function and its MCID is eight points.[60] The SPADI is a patient-reported outcome measure and consists of two subscales: pain intensity and functional disability.[61] The pain subscale has five items, and the disability subscale has eight items. Each item ranges from 0 (no pain/no difficulty) to 10 (the worst pain/so difficult required help).
Depression, anxiety and stress	21-item Depression, Anxiety and Stress Scale (DASS-21)	The DASS-21 is a patient-reported outcome measure and includes three subscales: depression, anxiety and stress.[62] Each item ranges from 0 to 3 with a total score ranging from 0 to 63. Higher scores indicate higher psychological impairment.
Dispositional pain catastrophising	Pain Catastrophising Scale (PCS)	The PCS has 13 items with each item ranging from 0 (not at all) to 4 (all the time).[63] Higher PCS scores indicate higher levels of pain catastrophising.
Fear-avoidance beliefs	Fear-Avoidance Beliefs Questionnaire (FABQ)	The FABQ has two subscales: work and physical activity.[64] The work subscale (FABQ) has seven items and the physical activity subscale (FABQ) has four items. Each item ranges from 0 to 6. The total maximum score is 66, and higher scores represent greater levels of fear-avoidance behaviour.
Pain self-efficacy	2-item Short Form of Pain Self-Efficacy Questionnaire (PSEQ-2)	The items of the PESQ-2 were selected from the original PSEQ version (Items 5 and 9).[65] The maximum PSEQ-2 score is 12 and higher values represent higher confidence levels despite the pain.
Health-related quality of life	EuroQol 5-Dimensional-5 Level Questionnaire (EQ-5D-5L)	The EQ-5D-5L can be used to report health-related quality of life in each of the five dimensions and these dimensions can be converted to a health utility score where 1 represents perfect health and 0 indicates health states equal to death.[66] The health thermometer Visual Analogue Scale (EQ-VAS) takes values between 0 and 100, where 0 indicates the worst imaginable health and 100 indicates the best imaginable health.
Patient expectation	Expectation for Treatment Scale (ETS)	The ETS has four items and each item scores from 1 (partially disagree) to 4 (definitely agree).[67] The total score of ETS is 20 and higher values represent higher expectations.

catastrophising, shoulder specific fear-avoidance beliefs, pain self-efficacy, health-related quality of life and patient expectation) will be assessed by validated questionnaires using patient-reported outcome measures (table 2).

Randomisation

Participants will be randomised to either MWM or sham MWM group with an allocation ratio of 1:1 using varying block sizes. Randomisation lists will be generated by the study statistician using R Software.[34] Treatment allocation will be concealed in numbered, opaque and sealed envelope, prepared by another researcher who is not involved in participant screening, outcome assessment and delivery of interventions.

Blinding

All participants and the outcome assessor (SW) will be blinded to the interventions. The physiotherapists delivering the interventions will not be blinded to group allocation due to the nature of the intervention.

Procedures

All included participants will visit our lab twice, with visits being at least 2 days apart and within 1 week. We selected

this timeframe based on a pragmatic decision to ensure we could book an appointment for participants to receive the treatment. In the first visit, participants with shoulder pain will be screened by a researcher (SW) with 5 years' clinical experience in musculoskeletal disorders not involved with random allocation or delivery of interventions. All participants will provide demographic information and complete baseline assessment using web-based or paper-based questionnaires. If participants are eligible, the intervention will be booked for the second visit. The second visit will be coordinated by the researcher (SW) and determined by the available time to participants, researcher (SW), and physiotherapists. In the second visit, patients' expectation of treatment assessed by the ETS will be recorded before participants receive MWM or sham MWM treatment. The schedule of enrolment, intervention and interventions are presented in online supplemental file 1.

Interventions

Interventions will be delivered by physiotherapists with experience in management of patients with musculoskeletal disorders and familiar with the MWM technique. When delivering the interventions, the physiotherapist will inform participants that the intervention (ie, MWM or sham MWM) must be pain-free and the technique should be stopped if any painful symptoms are aggravated during the procedure.

Mobilisation with movement

Participants allocated to the MWM group will receive a posterolateral glide MWM technique on the glenohumeral joint and subtle changes in glide direction are allowed. Participants will sit on a chair and the physiotherapist will stabilise but not fixate the scapula with one hand and place the other hand over the anterior aspect of the head of the humerus.[7 8] The physiotherapist will sustain the posterolateral glide on the humeral head during active shoulder abduction (elevation in the frontal plane). Passive overpressure at the end of shoulder abduction will be applied by the participant during the MWM procedure if the participant presents a full ROM that is pain-free.[7 8] The volume of intervention will consist of 3 sets of 10 repetitions of MWM with an interval of 60 s between sets.

Sham mobilisation with movement

The sham MWM will replicate the MWM condition, except for the posterolateral glide applied at the glenohumeral joint. During the sham condition, no pressure will be applied to the glenohumeral joint. The physiotherapist will stand on the contralateral side of the painful shoulder and place one hand along the clavicle and sternum and the other hand on the posterior aspect of the humeral head of the painful shoulder.[13 19] The physiotherapists will maintain the placement of the hands, simulating the MWM technique (but without pressure) while the participant performs shoulder abduction movements. However, the passive overpressure at the end of shoulder abduction will not be applied in case of aggravating shoulder pain. The number of sets, repetitions and time interval between sets will be identical to the MWM condition. This sham technique was successfully used in previous studies.[13 19]

Outcome measures

The primary outcome measure is the ROM at the onset of pain during shoulder abduction (ie, angular onset of pain). Patients may avoid abduction or elevation movements that aggravate RCRSP affecting their ability to carry out activities of daily living.[35] Hence, determining restrictions or changes of the angular onset of pain during active shoulder abduction as a result of MWM treatment will be clinically relevant.

The secondary outcome measures are the maximum ROM during active shoulder abduction, movement-evoked pain (MEP) measures (ie, pain intensity at the angular onset of pain, pain intensity during maximum shoulder abduction), pain at rest, measures of peripheral and central sensitisation, which includes PPT, MTS and GROC. We will standardise the measurements before and after interventions. The sequence of outcome measures will be (1) pain at rest, (2) angular onset of pain, (3) MEP at the angular onset of pain, (4) maximum ROM, (5) MEP during maximum ROM, (6) PPT at the shoulder and leg, (7) MTS at the shoulder and leg and (8) GROC. Prior to outcome measures, we will explain measurement procedures to participants using a preprinted protocol (online supplemental file 2) to familiarise participants with procedures. All participants will also complete BPI-SF to record pain severity and interference at baseline and days 1, 3, 5 and 7 after the intervention. Additionally, any adverse events will be recorded 48 hours after interventions.

Primary outcome

Angular onset of pain

The angular onset of pain will be measured using a digital inclinometer (Acumar, Model ACU 360, Lafayette Instrument Company) and expressed in degrees. The inclinometer will be zeroed using a vertical reference level to ensure accurate measurements.

If participants present no pain at rest, the researcher (SW) will record participants' angular onset of pain when participants report they started to feel pain during active shoulder abduction. If a participant presents pain at rest, the angular onset of pain is defined as the range in which participants feel their resting shoulder pain started to increase during active shoulder abduction. To standardise the angular onset of pain measurement, participants will be sitting with the trunk upright and will abduct their affected arm in the frontal plane with their thumb pointing up towards the ceiling. To ensure participants abduct their arms in the frontal plane, we will place a plastic stadiometer on their side.

Five trials of angular onset of pain during shoulder abduction will be measured. Once the end range of

angular onset of pain during active shoulder abduction is achieved, the inclinometer will be placed parallel to the humerus, on the distal arm and proximal to the elbow, and the measurement will be recorded.[36] Mean ROM will be calculated and used for statistical analysis.

Secondary outcomes

Maximum range of motion

Maximum ROM during active shoulder abduction will be measured using the digital inclinometer. The importance of maximum ROM measurement is to reflect the behaviour of daily activities. In order to standardise the ROM measurement, participants will be positioned the same way as described for measuring the angular onset of pain during shoulder abduction. Participants will be instructed to abduct their affected arm as much as they can in the frontal plane with the starting posture of thumb pointed up towards the ceiling.

Five trials of maximum ROM during shoulder abduction will be measured. Once the end range of maximum active shoulder abduction is achieved, the inclinometer will be placed parallel to the humerus, just on the distal arm and proximal to the elbow, and the measurement will be recorded.[36] Mean maximum ROM will be calculated and used for statistical analysis.

Pain measurements

We will measure pain at rest and MEP. An 11-point Numeric Pain Rating Scale (NPRS) ranging from 0 (no pain) to 10 (worst pain imaginable) will be used to measure pain intensity. We assessed the PPT and MTS to explore the potential mechanisms of MWM in patients with RCRSP.

The MEP, PPT and MTS will be used for exploratory purposes to help us understand whether MWM has any effect on pain improvement and whether the changes in MEP measures mediate the change in the angular onset of pain.

Pain at rest

Pain is a complex experience and symptoms may differ when at rest or during movement.[37] For that reason, pain at rest will be measured at baseline, immediately after receiving 1 set and 3 sets of 10 repetitions of MWM or sham MWM. Participants will be asked: 'Please rate how much pain you have right now on a scale of 0 (no pain) to 10 (worst pain imaginable)?' The NPRS is a valid and reliable tool for assessing pain level and it's minimum clinically important difference is 1.1 in patients with shoulder pain.[38]

Movement-evoked pain

MEP is the pain that is provoked and experienced during active or passive movement and is measured during or immediately after completing that movement.[39] The intensity of MEP will be measured immediately following each trial of angular onset of pain and maximum ROM during shoulder abduction. Mean pain severity will be calculated for both angular onset of pain and maximum ROM contexts.

Pressure pain threshold

The PPT is the minimal pressure intensity that induces a painful sensation.[40] Measuring PPT will allow us to assess for the presence of hyperalgesia or decreased response to mechanical pain stimuli.[41] This measure is valid and reliable for measuring pain threshold.[42 43] An electronic handheld pressure algometer (Wagner Force One FDIX, Wagner Instruments, Greenwich, USA) will be used to quantify pain intensity following standardised procedures.[18 19 44] A 1 cm^2 algometer probe will be used to apply pressure at a rate of 50 kPa/s perpendicularly to the skin of the mid-belly of the medial deltoid (5 cm caudal to the lateral border of the acromion) of the affected shoulder and one on the contralateral tibialis anterior (5 cm inferior and 2.5 cm lateral to the tibial tubercle).[44] The PPT of both sites will be measured alternatively and the procedure will be repeated three times. The PPT measure at the same location will have an interval of at least 60 s.

Mechanical temporal summation

We will assess MTS using a nylon monofilament (Semmes monofilament 6.65, 300 g).[45 46] MTS procedure will be carried out at two sites: on the mid-belly of the medial deltoid (4 cm caudal to the lateral border of the acromion) of the affected shoulder and in one remote, non-painful location (ie, contralateral tibialis anterior; 7 cm inferior and 2.5 cm lateral to the tibial tubercle).

Ten repetitive stimuli will be delivered at each site and externally cued by a metronome set at 1 Hz. Participants will immediately rate their pain intensity after the first stimulus and rate their greatest pain intensity during the 10 stimuli on the NPRS separately. MTS will be calculated for each participant by subtracting the mean first stimulus rating from the mean greatest 10^{th} stimulus rating. The MTS of both sites will be measured alternatively, and the procedure will be repeated two times.

We will identify the bone markers (acromion and tibial tubercle) by manual palpation and then measure the distance by a calliper for measurement sites, which will be marked with a marker pen to ensure standardisation between baseline measurement and postintervention measurement. We will follow the DFNS recommendations for measuring PPT and MTS and standardise the verbal instructions.[47]

Global rating of change

To quantify the extent to which participants improve or deteriorate immediately after MWM or sham MWM intervention, we will use an 11-point GROC to measure the global rarting of change immediately after receiving 3 sets of 10 repetitions of MWM or sham MWM separately. The GROC ranges from –5 (very much worse) through 0 (unchanged) to +5 (completely recovered).[29] All participants will be asked: 'Regarding your shoulder pain, how would you describe your arm movement now compared

with before receiving the gentle shoulder mobilisation?' A change of 2 points or more is considered clinically meaningful.[29]

Adverse events

A previous study reported near half of the patients receiving manual therapy presented minor to moderate adverse events within 24 hours.[48] Minor adverse events are defined as non-serious events, present within a short-term period after the intervention was delivered, with mild intensity and no medical treatment is required. Moderate adverse events are defined as unacceptable events, present within a medium to long-term period and with moderate intensity.[49] These adverse events tend to be more common after the first manual therapy treatment and are usually resolved within 72 hours.[48] Major adverse events are defined as unacceptable events, present with medium-term to long-term period, moderate to severe intensity and usually require further medical treatment, for example, fracture which needs further medical treatment.[49] The risk of major adverse events related to the MWM or sham MWM intervention is very low.[50]

To monitor the adverse events of interventions, any intervention-related adverse events will be reported. Participants will be contacted via email or phone within 48 hours after receiving the intervention and will be asked the following question: 'Have you experienced any discomfort or unpleasant sensation (eg, soreness, pain or any other symptoms) you might have perceived as a result of this treatment?'. If yes, the negative response will be recorded.

Time points and follow-up

Outcome measures will be recorded at baseline, immediately after the 1st set of 10 repetitions, immediately after the 3rd set of 10 repetitions of MWM or sham MWM intervention, days 1, 3, 5 and 7 after MWM or sham MWM intervention. A previous study reported that a single session MWM technique could improve current pain intensity in patients with RCRSP for 30 min but less than 24 hours or 7 days.[18] To explore if there are any changes in pain during the 7 days following the intervention, we will ask participants to complete the BPI-SF on days 1, 3, 5 and 7 after MWM or sham MWM intervention. We presented detailed information in online supplemental file 1.

Sample size

When calculating sample size, the assumed standard deviation (SD) was calculated based on a previous similar study conducted by our group, which compared the initial effects of MWM vs sham MWM on the angular onset of pain in the frontal plane in patients with RCRSP.[51] Assuming a SD of 19° for the difference in angular onset of pain changes from the baseline to the follow-up assessment (after receiving 3 sets of 10 repetitions of MWM) between the two treatment arms, a sample size of 28 participants per group is required to detect a 14.5° difference between the two treatment arms, with a power of 80% and a significance level of 5%. Therefore, a total number of 56 participants will be recruited. Assuming a drop-out rate of 5%, a total of 60 participants are required. The sample size was calculated using G*Power (V.3.1, University of Kiel, Germany).

Statistical analysis

A linear mixed effects model with a random intercept will be used to compare the changes in outcome measures (from baseline to the time after receiving 1 set, and 3 sets of treatments, respectively) between the MWM and sham MWM groups (objectives 1 and 2). The model includes time, treatment and an interaction between time and treatment as covariates. All the outcome measures (baseline, after one set of treatments and after three sets of treatments) will be retained as part of the outcome variable. We will also estimate the difference in changes in the outcome measures from time 1 (after receiving one set) to time 2 (after receiving three sets) between the MWM and sham MWM groups (objective 3). The 95% CIs of the estimates will also be reported. Sensitivity analyses will include adjustments for the baseline value of the outcome measure (treating baseline value of the outcome as a covariate in the model) and any baseline imbalance. We will also assess the difference in changes in BPI-SF over time (days 1, 3, 5 and 7 after treatment) between the MWM and sham MWM interventions (objective 4). An intention-to-treat analysis will be used. All statistical analyses will be performed using Stata V.17.0 software (Stata).[52]

DISCUSSION

This study will assess whether MWM improves the angular onset of pain and pain intensity during active shoulder abduction immediately in patients with RCRSP. We will also determine the clinical effects of an additional 2 sets of 10 repetitions of MWM treatment after receiving 1 set of 10 repetitions of MWM treatment.

In this study, we will compare the initial treatment effect of MWM on shoulder ROM and pain in patients with RCRSP as the initial MWM treatment is associated with the likelihood of successful management of the shoulder pain. Given MWM should only be implemented in patients who respond positively to the initial test, we will only include participants who respond positively to the MWM technique.[53] This decision is in agreement with classic textbooks[7 8] and increases the external validity of our findings. As MWM is a specific type of manual therapy, both movement performed by patients and manual contact by clinicians could induce context effects.[54] Therefore, we chose a sham MWM treatment as the comparator rather than no treatment as we want to evaluate the specific effects of MWM.[54]

Given the dosage of MWM could affect the effectiveness of treatment,[55] we will explore the initial treatment effects of high versus low-volume MWM on the angular onset of pain and pain intensity in patients with RCRSP.

This study is a step towards advancing knowledge in the field of MWM and shoulder rehabilitation for patients with RCRSP who respond positively to MWM. If findings support its effectiveness, they will inform the development of evidence-based recommendations for the use of MWM in patients with RCRSP who respond positively to the initial application of MWM.

DATA MANAGEMENT

Data will be collected by a researcher using hard copies of forms and questionnaires or web-based questionnaires. These data will be anonymous and remain confidential and will be kept in a safe and locked cupboard to be accessed only by the research team. These will be safely stored and locked in a filing cabinet based at the CHARR, School of Physiotherapy, University of Otago. The researcher will enter the data into a Microsoft Excel file, and only the research team will have access to that file. All trial documents will refer to participants with a unique ID (not by name).

TRIAL MONITORING

Data monitoring committee from the CHARR will monitor and oversee the trial. The research team has opted not to undertake interim analysis.

ETHICS AND DISSEMINATION

Research ethics approval

This study has been approved by the University of Otago Ethics Committee (Ref. H21/117).

Protocol amendments

We will report any important amendments of protocol that may benefit participants, impact participants' safety or that are likely to impact the outcomes of the study, such as study objectives and/or design changes, sample size, study procedures or significant administrative changes.

Consent

Detailed information about this study and experimental procedures will be provided to all participants before signing the written informed consent. All participants will be requested to sign a detailed informed consent before starting any experimental procedure.

Confidentiality

The research team will have access to personal information. We will use group mean data to present findings from the study. This will protect confidentiality before, during and after the trial.

Dissemination

Findings from this study will be disseminated through presentations at international and national conferences and will be submitted for publication in a peer-reviewed journal.

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Contributors SW and DCR conceived the research question. SW, JZ, CMC, RM and DCR were responsible for the design of this study. SW, JZ, CMC, RM and DCR were involved in writing the manuscript draft. All authors have contributed, edited and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

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