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The effectiveness of a tailored rehabilitation versus standard strengthening programme for patients with shoulder pain: a protocol for a feasibility randomized controlled trial (the Otago MASTER trial)

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Abstract

Introduction: We know that exercise therapy is more effective than placebo for the management of patients with shoulder subacromial pain. However, we do not know whether a tailored rehabilitation programme is more effective than a standardized strengthening programme. The aim of this feasibility trial is to assess: (1) participant recruitment rate; (2) the proportion of participants enrolled from the total number screened; (3) adherence to the rehabilitation programme; (4) drop-out rates; (5) obtain estimates of adverse reactions to treatment; (6) obtain estimates of intervention effects in order to inform the sample size of the fully-powered RCT; (7) conduct a preliminary cost-effectiveness analysis of the standardized strengthening and the tailored rehabilitation interventions.

Methods: The Management of subacromial disorders of the shoulder (MASTER) trial, is a two-arm, patient- and assessor-blinded, randomized controlled feasibility trial. Patients will be randomly allocated into one of the interventions group: tailored or standardized rehabilitation. To obtain estimates of intervention effects, we will compare changes in pain and shoulder-related disability scores between the two intervention groups using a repeated mixed-model analysis of variance, with alpha set at 0.05, and power at 80%. Since this is a feasibility study, we will not adjust alpha for multiple comparisons. To determine whether it is feasible to conduct the full trial, we will consider 75% CI as the probability threshold at 3-month follow-up.

Discussion: The short-term impact of this phase II trial is to inform whether or not it is feasible to conduct the full efficacy trial. The medium-term impact of this proposal will be to determine which intervention is superior for treating patients with shoulder subacromial pain.

Ethics and Dissemination: This study was approved by the University of Otago Ethics Committee [H17/080]. Findings from this study will be presented at conferences, and will be submitted for publication in a peer-reviewed journal.

Trial registration number: ANZCTR: 12617001405303.

Keywords: shoulder, rehabilitation, manual therapy, randomized controlled trial.

Word count: 3688

Article summary

Strengths and limitations of this study

- This protocol is to compare one intervention that is tailored to patient's physical impairments with a standardized strengthening programme.
- The feasibility trial will include economic evaluation, and implementation-based process evaluation of the intervention planned.
- Clinicians were not blinded to interventions due to nature of interventions, and that is a source of potential bias.

Introduction

Shoulder pain is the third most common musculoskeletal complaint, with a one-year prevalence of 18.1%.[1] Shoulder pain is associated with high socioeconomic burden.[2] In Sweden, the average annual cost of shoulder subacromial pain is estimated $4,139 per patient.[2] In NZ, a total of $134 million was spent by ACC in rehabilitation for shoulder injuries from 2005 to 2013 ($14 million/year).[3]

Exercise therapy is the first approach for the management of shoulder subacromial pain, and has moderate to strong effect on pain and function.[4 5] Exercise therapy is more effective than control or placebo;[5 6] and has the same effect as, while being less costly than, surgery.[5 7-9] Despite that, shoulder subacromial pain is a challenging disorder with slow recovery,[10] with only 50% of new episodes presenting full recovery within 6 months.[11] Optimal treatment strategies are needed to improve treatment effect, speed recovery, and decrease shoulder pain recurrence.

Patients with shoulder pain present with altered scapular and shoulder muscle recruitment patterns.[12 13] Due to such altered muscle pattern, it is recommended that rehabilitation should tailor specific muscle and joint impairments presented by the patient.[14] Manual therapy interventions, such as clinician-administered sustained shoulder mobilization, reduce pain and improve range of motion in patients with shoulder subacromial pain.[15] Interventions including sustained glides have been shown to be superior to standard treatment approaches in other musculoskeletal conditions.[16]

Laboratory-based studies suggest that: (1) clinician-administered sustained shoulder mobilization offloads shoulder muscles, providing mechanical support to the shoulder;[17] (2) patient-administered sustained shoulder mobilization leads to similar changes in muscle activity levels as clinician-administered mobilization, supporting the use of home-based mobilization for shoulder rehabilitation;[18] (3) patients with shoulder pain present immediate reduction in pain levels, increased range of motion, and altered muscle activity levels in response to sustained shoulder mobilization.[19] These findings, and anecdotal evidence from clinical practice, suggest that sustained mobilization temporarily changes the control of scapular and shoulder muscles. Such temporary change gives the clinician a therapeutic window to strengthen muscles with less pain while keeping a better control of scapular and shoulder muscles.

We propose investigating whether a tailored rehabilitation (combining sustained mobilization with specific motor control exercises) might be more effective than standard exercise for shoulder pain patients. Tailored rehabilitation focuses on patient's specific impairments.[20-24] On the other hand, standard shoulder rehabilitation adopts a 'one size fits all' approach, with standard stretching and strengthening exercises being prescribed for all patients, and may also be delivered in small group sessions, reducing the cost of the physiotherapy session. It is unclear which approach leads to better clinical outcomes and is more cost-effective. We hypothesize that the tailored rehabilitation programme is more effective and has a shorter time-to-recover, as it addresses patient's specific impairments.

Efficacy trials are designed to test if an intervention works under the ideal circumstances.[25] This type of trial maximises the probability of observing the effect of an intervention (assuming such effect exists), and emphasise internal validity of the study design.[25] In efficacy trials, the intervention is standardized, delivered under an ideal setting, with highly trained clinicians.[25] It is recommended for efficacy trials to incorporate economic evaluation (i.e. cost-efficacy) alongside the clinical efficacy assessment.[26] By conducting clinical and cost-efficacy assessment it is possible to determine whether an intervention is likely to be efficacious for a group of patients, delivering better health outcomes for healthcare expenditure.[27] Ideally, clinical and cost-efficacy studies should be conducted prior to clinical- and cost-effectiveness pragmatic trials.[26]

The aim of our full study is to assess the clinical- and cost-efficacy of tailored rehabilitation programme compared to standard rehabilitation for the treatment of shoulder subacromial pain. Prior to conducting a fully-powered randomized controlled trial (RCT), we propose an efficacy feasibility trial aiming to assess: (1) participant recruitment rate; (2) the proportion of participants enrolled from the total number screened; (3) adherence to the rehabilitation programme; (4) drop-out rates; (5) obtain estimates of adverse reactions to treatment; (6) obtain estimates of intervention effects in order to inform the sample size of the fully-powered RCT; (7) conduct a preliminary cost-effectiveness analysis of the standardized strengthening and the tailored rehabilitation interventions.

Methods

Design

The Management of subacromial disorders of the shoulder (MASTER) trial, is a two-arm, patient- and assessor-blinded, randomized controlled feasibility trial. Patients will be randomly allocated into one of the interventions group: tailored rehabilitation or standardized rehabilitation (Figure 1). We do not plan to have a 'no treatment group', as there is moderate to strong evidence showing that the planned standardized exercise is more effective than control or placebo.[7 28 29]

Figure 1

For preparing this protocol, we followed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement,[30] and the template for intervention description and replication (TIDieR) checklist and guide.[31] When reporting the feasibility trial, we will follow the Consolidated Standards of Reporting Trials (CONSORT) statement for non-pharmacological treatment.[32] The trial has been prospectively registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR: 12617001405303). World Health Organization trial registration data set information is described on Table 1.

Table 1. World Health Organization trial registration data set.

Data category	Information
Primary registry and trial identifying number	Australian New Zealand Clinical Trial Registry (ACTRN 12617001405303)
Date of registration in primary registry	04/10/2017
Source of monetary or material support	Health Research Council of New Zealand Feasibility Grant (17/536)
Primary sponsor	University of Otago
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	Tailored versus standard strengthening rehabilitation for patients with shoulder pain: a feasibility trial
Scientific title	The effectiveness of a tailored rehabilitation versus standard strengthening programme for patients with shoulder pain: a feasibility randomized controlled trial (the Otago MASTER trial)
Country of recruitment	New Zealand
Health condition or problem studied	Shoulder subacromial pain
Interventions	Tailored and standardized strengthening exercise
Key inclusion and exclusion criteria	Adult healthcare workers (from 18 to 65 years old), with subacromial shoulder pain.
Study type	Interventional
Date of first enrolment	12/02/2018
Target sample size	25
Recruitment status	Recruiting
Primary outcome	(1) Recruitment rate, (2) Proportion of participants enrolled from the total number screened, and (3) Adherence to the rehabilitation programme.
Key secondary outcome	(1) Drop-out rates, (2) Pain level, (3) Shoulder-related disability – patient specific functional scale, (4) quality-adjusted life year, (5) Shoulder Pain and Disability Index (SPADI), (6) Adverse reactions.

Participants

Patients with shoulder subacromial pain will be recruited to take part in the study.

Inclusion and exclusion criteria

Patients from 18 years and 65 years old, with mechanical shoulder pain will be recruited to participate in the study. Participants will be screened as per the British Elbow and Shoulder Society (BESS) guidelines.[33] Participants will be included if they present one positive finding on the following tests: (1) Painful arc movement during shoulder flexion or abduction; or (2) pain on resisted lateral rotation or abduction or Jobe's test.[33]

We will exclude participants with the history of shoulder dislocation, shoulder subluxation, shoulder surgery and cervical surgery within the last 6 months,[34] participants with symptoms of inflammation or systematic disease, signs of paraesthesia in the upper extremities, hemiplegic shoulder pain, frozen shoulder, or positive clinical signs of full thickness rotator cuff tear [35] will be excluded.

Sample size

Being a pilot RCT, the present study is not designed to assess the efficacy of the experimental intervention.[36 37] We estimated the sample size based on expected characteristics of the full trial.[38] Based on recommendations by Whitehead et al.[38], the sample size of a feasibility study should be estimated based on the expected range for the effect size, the power and alpha (both established *a priori*), and the total number of arms of treatment planned for the full trial.

When estimating the sample size for this feasibility study, we assumed the effect size of the full trial will range from 0.3 to 0.7, the power at 80%, alpha at 0.05, and we plan two parallel arms for the full trial. Therefore, the minimum sample size for this feasibility RCT is 10 participants per arm of treatment.[38] Assuming a 20% loss to follow-up,[39] a total sample size of 25 participants is required.

Recruitment

Participants will be recruited from the local community and hospitals, and medical practitioners. Participants will be screened by a physiotherapist with more than five years of clinical experience, and with a postgraduate qualification in Musculoskeletal or Sports Physiotherapy (or related field).

Informed consent and baseline assessment

Once participants are assessed for eligibility, a clinical researcher will seek informed consent from participants. Participants may consent to take part in the study after screening or few days later, if they request time for considering taking part in the study. Participants will be asked to complete the baseline assessments and questionnaires for recording demographic data, and baseline measurements for the primary and secondary outcomes.

Randomization

Participants will be individually randomly allocated (1:1 ratio) into one of the intervention groups (i.e. tailored physiotherapy or standardized physiotherapy). The randomisation schedule will be computer-generated by a research administrator, and concealed in numbered sealed and opaque envelopes. A research administrator will provide the envelope to the clinician delivering the interventions.

Blinding

Participants will be blinded to interventions. Outcome assessors will be blinded to group allocation. Clinicians delivering the interventions will not be blinded to group allocations due to nature of intervention.

Procedures

Experienced clinicians will deliver interventions for both groups. Clinicians will have a postgraduate diploma in musculoskeletal rehabilitation (or related field) and a minimum of 5 years of clinical experience. Outcome measures will be assessed by a physiotherapist who is blinded to group allocation.

Interventions

Both groups will receive 16 individual, face-to-face sessions, each lasting for 60 min, twice per week, over an 8-week period. This number and duration has been shown to improve clinical outcomes in patients with shoulder subacromial pain.[40] Eight weeks intervention period has been suggested as the minimum required to lead to improvement in pain and range of motion in patients with shoulder pain.[40] The tailored and standardized rehabilitation interventions are described on Tables 2 and 3 respectively. These descriptions were prepared following the template for intervention description and replication (TIDieR) checklist and guide.[31]

Both groups will receive similar dosage of exercises. Participants will perform a total of 8 exercises per session of treatment, plus three stretches (control group) or up to three manual therapy techniques (tailored group). To ensure optimal internal validity of the trial, dosage of exercises for each group are planned to be equivalent. Details of tailored and standardized interventions are described on the Exercise Description Forms (Supplementary Material 1 and 2, respectively). The intensity of strengthening exercises will be monitored using a modified Borg scale.[41] Rate of perceived exertion was shown to be valid for monitoring intensity of resistance training,[42] and has been used in a previous trial for monitoring exercise intensity.[43]

Tailored rehabilitation: participants allocated to the tailored rehabilitation group will receive sustained mobilization followed by exercises focusing on restoring normal movement pattern and the dynamic stability of the scapulothoracic and glenohumeral joints.[14 44] The intervention will involve manual therapy techniques focusing on restoring the shoulder and scapular movement to reduce pain,[45] and motor control and progressive resistance training of impaired muscles.[40 44]

Table 2. Description of tailored rehabilitation intervention, as per the template for intervention description and replication (TIDieR) guide.

Item number	Item	Description
1.	**BRIEF NAME** Tailored rehabilitation	
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.	The tailored rehabilitation programme will focus on specific impairments presented by the patient. This intervention will consist of mobilization with movement, passive accessory mobilization, specific motor control exercises and specific muscle strengthening exercises. The tailored rehabilitation

Item number	Item	Description
		programme might be more effective than a standardized strengthening programme for patients with subacromial shoulder pain.
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	The tailored rehabilitation group will receive manual therapy techniques (including mobilization with movement with taping)[45 46], motor control and strengthening exercises. Manual therapy interventions delivered by the clinician might be performed with a belt. Motor control and strengthening exercises might be performed with the use of elastic bands or dumbbells. Home-based exercises will consist of self-mobilization techniques that is performed with a belt.
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Clinicians will choose exercises based on physical impairments presented during the physical assessment.
5.	**WHO PROVIDED** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Experienced clinicians will deliver interventions for the tailored group. Clinicians will have a postgraduate diploma in musculoskeletal rehabilitation (or related field) and a minimum of 5 years of clinical experience. All clinicians will undergo a trial-specific training programme to ensure they understand the protocol and the rationale of the intervention. Clinicians will receive a detailed manual with information regarding the trial intervention.
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Participants will receive individual, face-to-face sessions.
7.	**WHERE** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Interventions will be delivered in a private clinical practice.
8.	**WHEN and HOW MUCH** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Participants will receive 16 sessions, each lasting for a maximum of 60 min, twice per week, over an 8-week period. The exercise programme will comprise of 8 exercises plus 3 optional manual therapy techniques (one for the cervical spine, one for the thoracic spine and one for the shoulder). Clinicians will decide on which

Item number	Item	Description
		technique to use based on participants' clinical presentation. The manual therapy techniques might consist of passive joint mobilizations (grade -IV, IV, or +IV) or manipulation (for the cervical or thoracic spine). Mobilization with movement techniques will count as one of the 8 possible exercises to be performed within a session. This technique will be performed with 3 sets of 10 repetitions, with 30 seconds of rest between each set. Passive joint mobilizations will be performed with the following dosage: 3 sets, 30 seconds duration. Grade: –III or –IV will be performed if pain is dominant (as per physical assessment) or grade +III or +IV if stiffness dominant (as per physical assessment). Joint manipulation will be performed once per session, if required, as per physical assessment. The clinician will have the freedom to decide which technique to perform. Isometric exercises will be delivered with the following dosage: 2 sets, 10 repetitions, with 10 seconds hold each repetition. The isometric exercises will be progressed in two stages. The first stage will have the following dosage: 3 sets, 10 repetitions, with 10 seconds hold each repetition. The second stage will have the following dosage: 3 sets, 10 repetitions, with 20 seconds hold each repetition. There will be 10 seconds rest between repetitions, and 30 seconds rest between sets. Dynamic strengthening exercises will be delivered with the following dosage: 2 sets of 10 repetitions. The dynamic strengthening exercises will be progressed in two stages. The first stage will have the following dosage: 3 sets of 10 repetitions. The second stage will have the following dosage: 3 sets of 20 repetitions. All exercises should initially be performed in slow and controlled pace. All motor control exercise should initially be of low intensity and then progressed as described. Clinicians can increase dosage (repetitions, sets, or load) if the participant is able to perform low intensity exercise for two consecutive sessions. The load for strengthening exercises will be determined through using the 10-point Rate of Perceived Exertion (RPE) scale, considering the affected side. Low intensity will be defined as 3-4 RPE, moderate intensity as 5-6 RPE, and high intensity as 7-8 RPE.

Item number	Item	Description
		Exercises will start with low intensity, and can progress to moderate and high intensity during the course of treatment.
9.	**TAILORING** If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Interventions will be tailored based on physical assessment. Participants will receive: - Shoulder mobilization with movement if, during assessment, participants improve range of motion and pain with the MWM technique. As part of the treatment, clinicians might use an MWM taping technique.[45 46] - Passive mobilization on the cervical, thoracic spine or shoulder (glenohumeral joint). These techniques will be performed if, during assessment, participants present with stiffness or pain on passive accessory movement at the cervical, thoracic spine or glenohumeral joint. - Motor control exercises if, during assessment, participants present with poor control of a specific muscle (e.g. scapular control exercises, dynamic control of glenohumeral joint).[47-50] - Strengthening exercises if, during assessment, participants present with muscle weakness.[50]
10.‡	**MODIFICATIONS** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Not applicable. This is a protocol.
11.	**HOW WELL** Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Participants' adherence to protocol will be assessed by quantifying the number of home-based exercises performed. It will be expressed as percentage of the total number of sessions that should be been performed. Clinician's adherence to protocol will be assessed by quantifying the number of exercises and progressions that were performed according to the protocol. This will be done through audits of clinical notes, and will be expressed as percentage of the total number of exercises and progressions that were performed during the course of treatment.
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Not applicable. This is a protocol.

Standardized rehabilitation: participants allocated to this group will receive a progressive resistance training for all scapular and shoulder muscles and stretching exercise programme.[51]

This intervention focuses on restoring muscle flexibility and strength and has been shown to be more effective than 'no intervention' or control for reducing pain and disability.[51]

Table 3. Description of standardized rehabilitation intervention, as per the template for intervention description and replication (TIDieR) guide.

Item number	Item	Description
1.	**BRIEF NAME** Standardized rehabilitation	
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.	The standardized rehabilitation intervention will focus on strengthening of scapular and shoulder muscles. Strengthening exercise were shown to improve pain and disability in participants with subacromial shoulder pain.
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	The standardized rehabilitation group will receive strengthening exercises. These exercises might be performed with the use of elastic bands or dumbbells. Stretching exercise for the thoracic spine will be done using a foam roller. Two home-based exercises (resisted internal and external rotation of the humerus) will be performed using an elastic band.
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Participants will start with 8 "core" strengthening exercises and 3 stretches. The clinician can replace one core strengthening exercises by another strengthening exercises from a list of "additional" exercises.
5.	**WHO PROVIDED** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Experienced clinicians will deliver interventions for the standardized rehabilitation group. Clinicians will have a postgraduate diploma in musculoskeletal rehabilitation (or related field) and a minimum of 5 years of clinical experience. All clinicians will undergo a trial-specific training programme to ensure they understand the protocol and the rationale of the intervention. Clinicians will receive a detailed manual with information regarding the trial intervention.
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Participants will receive individual, face-to-face sessions.
7.	**WHERE** Describe the type(s) of location(s) where the intervention occurred,	Interventions will be delivered in a private clinical practice.

Item number	Item	Description
	including any necessary infrastructure or relevant features.	
8.	**WHEN and HOW MUCH** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Participants will receive 16 sessions, each lasting for a maximum of 60 min, twice per week, over an 8-week period. The standardized rehabilitation will comprise of 8 exercises plus 3 stretching exercise (one for the cervical spine, one for the thoracic spine and one for the shoulder). Strengthening exercises will be delivered with the following dosage: 2 sets of 10 repetitions. The strengthening exercises will be progressed in three stages. The first will have the following dosage: 3 sets of 10 repetitions. The second stage will have the following dosage: 3 sets of 20 repetitions. For the third stage of progression, clinicians can choose to increase the load to moderate (based on RPE – see below) or replace the exercise by another one from the additional list. All the exercises should initially be performed in slow and controlled pace. The load for strengthening exercises will be determined through using the 10-point Rate of Perceived Exertion (RPE) scale, considering the affected side. Low intensity will be defined as 3-4 RPE, moderate intensity as 5-6 RPE, and high intensity as 7-8 RPE.
9.	**TAILORING** If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	This intervention is not planned to be tailored.
10.‡	**MODIFICATIONS** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Not applicable. This is a protocol.
11.	**HOW WELL** Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Participants' adherence to protocol will be assessed by quantifying the number of home-based exercises performed. It will be expressed as percentage of the total number of sessions that should be been performed. Clinician's adherence to protocol will be assessed by quantifying the number of exercises and progressions that were performed according to the protocol. This

Item number	Item	Description
		will be done through audits of clinical notes, and will be expressed as percentage of the total number of exercises and progressions that were performed during the course of treatment.
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Not applicable. This is a protocol.

Concomitant care

Participants may seek other healthcare services, if they wish to do so. In that case, we will ask them to record which healthcare services they accessed on a logbook while enrolled on the trial.

Criteria for modifying or discontinuing the exercises

Pain levels, as subjectively reported by participants, will be used for determining whether an exercise must be modified or discontinued.[52 53] For this purpose of this study, we adopted a criteria used in a previous study.[54] Participants will be encouraged to continue with an exercise as long as the reported pain levels ranging from slight to endurable. Participants should discontinue exercise or reduce load if: (1) pain increases beyond what is acceptable/ bearable for the participant; (2) participant reports an immediate increase of pain by 3 points (NPRS) during exercise; (3) pain persists longer than 30 sec after completion of exercise; (4) an exercise cannot be performed due to pain, clinicians will be asked not to include that specific exercise for the next 2 sessions and replace that exercise another exercise (for the tailored rehabilitation group) or with a longitudinal traction or pendulum exercise (for the standardized rehabilitation group).[5] All participants will receive home-based stretching and strengthening exercises, and will be asked to perform these once a day.

Primary outcome measures

The primary feasibility outcome measures are (Figure 2):

1. Participant's recruitment rate, measured as number of participants per month;
2. Proportion of participants enrolled from the total number screened, expressed as the ratio "number of enrolled participants/total number of screened participants", with reasons;
3. Adherence to the rehabilitation programme, measured as number of sessions attended, and expressed as a percentage of the total number of sessions;
4. Drop-out rates, measured as the number of participants who dropped-out, and expressed as a percentage of the total number of participants enrolled in the study.

Secondary outcome measures

The patient-reported outcome measures intended as the primary and secondary outcomes in the main trial will be used as secondary outcome measures in this feasibility trial (Figure 2). These are: pain level as measured by a numeric pain scale,[55] and shoulder-related disability assessed using the 'patient specific functional scale' (PSFS), the Shoulder Pain and Disability Index (SPADI).[56] The minimal clinically important difference for the numeric pain scale is 1 point,[57] and for the PSFS is 1.3 (for small changes), 2.3 (for medium changes) and 2.7 (large changes).[58] Although this feasibility trial is not powered to detect superiority, we will assess the magnitude

of mean treatment effects for pain and physical function in relation to clinically important change, to inform the choice of primary outcome and sample size calculation for the main trial.

We will assess safety by recording all adverse events, both related and unrelated to interventions, in each group. Potential adverse reactions to interventions may include muscle soreness or increased pain around the shoulder joint. The physiotherapist will record any adverse reactions to interventions, including duration and severity of adverse reaction to treatment, and how the adverse reaction was managed. We will include in the report the total number of participants who reported adverse events, relatedness to interventions, the duration and severity of the adverse reactions. In the small sample of this feasibility trial, we do not expect to observe a representative number of adverse events, so do not intend statistical comparisons; rather, we will assess the feasibility of the recording forms and systems for use in the main trial.

Figure 2

Health outcomes

Health outcomes will be expressed as quality-adjusted life years (QALYs) using the Short-Form 12 (SF-12v2).[59] The SF-12v2 will be converted to a six-dimensional health state classification (SF-6D).[60] The SF-6D allows estimating the quality-adjusted life year (QALY). A QALY is a year of life experienced with a particular health-related quality of life, and will be expressed as a score ranging from 0 to 1, with 0 = death and 1 = full health. Total QALY will be estimated for each participant by calculating the area under the curve (the product of utility values by time). We will calculate the mean QALYs for each group and adjust for baseline utility scores to minimize any bias due to chance baseline imbalance between the groups. As this feasibility trial is not powered to detect superiority, we will assess the magnitude of mean effect on QALYs in relation to clinically important change.

We will adapt the Otago Cost and Consequences Questionnaire (OCC-Q) to shoulder disorders, and use the adapted questionnaire to capture healthcare use and costs for participants enrolled in this study.[61] The OCC-Q is a patient-administered questionnaire developed for osteoarthritis that has demonstrated accuracy and agreement with administrative databases from the national healthcare system in NZ.[61] The OCC-Q will be administered at baseline and 12-week time points.

Time points

Outcome measures will be recorded at baseline, 4th, 8th and 12th week after baseline.

Missing data

When assessing secondary outcome measures, we will use a linear mixed-effect model to compare groups. This method can handle missing data. For the other analysis, in case of missing data, we will assess its distribution to confirm the assumption that data was missed at random. If missing at random is confirmed, we will perform multiple imputations.

Statistical analysis

All statistical analyses will be performed using R software.[62] Descriptive statistics will be used to analyse: (1) recruitment rates; (2) adherence to the rehabilitation programme; (3) proportion of participants enrolled from the total number screened; (4) drop-out rates; (5) adverse reactions.

We will use a linear mixed-effect model to obtain estimates of intervention effects, we will compare changes in pain and shoulder-related disability scores between the two intervention groups (i.e. tailored and standardized rehabilitation). Group intervention (tailored and

standardized rehabilitation) will be considered as between-subject factor, and 'time-point' (baseline, 4th, 8th week and 12th week) will be considered as within-subject factor. Baseline measurements will be considered as covariates. We will conduct an independent linear mixed-effect model for each outcome measure (i.e. pain levels and shoulder-related disability). Alpha will be set at 0.05, and power at 80% for all statistical analysis.[63] Since this is a feasibility study, we will not adjust alpha for multiple comparisons.[64] This will decrease the chance of Type II error, increasing the chance of identifying potentially important differences between groups. This statistical approach is considered appropriate for feasibility or exploratory studies.[64]

To determine whether or not it is worthwhile conducting the full trial, it is recommended that confidence interval (CI) ranges other than 95% should be used (e.g. 85% or 75%CI in addition to the mean difference estimate) when assessing differences between groups from feasibility trials.[65] For the purposes of this study, we will consider 75% CI as the probability threshold.[65] The mean difference between tailored rehabilitation and standardized rehabilitation will need to be larger than the minimum clinically important difference for either pain or shoulder-related disability. Therefore, we will consider appropriate to conduct the full trial if we can be, at least, 75% sure that tailored rehabilitation is superior to standardized rehabilitation at 3-month follow-up.

Economic Evaluation

We will use an incremental cost-utility analysis, following intention-to-treat principle, to assess differences in costs and utilities between tailored rehabilitation and standardized exercise, and report incremental net monetary benefit. We will use both a health system and a societal perspective to define and measure costs, as is recommended for cost-effectiveness studies.[66] We will also report the cost-efficacy and direct medical costs within the NZ healthcare system, and will calculate Bayesian credibility intervals (Bayesian analogue of 95% confidence intervals) to account for uncertainty in measurements due to sampling random variability,[67] and will plot cost-effectiveness acceptability curves.[68]

Nested qualitative study

We will include a nested qualitative study that will assess participants' experiences about the trial, and will use a thematic analysis to interpret the data.[69] We will invite all participants to take part in a semi-structured interview. The goal is to gather data about patients' experience in the trial, in particular about the difficulties and barriers faced by participants, the perceived value and positive aspects of the study and any other issue that may arise during the interviews. Findings from the nested qualitative study will add significant value into how we can minimize perceived barriers, and increase adherence with the trial. Interviews will take place once participants complete the intervention programme (i.e. at the 8-week follow-up).

We will use thematic qualitative analysis to analyse and interpret transcriptions from interviews with patients. We will conduct the thematic qualitative analysis in 5 steps: (1) generation of codes; (2) identification of themes; (3) revision of themes; (4) definition and naming of themes; (5) interpretation of findings.[69] We will keep an audit trail, and members of the research team will crosscheck the coding and interpretation of data. We will adopt an iterative approach during data analysis, and will discuss and reflect on each step to identify any inconsistencies during the thematic qualitative analysis. We will analyse, write, and submit for publication the qualitative study as a separate manuscript.

Nested process evaluation study

We will conduct a process evaluation study using a mixed-method design. As part of the process evaluation, we will assess the fidelity, dose and reach of interventions implemented during the

Otago MASTER Feasibility trial. We will assess fidelity of interventions by monitoring clinical notes, fortnightly, during the intervention period. Two clinical researchers (the PI and a research assistant) will be responsible for conducting the process evaluation. As per the Medical Research Council (MRC, United Kingdom – UK) guidelines,[70] we will adopt an active role, and provide feedback and additional training to clinicians if required. This approach will optimize fidelity of interventions. According to the MCR (UK) guidelines, this is the most appropriate approach for process evaluation during feasibility trials.

We will conduct a focus-group with clinicians once 70% of data collection has been completed. The focus-group will allow us to assess clinicians' perspectives (barriers and facilitators) about the interventions and the trial. We will use thematic qualitative analysis to analyse and interpret transcriptions from the focus-group. We will conduct the thematic qualitative analysis in 5 steps: (1) generation of codes; (2) identification of themes; (3) revision of themes; (4) definition and naming of themes; (5) interpretation of findings.[69] We will keep an audit trail, and members of the research team will crosscheck the coding and interpretation of data. We will adopt an iterative approach during data analysis, and will discuss and reflect on each step to identify any inconsistencies during the thematic qualitative analysis. We will analyse, write, and submit for publication the process evaluation study as a separate manuscript.

Data management

Data will be collected by trained researchers, using hard copies of forms and questionnaires. These will be safely stored and locked in a filing cabinet based at the Centre for Health, Activity and Rehabilitation Research School of Physiotherapy – University of Otago. A research assistant 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). We will use single-data entry, with 10% of the data being entered independently by two research assistants and crosschecked. In addition, we will use histograms, stem and leaf plots, clinical and data-driven range checks as part of quality control.[71 72]

Trial monitoring

The Health Research Council (HRC) Data Monitoring Core Committee (New Zealand) categorised this trial as low risk, and recommended that an independent Data Monitoring Committee was not necessary. The HRC Data Monitoring Core Committee recommended that an internal monitoring process is sufficient to monitor and oversee this trial. Based on these recommendations, the Data Monitoring Committee from the 'Centre for Health, Activity and Rehabilitation Research' (School of Physiotherapy—University of Otago) will monitor and oversee the trial. The research team has opted not to undertake interim analysis.

Ethics and Dissemination

This study was approved by the University of Otago Ethics Committee [Ref: H17/080]. Findings from this study will be presented at national and international conferences, and will be submitted for publication in a peer-reviewed journal.

Patient and Public Involvement

Patients and or public were not involved. Results of this study will be disseminated to study participants by inviting them to join an open-seminar in which the results of the study will be presented. In addition, we will prepare a short report with the main findings of the study and distribute this by e-mail to participants. The burden of the intervention will be assessed by participants through the nested qualitative study. In that study, we will participants' experiences and perceptions about the trial.

Declarations

Data collection, storage and sharing

We will store participants' data on a secure local server, and will use unique identification number on follow-up questionnaires. To protect participants' privacy, all identifying information will be stored separately, and deleted following the conclusion of the trial. We will not share or report identifying information. The datasets generated during the study will be available from the corresponding author on reasonable request.

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.

Adverse event management

The risk of a serious adverse event related to the intervention is minimal. If a participant presents with an adverse event, the primary investigator will report it to the internal Data Monitoring Committee (Centre for Health, Activity and Rehabilitation Research—University of Otago) to assess whether it is necessary to report the adverse event to the trial sponsor, and Ethics Committee. We will suspend the trial if more than one serious adverse event of any kind occurs and these are related or caused by the interventions from the trial. If the cause of the events cannot be determined or remediated, and is plausibly related to the intervention, we will terminate the trial.

Protocol amendments

We will report any protocol change that may benefit participants, impact on participant's safety or that is likely to impact on the outcomes of the study (e.g. study objectives and/or design changes, sample size, study procedures, or significant administrative changes).

Competing interests statement

None declared.

Authors' contributions

DCR and ZJT conceived the research question. DCR was responsible for the design of the trial, and is the guarantor. ZJT and GS contributed to the design of interventions. JHA provided guidance on the design the trial and economic analysis. DCR led efforts for securing funding, with the contributions from ZJT, GS and JHA. All authors revised and approved the protocol for the study. All authors revised the manuscript for important content and approved the final version.

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The Health Research Council – New Zealand had no role in the design of the trial and will have no role in its execution, data analysis and interpretation, or on the submission of the studies for publication.

Acknowledgements

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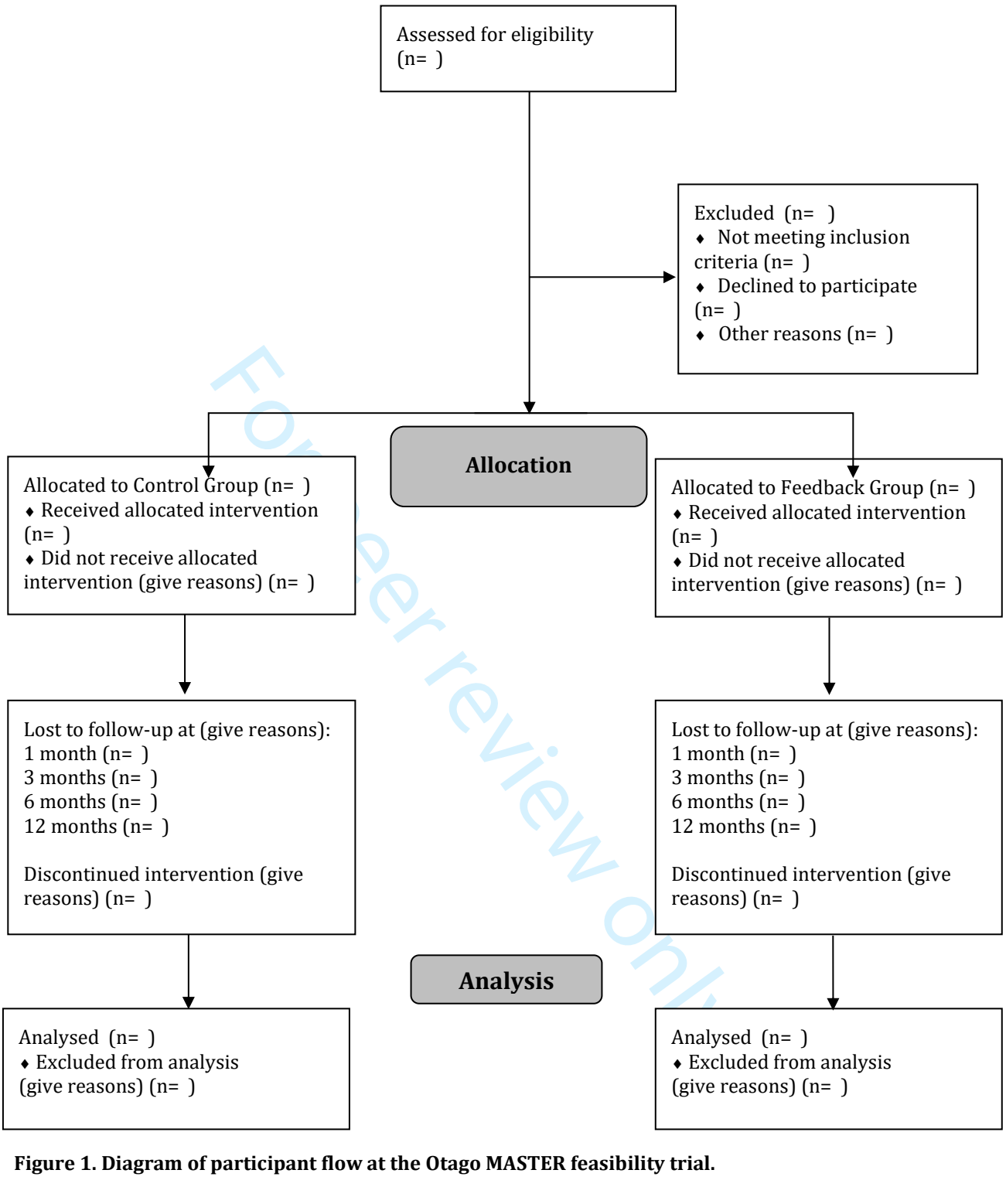

Figure 1. Diagram of participant flow at the Otago MASTER feasibility trial.

	Study Period					
	Enrolment	Allocation	Post allocation			
Time point	-t1	0	Baseline	4 weeks	8 weeks	12 weeks
Enrolment						
Eligibility screen	X					
Informed consent	X					
Allocation						
Intervention						
Standardized rehabilitation			←	—	→	
Tailored rehabilitation			←	—	→	
Assessments						
Baseline Demographic information	X					
Covariates:						
Age			X			
Height			X			
Weight			X			
Pain self-efficacy questionnaire			X			
Primary, and secondary outcome measures:						
Recruitment rates			X	X	X	X
Adherence to the rehabilitation programme			X	X	X	X
Proportion of participants enrolled			X	X	X	X
Drop-out rate			X	X	X	X
Adverse reaction			X	X	X	X
Pain intensity			X	X	X	X
Health outcomes						
Patient specific functional scale			X	X	X	X
SPADI			X	X	X	X
OCC-Q-Shoulder			X			X

Figure 2. Schedule for enrolment and intervention per group.
SPADI: Shoulder Pain and Disability Index; OCC-Q-Shoulder: Otago Cost and Consequences Questionnaire – Shoulder.

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Supplementary Material 1

Otago MASTER Feasibility Trial

Tailored rehabilitation programme

UNIVERSITY of OTAGO Te Whare Wānanga o Otāgo NEW ZEALAND
Centre for Health, Activity, and Rehabilitation Research
School of Physiotherapy

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Findings from physical examination & suggested exercises:

Findings from physical examination	Exercises
Pain or stiffness during passive accessory mobilization	Cervical or thoracic spine: HVT or PAIVM PAIVM If Grade –III or -IV if pain dominant Grade –IV or +IV if stiffness Gleno-humeral joint: Passive accessory mobilization - Grade –III or -IV if pain dominant - Grade –IV or +IV if stiffness
Painful or limited arm elevation during active resistive arm movement (flexion, abduction, internal rotation and external rotation) **Positive MWM** during shoulder scaption, shoulder external rotation, hand behind back position	# **1.A.** MWM for increasing shoulder scaption **#1.B.** MWM for increasing shoulder external rotation **#1.C.** MWM during shoulder elevation **#1.D.** MWM during hand behind back motion **#T.1.** Taping for sustained postero-lateral glide on humeral head (end of session) **# 11** Isolated motor control training around the shoulder
Positive scapular dyskinesis test: Scapular winging, tipping or hiking	**#4** Scapular setting in static postural position **#5** Scapular setting during dynamic elevation and rotation **#6** Shoulder shrugs with shoulder higher than 90^0 abduction

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Findings from physical examination	Exercises
	#7 Shoulder horizontal exercise with multiple feedbacks
Anterior translation humeral head, positive dynamic relocation test **Positive dynamic rotary stability test or shoulder pain during arm rotation (active or resistive)**	**#10** Dynamic relocation training **#11** Isolated motor control training around the shoulder
Positive Scapular MWM during scaption	**#1.C.** Mobilization with movement for scapular upward rotation
Positive Scapular upward rotation test	**#3** Scapular upward rotation training (retraining serratus anterior and upper trapezius)
Positive scapular weight bearing test	**#7** Shoulder horizontal exercise with multiple feedbacks **#8** Dissociation of scapular movements to thoracic in four point kneeling position and in for challenging situation by holding weight on just one hand **#9** Scapular holding training at mid protraction position (we perform this exercise when participant is able to scapular protraction and retraction
Positive scapular control test	**#2** Scapular exercises

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Quick Exercise Reference:

Mobilization with movement techniques

(1 MWM counts as **one** exercise. Start with 3 sets of 10 reps with 30 sec rest between sets)

Exercise	**Stage 1 (Basic)**	**Stage 2 (Intermediate)**	**Stage 3 (Advanced)**
1.A. **Shoulder scaption**	**1. A.1** In sitting, participant performs active shoulder scaption with ***elbow flexed*.**	**1. A.2** In sitting, participant performs active shoulder scaption with ***elbow extended***.	**1. A.3.** In sitting, participant performs shoulder scaption ***against a light weight*** or theraband (low intensity).
1.B. **Shoulder external rotation (ER)**	**1. B.1** In supine, participant performs ***active-assisted*** *shoulder ER* with the help of a wand. Therapist applies a posterolateral humeral glide.	**1. B.2** In sitting with arm at 90^0 abduction and elbow flexed, participant performs an ***active*** *shoulder ER*. Therapist sustains a posterolateral humeral glide.	**1. B.3** In sitting, participant performs shoulder ER *against* ***light resistance*** (low intensity). Therapist sustains a posterolateral humeral glide.
1.C. **Scapular up ward rotation**	**1. C.1** In sitting, participant performs active shoulder flexion with ***elbow flexed*.** Therapist assists scapular upward rotation	**1. C.2** In sitting, participant performs active shoulder flexion and ***elbows extended***. *T*herapist assists scapular upward rotation	**1. C.3** In sitting, participant performs active shoulder flexion and elbows extended ***against resistance*** (low intensity). *T*herapist assists scapular upward rotation

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Mobilization with movement techniques

1 MWM counts as **one** exercise. Start with 3 sets of 10 reps with 30 sec rest between sets

1.D. **Hand behind back motion**	**1. D.1** In sitting, participant moves hand behind back by ***pulling a belt*** *with other hand* while physiotherapist applies inferior glide on the shoulder.	**1. D.2** In sitting, participant moves hand behind back ***actively*** while physiotherapist applies inferior glide on the shoulder.	

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Scapular Control Training

Exercise	Stage 1	Stage 2	Stage 3	Home ex.
2. Scapular exercise	**2. A.1**. In side lying position physiotherapist uses ***resistance*** against shoulder D1 pattern.	**2. A.2**. *In* side lying, participant performs the shoulder D1 pattern in side lying position as ***free active*** movement.	2. A.3. ***In sitting,*** participant performs the shoulder D1 pattern as **free active** movement.	#7
	2. B.1. In side lying position physiotherapist *uses* ***resistance*** against shoulder D2 pattern.	**2. B.2.** In side lying, participant performs the shoulder D2 pattern in side lying position *as* ***free active*** movement.	2. B.3. ***In sitting***, participant performs the shoulder D2 pattern in side lying position as **free active** movement.	
3. Scapular upward rotation training (retraining serratus anterior and upper trapezius)	**3. A.1.** In the side lying position, participant elevates their arm while the therapist ***assists*** *serratus anterior* activity through feedback.	**3. A.2.** In the side lying position, participant elevates their arm against gentle resistance. The therapist **gently resists** serratus anterior activity by *resisting scapula upward rotation*.	**3. A.3.** In the side lying position, participant elevates their arm while the therapist ***increases resistance*** *against serratus anterior* activity by resisting scapular upward rotation.	#6

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4. Scapular setting in the ideal postural position *(static position*)	**4. A.1** In sitting *with* ***elbows resting on the armchair***. Participant is asked to tighten the scapula on their upper back. Physiotherapist uses feedback to inform participant of normal scapular position	**4.A.2** In sitting, participant is asked to tighten the scapula on their upper back *at* ***60°, 90° and 120° of shoulder elevation*** while the physiotherapist uses feedback to inform participant of normal scapular position	**4. A.3** In sitting, participant is asked to tighten the scapula on their upper back **at 60°, 90° and 120° of shoulder *elevation with a dumbbell*** (low intensity)**.** Physiotherapist informs participant of normal scapular position	#3
5. Scapular setting during dynamic elevation and rotation	**5 .A.1** In standing, participant performs shoulder flexion with the help of a ***ball on horizontal surface***. The physiotherapist prevents any abnormal scapular or shoulder movement.	**5 .A.2.** In standing, participant performs shoulder flexion with the help of a ***ball on inclined surface.*** The physiotherapist prevents any abnormal scapular or shoulder movement.	**5 .A.3.** In standing, participant performs shoulder flexion with the help of a ***ball on the wall.*** The physiotherapist prevents any abnormal scapular or shoulder movement.	#4a, #4b, #4c and #4d
	5. B.1 In sitting or standing, participant is asked to maintain normal scapular movement during arm **flexion *to 90° or arm abduction to 60°.*** The therapist prevents excessive shoulder hiking.	**5 .B.2** In sitting or standing, participant performs long lever arm shoulder elevation to ***beyond 90 degrees.*** Therapist ensures smooth movement of scapula without compensatory movements.		

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	5 .C.1 In sitting or standing, participant is asked to maintain normal scapular movement during **arm flexion to 90° or arm abduction to 60°** *against light resistance* (low intensity). Therapist prevents excessive shoulder hiking.	**5. C.2.** In sitting or standing, participant performs shoulder elevation to **greater than *90°*** *against light resistance* (low intensity). The therapist ensures participant can maintain normal scapular and shoulder movement.		#4F & G
	5. D.1. Participant is standing with arm and side and elbow flexed to 90°. Participant performs bilateral shoulder elevation with isometric shoulder external rotation against ***resistance (low intensity)*.**	**5. D.2.** Participant is standing with arm and side and elbow flexed to 90°. Participant performs bilateral shoulder elevation with isometric shoulder external rotation against ***resistance (mod intensity)***.	**5. D.3.** Participant is standing with arm and side and elbow flexed to 90°. Participant performs bilateral shoulder elevation with isometric shoulder external rotation against ***resistance (high intensity)*.**	
	5. E.1. Participant is s*itting* with shoulder abducted 90°and elbow flexed to 90°. Participant performs ***unloaded arm internal and external* rotation** without any compensatory scapular or shoulder movements.	**5. E.2.** Participant is standing or sitting with shoulder abducted 90°and elbow flexed to 90°. Participant performs ***arm internal and external rotation* against *theraband*** (low intensity) without any compensatory scapular or		

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		shoulder movements.		
	5. F.1. Participant is in *prone* with shoulder abducted 90° and elbow flexed to 90°- The ***shoulder and forearm is supported*** using a towel roll or a pillow. Participant performs *arm internal and external* rotation without any compensatory scapular or shoulder movements.	**5. F.2.** Participant is in *prone* with shoulder abducted 90° and elbow flexed to 90°- The shoulder and **forearm is unsupported** (*participant actively holds the shoulder off the bed)*. Participant performs *arm internal and external* rotation without any compensatory scapular or shoulder movements.	**5. F.3.** Participant is in *prone* with shoulder abducted 90° and elbow flexed to 90°- The shoulder and forearm is **unsupported** (participant actively holds the shoulder off the bed). Participant performs *arm* internal and external rotation ***against resistance*** without any compensatory scapular or shoulder movements.	
6. Shoulder shrug exercise with <u>shoulder higher than 90° of abduction</u>	**6. A.1** In standing, shoulder flexed, participant performs **assisted** *shoulder shrug (*wall slide or pulley). Physiotherapist prevents over activity of the levator scapulae.	**6. A.2** In standing, shoulder flexed, and participant does ***active*** *shoulder shrug without wall support. P*hysiotherapist prevents over activity of the levator scapulae.	**6. A.3** In standing, shoulder flexed, participant shrugs shoulders ***against resistance.*** *P*hysiotherapist prevents over activity of the levator scapulae.	#2

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7. Shoulder horizontal exercise with multiple feedbacks	**7. A.1**. Participant ***stands in front of a wall*** with their hands overhead on the wall. Participant is then asked to take their hands on and off the wall. The physiotherapist facilitates activity of the lower trapezius.	**7. A.2.** Participant is in ***side lying*** position with arm overhead (100° of flexion). Participant performs *horizontal shoulder abduction.* The physiotherapist facilitates activity of the lower trapezius.		#5
	7. B.1. Participant is either in ***prone*** with arms hanging off the side of bed or in 4-point kneeling position. Participant then extends and abducts their arm to 90 degrees.	**7. B.2.** Participant is in prone or in 4-point kneeing with **arm abducted greater than 90 degrees.** They are asked to lift their arms off the bed against appropriate resistance.		
8. Dissociation of scapular movements to thoracic in four point kneeling position	8. A.1. Leaning over table with **partial weight bearing on hands**, participant performs scapular protraction and retraction	8. A.2 **In four-point keeling position**, participant performs scapular protraction and retraction	8. A.3. In four-point keeling position while **weight bearing on one hand**, participant performs scapular protraction and retraction	NA
9. Scapular holding training at mid protraction position	9. A.1. In standing position, participant performs resisted scapular protraction against **light resistance.**	9. A.2. In **4-point kneeling**, participant holds scapula in mid protraction for 10 seconds.	9. A.3. Participant is in **three-point kneeling** (weight on affected extremity) and holds the scapula in mid-protraction for 10 secs.	NA

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Rotator Cuff Motor Training				
Exercise	**Stage 1**	**Stage 2**	**Stage 3**	**Home exercise**
10. Dynamic relocation training	10 .A.1. In sitting or supine position, participant draws their shoulder head towards the socket as physiotherapist applies gentle traction on the humerus.	10 .A.2 In sitting, participant draws their shoulder "in and back" towards their socket, *without humeral traction*, at the outer or inner shoulder rotation degrees.		#8 for Stage 3
11. Isolated motor control training around the shoulder	11 .A.1. In prone position with arm abducted to 90 degree, participant tightens their scapula and draws the humeral head gently down and in as they externally rotate their shoulder.	11 .A.2. In sitting with arm abducted to 90 and elbow flexed to 90, participant tightens their scapula and draws the humeral head gently down and in as they externally rotate their shoulder.	11 .A.3. In sitting with arm abducted to 90 and elbow flexed to 90, participant tightens their scapula and draws the humeral head gently down and in as they externally rotate their shoulder against resistance.	Home exercise #9 for Stage 3

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Proprioception, and plyometric training		
12. Proprioception training	**12. A.** The participant is sitting with a ball beneath their hand. Participant alternately presses and releases the ball	**12. C.** In sitting, pressing down the hands on the seat and lifting their bottoms off the bed.
	12. B. The participant pushes and releases a ball on the wall. The therapist ensures that participants stabilizes the scapula to prevent winging	**12. D.** Plyometric ball catching and throwing exercise.

Taping
T.1. Taping for sustained postero-lateral glide on humeral head.

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Exercise description

1. Monilization with Movement

1.A. Mobilization with movement for increasing shoulder scaption

Equipment: Mulligan Belt (for stage 3).

Participant position: Sitting.

Therapist position: Therapist places their hand on humeral head anteriorly.

Direction of force: Physiotherapist sustains posterolateral glide on humeral head.

Joint Movement: Participant performs scaption. It is important that physiotherapist allows normal motion between scapula and thorax to ensure pain free scaption.

1. A.1. Stage 1: Participant performs the arm scaption with elbow flexed.

1. A.2 Stage 2: Participant performs the technique with elbow extended.

1. A.3 Stage 3: Participant performs scaption against a light weight or a Thera band with elbows extended.

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1.B. Mobilization with movement for increasing shoulder external rotation

Equipment: Wand (for stage 1), Theraband (stage 3).

Participant position: Variable based on stage. Please refer to individual stages below.

Therapist position: Variable based on stage.

Direction of force: Physiotherapist sustains posterolateral glide.

Joint movement: Participant externally rotates the shoulder.

1. B.1. Stage 1: Participant is in supine with arms in comfortable abduction and elbows flexed to 90º, holding a stick in both hands to assist the external rotation of the involved shoulder. Physiotherapists sustain posterolateral humeral glide while participant performs passive shoulder external rotation (figure above).

1. B.2. Stage 2: Participant is sitting with shoulder abducted to 90, elbow flexed to 90 and then performs active external rotation as physiotherapist applies posterolateral glide.

1. B.3. Stage 3: Same as above but participant performs ER against light resistance.

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1.C. Mobilization with movement for scapular upward rotation

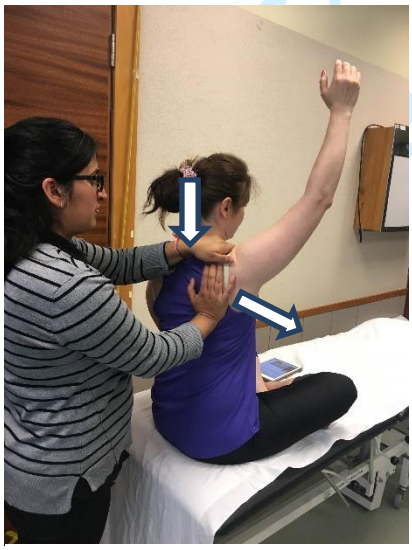
Equipment: Theraband (for stage 3)

Participant position: Sitting without back support.

Therapist position: Behind the participant. One hand on the spine of scapula and other on the medial aspect of scapular body.

Direction of force: Physiotherapist sustains downward and medial glide over the spine of scapula with one hand and rotates scapula upwardly with other hand while preventing scapular winging and tipping

Joint Movement: Participant performs shoulder elevation.



1.C.1 – Stage 1

1.C.1 – Stage 2

1. C.1. Stage 1: Participant performs shoulder flexion with elbow flexed

1. C.2. Stage 2: Participant performs shoulder flexion with elbow extended

1. C.3. Stage 3: Participant performs resisted shoulder flexion with elbow extended against light resistance.

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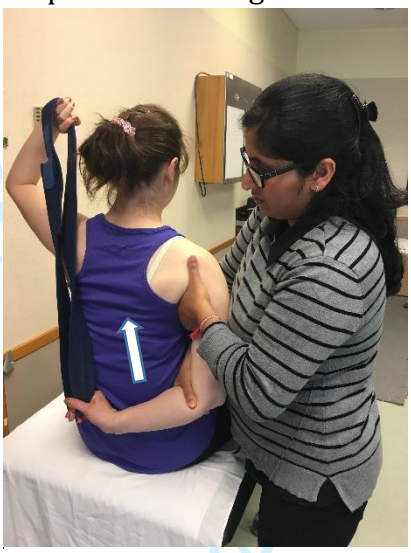
1.D. Mobilization with movement for hand behind back motion

Equipment: Belt (for stage 1)

Participant position: Sitting or standing.

Therapist position: Standing on the affected side. One hand on the lateral border of scapula and other hand on distal humerus for applying inferior glide.

Direction of force/ Movement: Physiotherapist stabilizes the scapula and applies *inferior glide (traction)* while participant is reaching to the back with the involved hand.



1. D.1 Stage 1: Participant reaches the affected hand behind back with the help of a belt.

1. D.2. Stage 2: Participant actively holds hand behind back without assistance

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2. Scapular exercise

In participants with poor awareness or control, the scapula tends to follow a curvilinear path rather than a diagonal, with jerky uncoordinated movement. Frequently, the scapula moves into excessive protraction and anterior tilt when attempting the 'up and forward' direction.

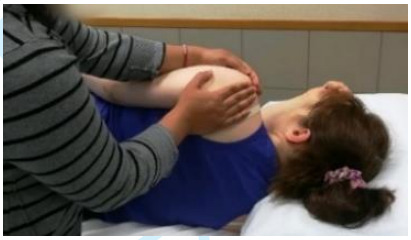
2 .A. The D1 pattern (elevation-protraction to depression-retraction)
Participant moves the tip of the shoulder towards the corner of the eye. And then returns it down and back to the opposite hip. Please make sure that participant has the chin tucked in.

2. A.1. (**Stage 1) - (Picture below, left):** Participant performs the D1 pattern in side lying. Physiotherapist applies resistance against the movement.

2. A.2. (Stage 2) - (figure below, right): Participant performs the pattern in side lying without resistance.

2. A.3. (**Stage 3):** Participant performs the pattern in sitting without resistance.


2.A.1


2.A.2

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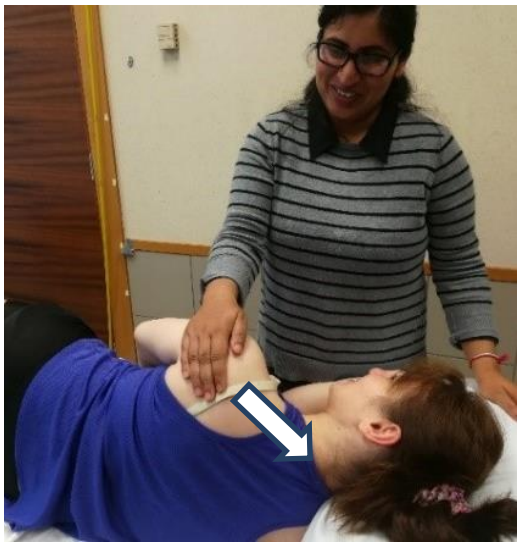
2. B. The D2 pattern (depression-protraction to elevation-retraction)

Participant moves the tip of the shoulder down and forward towards your opposite hip, then returns it up and back.

2. B.1. Stage 1: Participant performs the pattern in side-lying. Physiotherapist applies light resistance against the movement (Picture below).



2. B.2. (**Stage 2) (Picture below):** Participant performs the pattern in side lying without resistance

2. B.3. (**Stage 3):** Participant performs the pattern *in sitting* without resistance.

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3. Scapular upward rotation training (retraining serratus anterior and upper trapezius)

Equipment: None

Participant position: Participant in side-lying on the uninvolved arm.

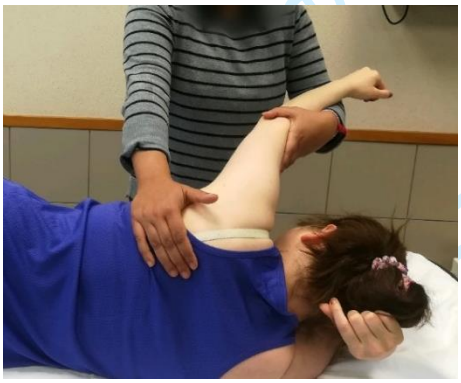
Feedback: Physiotherapist supports the upper arm in shoulder flexion greater than 90^0. Physiotherapist resists against shoulder motion and palpates the lateral border of scapula to activate serratus anterior.

Movement: Participant tries to bring the shoulder into more flexion and external rotation with scapular upward rotation.

3 .A.1. Stage 1(picture below). Physiotherapist *assists* in activation of serratus anterior by using palpation, tapping or repeated contraction or stretch

3 .A.2. Stage 2: Physiotherapist *resists gently* against scapular upward rotation.

3 .A.3. Stage 3: Physiotherapist *increases resistance* against scapular upward rotation.



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4. Scapular setting in postural position

Equipment: Mirror (if required for visual feedback).

Participant position: Upright sitting.

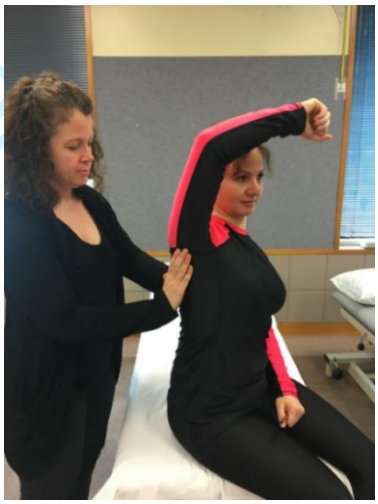
Feedback: The physiotherapist provides feedback (visual, tactile or verbal) to inform the participant of normal scapular resting position.

Movement: Participant is asked to tighten the scapula by contracting the serratus anterior and trapezius so that the inferior angle and medial border lies flat over the upper back. Participant holds this position for 10 seconds.

4. A.1. Stage 1: This stage is used for participants who have winging or tipping in upright position. The participant's arms are unloaded by placing the elbow over armchair. Participant is asked to "tighten their scapula on their upper back" and hold it for 10 seconds.

4. A.2. Stage 2 (Picture below): Scapular setting exercise is performed while participant holds the involved arm isometrically in 60°, 90° and 120° shoulder elevation. The shoulder may be internally rotated or externally rotated while the arm is held at 0°, 60°, 90° or 120°.





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4. A.3. –(Stage 3) (Picture below): Scapular setting exercise is performed at 60°, 90° and 120° shoulder elevation against light resistance provided by a dumbbell.

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5. Scapular setting during arm movements

(These exercises are used for participants with observable tipping or winging of the scapula *during arm movement*.)

Equipment: Mirror (if required for visual feedback), Gym ball (based on exercise) please refer to individual exercises

Participant position: Variable based on exercise.

Feedback: The physiotherapist provides feedback (visual, tactile or verbal) to inform the participant of normal scapular resting position.

Movement: Participant is then asked to maintain normal scapular position/ movement while preventing tipping and winging as they perform various arm movements.

5. A. Scapular setting during shoulder flexion with ball (pictures below)

5 .A.1 (Stage 1): Participant performs shoulder flexion on the bed with no inclination with the help of a ball.

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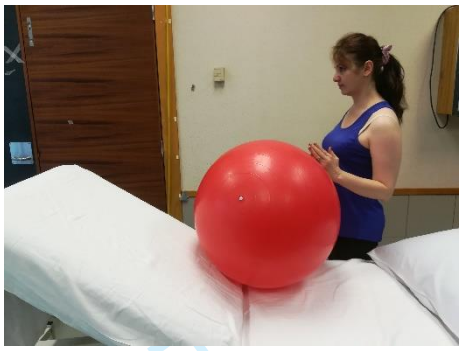
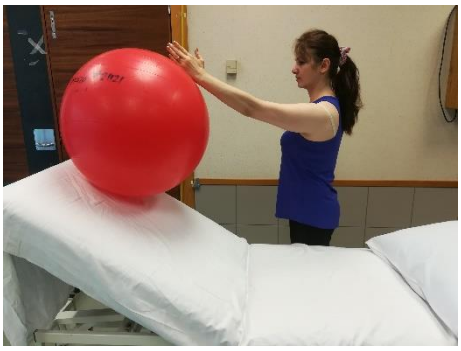
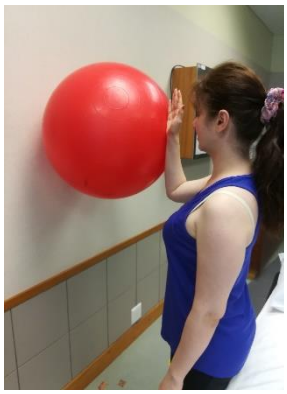
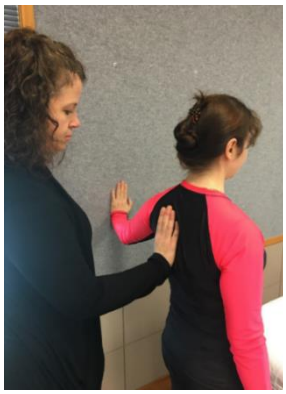
5 .A.2 (Stage 2): Participant performs shoulder flexion with the help of a ball on a surface inclined to 45°.

5 .A.3 (Stage 3): Participant performs shoulder flexion using a ball on a wall. Alternately, participant performs a simple wall slide.





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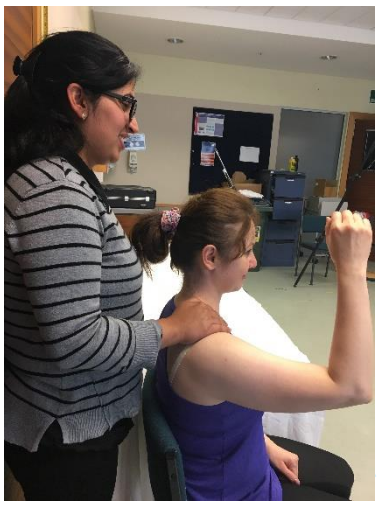
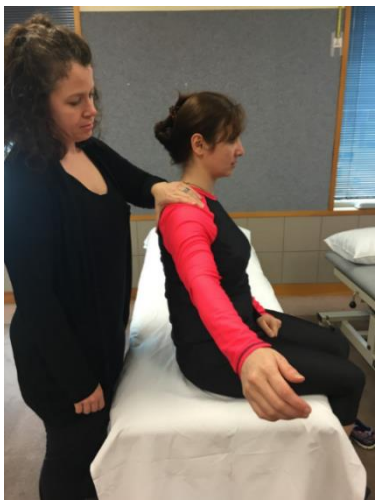
5. B. Scapular setting during arm elevation

5 .B.1. (Stage 1): Scapular setting during arm elevation to 90

Participant is asked to maintain normal scapular position during arm *flexion to 90°* or arm *abduction to 60°* with elbow flexed (easier) or extended (more difficult). The therapist prevents excessive shoulder hiking through appropriate feedback.





5. B.2 (Stage 2): Scapular setting during long lever arm elevation >90° (flexion and abduction) as free active

Participants actively elevates the arm (either flexion or abduction) to above 90° with elbows extended without any assistance or resistance. The therapist ensures smooth normal movement of the scapula without compensatory scapular hiking, tipping or winging.

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5. C. Scapular setting during arm elevation against resistance

5. C.1 (Stage 1): Scapular setting during gentle resisted arm flexion to 90° and abduction to 60°

Participant performs shoulder flexion to 90° or shoulder abduction to 60° against a light resistance (Theraband or dumbbell) while the physiotherapist provides feedback to prevent excessive shoulder hiking.

5. C.2 (Stage 2): Scapular setting during long lever arm elevation >90° against resistance

Participant performs shoulder elevation to *greater than 90°*, with elbows extended, against light resistance. Physiotherapist should ensure participant is able to control scapular winging during raising and lowering phases and that participant avoids scapular hiking.

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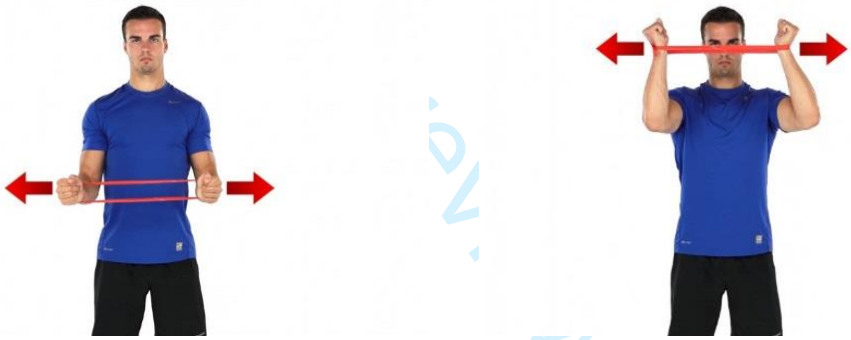
5. D. Scapular setting during bilateral shoulder elevation combined with external rotation resistance

5. D.1 Participant elevates both their arms to 90°, while isometrically contracting external rotation against light resistance (RPE 3 to 4), with elbows flexed.

5. D.2. Participant elevates both their arms to 90°, while isometrically contracting external rotation against moderate resistance (RPE 5 to 6), with elbows flexed.

5. D.3. Participant elevates both their arms to 90°, while isometrically contracting external rotation against high resistance (RPE 7 to 8), with elbows flexed.



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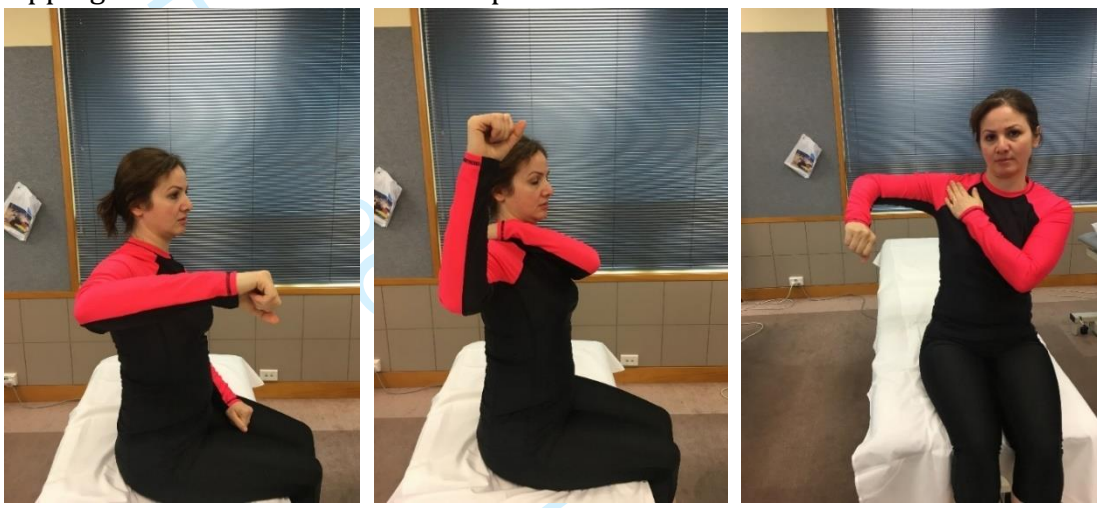
5. E. Scapular setting exercise during internal and external rotation in upright position

5. E.1.: Participant performs shoulder external rotation and internal rotation with shoulder flexed to 90° in sitting.
For ER: Physiotherapist makes sure that participant avoids shoulder depression and retraction.
For IR: Physiotherapist makes sure that participant avoids scapular anterior tipping and shoulder elevation and protraction.



5. E.2. Participant tightens the scapula during shoulder external rotation with arm at 90°. It is better to perform this exercise in front of mirror for added feedback.

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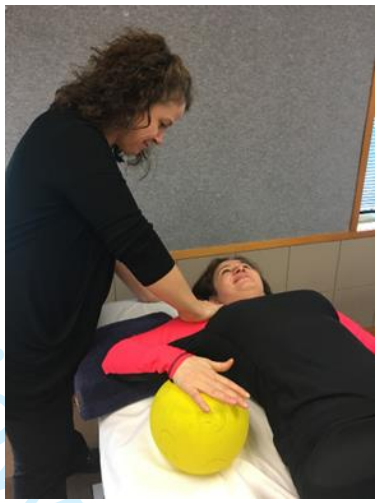
5. F. Scapular setting during shoulder rotation in prone:

Participant is asked to rotate the shoulder externally or internally without excessive scapular depression and retraction. The goal is to dissociate shoulder movement from scapular movement.

However, if the participant is unable to perform full internal rotation, they are asked to press on a ball in supine lying without lifting their shoulder from the bed (picture below- right). This activates the subscapularis muscle.

5. F.1 (Stage 1): Participant is in prone with arm flexed to 90° and elbow flexed to 90°. A towel roll is placed under the shoulder to support the arm as well as to prevent shoulder anterior tilting.



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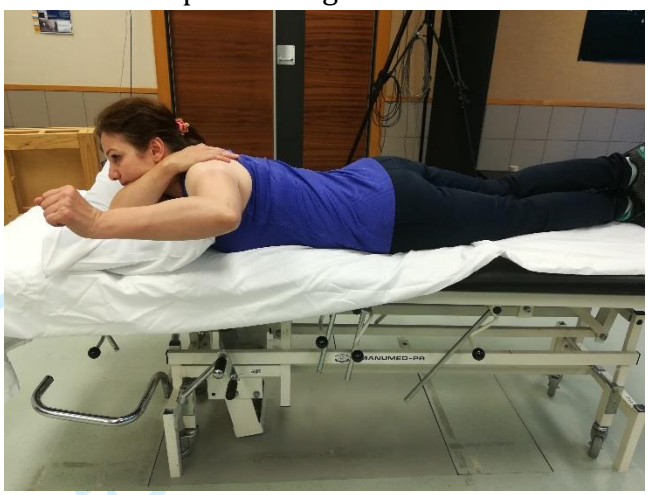
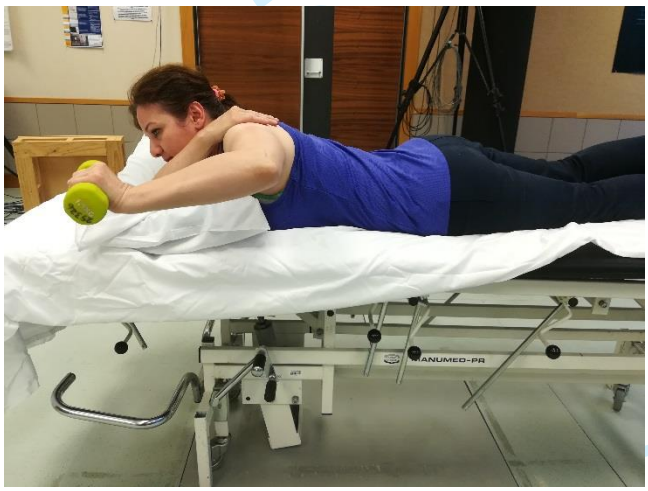
5. F.2 (Stage 2): Participant is in prone with arm flexed to 90° and elbow flexed to 90°. No support is provided and participant is asked to actively hold the shoulder off the bed while performing shoulder internal and external rotation.



5 .F.3. (Stage 3): Participant is in prone with arm flexed to 90° and elbow flexed to 90°. No support is provided and participant is asked to actively hold the shoulder off the bed while performing shoulder internal and external rotation against resistance.



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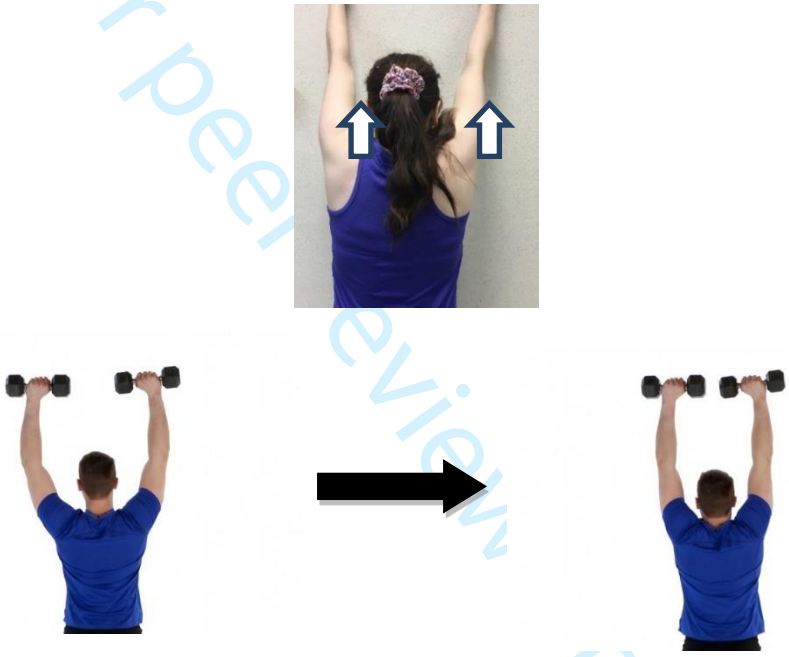
6. Shoulder shrug exercise where arms are higher than 90^0 of abduction

Equipment: Dumbbell (for stage 3).

Participant position: Standing.

Feedback: Physiotherapist uses appropriate feedback to facilitate the activation of the upper trapezius while preventing over activity of the levator scapula.

Movement: Participant raises the tip of shoulder towards the ear lobe while keeping their chin tucked.



6 .A.1 Stage 1: Participants elevate their arms and then perform shoulder shrug by sliding their hands up a wall or by using a pair of hanging strings from the ceiling.

6 .A.2. Stage 2: Participants perform the task as free active movement.

6 .A.3. Stage 3: Participants performs the task with light resistance (dumbbell).

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7. Shoulder horizontal exercise with multiple feedbacks

Equipment: Mirror (if required for visual feedback), Theraband (for stage 3).

Participant position: Variable based on stage.

Feedback: Physiotherapist **continuously taps the lower trapezius** to facilitate muscle activity and gives participant the verbal ques to tip the scapula posteriorly and avoid shoulder shrug.

Movement: The participant is instructed to "lift the arm from the scapula (by moving your scapula) and not from shoulder joint while keeping your arm in external rotation". This instruction is given to prevent excessive humeral head anterior translation.

7 .A Non-weight bearing exercises

7. A.1. (Stage 1): Participant stands in front of a wall with the hands overhead on the wall. Participant is then asked to take their hands on and off the wall. This exercise is applicable when participant is not able to do horizontal abduction in 4-point kneeling. Make sure that Participant performs the movement from their scapula.

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7. A.2. Stage 2: Participant is in side lying position with arm overhead (100° of flexion). Participant then performs subsequent ***arm extension and abduction***. The physiotherapist prevents arm hyperextension and encourages participant to elevate their arm from the scapula at the end range of arm extension. (Continuous tapping over lower trapezius is recommended).

7. B. Exercises in weight bearing

7. B.1. (Stage 1): Participant is either in prone with arms hanging off the side of bed or in 4-point kneeling position. Participant flexes and abducts their arm to 90 degrees. The physiotherapist prevents hyper abduction and encourages scapular movement.

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7. B.2. (Stage 2): Participant is in prone or in 4-point kneeing positions with arm abducted greater than 90 degrees. They are asked to lift their shoulders off the bed against appropriate resistance.

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8. Dissociation of scapular movements from thoracic movements in 4-point kneeling

Equipment: Wand for feedback
Participant Position: Variable based on the stage
Feedback: Physiotherapist encourages participant to do scapular protraction and retraction without spine movements. In particular, participants should avoid thoracic extension (lordosis) during retraction, and thoracic flexion (kyphosis) during protraction.

Other possible compensatory movements:

- full extension of the elbows
- end range rotation of the arm
- passive scapular retraction
- forward head position or cervical flexion
- increased lumbar lordosis
- elevation of shoulder girdle towards the ears
- Scapular winging.

If participant has tremor of the shoulder girdle or arm muscles during the exercise, physiotherapist reduces sets/repetitions/resistance.

Movement: Widen your shoulder blades and return them as if closing and opening a book.

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8. A.1. (Stage 1) (Picture below): Participant is leaning over a table while weight bearing on both hands. To increase the difficulty, participants may be asked to shift their weight to the affected side.

8 .A.2 (Stage 2 -Picture below): In 4-point keeling position, participant performs scapular protraction and retraction while bearing weight on both hands. To increase the challenge participant may *shift* their weight to the affected side.

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8. A.3 (Stage 3-figure below): In 4-point keeling position, participant performs scapular protraction and retraction with weight bearing on one hand.

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9. Scapular holding training at mid protraction position

(This exercise is used when participant can perform each scapular protraction and retraction for 10 seconds)

Equipment: Theraband

Participant Position: Variable based on stage

Feedback: Ensure that when participant is holding scapula in mid protraction, he/she should keep spine in straight and neutral position. In the case that participant has a weak control of spinal column, when you ask participant to have their neck in neutral position, participant performs thoracic or lumbar extension

Movement: Participant holds the scapula in mid protraction for 10 second, 10 reps, and 2-3 sets.

9. A.1. - (Stage 1): Participant is in standing, with a theraband wrapped around their back or on a door. Participant performs scapular protraction against light resistance.

9. A.2 (Stage 2): Scapular holding training in four-point kneeling position. Participants holds the scapula in mid-protraction for 10 seconds. To increase difficulty, participant may be asked to transfer weight to affected side by leaning towards the affected side.

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9. A.3 (Stage 3): Participant is in three-point kneeling (weight bearing on the affected extremity only) and holds the scapula in mid-protraction for 10 secs.

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10. Dynamic relocation training

These exercises focus on increasing the isolated contraction of rotator cuff (co-contraction of subscapularis, teres minor and infraspinatus) while decreasing contraction of superficial muscles.

As described by:

Magarey ME, Jones MA. Dynamic evaluation and early management of altered motor control around the shoulder complex. Manual therapy. 2003 Nov;8(4):195-206.

Magarey ME, Jones MA. Specific evaluation of the function of force couples relevant for stabilization of the glenohumeral joint. Manual therapy. 2003 Nov;8(4):247-53.

10. A.1. (Stage 1):
Participant position: Participant is either lying supine or sitting, with arm supported between 60^0 to 80^0 of scaption by the therapist.

Direction of force: The physiotherapist applies a gentle longitudinal distraction force and asks participant to draw their humerus into the the glenoid cavity.

Movement: Physiotherapist asks participant to draw the arm "in and backward". The participant is asked to perform a gentle depression of the scapula while drawing the humerus toward the glenoid cavity.

Feedback: Physiotherapist encourages participant to activate more subscapularis and concurrently decrease superficial muscle activity (e.g. latissimus dorsi, posterior deltoid, pectoralis major and upper trapezius). Initially, participant may pull the arm strongly with superficial muscles with or without rotator cuff contraction. In this case, they should be instructed to reduce the effort.

10. A.2. (Stage 2): Participant draws their shoulder "in and back" towards the glenoid cavit, ***without humeral traction***, at the outer or inner range of shoulder rotation.

Participants should be taught to feel the contraction for themselves by palpating near the axilla. When the physiotherapist is confident that the participant can dissociate the co-contraction without external feedback, he/she can ask participants to do the exercise at home.

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11. Isolated motor control training around the shoulder

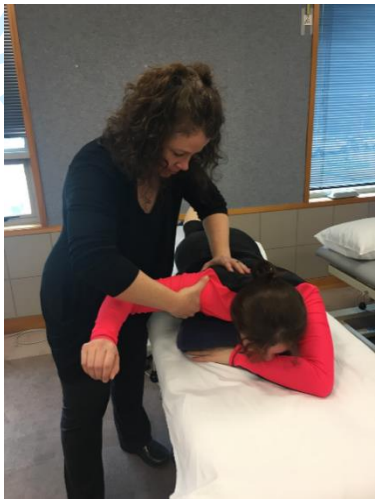
When there is lack of dynamic rotator cuff stability, the humeral head often translates anteriorly or superiorly. The aim of this training is to find a position where participant has the most control on humeral head, as close as to the position where there is the least control. Physiotherapist asks participant to rotate shoulder while centering the humeral head to the glenoid. Stabilizing scapular concomitant with humeral head depression prevent clicking sound and pain in the shoulder.

11. A.1. (Stage 1): Assisted External Rotation

Participant Position: Lying prone with chest supported by a folded towel

Feedback: The physiotherapist palpates the participant's humeral head from anterior and superior direction. The aim is to teach participant to relax their deltoid.

Movement: The participant is asked to tighten their scapula and draw the humeral head gently "down and in" as they externally rotate their shoulder actively. This exercise is applicable when we observe humeral head anterior protrusion during shoulder external rotation.



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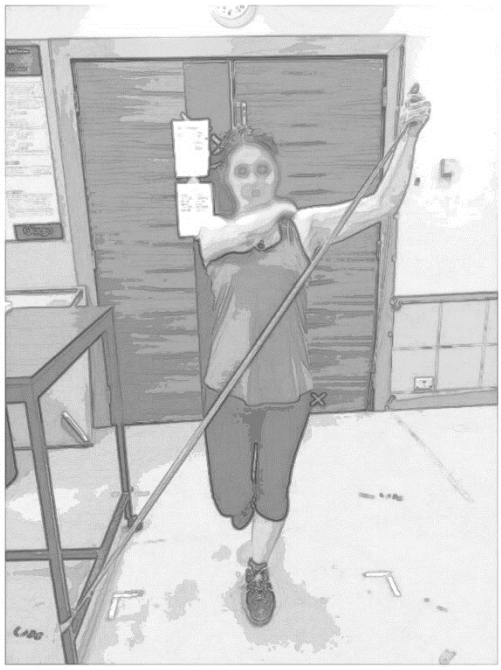
11.A.2 (Stage 2): In sitting, participant performs active ER while physiotherapist ensures there is no excessive anterior and superior glide of the humeral head.

11.A.3. (Stage 3): Progressed to resisted ER motion. Physiotherapist should make sure that the participant can control humeral head anterior translation during arm external rotation. For increasing difficulty, the movement can be performed with resistance of a theraband, while participant stands in one leg.



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12. Proprioception, balance and plyometric trainings

12. A.: The participant is sitting with a ball beneath their forearm. Participant presses and releases the ball while ensuring the scapula and shoulder are properly stabilized.

12. B.: The participant pushes a swiss ball against the wall. The therapist ensures that participants stabilizes the scapula to prevent winging.

12. C. The participant tries to lift their bottoms off the bed in sitting by pressing down through their hands. The force is generated from the shoulder joint.

12. D.: Plyometric catching exercise.

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Scapular Taping for postero-lateral glide

Start the tape on the anterior aspect of the humeral head crossing the acromion lateral to the acromioclavicular joint, ending at the inferior border of the scapula. Therapist glides the humeral head posteriorly when applying the tape. Take care not to apply too much tension initially at the humeral head as the skin is liable to breakdown.

As described by:

Teys P, Bisset L, Collins N, et al. One-week time course of the effects of Mulligan's Mobilisation with Movement and taping in painful shoulders. Manual therapy 2013;18(5):372-77. doi: 10.1016/j.math.2013.01.001

Hing W, Hall T, Rivett DA, et al. The Mulligan Concept of Manual Therapy: Textbook of Techniques: Elsevier Health Sciences 2015.

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Supplementary Material 2

Otago MASTER Feasibility Trial

Standardized rehabilitation programme

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Contents

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Exercise Overview – Quick reference

Shoulder Core Exercises

Exercise			
1. Shoulder extension Resistance type: elastic band	**1. A.** Bilateral Low row: Subjects extends both shoulders from 80°of shoulder flexion (elbow flexed).	OR	**1. B.** Bilateral High row Subject extends both shoulders from 100° shoulder flexion to neutral with elbow extended
2. Shoulder adduction in scapular plane	**2.** Subject adducts shoulder from 80° of shoulder abduction (elbow extended)		
3. Shoulder external rotation (ER) Note: rolled towel placed between arm and trunk	**3.A.** Shoulder ER in sitting/standing: Subject externally rotates shoulder from a standing/sitting position with shoulder in neutral (elbow flexed to 90°).	OR	**3. B.** Shoulder ER in side lying: Subject performs shoulder ER from a side lying position with shoulder in neutral (elbow flexed to 90°).
4. Shoulder internal rotation (IR) Note: rolled towel between arm & trunk	**4. A.** Shoulder IR in sitting/standing: Subject internally rotates shoulder from a standing/sitting position with shoulder in neutral (elbow flexed to 90°).	OR	**4. B.** Shoulder IR in side-lying*: Subject performs shoulder ER from a side lying position with shoulder in neutral (elbow flexed to 90°). *only if participant able to lie down on affected side
5. Elbow flexion with forearm supination:	**5.** Subjects gradually performs elbow flexion with forearm supination from neutral shoulder rotation.		

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Scapular Core Exercises

Exercise			
6. Scapular protraction	**6. A.** Scapular protraction in standing Subject is standing with shoulder in neutral with elbow flexed to 90. From here participant gradually flexes *shoulder to 80* while extending elbow and then performs scapular protraction.	**OR**	**6. B.** Scapular protraction in supine In supine lying with shoulder in neutral and elbow flexed to 90, participant gradually flexes *shoulder to 90* and extends elbow, then scapular protraction.
7. Scapular protraction in 4-point kneeling	**7.** Subject is in 4-point kneeling position with hands underneath shoulder. Participant performs scapular protraction.		
8. Scapular muscle strengthening (Isometric scapular setting)	**8**. Subject starts in prone position, with hands by the sides, arms in external rotation; then depresses and retracts the scapula and holds it isometrically.		

Shoulder Stretch (Core exercises)

Exercise	Instruction
9. Posterior shoulder stretch	Subject is in standing. Participant stretches affected shoulder into horizontal adduction by pulling fully flexed elbow with opposite hand
10. Lateral neck stretch	Subject is in standing. Participant pulls the head into lateral flexion with opposite arm and adds shoulder depression to increase the stretch
11. Thoracic spine extension	Subject is supine with hips and knees flexed, towel roll Under the thoracic spine and hands supporting the neck. Participant maintains this posture to sustain a stretch of anterior thoracic muscles

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Additional Exercises

	Exercise	Pg no.
12. Shoulder scaption in standing position	Subject performs 80° scaption with elbow in slight flexion and slight shoulder external rotation (thumbs up)	18
13. Shoulder flexion in standing	Subject flexes arm to 80° with arm slightly flexed and externally rotated (thumbs up)	19
14. Shoulder press via flexion (Sitting with back support)	Subject performs full shoulder ***flexion*** with elbow extension *Arms against trunk, elbows fully flexed, hands lateral to shoulder.*	**20**
15. Shoulder press via abduction in (Sitting with back support) (Elastic band only)	Subject performs full shoulder ***abduction*** with elbow extension against *Arms against trunk, elbows fully flexed, hands lateral to shoulder.*	**20**
16. Horizontal abduction in sitting (Elastic band only)	Perform shoulder abduction against Elastic band attached at shoulder height *Shoulder in 80 flexion and ER (thumb laterally)*	**21**
17. External rotation in sitting with elbow supported on plinth/table (Elastic band only)	Subject performs 90 external rotation against a Elastic band. *Shoulder flexed to 80° with 90° elbow flexion.*	**22**
18. Internal rotation (IR) in sitting with elbow supported on plinth/table (Elastic band only)	Subject performs 90 internal rotation against a Elastic band. *Shoulder flexed to 80° with 90° elbow flexion.*	**22**
19. Scapular protraction	Subject perfroms dynamic scapular protraction	**23/4**

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Additional Stretching and ROM Exercises

Exercise	Instruction	Pg no.
20. Internal rotation positioning	Subject places the involved hand on the buttock or lower back in pain free manner, supported by the other hand	25
21. Longitudinal shoulder traction with an Elastic band wrapped	Subject stands while bending sideways slightly. One end of an Elastic band is wrapped around the wrist while the other end is fixed with the feet allowing tension in the band. Participant relaxes the shoulder and allows the longitudinal traction.	25
22. Pendulum exercise	Participant stands and leans over a chair or a table with the good arm, relaxes the affected shoulder blade and let the arm drop. In this position, performs forward-backward swings and circle swings using body motion.	26

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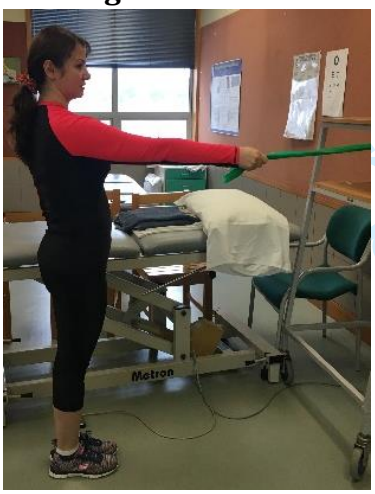
Descriptions of Core Exercises

1. Shoulder extension

1. A. Bilateral Low row:

Starting position: Standing with shoulder flexed at 80° and neutral rotation.
Exercise: Subject performs ***bilateral*** shoulder extension till neutral with elbow flexed.
Resistance type: Theraband

Starting Position



Ending Position

1. B. Bilateral High row

Starting position: Standing with shoulder flexed at 100° and neutral rotation.
Exercise: Subject performs ***bilateral*** shoulder extension till neutral with elbow extended.
Resistance type: Thera band

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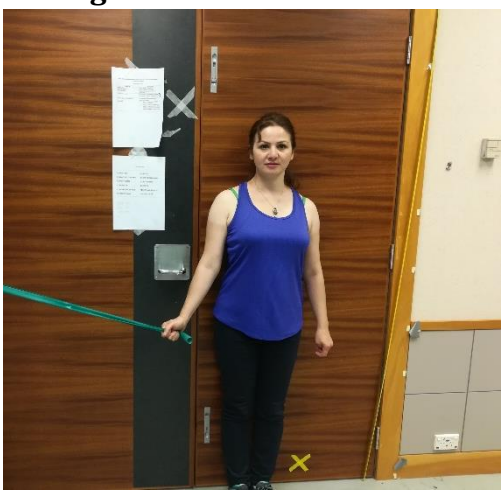
2. Shoulder adduction in scapular plane

Starting position: Standing with shoulder abducted at 80° in scapular plane (Scaption) and neutral rotation.
Exercise: Subject performs shoulder adduction with elbow extended to neutral.
Resistance type: Thera band

Starting Position

Ending Position



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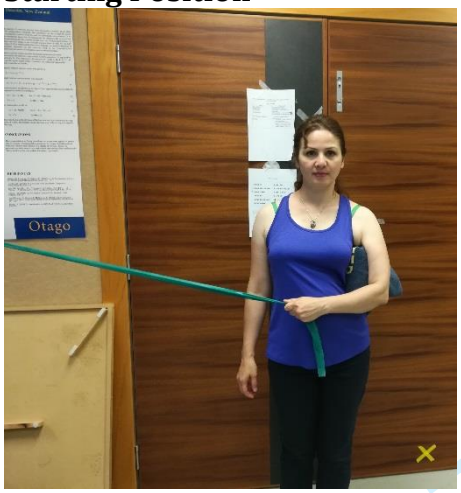
3. Shoulder external rotation (ER)

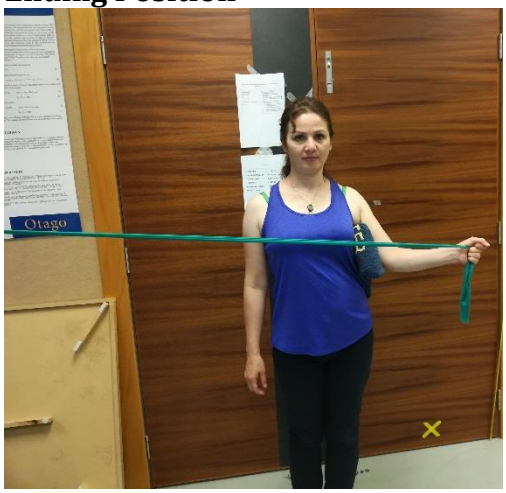
3. A. Shoulder ER in standing with 0 abduction

Starting position: Standing with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.
Exercise: Subject performs shoulder external rotation. Please ensure the participant is not compressing the towel; they should be holding it in a relaxed manner.
Resistance type: Thera band

Starting Position



Ending Position



3. B. Shoulder ER in side-lying

Starting position: Side-lying with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.
Exercise: Subject performs shoulder external rotation.
Resistance type: Dumbbell

4. Shoulder internal rotation (IR) in neutral

4. A. : Shoulder IR in standing

Starting position: Standing with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.

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Exercise: Subject performs shoulder internal rotation. Please ensure the participant is not compressing the towel; they should be holding it in a relaxed manner.
Resistance type: Thera band

4. B. Shoulder IR in side-lying (progress only if participant is able to lie down on affected side)

Starting position: Side-lying with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.
Exercise: Subject performs shoulder internal rotation.
Resistance type: Dumbbell

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5. Elbow flexion with forearm supination

Starting position: Standing or sitting with arms at side; neutral rotation.
Exercise: Subject performs elbow flexion with forearm supination.
Resistance type: Thera band or Dumbbell

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6. Scapular protraction

6. A. Scapular Protraction in standing:

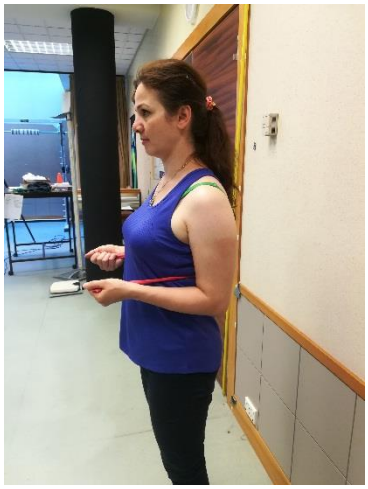
Starting position: Standing with arms at side; shoulder in neutral rotation; elbows flexed at 90˚.

Exercise: Subject performs shoulder flexion to 80˚, elbow extension, and then scapular protraction

Resistance type: Thera band

Starting Position (Front view)

Starting Position (side view)



Ending Position (front view)

Ending Position (Side view)

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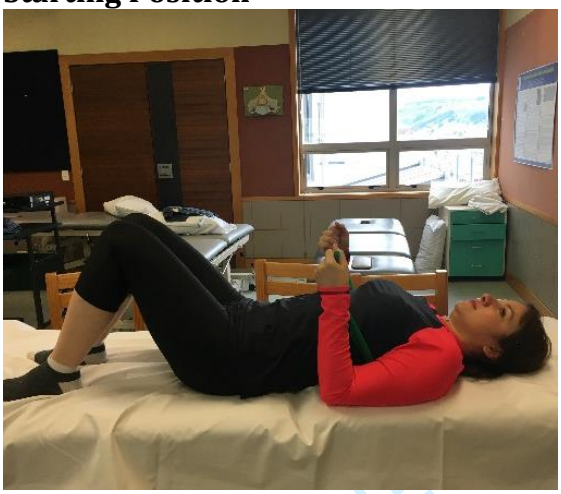
6. B. Scapular protraction in supine

Starting position: Supine lying, arms resting at side in neutral, elbows flexed at 90°

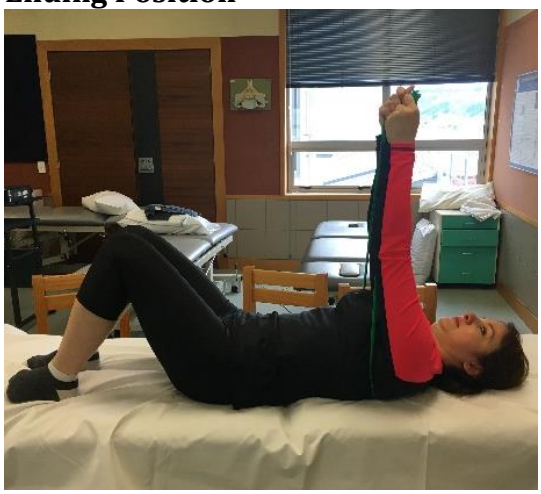
Exercise: Subject concurrently flexes shoulder to 90° and extends elbow, and then protracts scapula against resistance.

Resistance type: Thera band

Starting Position



Ending Position



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7. Scapular protraction in four-point kneeling

Starting position: 4 point kneeling, hands underneath shoulder
Exercise: Subject performs dynamic scapula protraction without compensatory movements at the spine
Resistance type: Body Weight

8. Scapular muscle strengthening (isometric)

Starting position: Prone with arms at side in external rotation
Exercise: Subject depresses and retracts the scapula with elbows slightly flexed and holds the position for 10 seconds. The therapist can provide feedback and ensure participant is not over activating their shoulder extensors and external rotators.
Resistance: None

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9. Posterior Shoulder Stretch

Position: Standing or sitting

Exercise: Subject pulls the elbow passively across the body into horizontal adduction with the opposite arm. Hold the stretch for 10 seconds and repeat.

10. Lateral neck stretch

Position: Standing or sitting

Exercise: Participant pulls the head into lateral flexion with the opposite arm and adds scapular depression to stretch ipsilateral neck.

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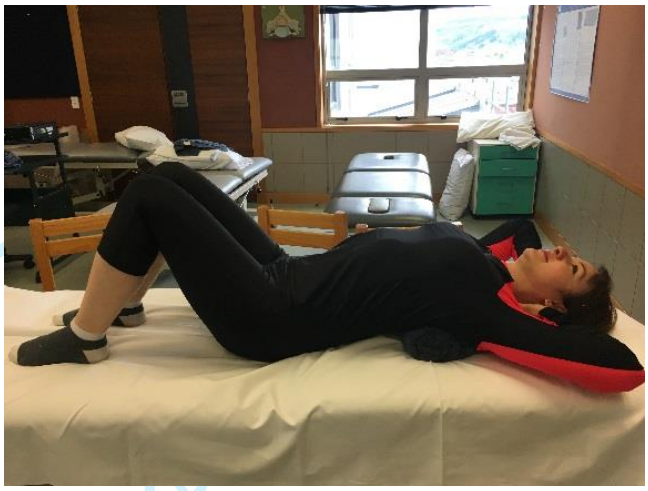
11. Thoracic spine extension stretch

Position: Supine with hip and knee flexed. A towel roll is placed under their upper thoracic spine and participant supports their neck with both hands.

Exercise: Participant allows sustained stretch of thoracic kyphosis by lying on a towel roll and relaxing their spine.



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Additional exercises:

12. Shoulder scaption to 80^0

Starting Position: Standing with feet on the theraband. Shoulder at neutral.
Exercise: Participant performs shoulder scaption to 80˚ while keeping shoulder external rotation (thumb up). Elbow slightly flexed.
Resistance: Thera band or dumbbell

Starting Position

Ending Position

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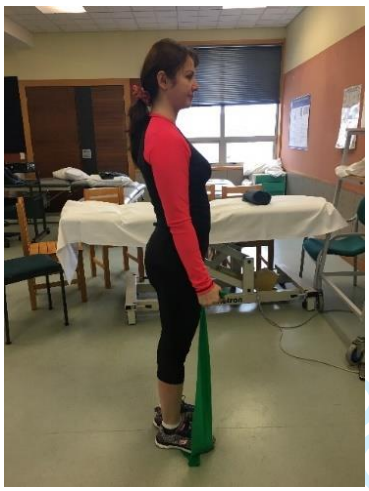
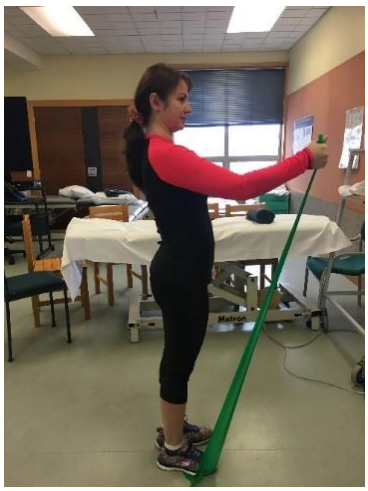
13. Shoulder flexion to 80°

Starting position: Participant is standing with feet on Thera band. Arm at side of body.
Exercise: Participant performs shoulder flexion to 80^0 and external rotation (thumb up) with elbow slightly flexed against light to high resistance.
Resistance: Thera band or dumbbell

Starting Position



Ending Position



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14. Shoulder press via flexion

Starting position: Subject is in sitting position with back supported, arms are in contact with trunk, and elbows are fully flexed.
Exercise: Participant performs full shoulder flexion and elbow extension against resistance.
Resistance: Thera band or dumbbell


15. Shoulder press via abduction

Starting Position: Participant in sitting, with back supported, arm in contact with trunk, and elbow fully flexed, and hand next to the shoulder.
Exercise: Participant performs full shoulder abduction and elbow extension against resistance.
Resistance: Theraband


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16. Horizontal abduction in sitting

Starting position: Participant is sitting with shoulder flexed at 80°. A theraband is attached at shoulder height directly in front of them (theraband is aligned with their forearm).

Exercise: Participant performs horizontal shoulder abduction with nearly extended elbow.

Resistance: Theraband

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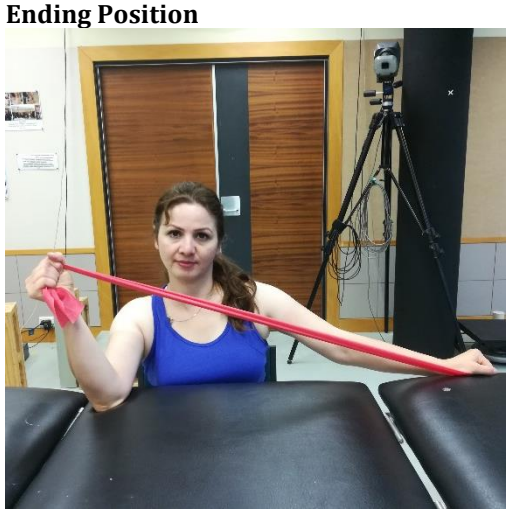
17. External rotation with arm supported

Starting Position: In sitting with elbow supported on a table. Shoulder flexed at 80°, no rotation and elbow flexed at 90°. Thera band is fixed with other hand.
Exercise: Subject performs 90° of external rotation against resistance.
Resistance: Theraband

Starting Position

Ending Position



18. Internal rotation in supported 80^0 shoulder flexion

Starting Position: In sitting with elbow supported on a table. Shoulder flexed at 80° with no rotation and elbow flexed at 90°. Thera band is fixed on the table with other hand
Exercise: Subject performs 90° of internal rotation against resistance.
Resistance: Thera band

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19. Scapular protraction

19. A.: In kneeling push up position

Starting Position: Half plank position (4 point kneeling with hands underneath shoulders and hip in neutral, knee flexed at 90˚)

Exercise: Participant performs dynamic scapular protraction.

Resistance: Body Weight

19. B. Scapula protraction in push-up position:

Starting position: Participant is in push up position with hands directly below shoulder.

Exercise: Participant performs dynamic scapular protraction without spinal compensatory movements.

Resistance: Body weight

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19. C. Half way push up position:

Starting position: Participant is in push up position with hands below shoulder.

Exercise: Participant performs a half way push up with a dynamic scapular protraction at the end of arm extension.

Resistance: Body weight

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20. Internal rotation positioning

Participant places their involved hand on the buttock or lower back in a pain-free manner, supported by the other hand

21. Longitudinal shoulder traction

Standing with trunk side-flexed towards the affected side. A Thera band is wrapped around the wrist and fixed with the feet on one side with tension. Participant relaxes shoulder and allows for longitudinal traction.

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22. Pendulum exercise

Participant leans on a chair or table by bearing weight on the good arm and bending forward at the waist. Participant relaxes the affected shoulder blade and lets it drop. Participant then performs relaxed forward-backward swings and circle swings using body motion (with dumbbell or bottle).

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Table 1 – page 5
	2b	All items from the World Health Organization Trial Registration Data Set	Table 1 – page 5
Protocol version	3	Date and version identifier	Table 1 – page 5
Funding	4	Sources and types of financial, material, and other support	Table 1 – page 5
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 17
	5b	Name and contact information for the trial sponsor	Page 5
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 17
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15 and 16

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Pages 3 to 4
	6b	Explanation for choice of comparators	Pages 3 to 4
Objectives	7	Specific objectives or hypotheses	Page 4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Tables 2 and 3
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Refer to TIDieR checklist
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Refer to TIDieR checklist
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Refer to TIDieR checklist
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Refer to TIDieR checklist
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 13 and 14

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 6
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 6
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 7 to 13

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 13
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 15 and 16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Pages 15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Pages 15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 14
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 16
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 16
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 16 and 17
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Page 16
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 17

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 16
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 16
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N.A.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 16
	31b	Authorship eligibility guidelines and any intended use of professional writers	Page 16
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Not submitted
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	12 to 13	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Tables 2 and 3	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Tables 2 and 3	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Tables 2 and 3	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Tables 2 and 3	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Tables 2 and 3	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Tables 2 and 3	

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Tables 2 and 3	
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Tables 2 and 3	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Tables 2 and 3	
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Tables 2 and 3	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Tables 2 and 3	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

BMJ Open

The effectiveness of a tailored rehabilitation versus standard strengthening programme for patients with shoulder pain: a protocol for a feasibility randomized controlled trial (the Otago MASTER trial)

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The effectiveness of a tailored rehabilitation versus standard strengthening programme for patients with shoulder pain: a protocol for a feasibility randomized controlled trial (the Otago MASTER trial)

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Abstract

Introduction: Exercise therapy is the treatment of choice for the management of patients with shoulder subacromial pain. However, we do not know whether a tailored rehabilitation programme is more effective than a standardized strengthening programme. The aim of this feasibility trial is to assess: (1) participant recruitment rate; (2) the proportion of participants enrolled from the total number screened; (3) adherence to the rehabilitation programme; (4) drop-out rates; (5) obtain estimates of adverse reactions to treatment; (6) obtain estimates of intervention effects in order to inform the sample size of the fully-powered RCT; (7) conduct a preliminary cost-effectiveness analysis of the standardized strengthening and the tailored rehabilitation interventions.

Methods: The Management of subacromial disorders of the shoulder (MASTER) trial, is a two-arm, patient- and assessor-blinded, randomized controlled feasibility trial. Patients will be randomly allocated into one of the interventions group: tailored or standardized rehabilitation. To obtain estimates of intervention effects, we will compare changes in pain and shoulder-related disability scores between the two intervention groups using a repeated mixed-model analysis of variance, with alpha set at 0.05, and power at 80%. Since this is a feasibility study, we will not adjust alpha for multiple comparisons. To determine whether it is feasible to conduct the full trial, we will consider 75% CI as the probability threshold at 3-month follow-up.

Discussion: The short-term impact of this phase II trial is to inform whether or not it is feasible to conduct the full efficacy trial. The medium-term impact of this proposal will be to determine which intervention is superior for treating patients with shoulder subacromial pain.

Ethics and Dissemination: This study was approved by the University of Otago Ethics Committee [H17/080]. Findings from this study will be presented at conferences, and will be submitted for publication in a peer-reviewed journal.

Trial registration number: ANZCTR: 12617001405303.

Keywords: shoulder, rehabilitation, manual therapy, randomized controlled trial.

Word count: 3688

Article summary

Strengths and limitations of this study

- This protocol will compare one intervention that is tailored to patient's physical impairments with a standardized strengthening programme.
- The feasibility trial will include economic evaluation, and implementation-based process evaluation of the intervention planned.
- Clinicians were not blinded to interventions due to nature of interventions, and that is a source of potential bias.

Introduction

Shoulder pain is the third most common musculoskeletal complaint, with a one-year prevalence of 18.1%.[1] Shoulder pain is associated with high socioeconomic burden.[2] In Sweden, the average annual cost of shoulder subacromial pain is estimated $4,139 per patient.[2] In NZ, a total of $134 million was spent by ACC in rehabilitation for shoulder injuries from 2005 to 2013 ($14 million/year).[3] Shoulder subacromial pain is a challenging disorder with slow recovery,[4] with only 50% of new episodes presenting full recovery within 6 months.[5]

Exercise therapy is the first approach for the management of shoulder subacromial pain, and is recommended, for example, by the British Elbow & Shoulder Society (BESS)[6]. A number of systematic reviews have been published in this area.[7-13] Some reviews suggest exercise therapy and or manual therapy to be effective for improving pain and function in patients with shoulder pain, but highlight the limited strength of evidence to support this.[7 8 14] Three reviews reported exercise therapy to be more effective than control or placebo,[8 10 11] while a Cochrane Review reported no clinically important difference between manual therapy and exercise versus placebo.[9] The addition of manual therapy to exercise has been supported in incremental effects trials [15-17] and by another recent systematic review.[10] Optimal treatment strategies are needed to improve treatment effect, speed recovery, and decrease shoulder pain recurrence. There are uncertainties regarding which types of exercise are more effective and cost-effective for the management of patients with shoulder subacromial pain.[10 18 19] In addition, there are competing approaches of exercise regimen (e.g. specific exercise,[20] general strengthening exercise), with limited number of head-to-head trials comparing different combinations of exercise therapy and manual therapy interventions.[9 10]

The lack of data about process evaluation of previous trials hinder our ability to identify whether tested interventions failed to improve clinical outcomes due to being ineffective or poorly implemented.[21] To address this, it is recommended trials to include process evaluation alongside the *outcome* evaluation, ideally from Phase II to Phase IV.[21] Process evaluation studies provide valuable information regarding how, what and why interventions were delivered to patients during the trial,[21-24] and help to understand why an intervention achieved (or not) its expected clinical outcomes.[25] Such information is valuable for a number of stakeholders (e.g. clinicians, government and policy-maker agencies) and improve translation of findings from trials to clinical practice.[21] Hence, future trials on the management of shoulder subacromial pain should include process evaluation[21] and economic evaluation[10] conducted alongside the outcome evaluation. In addition, it has been recommended that future trials combining novel exercise therapy programme to be compared to a valid placebo intervention.[9]

Shoulder subacromial pain is a complex disorder, with psychological factors and physical impairments influencing clinical outcomes.[26-29] Pain beliefs seem to be associated with course of pain and disability, but the current level of evidence is low.[29] A longitudinal prospective cohort study reported that psychosocial factors are associated with clinical outcomes,[28] while a secondary analysis of a trial found that fear-avoidance beliefs contribute significantly to baseline disability but not to disability change scores after 3-month follow-up.[26] Psychosocial factors and pain beliefs seem to play a role on clinical outcomes, however, high quality longitudinal studies are still required to clarify the influence of psychological factors on disability and pain in patients with shoulder suabcromial disorders.[26-29]

As patients with shoulder pain present with physical impairments, and altered scapular and shoulder muscle recruitment patterns[30 31], these impairments are a potential target for therapeutic intervention.[32] For example, patients with shoulder subacromial pain may show altered coordination between lower trapezius and serratus anterior, and the upper trapezius and lower trapezius during arm elevation task,[31] and patients with symptomatic rotator cuff tear may show increased activity of latissimus dorsi when compared to healthy controls.[30] Due to the

variability of such altered muscle patterns, it is recommended that rehabilitation should tailor specific muscle and joint impairments presented by the patient.[33] Further, preliminary evidence suggests that sustained shoulder mobilization may reduce pain and improve range of motion in patients with shoulder subacromial pain, compared to sham sustained mobilization.[34] Trials of the effect of sustained glide and exercise on the management of other musculotendinous disorders (e.g. tennis elbow) have found this intervention to be more effective than corticosteroid injection and wait-and-see.[35]

Laboratory-based studies suggest that: (1) clinician-administered sustained shoulder mobilization offloads shoulder muscles, providing mechanical support to the shoulder;[36] (2) patient-administered sustained shoulder mobilization leads to similar changes in muscle activity levels as clinician-administered mobilization, supporting the use of home-based mobilization for shoulder rehabilitation;[37] (3) patients with shoulder pain present immediate reduction in pain levels, increased range of motion, and altered muscle activity levels in response to sustained shoulder mobilization.[38] These findings, and anecdotal evidence from clinical practice, suggest that sustained mobilization temporarily changes the control of scapular and shoulder muscles. Such temporary change gives the clinician a therapeutic window to strengthen muscles with less pain while keeping a better control of scapular and shoulder muscles.

We propose investigating whether a tailored rehabilitation (combining sustained mobilization with specific motor control exercises) might be more effective than standardized exercise for shoulder pain patients. Tailored rehabilitation focuses on each patient's specific impairments.[20 39-42] On the other hand, standardized shoulder rehabilitation adopts a more generic approach, with standardized stretching and strengthening exercises being prescribed for all patients, and may also be delivered in small group sessions, reducing the cost of the physiotherapy session. It is unclear which approach leads to better clinical outcomes and is more cost-effective. We hypothesize that the tailored rehabilitation programme is more effective and has a shorter time-to-recover, as it addresses patients' specific impairments.

Efficacy trials are designed to test if an intervention works under the ideal circumstances.[43] This type of trial maximises the probability of observing the effect of an intervention (assuming such effects exist), and prioritize internal validity of the study design.[43] In efficacy trials, the intervention is standardized, delivered under an ideal setting, with highly trained clinicians.[43] It is recommended for efficacy trials to incorporate economic evaluation (i.e. cost-efficacy) alongside the clinical efficacy assessment.[44] By conducting clinical and cost-efficacy assessment it is possible to determine whether an intervention is likely to be efficacious for a group of patients, and whether delivering the health outcomes are likely to be good value for money.[45] Ideally, clinical and cost-efficacy studies should be conducted prior to clinical- and cost-effectiveness pragmatic trials.[44]

The aim of our full study is to assess the clinical- and cost-efficacy of tailored rehabilitation programme for the treatment of shoulder subacromial pain. Prior to conducting a fully-powered randomized controlled trial (RCT), we propose an efficacy feasibility trial aiming to assess: (1) participant recruitment rate; (2) the proportion of participants enrolled from the total number screened; (3) adherence to the rehabilitation programme; (4) drop-out rates; (5) obtain estimates of adverse reactions to treatment; (6) obtain estimates of intervention effects in order to inform the sample size of the fully-powered RCT; (7) conduct a preliminary cost-effectiveness analysis of the standardized strengthening and the tailored rehabilitation interventions.

Methods

Design

The Management of subacromial disorders of the shoulder (MASTER) trial, is a two-arm, patient- and assessor-blinded, randomized controlled feasibility trial. Patients will be randomly allocated into one of the interventions group: tailored rehabilitation or standardized rehabilitation (Figure 1).

Figure 1

For preparing this protocol, we followed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement,[46] and the template for intervention description and replication (TIDieR) checklist and guide.[47] When reporting the feasibility trial, we will follow the Consolidated Standards of Reporting Trials (CONSORT) statement for non-pharmacological treatment.[48] The trial has been prospectively registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR: 12617001405303). World Health Organization trial registration data set information is described in Table 1.

Table 1. World Health Organization trial registration data set.

Data category	Information
Primary registry and trial identifying number	Australian New Zealand Clinical Trial Registry (ACTRN 12617001405303)
Date of registration in primary registry	04/10/2017
Source of monetary or material support	Health Research Council of New Zealand Feasibility Grant (17/536)
Primary sponsor	University of Otago
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	Tailored versus standard strengthening rehabilitation for patients with shoulder pain: a feasibility trial
Scientific title	The effectiveness of a tailored rehabilitation versus standard strengthening programme for patients with shoulder pain: a feasibility randomized controlled trial (the Otago MASTER trial)
Country of recruitment	New Zealand
Health condition or problem studied	Shoulder subacromial pain
Interventions	Tailored and standardized strengthening exercise
Key inclusion and exclusion criteria	Adult healthcare workers (from 18 to 65 years old), with subacromial shoulder pain.
Study type	Interventional
Date of first enrolment	12/02/2018
Target sample size	25
Recruitment status	Recruiting
Primary outcome	(1) Recruitment rate, (2) Proportion of participants enrolled from the total number screened, and (3) Adherence to the rehabilitation programme.
Key secondary outcome	(1) Drop-out rates, (2) Pain level, (3) Shoulder-related disability – patient specific functional scale, (4) quality-adjusted life year, (5) Shoulder Pain and Disability Index (SPADI), (6) Pain self-efficacy questionnaire; (7) Adverse reactions.

Participants

Patients with shoulder subacromial pain will be recruited to take part in the study.

Inclusion and exclusion criteria

Patients from 18 years and 65 years old, with mechanical shoulder pain will be recruited to participate in the study. Participants will be screened as per the British Elbow and Shoulder Society (BESS) guidelines.[49] The process recommended by the BESS guidelines screens for: red flags (e.g. tumour, unreduced dislocation, acute rotator cuff tear, infection), shoulder pain arising from the cervical spine, the shoulder instability, acromioclavicular joint disease, and adhesive capsulitis.[49]

Participants will be included if they present one positive finding on the following tests: (1) Painful arc movement during shoulder flexion or abduction; (2) Jobe's test.[49]; or (3) pain on resisted lateral rotation or abduction.[50]. Given the limited evidence from clinical tests for diagnosing patients with shoulder subacromial pain,[51] we opted to widen the criteria proposed by BESS and add criteria #3. We include two additional tests (resisted lateral rotation and shoulder abduction).[50] A previous study reported pain on external rotation has 34.5% of sensitivity, 100% specificity, 42% accuracy for identifying any degree of subacromial disorder. [50] Pain on shoulder abduction presented 55% of sensitivity, 75% specificity, 57% accuracy and a likelihood ratio of 2.2% for identifying any degree of subacromial disorder. In addition, pain on external rotation was the most accurate test for identifying partial-thickness tear.[50 51]

We will exclude participants with the history of shoulder dislocation, shoulder subluxation, shoulder surgery and cervical surgery within the last 6 months,[52] participants with symptoms of inflammation or systematic disease, signs of paraesthesia in the upper extremities, hemiplegic shoulder pain, frozen shoulder, or positive clinical signs of full thickness rotator cuff tear [53] will be excluded.

Sample size

Being a feasibility RCT, the present study is not designed to assess the efficacy of the experimental intervention.[54 55] We estimated the sample size based on expected characteristics of the full trial.[56] Based on recommendations by Whitehead et al.[56], the sample size of a feasibility study should be estimated based on the expected range for the effect size, the power and alpha (both established *a priori*), and the total number of arms of treatment planned for the full trial.

Whitehead et al.[56] estimated the sample size based on standardized differences of different magnitudes (i.e. extra small, small, medium and large). To estimate sample size, we used the Shoulder Pain and Disability Index (SPADI) as primary outcome measure; we assumed a minimum clinically important difference of 8 points [57] and a standard deviation of 24 points on SPADI total score.[57] This represents a standardized effect size of 0.3. For estimating the sample size, we set power at 80%, two-tailed between-group comparison, with alpha at 0.05. Therefore, the minimum sample size for this feasibility RCT is 10 participants per arm of treatment.[56] Assuming a 20% loss to follow-up,[58] a total sample size of 25 participants is required.

Recruitment

Recruitment will take place in Dunedin, New Zealand. Participants will be recruited through general practitioners and hospitals and newspaper advertisements. Participants will be screened by a physiotherapist with more than five years of clinical experience, and with a postgraduate qualification in Musculoskeletal or Sports Physiotherapy (or related field).

Informed consent and baseline assessment

Once participants are assessed for eligibility, a clinical researcher will seek informed consent from participants. Participants may consent to take part in the study after screening or few days later, if they request time for considering taking part in the study. Participants will be asked to complete the baseline assessments and questionnaires for recording demographic data (age, height, weight), and baseline measurements for the primary and secondary outcomes.

Randomization

Participants will be individually randomly allocated (1:1 ratio) into one of the intervention groups (i.e. tailored physiotherapy or standardized physiotherapy). The randomisation schedule will be computer-generated by a research administrator, and concealed in numbered sealed and opaque envelopes. A research administrator will provide the envelope to the clinician delivering the interventions.

Blinding

Participants will be blinded to interventions. Outcome assessors will be blinded to group allocation. Clinicians delivering the interventions will not be blinded to group allocations due to nature of intervention.

Procedures

Experienced clinicians will deliver interventions for both groups. Clinicians will have a postgraduate diploma in musculoskeletal rehabilitation (or related field) and a minimum of 5 years of clinical experience. Outcome measures will be assessed by a physiotherapist who is blinded to group allocation.

Interventions

Both groups will receive 16 individual, face-to-face sessions, each lasting for 60 min, twice per week, over an 8-week period. This number and duration has been shown to improve clinical outcomes in patients with shoulder subacromial pain.[59] Eight weeks intervention period has been suggested as the minimum required to lead to improvement in pain and range of motion in patients with shoulder pain.[59] The tailored and standardized rehabilitation interventions are described on Tables 2 and 3 respectively. These descriptions were prepared following the template for intervention description and replication (TIDieR) checklist and guide.[47]

Both groups will receive similar dosage of exercises. Participants will perform a total of 8 exercises per session of treatment, plus three stretches (control group) or up to three manual therapy techniques (tailored group). To ensure optimal internal validity of the trial, dosage of exercises for each group are planned to be equivalent. Details of tailored and standardized interventions are described on the Exercise Description Forms (Supplementary Material 1 and 2, respectively). The intensity of strengthening exercises will be monitored using a modified Borg scale.[60] Rate of perceived exertion was shown to be valid for monitoring intensity of resistance training,[61] and has been used in a previous trial for monitoring exercise intensity.[62]

Tailored rehabilitation: participants allocated to the tailored rehabilitation group will receive sustained mobilization followed by exercises focusing on restoring normal movement pattern and the dynamic stability of the scapulothoracic and glenohumeral joints.[33 63] The intervention will involve manual therapy techniques focusing on restoring the shoulder and scapular movement to reduce pain,[64] and motor control and progressive resistance training of impaired muscles.[59 63]

Table 2. Description of tailored rehabilitation intervention, as per the template for intervention description and replication (TIDieR) guide.

Item number	Item	Description
1.	**BRIEF NAME** Tailored rehabilitation	
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.	The tailored rehabilitation programme will focus on specific impairments presented by the patient. This intervention will consist of mobilization with movement, passive accessory mobilization, specific motor control exercises and specific muscle strengthening exercises. The tailored rehabilitation programme might be more effective than a standardized strengthening programme for patients with subacromial shoulder pain.
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	The tailored rehabilitation group will receive manual therapy techniques (including mobilization with movement with taping)[64 65], motor control and strengthening exercises. Manual therapy interventions delivered by the clinician might be performed with a belt. Motor control and strengthening exercises might be performed with the use of elastic bands or dumbbells. Home-based exercises will consist of self-mobilization techniques that is performed with a belt.
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Clinicians will choose exercises based on physical impairments presented during the physical assessment.
5.	**WHO PROVIDED** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Experienced clinicians will deliver interventions for the tailored group. Clinicians will have a postgraduate diploma in musculoskeletal rehabilitation (or related field) and a minimum of 5 years of clinical experience. All clinicians will undergo a trial-specific training programme to ensure they understand the protocol and the rationale of the intervention. Clinicians will receive a detailed manual with information regarding the trial intervention.
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Participants will receive individual, face-to-face sessions.
7.	**WHERE**	

Item number	Item	Description
	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Interventions will be delivered in a private clinical practice.
8.	**WHEN and HOW MUCH** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Participants will receive 16 sessions, each lasting for a maximum of 60 min, twice per week, over an 8-week period. The exercise programme will comprise of 8 exercises plus 3 optional manual therapy techniques (one for the cervical spine, one for the thoracic spine and one for the shoulder). Clinicians will decide on which technique to use based on participants' clinical presentation. The manual therapy techniques might consist of passive joint mobilizations (grade -IV, IV, or +IV) or manipulation (for the cervical or thoracic spine). Mobilization with movement techniques will count as one of the 8 possible exercises to be performed within a session. This technique will be performed with 3 sets of 10 repetitions, with 30 seconds of rest between each set. Passive joint mobilizations will be performed with the following dosage: 3 sets, 30 seconds duration. Grade: –III or –IV will be performed if pain is dominant (as per physical assessment) or grade +III or +IV if stiffness dominant (as per physical assessment). Joint manipulation will be performed once per session, if required, as per physical assessment. The clinician will have the freedom to decide which technique to perform. Isometric exercises will be delivered with the following dosage: 2 sets, 10 repetitions, with 10 seconds hold each repetition. The isometric exercises will be progressed in two stages. The first stage will have the following dosage: 3 sets, 10 repetitions, with 10 seconds hold each repetition. The second stage will have the following dosage: 3 sets, 10 repetitions, with 20 seconds hold each repetition. There will be 10 seconds rest between repetitions, and 30 seconds rest between sets. Dynamic strengthening exercises will be delivered with the following dosage: 2 sets of 10 repetitions. The dynamic strengthening exercises will be progressed in two stages. The first stage will have the following dosage: 3 sets of 10 repetitions. The second stage will have the following dosage: 3 sets of 20 repetitions.

Item number	Item	Description
		All exercises should initially be performed in slow and controlled pace. All motor control exercise should initially be of low intensity and then progressed as described. Clinicians can increase dosage (repetitions, sets, or load) if the participant is able to perform low intensity exercise for two consecutive sessions. The load for strengthening exercises will be determined through using the 10-point Rate of Perceived Exertion (RPE) scale, considering the affected side. Low intensity will be defined as 3-4 RPE, moderate intensity as 5-6 RPE, and high intensity as 7-8 RPE. Exercises will start with low intensity, and can progress to moderate and high intensity during the course of treatment.
9.	**TAILORING** If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Interventions will be tailored based on physical assessment. Participants will receive: - Shoulder mobilization with movement if, during assessment, participants improve range of motion and pain with the MWM technique. As part of the treatment, clinicians might use an MWM taping technique.[64 65] - Passive mobilization on the cervical, thoracic spine or shoulder (glenohumeral joint). These techniques will be performed if, during assessment, participants present with stiffness or pain on passive accessory movement at the cervical, thoracic spine or glenohumeral joint. - Motor control exercises if, during assessment, participants present with poor control of a specific muscle (e.g. scapular control exercises, dynamic control of glenohumeral joint).[32 66-68] - Strengthening exercises if, during assessment, participants present with muscle weakness.[32]
10.‡	**MODIFICATIONS** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Not applicable. This is a protocol.
11.	**HOW WELL** Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Participants' adherence to protocol will be assessed by quantifying the number of home-based exercises performed. It will be expressed as percentage of the total number of sessions that should be been performed. Clinician's adherence to protocol will be assessed by quantifying the number of exercises and progressions

Item number	Item	Description
		that were performed according to the protocol. This will be done through audits of clinical notes, and will be expressed as percentage of the total number of exercises and progressions that were performed during the course of treatment.
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Not applicable. This is a protocol.

Standardized rehabilitation: participants allocated to this group will receive a progressive resistance training for all scapular and shoulder muscles and stretching exercise programme.[69] This intervention focuses on restoring muscle flexibility and strength and has been shown to be more effective than 'no intervention' or control for reducing pain and disability.[69]

Table 3. Description of standardized rehabilitation intervention, as per the template for intervention description and replication (TIDieR) guide.

Item number	Item	Description
1.	**BRIEF NAME** Standardized rehabilitation	
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.	The standardized rehabilitation intervention will focus on strengthening of scapular and shoulder muscles. Strengthening exercise were shown to improve pain and disability in participants with subacromial shoulder pain.
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	The standardized rehabilitation group will receive strengthening exercises. These exercises might be performed with the use of elastic bands or dumbbells. Stretching exercise for the thoracic spine will be done using a foam roller. Two home-based exercises (resisted internal and external rotation of the humerus) will be performed using an elastic band.
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Participants will start with 8 "core" strengthening exercises and 3 stretches. The clinician can replace one core strengthening exercises by another strengthening exercises from a list of "additional" exercises.
5.	**WHO PROVIDED** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Experienced clinicians will deliver interventions for the standardized rehabilitation group. Clinicians will have a postgraduate diploma in musculoskeletal rehabilitation (or related field) and a minimum of 5 years of clinical experience. All clinicians will undergo

Item number	Item	Description
		a trial-specific training programme to ensure they understand the protocol and the rationale of the intervention. Clinicians will receive a detailed manual with information regarding the trial intervention.
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Participants will receive individual, face-to-face sessions.
7.	**WHERE** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Interventions will be delivered in a private clinical practice.
8.	**WHEN and HOW MUCH** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Participants will receive 16 sessions, each lasting for a maximum of 60 min, twice per week, over an 8-week period. The standardized rehabilitation will comprise of 8 exercises plus 3 stretching exercise (one for the cervical spine, one for the thoracic spine and one for the shoulder). Strengthening exercises will be delivered with the following dosage: 2 sets of 10 repetitions. The strengthening exercises will be progressed in three stages. The first will have the following dosage: 3 sets of 10 repetitions. The second stage will have the following dosage: 3 sets of 20 repetitions. For the third stage of progression, clinicians can choose to increase the load to moderate (based on RPE – see below) or replace the exercise by another one from the additional list. All the exercises should initially be performed in slow and controlled pace. The load for strengthening exercises will be determined through using the 10-point Rate of Perceived Exertion (RPE) scale, considering the affected side. Low intensity will be defined as 3-4 RPE, moderate intensity as 5-6 RPE, and high intensity as 7-8 RPE.
9.	**TAILORING** If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	This intervention is not planned to be tailored.

Item number	Item	Description
10.‡	**MODIFICATIONS** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Not applicable. This is a protocol.
11.	**HOW WELL** Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Participants' adherence to protocol will be assessed by quantifying the number of home-based exercises performed. It will be expressed as percentage of the total number of sessions that should be been performed. Clinician's adherence to protocol will be assessed by quantifying the number of exercises and progressions that were performed according to the protocol. This will be done through audits of clinical notes, and will be expressed as percentage of the total number of exercises and progressions that were performed during the course of treatment.
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Not applicable. This is a protocol.

Concomitant care

Participants may seek other healthcare services, if they wish to do so. In that case, we will ask them to record which healthcare services they accessed on a logbook while enrolled on the trial.

Criteria for modifying or discontinuing the exercises

Pain levels, as subjectively reported by participants, will be used for determining whether an exercise must be modified or discontinued.[70 71] For this purpose of this study, we adopted a criteria used in a previous study.[72] Participants will be encouraged to continue with an exercise as long as the reported pain levels ranging from slight to endurable. Participants should discontinue exercise or reduce load if: (1) pain increases beyond what is acceptable/ bearable for the participant; (2) participant reports an immediate increase of pain by 3 points (NPRS) during exercise; (3) pain persists longer than 30 sec after completion of exercise; (4) an exercise cannot be performed due to pain, clinicians will be asked not to include that specific exercise for the next 2 sessions and replace that exercise another exercise (for the tailored rehabilitation group) or with a longitudinal traction or pendulum exercise (for the standardized rehabilitation group).[8] All participants will receive home-based stretching and strengthening exercises, and will be asked to perform these once a day.

Primary outcome measures

The primary feasibility outcome measures are (Figure 2):

1. Participant's recruitment rate, measured as number of participants per month;
2. Proportion of participants enrolled from the total number screened, expressed as the ratio "number of enrolled participants/total number of screened participants", with reasons;

3. Adherence to the rehabilitation programme, measured as number of sessions attended, and expressed as a percentage of the total number of sessions;
4. Drop-out rates, measured as the number of participants who dropped-out, and expressed as a percentage of the total number of participants enrolled in the study.

Secondary outcome measures

The patient-reported outcome measures intended as the primary and secondary outcomes in the main trial will be used as secondary outcome measures in this feasibility trial (Figure 2). These are: pain level as measured by a numeric pain scale,[73] and shoulder-related disability assessed using the 'patient specific functional scale' (PSFS), the Shoulder Pain and Disability Index (SPADI),[74] and the pain self-efficacy questionnaire.[75] The minimal clinically important difference for the numeric pain scale is 1 point,[76] and for the PSFS is 1.3 (for small changes), 2.3 (for medium changes) and 2.7 (large changes).[77] Although this feasibility trial is not powered to detect superiority, we will assess the magnitude of mean treatment effects for pain and physical function in relation to clinically important change, to inform the choice of primary outcome and sample size calculation for the main trial.

We will assess safety by recording all adverse events, both related and unrelated to interventions, in each group. Potential adverse reactions to interventions may include muscle soreness or increased pain around the shoulder joint. The physiotherapist will record any adverse reactions to interventions, including duration and severity of adverse reaction to treatment, and how the adverse reaction was managed. We will include in the report the total number of participants who reported adverse events, relatedness to interventions, the duration and severity of the adverse reactions. In the small sample of this feasibility trial, we do not expect to observe a representative number of adverse events, so do not intend statistical comparisons; rather, we will assess the feasibility of the recording forms and systems for use in the main trial.

Figure 2

Health outcomes

Health outcomes will be expressed as quality-adjusted life years (QALYs) using the Short-Form 12 (SF-12v2).[78] The SF-12v2 will be converted to a six-dimensional health state classification (SF-6D).[79] The SF-6D allows estimating the quality-adjusted life year (QALY). A QALY is a year of life experienced with a particular health-related quality of life, and will be expressed as a score ranging from 0 to 1, with 0 = death and 1 = full health. Total QALY will be estimated for each participant by calculating the area under the curve (the product of utility values by time). We will calculate the mean QALYs for each group and adjust for baseline utility scores to minimize any bias due to chance baseline imbalance between the groups. As this feasibility trial is not powered to detect superiority, we will assess the magnitude of mean effect on QALYs in relation to clinically important change.

We will adapt the Otago Cost and Consequences Questionnaire (OCC-Q) to shoulder disorders, and use the adapted questionnaire to capture healthcare use and costs for participants enrolled in this study.[80] The OCC-Q is a patient-administered questionnaire developed for osteoarthritis that has demonstrated accuracy and agreement with administrative databases from the national healthcare system in NZ.[80] The OCC-Q will be administered at baseline and 12-week time points.

Time points

Outcome measures will be recorded at baseline, 4th, 8th and 12th week after baseline.

Missing data

When assessing secondary outcome measures, we will use a linear mixed-effect model to compare groups. This method can handle missing data. For the other analysis, in case of missing data, we will assess its distribution to confirm the assumption that data was missed at random. If missing at random is confirmed, we will perform multiple imputations.

Statistical analysis

All statistical analyses will be performed using R software.[81] Descriptive statistics will be used to analyse: (1) recruitment rates; (2) adherence to the rehabilitation programme; (3) proportion of participants enrolled from the total number screened; (4) drop-out rates; (5) adverse reactions.

We will use a linear mixed-effect model to obtain estimates of intervention effects, we will compare changes in pain and shoulder-related disability scores between the two intervention groups (i.e. tailored and standardized rehabilitation). Group intervention (tailored and standardized rehabilitation) will be considered as between-subject factor, and 'time-point' (baseline, 4th, 8th week and 12th week) will be considered as within-subject factor. Baseline measurements will be considered as covariates. We will conduct an independent linear mixed-effect model for each outcome measure (i.e. pain levels and shoulder-related disability). Alpha will be set at 0.05, and power at 80% for all statistical analysis.[82] Since this is a feasibility study, we will not adjust alpha for multiple comparisons.[83] This will decrease the chance of Type II error, increasing the chance of identifying potentially important differences between groups. This statistical approach is considered appropriate for feasibility or exploratory studies.[83]

To determine whether or not it is worthwhile conducting the full trial, it is recommended that confidence interval (CI) ranges other than 95% should be used (e.g. 85% or 75%CI in addition to the mean difference estimate) when assessing differences between groups from feasibility trials.[84] For the purposes of this study, we will consider 75% CI as the probability threshold.[84] The mean difference between tailored rehabilitation and standardized rehabilitation will need to be larger than the minimum clinically important difference for either pain or shoulder-related disability. Therefore, we will consider appropriate to conduct the full trial if we can be, at least, 75% sure that tailored rehabilitation is superior to standardized rehabilitation at 3-month follow-up.

Economic Evaluation

We will use an incremental cost-utility analysis, following intention-to-treat principle, to assess differences in costs and utilities between tailored rehabilitation and standardized exercise, and report incremental net monetary benefit. We will use both a health system and a societal perspective to define and measure costs, as is recommended for cost-effectiveness studies.[85] We will also report the cost-efficacy and direct medical costs within the NZ healthcare system, and will calculate Bayesian credibility intervals (Bayesian analogue of 95% confidence intervals) to account for uncertainty in measurements due to sampling random variability,[86] and will plot cost-effectiveness acceptability curves.[87]

Nested qualitative study

We will include a nested qualitative study that will assess participants' experiences about the trial, and will use a thematic analysis to interpret the data.[88] We will invite all participants to take part in a semi-structured interview. The goal is to gather data about patients' experience in the trial, in particular about the difficulties and barriers faced by participants, the perceived value and positive aspects of the study and any other issue that may arise during the interviews. Findings from the nested qualitative study will add significant value into how we can minimize

perceived barriers, and increase adherence with the trial. Interviews will take place once participants complete the intervention programme (i.e. at the 8-week follow-up).

We will use thematic qualitative analysis to analyse and interpret transcriptions from interviews with patients. We will conduct the thematic qualitative analysis in 5 steps: (1) generation of codes; (2) identification of themes; (3) revision of themes; (4) definition and naming of themes; (5) interpretation of findings.[88] We will keep an audit trail, and members of the research team will crosscheck the coding and interpretation of data. We will adopt an iterative approach during data analysis, and will discuss and reflect on each step to identify any inconsistencies during the thematic qualitative analysis. We will analyse, write, and submit for publication the qualitative study as a separate manuscript.

Nested process evaluation study

We will conduct a process evaluation study using a mixed-method design. As part of the process evaluation, we will assess the fidelity, dose and reach of interventions implemented during the Otago MASTER Feasibility trial. We will assess fidelity of interventions by monitoring clinical notes, fortnightly, during the intervention period. Two clinical researchers (the PI and a research assistant) will be responsible for conducting the process evaluation. As per the Medical Research Council (MRC, United Kingdom – UK) guidelines,[21] we will adopt an active role, and provide feedback and additional training to clinicians if required. This approach will optimize fidelity of interventions. According to the MCR (UK) guidelines, this is the most appropriate approach for process evaluation during feasibility trials.

We will conduct a focus-group with clinicians once 70% of data collection has been completed. The focus-group will allow us to assess clinicians' perspectives (barriers and facilitators) about the interventions and the trial. We will use thematic qualitative analysis to analyse and interpret transcriptions from the focus-group. We will conduct the thematic qualitative analysis in 5 steps: (1) generation of codes; (2) identification of themes; (3) revision of themes; (4) definition and naming of themes; (5) interpretation of findings.[88] We will keep an audit trail, and members of the research team will crosscheck the coding and interpretation of data. We will adopt an iterative approach during data analysis, and will discuss and reflect on each step to identify any inconsistencies during the thematic qualitative analysis. We will analyse, write, and submit for publication the process evaluation study as a separate manuscript.

Discussion

In the short-term, the impact of this phase II trial is inform whether or not it is feasible to conduct the full efficacy trial. If the full trial is feasible, the medium-term impact of this proposal will be to determine which exercise therapy intervention is superior for managing patients with shoulder subacromial pain.

This protocol has limitations. We did not include in the initial plan a control arm, to optimize costs at phase II, and given that some reviews and guidelines suggest exercise therapy as the treatment of choice.[10 11 49] A recent Cochrane Review recommends future trials to compare exercise therapy interventions with placebo.[9] In addition, during the peer-review process of this protocol, one reviewer raised the relevance of including a placebo arm. If findings from this feasibility trial suggest that it is feasible to conduct a full trial, we will design a three-arm intervention trial to address recommendations from the Cochrane Review. The full trial will consist of: (1) placebo; (2) tailored rehabilitation; (3) standardized rehabilitation. For this feasibility trial, we estimated sample size based on a two-arm intervention. The advantage of this approach is to reduce the required sample size for the feasibility phase, however, it increases uncertainty on estimates of treatment effects. [56] This will impact on sample size estimation of the full trial, if findings from

this trial supports the next trial stage.[56] To address that uncertainty on treatment effect estimates, we will take this into account when preparing the future trial.

Data management

Data will be collected by trained researchers, using hard copies of forms and questionnaires. These will be safely stored and locked in a filing cabinet based at the Centre for Health, Activity and Rehabilitation Research School of Physiotherapy – University of Otago. A research assistant 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). We will use single-data entry, with 10% of the data being entered independently by two research assistants and crosschecked. In addition, we will use histograms, stem and leaf plots, clinical and data-driven range checks as part of quality control.[89 90]

Trial monitoring

The Health Research Council (HRC) Data Monitoring Core Committee (New Zealand) categorised this trial as low risk, and recommended that an independent Data Monitoring Committee was not necessary. The HRC Data Monitoring Core Committee recommended that an internal monitoring process is sufficient to monitor and oversee this trial. Based on these recommendations, the Data Monitoring Committee from the 'Centre for Health, Activity and Rehabilitation Research' (School of Physiotherapy – University of Otago) will monitor and oversee the trial. The research team has opted not to undertake interim analysis.

Ethics and Dissemination

This study was approved by the University of Otago Ethics Committee [Ref: H17/080]. Findings from this study will be presented at national and international conferences, and will be submitted for publication in a peer-reviewed journal.

Patient and Public Involvement

Patients and or public were not involved. Results of this study will be disseminated to study participants by inviting them to join an open-seminar in which the results of the study will be presented. In addition, we will prepare a short report with the main findings of the study and distribute this by e-mail to participants. The burden of the intervention will be assessed by participants through the nested qualitative study. In that study, we will participants' experiences and perceptions about the trial.

Declarations

Data collection, storage and sharing

We will store participants' data on a secure local server, and will use unique identification number on follow-up questionnaires. To protect participants' privacy, all identifying information will be stored separately, and deleted following the conclusion of the trial. We will not share or report identifying information. The datasets generated during the study will be available from the corresponding author on reasonable request.

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.

Adverse event management

The risk of a serious adverse event related to the intervention is minimal. If a participant presents with an adverse event, the primary investigator will report it to the internal Data Monitoring Committee (Centre for Health, Activity and Rehabilitation Research—University of Otago) to assess whether it is necessary to report the adverse event to the trial sponsor, and Ethics Committee. We will suspend the trial if more than one serious adverse event of any kind occurs and these are related or caused by the interventions from the trial. If the cause of the events cannot be determined or remediated, and is plausibly related to the intervention, we will terminate the trial.

Protocol amendments

We will report any protocol change that may benefit participants, impact on participant's safety or that is likely to impact on the outcomes of the study (e.g. study objectives and/or design changes, sample size, study procedures, or significant administrative changes).

Competing interests statement

None declared.

Authors' contributions

DCR and ZJT conceived the research question. DCR was responsible for the design of the trial, and is the guarantor. ZJT and GS contributed to the design of interventions. JHA provided guidance on the design the trial and economic analysis. DCR led efforts for securing funding, with the contributions from ZJT, GS and JHA. All authors revised and approved the protocol for the study. All authors revised the manuscript for important content and approved the final version.

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The Health Research Council – New Zealand had no role in the design of the trial and will have no role in its execution, data analysis and interpretation, or on the submission of the studies for publication.

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Figure captions

Figure 1. Diagram of participant flow at the Otago MASTER feasibility trial.

Figure 2. Schedule for enrolment and intervention per group.
SPADI: Shoulder Pain and Disability Index; OCC-Q-Shoulder: Otago Cost and Consequences Questionnaire – Shoulder.

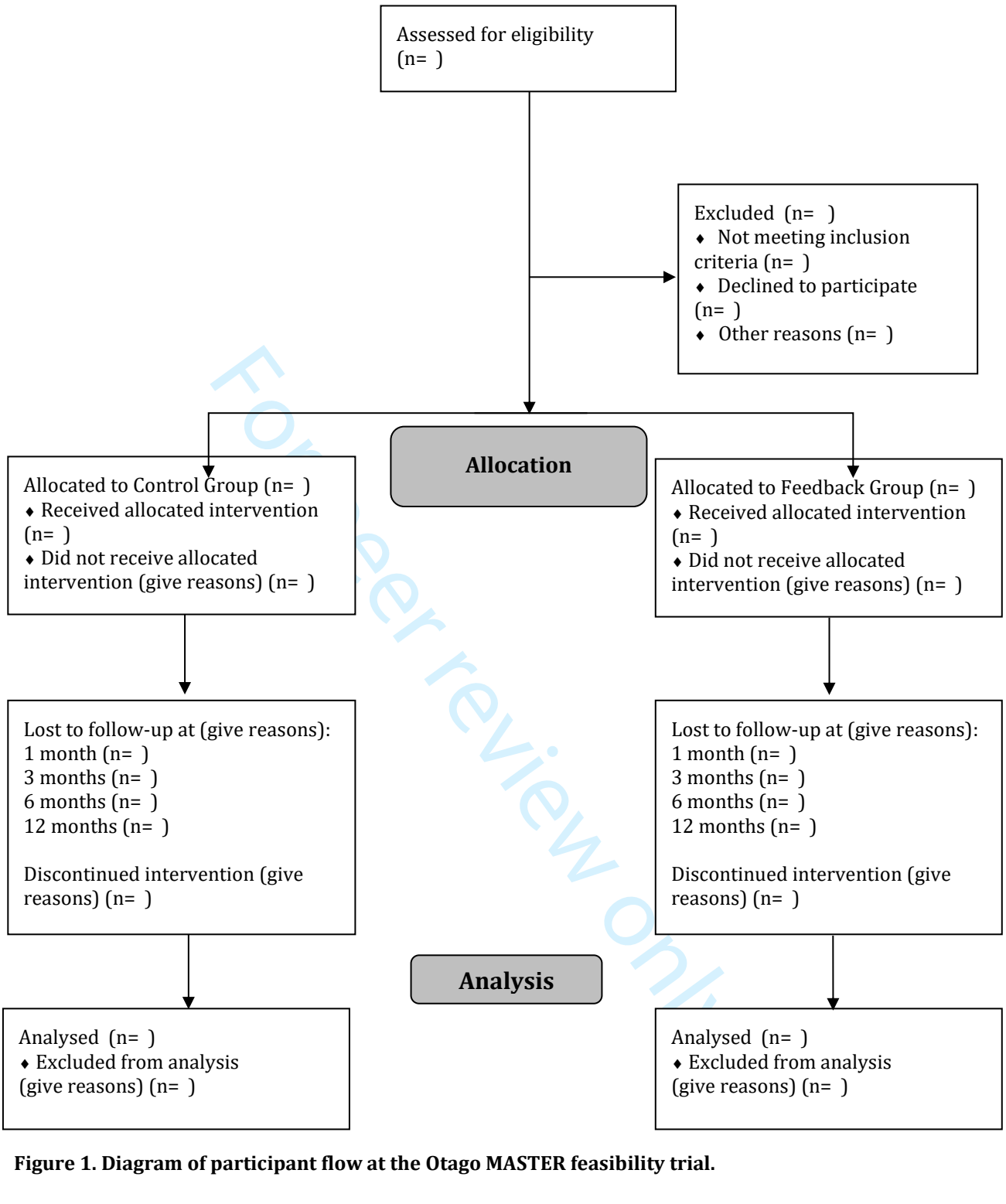

Figure 1. Diagram of participant flow at the Otago MASTER feasibility trial.

	Study Period					
	Enrolment	Allocation	Post allocation			
Time point	-t1	0	Baseline	4 weeks	8 weeks	12 weeks
Enrolment						
Eligibility screen	X					
Informed consent	X					
Allocation						
Intervention						
Standardized rehabilitation			←	—	→	
Tailored rehabilitation			←	—	→	
Assessments						
Baseline Demographic information	X					
Covariates:						
Age			X			
Height			X			
Weight			X			
Primary, and secondary outcome measures:						
Recruitment rates			X	X	X	X
Adherence to the rehabilitation programme			X	X	X	X
Proportion of participants enrolled			X	X	X	X
Drop-out rate			X	X	X	X
Adverse reaction			X	X	X	X
Pain intensity			X	X	X	X
Health outcomes						
Patient specific functional scale			X	X	X	X
SPADI			X	X	X	X
OCC-Q-Shoulder			X			X
Pain self-efficacy questionnaire			X	X	X	X

Figure 2. Schedule for enrolment and intervention per group.
SPADI: Shoulder Pain and Disability Index; OCC-Q-Shoulder: Otago Cost and Consequences Questionnaire – Shoulder.

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Supplementary Material 1

Otago MASTER Feasibility Trial

Tailored rehabilitation programme

UNIVERSITY of OTAGO Te Whare Wānanga o Otāgo NEW ZEALAND
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Findings from physical examination & suggested exercises:

Findings from physical examination	Exercises
Pain or stiffness during passive accessory mobilization	Cervical or thoracic spine: HVT or PAIVM PAIVM If Grade –III or -IV if pain dominant Grade –IV or +IV if stiffness Gleno-humeral joint: Passive accessory mobilization - Grade –III or -IV if pain dominant - Grade –IV or +IV if stiffness
Painful or limited arm elevation during active resistive arm movement (flexion, abduction, internal rotation and external rotation) **Positive MWM** during shoulder scaption, shoulder external rotation, hand behind back position	# **1.A.** MWM for increasing shoulder scaption **#1.B.** MWM for increasing shoulder external rotation **#1.C.** MWM during shoulder elevation **#1.D.** MWM during hand behind back motion **#T.1.** Taping for sustained postero-lateral glide on humeral head (end of session) **# 11** Isolated motor control training around the shoulder
Positive scapular dyskinesis test: Scapular winging, tipping or hiking	**#4** Scapular setting in static postural position **#5** Scapular setting during dynamic elevation and rotation **#6** Shoulder shrugs with shoulder higher than 90^0 abduction

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Findings from physical examination	Exercises
	#7 Shoulder horizontal exercise with multiple feedbacks
Anterior translation humeral head, positive dynamic relocation test **Positive dynamic rotary stability test or shoulder pain during arm rotation (active or resistive)**	**#10** Dynamic relocation training **#11** Isolated motor control training around the shoulder
Positive Scapular MWM during scaption	**#1.C.** Mobilization with movement for scapular upward rotation
Positive Scapular upward rotation test	**#3** Scapular upward rotation training (retraining serratus anterior and upper trapezius)
Positive scapular weight bearing test	**#7** Shoulder horizontal exercise with multiple feedbacks **#8** Dissociation of scapular movements to thoracic in four point kneeling position and in for challenging situation by holding weight on just one hand **#9** Scapular holding training at mid protraction position (we perform this exercise when participant is able to scapular protraction and retraction
Positive scapular control test	**#2** Scapular exercises

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Quick Exercise Reference:

Mobilization with movement techniques

(1 MWM counts as **one** exercise. Start with 3 sets of 10 reps with 30 sec rest between sets)

Exercise	**Stage 1 (Basic)**	**Stage 2 (Intermediate)**	**Stage 3 (Advanced)**
1.A. **Shoulder scaption**	**1. A.1** In sitting, participant performs active shoulder scaption with ***elbow flexed*.**	**1. A.2** In sitting, participant performs active shoulder scaption with ***elbow extended***.	**1. A.3.** In sitting, participant performs shoulder scaption ***against a light weight*** or theraband (low intensity).
1.B. **Shoulder external rotation (ER)**	**1. B.1** In supine, participant performs ***active-assisted*** *shoulder ER* with the help of a wand. Therapist applies a posterolateral humeral glide.	**1. B.2** In sitting with arm at 90^0 abduction and elbow flexed, participant performs an ***active*** *shoulder ER*. Therapist sustains a posterolateral humeral glide.	**1. B.3** In sitting, participant performs shoulder ER *against* ***light resistance*** (low intensity). Therapist sustains a posterolateral humeral glide.
1.C. **Scapular up ward rotation**	**1. C.1** In sitting, participant performs active shoulder flexion with ***elbow flexed*.** Therapist assists scapular upward rotation	**1. C.2** In sitting, participant performs active shoulder flexion and ***elbows extended***. *T*herapist assists scapular upward rotation	**1. C.3** In sitting, participant performs active shoulder flexion and elbows extended ***against resistance*** (low intensity). *T*herapist assists scapular upward rotation

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Mobilization with movement techniques

1 MWM counts as **one** exercise. Start with 3 sets of 10 reps with 30 sec rest between sets

1.D. **Hand behind back motion**	**1. D.1** In sitting, participant moves hand behind back by ***pulling a belt*** *with other hand* while physiotherapist applies inferior glide on the shoulder.	**1. D.2** In sitting, participant moves hand behind back ***actively*** while physiotherapist applies inferior glide on the shoulder.	

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Scapular Control Training

Exercise	Stage 1	Stage 2	Stage 3	Home ex.
2. Scapular exercise	**2. A.1**. In side lying position physiotherapist uses ***resistance*** against shoulder D1 pattern.	**2. A.2**. *In* side lying, participant performs the shoulder D1 pattern in side lying position as ***free active*** movement.	2. A.3. ***In sitting,*** participant performs the shoulder D1 pattern as **free active** movement.	#7
	2. B.1. In side lying position physiotherapist *uses* ***resistance*** against shoulder D2 pattern.	**2. B.2.** In side lying, participant performs the shoulder D2 pattern in side lying position *as* ***free active*** movement.	2. B.3. ***In sitting***, participant performs the shoulder D2 pattern in side lying position as **free active** movement.	
3. Scapular upward rotation training (retraining serratus anterior and upper trapezius)	**3. A.1.** In the side lying position, participant elevates their arm while the therapist ***assists*** *serratus anterior* activity through feedback.	**3. A.2.** In the side lying position, participant elevates their arm against gentle resistance. The therapist **gently resists** serratus anterior activity by *resisting scapula upward rotation*.	**3. A.3.** In the side lying position, participant elevates their arm while the therapist ***increases resistance*** *against serratus anterior* activity by resisting scapular upward rotation.	#6

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4. Scapular setting in the ideal postural position *(static position*)	**4. A.1** In sitting *with* ***elbows resting on the armchair***. Participant is asked to tighten the scapula on their upper back. Physiotherapist uses feedback to inform participant of normal scapular position	**4.A.2** In sitting, participant is asked to tighten the scapula on their upper back *at* ***60°, 90° and 120° of shoulder elevation*** while the physiotherapist uses feedback to inform participant of normal scapular position	**4. A.3** In sitting, participant is asked to tighten the scapula on their upper back **at 60°, 90° and 120° of shoulder *elevation with a dumbbell*** (low intensity)**.** Physiotherapist informs participant of normal scapular position	#3
5. Scapular setting during dynamic elevation and rotation	**5 .A.1** In standing, participant performs shoulder flexion with the help of a ***ball on horizontal surface***. The physiotherapist prevents any abnormal scapular or shoulder movement.	**5 .A.2.** In standing, participant performs shoulder flexion with the help of a ***ball on inclined surface.*** The physiotherapist prevents any abnormal scapular or shoulder movement.	**5 .A.3.** In standing, participant performs shoulder flexion with the help of a ***ball on the wall.*** The physiotherapist prevents any abnormal scapular or shoulder movement.	#4a, #4b, #4c and #4d
	5. B.1 In sitting or standing, participant is asked to maintain normal scapular movement during arm **flexion *to 90° or arm abduction to 60°.*** The therapist prevents excessive shoulder hiking.	**5 .B.2** In sitting or standing, participant performs long lever arm shoulder elevation to ***beyond 90 degrees.*** Therapist ensures smooth movement of scapula without compensatory movements.		

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	5 .C.1 In sitting or standing, participant is asked to maintain normal scapular movement during **arm flexion to 90° or arm abduction to 60°** *against light resistance* (low intensity). Therapist prevents excessive shoulder hiking.	**5. C.2.** In sitting or standing, participant performs shoulder elevation to **greater than *90°*** *against light resistance* (low intensity). The therapist ensures participant can maintain normal scapular and shoulder movement.		#4F & G
	5. D.1. Participant is standing with arm and side and elbow flexed to 90°. Participant performs bilateral shoulder elevation with isometric shoulder external rotation against ***resistance (low intensity)*.**	**5. D.2.** Participant is standing with arm and side and elbow flexed to 90°. Participant performs bilateral shoulder elevation with isometric shoulder external rotation against ***resistance (mod intensity)***.	**5. D.3.** Participant is standing with arm and side and elbow flexed to 90°. Participant performs bilateral shoulder elevation with isometric shoulder external rotation against ***resistance (high intensity)*.**	
	5. E.1. Participant is s*itting* with shoulder abducted 90°and elbow flexed to 90°. Participant performs ***unloaded arm internal and external* rotation** without any compensatory scapular or shoulder movements.	**5. E.2.** Participant is standing or sitting with shoulder abducted 90°and elbow flexed to 90°. Participant performs ***arm internal and external rotation*** **against *theraband*** (low intensity) without any compensatory scapular or		

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		shoulder movements.		
	5. F.1. Participant is in *prone* with shoulder abducted 90° and elbow flexed to 90°- The ***shoulder and forearm is supported*** using a towel roll or a pillow. Participant performs *arm internal and external* rotation without any compensatory scapular or shoulder movements.	**5. F.2.** Participant is in *prone* with shoulder abducted 90° and elbow flexed to 90°- The shoulder and **forearm is unsupported** (*participant actively holds the shoulder off the bed)*. Participant performs *arm internal and external* rotation without any compensatory scapular or shoulder movements.	**5. F.3.** Participant is in *prone* with shoulder abducted 90° and elbow flexed to 90°- The shoulder and forearm is **unsupported** (participant actively holds the shoulder off the bed). Participant performs *arm* internal and external rotation ***against resistance*** without any compensatory scapular or shoulder movements.	
6. Shoulder shrug exercise with <u>shoulder higher than 90° of abduction</u>	**6. A.1** In standing, shoulder flexed, participant performs **assisted** *shoulder shrug (*wall slide or pulley). Physiotherapist prevents over activity of the levator scapulae.	**6. A.2** In standing, shoulder flexed, and participant does ***active*** *shoulder shrug without wall support. P*hysiotherapist prevents over activity of the levator scapulae.	**6. A.3** In standing, shoulder flexed, participant shrugs shoulders ***against resistance.*** *P*hysiotherapist prevents over activity of the levator scapulae.	#2

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7. Shoulder horizontal exercise with multiple feedbacks	**7. A.1**. Participant ***stands in front of a wall*** with their hands overhead on the wall. Participant is then asked to take their hands on and off the wall. The physiotherapist facilitates activity of the lower trapezius.	**7. A.2.** Participant is in ***side lying*** position with arm overhead (100° of flexion). Participant performs *horizontal shoulder abduction.* The physiotherapist facilitates activity of the lower trapezius.		#5
	7. B.1. Participant is either in ***prone*** with arms hanging off the side of bed or in 4-point kneeling position. Participant then extends and abducts their arm to 90 degrees.	**7. B.2.** Participant is in prone or in 4-point kneeing with **arm abducted greater than 90 degrees.** They are asked to lift their arms off the bed against appropriate resistance.		
8. Dissociation of scapular movements to thoracic in four point kneeling position	8. A.1. Leaning over table with **partial weight bearing on hands**, participant performs scapular protraction and retraction	8. A.2 **In four-point keeling position**, participant performs scapular protraction and retraction	8. A.3. In four-point keeling position while **weight bearing on one hand**, participant performs scapular protraction and retraction	NA
9. Scapular holding training at mid protraction position	9. A.1. In standing position, participant performs resisted scapular protraction against **light resistance.**	9. A.2. In **4-point kneeling**, participant holds scapula in mid protraction for 10 seconds.	9. A.3. Participant is in **three-point kneeling** (weight on affected extremity) and holds the scapula in mid-protraction for 10 secs.	NA

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Rotator Cuff Motor Training				
Exercise	**Stage 1**	**Stage 2**	**Stage 3**	**Home exercise**
10. Dynamic relocation training	10 .A.1. In sitting or supine position, participant draws their shoulder head towards the socket as physiotherapist applies gentle traction on the humerus.	10 .A.2 In sitting, participant draws their shoulder "in and back" towards their socket, *without humeral traction*, at the outer or inner shoulder rotation degrees.		#8 for Stage 3
11. Isolated motor control training around the shoulder	11 .A.1. In prone position with arm abducted to 90 degree, participant tightens their scapula and draws the humeral head gently down and in as they externally rotate their shoulder.	11 .A.2. In sitting with arm abducted to 90 and elbow flexed to 90, participant tightens their scapula and draws the humeral head gently down and in as they externally rotate their shoulder.	11 .A.3. In sitting with arm abducted to 90 and elbow flexed to 90, participant tightens their scapula and draws the humeral head gently down and in as they externally rotate their shoulder against resistance.	Home exercise #9 for Stage 3

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Proprioception, and plyometric training		
12. Proprioception training	**12. A.** The participant is sitting with a ball beneath their hand. Participant alternately presses and releases the ball	**12. C.** In sitting, pressing down the hands on the seat and lifting their bottoms off the bed.
	12. B. The participant pushes and releases a ball on the wall. The therapist ensures that participants stabilizes the scapula to prevent winging	**12. D.** Plyometric ball catching and throwing exercise.

Taping
T.1. Taping for sustained postero-lateral glide on humeral head.

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Exercise description

1. Monilization with Movement

1.A. Mobilization with movement for increasing shoulder scaption

Equipment: Mulligan Belt (for stage 3).

Participant position: Sitting.

Therapist position: Therapist places their hand on humeral head anteriorly.

Direction of force: Physiotherapist sustains posterolateral glide on humeral head.

Joint Movement: Participant performs scaption. It is important that physiotherapist allows normal motion between scapula and thorax to ensure pain free scaption.

1. A.1. Stage 1: Participant performs the arm scaption with elbow flexed.

1. A.2 Stage 2: Participant performs the technique with elbow extended.

1. A.3 Stage 3: Participant performs scaption against a light weight or a Thera band with elbows extended.

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1.B. Mobilization with movement for increasing shoulder external rotation

Equipment: Wand (for stage 1), Theraband (stage 3).

Participant position: Variable based on stage. Please refer to individual stages below.

Therapist position: Variable based on stage.

Direction of force: Physiotherapist sustains posterolateral glide.

Joint movement: Participant externally rotates the shoulder.

1. B.1. Stage 1: Participant is in supine with arms in comfortable abduction and elbows flexed to 90º, holding a stick in both hands to assist the external rotation of the involved shoulder. Physiotherapists sustain posterolateral humeral glide while participant performs passive shoulder external rotation (figure above).

1. B.2. Stage 2: Participant is sitting with shoulder abducted to 90, elbow flexed to 90 and then performs active external rotation as physiotherapist applies posterolateral glide.

1. B.3. Stage 3: Same as above but participant performs ER against light resistance.

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1.C. Mobilization with movement for scapular upward rotation

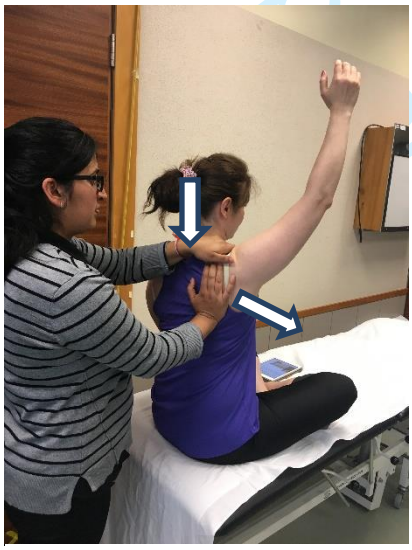
Equipment: Theraband (for stage 3)

Participant position: Sitting without back support.

Therapist position: Behind the participant. One hand on the spine of scapula and other on the medial aspect of scapular body.

Direction of force: Physiotherapist sustains downward and medial glide over the spine of scapula with one hand and rotates scapula upwardly with other hand while preventing scapular winging and tipping

Joint Movement: Participant performs shoulder elevation.



1.C.1 – Stage 1

1.C.1 – Stage 2

1. C.1. Stage 1: Participant performs shoulder flexion with elbow flexed

1. C.2. Stage 2: Participant performs shoulder flexion with elbow extended

1. C.3. Stage 3: Participant performs resisted shoulder flexion with elbow extended against light resistance.

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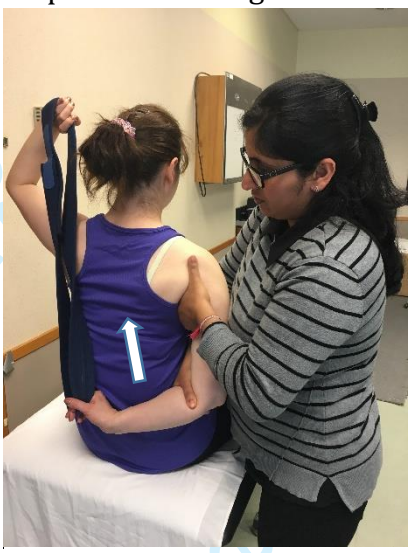
1.D. Mobilization with movement for hand behind back motion

Equipment: Belt (for stage 1)

Participant position: Sitting or standing.

Therapist position: Standing on the affected side. One hand on the lateral border of scapula and other hand on distal humerus for applying inferior glide.

Direction of force/ Movement: Physiotherapist stabilizes the scapula and applies *inferior glide (traction)* while participant is reaching to the back with the involved hand.



1. D.1 Stage 1: Participant reaches the affected hand behind back with the help of a belt.

1. D.2. Stage 2: Participant actively holds hand behind back without assistance

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2. Scapular exercise

In participants with poor awareness or control, the scapula tends to follow a curvilinear path rather than a diagonal, with jerky uncoordinated movement. Frequently, the scapula moves into excessive protraction and anterior tilt when attempting the 'up and forward' direction.

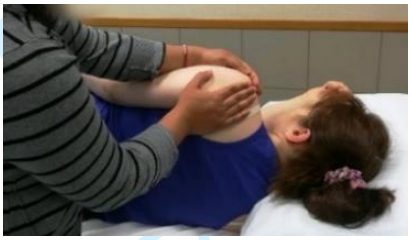
2 .A. The D1 pattern (elevation-protraction to depression-retraction)
Participant moves the tip of the shoulder towards the corner of the eye. And then returns it down and back to the opposite hip. Please make sure that participant has the chin tucked in.

2. A.1. (**Stage 1) - (Picture below, left):** Participant performs the D1 pattern in side lying. Physiotherapist applies resistance against the movement.

2. A.2. (Stage 2) - (figure below, right): Participant performs the pattern in side lying without resistance.

2. A.3. (**Stage 3):** Participant performs the pattern in sitting without resistance.


2.A.1


2.A.2

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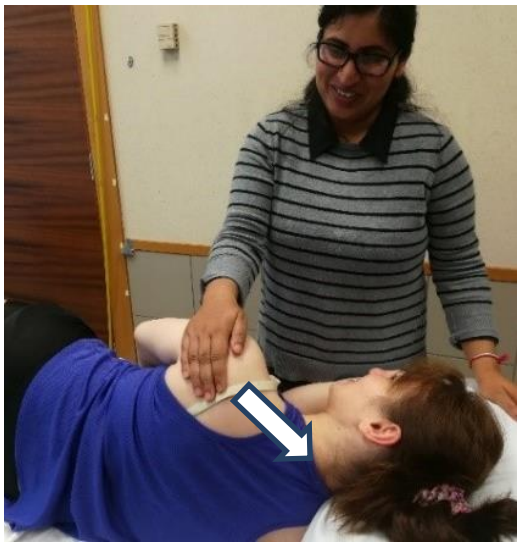
2. B. The D2 pattern (depression-protraction to elevation-retraction)

Participant moves the tip of the shoulder down and forward towards your opposite hip, then returns it up and back.

2. B.1. Stage 1: Participant performs the pattern in side-lying. Physiotherapist applies light resistance against the movement (Picture below).



2. B.2. (**Stage 2) (Picture below):** Participant performs the pattern in side lying without resistance

2. B.3. (**Stage 3):** Participant performs the pattern *in sitting* without resistance.

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3. Scapular upward rotation training (retraining serratus anterior and upper trapezius)

Equipment: None

Participant position: Participant in side-lying on the uninvolved arm.

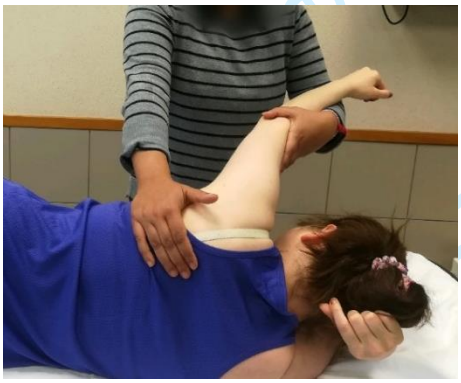
Feedback: Physiotherapist supports the upper arm in shoulder flexion greater than 90^0. Physiotherapist resists against shoulder motion and palpates the lateral border of scapula to activate serratus anterior.

Movement: Participant tries to bring the shoulder into more flexion and external rotation with scapular upward rotation.

3 .A.1. Stage 1(picture below). Physiotherapist *assists* in activation of serratus anterior by using palpation, tapping or repeated contraction or stretch

3 .A.2. Stage 2: Physiotherapist *resists gently* against scapular upward rotation.

3 .A.3. Stage 3: Physiotherapist *increases resistance* against scapular upward rotation.



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4. Scapular setting in postural position

Equipment: Mirror (if required for visual feedback).

Participant position: Upright sitting.

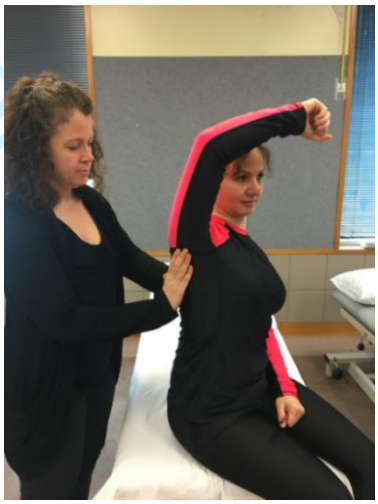
Feedback: The physiotherapist provides feedback (visual, tactile or verbal) to inform the participant of normal scapular resting position.

Movement: Participant is asked to tighten the scapula by contracting the serratus anterior and trapezius so that the inferior angle and medial border lies flat over the upper back. Participant holds this position for 10 seconds.

4. A.1. Stage 1: This stage is used for participants who have winging or tipping in upright position. The participant's arms are unloaded by placing the elbow over armchair. Participant is asked to "tighten their scapula on their upper back" and hold it for 10 seconds.

4. A.2. Stage 2 (Picture below): Scapular setting exercise is performed while participant holds the involved arm isometrically in 60°, 90° and 120° shoulder elevation. The shoulder may be internally rotated or externally rotated while the arm is held at 0°, 60°, 90° or 120°.





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4. A.3. –(Stage 3) (Picture below): Scapular setting exercise is performed at 60°, 90° and 120° shoulder elevation against light resistance provided by a dumbbell.

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5. Scapular setting during arm movements

(These exercises are used for participants with observable tipping or winging of the scapula *during arm movement*.)

Equipment: Mirror (if required for visual feedback), Gym ball (based on exercise) please refer to individual exercises

Participant position: Variable based on exercise.

Feedback: The physiotherapist provides feedback (visual, tactile or verbal) to inform the participant of normal scapular resting position.

Movement: Participant is then asked to maintain normal scapular position/ movement while preventing tipping and winging as they perform various arm movements.

5. A. Scapular setting during shoulder flexion with ball (pictures below)

5 .A.1 (Stage 1): Participant performs shoulder flexion on the bed with no inclination with the help of a ball.

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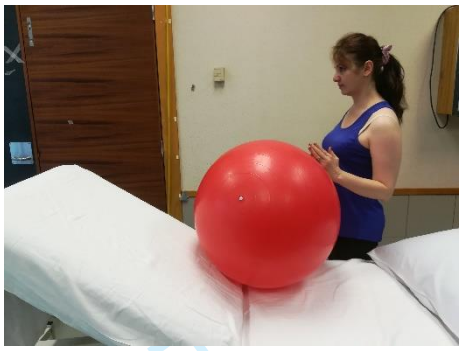
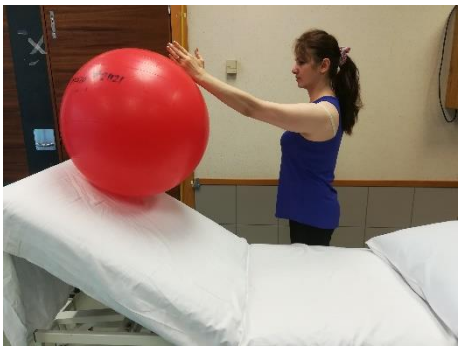
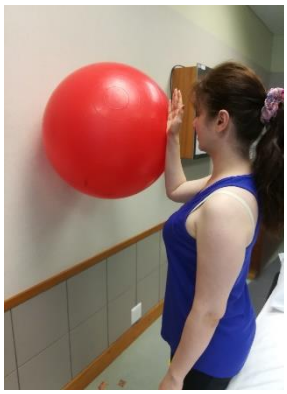
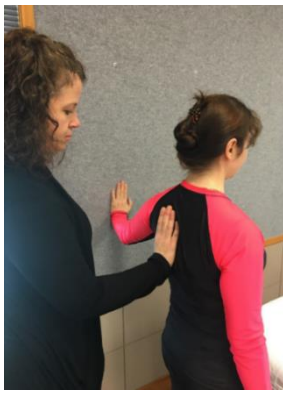
5 .A.2 (Stage 2): Participant performs shoulder flexion with the help of a ball on a surface inclined to 45°.

5 .A.3 (Stage 3): Participant performs shoulder flexion using a ball on a wall. Alternately, participant performs a simple wall slide.





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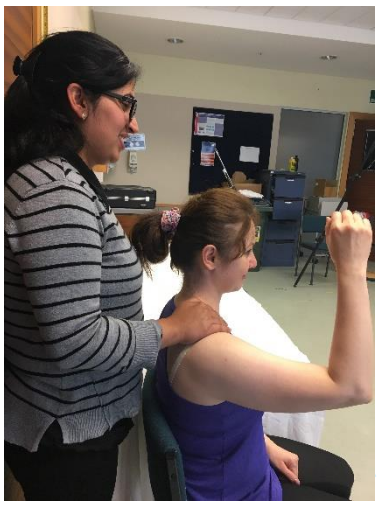
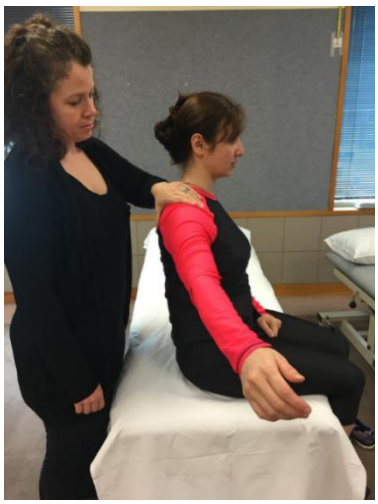
5. B. Scapular setting during arm elevation

5 .B.1. (Stage 1): Scapular setting during arm elevation to 90

Participant is asked to maintain normal scapular position during arm *flexion to 90°* or arm *abduction to 60°* with elbow flexed (easier) or extended (more difficult). The therapist prevents excessive shoulder hiking through appropriate feedback.





5. B.2 (Stage 2): Scapular setting during long lever arm elevation >90° (flexion and abduction) as free active

Participants actively elevates the arm (either flexion or abduction) to above 90° with elbows extended without any assistance or resistance. The therapist ensures smooth normal movement of the scapula without compensatory scapular hiking, tipping or winging.

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5. C. Scapular setting during arm elevation against resistance

5. C.1 (Stage 1): Scapular setting during gentle resisted arm flexion to 90° and abduction to 60°

Participant performs shoulder flexion to 90° or shoulder abduction to 60° against a light resistance (Theraband or dumbbell) while the physiotherapist provides feedback to prevent excessive shoulder hiking.

5. C.2 (Stage 2): Scapular setting during long lever arm elevation >90° against resistance

Participant performs shoulder elevation to *greater than 90°*, with elbows extended, against light resistance. Physiotherapist should ensure participant is able to control scapular winging during raising and lowering phases and that participant avoids scapular hiking.

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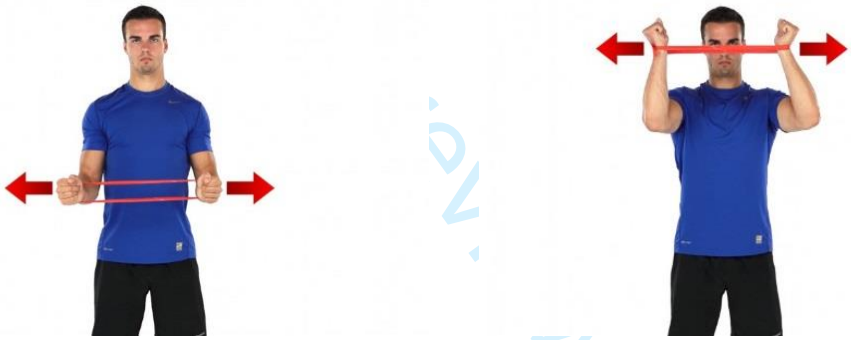
5. D. Scapular setting during bilateral shoulder elevation combined with external rotation resistance

5. D.1 Participant elevates both their arms to 90°, while isometrically contracting external rotation against light resistance (RPE 3 to 4), with elbows flexed.

5. D.2. Participant elevates both their arms to 90°, while isometrically contracting external rotation against moderate resistance (RPE 5 to 6), with elbows flexed.

5. D.3. Participant elevates both their arms to 90°, while isometrically contracting external rotation against high resistance (RPE 7 to 8), with elbows flexed.



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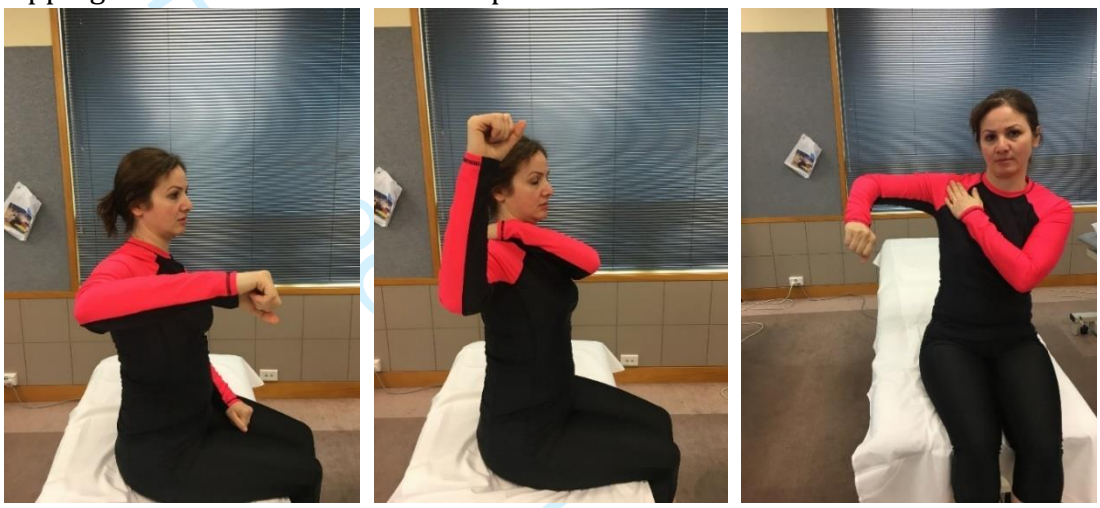
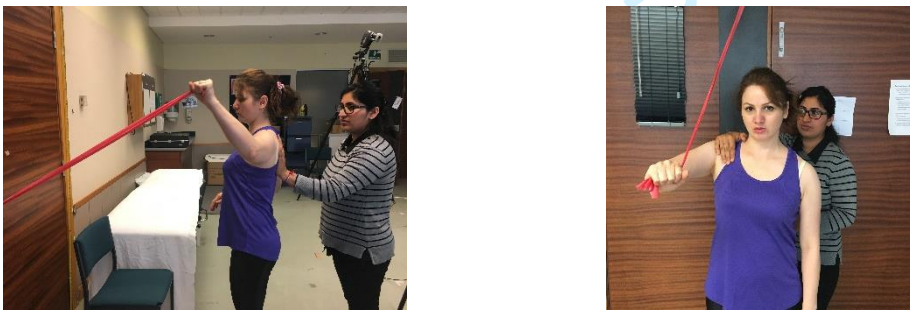
5. E. Scapular setting exercise during internal and external rotation in upright position

5. E.1.: Participant performs shoulder external rotation and internal rotation with shoulder flexed to 90° in sitting.
For ER: Physiotherapist makes sure that participant avoids shoulder depression and retraction.
For IR: Physiotherapist makes sure that participant avoids scapular anterior tipping and shoulder elevation and protraction.



5. E.2. Participant tightens the scapula during shoulder external rotation with arm at 90°. It is better to perform this exercise in front of mirror for added feedback.



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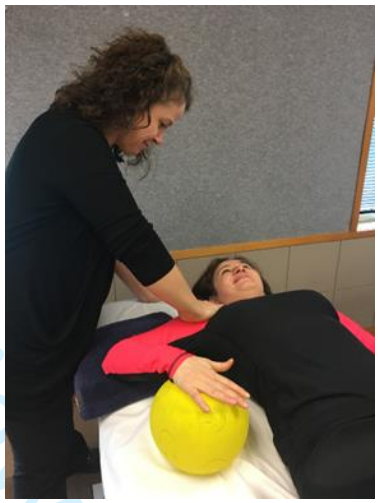
5. F. Scapular setting during shoulder rotation in prone:

Participant is asked to rotate the shoulder externally or internally without excessive scapular depression and retraction. The goal is to dissociate shoulder movement from scapular movement.

However, if the participant is unable to perform full internal rotation, they are asked to press on a ball in supine lying without lifting their shoulder from the bed (picture below- right). This activates the subscapularis muscle.

5. F.1 (Stage 1): Participant is in prone with arm flexed to 90° and elbow flexed to 90°. A towel roll is placed under the shoulder to support the arm as well as to prevent shoulder anterior tilting.



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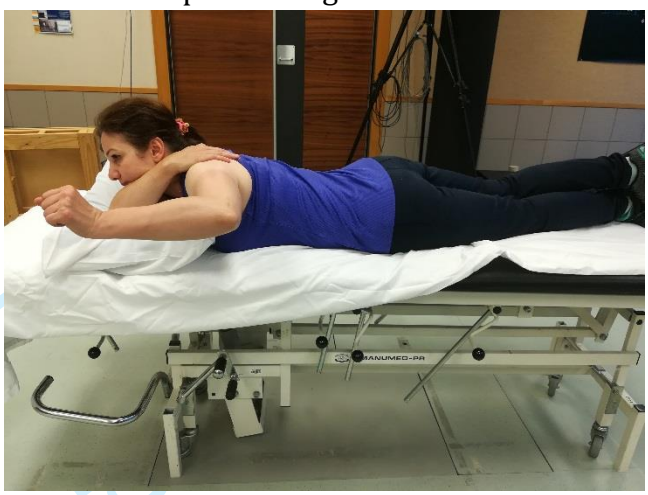
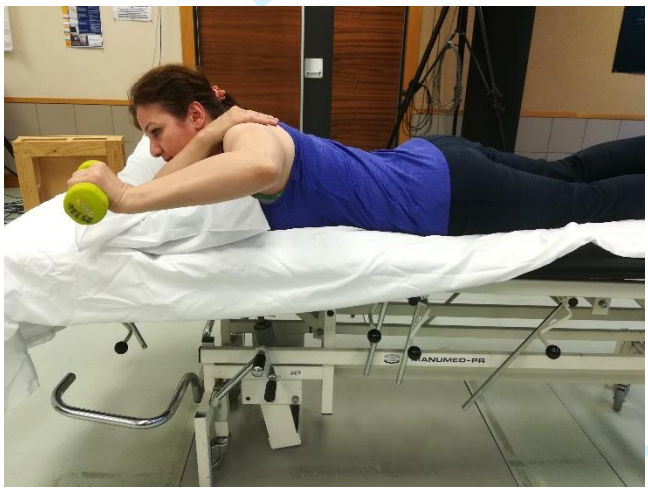
5. F.2 (Stage 2): Participant is in prone with arm flexed to 90° and elbow flexed to 90°. No support is provided and participant is asked to actively hold the shoulder off the bed while performing shoulder internal and external rotation.



5 .F.3. (Stage 3): Participant is in prone with arm flexed to 90° and elbow flexed to 90°. No support is provided and participant is asked to actively hold the shoulder off the bed while performing shoulder internal and external rotation against resistance.



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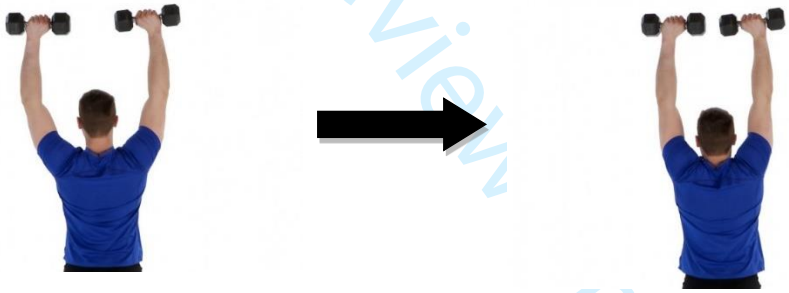
6. Shoulder shrug exercise where arms are higher than 90^0 of abduction

Equipment: Dumbbell (for stage 3).

Participant position: Standing.

Feedback: Physiotherapist uses appropriate feedback to facilitate the activation of the upper trapezius while preventing over activity of the levator scapula.

Movement: Participant raises the tip of shoulder towards the ear lobe while keeping their chin tucked.



6 .A.1 Stage 1: Participants elevate their arms and then perform shoulder shrug by sliding their hands up a wall or by using a pair of hanging strings from the ceiling.

6 .A.2. Stage 2: Participants perform the task as free active movement.

6 .A.3. Stage 3: Participants performs the task with light resistance (dumbbell).

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7. Shoulder horizontal exercise with multiple feedbacks

Equipment: Mirror (if required for visual feedback), Theraband (for stage 3).

Participant position: Variable based on stage.

Feedback: Physiotherapist **continuously taps the lower trapezius** to facilitate muscle activity and gives participant the verbal ques to tip the scapula posteriorly and avoid shoulder shrug.

Movement: The participant is instructed to "lift the arm from the scapula (by moving your scapula) and not from shoulder joint while keeping your arm in external rotation". This instruction is given to prevent excessive humeral head anterior translation.

7 .A Non-weight bearing exercises

7. A.1. (Stage 1): Participant stands in front of a wall with the hands overhead on the wall. Participant is then asked to take their hands on and off the wall. This exercise is applicable when participant is not able to do horizontal abduction in 4-point kneeling. Make sure that Participant performs the movement from their scapula.

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7. A.2. Stage 2: Participant is in side lying position with arm overhead (100° of flexion). Participant then performs subsequent ***arm extension and abduction***. The physiotherapist prevents arm hyperextension and encourages participant to elevate their arm from the scapula at the end range of arm extension. (Continuous tapping over lower trapezius is recommended).

7. B. Exercises in weight bearing

7. B.1. (Stage 1): Participant is either in prone with arms hanging off the side of bed or in 4-point kneeling position. Participant flexes and abducts their arm to 90 degrees. The physiotherapist prevents hyper abduction and encourages scapular movement.

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7. B.2. (Stage 2): Participant is in prone or in 4-point kneeing positions with arm abducted greater than 90 degrees. They are asked to lift their shoulders off the bed against appropriate resistance.

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8. Dissociation of scapular movements from thoracic movements in 4-point kneeling

Equipment: Wand for feedback
Participant Position: Variable based on the stage
Feedback: Physiotherapist encourages participant to do scapular protraction and retraction without spine movements. In particular, participants should avoid thoracic extension (lordosis) during retraction, and thoracic flexion (kyphosis) during protraction.

Other possible compensatory movements:

- full extension of the elbows
- end range rotation of the arm
- passive scapular retraction
- forward head position or cervical flexion
- increased lumbar lordosis
- elevation of shoulder girdle towards the ears
- Scapular winging.

If participant has tremor of the shoulder girdle or arm muscles during the exercise, physiotherapist reduces sets/repetitions/resistance.

Movement: Widen your shoulder blades and return them as if closing and opening a book.

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8. A.1. (Stage 1) (Picture below): Participant is leaning over a table while weight bearing on both hands. To increase the difficulty, participants may be asked to shift their weight to the affected side.

8 .A.2 (Stage 2 -Picture below): In 4-point keeling position, participant performs scapular protraction and retraction while bearing weight on both hands. To increase the challenge participant may *shift* their weight to the affected side.

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8. A.3 (Stage 3-figure below): In 4-point keeling position, participant performs scapular protraction and retraction with weight bearing on one hand.

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9. Scapular holding training at mid protraction position

(This exercise is used when participant can perform each scapular protraction and retraction for 10 seconds)

Equipment: Theraband

Participant Position: Variable based on stage

Feedback: Ensure that when participant is holding scapula in mid protraction, he/she should keep spine in straight and neutral position. In the case that participant has a weak control of spinal column, when you ask participant to have their neck in neutral position, participant performs thoracic or lumbar extension

Movement: Participant holds the scapula in mid protraction for 10 second, 10 reps, and 2-3 sets.

9. A.1. - (Stage 1): Participant is in standing, with a theraband wrapped around their back or on a door. Participant performs scapular protraction against light resistance.

9. A.2 (Stage 2): Scapular holding training in four-point kneeling position. Participants holds the scapula in mid-protraction for 10 seconds. To increase difficulty, participant may be asked to transfer weight to affected side by leaning towards the affected side.

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9. A.3 (Stage 3): Participant is in three-point kneeling (weight bearing on the affected extremity only) and holds the scapula in mid-protraction for 10 secs.

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10. Dynamic relocation training

These exercises focus on increasing the isolated contraction of rotator cuff (co-contraction of subscapularis, teres minor and infraspinatus) while decreasing contraction of superficial muscles.

As described by:

Magarey ME, Jones MA. Dynamic evaluation and early management of altered motor control around the shoulder complex. Manual therapy. 2003 Nov;8(4):195-206.

Magarey ME, Jones MA. Specific evaluation of the function of force couples relevant for stabilization of the glenohumeral joint. Manual therapy. 2003 Nov;8(4):247-53.

10. A.1. (Stage 1):
Participant position: Participant is either lying supine or sitting, with arm supported between 60^0 to 80^0 of scaption by the therapist.

Direction of force: The physiotherapist applies a gentle longitudinal distraction force and asks participant to draw their humerus into the the glenoid cavity.

Movement: Physiotherapist asks participant to draw the arm "in and backward". The participant is asked to perform a gentle depression of the scapula while drawing the humerus toward the glenoid cavity.

Feedback: Physiotherapist encourages participant to activate more subscapularis and concurrently decrease superficial muscle activity (e.g. latissimus dorsi, posterior deltoid, pectoralis major and upper trapezius). Initially, participant may pull the arm strongly with superficial muscles with or without rotator cuff contraction. In this case, they should be instructed to reduce the effort.

10. A.2. (Stage 2): Participant draws their shoulder "in and back" towards the glenoid cavit, ***without humeral traction***, at the outer or inner range of shoulder rotation.

Participants should be taught to feel the contraction for themselves by palpating near the axilla. When the physiotherapist is confident that the participant can dissociate the co-contraction without external feedback, he/she can ask participants to do the exercise at home.

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11. Isolated motor control training around the shoulder

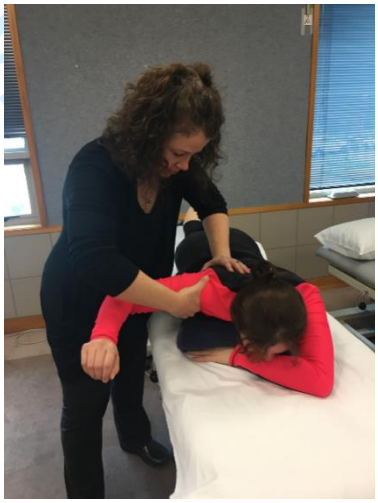
When there is lack of dynamic rotator cuff stability, the humeral head often translates anteriorly or superiorly. The aim of this training is to find a position where participant has the most control on humeral head, as close as to the position where there is the least control. Physiotherapist asks participant to rotate shoulder while centering the humeral head to the glenoid. Stabilizing scapular concomitant with humeral head depression prevent clicking sound and pain in the shoulder.

11. A.1. (Stage 1): Assisted External Rotation

Participant Position: Lying prone with chest supported by a folded towel

Feedback: The physiotherapist palpates the participant's humeral head from anterior and superior direction. The aim is to teach participant to relax their deltoid.

Movement: The participant is asked to tighten their scapula and draw the humeral head gently "down and in" as they externally rotate their shoulder actively. This exercise is applicable when we observe humeral head anterior protrusion during shoulder external rotation.



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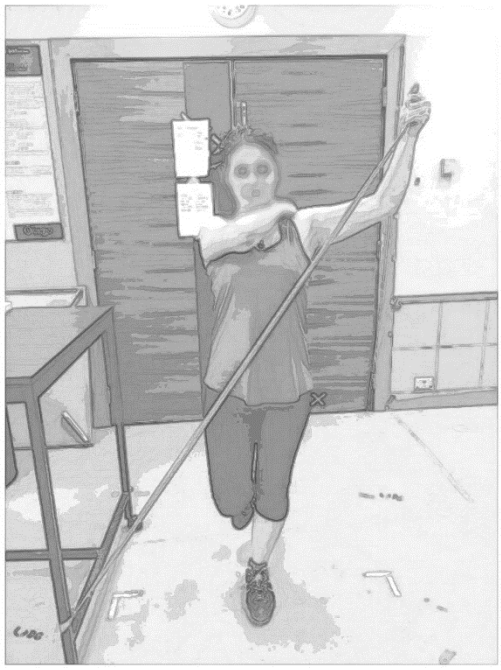
11.A.2 (Stage 2): In sitting, participant performs active ER while physiotherapist ensures there is no excessive anterior and superior glide of the humeral head.

11.A.3. (Stage 3): Progressed to resisted ER motion. Physiotherapist should make sure that the participant can control humeral head anterior translation during arm external rotation. For increasing difficulty, the movement can be performed with resistance of a theraband, while participant stands in one leg.



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12. Proprioception, balance and plyometric trainings

12. A.: The participant is sitting with a ball beneath their forearm. Participant presses and releases the ball while ensuring the scapula and shoulder are properly stabilized.

12. B.: The participant pushes a swiss ball against the wall. The therapist ensures that participants stabilizes the scapula to prevent winging.

12. C. The participant tries to lift their bottoms off the bed in sitting by pressing down through their hands. The force is generated from the shoulder joint.

12. D.: Plyometric catching exercise.

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Scapular Taping for postero-lateral glide

Start the tape on the anterior aspect of the humeral head crossing the acromion lateral to the acromioclavicular joint, ending at the inferior border of the scapula. Therapist glides the humeral head posteriorly when applying the tape. Take care not to apply too much tension initially at the humeral head as the skin is liable to breakdown.

As described by:

Teys P, Bisset L, Collins N, et al. One-week time course of the effects of Mulligan's Mobilisation with Movement and taping in painful shoulders. Manual therapy 2013;18(5):372-77. doi: 10.1016/j.math.2013.01.001

Hing W, Hall T, Rivett DA, et al. The Mulligan Concept of Manual Therapy: Textbook of Techniques: Elsevier Health Sciences 2015.

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Supplementary Material 2

Otago MASTER Feasibility Trial

Standardized rehabilitation programme

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Contents

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Exercise Overview – Quick reference

Shoulder Core Exercises

Exercise			
1. Shoulder extension Resistance type: elastic band	**1. A.** Bilateral Low row: Subjects extends both shoulders from 80°of shoulder flexion (elbow flexed).	OR	**1. B.** Bilateral High row Subject extends both shoulders from 100° shoulder flexion to neutral with elbow extended
2. Shoulder adduction in scapular plane	**2.** Subject adducts shoulder from 80° of shoulder abduction (elbow extended)		
3. Shoulder external rotation (ER) Note: rolled towel placed between arm and trunk	**3.A.** Shoulder ER in sitting/standing: Subject externally rotates shoulder from a standing/sitting position with shoulder in neutral (elbow flexed to 90°).	OR	**3. B.** Shoulder ER in side lying: Subject performs shoulder ER from a side lying position with shoulder in neutral (elbow flexed to 90°).
4. Shoulder internal rotation (IR) Note: rolled towel between arm & trunk	**4. A.** Shoulder IR in sitting/standing: Subject internally rotates shoulder from a standing/sitting position with shoulder in neutral (elbow flexed to 90°).	OR	**4. B.** Shoulder IR in side-lying*: Subject performs shoulder ER from a side lying position with shoulder in neutral (elbow flexed to 90°). *only if participant able to lie down on affected side
5. Elbow flexion with forearm supination:	**5.** Subjects gradually performs elbow flexion with forearm supination from neutral shoulder rotation.		

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Scapular Core Exercises

Exercise			
6. Scapular protraction	**6. A.** Scapular protraction in standing Subject is standing with shoulder in neutral with elbow flexed to 90. From here participant gradually flexes *shoulder to 80* while extending elbow and then performs scapular protraction.	**OR**	**6. B.** Scapular protraction in supine In supine lying with shoulder in neutral and elbow flexed to 90, participant gradually flexes *shoulder to 90* and extends elbow, then scapular protraction.
7. Scapular protraction in 4-point kneeling	**7.** Subject is in 4-point kneeling position with hands underneath shoulder. Participant performs scapular protraction.		
8. Scapular muscle strengthening (Isometric scapular setting)	**8**. Subject starts in prone position, with hands by the sides, arms in external rotation; then depresses and retracts the scapula and holds it isometrically.		

Shoulder Stretch (Core exercises)

Exercise	Instruction
9. Posterior shoulder stretch	Subject is in standing. Participant stretches affected shoulder into horizontal adduction by pulling fully flexed elbow with opposite hand
10. Lateral neck stretch	Subject is in standing. Participant pulls the head into lateral flexion with opposite arm and adds shoulder depression to increase the stretch
11. Thoracic spine extension	Subject is supine with hips and knees flexed, towel roll Under the thoracic spine and hands supporting the neck. Participant maintains this posture to sustain a stretch of anterior thoracic muscles

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Additional Exercises

	Exercise	Pg no.
12. Shoulder scaption in standing position	Subject performs 80° scaption with elbow in slight flexion and slight shoulder external rotation (thumbs up)	18
13. Shoulder flexion in standing	Subject flexes arm to 80° with arm slightly flexed and externally rotated (thumbs up)	19
14. Shoulder press via flexion (Sitting with back support)	Subject performs full shoulder ***flexion*** with elbow extension *Arms against trunk, elbows fully flexed, hands lateral to shoulder.*	**20**
15. Shoulder press via abduction in (Sitting with back support) (Elastic band only)	Subject performs full shoulder ***abduction*** with elbow extension against *Arms against trunk, elbows fully flexed, hands lateral to shoulder.*	**20**
16. Horizontal abduction in sitting (Elastic band only)	Perform shoulder abduction against Elastic band attached at shoulder height *Shoulder in 80 flexion and ER (thumb laterally)*	**21**
17. External rotation in sitting with elbow supported on plinth/table (Elastic band only)	Subject performs 90 external rotation against a Elastic band. *Shoulder flexed to 80° with 90° elbow flexion.*	**22**
18. Internal rotation (IR) in sitting with elbow supported on plinth/table (Elastic band only)	Subject performs 90 internal rotation against a Elastic band. *Shoulder flexed to 80° with 90° elbow flexion.*	**22**
19. Scapular protraction	Subject perfroms dynamic scapular protraction	**23/4**

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Additional Stretching and ROM Exercises

Exercise	Instruction	Pg no.
20. Internal rotation positioning	Subject places the involved hand on the buttock or lower back in pain free manner, supported by the other hand	25
21. Longitudinal shoulder traction with an Elastic band wrapped	Subject stands while bending sideways slightly. One end of an Elastic band is wrapped around the wrist while the other end is fixed with the feet allowing tension in the band. Participant relaxes the shoulder and allows the longitudinal traction.	25
22. Pendulum exercise	Participant stands and leans over a chair or a table with the good arm, relaxes the affected shoulder blade and let the arm drop. In this position, performs forward-backward swings and circle swings using body motion.	26

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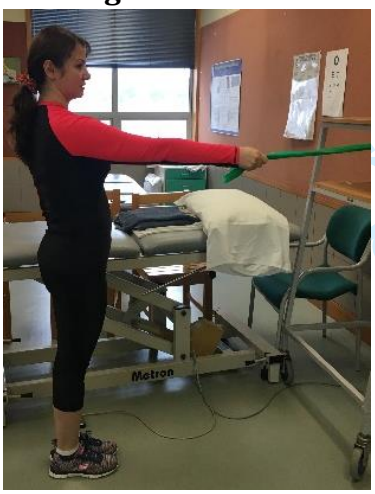
Descriptions of Core Exercises

1. Shoulder extension

1. A. Bilateral Low row:

Starting position: Standing with shoulder flexed at 80° and neutral rotation.
Exercise: Subject performs ***bilateral*** shoulder extension till neutral with elbow flexed.
Resistance type: Theraband

Starting Position



Ending Position

1. B. Bilateral High row

Starting position: Standing with shoulder flexed at 100° and neutral rotation.
Exercise: Subject performs ***bilateral*** shoulder extension till neutral with elbow extended.
Resistance type: Thera band

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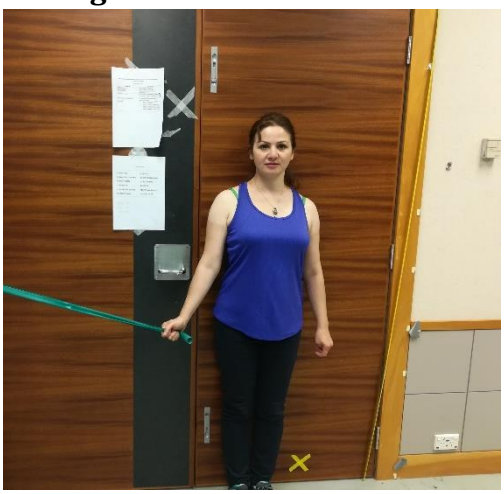
2. Shoulder adduction in scapular plane

Starting position: Standing with shoulder abducted at 80° in scapular plane (Scaption) and neutral rotation.
Exercise: Subject performs shoulder adduction with elbow extended to neutral.
Resistance type: Thera band

Starting Position

Ending Position



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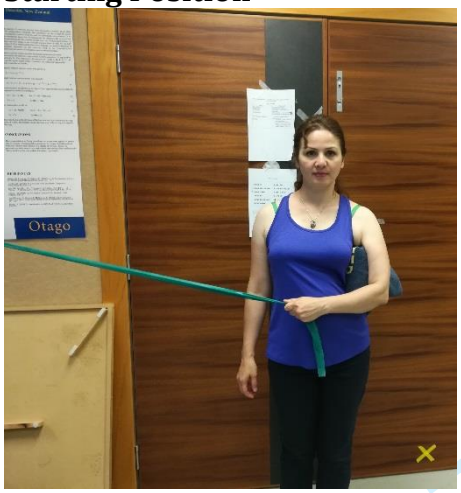
3. Shoulder external rotation (ER)

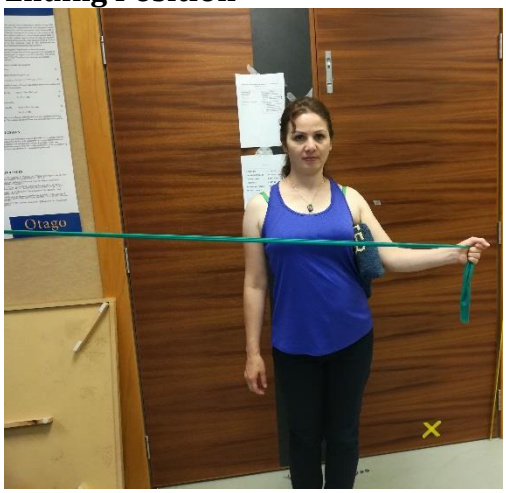
3. A. Shoulder ER in standing with 0 abduction

Starting position: Standing with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.
Exercise: Subject performs shoulder external rotation. Please ensure the participant is not compressing the towel; they should be holding it in a relaxed manner.
Resistance type: Thera band

Starting Position



Ending Position



3. B. Shoulder ER in side-lying

Starting position: Side-lying with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.
Exercise: Subject performs shoulder external rotation.
Resistance type: Dumbbell

4. Shoulder internal rotation (IR) in neutral

4. A. : Shoulder IR in standing

Starting position: Standing with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.

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Exercise: Subject performs shoulder internal rotation. Please ensure the participant is not compressing the towel; they should be holding it in a relaxed manner.
Resistance type: Thera band

4. B. Shoulder IR in side-lying (progress only if participant is able to lie down on affected side)

Starting position: Side-lying with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.
Exercise: Subject performs shoulder internal rotation.
Resistance type: Dumbbell

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5. Elbow flexion with forearm supination

Starting position: Standing or sitting with arms at side; neutral rotation.
Exercise: Subject performs elbow flexion with forearm supination.
Resistance type: Thera band or Dumbbell

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6. Scapular protraction

6. A. Scapular Protraction in standing:

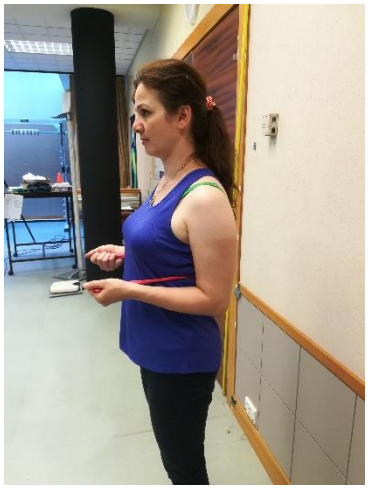
Starting position: Standing with arms at side; shoulder in neutral rotation; elbows flexed at 90˚.

Exercise: Subject performs shoulder flexion to 80˚, elbow extension, and then scapular protraction

Resistance type: Thera band

Starting Position (Front view)

Starting Position (side view)



Ending Position (front view)

Ending Position (Side view)

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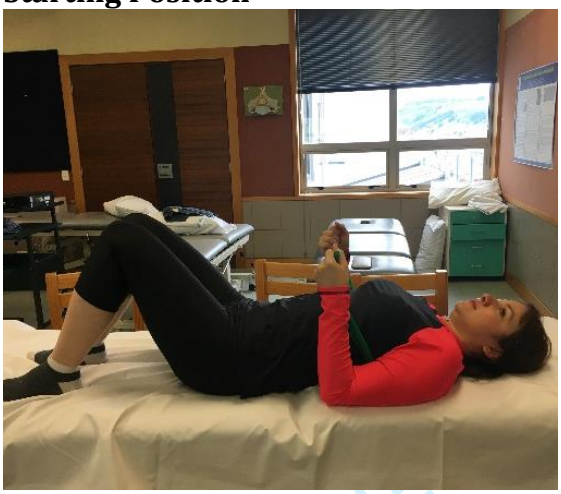
6. B. Scapular protraction in supine

Starting position: Supine lying, arms resting at side in neutral, elbows flexed at 90°

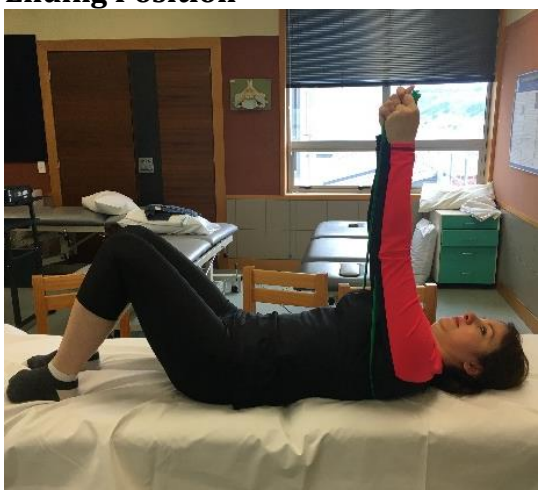
Exercise: Subject concurrently flexes shoulder to 90° and extends elbow, and then protracts scapula against resistance.

Resistance type: Thera band

Starting Position



Ending Position



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7. Scapular protraction in four-point kneeling

Starting position: 4 point kneeling, hands underneath shoulder
Exercise: Subject performs dynamic scapula protraction without compensatory movements at the spine
Resistance type: Body Weight

8. Scapular muscle strengthening (isometric)

Starting position: Prone with arms at side in external rotation
Exercise: Subject depresses and retracts the scapula with elbows slightly flexed and holds the position for 10 seconds. The therapist can provide feedback and ensure participant is not over activating their shoulder extensors and external rotators.
Resistance: None

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9. Posterior Shoulder Stretch

Position: Standing or sitting

Exercise: Subject pulls the elbow passively across the body into horizontal adduction with the opposite arm. Hold the stretch for 10 seconds and repeat.

10. Lateral neck stretch

Position: Standing or sitting

Exercise: Participant pulls the head into lateral flexion with the opposite arm and adds scapular depression to stretch ipsilateral neck.

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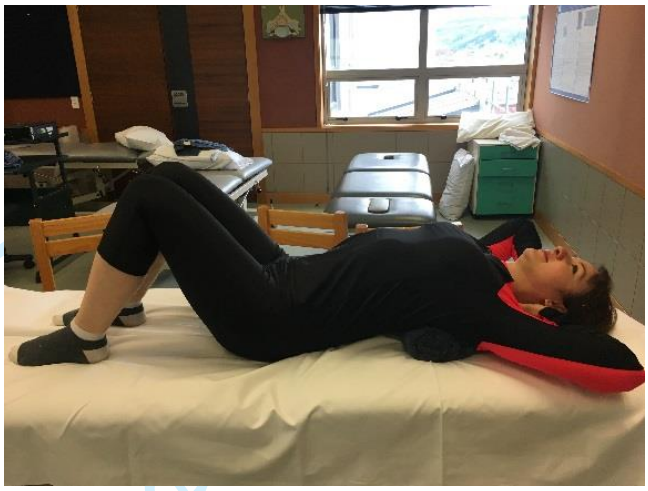
11. Thoracic spine extension stretch

Position: Supine with hip and knee flexed. A towel roll is placed under their upper thoracic spine and participant supports their neck with both hands.

Exercise: Participant allows sustained stretch of thoracic kyphosis by lying on a towel roll and relaxing their spine.



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Additional exercises:

12. Shoulder scaption to 80^0

Starting Position: Standing with feet on the theraband. Shoulder at neutral.
Exercise: Participant performs shoulder scaption to 80˚ while keeping shoulder external rotation (thumb up). Elbow slightly flexed.
Resistance: Thera band or dumbbell

Starting Position

Ending Position

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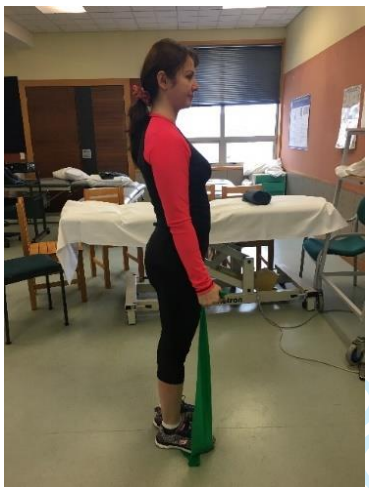
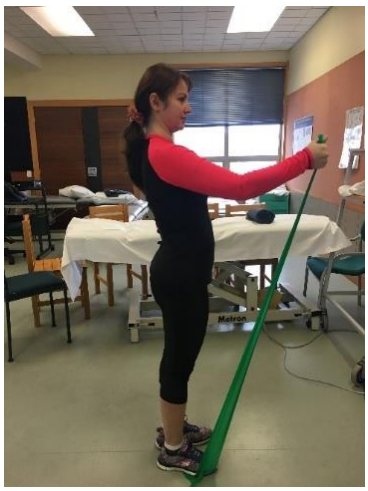
13. Shoulder flexion to 80°

Starting position: Participant is standing with feet on Thera band. Arm at side of body.
Exercise: Participant performs shoulder flexion to 80^0 and external rotation (thumb up) with elbow slightly flexed against light to high resistance.
Resistance: Thera band or dumbbell

Starting Position



Ending Position



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14. Shoulder press via flexion

Starting position: Subject is in sitting position with back supported, arms are in contact with trunk, and elbows are fully flexed.
Exercise: Participant performs full shoulder flexion and elbow extension against resistance.
Resistance: Thera band or dumbbell


15. Shoulder press via abduction

Starting Position: Participant in sitting, with back supported, arm in contact with trunk, and elbow fully flexed, and hand next to the shoulder.
Exercise: Participant performs full shoulder abduction and elbow extension against resistance.
Resistance: Theraband


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16. Horizontal abduction in sitting

Starting position: Participant is sitting with shoulder flexed at 80°. A theraband is attached at shoulder height directly in front of them (theraband is aligned with their forearm).

Exercise: Participant performs horizontal shoulder abduction with nearly extended elbow.

Resistance: Theraband

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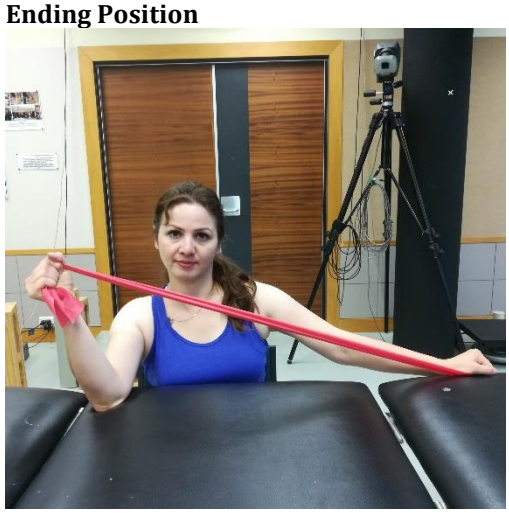
17. External rotation with arm supported

Starting Position: In sitting with elbow supported on a table. Shoulder flexed at 80°, no rotation and elbow flexed at 90°. Thera band is fixed with other hand.
Exercise: Subject performs 90° of external rotation against resistance.
Resistance: Theraband

Starting Position

Ending Position



18. Internal rotation in supported 80^0 shoulder flexion

Starting Position: In sitting with elbow supported on a table. Shoulder flexed at 80° with no rotation and elbow flexed at 90°. Thera band is fixed on the table with other hand
Exercise: Subject performs 90° of internal rotation against resistance.
Resistance: Thera band

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19. Scapular protraction

19. A.: In kneeling push up position

Starting Position: Half plank position (4 point kneeling with hands underneath shoulders and hip in neutral, knee flexed at 90˚)

Exercise: Participant performs dynamic scapular protraction.

Resistance: Body Weight

19. B. Scapula protraction in push-up position:

Starting position: Participant is in push up position with hands directly below shoulder.

Exercise: Participant performs dynamic scapular protraction without spinal compensatory movements.

Resistance: Body weight

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19. C. Half way push up position:

Starting position: Participant is in push up position with hands below shoulder.

Exercise: Participant performs a half way push up with a dynamic scapular protraction at the end of arm extension.

Resistance: Body weight

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20. Internal rotation positioning

Participant places their involved hand on the buttock or lower back in a pain-free manner, supported by the other hand

21. Longitudinal shoulder traction

Standing with trunk side-flexed towards the affected side. A Thera band is wrapped around the wrist and fixed with the feet on one side with tension. Participant relaxes shoulder and allows for longitudinal traction.

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22. Pendulum exercise

Participant leans on a chair or table by bearing weight on the good arm and bending forward at the waist. Participant relaxes the affected shoulder blade and lets it drop. Participant then performs relaxed forward-backward swings and circle swings using body motion (with dumbbell or bottle).

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Table 1 – page 5
	2b	All items from the World Health Organization Trial Registration Data Set	Table 1 – page 5
Protocol version	3	Date and version identifier	Table 1 – page 5
Funding	4	Sources and types of financial, material, and other support	Table 1 – page 5
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 17
	5b	Name and contact information for the trial sponsor	Page 5
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 17
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15 and 16

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Pages 3 to 4
	6b	Explanation for choice of comparators	Pages 3 to 4
Objectives	7	Specific objectives or hypotheses	Page 4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Pages 4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Tables 2 and 3
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Refer to TIDieR checklist
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Refer to TIDieR checklist
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Refer to TIDieR checklist
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Refer to TIDieR checklist
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 13 and 14

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 6
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 6
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 7 to 13

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 13
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 15 and 16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Pages 15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Pages 15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 14
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 16
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 16
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 16 and 17
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Page 16
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 17

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 16
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 16
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N.A.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 16
	31b	Authorship eligibility guidelines and any intended use of professional writers	Page 16
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Not submitted
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	12 to 13	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Tables 2 and 3	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Tables 2 and 3	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Tables 2 and 3	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Tables 2 and 3	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Tables 2 and 3	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Tables 2 and 3	

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Tables 2 and 3	
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Tables 2 and 3	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Tables 2 and 3	
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Tables 2 and 3	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Tables 2 and 3	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

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The effectiveness of a tailored rehabilitation versus standard strengthening programme for patients with shoulder pain: a protocol for a feasibility randomized controlled trial (the Otago MASTER trial)

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The effectiveness of a tailored rehabilitation versus standard strengthening programme for patients with shoulder pain: a protocol for a feasibility randomized controlled trial (the Otago MASTER trial)

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Abstract

Introduction: Exercise therapy is the treatment of choice for the management of patients with shoulder subacromial pain. However, we do not know whether a tailored rehabilitation programme is more effective than a standardized strengthening programme. The aim of this feasibility trial is to assess: (1) participant recruitment rate; (2) the proportion of participants enrolled from the total number screened; (3) adherence to the rehabilitation programme; (4) drop-out rates; (5) obtain estimates of adverse reactions to treatment; (6) obtain estimates of intervention effects in order to inform the sample size of the fully-powered RCT; (7) pre-test the methods for a cost-effectiveness evaluation of the standardized strengthening and the tailored rehabilitation interventions.

Methods: The Management of subacromial disorders of the shoulder (MASTER) trial, is a two-arm, patient- and assessor-blinded, randomized controlled feasibility trial. Participants will be randomly allocated into one of the interventions group: tailored or standardized rehabilitation. To obtain estimates of intervention effects, we will compare changes in pain and shoulder-related disability scores between the two intervention groups using a repeated mixed-model analysis of variance, with alpha set at 0.05, and power at 80%. Since this is a feasibility study, we will not adjust alpha for multiple comparisons. To determine whether it is feasible to conduct the full trial, we will consider 75% CI as the probability threshold at 3-month follow-up.

Discussion: The short-term impact of this phase II trial is to inform whether or not it is feasible to conduct the full efficacy trial. The medium-term impact of this proposal will be to determine which intervention is superior for treating patients with shoulder subacromial pain.

Ethics and Dissemination: This study was approved by the University of Otago Ethics Committee [H17/080]. Findings from this study will be presented at conferences, and will be submitted for publication in a peer-reviewed journal.

Trial registration number: ANZCTR: 12617001405303.

Keywords: shoulder, rehabilitation, manual therapy, randomized controlled trial.

Word count: 3688

Article summary

Strengths and limitations of this study

- This protocol will compare one intervention that is tailored to patient's physical impairments with a standardized strengthening programme.
- The feasibility trial will include economic evaluation, and implementation-based process evaluation of the intervention planned.
- Clinicians were not blinded to interventions due to nature of interventions, and that is a source of potential bias.

Introduction

Shoulder pain is the third most common musculoskeletal complaint, with a one-year prevalence of 18.1%.[1] Shoulder pain is associated with high socioeconomic burden.[2] In Sweden, the average annual cost of shoulder subacromial pain is estimated $4,139 per patient.[2] In NZ, a total of $134 million was spent by ACC in rehabilitation for shoulder injuries from 2005 to 2013 ($14 million/year).[3] Shoulder subacromial pain is a challenging disorder with slow recovery,[4] with only 50% of new episodes presenting full recovery within 6 months.[5]

Exercise therapy is the first-line approach for the management of shoulder subacromial pain [6]. A number of systematic reviews have been published in this area.[7-13] Some reviews suggest exercise therapy and or manual therapy to be effective for improving pain and function in patients with shoulder pain, but highlight the limited strength of evidence to support this.[7 8 14] Three reviews reported exercise therapy to be more effective than control or placebo,[8 10 11] while a Cochrane Review reported no clinically important difference between manual therapy and exercise versus placebo.[9] The addition of manual therapy to exercise has been supported in incremental effects trials [15-17] and by another recent systematic review.[10] Optimal treatment strategies are needed to improve treatment effect, speed recovery, and decrease shoulder pain recurrence. There are uncertainties regarding which types of exercise are more effective and cost-effective for the management of patients with shoulder subacromial pain.[10 18 19] In addition, there are competing approaches of exercise regimen (e.g. specific exercise,[20] general strengthening exercise), with limited number of head-to-head trials comparing different combinations of exercise therapy and manual therapy interventions.[9 10]

The lack of data about process evaluation of previous trials hinder our ability to identify whether tested interventions failed to improve clinical outcomes due to being ineffective or poorly implemented.[21] To address this, it is recommended trials to include process evaluation alongside the *outcome* evaluation, ideally from Phase II to Phase IV.[21] Process evaluation studies provide valuable information regarding how, what and why interventions were delivered to patients during the trial,[21-24] and help to understand why an intervention achieved (or not) its expected clinical outcomes.[25] Such information is valuable for a number of stakeholders (e.g. clinicians, government and policy-maker agencies) and improve translation of findings from trials to clinical practice.[21] Hence, future trials on the management of shoulder subacromial pain should include process evaluation[21] and economic evaluation[10] conducted alongside the outcome evaluation. In addition, it has been recommended that future trials combining novel exercise therapy programme to be compared to a valid placebo intervention.[9]

Shoulder subacromial pain is a complex disorder, with psychological factors and physical impairments influencing clinical outcomes.[26-29] Pain beliefs seem to be associated with course of pain and disability, but the current level of evidence is low.[29] A longitudinal prospective cohort study reported that psychosocial factors are associated with clinical outcomes,[28] while a secondary analysis of a trial found that fear-avoidance beliefs contribute significantly to baseline disability but not to disability change scores after 3-month follow-up.[26] Psychosocial factors and pain beliefs seem to play a role on clinical outcomes. Further longitudinal studies are still required to clarify which psychological factors can be targeted by treatment and whether modifying these psychological factors impact on clinical outcomes (i.e. disability and pain) in patients with shoulder subacromial disorders.[26 27 29 30]

Rehabilitation of shoulder pain is usually based on a person-specific assessment [31 32]. Findings suggestive of structural diagnosis have inconsistent association with clinical outcomes[30] and the diagnostic accuracy of orthopaedic tests is very limited[33]. Hence, clinicians perform a thorough clinical examination, often with the aim of defining movement- or posture-related procedures that modify the individual's symptoms.[31 33 34]

Such procedures may target patients' individual physical impairments, which may include altered scapular movement patterns or shoulder muscle recruitment patterns[35 36]. For example, patients with shoulder subacromial pain have been shown to have altered coordination between lower trapezius and serratus anterior, and the upper trapezius and lower trapezius during arm elevation task,[36] and patients with symptomatic rotator cuff tear may show increased activity of latissimus dorsi when compared to healthy controls.[35] Due to the variability of such altered muscle patterns, it is recommended that rehabilitation should tailor specific muscle and joint impairments presented by the patient [31] and restore shoulder movement pattern[34]. Further, preliminary evidence suggests that sustained shoulder mobilization may reduce pain and improve range of motion in patients with shoulder subacromial pain, compared to sham sustained mobilization.[37] Trials of the effect of sustained glide and exercise on the management of other musculotendinous disorders (e.g. tennis elbow) have found this intervention to be more effective than corticosteroid injection and wait-and-see.[38]

Laboratory-based studies suggest that: (1) clinician-administered sustained shoulder mobilization offloads shoulder muscles, providing mechanical support to the shoulder;[39] (2) patient-administered sustained shoulder mobilization leads to similar changes in muscle activity levels as clinician-administered mobilization, supporting the use of home-based mobilization for shoulder rehabilitation;[40] (3) patients with shoulder pain present immediate reduction in pain levels, increased range of motion, and altered muscle activity levels in response to sustained shoulder mobilization.[41] These findings, and anecdotal evidence from clinical practice, suggest that sustained mobilization temporarily changes the control of scapular and shoulder muscles. Such temporary change gives the clinician a therapeutic window to strengthen muscles with less pain while keeping a better control of scapular and shoulder muscles.

It is unclear whether a tailored rehabilitation (combining sustained mobilization with specific motor control exercises) is more effective than standardized exercise for shoulder pain patients. Tailored rehabilitation focuses on each patient's specific impairments and some studies found preliminary findings that a tailored programme is effective for managing patients with shoulder pain.[20 42-45] An alternative to a tailored programme is a standardized shoulder rehabilitation that adopts a more generic approach, with standardized stretching and strengthening exercises being prescribed for all patients, and may also be delivered in small group sessions, reducing the cost of the physiotherapy session. It is unclear which approach leads to better clinical outcomes and is more cost-effective.

Efficacy trials are designed to test if an intervention works under the ideal circumstances.[46] This type of trial maximises the probability of observing the effect of an intervention (assuming such effects exist), and prioritize internal validity of the study design.[46] In efficacy trials, the intervention is standardized, delivered under an ideal setting, with highly trained clinicians.[46] It is recommended for efficacy trials to incorporate economic evaluation (i.e. cost-efficacy) alongside the clinical efficacy assessment.[47] By conducting clinical and cost-efficacy assessment it is possible to determine whether an intervention is likely to be efficacious for a group of patients, and whether delivering the health outcomes are likely to be good value for money.[48] Ideally, clinical and cost-efficacy studies should be conducted prior to clinical- and cost-effectiveness pragmatic trials.[47]

The aim of our full study is to assess the clinical- and cost-efficacy of tailored rehabilitation programme for the treatment of shoulder subacromial pain. Prior to conducting a fully-powered randomized controlled trial (RCT), we propose an efficacy feasibility trial aiming to assess: (1) participant recruitment rate; (2) the proportion of participants enrolled from the total number screened; (3) adherence to the rehabilitation programme; (4) drop-out rates; (5) obtain exploratory estimates of adverse events; (6) obtain exploratory estimates of intervention effects in order to inform the sample size of the fully-powered RCT; (7) conduct a preliminary cost-

effectiveness analysis of the standardized strengthening and the tailored rehabilitation interventions.

Methods

Design

The Management of subacromial disorders of the shoulder (MASTER) trial, is a two-arm, patient- and assessor-blinded, feasibility randomized controlled trial. Participants will be randomly allocated into one of the interventions group: tailored rehabilitation or standardized rehabilitation (Figure 1).

Figure 1

For preparing this protocol, we followed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement,[49] and the template for intervention description and replication (TIDieR) checklist and guide.[50] When reporting the feasibility trial, we will follow the Consolidated Standards of Reporting Trials (CONSORT) statement for non-pharmacological treatment.[51] The trial has been prospectively registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR: 12617001405303). World Health Organization trial registration data set information is described in Table 1.

Table 1. World Health Organization trial registration data set.

Data category	Information
Primary registry and trial identifying number	Australian New Zealand Clinical Trial Registry (ACTRN 12617001405303)
Date of registration in primary registry	04/10/2017
Source of monetary or material support	Health Research Council of New Zealand Feasibility Grant (17/536)
Primary sponsor	University of Otago
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	Tailored versus standard strengthening rehabilitation for patients with shoulder pain: a feasibility trial
Scientific title	The effectiveness of a tailored rehabilitation versus standard strengthening programme for patients with shoulder pain: a feasibility randomized controlled trial (the Otago MASTER trial)
Country of recruitment	New Zealand
Health condition or problem studied	Shoulder subacromial pain
Interventions	Tailored and standardized strengthening exercise
Key inclusion and exclusion criteria	Adult healthcare workers (from 18 to 65 years old), with subacromial shoulder pain.
Study type	Interventional
Date of first enrolment	12/02/2018
Target sample size	25
Recruitment status	Recruiting
Primary outcome	(1) Recruitment rate, (2) Proportion of participants enrolled from the total number screened, and (3) Adherence to the rehabilitation programme.
Key secondary outcome	(1) Drop-out rates, (2) Pain level, (3) Shoulder-related disability – patient specific functional scale, (4) quality-adjusted life year, (5) Shoulder Pain and Disability Index (SPADI), (6) Pain self-efficacy questionnaire; (7) Adverse reactions.

Participants

Participants with shoulder subacromial pain will be recruited to take part in the study.

Inclusion and exclusion criteria

Participants from 18 years and 65 years old, with mechanical shoulder pain will be recruited to participate in the study. Participants will be screened as per the British Elbow and Shoulder Society (BESS) guidelines.[52] The process recommended by the BESS guidelines screens for: red flags (e.g. tumour, unreduced dislocation, acute rotator cuff tear, infection), shoulder pain arising from the cervical spine, the shoulder instability, acromioclavicular joint disease, and adhesive capsulitis.[52]

Participants will be included if they present one positive finding on the following tests: (1) Painful arc movement during shoulder flexion or abduction; (2) Jobe's test.[52]; or (3) pain on resisted lateral rotation or abduction.[53]. Given the limited evidence from clinical tests for diagnosing patients with shoulder subacromial pain,[33] we opted to widen the criteria proposed by BESS and add criteria #3. We include two additional tests (resisted lateral rotation and shoulder abduction).[53] A previous study reported pain on external rotation has 34.5% of sensitivity, 100% specificity, 42% accuracy for identifying any degree of subacromial disorder. [53] Pain on shoulder abduction presented 55% of sensitivity, 75% specificity, 57% accuracy and a likelihood ratio of 2.2% for identifying any degree of subacromial disorder. In addition, pain on external rotation was the most accurate test for identifying partial-thickness tear.[33 53]

We will exclude participants with the history of shoulder dislocation, shoulder subluxation, shoulder surgery and cervical surgery within the last 6 months,[54] participants with any kind of symptoms of systematic inflammation or disease, signs of paraesthesia in the upper extremities, hemiplegic shoulder pain, frozen shoulder, or positive clinical signs of full thickness rotator cuff tear [55] will be excluded.

Sample size

Being a feasibility RCT, the present study is not designed to assess the efficacy of the experimental intervention.[56 57] We estimated the sample size based on expected characteristics of the full trial.[58] Based on recommendations by Whitehead et al.[58], the sample size of a feasibility study should be estimated based on the expected range for the effect size, the power and alpha (both established *a priori*), and the total number of arms of treatment planned for the full trial.

Whitehead et al.[58] recommend estimating sample size on the basis of standardized differences of different magnitudes (i.e. extra small, small, medium and large). For a standardized effect size of 0.3 on our primary outcome measure, the Shoulder Pain and Disability Index (SPADI), we assumed a minimum clinically important between-group difference of 8 points [59] and a standard deviation of 24 points around the SPADI total score.[59] On this basis, we set power at 80%, two-tailed between-group comparison, with alpha at 0.05, resulting in a minimum sample size for this feasibility RCT of 10 participants per arm of treatment.[58] Assuming a 20% loss to follow-up,[60] a total sample size of 25 participants is required.

Recruitment

Recruitment will take place in Dunedin, New Zealand. Participants will be recruited through general practitioners and hospitals and newspaper advertisements. In previous studies, we have successfully recruited participants with these methods of recruitment. Participants will be screened by a physiotherapist with more than five years of clinical experience, and with a postgraduate qualification in Musculoskeletal or Sports Physiotherapy (or related field).

Informed consent and baseline assessment

Once participants are assessed for eligibility, a clinical researcher will seek informed consent from participants. Participants may consent to take part in the study after screening or few days later, if they request time for considering taking part in the study. Participants will be asked to complete the baseline assessments and questionnaires for recording demographic data (age, height, weight), and baseline measurements for the primary and secondary outcomes.

Randomization

Participants will be individually randomly allocated (1:1 ratio) into one of the intervention groups (i.e. tailored physiotherapy or standardized physiotherapy). The randomisation schedule will be computer-generated by a research administrator, and concealed in numbered sealed and opaque envelopes. A research administrator will provide the envelope to the clinician delivering the interventions.

Blinding

Participants will be blinded to interventions. Outcome assessors will be blinded to group allocation. Clinicians delivering the interventions will not be blinded to group allocations due to nature of intervention.

Procedures

Experienced clinicians will deliver interventions for both groups. Clinicians will have a postgraduate diploma in musculoskeletal rehabilitation (or related field) and a minimum of 5 years of clinical experience. Outcome measures will be assessed by a physiotherapist who is blinded to group allocation. We will provide a minimum of 4 training sessions, each lasting one hour, with clinicians to ensure they are familiarized with the protocol and confident in delivering the planned interventions. The training sessions will include a manual containing detailed descriptions of the planned intervention. We will meet with the clinicians regularly during the study to clarify any questions or concerns that may arise.

Interventions

Both groups will receive 16 individual, face-to-face sessions, each lasting for 60 min, twice per week, over an 8-week period. This number and duration has been shown to improve clinical outcomes in patients with shoulder subacromial pain.[61] Eight weeks intervention period has been suggested as the minimum required to lead to improvement in pain and range of motion in patients with shoulder pain.[61] The tailored and standardized rehabilitation interventions are described on Tables 2 and 3 respectively. These descriptions were prepared following the template for intervention description and replication (TIDieR) checklist and guide.[50]

Both groups will receive similar dosage of exercises. Participants will perform a total of 8 exercises per session of treatment, plus three stretches (control group) or up to three manual therapy techniques (tailored group). To ensure optimal internal validity of the trial, dosage of exercises for each group are planned to be equivalent. Details of tailored and standardized interventions are described on the Exercise Description Forms (Supplementary Material 1 and 2, respectively). The intensity of strengthening exercises will be monitored using a modified Borg scale.[62] Rate of perceived exertion was shown to be valid for monitoring intensity of resistance training,[63] and has been used in a previous trial for monitoring exercise intensity.[64]

Tailored rehabilitation: participants allocated to the tailored rehabilitation group will receive sustained mobilization followed by exercises focusing on restoring normal movement pattern and the dynamic stability of the scapulothoracic and glenohumeral joints.[31 65] The intervention will involve manual therapy techniques focusing on restoring the shoulder and scapular movement to reduce pain,[66] and motor control and progressive resistance training of impaired muscles.[61 65]

Table 2. Description of tailored rehabilitation intervention, as per the template for intervention description and replication (TIDieR) guide.

Item number	Item	Description
1.	**BRIEF NAME** Tailored rehabilitation	
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.	The tailored rehabilitation programme will focus on specific impairments presented by the patient. This intervention will consist of mobilization with movement, passive accessory mobilization, specific motor control exercises and specific muscle strengthening exercises. The tailored rehabilitation programme might be more effective than a standardized strengthening programme for patients with subacromial shoulder pain.
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	The tailored rehabilitation group will receive manual therapy techniques (including mobilization with movement with taping)[66 67], motor control and strengthening exercises. Manual therapy interventions delivered by the clinician might be performed with a belt. Motor control and strengthening exercises might be performed with the use of elastic bands or dumbbells. Home-based exercises will consist of self-mobilization techniques that is performed with a belt.
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Clinicians will choose exercises based on physical impairments presented during the physical assessment.
5.	**WHO PROVIDED** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Experienced clinicians will deliver interventions for the tailored group. Clinicians will have a postgraduate diploma in musculoskeletal rehabilitation (or related field) and a minimum of 5 years of clinical experience. All clinicians will undergo a trial-specific training programme to ensure they understand the protocol and the rationale of the intervention. Clinicians will receive a detailed manual with information regarding the trial intervention.
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or	Participants will receive individual, face-to-face sessions.

Item number	Item	Description
	telephone) of the intervention and whether it was provided individually or in a group.	
7.	**WHERE** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Interventions will be delivered in a private clinical practice.
8.	**WHEN and HOW MUCH** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Participants will receive 16 sessions, each lasting for a maximum of 60 min, twice per week, over an 8-week period. The exercise programme will comprise of 8 exercises plus 3 optional manual therapy techniques (one for the cervical spine, one for the thoracic spine and one for the shoulder). Clinicians will decide on which technique to use based on participants' clinical presentation. The manual therapy techniques might consist of passive joint mobilizations (grade -IV, IV, or +IV) or manipulation (for the cervical or thoracic spine). Mobilization with movement techniques will count as one of the 8 possible exercises to be performed within a session. This technique will be performed with 3 sets of 10 repetitions, with 30 seconds of rest between each set. Passive joint mobilizations will be performed with the following dosage: 3 sets, 30 seconds duration. Grade: –III or –IV will be performed if pain is dominant (as per physical assessment) or grade +III or +IV if stiffness dominant (as per physical assessment). Joint manipulation will be performed once per session, if required, as per physical assessment. The clinician will have the freedom to decide which technique to perform. Isometric exercises will be delivered with the following dosage: 2 sets, 10 repetitions, with 10 seconds hold each repetition. The isometric exercises will be progressed in two stages. The first stage will have the following dosage: 3 sets, 10 repetitions, with 10 seconds hold each repetition. The second stage will have the following dosage: 3 sets, 10 repetitions, with 20 seconds hold each repetition. There will be 10 seconds rest between repetitions, and 30 seconds rest between sets. Dynamic strengthening exercises will be delivered with the following dosage: 2 sets of 10 repetitions. The dynamic strengthening exercises will be

Item number	Item	Description
		progressed in two stages. The first stage will have the following dosage: 3 sets of 10 repetitions. The second stage will have the following dosage: 3 sets of 20 repetitions. All exercises should initially be performed in slow and controlled pace. All motor control exercise should initially be of low intensity and then progressed as described. Clinicians can increase dosage (repetitions, sets, or load) if the participant is able to perform low intensity exercise for two consecutive sessions. The load for strengthening exercises will be determined through using the 10-point Rate of Perceived Exertion (RPE) scale, considering the affected side. Low intensity will be defined as 3-4 RPE, moderate intensity as 5-6 RPE, and high intensity as 7-8 RPE. Exercises will start with low intensity, and can progress to moderate and high intensity during the course of treatment.
9.	**TAILORING** If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Interventions will be tailored based on physical assessment. Participants will receive: - Shoulder mobilization with movement if, during assessment, participants improve range of motion and pain with the MWM technique. As part of the treatment, clinicians might use an MWM taping technique.[66 67] - Passive mobilization on the cervical, thoracic spine or shoulder (glenohumeral joint). These techniques will be performed if, during assessment, participants present with stiffness or pain on passive accessory movement at the cervical, thoracic spine or glenohumeral joint. - Motor control exercises if, during assessment, participants present with poor control of a specific muscle (e.g. scapular control exercises, dynamic control of glenohumeral joint).[68-71] - Strengthening exercises if, during assessment, participants present with muscle weakness.[71]
10.‡	**MODIFICATIONS** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Not applicable. This is a protocol.
11.	**HOW WELL** Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any	Participants' adherence to protocol will be assessed by quantifying the number of home-based exercises performed. It will be expressed as percentage of the

Item number	Item	Description
	strategies were used to maintain or improve fidelity, describe them.	total number of sessions that should be been performed. Clinician's adherence to protocol will be assessed by quantifying the number of exercises and progressions that were performed according to the protocol. This will be done through audits of clinical notes, and will be expressed as percentage of the total number of exercises and progressions that were performed during the course of treatment.
12.[‡]	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Not applicable. This is a protocol.

Standardized rehabilitation: participants allocated to this group will receive a progressive resistance training for all scapular and shoulder muscles and stretching exercise programme.[72] This intervention focuses on restoring muscle flexibility and strength and has been shown to be more effective than 'no intervention' or control for reducing pain and disability.[72]

Table 3. Description of standardized rehabilitation intervention, as per the template for intervention description and replication (TIDieR) guide.

Item number	Item	Description
1.	**BRIEF NAME** Standardized rehabilitation	
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.	The standardized rehabilitation intervention will focus on strengthening of scapular and shoulder muscles. Strengthening exercise were shown to improve pain and disability in participants with subacromial shoulder pain.
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	The standardized rehabilitation group will receive strengthening exercises. These exercises might be performed with the use of elastic bands or dumbbells. Stretching exercise for the thoracic spine will be done using a foam roller. Two home-based exercises (resisted internal and external rotation of the humerus) will be performed using an elastic band.
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Participants will start with 8 "core" strengthening exercises and 3 stretches. The clinician can replace one core strengthening exercises by another strengthening exercises from a list of "additional" exercises.
5.	**WHO PROVIDED**	

Item number	Item	Description
	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Experienced clinicians will deliver interventions for the standardized rehabilitation group. Clinicians will have a postgraduate diploma in musculoskeletal rehabilitation (or related field) and a minimum of 5 years of clinical experience. All clinicians will undergo a trial-specific training programme to ensure they understand the protocol and the rationale of the intervention. Clinicians will receive a detailed manual with information regarding the trial intervention.
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Participants will receive individual, face-to-face sessions.
7.	**WHERE** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Interventions will be delivered in a private clinical practice.
8.	**WHEN and HOW MUCH** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Participants will receive 16 sessions, each lasting for a maximum of 60 min, twice per week, over an 8-week period. The standardized rehabilitation will comprise of 8 exercises plus 3 stretching exercise (one for the cervical spine, one for the thoracic spine and one for the shoulder). Strengthening exercises will be delivered with the following dosage: 2 sets of 10 repetitions. The strengthening exercises will be progressed in three stages. The first will have the following dosage: 3 sets of 10 repetitions. The second stage will have the following dosage: 3 sets of 20 repetitions. For the third stage of progression, clinicians can choose to increase the load to moderate (based on RPE – see below) or replace the exercise by another one from the additional list. All the exercises should initially be performed in slow and controlled pace. The load for strengthening exercises will be determined through using the 10-point Rate of Perceived Exertion (RPE) scale, considering the affected side. Low intensity will be defined as 3-4 RPE, moderate intensity as 5-6 RPE, and high intensity as 7-8 RPE.
9.	**TAILORING**	

Item number	Item	Description
	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	This intervention is not planned to be tailored.
10.‡	**MODIFICATIONS** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Not applicable. This is a protocol.
11.	**HOW WELL** Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Participants' adherence to protocol will be assessed by quantifying the number of home-based exercises performed. It will be expressed as percentage of the total number of sessions that should be been performed. Clinician's adherence to protocol will be assessed by quantifying the number of exercises and progressions that were performed according to the protocol. This will be done through audits of clinical notes, and will be expressed as percentage of the total number of exercises and progressions that were performed during the course of treatment.
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Not applicable. This is a protocol.

Concomitant care

Participants may seek other healthcare services, if they wish to do so. In that case, we will ask them to record which healthcare services they accessed on a logbook while enrolled on the trial.

Criteria for modifying or discontinuing the exercises

Pain levels, as subjectively reported by participants, will be used for determining whether an exercise must be modified or discontinued.[73 74] For this purpose of this study, we adopted a criteria used in a previous study.[75] Participants will be encouraged to continue with an exercise as long as the reported pain levels ranging from slight to endurable. Participants should discontinue exercise or reduce load if: (1) pain increases beyond what is acceptable/ bearable for the participant; (2) participant reports an immediate increase of pain by 3 points (NPRS) during exercise; (3) pain persists longer than 30 min after completion of exercise; (4) an exercise cannot be performed due to pain, clinicians will be asked not to include that specific exercise for the next 2 sessions and replace that exercise another exercise (for the tailored rehabilitation group) or with a longitudinal traction or pendulum exercise (for the standardized rehabilitation group).[8] All participants will receive home-based stretching and strengthening exercises, and will be asked to perform these once a day.

Primary outcome measures

The primary feasibility outcome measures are (Figure 2):

1. Participant's recruitment rate, measured as number of eligible participants per month;
2. Proportion of participants enrolled from the total number screened, expressed as the ratio "number of enrolled participants/total number of screened participants", with reasons;
3. Adherence to the rehabilitation programme, measured as number of sessions attended, and expressed as a percentage of the total number of sessions;
4. Drop-out rates, measured as the number of participants who dropped-out, and expressed as a percentage of the total number of participants enrolled in the study.

Secondary outcome measures

The patient-reported outcome measures intended as the primary and secondary outcomes in the main trial will be used as secondary outcome measures in this feasibility trial (Figure 2). These are: pain level as measured by a numeric pain scale,[76] and shoulder-related disability assessed using the 'patient specific functional scale' (PSFS), [77] the Shoulder Pain and Disability Index (SPADI), and the pain self-efficacy questionnaire.[78] The minimal clinically important difference for the numeric pain scale is 1 point,[79] and for the PSFS is 1.3 (for small changes), 2.3 (for medium changes) and 2.7 (large changes).[80] Although this feasibility trial is not powered to detect superiority, we will assess the magnitude of mean treatment effects for pain and physical function in relation to clinically important change, to inform the choice of primary outcome and sample size calculation for the main trial. Findings from this feasibility trial will help us selecting the primary outcome measure for the full trial.[81]

We will assess safety by recording all adverse events, both related and unrelated to interventions, in each group. Potential adverse reactions to interventions may include muscle soreness or increased pain around the shoulder joint. The physiotherapist will record any adverse reactions to interventions, including duration and severity of adverse reaction to treatment, and how the adverse reaction was managed. We will include in the report the total number of participants who reported adverse events, relatedness to interventions, the duration and severity of the adverse reactions. In the small sample of this feasibility trial, we do not expect to observe a representative number of adverse events, so do not intend statistical comparisons; rather, we will assess the feasibility of the recording forms and systems for use in the main trial.

Figure 2

Health outcomes

Health outcomes will be expressed as quality-adjusted life years (QALYs) using the Short-Form 12 (SF-12v2).[82] The SF-12v2 will be converted to a six-dimensional health state classification (SF-6D).[83] The SF-6D allows estimating the quality-adjusted life year (QALY). A QALY is a year of life experienced with a particular health-related quality of life, and will be expressed as a score ranging from 0 to 1, with 0 = death and 1 = full health. Total QALY will be estimated for each participant by calculating the area under the curve (the product of utility values by time). We will calculate the mean QALYs for each group and adjust for baseline utility scores to minimize any bias due to chance baseline imbalance between the groups. As this feasibility trial is not powered to detect superiority, we will assess the magnitude of mean effect on QALYs in relation to clinically important change.

We will adapt the Otago Cost and Consequences Questionnaire (OCC-Q) to shoulder disorders, and use the adapted questionnaire to capture healthcare use and costs for participants enrolled in this study.[84] The OCC-Q is a patient-administered questionnaire developed for osteoarthritis that has demonstrated accuracy and agreement with administrative databases from the national healthcare system in NZ.[84] The OCC-Q will be administered at baseline and 12-week time points.

Time points

Outcome measures will be recorded at baseline, 4th, 8th and 12th week after baseline.

Missing data

When assessing secondary outcome measures, we will use a linear mixed-effect model to compare groups. This method can handle missing data. For the other analysis, in case of missing data, we will assess its distribution to confirm the assumption that data was missed at random. If missing at random is confirmed, we will perform multiple imputations.

Statistical analysis

All statistical analyses will be performed using R software.[85] Descriptive statistics will be used to analyse: (1) recruitment rates; (2) adherence to the rehabilitation programme; (3) proportion of participants enrolled from the total number screened; (4) drop-out rates; (5) adverse reactions.

We will use a linear mixed-effect model to obtain estimates of intervention effects, we will compare changes in pain and shoulder-related disability scores between the two intervention groups (i.e. tailored and standardized rehabilitation). Group intervention (tailored and standardized rehabilitation) will be considered as between-subject factor, and 'time-point' (baseline, 4th, 8th week and 12th week) will be considered as within-subject factor. Baseline measurements will be considered as covariates. We will conduct an independent linear mixed-effect model for each outcome measure (i.e. pain levels and shoulder-related disability). Given this is a feasibility trial, our goal is not to perform hypothesis testing, but rather to perform these analyses as preliminary assessment of any trend in between-group comparisons. This statistical approach is considered appropriate for feasibility or exploratory studies.[86]

To help informing whether or not it is worthwhile conducting the full trial, it is recommended that preliminary between-group comparisons to be performed at the feasibility trial stage.[87 88] For that, confidence interval (CI) ranges other than 95% should be used (e.g. 85% or 75%CI in addition to the mean difference estimate) when assessing differences between groups from feasibility trials.[87] For the purposes of this study, we will consider 75% CI as the probability threshold.[87] The mean difference between tailored rehabilitation and standardized rehabilitation will need to be larger than the minimum clinically important difference for either pain or shoulder-related disability. Therefore, if we can be, at least, 75% sure that one arm is superior to the other arm at 3-month follow-up, then we will consider to have sufficient preliminary evidence of a treatment difference.[87] Such information will be taken into account when assessing whether or not to conduct the full trial.[87 88]

Economic Evaluation

We will use an incremental cost-utility analysis, following intention-to-treat principle, to assess differences in costs and utilities between tailored rehabilitation and standardized exercise, and report incremental net monetary benefit. We will use both a health system and a societal perspective to define and measure costs, as is recommended for cost-effectiveness studies.[89] We will also report the cost-efficacy and direct medical costs within the NZ healthcare system, and will calculate Bayesian credibility intervals (Bayesian analogue of 95% confidence intervals) to account for uncertainty in measurements due to sampling random variability,[90] and will plot cost-effectiveness acceptability curves.[91]

Nested qualitative study

We will include a nested qualitative study that will assess participants' experiences about the trial, and will use a thematic analysis to interpret the data.[92] We will invite all participants to take part in a semi-structured interview. The goal is to gather data about participants' experience in the trial, in particular about the difficulties and barriers faced by participants, the perceived value and positive aspects of the study and any other issue that may arise during the interviews. Findings from the nested qualitative study will add significant value into how we can minimize perceived barriers, and increase adherence with the trial. Interviews will take place once participants complete the intervention programme (i.e. at the 8-week follow-up).

We will use thematic qualitative analysis to analyse and interpret transcriptions from interviews with participants. We will conduct the thematic qualitative analysis in 5 steps: (1) generation of codes; (2) identification of themes; (3) revision of themes; (4) definition and naming of themes; (5) interpretation of findings.[92] We will keep an audit trail, and members of the research team will crosscheck the coding and interpretation of data. We will adopt an iterative approach during data analysis, and will discuss and reflect on each step to identify any inconsistencies during the thematic qualitative analysis. We will analyse, write, and submit for publication the qualitative study as a separate manuscript.

Nested process evaluation study

We will conduct a process evaluation study using a mixed-method design. As part of the process evaluation, we will assess the fidelity, dose and reach of interventions implemented during the Otago MASTER Feasibility trial. We will assess fidelity of interventions by monitoring clinical notes, fortnightly, during the intervention period. Two clinical researchers (the PI and a research assistant) will be responsible for conducting the process evaluation. As per the Medical Research Council (MRC, United Kingdom – UK) guidelines,[21] we will adopt an active role, and provide feedback and additional training to clinicians if required. This approach will optimize fidelity of interventions. According to the MCR (UK) guidelines, this is the most appropriate approach for process evaluation during feasibility trials.

We will conduct a focus-group with clinicians once 70% of data collection has been completed. The focus-group will allow us to assess clinicians' perspectives (barriers and facilitators) about the interventions and the trial. We will use thematic qualitative analysis to analyse and interpret transcriptions from the focus-group. We will conduct the thematic qualitative analysis in 5 steps: (1) generation of codes; (2) identification of themes; (3) revision of themes; (4) definition and naming of themes; (5) interpretation of findings.[92] We will keep an audit trail, and members of the research team will crosscheck the coding and interpretation of data. We will adopt an iterative approach during data analysis, and will discuss and reflect on each step to identify any inconsistencies during the thematic qualitative analysis. We will analyse, write, and submit for publication the process evaluation study as a separate manuscript.

Discussion

In the short-term, the impact of this phase II trial is inform whether or not it is feasible to conduct the full efficacy trial. If the full trial is feasible, the medium-term impact of this proposal will be to determine which exercise therapy intervention is superior for managing patients with shoulder subacromial pain.

This protocol has limitations. We did not include in the initial plan a control arm, to optimize costs at phase II, and given that some reviews and guidelines suggest exercise therapy as the treatment of choice.[10 11 52] During the peer-review process of this protocol, one reviewer raised the relevance of including a placebo arm, and a recent Cochrane Review recommends future trials to compare

exercise therapy interventions with placebo.[9] If findings from this feasibility trial suggest that it is feasible to conduct a full trial, we will design a three-arm intervention trial to address recommendations from the Cochrane Review. The full trial will consist of: (1) placebo; (2) tailored rehabilitation; (3) standardized rehabilitation. For this feasibility trial, we estimated sample size based on a two-arm intervention. The advantage of this approach is to reduce the required sample size for the feasibility phase, however, it increases uncertainty on estimates of treatment effects.[58] This will impact on sample size estimation of the full trial, if findings from this trial supports the next trial stage.[58] To address that uncertainty on treatment effect estimates, we will take this into account when preparing the future trial.

Data management

Data will be collected by trained researchers, using hard copies of forms and questionnaires. These will be safely stored and locked in a filing cabinet based at the Centre for Health, Activity and Rehabilitation Research School of Physiotherapy – University of Otago. A research assistant 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). We will use single-data entry, with 10% of the data being entered independently by two research assistants and crosschecked. In addition, we will use histograms, stem and leaf plots, clinical and data-driven range checks as part of quality control.[93 94]

Trial monitoring

The Health Research Council (HRC) Data Monitoring Core Committee (New Zealand) categorised this trial as low risk, and recommended that an independent Data Monitoring Committee was not necessary. The HRC Data Monitoring Core Committee recommended that an internal monitoring process is sufficient to monitor and oversee this trial. Based on these recommendations, the Data Monitoring Committee from the 'Centre for Health, Activity and Rehabilitation Research' (School of Physiotherapy – University of Otago) will monitor and oversee the trial. The research team has opted not to undertake interim analysis.

Ethics and Dissemination

This study was approved by the University of Otago Ethics Committee [Ref: H17/080]. Findings from this study will be presented at national and international conferences, and will be submitted for publication in a peer-reviewed journal.

Patient and Public Involvement

Patients and or public were not involved. Results of this study will be disseminated to study participants by inviting them to join an open-seminar in which the results of the study will be presented. In addition, we will prepare a short report with the main findings of the study and distribute this by e-mail to participants. The burden of the intervention will be assessed by participants through the nested qualitative study. In that study, we will participants' experiences and perceptions about the trial.

Declarations

Data collection, storage and sharing

We will store participants' data on a secure local server, and will use unique identification number on follow-up questionnaires. To protect participants' privacy, all identifying information will be stored separately, and deleted following the conclusion of the trial. We will not share or report

identifying information. The datasets generated during the study will be available from the corresponding author on reasonable request.

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.

Adverse event management

The risk of a serious adverse event related to the intervention is minimal. However, the literature suggests adverse events to exercise therapy might be common, but not serious.[95] If a participant presents with an adverse event, the primary investigator will report it to the internal Data Monitoring Committee (Centre for Health, Activity and Rehabilitation Research—University of Otago) to assess whether it is necessary to report the adverse event to the trial sponsor, and Ethics Committee. We will suspend the trial if more than one serious adverse event of any kind occurs and these are related or caused by the interventions from the trial. If the cause of the events cannot be determined or remediated, and is plausibly related to the intervention, we will terminate the trial.

Protocol amendments

We will report any protocol change that may benefit participants, impact on participant's safety or that is likely to impact on the outcomes of the study (e.g. study objectives and/or design changes, sample size, study procedures, or significant administrative changes).

Competing interests statement

None declared.

Authors' contributions

DCR and ZJT conceived the research question. DCR was responsible for the design of the trial, and is the guarantor. ZJT and GS contributed to the design of interventions. JHA provided guidance on the design the trial and economic analysis. DCR led efforts for securing funding, with the contributions from ZJT, GS and JHA. All authors revised and approved the protocol for the study. All authors revised the manuscript for important content and approved the final version.

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References

Figure captions

Figure 1. Diagram of participant flow at the Otago MASTER feasibility trial.

Figure 2. Schedule for enrolment and intervention per group.
SPADI: Shoulder Pain and Disability Index; OCC-Q-Shoulder: Otago Cost and Consequences Questionnaire – Shoulder.

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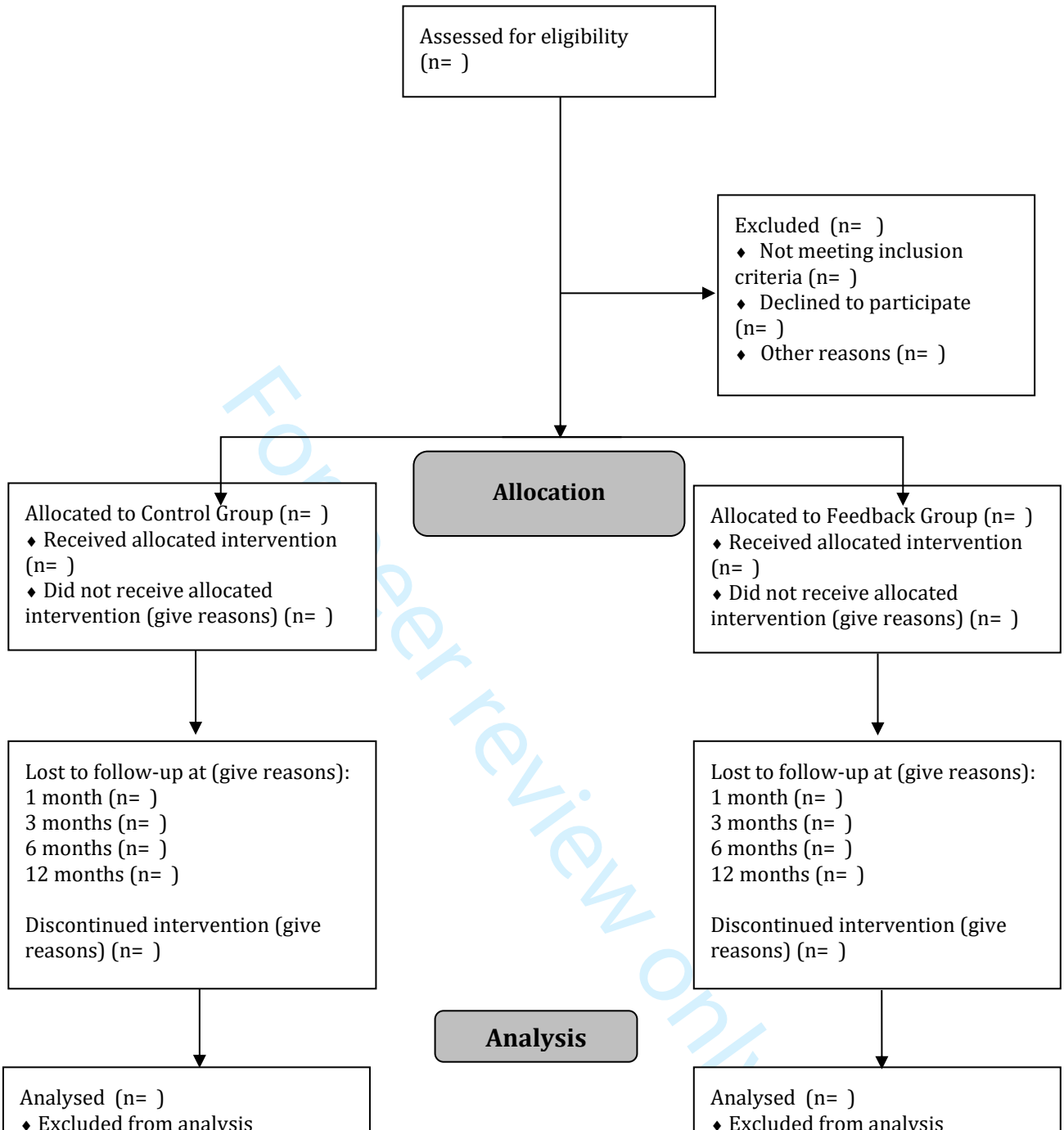

Figure 1. Diagram of participant flow at the Otago MASTER feasibility trial.

	Study Period					
	Enrolment	Allocation	Post allocation			
Time point	-t1	0	Baseline	4 weeks	8 weeks	12 weeks
Enrolment						
Eligibility screen	X					
Informed consent	X					
Allocation						
Intervention						
Standardized rehabilitation			←	—	→	
Tailored rehabilitation			←	—	→	
Assessments						
Baseline Demographic information	X					
Covariates:						
Age			X			
Height			X			
Weight			X			
Primary, and secondary outcome measures:						
Recruitment rates			X	X	X	X
Adherence to the rehabilitation programme			X	X	X	X
Proportion of participants enrolled			X	X	X	X
Drop-out rate			X	X	X	X
Adverse reaction			X	X	X	X
Pain intensity			X	X	X	X
Health outcomes						
Patient specific functional scale			X	X	X	X
SPADI			X	X	X	X
OCC-Q-Shoulder			X			X
Pain self-efficacy questionnaire			X	X	X	X

Figure 2. Schedule for enrolment and intervention per group.
SPADI: Shoulder Pain and Disability Index; OCC-Q-Shoulder: Otago Cost and Consequences Questionnaire – Shoulder.

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Supplementary Material 1

Otago MASTER Feasibility Trial

Tailored rehabilitation programme

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Findings from physical examination & suggested exercises:

Findings from physical examination	Exercises
Pain or stiffness during passive accessory mobilization	Cervical or thoracic spine: HVT or PAIVM PAIVM If Grade –III or -IV if pain dominant Grade –IV or +IV if stiffness Gleno-humeral joint: Passive accessory mobilization - Grade –III or -IV if pain dominant - Grade –IV or +IV if stiffness
Painful or limited arm elevation during active resistive arm movement (flexion, abduction, internal rotation and external rotation) **Positive MWM** during shoulder scaption, shoulder external rotation, hand behind back position	# **1.A.** MWM for increasing shoulder scaption **#1.B.** MWM for increasing shoulder external rotation **#1.C.** MWM during shoulder elevation **#1.D.** MWM during hand behind back motion **#T.1.** Taping for sustained postero-lateral glide on humeral head (end of session) **# 11** Isolated motor control training around the shoulder
Positive scapular dyskinesis test: Scapular winging, tipping or hiking	**#4** Scapular setting in static postural position **#5** Scapular setting during dynamic elevation and rotation **#6** Shoulder shrugs with shoulder higher than 90^0 abduction

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Findings from physical examination	Exercises
	#7 Shoulder horizontal exercise with multiple feedbacks
Anterior translation humeral head, positive dynamic relocation test **Positive dynamic rotary stability test or shoulder pain during arm rotation (active or resistive)**	**#10** Dynamic relocation training **#11** Isolated motor control training around the shoulder
Positive Scapular MWM during scaption	**#1.C.** Mobilization with movement for scapular upward rotation
Positive Scapular upward rotation test	**#3** Scapular upward rotation training (retraining serratus anterior and upper trapezius)
Positive scapular weight bearing test	**#7** Shoulder horizontal exercise with multiple feedbacks **#8** Dissociation of scapular movements to thoracic in four point kneeling position and in for challenging situation by holding weight on just one hand **#9** Scapular holding training at mid protraction position (we perform this exercise when participant is able to scapular protraction and retraction
Positive scapular control test	**#2** Scapular exercises

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Quick Exercise Reference:

Mobilization with movement techniques

(1 MWM counts as **one** exercise. Start with 3 sets of 10 reps with 30 sec rest between sets)

Exercise	**Stage 1 (Basic)**	**Stage 2 (Intermediate)**	**Stage 3 (Advanced)**
1.A. **Shoulder scaption**	**1. A.1** In sitting, participant performs active shoulder scaption with ***elbow flexed*.**	**1. A.2** In sitting, participant performs active shoulder scaption with ***elbow extended***.	**1. A.3.** In sitting, participant performs shoulder scaption ***against a light weight*** or theraband (low intensity).
1.B. **Shoulder external rotation (ER)**	**1. B.1** In supine, participant performs ***active-assisted*** *shoulder ER* with the help of a wand. Therapist applies a posterolateral humeral glide.	**1. B.2** In sitting with arm at 90^0 abduction and elbow flexed, participant performs an ***active*** *shoulder ER*. Therapist sustains a posterolateral humeral glide.	**1. B.3** In sitting, participant performs shoulder ER *against* ***light resistance*** (low intensity). Therapist sustains a posterolateral humeral glide.
1.C. **Scapular up ward rotation**	**1. C.1** In sitting, participant performs active shoulder flexion with ***elbow flexed*.** Therapist assists scapular upward rotation	**1. C.2** In sitting, participant performs active shoulder flexion and ***elbows extended***. *T*herapist assists scapular upward rotation	**1. C.3** In sitting, participant performs active shoulder flexion and elbows extended ***against resistance*** (low intensity). *T*herapist assists scapular upward rotation

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Mobilization with movement techniques

1 MWM counts as **one** exercise. Start with 3 sets of 10 reps with 30 sec rest between sets

1.D. **Hand behind back motion**	**1. D.1** In sitting, participant moves hand behind back by ***pulling a belt*** *with other hand* while physiotherapist applies inferior glide on the shoulder.	**1. D.2** In sitting, participant moves hand behind back ***actively*** while physiotherapist applies inferior glide on the shoulder.	

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Scapular Control Training

Exercise	Stage 1	Stage 2	Stage 3	Home ex.
2. Scapular exercise	**2. A.1**. In side lying position physiotherapist uses ***resistance*** against shoulder D1 pattern.	**2. A.2**. *In* side lying, participant performs the shoulder D1 pattern in side lying position as ***free active*** movement.	2. A.3. ***In sitting,*** participant performs the shoulder D1 pattern as **free active** movement.	#7
	2. B.1. In side lying position physiotherapist *uses* ***resistance*** against shoulder D2 pattern.	**2. B.2.** In side lying, participant performs the shoulder D2 pattern in side lying position *as* ***free active*** movement.	2. B.3. ***In sitting***, participant performs the shoulder D2 pattern in side lying position as **free active** movement.	
3. Scapular upward rotation training (retraining serratus anterior and upper trapezius)	**3. A.1.** In the side lying position, participant elevates their arm while the therapist ***assists*** *serratus anterior* activity through feedback.	**3. A.2.** In the side lying position, participant elevates their arm against gentle resistance. The therapist **gently resists** serratus anterior activity by *resisting scapula upward rotation*.	**3. A.3.** In the side lying position, participant elevates their arm while the therapist ***increases resistance*** *against serratus anterior* activity by resisting scapular upward rotation.	#6

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4. Scapular setting in the ideal postural position *(static position*)	**4. A.1** In sitting *with **elbows resting on the armchair***. Participant is asked to tighten the scapula on their upper back. Physiotherapist uses feedback to inform participant of normal scapular position	**4.A.2** In sitting, participant is asked to tighten the scapula on their upper back *at **60°, 90° and 120° of shoulder elevation*** while the physiotherapist uses feedback to inform participant of normal scapular position	**4. A.3** In sitting, participant is asked to tighten the scapula on their upper back **at 60°, 90° and 120° of shoulder *elevation with a dumbbell*** (low intensity)**.** Physiotherapist informs participant of normal scapular position	#3
5. Scapular setting during dynamic elevation and rotation	**5 .A.1** In standing, participant performs shoulder flexion with the help of a ***ball on horizontal surface***. The physiotherapist prevents any abnormal scapular or shoulder movement.	**5 .A.2.** In standing, participant performs shoulder flexion with the help of a ***ball on inclined surface.*** The physiotherapist prevents any abnormal scapular or shoulder movement.	**5 .A.3.** In standing, participant performs shoulder flexion with the help of a ***ball on the wall.*** The physiotherapist prevents any abnormal scapular or shoulder movement.	#4a, #4b, #4c and #4d
	5. B.1 In sitting or standing, participant is asked to maintain normal scapular movement during arm **flexion *to 90° or arm abduction to 60°.*** The therapist prevents excessive shoulder hiking.	**5 .B.2** In sitting or standing, participant performs long lever arm shoulder elevation to ***beyond 90 degrees*.** Therapist ensures smooth movement of scapula without compensatory movements.		

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	5 .C.1 In sitting or standing, participant is asked to maintain normal scapular movement during **arm flexion to 90° or arm abduction to 60°** *against light resistance* (low intensity). Therapist prevents excessive shoulder hiking.	**5. C.2.** In sitting or standing, participant performs shoulder elevation to **greater than *90°*** *against light resistance* (low intensity). The therapist ensures participant can maintain normal scapular and shoulder movement.		#4F & G
	5. D.1. Participant is standing with arm and side and elbow flexed to 90°. Participant performs bilateral shoulder elevation with isometric shoulder external rotation against ***resistance (low intensity)*.**	**5. D.2.** Participant is standing with arm and side and elbow flexed to 90°. Participant performs bilateral shoulder elevation with isometric shoulder external rotation against ***resistance (mod intensity)***.	**5. D.3.** Participant is standing with arm and side and elbow flexed to 90°. Participant performs bilateral shoulder elevation with isometric shoulder external rotation against ***resistance (high intensity)*.**	
	5. E.1. Participant is s*itting* with shoulder abducted 90°and elbow flexed to 90°. Participant performs ***unloaded arm internal and external* rotation** without any compensatory scapular or shoulder movements.	**5. E.2.** Participant is standing or sitting with shoulder abducted 90°and elbow flexed to 90°. Participant performs ***arm internal and external rotation* against *theraband*** (low intensity) without any compensatory scapular or		

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		shoulder movements.		
	5. F.1. Participant is in *prone* with shoulder abducted 90° and elbow flexed to 90°- The ***shoulder and forearm is supported*** using a towel roll or a pillow. Participant performs *arm internal and external* rotation without any compensatory scapular or shoulder movements.	**5. F.2.** Participant is in *prone* with shoulder abducted 90° and elbow flexed to 90°- The shoulder and **forearm is unsupported** (*participant actively holds the shoulder off the bed)*. Participant performs *arm internal and external* rotation without any compensatory scapular or shoulder movements.	**5. F.3.** Participant is in *prone* with shoulder abducted 90° and elbow flexed to 90°- The shoulder and forearm is **unsupported** (participant actively holds the shoulder off the bed). Participant performs *arm* internal and external rotation ***against resistance*** without any compensatory scapular or shoulder movements.	
6. Shoulder shrug exercise with <u>shoulder higher than 90° of abduction</u>	**6. A.1** In standing, shoulder flexed, participant performs **assisted** *shoulder shrug (*wall slide or pulley). Physiotherapist prevents over activity of the levator scapulae.	**6. A.2** In standing, shoulder flexed, and participant does ***active*** *shoulder shrug without wall support. P*hysiotherapist prevents over activity of the levator scapulae.	**6. A.3** In standing, shoulder flexed, participant shrugs shoulders ***against resistance.*** *P*hysiotherapist prevents over activity of the levator scapulae.	#2

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7. Shoulder horizontal exercise with multiple feedbacks	**7. A.1**. Participant ***stands in front of a wall*** with their hands overhead on the wall. Participant is then asked to take their hands on and off the wall. The physiotherapist facilitates activity of the lower trapezius.	**7. A.2.** Participant is in ***side lying*** position with arm overhead (100° of flexion). Participant performs *horizontal shoulder abduction.* The physiotherapist facilitates activity of the lower trapezius.		#5
	7. B.1. Participant is either in ***prone*** with arms hanging off the side of bed or in 4-point kneeling position. Participant then extends and abducts their arm to 90 degrees.	**7. B.2.** Participant is in prone or in 4-point kneeing with **arm abducted greater than 90 degrees.** They are asked to lift their arms off the bed against appropriate resistance.		
8. Dissociation of scapular movements to thoracic in four point kneeling position	8. A.1. Leaning over table with **partial weight bearing on hands**, participant performs scapular protraction and retraction	8. A.2 **In four-point keeling position**, participant performs scapular protraction and retraction	8. A.3. In four-point keeling position while **weight bearing on one hand**, participant performs scapular protraction and retraction	NA
9. Scapular holding training at mid protraction position	9. A.1. In standing position, participant performs resisted scapular protraction against **light resistance.**	9. A.2. In **4-point kneeling**, participant holds scapula in mid protraction for 10 seconds.	9. A.3. Participant is in **three-point kneeling** (weight on affected extremity) and holds the scapula in mid-protraction for 10 secs.	NA

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Rotator Cuff Motor Training				
Exercise	**Stage 1**	**Stage 2**	**Stage 3**	**Home exercise**
10. Dynamic relocation training	10 .A.1. In sitting or supine position, participant draws their shoulder head towards the socket as physiotherapist applies gentle traction on the humerus.	10 .A.2 In sitting, participant draws their shoulder "in and back" towards their socket, *without humeral traction*, at the outer or inner shoulder rotation degrees.		#8 for Stage 3
11. Isolated motor control training around the shoulder	11 .A.1. In prone position with arm abducted to 90 degree, participant tightens their scapula and draws the humeral head gently down and in as they externally rotate their shoulder.	11 .A.2. In sitting with arm abducted to 90 and elbow flexed to 90, participant tightens their scapula and draws the humeral head gently down and in as they externally rotate their shoulder.	11 .A.3. In sitting with arm abducted to 90 and elbow flexed to 90, participant tightens their scapula and draws the humeral head gently down and in as they externally rotate their shoulder against resistance.	Home exercise #9 for Stage 3

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Proprioception, and plyometric training		
12. Proprioception training	**12. A.** The participant is sitting with a ball beneath their hand. Participant alternately presses and releases the ball	**12. C.** In sitting, pressing down the hands on the seat and lifting their bottoms off the bed.
	12. B. The participant pushes and releases a ball on the wall. The therapist ensures that participants stabilizes the scapula to prevent winging	**12. D.** Plyometric ball catching and throwing exercise.

Taping
T.1. Taping for sustained postero-lateral glide on humeral head.

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Exercise description

1. Monilization with Movement

1.A. Mobilization with movement for increasing shoulder scaption

Equipment: Mulligan Belt (for stage 3).

Participant position: Sitting.

Therapist position: Therapist places their hand on humeral head anteriorly.

Direction of force: Physiotherapist sustains posterolateral glide on humeral head.

Joint Movement: Participant performs scaption. It is important that physiotherapist allows normal motion between scapula and thorax to ensure pain free scaption.

1. A.1. Stage 1: Participant performs the arm scaption with elbow flexed.

1. A.2 Stage 2: Participant performs the technique with elbow extended.

1. A.3 Stage 3: Participant performs scaption against a light weight or a Thera band with elbows extended.

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1.B. Mobilization with movement for increasing shoulder external rotation

Equipment: Wand (for stage 1), Theraband (stage 3).

Participant position: Variable based on stage. Please refer to individual stages below.

Therapist position: Variable based on stage.

Direction of force: Physiotherapist sustains posterolateral glide.

Joint movement: Participant externally rotates the shoulder.

1. B.1. Stage 1: Participant is in supine with arms in comfortable abduction and elbows flexed to 90º, holding a stick in both hands to assist the external rotation of the involved shoulder. Physiotherapists sustain posterolateral humeral glide while participant performs passive shoulder external rotation (figure above).

1. B.2. Stage 2: Participant is sitting with shoulder abducted to 90, elbow flexed to 90 and then performs active external rotation as physiotherapist applies posterolateral glide.

1. B.3. Stage 3: Same as above but participant performs ER against light resistance.

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1.C. Mobilization with movement for scapular upward rotation

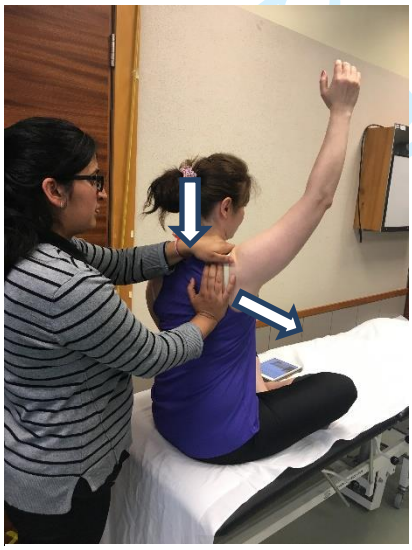
Equipment: Theraband (for stage 3)

Participant position: Sitting without back support.

Therapist position: Behind the participant. One hand on the spine of scapula and other on the medial aspect of scapular body.

Direction of force: Physiotherapist sustains downward and medial glide over the spine of scapula with one hand and rotates scapula upwardly with other hand while preventing scapular winging and tipping

Joint Movement: Participant performs shoulder elevation.



1.C.1 – Stage 1

1.C.1 – Stage 2

1. C.1. Stage 1: Participant performs shoulder flexion with elbow flexed

1. C.2. Stage 2: Participant performs shoulder flexion with elbow extended

1. C.3. Stage 3: Participant performs resisted shoulder flexion with elbow extended against light resistance.

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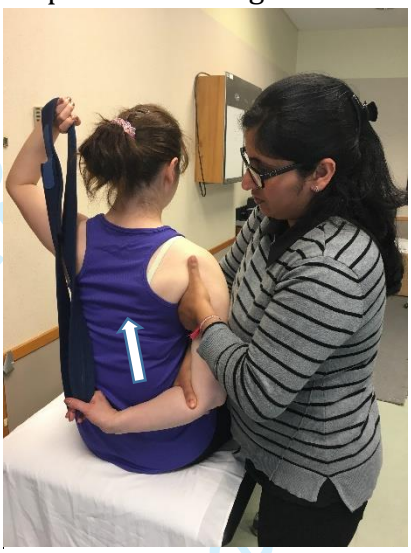
1.D. Mobilization with movement for hand behind back motion

Equipment: Belt (for stage 1)

Participant position: Sitting or standing.

Therapist position: Standing on the affected side. One hand on the lateral border of scapula and other hand on distal humerus for applying inferior glide.

Direction of force/ Movement: Physiotherapist stabilizes the scapula and applies *inferior glide (traction)* while participant is reaching to the back with the involved hand.



1. D.1 Stage 1: Participant reaches the affected hand behind back with the help of a belt.

1. D.2. Stage 2: Participant actively holds hand behind back without assistance

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2. Scapular exercise

In participants with poor awareness or control, the scapula tends to follow a curvilinear path rather than a diagonal, with jerky uncoordinated movement. Frequently, the scapula moves into excessive protraction and anterior tilt when attempting the 'up and forward' direction.

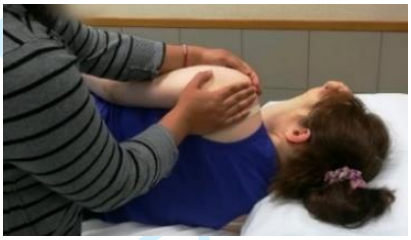
2 .A. The D1 pattern (elevation-protraction to depression-retraction)
Participant moves the tip of the shoulder towards the corner of the eye. And then returns it down and back to the opposite hip. Please make sure that participant has the chin tucked in.

2. A.1. (**Stage 1) - (Picture below, left):** Participant performs the D1 pattern in side lying. Physiotherapist applies resistance against the movement.

2. A.2. (Stage 2) - (figure below, right): Participant performs the pattern in side lying without resistance.

2. A.3. (**Stage 3):** Participant performs the pattern in sitting without resistance.


2.A.1


2.A.2

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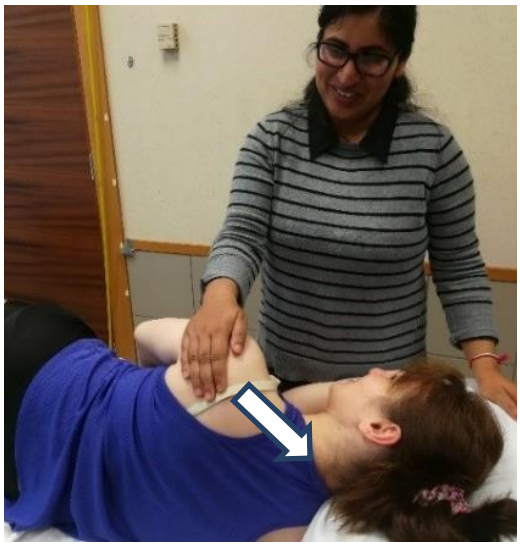
2. B. The D2 pattern (depression-protraction to elevation-retraction)

Participant moves the tip of the shoulder down and forward towards your opposite hip, then returns it up and back.

2. B.1. Stage 1: Participant performs the pattern in side-lying. Physiotherapist applies light resistance against the movement (Picture below).



2. B.2. (**Stage 2) (Picture below):** Participant performs the pattern in side lying without resistance

2. B.3. (**Stage 3):** Participant performs the pattern *in sitting* without resistance.

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3. Scapular upward rotation training (retraining serratus anterior and upper trapezius)

Equipment: None

Participant position: Participant in side-lying on the uninvolved arm.

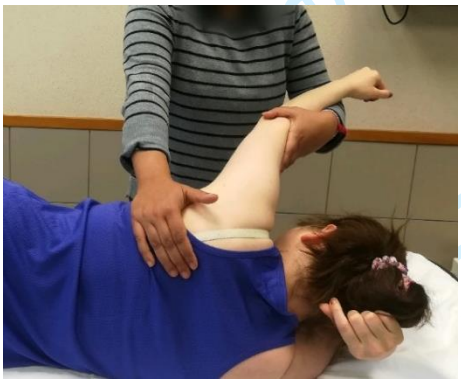
Feedback: Physiotherapist supports the upper arm in shoulder flexion greater than 90^0. Physiotherapist resists against shoulder motion and palpates the lateral border of scapula to activate serratus anterior.

Movement: Participant tries to bring the shoulder into more flexion and external rotation with scapular upward rotation.

3 .A.1. Stage 1(picture below). Physiotherapist *assists* in activation of serratus anterior by using palpation, tapping or repeated contraction or stretch

3 .A.2. Stage 2: Physiotherapist *resists gently* against scapular upward rotation.

3 .A.3. Stage 3: Physiotherapist *increases resistance* against scapular upward rotation.



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4. Scapular setting in postural position

Equipment: Mirror (if required for visual feedback).

Participant position: Upright sitting.

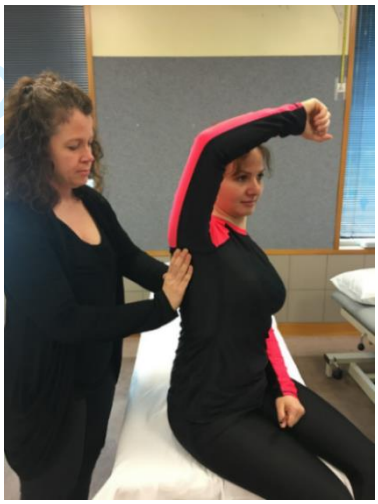
Feedback: The physiotherapist provides feedback (visual, tactile or verbal) to inform the participant of normal scapular resting position.

Movement: Participant is asked to tighten the scapula by contracting the serratus anterior and trapezius so that the inferior angle and medial border lies flat over the upper back. Participant holds this position for 10 seconds.

4. A.1. Stage 1: This stage is used for participants who have winging or tipping in upright position. The participant's arms are unloaded by placing the elbow over armchair. Participant is asked to "tighten their scapula on their upper back" and hold it for 10 seconds.

4. A.2. Stage 2 (Picture below): Scapular setting exercise is performed while participant holds the involved arm isometrically in 60°, 90° and 120° shoulder elevation. The shoulder may be internally rotated or externally rotated while the arm is held at 0°, 60°, 90° or 120°.





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4. A.3. –(Stage 3) (Picture below): Scapular setting exercise is performed at 60°, 90° and 120° shoulder elevation against light resistance provided by a dumbbell.

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5. Scapular setting during arm movements

(These exercises are used for participants with observable tipping or winging of the scapula *during arm movement*.)

Equipment: Mirror (if required for visual feedback), Gym ball (based on exercise) please refer to individual exercises

Participant position: Variable based on exercise.

Feedback: The physiotherapist provides feedback (visual, tactile or verbal) to inform the participant of normal scapular resting position.

Movement: Participant is then asked to maintain normal scapular position/ movement while preventing tipping and winging as they perform various arm movements.

5. A. Scapular setting during shoulder flexion with ball (pictures below)

5 .A.1 (Stage 1): Participant performs shoulder flexion on the bed with no inclination with the help of a ball.

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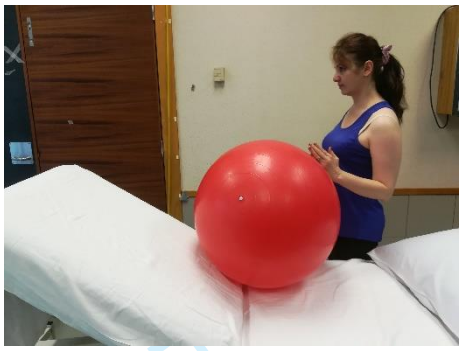
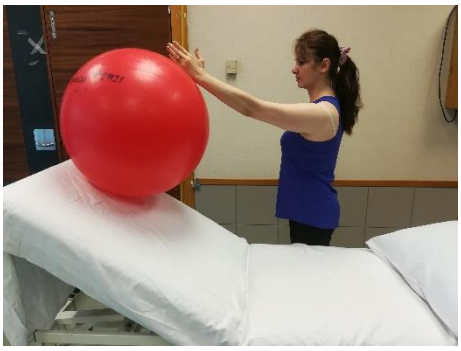
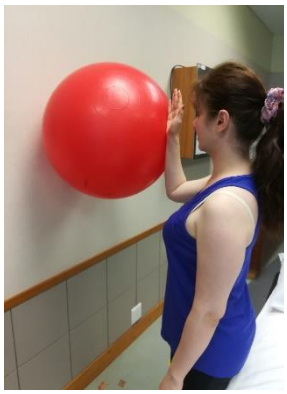
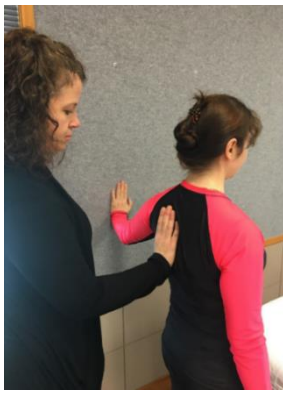
5 .A.2 (Stage 2): Participant performs shoulder flexion with the help of a ball on a surface inclined to 45°.

5 .A.3 (Stage 3): Participant performs shoulder flexion using a ball on a wall. Alternately, participant performs a simple wall slide.





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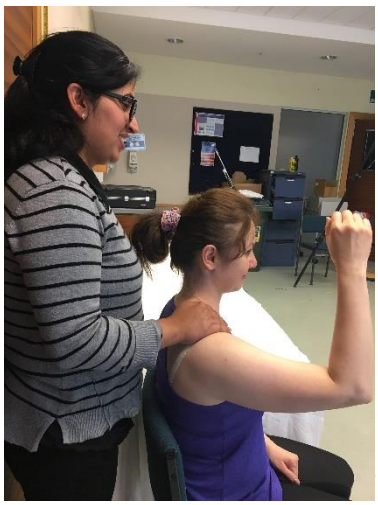
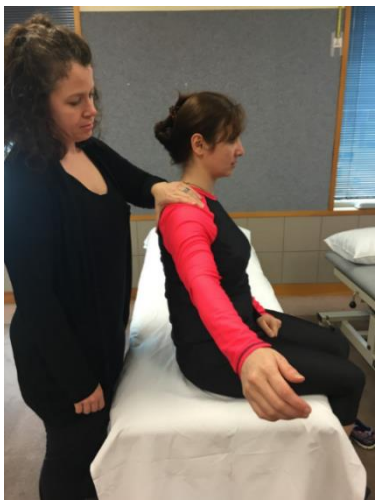
5. B. Scapular setting during arm elevation

5 .B.1. (Stage 1): Scapular setting during arm elevation to 90

Participant is asked to maintain normal scapular position during arm *flexion to 90°* or arm *abduction to 60°* with elbow flexed (easier) or extended (more difficult). The therapist prevents excessive shoulder hiking through appropriate feedback.





5. B.2 (Stage 2): Scapular setting during long lever arm elevation >90° (flexion and abduction) as free active

Participants actively elevates the arm (either flexion or abduction) to above 90° with elbows extended without any assistance or resistance. The therapist ensures smooth normal movement of the scapula without compensatory scapular hiking, tipping or winging.

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5. C. Scapular setting during arm elevation against resistance

5. C.1 (Stage 1): Scapular setting during gentle resisted arm flexion to 90° and abduction to 60°

Participant performs shoulder flexion to 90° or shoulder abduction to 60° against a light resistance (Theraband or dumbbell) while the physiotherapist provides feedback to prevent excessive shoulder hiking.

5. C.2 (Stage 2): Scapular setting during long lever arm elevation >90° against resistance

Participant performs shoulder elevation to *greater than 90°*, with elbows extended, against light resistance. Physiotherapist should ensure participant is able to control scapular winging during raising and lowering phases and that participant avoids scapular hiking.

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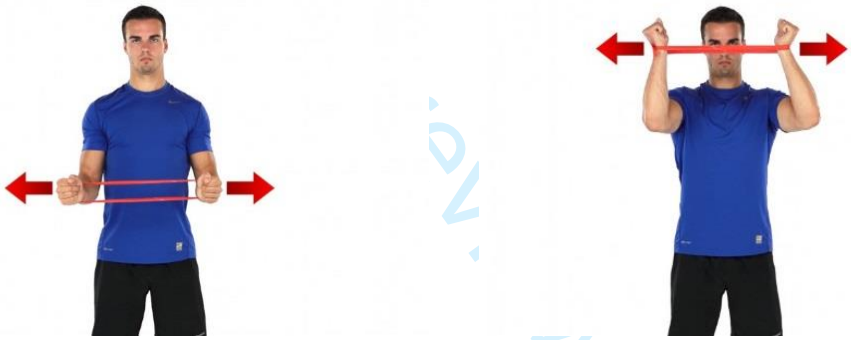
5. D. Scapular setting during bilateral shoulder elevation combined with external rotation resistance

5. D.1 Participant elevates both their arms to 90°, while isometrically contracting external rotation against light resistance (RPE 3 to 4), with elbows flexed.

5. D.2. Participant elevates both their arms to 90°, while isometrically contracting external rotation against moderate resistance (RPE 5 to 6), with elbows flexed.

5. D.3. Participant elevates both their arms to 90°, while isometrically contracting external rotation against high resistance (RPE 7 to 8), with elbows flexed.



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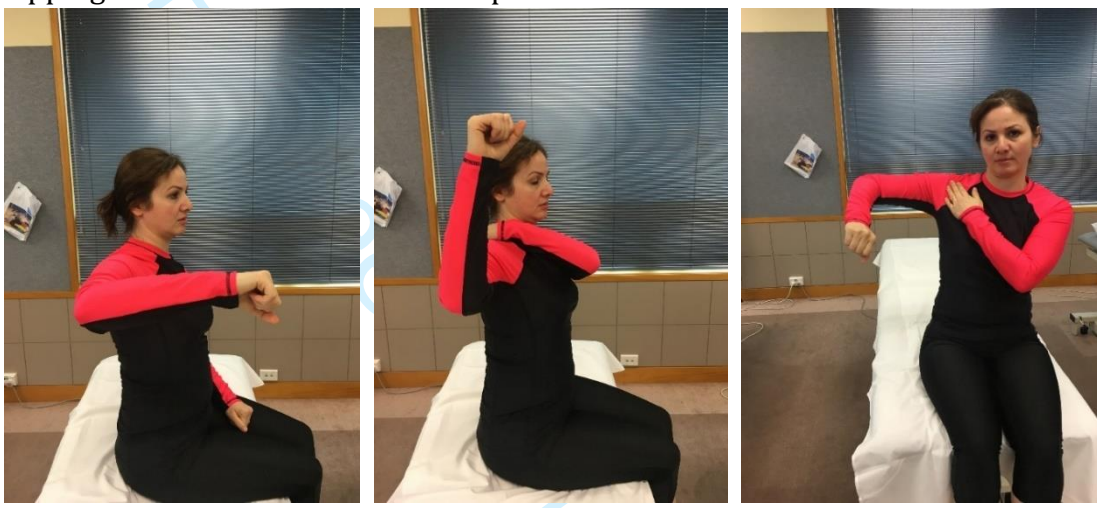
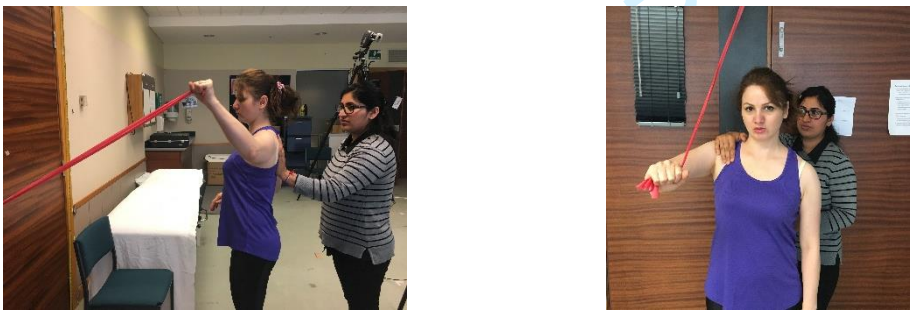
5. E. Scapular setting exercise during internal and external rotation in upright position

5. E.1.: Participant performs shoulder external rotation and internal rotation with shoulder flexed to 90° in sitting.
For ER: Physiotherapist makes sure that participant avoids shoulder depression and retraction.
For IR: Physiotherapist makes sure that participant avoids scapular anterior tipping and shoulder elevation and protraction.



5. E.2. Participant tightens the scapula during shoulder external rotation with arm at 90°. It is better to perform this exercise in front of mirror for added feedback.



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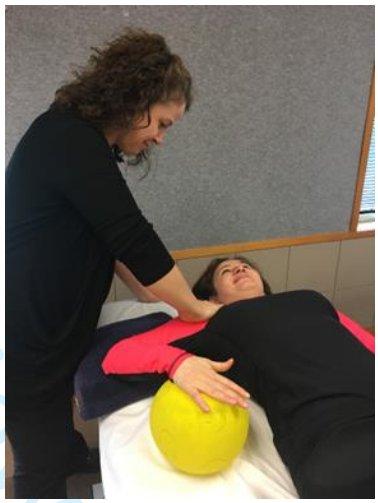
5. F. Scapular setting during shoulder rotation in prone:

Participant is asked to rotate the shoulder externally or internally without excessive scapular depression and retraction. The goal is to dissociate shoulder movement from scapular movement.

However, if the participant is unable to perform full internal rotation, they are asked to press on a ball in supine lying without lifting their shoulder from the bed (picture below- right). This activates the subscapularis muscle.

5. F.1 (Stage 1): Participant is in prone with arm flexed to 90° and elbow flexed to 90°. A towel roll is placed under the shoulder to support the arm as well as to prevent shoulder anterior tilting.



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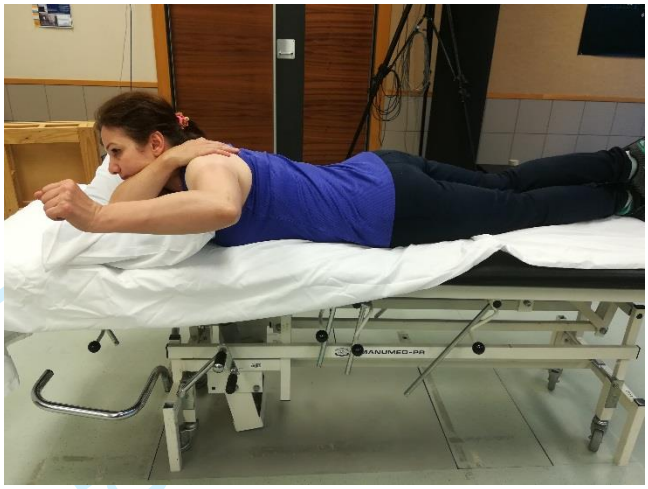
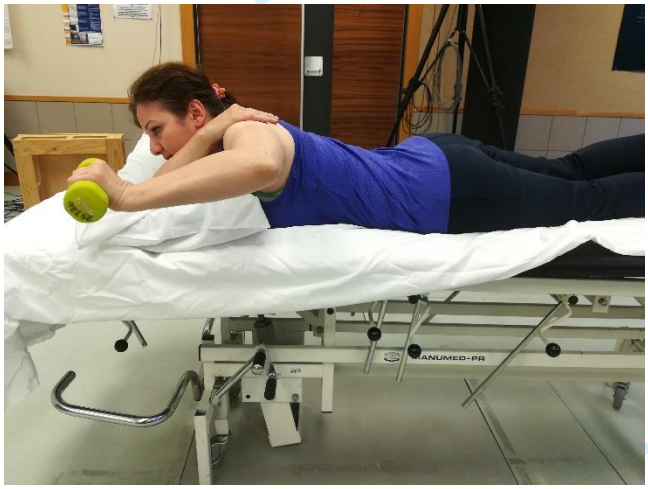
5. F.2 (Stage 2): Participant is in prone with arm flexed to 90° and elbow flexed to 90°. No support is provided and participant is asked to actively hold the shoulder off the bed while performing shoulder internal and external rotation.



5 .F.3. (Stage 3): Participant is in prone with arm flexed to 90° and elbow flexed to 90°. No support is provided and participant is asked to actively hold the shoulder off the bed while performing shoulder internal and external rotation against resistance.



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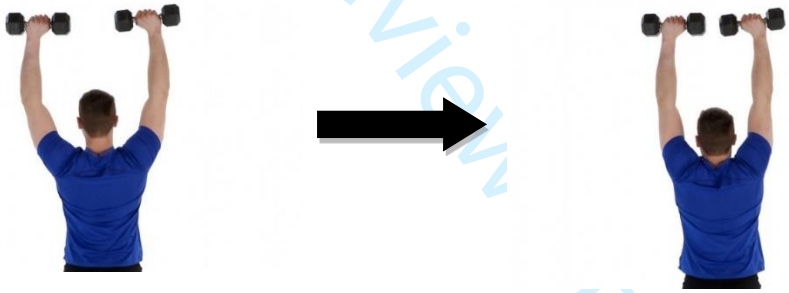
6. Shoulder shrug exercise where arms are higher than 90^0 of abduction

Equipment: Dumbbell (for stage 3).

Participant position: Standing.

Feedback: Physiotherapist uses appropriate feedback to facilitate the activation of the upper trapezius while preventing over activity of the levator scapula.

Movement: Participant raises the tip of shoulder towards the ear lobe while keeping their chin tucked.



6 .A.1 Stage 1: Participants elevate their arms and then perform shoulder shrug by sliding their hands up a wall or by using a pair of hanging strings from the ceiling.

6 .A.2. Stage 2: Participants perform the task as free active movement.

6 .A.3. Stage 3: Participants performs the task with light resistance (dumbbell).

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7. Shoulder horizontal exercise with multiple feedbacks

Equipment: Mirror (if required for visual feedback), Theraband (for stage 3).

Participant position: Variable based on stage.

Feedback: Physiotherapist **continuously taps the lower trapezius** to facilitate muscle activity and gives participant the verbal ques to tip the scapula posteriorly and avoid shoulder shrug.

Movement: The participant is instructed to "lift the arm from the scapula (by moving your scapula) and not from shoulder joint while keeping your arm in external rotation". This instruction is given to prevent excessive humeral head anterior translation.

7 .A Non-weight bearing exercises

7. A.1. (Stage 1): Participant stands in front of a wall with the hands overhead on the wall. Participant is then asked to take their hands on and off the wall. This exercise is applicable when participant is not able to do horizontal abduction in 4-point kneeling. Make sure that Participant performs the movement from their scapula.

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7. A.2. Stage 2: Participant is in side lying position with arm overhead (100° of flexion). Participant then performs subsequent ***arm extension and abduction***. The physiotherapist prevents arm hyperextension and encourages participant to elevate their arm from the scapula at the end range of arm extension. (Continuous tapping over lower trapezius is recommended).

7. B. Exercises in weight bearing

7. B.1. (Stage 1): Participant is either in prone with arms hanging off the side of bed or in 4-point kneeling position. Participant flexes and abducts their arm to 90 degrees. The physiotherapist prevents hyper abduction and encourages scapular movement.

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7. B.2. (Stage 2): Participant is in prone or in 4-point kneeing positions with arm abducted greater than 90 degrees. They are asked to lift their shoulders off the bed against appropriate resistance.

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8. Dissociation of scapular movements from thoracic movements in 4-point kneeling

Equipment: Wand for feedback
Participant Position: Variable based on the stage
Feedback: Physiotherapist encourages participant to do scapular protraction and retraction without spine movements. In particular, participants should avoid thoracic extension (lordosis) during retraction, and thoracic flexion (kyphosis) during protraction.

Other possible compensatory movements:

- full extension of the elbows
- end range rotation of the arm
- passive scapular retraction
- forward head position or cervical flexion
- increased lumbar lordosis
- elevation of shoulder girdle towards the ears
- Scapular winging.

If participant has tremor of the shoulder girdle or arm muscles during the exercise, physiotherapist reduces sets/repetitions/resistance.

Movement: Widen your shoulder blades and return them as if closing and opening a book.

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8. A.1. (Stage 1) (Picture below): Participant is leaning over a table while weight bearing on both hands. To increase the difficulty, participants may be asked to shift their weight to the affected side.

8 .A.2 (Stage 2 -Picture below): In 4-point keeling position, participant performs scapular protraction and retraction while bearing weight on both hands. To increase the challenge participant may *shift* their weight to the affected side.

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8. A.3 (Stage 3-figure below): In 4-point keeling position, participant performs scapular protraction and retraction with weight bearing on one hand.

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9. Scapular holding training at mid protraction position

(This exercise is used when participant can perform each scapular protraction and retraction for 10 seconds)

Equipment: Theraband

Participant Position: Variable based on stage

Feedback: Ensure that when participant is holding scapula in mid protraction, he/she should keep spine in straight and neutral position. In the case that participant has a weak control of spinal column, when you ask participant to have their neck in neutral position, participant performs thoracic or lumbar extension

Movement: Participant holds the scapula in mid protraction for 10 second, 10 reps, and 2-3 sets.

9. A.1. - (Stage 1): Participant is in standing, with a theraband wrapped around their back or on a door. Participant performs scapular protraction against light resistance.

9. A.2 (Stage 2): Scapular holding training in four-point kneeling position. Participants holds the scapula in mid-protraction for 10 seconds. To increase difficulty, participant may be asked to transfer weight to affected side by leaning towards the affected side.

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9. A.3 (Stage 3): Participant is in three-point kneeling (weight bearing on the affected extremity only) and holds the scapula in mid-protraction for 10 secs.

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10. Dynamic relocation training

These exercises focus on increasing the isolated contraction of rotator cuff (co-contraction of subscapularis, teres minor and infraspinatus) while decreasing contraction of superficial muscles.

As described by:

Magarey ME, Jones MA. Dynamic evaluation and early management of altered motor control around the shoulder complex. Manual therapy. 2003 Nov;8(4):195-206.

Magarey ME, Jones MA. Specific evaluation of the function of force couples relevant for stabilization of the glenohumeral joint. Manual therapy. 2003 Nov;8(4):247-53.

10. A.1. (Stage 1):
Participant position: Participant is either lying supine or sitting, with arm supported between 60^0 to 80^0 of scaption by the therapist.

Direction of force: The physiotherapist applies a gentle longitudinal distraction force and asks participant to draw their humerus into the the glenoid cavity.

Movement: Physiotherapist asks participant to draw the arm "in and backward". The participant is asked to perform a gentle depression of the scapula while drawing the humerus toward the glenoid cavity.

Feedback: Physiotherapist encourages participant to activate more subscapularis and concurrently decrease superficial muscle activity (e.g. latissimus dorsi, posterior deltoid, pectoralis major and upper trapezius). Initially, participant may pull the arm strongly with superficial muscles with or without rotator cuff contraction. In this case, they should be instructed to reduce the effort.

10. A.2. (Stage 2): Participant draws their shoulder "in and back" towards the glenoid cavit, ***without humeral traction***, at the outer or inner range of shoulder rotation.

Participants should be taught to feel the contraction for themselves by palpating near the axilla. When the physiotherapist is confident that the participant can dissociate the co-contraction without external feedback, he/she can ask participants to do the exercise at home.

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11. Isolated motor control training around the shoulder

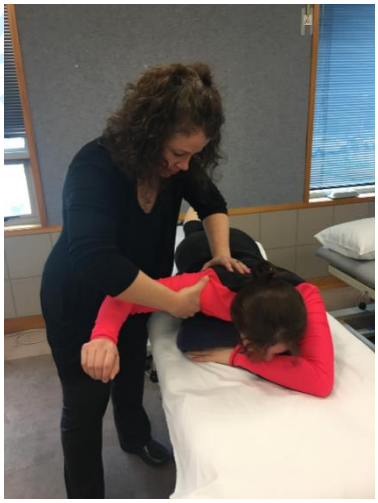
When there is lack of dynamic rotator cuff stability, the humeral head often translates anteriorly or superiorly. The aim of this training is to find a position where participant has the most control on humeral head, as close as to the position where there is the least control. Physiotherapist asks participant to rotate shoulder while centering the humeral head to the glenoid. Stabilizing scapular concomitant with humeral head depression prevent clicking sound and pain in the shoulder.

11. A.1. (Stage 1): Assisted External Rotation

Participant Position: Lying prone with chest supported by a folded towel

Feedback: The physiotherapist palpates the participant's humeral head from anterior and superior direction. The aim is to teach participant to relax their deltoid.

Movement: The participant is asked to tighten their scapula and draw the humeral head gently "down and in" as they externally rotate their shoulder actively. This exercise is applicable when we observe humeral head anterior protrusion during shoulder external rotation.



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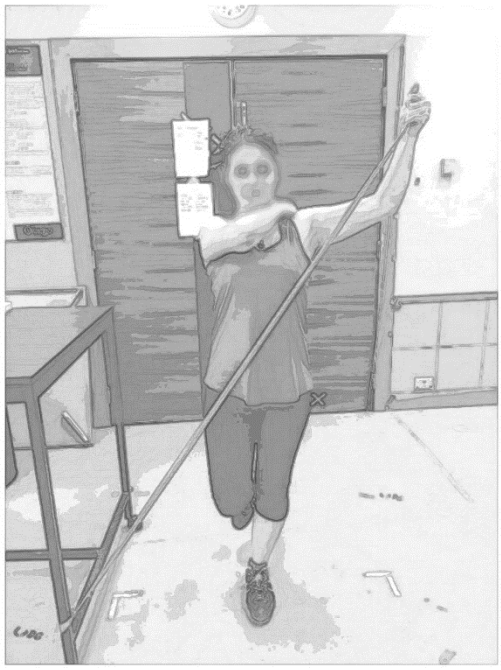
11.A.2 (Stage 2): In sitting, participant performs active ER while physiotherapist ensures there is no excessive anterior and superior glide of the humeral head.

11.A.3. (Stage 3): Progressed to resisted ER motion. Physiotherapist should make sure that the participant can control humeral head anterior translation during arm external rotation. For increasing difficulty, the movement can be performed with resistance of a theraband, while participant stands in one leg.



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12. Proprioception, balance and plyometric trainings

12. A.: The participant is sitting with a ball beneath their forearm. Participant presses and releases the ball while ensuring the scapula and shoulder are properly stabilized.

12. B.: The participant pushes a swiss ball against the wall. The therapist ensures that participants stabilizes the scapula to prevent winging.

12. C. The participant tries to lift their bottoms off the bed in sitting by pressing down through their hands. The force is generated from the shoulder joint.

12. D.: Plyometric catching exercise.

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Scapular Taping for postero-lateral glide

Start the tape on the anterior aspect of the humeral head crossing the acromion lateral to the acromioclavicular joint, ending at the inferior border of the scapula. Therapist glides the humeral head posteriorly when applying the tape. Take care not to apply too much tension initially at the humeral head as the skin is liable to breakdown.

As described by:

Teys P, Bisset L, Collins N, et al. One-week time course of the effects of Mulligan's Mobilisation with Movement and taping in painful shoulders. Manual therapy 2013;18(5):372-77. doi: 10.1016/j.math.2013.01.001

Hing W, Hall T, Rivett DA, et al. The Mulligan Concept of Manual Therapy: Textbook of Techniques: Elsevier Health Sciences 2015.

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Supplementary Material 2

Otago MASTER Feasibility Trial

Standardized rehabilitation programme

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Contents

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Exercise Overview – Quick reference

Shoulder Core Exercises

Exercise			
1. Shoulder extension Resistance type: elastic band	**1. A.** Bilateral Low row: Subjects extends both shoulders from 80°of shoulder flexion (elbow flexed).	OR	**1. B.** Bilateral High row Subject extends both shoulders from 100° shoulder flexion to neutral with elbow extended
2. Shoulder adduction in scapular plane	**2.** Subject adducts shoulder from 80° of shoulder abduction (elbow extended)		
3. Shoulder external rotation (ER) Note: rolled towel placed between arm and trunk	**3.A.** Shoulder ER in sitting/standing: Subject externally rotates shoulder from a standing/sitting position with shoulder in neutral (elbow flexed to 90°).	OR	**3. B.** Shoulder ER in side lying: Subject performs shoulder ER from a side lying position with shoulder in neutral (elbow flexed to 90°).
4. Shoulder internal rotation (IR) Note: rolled towel between arm & trunk	**4. A.** Shoulder IR in sitting/standing: Subject internally rotates shoulder from a standing/sitting position with shoulder in neutral (elbow flexed to 90°).	OR	**4. B.** Shoulder IR in side-lying*: Subject performs shoulder ER from a side lying position with shoulder in neutral (elbow flexed to 90°). *only if participant able to lie down on affected side
5. Elbow flexion with forearm supination:	**5.** Subjects gradually performs elbow flexion with forearm supination from neutral shoulder rotation.		

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Scapular Core Exercises

Exercise			
6. Scapular protraction	**6. A.** Scapular protraction in standing Subject is standing with shoulder in neutral with elbow flexed to 90. From here participant gradually flexes *shoulder to 80* while extending elbow and then performs scapular protraction.	**OR**	**6. B.** Scapular protraction in supine In supine lying with shoulder in neutral and elbow flexed to 90, participant gradually flexes *shoulder to 90* and extends elbow, then scapular protraction.
7. Scapular protraction in 4-point kneeling	**7.** Subject is in 4-point kneeling position with hands underneath shoulder. Participant performs scapular protraction.		
8. Scapular muscle strengthening (Isometric scapular setting)	**8**. Subject starts in prone position, with hands by the sides, arms in external rotation; then depresses and retracts the scapula and holds it isometrically.		

Shoulder Stretch (Core exercises)

Exercise	Instruction
9. Posterior shoulder stretch	Subject is in standing. Participant stretches affected shoulder into horizontal adduction by pulling fully flexed elbow with opposite hand
10. Lateral neck stretch	Subject is in standing. Participant pulls the head into lateral flexion with opposite arm and adds shoulder depression to increase the stretch
11. Thoracic spine extension	Subject is supine with hips and knees flexed, towel roll Under the thoracic spine and hands supporting the neck. Participant maintains this posture to sustain a stretch of anterior thoracic muscles

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Additional Exercises

	Exercise	Pg no.
12. Shoulder scaption in standing position	Subject performs 80° scaption with elbow in slight flexion and slight shoulder external rotation (thumbs up)	18
13. Shoulder flexion in standing	Subject flexes arm to 80° with arm slightly flexed and externally rotated (thumbs up)	19
14. Shoulder press via flexion (Sitting with back support)	Subject performs full shoulder ***flexion*** with elbow extension *Arms against trunk, elbows fully flexed, hands lateral to shoulder.*	**20**
15. Shoulder press via abduction in (Sitting with back support) (Elastic band only)	Subject performs full shoulder ***abduction*** with elbow extension against *Arms against trunk, elbows fully flexed, hands lateral to shoulder.*	**20**
16. Horizontal abduction in sitting (Elastic band only)	Perform shoulder abduction against Elastic band attached at shoulder height *Shoulder in 80 flexion and ER (thumb laterally)*	**21**
17. External rotation in sitting with elbow supported on plinth/table (Elastic band only)	Subject performs 90 external rotation against a Elastic band. *Shoulder flexed to 80° with 90° elbow flexion.*	**22**
18. Internal rotation (IR) in sitting with elbow supported on plinth/table (Elastic band only)	Subject performs 90 internal rotation against a Elastic band. *Shoulder flexed to 80° with 90° elbow flexion.*	**22**
19. Scapular protraction	Subject perfroms dynamic scapular protraction	**23/4**

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Additional Stretching and ROM Exercises

Exercise	Instruction	Pg no.
20. Internal rotation positioning	Subject places the involved hand on the buttock or lower back in pain free manner, supported by the other hand	25
21. Longitudinal shoulder traction with an Elastic band wrapped	Subject stands while bending sideways slightly. One end of an Elastic band is wrapped around the wrist while the other end is fixed with the feet allowing tension in the band. Participant relaxes the shoulder and allows the longitudinal traction.	25
22. Pendulum exercise	Participant stands and leans over a chair or a table with the good arm, relaxes the affected shoulder blade and let the arm drop. In this position, performs forward-backward swings and circle swings using body motion.	26

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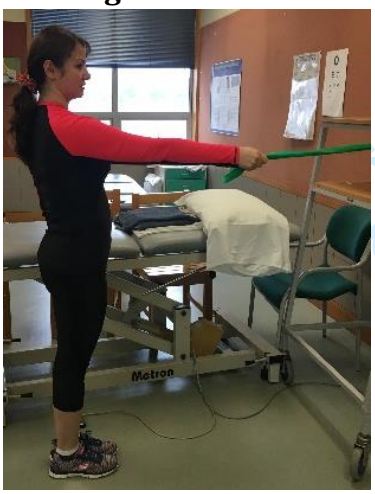
Descriptions of Core Exercises

1. Shoulder extension

1. A. Bilateral Low row:

Starting position: Standing with shoulder flexed at 80° and neutral rotation.
Exercise: Subject performs ***bilateral*** shoulder extension till neutral with elbow flexed.
Resistance type: Theraband

Starting Position



Ending Position

1. B. Bilateral High row

Starting position: Standing with shoulder flexed at 100° and neutral rotation.
Exercise: Subject performs ***bilateral*** shoulder extension till neutral with elbow extended.
Resistance type: Thera band

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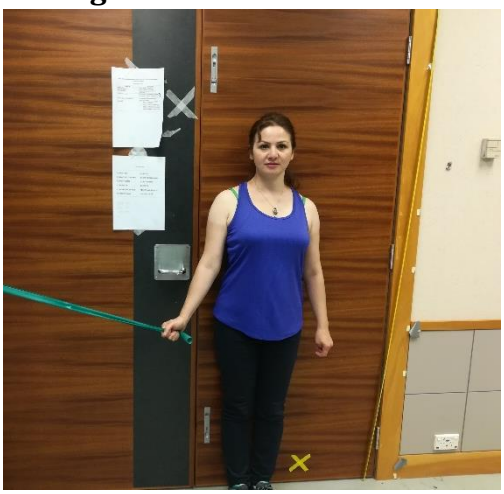
2. Shoulder adduction in scapular plane

Starting position: Standing with shoulder abducted at 80° in scapular plane (Scaption) and neutral rotation.
Exercise: Subject performs shoulder adduction with elbow extended to neutral.
Resistance type: Thera band

Starting Position

Ending Position



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3. Shoulder external rotation (ER)

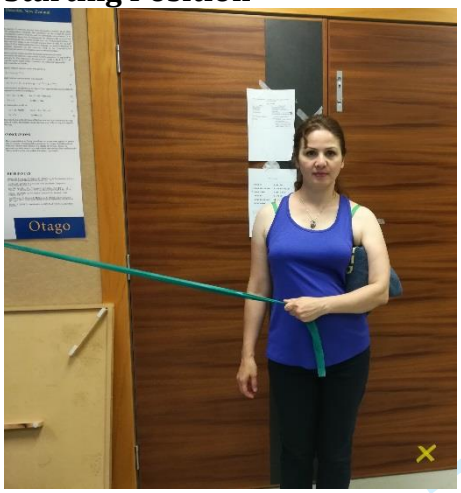
3. A. Shoulder ER in standing with 0 abduction

Starting position: Standing with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.

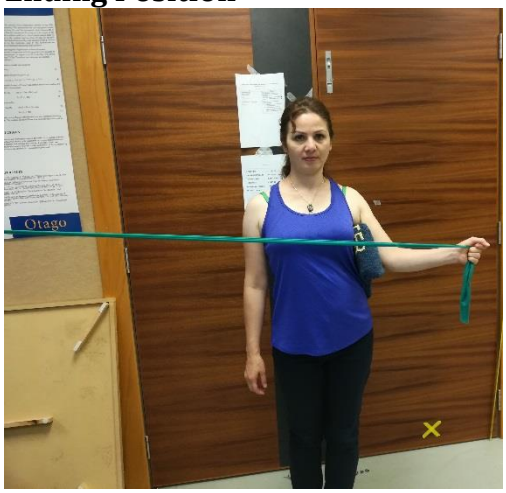
Exercise: Subject performs shoulder external rotation. Please ensure the participant is not compressing the towel; they should be holding it in a relaxed manner.

Resistance type: Thera band

Starting Position



Ending Position



3. B. Shoulder ER in side-lying

Starting position: Side-lying with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.

Exercise: Subject performs shoulder external rotation.

Resistance type: Dumbbell

4. Shoulder internal rotation (IR) in neutral

4. A. : Shoulder IR in standing

Starting position: Standing with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.

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Exercise: Subject performs shoulder internal rotation. Please ensure the participant is not compressing the towel; they should be holding it in a relaxed manner.
Resistance type: Thera band

4. B. Shoulder IR in side-lying (progress only if participant is able to lie down on affected side)

Starting position: Side-lying with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.
Exercise: Subject performs shoulder internal rotation.
Resistance type: Dumbbell

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5. Elbow flexion with forearm supination

Starting position: Standing or sitting with arms at side; neutral rotation.
Exercise: Subject performs elbow flexion with forearm supination.
Resistance type: Thera band or Dumbbell

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6. Scapular protraction

6. A. Scapular Protraction in standing:

Starting position: Standing with arms at side; shoulder in neutral rotation; elbows flexed at 90˚.

Exercise: Subject performs shoulder flexion to 80˚, elbow extension, and then scapular protraction

Resistance type: Thera band

Starting Position (Front view)

Starting Position (side view)

Ending Position (front view)

Ending Position (Side view)

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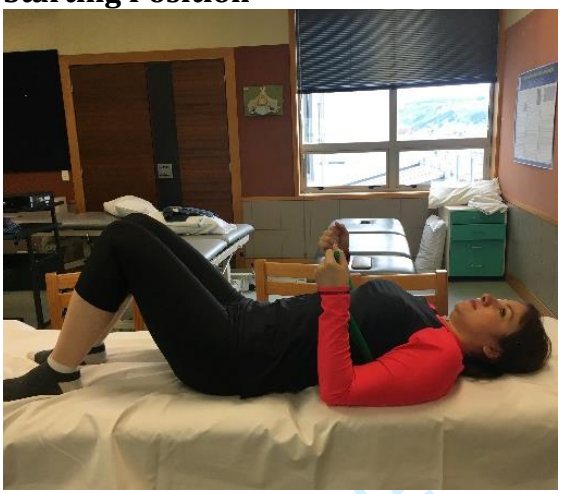
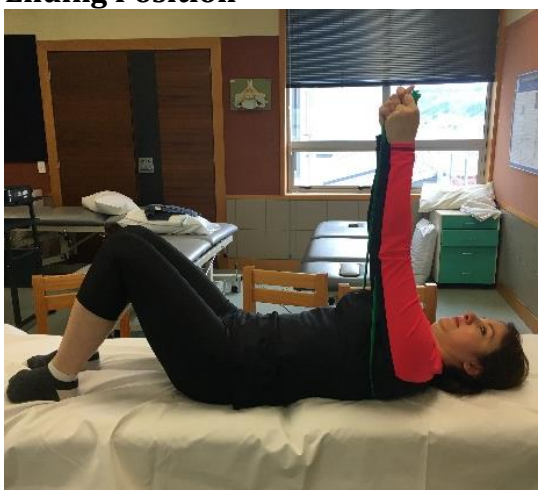
6. B. Scapular protraction in supine

Starting position: Supine lying, arms resting at side in neutral, elbows flexed at 90°
Exercise: Subject concurrently flexes shoulder to 90° and extends elbow, and then protracts scapula against resistance.
Resistance type: Thera band

Starting Position



Ending Position



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7. Scapular protraction in four-point kneeling

Starting position: 4 point kneeling, hands underneath shoulder
Exercise: Subject performs dynamic scapula protraction without compensatory movements at the spine
Resistance type: Body Weight

8. Scapular muscle strengthening (isometric)

Starting position: Prone with arms at side in external rotation
Exercise: Subject depresses and retracts the scapula with elbows slightly flexed and holds the position for 10 seconds. The therapist can provide feedback and ensure participant is not over activating their shoulder extensors and external rotators.
Resistance: None

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9. Posterior Shoulder Stretch

Position: Standing or sitting

Exercise: Subject pulls the elbow passively across the body into horizontal adduction with the opposite arm. Hold the stretch for 10 seconds and repeat.

10. Lateral neck stretch

Position: Standing or sitting

Exercise: Participant pulls the head into lateral flexion with the opposite arm and adds scapular depression to stretch ipsilateral neck.

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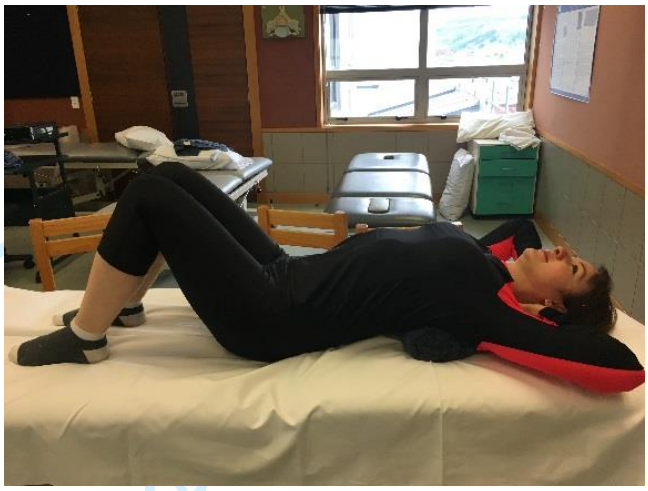
11. Thoracic spine extension stretch

Position: Supine with hip and knee flexed. A towel roll is placed under their upper thoracic spine and participant supports their neck with both hands.

Exercise: Participant allows sustained stretch of thoracic kyphosis by lying on a towel roll and relaxing their spine.



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Additional exercises:

12. Shoulder scaption to 80^0

Starting Position: Standing with feet on the theraband. Shoulder at neutral.
Exercise: Participant performs shoulder scaption to 80˚ while keeping shoulder external rotation (thumb up). Elbow slightly flexed.
Resistance: Thera band or dumbbell

Starting Position

Ending Position

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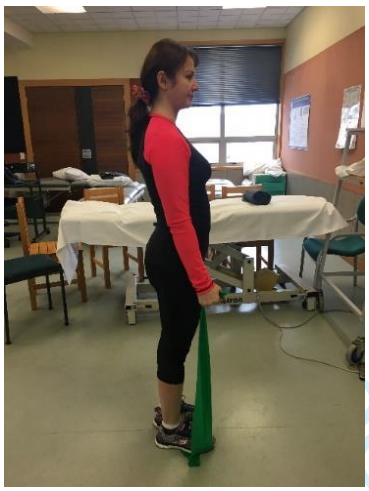
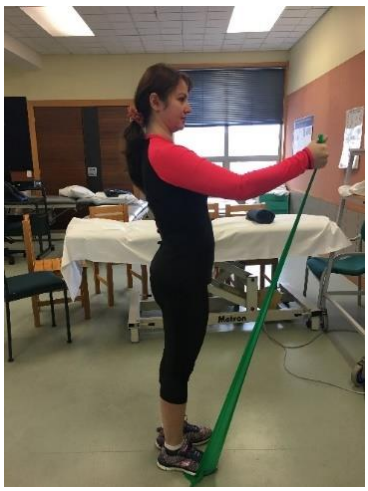
13. Shoulder flexion to 80°

Starting position: Participant is standing with feet on Thera band. Arm at side of body.
Exercise: Participant performs shoulder flexion to 80^0 and external rotation (thumb up) with elbow slightly flexed against light to high resistance.
Resistance: Thera band or dumbbell

Starting Position



Ending Position



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14. Shoulder press via flexion

Starting position: Subject is in sitting position with back supported, arms are in contact with trunk, and elbows are fully flexed.
Exercise: Participant performs full shoulder flexion and elbow extension against resistance.
Resistance: Thera band or dumbbell


15. Shoulder press via abduction

Starting Position: Participant in sitting, with back supported, arm in contact with trunk, and elbow fully flexed, and hand next to the shoulder.
Exercise: Participant performs full shoulder abduction and elbow extension against resistance.
Resistance: Theraband


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16. Horizontal abduction in sitting

Starting position: Participant is sitting with shoulder flexed at 80°. A theraband is attached at shoulder height directly in front of them (theraband is aligned with their forearm).

Exercise: Participant performs horizontal shoulder abduction with nearly extended elbow.

Resistance: Theraband

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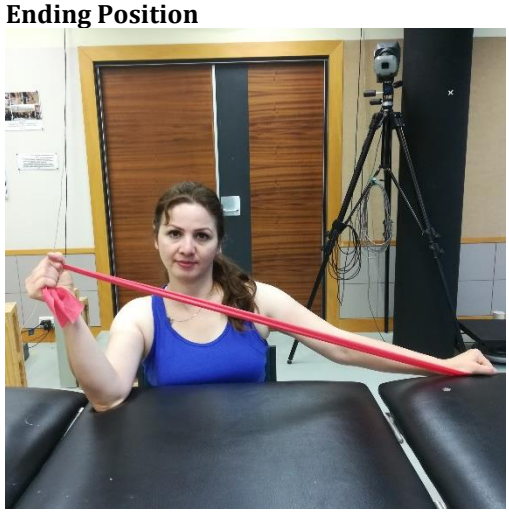
17. External rotation with arm supported

Starting Position: In sitting with elbow supported on a table. Shoulder flexed at 80°, no rotation and elbow flexed at 90°. Thera band is fixed with other hand.
Exercise: Subject performs 90° of external rotation against resistance.
Resistance: Theraband

Starting Position

Ending Position



18. Internal rotation in supported 80^0 shoulder flexion

Starting Position: In sitting with elbow supported on a table. Shoulder flexed at 80° with no rotation and elbow flexed at 90°. Thera band is fixed on the table with other hand
Exercise: Subject performs 90° of internal rotation against resistance.
Resistance: Thera band

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19. Scapular protraction

19. A.: In kneeling push up position

Starting Position: Half plank position (4 point kneeling with hands underneath shoulders and hip in neutral, knee flexed at 90˚)

Exercise: Participant performs dynamic scapular protraction.

Resistance: Body Weight

19. B. Scapula protraction in push-up position:

Starting position: Participant is in push up position with hands directly below shoulder.

Exercise: Participant performs dynamic scapular protraction without spinal compensatory movements.

Resistance: Body weight

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19. C. Half way push up position:

Starting position: Participant is in push up position with hands below shoulder.

Exercise: Participant performs a half way push up with a dynamic scapular protraction at the end of arm extension.

Resistance: Body weight

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20. Internal rotation positioning

Participant places their involved hand on the buttock or lower back in a pain-free manner, supported by the other hand

21. Longitudinal shoulder traction

Standing with trunk side-flexed towards the affected side. A Thera band is wrapped around the wrist and fixed with the feet on one side with tension. Participant relaxes shoulder and allows for longitudinal traction.

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22. Pendulum exercise

Participant leans on a chair or table by bearing weight on the good arm and bending forward at the waist. Participant relaxes the affected shoulder blade and lets it drop. Participant then performs relaxed forward-backward swings and circle swings using body motion (with dumbbell or bottle).

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Table 1 – page 5
	2b	All items from the World Health Organization Trial Registration Data Set	Table 1 – page 5
Protocol version	3	Date and version identifier	Table 1 – page 5
Funding	4	Sources and types of financial, material, and other support	Table 1 – page 5
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 17
	5b	Name and contact information for the trial sponsor	Page 5
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 17
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15 and 16

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Pages 3 to 4
	6b	Explanation for choice of comparators	Pages 3 to 4
Objectives	7	Specific objectives or hypotheses	Page 4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Pages 4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Tables 2 and 3
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Refer to TIDieR checklist
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Refer to TIDieR checklist
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Refer to TIDieR checklist
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Refer to TIDieR checklist
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 13 and 14

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 6
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 6
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 7 to 13

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 13
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 15 and 16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Pages 15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Pages 15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 14
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 16
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 16
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 16 and 17
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Page 16
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 17

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 16
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 16
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N.A.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 16
	31b	Authorship eligibility guidelines and any intended use of professional writers	Page 16
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Not submitted
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

TIDieR Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	12 to 13	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Tables 2 and 3	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Tables 2 and 3	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Tables 2 and 3	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Tables 2 and 3	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Tables 2 and 3	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Tables 2 and 3	

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Tables 2 and 3	
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Tables 2 and 3	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Tables 2 and 3	
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Tables 2 and 3	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Tables 2 and 3	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

BMJ Open

The effectiveness of a tailored rehabilitation versus standard strengthening programme for patients with shoulder pain: a protocol for a feasibility randomized controlled trial (the Otago MASTER trial)

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The effectiveness of a tailored rehabilitation versus standard strengthening programme for patients with shoulder pain: a protocol for a feasibility randomized controlled trial (the Otago MASTER trial)

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Abstract

Introduction: Exercise therapy is the treatment of choice for the management of patients with shoulder subacromial pain. However, we do not know whether a tailored rehabilitation programme is more effective than a standardized strengthening programme. The aim of this feasibility trial is to assess: (1) participant recruitment rate; (2) the proportion of participants enrolled from the total number screened; (3) adherence to the rehabilitation programme; (4) drop-out rates; (5) obtain estimates of adverse reactions to treatment; (6) obtain estimates of intervention effects in order to inform the sample size of the fully-powered RCT; (7) conduct a preliminary cost-effectiveness analysis of the standardized strengthening and the tailored rehabilitation interventions.

Methods: The Management of subacromial disorders of the shoulder (MASTER) trial, is a two-arm, patient- and assessor-blinded, randomized controlled feasibility trial. Participants will be randomly allocated into one of the interventions group: tailored or standardized rehabilitation. To obtain estimates of intervention effects, we will compare changes in pain and shoulder-related disability scores between the two intervention groups using a repeated mixed-model analysis of variance, with alpha set at 0.05, and power at 80%. Since this is a feasibility study, we will not adjust alpha for multiple comparisons. To determine whether it is feasible to conduct the full trial, we will consider 75% CI as the probability threshold at 3-month follow-up.

Ethics and Dissemination: This study was approved by the University of Otago Ethics Committee [H17/080]. Findings from this study will be presented at conferences, and will be submitted for publication in a peer-reviewed journal.

Trial registration number: ANZCTR: 12617001405303.

Keywords: shoulder, rehabilitation, manual therapy, randomized controlled trial.

Word count: 3688

Article summary

Strengths and limitations of this study

- This protocol will compare one intervention that is tailored to patient's physical impairments with a standardized strengthening programme.
- The feasibility trial will include economic evaluation, and implementation-based process evaluation of the intervention planned.
- Clinicians were not blinded to interventions due to nature of interventions, and that is a source of potential bias.

Introduction

Shoulder pain is the third most common musculoskeletal complaint, with a one-year prevalence of 18.1%.[1] Shoulder pain is associated with high socioeconomic burden.[2] In Sweden, the average annual cost of shoulder subacromial pain is estimated $4,139 per patient.[2] In NZ, a total of $134 million was spent by ACC in rehabilitation for shoulder injuries from 2005 to 2013 ($14 million/year).[3] Shoulder subacromial pain is a challenging disorder with slow recovery,[4] with only 50% of new episodes presenting full recovery within 6 months.[5]

Exercise therapy is the first approach for the management of shoulder subacromial pain, and is recommended, for example, by the British Elbow & Shoulder Society (BESS)[6]. A number of systematic reviews have been published in this area.[7-13] Some reviews suggest exercise therapy and or manual therapy to be effective for improving pain and function in patients with shoulder pain, but highlight the limited strength of evidence to support this.[7 8 14] Three reviews reported exercise therapy to be more effective than control or placebo,[8 10 11] while a Cochrane Review reported no clinically important difference between manual therapy and exercise versus placebo.[9] The addition of manual therapy to exercise has been supported in incremental effects trials [15-17] and by another recent systematic review.[10] Optimal treatment strategies are needed to improve treatment effect, speed recovery, and decrease shoulder pain recurrence. There are uncertainties regarding which types of exercise are more effective and cost-effective for the management of patients with shoulder subacromial pain.[10 18 19] In addition, there are competing approaches of exercise regimen (e.g. specific exercise,[20] general strengthening exercise), with limited number of head-to-head trials comparing different combinations of exercise therapy and manual therapy interventions.[9 10]

The lack of data about process evaluation of previous trials hinder our ability to identify whether tested interventions failed to improve clinical outcomes due to being ineffective or poorly implemented.[21] To address this, it is recommended trials to include process evaluation alongside the *outcome* evaluation, ideally from Phase II to Phase IV.[21] Process evaluation studies provide valuable information regarding how, what and why interventions were delivered to patients during the trial,[21-24] and help to understand why an intervention achieved (or not) its expected clinical outcomes.[25] Such information is valuable for a number of stakeholders (e.g. clinicians, government and policy-maker agencies) and improve translation of findings from trials to clinical practice.[21] Hence, future trials on the management of shoulder subacromial pain should include process evaluation[21] and economic evaluation[10] conducted alongside the outcome evaluation. In addition, it has been recommended that future trials combining novel exercise therapy programme to be compared to a valid placebo intervention.[9]

Shoulder subacromial pain is a complex disorder, with psychological factors and physical impairments influencing clinical outcomes.[26-29] Pain beliefs seem to be associated with course of pain and disability, but the current level of evidence is low.[29] A longitudinal prospective cohort study reported that psychosocial factors are associated with clinical outcomes,[28] while a secondary analysis of a trial found that fear-avoidance beliefs contribute significantly to baseline disability but not to disability change scores after 3-month follow-up.[26] Psychosocial factors and pain beliefs seem to play a role on clinical outcomes. Further longitudinal studies are still required to clarify which psychological factors can be targeted by treatment and whether modifying these psychological factors impact on clinical outcomes (i.e. disability and pain) in patients with shoulder subacromial disorders.[26 27 29 30]

Clinical examination is commonly performed by clinicians[31 32] to inform management of patients with shoulder pain. Findings suggestive of structural diagnosis have inconsistent association with clinical outcomes[30] and the diagnostic accuracy of orthopaedic tests is very limited[33]. Hence, it has been suggested clinicians to perform a thorough clinical examination when assessing patients with shoulder disorders.[31 33 34]

The role of scapular and shoulder muscle recruitment pattern and clinical outcomes is unclear. [35] The report from the "Scapular Summit" suggests a potential role of scapular movement pattern on shoulder disorders, but highlighted it is currently not clear whether there is a causative effect between movement pattern and shoulder disorders.[36] A recent study reported increased risk of shoulder pain among asymptomatic individuals, suggesting movement pattern might play a role on shoulder symptoms,[37], while a recent review found some preliminary evidence supporting the use of scapula-focused exercises when managing patients with shoulder pain , but it is unclear whether these exercises have any impact on pain and disability outcomes.[35]

Patients with shoulder pain present with physical impairments, and altered scapular and shoulder muscle recruitment patterns[38 39], these impairments are a potential target for therapeutic intervention.[40] For example, patients with shoulder subacromial pain may show altered coordination between lower trapezius and serratus anterior, and the upper trapezius and lower trapezius during arm elevation task,[39] and patients with symptomatic rotator cuff tear may show increased activity of latissimus dorsi when compared to healthy controls.[38] Due to the variability of such altered muscle patterns, it is recommended that rehabilitation should tailor specific muscle and joint impairments presented by the patient [31] and restore shoulder movement pattern[34]. Further, preliminary evidence suggests that sustained shoulder mobilization may reduce pain and improve range of motion in patients with shoulder subacromial pain, compared to sham sustained mobilization.[41] Trials of the effect of sustained glide and exercise on the management of other musculotendinous disorders (e.g. tennis elbow) have found this intervention to be more effective than corticosteroid injection and wait-and-see.[42]

Laboratory-based studies suggest that: (1) clinician-administered sustained shoulder mobilization offloads shoulder muscles, providing mechanical support to the shoulder;[43] (2) patient-administered sustained shoulder mobilization leads to similar changes in muscle activity levels as clinician-administered mobilization, supporting the use of home-based mobilization for shoulder rehabilitation;[44] (3) patients with shoulder pain present immediate reduction in pain levels, increased range of motion, and altered muscle activity levels in response to sustained shoulder mobilization.[45] These findings, and anecdotal evidence from clinical practice, suggest that sustained mobilization temporarily changes the control of scapular and shoulder muscles. Such temporary change gives the clinician a therapeutic window to strengthen muscles with less pain while keeping a better control of scapular and shoulder muscles.

It is unclear whether a tailored rehabilitation (combining sustained mobilization with specific motor control exercises) is more effective than standardized exercise for shoulder pain patients. Tailored rehabilitation focuses on each patient's specific impairments and some studies found preliminary findings that a tailored programme is effective for managing patients with shoulder pain.[20 46-49] An alternative to a tailored programme is a standardized shoulder rehabilitation that adopts a more generic approach, with standardized stretching and strengthening exercises being prescribed for all patients, and may also be delivered in small group sessions, reducing the cost of the physiotherapy session. It is unclear which approach leads to better clinical outcomes and is more cost-effective.

Efficacy trials are designed to test if an intervention works under the ideal circumstances.[50] This type of trial maximises the probability of observing the effect of an intervention (assuming such effects exist), and prioritize internal validity of the study design.[50] In efficacy trials, the intervention is standardized, delivered under an ideal setting, with highly trained clinicians.[50] It is recommended for efficacy trials to incorporate economic evaluation (i.e. cost-efficacy) alongside the clinical efficacy assessment.[51] By conducting clinical and cost-efficacy assessment it is possible to determine whether an intervention is likely to be efficacious for a group of patients, and whether delivering the health outcomes are likely to be good value for money.[52] Ideally,

clinical and cost-efficacy studies should be conducted prior to clinical- and cost-effectiveness pragmatic trials.[51]

The aim of our full study is to assess the clinical- and cost-efficacy of tailored rehabilitation programme for the treatment of shoulder subacromial pain. Prior to conducting a fully-powered randomized controlled trial (RCT), we propose an efficacy feasibility trial aiming to assess: (1) participant recruitment rate; (2) the proportion of participants enrolled from the total number screened; (3) adherence to the rehabilitation programme; (4) drop-out rates; (5) obtain exploratory estimates of adverse events; (6) obtain exploratory estimates of intervention effects in order to inform the sample size of the fully-powered RCT; (7) conduct a preliminary cost-effectiveness analysis of the standardized strengthening and the tailored rehabilitation interventions.

Methods

Design

The Management of subacromial disorders of the shoulder (MASTER) trial, is a two-arm, patient- and assessor-blinded, feasibility randomized controlled trial. Participants will be randomly allocated into one of the interventions group: tailored rehabilitation or standardized rehabilitation (Figure 1).

Figure 1

For preparing this protocol, we followed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement,[53] and the template for intervention description and replication (TIDieR) checklist and guide.[54] When reporting the feasibility trial, we will follow the Consolidated Standards of Reporting Trials (CONSORT) statement for non-pharmacological treatment.[55] The trial has been prospectively registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR: 12617001405303). World Health Organization trial registration data set information is described in Table 1.

Table 1. World Health Organization trial registration data set.

Data category	Information
Primary registry and trial identifying number	ACTRN 12617001405303
Date of registration in primary registry	04/10/2017
Source of monetary or material support	Health Research Council of New Zealand Feasibility Grant (17/536)
Primary sponsor	University of Otago
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	Tailored versus standard strengthening rehabilitation for patients with shoulder pain: a feasibility trial
Scientific title	The effectiveness of a tailored rehabilitation versus standard strengthening programme for patients with shoulder pain: a feasibility randomized controlled trial (the Otago MASTER trial)
Country of recruitment	New Zealand
Health condition or problem studied	Shoulder subacromial pain
Interventions	Tailored and standardized strengthening exercise
Key inclusion and exclusion criteria	Adult healthcare workers (from 18 to 65 years old), with subacromial shoulder pain.
Study type	Interventional
Date of first enrolment	12/02/2018
Target sample size	25
Recruitment status	Recruiting
Primary outcome	(1) Recruitment rate, (2) Proportion of participants enrolled from the total number screened, and (3) Adherence to the rehabilitation programme.
Key secondary outcome	(1) Drop-out rates, (2) Pain level, (3) Shoulder-related disability – patient specific functional scale, (4) quality-adjusted life year, (5) Shoulder Pain and Disability Index (SPADI), (6) Pain self-efficacy questionnaire; (7) Adverse reactions.

Participants

Participants with shoulder subacromial pain will be recruited to take part in the study.

Inclusion and exclusion criteria

Participants from 18 years and 65 years old, with mechanical shoulder pain will be recruited to participate in the study. Participants will be screened as per the British Elbow and Shoulder Society (BESS) guidelines.[56] The process recommended by the BESS guidelines screens for: red flags (e.g. tumour, unreduced dislocation, acute rotator cuff tear, infection), shoulder pain arising from the cervical spine, the shoulder instability, acromioclavicular joint disease, and adhesive capsulitis.[56]

Participants will be included if they present one positive finding on the following tests: (1) Painful arc movement during shoulder flexion or abduction; (2) Jobe's test.[56]; or (3) pain on resisted lateral rotation or abduction.[57]. Given the limited evidence from clinical tests for diagnosing patients with shoulder subacromial pain,[33] we opted to widen the criteria proposed by BESS and add criteria #3. We include two additional tests (resisted lateral rotation and shoulder abduction).[57] A previous study reported pain on external rotation has 34.5% of sensitivity, 100% specificity, 42% accuracy for identifying any degree of subacromial disorder. [57] Pain on shoulder abduction presented 55% of sensitivity, 75% specificity, 57% accuracy and a likelihood ratio of 2.2% for identifying any degree of subacromial disorder. In addition, pain on external rotation was the most accurate test for identifying partial-thickness tear.[33 57]

We will exclude participants with the history of shoulder dislocation, shoulder subluxation, shoulder surgery and cervical surgery within the last 6 months,[58] participants with any kind of symptoms of systematic inflammation or disease, signs of paraesthesia in the upper extremities, hemiplegic shoulder pain, frozen shoulder, or positive clinical signs of full thickness rotator cuff tear [59] will be excluded.

Sample size

Being a feasibility RCT, the present study is not designed to assess the efficacy of the experimental intervention.[60 61] We estimated the sample size based on expected characteristics of the full trial.[62] Based on recommendations by Whitehead et al.[62], the sample size of a feasibility study should be estimated based on the expected range for the effect size, the power and alpha (both established *a priori*), and the total number of arms of treatment planned for the full trial.

Whitehead et al.[62] estimated the sample size based on standardized differences of different magnitudes (i.e. extra small, small, medium and large). To estimate sample size, we used the Shoulder Pain and Disability Index (SPADI) as primary outcome measure; we assumed a minimum clinically important difference of 8 points [63] and a standard deviation of 24 points on SPADI total score.[63] This represents a standardized effect size of 0.3. For estimating the sample size, we set power at 80%, two-tailed between-group comparison, with alpha at 0.05. Therefore, the minimum sample size for this feasibility RCT is 10 participants per arm of treatment.[62] Assuming a 20% loss to follow-up,[64] a total sample size of 25 participants is required.

Recruitment

Recruitment will take place in Dunedin, New Zealand. Participants will be recruited through general practitioners and hospitals and newspaper advertisements. In previous studies, we have successfully recruited participants with these methods of recruitment. Participants will be screened by a physiotherapist with more than five years of clinical experience, and with a postgraduate qualification in Musculoskeletal or Sports Physiotherapy (or related field).

Informed consent and baseline assessment

Once participants are assessed for eligibility, a clinical researcher will seek informed consent from participants. Participants may consent to take part in the study after screening or few days later, if they request time for considering taking part in the study. Participants will be asked to complete the baseline assessments and questionnaires for recording demographic data (age, height, weight), and baseline measurements for the primary and secondary outcomes.

Randomization

Participants will be individually randomly allocated (1:1 ratio) into one of the intervention groups (i.e. tailored physiotherapy or standardized physiotherapy). The randomisation schedule will be computer-generated by a research administrator, and concealed in numbered sealed and opaque envelopes. A research administrator will provide the envelope to the clinician delivering the interventions.

Blinding

Participants will be blinded to interventions. Outcome assessors will be blinded to group allocation. Clinicians delivering the interventions will not be blinded to group allocations due to nature of intervention.

Procedures

Experienced clinicians will deliver interventions for both groups. Clinicians will have a postgraduate diploma in musculoskeletal rehabilitation (or related field) and a minimum of 5 years of clinical experience. Outcome measures will be assessed by a physiotherapist who is blinded to group allocation. We will run a minimum of 4 training sessions lasting for one hour with clinicians to ensure they are familiarized with the protocol. To ensure they are confident in delivering the planned interventions, we will provide them with manuals containing a detailed description of the planned intervention and will meet with them during the study to clarify any questions or concerns that may arise.

Interventions

Both groups will receive 16 individual, face-to-face sessions, each lasting for 60 min, twice per week, over an 8-week period. This number and duration has been shown to improve clinical outcomes in patients with shoulder subacromial pain.[65] Eight weeks intervention period has been suggested as the minimum required to lead to improvement in pain and range of motion in patients with shoulder pain.[65] The tailored and standardized rehabilitation interventions are described on Tables 2 and 3 respectively. These descriptions were prepared following the template for intervention description and replication (TIDieR) checklist and guide.[54]

Both groups will receive similar dosage of exercises. Participants will perform a total of 8 exercises per session of treatment, plus three stretches (control group) or up to three manual therapy techniques (tailored group). To ensure optimal internal validity of the trial, dosage of exercises for each group are planned to be equivalent. Details of tailored and standardized interventions are described on the Exercise Description Forms (Supplementary Material 1 and 2, respectively). The intensity of strengthening exercises will be monitored using a modified Borg scale.[66] Rate of perceived exertion was shown to be valid for monitoring intensity of resistance training,[67] and has been used in a previous trial for monitoring exercise intensity.[68]

Tailored rehabilitation: participants allocated to the tailored rehabilitation group will receive sustained mobilization followed by exercises focusing on restoring normal movement pattern and the dynamic stability of the scapulothoracic and glenohumeral joints.[31 69] The intervention will involve manual therapy techniques focusing on restoring the shoulder and scapular movement to reduce pain,[70] and motor control and progressive resistance training of impaired muscles.[65 69]

Table 2. Description of tailored rehabilitation intervention, as per the template for intervention description and replication (TIDieR) guide.

Item number	Item	Description
1.	**BRIEF NAME** Tailored rehabilitation	
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.	The tailored rehabilitation programme will focus on specific impairments presented by the patient. This intervention will consist of mobilization with movement, passive accessory mobilization, specific motor control exercises and specific muscle strengthening exercises. The tailored rehabilitation programme might be more effective than a standardized strengthening programme for patients with subacromial shoulder pain.
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	The tailored rehabilitation group will receive manual therapy techniques (including mobilization with movement with taping)[70 71], motor control and strengthening exercises. Manual therapy interventions delivered by the clinician might be performed with a belt. Motor control and strengthening exercises might be performed with the use of elastic bands or dumbbells. Home-based exercises will consist of self-mobilization techniques that is performed with a belt.
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Clinicians will choose exercises based on physical impairments presented during the physical assessment.
5.	**WHO PROVIDED** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Experienced clinicians will deliver interventions for the tailored group. Clinicians will have a postgraduate diploma in musculoskeletal rehabilitation (or related field) and a minimum of 5 years of clinical experience. All clinicians will undergo a trial-specific training programme to ensure they understand the protocol and the rationale of the intervention. Clinicians will receive a detailed manual with information regarding the trial intervention.
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or	Participants will receive individual, face-to-face sessions.

Item number	Item	Description
	telephone) of the intervention and whether it was provided individually or in a group.	
7.	**WHERE** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Interventions will be delivered in a private clinical practice.
8.	**WHEN and HOW MUCH** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Participants will receive 16 sessions, each lasting for a maximum of 60 min, twice per week, over an 8-week period. The exercise programme will comprise of 8 exercises plus 3 optional manual therapy techniques (one for the cervical spine, one for the thoracic spine and one for the shoulder). Clinicians will decide on which technique to use based on participants' clinical presentation. The manual therapy techniques might consist of passive joint mobilizations (grade -IV, IV, or +IV) or manipulation (for the cervical or thoracic spine). Mobilization with movement techniques will count as one of the 8 possible exercises to be performed within a session. This technique will be performed with 3 sets of 10 repetitions, with 30 seconds of rest between each set. Passive joint mobilizations will be performed with the following dosage: 3 sets, 30 seconds duration. Grade: –III or –IV will be performed if pain is dominant (as per physical assessment) or grade +III or +IV if stiffness dominant (as per physical assessment). Joint manipulation will be performed once per session, if required, as per physical assessment. The clinician will have the freedom to decide which technique to perform. Isometric exercises will be delivered with the following dosage: 2 sets, 10 repetitions, with 10 seconds hold each repetition. The isometric exercises will be progressed in two stages. The first stage will have the following dosage: 3 sets, 10 repetitions, with 10 seconds hold each repetition. The second stage will have the following dosage: 3 sets, 10 repetitions, with 20 seconds hold each repetition. There will be 10 seconds rest between repetitions, and 30 seconds rest between sets. Dynamic strengthening exercises will be delivered with the following dosage: 2 sets of 10 repetitions. The dynamic strengthening exercises will be

Item number	Item	Description
		progressed in two stages. The first stage will have the following dosage: 3 sets of 10 repetitions. The second stage will have the following dosage: 3 sets of 20 repetitions. All exercises should initially be performed in slow and controlled pace. All motor control exercise should initially be of low intensity and then progressed as described. Clinicians can increase dosage (repetitions, sets, or load) if the participant is able to perform low intensity exercise for two consecutive sessions. The load for strengthening exercises will be determined through using the 10-point Rate of Perceived Exertion (RPE) scale, considering the affected side. Low intensity will be defined as 3-4 RPE, moderate intensity as 5-6 RPE, and high intensity as 7-8 RPE. Exercises will start with low intensity, and can progress to moderate and high intensity during the course of treatment.
9.	**TAILORING** If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Interventions will be tailored based on physical assessment. Participants will receive: - Shoulder mobilization with movement if, during assessment, participants improve range of motion and pain with the MWM technique. As part of the treatment, clinicians might use an MWM taping technique.[70 71] - Passive mobilization on the cervical, thoracic spine or shoulder (glenohumeral joint). These techniques will be performed if, during assessment, participants present with stiffness or pain on passive accessory movement at the cervical, thoracic spine or glenohumeral joint. - Motor control exercises if, during assessment, participants present with poor control of a specific muscle (e.g. scapular control exercises, dynamic control of glenohumeral joint).[40 72-74] - Strengthening exercises if, during assessment, participants present with muscle weakness.[40]
10.‡	**MODIFICATIONS** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Not applicable. This is a protocol.
11.	**HOW WELL** Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any	Participants' adherence to protocol will be assessed by quantifying the number of home-based exercises performed. It will be expressed as percentage of the

Item number	Item	Description
	strategies were used to maintain or improve fidelity, describe them.	total number of sessions that should be been performed. Clinician's adherence to protocol will be assessed by quantifying the number of exercises and progressions that were performed according to the protocol. This will be done through audits of clinical notes, and will be expressed as percentage of the total number of exercises and progressions that were performed during the course of treatment.
12.[‡]	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Not applicable. This is a protocol.

Standardized rehabilitation: participants allocated to this group will receive a progressive resistance training for all scapular and shoulder muscles and stretching exercise programme.[75] This intervention focuses on restoring muscle flexibility and strength and has been shown to be more effective than 'no intervention' or control for reducing pain and disability.[75]

Table 3. Description of standardized rehabilitation intervention, as per the template for intervention description and replication (TIDieR) guide.

Item number	Item	Description
1.	**BRIEF NAME** Standardized rehabilitation	
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.	The standardized rehabilitation intervention will focus on strengthening of scapular and shoulder muscles. Strengthening exercise were shown to improve pain and disability in participants with subacromial shoulder pain.
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	The standardized rehabilitation group will receive strengthening exercises. These exercises might be performed with the use of elastic bands or dumbbells. Stretching exercise for the thoracic spine will be done using a foam roller. Two home-based exercises (resisted internal and external rotation of the humerus) will be performed using an elastic band.
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Participants will start with 8 "core" strengthening exercises and 3 stretches. The clinician can replace one core strengthening exercises by another strengthening exercises from a list of "additional" exercises.
5.	**WHO PROVIDED**	

Item number	Item	Description
	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Experienced clinicians will deliver interventions for the standardized rehabilitation group. Clinicians will have a postgraduate diploma in musculoskeletal rehabilitation (or related field) and a minimum of 5 years of clinical experience. All clinicians will undergo a trial-specific training programme to ensure they understand the protocol and the rationale of the intervention. Clinicians will receive a detailed manual with information regarding the trial intervention.
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Participants will receive individual, face-to-face sessions.
7.	**WHERE** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Interventions will be delivered in a private clinical practice.
8.	**WHEN and HOW MUCH** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Participants will receive 16 sessions, each lasting for a maximum of 60 min, twice per week, over an 8-week period. The standardized rehabilitation will comprise of 8 exercises plus 3 stretching exercise (one for the cervical spine, one for the thoracic spine and one for the shoulder). Strengthening exercises will be delivered with the following dosage: 2 sets of 10 repetitions. The strengthening exercises will be progressed in three stages. The first will have the following dosage: 3 sets of 10 repetitions. The second stage will have the following dosage: 3 sets of 20 repetitions. For the third stage of progression, clinicians can choose to increase the load to moderate (based on RPE – see below) or replace the exercise by another one from the additional list. All the exercises should initially be performed in slow and controlled pace. The load for strengthening exercises will be determined through using the 10-point Rate of Perceived Exertion (RPE) scale, considering the affected side. Low intensity will be defined as 3-4 RPE, moderate intensity as 5-6 RPE, and high intensity as 7-8 RPE.
9.	**TAILORING**	

Item number	Item	Description
	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	This intervention is not planned to be tailored.
10.‡	**MODIFICATIONS** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Not applicable. This is a protocol.
11.	**HOW WELL** Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Participants' adherence to protocol will be assessed by quantifying the number of home-based exercises performed. It will be expressed as percentage of the total number of sessions that should be been performed. Clinician's adherence to protocol will be assessed by quantifying the number of exercises and progressions that were performed according to the protocol. This will be done through audits of clinical notes, and will be expressed as percentage of the total number of exercises and progressions that were performed during the course of treatment.
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Not applicable. This is a protocol.

Concomitant care

Participants may seek other healthcare services, if they wish to do so. In that case, we will ask them to record which healthcare services they accessed on a logbook while enrolled on the trial.

Criteria for modifying or discontinuing the exercises

Pain levels, as subjectively reported by participants, will be used for determining whether an exercise must be modified or discontinued.[76 77] For this purpose of this study, we adopted a criteria used in a previous study.[78] Participants will be encouraged to continue with an exercise as long as the reported pain levels ranging from slight to endurable. Participants should discontinue exercise or reduce load if: (1) pain increases beyond what is acceptable/ bearable for the participant; (2) participant reports an immediate increase of pain by 3 points (NPRS) during exercise; (3) pain persists longer than 30 sec after completion of exercise; (4) an exercise cannot be performed due to pain, clinicians will be asked not to include that specific exercise for the next 2 sessions and replace that exercise another exercise (for the tailored rehabilitation group) or with a longitudinal traction or pendulum exercise (for the standardized rehabilitation group).[8] All participants will receive home-based stretching and strengthening exercises, and will be asked to perform these once a day.

Primary outcome measures

The primary feasibility outcome measures are (Figure 2):

1. Participant's recruitment rate, measured as number of participants per month;
2. Proportion of participants enrolled from the total number screened, expressed as the ratio "number of enrolled participants/total number of screened participants", with reasons;
3. Adherence to the rehabilitation programme, measured as number of sessions attended, and expressed as a percentage of the total number of sessions;
4. Drop-out rates, measured as the number of participants who dropped-out, and expressed as a percentage of the total number of participants enrolled in the study.

Secondary outcome measures

The patient-reported outcome measures intended as the primary and secondary outcomes in the main trial will be used as secondary outcome measures in this feasibility trial (Figure 2). These are: pain level as measured by a numeric pain scale,[79] and shoulder-related disability assessed using the 'patient specific functional scale' (PSFS), the Shoulder Pain and Disability Index (SPADI),[80] and the pain self-efficacy questionnaire.[81] The minimal clinically important difference for the numeric pain scale is 1 point,[82] and for the PSFS is 1.3 (for small changes), 2.3 (for medium changes) and 2.7 (large changes).[83] Although this feasibility trial is not powered to detect superiority, we will assess the magnitude of mean treatment effects for pain and physical function in relation to clinically important change, to inform the choice of primary outcome and sample size calculation for the main trial. Findings from this feasibility trial will help us selecting the primary outcome measure for the full trial.[84]

We will assess safety by recording all adverse events, both related and unrelated to interventions, in each group. The literature suggests adverse events to exercise therapy might be common, but not serious.[85] Potential adverse reactions to interventions may include muscle soreness or increased pain around the shoulder joint. The physiotherapist will record any adverse reactions to interventions, including duration and severity of adverse reaction to treatment, and how the adverse reaction was managed. We will include in the report the total number of participants who reported adverse events, relatedness to interventions, the duration and severity of the adverse reactions. In the small sample of this feasibility trial, we do not expect to observe a representative number of adverse events, so do not intend statistical comparisons; rather, we will assess the feasibility of the recording forms and systems for use in the main trial.

Figure 2

Health outcomes

Health outcomes will be expressed as quality-adjusted life years (QALYs) using the Short-Form 12 (SF-12v2).[86] The SF-12v2 will be converted to a six-dimensional health state classification (SF-6D).[87] The SF-6D allows estimating the quality-adjusted life year (QALY). A QALY is a year of life experienced with a particular health-related quality of life, and will be expressed as a score ranging from 0 to 1, with 0 = death and 1 = full health. Total QALY will be estimated for each participant by calculating the area under the curve (the product of utility values by time). We will calculate the mean QALYs for each group and adjust for baseline utility scores to minimize any bias due to chance baseline imbalance between the groups. As this feasibility trial is not powered to detect superiority, we will assess the magnitude of mean effect on QALYs in relation to clinically important change.

We will adapt the Otago Cost and Consequences Questionnaire (OCC-Q) to shoulder disorders, and use the adapted questionnaire to capture healthcare use and costs for participants enrolled in this study.[88] The OCC-Q is a patient-administered questionnaire developed for osteoarthritis that has demonstrated accuracy and agreement with administrative databases from the national healthcare system in NZ.[88] The OCC-Q will be administered at baseline and 12-week time points.

Time points

Outcome measures will be recorded at baseline, 4th, 8th and 12th week after baseline.

Missing data

When assessing secondary outcome measures, we will use a linear mixed-effect model to compare groups. This method can handle missing data. For the other analysis, in case of missing data, we will assess its distribution to confirm the assumption that data was missed at random. If missing at random is confirmed, we will perform multiple imputations.

Statistical analysis

All statistical analyses will be performed using R software.[89] Descriptive statistics will be used to analyse: (1) recruitment rates; (2) adherence to the rehabilitation programme; (3) proportion of participants enrolled from the total number screened; (4) drop-out rates; (5) adverse reactions.

We will use a linear mixed-effect model to obtain estimates of intervention effects, we will compare changes in pain and shoulder-related disability scores between the two intervention groups (i.e. tailored and standardized rehabilitation). Group intervention (tailored and standardized rehabilitation) will be considered as between-subject factor, and 'time-point' (baseline, 4th, 8th week and 12th week) will be considered as within-subject factor. Baseline measurements will be considered as covariates. We will conduct an independent linear mixed-effect model for each outcome measure (i.e. pain levels and shoulder-related disability). Given this is a feasibility trial, our goal is not to perform hypothesis testing, but rather to perform these analyses as preliminary assessment of any trend in between-group comparisons. This statistical approach is considered appropriate for feasibility or exploratory studies.[90]

To help informing whether or not it is worthwhile conducting the full trial, it is recommended that preliminary between-group comparisons to be performed at the feasibility trial stage.[91 92] For that, confidence interval (CI) ranges other than 95% should be used (e.g. 85% or 75%CI in addition to the mean difference estimate) when assessing differences between groups from feasibility trials.[91] For the purposes of this study, we will consider 75% CI as the probability threshold.[91] The mean difference between tailored rehabilitation and standardized rehabilitation will need to be larger than the minimum clinically important difference for either pain or shoulder-related disability. Therefore, if we can be, at least, 75% sure that one arm is superior to the other arm at 3-month follow-up, then we will consider to have sufficient preliminary evidence of a treatment difference.[91] Such information will be taken into account when assessing whether or not to conduct the full trial.[91 92]

Economic Evaluation

We will use an incremental cost-utility analysis, following intention-to-treat principle, to assess differences in costs and utilities between tailored rehabilitation and standardized exercise, and report incremental net monetary benefit. We will use both a health system and a societal perspective to define and measure costs, as is recommended for cost-effectiveness studies.[93] We will also report the cost-efficacy and direct medical costs within the NZ healthcare system, and will calculate Bayesian credibility intervals (Bayesian analogue of 95% confidence intervals) to account for uncertainty in measurements due to sampling random variability,[94] and will plot cost-effectiveness acceptability curves.[95]

Nested qualitative study

We will include a nested qualitative study that will assess participants' experiences about the trial, and will use a thematic analysis to interpret the data.[96] We will invite all participants to take part in a semi-structured interview. The goal is to gather data about participants' experience in the trial, in particular about the difficulties and barriers faced by participants, the perceived value and positive aspects of the study and any other issue that may arise during the interviews. Findings from the nested qualitative study will add significant value into how we can minimize perceived barriers, and increase adherence with the trial. Interviews will take place once participants complete the intervention programme (i.e. at the 8-week follow-up).

We will use thematic qualitative analysis to analyse and interpret transcriptions from interviews with participants. We will conduct the thematic qualitative analysis in 5 steps: (1) generation of codes; (2) identification of themes; (3) revision of themes; (4) definition and naming of themes; (5) interpretation of findings.[96] We will keep an audit trail, and members of the research team will crosscheck the coding and interpretation of data. We will adopt an iterative approach during data analysis, and will discuss and reflect on each step to identify any inconsistencies during the thematic qualitative analysis. We will analyse, write, and submit for publication the qualitative study as a separate manuscript.

Nested process evaluation study

We will conduct a process evaluation study using a mixed-method design. As part of the process evaluation, we will assess the fidelity, dose and reach of interventions implemented during the Otago MASTER Feasibility trial. We will assess fidelity of interventions by monitoring clinical notes, fortnightly, during the intervention period. Two clinical researchers (the PI and a research assistant) will be responsible for conducting the process evaluation. As per the Medical Research Council (MRC, United Kingdom – UK) guidelines,[21] we will adopt an active role, and provide feedback and additional training to clinicians if required. This approach will optimize fidelity of interventions. According to the MCR (UK) guidelines, this is the most appropriate approach for process evaluation during feasibility trials.

We will conduct a focus-group with clinicians once 70% of data collection has been completed. The focus-group will allow us to assess clinicians' perspectives (barriers and facilitators) about the interventions and the trial. We will use thematic qualitative analysis to analyse and interpret transcriptions from the focus-group. We will conduct the thematic qualitative analysis in 5 steps: (1) generation of codes; (2) identification of themes; (3) revision of themes; (4) definition and naming of themes; (5) interpretation of findings.[96] We will keep an audit trail, and members of the research team will crosscheck the coding and interpretation of data. We will adopt an iterative approach during data analysis, and will discuss and reflect on each step to identify any inconsistencies during the thematic qualitative analysis. We will analyse, write, and submit for publication the process evaluation study as a separate manuscript.

Discussion

In the short-term, the impact of this phase II trial is inform whether or not it is feasible to conduct the full efficacy trial. If the full trial is feasible, the medium-term impact of this proposal will be to determine which exercise therapy intervention is superior for managing patients with shoulder subacromial pain.

This protocol has limitations. We did not include in the initial plan a control arm, to optimize costs at phase II, and given that some reviews and guidelines suggest exercise therapy as the treatment of choice.[10 11 56] A recent Cochrane Review recommends future trials to compare exercise therapy interventions with placebo.[9] In addition, during the peer-review process of this protocol, one

reviewer raised the relevance of including a placebo arm. If findings from this feasibility trial suggest that it is feasible to conduct a full trial, we will design a three-arm intervention trial to address recommendations from the Cochrane Review. The full trial will consist of: (1) placebo; (2) tailored rehabilitation; (3) standardized rehabilitation. For this feasibility trial, we estimated sample size based on a two-arm intervention. The advantage of this approach is to reduce the required sample size for the feasibility phase, however, it increases uncertainty on estimates of treatment effects. [62] This will impact on sample size estimation of the full trial, if findings from this trial supports the next trial stage.[62] To address that uncertainty on treatment effect estimates, we will take this into account when preparing the future trial.

Data management

Data will be collected by trained researchers, using hard copies of forms and questionnaires. These will be safely stored and locked in a filing cabinet based at the Centre for Health, Activity and Rehabilitation Research School of Physiotherapy – University of Otago. A research assistant 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). We will use single-data entry, with 10% of the data being entered independently by two research assistants and crosschecked. In addition, we will use histograms, stem and leaf plots, clinical and data-driven range checks as part of quality control.[97 98]

Trial monitoring

The Health Research Council (HRC) Data Monitoring Core Committee (New Zealand) categorised this trial as low risk, and recommended that an independent Data Monitoring Committee was not necessary. The HRC Data Monitoring Core Committee recommended that an internal monitoring process is sufficient to monitor and oversee this trial. Based on these recommendations, the Data Monitoring Committee from the 'Centre for Health, Activity and Rehabilitation Research' (School of Physiotherapy – University of Otago) will monitor and oversee the trial. The research team has opted not to undertake interim analysis.

Ethics and Dissemination

This study was approved by the University of Otago Ethics Committee [Ref: H17/080]. Findings from this study will be presented at national and international conferences, and will be submitted for publication in a peer-reviewed journal.

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Declarations

Patient and Public Involvement

Patients and or public were not involved. Results of this study will be disseminated to study participants by inviting them to join an open-seminar in which the results of the study will be presented. In addition, we will prepare a short report with the main findings of the study and distribute this by e-mail to participants. The burden of the intervention will be assessed by participants through the nested qualitative study. In that study, we will participants' experiences and perceptions about the trial.

Data collection, storage and sharing

We will store participants' data on a secure local server, and will use unique identification number on follow-up questionnaires. To protect participants' privacy, all identifying information will be stored separately, and deleted following the conclusion of the trial. We will not share or report identifying information. The datasets generated during the study will be available from the corresponding author on reasonable request.

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.

Adverse event management

The risk of a serious adverse event related to the intervention is minimal. If a participant presents with an adverse event, the primary investigator will report it to the internal Data Monitoring Committee (Centre for Health, Activity and Rehabilitation Research—University of Otago) to assess whether it is necessary to report the adverse event to the trial sponsor, and Ethics Committee. We will suspend the trial if more than one serious adverse event of any kind occurs and these are related or caused by the interventions from the trial. If the cause of the events cannot be determined or remediated, and is plausibly related to the intervention, we will terminate the trial.

Protocol amendments

We will report any protocol change that may benefit participants, impact on participant's safety or that is likely to impact on the outcomes of the study (e.g. study objectives and/or design changes, sample size, study procedures, or significant administrative changes).

Competing interests statement

None declared.

Authors' contributions

DCR and ZJT conceived the research question. DCR was responsible for the design of the trial, and is the guarantor. ZJT and GS contributed to the design of interventions. JHA provided guidance on the design the trial and economic analysis. DCR led efforts for securing funding, with the contributions from ZJT, GS and JHA. All authors revised and approved the protocol for the study. All authors revised the manuscript for important content and approved the final version.

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The Health Research Council – New Zealand had no role in the design of the trial and will have no role in its execution, data analysis and interpretation, or on the submission of the studies for publication.

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Figure captions

Figure 1. Diagram of participant flow at the Otago MASTER feasibility trial.

Figure 2. Schedule for enrolment and intervention per group.
SPADI: Shoulder Pain and Disability Index; OCC-Q-Shoulder: Otago Cost and Consequences Questionnaire – Shoulder.

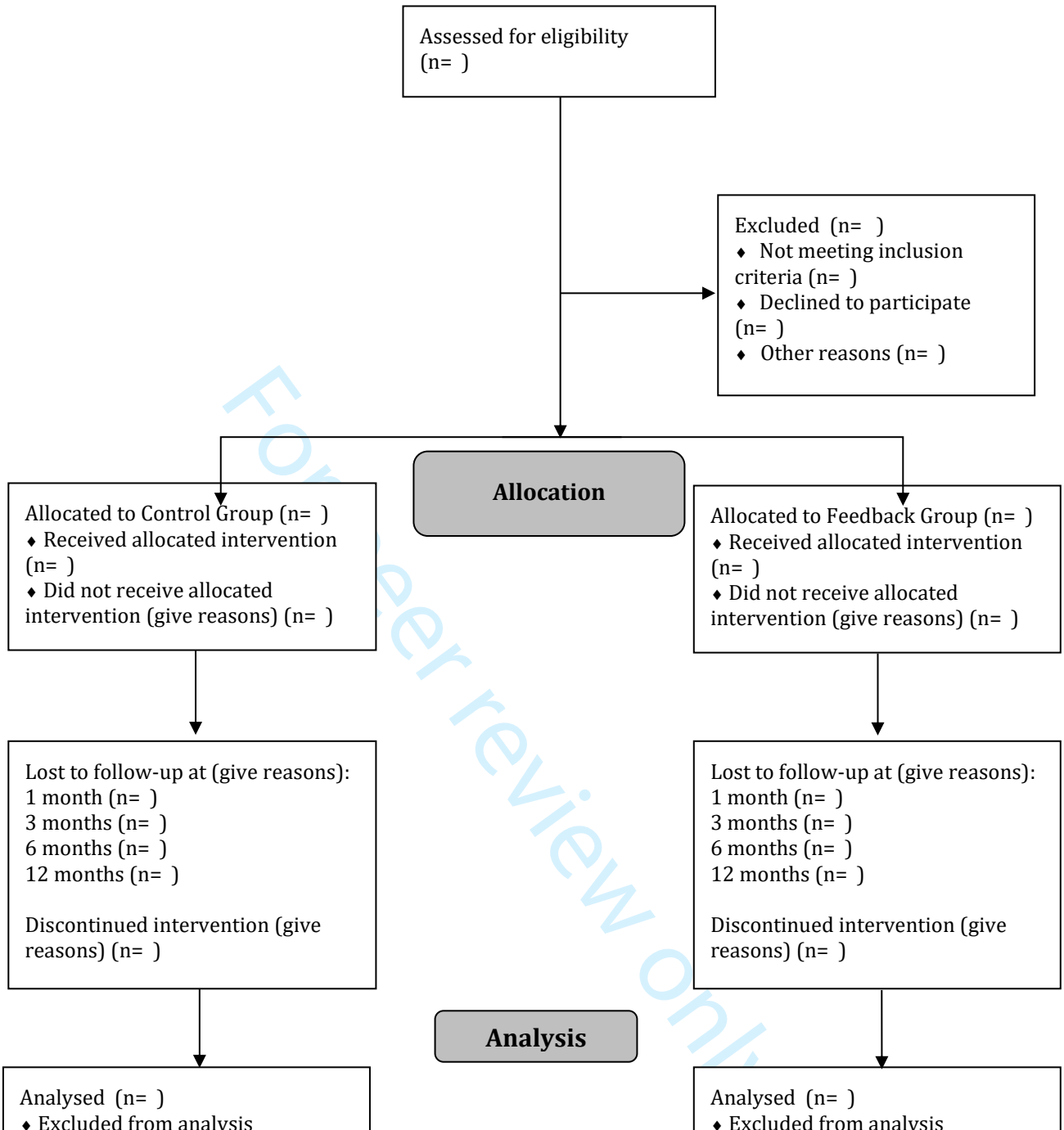

Figure 1. Diagram of participant flow at the Otago MASTER feasibility trial.

	Study Period					
	Enrolment	Allocation	Post allocation			
Time point	-t1	0	Baseline	4 weeks	8 weeks	12 weeks
Enrolment						
Eligibility screen	X					
Informed consent	X					
Allocation						
Intervention						
Standardized rehabilitation			←	—	→	
Tailored rehabilitation			←	—	→	
Assessments						
Baseline Demographic information	X					
Covariates:						
Age			X			
Height			X			
Weight			X			
Primary, and secondary outcome measures:						
Recruitment rates			X	X	X	X
Adherence to the rehabilitation programme			X	X	X	X
Proportion of participants enrolled			X	X	X	X
Drop-out rate			X	X	X	X
Adverse reaction			X	X	X	X
Pain intensity			X	X	X	X
Health outcomes						
Patient specific functional scale			X	X	X	X
SPADI			X	X	X	X
OCC-Q-Shoulder			X			X
Pain self-efficacy questionnaire			X	X	X	X

Figure 2. Schedule for enrolment and intervention per group.
SPADI: Shoulder Pain and Disability Index; OCC-Q-Shoulder: Otago Cost and Consequences Questionnaire – Shoulder.

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Supplementary Material 1

Otago MASTER Feasibility Trial

Tailored rehabilitation programme

UNIVERSITY of OTAGO Te Whare Wānanga o Otāgo NEW ZEALAND
Centre for Health, Activity, and Rehabilitation Research
School of Physiotherapy

Table of Contents

University of Otago Te Whare Wānanga o Otāgo New Zealand
Centre for Health, Activity, and Rehabilitation Research
School of Physiotherapy

Findings from physical examination & suggested exercises:

Findings from physical examination	Exercises
Pain or stiffness during passive accessory mobilization	Cervical or thoracic spine: HVT or PAIVM PAIVM If Grade –III or -IV if pain dominant Grade –IV or +IV if stiffness Gleno-humeral joint: Passive accessory mobilization - Grade –III or -IV if pain dominant - Grade –IV or +IV if stiffness
Painful or limited arm elevation during active resistive arm movement (flexion, abduction, internal rotation and external rotation) **Positive MWM** during shoulder scaption, shoulder external rotation, hand behind back position	# **1.A.** MWM for increasing shoulder scaption **#1.B.** MWM for increasing shoulder external rotation **#1.C.** MWM during shoulder elevation **#1.D.** MWM during hand behind back motion **#T.1.** Taping for sustained postero-lateral glide on humeral head (end of session) **# 11** Isolated motor control training around the shoulder
Positive scapular dyskinesis test: Scapular winging, tipping or hiking	**#4** Scapular setting in static postural position **#5** Scapular setting during dynamic elevation and rotation **#6** Shoulder shrugs with shoulder higher than 90^0 abduction

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Findings from physical examination	Exercises
	#7 Shoulder horizontal exercise with multiple feedbacks
Anterior translation humeral head, positive dynamic relocation test **Positive dynamic rotary stability test or shoulder pain during arm rotation (active or resistive)**	**#10** Dynamic relocation training **#11** Isolated motor control training around the shoulder
Positive Scapular MWM during scaption	**#1.C.** Mobilization with movement for scapular upward rotation
Positive Scapular upward rotation test	**#3** Scapular upward rotation training (retraining serratus anterior and upper trapezius)
Positive scapular weight bearing test	**#7** Shoulder horizontal exercise with multiple feedbacks **#8** Dissociation of scapular movements to thoracic in four point kneeling position and in for challenging situation by holding weight on just one hand **#9** Scapular holding training at mid protraction position (we perform this exercise when participant is able to scapular protraction and retraction
Positive scapular control test	**#2** Scapular exercises

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Quick Exercise Reference:

Mobilization with movement techniques

(1 MWM counts as **one** exercise. Start with 3 sets of 10 reps with 30 sec rest between sets)

Exercise	**Stage 1 (Basic)**	**Stage 2 (Intermediate)**	**Stage 3 (Advanced)**
1.A. **Shoulder scaption**	**1. A.1** In sitting, participant performs active shoulder scaption with ***elbow flexed*.**	**1. A.2** In sitting, participant performs active shoulder scaption with ***elbow extended***.	**1. A.3.** In sitting, participant performs shoulder scaption ***against a light weight*** or theraband (low intensity).
1.B. **Shoulder external rotation (ER)**	**1. B.1** In supine, participant performs ***active-assisted*** *shoulder ER* with the help of a wand. Therapist applies a posterolateral humeral glide.	**1. B.2** In sitting with arm at 90^0 abduction and elbow flexed, participant performs an ***active*** *shoulder ER*. Therapist sustains a posterolateral humeral glide.	**1. B.3** In sitting, participant performs shoulder ER *against* ***light resistance*** (low intensity). Therapist sustains a posterolateral humeral glide.
1.C. **Scapular up ward rotation**	**1. C.1** In sitting, participant performs active shoulder flexion with ***elbow flexed*.** Therapist assists scapular upward rotation	**1. C.2** In sitting, participant performs active shoulder flexion and ***elbows extended***. *T*herapist assists scapular upward rotation	**1. C.3** In sitting, participant performs active shoulder flexion and elbows extended ***against resistance*** (low intensity). *T*herapist assists scapular upward rotation

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Mobilization with movement techniques

1 MWM counts as **one** exercise. Start with 3 sets of 10 reps with 30 sec rest between sets

1.D. **Hand behind back motion**	**1. D.1** In sitting, participant moves hand behind back by ***pulling a belt*** *with other hand* while physiotherapist applies inferior glide on the shoulder.	**1. D.2** In sitting, participant moves hand behind back ***actively*** while physiotherapist applies inferior glide on the shoulder.	

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Scapular Control Training

Exercise	Stage 1	Stage 2	Stage 3	Home ex.
2. Scapular exercise	**2. A.1**. In side lying position physiotherapist uses ***resistance*** against shoulder D1 pattern.	**2. A.2**. *In* side lying, participant performs the shoulder D1 pattern in side lying position as ***free active*** movement.	2. A.3. ***In sitting,*** participant performs the shoulder D1 pattern as **free active** movement.	#7
	2. B.1. In side lying position physiotherapist *uses* ***resistance*** against shoulder D2 pattern.	**2. B.2.** In side lying, participant performs the shoulder D2 pattern in side lying position *as* ***free active*** movement.	2. B.3. ***In sitting***, participant performs the shoulder D2 pattern in side lying position as **free active** movement.	
3. Scapular upward rotation training (retraining serratus anterior and upper trapezius)	**3. A.1.** In the side lying position, participant elevates their arm while the therapist ***assists*** *serratus anterior* activity through feedback.	**3. A.2.** In the side lying position, participant elevates their arm against gentle resistance. The therapist **gently resists** serratus anterior activity by *resisting scapula upward rotation*.	**3. A.3.** In the side lying position, participant elevates their arm while the therapist ***increases resistance*** *against serratus anterior* activity by resisting scapular upward rotation.	#6

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4. Scapular setting in the ideal postural position *(static position*)	**4. A.1** In sitting *with **elbows resting on the armchair***. Participant is asked to tighten the scapula on their upper back. Physiotherapist uses feedback to inform participant of normal scapular position	**4.A.2** In sitting, participant is asked to tighten the scapula on their upper back *at **60°, 90° and 120° of shoulder elevation*** while the physiotherapist uses feedback to inform participant of normal scapular position	**4. A.3** In sitting, participant is asked to tighten the scapula on their upper back **at 60°, 90° and 120° of shoulder *elevation with a dumbbell*** (low intensity)**.** Physiotherapist informs participant of normal scapular position	#3
5. Scapular setting during dynamic elevation and rotation	**5 .A.1** In standing, participant performs shoulder flexion with the help of a ***ball on horizontal surface***. The physiotherapist prevents any abnormal scapular or shoulder movement.	**5 .A.2.** In standing, participant performs shoulder flexion with the help of a ***ball on inclined surface.*** The physiotherapist prevents any abnormal scapular or shoulder movement.	**5 .A.3.** In standing, participant performs shoulder flexion with the help of a ***ball on the wall.*** The physiotherapist prevents any abnormal scapular or shoulder movement.	#4a, #4b, #4c and #4d
	5. B.1 In sitting or standing, participant is asked to maintain normal scapular movement during arm **flexion *to 90° or arm abduction to 60°.*** The therapist prevents excessive shoulder hiking.	**5 .B.2** In sitting or standing, participant performs long lever arm shoulder elevation to ***beyond 90 degrees*.** Therapist ensures smooth movement of scapula without compensatory movements.		

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	5 .C.1 In sitting or standing, participant is asked to maintain normal scapular movement during **arm flexion to 90° or arm abduction to 60°** *against light resistance* (low intensity). Therapist prevents excessive shoulder hiking.	**5. C.2.** In sitting or standing, participant performs shoulder elevation to **greater than *90°*** *against light resistance* (low intensity). The therapist ensures participant can maintain normal scapular and shoulder movement.		#4F & G
	5. D.1. Participant is standing with arm and side and elbow flexed to 90°. Participant performs bilateral shoulder elevation with isometric shoulder external rotation against ***resistance (low intensity)*.**	**5. D.2.** Participant is standing with arm and side and elbow flexed to 90°. Participant performs bilateral shoulder elevation with isometric shoulder external rotation against ***resistance (mod intensity)***.	**5. D.3.** Participant is standing with arm and side and elbow flexed to 90°. Participant performs bilateral shoulder elevation with isometric shoulder external rotation against ***resistance (high intensity)*.**	
	5. E.1. Participant is s*itting* with shoulder abducted 90°and elbow flexed to 90°. Participant performs ***unloaded arm internal and external* rotation** without any compensatory scapular or shoulder movements.	**5. E.2.** Participant is standing or sitting with shoulder abducted 90°and elbow flexed to 90°. Participant performs ***arm internal and external rotation* against *theraband*** (low intensity) without any compensatory scapular or		

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		shoulder movements.		
	5. F.1. Participant is in *prone* with shoulder abducted 90° and elbow flexed to 90°- The ***shoulder and forearm is supported*** using a towel roll or a pillow. Participant performs *arm internal and external* rotation without any compensatory scapular or shoulder movements.	**5. F.2.** Participant is in *prone* with shoulder abducted 90° and elbow flexed to 90°- The shoulder and **forearm is unsupported** (*participant actively holds the shoulder off the bed)*. Participant performs *arm internal and external* rotation without any compensatory scapular or shoulder movements.	**5. F.3.** Participant is in *prone* with shoulder abducted 90° and elbow flexed to 90°- The shoulder and forearm is **unsupported** (participant actively holds the shoulder off the bed). Participant performs *arm* internal and external rotation ***against resistance*** without any compensatory scapular or shoulder movements.	
6. Shoulder shrug exercise with <u>shoulder higher than 90° of abduction</u>	**6. A.1** In standing, shoulder flexed, participant performs **assisted** *shoulder shrug (*wall slide or pulley). Physiotherapist prevents over activity of the levator scapulae.	**6. A.2** In standing, shoulder flexed, and participant does ***active*** *shoulder shrug without wall support. P*hysiotherapist prevents over activity of the levator scapulae.	**6. A.3** In standing, shoulder flexed, participant shrugs shoulders ***against resistance.*** *P*hysiotherapist prevents over activity of the levator scapulae.	#2

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7. Shoulder horizontal exercise with multiple feedbacks	**7. A.1**. Participant ***stands in front of a wall*** with their hands overhead on the wall. Participant is then asked to take their hands on and off the wall. The physiotherapist facilitates activity of the lower trapezius.	**7. A.2.** Participant is in ***side lying*** position with arm overhead (100° of flexion). Participant performs *horizontal shoulder abduction.* The physiotherapist facilitates activity of the lower trapezius.		#5
	7. B.1. Participant is either in ***prone*** with arms hanging off the side of bed or in 4-point kneeling position. Participant then extends and abducts their arm to 90 degrees.	**7. B.2.** Participant is in prone or in 4-point kneeing with **arm abducted greater than 90 degrees.** They are asked to lift their arms off the bed against appropriate resistance.		
8. Dissociation of scapular movements to thoracic in four point kneeling position	8. A.1. Leaning over table with **partial weight bearing on hands**, participant performs scapular protraction and retraction	8. A.2 **In four-point keeling position**, participant performs scapular protraction and retraction	8. A.3. In four-point keeling position while **weight bearing on one hand**, participant performs scapular protraction and retraction	NA
9. Scapular holding training at mid protraction position	9. A.1. In standing position, participant performs resisted scapular protraction against **light resistance.**	9. A.2. In **4-point kneeling**, participant holds scapula in mid protraction for 10 seconds.	9. A.3. Participant is in **three-point kneeling** (weight on affected extremity) and holds the scapula in mid-protraction for 10 secs.	NA

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Rotator Cuff Motor Training				
Exercise	**Stage 1**	**Stage 2**	**Stage 3**	**Home exercise**
10. Dynamic relocation training	10 .A.1. In sitting or supine position, participant draws their shoulder head towards the socket as physiotherapist applies gentle traction on the humerus.	10 .A.2 In sitting, participant draws their shoulder "in and back" towards their socket, *without humeral traction*, at the outer or inner shoulder rotation degrees.		#8 for Stage 3
11. Isolated motor control training around the shoulder	11 .A.1. In prone position with arm abducted to 90 degree, participant tightens their scapula and draws the humeral head gently down and in as they externally rotate their shoulder.	11 .A.2. In sitting with arm abducted to 90 and elbow flexed to 90, participant tightens their scapula and draws the humeral head gently down and in as they externally rotate their shoulder.	11 .A.3. In sitting with arm abducted to 90 and elbow flexed to 90, participant tightens their scapula and draws the humeral head gently down and in as they externally rotate their shoulder against resistance.	Home exercise #9 for Stage 3

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Proprioception, and plyometric training		
12. Proprioception training	**12. A.** The participant is sitting with a ball beneath their hand. Participant alternately presses and releases the ball	**12. C.** In sitting, pressing down the hands on the seat and lifting their bottoms off the bed.
	12. B. The participant pushes and releases a ball on the wall. The therapist ensures that participants stabilizes the scapula to prevent winging	**12. D.** Plyometric ball catching and throwing exercise.

Taping
T.1. Taping for sustained postero-lateral glide on humeral head.

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Exercise description

1. Monilization with Movement

1.A. Mobilization with movement for increasing shoulder scaption

Equipment: Mulligan Belt (for stage 3).

Participant position: Sitting.

Therapist position: Therapist places their hand on humeral head anteriorly.

Direction of force: Physiotherapist sustains posterolateral glide on humeral head.

Joint Movement: Participant performs scaption. It is important that physiotherapist allows normal motion between scapula and thorax to ensure pain free scaption.

1. A.1. Stage 1: Participant performs the arm scaption with elbow flexed.

1. A.2 Stage 2: Participant performs the technique with elbow extended.

1. A.3 Stage 3: Participant performs scaption against a light weight or a Thera band with elbows extended.

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1.B. Mobilization with movement for increasing shoulder external rotation

Equipment: Wand (for stage 1), Theraband (stage 3).

Participant position: Variable based on stage. Please refer to individual stages below.

Therapist position: Variable based on stage.

Direction of force: Physiotherapist sustains posterolateral glide.

Joint movement: Participant externally rotates the shoulder.

1. B.1. Stage 1: Participant is in supine with arms in comfortable abduction and elbows flexed to 90º, holding a stick in both hands to assist the external rotation of the involved shoulder. Physiotherapists sustain posterolateral humeral glide while participant performs passive shoulder external rotation (figure above).

1. B.2. Stage 2: Participant is sitting with shoulder abducted to 90, elbow flexed to 90 and then performs active external rotation as physiotherapist applies posterolateral glide.

1. B.3. Stage 3: Same as above but participant performs ER against light resistance.

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1.C. Mobilization with movement for scapular upward rotation

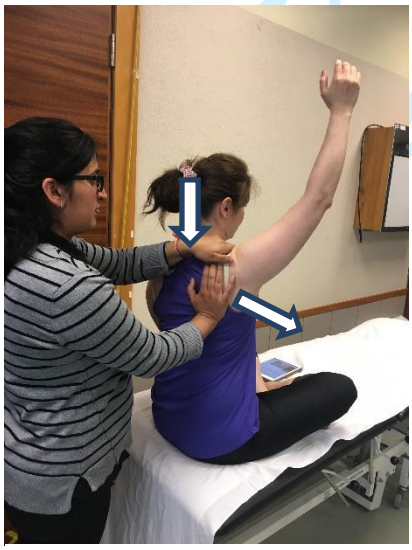
Equipment: Theraband (for stage 3)

Participant position: Sitting without back support.

Therapist position: Behind the participant. One hand on the spine of scapula and other on the medial aspect of scapular body.

Direction of force: Physiotherapist sustains downward and medial glide over the spine of scapula with one hand and rotates scapula upwardly with other hand while preventing scapular winging and tipping

Joint Movement: Participant performs shoulder elevation.



1.C.1 – Stage 1

1.C.1 – Stage 2

1. C.1. Stage 1: Participant performs shoulder flexion with elbow flexed

1. C.2. Stage 2: Participant performs shoulder flexion with elbow extended

1. C.3. Stage 3: Participant performs resisted shoulder flexion with elbow extended against light resistance.

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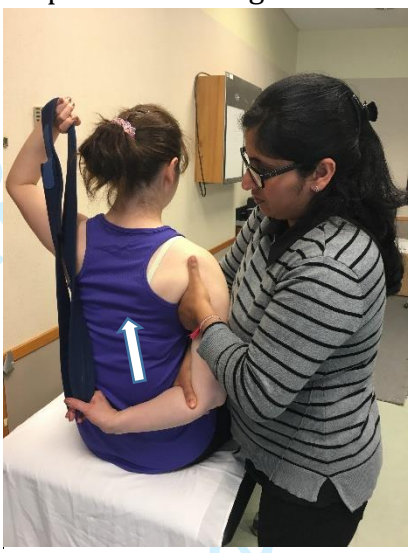
1.D. Mobilization with movement for hand behind back motion

Equipment: Belt (for stage 1)

Participant position: Sitting or standing.

Therapist position: Standing on the affected side. One hand on the lateral border of scapula and other hand on distal humerus for applying inferior glide.

Direction of force/ Movement: Physiotherapist stabilizes the scapula and applies *inferior glide (traction)* while participant is reaching to the back with the involved hand.



1. D.1 Stage 1: Participant reaches the affected hand behind back with the help of a belt.

1. D.2. Stage 2: Participant actively holds hand behind back without assistance

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2. Scapular exercise

In participants with poor awareness or control, the scapula tends to follow a curvilinear path rather than a diagonal, with jerky uncoordinated movement. Frequently, the scapula moves into excessive protraction and anterior tilt when attempting the 'up and forward' direction.

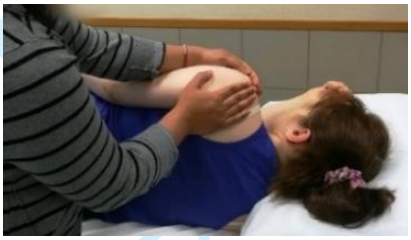
2 .A. The D1 pattern (elevation-protraction to depression-retraction)
Participant moves the tip of the shoulder towards the corner of the eye. And then returns it down and back to the opposite hip. Please make sure that participant has the chin tucked in.

2. A.1. (**Stage 1) - (Picture below, left):** Participant performs the D1 pattern in side lying. Physiotherapist applies resistance against the movement.

2. A.2. (Stage 2) - (figure below, right): Participant performs the pattern in side lying without resistance.

2. A.3. (**Stage 3):** Participant performs the pattern in sitting without resistance.


2.A.1


2.A.2

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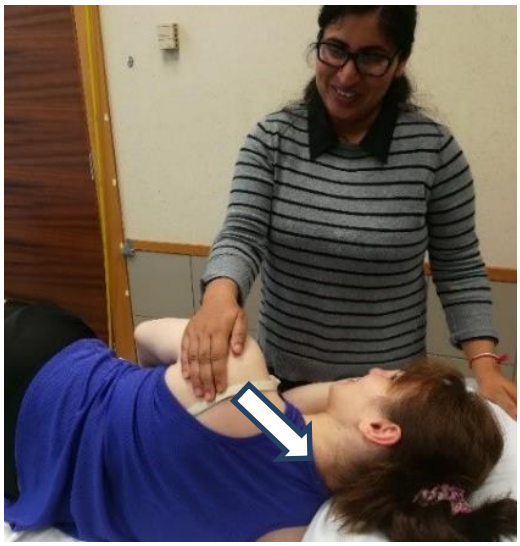
2. B. The D2 pattern (depression-protraction to elevation-retraction)

Participant moves the tip of the shoulder down and forward towards your opposite hip, then returns it up and back.

2. B.1. Stage 1: Participant performs the pattern in side-lying. Physiotherapist applies light resistance against the movement (Picture below).



2. B.2. (**Stage 2) (Picture below):** Participant performs the pattern in side lying without resistance

2. B.3. (**Stage 3):** Participant performs the pattern *in sitting* without resistance.

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3. Scapular upward rotation training (retraining serratus anterior and upper trapezius)

Equipment: None

Participant position: Participant in side-lying on the uninvolved arm.

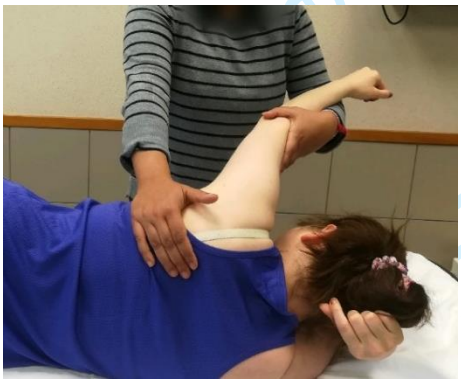
Feedback: Physiotherapist supports the upper arm in shoulder flexion greater than 90^0. Physiotherapist resists against shoulder motion and palpates the lateral border of scapula to activate serratus anterior.

Movement: Participant tries to bring the shoulder into more flexion and external rotation with scapular upward rotation.

3 .A.1. Stage 1(picture below). Physiotherapist *assists* in activation of serratus anterior by using palpation, tapping or repeated contraction or stretch

3 .A.2. Stage 2: Physiotherapist *resists gently* against scapular upward rotation.

3 .A.3. Stage 3: Physiotherapist *increases resistance* against scapular upward rotation.



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4. Scapular setting in postural position

Equipment: Mirror (if required for visual feedback).

Participant position: Upright sitting.

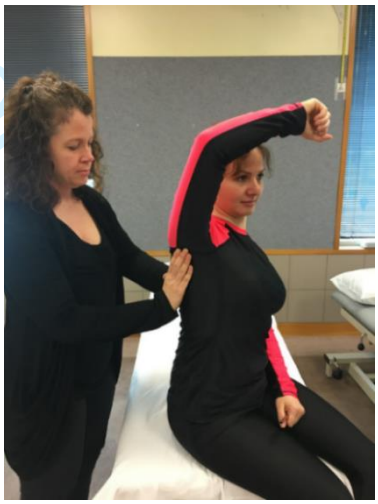
Feedback: The physiotherapist provides feedback (visual, tactile or verbal) to inform the participant of normal scapular resting position.

Movement: Participant is asked to tighten the scapula by contracting the serratus anterior and trapezius so that the inferior angle and medial border lies flat over the upper back. Participant holds this position for 10 seconds.

4. A.1. Stage 1: This stage is used for participants who have winging or tipping in upright position. The participant's arms are unloaded by placing the elbow over armchair. Participant is asked to "tighten their scapula on their upper back" and hold it for 10 seconds.

4. A.2. Stage 2 (Picture below): Scapular setting exercise is performed while participant holds the involved arm isometrically in 60°, 90° and 120° shoulder elevation. The shoulder may be internally rotated or externally rotated while the arm is held at 0°, 60°, 90° or 120°.





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4. A.3. –(Stage 3) (Picture below): Scapular setting exercise is performed at 60°, 90° and 120° shoulder elevation against light resistance provided by a dumbbell.

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5. Scapular setting during arm movements

(These exercises are used for participants with observable tipping or winging of the scapula *during arm movement*.)

Equipment: Mirror (if required for visual feedback), Gym ball (based on exercise) please refer to individual exercises

Participant position: Variable based on exercise.

Feedback: The physiotherapist provides feedback (visual, tactile or verbal) to inform the participant of normal scapular resting position.

Movement: Participant is then asked to maintain normal scapular position/ movement while preventing tipping and winging as they perform various arm movements.

5. A. Scapular setting during shoulder flexion with ball (pictures below)

5 .A.1 (Stage 1): Participant performs shoulder flexion on the bed with no inclination with the help of a ball.

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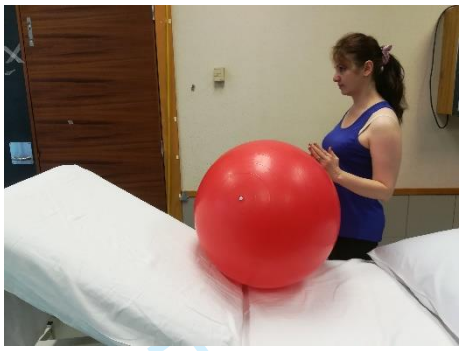
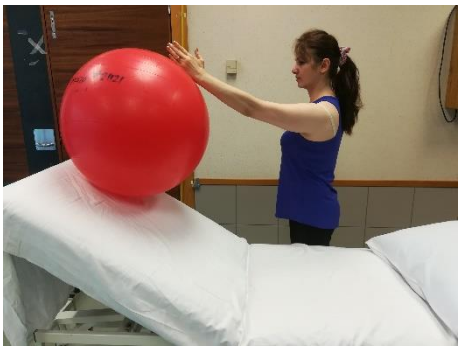
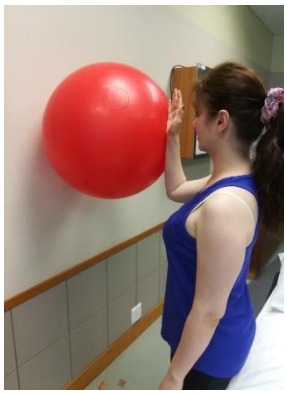
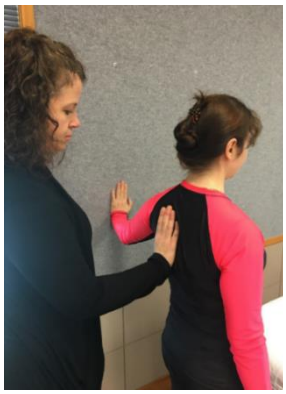
5 .A.2 (Stage 2): Participant performs shoulder flexion with the help of a ball on a surface inclined to 45°.

5 .A.3 (Stage 3): Participant performs shoulder flexion using a ball on a wall. Alternately, participant performs a simple wall slide.





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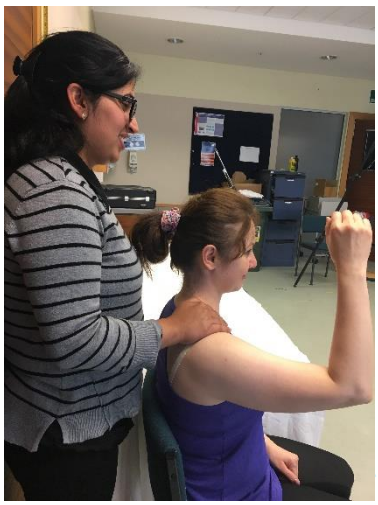
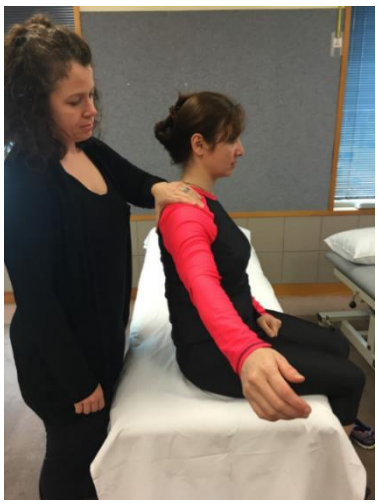
5. B. Scapular setting during arm elevation

5 .B.1. (Stage 1): Scapular setting during arm elevation to 90

Participant is asked to maintain normal scapular position during arm *flexion to 90°* or arm *abduction to 60°* with elbow flexed (easier) or extended (more difficult). The therapist prevents excessive shoulder hiking through appropriate feedback.





5. B.2 (Stage 2): Scapular setting during long lever arm elevation >90° (flexion and abduction) as free active

Participants actively elevates the arm (either flexion or abduction) to above 90° with elbows extended without any assistance or resistance. The therapist ensures smooth normal movement of the scapula without compensatory scapular hiking, tipping or winging.

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5. C. Scapular setting during arm elevation against resistance

5. C.1 (Stage 1): Scapular setting during gentle resisted arm flexion to 90° and abduction to 60°

Participant performs shoulder flexion to 90° or shoulder abduction to 60° against a light resistance (Theraband or dumbbell) while the physiotherapist provides feedback to prevent excessive shoulder hiking.

5. C.2 (Stage 2): Scapular setting during long lever arm elevation >90° against resistance

Participant performs shoulder elevation to *greater than 90°*, with elbows extended, against light resistance. Physiotherapist should ensure participant is able to control scapular winging during raising and lowering phases and that participant avoids scapular hiking.

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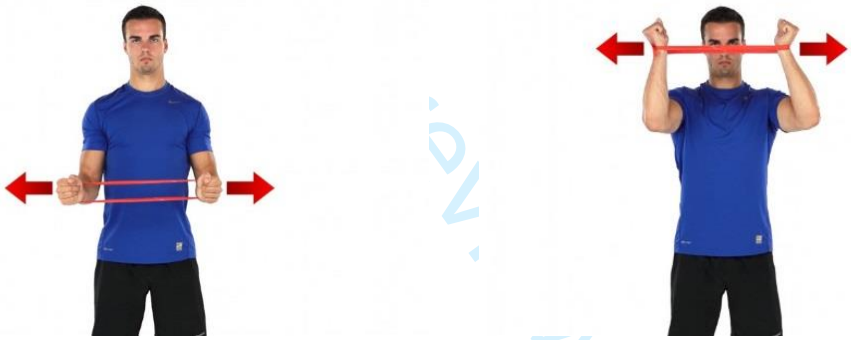
5. D. Scapular setting during bilateral shoulder elevation combined with external rotation resistance

5. D.1 Participant elevates both their arms to 90°, while isometrically contracting external rotation against light resistance (RPE 3 to 4), with elbows flexed.

5. D.2. Participant elevates both their arms to 90°, while isometrically contracting external rotation against moderate resistance (RPE 5 to 6), with elbows flexed.

5. D.3. Participant elevates both their arms to 90°, while isometrically contracting external rotation against high resistance (RPE 7 to 8), with elbows flexed.



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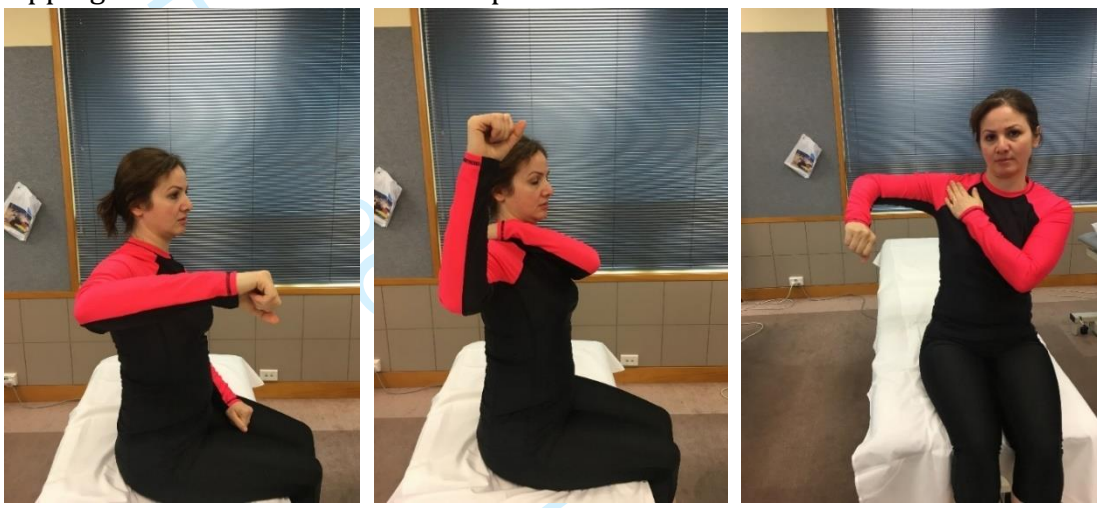
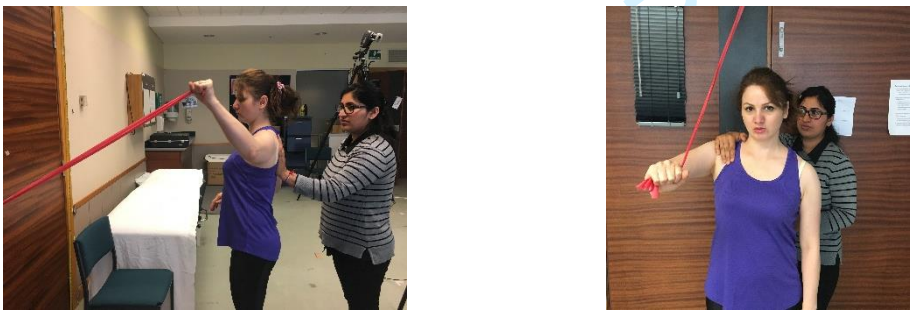
5. E. Scapular setting exercise during internal and external rotation in upright position

5. E.1.: Participant performs shoulder external rotation and internal rotation with shoulder flexed to 90° in sitting.
For ER: Physiotherapist makes sure that participant avoids shoulder depression and retraction.
For IR: Physiotherapist makes sure that participant avoids scapular anterior tipping and shoulder elevation and protraction.



5. E.2. Participant tightens the scapula during shoulder external rotation with arm at 90°. It is better to perform this exercise in front of mirror for added feedback.



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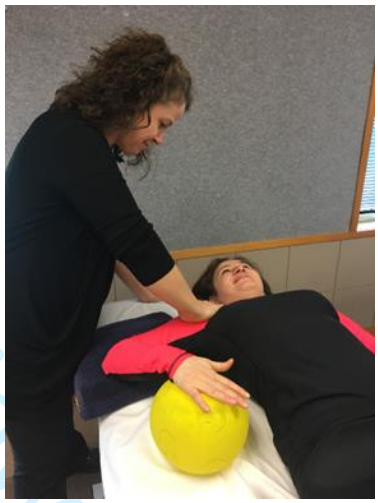
5. F. Scapular setting during shoulder rotation in prone:

Participant is asked to rotate the shoulder externally or internally without excessive scapular depression and retraction. The goal is to dissociate shoulder movement from scapular movement.

However, if the participant is unable to perform full internal rotation, they are asked to press on a ball in supine lying without lifting their shoulder from the bed (picture below- right). This activates the subscapularis muscle.

5. F.1 (Stage 1): Participant is in prone with arm flexed to 90° and elbow flexed to 90°. A towel roll is placed under the shoulder to support the arm as well as to prevent shoulder anterior tilting.



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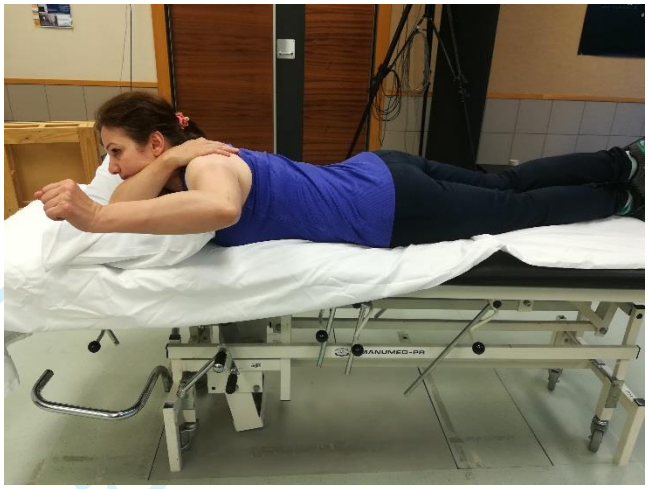
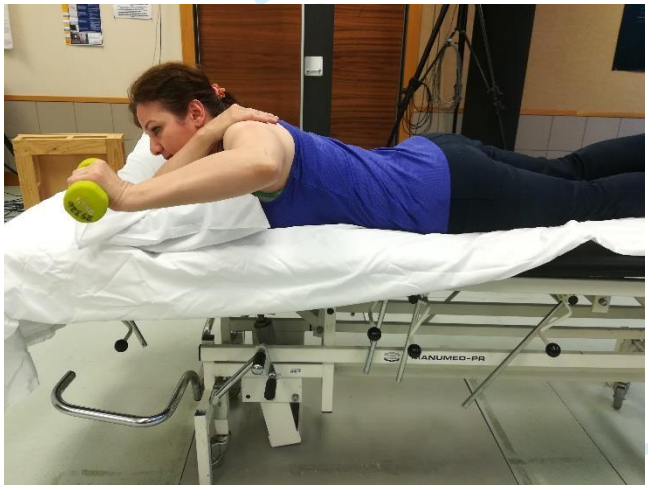
5. F.2 (Stage 2): Participant is in prone with arm flexed to 90° and elbow flexed to 90°. No support is provided and participant is asked to actively hold the shoulder off the bed while performing shoulder internal and external rotation.



5 .F.3. (Stage 3): Participant is in prone with arm flexed to 90° and elbow flexed to 90°. No support is provided and participant is asked to actively hold the shoulder off the bed while performing shoulder internal and external rotation against resistance.



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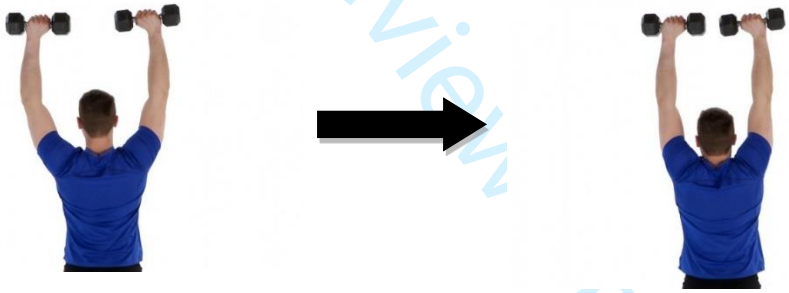
6. Shoulder shrug exercise where arms are higher than 90^0 of abduction

Equipment: Dumbbell (for stage 3).

Participant position: Standing.

Feedback: Physiotherapist uses appropriate feedback to facilitate the activation of the upper trapezius while preventing over activity of the levator scapula.

Movement: Participant raises the tip of shoulder towards the ear lobe while keeping their chin tucked.



6 .A.1 Stage 1: Participants elevate their arms and then perform shoulder shrug by sliding their hands up a wall or by using a pair of hanging strings from the ceiling.

6 .A.2. Stage 2: Participants perform the task as free active movement.

6 .A.3. Stage 3: Participants performs the task with light resistance (dumbbell).

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7. Shoulder horizontal exercise with multiple feedbacks

Equipment: Mirror (if required for visual feedback), Theraband (for stage 3).

Participant position: Variable based on stage.

Feedback: Physiotherapist **continuously taps the lower trapezius** to facilitate muscle activity and gives participant the verbal ques to tip the scapula posteriorly and avoid shoulder shrug.

Movement: The participant is instructed to "lift the arm from the scapula (by moving your scapula) and not from shoulder joint while keeping your arm in external rotation". This instruction is given to prevent excessive humeral head anterior translation.

7 .A Non-weight bearing exercises

7. A.1. (Stage 1): Participant stands in front of a wall with the hands overhead on the wall. Participant is then asked to take their hands on and off the wall. This exercise is applicable when participant is not able to do horizontal abduction in 4-point kneeling. Make sure that Participant performs the movement from their scapula.

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7. A.2. Stage 2: Participant is in side lying position with arm overhead (100° of flexion). Participant then performs subsequent ***arm extension and abduction***. The physiotherapist prevents arm hyperextension and encourages participant to elevate their arm from the scapula at the end range of arm extension. (Continuous tapping over lower trapezius is recommended).

7. B. Exercises in weight bearing

7. B.1. (Stage 1): Participant is either in prone with arms hanging off the side of bed or in 4-point kneeling position. Participant flexes and abducts their arm to 90 degrees. The physiotherapist prevents hyper abduction and encourages scapular movement.

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7. B.2. (Stage 2): Participant is in prone or in 4-point kneeing positions with arm abducted greater than 90 degrees. They are asked to lift their shoulders off the bed against appropriate resistance.

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8. Dissociation of scapular movements from thoracic movements in 4-point kneeling

Equipment: Wand for feedback
Participant Position: Variable based on the stage
Feedback: Physiotherapist encourages participant to do scapular protraction and retraction without spine movements. In particular, participants should avoid thoracic extension (lordosis) during retraction, and thoracic flexion (kyphosis) during protraction.

Other possible compensatory movements:

- full extension of the elbows
- end range rotation of the arm
- passive scapular retraction
- forward head position or cervical flexion
- increased lumbar lordosis
- elevation of shoulder girdle towards the ears
- Scapular winging.

If participant has tremor of the shoulder girdle or arm muscles during the exercise, physiotherapist reduces sets/repetitions/resistance.

Movement: Widen your shoulder blades and return them as if closing and opening a book.

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8. A.1. (Stage 1) (Picture below): Participant is leaning over a table while weight bearing on both hands. To increase the difficulty, participants may be asked to shift their weight to the affected side.

8 .A.2 (Stage 2 -Picture below): In 4-point keeling position, participant performs scapular protraction and retraction while bearing weight on both hands. To increase the challenge participant may *shift* their weight to the affected side.

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8. A.3 (Stage 3-figure below): In 4-point keeling position, participant performs scapular protraction and retraction with weight bearing on one hand.

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9. Scapular holding training at mid protraction position

(This exercise is used when participant can perform each scapular protraction and retraction for 10 seconds)

Equipment: Theraband

Participant Position: Variable based on stage

Feedback: Ensure that when participant is holding scapula in mid protraction, he/she should keep spine in straight and neutral position. In the case that participant has a weak control of spinal column, when you ask participant to have their neck in neutral position, participant performs thoracic or lumbar extension

Movement: Participant holds the scapula in mid protraction for 10 second, 10 reps, and 2-3 sets.

9. A.1. - (Stage 1): Participant is in standing, with a theraband wrapped around their back or on a door. Participant performs scapular protraction against light resistance.

9. A.2 (Stage 2): Scapular holding training in four-point kneeling position. Participants holds the scapula in mid-protraction for 10 seconds. To increase difficulty, participant may be asked to transfer weight to affected side by leaning towards the affected side.

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9. A.3 (Stage 3): Participant is in three-point kneeling (weight bearing on the affected extremity only) and holds the scapula in mid-protraction for 10 secs.

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10. Dynamic relocation training

These exercises focus on increasing the isolated contraction of rotator cuff (co-contraction of subscapularis, teres minor and infraspinatus) while decreasing contraction of superficial muscles.

As described by:

Magarey ME, Jones MA. Dynamic evaluation and early management of altered motor control around the shoulder complex. Manual therapy. 2003 Nov;8(4):195-206.

Magarey ME, Jones MA. Specific evaluation of the function of force couples relevant for stabilization of the glenohumeral joint. Manual therapy. 2003 Nov;8(4):247-53.

10. A.1. (Stage 1):
Participant position: Participant is either lying supine or sitting, with arm supported between 60^0 to 80^0 of scaption by the therapist.

Direction of force: The physiotherapist applies a gentle longitudinal distraction force and asks participant to draw their humerus into the the glenoid cavity.

Movement: Physiotherapist asks participant to draw the arm "in and backward". The participant is asked to perform a gentle depression of the scapula while drawing the humerus toward the glenoid cavity.

Feedback: Physiotherapist encourages participant to activate more subscapularis and concurrently decrease superficial muscle activity (e.g. latissimus dorsi, posterior deltoid, pectoralis major and upper trapezius). Initially, participant may pull the arm strongly with superficial muscles with or without rotator cuff contraction. In this case, they should be instructed to reduce the effort.

10. A.2. (Stage 2): Participant draws their shoulder "in and back" towards the glenoid cavit, ***without humeral traction***, at the outer or inner range of shoulder rotation.

Participants should be taught to feel the contraction for themselves by palpating near the axilla. When the physiotherapist is confident that the participant can dissociate the co-contraction without external feedback, he/she can ask participants to do the exercise at home.

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11. Isolated motor control training around the shoulder

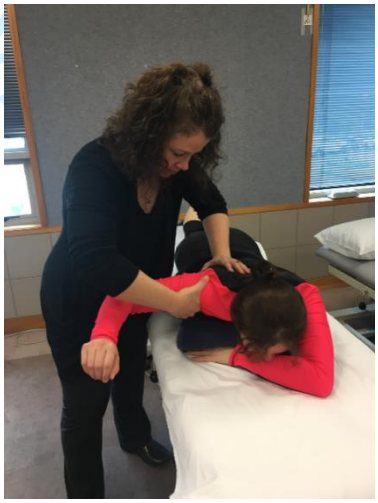
When there is lack of dynamic rotator cuff stability, the humeral head often translates anteriorly or superiorly. The aim of this training is to find a position where participant has the most control on humeral head, as close as to the position where there is the least control. Physiotherapist asks participant to rotate shoulder while centering the humeral head to the glenoid. Stabilizing scapular concomitant with humeral head depression prevent clicking sound and pain in the shoulder.

11. A.1. (Stage 1): Assisted External Rotation

Participant Position: Lying prone with chest supported by a folded towel

Feedback: The physiotherapist palpates the participant's humeral head from anterior and superior direction. The aim is to teach participant to relax their deltoid.

Movement: The participant is asked to tighten their scapula and draw the humeral head gently "down and in" as they externally rotate their shoulder actively. This exercise is applicable when we observe humeral head anterior protrusion during shoulder external rotation.



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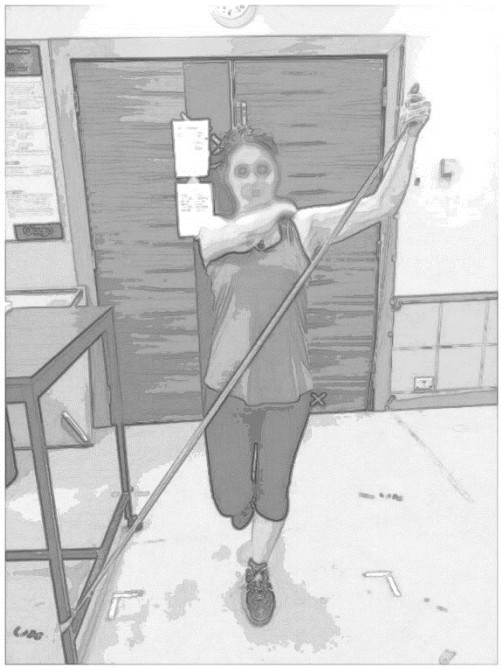
11.A.2 (Stage 2): In sitting, participant performs active ER while physiotherapist ensures there is no excessive anterior and superior glide of the humeral head.

11.A.3. (Stage 3): Progressed to resisted ER motion. Physiotherapist should make sure that the participant can control humeral head anterior translation during arm external rotation. For increasing difficulty, the movement can be performed with resistance of a theraband, while participant stands in one leg.



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12. Proprioception, balance and plyometric trainings

12. A.: The participant is sitting with a ball beneath their forearm. Participant presses and releases the ball while ensuring the scapula and shoulder are properly stabilized.

12. B.: The participant pushes a swiss ball against the wall. The therapist ensures that participants stabilizes the scapula to prevent winging.

12. C. The participant tries to lift their bottoms off the bed in sitting by pressing down through their hands. The force is generated from the shoulder joint.

12. D.: Plyometric catching exercise.

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Scapular Taping for postero-lateral glide

Start the tape on the anterior aspect of the humeral head crossing the acromion lateral to the acromioclavicular joint, ending at the inferior border of the scapula. Therapist glides the humeral head posteriorly when applying the tape. Take care not to apply too much tension initially at the humeral head as the skin is liable to breakdown.

As described by:

Teys P, Bisset L, Collins N, et al. One-week time course of the effects of Mulligan's Mobilisation with Movement and taping in painful shoulders. Manual therapy 2013;18(5):372-77. doi: 10.1016/j.math.2013.01.001

Hing W, Hall T, Rivett DA, et al. The Mulligan Concept of Manual Therapy: Textbook of Techniques: Elsevier Health Sciences 2015.

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Supplementary Material 2

Otago MASTER Feasibility Trial

Standardized rehabilitation programme

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Exercise Overview – Quick reference

Shoulder Core Exercises

Exercise			
1. Shoulder extension Resistance type: elastic band	**1. A.** Bilateral Low row: Subjects extends both shoulders from 80°of shoulder flexion (elbow flexed).	OR	**1. B.** Bilateral High row Subject extends both shoulders from 100° shoulder flexion to neutral with elbow extended
2. Shoulder adduction in scapular plane	**2.** Subject adducts shoulder from 80° of shoulder abduction (elbow extended)		
3. Shoulder external rotation (ER) Note: rolled towel placed between arm and trunk	**3.A.** Shoulder ER in sitting/standing: Subject externally rotates shoulder from a standing/sitting position with shoulder in neutral (elbow flexed to 90°).	OR	**3. B.** Shoulder ER in side lying: Subject performs shoulder ER from a side lying position with shoulder in neutral (elbow flexed to 90°).
4. Shoulder internal rotation (IR) Note: rolled towel between arm & trunk	**4. A.** Shoulder IR in sitting/standing: Subject internally rotates shoulder from a standing/sitting position with shoulder in neutral (elbow flexed to 90°).	OR	**4. B.** Shoulder IR in side-lying*: Subject performs shoulder ER from a side lying position with shoulder in neutral (elbow flexed to 90°). *only if participant able to lie down on affected side
5. Elbow flexion with forearm supination:	**5.** Subjects gradually performs elbow flexion with forearm supination from neutral shoulder rotation.		

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Scapular Core Exercises

Exercise			
6. Scapular protraction	**6. A.** Scapular protraction in standing Subject is standing with shoulder in neutral with elbow flexed to 90. From here participant gradually flexes *shoulder to 80* while extending elbow and then performs scapular protraction.	**OR**	**6. B.** Scapular protraction in supine In supine lying with shoulder in neutral and elbow flexed to 90, participant gradually flexes *shoulder to 90* and extends elbow, then scapular protraction.
7. Scapular protraction in 4-point kneeling	**7.** Subject is in 4-point kneeling position with hands underneath shoulder. Participant performs scapular protraction.		
8. Scapular muscle strengthening (Isometric scapular setting)	**8**. Subject starts in prone position, with hands by the sides, arms in external rotation; then depresses and retracts the scapula and holds it isometrically.		

Shoulder Stretch (Core exercises)

Exercise	Instruction
9. Posterior shoulder stretch	Subject is in standing. Participant stretches affected shoulder into horizontal adduction by pulling fully flexed elbow with opposite hand
10. Lateral neck stretch	Subject is in standing. Participant pulls the head into lateral flexion with opposite arm and adds shoulder depression to increase the stretch
11. Thoracic spine extension	Subject is supine with hips and knees flexed, towel roll Under the thoracic spine and hands supporting the neck. Participant maintains this posture to sustain a stretch of anterior thoracic muscles

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Additional Exercises

	Exercise	Pg no.
12. Shoulder scaption in standing position	Subject performs 80° scaption with elbow in slight flexion and slight shoulder external rotation (thumbs up)	18
13. Shoulder flexion in standing	Subject flexes arm to 80° with arm slightly flexed and externally rotated (thumbs up)	19
14. Shoulder press via flexion (Sitting with back support)	Subject performs full shoulder ***flexion*** with elbow extension *Arms against trunk, elbows fully flexed, hands lateral to shoulder.*	**20**
15. Shoulder press via abduction in (Sitting with back support) (Elastic band only)	Subject performs full shoulder ***abduction*** with elbow extension against *Arms against trunk, elbows fully flexed, hands lateral to shoulder.*	**20**
16. Horizontal abduction in sitting (Elastic band only)	Perform shoulder abduction against Elastic band attached at shoulder height *Shoulder in 80 flexion and ER (thumb laterally)*	**21**
17. External rotation in sitting with elbow supported on plinth/table (Elastic band only)	Subject performs 90 external rotation against a Elastic band. *Shoulder flexed to 80° with 90° elbow flexion.*	**22**
18. Internal rotation (IR) in sitting with elbow supported on plinth/table (Elastic band only)	Subject performs 90 internal rotation against a Elastic band. *Shoulder flexed to 80° with 90° elbow flexion.*	**22**
19. Scapular protraction	Subject perfroms dynamic scapular protraction	**23/4**

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Additional Stretching and ROM Exercises

Exercise	Instruction	Pg no.
20. Internal rotation positioning	Subject places the involved hand on the buttock or lower back in pain free manner, supported by the other hand	25
21. Longitudinal shoulder traction with an Elastic band wrapped	Subject stands while bending sideways slightly. One end of an Elastic band is wrapped around the wrist while the other end is fixed with the feet allowing tension in the band. Participant relaxes the shoulder and allows the longitudinal traction.	25
22. Pendulum exercise	Participant stands and leans over a chair or a table with the good arm, relaxes the affected shoulder blade and let the arm drop. In this position, performs forward-backward swings and circle swings using body motion.	26

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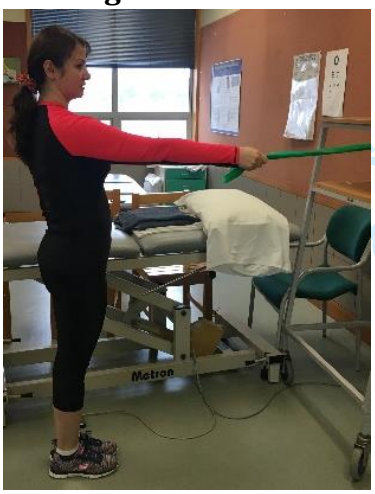
Descriptions of Core Exercises

1. Shoulder extension

1. A. Bilateral Low row:

Starting position: Standing with shoulder flexed at 80° and neutral rotation.
Exercise: Subject performs ***bilateral*** shoulder extension till neutral with elbow flexed.
Resistance type: Theraband

Starting Position



Ending Position

1. B. Bilateral High row

Starting position: Standing with shoulder flexed at 100° and neutral rotation.
Exercise: Subject performs ***bilateral*** shoulder extension till neutral with elbow extended.
Resistance type: Thera band

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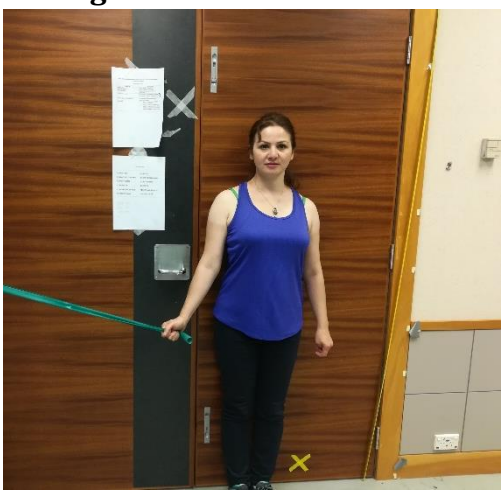
2. Shoulder adduction in scapular plane

Starting position: Standing with shoulder abducted at 80° in scapular plane (Scaption) and neutral rotation.
Exercise: Subject performs shoulder adduction with elbow extended to neutral.
Resistance type: Thera band

Starting Position

Ending Position



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3. Shoulder external rotation (ER)

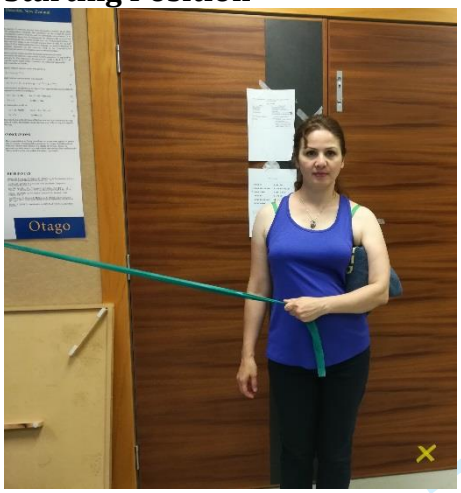
3. A. Shoulder ER in standing with 0 abduction

Starting position: Standing with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.

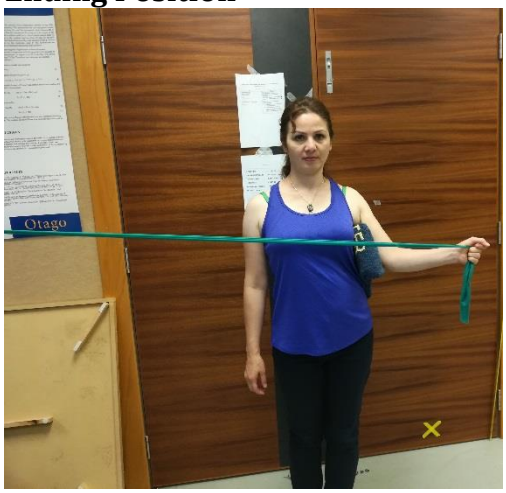
Exercise: Subject performs shoulder external rotation. Please ensure the participant is not compressing the towel; they should be holding it in a relaxed manner.

Resistance type: Thera band

Starting Position



Ending Position



3. B. Shoulder ER in side-lying

Starting position: Side-lying with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.

Exercise: Subject performs shoulder external rotation.

Resistance type: Dumbbell

4. Shoulder internal rotation (IR) in neutral

4. A. : Shoulder IR in standing

Starting position: Standing with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.

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Exercise: Subject performs shoulder internal rotation. Please ensure the participant is not compressing the towel; they should be holding it in a relaxed manner.
Resistance type: Thera band

4. B. Shoulder IR in side-lying (progress only if participant is able to lie down on affected side)

Starting position: Side-lying with towel between arm and trunk to prevent compensatory movements, elbow flexed at 90°.
Exercise: Subject performs shoulder internal rotation.
Resistance type: Dumbbell

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5. Elbow flexion with forearm supination

Starting position: Standing or sitting with arms at side; neutral rotation.
Exercise: Subject performs elbow flexion with forearm supination.
Resistance type: Thera band or Dumbbell

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6. Scapular protraction

6. A. Scapular Protraction in standing:

Starting position: Standing with arms at side; shoulder in neutral rotation; elbows flexed at 90˚.

Exercise: Subject performs shoulder flexion to 80˚, elbow extension, and then scapular protraction

Resistance type: Thera band

Starting Position (Front view)

Starting Position (side view)

Ending Position (front view)

Ending Position (Side view)

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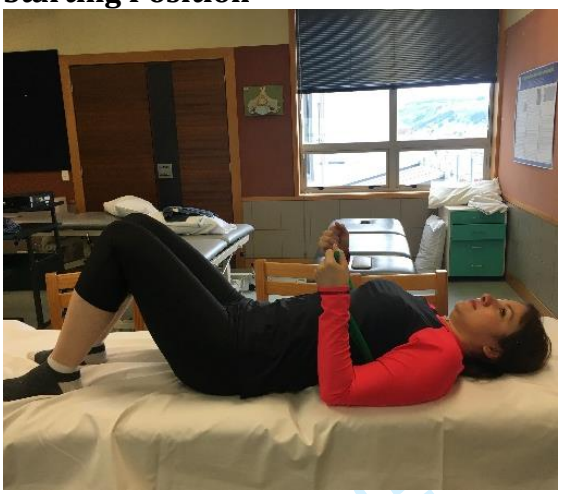
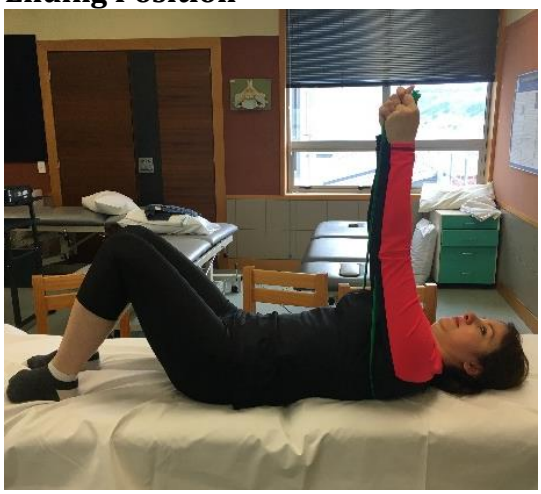
6. B. Scapular protraction in supine

Starting position: Supine lying, arms resting at side in neutral, elbows flexed at 90°
Exercise: Subject concurrently flexes shoulder to 90° and extends elbow, and then protracts scapula against resistance.
Resistance type: Thera band

Starting Position



Ending Position



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7. Scapular protraction in four-point kneeling

Starting position: 4 point kneeling, hands underneath shoulder
Exercise: Subject performs dynamic scapula protraction without compensatory movements at the spine
Resistance type: Body Weight

8. Scapular muscle strengthening (isometric)

Starting position: Prone with arms at side in external rotation
Exercise: Subject depresses and retracts the scapula with elbows slightly flexed and holds the position for 10 seconds. The therapist can provide feedback and ensure participant is not over activating their shoulder extensors and external rotators.
Resistance: None

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9. Posterior Shoulder Stretch

Position: Standing or sitting

Exercise: Subject pulls the elbow passively across the body into horizontal adduction with the opposite arm. Hold the stretch for 10 seconds and repeat.

10. Lateral neck stretch

Position: Standing or sitting

Exercise: Participant pulls the head into lateral flexion with the opposite arm and adds scapular depression to stretch ipsilateral neck.

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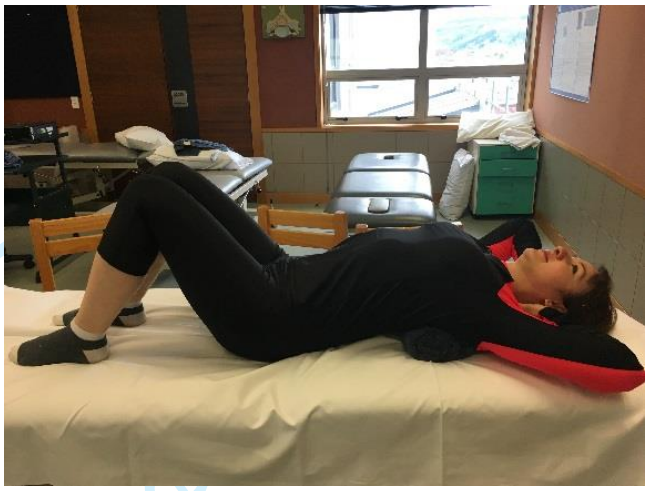
11. Thoracic spine extension stretch

Position: Supine with hip and knee flexed. A towel roll is placed under their upper thoracic spine and participant supports their neck with both hands.

Exercise: Participant allows sustained stretch of thoracic kyphosis by lying on a towel roll and relaxing their spine.



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Additional exercises:

12. Shoulder scaption to 80^0

Starting Position: Standing with feet on the theraband. Shoulder at neutral.
Exercise: Participant performs shoulder scaption to 80˚ while keeping shoulder external rotation (thumb up). Elbow slightly flexed.
Resistance: Thera band or dumbbell

Starting Position

Ending Position

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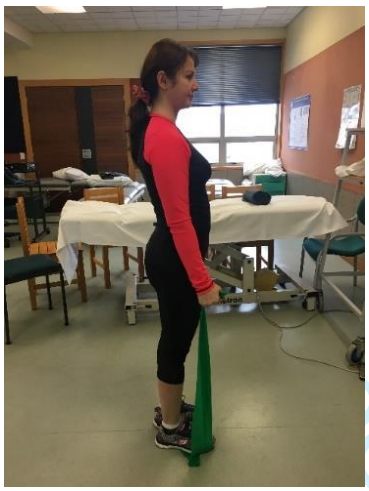
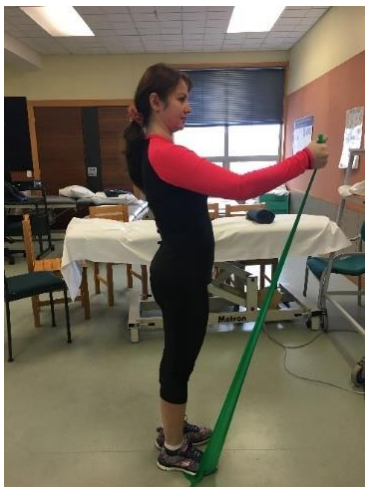
13. Shoulder flexion to 80°

Starting position: Participant is standing with feet on Thera band. Arm at side of body.
Exercise: Participant performs shoulder flexion to 80^0 and external rotation (thumb up) with elbow slightly flexed against light to high resistance.
Resistance: Thera band or dumbbell

Starting Position



Ending Position



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14. Shoulder press via flexion

Starting position: Subject is in sitting position with back supported, arms are in contact with trunk, and elbows are fully flexed.
Exercise: Participant performs full shoulder flexion and elbow extension against resistance.
Resistance: Thera band or dumbbell


15. Shoulder press via abduction

Starting Position: Participant in sitting, with back supported, arm in contact with trunk, and elbow fully flexed, and hand next to the shoulder.
Exercise: Participant performs full shoulder abduction and elbow extension against resistance.
Resistance: Theraband


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16. Horizontal abduction in sitting

Starting position: Participant is sitting with shoulder flexed at 80°. A theraband is attached at shoulder height directly in front of them (theraband is aligned with their forearm).

Exercise: Participant performs horizontal shoulder abduction with nearly extended elbow.

Resistance: Theraband

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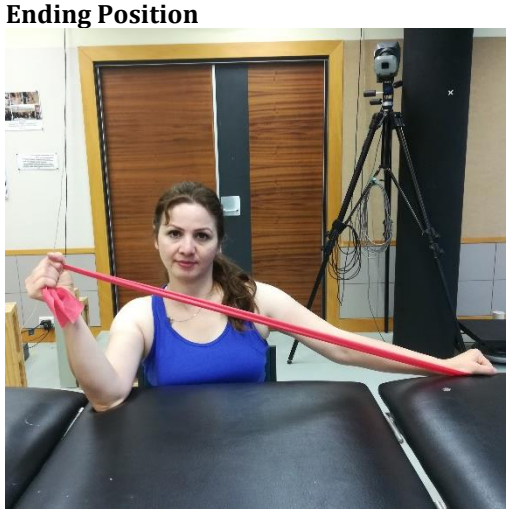
17. External rotation with arm supported

Starting Position: In sitting with elbow supported on a table. Shoulder flexed at 80°, no rotation and elbow flexed at 90°. Thera band is fixed with other hand.
Exercise: Subject performs 90° of external rotation against resistance.
Resistance: Theraband

Starting Position

Ending Position



18. Internal rotation in supported 80^0 shoulder flexion

Starting Position: In sitting with elbow supported on a table. Shoulder flexed at 80° with no rotation and elbow flexed at 90°. Thera band is fixed on the table with other hand
Exercise: Subject performs 90° of internal rotation against resistance.
Resistance: Thera band

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19. Scapular protraction

19. A.: In kneeling push up position

Starting Position: Half plank position (4 point kneeling with hands underneath shoulders and hip in neutral, knee flexed at 90˚)

Exercise: Participant performs dynamic scapular protraction.

Resistance: Body Weight

19. B. Scapula protraction in push-up position:

Starting position: Participant is in push up position with hands directly below shoulder.

Exercise: Participant performs dynamic scapular protraction without spinal compensatory movements.

Resistance: Body weight

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19. C. Half way push up position:

Starting position: Participant is in push up position with hands below shoulder.

Exercise: Participant performs a half way push up with a dynamic scapular protraction at the end of arm extension.

Resistance: Body weight

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20. Internal rotation positioning

Participant places their involved hand on the buttock or lower back in a pain-free manner, supported by the other hand

21. Longitudinal shoulder traction

Standing with trunk side-flexed towards the affected side. A Thera band is wrapped around the wrist and fixed with the feet on one side with tension. Participant relaxes shoulder and allows for longitudinal traction.

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22. Pendulum exercise

Participant leans on a chair or table by bearing weight on the good arm and bending forward at the waist. Participant relaxes the affected shoulder blade and lets it drop. Participant then performs relaxed forward-backward swings and circle swings using body motion (with dumbbell or bottle).

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Table 1 – page 5
	2b	All items from the World Health Organization Trial Registration Data Set	Table 1 – page 5
Protocol version	3	Date and version identifier	Table 1 – page 5
Funding	4	Sources and types of financial, material, and other support	Table 1 – page 5
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 17
	5b	Name and contact information for the trial sponsor	Page 5
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 17
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15 and 16

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Pages 3 to 4
	6b	Explanation for choice of comparators	Pages 3 to 4
Objectives	7	Specific objectives or hypotheses	Page 4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Pages 4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Tables 2 and 3
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Refer to TIDieR checklist
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Refer to TIDieR checklist
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Refer to TIDieR checklist
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Refer to TIDieR checklist
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 13 and 14

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 6
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 6
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 7 to 13

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 13
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 15 and 16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Pages 15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Pages 15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 14
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 16
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 16
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 16 and 17
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Page 16
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 17

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 16
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 16
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N.A.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 16
	31b	Authorship eligibility guidelines and any intended use of professional writers	Page 16
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Not submitted
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

TIDieR Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	12 to 13	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Tables 2 and 3	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Tables 2 and 3	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Tables 2 and 3	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Tables 2 and 3	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Tables 2 and 3	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Tables 2 and 3	

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Tables 2 and 3	
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Tables 2 and 3	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Tables 2 and 3	
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Tables 2 and 3	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Tables 2 and 3	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).