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Effect of exercise-based management on multidirectional instability of the glenohumeral joint: a pilot randomised controlled trial protocol

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ABSTRACT

Introduction: The most commonly recommended treatment for multidirectional instability (MDI) of the shoulder is exercise. Despite this recommendation, there is limited evidence to support the effectiveness of exercise. The aim of this paper is to describe a pilot randomised controlled trial comparing the effectiveness of 2 exercise programmes on outcomes of participants with MDI.

Methods and analysis: Consenting participants between 12 and 35 years, with non-traumatic MDI will be randomly allocated to participate in either the Rockwood Instability programme or the Watson MDI programme. Both programmes involve 1 consultation per week for 12 weeks with a physiotherapist to prescribe and progress a home exercise programme. Outcomes will be assessed at baseline, 6, 12, 24 and 52 weeks. Primary outcome measures include the Melbourne Instability Shoulder Score and Western Ontario Shoulder Index. Secondary outcomes include scapular coordinates, scapular upward rotation angles, muscle strength, symptomatic onset, limiting factor and angle of limiting factor in abduction range, incidence of complete glenohumeral joint dislocation, global rating of change, satisfaction scores, the Orebro Musculoskeletal Pain Questionnaire, adverse events and compliance with the home exercise programme. Data will be analysed on intention-to-treat principles and a per protocol basis.

Discussion: This trial will evaluate whether there are differences in outcomes between the Rockwood and the Watson MDI programmes for participants with MDI.

Ethics and dissemination: Participant confidentiality will be maintained with publication of results. Ethics approval: Faculty of Health Sciences (FHEC12/201).

Trial registration number: ACTRN12613001240730; Pre-results.

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Strengths and limitations of this study

- To the authors' knowledge this is the first pilot randomised controlled trial (RCT) comparing the effect of two rehabilitation programmes for patients with multidirectional instability (MDI), and the first RCT to test this patient population using instability-specific outcomes. Findings are likely to be clinically relevant and useful for physiotherapists treating MDI conservatively.
- Our strict inclusion criteria for MDI participants will increase the likelihood of a more homogeneous MDI group and reduce selection bias.
- Blinding of participants, blinding of assessors of outcomes, detailed standardisation of treatment protocols and a rigorous physiotherapy training and mentoring programme all enhance internal validity of this trial.
- Owing to PhD time limits of the primary researcher and the lack of available data on primary outcome measures to calculate more accurate sample sizes, this study will not be able to reach the sample size required for a definitive RCT. Therefore, it will be a pilot trial to determine the feasibility of a full powered RCT and allow more accurate sample size calculations.
- Physiotherapists remain unblinded to the intervention they are delivering which could introduce therapist bias.

INTRODUCTION

Multidirectional instability (MDI) is symptomatic glenohumeral joint subluxation or dislocation occurring in more than one direction.[1–3] There is general agreement that the aetiology of this condition is due to repetitive microtrauma imposed on a congenitally lax and redundant joint capsule.[3–7] People with MDI typically have reduced scapular upward rotation, an imbalance of muscle strength and suboptimal neuromuscular control of shoulder function when compared with normal controls.[3 6 8] People with MDI can present with a variety of symptoms ranging from reports of vague shoulder pain to daily occurrences of symptomatic subluxations and dislocations with activities of daily

living.[1] Depending on the severity of the condition, MDI can adversely affect quality of life due to pain, activity avoidance, occupational restrictions or reduced sporting performance.[1 4] Shoulder instability is one of the most common shoulder pathologies,[9] especially in the younger sporting population.[10–13] MDI is a subset of atraumatic shoulder instability[1 14] and although prevalence data are lacking,[15] experts report that the condition is becoming more recognised in the clinical setting.[16]

The most commonly recommended treatment for MDI is exercise-based management.[1–4 6 17 18] This approach is based on the mechanism of strengthening the scapular and rotator cuff muscles, compensating for the lack of passive stability and thereby assisting in active control of the shoulder.[2 3 6] Recent systematic reviews have found some evidence supporting the effectiveness of exercise for MDI; however, the quality of evidence was very low.[19 20] Issues identified in these reviews included a high level of bias across the included studies, heterogeneous patient samples, poorly defined exercise protocols and a lack of baseline outcome measures. On the basis of this literature, therapists have very low-quality evidence on which to base their treatment choices.

To date, the Rockwood Instability programme is the only published MDI protocol that outlines enough detail for physiotherapists to replicate in the clinical setting.[17] Rockwood and Burkhead reported that 87% of their MDI participants had a good-to-excellent outcome with their programme; yet, their sample size was small, outcomes measures were not specific or sensitive to measuring change in the instability population, and were only taken retrospectively.[19 20] In addition, the Rockwood programme has no specific scapular muscle retraining and lacks exercise drills in higher degrees of shoulder elevation.[17]

The Watson MDI programme[21 22] has been developed for the conservative treatment of MDI. The programme has been shown to significantly improve scores on the Melbourne Instability Shoulder Score (MISS) and the Western Ontario Shoulder Index (WOSI) for a group of MDI participants in a pre-post trial design.[23] The Watson programme focuses on re-establishing patient-specific scapular control, typically scapular upward rotation, prior to any rotator cuff or deltoid strengthening. Scapular control is emphasised throughout the programme and exercises progress into functional and sports-specific ranges.

Currently, no published RCTs have compared the effect of one standardised exercise programme against another, nor have functional and instability-specific outcomes been used to measure change in this population. The aim of this paper is to describe the design of a pilot randomised controlled trial (RCT) comparing the Rockwood Instability programme with the Watson MDI programme for people with MDI. We hypothesise that the Watson MDI programme will produce clinically and statistically better outcomes over the Rockwood programme at the primary 12-week time point, due to its focus on achieving and maintaining scapular control and progressing exercises into functional ranges.

This trial may assist in establishing guidelines for exercise prescription, improve outcomes for people with MDI and lay foundations for larger RCTs to evaluate exercise for shoulder instability.

METHODS AND ANALYSES
Reporting of this protocol will adhere to the Standard Protocol Items for Randomised Trials (SPIRIT)[24] and CONSORT[25] statements.

Study aims
The primary aim of this trial is to compare the relative effectiveness of the Rockwood Instability programme and the Watson MDI programme on functional and instability-specific outcomes, scapular measures and muscle strength of participants with non-traumatic MDI.

Study design
This will be a multicentre pilot RCT. An overview of the trial procedure is outlined in figure 1. Participants will be randomly allocated to one of two 12-week exercise programmes, the Rockwood Instability programme or the Watson MDI programme. The fundamentals of both programmes have evidence of beneficial effects on people with MDI,[7 17 23 26] thus clinical equipoise is maintained.[27] Outcome measures will be taken at baseline, 6, 12, 24 and 52 weeks postrandomisation. The primary comparison for this study will be at the 12-week time point.

After the 12-week outcome measures have been obtained, participants who score less than the minimal clinically important difference (MCID) on both primary outcome measures (5 points on the MISS and 10.4% on the WOSI) will have the option to swap to the other exercise programme for a subsequent 12 weeks. The feasibility of this study would be limited without an optional cross-over design as referrers expressed a reluctance to refer patients with this complex pathology into the trial without the option of receiving the alternative treatment programme, should they score less than the MCID on both primary outcomes. The authors acknowledge that this study design is not a true cross-over design due to the second phase of treatment being optional and the absence of a washout period.[28] A true washout period is almost impossible to implement in any exercise-based study due to the central effect of motor learning;[29 30] however, as the threshold for cross-over is to score less than the MCID on both primary outcome measures, it can be considered that the participant's functional measures are close to baseline[31] and the exercise programme was of little benefit. Owing to the cross-over, the 12-week follow-up will be the primary outcome point. The 24-week and 52-week follow-ups will be secondary outcome points of this study. Confounding due to any carry over effect will be minimised by detailed reporting of the cross-over procedure.[28]
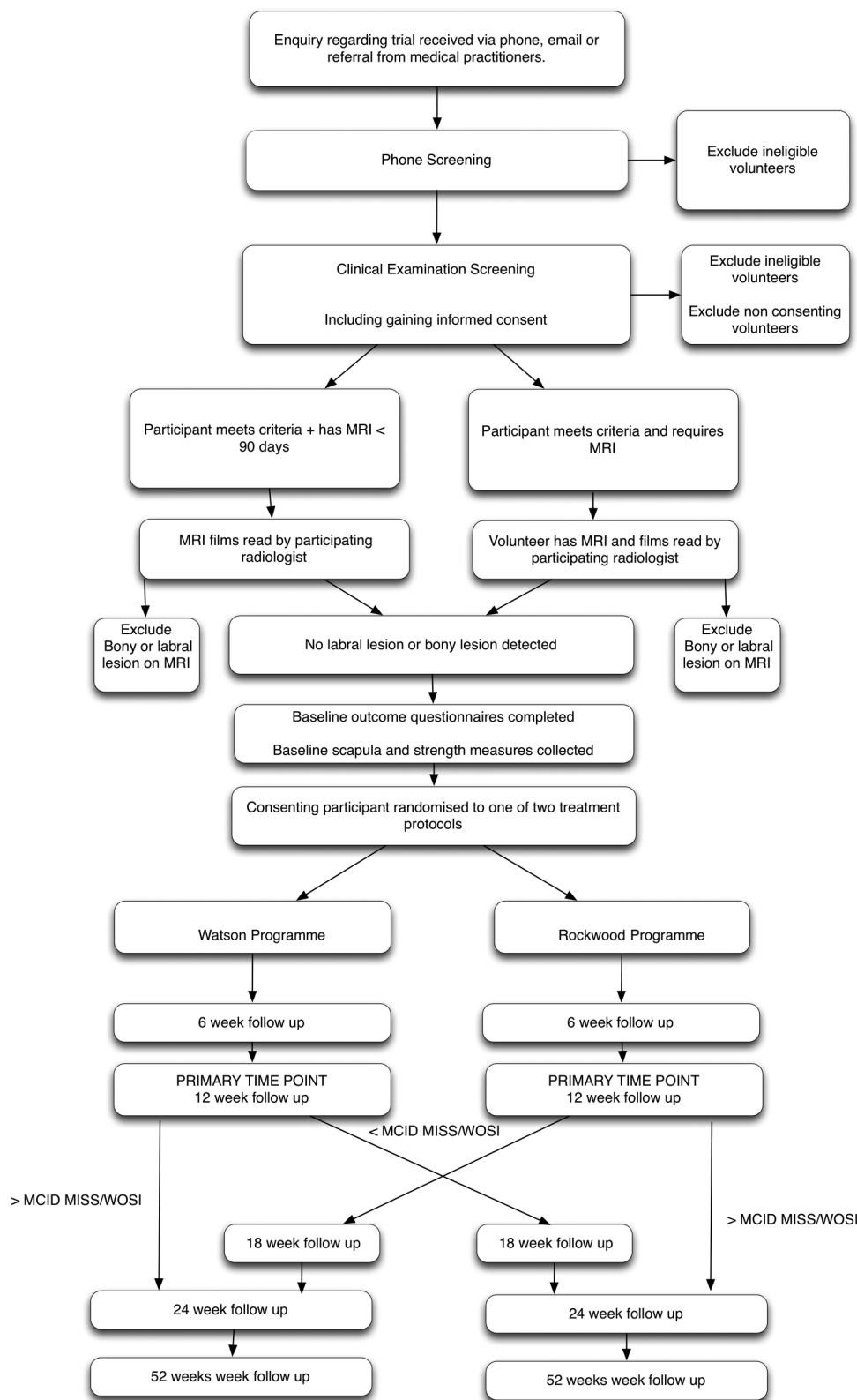
Figure 1 Overview of trial procedure. MCID, minimal clinically important difference; MISS, Melbourne Instability Shoulder Score; WOSI, Western Ontario Shoulder Index.

Sample size

The sample size required for a definitive RCT would be a total of 328 participants (164 in each group) to detect a MCID of 5 points on the MISS outcome measure, assuming a SD of 16 (α of 0.05 and a power of 80%).[32 33] Only one pre-post study has reported the SD for the MISS[32] and none are reported for the WOSI. Therefore, the proposed study will be a pilot study to

determine the feasibility of a fully powered RCT, and to clarify the sample size calculation. Recruitment for this study started in January 2014.

Setting and recruitment

The treatments will be conducted at one of seven private physiotherapy practices that are part of the LifeCare Health network throughout metropolitan Melbourne, Australia. Participants will be sought via referrals from orthopaedic surgeons, sports physicians and physiotherapists. Potential referrers will be informed of the trial and the referral process via formal meetings, personal correspondence, department lectures and trial information sheets.

Eligibility and screening

Participants

Participants included in this trial will be between the ages of 12 and 35 years[34] with non-traumatic, symptomatic shoulder instability in at least two directions[1][3] and no labral or bony lesions detected on MRI. Table 1 summarises the inclusion and exclusion criteria.

Phone screening

Potential participants will initially undergo a preliminary screening for eligibility via telephone. The purpose of the phone screening is to eliminate participants who are clearly ineligible. In particular, the assessor will carefully question potential participants to determine if any significant history of trauma to the shoulder exists. Participants will be excluded if they report any significant history of trauma to the affected shoulder as participants with a significant history of trauma are more likely to have a structural lesion and predominantly unidirectional pathology.[14][35] A significant history trauma was defined as contact with an external object (such as a fall, impact with another body or surface) with lock out of the glenohumeral joint and conscious awareness by the participant of a sudden onset of pain.[18]

Clinical examination screening

Participants found to be potentially eligible after the phone screening will be invited to attend a subjective and physical examination by one of the three experienced shoulder physiotherapists. Table 2 outlines the components of the clinical examination. Additional details and rationale for each clinical examination component are outlined in the online supplementary appendix 1. For the purposes of this trial, MDI will be defined as symptomatic instability in at least two directions.[8][52][53] To be positive for instability, the participant must have apprehension (which may include muscles spasm or guarding) on testing and not just pain or signs of laxity.[38][44][54]

Signing of consent forms

On meeting all of the inclusion criteria in the clinical examination, participants will again be informed of the nature of the trial and asked to sign a consent form. In addition to signing their own consent form, participants under the age of 18 years will need to have their parent or guardian sign a separate consent form to participate in the study (see online supplementary appendix 2). At the time of signing the consent form, potential participants will be informed that inclusion in the trial is on the provision that their MRI meets the inclusion criteria.

MRI

On meeting the assessment criteria in the clinical examination screening, the potential participant will be invited to have an MRI to investigate the presence of any structural lesion of the affected shoulder. Participants with a bony lesion (Hill Sachs or bony Bankart) or labral lesion (SLAP, labral Bankart) will be excluded from the trial as they are more likely to have a history of major shoulder trauma, and predominantly unidirectional pathology,[14][18] and better outcomes with surgical stabilisation.[6][14][17][18] All MRI films will be read and reported on by a senior radiologist. Participants will be informed of their MRI results by the primary researcher (SAW) by phone, and if eligible, have their first treatment session arranged at their closest participating treatment centre.

Randomisation and allocation

Eligible participants who provide written consent will be randomised into the Rockwood Instability programme or the Watson MDI programme. To ensure allocation concealment, an offsite randomisation schedule will be used. The randomisation schedule will be prepared in advance by a researcher at La Trobe University (AJH) who will have no contact with any participants throughout the trial and will not be involved in the recruitment, screening, assessment, enrolment or treatment process. The randomisation sequence (with random block sizes) will be generated using a web-based randomisation programme (http://www.randomisation.com) with the sequence transferred onto a computer spreadsheet. Randomisation will be stratified for the treating practitioner. Allocation of participants in accordance with the randomisation schedule will be undertaken by the same researcher at La Trobe University (AJH) who will be the only person with access to the allocation spreadsheet during the trial. To enrol a participant, the primary researcher (SAW) will email the consenting participant's name, date of birth and treating physiotherapist to the La Trobe University researcher (AJH). These details will be entered into the allocation spreadsheet and the next treatment allocation and participant identification number with be emailed directly to the treating physiotherapist.

Treating physiotherapists and treatment fidelity

Treating physiotherapists will have worked in private practice for at least 2 years and be engaged with an ongoing clinical mentoring programme. An additional

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Initial phone screening	
Reports of shoulder region discomfort, pain or apprehension/guarding with movement	History of significant trauma*
Willingness to participate in a 12-week exercise programme	History of glenohumeral dislocation that requires relocation†
Age between 12 and 35 years inclusive	Prior surgical history of the affected shoulder(s)
	Unable to understand and follow instructions in English
MRI	
Normal MRI	Bony lesion (bony Bankart, Hill Sach's) or fracture
Normal anatomical variant accepted: labral deficiency, labral recess, glenoid dysplasia	Labral lesions (SLAP, labral Bankart)
Minor pathologies accepted: bursitis, small rotator cuff tears, labral 'fraying'	Full thickness rotator cuff tears
	Full thickness bicep tear
	Frank labral tears
	Contraindications to MRI (eg, pacemaker, claustrophobia, pregnancy)
Clinical examination screening	
Clinically diagnosed MDI, with symptomatic instability in *at least 2 directions.*	Non-correctable volitional instability
The diagnosis of MDI must be defined by apprehension or guarding with the following tests:	Non-compliance
A positive‡ sulcus sign	Neurological motor deficit
AND	Instability due to UMN or LMN lesion
For one direction, at least 2 out of 3 positive for the following tests:	Ehlers-Danlos syndrome/Marfan's syndrome
▶ Draw test adducted	Shoulder pain that is predominantly due to cervical dysfunction including:
▶ Draw test abducted	Cervical spine somatic referred pain
▶ Apprehension test	Cervical spine radicular pain
The 'effect of manual correction on scapula biomechanics' MUST symptomatically improve a participant's abduction range of motion by a minimum of 20°, significantly reduce a participant's pain or guarding in abduction, or improve a participant's strength on an isometric test[21] (table 2 and online supplementary appendix 1).	Cervical spine radiculopathy
	TOS

*Significant trauma defined as contact with an external object (such as a fall, impact with another body or surface) with lock out of the glenohumeral joint and conscious awareness by the patient of a sudden onset of pain.
†Relocation defined as MUA by a health professional or force applied externally by patient or other person at the time of injury to relocate the glenohumeral joint.
‡To be positive for instability the participant must have apprehension (which may include muscles spasm or guarding) on testing and not just pain or signs of laxity.
LMN, lower motor neuron lesion; MUA, manipulation under anesthetic; TOS, thoracic outlet syndrome; UMN, upper motor neuron lesion.

2-day training programme will occur for all treating physiotherapists led by LW and the primary researcher (SAW) and include group discussions and portions of experimental learning as outlined by Main *et al*,[55] for training physiotherapists delivering interventions. For the duration of the trial, quarterly workshops will be undertaken involving all treating physiotherapists to review specific cases in the context of the treatment programmes.

Trial physiotherapists will be provided with a 364 page treatment manual outlining the trial protocol, the requirements of trial physiotherapists and the details of each treatment programme. Both programmes have been standardised via detailed flow charts, adhering to guidelines outlined by either Burkhead and Rockwood[17] or Watson *et al*.[21 22] The flow charts contain guidelines for exercise prescription and progressions and algorithms for clinical decision-making. The treating physiotherapist will also be required to complete electronic clinical notes at each treatment session to document the assessment findings, clinical decision-making rationale, exercises prescribed and any adverse events attributed to the exercise programme. These measures adhere to the recommended requirements for ensuring treatment fidelity.[55]

To evaluate treatment integrity, the clinical notes for both programmes will be reviewed at 3, 6 and 12 weeks to ensure that all documentation is standardised, legible and complete. The review of clinical notes will be carried out by three of the researchers (JJF, TP, RL), who are not blinded to the treatment allocation of participants.

Treatment programmes

Two different 12-week exercise programmes will be compared (table 3). All participants will attend 1 session of

Table 2 Clinical examination screening

Clinical examination components	
History of presenting condition	A full history of the patient's condition will be recorded, including frequency, aetiology, direction and severity of subluxations.[36]
The presence of volitional instability	Patients who present or report a predominance of volitional instability (voluntarily sublux their glenohumeral joint on a regular basis) will be excluded, as treatment for this type of instability primarily focuses on counselling to cease the habitual subluxation.[14]
Diagnosis of MDI with instability tests	Diagnosis must be based on: 1. A positive sulcus sign.[37] The sulcus test is a valid and reliable test for inferior laxity[38] with a fair to good interexaminer reliability (60–85%).[38–40] AND 2. For at least one direction (anterior and/or posterior), a positive result for *at least 2 out of 3* following tests: ▶ Anterior and posterior draw tests (10–30° abduction)[37 41] ▶ Anterior and posterior draw tests in (80–120° abduction)[37 41] ▶ Anterior[38 42 43] and posterior apprehension tests[44 45]
Effect of manual correction on scapula biomechanics	The 'effect of manual correction on scapula biomechanics' is defined as the effect that therapist-assisted manual assistance of the scapula has on an objective test.[21 46 47] The effect of manual correction of the scapula will be assessed via active abduction, active flexion and isometric external rotation. In order for participants to be eligible, the effect of manual correction of the scapula must symptomatically improve abduction range by a minimum of 20°, significantly reduce pain or guarding in range or improve strength on an isometric test. Poor scapular positioning through range and altered muscle patterning are predominant characteristics of non-traumatic MDI.[3 14] An immediate improvement with manual assistance is likely to confirm the presence of these characteristics and indicate that the participant is appropriate for treatment with exercise.
Upward rotation test	To be eligible, participants must be able to perform a minimum of 5 repetitions of scapular upward rotation in standing position without the reproduction of any cervical spine pain or headaches.[21] As both rehabilitation programmes require the participant to perform some scapular strengthening, inability to perform this test indicates that they are not appropriate for either exercise programme and may have a predominant cervical spine component to their pathology.
Generalised ligament laxity	The Beighton Scale[48] will be used to assess generalised ligament laxity and has a good to excellent reliability.[49]
Cervical spine examination	Potential participants with a positive Spurlings test for cervical radiculopathy and radicular pain with be excluded.[50 51] The test has a high sensitivity (92%)[51] and specificity (93–95%)[50 51] for cervical radiculopathy.

MDI, multidirectional instability.

60 min and 11 sessions of 30 min each where they will be assessed/reassessed and prescribed/progressed with a specific set of exercises. Participants in the both groups will be instructed to perform their exercises at home and/or in their gym. Equipment for the relevant programme will be supplied. Resistance bands (Theraband) for both groups will be cut to a length of 1.5 m. Each participant will be provided with an exercise logbook, in which the participant will record the date of every home session. The treating physiotherapist will fill out these log books with the relevant programme exercise parameters at each session.

The Rockwood programme
The Rockwood programme focuses on concurrently strengthening all three parts of the deltoid, the internal and external rotators of the glenohumeral joint in two phases. Phase 1 involves five exercises for the rotator cuff and deltoid using a set of six rubber Therabands with varying resistances of 0.5, 1.0, 1.5, 2.0, 2.5 and 3 kg. The second phase of strengthening begins when the participant has progressed through all the resistance bands. The participant is then instructed to perform the same exercises as of phase 1 with a 4 kg weight using a pulley kit. The weight is then progressed in increments of 1 kg. Therabands or weight resistance is progressed once the participant reports that the current resistance is 'relatively easy'.[17] All exercises must be pain free to perform.

Watson MDI programme
The Watson programme is primarily based around maintaining good scapular control through all stages of the programme.[21 22] Most stages have a scapula phase that the participant has to master before moving on to the arc of motion phase. Stage 1 is the foundation phase

Table 3 Treatment programmes

Rockwood programme	Watson programme
Focus: concurrent rotator cuff and deltoid strengthening and push ups for scapular stability. Majority of exercises performed at 0° of elevation. *Aims and exercise drills* **Phase 1**: aim: strength through progressive levels of Theraband resistance Load: tan, yellow, red, green, blue Theraband Patient standing ▸ ER (0–45° ER) at 0° abduction ▸ IR (0–45° IR) at 0° abduction ▸ Extension row to 45° ▸ Flexion ▸ Short lever abduction to 45° ▸ Wall, knee or full push ups (no Theraband resistance) **Phase 2**: aim: strength through resistance with weights Load: 4–5–6–7–8–9–10–11 kg with weight and pulley system Load begins at 4 kg Progresses in 1 kg increments 9 kg maximum for females, 11 kg maximum for males Patient standing ▸ ER (0–45° ER) at 0° abduction ▸ IR (0–45° IR) at 0° abduction ▸ Extension row to 45° ▸ Flexion ▸ Short lever abduction to 45° Wall, knee or full push ups (no Theraband resistance) Addition of shoulder shrug holding weight anteriorly with both hands Not all exercises need to be progressed at the same time and participants may be on a different band or weight/resistance for different exercises.	Focus: retraining specific scapular faulty biomechanics prior to any rotator cuff/deltoid strengthening. Exercises progress into functional/sports-specific ranges. **Stage 1**: *scapular phase*: aim: retrain scapular control Load: 0–0.5–1 kg ▸ Scapular upward rotation/elevation drills in standing *Arc of motion phase*: aim: controlling arcs of motion (0–45°elevation) Load: yellow–red Theraband Patient standing ▸ Extension rows (from 45° flexion to neutral) ▸ ER (0–45° ER) at 0° abduction ▸ IR (0–45° IR) at 0° abduction **Stage 2**: aim: building posterior GHJ muscle bulk Load: green Theraband/1–2 kg Patient standing ▸ Bent arm rows ▸ Side lying ER ▸ Standing Theraband rows **Stage 3**: *scapular phase*: aim: scapular control in sagittal plane Load: 0–0.5–1–2 kg ▸ Scapular upward rotation/elevation drills in standing (sagittal plane) *Arc of motion phase*: aim: sagittal plane (flexion control) in 0–90° elevation Load: yellow–green Therabands/1–3 kg Patient standing ▸ Flexion with Therabands and weights **Stage 4**: *scapular phase*: aim: scapular control at 90° of elevation Load: red–green Therabands ▸ Standing row at 90° of elevation *Arc of motion phase*: aim: controlling arcs of motion (45–90° elevation) Patient standing Load: yellow–green Therabands/2–5 kg ▸ ER at 90° ▸ IR at 90° ▸ Flexion at 90° **Stage 5**: aim: specific deltoid strengthening Load: 1–4 kg+ Patient standing ▸ Bent over rows ▸ Supine and sitting flexion ▸ Short lever abduction 45–60° **Stage 6**: aim: sports-specific/functional control and strength Load: depends on participant's requirements Drills mimic specific sporting or functional activates Part practise to full practise
Dosage All exercises 5 repetitions with a 5 s hold at the end range of the exercise. All exercises are performed twice a day	Typically start with a recruitment dosage for motor relearning (3×20, 2×day),[56] followed by an endurance dosage (3×10–15, 2×day), then strength dosage in later stages (4×8–12, every second day).[57] For most exercises, repetitions are held for 3 s.

Theraband (Theraband Hygenic Corporation, 1245 Home Ave, Akron, Ohio 44310, USA).
ER, external rotation; GHJ, glenohumeral joint; IR, internal rotation; RC, rotator cuff.

and focuses on retraining faulty scapular biomechanics. The clinical assessment determines the exact scapular mechanics that the patient must retrain and maintain throughout the programme,[21] and most commonly incorporates scapular upward rotation.[2 21] The stages progress via an increase in load and an increase in range of glenohumeral joint elevation. The final stages incorporate functional and/or sports-specific exercises. Progression to a more difficult exercise or to the next stage of the programme is determined by the participant reaching specific exercise called 'goals'. Goals are a combination of meeting a certain number of exercise repetitions with a specified load, while maintaining adequate scapular control. The trial physiotherapist must observe the participant performing one set of each drill while maintaining adequate scapular stability (eg, maintaining scapular upward rotation and avoiding downward rotation or anterior tilt) to determine if they are ready to progress. Details of each stage and every goal of the Watson programme have been published.[21 22]

Participant education and other co-interventions
All participants will be educated regarding the nature of their pathology, the rationale for exercise treatment, the importance of compliance to their home programme, timeframes, goal setting and avoiding aggravating or unsafe activates. Participants will be specifically educated on the difference between pain and muscle fatigue in response to their home programme. If a participant reports a significant increase in pain during or after exercises, the trial physiotherapist can regress or alter the exercise as per programme guidelines. Manual treatment and management of glenohumeral joint inflammation are other co-interventions that may be implemented (see online supplementary appendix 3).

Outcome measures
The 12-week outcome point will be the primary outcome point. The majority of outcomes will be assessed via a set of self-administered questionnaires, that will be delivered to the participants via email as a secure online link, or as a hard copy booklet mailed to participants, based on participant preference. The set of questionnaires will be sent to the participants 1 week prior to their first physiotherapy session (baseline time point) and at each of the follow-up time points (6, 12, 24 and 52 weeks). Participants who cross-over will also be sent the self-administered questionnaires at 6 and 12 weeks into the new intervention (18 and 24 weeks postrandomisation) and at 52 weeks postrandomisation. The results of these questionnaires will be marked only with the participant's identification number to ensure data confidentiality.[58] The remaining outcomes will be measured by a researcher blinded to the participant's treatment allocation and include shoulder strength, scapular upward rotation angles, scapular coordinates and symptomatic onset in abduction range. These outcomes will be taken at baseline and 12 weeks

postrandomisation. The outcomes to be measured in the trial are summarised in table 4. The protocol for missed physiotherapy appointments and outcome time points is outlined in the online supplementary appendix 4.

Primary outcome measures
The Melbourne Instability Shoulder Scale
The MISS is a self-administered tool, with a total of 100 points, divided into four categories that assess pain, instability, function and occupational and sporting demands. The total score for the MISS can range between 0 and 100 points (where 0 represents no deficit and 100 the worst). The total score will be converted into as percentage of a normal healthy shoulder[32] which may be more meaningful for clinical interpretation.[61 80] The MISS is a valid and reliable tool, with an ability to accurately highlight the severity of a person's instability,[59] and has also been shown to have a good test–retest reliability.[32]

The Western Ontario Instability Index
The WOSI is a self-administered tool with 21 items over the four domains of physical symptoms, sport/recreation/work, lifestyle function and emotional function.[80] Each question results in a number between 0 and 100, with a total score between 0 and 2100 points (where 0 represents no deficit and 2100 the worst). The total score will be converted into a percentage of a normal healthy shoulder.[61 80] The WOSI has been shown to be responsive[59] and sensitive to change as well as being a reliable and valid tool, with a high test–retest reliability.[61]

Data integrity
Questionnaire data completed via the online link will be automatically scored and downloaded into a computer spreadsheet via Survey Monkey.[81] Questionnaire data completed in hard copy format, once returned via mail, will be entered automatically into the computer spreadsheet by a researcher blinded to the group allocation of the participant. Data will be checked for omissions and outliers to identify potential data entry errors. Data will then be exported from the computer to SPSS software program for analyses.

Blinding
For trial validity, the participants will not be informed of which programme they are allocated to complete.[82] A lack of blinding can influence participant response to treatment, compliance, use of co-interventions and risk of dropouts.[83] Participants in both groups will receive the same number of treatment sessions with the same treatment duration (1 session of 60 min initial consultation and 11 sessions of 30 min follow-up consultation) and both undertake a home exercise programme. The assessor collecting the scapular and strength measures at baseline, 6 and 12 weeks will also be blinded to the

Table 4 Outcome measures

Outcome measure	Explanation	Time point for assessment
Primary outcomes		
The MISS	Valid and reliable with good test–retest reliability[32 59 60]	Baseline, 6, 12, 24 and 52 weeks postrandomisation*
The WOSI	Responsive and sensitive to change[59] Reliable and valid with a high test–retest reliability[61]	
Secondary outcomes		
Scapular coordinates	Taken at rest, 90° and EROM GHJ abduction[62]	Baseline and 12 weeks postrandomisation
Scapular upward rotation	Measured at 30°, 45°, 60°, 90°, 120°, 135°, EROM of GHJ abduction with an inclinometer which is valid and reliable tool for measuring upward rotation[63]	Baseline and 12 weeks postrandomisation
Scapular and GHJ muscle strength	Assessed with a hand-held dynamometer which is a valid and reliable tool to measure shoulder strength[64–66]	Baseline and 12 weeks postrandomisation
Symptomatic onset, limiting factor and angle of limiting factor in abduction	Onset=the angle at which the participant first reports their symptoms in active abduction Limiting factor=reason for limit (p1/p2, r1/r2, apprehension)	Baseline and 12 weeks postrandomisation
Incidence of complete glenohumeral joint dislocation	The number of times a participant reports an episode of full glenohumeral joint dislocation (if any)	Baseline, 6, 12, 24 and 52 weeks postrandomisation*
Global rating of change	7-point Likert scale from 'completely recovered' to 'vastly worsened'.[67 68] Reliable, responsive and valid[68 69]	Baseline, 6, 12, 24 and 52 weeks postrandomisation*
Patient satisfaction score (with treatment and results)	5-point Likert scales from 'very satisfied' to 'very dissatisfied'[70–72] Good reliability, validity and responsiveness[73 74]	Baseline, 6, 12, 24 and 52 weeks postrandomisation*
The Orebro Musculoskeletal Pain Questionnaire	Measures psychosocial risk factors[75 76] Valid and reliable tool for predicting recovery[77 78]	Baseline, 6, 12, 24 and 52 weeks postrandomisation*
Compliance with home programme	Compliance score given by trial physiotherapist from sessions 2 to 12. The sum of scores from sessions 2 to 12 used to calculate a total compliance score at the end of the 12-week programme	Recorded in the clinical notes from sessions 2 to 12
Adverse events	Classified as minor, significant or serious (see online supplementary appendix 5)	Recorded in the clinical notes for every session and formally assessed at 6, 12, 24 and 52 weeks postrandomisation*
Success of blinding	Participants will be asked if they were aware of what programme they received. Important to determine if protection was maintained against participant expectation effects[79]	12 weeks postrandomisation

A detailed explanation of secondary outcomes measures is outlined in the online supplementary appendix 5.
*Any participant who scores less than the MCID on both primary outcomes measures after the primary 12-week time point will be offered the alternative intervention for a subsequent 12 weeks. For these participants, outcomes measures will also be taken at 6 and 12 weeks into the new intervention (18 and 24 weeks postcross-over) as well as 52 weeks postrandomisation.
EROM, end range of motion; GHJ, glenohumeral joint; HEP, home exercise programme; MCID, minimal clinically important difference; MISS, Melbourne Instability Shoulder Score; WOSI, Western Ontario Shoulder Index.

treatment allocation of participants. Owing to the nature of the trial it is not possible to blind the treating physiotherapist to the programme they are delivering. However, the treating physiotherapists will be instructed to treat participants in both groups with the same degree of rigour, enthusiasm and optimism.

Data analyses

The primary method for data analyses with be performed using intention-to-treat principles, including post cross-over. This means that all participants will be analysed according to their randomised groups regardless of whether they crossed over or not.[84 85] Secondary

data analyses will be performed on a per protocol basis approach where participants will be analysed dependent on the treatment they actually receive, regardless of which treatment arm they were randomised to.[85]

Data analysed will focus on detecting the between-group treatment and within-group treatment effects (with effect sizes and 95% CIs) at each of the follow-up time points.[86] Primary analyses for the MISS, the WOSI, scapular coordinates, scapular angles, strength, angle of symptom onset in abduction, limiting angle in abduction, compliance with the home programme and the Orebro will be performed using linear mixed models, due to its advantages in modelling repeated measures over time.[87] Mixed models will be adjusted for baseline scores. If the sample size is inappropriate for the use of a linear mixed models,[88] repeated measures ANCOVA will be used and adjusted for baseline score.[89]

At each follow-up time point, participants will be dichotomised according to whether they achieved the MCID or not on the MISS and the WOSI.[90][91] The difference between the proportions of participants who experience an improvement greater than the MCID in the two groups will then be analysed with risk ratios, risk differences and numbers needed to treat.[83][92][93] using intention-to-treat principles. Statistical significance will be evaluated using χ^2 analyses. For these purposes, the MCID will be defined as above 5 points on the MISS[32] and above 10.4% on the WOSI.[94]

Global rating of change and satisfaction scores will be measured with Mann-Whitney U tests.[86] The reason for limit in abduction and incidence of dislocation will be analysed with χ^2 tests.[95] Adverse events, medications taken, co-interventions and success of blinding will be recorded.

DISCUSSION

In this pilot RCT, we aim to compare the Rockwood Instability programme to the Watson MDI programme for people with non-traumatic MDI. We hypothesise that the Watson programme will produce clinically and statistically better outcomes over the Rockwood programme at the primary 12-week time point, due to its focus on achieving and maintaining scapular upward rotation control and progressing exercises into functional ranges. Downward rotation of the scapula reduces joint congruency and therefore increases the potential for glenohumeral joint instability.[1][96] People with MDI typically present with scapular downward rotation at rest[2] and an exercise programme focusing on scapular upward rotation has been shown to significantly improve the strength of the scapula upward rotators and functional outcome measures of patients with MDI.[23] While the Rockwood programme does involve one scapula shrug exercise in phase 2, scapular position and control is not emphasised as a primary component. As the scapulothoracic joint is the base of support from which the

glenohumeral functions,[97] and rehabilitation often emphasises gaining proximal control in the kinetic chain initially, a failure to address this early on may be unfavourable. In addition, the majority of the Rockwood exercises are not executed in functional ranges of motion. As strength output is position specific,[98] this may be unsuitable for activity or sports-specific requirements.

We will be using several strategies to maximise and assess treatment integrity for both groups to ensure our hypothesis is tested in an unbiased manner. A comprehensive treatment manual, teacher led training of physiotherapists, quarterly workshops, the use of standardised participant information sheets (see online supplementary appendix 6) and treatment programme flow charts are methods chosen to ensure that all participants receive treatment that is standardised, accountable and reproducible.[99][100] The algorithmic lay out of the treatment flow charts does permit some flexibility of exercise prescription, to ensure that treatment is relevant and specific, or at least safe and pain free for the participant.

A definitive diagnosis of MDI is challenging due to a variety of shoulder classification systems.[2][54] Our definition and diagnostic criteria for MDI for this trial was developed based on convergence of validity principles. George and Delitto[101] described this approach as being useful in developing classification systems where no one study or research design can provide complete validation. They defined convergence of validity for a classification system as "…evidence supporting or refuting the system (being) gathered from different sources and from the use of different methods. In the best case scenario, these sources converge and indicate similar meanings of the underlying constructs being studied" (refs. 101 and 102, p. 312). For the purpose of this trial, these principles refer to expert opinion, research on biological plausibility as well as diagnostic tests and strategies for minimising false-positive diagnosis.

In this trial, we have defined MDI as symptomatic instability in at least two directions, which is consistent with expert opinions.[1][2][4][5][7][8][18][54][103–105] It has also been specifically recommended[54] that future studies investigating MDI should (1) consider aetiology of instability as a key element for classification[54][106] (2) clearly state their inclusion criteria for MDI and whether the patient population has instability in two or three directions,[54] (3) ensure that the sulcus sign produces symptomatic instability to be positive, and not just show signs of laxity[54] and (4) ensure reproducible and reliable assessment between assessors for participant inclusion.[54] This trial will address these criteria when making the diagnosis of MDI as outlined in this protocol.

The validity of MDI as a clinical entity is supported by research on biological plausibility. Glenohumeral joint stability is the ability to maintain centring of the humeral head at rest and through motion[57][107] and depends on passive capsular restraints as well as dynamic muscular

control.[108] Studies have shown that patients with MDI have significantly larger joint capsules,[109] significantly larger rotator intervals[109 110] and altered muscle patterning[8 105 111] when compared with normal controls. The general agreement that MDI is, in part, due to capsular redundancy,[3–7] is supported by these pathoanatomical findings. On the basis of this biological plausibility, tests that evaluate the integrity of the passive restraints of the shoulder should be employed for the diagnosis of MDI. The multiple diagnostic criteria defined in this trial are commonly employed by authors investigating MDI in the literature[7 17 26 52 104 112–114] and support exists for individual criterion. Studies[109 110] have shown that patients with MDI with a symptomatic sulcus sign had significantly longer rotator intervals on MRI compared with controls. The major static constraint against inferior instability is provided by the rotator interval complex, and its redundancy results in a sulcus.[109 115] The patients in these studies had no history of trauma and no structural damage as seen on MRI.[109 110] Yoldas et al[116] evaluated anterior and posterior translation testing on 48 MDI participants and compared this to evaluation under anaesthesia. There was a significantly greater degree of glenohumeral translation of the symptomatic shoulder compared with the non-symptomatic shoulder using these tests when awake as well as under anaesthesia. The anterior apprehension test and anterior draw test have also been shown to have a high diagnostic value for anterior shoulder instability when compared with radiographic or arthroscopic findings.[113 117] Although these studies were investigating patients with traumatic structural instability, the presence of a positive test in the absence of a structural lesion on MRI has some validity for diagnosing atraumatic instability.

Despite the limitations in diagnosing MDI[36 54] there are aspects of our diagnostic criteria that are likely to improve the diagnostic accuracy. First, we are combining more than one type of test to assess any one direction of instability; draw tests and the apprehension tests. This is likely to increase the diagnostic accuracy for any one direction of instability.[117] Second, these tests must produce the patient's symptoms, which reduces the likelihood that patients with directional laxity only will be included. Third, MRI evaluation will exclude participants with any structural damage to the shoulder. This reduces the likelihood that a participant with a traumatic unidirectional instability will be included.[14 35] These methods reduce the likelihood of a false-positive diagnosis[14 41] and therefore increases the validity of our approach. We also aim to keep our participant group as heterogeneous as possible by excluding participants with primary neck pathology, connective tissue disorders and volitional instability.

Based on the convergence of this quantitative and qualitative research, as well as the expertise of one of the authors (LW) comprising over 25 years of clinical practice as a shoulder physiotherapist, the diagnostic criteria used for MDI in this study have acceptable validity.

CONCLUSION

This project will establish the effect of two standardised exercise-based management programmes on the outcomes of people with non-traumatic MDI. This will establish guidelines for exercise prescription, improve the outcomes of people with MDI and lay foundations for larger RCTs for exercise of shoulder instability.

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