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Rotator Cuff Related Shoulder Pain: Does The Type of Exercise Influence The Outcomes? – Protocol of a Randomized Controlled Trial

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ROTATOR CUFF RELATED SHOULDER PAIN: DOES THE TYPE OF EXERCISE INFLUENCE THE OUTCOMES? – PROTOCOL OF A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

INTRODUCTION: Lifetime prevalence of shoulder pain is 70%, and approximately 50% of people with shoulder pain will experience pain for more than a year. Rotator cuff related shoulder pain (RCRSP) is the most common shoulder condition and the main non-surgical intervention is exercise therapy. Approximately for 30% of people with RCRSP, this approach does not lead to a significant reduction in symptoms. This may be due to an inappropriate dosage or choice of exercises. The aim of this investigation is to compare the short, mid and long-term effects, in terms of symptoms, functional limitations, kinesiophobia and pain catastrophizing, of 3 different shoulder rehabilitation approaches (education, strengthening, motor control) in adults with RCRSP.

METHODS AND ANALYSIS: In this single-blind (assessor), parallel group randomized clinical trial, 123 adults presenting with RCRSP will take part in a 12-week rehabilitation program. They will be randomly assigned to 1 of 3 groups (education only, strengthening approach or motor control focused approach). *Quick*DASH, the primary outcome, Western Ontario Rotator Cuff index and Brief Pain Inventory will evaluate symptoms and functional limitations, while Tampa Scale of Kinesiophobia and Pain Catastrophizing Scale will evaluate pain-related fear and catastrophizing at baseline and at 3, 6, 12 and 24 weeks. Ultrasonographic acromiohumeral distances and tendon thickness will be assessed at baseline and 12 weeks. Treatment effects will be assessed using a two-way repeated measures analysis of variance.

ETHICS AND DISSEMINATION: Ethics approval was obtained from the Ethics Committee of the Centre Integrated University Health and Social Services. Results will be disseminated through international publications in peer-reviewed journals, in addition to international conference presentations.

TRIAL REGISTRATION NUMBER: Protocol was registered at ClinicalTrials.gov (NCT03892603) on May 22, 2019.

ARTICLE SUMARY

Strengths And Limitations of This Study

- This randomized controlled trial directly compares three of the most widely used interventions for RCRSP (education, strengthening and motor control exercises) to highlight the most efficient and guide shoulder rehabilitation.
- Effects on symptoms, kinesiophobia, catastrophisation, acromiohumeral distance and tendon thickness of different exercise programs as well as education will be analyzed.
- Methods to reduce the risk of bias will be implemented throughout the study, which includes a statistically justified sample size, blinding, randomization and adequate concealment of group allocation for the assessors.
- Patients will be blinded to the treatment provided to the other groups as it is not feasible to completely blind the participants and the treating therapist due to the nature of the allocated treatments.
- A true control group (wait-and-see approach) will not be included as it would be difficult to maintain a high retention and avoid co-interventions during the mid- and long-term follow-up.

INTRODUCTION

Shoulder pain is one of the most frequent musculoskeletal complaints in the general population with a lifetime prevalence of up to 70%.[1] The overall prognosis is highly variable, with up to 50% of patients still reporting persistent pain 6 to 12 months after seeking an initial primary care consultation.[1] Rotator cuff related shoulder pain (RCRSP), a broad term that includes rotator cuff tendinopathy, tendinitis, tendinosis, partial and atraumatic full-thickness rotator cuff tears, impingement and subacromial pain, accounts for 50 to 85% of diagnoses for shoulder pain.[2]

Several interventions are available for RCRSP such as education, exercise, manual therapy, electrotherapy, injection, medication and surgery. Clinical trials suggest that the long-term outcomes of patients pharmacologically or surgically treated are comparable to those receiving rehabilitation.[6-9] Regardless of modality, treatment is unsuccessful for more than one third of patients who continue to have pain and disability following care. Several reasons may explain this lack of effectiveness and include; psychosocial factors (including kinesiophobia[3] and pain catastrophizing)[4], occupational factors, lifestyle factors,[5] lack of adherence to the exercise program,[6] low expectations regarding recovery and low levels of self-efficacy[7,8]. Other reasons behind this lack of success might be inadequate choice of exercise.

Education and exercises are two of the most frequently used interventions for RCRSP with evidence supporting their effectiveness.[9–11] Patient education often constitutes the first management strategy in health-related conditions as it doesn't necessitate extensive resources and is available to all. It helps reduce false beliefs and fears related to the pathology as well as increase patient's knowledge of their condition in order to improve their self-efficacy.[9] However, education alone might not be sufficient for all patients, as some may present deficits such as muscular weakness or inhibition, altered shoulder muscle recruitment patterns and kinematics.[12,13] These deficits might explain the persistence of symptoms in some patients. Recent systematic reviews strongly recommend with low to moderate quality evidence that exercises be prioritized as a first line intention treatment since it presents better outcome on pain and function than placebo or wait-and-see.[14,15] However, we still don't know which types of exercise are better and thus lead to better outcomes.[13] Motor control exercises have been shown to reduce pain and disability in individuals with RCRSP.[10] One rationale behind these effects is that improving muscle recruitment patterns and kinematics could prevent the compression of the subacromial soft tissues underneath the coracoacromial arch as the arm elevates.[12] Apart from this potential explanation that is still debated,[2] efficiency of motor control exercises might reside in the reduction of fear-avoidance behavior or pain catastrophizing as the patients are encouraged to move in previously feared positions.[16] It could also have a direct neurophysiological central effect on pain-related brain areas, similar to the one observed with manual therapy,[17,18] and bring change in pain sensitivity and sensorimotor processing. On the other hand, by progressively loading contractile tissue, strengthening exercises have been shown to decrease pain and muscle weakness.[11] This could be the result of an increased capacity by the tendon to sustain load or to a decrease in rotator cuff tendon inhibition.[19]

Although their clinical usefulness has already been assessed separately,[20,21] no study has directly compared those three interventions for the management of RCRSP in order to better highlight recovery over time as well as the choice of intervention provided. Identifying the most effective and efficient intervention(s) for RCRSP is of paramount importance to prevent symptoms persistence, limit health care costs associated with these disorders and all resulting consequences.

Objective and hypotheses

The primary objective of this randomized controlled trial (RCT) is to compare the short, mid and long-term effects of three different approaches (education, strengthening, motor control) of delivering shoulder management on the symptoms and functional limitations of individuals with RCRSP. A

secondary objective is to explore the effects of the programs on shoulder control (acromiohumeral distance), subacromial structures (supraspinatus and infraspinatus tendon thickness) kinesiophobia and catastrophisation related to shoulder pain. The hypothesis is that both exercises groups will demonstrate a better outcome in pain and function compared to the education group. The motor control program should lead to a quicker improvement in symptoms and functional limitations than the strengthening program because, by improving muscle recruitment patterns, it will decrease control deficits and thus lower the odds of individuals experiencing pain. Its effect on kinesiophobia should also contribute to a quicker reintegration of movements into patients' life, hence improve function. Finally, all groups should lead to a decrease in kinesiophobia and pain catastrophisation, but the motor control and strengthening groups should lead to a greater reduction since participants will be guided to move in amplitudes that were previously limited by pain or pain-related fears or perform near-maximal intensity muscle contractions.

METHODS AND ANALYSIS

Study Design

This single-blind parallel group RCT will include 5 evaluation sessions over 24 weeks (baseline, 3, 6, 12 and 24 weeks), 6 intervention sessions over 12 weeks for both exercises groups and 2 education sessions over 12 weeks for the education group (Figure 1). All participants will take part in the baseline evaluation. They will complete self-administered questionnaires on sociodemographic characteristics, symptomatology, comorbidities, functional limitations, kinesiophobia, and pain catastrophizing using self-reported questionnaires. Then, ultrasonographic (US) measurements of the acromiohumeral distance (ADH) and of the supraspinatus (SS) and infraspinatus (IS) tendons thickness will be conducted. Thereafter, participants will be randomly assigned to one of three intervention groups, and take part in their assigned program. All study outcomes will be revaluated at 12 weeks, while the self-administered questionnaires will also be re-administrated at 3, 6- and 24-weeks using web-based questionnaires. A global rating of change question will be completed at 3, 6, 12 and 24 weeks. The study will be conducted at the *Centre interdisciplinaire de recherche en réadaptation et en intégration sociale* (CIRRIS). This RCT is registered on ClinicalTrials.gov (NCT03892603) and we used the SPIRIT checklist when writing our report.[22]

INSERT FIGURE 1

Participants and Sample size

Adults presenting with RCRSP will be recruited using the following inclusion criteria: 1) 18-75 years of age, 2) symptoms lasting longer than 3 months, 3) presence of a painful arc in flexion or abduction, 4) presence of a positive Neer sign or Hawkin's Kennedy Test, 5) presence of pain when resisting humeral external rotation or abduction, or positive Jobe Test, and 6) ability to speak English or French. A positive cluster of criteria 3, 4 and 5 represents an adequate diagnostic tool for RCRSP (Sn: 0.75, Sp: 0.74).[23] Participants will be excluded if they present any of the following criteria: 1) clinical signs of massive rotator cuff tears as defined by presence of gross weakness in the absence of limited pain, 2) other shoulder disorders e.g. adhesive capsulitis, severe osteoarthritis, fracture, dislocation, severe acromioclavicular joint pathology, 3) previous shoulder surgery, 4) presence of significant co-morbidity e.g. neurological disorders, rheumatoid arthritis, 5) current or past carcinoma, 6) unlikely to be able to perform required clinical assessment tasks or attend the required evaluation and intervention sessions, 7) symptomatic cervical spine pathology, defined as reproduction of symptoms with active physiological cervical spine movements, and 8) corticosteroid injection in the last 6 weeks. All recruited participants will be evaluated by a physiotherapist in order to confirm their eligibility.

Based on our sample size calculation, calculated for our primary outcome (*Quick*DASH), **41 participants are required per group** (G*Power 3.1.9; effect size: 0.80, $\alpha = 0.05$, Power = 0.95, SD =

13 DASH points, clinically important difference (CID) = 11 DASH points, expected lost at follow-up = 15%). Therefore, 123 patients with RCRSP will be recruited. This sample size should be sufficient to detect a clinically important difference (CID) between groups.

Potential participants will be recruited in outpatient physiotherapy clinics of hospitals and in private physiotherapy clinics in the Quebec City region, and through electronic mailing lists of employees and students at *Université Laval* (> 52,000 individuals). Since our research team has performed studies evaluating the same population in the same metropolitan area, we are confident to recruit the targeted population.[24–26] With an average rate of 7 new participants per month, we estimate that 18 months will be ample time to reach our goal of 123 participants.

Randomisation and blinding

A randomisation list has been generated prior to the initiation of the study by an independent research assistant not involved in data collection using a random number generator. Allocation is concealed in sealed and opaque envelopes that are sequentially numbered. Randomisation was stratified to ensure balance of the treatment groups with respect to sex (male / female) and age (18-55 / 55-75). A blocked randomisation was also used to make sure that three equal groups of 41 participants will be obtained (random blocks of 3, 6 or 9). Given that it is impossible to blind the treating PT and participants, a single-blind design will be used. To reduce potential contamination bias, the three programs will be given at different time periods. Further, participants will be instructed not to discuss their group assignment, exercises performed, or advice received with other potential participants and with the evaluator. To evaluate the effectiveness of blinding at the 3 month follow-up, the evaluator will answer the following question: *What intervention do you think the participant received?;* with one of the following answers: 1) Education and advice, 2) Strengthening, 3) Motor control, or 4) No idea. If they answer 1, 2 and 3, they will have to explain why they think the participant received this intervention.

Interventions:

Advice and education program: During two education sessions of 30 minutes each, participants will be given written information about the shoulder (anatomy and function), basic pain science and will be directed to watch a series of six educational videos on shoulder pain and function, persistent pain, physical activity, stress, sleep and eating habits. For each video, they will have two questions to answer: 1) What was the most important message? and 2) Was there anything you didn't understand in the video? The comprehensive written information includes advices on:

- The shoulder and their condition
- The relevance of pain
- Pain management (night and day)
- Activity modification (when to increase and decrease)
- Reassurance

Shoulder muscle strengthening program: In addition to the same advice and education the control group receives, participants from this group will be given a shoulder progressive strengthening exercises program (based on 1 RM) that will involve concentric and eccentric contractions with free weights and resistance elastic tubes. Exercises will target humeral internal/external rotators and abductors and the scapular muscles (protractors, retractors, elevators and depressors). Number of repetitions will be one set of the maximum number of repetitions until muscular exertion or until pain reaches 3/10. Participants will be asked to complete the exercises every day for 12 weeks. At each session with the therapist (6 over a 12-week period), shoulder movements and strength will be reassessed, and the program will be progressed accordingly. Any questions or concerns will also be addressed, and participants will be

requested to complete a digital record of their exercise adherence.

INSERT SUPPLEMENTARY FILE 1

Motor control and functional rehabilitation exercise program: Participants will receive the same advice and education as the other groups as well as a motor control exercises program. Each session (6 over a 12-week period) will start with a pain neuro-modulatory (motor control) technique in order to look at the influence of different corrections to alleviate symptoms during upper limb movements. A series of quick clinical tests will be conducted taking no more than 3 minutes. The tests will be performed in a sequential format through three key areas: thoracic 'finger on sternum technique', scapular facilitation, 'humeral head' procedures.[27,28] If a technique reduces pain, that technique will then be performed as exercises and incorporated into the participant's functional movement. In addition, motor control exercises during arm elevation, progressed through a standardized 6-phase retraining sequence, will be executed.[24,29–31] Retraining phases will be graded according to: 1) resistance applied to the shoulder; and 2) use or non-use of feedback. Once participants have reached pain free execution, the program will be progressed into re-education exercises according to the participants' work, sports and activities of daily living and incorporate a series of functional activities involving the whole body. Number of repetitions will vary from one to three sets of 10 to 30 repetitions. Participants will be asked to complete the exercises every day. Participants will be requested to complete a digital record of their exercise adherence.

Both exercise groups will be given information about pain related to the execution of their exercise program (Supplementary file 3).

INSERT SUPPLEMENTARY FILE 2

INSERT SUPPLEMENTARY FILE 3

Data collection

An evaluator blinded to group assignment will perform all evaluations according to standardised procedures.

Symptoms & Functional limitations will be evaluated using the *Quick*DASH (generic questionnaire assessing any upper limb disorders), the primary outcome, as well as two other validated self-reported questionnaires: Western Ontario Rotator Cuff index (WORC; specific to RCRSP), and the short form of Brief Pain Inventory (BPI-SF). The *Quick*DASH is a self-reported questionnaire that includes 11 items measuring physical disability and symptoms of the upper extremity. It presents excellent reliability, is responsive to change, has a MDC and CID around 11%.[32] The WORC index is a disease-specific questionnaire developed to measure, pain, function and health related quality-of-life of individuals suffering from RCRSP. It contains 21 items divided into five sections: physical symptoms, sports/recreation, work, lifestyle and emotions. It has demonstrated excellent reliability, is responsive to change for patients with RCRSP, has a MDC around 12% and a CID varying from 12% to 13%.[33] Finally, the BPI-SF is a validated questionnaire used to assess the intensity of pain and the interference of the pain on the patient's life. It has shown to be reliable, internally consistent over time and valid with several MSK population including RCRSP.[34]

Pain-related fear & catastrophizing: The Tampa Scale of Kinesiophobia (TSK) is a self-administered questionnaire that measures beliefs and behaviours related with pain, specially focusing on beliefs that pain is damaging and painful movements should be avoided.[35] The psychometric properties of the TSK have been confirmed for different pain disorders.[36] The Pain Catastrophizing Scale (PCS) is a self-administered questionnaire measuring the range of catastrophic thoughts and feelings (magnified threat, ruminating thoughts and feelings of helplessness) associated with pain that individuals may experience. High internal reliability has been reported in patients with chronic pain with adequate validity and test-retest reliability.[37]

US measurement of acromiohumeral distance and supraspinatus and infraspinatus tendon will be assessed with a 12-MHz linear array probe (Logic e9, GE Healthcare, Milwaukee, WI, USA). US images of AHD will be obtained with the participants seated in a standardized position with the arm at rest and at 60° of active abduction. US measures will be obtained by placing the transducer on the anterior aspect of the lateral surface of acromion along the longitudinal axis of the humerus in a frontal plane. The AHD will be measured using the built-in electronic caliper option by manually locating the superior aspect of the humeral head and the inferior aspect of acromion and then measuring the shortest linear distance between those two landmarks. For each upper limb position, three measurements will be taken (intraclass correlation coefficient [ICC]: 0.98; MDC: 0.7 mm).[38] Thickness of the supraspinatus (SS) tendon will be obtained with the medial aspect of the wrist against the ipsilateral anterior superior iliac spine. Measures will be obtained with the transducer perpendicularly, one centimeter behind to the anterolateral aspect of the surface of the acromion. The thickness of the SS tendon borders will be defined inferiorly as the first hyperechoic region above the anechoic articular cartilage of the humeral head, and the hyperechoic superior border of the tendon before the anechoic subdeltoid bursa. Infraspinatus tendon thickness will be measured at the level of the posterior border of the acromion with the hand placed on the opposite shoulder. The thickness of the IS tendon borders will be defined inferiorly as the first hyperechoic region above the anechoic articular cartilage of the humeral head, and the hyperechoic superior border of the tendon. These US tendon measures have been shown reliable (ICC > 0.92).[38]

Withdrawal of individuals participants

All dropouts and their underlying reasons will be reported. Principles underlying 'intention-to-treat' analysis will be followed, meaning that every participant will be analyzed according to the randomized treatment assignment. Therefore, non-compliance, protocol deviation and withdrawal will all be ignored in the primary analyses. Additionally, 'per-protocol' analysis (i.e., the analysis will be restricted to participants who adhered to the intervention as stipulated in the protocol) will also be performed. To ensure appropriate insight of mechanisms underlying changes in symptoms and function, only participants who completed evaluation at week 12 will be considered for the US-based outcomes. Any harm or unintended effects during the interventions will be recorded.

Data integrity and analysis

All collected data will be accessible only to the research team. All data will be kept for 5 years after the end of the study to ensure the completion of planned publications. After this period, all data will be destroyed.

Statistical Analyses

Descriptive statistics will be used for all outcome measures at each measurement time to summarise results. Baseline demographic data will be compared (independent *t*-tests and Chi-squared tests) to establish the comparability of groups. All data will be tested to check the distributional assumptions for inferential statistical analyses. A 2-way repeated-measures ANOVA (3 interventions [Control or Strengthening or Motor control] x 5 Time [0, 3, 6, 12 and 24 weeks]) will be used to analyse and compare the effects of the three programs on primary outcome (quick-DASH) as well as secondary outcomes (X 2 time for the US-based outcomes [0 and 12 weeks]) (SPSS 25, proc GENLIN). Alpha level was set at 0.05.

Patient and Public Involvement

This research was done without patient involvement. Patients were not invited to comment on the study design and were not consulted to develop patient relevant outcomes or interpret the results. Patients were not invited to contribute to the writing or editing of this document for readability or accuracy.

DISCUSSION

It is essential to develop and identify effective interventions for the management of shoulder pain since it may become chronic and lead to harmful consequences. Among these are a decreased participation and quality of life, absenteeism at work, early retirement, multiple medical consultations as well as high associated health costs. As stated earlier, up to 30% of individuals with RCRSP still present pain and disability after rehabilitation interventions such as rehabilitation exercises. A recent study conducted by our research team showed that a rehabilitation program comprising mainly motor control exercises led to fewer than 15% of individuals showing unsatisfactory results.[24] In order to further decrease this percentage, we have attempted to compare different bonified exercise programs. We have added exercises targeting the whole body, not only the shoulder, to our motor control program because we believe it is essential to involve the whole body since deficits in trunk or lower limb capacity may overload the upper limb during ADL's. On the other hand, multiple studies have shown promising results from strengthening programs primarily targeting shoulder abductors and external rotators.[2] We believe that adding strengthening exercises for other shoulder muscles such as scapular muscles could lead to even better results. Defining more efficient rehabilitation regimens for common conditions such as RCRSP is therefore important as it may lead to a reduction in associated costs. Therefore, the present study will establish the effectiveness of these two programs and determine if one is more effective than the other or more effective than education.

ETHICS

Ethics approval was obtained from the sectorial rehabilitation and social integration research ethics committee of the CIUSSS-CN (#2019-1762).

Consent

Detailed information about the research and experimental procedures will be provided to all participants before signature of the written informed consent. Participants will be requested to sign a detailed informed consent before starting any experimental procedure

Confidentiality

All research team members will respect the data confidentiality of the patients, in agreement with the law. Patients' names will be coded to keep their identity confidential; however, a list of name and respective codes will be stored in a locked and filing cabinet. All information collected during the study, including test results, will be treated as confidential. The trial data set will be accessible only to the research team and the Ethics Committee of the CIUSSS-CN for purposes of management or audit of research development. Publications related to these data will respect all principles of confidentiality.

Dissemination

Results of this protocol will be disseminated through international publication in peer-reviewed journals, in addition to international conference presentations. Participants, clinicians and relevant research staff in the field will be informed about the results of the study.

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Author statement

MOD contributed to conception, design and preparation of the procedures, and data collection, and will conduct the recruitment, interventions, interpretation, data analyses and writing. FD and JSR contributed to study design and will contribute to the statistical analysis and interpretation of the data. JL contributed to conception, design and preparation of the procedures. All authors commented on the study protocol. All authors approved its final version.

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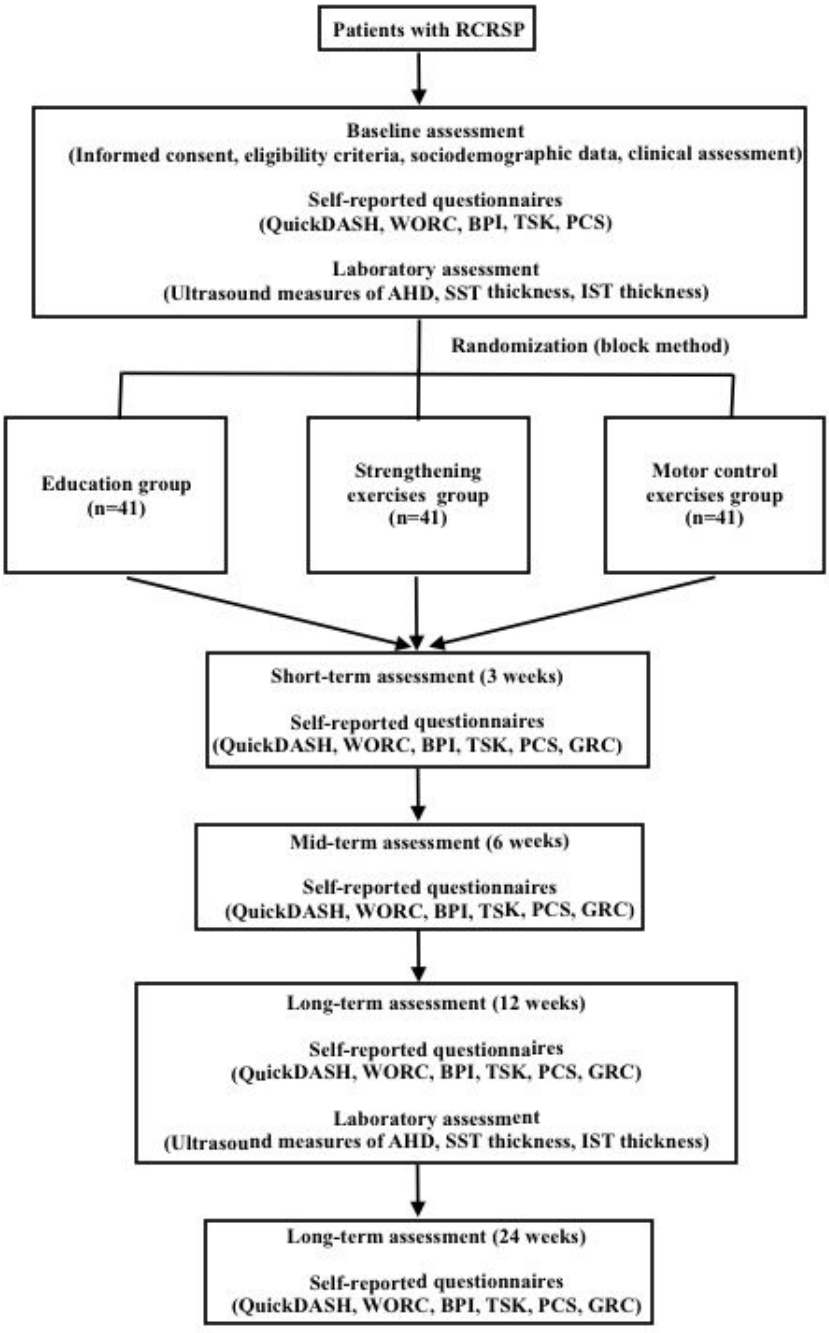
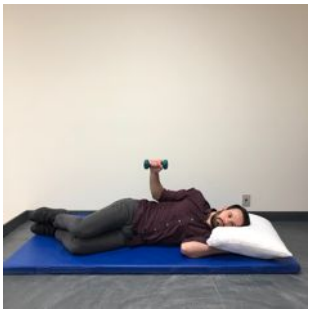
Competing interests statement

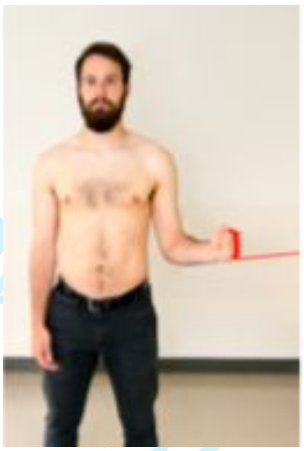
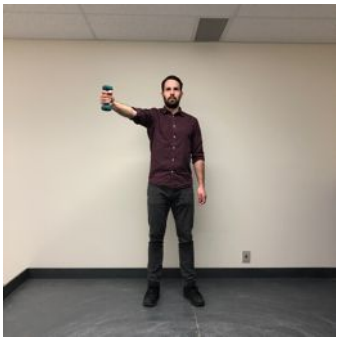
All authors declare that they have no competing interests.

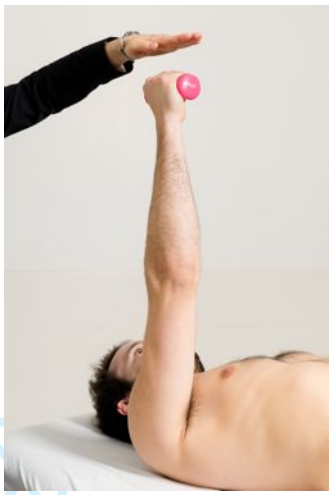
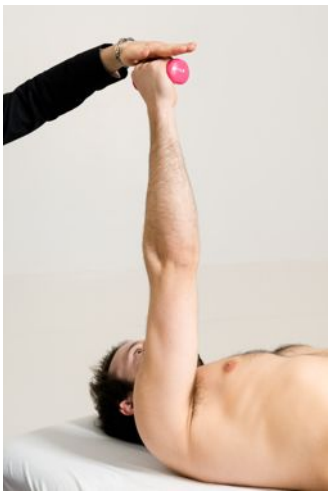
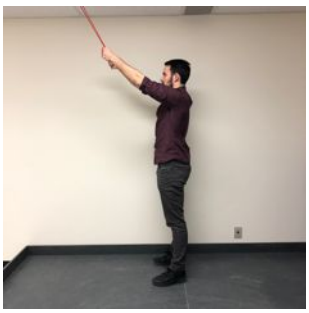
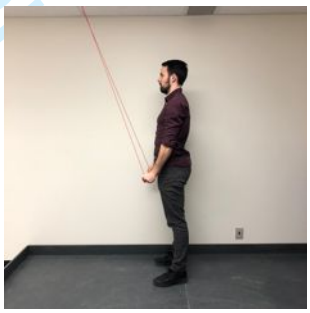
Figure 1: Schematic diagram of the study design. *Quick*DASH, Abbreviated version of the Disabilities of the Arm, Shoulder and Hand questionnaire; WORC, Western Ontario Rotator Cuff Index; BPI, Brief Pain Inventory; TSK, Tampa Scale of Kinesiophobia; PCS, Pain Catastrophizing Scale; AHD, Acromiohumeral distance; SST, supraspinatus tendon; IST, infraspinatus tendon; GRC, Global rating of change



Supplementary file 1: Shoulder muscles strengthening program.

EXERCISES PROGRAM		
A) SHOULDER EXTERNAL ROTATION		
1. Shoulder external rotation at 0° • Hold a weight in your hand. • Lie on the opposite side of the hand holding the weight. • With the trunk upright, flex the elbow 90 degrees. Tighten the abs. • Lift the weight so that your hand is upward, keeping your elbow at 90 degrees.		
2. Shoulder external rotation at 45° • Hold a weight in your hand. • With the trunk upright, flex the elbow 90 degrees. Tighten the abs. • Lift your arm to 90° of abduction while		

keeping your elblow flexed at 90°. • Lift the weight in order to bring your hand upwards and backwards while keeping your elbow flexed at 90° and your arm abducted at 45°.		
B) SHOULDER INTERNAL ROTATION		
1. Shoulder internal rotation at 0° • Tie an elastic band level to your hips. Turn aside. • With your trunk straight, flex the elbow 90 degrees. Tighten the abs. • Pull the elastic to bring the hand from the outside to the inside, make sure that the elbow does not take off from the body. Keep the elbow at 90 °.		
C) ARM ELEVATION (SCAPTION)		
1. Scaption with weight • Use a weight to make the scaption movement. • Raise your arm by keeping your elbow extended in a 45° motion plane. • Do not lift the shoulder up or lean the trunk to the opposite side.		

D) SHOULDER PROTRACTION		
1. Protraction with weight • Lie on your back with your knees bent and your back in a neutral position. Contract your abs. • Raise your arm up to reach 90°. When your arm is upright, push your hand toward the ceiling keeping your back flat, without lifting your shoulders.		
E) SHOULDER EXTENSION		
1. Shoulder extension with an elastic band • With both hands, grasp the ends of a rubber band attached at shoulder height. • Keep your back straight and your shoulders slightly back. Tighten the abdominals, tuck in the chin.		

• With arms outstretched, slowly pull backwards so that your hands are shifted to the outside of your hip. Keep your back straight and your shoulders slightly backwards throughout the exercise.		
F) HORIZONTAL ABDUCTION		
1. Horizontal abduction with weight • Lying prone, with your elbow flexed 90° and a weight in each hand. • Lift your ams up 1 or 2 cm without lifting your shoulders from the table. • Extend your elbows. • Flex back your elbows to 90° and lower your arms in the starting position.		

G) ELEVATION		
1. Elevation with weight • With arms raised about 30 ° to the side, bring both shoulders slightly back and towards the eyes. • Tighten the abdominals, tuck in the chin.		

Consent form

For a patient's consent to publication of images and/or information about them in BMJ publications.

Name of patient:	_____*Marc-Olivier Dubé*_____
Relationship to patient (if patient not signing this form):	_____
*Description of the photo, image, text or other material (**Material)** about the patient. **A copy of the Material must be attached to this form**:*	_____*Photos for exercise program*_____
Provisional title of article in which Material will be included:	*Rotator cuff related shoulder pain: Does the type of exercise influence the outcomes – Protocol of a randomized controlled trial*

CONSENT

I_____Marc-Olivier Dubé_____ *[PRINT FULL NAME]* give my consent for the Material about me/the patient to appear in a BMJ publication.

I confirm that I: *(please tick boxes to confirm)*

☒ ***have seen the photo, image, text or other material about me/the patient***

☒ ***have read the article to be submitted to BMJ*** ☒ ***am legally entitled to give this consent.***

I understand the following:

(1) The Material will be published without my/the patient's name attached, however I understand that complete anonymity cannot be guaranteed. It is possible that somebody somewhere - for example, somebody who looked after me/the patient or a relative - may recognise me/the patient.

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Signed: Marc-Olivier Dubé *Print name:* Marc-Olivier Dubé

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G1V0E2 Quebec (Qc), Canada *Telephone no:* 418-906-2071

If signing on behalf of the patient, please give the reason why the patient can't consent for themselves (e.g. patient is under 18 or has cognitive or intellectual impairment).

_____ *Date:* _____

☐ *If you are signing for a family or other group, please tick the box to confirm that all relevant members of the family or group have been informed.*

Details of person who has explained and administered the form to the patient or their representative (e.g. the corresponding author or other person who has the authority to obtain consent).

*Signed:__Marc-Olivier Dubé_*

Print name: ___Marc-Olivier Dubé

Position: ___PhD candidate (student)

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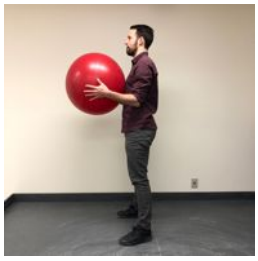
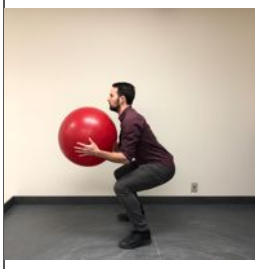
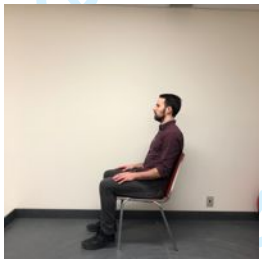
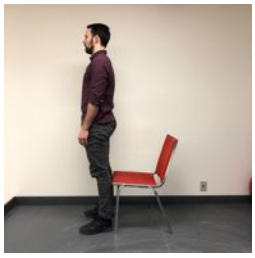
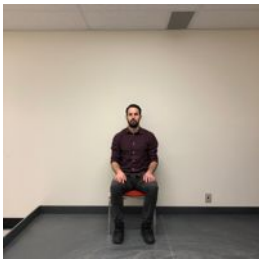
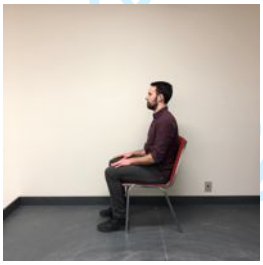
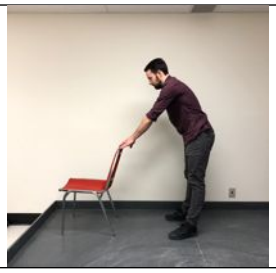
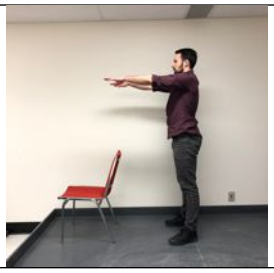
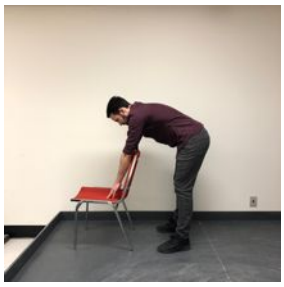
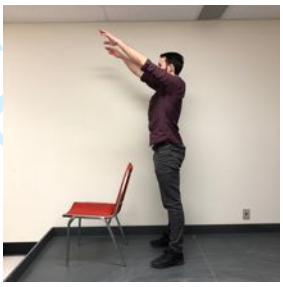
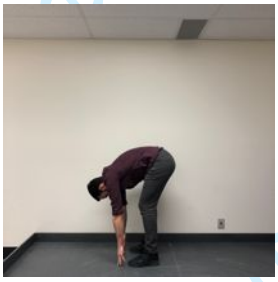
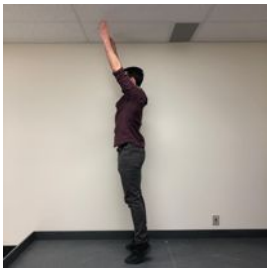
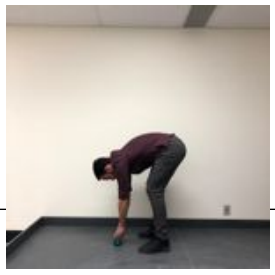
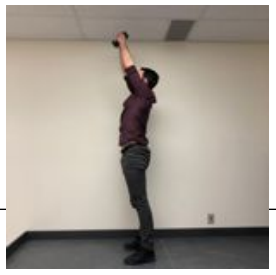
Date: __May 1, 2020__

Supplementary file 2: Motor control and functional exercise program.

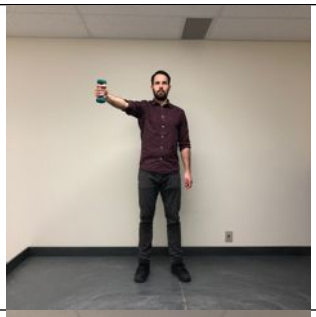
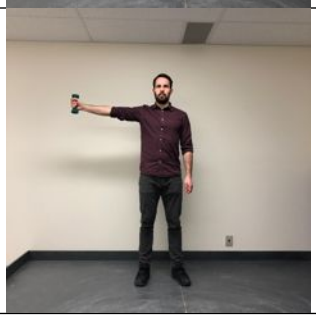
<table>
<tr><th colspan="3">EXERCISES PROGRAM</th></tr>
<tr><td colspan="3">A) Exercise 1 : Lower limbs</td></tr>
<tr><td>1.
Hold a ball in front of you and bend your knees
Aim for 15 repetitions.</td><td>  </td><td>  </td></tr>
<tr><td>2.
Perform sit-to-stand for 1 minute.
Stop if you experience significant fatigue or if you reach 1 minute.</td><td>  </td><td>  </td></tr>
<tr><td>3.
Continue the same exercise by adding the lifting of one leg and arm from the opposite side as high as possible.
Perform the same</td><td>  </td><td>  </td></tr>
</table>

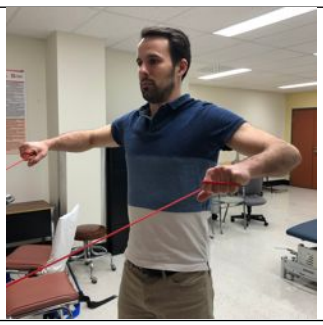
movement on the other side and sit down after. • Aim for 1 minute.		
4. • Progress to this level when you are able to achieve at least 15 repetitions of level 3 in 1 minute. • Continue sit-to-stand transfers, but this time, tip-toe up when you arrive in a standing position. • Aim for 1 minute and incrementally add weights.		
B) Exercise 2 : Upper limbs		
1. • Without weight in the hands, bend the trunk		

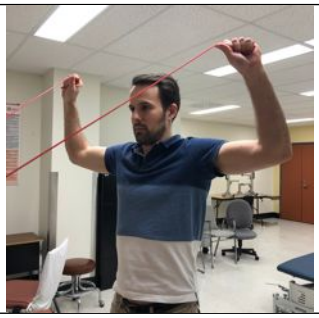
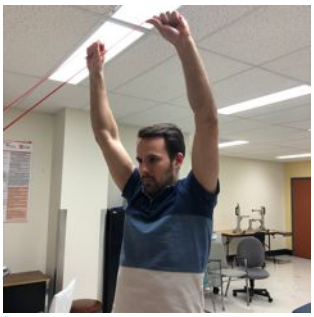
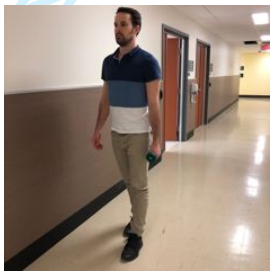
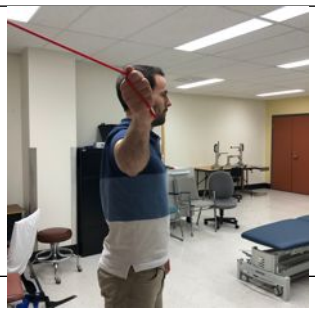
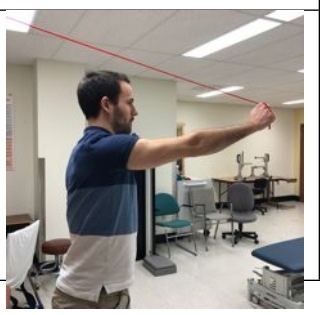
slightly to touch the top of a chair and raise your arms at shoulder height. • Movement should be slow and until you feel tired or in pain (3/10).		
2. • Start when you are able to perform at least 15 consecutive level 1 repetitions. • Still without weight in your hands, bend further to touch the chair seat and raise your arms even higher than the previous level.		

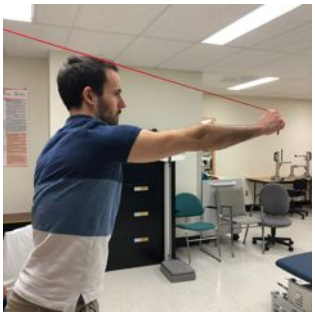
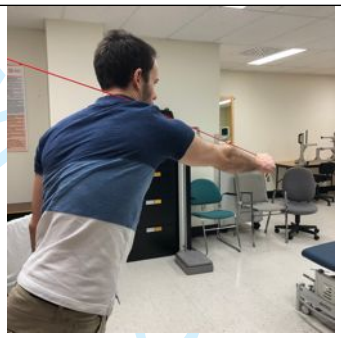
• Movement should be slow and until you feel tired or in pain (3/10).		
3. • Start when you are able to perform at least 15 consecutive level 2 repetitions. • Still without weight in your hands, bend further to touch the ground and raise your arms as high as possible. • Movement should be slow and until you feel tired or in pain (3/10).		
4. • Start when you are able to perform at least 15		

consecutive level 3 repetitions. • Bend to pick-up a light weight from the ground and raise it as high as possible.		
5. • Start when you are able to perform at least 15 consecutive level 3 repetitions. • Progressively lift heavier weights.	Same pictures as level 4	
C) Exercise 3 : Arm elevation in 3 different planes		
C1. Flexion (starting with a short lever if necessary)		

C2. Scaption (starting with a short lever if necessary)	
C3. Abduction (starting with a short lever if necessary)	
D) Pushing	
1. Wall push up • Standing, hands resting on the wall, arms a little narrower than the shoulders at an angle of about 45 degrees. Tighten the abdominals, tuck in the chin. Do not lift your shoulders. • Push against the wall, pushing apart the shoulder blades (round the back), imagining that someone is pushing you on the sternum.	
2. Push up on knees • Place your hands slightly greater than shoulder-	

width apart and your knees comfortably apart. Tighten the abdominals, tuck in the chin. • Slowly bend your elbows and lower your chest until your elbows are flexed 90°, then slowly return to the starting position.	
3. Push up • Place your hands slightly greater than shoulder-width apart and your feet comfortably apart. Tighten the abdominals, tuck in the chin. • Slowly bend your elbows and lower your chest until your elbows are flexed 90°, then slowly return to the starting position.	
E) Pulling	
1. Rowing at shoulder height • Tie an elastic band in front of you at shoulder height. • Pull the elastic until your elbows are level with your	

trunk while keeping your hands parallel to the ground. Keep your trunk right, tighten your abdominals and tuck you chin.	
2. Rowing + ER • Perform level 1. • Once in position, rotate your arm in order to bring your hands backwards.	
3. Rowing + ER + elbow extension (+squat) • Perform level 2. • Once in position, extend your elbows and lift your hands as high as possible.	
G) Carrying	
1. Walking while carrying a weight • Pick up a weight with your hand and walk for 5 meters while keeping yout trunk right. Walk back with the weight in your other hand.	
H) Throwing	
1. Simple throwing motion with rubber band • Tie a rubber band to the top of a door.	 

• Take the rubber band in your hand and turn your back to the door. • Bring your arm forward as if you were throwing an object. Keep your trunk right, tighten your abdominals and tuck you chin.		
2. Simple throwing motion with rubber band + shoulder protraction • Same as level 1 but bring your shoulder forward at the end of the movement.		
3. Simple throwing motion with rubber band + trunk rotation • Same as level 2 but add a trunk rotation to the opposite side of your throwing hand.		
I) Precision		
1. Drawing the alphabet on the wall with a ball • Slowly draw the letters of the alphabet on a wall using a rolling ball.		

• As you progress, try to draw letters as little as possible.	

BMJ

Consent form

For a patient's consent to publication of images and/or information about them in BMJ publications.

Name of patient:	_____*Marc-Olivier Dubé*____
Relationship to patient (if patient not signing this form):	_____
*Description of the photo, image, text or other material (**Material)** about the patient. **A copy of the Material must be attached to this form**:*	_____*Photos for exercise program*_____
Provisional title of article in which Material will be included:	*Rotator cuff related shoulder pain: Does the type of exercise influence the outcomes – Protocol of a randomized controlled trial*

CONSENT

I_____Marc-Olivier Dubé_____ *[PRINT FULL NAME]* give my consent for the Material about me/the patient to appear in a BMJ publication.

I confirm that I: *(please tick boxes to confirm)*

☒ ***have seen the photo, image, text or other material about me/the patient***

☒ ***have read the article to be submitted to BMJ*** ☒ ***am legally entitled to give this consent.***

I understand the following:

(1) The Material will be published without my/the patient's name attached, however I understand that complete anonymity cannot be guaranteed. It is possible that somebody somewhere - for example, somebody who looked after me/the patient or a relative - may recognise me/the patient.

(2) The Material may show or include details of my/the patient's medical condition or injury and any prognosis, treatment or surgery that I have/the patient has, had or may have in the future.

(3) The article may be published in a journal which is distributed worldwide. BMJ's publications go mainly to doctors and other healthcare professionals but are also seen by many others including academics, students and journalists.

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(9) This consent form will be retained securely and in confidence by BMJ in accordance with the law, for no longer than necessary. Personal data provided in this form will be used and retained in accordance with BMJ's Privacy Policy available at https://www.bmj.com/company/your-privacy/.

Please tick box to confirm the following:

☐ Where this consent relates to an article in *BMJ Case Reports*, I have/the patient has had the opportunity to comment on the article and I am satisfied that the comments, if any, have been reflected in the article.

Signed: Marc-Olivier Dubé *Print name:* Marc-Olivier Dubé

Address: 2507-2818 Boulevard Laurier *Email address:* marcolivier.dub@gmail.com

G1V0E2 Quebec (Qc), Canada *Telephone no:* 418-906-2071

If signing on behalf of the patient, please give the reason why the patient can't consent for themselves (e.g. patient is under 18 or has cognitive or intellectual impairment).

_____ *Date:* _____

☐ *If you are signing for a family or other group, please tick the box to confirm that all relevant members of the family or group have been informed.*

Details of person who has explained and administered the form to the patient or their representative (e.g. the corresponding author or other person who has the authority to obtain consent).

*Signed:__Marc-Olivier Dubé_*

Print name: ___Marc-Olivier Dubé

Position: ___PhD candidate (student)

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Québec (Québec) G1M 2S8

Institution:____Université Laval

Email address:marc-olivier.dube.1@ulaval.ca

Telephone no:__418-906-2071__

Date: __May 1, 2020__

Patient consent form 050419

Supplementary file 3: Information about pain given to both exercise groups

1	Feeling pain in the shoulder is permissible and even encouraged during the exercise program. Any level of pain is permissible as long as it is tolerable for the individual, and, that there is no increase or exacerbation in pain in the evening and the following day.
2	If more guidance as to the amount of pain is required then the participant can perform the exercises in pain with a subjective level of pain between 1 to 3 on a 10-point pain scale, where 0 represents no pain and 10, worst imaginable pain. If this level of pain does not produce an improvement in exercise tolerance, higher levels of pain may be encouraged.
3	Participants will be informed that if increased pain is experienced in the evening or the following day and if this pain is not acceptable for the individual then the number of repetitions per set, number of sets, amount of weight should be reduced accordingly.
4	If there is no exacerbation of pain and the participant perceives that the amount of weight and number of repetitions are being performed at a moderate intensity (on a scale ranging from: no exertion/ easy, mild, moderate, hard, impossible), then heavier weights, or more repetitions may be incrementally used.

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a no data
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	13
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1 and 13

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a no trial sponsor
Roles and responsibilities: sponsor and funder	#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	n/a none
Roles and responsibilities: committees	#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)	n/a none
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	3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	3
Objectives	#7	Specific objectives or hypotheses	3 and 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, non-inferiority, exploratory)	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	4

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)	4
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5 and 6
Interventions: modifications	#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)	5 and 6
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	5 and 6
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
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	6 and 7
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)	4 + figure 1
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	4 and 5
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	4 and 5
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	5

		provided in a separate document that is unavailable to those who enrol participants or assign interventions	
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	5
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	5
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	5
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#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	6 and 7
Data collection plan: retention	#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	6 and 7
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	7
Statistics: outcomes	#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	7

Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	7
Statistics: analysis population and missing data	#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)	7
Methods: Monitoring			
Data monitoring: formal committee	#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	n/a
Data monitoring: interim analysis	#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	n/a
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	7
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	8
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)	8
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8

Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
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	8
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/a
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: trial results	#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	8
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
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	n/a

Notes:

- 2b: n/a no data
- 5b: n/a no trial sponsor

- 13: 4 + figure 1

BMJ Open

Rotator Cuff Related Shoulder Pain: Does The Type of Exercise Influence The Outcomes? – Protocol of a Randomized Controlled Trial

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Rotator Cuff Related Shoulder Pain: Does The Type of Exercise Influence The Outcomes? – Protocol of A Randomized Controlled Trial

Version 7.3 (September 14, 2020)

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ABSTRACT

INTRODUCTION: Lifetime prevalence of shoulder pain is 70%, and approximately 50% of people with shoulder pain will experience pain for more than a year. Rotator cuff related shoulder pain (RCRSP) is the most common shoulder condition and the main non-surgical intervention is exercise therapy. For approximately 30% of people with RCRSP, this approach does not lead to a significant reduction in symptoms. This may be due to an inappropriate dosage or choice of exercises. The aim of this investigation is to compare the short, mid and long-term effects, in terms of symptoms, functional limitations, kinesiophobia and pain catastrophizing, of 3 different shoulder rehabilitation approaches (education, strengthening, motor control) in adults with RCRSP.

METHODS AND ANALYSIS: In this single-blind (assessor), parallel group randomized clinical trial, 123 adults presenting with RCRSP will take part in a 12-week rehabilitation program. They will be randomly assigned to 1 of 3 groups (education only, strengthening approach or motor control focused approach). *Quick*DASH, the primary outcome, Western Ontario Rotator Cuff index and Brief Pain Inventory will evaluate symptoms and functional limitations, while Tampa Scale of Kinesiophobia and Pain Catastrophizing Scale will evaluate pain-related fear and catastrophizing at baseline and at 3, 6, 12 and 24 weeks. Ultrasonographic acromiohumeral distances and tendon thickness will be assessed at baseline and 12 weeks. Intervention groups will be compared on outcomes with intention-to-treat analyses using two-way repeated measures analysis of variance if the data are normally distributed or Nonparametric Analysis for Longitudinal Data (nparLD) if they are not.

ETHICS AND DISSEMINATION: Ethics approval was obtained from the Ethics Committee of the Centre Integrated University Health and Social Services. Results will be disseminated through international publications in peer-reviewed journals, in addition to international conference presentations.

TRIAL REGISTRATION NUMBER: Protocol was registered at ClinicalTrials.gov (NCT03892603) on May 22, 2019. Data from this trial will be available from the corresponding author on request.

ARTICLE SUMMARY

Strengths And Limitations of This Study

- This randomized controlled trial directly compares three of the most widely used interventions for RCRSP (education, strengthening and motor control exercises) to highlight the most efficient and guide shoulder rehabilitation.
- Effects on symptoms, kinesiophobia, catastrophisation, acromiohumeral distance and tendon thickness of different exercise programs as well as education will be analyzed.
- Methods to reduce the risk of bias will be implemented throughout the study, which includes a statistically justified sample size, blinding, randomization and adequate concealment of group allocation for the assessors.
- Patients will be blinded to the treatment provided to the other groups as it is not feasible to completely blind the participants and the treating therapist due to the nature of the allocated treatments.
- A true control group (wait-and-see approach) will not be included as it would be difficult to maintain a high retention and avoid co-interventions during the mid- and long-term follow-up.

INTRODUCTION

Shoulder pain is one of the most frequent musculoskeletal complaints in the general population with a lifetime prevalence of up to 70%.[1] The overall prognosis is highly variable, with up to 50% of patients still reporting persistent pain 6 to 12 months after seeking an initial primary care consultation.[1] Rotator cuff related shoulder pain (RCRSP), a broad term that includes rotator cuff tendinopathy, tendinitis, tendinosis, partial and atraumatic full-thickness rotator cuff tears, impingement and subacromial pain, accounts for 50 to 85% of diagnoses for shoulder pain.[2]

Several interventions are available for RCRSP such as education, exercise, manual therapy, electrotherapy, injection, medication and surgery. Clinical trials suggest that the long-term outcomes of patients pharmacologically or surgically treated are comparable to those receiving rehabilitation.[3–6] Regardless of modality, treatment is unsuccessful for more than one third of patients who continue to have pain and disability following care.[7] Several reasons may explain this lack of effectiveness and include; psychosocial factors (including kinesiophobia[7] and pain catastrophizing[8]), occupational factors, lifestyle factors[9], lack of adherence to the exercise program[3], low expectations regarding recovery and low levels of self-efficacy[4,5]. Other reasons behind this lack of success might be inadequate choice of exercise.

Education and exercises are two of the most frequently used interventions for RCRSP with evidence supporting their effectiveness.[6,10,11] Patient education often constitutes the first management strategy in health-related conditions as it doesn't necessitate extensive resources and is available to all. It helps reduce false beliefs and fears related to the pathology as well as increase patient's knowledge of their condition in order to improve their self-efficacy.[6] However, education alone might not be sufficient for all patients, as some may present deficits such as muscular weakness or inhibition, altered shoulder muscle recruitment patterns and kinematics.[12,13] These deficits might explain the persistence of symptoms in some patients. Recent systematic reviews strongly recommend with low to moderate quality evidence that exercises be prioritized as a first line intention treatment since it presents better outcome on pain and function than placebo or wait-and-see.[14,15] However, we still don't know which types of exercise are better and thus lead to better outcomes.[13] There is even some evidence in the literature suggesting that some types of exercise may not be more effective than a placebo.[16,17] These findings highlight the need for higher quality studies evaluating the effect of different exercises for RCRSP.

Motor control exercises have been shown to reduce pain and disability in individuals with RCRSP.[10] One rationale behind these effects is that improving muscle recruitment patterns and kinematics could prevent the compression of the subacromial soft tissues underneath the coracoacromial arch as the arm elevates.[12] Apart from this potential explanation that is still debated,[2] efficiency of motor control exercises might reside in the reduction of fear-avoidance behavior or pain catastrophizing as the patients are encouraged to move in previously feared positions.[18] It could also have a direct neurophysiological central effect on pain-related brain areas, similar to the one observed with manual therapy,[19,20] and bring change in pain sensitivity and sensorimotor processing. On the other hand, by progressively loading contractile tissue, strengthening exercises have been shown to decrease pain and muscle weakness.[11] This could be the result of an increased capacity by the tendon to sustain load or to a decrease in rotator cuff tendon inhibition.[21]

Although their clinical usefulness has already been assessed separately,[22,23] no study has directly compared those three interventions for the management of RCRSP in order to better highlight recovery over time as well as the choice of intervention provided. Identifying the most effective and efficient intervention(s) for RCRSP is of paramount importance to prevent symptoms persistence, limit health care costs associated with these disorders and all resulting consequences.

Objective and hypotheses

The primary objective of this randomized controlled trial (RCT) is to compare the short, mid and long-term effects of three different approaches (education, strengthening, motor control) of delivering shoulder management on the symptoms and functional limitations of individuals with RCRSP. A secondary objective is to explore the effects of the programs on shoulder control (acromiohumeral distance), subacromial structures (supraspinatus and infraspinatus tendon thickness), kinesiophobia and catastrophisation related to shoulder pain. The hypothesis is that both exercises groups will demonstrate a better outcome in pain and function compared to the education group. The motor control program should lead to a quicker improvement in symptoms and functional limitations than the strengthening program because, by improving muscle recruitment patterns, it will decrease control deficits and thus lower the odds of individuals experiencing pain. Its effect on kinesiophobia should also contribute to a quicker reintegration of movements into patients' life, hence improve function. Finally, all groups should lead to a decrease in kinesiophobia and pain catastrophisation, but the motor control and strengthening groups should lead to a greater reduction since participants will be guided to move in amplitudes that were previously limited by pain or pain-related fears or perform near-maximal intensity muscle contractions.

METHODS AND ANALYSIS

Study Design

This single-blind parallel group RCT will include 5 evaluation sessions over 24 weeks (baseline, 3, 6, 12 and 24 weeks), 6 intervention sessions over 12 weeks for both exercises groups and 2 education sessions over 12 weeks for the education group (Figure 1). All participants will take part in the baseline evaluation. They will complete self-administered questionnaires on sociodemographic characteristics, symptomatology, comorbidities, functional limitations, kinesiophobia, and pain catastrophizing using self-reported questionnaires. Then, ultrasonographic (US) measurements of the acromiohumeral distance (ADH) and of the supraspinatus (SS) and infraspinatus (IS) tendons thickness will be conducted. Thereafter, participants will be randomly assigned to one of three intervention groups, and take part in their assigned program. All study outcomes will be revaluated at 12 weeks, while the self-administered questionnaires will also be re-administrated at 3, 6- and 24-weeks using web-based questionnaires. A global rating of change question will be completed at 3, 6, 12 and 24 weeks. The study will be conducted at the *Centre interdisciplinaire de recherche en réadaptation et en intégration sociale* (CIRRIS). This RCT is registered on ClinicalTrials.gov (NCT03892603) and the SPIRIT checklist was used when writing the protocol.[24]

INSERT FIGURE 1

Participants and Sample size

Adults presenting with RCRSP will be recruited using the following inclusion criteria: 1) 18-75 years of age, 2) symptoms lasting longer than 3 months, 3) presence of a painful arc in flexion or abduction, 4) presence of a positive Neer sign or Hawkin's Kennedy Test, 5) presence of pain when resisting humeral external rotation or abduction, or positive Jobe Test, and 6) ability to speak English or French. A positive cluster of criteria 3, 4 and 5 represents an adequate diagnostic tool for RCRSP (Sn: 0.75, Sp: 0.74).[25] Participants will be excluded if they present any of the following criteria: 1) clinical signs of massive rotator cuff tears as defined by presence of gross weakness in the absence of limited pain, 2) other shoulder disorders e.g. adhesive capsulitis (restriction of passive glenohumeral movement of at least 30% for 2 or more directions), severe osteoarthritis, fracture, dislocation, severe acromioclavicular joint pathology, 3) previous shoulder surgery, 4) presence of significant co-morbidity e.g. neurological disorders, rheumatoid arthritis, 5) current or past carcinoma, 6) unlikely to be able to perform required clinical assessment tasks or attend the required evaluation and intervention sessions, 7) symptomatic cervical spine pathology, defined as reproduction of symptoms with active physiological cervical spine

movements, and 8) corticosteroid injection in the last 6 weeks. All recruited participants will be evaluated by a physiotherapist in order to confirm their eligibility.

Based on our sample size calculation, calculated for our primary outcome (*Quick*DASH), **41 participants are required per group** (G*Power 3.1.9; effect size: 0.80, α = 0.05, Power = 0.95, SD = 13 DASH points, clinically important difference (CID) = 11 DASH points, expected lost at follow-up = 15%). Therefore, 123 participants with RCRSP will be recruited. This sample size should be sufficient to detect a clinically important difference (CID) between groups.

Potential participants will be recruited in outpatient physiotherapy clinics of hospitals and in private physiotherapy clinics in the Quebec City region, and through electronic mailing lists of employees and students at *Université Laval* (> 52,000 individuals). Since our research team has performed studies evaluating the same population in the same metropolitan area, we are confident to recruit the targeted population.[26–28] With an average rate of 7 new participants per month, we estimate that 18 months will be ample time to reach our goal of 123 participants.

Randomisation and blinding

A randomisation list has been generated prior to the initiation of the study by an independent research assistant not involved in data collection using a random number generator. Allocation is concealed in sealed and opaque envelopes that are sequentially numbered. Randomisation was stratified to ensure balance of the treatment groups with respect to sex (male / female) and age (18-55 / 55-75). A blocked randomisation was also used to make sure that three equal groups of 41 participants will be obtained (random blocks of 3, 6 or 9). Given that it is impossible to blind the treating PT and participants, a single-blind design will be used. To reduce potential contamination bias, the three programs will be given at different time periods. Further, participants will be instructed not to discuss their group assignment, exercises performed, or advice received with other potential participants and with the evaluator. To evaluate the effectiveness of blinding at the 3 month follow-up, the evaluator will answer the following question: *What intervention do you think the participant received?;* with one of the following answers: 1) Education and advice, 2) Strengthening, 3) Motor control, or 4) No idea. If they answer 1, 2 and 3, they will have to explain why they think the participant received this intervention.

Interventions:

Advice and education program: During two education sessions of 30 minutes each, participants will be given written information by a physiotherapist about the shoulder (anatomy and function), basic pain science and will be directed to watch a series of six educational videos on shoulder pain and function, persistent pain, physical activity, stress, sleep and eating habits. For each video, they will have two questions to answer: 1) What was the most important message? and 2) Was there anything you didn't understand in the video? The comprehensive written information includes advice on:

- The shoulder and their condition
- The relevance of pain
- Pain management (night and day)
- Activity modification (when to increase and decrease)
- Reassurance

Shoulder muscle strengthening program: In addition to the same advice and education the control group receives, participants from this group will be given a shoulder progressive strengthening exercises program (Supplementary file 1) based on 1 RM that will involve concentric and eccentric contractions with free weights and resistance elastic tubes. Exercises will target humeral internal/external rotators and

abductors and the scapular muscles (protractors, retractors, elevators and depressors). Number of repetitions will be one set of the maximum number of repetitions until muscular exertion or until pain reaches 3/10. If the pain level is 3/10 or more at rest, participants will be asked to start with a lower number of repetitions and increase or decrease depending on their pain behavior in the following hours and the next day. Participants will be asked to complete the exercises every day for 12 weeks. At each session with the physiotherapist (6 over a 12-week period), shoulder movements and strength will be reassessed, and the program will be progressed accordingly. The necessary equipment (dumbbells, elastic bands) will be provided to the participants. Any questions or concerns will also be addressed by the treating physiotherapist, and participants will be requested to complete a daily diary of their exercise adherence.

INSERT SUPPLEMENTARY FILE 1

Motor control and functional rehabilitation exercise program: Participants will receive the same advice and education as the other groups as well as a motor control exercises program (Supplementary file 2). Each session with the physiotherapist (6 over a 12-week period) will start with a pain neuro-modulatory (motor control) technique in order to look at the influence of different corrections to alleviate symptoms during upper limb movements. A series of quick clinical tests will be conducted taking no more than 3 minutes. The tests will be performed in a sequential format through three key areas: thoracic 'finger on sternum technique', scapular facilitation, 'humeral head' procedures.[29,30] If a technique reduces pain, that technique will then be performed as exercises and incorporated into the participant's functional movement. In addition, motor control exercises during arm elevation, progressed through a standardized 6-phase retraining sequence, will be executed.[26,31–33] Retraining phases will be graded according to: 1) resistance applied to the shoulder; and 2) use or non-use of feedback. Once participants have reached pain free execution, the program will be progressed into re-education exercises according to the participants' work, sports and activities of daily living and incorporate a series of functional activities involving the whole body. Number of repetitions will vary from one to three sets of 10 to 30 repetitions. Participants will be asked to complete the exercises every day. The necessary equipment (dumbbells, elastic bands) will be provided to the participants. Participants will be requested to complete a daily diary of their exercise adherence.

Both exercise groups will be given information about pain related to the execution of their exercise program (Supplementary file 3).

INSERT SUPPLEMENTARY FILE 2

INSERT SUPPLEMENTARY FILE 3

Data collection

An evaluator blinded to group assignment will perform all evaluations according to standardised procedures.

Symptoms & Functional limitations will be evaluated using the *Quick*DASH (generic questionnaire assessing any upper limb disorders), the primary outcome, as well as two other validated self-reported questionnaires: Western Ontario Rotator Cuff index (WORC; specific to RCRSP), and the short form of Brief Pain Inventory (BPI-SF). The *Quick*DASH is a self-reported questionnaire that includes 11 items measuring physical disability and symptoms of the upper extremity. It presents excellent reliability, is responsive to change, has a minimal detectable change (MDC) and CID around 11%.[34] The WORC index is a disease-specific questionnaire developed to measure, pain, function and health related quality-of-life of individuals suffering from RCRSP. It contains 21 items divided into five sections: physical symptoms, sports/recreation, work, lifestyle and emotions. It has demonstrated excellent reliability, is responsive to change for patients with RCRSP, has a MDC around 12% and a CID varying from 12% to 13%.[35] Finally,

the BPI-SF is a validated questionnaire used to assess the intensity of pain and the interference of the pain on the patient's life. It has shown to be reliable, internally consistent over time and valid with several MSK population including RCRSP.[36]

Pain-related fear & catastrophizing: The Tampa Scale of Kinesiophobia (TSK) is a self-administered questionnaire that measures beliefs and behaviours related with pain, specially focusing on beliefs that pain is damaging and painful movements should be avoided.[37] The psychometric properties of the TSK have been confirmed for different pain disorders.[38] The Pain Catastrophizing Scale (PCS) is a self-administered questionnaire measuring the range of catastrophic thoughts and feelings (magnified threat, ruminating thoughts and feelings of helplessness) associated with pain that individuals may experience. High internal reliability has been reported in patients with chronic pain with adequate validity and test-retest reliability.[39]

US measurement of acromiohumeral distance and supraspinatus and infraspinatus tendon will be assessed with a 12-MHz linear array probe (Logic e9, GE Healthcare, Milwaukee, WI, USA). US images of AHD will be obtained with the participants seated in a standardized position with the arm at rest and at 60° of active abduction. US measures will be obtained by placing the transducer on the anterior aspect of the lateral surface of acromion along the longitudinal axis of the humerus in a frontal plane. The AHD will be measured using the built-in electronic caliper option by manually locating the superior aspect of the humeral head and the inferior aspect of acromion and then measuring the shortest linear distance between those two landmarks. For each upper limb position, three measurements will be taken (intraclass correlation coefficient [ICC]: 0.98; MDC: 0.7 mm).[40] Thickness of the supraspinatus (SS) tendon will be obtained with the medial aspect of the wrist against the ipsilateral anterior superior iliac spine. Measures will be obtained with the transducer perpendicularly, one centimeter behind to the anterolateral aspect of the surface of the acromion. The thickness of the SS tendon borders will be defined inferiorly as the first hyperechoic region above the anechoic articular cartilage of the humeral head, and the hyperechoic superior border of the tendon before the anechoic subdeltoid bursa. Infraspinatus tendon thickness will be measured at the level of the posterior border of the acromion with the hand placed on the opposite shoulder. The thickness of the IS tendon borders will be defined inferiorly as the first hyperechoic region above the anechoic articular cartilage of the humeral head, and the hyperechoic superior border of the tendon. These US tendon measures have been shown reliable (ICC > 0.92).[40]

Withdrawal of individuals participants

All dropouts and their underlying reasons will be reported. Principles underlying 'intention-to-treat' analysis will be followed, meaning that every participant will be analyzed according to the randomized treatment assignment. Therefore, non-compliance, protocol deviation and withdrawal will all be ignored in the primary analyses. Additionally, 'per-protocol' analysis (i.e., the analysis will be restricted to participants who adhered to the intervention as stipulated in the protocol) will also be performed. To ensure appropriate insight of mechanisms underlying changes in symptoms and function, only participants who completed evaluation at week 12 will be considered for the US-based outcomes. Any harm or unintended effects during the interventions will be recorded. If a participant presents with an adverse event, the primary investigator will report it to the Ethics Committee.

Data integrity and analysis

All collected data will be accessible only to the research team. All data will be kept for 5 years after the end of the study to ensure the completion of planned publications. After this period, all data will be destroyed. A Data Monitoring Committee is not necessary as this trial is low risk since it is not a very large RCT. The research team has opted not to undertake interim analysis.

Statistical Analyses

Descriptive statistics will be used for all outcome measures at each measurement time to summarise results. Baseline demographic data will be compared (independent *t*-tests and Chi-squared tests) to establish the comparability of groups. All data will be tested to check the distributional assumptions for inferential statistical analyses. If data are normally distributed, a 2-way repeated-measures ANOVA (3 interventions [Control or Strengthening or Motor control] x 5 Time [0, 3, 6, 12 and 24 weeks]) will be used to analyse and compare the effects of the three programs on primary outcome (quick-DASH) as well as secondary outcomes (X 2 time for the US-based outcomes [0 and 12 weeks]). Analyses will be made using nparLD package (R software) if parametric criteria are not met since it is not possible to assume that the covariance matrix is a compound-symmetry matrix. For the multiple comparisons, Bonferroni post-hoc test will be used. Alpha level was set at 0.05.

Patient and Public Involvement

This research was done without patient involvement. Patients were not invited to comment on the study design and were not consulted to develop patient relevant outcomes. Patients will not be invited to contribute to the writing or editing of this document for readability or accuracy.

DISCUSSION

It is essential to develop and identify effective interventions for the management of shoulder pain since it may become chronic and lead to adverse consequences such as decreased participation and quality of life, absenteeism at work, early retirement, multiple medical consultations as well as high associated health costs. As stated earlier, up to 30% of individuals with RCRSP still present pain and disability after rehabilitation interventions such as rehabilitation exercises. A recent study conducted by our research team showed that a rehabilitation program comprising mainly motor control exercises led to fewer than 15% of individuals showing unsatisfactory results.[26] In order to further decrease this percentage, we have attempted to compare different bonified exercise programs. We have added exercises targeting the whole body, not only the shoulder, to our motor control program because we believe it is essential to involve the whole body since deficits in trunk or lower limb capacity may overload the upper limb during activities of daily living. On the other hand, multiple studies have shown promising results from strengthening programs primarily targeting shoulder abductors and external rotators.[2] We believe that adding strengthening exercises for other shoulder muscles such as scapular muscles could lead to even better results.

A true control group (wait-and-see approach) will not be included as it would be difficult to maintain a high retention and avoid co-interventions during the mid- and long-term follow-up. We also chose not to include a placebo group, as it is hard to have a real placebo for this type of study and it is not really ethically fair for the participants given that they will be followed for the 6 months and that the exercises used in the programs have been shown to be superior to placebo.[14]

Defining more efficient rehabilitation regimens for common conditions such as RCRSP is important as it may lead to a reduction in associated costs. Therefore, the present study will establish the effectiveness of these two programs and determine if one is more effective than the other or more effective than education.

ETHICS

Ethics approval was obtained from the sectorial rehabilitation and social integration research ethics committee of the CIUSSS-CN (#2019-1762).

Consent

Detailed information about the research and experimental procedures will be provided to all participants before signature of the written informed consent. Participants will be requested to sign a detailed informed consent before starting any experimental procedure (supplementary file 4).

Confidentiality

All research team members will respect the data confidentiality of the patients, in agreement with the law. Patients' names will be coded to keep their identity confidential; however, a list of name and respective codes will be stored in a locked and filing cabinet. All information collected during the study, including test results, will be treated as confidential. The trial data set will be accessible only to the research team and the Ethics Committee of the CIUSSS-CN for purposes of management or audit of research development. Publications related to these data will respect all principles of confidentiality.

Dissemination

Results of this protocol will be disseminated through international publication in peer-reviewed journals, in addition to international conference presentations. Participants, clinicians and relevant research staff in the field will be informed about the results of the study.

Caption : Figure 1: Schematic diagram of the study design. QuickDASH, Abbreviated version of the Disabilities of the Arm, Shoulder and Hand questionnaire; WORC, Western Ontario Rotator Cuff Index; BPI, Brief Pain Inventory; TSK, Tampa Scale of Kinesiophobia; PCS, Pain Catastrophizing Scale; AHD, Acromiohumeral distance; SST, supraspinatus tendon; IST, infraspinatus tendon; GRC, Global rating of change

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Author statement

MOD contributed to conception, design and preparation of the procedures, and data collection, and will conduct the recruitment, interventions, interpretation, data analyses and writing. FD and JSR contributed to study design and will contribute to the statistical analysis and interpretation of the data. JL contributed to conception, design and preparation of the procedures. All authors commented on the study protocol. All authors approved its final version.

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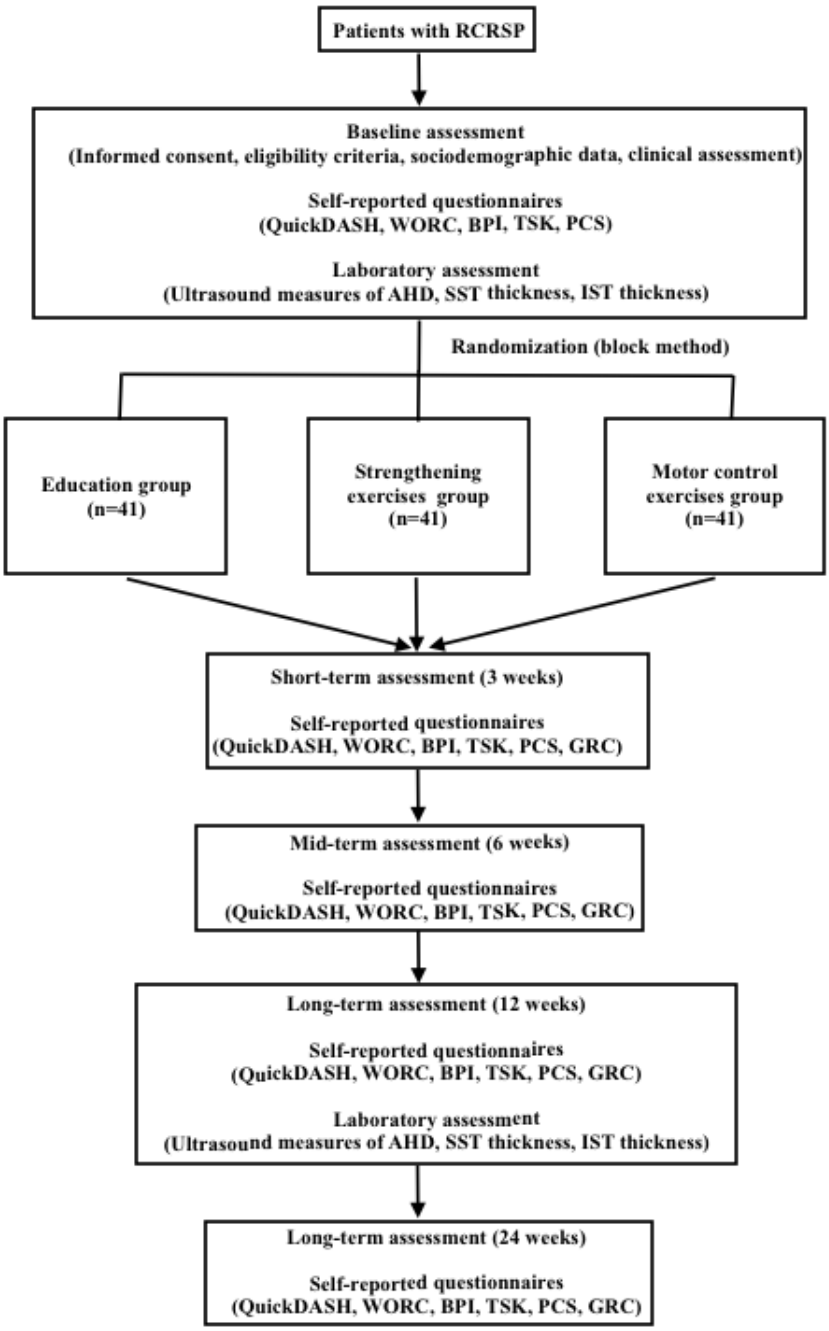
Competing interests statement

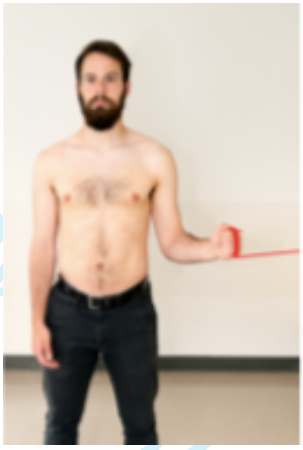
All authors declare that they have no competing interests.

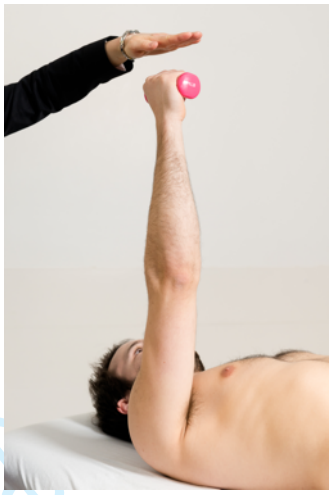
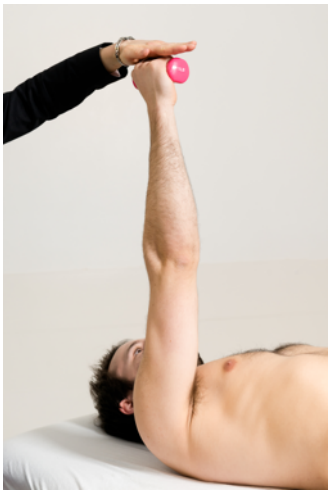
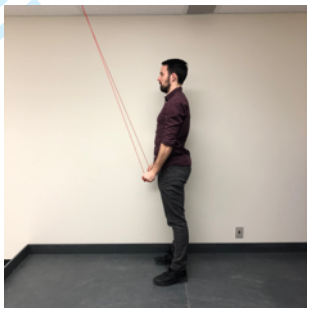
Figure 1: Schematic diagram of the study design. *Quick*DASH, Abbreviated version of the Disabilities of the Arm, Shoulder and Hand questionnaire; WORC, Western Ontario Rotator Cuff Index; BPI, Brief Pain Inventory; TSK, Tampa Scale of Kinesiophobia; PCS, Pain Catastrophizing Scale; AHD, Acromiohumeral distance; SST, supraspinatus tendon; IST, infraspinatus tendon; GRC, Global rating of change



Supplementary file 1: Shoulder muscles strengthening program.

EXERCISES PROGRAM		
A) SHOULDER EXTERNAL ROTATION		
1. Shoulder external rotation at 0° • Hold a weight in your hand. • Lie on the opposite side of the hand holding the weight. • With the trunk upright, flex the elbow 90 degrees. Tighten the abs. • Lift the weight so that your hand is upward, keeping your elbow at 90 degrees.		
2. Shoulder external rotation at 45° • Hold a weight in your hand. • With the trunk upright, flex the elbow 90 degrees. Tighten the abs. • Lift your arm to 90° of abduction while		

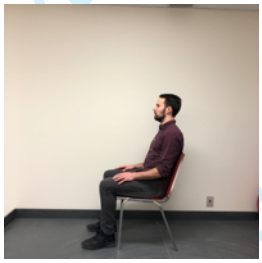
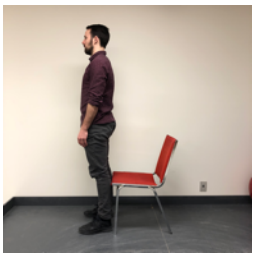
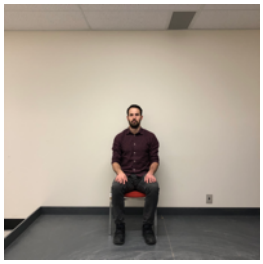
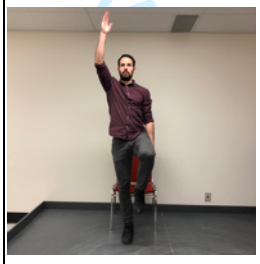
keeping your elblow flexed at 90°. • Lift the weight in order to bring your hand upwards and backwards while keeping your elbow flexed at 90° and your arm abducted at 45°.		
B) SHOULDER INTERNAL ROTATION		
1. Shoulder internal rotation at 0° • Tie an elastic band level to your hips. Turn aside. • With your trunk straight, flex the elbow 90 degrees. Tighten the abs. • Pull the elastic to bring the hand from the outside to the inside, make sure that the elbow does not take off from the body. Keep the elbow at 90 °.		
C) ARM ELEVATION (SCAPTION)		
1. Scaption with weight • Use a weight to make the scaption movement. • Raise your arm by keeping your elbow extended in a 45° motion plane. • Do not lift the shoulder up or lean the trunk to the opposite side.		

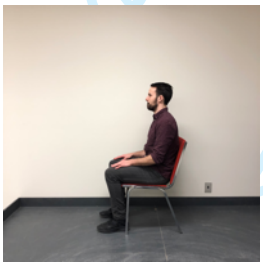
D) SHOULDER PROTRACTION		
1. Protraction with weight • Lie on your back with your knees bent and your back in a neutral position. Contract your abs. • Raise your arm up to reach 90°. When your arm is upright, push your hand toward the ceiling keeping your back flat, without lifting your shoulders.		
E) SHOULDER EXTENSION		
1. Shoulder extension with an elastic band • With both hands, grasp the ends of a rubber band attached at shoulder height. • Keep your back straight and your shoulders slightly back. Tighten the abdominals, tuck in the chin.		

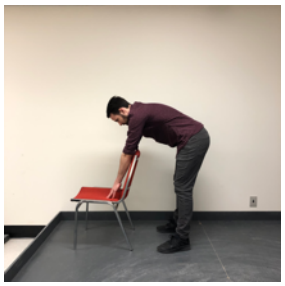
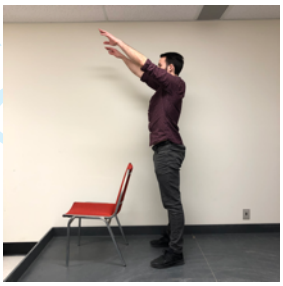
• With arms outstretched, slowly pull backwards so that your hands are shifted to the outside of your hip. Keep your back straight and your shoulders slightly backwards throughout the exercise.		
F) HORIZONTAL ABDUCTION		
1. Horizontal abduction with weight • Lying prone, with your elbow flexed 90° and a weight in each hand. • Lift your ams up 1 or 2 cm without lifting your shoulders from the table. • Extend your elbows. • Flex back your elbows to 90° and lower your arms in the starting position.		

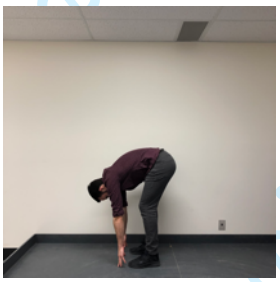
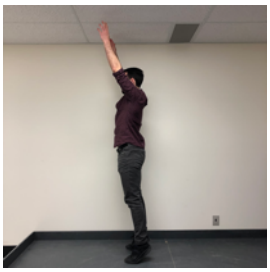
G) ELEVATION		
1. Elevation with weight • With arms raised about 30 ° to the side, bring both shoulders slightly back and towards the eyes. • Tighten the abdominals, tuck in the chin.		

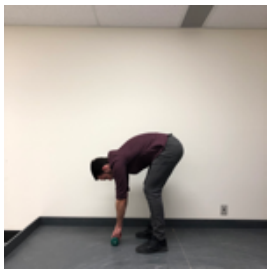
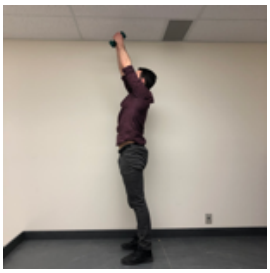
Supplementary file 2: Motor control and functional exercise program.

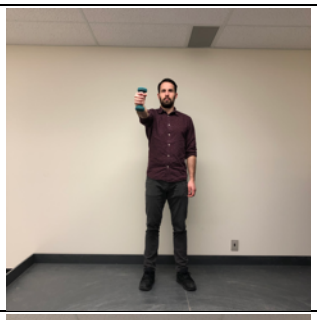
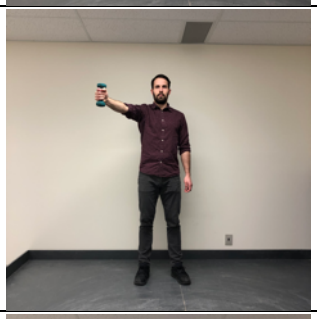
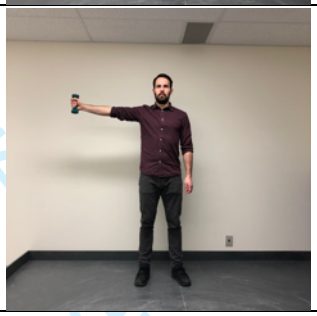
<table>
<tr><th colspan="3">EXERCISES PROGRAM</th></tr>
<tr><td colspan="3">A) Exercise 1 : Lower limbs</td></tr>
<tr><td>1.
Hold a ball in front of you and bend your knees
Aim for 15 repetitions.</td><td>  </td><td>  </td></tr>
<tr><td>2.
Perform sit-to-stand for 1 minute.
Stop if you experience significant fatigue or if you reach 1 minute.</td><td>  </td><td>  </td></tr>
<tr><td>3.
Continue the same exercise by adding the lifting of one leg and arm from the opposite side as high as possible.
Perform the same</td><td>  </td><td>  </td></tr>
</table>

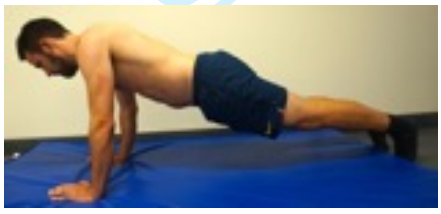
movement on the other side and sit down after. • Aim for 1 minute.		
4. • Progress to this level when you are able to achieve at least 15 repetitions of level 3 in 1 minute. • Continue sit-to-stand transfers, but this time, tip-toe up when you arrive in a standing position. • Aim for 1 minute and incrementally add weights.		
B) Exercise 2 : Upper limbs		
1. • Without weight in the hands, bend the trunk		

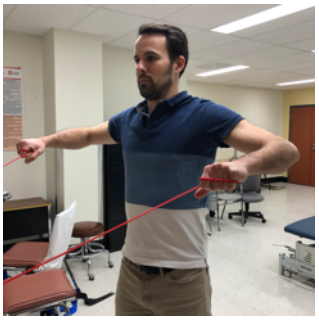
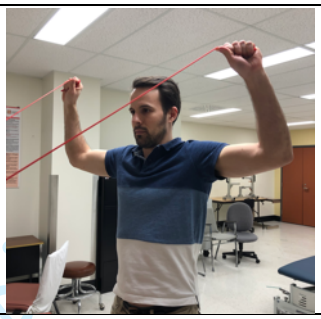
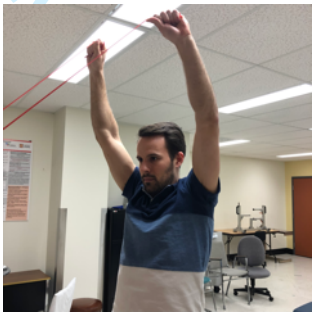
slightly to touch the top of a chair and raise your arms at shoulder height. • Movement should be slow and until you feel tired or in pain (3/10).		
2. • Start when you are able to perform at least 15 consecutive level 1 repetitions. • Still without weight in your hands, bend further to touch the chair seat and raise your arms even higher than the previous level.		

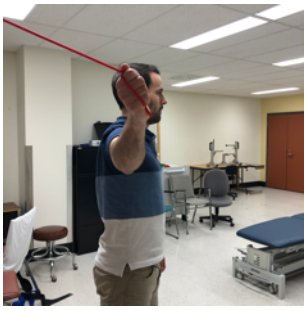
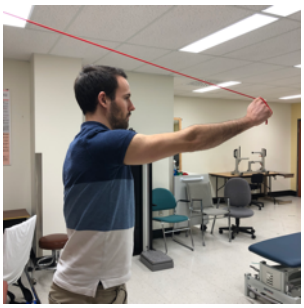
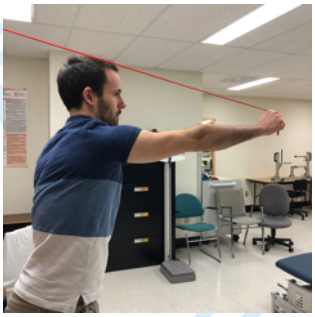
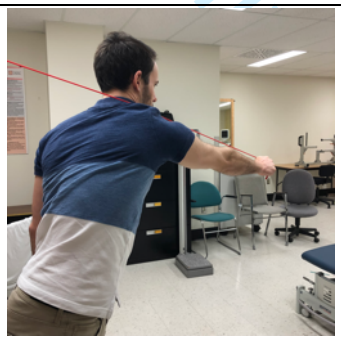
• Movement should be slow and until you feel tired or in pain (3/10).		
3. • Start when you are able to perform at least 15 consecutive level 2 repetitions. • Still without weight in your hands, bend further to touch the ground and raise your arms as high as possible. • Movement should be slow and until you feel tired or in pain (3/10).		

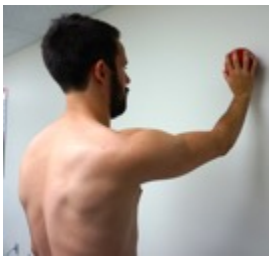
4. • Start when you are able to perform at least 15 consecutive level 3 repetitions. • Bend to pick-up a light weight from the ground and raise it as high as possible.		
5. • Start when you are able to perform at least 15 consecutive level 3 repetitions. • Progressively lift heavier weights.	Same pictures as level 4	

C) Exercise 3 : Arm elevation in 3 different planes	
C1. Flexion (starting with a short lever if necessary)	
C2. Scaption (starting with a short lever if necessary)	
C3. Abduction (starting with a short lever if necessary)	
D) Pushing	
1. Wall push up • Standing, hands resting on the wall, arms a little narrower than the shoulders at an angle of about 45 degrees. Tighten the abdominals, tuck in the chin. Do not lift your shoulders. • Push against the wall, pushing apart the shoulder blades (round the back),	

imagining that someone is pushing you on the sternum.	
2. Push up on knees • Place your hands slightly greater than shoulder-width apart and your knees comfortably apart. Tighten the abdominals, tuck in the chin. • Slowly bend your elbows and lower your chest until your elbows are flexed 90°, then slowly return to the starting position.	
3. Push up • Place your hands slightly greater than shoulder-width apart and your feet comfortably apart. Tighten the abdominals, tuck in the chin. • Slowly bend your elbows and lower your chest until your elbows are flexed 90°, then slowly return to the starting position.	

E) Pulling	
1. Rowing at shoulder height • Tie an elastic band in front of you at shoulder height. • Pull the elastic until your elbows are level with your trunk while keeping your hands parallel to the ground. Keep your trunk right, tighten your abdominals and tuck you chin.	
2. Rowing + ER • Perform level 1. • Once in position, rotate your arm in order to bring your hands backwards.	
3. Rowing + ER + elbow extension (+squat) • Perform level 2. • Once in position, extend your elbows and lift your hands as high as possible.	
G) Carrying	
1. Walking while carrying a weight • Pick up a weight with your hand and walk for 5 meters while keeping yout trunk	

right. Walk back with the weight in your other hand.		
H) Throwing		
1. Simple throwing motion with rubber band • Tie a rubber band to the top of a door. • Take the rubber band in your hand and turn your back to the door. • Bring your arm forward as if you were throwing an object. Keep your trunk right, tighten your abdominals and tuck you chin.		
2. Simple throwing motion with rubber band + shoulder protraction • Same as level 1 but bring your shoulder forward at the end of the movement.		
3. Simple throwing motion with rubber band + trunk rotation • Same as level 2 but add a trunk rotation to the opposite side of your throwing hand.		

I) Precision	
1. Drawing the alphabet on the wall with a ball • Slowly draw the letters of the alphabet on a wall using a rolling ball. • As you progress, try to draw letters as little as possible.	

Consent form

For a patient's consent to publication of images and/or information about them in BMJ publications.

Name of patient:	_____*Marc-Olivier Dubé*_____
Relationship to patient (if patient not signing this form):	_____
*Description of the photo, image, text or other material (**Material)** about the patient. **A copy of the Material must be attached to this form**:*	_____*Photos for exercise program*_____
Provisional title of article in which Material will be included:	*Rotator cuff related shoulder pain: Does the type of exercise influence the outcomes – Protocol of a randomized controlled trial*

CONSENT

I_____Marc-Olivier Dubé_____*[PRINT FULL NAME]* give my consent for the Material about me/the patient to appear in a BMJ publication.

I confirm that I: *(please tick boxes to confirm)*

☒ ***have seen the photo, image, text or other material about me/the patient***

☒ ***have read the article to be submitted to BMJ*** ☒ ***am legally entitled to give this consent.***

I understand the following:

(1) The Material will be published without my/the patient's name attached, however I understand that complete anonymity cannot be guaranteed. It is possible that somebody somewhere - for example, somebody who looked after me/the patient or a relative - may recognise me/the patient.

(2) The Material may show or include details of my/the patient's medical condition or injury and any prognosis, treatment or surgery that I have/the patient has, had or may have in the future.

(3) The article may be published in a journal which is distributed worldwide. BMJ's publications go mainly to doctors and other healthcare professionals but are also seen by many others including academics, students and journalists.

(4) The article, including the Material, may be the subject of a press release, and may be linked to from social media and/or used in other promotional activities. Once published, the article will be placed on a BMJ website and may also be available on other websites.

(5) The text of the article will be edited for style, grammar and consistency before publication.

(6) I/the patient will not receive any financial benefit from publication of the article.

(7) The article may also be used in full or in part in other publications and products published by BMJ and/or by other publishers. This includes publication in English and in translation, in print, in digital formats, and in any other formats that may be used by BMJ or other publishers now and in the future. The article may appear in local editions of journals or other publications, published in the UK and overseas.

(8) I can revoke my consent at any time before publication, but once the article has been committed to publication ("gone to press") it will not be possible to revoke the consent.

(9) This consent form will be retained securely and in confidence by BMJ in accordance with the law, for no longer than necessary. Personal data provided in this form will be used and retained in accordance with BMJ's Privacy Policy available at https://www.bmj.com/company/your-privacy/.

Please tick box to confirm the following:

☐ Where this consent relates to an article in *BMJ Case Reports*, I have/the patient has had the opportunity to comment on the article and I am satisfied that the comments, if any, have been reflected in the article.

Signed: Marc-Olivier Dubé *Print name:* Marc-Olivier Dubé

Address: 2507-2818 Boulevard Laurier *Email address:* marcolivier.dub@gmail.com

G1V0E2 Quebec (Qc), Canada *Telephone no:* 418-906-2071

If signing on behalf of the patient, please give the reason why the patient can't consent for themselves (e.g. patient is under 18 or has cognitive or intellectual impairment).

_____ *Date:* _____

☐ *If you are signing for a family or other group, please tick the box to confirm that all relevant members of the family or group have been informed.*

Details of person who has explained and administered the form to the patient or their representative (e.g. the corresponding author or other person who has the authority to obtain consent).

*Signed:__Marc-Olivier Dubé_*

Print name: ___Marc-Olivier Dubé

Position: ___PhD candidate (student)

Institution:____Université Laval

Address:

525, boul. Wilfrid-Hamel, Office H-1300

Québec (Québec) G1M 2S8

Email address:marc-olivier.dube.1@ulaval.ca

Telephone no:__418-906-2071__

Date: __May 1, 2020__

Supplementary file 3: Information about pain given to both exercise groups

1	Feeling pain in the shoulder is permissible and even encouraged during the exercise program. Any level of pain is permissible as long as it is tolerable for the individual, and, that there is no increase or exacerbation in pain in the evening and the following day.
2	If more guidance as to the amount of pain is required then the participant can perform the exercises in pain with a subjective level of pain between 1 to 3 on a 10-point pain scale, where 0 represents no pain and 10, worst imaginable pain. If this level of pain does not produce an improvement in exercise tolerance, higher levels of pain may be encouraged.
3	Participants will be informed that if increased pain is experienced in the evening or the following day and if this pain is not acceptable for the individual then the number of repetitions per set, number of sets, amount of weight should be reduced accordingly.
4	If there is no exacerbation of pain and the participant perceives that the amount of weight and number of repetitions are being performed at a moderate intensity (on a scale ranging from: no exertion/ easy, mild, moderate, hard, impossible), then heavier weights, or more repetitions may be incrementally used.

Centre intégré universitaire de santé et de services sociaux de la Capitale-Nationale
Québec

Formulaire de consentement

Page 1 sur 1

Numéro de projet : 2019-1762

Titre du projet : Douleur à l'épaule reliée à la coiffe des rotateurs : Est-ce que le type d'exercices influence les résultats? – Un essai clinique randomisé

Chercheur responsable du projet : Jean-Sébastien Roy, pht, Ph.D.

1) Le (la) responsable m'a informé(e) de la nature et des buts de ce projet de recherche ainsi que de son déroulement;
2) Le (la) responsable m'a informé(e) des risques et inconvénients associés à ma participation;
3) Ma participation à cette étude est volontaire et je peux me retirer en tout temps sans préjudice;
4) Les données de cette étude seront traitées en toute confidentialité et elles ne seront utilisées qu'aux fins scientifiques et par les partenaires identifiés au formulaire d'information;
5) J'ai pu poser toutes les questions voulues concernant ce projet et j'ai obtenu des réponses satisfaisantes;
6) Ma décision de participer à cette étude ne libère ni les chercheurs, ni l'établissement hôte de leurs obligations envers moi;
7) Je sais qu'aucune rémunération n'est rattachée à ma participation;
8) Le (la) responsable m'a remis un exemplaire du feuillet d'information et du formulaire de consentement;
9) J'ai lu le présent formulaire et je consens volontairement à participer à cette étude;
10) Je désire recevoir une copie des résultats de l'étude ❑ oui ❑ non

* Pour les **personnes majeures inaptes**, remplacer la signature du participant par celle du mandataire.

Nom du participant	**Date de naissance**	**Numéro de téléphone**
Signature du participant *	Date	
Nom du chercheur	Date	Signature

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a no data
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	13
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1 and 13

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a no trial sponsor
Roles and responsibilities: sponsor and funder	#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	n/a none
Roles and responsibilities: committees	#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)	n/a none
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	3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	3
Objectives	#7	Specific objectives or hypotheses	3 and 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, non-inferiority, exploratory)	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	4

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)	4
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5 and 6
Interventions: modifications	#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)	5 and 6
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	5 and 6
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
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	6 and 7
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)	4 + figure 1
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	4 and 5
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	4 and 5
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	5

		provided in a separate document that is unavailable to those who enrol participants or assign interventions	
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	5
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	5
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	5
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#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	6 and 7
Data collection plan: retention	#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	6 and 7
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	7
Statistics: outcomes	#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	7

Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	7
Statistics: analysis population and missing data	#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)	7
Methods: Monitoring			
Data monitoring: formal committee	#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	7
Data monitoring: interim analysis	#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	7
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	7
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	8
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)	8
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8

Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
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	8
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	13
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/a
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: trial results	#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	8
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Supp file
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	n/a

Notes:

- 2b: n/a no data
- 5b: n/a no trial sponsor

- 13: 4 + figure 1 This checklist was completed on 30. April 2020 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai