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SYSTEMATIC REVIEW

The Efficacy of Higher Versus Lower Dose Exercise in Rotator Cuff Tendinopathy: A Systematic Review of Randomized Controlled Trials

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Abstract

Objectives: To compare the effectiveness and harms of higher exercise dose, including higher exercise load or higher volume, with lower exercise dose (lower load or lower volume) in individuals with rotator cuff tendinopathy.

Design: Systematic review.

Data Sources: Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, and CINAHL from inception to March 2019.

Study Selection: Randomized controlled trials comparing higher versus lower dose exercise that investigated function and pain (overall, activity, night) and adverse event outcomes were independently determined by 2 reviewers.

Data Extraction: Two authors independently extracted data and assessed risk of bias using the Cochrane tool. The primary endpoint was at least 6 weeks to 3 months (other endpoints included up to 6 weeks and beyond 3 months) and the Grades of Recommendation, Assessment, Development and Evaluation was used to assess evidence certainty.

Data Synthesis: Three trials (N = 283), none at low risk of bias for all domains, were included. Low-certainty evidence (1 trial, N = 102) indicated improved function (20 points [95% confidence interval, 12-28] on a 0-100 point scale) with higher load and volume exercise at 3 months, but little or no clinically important between-group difference in activity or night pain (overall pain not reported). Very low-certainty evidence (1 trial, N = 120) indicated higher load exercise conferred no function benefits over lower load exercise at 6 weeks. Very low-certainty evidence (1 trial, N = 61) indicated benefit of uncertain clinical importance in function with higher versus lower volume exercise at 3 months and clinically important benefit at more than 3 months (pain outcomes not reported). The risk of adverse events was uncertain.

Conclusions: There are few studies that have investigated higher dose exercise for rotator cuff tendinopathy. There was low to very low certainty and conflicting evidence regarding the value of higher exercise dose in individuals with rotator cuff tendinopathy.

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Shoulder pain is estimated to have a prevalence between 15% and 30% in the general population, with prevalence increasing with age.[1] Rotator cuff tendinopathy is the most common cause, accounting for up to 80% of all cases of shoulder pain in primary care.[2] Although often self-limiting, up to 50% of patients who present for care may continue to experience ongoing pain and disability beyond 12 months.[2] This results in significant morbidity and health resource utilization, given that shoulder function is essential to personal hygiene, dressing, and work.[2]

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Clinical guidelines recommend clinician-prescribed exercise for rotator cuff tendinopathy.[3,4] However, there are conflicting data regarding its benefits.[5-7] An updated Cochrane review synthesized exercise and manual therapy evidence for rotator cuff tendinopathy from 60 trials (3620 participants) until 2015. The authors reported high quality evidence from a single trial (120 participants),[8] indicating that manual therapy and exercise provided no patient-reported benefits in pain and function outcomes over placebo at 22 weeks of follow-up. However, the exercise component was not loaded progressively and could be defined as lower load.[6] This lack of benefit in pain and function outcomes was supported by very low quality evidence from 2 trials (89 participants) that compared manual therapy and exercise with no treatment, although only 1 trial progressed the exercise load in the active group.[9,10] By contrast, low quality evidence from 1 trial of exercise versus placebo (80 participants in these treatment groups) that did progress load in the exercise group reported pain and function outcome benefit favoring the exercise group for overall pain and function but not activity pain or night pain.[11]

Although the overall body of evidence indicates a lack of consensus regarding the benefit of exercise for rotator cuff tendinopathy, previous systematic reviews have not generally considered whether exercise dose parameters such as load progression and repetitions influence outcomes. Higher load may be more beneficial for neuromuscular adaptation and higher volume might develop greater muscular endurance.[12,13] Greater neuromuscular adaptation and muscular endurance could improve function and improve shoulder symptoms.[14] In a systematic review of prescription parameters reported in randomized controlled trials (RCTs) of exercise interventions for rotator cuff tendinopathy, trials that progressively loaded exercise were more likely to report improvements in shoulder function compared with trials in which exercise was not progressively loaded.[15] However, it is unclear whether these improvements are clinically important or if these findings are robust in view of potential biases in the included studies. Further exploration of the relationship between exercise dose and outcomes in rotator cuff tendinopathy therefore appears warranted.

The aim of this systematic review was to compare the effectiveness and harms of higher exercise dose, including higher exercise load or higher volume, with lower exercise dose (lower load or lower volume) in individuals with rotator cuff tendinopathy.

Methods

Criteria for considering studies for this review

We adopted similar methods to the updated Cochrane review of manual therapy and exercise interventions for rotator cuff tendinopathy.[6] Our review was conducted in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses statement guidelines[16] and was registered with the International Prospective Register of Systematic Reviews (PROSPERO: CRD42017077478).

List of abbreviations:

CI **confidence interval**
RCT **randomized controlled trial**
SRQ **Shoulder Rating Questionnaire**

Types of studies

We included RCTs of any design (eg, parallel, factorial, crossover) and controlled trials using a quasi-randomized method of allocation. There were no restrictions based on language.

Types of participants

We included trials that recruited participants aged 16 years and older with a primary complaint (any duration) of shoulder pain (with or without referral into the arm) labelled or diagnosed as rotator cuff tendinopathy by any means. Rotator cuff tendinopathy has many synonyms in the literature, including rotator cuff disease, rotator cuff related pain, subacromial impingement syndrome, rotator cuff tendinitis, supraspinatus, infraspinatus or subscapularis tendonitis or tendinopathy, subacromial bursitis, and rotator cuff tears. Trials using these synonyms were included as were trials in which participants had unspecified shoulder pain provided that the inclusion and exclusion criteria were compatible with a diagnosis of rotator cuff tendinopathy (ie, anterolateral shoulder pain that is made worse by active and resisted shoulder elevation and associated with preserved passive range of motion[4]). We included trials with participants with multiple shoulder disorders if data were presented separately for our population of interest.

Trials were excluded if they included participants with a full thickness tear involving more than 1 rotator cuff tendon (based on presentation or imaging findings), gross shoulder instability, significant shoulder trauma, previous shoulder surgery, shoulder osteoarthritis, patients with hemiplegia affecting the shoulder, a complex myofascial neck/shoulder/arm pain condition, suspected cervical spine referred pain, or a systemic inflammatory condition (eg, rheumatoid arthritis).

Types of interventions

We included trials that used exercise designed to load the shoulder joint. This could include any active movement in any shoulder plane. Passive movements and pendular movements (also classified as passive[17]) were excluded. Trials were included if they compared higher versus lower dose exercise as defined in the trials. Higher dose could include heavier load (using external weight or resistance) or greater volume (repetitions × sets × frequency). The volume was defined as a total of all sessions they performed, including supervised or home-based exercise. There was no minimum dose (volume or load) because diverse exercise interventions can lead to neuromuscular adaptations.[12,13] Trials needed to explicitly state the load or volume, or both, in each group to ensure certainty that these dose parameters varied. The comparator group needed to be the same setting (eg, home-based, supervised, or a combination) and type of exercise (eg, isometric, isotonic, eccentric) to ensure that dose was the primary variable being investigated. Trials that also progressed other exercise parameters such as the range of motion or the type of exercise (static to dynamic) were included if these were identical in both treatment groups. Co-interventions, including mobilization, manipulation and massage modalities, glucocorticoid injections, and analgesia were allowed, even if they were not applied equally to groups.

Types of outcome measures

For effectiveness, we included patient-reported shoulder function, and the following pain outcomes (as per the review of Page et al[6]): overall shoulder pain, activity, and night pain in the shoulder. When data for more than 1 function scale was reported within a

trial, we extracted data from the function scale highest on the shoulder function scale hierarchy reported by Page et al[6]:

(1) Shoulder Pain and Disability Index[18]: Scored on a 0- to 100-point scale, where 0 is the best.
(2) Croft Shoulder Disability Questionnaire[19]: Scored on a 0- to 22-point scale, where 0 is the best.
(3) Constant-Murley Score[20]: Scored on a 0- to 100-point scale, where 100 is the best.
(4) Any other shoulder-specific function scale.

Overall pain, pain with activity, and night pain could be measured on a visual analog, numerical, or categorical rating scale. For harms, we included the proportion of participants who experienced adverse events.

Outcome times were selected to identify short (≤6wk), medium (6wk-3mo), and longer-term (>3mo) effects of the exercise interventions. The longest timepoint was extracted when multiple timepoints were reported within a given range. We chose greater than 6 weeks and up to 3 months as the primary endpoint, given that this is enough time for exercise to result in greater muscle volume and strength, and potentially better function.[12]

Data sources and search

Relevant trials published up to March 2015 were identified from the updated Cochrane review of manual therapy exercise interventions for rotator cuff tendinopathy.[6]Because we focused on exercise for rotator cuff tendinopathy, the search strategy from Page et al[6]was modified to exclude terms related to adhesive capsulitis as well as non-exercise interventions. For more recent studies, we repeated the search in the Cochrane Central Register of Controlled Trials, Ovid MEDLINE (March 2015-March 2020), Ovid EMBASE (March 2015-March 2020), and CINAHL Plus (EBSCO, March 2015-March 2020).

The updated search strategies for all databases are shown in supplemental appendix S1(available online only at http://www.archives-pmr.org/). We also searched gray literature via OpenGray and ongoing trials via the National Institute of Health (clinicaltrials.gov) and the World Health Organization (http://www.who.int/ictrp) International Clinical Trials Registries, using the terms "rotator cuff disease" [condition] and "exercise" [intervention] up to March 2019.

Selection of studies

Two authors (P.M., G.S.) independently screened titles and abstracts for potentially eligible trials, based on a predetermined checklist of inclusion criteria. The full text of potentially eligible trials was retrieved and independently assessed by the same 2 authors to determine eligibility. Any discrepancies were resolved via discussion or by consulting a third author when necessary (C.L.).

Data extraction

Two authors (P.M., G.S.) independently extracted data onto a standard data extraction form. Discrepancies were resolved through discussion until a consensus was reached. Otherwise, a third author (R.B.) was consulted to adjudicate.

The following data were extracted from each study:

(1) Trial characteristics (sample size, first author name, year of publication, type of trial [eg, parallel, crossover], country, source of funding, trial registration status [registration number if reported]).
(2) Participant characteristics (inclusion and exclusion criteria, age, sex, duration of symptoms).
(3) Intervention including exercise characteristics (exercises performed, sets, repetitions, frequency, duration, how exercise was loaded, how exercise was progressed and how often, adherence measures, advice about pain during exercise).
(4) Comparator intervention exercise characteristics.
(5) Co-interventions, if any, in each group.
(6) Outcomes reported, including the measurement instrument used and timing of outcome assessment.

To minimize potential bias, we used the following a priori decision rules for selecting outcome data:

(1) Preference was given to data that were adjusted for baseline values (eg, analysis of covariance) if available and intention-to-treat.
(2) When follow-up and change scores were reported for the same outcome, we planned to extract follow up scores.
(3) For cross-over RCTs, we planned to only extract data for the first period.

Risk of bias assessment

Risk of bias for each study was performed using the Cochrane Collaboration's tool for assessing risk of bias, described fully in the Cochrane Handbook for Systematic Reviews of Interventions.[21]Risk of bias was performed independently by 2 of 3 authors (P.M., G.S., or R.J.) and discrepancies were resolved through discussion until a consensus was reached. Otherwise, a third author (R.B.) was consulted to adjudicate.

The following domains were rated as high risk of bias if they were not performed adequately, unclear risk of bias if it was not clearly reported, or low risk of bias if performed adequately: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, outcome reporting bias, and other sources of bias (ie, baseline imbalance, unequal application of co-interventions across treatment groups). All domains had to achieve a low risk of bias rating for the study to be classified as being at low overall risk of bias.

Measures of treatment effect

Review Manager 5.3[a]was used to calculate measures of treatment effect. Adverse events were expressed as relative risk and 95% confidence intervals (CI). Mean pain was expressed as mean difference and 95% CIs on a 0- to 100-point visual analog scale, with a higher score indicating more pain. Mean function was also expressed as mean difference and 95% CIs, with a lower score indicating less disability or better function. To make zero the best function in all scales, we reversed scores for scales such as the Constant-Murley score and Shoulder Rating Questionnaire (SRQ) in which a higher score indicates less disability or better function. For the SRQ, we also transformed scores from a scale of 17 to 90 to a scale of 0 to 100.[22]We assumed a minimal clinically important difference of 10 points on a 100-point scale for function and 15 points on a 100-point scale for pain.[6]A clinically important

difference was defined as a CI in which even the lower band (closest to null) was greater than 10 (for function) or 15 points (for pain).

Study authors were contacted (twice during 4 weeks) via email in any instances of missing data. If the data were not retrieved from the study authors, we planned to calculate SD from the standard errors, 95% CIs, or *P* values, or to use median and interquartile ranges to approximate the mean and SD (SD = width of interquartile range/35), respectively.

Data synthesis

Meta-analysis was planned to pool results of trials with similar characteristics (eg, participants, interventions, outcomes). However, there was insufficient data to undertake data pooling.

Summary of findings

We created summary of findings tables[23] for a priori comparisons that included outcomes at the primary endpoint of 6 weeks to 3 months. We rated the overall grading of the certainty of the evidence based on the Grades of Recommendation, Assessment, Development and Evaluation Working Group approach.[24] From an initial starting point of high-certainty evidence, the level of evidence was downgraded (to moderate, low, or very low) for each of the following: risk of bias, inconsistency of results, indirectness, imprecision, and publication bias.

For dichotomous outcomes (eg, adverse events), we planned to calculate absolute risk difference expressed as a percentage and relative percent change (risk ratio−1) expressed as a percentage. For continuous outcomes (eg, function), we planned to calculate absolute change, which is the difference in the mean of higher and lower load groups at follow-up standardized to the original units and expressed as a percentage. The relative percent change was also calculated as the mean difference between groups at follow-up divided by the mean of the lower load group at baseline, expressed as a percentage.

Results

Study selection

Two eligible trials were identified from the Page et al[6] systematic review.[14,25] An additional 3927 records (3287 unique studies) were identified from the updated search conducted from 2015 to June 5, 2020. Of these, we assessed 13 in full text and identified 1 additional trial for inclusion (fig 1).[26] Two trials were registered in trial registries (table 1),[14,26] but neither published their protocol.

We excluded 11 trials after full text assessment for the following reasons: 4 compared different types of exercise rather than dose,[27-30] 1 compared home versus group supervised group exercise,[31] 1 compared pendular exercise with and without load,[32] 1

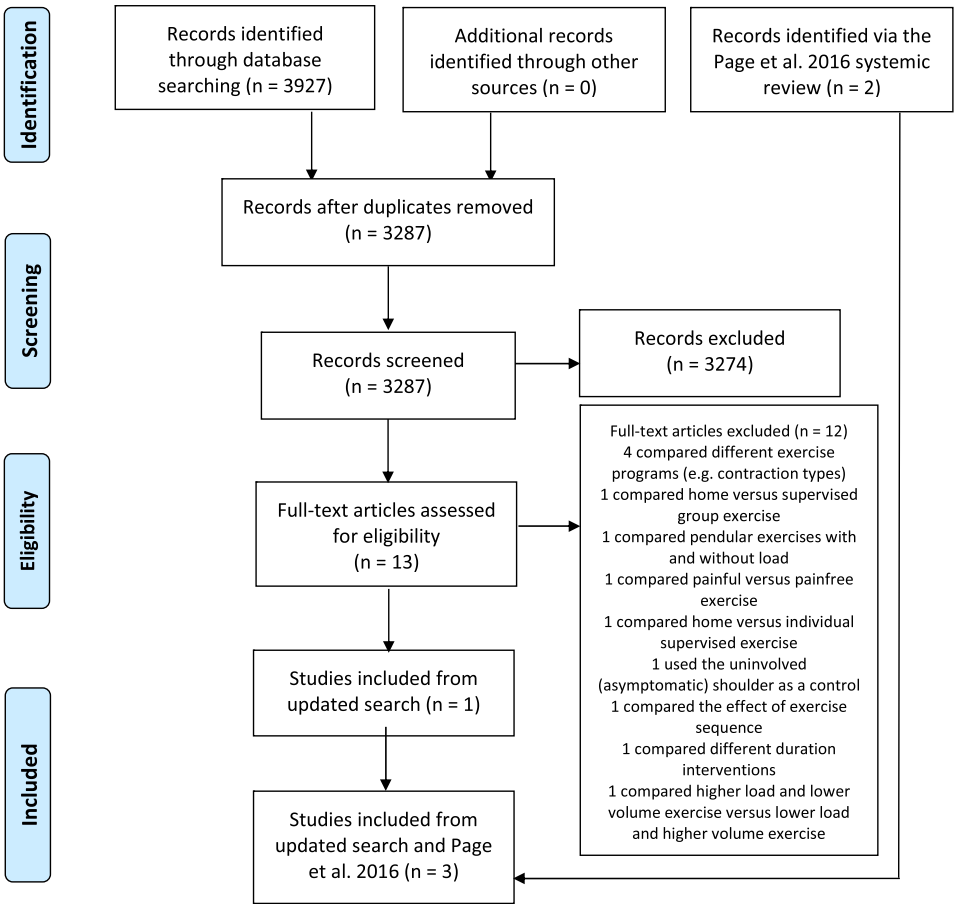

Fig 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2009 flow diagram for literature search results.

Table 1 Study, participants, and intervention characteristics

Author, Year, Trial Type, Country, Funding, Trial Registration	Participants, Number Screened, Number Randomized Total, Per Group, Number Available at Follow-Up	Mean Age, Function,* Pain,† Symptoms Duration	Progressive and Resisted Exercise (Group A) Type, Supervised or Home, Additional Interventions	Group A Sets × Reps or Time, Frequency, Duration, Total Sessions, Time Under Tension, Rest Time	Group A Load, Progression Criteria	Group A Pain During Exercise	Lower Dose Exercise (Group B) Type, Supervised or Home, Additional Interventions	Group B Sets × Reps or Time, Frequency, Duration, Total Sessions, Time Under Tension, Rest Time	Group B Load, Progression Criteria	Group B Pain During Exercise	Adherence	Outcomes, Extracted Outcomes
Heron et al,[26] 2016, RCT, UK, Penine Hospital NHS Research and Development, ISRCTN76701121	473 screened, 120 randomized, 40 range of movement (31 at final follow-up [6 wk]), 40 open chain (30 at final follow-up), 40 closed chain (21 at final follow-up)	Range of motion group: 49.5 y, 63% men, 51 (0-100, 0 best), duration of pain 3 mo to 1 y in 58%, >1 y in 43% Open chain group: 50.4 y, 60% men, 49 (0-100, 0 best), duration of pain 3 mo to 1 y 73%, >1 y 28% Closed chain group: 49.8 y, 55% men, 53 (0-100, 0 best), duration of pain 3 mo to 1 y 65%, >1 y 35%	Stretching anterior and posterior shoulder, and progressive and resisted shoulder abduction to 90 degrees, external and internal rotation Home, 3 sessions in 6 wk	3 x 10, 2x/d, 6 wk, 84 sessions, ?, ?	Theraband progressed every 2 wk, based on pain at correct level and fatigue	Allowed pain if settled within an h	Stretching anterior and posterior shoulder, and passive or active (unloaded) abduction, external and internal rotation Home, 3 sessions in 6 wk Other group: excluded owing to different exercise type	As per group A	No load or progression	Allowed pain if settled within an h	Exercise log (83% higher and 86% in lower load group completed >75% of prescribed exercise)	Outcomes: Function with the shoulder pain and disability index (0-100, 0 best), 6 wk Outcomes extracted: function Note: the authors provided follow-up standard deviation for function scores so treatment effects could be calculated
Holmgren et al,[14] 2012, RCT, Sweden, no funding, NCT01037673	152 screened, 102 randomized, control exercise group 50 (46 at final follow-up [3 mo]), specific exercise group 52 (51 at final follow-up)	Control exercise group: 52 y, 52.2% men, 51 (0-100, 0 best), activity pain 61 (0-100, 0 best), 12 mo Specific exercise group: 72.5% men, 56 (0-100, 0 best), activity pain 66 (0-100, 0 best), 24 mo	2 eccentric rotator cuff exercises, three scapular exercises, posterior shoulder stretch. Home, 6 sessions in 12 wk Other interventions: Ergonomic and posture advice, steroid injection at baseline, manual treatment when necessary	3x15, 2x/d, 0-8 wk, 1x/d 8-12 wk, 12 wk, 140 sessions, ?, ?	Weights or theraband, based on producing some pain during exercise	Should feel some pain but not exceeding 5/10 (0=no pain, 10=worst imaginable pain)	Movement exercises including abduction, scapular retraction and elevation, neck retraction; and stretches including upper trapezius and pectoralis major Home, 6 sessions in 12 wk Other interventions: Ergonomic and posture advice, steroid injection at baseline	1x10, 2x/d, 12 wk, 168 sessions, ?, ?	No load or progression	Not reported	Exercise log (86% in higher and 87% in lower volume group >82% of prescribed exercise)	Outcomes: Function with disability of arm and shoulder score (0-100, 0=best) and Constant score (0-100, 100 is best), activity and night pain with VAS (0-100, 0=best), quality of life with the Euroqol 5D-5L, 3 mo Outcomes extracted: function, activity pain, night pain

(*continued on next page*)

Table 1 (*continued*)

Author, Year, Trial Type, Country, Funding, Trial Registration	Participants, Number Screened, Number Randomized Total, Per Group, Number Available at Follow-Up	Mean Age, Function,* Pain,† Symptoms Duration	Progressive and Resisted Exercise (Group A) Type, Supervised or Home, Additional Interventions	Group A Sets × Reps or Time, Frequency, Duration, Total Sessions, Time Under Tension, Rest Time	Group A Load, Progression Criteria	Group A Pain During Exercise	Lower Dose Exercise (Group B) Type, Supervised or Home, Additional Interventions	Group B Sets × Reps or Time, Frequency, Duration, Total Sessions, Time Under Tension, Rest Time	Group B Load, Progression Criteria	Group B Pain During Exercise	Adherence	Outcomes, Extracted Outcomes
Østerås et al,[25] 2008, RCT, Norway, no funding, no trial registration	Unknown amount screened, 61 randomized, higher volume group 31 (23 at final follow-up [15 months]), lower volume group 30 (26 at final follow-up)	Higher volume exercise group: 46.1 y, 65.2% men, 63 (0-100, 0 best), 4 y Lower volume exercise group: 41.8 y, 52.9% men, 63 (0-100, 0 best), 3 years	11 exercises: 3x10 minutes aerobic 70-80% of maximum HR. 8 exercise loading all muscles acting on the shoulder, shoulder girdle and entire upper extremity Supervised, 36 sessions in 12 wk	3x30, 3x/wk, 12 wk, 36 sessions, ?, ?	Pulley machine weights, dumbbell, barbells, progressed when exercise became pain-free	Close to pain-free threshold (ie, with minimal pain)	6 exercises: 1x10 min of aerobic, and 5 strength and flexibility exercises Supervised, 36 sessions in 12 wk	2x10, 3x/wk, 12 wk, 36 sessions, ?, ?	Pulley machine weights, dumbbell, barbells, progressed when exercise became pain-free	Close to pain-free threshold (ie, with minimal pain)	Not reported	Outcomes: Function with shoulder rating questionnaire (17-90, 90=best), rest pain with VAS (0-100, 0=best), adverse events, 3 and 15 mo Outcomes extracted: function, adverse events Note: Reversed direction of function scale for consistency with other studies.

Abbreviations: ?, data missing; HR, heart rate; ISRCTN, International Standard Randomized Controlled Trial Number; NHS, National Health Service; rep, repetitions; UK, United Kingdom; VAS, visual analog scale.

* All function scales were converted to 0-100, where 0 is best.

† Activity pain was reported (where available) and all scales were converted to 0-100, where 0 is best.

compared painful versus pain-free exercise,[33]1 compared home versus individual supervised exercise,[34]1 used the uninvolved asymptomatic shoulder as a control,[35]1 compared the effect of the sequence in which exercises were performed,[36]1 compared different duration interventions,[37]and 1 included high dose exercise in both treatment arms (higher load and lower volume exercise vs lower load and higher volume exercise),[38]and therefore could not contribute to an understanding of the role of high versus low dose of exercise.

Trial, participants, and intervention characteristics

The 3 trials included were all parallel group RCTs and included 283 participants.[14,25,26]All trials had similar inclusion criteria (supplemental appendix S2, available online only at http://www.archives-pmr.org/). The trial, participants, and intervention characteristics of the included trials are shown in table 1. The mean age varied between 46 and 55 years, there was a slight male dominance, and symptom duration was between 3 months and 4 years. The mean baseline function scores varied between 49 and 63 out of 100, with lower scores indicating better function.

One trial compared 12 weeks of either higher load and higher volume exercise or lower load and lower volume exercise,[14]1 trial compared higher versus lower load exercise over 6 weeks,[26]and 1 trial compared 12 weeks of either higher or lower volume exercise.[25]With regards to the comparators, 2 trials simply used active shoulder movements without additional load that can be considered subtherapeutic.[14,26]In contrast, the comparator in the study by Osteras et al[25]still contained progressive load exercise but of lower volume. No trials reported the actual load during exercise or exercise intensity (eg, >70% 1 repetition maximum).[12]Repetitions per week were higher in the "higher volume" (2160-3150) compared with the "lower volume" comparators (300-420).[14,25]

One trial supervised all exercise sessions,[25]whereas the other 2 trials included home exercise. Pain during exercise was permitted in all intervention and comparator groups, aside from the trial by Holmgren et al,[14]in which this detail was not described for the comparator group. All trials included active non-weightbearing exercises in anatomical planes (eg, flexion, abduction, external rotation). All trial participants received a glucocorticoid injection at baseline in 1 trial.[14]This trial also provided manual therapy "when necessary" to participants in only the higher load and volume exercise group.

All 3 trials assessed function, with 1 trial measuring function using 2 instruments.[14]One trial used the Shoulder Pain and Disability Index,[26]1 used the Constant-Murley Score,[14]and 1 used the SRQ.[25]Holmgren et al[14]also used the Disability of the Arm and Shoulder Score, but we extracted data from the Constant-Murley Score. No trial reported overall pain, and Heron et al[26]did not report pain at all. One trial reported activity pain,[14]and 1 trial reported night pain.[14]Two trials also reported pain at rest (or inactivity),[14,25]but as this was not a prespecified outcome, we did not extract data for this outcome. Only 2 trials reported outcomes at our primary endpoint of 6 weeks to 3 months (both at 3mo).[14,25]Østeras et al[25]also reported outcomes at 9 and 15 months, and data were extracted at 15 months for the greater than 3 months endpoint. Although Holmgren et al[14]reported results at 12 months, participants were offered surgery after the 3-month assessment and reported data were sub-grouped by whether or not participants underwent surgery. Therefore, the 12-month data were not extracted for this review. One trial only reported outcomes at 6 weeks.[26]

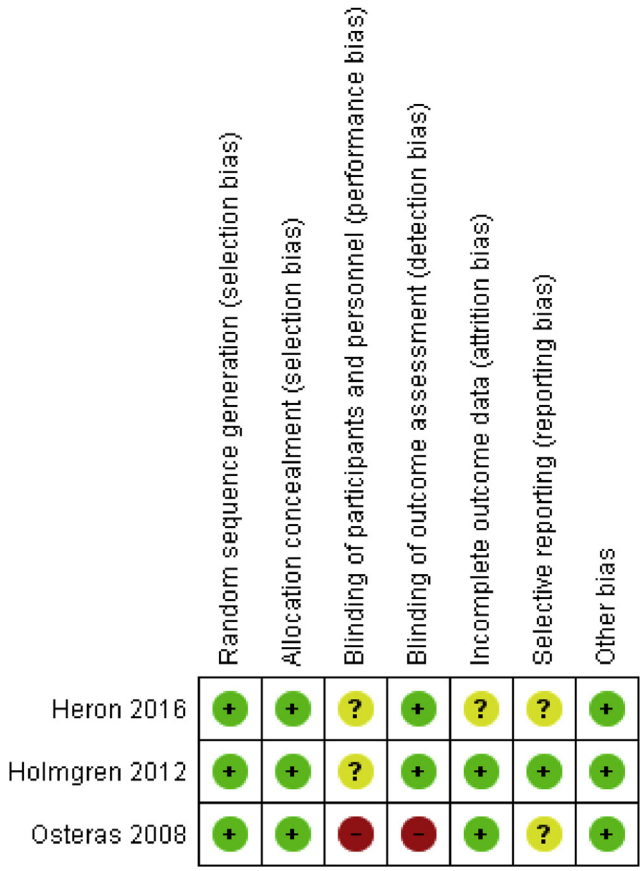

Fig 2 Risk of bias summary: judgements about each risk of bias item for each included study.

Risk of bias in included trials

The risk of bias for each of the included trials is summarized in figure 2. One trial was rated at low risk of bias for all domains other than performance bias, which was rated as uncertain.[14]Of note, this trial was rated at low risk of bias for all domains in the Page et al Cochrane review.[6]Although participants and the outcome assessor were blinded, the trial did not report whether the exercise explanations and verbal interaction (of potential effect and mechanisms) were identical between the groups. Two of the remaining trials were susceptible to performance bias,[25,26]and 1 trial was at risk of detection bias,[25]owing to lack of blinding of either participants or investigators. One trial was also at risk of attrition bias owing to differences in the proportion of dropouts between groups.[26]Two trials were at risk of selective reporting,[25,26]because they reported 1 self-reported outcome measure and there were no associated trial protocols, so it is unclear whether all outcomes were reported.

Comparison 1: higher load and higher volume versus lower load and lower volume

There may be clinically important improvement in function with higher load and higher volume exercise at 3 months (figs 3 and 4). Function was 47.5 points in the lower dose group, and this improvement was 20 points better (95% CI, 12.0-28.5) in the high dose group. There was little or no clinically important benefit of higher dose exercise for pain outcomes at 6 weeks to 3 months.

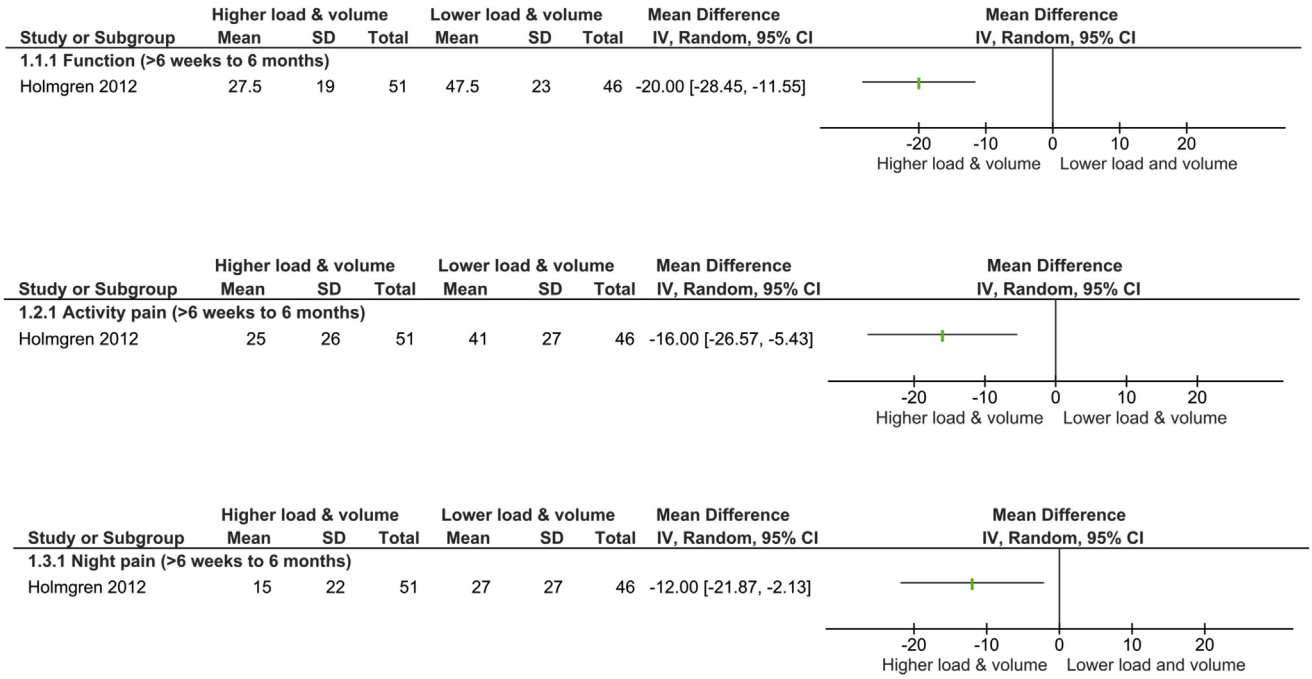

Fig 3 Effects of higher load and higher volume versus lower load and lower volume.

Activity pain was 41 points with low dose exercise and 16.0 (95% CI, 5.4-26.6) points better with high dose. Similarly, night pain was 27 points with low dose exercise and 12.0 points better (95% CI, 2.1-21.9) with high dose. Overall pain and adverse events were not reported. This evidence arose from a single trial (97 participants for all reported outcomes)[14]and was low certainty (downgraded for bias and imprecision).

Comparison 2: higher load versus lower load

Because outcomes were not reported at the primary endpoint for this comparison, no summary of findings table was produced. There was no benefit with higher compared with lower load exercise for function at 6 weeks (fig 5). Function was 42 points in the lower load group, and this improvement was 5 points better in the higher load group (95% CI, 15.9-5.9; better to worse). Overall, activity or night pain and adverse events outcomes were not reported. This evidence was from a single trial (61 participants for function outcome) and was low certainty (downgraded for risk of bias and imprecision owing to the very short follow-up time). Note that only 2 (open chain and range of movement) of the 3 trial arms were eligible and included in this review.

Comparison 3: higher volume versus lower volume

There was benefit of uncertain clinical importance with higher volume exercise in function at 3 months (figs 6 and 7). Function was 45.4 points in the lower volume group and 12.9 points better (95% CI, 7.6-18.1) in the higher volume group. There was a clinically important benefit at more than 3 months. Function was 43.1 points in the lower volume group and 17.8 points better in the higher volume group (95% CI, 11.8-23.8). Overall, activity or night pain were not reported. There was no reliable estimate of the adverse event rates. One participant in the higher volume group was reported to sustain a neck injury (no adverse events were reported for the lower volume group). This evidence arose from one trial (56 participants for all reported outcomes) and was very low certainty (downgraded for risk of bias and imprecision).

Discussion

We found low to very low certainty and somewhat conflicting evidence regarding the value of higher exercise dose in people with rotator cuff tendinopathy. There was low-certainty evidence from a single trial suggesting that higher load and higher volume exercise may result in a clinically important benefit in function but not activity or night pain at 6 weeks to 3 months. There was also very low-certainty evidence from another small single trial indicating that higher volume exercise might provide benefit of uncertain clinical importance for function at 6 weeks to 3 months compared with lower volume exercise, although no data for pain were collected. Very low-certainty evidence from 1 trial indicated that higher load exercise does not provide clinically important benefit compared with lower load exercise with respect to function up to 6 weeks. We are uncertain whether there is an increased risk of adverse events with higher dose exercise, given the incomplete reporting of events and the low event rates. The evidence was downgraded for a variety of reasons, including risk of performance and detection bias, imprecision, and indirectness owing to short follow-up times.

The exercise programs evaluated in the 3 included trials generally reflected the interventions that are delivered in practice and in the rotator cuff tendinopathy literature.[6]Load was progressed when the exercise could be performed easily or with a defined pain response. None of the studies reported the specific intensity (eg, repetition maximum) or absolute load. In contrast, trials that evaluated the effect of volume utilized fixed rather than progressive volumes, and these were at least 5 times greater in the high volume (2160-3150 repetitions/wk) versus the lower volume (300-420

Comparison 1: higher load and higher volume versus lower load and lower volume at >6 weeks to 3 months

Patient or population: rotator cuff tendinopathy
Setting: Secondary care patients (Sweden)
Intervention: Higher load and higher volume exercise
Comparison: Lower load and lower volume exercise

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Lower load and low volume	Higher load and higher volume				
Function Assessed with Constant Murley Score total score (0 to 100, zero is best) Follow-up: 3 months	The mean function in the control group was **47.5 points**	The mean function in the intervention group was **20 points better** (12 better to 28 better)	-	102 (1 RCT)	⊕⊕◯◯ LOW[1,2]	Clinically important improvement with higher load and higher volume[3] Absolute change 20% better (12% better to 28% better); relative change 35% better (21% better to 50% better)[4]
Overall pain	-	-	-	-	-	Unclear as overall pain not measured
Pain with activity Assessed with visual analogue scale (0 to 100, zero is best) Follow-up: 3 months	The mean pain in the control group was **41 points**[1]	The mean pain in the intervention group was **16 points better** (5 better to 27 better)	-	102 (1 RCT)	⊕⊕◯◯ LOW[1,2]	Clinically unimportant improvement[3] Absolute change 16% better (6% better to 26% better); relative change 24% better (8% better to 40% better)[4]
Pain at night Assessed with visual analogue (VAS) scale (0 to 100, zero is best) Follow-up: 3 months	The mean pain in the control group was **27 points**[1]	The mean pain in the intervention group was **12 points better** (2 better to 22 better)	-	102 (1 RCT)	⊕⊕◯◯ LOW[1,2]	Clinically unimportant improvement[3] Absolute change 12% better (2% better to 22% better); relative change 30% better (5% better to 55% better)[4]
Adverse events	-	-	-	-	-	Uncertain as adverse events not reported

*The **assumed risk** is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95%CI).

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1]Downgraded (-1) for imprecision as data were from one study only
[2]Downgraded (-1) for possible risk of performance bias
[3]We assumed a clinically important improvement in function of 10 points on a 100-point scale (or 10%) and a clinically important improvement in pain of 15 points on a 100-point scale (or 15%)
[4]Relative changes calculated as absolute change divided by mean at baseline in the control group from Holmgren 2012: Mean (SD) values were 56.5 (15) for function on a 0-100 point Constant-Murley scale; 66 (20) for activity pain on 0-100 point VAS; 40 (30) for night pain on 0-100 point VAS

Fig 4 Summary of findings for the comparison of higher load and higher volume versus lower load and lower volume.

repetitions/wk) trial arms. Importantly, comparisons were unloaded active movements in 2 studies,[14,26] but still contained progressive load with lower volume[25] in 1 study. Considering the poorly reported and heterogeneous interventions, we cannot make any specific comments regarding the level of load (or intensity) and volume that may confer greater benefit. Final follow-up for the trial included in the higher load versus lower load exercise comparison was between 4 and 6 weeks, which may not be enough time to demonstrate a beneficial effect of higher load exercise if one is present. Littlewood et al[15] reported that maintenance of an exercise program for at least 12 weeks may be needed to demonstrate improvements in function.

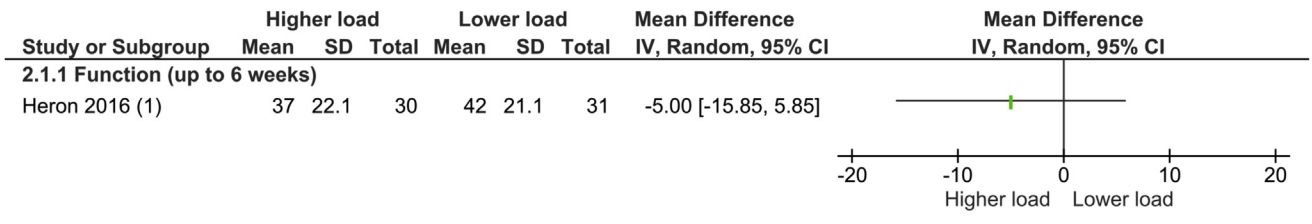

Fig 5 Effects of higher versus lower load exercise.

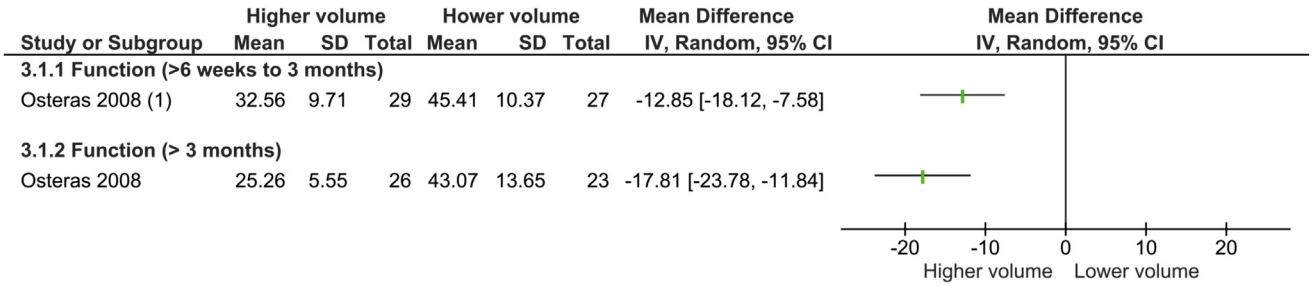

Fig 6 Effects of higher versus lower volume.

Adequate description of comparative load and volumes were part of our inclusion criteria. It was common across studies for other exercise parameters to be incompletely described, including pain during loading, exercise adherence, rest between exercise sets, and exercise tempo (seetable 1). This limitation is important because clinicians are unable to implement incompletely described exercise interventions. Furthermore, because adherence was poorly described, it is impossible to be certain of the dose in each comparator group, and therefore whether exercise dose or other mechanisms influenced outcome. For example, giving a patient permission to perform progressively loaded exercise, or to do more exercise, may reduce fear, increase general shoulder use,

Comparison 3: higher volume versus lower volume at >6 weeks to 3 months

Patient or population: rotator cuff tendinopathy
Setting: Primary care patients (Norway)
Intervention: Higher volume exercise
Comparison: Lower volume exercise

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk Lower volume exercise	Corresponding risk Higher volume exercise				
Function Assessed with shoulder rating questionnaire (SRQ) (converted from 17 to 90 scale and reversed to 0 to 100 points, zero is best) Follow-up: 3 months	The mean function in the control group was **45.4 points**	The mean function in the intervention group was **13 points better** (8 better to 18 better)	-	56 (1 RCT)	⊕◯◯◯ VERY LOW[1,2]	Little or no clinically important improvement with higher volume with higher volume[3] Absolute change 13% better (8% better to 18% better); relative change 25% better (16% better to 35% better)[4]
Overall pain	-	-	-	-	-	Unclear as overall pain not measured
Pain with activity	-	-	-	-	-	Unclear as pain with activity not measured
Pain at night	-	-	-	-	-	Unclear as pain at night not measured
Adverse events	No events reported	One event	No reliable estimate	56 (1 RCT)	⊕◯◯◯ VERY LOW[1,5]	One participant in the higher volume group sustained a neck injury at work and withdrew from the study

*The **assumed risk** is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95%CI)

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1]Downgraded (-1) due to performance and detection bias
[2]Downgraded (-2) for imprecision as data were from a single small study
[3]We assumed a clinically important improvement in function of 10% and a clinically important improvement in pain of 1.5 points on a 10-point scale (or 15%)
[4]Relative changes calculated as absolute change divided by mean at baseline in the control group from Østeras 2010: Mean SD values were 51.0 (9.71) for function on a 0-100 point scale (converted from 17 to 90 scale and score reversed to 0-100 points, zero is best)
[5]Downgraded (-2) for imprecision as data were from a single small study and only one event was reported in one of the trial arms

Fig 7 Summary of findings for the comparison of higher volume versus lower volume.

and thereby improve outcome. Future exercise trials should consider reporting guidelines such as the Consensus on Exercise Reporting Template[39]to improve the extent to which findings are translatable to practice.

Comparison to the literature

Littlewood et al[15]reported superior function outcomes with resisted and greater volume (repetitions and sets), but this was based on a narrative synthesis. Fourteen studies were included in the Littlewood review, and only 1 of these studies specifically examined the effect of exercise dose and was also included in the current review.[25]Our systematic review investigated the effect of higher exercise dose (load or volume) on function and pain outcomes in rotator cuff tendinopathy. Although our review suggested that higher load and higher volume exercise or higher volume exercise might confer superior functional outcomes compared with their lower dose comparisons, we did not find that higher load exercise was better than lower load exercise. However, if an exercise program needs to be maintained for at least 12 weeks before any benefit on function is evident, as proposed by Littlewood et al,[15]this may explain the lack of observed benefit in the higher load versus lower load exercise comparison as exercise intervention and outcome reported extended only 6 weeks.

A randomized trial by Ingwersen et al[38]compared higher load but lower volume with lower load but higher volume exercise for rotator cuff tendinopathy. This study was not eligible for the current review but is worthy of discussion. The authors in this study equalized the work (volume multiplied by intensity) undertaken in each group. This is a worthwhile approach because it is allows identification of whether load or volume is beneficial when accounting for overall work. In contrast, in the current review, we were interested in whether additional load (and work) or additional volume (and work) or a combination of both were beneficial. The Ingwersen et al[38]trial reported meaningful benefit in pain and function in both groups at 12 weeks with no between-group differences for higher intensity or higher volume exercise when work was equalized. This suggests that greater work may explain the between-group differences observed in studies in this review with higher load and volume or higher volume interventions, but this requires investigation in future trials.

Strengths of the systematic review

Our methods were based on a previous Cochrane review of exercise interventions for rotator cuff tendinopathy and adhered to best practice guidelines as outlined by the Cochrane collaboration and Preferred Reporting Items for Systematic reviews and Meta-Analyses to minimize potential sources of bias. Inclusion and exclusion criteria were determined a priori and were clearly defined to minimize selection bias.

Study limitations

The main limitation of this study is that only 3 trials met our inclusion criteria. We performed a comprehensive search but did not find any ongoing or completed trials in trial registries, so publication bias is not likely. A further substantial limitation is diversity between exercise interventions. Comparators in 2 of the 3 trials were unloaded and could be considered subtherapeutic,[14,26]whereas the third trial included substantial progressive load in the higher load arm.[25]This, coupled with the sparse literature, makes it impossible to provide guidance about specific levels of load (or intensity) or volume that may be beneficial for individuals. A potential limitation among the included trials that may influence interpretation is contamination (eg, lower dose groups receiving higher dose or vice versa) between exercise interventions.

Future research

Only 3 studies were identified that met our selection criteria. High quality adequately powered randomized trials are needed to investigate the value of exercise for rotator cuff tendinopathy. Future research should seek to determine optimal dose parameters for improvement in pain and function outcomes among individuals with rotator cuff tendinopathy. Future trialists should consider using function as the primary outcome, considering that the higher dose interventions in this review appeared to confer less differential benefit between exercise interventions. These trials should adequately describe exercise interventions according to published guidelines such as the Consensus on Exercise Reporting Template[39]and the Template for Intervention Description and Replication Checklist.[40]Robust monitoring of exercise fidelity (eg, appropriately implementing progressive load) and adherence is also required to draw valid conclusions regarding the effect of dose on outcomes.

Implications for practice

Despite conflicting data, clinical guidelines continue to recommend clinician-prescribed exercise for rotator cuff tendinopathy. Based on the currently available low to very low-certainty evidence, exercise that progressively increases load and utilizes greater volume may confer superior function outcomes compared with lower dose exercise regimens, although the certainty of these findings needs to be confirmed in high quality trials. Clinicians should explain to patients that it is unclear whether exercise improves pain, and that exercise may need to be maintained for at least 12 weeks before benefits in function become evident.

Conclusions

There are few studies that have investigated higher dose exercise for rotator cuff tendinopathy. There was low to very low certainty and conflicting evidence about the value of higher exercise dose in people with rotator cuff tendinopathy.

Supplier

a. Cochrane Training.

Keywords

Exercise; Rehabilitation; Tendinopathy; Shoulder

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