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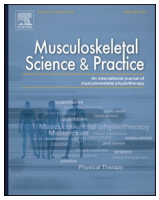

Systematic review

Exercise as effective as surgery in improving quality of life, disability, and pain for large to massive rotator cuff tears: A systematic review & meta-analysis

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ABSTRACT

Questions: To report the characteristics of exercise interventions and ascertain their effectiveness compared to surgery on quality of life, disability, and pain for people with large to massive rotator cuff tendon tears (L-MRCTTs).
Design: Systematic review with meta-analysis of randomised controlled trials (RCTs).
Participants: Adults with L-MRCTTs defined as; >5 cm, 2 or more tendons.
Intervention: Exercise as an intervention for L-MRCTTs.
Outcome measures: Primary: quality of life, disability, and pain. Secondary: range of motion (ROM). The Consensus on Exercise Reporting Template (CERT) was used to extract data on the individual characteristics of each exercise intervention. The Cochrane Risk of Bias Tool V2 was used to assess study quality with the certainty of evidence assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria.
Results: Five trials (n = 297 participants, average age 66.7 years, 55% male) were included in analysis. Three trials compared exercise to another non-surgical intervention and 2 trials compared exercise to surgery. At 12 months a significant improvement in pain of 0.47 (95% CI 0.07–0.88, I^2 = 53%, REM) favoured the surgical group and a significant improvement in shoulder external rotation ROM of 9° (95% CI 2.16–16.22, I^2 = 0%, FEM) favoured the exercise group. The median CERT score was 7/19 (range 4–12). The certainty of evidence was low or very low across all outcomes.
Conclusion: A paucity of high-quality research on the role of exercise in the management of L-MRCTTs exists with substantial discrepancies in the reporting of the exercise interventions in the published research.

1. Introduction

Rotator cuff tendon tears and cuff abnormality are common in the adult population and the incidence increases exponentially with age from 9.7% in patients aged ≥20 years to 62% in patients aged ≥80 years (Teunis et al., 2014) based on a review in 2014 of 6112 shoulders in 4331 participants. A high percentage of small to medium rotator cuff tendon tears are asymptomatic and may represent 'normal' age related changes (Tempelhof et al., 1999). In contrast, two in every three people diagnosed with large to massive rotator cuff tendon tears (L-MRCTTs) defined as a tear >5 cm involving two or more tendons, develop symptoms including recurrent and persistent shoulder pain, night pain, painful shoulder abduction, and weakness commonly involving shoulder abduction and/or external rotation (Edwards et al., 2016). Symptomatic L-MRCTTs significantly impact daily tasks, valued activities and lead to sleep disturbances (Moosmayer et al., 2013). Risk factors for developing L-MRCTTs include; Age >60 years, hand dominance, high body mass index, smoking, hypertension and diabetes (Sayampanathan and Andrew, 2017). Management options for L-MRCTTs are heterogeneous (Gagnier et al., 2021; Piper et al., 2018; Jeanfavre et al., 2018) and there is no certainty what represents best management, due principally to the paucity of high-quality evidence. Recommendations for

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surgical or non-surgical management are primarily based on expert opinion (Doiron-Cadrin et al., 2020) or studies of high risk of bias due to design (e.g. observational studies) or methods (Gagnier et al., 2021). Clinically, non-surgical treatment, commonly involving stretching, strengthening patient shoulder muscles, postural correction and range of motion exercises are the mainstay of the intervention. Non-surgical treatment of LMRCTTs may be effective for some individuals and if unsuccessful, this typically becomes apparent within the first 12 weeks (Edwards et al., 2016). Progression to surgery may be considered if the non-surgical treatment does not achieve the desired outcomes (Moosmayer et al., 2013; Kuhn et al., 2013; Levy et al., 2008).

A substantial worldwide rise in rotator cuff repairs is evident with numbers almost tripling in the United Kingdom over 14 years to 2009 (Ensor et al., 2013) and numbers reaching 250,000 repairs annually in the United States (Vitale et al., 2007). For the right surgical candidate (younger <65 years (Ramme et al., 2019)) diagnosed with a small to medium size rotator cuff tear (often acute) a surgical repair is often a successful outcome (Gagnier et al., 2021). Surgery for L-MRCTTs presents more of a challenge due to poor healing and high retear rates (18–94%) which, is in part, associated with increasing age, tissue quality, and endogenous ability to repair, in the patient group undergoing this type of surgery (Schumaier et al., 2020). Poorer surgical outcomes are influenced by factors such as retraction of the rotator cuff tendons towards the glenoid fossa, and deposits of intramuscular adipose tissue (Kucirek et al., 2021). There is no high quality evidence for superiority of non-surgical or surgical interventions for L-MRCTT management (Longo et al., 2021; Brindisino et al., 2020a) but some promising results are emerging specific to these L-MRCTTs based on case reports (Brindisino et al., 2020a, 2020b) that progressive exercise over 3 months can help elderly patients achieve a return to pre-injury level of function. The most recent systematic review by Shepet (Shepet et al., 2021) focused on the components of non-surgical treatment in these L-MRCTTs. Based on level 3 and 4 evidence, a synthesised non-surgical treatment protocol was developed to include supervised physical therapy of 12 weeks or more that had a focus around supine-based exercises progressing to upright with the use of analgesics if needed. The review highlighted the large variations in protocols available to manage this patient group, with no gold standard exercise program yet available to

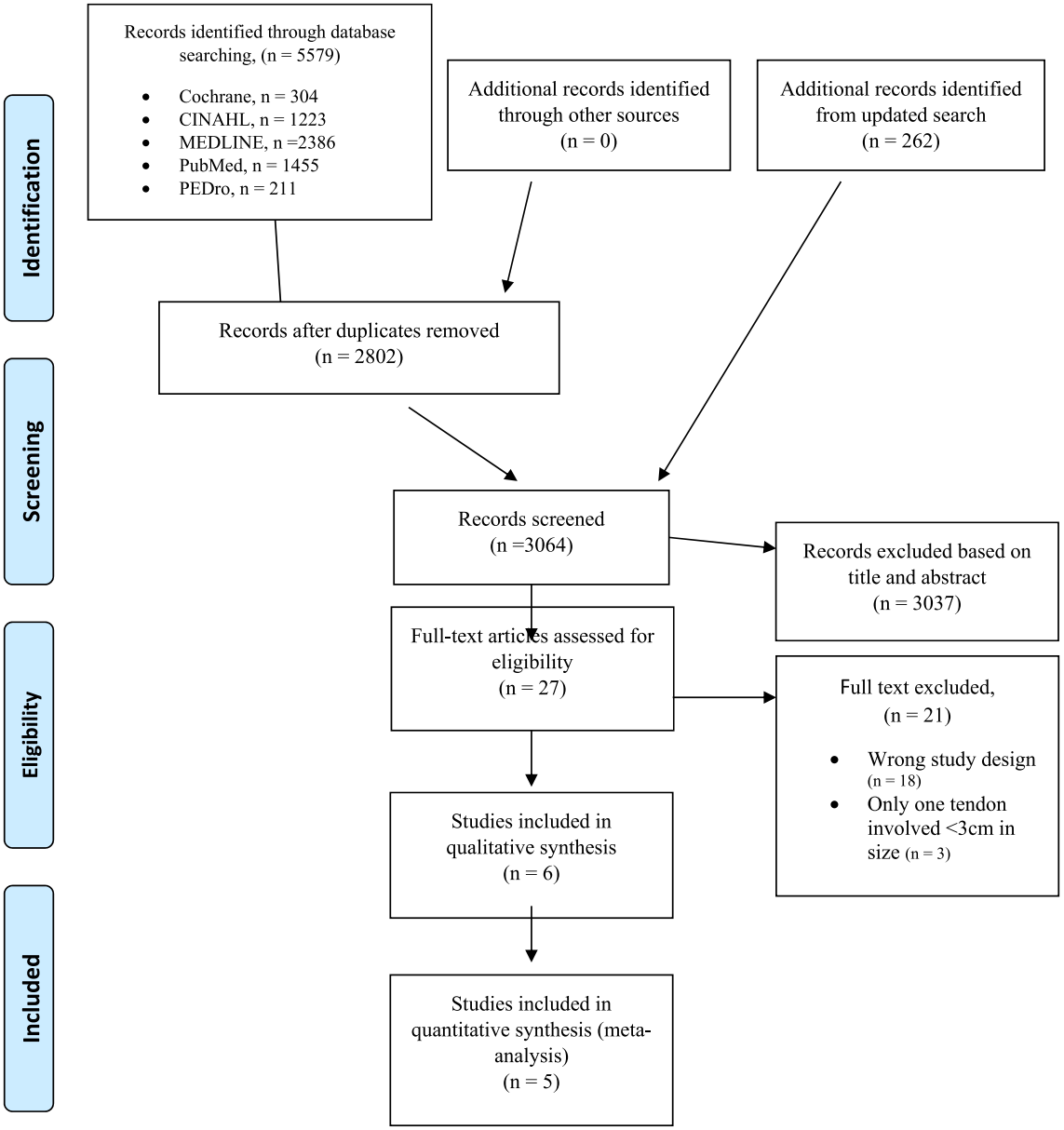

Fig. 1. PRISMA 2009 Flow of studies through the review.

guide treatment.

As a result of the socio-economic impact of L-MRCTTs (Garibaldi et al., 2021) and the absence of a standardised rehabilitation program for non-surgical management, the purpose of this systematic review is to provide a synthesis of exercise programs used in the non-surgical management of L-MRCTTs and appraise their relative effectiveness on impairments, activity limitations and participation restrictions when compared to non-exercise interventions.

The objectives of this review are to:

1. Synthesise the evidence on the effectiveness of exercise interventions when compared to another intervention, or a control, on clinical and functional outcomes (shoulder pain, function, and QoL) in adults with L-MRCTTs.
2. Using the CERT checklist, report on the completeness of reporting of exercise interventions in randomised controlled trials for adults diagnosed with symptomatic L-MRCTTs.

2. Methods

2.1. Identification of studies

The systematic review and meta-analysis were conducted according to the 2009 Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement guidelines (Moher et al., 2009)- see Fig. 1. This review was registered with PROSPERO, registration number 244502 and the protocol has been published (Fahy et al., 2021). A literature search was performed on EBSCO (Medline and CINAHL) databases on the March 19, 2020 and on the PubMed, Cochrane Library and PEDro databases on the April 11, 2020. Due to delays imposed by the SARS-CoV2 pandemic, an updated search on all databases was performed on the October 14, 2021. The search strategy was developed by the primary author (KF) in collaboration with (LD) the Health Science Librarian.

Keywords were derived from the research question along with reviewing recent literature on the topic. The following is an example of the key words used to achieve maximum search strategy sensitivity: shoulder, glenohumeral, irreparable rotator cuff tear, full thickness rotator cuff tear, massive rotator cuff tear, large rotator cuff tear, conservative, nonoperative, nonsurgical, exercise, physio, and strength. A sample search strategy from the CINAHL Database is detailed in Appendix 1.

2.1.1. Deviation from protocol

After screening studies using the original inclusion criteria in the protocol, only one study met '*In studies that have a mix of aetiology, we will include the study where over 80% of the population meet the inclusion criteria on the aetiology of rotator cuff tear*'. The research team observed potential key papers would have been exclused due to the strict inclusion criteria and agreed to deviate from the protocol and include studies that met the remaining inclusion criteria and when it was possible to report the percentage (i.e., <80%) of L-MRCTTs in the intervention and control groups to give context to the results.

2.2. Selection of studies

One researcher (KF) independently reviewed all identified studies by title and abstract on the Rayyan QCRI platform (Ouzzani et al., 2016). Two independent researchers (KF and KMcC) then screened the remaining articles in full text for inclusion (see Box 1). A third author

Box 1
Inclusion Criteria

Design.

- Randomised or quasi-randomised control trial

Participants.

- Adults (18 years of age or older)
- Clinical diagnosis of a large to massive rotator cuff tendon tears which meet one or more of the following criteria: two or more tendons, size of the tear being at least 3 cm or non-operable.
- Concomitant shoulder conditions such as osteoarthritis secondary to rotator cuff tear arthropathy (RCTA) can be included
- No traumatic acute tendon tears or fractures, experiencing neurological signs, adhesive capsulitis, shoulder instability or systemic inflammatory diseases such as rheumatoid arthritis.

Intervention.

- Shoulder exercise (active supported, closed chain, active mobilisation with resistance, proprioceptive) as a standalone intervention or as part of an active multimodal approach (strengthening, range of motion, flexibility)
- If exercise was combined with alternative modalities such as joint mobilisations, injection therapy (corticosteroids) and/or analgesia the control group must have received the same alternative modalities.

Comparisons.

- Non-surgical interventions (usual care or passive) or surgical interventions

Outcome measures.

- Primary: quality of life, disability, and pain
- Secondary: range of motion, strength, and surgical intervention within one year

(JL) was available to consult where disagreements occurred however this was not necessary. A physical search of the reference lists of all included studies and relevant systematic reviews were reviewed and reconciled by (KF) to ensure all applicable publications were identified. The updated search was performed by KF.

2.3. Assessment of characteristics of studies

Two independent reviewers (KF and RG) assessed the methodological quality of the included RCT's using the Cochrane risk of Bias Tool V2 (RoB 2.0) (Higgins et al., 2011). The risk of bias tool covers five domains and assesses how trial conduct may bias results rendering evidence either more or less reliable. Patient demographics, diagnostic criteria, location of tear, intervention group, length of intervention, and clinical outcome scores and associated timepoints were extracted using a standardised data extraction tool and recorded independently by (KF) and (KMcC).

The 19-item Consensus on Exercise Reporting Template (CERT) was used to extract the specific details of the exercise interventions that have been used in the included studies. The CERT has demonstrated good inter-rater reliability (ICC = 0.61–0.80) (Slade et al., 2018). KF independently extracted the data that was cross checked by KMcC, and JL. Data reported in the paper, appendices or as supplementary material was used.

2.4. Data analysis

The primary outcomes of interest were any standard assessment of self-reported pain and disability individually or combined and/or health related quality of life.

2.4.1. Deviation from protocol

The secondary outcomes of interest were shoulder range of motion, strength, and surgical intervention within one year. However, shoulder range of motion was the only outcome that was reported in two or more papers to conduct statistical analysis and therefore the other secondary analysis could not be reported on.

When available, the change in functional outcome score from baseline to 3-months, 6 months and 12 months was recorded by KF and verified by RG. When additional information was required from the included studies, study authors were contacted. Change scores for one outcome measure of interest were provided on request from the authors of one of the included studies.

The Cochrane Review Manager software (RevMan 5) was used to conduct the statistical analyses. All continuous variables were reported as a mean/standard deviation. As a measure of exercise impact, the mean difference (MD) with 95% confidence interval (CI) between the exercise and control group was used as the mode of analysis. Where different outcomes were used to measure the same construct (e.g., pain), a standardised mean difference (SMD) was reported with 95% CI. Heterogeneity across the studies was evaluated using the I^2 statistic (Higgins et al., 2003), greater than 50% was considered as substantial heterogeneity and thus a random affects model was applied. For less than or equal to 50% a fixed affect meta-analysis was used. Any change in score observed was also checked to see if it met the minimally clinically important difference (MCID) for that outcome.

2.5. Certainty of evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) (Guyatt et al., 2011) was used to assess the certainty of evidence of the main outcomes independently by two authors KF and RG. Using GRADE, the evidence extracted from randomised control trials starts at high certainty rating and is downgraded to moderate, low or very low certainty based on concerns relating to RoB, consistency, directness, precision, and publication bias. Disagreements between the reviewers on the quality of evidence were resolved by a third-part adjudication (KMcC).

3. Results

3.1. Flow of studies in the review

Overall, the search strategy identified 5579 related articles with an additional 262 papers following the updated search (October 14, 2021). After screening articles by title and abstract, 27 potential eligible studies were identified, and their full texts were retrieved. In total, five randomised control trials evaluating exercise in the management of L-MRCTTs were included in the meta-analysis. An outline of the screening and reviewing process is detailed in Fig. 1.

3.2. Characteristics of studies

3.2.1. Participants

The five studies included in our review consisted of a total of 297 participants. The average age of the participants was 66.7 years, where 55% were men. Three studies investigated exercise in comparison to another non-surgical intervention (Ainsworth et al., 2009; Gialanella et al., 2018; Krischak et al., 2013) while two trials investigated surgical repair compared to exercise (Heerspink et al., 2015; Moosmayer et al., 2014). Table 1 details a synopsis of all the randomised trials included in the present meta-analysis. Table 2 provides a breakdown of the number of people with L-MRCTTs included in each study.

3.2.2. Risk of bias

The results of the assessment by the Cochrane RoB 2 for RCT's are detailed in Table 3. Overall, the included studies revealed a good methodological quality. The only parameter which was not satisfied in any of the randomised trials was performance bias. In one study, a high risk of bias was ascribed to detection bias.

3.3. Outcomes

3.3.1. Pain

Two studies (Ainsworth et al., 2009; Krischak et al., 2013) reported changes in pain intensity at 2–3 months. There was no significant difference between the experimental (exercise) n = 53 (of which 33 participants had L-MRCTTs) and the control group n = 50 (32 L-MRCTTs) (FEM, SMD -0.14 95% CI, −0.53, 0.25, I^2 = 20%, p = 0.48). Three studies (Ainsworth et al., 2009; Gialanella et al., 2018; Moosmayer et al., 2014) investigated pain at 6 months with no significant difference between the experimental n = 101 (46 L-MRCTTs) and control group n = 102 (51 L-MRCTTs) (REM, SMD -0.09 95% CI, −1.23, 1.05, 1^2 = 93%, p = 0.88).

However, at 12 months in three studies (Ainsworth et al., 2009; Heerspink et al., 2015; Moosmayer et al., 2014) a significant difference was observed in pain scores in favour of the control group n = 107 (46 L-MRCTTs) compared to the experimental group n = 112 (46 L-MRCTTs) (REM, SMD 0.47 95% CI, 0.07, 0.88, I^2 = 53%, p = 0.02) (Fig. 2). Two of the three control groups underwent surgical repair (Heerspink et al., 2015; Moosmayer et al., 2014). The certainty of evidence was very low across all three time points (Table 4).

3.3.2. Range of motion

3.3.2.1. Flexion. Two studies (Ainsworth et al., 2009; Krischak et al., 2013) found no significant difference in flexion range between the experimental (n = 53) and control group (n = 50) at 2–3 months (REM, MD 10.84 95% CI, −17.47, 39.15, I^2 = 77%, p = 0.45), three studies (Ainsworth et al., 2009; Gialanella et al., 2018; Moosmayer et al., 2014) (n = 203) also found no significant difference at 6 months (REM, MD

Table 1
Characteristics of the included studies.

Study Study Design	Participants	Diagnostic Criteria & Tear Site	Intervention Groups & Length of Intervention	Clinical outcome scores & time points	Results/Comments
1.Ainsworth et al., 2009 Randomised placebo-controlled trial Exercise v Control	**Exercise** (n = 30) (Age 78.4 yr) (range 65–96) 14 M:16 F Baseline Co-morbidity = 63 **Control** (n = 30) (Age 78 yr) (range 68–88) 15 M:15 F Baseline Co – morbidity = 62 Level co-morbidity high - 8/60 none Symptom Duration -Only 26/60 one year or less	All Radiologically confirmed FTT/MRCT (>5 cm)	**Exercise** Individually Tailored exercise programme, Ultrasound, advice, steroid injection (pain) **Control** Ultrasound, advice, Steroid Injection (pain) 6 sessions in PT Dept	Baseline – 3m–6m–12m **Primary Outcome** *Shoulder Function (Oxford Shoulder Score)* **Secondary Outcome** *Short Form- 36* *Measure yourself medical outcome profile (MYMOP)* **ROM** *Elevation* *External Rotation (standing/sitting)* *External Rotation (Lying)* *Internal Rotation (lying)*	Rehabilitation programme for MRCT significantly improved shoulder pain and function in the short term. A Specific exercise programme produced speedier improvements than when it was omitted from the patient rehabilitation. Early improvement in function deemed to be important to the patients as this reduced the challenges, they faced in their independence
2.Gialanella et al., 2018 Prospective randomised controlled pilot study Exercise v Exercise with an Arm Cycloergometer (CYC)	**Intervention CYC** (n = 20) (Age 79.6 (4.1) (77.6–81.7) 0 M: 20 F Duration of Symptom 49.2 (32) days **Control** (n = 20) (Age 79.9 (4.3) (77.8–82.0) 2 M: 18 F 51.8 (28) days	Positive diagnostic imaging of full-thickness RCT, a non-traumatic first tear which had not undergone surgical intervention Tear size: Int: 9 small, 5 med, **3 large, 2 massive)** Tendons involved: **25** Cont.: 7 small, 6 med, **3 large, 3 massive** Tendons involved: **27**	**All:** 2 weeks of supervised PT 10 sessions of 30mins **Intervention CYC** Rehab prog using Cycloergometer for 20 min twice daily for 6 months + once a month phone call from nurse to check adherence **Control:** Advised to keep doing exercises at home	Baseline-6m **Primary Outcome** Pain: (VNS activity) "revised" Constant Total Score (function) (Scored out of 75 only[a]): Active/Passive ROM & ROM SUM (sum of multiple directions): Health Assessment Questionnaire (HAQ)	Addition of a 6-month daily Cycloergometer programme to a 2-week supervised physiotherapy programme reduces pain and improve shoulder function compared to the 2-week programme alone.
3.Krischak et al., 2013 Randomised Control Trial Physiotherapy (supervised) v home exercise programme.	**Intervention** (n = 22) (Age 56.4) (10.8) 16 M: 6 F Duration of symptoms 3–6 m (50%) 6m -2y (25%) 2y + (25%) **Control** (n = 16) (Age 53.7 (12.9) 8 M: 8 F 3–6 m (38%) 6m -2y (50%) 2y + (12%)	Unilateral, symptomatic, atraumatic rotator cuff tears (MRI) [a]Massive RC tears excluded **Tears (N=):** **<1 cm: 14** **1-3 cm: 20** **3-5 cm: 5**	**Intervention** 'occupational physiotherapy' supervised exercises (8 weeks, 3x/week) Exercises chosen by treating therapist. **Control:** Home based exercises guided by a booklet (x2 units of 30 min daily)	Baseline – 2m **Primary Outcome** *Pain (VAS)* **Secondary Outcome** *Constant-Murley Score (CMS)* *EuroQol Questionnaire (EQ-5D)* *Shoulder ROM* *Strength Abduction/ adduction and Rotation.*	Home-based exercise were equally effective as supervised exercises for people with rotator cuff tears.
4.Lambers Heerspink et al., 2015 Randomised Controlled Trial Surgery V Exercise	**Tendon Repair** (n = 25) (Age 60.8 ± 7.2) 15 M: 10 F Duration: months (Med, IQR) 12.5 (4.8; 25.6) Physio + subacromial steroid infiltration + analgesic medication (N = 31) (Age 60.5 ± 7.0) 20 M: 11 F 12.0 (7.8; 24)	Degenerative, nontraumatic full-thickness rotator cuff tears (MIR confirmed) **Supraspinatus** 24 (Rotator cuff repair) 26 (Physiotherapy) **Supraspinatus and Infraspinatus** 0 (Rotator cuff repair) 1 (Physiotherapy) **Supraspinatus and Subscapularis** 1 (Rotator cuff repair) 4 (Physiotherapy)	**Tendon Repair:** RC repair, bursectomy, acromioplasty followed by physiotherapy **Conservative:** Subacromial steroid infiltration injection (up to 3), physiotherapy (Up to 3 months), Analgesic medications	Baseline, 6 weeks, 3 months, 6. Months, 12 months **Primary Outcome** Constant Murley Score (CMS) **Secondary Outcomes** Dutch Simple Shoulder Test Pain VAS Radiological Outcome	No difference in primary outcome (function) between the groups (p = 0.08) at 1 year follow-up. Pain intensity and disability was significantly lower in the surgical group (p = 0.04) Best outcomes in function and pain were seen in surgically treated patients. Patients with larger cuff tears/ Subscapularis tears were in the conservative group.
5.Moosmayer et al., 2014 Randomised Controlled Trial Surgery v Exercise	Tendon Repair (n = 52) (Age 59 ± 7.5) 37 M: 15 F Duration of Symptoms (12.3 ± 18.7 months) Two or more Tendons (15/52) Acute tear 24/52 **Physiotherapy** n =	Acute, Acute on Chronic and Chronic US and MRI examined demonstrating: a full thickness tear not exceeding 3 cm, muscle atrophy not exceeding stage 2, traumatic or atraumatic. **Supraspinatus** 37 (Tendon repair) 40 (Physio)	**Tendon Repair** Open (42), mini (9), 1 case did not get surgery. Mason-Allen technique Arm immobilised for & PROM for 6 weeks, AAROM 6–12 weeks, Strengthening from 12 weeks. **Physiotherapy** 52 exercises. Individually tailored and selected	Baseline – 6m–1 yr – 2 yr – 5 yr – [a] 10 **Primary Outcome** Constant Murley score (CMS) **Secondary Outcome** American Shoulder and Elbow Surgeons Score (ASES): Self report section	Both Groups improved during the first 1–2 years. 12 of the 51 PT patients were treated with secondary tendon repair Results from the primary repair were superior to those from Physiotherapy plus secondary repair. Both the primary repair and PT pus repair improved from baseline

(*continued on next page*)

Table 1 (*continued*)

Study Study Design	Participants	Diagnostic Criteria & Tear Site	Intervention Groups & Length of Intervention	Clinical outcome scores & time points	Results/Comments
	51 Age 61 ± 7.6 36 M 9.8 ± 9.8 months Two or more Tendons 11/51 Acute Tear 16/52 [a] Ninety-one of 103 patients attended the last follow-up.	**Supraspinatus & infraspinatus** 14 (Tendon repair) 10 (Physio) **Suprascapular & subscapularis** 1 (Tendon repair) 1 (Physio)	according to findings + education **40 min 2/week for 12 weeks** Exercises patients were competent at were given as HEP No Pain meds/Injections After 15 PT sessions Surgery was offered if Patient was not happy with improvement or clinical findings.	Short Form- 36 (SF-36): physical component Pain (VAS) Strength Pain free mobility Treatment Satisfaction (VAS) MRI/Sonography findings	to 5 yr follow up Better statistically significant results for most outcome scores for tendon repair at all follow-ups. [a] At 10 years, the differences in outcome between primary tendon repair and physiotherapy for small and medium-sized rotator cuff tears had increased, with better results for primary tendon repair.

Abbreviations: FTT; Full thickness tear, MRCT; Massive rotator cuff tear, PT; Physiotherapy, CYC; Cycloergometer, RCT; Rotator cuff tear, VNS; Visual numeric scale, ROM; Range of motion, MRI; Magnetic resonance imaging, VAS; Visual analogue scale. PROM; Passive range of motion, AAROM; Active assisted range of motion.
[a] Moosmayer et al., 2019

Table 2
Number and percentage (%) of Large to Massive rotator cuff tears in each study.

First author, year	Participants	Large to massive rotator cuff tears	Percentage
Ainsworth et al., 2009	Intervention (Exercise) n = 27 Control n = 30	Intervention (Exercise) n = 27 Control n = 30	100% 100%
Gialanella et al., 2018	Intervention (CYC) n = 19 * 25 tendons/19 participants* * Subscapularis n = 2 Control n = 19 *27 tendons/19 participants * Subscapularis n = 4	Intervention (CYC) n = 5 Control n = 6	26%* 32%*
Krischak et al., 2013	Intervention (occupational therapy) n = 22 Control n = 16 * Subscapularis n = 1	Intervention (occupational therapy) n = 3 Control n = 2	14% 13%
Lambers Heerspink et al., 2015	Intervention (Exercise) n = 31 * Subscapularis n = 4 Control (Surgery) n = 25 * Subscapularis n = 1	Intervention (Exercise) n = 5 Control n = 1	16% 4%
Moosmayer et al., 2014	Intervention (Exercise) n = 51 * Acute n = 16 * Subscapularis n = 1 Control (Surgery) n = 52 * Acute n = 24 * Subscapularis n = 1	Intervention (Exercise) n = 11 Control n = 15	22% 29%

13.54 95% CI, −3.01, 30.10, $I^2 = 55\%$, p = 0.11) and this was replicated at 12 months in two studies (Ainsworth et al., 2009; Moosmayer et al., 2014) (n = 163) (REM, MD -1.84 95% CI, −22.97, 19.29, $I^2 = 61\%$, p = 0.86). The certainty of evidence was very low for 3 and 12 months and low for 6 months (Table 4).

3.3.2.2. External rotation. Again, pooling two studies (Ainsworth et al., 2009; Krischak et al., 2013) at 2–3 months no significant difference was observed between the two groups for external rotation range (FEM, MD -0.42 95% CI, −8.14, 7.31, $I^2 = 0\%$, p = 0.92). The certainty of evidence was very low (Table 4). However pooling two studies (Ainsworth et al., 2009; Gialanella et al., 2018) a significant improvement was observed in external rotation range of motion at 6 months for the experimental group n = 50 (32 L-MRCTTs) compared to the control group n = 50 (36 L-MRCTTs) (FEM, MD 9.19 95% CI, 2.16, 16.22, $I^2 = 0\%$, p = 0.01) (Fig. 3). The certainty of evidence was low (Table 4).

3.3.2.3. Abduction. Pooling three studies (Gialanella et al., 2018; Krischak et al., 2013; Moosmayer et al., 2014) no significant difference in abduction range was observed between the experimental group n = 94 (19 L-MRCTTs) and the control group n = 92 (23 L-MRCTTs) up to 6 months (FEM, MD 3.55 95% CI, −8.32, 15.42, $I^2 = 38\%$, p = 0.56). The certainty of evidence was very low (Table 5).

3.3.3. Activity (function)

There was no significant difference in shoulder function identified between both groups when pooling two studies (Ainsworth et al., 2009; Krischak et al., 2013) at 2–3 months (REM, SMD 0.40 95% CI, −0.54, 1.33, $I^2 = 82\%$, p = 0.40), three studies (Ainsworth et al., 2009; Gialanella et al., 2018; Moosmayer et al., 2014) at 6 months (REM, SMD 0.49 95% CI, −0.18, 1.15, $I^2 = 80\%$, p = 0.15) and three studies (Ainsworth et al., 2009; Heerspink et al., 2015; Moosmayer et al., 2014) at 12 months (REM, SMD -0.18 95% CI, −0.72, 0.35, $I^2 = 74\%$, p = 0.50). Outcome measures used were Oxford Shoulder score, Constant Murley Scale, and a revised edition of the Constant Murley Scale. The certainty of evidence was very low for 3 and 12 months and low for 6 months (Table 4).

3.3.4. Participation (QoL)

There was no significant difference in participation across the groups when pooling two studies (Ainsworth et al., 2009; Krischak et al., 2013) at 2–3 months using the SF-36 and EQ-5D QoL outcome measures (FEM, SMD 0.11 95% CI, −0.28, 0.49, $I^2 = 0\%$, p = 0.59). No significant difference was identified pooling two studies (Ainsworth et al., 2009; Moosmayer et al., 2014) at 6 months (REM, SMD 2.03 95% CI, −5.98, 9.95, $I^2 = 63\%$, p = 0.62) and two studies (Ainsworth et al., 2009; Moosmayer et al., 2014) at 12 months (REM, SMD 0.20 95% CI, −0.42 0.81, $I^2 = 73\%$, p = 0.53) using the SF-36 physical component and physical functioning outcome measures. The certainty of evidence was very low for 3 and 6 months and low for 12 months (Table 4).

3.3.5. Strength

Moosymayer et al. (2014) was the only paper to compare strength outcomes between an exercise and surgical intervention. The primary tendon repair group reported significantly lower levels of strength on active shoulder abduction measured in kilograms (kg) at six months (MD -2.5 kg 95% CI, −0.7 to −4.2 kg), when compared to the physiotherapy group. This difference did not remain significant at the 12-month follow-up.

Table 3
Cochrane Risk of Bias assessment for all the included studies. + Low risk of Bias; - High risk of bias.

	Selection Bias **Random Sequence Generation**	Selection Bias **Allocation Concealment**	Reporting Bias **Selective Reporting**	Performance Bias Blinding **(Participants And Personnel)**	Detection Bias Blinding **(Outcome Assessment)**	Attrition Bias Blinding **(Outcome Data)**	Incomplete Other Bias	Overall
Ainsworth et al., 2009	+	+	+	–	–	+	+	Some concerns
Gialanella et al., 2018	+	+	+	–	+	+	+	Low
Krischak et al., 2013	+	+	+	–	+	+	+	Low
Lambers Heerspink et al., 2015	+	+	+	–	+	+	+	Low
Moosmayer et al., 2014	+	+	+	–	+	+	+	Low

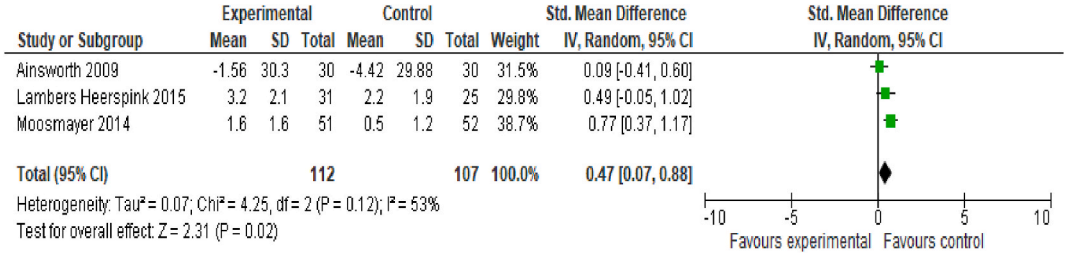

Fig. 2. Standardised mean difference (95% CI) of effect of exercise on pain compared with a non-exercise intervention at 12 months post intervention.

3.3.6. Surgical intervention at one year

Moosmayer et al. (2014) was the only paper to report on surgical intervention within one year. 9 of the 51 patients (18%) in the physiotherapy group opted for a secondary repair within one year and it is not clear how many of these tears were large to massive.

3.4. Consensus of Exercise Reporting Template (CERT)

Each of the five trials was conducted in a different country (United Kingdom, Italy, Germany, Netherlands, Norway). Three of the five publications were available from open access sources. Two studies used supplementary material to detail their exercise intervention, and one of these studies was not open access. Shoulder muscle performance exercises, stretching, posture and scapular correction were the main interventions used in the studies. A summary table is detailed in Appendix 2.

The CERT evaluation of the reporting of the interventions of the 5 included trials is presented in Table 5. The median score was 7 (range 4–12) out of a possible 19. Only one trial (Gialanella et al., 2018) had a CERT score of >10, a mean number of CERT items fulfilled when applied to exercise interventions across musculoskeletal trials (Slade et al., 2018), indicating that the majority of the details of the exercise interventions were not reported. Two CERT items were outlined by all trials: Item 1: whether the intervention was supervised or not supervised and Item 2: the setting in which the intervention took place. Five CERT items were outlined by at least three trials (60%). This included description of the exercise equipment, if it was an individual or group intervention, outlining a progression rule, if the intervention included a non-exercise component and whether it was generic or individually tailored.

The following items were poorly reported across most trials: reporting of adherence (1 trial) (Gialanella et al., 2018), motivation (0 trial), progression description (1 trial) (Ainsworth et al., 2009), exercise description (1 trial) (Moosmayer et al., 2014), adverse events (1 trial) (Moosmayer et al., 2014), intervention details (1 trial) (Gialanella et al., 2018), Tailored (how) (0 trial), starting level (0 trial), adherence (planned) (1 trial) (Gialanella et al., 2018) and adherence (actual) (0 trial).

4. Discussion

Our findings demonstrate that the reporting of exercise interventions is poor and the effectiveness of exercise on clinical and functional outcomes in adults with L-MRCTTs is similar to other interventions or a control intervention. The primary outcome measures of interest were QoL, self-reported pain and disability. These outcomes were chosen because they have previously been established in similar reviews (Jeanfavre et al., 2018; Shepet et al., 2021). The overall quality of the trials was satisfactory based upon the Cochrane ROB2 Assessment tool.

Self-reported pain was the only primary outcome to show a statistically significant improvement which was in favour of the non-exercise group. This improvement in pain of 0.5 on the VAS scale was observed at 12 months, lacking a clear clinical impact since the difference between treatments is smaller than the MCID for this measure (VAS MCID = 1.4)[36]. On further analysis of the data, this included two surgical interventions as the non-exercise group and one of these studies had the lowest percentage of L-MRCTTs. This finding is in keeping with the current literature that short-medium term improvements (12 months) have a trend towards better reported pain outcomes with surgical intervention (Brindisino et al., 2020a; Garibaldi et al., 2021). Similar to our findings often these differences are often statistical in nature but not clinically meaningful and there was no resultant improvement in function measured by the Constant Score (Brindisino et al., 2020a). Although the surgical groups improved more faster (12 months), research indicates that both groups improve to a similar level by 2 years (Moosmayer et al., 2014).

A secondary outcome, range of motion, identified an average clinically significant improvement in shoulder external rotation range of motion of 9° that was observed at 6 months in favour of the exercise intervention (Ainsworth et al., 2009; Gialanella et al., 2018) when compared to a control intervention. These two studies had the highest percentage of L-MRCTTs in their studies (100% and 32% respectively)

Table 4
Certainty of evidence for each outcome based on GRADE Framework.

Outcome	Study design/ measurement instrument	Risk of bias	Inconsistency (Forest Plot)	Indirectness No Indirectness/ serious/very serious	Imprecision CI large or wide	Estimate of outcome (95% CI or other method of variability)	Quality
Pain @ 3 months	2 RCTs; 103 participants; SF-36 (pain domain) & VAS	Not serious limitations do not downgrade	Serious Inconsistency (down grade by 1)	Very serious indirectness (down grade by 2)	Not serious	SMD -0.14, 95% CI -0.53–0.25	Very low certain ⊕
Pain @ 6 months	3 RCTs; 203 participants; SF-36 (pain domain), VNS & VAS	Not serious limitations do not downgrade	Very serious Inconsistency (down grade by 2)	Serious indirectness (down grade by 1)	Not serious	SMD -0.09, 95% CI -1.23 – 1.05	Very low certainty ⊕
Pain @ 12 months	3 RCTs; 219 participants; SF-36 (pain domain) & VAS	Not serious limitations do not downgrade	Serious Inconsistency (down grade by 1)	Very serious indirectness (down grade by 2)	Not serious	SMD 0.47, 95% CI 0.07–0.88	Very low certainty ⊕
Flexion @ 3 months	2 RCTs; 103 participants; Degree's	Not serious limitations do not downgrade	Very serious Inconsistency (down grade by 2)	Very serious indirectness (down grade by 2)	Not serious	MD 10.84, 95% CI -17.47 – 39.15	Very low certainty ⊕
Flexion @ 6 months	3 RCTs; 203 participants; Degree's	Not serious limitations do not downgrade	Serious Inconsistency (down grade by 1)	Serious indirectness (down grade by 1)	Not serious	MD 13.54, 95% CI -3.01- 30.10	Low certainty ⊕⊕
Flexion @ 12 months	2 RCTs; 163 participants; Degree's	Not serious limitations do not downgrade	Very serious Inconsistency (down grade by 2)	Serious indirectness (down grade by 1)	Not serious	MD -1.84, 95% CI -22.97, 19.29	Very low certainty ⊕
External Rotation @ 3 months	2 RCTs; 103 participants; Degree's	Not serious limitations do not downgrade	Serious Inconsistency (down grade by 1)	Very serious indirectness (down grade by 2)	Not serious	MD -0.42, 95% CI -8.14, 7.31	Very low certainty ⊕
External Rotation @ 6 months	2 RCTs; 100 participants; Degree's	Not serious limitations do not downgrade	Serious Inconsistency (down grade by 1)	Serious indirectness (down grade by 1)	Not serious	MD 9.19, 95% CI 2.16–16.22	Low certainty ⊕⊕
Abduction @ 6 months	3 RCTs; 186 participants; Degree's	Not serious limitations do not downgrade	Very serious Inconsistency (down grade by 2)	Very serious indirectness (down grade by 2)	Serious impression (down grade by 1)	MD 3.55, 95% CI -8.32–15.42	Very Low certainty ⊕
Activity (Function) @ 3 months	2 RCTs; 103 participants; OSS & CMS	Not serious limitations do not downgrade	Serious Inconsistency (down grade by 1)	Very serious indirectness (down grade by 2)	Not serious	SMD 0.40, 95% CI -0.54, 1.33	Very low certainty ⊕
Activity (Function) @ 6 months	3 RCTs; 203 participants; OSS, CMS & CMS revised	Not serious limitations do not downgrade	Serious Inconsistency (down grade by 1)	Serious indirectness (down grade by 1)	Not serious	SMD 0.49, 95% CI -0.18–1.15	Low certainty ⊕⊕
Activity (Function) @ 12 months	3 RCT; 219 participants; OSS & CMS	Not serious limitations do not downgrade	Serious Inconsistency (down grade by 1)	Very serious indirectness (down grade by 2)	Not serious	SMD -0.18, 95% CI -0.72 – 0.35	Very low certainty ⊕
Participation (QoL) @ 3 months	2 RCTs; 103 participants; SF – 36 (role limitation) & EQ – 5D QoL	Not serious limitations do not downgrade	Serious Inconsistency (down grade by 1)	Very serious indirectness (down grade by 2)	Not serious	SMD 0.11, 95% CI -0.28–0.49	Very low certainty ⊕
Participation (QoL) @ 6 months	2 RCT; 163 participants; SF-36 (Physical component)	Not serious limitations do not downgrade	Serious Inconsistency (down grade by 1)	Serious indirectness (down grade by 1)	Serious	SMD 2.03, 95% CI -5.89 – 9.95	Very low certainty ⊕
Participation (QoL) @ 12 months	2 RCT; 163 participants; SF-36 (Physical component)	Not serious limitations do not downgrade	Serious Inconsistency (down grade by 1)	Serious indirectness (down grade by 1)	Serious	SMD 3.07, 95% CI -5.93 – 12.07	Low certainty ⊕⊕

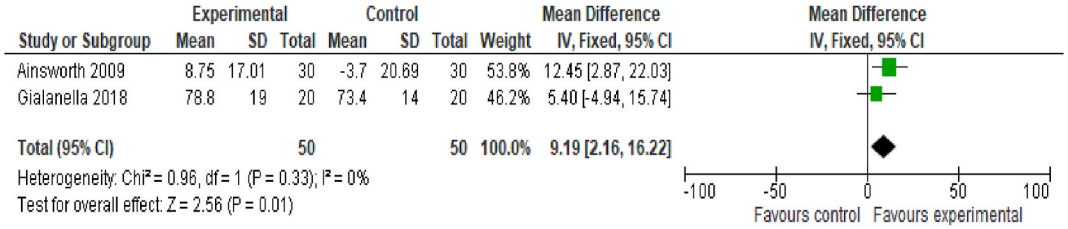

Fig. 3. Mean difference (95% CI) of effect of exercise on external rotation range compared with a non-exercise intervention at 6 months post intervention.

and their exercise intervention was a combination of stretching, ROM, strengthening, posture correction and adaptation of functional activities. This finding is consistent with prior cohort studies of a similar population (>65, massive tears) that have also demonstrated improvements in shoulder range of motion following similar exercise interventions in the shorter term (>1 year), specifically external rotation (Levy et al., 2008; Collin et al., 2015; Christensen et al., 2016).The most recent systematic review (Shepet et al., 2021) in 2021 on non-operative management of chronic, massive irreparable tears included lower quality evidence from level III and IV studies but again found improvements in active external rotation despite significant variations in the non-surgical interventions, specifically exercise. However, the question remains as to the importance of an improvement in range of motion when there is no correlating enhancement in QoL or disability.

Determining the optimal exercise intervention using the CERT checklist to extract the specific characteristics of the intervention proved difficult. Firstly, RCTs investigating the effectiveness of exercise on pain, disability, and quality of life in people with L-MRCTTs included only a

Table 5
Results of application of the Consensus on Exercise Reporting Template to each included trial and total number (%) of items fulfilling criteria of acceptable reporting by final consensus.

FIRSTAUTHOR, YEAR	1.Exercise Equipment	2.InstructorQualification	3.IndividualorGroup	4.Supervisedorunsupervised	5.Adherence	6.Motivation	7.a.Progressionrule	7.b.Progressiondescription	8.Exercisedescription	9.Homeprogramme	10.Non – exercisecomponents	11.Adverseevents	12.Setting	13.Interventiondetails	14.a.Genericorindividuallytailored	14.b.Tailored(how)	15.StartingLevelRule	16.aAdherence(planned)	16.b.Adherence(actual)	Totalnumber(%)ofitemsfulfillingcriteria
Ainsworth et al., 2009	1	0	1	1	0	0	1	1	0	0	1	0	1	0	1	0	0	0	0	8 (42)
Gialanella et al., 2018	1	1	1	1	1	0	1	0	0	1	1	0	1	1	1	0	0	1	0	12 (63)
Krischak et al., 2013	0	0	1	1	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	4 (21)
Lambers Heerspink et al., 2015	0	0	0	1	0	0	1	0	0	0	1	0	1	0	0	0	0	0	0	4 (21)
Moosmayer et al., 2014	1	1	0	1	0	0	0	0	1	1	1	1	1	0	1	0	0	0	0	9 (47)

small percentage (4–32%) that met the clinical diagnosis of a large to massive tear and secondly, the exercise interventions were not only poorly described but the content of these interventions was inconsistent across the studies. Most CERT items did not include enough detail to ensure replication with only two CERT items reported by all trials; setting and if the intervention was supervised or not. Exercise was often labelled as the intervention with no further description on the theory behind its selection, prescription, or delivery. Thus, identifying the essential characteristics of the exercise intervention to improve outcomes was not possible. The CERT is a reliable tool to evaluate the completeness of reporting of exercise interventions (Slade et al., 2018) thus journals should encourage researchers to adopt a more widespread use of CERT when reporting exercise interventions. Using the CERT reporting guidelines will ensure that all relevant aspects of the exercise intervention will be reported such as, patients' expectations about the effectiveness of rehabilitation which research has shown is a strong predicator of non-operative treatment success (Dunn et al., 2013).

The incompleteness of content reporting of exercise intervention in randomised controlled trials is in keeping with the work by Major (Major et al., 2019), who reported a median CERT score of 5 in a range 0–19 in randomised controlled trials of people with rotator cuff disease. Shepet (Shepet et al., 2021) synthesised a standardised non-operative treatment protocol for massive irreparable rotator cuff tears from four of the ten studies included in their review. Three of the other six did not describe their treatment protocols in sufficient detail for replication. As a result Shepet focused on trends across the four included papers, to synthesis a non-operative programme. The proposed program comprised of a supervised exercise program, 2 to 3 sessions a week for a minimum 12 weeks, ROM initially moving from supine to standing, followed by strengthening, scapular stabilisations and proprioception and the use of pain relief. This research has certainly provided a standard to build upon, but until we improve reporting and standardise protocols the variability will continue to influence outcomes and introduce performance bias. It is clear a gap exists in research by the omission of standardised exercise reporting guidelines when essential aspects such as motivation, adherence, home exercise prescription are not reported. A more comprehensive approach to exercise prescription is needed using the wider behavioural literature, stakeholder involvement and identifying what is important to the patient. Until such we may never get closer to the essential aspects of a program that optimises outcomes, while equally being feasible to deliver, and acceptable to patients.

4.1. Strength/weaknesses

We used systematic and transparent methods to identify, select, appraise, and synthesise the findings of our review. The strengths of this systematic review include a pre-published protocol, the selection of only Level-1 studies and the use of an internationally endorsed reporting guideline for assessing the completeness of descriptions of exercise interventions in the clinical trials. Nevertheless, there are several limitations.

In relation to the included studies and body of literatiore. The major limitations are, the low certainty of evidence for most outcomes, large age range and the extremely low percentage of the participants that met our inclusion criteria, which created high levels heterogeneity across studies and did not allow for sub-group analysis. The lack of consistency and precision of results across the studies was primarily due to varied comparisons made; relatively few studies compared the same intervention (type of exercise) or control (active versus surgical) and with such low study numbers we had to pool these variations for analysis. Additionally, the variation in the pathological and biological presentation of the rotator cuff tears contributed significantly to the inconsistency among the studies. The percentage of patients with full thickness tears, did not only vary between the studies but the size, configuration, and affected tendons also varied across the included studies.

Whilst again this highlights a weakness in the review it strengthens

our findings that research on this specific population is limited and the reporting of interventions was poor.

4.2. Clinical/policy implications

The lack of clinically meaningful differences in the outcomes for surgical and non-surgical/exercise interventions suggests that non-surgical interventions should remain the first line option for people with L-MRCTTs. No specific recommendations on exercise guidance can be summarised presently due to the poor reporting, quality, and quantity of the current research evidence.

4.3. Area for further study

An exercise program with full and accurate reporting of each CERT item needs to be developed and tested to determine its feasibility and acceptability in a complete sample of people with L-MRCTTs. This comprehensive program needs to be informed by stakeholders (surgeons, physiotherapists, and patients with L-MRCTTs) and underpinned by what is important to the patient.

4.4. Brief conclusion

Currently there is a dearth of evidence that focuses specifically on people with L-MRCTTs which highlights the pressing need for trials that focus on this group. Based on the available evidence exercise is as effective as surgery for improving quality of life, disability and pain for L-MRCTTs but the conclusion is based on low certainty of evidence The completeness of content reporting of exercise interventions in the management of people with L-MRCTTs is extremely poor.

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Declaration of competing interest

Nil.

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Appendices

Appendix 1. Sample Search Strategy on the Cinahl Database

Search History

#	Query	Limiters/Expanders	Last Run Via	Results	Action
S9	S7 AND S8	Limiters - Published Date: 20200301-20211031; Randomized Controlled Trials Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	33	Edit
SB	TI 'rotator cuff'	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	3,888	Edit
S7	S3AND S6	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	194	Edit
S6	S4 OR S5	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	1,451,851	Edit
S5	AB 'concentric' OR AB 'eccentric' OR AB 'isometric' OR AB 'isokinetic' OR AB 'load' OR AB 'flexibility'	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	63,570	Edit
S4	AB 'conservative' OR AB 1reatment' OR AB 'nonoperative' OR AB 'management' OR AB 'nonsurgical' OR AB 'rehab*' OR AB 'exercise' OR AB 'training' OR AB 'physio*' OR AB 'physical therapy' OR AB 'strength*' OR AB 'resistance'	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	1,423,271	Edit
S3	S1 OR S2	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Complete	234	Edit

Appendix 2. Description of the included studies

First author, year	Country	Main components of the exercise intervention	Open access	Supplementary material
Ainsworth et al., 2009	United Kingdom	Stretching, strengthening, posture correction and adaptation of functional exercises	Yes	No
Gialanella et al., 2018	Italy	Cycloergometer, range of motion, strengthening exercises	Yes	No

(*continued on next page*)

(*continued*)

First author, year	Country	Main components of the exercise intervention	Open access	Supplementary material
Krischak et al., 2013	Germany	Determined by the physiotherapist	No	Yes for the control group
Lambers Heerspink 2015	Holland	Stretching, strengthening and posture correction	No	No
Moosmayer et al., 2014	Norway	Individualised exercises treatment aimed at correction of scapula mal positioning at rest and the restoration of ideal scapula positioning and centring of the humeral head during movement	Yes	A Norwegian book and an appendix

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