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## **Exercise for rotator cuff tendinopathy: A systematic review**

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## Abstract

**Background** Shoulder pain due to rotator cuff tendinopathy is a common problem. Exercise is one intervention used to address this problem but conclusions from previous reviews have been mixed.

**Objective:** To systematically review the effectiveness of exercise, incorporating loaded exercise (against gravity or resistance), for rotator cuff tendinopathy.

**Data sources:** An electronic search of AMED, CiNAHL, Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, PEDro and SPORTDiscus was undertaken from their inception to November 2010 and supplemented by hand searching related articles and contact with topic experts.

**Study eligibility criteria** Randomised controlled trials evaluating the effectiveness of exercise, incorporating loaded exercise, in participants with rotator cuff tendinopathy.

**Study appraisal and synthesis methods** Included studies were appraised for risk of bias using the tool developed by the Cochrane Back review Group. Due to heterogeneity of studies, a narrative synthesis was undertaken based upon levels of evidence.

**Results:** Five articles detailing four studies were included, all of which were regarded as presenting a low risk of bias. Overall, the literature was supportive of the use of exercise in terms of pain and functional disability.

**Limitations:** The results should be regarded with some degree of caution due to limitations associated with the studies including lack of blinding, no intervention control groups and limitations of the outcome measures used.

**Conclusion and implications of key findings:** The available literature is supportive of the use of exercise but due to the paucity of research and associated limitations further study is indicated.

**Funding:** None.

**Keywords:** rotator cuff, tendinopathy, exercise, systematic review

## **Introduction**

Shoulder pain is a common problem with up to half of the population experiencing at least one episode per year <sup>(1)</sup>. The morbidity associated with shoulder pain is commonly encountered in primary care and physiotherapy <sup>(2)</sup> where pathology of the rotator cuff is thought to be the commonest cause <sup>(3)</sup>. The natural history of these disorders is not always favourable and the long-term outcome is frequently poor <sup>(4)</sup>.

Systematic reviews have been undertaken which assess the effect of various interventions, including exercise, for problems relating to the rotator cuff <sup>(5-12)</sup> but results have been mixed. One reason for this conflict might be the failure to define adequately the conditions being treated <sup>(13)</sup>. Studies refer to 'subacromial impingement' which, although a common diagnosis in clinical practice, is nothing more than an umbrella term used to describe a variety of conditions which present with varied signs and symptoms <sup>(14)</sup>. It is perhaps unsurprising that conflict arises when the effects of poorly defined interventions are evaluated in studies where the condition under treatment is also poorly defined.

As with low back pain, diagnostic sub-groups have been identified in the shoulder which when targeted with appropriate intervention might demonstrate superior outcomes <sup>(15)</sup>. One such diagnostic sub-group is rotator cuff tendinopathy, which would be termed contractile dysfunction in one classification system and has been recognised as a useful classification upon which to base treatment <sup>(4)</sup>. The signs and symptoms associated with rotator cuff tendinopathy have been reported to include symptom duration greater than three months, minimal resting pain, largely preserved range of shoulder motion and pain exacerbated through resisted testing <sup>(4)</sup>. This is in stark contrast to other presentations of 'subacromial impingement' which might include constant pain and marked limitation of motion <sup>(14)</sup>. With such varied clinical presentations, it seems sensible to suggest that the underlying pathology might also vary.

The pathology of rotator cuff tendinopathy has been shown to demonstrate similar pathological changes to tendon disorders in other areas of the body, e.g. the elbow, where loaded (against gravity or resistance) exercise has shown beneficial results <sup>(16)</sup>. Hence, it seems plausible that loaded exercise may also have a role to play in the management of these disorders.

No previous reviews have been identified that define this diagnostic sub-group as a focus for evaluation and considering that previous reviews have been guarded regarding the effectiveness of exercise in the treatment of 'subacromial impingement' there is justification to undertake a review with the aim of assessing the effectiveness of exercise in the management of rotator cuff tendinopathy.

## **Methods**

This systematic review was carried out using a predetermined protocol in accordance with the PRISMA statement <sup>(17)</sup>.

## Data Sources & Search Strategy

An electronic search of AMED, CiNAHL, Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, PEDro and SPORTDiscus was undertaken from their inception to November 2010. The Cochrane highly sensitive search for identify randomised trials was adopted (<sup>18</sup>). The search terms used for the MEDLINE search are displayed in table 1.

The electronic search was complemented by hand searching the reference lists of the articles found and previous systematic reviews. Where pilot studies were identified the authors of these studies were contacted to determine whether further subsequent published or unpublished research had been undertaken. In addition to this a recognised expert in this field was consulted in an attempt to identify any further published or unpublished studies (<sup>19</sup>). This process was undertaken by CL and BS.

## Study Selection

Studies had to meet the following criteria to be included:

### **Participants**

Studies of adult patients presenting with signs and symptoms suggestive of rotator cuff tendinopathy, defined as:

1. Symptom duration greater than three months
2. Minimal resting pain
3. Largely preserved range of shoulder motion
4. Pain exacerbated consistently through resisted testing, usually abduction and / or lateral rotation
5. No cervical spine involvement (<sup>4</sup>).

For inclusion, criteria 3 and 5 had to be met along with at least one from criteria 1, 2 and 4. Studies which included participants with painful/ stiff shoulder associated with other diagnoses, e.g. frozen shoulder, were excluded.

### **Interventions**

Any exercise intervention which included loaded (against gravity or resistance) exercise as a component. Initial scoping searches highlighted that it would be unlikely that studies evaluating the effect of loaded exercise alone would be identified. Combined interventions, e.g. exercise and electrotherapy or exercise and manual therapy, which do not enable a judgement about the comparative efficacy of exercise were excluded.

### **Outcomes**

Any clinical outcome including, but not restricted to, measures of pain and disability.

## **Study design**

Randomised controlled trials (RCTs). Quasi-experimental and case studies/ series were excluded due to the risk of bias associated with these designs <sup>(20)</sup>.

## **Language**

No restriction.

Following the search, screening of titles and abstracts was undertaken independently by two reviewers (BS/ CL) who subsequently agreed upon the articles that should be retrieved for full-text review. In the event of disagreement, a third reviewer (SM) was available to arbitrate but this was not needed.

Following a pilot phase, two reviewers (CL/ KCL) assessed the full-text articles that had been retrieved. One reviewer (KCL) translated three German language papers that were retrieved. At this stage, percentage agreement for inclusion was 87% with Kappa (K) = 0.67 which is regarded as a good level of agreement between the reviewers <sup>(21)</sup>. The reviewers agreed that one study <sup>(22)</sup> required further clarification regarding the intervention before a decision could be made. The author of this study was contacted and subsequently the study was excluded as the interventions did not meet the inclusion criteria. Disagreements were resolved through discussion without the need for further arbitration.

## Data Extraction

Two independent reviewers (JA/ BS) used a standardised form to extract data regarding study characteristics, participant characteristics, interventions, settings and outcome data/ results <sup>(23)</sup>. The data extraction process was initially piloted by the two reviewers before the process proper was undertaken. Upon completion the reviewers met to agree upon the data to be extracted. A third reviewer (CL) was available in the event of disagreement but this was not needed.

## Risk of Bias Assessment

The risk of bias of the included studies was undertaken independently by two reviewers (CL/ SM) using the Cochrane Back Review Group (CBRG) risk of bias tool <sup>(19)</sup>. It has been recognised that this tool is also useful for the assessment of trials in other conditions <sup>(24)</sup>. The completed risk of bias tool is displayed in table 2 and the guidelines upon which judgments were made are displayed in table 3 <sup>(19)</sup>. Each item was rated as yes (= 1), no (= 0), unclear (= 0). In all cases study authors were contacted for clarification of methodological issues where information offered in the article was unclear. The level of agreement between reviewers was 90% and K = 0.74 which is regarded as a good level of agreement <sup>(21)</sup>. Disagreements relating to interpretation of the criteria were resolved through discussion except where 2 of the studies <sup>(25,27)</sup> presented with differences in baseline characteristics (criteria 9). Both studies had undertaken statistical adjustment for these baseline differences and as the adjusted analysis was similar to the unadjusted analysis and the outcomes were consistent these studies were rated favourably with regards to this criterion. A third reviewer (KCL) was available to arbitrate at this stage but was not needed.

A study with a low risk of bias was defined as one fulfilling six or more of the criteria items and with no fatal flaw which is defined as:

1. Drop-out > 50%.
2. Statistically and clinically significant differences between groups at baseline indicating unsuccessful randomisation.

This approach has previously been validated <sup>(24)</sup>.

## Data Synthesis

Due to the low number of studies retrieved and heterogeneity with regards to the exercise interventions offered a qualitative synthesis using a rating system for levels of evidence from the CBRG was used <sup>(30)</sup>. This rating system, displayed in table 4, is used to summarise the results in which the quality and outcomes of individual studies are taken into account <sup>(30)</sup>.

## **Results**

### Study Selection

Figure 1 depicts the study selection process. The electronic search yielded a total of 2224 records which reduced to 1800 when the duplicates were removed. One additional source was retrieved through hand searching <sup>(31)</sup>. Two pilot studies were identified in this initial search <sup>(13,32)</sup> and in the first instance <sup>(13)</sup> no further study had been conducted and in the second <sup>(32)</sup> a potentially relevant study was underway but further data was not available. No further studies were identified through expert consultation.

The title and abstracts of 1801 articles were screened with 30 potentially relevant studies identified for full-text review. Of these 30, three were published in German and 27 in English. No unpublished studies were retrieved. Finally, 5 articles describing 4 studies were selected <sup>(25-29)</sup>. A list of the excluded studies is available from the corresponding author.

### Risk of Bias Assessment

The results of the risk of bias assessment are shown in table 2. All studies were regarded as presenting a low risk of bias in accordance with the CBRG guidance <sup>(24)</sup> and other previously published systematic reviews <sup>(33)</sup>. It is interesting to note that the rating of all studies improved when clarification was received from the authors of the studies.

### Study Characteristics

A summary of the characteristics of the included studies along with the main results is shown in table 5. All of the studies included symptomatic participants but three of the studies <sup>(25,26,28,29)</sup> included participants accessing health care and one study <sup>(27)</sup> included participants not currently accessing health care for their shoulder problem.

## Interventions

The studies compared supervised exercise, with a resisted component, to no intervention<sup>(28)</sup>, placebo<sup>(25,26)</sup>, and surgery<sup>(25,26)</sup> or home exercise, with a resisted component, to no intervention<sup>(27)</sup>, functional brace<sup>(29)</sup> and multimodal physiotherapy<sup>(29)</sup>. For the purpose of this review home exercise was defined as exercise undertaken without regular contact with a health care professional (HCP). Supervised exercise was defined as exercise undertaken with regular contact, e.g. 1/ week, 2/ week over the duration of the intervention, with the HCP. The content of the exercise programmes was heterogeneous across the studies but generally consisted of stretching and progressive resistance exercises using Theraband or other external exercise equipment.

### - *Supervised exercise versus no intervention*

With regards to supervised exercise versus no intervention there is moderate evidence from one RCT (n = 60)<sup>(28)</sup> with a low risk of bias to support effectiveness of exercise in terms of pain and function in the short term.

### - *Supervised exercise versus placebo*

With regards to supervised exercise versus placebo there is moderate evidence from one RCT (n = 125)<sup>(25,26)</sup> with a low risk of bias to support effectiveness of exercise in terms of pain and function in the short, intermediate and long term but the clinical significance of this result is not clear because the outcome measure utilised has not been formally validated and a minimally clinically importance difference (MCID) has not been established.

### - *Supervised exercise versus surgery*

With regards to supervised exercise versus surgery there is moderate evidence from one RCT<sup>(25,26)</sup> with a low risk of bias suggesting no difference between the interventions in terms of pain and function in the short, intermediate and long term but the clinical significance of this result is not clear because the outcome measure utilised has not been formally validated and a MCID has not been established.

### - *Home exercise versus no intervention*

With regards to a home exercise programme versus no intervention there is moderate evidence from one RCT (n = 92)<sup>(27)</sup> with a low risk of bias to support effectiveness of exercise in terms of shoulder pain and disability in the short term but this result might not be clinically significant.

### - *Home exercise versus functional brace*

With regards to a home exercise programme versus functional brace there is moderate evidence from one RCT (n = 60)<sup>(29)</sup> with a low risk of bias suggesting no difference between the interventions in the short term.

- *Home exercise versus multimodal physiotherapy*

With regards to a home exercise programme versus multimodal physiotherapy there is moderate evidence from one RCT<sup>(29)</sup> with a low risk of bias suggesting no difference between the interventions in the short term.

## **Discussion**

This systematic review summarises the results of four studies that have evaluated the effect of exercise programmes, incorporating loaded exercise, for rotator cuff tendinopathy. It is suggested that both home and supervised exercise programmes might be more effective than no intervention or placebo and as effective as minimal comparators, e.g. functional brace, or active comparators, e.g. multimodal physiotherapy, surgery.

These findings are more optimistic than some previous reviews<sup>(8,10,12,40,41)</sup> but in keeping with others<sup>(9,11)</sup>. One possible reason for the difference in outcomes of this systematic review with others could be the more specific inclusion criteria relating to study population, i.e. rotator cuff tendinopathy, rather than the more generic term 'sub-acromial impingement, the intervention, i.e. exercise incorporating a loading strategy, and study type, i.e. RCT's only to minimise the impact of bias associated with other study types.

A second possible reason for the discrepancy could relate to the systematic review methods employed. Whilst undertaking this review it became clear that the studies included in this review have been included in other reviews but different conclusions regarding the risk of bias or quality and hence the strength of evidence have been reported<sup>(8,9,11,40,41)</sup>. One reason for this discrepancy might be that all of the authors of the included studies were contacted for study clarification. A response was gained from all which, without exception, resulted in favourable modification of the risk of bias tool. This means that a full assessment of the risk of bias was undertaken rather than just an assessment of the quality of the report writing. This has implications for previous reviews that have not carried out this process which might be misrepresentative of the strength of the available evidence.

### **Limitations of the included studies**

Although these results are favourable there are limitations associated with the included studies that warrant consideration. One of the studies<sup>(27)</sup> utilised a non-clinical population which might limit the capacity to generalise these findings. In the context of only four included studies, this aspect needs to be carefully considered but it is reassuring that findings are consistent across studies.

Two of the studies<sup>(27,28)</sup> compared their intervention to no intervention control groups. The limitations of such a design should be recognised for not taking into account the possible effect of the working alliance between therapist and patient<sup>(42-44)</sup>. However, again, it is reassuring to note that the exercise programmes still returned better outcomes when compared to a placebo group in one study<sup>(25,26)</sup> which would tend to control for such confounding factors.

One of the studies <sup>(25,26)</sup> utilised a primary outcome measure, i.e. the Neer shoulder score, that, as far as the review authors are aware, has not been validated and another study <sup>(29)</sup> utilised a measure, i.e. the Constant-Murley score, where a MCID has not been established. These factors are important as a means of reassurance that the measure is measuring what it is expected to measure as well as enabling research consumers to interpret the outcomes of a study in relation to practice. The MCID is the smallest change in status on the outcome measure which is considered to be clinically relevant <sup>(45)</sup>. Where this has not been determined <sup>(29)</sup> any positive outcomes associated with an intervention remain uncertain. Two of the four studies measured change in pain status <sup>(28,29)</sup> by utilising accepted formats of the Visual Analogue scale which have been validated and an MCID detected <sup>(36)</sup> and two studies utilised measures of function that had been validated and an MCID detected <sup>(27,28)</sup> although only one of these studies reported a change which met the MCID <sup>(28)</sup>. Although the treatment effects of all included studies across varied outcome measures suggests a beneficial response to exercise, the limitations of utilising unvalidated outcome measures should not be underestimated.

Finally, a consistent feature across all included studies is a failure to blind care givers and a majority of the studies did not incorporate participant blinding. These short-comings are widely regarded as typical in pragmatic studies of this nature <sup>(46)</sup>. However, it is important to recognise the possible influence of care giver and patient expectations or preferences upon treatment outcome in terms of an under or over exaggeration of treatment effect <sup>(47)</sup>.

#### Implications for practice

Despite the aforementioned limitations there appears to be a trend suggesting that exercise, incorporating a loading strategy, has a useful role to play in the management of rotator cuff tendinopathy. Clearly loaded exercise is safe and not detrimental to outcome. However, the optimal parameters of exercise and load have yet to be determined as has the mechanism by which therapeutic response occurs. The apparent anomaly to consider is the comparable effects that a functional shoulder brace has upon pain and function in this population which suggests that responses other than purely mechanical, e.g. vascular, neural or a combination of factors might be involved <sup>(48)</sup>.

Furthermore, it should be recognised that home based exercise appears to confer consistent benefit and that multimodal physiotherapy did not offer any additional benefit <sup>(29)</sup>.

#### Implications for future research

Due to the paucity of high quality research and aforementioned limitations associated with the current literature, clearly, further studies are warranted. These studies should consider the role of loaded exercise and clearly define the parameters employed to enable translation of any positive findings into practice. Furthermore, studies should include comparators consisting of credible usual care and measure outcomes using tools that have been validated and an MCID detected.

It is recognised that there might be difficulties associated with patient blinding in some studies, e.g. exercise versus surgery, but it seems possible to achieve blinding

or patient 'naivety' where interventions might be regarded as similar, e.g. supervised exercise versus multimodal physiotherapy. Including this feature in future studies might help to counteract the influence of patient expectations or preference on treatment outcome. Furthermore, the differential influence of care givers when they are asked to deliver both interventions in a two arm RCT might be minimised through the design of RCT's utilising cluster randomisation by site or randomisation by therapist in accordance with any pre-defined preference.

Alongside such pragmatic RCT's, economic analyses could consider self-managed or home based regimes versus usual interventions.

### Strengths and limitations of this review

This review was undertaken in accordance with published guidelines by a team of reviewers with more than one member involved at each stage to minimise bias. This is a clear strength of the review as is the extensive search strategy employed. However, no unpublished studies were identified for inclusion. It has been suggested that identifying unpublished studies for inclusion is important to minimise publication bias<sup>(18)</sup>. However, others have questioned this suggesting that many unpublished studies eventually become published and truly unpublished studies might have poor or unclear methodology which in turn might serve to introduce bias to the review<sup>(49)</sup>. It might be preferable to devote time to regularly updating reviews to capture studies when they are published<sup>(49)</sup>. It is difficult to determine whether a lack of unpublished studies is a weakness of this review and whether inclusion, if available, would alter the conclusions drawn.

### Conclusions

The role of exercise in the treatment of rotator cuff tendinopathy is promising but due to the paucity of high quality research and limitations relating to lack of blinding, treatment comparisons and outcome measures employed further research is warranted to fully evaluate the likely benefit.

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	Search Term	Limited to:
1	shoulder pain or shoulder impingement\$ or shoulder tend\$ or shoulder burs\$ or rotator cuff\$ or subacromial impingement\$ or subacromial burs\$ or supraspinatus\$ or impingement\$ or contractile dysfunction or painful arc\$	Title & Abstract
2	rotator cuff/ shoulder pain/ shoulder impingement syndrome	MeSH
3	1 or 2	
4	Exercis\$ or eccentric\$ or concentric\$ or loaded\$ or resistance\$ or muscle\$ or physiotherap\$ or physical therap\$ or rehabil\$ or conservative management	Title & Abstract
5	exercise/ resistance training/ physical therapy modalities/ physical therapy speciality/ rehabilitation/ muscle strength/ exercise therapy	MeSH
6	4 or 5	
7	Randomized controlled\$ or randomised controlled\$ or controlled clinical trial or randomized or placebo or randomly or trial or groups	
8	animals NOT humans	
9	3 and 6 and 7 not 8	

Table 1 MEDLINE Search Strategy

✓ = Yes	Was the method of randomisation adequate?	Was the treatment allocation concealed?	Was the patient blinded to the intervention?	Was the care giver blinded to the intervention?	Was the outcome assessor blinded to the intervention?	Was the drop-out rate described and acceptable?	Were all randomised participants analysed in the group to which they were allocated?	Free of selective reporting?	Similarity of baseline characteristics?	Co-interventions avoided or similar?	Compliance acceptable?	Timing of outcome assessments similar?	Total
-- = No													
? = Unclear													
Brox et al (1993) <sup>(25)</sup>	✓	✓	--	--	✓	✓	✓	✓	✓	--	✓	✓	9
Brox et al (1999) <sup>(26)</sup>					--								8
Lombardi et al (2008) <sup>(28)</sup>	✓	✓	--	--	✓	✓	✓	✓	✓	✓	✓	✓	10
Ludewig & Borstad (2003) <sup>(27)</sup>	✓	✓	--	--	--	✓	✓	✓	✓	✓	?	✓	8
Walther et al (2004) <sup>(29)</sup>	✓	✓	✓	--	✓	✓	✓	✓	✓	✓	✓	✓	11

Table 2 Completed risk of bias tool

1	<p><b><u>Was the method of randomisation adequate?</u></b></p> <p>A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with 2 groups), rolling a dice (for studies with 2 or more groups), drawing of balls of different colours, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, pre-ordered sealed envelopes, sequentially-ordered vials, telephone call to a central office, and pre-ordered list of treatment assignments. Examples of inadequate methods are: alternation, birth date, social insurance/ security number, date in which they are invited to participate in the study, and hospital registration number.</p>
2	<p><b><u>Was the treatment allocation concealed?</u></b></p> <p>Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.</p>
3	<p><b><u>Was the patient blinded to the intervention?</u></b></p> <p>This item should be scored "yes" if the index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.</p>
4	<p><b><u>Was the care giver blinded to the intervention?</u></b></p> <p>This item should be scored "yes" if the index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful.</p>
5	<p><b><u>Was the outcome assessor blinded to the intervention?</u></b></p> <p>Adequacy of blinding should be assessed for the primary outcomes. This item should be scored "yes" if the success of blinding was tested among the outcome assessors and it was successful or:</p> <ul style="list-style-type: none"> <li>- for patient-reported outcomes in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored "yes"</li> <li>- for outcome criteria assessed during scheduled visit and that supposes a contact between participants and outcome assessors (e.g., clinical examination): the blinding procedure is adequate if patients are blinded, and the treatment or adverse effects of the treatment cannot be noticed during clinical examination</li> <li>- for outcome criteria that do not suppose a contact with participants (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome</li> <li>- for outcome criteria that are clinical or therapeutic events that will be determined by the interaction between patients and care providers (e.g., co-interventions, hospitalization length, treatment failure), in which the care provider is the outcome assessor: the blinding procedure is adequate for outcome assessors if item "4" (caregivers) is scored "yes"</li> <li>- for outcome criteria that are assessed from data of the medical forms: the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed on the extracted data</li> </ul>
6	<p><b><u>Was the drop-out rate described and acceptable?</u></b></p> <p>The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a "yes" is scored. (N.B. these percentages are arbitrary, not supported by literature).</p>
7	<p><b><u>Were all randomised participants analysed in the group to which they were allocated?</u></b></p>

	All randomised patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of non-compliance and co-interventions.
8	<p><b><u>Are reports of the study free of suggestion of selective outcome reporting?</u></b></p> <p>In order to receive a “yes”, the review author determines if all the results from all pre-specified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment.</p>
9	<p><b><u>Were the groups similar at baseline regarding the most important prognostic indicators?</u></b></p> <p>In order to receive a “yes”, groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, and value of main outcome measure(s).</p>
10	<p><b><u>Were co-interventions avoided or similar?</u></b></p> <p>This item should be scored “yes” if there were no co-interventions or they were similar between the index and control groups.</p>
11	<p><b><u>Was the compliance acceptable in all groups?</u></b></p> <p>The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered over several sessions; therefore it is necessary to assess how many sessions each patient attended. For single session interventions (e.g., surgery), this item is irrelevant.</p>
12	<p><b><u>Was the timing of outcome assessment similar in all groups?</u></b></p> <p>Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.</p>

Table 3 The Cochrane Back Review Groups guidelines for assessing risk of bias (19)

Strong Evidence	Consistent findings in multiple high quality RCTs (n> 2)
Moderate Evidence	Consistent findings among multiple lower quality RCTs and/ or 1 higher quality RCT
Limited Evidence	Only one relevant low quality RCT
Conflicting evidence	Inconsistent findings amongst multiple RCTs
No evidence from trials	No RCTs

Table 4 Levels of Evidence (30)

Study Characteristics	Participant Characteristics	Interventions & settings	Outcome data/ results
<p><u>Brox et al (1993, 1999) (25;26)</u></p> <p>RCT with concealed allocation. Outcome assessor blinding at short term follow-up.</p> <p>3 groups:</p> <ol style="list-style-type: none"> <li>1. Arthroscopic subacromial decompression followed by supervised exercise.</li> <li>2. Supervised exercise.</li> <li>3. Detuned laser (placebo).</li> </ol>	<p>125 patients referred from General Practitioners in Norway (Mean age = 47.6 years/ 47.2% female).</p> <p>Diagnosis established through:</p> <ol style="list-style-type: none"> <li>a. Shoulder pain &gt; 3 months,</li> <li>b. Painful arc on abduction,</li> <li>c. Pain with resisted shoulder movements,</li> <li>d. Maintained glenohumeral ROM.</li> <li>e. Positive impingement tests.</li> </ol>	<p>Hospital setting.</p> <ol style="list-style-type: none"> <li>1. N = 45. Arthroscopic surgery including bursectomy and resection of the anterior and lateral part of the acromion and corocoacromial ligament followed by supervised physiotherapy.</li> <li>2. N = 50. Supervised exercise undertaken for 1 hour x2/ week plus home exercises involving gradual addition of resistance.</li> <li>3. N = 30. 12 sessions of detuned laser within 6 weeks.</li> </ol>	<p>Main outcomes assessed using:</p> <ol style="list-style-type: none"> <li>1. Neer Shoulder score at 3, 6 months and 2 ½ years.</li> </ol> <p>Groups 1 and 2 demonstrated statistically significantly improvements with regard to Group 3 but no statistically significant differences between groups 1 and 2 at any point except 2 ½ years with statistically significant change in favour of exercise group being able to take something down from a wall cupboard (p &lt; 0.01).</p> <p>Neer score has not been formally validated and minimal clinical important difference (MCID) not reported (34).</p>
<p><u>Lombardi et al (2008) (28)</u></p> <p>RCT with concealed allocation. Outcome assessor blinding.</p> <p>2 groups:</p> <ol style="list-style-type: none"> <li>1. Supervised exercise.</li> <li>2. Waiting list control.</li> </ol>	<p>60 participants selected from clinics in Sao Paulo, Brazil (Mean age = 55.6 years/ 76.7% female).</p> <p>Diagnosis established through:</p> <ol style="list-style-type: none"> <li>a. Painful arc,</li> <li>b. Positive impingement tests.</li> </ol>	<p>Home or physiotherapy department.</p> <ol style="list-style-type: none"> <li>1. N = 30. Progressive resistance training x2/ week over 8 weeks with level of resistance determined by 6 repetition maximum.</li> <li>2. N = 30. Waiting list (Physiotherapy) control.</li> </ol> <p>Both groups were also offered the same advice regarding use of analgesics/ NSAID's.</p>	<p>Main outcomes assessed using:</p> <ol style="list-style-type: none"> <li>1. Visual analogue scale.</li> <li>2. Disabilities of the arm and shoulder questionnaire (DASH).</li> </ol> <p>Statistically significant (p &lt; 0.05) improvement across all outcomes in favour of intervention group at 2 month follow-up. A mean change in VAS of 1.8 and DASH of 11.8 is regarded as clinically significant (34-36).</p>
<p><u>Ludewig &amp; Borstad (2003) (27)</u></p> <p>RCT with concealed allocation. No</p>	<p>92 construction journeymen volunteers in the USA (Mean age = 48.8 years/ 100% male).</p>	<p>Home based setting.</p> <ol style="list-style-type: none"> <li>1. N = 34. Home exercise</li> </ol>	<p>Main outcomes assessed using:</p> <ol style="list-style-type: none"> <li>1. Shoulder rating questionnaire</li> </ol>

<p>blinding.</p> <p>3 groups:</p> <ol style="list-style-type: none"> <li>1. Symptomatic subjects with impingement syndrome (intervention group).</li> <li>2. Symptomatic control (no treatment).</li> <li>3. Asymptomatic control (no treatment).</li> </ol>	<p>Diagnosis established through clinical examination including presence of:</p> <ol style="list-style-type: none"> <li>a. Minimum of 130° abduction</li> <li>b. Painful arc on abduction,</li> <li>c. Local tenderness to palpation,</li> <li>d. Pain with resisted shoulder movements.</li> <li>e. Positive impingement tests.</li> </ol>	<p>programme, with up to 3 contacts with a physiotherapist permitted, including stretching and strengthening exercises x3/ week. 3 sets of 10 repetitions 1<sup>st</sup> week. 15 repetitions 2<sup>nd</sup> week. 20 repetitions 3<sup>rd</sup> week with increasing resistance using Theraband subsequently over an 8 week period.</p> <ol style="list-style-type: none"> <li>2. N = 33. Symptomatic control.</li> <li>3. N = 25. Asymptomatic control.</li> </ol>	<p>SRQ).</p> <p><b>ITT analysis:</b> Statistically significant (<math>p &lt; 0.01</math>) improvements in favour of the intervention group at 8 to 12 weeks. A mean change in SRQ of 9.9 might not be regarded as clinically significant (<sup>37</sup>).</p>
<p><u>Walther et al (2004) (<sup>29</sup>)</u></p> <p>RCT with concealed allocation. Participant and outcome assessor blinding.</p> <p>3 groups:</p> <ol style="list-style-type: none"> <li>1. Self-training.</li> <li>2. Conventional physiotherapy.</li> <li>3. Functional shoulder brace.</li> </ol>	<p>60 consecutive patients in Dusseldorf, Germany (Mean age = 50.7 years/ 43.3% female) with painful disabling impingement of the shoulder.</p> <p>Diagnosis established through clinical examination including presence of:</p> <ol style="list-style-type: none"> <li>a. Positive impingement test,</li> </ol> <p>and radiographs and ultrasound.</p>	<p>Home or physiotherapy department.</p> <ol style="list-style-type: none"> <li>1. Self-training (using Theraband) including 7 strengthening exercises and 1 cervical stretch at least x5/ week for 10-15 minutes with guidance from a physiotherapist for a maximum of 4 sessions.</li> <li>2. Conventional physiotherapy for up to 10 sessions x 2-3/ week.</li> <li>3. Functional shoulder brace worn during the day and night if possible.</li> </ol> <p>12 weeks in total.</p>	<p>Main outcomes assessed using:</p> <ol style="list-style-type: none"> <li>1. Constant-Murley score.</li> <li>2. Visual Analogue Scale.</li> </ol> <p>All groups demonstrated statistically significant (<math>p &lt; 0.05</math>) within group changes at follow-up but no statistically significant difference between groups at baseline and 6 and 12 weeks follow-up (<math>p &lt; 0.05</math>).</p> <p>A mean change at 12 weeks in VAS of 2.0, 2.0, 2.0 for Groups 1, 2 and 3 for pain at night and change in VAS of 4.5, 2.8, 3.5 for Groups 1, 2 and 3 for pain under load is regarded as clinically significant but change in VAS of 1.1, 0.7, 1.3 for pain at rest is not (<sup>36</sup>). MCID for the Constant-Murley score has not been reported (<sup>38;39</sup>).</p>

Table 5 Characteristics of included studies

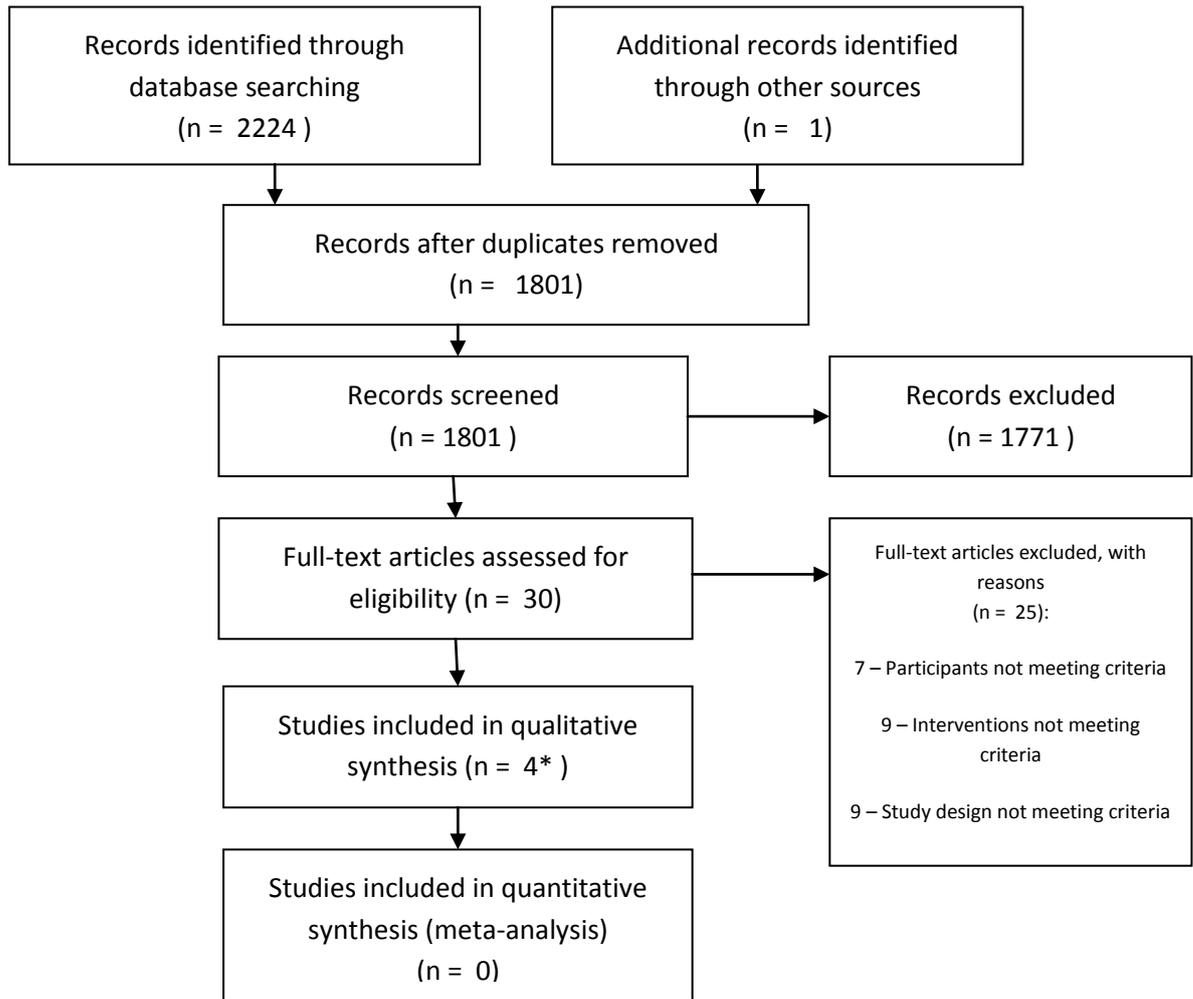


Figure 1 Study selection process (\* The findings of 2 full-text articles (25;26) were combined and treated as one study because the second article reported the long-term follow-up only).