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Rehabilitation following rotator cuff repair: A systematic review

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Introduction

Shoulder pain is a highly prevalent complaint and disorders of the rotator cuff are thought to be the most common cause [1]. Typically such disorders would initially be treated using conservative means, including physiotherapy, but if non-responsive then surgery may be considered [2]. There is evidence to suggest that the incidence of surgery to repair the rotator cuff is rising [3].

Surgical techniques to repair the rotator cuff have progressed over time. With the development of arthroscopic techniques, cuff repair has become less invasive, raising the possibility of more rapid patient recovery. Evolution of suture anchors and suture configurations have also resulted in more secure repairs [4]. Additionally, there has been a plethora of research relating to the effectiveness of surgical repair [5]. Despite all this, our understanding of the optimal approach to post-operative rehabilitation, a critical component of the recovery process, is not well developed [4]. Rehabilitation programmes have remained largely similar to those initially developed when surgical techniques were less robust [4]. Uncertainty currently appears to exist around two related parameters: 1) the period of post-surgical immobilisation; 2) the amount of early load permitted at the repair site [2]. In the context of this uncertainty a generally cautious approach to post-surgical rehabilitation seems to prevail including long periods of immobilisation and avoidance of active rehabilitation. largely due to apparent fear of contributing to failure or re-tear of the repair site. This is despite good clinical outcomes reported in the presence of re-tear [6,7], which for some raises questions about the mechanism of action of the surgery. In fact, excessive immobilisation not only has the potential to cause stiffness and delayed functional recovery, but might actually be detrimental to tendon healing. Improved clinical outcomes have been reported in other areas with early mobilisation [8].

Hence, the aim of this systematic review is to evaluate the effectiveness of rotator cuff repair rehabilitation programmes with a view to informing current clinical practice and also to develop a platform upon which future useful research might be conducted.

Methods

This systematic review was carried out using a predetermined protocol (http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014013215) in accordance with the PRISMA statement [9].

Data Sources & Search Strategy

An electronic search of the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and PEDro was undertaken from their inception to August 2014. The Cochrane highly sensitive search for identifying randomised trials was adopted [10]. 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. This process was undertaken by one reviewer.

Study Selection

Studies had to meet the following criteria to be included:

Participants

Adult (> 18 years) patients who had undergone surgical repair of the rotator cuff.

Interventions

Any post-operative rehabilitation programme.

Outcomes

Any patient-reported outcome of pain and disability.

Study design

Randomised controlled trials (RCTs).

Language

English language.

Data Extraction

One reviewer extracted data in relation to study characteristics, participant characteristics, interventions and results.

Quality Appraisal

Included studies were appraised for quality using the PEDro scale [11,12]. The PEDro scale was developed to facilitate appraisal of clinical trials in terms of internal validity and also the extent to which the statistical information provided makes their results interpretable [11]. The 11 item scale has been widely adopted for use in systematic reviews. The domains of the scale are detailed in table 2 where items 2 – 9 refer to the internal validity of a paper, and items 10 and 11 refer to the statistical analysis, ensuring sufficient data to enable appropriate interpretation of the results. Item 1 is related to the external validity and therefore not included in the total PEDro score [13].

All included articles were already scored within the PEDro database, and these data were extracted from the PEDro website with studies scoring ≥6 out of 10 considered to be high quality [14].

Data Synthesis

Due to the heterogeneity with regards to the patient reported outcomes a narrative synthesis using a rating system for levels of evidence was used [15]. This rating system, displayed in table 3, is used to summarise the results in which the quality and outcomes of individual studies are taken into account.

To evaluate the effect of early versus delayed rehabilitation programmes in terms of recurrent rotator cuff tendon re-tear, odds ratios (ORs) and 95% confidence intervals were calculated. The data were pooled using a random effects model via OpenMetaAnalyst software (http://www.cebm.brown.edu/open_meta). Statistical heterogeneity was assessed using the l^2 statistic with p < 0.05 taken to indicate statistical heterogeneity that would preclude data pooling.

Results

Study Selection

Figure 1 depicts the study selection process. The electronic search yielded a total of 1351 records. One additional source was retrieved through hand searching. The title and abstracts of 1352 articles were screened with 14 potentially relevant studies identified for full-text review. Of these 14, two did not report patient reported outcomes of pain and disability leaving a total of 12 studies for inclusion.

Quality Appraisal Assessment

The results of the quality appraisal assessment are shown in table 2. Four of 12 (33%) studies were regarded as high quality clinical trials.

Study Characteristics

A summary of the characteristics of the 12 included studies (819 patients; mean age 58.1 years) along with the main results is shown in table 4.

Interventions

Seven of 12 studies [8,16–21] evaluated early versus delayed initiation of rehabilitation. Typically this referred to initiation of passive ROM with the exception of Klintberg et al [8] who commenced low-level active ROM from day two post-operatively. There is strong evidence (consistent findings in multiple high quality RCTs) that early initiation of rehabilitation does not adversely affect outcome in terms of patient reported outcome of pain and disability in the short (3 months), mid (6 months) or long term (≥12 months).

There is limited evidence (only one relevant low quality RCT) that early initiation of rehabilitation might favourably affect outcome in terms of patient reported outcome of pain and disability in the short term (≤ 4 months) [18].

Five of 12 studies [16,17,19-21] (n = 469) evaluated early versus delayed initiation of rehabilitation and reported outcomes in terms of rate of tendon re-tear. The pooled OR of tendon re-tear in the early rehabilitation group was 1.3 (95% CI 0.72 to 2.2; p = 0.41).

There is moderate evidence (consistent findings among multiple lower quality RCTs and/ or 1 higher quality RCT) that the means of initiating passive range of movement (ROM); continuous passive movement, physiotherapist or patient directed, does not affect outcome in terms of patient reported outcome of pain and disability or rate of tendon re-tear in the short (3 months) or mid-term (6 months) [22–24]. Similarly, there is limited evidence (only one relevant low quality RCT) that the nature of exercise instruction; videotape or face to face, does not affect outcome in terms of patient reported outcome of pain and disability in the short (3 months), mid (6 months), or long term (≥12 months).

There is strong evidence (consistent findings in multiple high quality RCTs) that initiation of functional loading, for example active exercise, early in the rehabilitation programme does not adversely affect outcome in terms of patient reported outcome of pain and disability in the short (≤ 3 months), mid (6 months) or long term (≥12 months) [8,25].

Discussion

This systematic review summarises the results of twelve studies that have evaluated the effectiveness of rehabilitation programmes following surgical repair of the rotator cuff. It is suggested that concern about early initiation of rehabilitation and introduction of functional load, in the form of patient directed active exercise, following surgical repair of the rotator cuff might not be warranted in terms of adverse patient reported outcome. Concern surrounding tendon re-tear as an adverse outcome secondary to early initiation of rehabilitation programmes has been raised by some, but this is not supported by this current review where a marginal increase in tendon re-tear is evident but not statistically significant.

The recommendations from this current systematic review build upon previous reviews which highlighted the limited nature of the evidence base and suggested caution in relation to early initiation of rehabilitation and introduction of functional load [2,26–28]. The strength of these current recommendations recognise development of the evidence base in this area in terms of publication of further related RCTs. But, although we conclude that there is no evidence to delay the initiation of rehabilitation, this does not suggest that such approaches are superior to existing, delayed protocols, based upon the available data. However, in the context of the potential for superior short term outcomes, including return to work, and also the potential to reduce the early morbidity enforced through sling immobilisation, further high-quality studies are indicated to enhance our understanding.

The mean age of participants within the included studies was 58 years which suggests that a significant proportion of patients undergoing surgical repair of the rotator cuff will be engaged in gainful employment. Hence, greater understanding of the short, mid and long-term implications of early initiation of rehabilitation and introduction of functional load in terms of patient reported outcome and return to work would be useful.

The size of the initial rotator cuff tendon tear has been cited by some as a means of guiding post-operative rehabilitation where larger tears might indicate the need for a more delayed and/ or relatively conservative rehabilitation protocol due to integrity of

the subsequent repair. However, the data presented from the included studies in this review somewhat challenge that notion. Whereas some studies [18,25] appear to make no attempt to quantify and include all rotator cuff tears irrespective of size; some [19,20] quantify the size of tear and include patients diagnosed with small to medium sized tears; others [23] include patients diagnosed with medium to large sized tears. But, in doing so, all still report comprarable outcomes between early and/ or relatively aggressive rehabilitation protocols versus delayed and/ or relatively conservative rehabilitation protocols. Hence, again, the data presented in this review might serve to challenge a clinical reasoning approach based upon size of the rotator cuff tear.

Following on from this point, in an attempt to offer a potential rationale for the idea that the size of the initial rotator cuff tear might not be a useful basis upon which to guide rehabilitation prescription, it is apparent that good patient reported outcomes can still be acheived in the presence of re-tear [6,7]. Thus, it is plausible that the primary mechanism of action of the surgery is not wholly biomechanical in terms of structural repair but might be impacting in some other, currently unknown, way. So, whether the tendon re-tears or not might not actually be the important factor and probably should not be the primary concern of the patient or clinician.

One outcome not considered in this review is post-operative stiffness which has been one of the suggested advantages of early versus delayed mobilisation. Typically stiffness would be quantified in terms of shoulder ROM. However, due to concerns about the level of reliability of ROM measurement and also concerns about validity [29], i.e. apparent stiffness or loss of ROM not reflecting patient report of disability, this outcome was omitted in preference for patient reported measures of pain and disability, refecting the wider movement in outcome measurement, and retear rate. The former, an outcome important to the patient; and the latter an outcome that appears to be important to many clinicians, particularly surgeons.

Implications for clinical practice and further research

From a clinical perspective, this review challenges the belief that a period of enforced immobilisation and unloading is necessary to achieve a good outcome following surgical repair of the rotator cuff. However, development of the evidence base is indicated in terms of the need to evaluate both short and long term outcomes of approaches to rehabilitation that foster early initiation of rehabilitation and gradual introduction of functional load. Important outcomes include validated measures of patient reported outcome, for example the Oxford Shoulder Score and Disabilities of the Arm Shoulder & Hand, as well as return to work outcomes and associated economic data.

Limitations

The twelve RCTs included in this systematic review comprised an average of 68 participants. Hence, one potential caveat to consider alongside the recommendations from this review is the potential for Type II error. Although the findings are reasonably consistent across studies the relatively small mean number of included participants per trial might indicate that any true differences between interventions could have been missed.

For pragmatic reasons one reviewer identified relevant studies, extracted data and synthesised the findings. This approach somewhat challenges traditional systematic review guidance where it is frequently suggested that multiple reviewers should be involved at each stage [30]. However, it is interesting to note that there is movement in the field of systematic review methodology towards an appreciation of rapid reviews [31]. Frequently such reviews use one reviewer at the various stages for pragmatic reasons and although it is recognised that the potential for error might be higher, it is generally suggested that most errors or omissions do not lead to substantial changes in any conclusion [32] while delivering in a timely manner.

Conclusion

Concern about early initiation of rehabilitation and introduction of gradual functional load, in the form of patient directed active exercise, following surgical repair of the rotator cuff might not be warranted in terms of adverse patient reported outcome or tendon re-tear. Although the evidence base relating to rehabilitation of the rotator cuff following surgical repair has developed, these conclusions are offered with the caveat of the potential for Type II error and hence there is further need to evaluate approaches that foster early initiation of rehabilitation and gradual introduction of functional load both in the short and long term using high-quality, adequately powered, trials.

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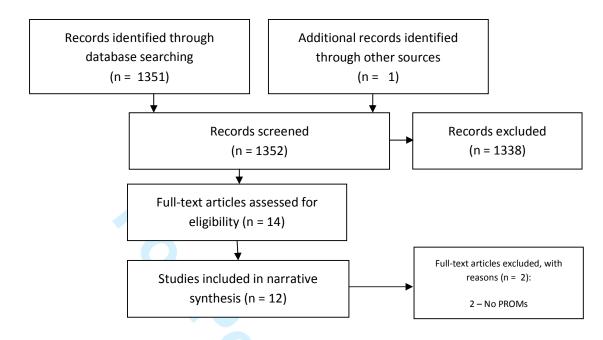
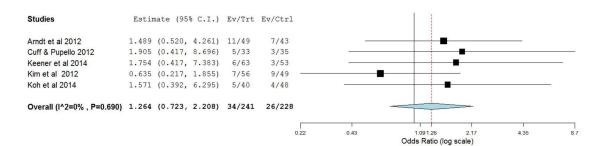


Figure 1 Study selection process



, of early versus Figure 2 Forest plot of odds ratios (ORs) of early versus delayed initiation of rehabilitation (OR > 1 suggests higher rate of tendon re-tear in early group)

	Search Term	Limited to:
1	Rotator cuff repair	Title & Abstract
2	Exercis\$ or physiotherap\$ or physical therap\$ or rehabil\$	Title & Abstract
3	Randomized controlled\$ or randomised controlled\$ or controlled clinical trial or randomized or placebo or randomly or trial or groups	
9	1 and 2 and 3	

Table 1 MEDLINE Search Strategy



(- aritania maat												
✓ = criteria met	-	2	က	4	2	9	7	ω	o o	10	7	Total
x = criteria not met												Ĕ
Arndt et al [16]	✓	✓	Х	✓	Х	Х	Х	✓	Х	✓	✓	5
Cuff & Pupello [17]	✓	✓	✓	Х	Х	Х	✓	Х	Х	✓	Х	4
Duzgun et al [18]	✓	✓	Х	✓	Х	Х	Х	✓	Х	✓	✓	5
Hayes et al [25]	✓	✓	Х	✓	Х	Х	✓	✓	✓	✓	✓	7
Keener et al [19]	✓	✓	✓	✓	Х	Х	✓	✓	Х	✓	✓	7
Kim et al [20]	Х	✓	Х	✓	Х	Х	Χ	✓	Х	✓	✓	5
Klintberg et al [8]	✓	✓	✓	✓	Х	Х	Χ	✓	Х	✓	✓	6
Koh et al [21]	х	✓	✓	✓	Х	Х	✓	✓	✓	✓	✓	8
Lastayo et al [22]	✓	✓	Х	✓	Х	Х	Χ	✓	Х	✓	✓	5
Lee et al [23]	Х	V	✓	✓	Х	Х	Х	х	Х	✓	✓	5
Raab et al [24]	✓	✓	✓	✓	Х	Х	✓	х	Х	✓	Х	5
Roddey et al [33]	V	✓	Х	✓	Х	Х	Х	Х	Х	✓	✓	4

Table 2 Completed PEDro quality appraisal (1. Eligibility criteria were specified'; 2. Subjects were randomly allocated to groups; 3. Allocation was concealed; 4. Groups were similar at baseline regarding the most important prognostic indicators; 5. There was blinding of all subjects; 6. There was blinding of all therapists who administered the therapy; 7. There was blinding of all assessors who measured at least one key outcome; 8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups; 9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case data for at least one key outcome was analysed by "intention to treat"; 10. The results of between-group statistical comparisons are reported for at least one key outcome; 11. The study provides both point measures and measures of variability for at least one key outcome)

Consistent findings in multiple high quality RCTs (n> 2)
Consistent findings among multiple lower quality RCTs and/ or 1 higher quality RCT
Only one relevant low quality RCT
Inconsistent findings amongst multiple RCTs
No RCTs

Table 3 Levels of Evidence



Study Characteristics	Participant Characteristics	Interventions	Results
Arndt et al [16]	92 patients (mean age = 55.3 years/	100 patients randomised and 92	Main outcomes assessed using
	37% male)	patients followed-up	Constant score at 12 months:
RCT comparing early versus			
delayed initiation of passive ROM	Main inclusion criteria:	1. n = 49; early ROM, commencing	Statistically significant difference of
followed by formal physiotherapy	a. Non-retracted, isolated tear of	day 2 post-operatively, including	7.9 points (p = 0.045) in favour of
	supraspinatus repaired	passive ROM, CPM without ROM	early group. This difference is not
Conducted in France	arthroscopically	limitation and daily pendular	regarded as clinically important
		exercises	No statistically significant
		2. n = 43; maintenance of sling	No statistically significant
		immobilisation for 6 weeks before	differences between groups in terms of re-tear rate (11/49 versus
		commencement of formal	7/43; p = 0.5)
		physiotherapy but still undertook	7740, β = 0.0)
		daily pendular exercises	
Cuff & Pupello [17]	68 patients (mean age = 63.2 years/	1. n = 33; early ROM, commencing	Main outcomes assessed using
-	58% male)	day 2 post-operatively, including	American Shoulder & Elbow score
RCT comparing early versus	•	passive elevation and external	at 12 months:
delayed initiation of passive ROM	Main inclusion criteria:	rotation directed by a PT x 3/ week	
followed by formal physiotherapy	a. Isolated full-thickness tear of	and supplemented by patient	No statistically significant
0 1 1 1 1 1 1 0 1	supraspinatus repaired	directed pendular exercises	differences between groups
Conducted in USA	arthroscopically	between formal sessions	including re-tear rate (5/33 versus 3/35; p > 0.05)
		2. n = 35; maintenance of shoulder	
		immobiliser for 6 weeks before	
		commencement of formal	
		physiotherapy but still undertook	
Durana et el [40]	20 notionts (mann and = EG 2 years)	daily pendular exercises	Main outcomes assessed using
Duzgun et al [18]	29 patients (mean age = 56.3 years/ 10% male)	1. n = 13; early passive ROM,	Main outcomes assessed using: Disabilities of the Arm, Shoulder &
RCT comparing an accelerated	10% male)	commencing day 7 post-operatively, followed by active ROM	Hand at 8, 12, 16 and 24 weeks:
rehabilitation programme versus a	Main inclusion criteria:	commencing day 21 and resistance	Tianu at 0, 12, 10 and 24 weeks.
delayed programme	a. Rotator cuff rupture repaired	from day 28.	Statistical (p < 0.05) and clinically (>
acia, ca programmo	arthroscopically		10 points) significant difference in
Conducted in Turkey		2. n = 16; delayed programme with	favour of the accelerated group at
		active ROM commencing day 42	8, 12 and 16 weeks but no

		post-operatively	significant difference by 24 weeks
Hayes et al [25] RCT comparing a standardised home exercise programme plus individualised treatment versus a standardised home exercise programme alone Conducted in Australia	58 patients (mean age = 60.2 years/71% male) Main inclusion criteria: a. Diagnosis of rotator cuff rupture, of any size repaired surgically	1. n = 26; sling immobilisation for 1 day post-operatively followed by encouragement to commence light functional activity and pendular exercises for further 7 days. Active-assisted ROM from day 8 onwards and active and resisted exercise commenced from day 42 onwards. Supplemented by individualised physiotherapy from second week post-operatively including exercise, MT, ET at the discretion of the treating physiotherapist	Main outcomes assessed using Shoulder service questionnaire (SSQ) at 6, 12 and 24 weeks: No statistically significant differences between groups across all time points except physical symptoms, lifestyle and overall shoulder status domains of SSQ at 24 weeks in favour of home exercise plus individualised treatment group. Clinical importance of this difference is unclear
	2.6	2. n = 32; standardised home exercise programme alone	
Keener et al [19]	124 patients (mean age = 55.3	1. n = 65; pendular exercises	Main outcomes assessed using American Shoulder & Elbow score
RCT comparing early passive ROM	years/ 59% male)	immediately post-operatively and therapist supervised passive ROM	at 6, 12 and 24 months:
versus delayed ROM with sling	Main inclusion criteria:	from 7 days post-operatively. Active	at 0, 12 and 24 months.
immobilisation for 6 weeks	a. <65 years of age	ROM initiated from day 42 onwards	No statistically significant
The second second	b. Diagnosis of full thickness rotator	Trem initiated from day 12 entital as	differences between groups
Conducted in USA	cuff tear <30mm repaired arthroscopically	2. n = 59; shoulder immobilised for 6 weeks post-operatively before commencement of therapist supervised passive ROM	including re-tear rate (6/63 versus 3/53; p = 0.46)
Kim et al [20]	105 patients (mean age = 60 years/	1. n = 56; abduction brace for up to	Main outcomes assessed using
RCT comparing early passive ROM versus delayed ROM with brace	42% male Main inclusion criteria:	35 days post-operatively supplemented by passive ROM 3 to 4 times per day during this period	American Shoulder & Elbow score at 6 and 12 months:
immobilisation for 5 weeks	a. Diagnosis of small to medium-		No statistically significant
Conducted in South Korea	sized full-thickness rotator cuff tears repaired arthroscopically	2. n = 49; abduction brace only with no passive motion during this period	differences between groups including re-tear rate (7/56 versus 9/49; p = 0.43)
Klintberg et al [8]	14 patients (mean age = 55 years/	1. n = 7; low-level active ROM x3/	Main outcomes assessed using

RCT comparing early loading versus delayed loading Conducted in Sweden	64% male) Main inclusion criteria: a. Diagnosis of full-thickness tear repaired surgically	day from day 2 post-operatively supplemented by passive ROM directed by the physiotherapist. Load was progressed from day 28 post-operatively when sling immobilisation was ceased. 2. n = 7; 6 weeks of sling immobilisation supplemented by passive ROM	Constant score at 6, 12 and 24 months: Between group difference inadequately reported; reported as no difference in adverse effects but statistical significance unclear
Koh et al [21] RCT comparing immobilisation for four versus eight weeks Conducted in South Korea	100 patients (mean age 59.9 years/ 50% male) a. Diagnosis of full-thickness tear, 2 to 4cm in size, repaired arthroscopically	1. n = 47; 4 weeks of immobilisation without passive ROM 2. n = 53; 8 weeks of immobilisation without passive ROM	Main outcomes assessed using Constant score and ASES at 6 and 24 months: No statistically significant differences between groups including re-tear rate (5/40 versus 4/48; p = 0.73)
Lastayo et al [22] RCT comparing continuous passive motion versus manual passive ROM exercises Conducted in USA	31 patients (mean age 63.3 years/ 44% male) a. Rotator cuff tear repaired surgically	1. n = 17; home continuous passive motion for 4 hours per day after discharge from hospital for 4 weeks, supplemented by daily pendular exercises 2. n = 15; manual passive ROM exercises three times per day performed by carer or similar for 4 weeks supplemented by daily pendular exercises	Main outcomes assessed using Shoulder Pain and Disability Index at unclear time point: No statistically significant (p > 0.05) differences between groups
Lee et al [23] RCT comparing aggressive versus limited passive exercises Conducted in South Korea	64 shoulders (mean age 54.9 years/64% male) a. Diagnosis of medium- or large-sized full-thickness rotator cuff tear repaired arthroscopically	1. n = 30; immediate passive ROM x 2/day without limit on ROM supplemented by daily pendular exercises with shoulder brace maintained in situ for 6 weeks 2. n = 34; continuous passive movement limited to 90° x 2/ day	Main outcomes assessed using University of California Los Angeles shoulder rating scale at 3 and 6 months: Statistically significant (p < 0.01) difference in favour of aggressive exercise at 3 months but unknown if

		and passive ROM with shoulder brace maintained in situ for 6 weeks	difference of 2.9 points is clinically significant. No statistically significant difference by 6 months (p = 0.16). No statistically significant difference between groups in terms of re-tear
Raab et al [24] RCT comparing physiotherapy	26 patients (mean age 55.8 years/ 69% male)	1. n = 12; physiotherapy (no further description)	rate (7/30 versus 3/34; p = 0.11) Main outcomes assessed using an author generated patient-reported shoulder score at 3 months:
versus physiotherapy with continuous passive motion Conducted in USA	a. Rotator cuff tear repaired surgically	2. n = 14; physiotherapy with continuous passive movement commencing in the recovery room, progressed within pain-free limits, and continuing for 8 hours/ day for 3 weeks limited to 90° x 2/ day and passive ROM with shoulder brace maintained in situ for 6 weeks	No statistically significant difference between groups (p = not reported)
Roddey et al [33] RCT comparing two approaches to home exercise instruction	108 patients (mean age 58 years/ 64% male) a. Diagnosis of full-thickness tear	1. n = 54; videotape based home exercise instruction while sling remained in situ for 6 weeks. Passive exercise for 4 to 6 weeks,	Main outcomes assessed using Shoulder Pain & Disability Index at 3, 6 and 12 months:
Conducted in USA	repaired arthroscopically	followed by active exercise between 6 to 12 weeks and then strengthening exercises > 3 months	No statistically significant difference between groups (p = 0.17, 0.40, 0.99 respectively)
Table 4 Common of the above to right		2. n = 54; personal PT instruction while sling remained in situ for 6 weeks. Principles of exercise progression as group 1	

Table 4 Summary of the characteristics of the included studies along with main results (RCT = randomised controlled trial; ROM = range of motion; PT = physiotherapist/ physical therapist; MT = manual therapy; ET = electrotherapy including heat and ice)