REVIEW ARTICLE

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CLINICAL EFFECTIVENESS OF NON-SURGICAL INTERVENTIONS FOR PRIMARY FROZEN SHOULDER: A SYSTEMATIC REVIEW

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Objective: To update an existing systematic review of randomized clinical trials evaluating the clinical effectiveness of non-surgical management interventions for people with primary frozen shoulder in terms of pain, movement, self-reported function and disability, quality of life, recovery time, return to work and recreation, and adverse events.
Data sources: Cochrane CENTRAL, SCI and MEDLINE, CENTRAL between 1 January 2010 and June 2017, plus reference lists of included trials and trial registers. Abstracts were independently screened by 2 reviewers and discussed.
Data extraction: Two reviewers evaluated eligibility. Data were extracted by one reviewer and checked by another. Two reviewers evaluated risk of bias. Meta-analyses were not appropriate. Narrative analyses were performed for trials evaluated as low risk of bias.
Results: Thirty trials were included, with the majority of studies evaluated as being at high risk of potential bias. Only 4 trials were evaluated as being at low risk of bias and this, plus the variety of participants included/excluded in trials and the variety of methods, interventions and outcomes used across the trials provided limited new evidence to inform the non-surgical management and treatment of people with frozen shoulder.
Conclusion: Substantial evidence gaps remain for the non-surgical treatment of people with frozen shoulder.

LAY ABSTRACT

Frozen shoulder commonly affects people aged around 50 years and is associated with substantial levels of shoulder pain and stiffness that may last for many years. Many people with frozen shoulder report that simple activities, such as dressing, and washing or drying their hair, become almost impossible. The condition may adversely affect the ability to work and frequently causes severe interruptions to sleep. The reasons why up to 5% of the population develop frozen shoulder are unknown. Many treatments, often lacking sound research evidence, have been recommended. Inappropriate treatment may not resolve the symptoms, may be associated with unnecessary expense, and may even cause harm. We have updated a review of the available literature to synthesize the findings of the available research so that we can make recommendations for the best current treatment alternatives to help people with frozen shoulder and for future research.

Frozen shoulder (FS) is associated with prolonged shoulder disability and is often characterized by severe pain, loss of movement and disrupted sleep (1). The main priority for people experiencing FS is to achieve pain-free freedom of movement as soon as possible, and they are concerned about delays in receiving care and receiving contradictory advice regarding treatment (1). Estimates of incidence of FS range from 0.75% to 5.0%

of the population (2, 3) and are higher in people with diabetes (10–46%) (4, 6). Uncertainty remains regarding the distribution of FS between men and women (2), and whether FS is more common in women or is evenly distributed (3). Uncertainty also remains regarding the time course of FS: reports include a mean of 15 months (7), 30 months (8), and 41% of people with symptoms at 52 months (9). One case series (*n* = 62) suggested that 50% of people reported mild shoulder pain and stiffness and 60% restricted range of movement at a mean of 84 months (10).

A definitive understanding of the pathogenesis of FS remains elusive (11). Inflammation, fibrosis and contraction of the glenohumeral joint capsule are suggested to explain the symptoms (12) and may be triggered by increased expression of cytokines and neuropeptides (11). However, capsular contraction may not be the only explanation; a small pilot study (*n* = 5) by Hollmann et al. (13) reported that, when given a general anaesthetic, people presenting with FS exhibited increased range of movement in shoulder elevation (minimum increase 55°, maximum 110°), suggesting that muscle guarding may partly explain the movement restriction in a percentage of people with FS. FS appears to be most common in people aged in their 50s and 60s (14), and so may relate to

genetic (15) or endocrine disorders, such as diabetes and thyroid problems that may become more prevalent at this time (11). FS has been described to occur in 3 transitionary phases: increasing pain and progressive stiffness, ongoing stiffness and decreasing pain, and a resolution phase, in which the remaining pain settles, and movement improves (2, 8, 16). Lewis (17) suggested a simplified method of classification; a pain greater than stiffness phase and a stiffness greater than pain phase. When there is no known reason for onset, such as following surgery, or if the condition is not associated with comorbidities, the term primary (or alternatively idiopathic) FS is recommended (18).

Whether FS is a self-limiting condition that may do well without intervention (7) or whether resolution requires treatment remains unclear (19). A retrospective study suggests that a "no treatment" option may be considered (20): 94% of people (*n* = 83, mean time after onset = 9 years) with FS, recovered to normal levels of function and motion without treatment. Management options for FS broadly fall into 3 categories; advice, support and empathy, while allowing natural history to take its course (wait and watch); more formal non-surgical management; and surgical intervention.

A comprehensive, high-quality systematic review of non-surgical management for people with FS concluded that data from studies with a low risk of bias were sparse (21). The following conclusions were drawn from a minority of studies deemed to be of low risk of bias (21): possible short-term benefit from adding a single intra-articular steroid injection to home exercise for patients with primary FS of less than 6 months' duration, adding physiotherapy (including mobilization in 8–10 sessions over 4 weeks) to a single steroid injection, adding shortwave diathermy (SWD) to passive mobilization and home exercise (for some outcomes only), and high-grade mobilization may be more effective than low-grade mobilization in a population of patients who have already had physiotherapy and/or steroid injection (for some outcomes).

Recommendations to classify FS into diagnostic subcategories have been made, with the aim of developing more homogeneous research investigations and better understanding of whether differences in pathogenesis and management exist within the different subgroups (17). The term primary or idiopathic FS appears to be the most common presentation and is the diagnostic category when there is no identifiable reason for onset. Secondary FS is used when there is an identifiable potential cause preceding the onset of the condition. Secondary systemic FS describes FS in the presence of diabetes. When the condition is preceded by a humeral or clavicular fracture, a chest wall tumour, cervical radiculopathy, ipsilateral breast surgery or cerebrovascular accident, the diagnostic

label secondary extrinsic FS has been suggested. FS occurring post-surgery is termed iatrogenic FS.

The current review aims to update the existing review (21) and evaluate the clinical effectiveness of non-surgical management interventions focussing on primary or idiopathic FS, in terms of pain, range of shoulder joint movement, self-reported function and disability, quality of life, recovery time, return to work and recreation and adverse events.

METHODS

This review was carried out following recommended advice from the Cochrane Handbook, reported according to the PRISMA statement (22) and registered in advance with PROSPERO (reference number: CRD42015013728).

Population

Randomized controlled trials (RCTs) containing participants with primary (idiopathic) FS or its synonyms, such as adhesive capsulitis, were included. FS in people with diabetes has been considered as both primary and secondary. For this review, unlike Maund et al. (21), but in agreement with a consensus on defining the subcategories of FS (18), people with diabetes were considered to have systemic secondary FS and these studies were excluded. Participants with other non-idiopathic or secondary causes of FS (for example trauma or surgery), as well as participants with symptoms indicating an alternative source of shoulder pain (for example, referred pain, paraesthesia, instability, rotator cuff tendinopathy) were excluded. Studies with participants with general shoulder symptoms (shoulder pain or symptoms or non-specific shoulder pain) were not included. Studies needed to state they were RCTs; studies stating participants were "divided"' or "assigned"' to groups were not assumed to be RCTs and were not included.

Non-surgical interventions

Physiotherapy and rehabilitative interventions, distension, oral medications, and injection procedures were included. Surgical procedures, such as arthroscopic and open capsular releases, were excluded.

Comparators

Trials comparing an intervention and control group, or, comparing 2 of the included interventions were included. Trials comparing an intervention, a further intervention outside of the review and a control were included only if the data could be extracted for the intervention and control arms.

Outcomes

Outcomes were: adverse events, pain, range of shoulder joint motion, self-reported function and disability, strength, quality of life, recovery time to recreation and return to work.

Data sources and search strategy

Electronic searches were initially conducted in December 2014 by 2 independent reviewers (EB, NDB) and subsequently updated by 2 independent reviewers between November 2016 and

June 2017 (CML and an experienced healthcare librarian). The original review (21) searched 19 sources, but concluded that 2 databases (Cochrane CENTRAL and either the Science Citation Index or MEDLINE), plus reference checking, proved effective in identifying included papers and this approach was utilized in this review (23). The original MEDLINE search (Table SI[1]) was re-run in OVID (Epub Ahead of Print, In Process & Other Non-Indexed Citations, Ovid MEDLINE (R) Daily and Ovid MEDLINE (R) 1946 to Present) with search date limits 1 January 2010 to 8 December 2016. In addition, Cochrane CENTRAL, SCI MED-LINE, CENTRAL databases were searched, following the search strategies detailed by Maund et al. (21), to retrieve randomized clinical trials published between 1 January 2010 and 6 June 2017. Reference lists of included trials were manually searched for other relevant trials (no new hits). Clinical trials registers were searched to identify any additional publications and to identify on-going trials to further inform the review. ClinicalTrials.gov (searched 8 June 2017, *n*=42: no new hits), ISRCTN (searched 7 June 2017, *n*=20: no new hits) and the European Union Clinical Trials Register (searched 8 June 2017, *n*=3: no new hits). Although resources for translation were not available, searches were not restricted to English language, so that the quantity of non-English-language research could be established.

Study selection

Two reviewers independently screened the retrieved title and abstracts against the inclusion criteria (EB and NDB in 2014, CML and JL in 2016/17). When potentially relevant studies were identified, or information was insufficient, the full-length article was screened and discussed by 2 reviewers. Two reviewers independently screened the full articles for inclusion (EB and NDB in 2014, CML and JL in 2016/17) and then discussed them together. In the case of disagreement between the 2 reviewers, a third reviewer was consulted (JL in 2014 and NDB in 2016). This occurred in the case of 2 trials in 2014, but was unnecessary in 2016/17.

Risk of bias assessment

Risk of bias was assessed by 2 independent reviewers using a domain-based, risk of bias assessment approach (24). Domains included sequence generation, allocation concealment, intervention integrity, effective blinding and whether outcomes were pre-specified, analysed, and reported appropriately. Any additional aspects of study methodology relevant to validity or generalizability were also evaluated (e.g. appropriateness of study measures and sample size). Items relevant to each trial's internal validity were reviewed and graded as adequate (low risk of bias), partial (moderate risk of bias), inadequate (high risk of bias), or unclear (uncertain risk of bias). Blinding of participants and intervention providers was not thought feasible, and thus lack of blinding here was rated as low risk. Any items judged differently by reviewers were discussed and resolved by 2 reviewers (CML, JL) until consensus was reached and an evaluation of overall risk of bias was achieved.

Data extraction

Study characteristics for all trials included in the review were extracted by one reviewer using a standardized form (CML) and checked against their source article by a second reviewer (JL).

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[1]http://www.medicaljournals.se/jrm/content/?doi=10.2340/16501977-2578

Data synthesis

Data syntheses were undertaken for trials evaluated as low risk of bias. There are different methods and approaches towards undertaking systematic reviews, and a lack of consensus regarding the optimal approach researchers should utilize in reviews. Whilst some researchers decide to include all studies, including those at high risk of bias, in syntheses, others consider it to be inappropriate and potentially misleading to include studies at high risk of bias in all parts of data analyses/syntheses within a review (25, 26). It was unclear from the written publication whether participants with diabetes mellitus were included or excluded in trials for 10 trials evaluated at low risk of bias. The corresponding authors for these trials were emailed requesting additional information, with a follow-up email at least 2 weeks later, where necessary. Following this, it was confirmed that 4 trials were eligible for inclusion and 6 were excluded because they included participants with diabetes mellitus or because they did not reply to confirm eligibility. A further author (Ma et al.) (27) was emailed to clarify how participants were randomized; no reply was received, therefore this trial could not be evaluated as low risk of bias.

RESULTS

Study selection

In the OVID MEDLINE search for trials 2,724 records were identified, 76 records were screened, and 55 full papers were subsequently assessed against the review's inclusion criteria. Of these, a total of 30 trials were included in the review. No additional studies were identified from searches of the additional databases. A summary is provided in the PRISMA flow diagram in Fig. 1. Table SII[1] contains a list of excluded studies. The characteristics of the trials included in the review and their risk of bias assessments are summarized in Tables I and II. Four studies were included in data syntheses.

Comparison of joint mobilization and stretching vs stretching alone.

Celik & Mutlu (28) compared the effectiveness of joint mobilization and stretching vs stretching alone. Joint mobilization techniques included glenohumeral joint distractions, caudal glides, posterior and anterior glides at a rate of 2–3 oscillations/s for 1–2 min and progressing from Grades I–II to III–IV if pain allowed. The stretching programme involved 20 s of stretching and 10 s of rest and was performed 10 times in the directions of flexion, abduction in the scapular plane, external and internal rotation. Both groups performed a home exercise programme; self-stretching and exercises (scapular retraction, external rotation, extension against resistance, wall and table push-ups, and scapular adduction in prone). All participants received 18 sessions, including the home exercise programme (Table I). This study is a pilot trial, but is reported as a trial, including a sample size calculation and statistical testing, rather than as a pilot trial (29). Both groups
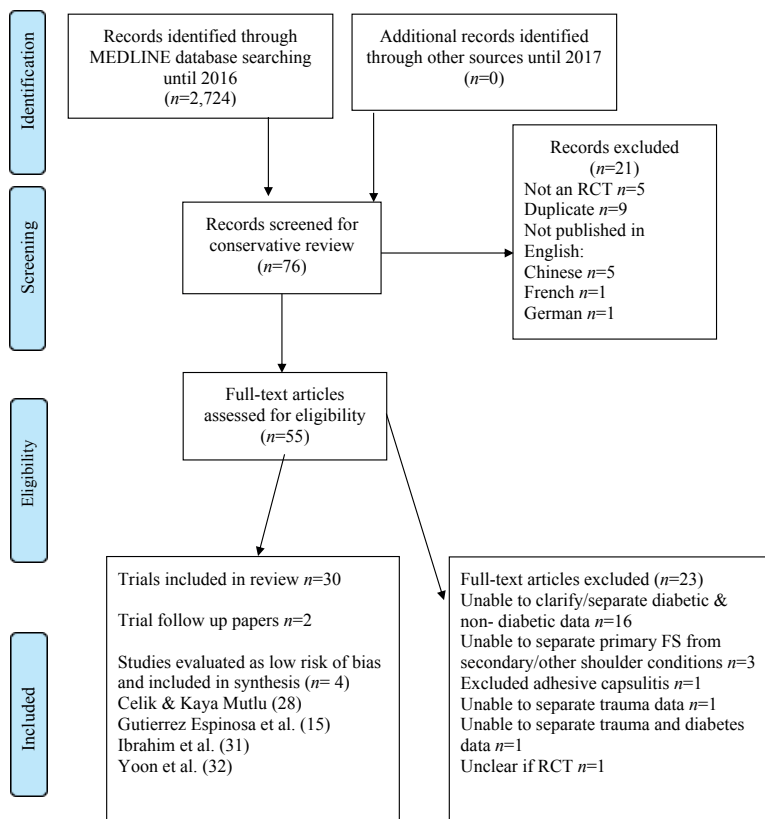
Fig. 1. PRISMA 2009 flow diagram. RCT: randomized controlled trial; FS: frozen shoulder. From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6 (7): e1000097. doi:10.1371/journal.pmed1000097 (22).

improved over time. The sample size (*n* = 30) was small and between-group comparisons showed that the effect size for the primary outcome used in the power calculation, the Disabilities of the Arm, Shoulder and Hand (DASH), was 0.03. Although the trend (8 points at the end of treatment and 6 points at 12 months) in the DASH was better in the mobilization and stretching group over the stretching alone group this would not be considered clinically meaningful. The mobilizations and stretching group had improved Constant score and abduction and external rotation range at the end of treatment, and this was maintained at 1-year follow-up. However, it is unclear if the 14° increase in abduction, and 6° increase in external rotation at 1 year is of clinical relevance, although the 17.2 increase in Constant score might be relevant.

Comparison of joint mobilization and upper extremity cycle ergometer vs ultrasound and exercises

Gutierrez Espinosa et al. (30) also evaluated joint mobilization combined with 15 min on an upper extremity

cycle ergometer (*n* = 29), compared with ultrasound, self-assisted exercises, Codman exercise, Swiss ball exercises and isometric exercises (*n* = 28) (Table I). In this study, the participants were positioned in supine in 30–40° of shoulder abduction and external rotation (according to tolerance). A Kaltenborn type III axial distraction was applied, followed by a posterior glide, without oscillations, for 1 min. This was repeated 15 times, with a 1-min rest, and 10 sessions were delivered, 2 or 3 times per week. Pain, range of motion, and function improved with statistical differences in favour of the mobilization and cycle ergometer group (Table I). There was no loss to follow-up.

Only the short-term results were reported (at the end of the 10th treatment session). The authors reported a mean increase, in favour of the mobilization and ergometer group for the primary outcome measures; passive external rotation of 27° (56.8° vs 30°), passive flexion of 37° (107° vs 69.7°), passive abduction of 22° (70.7° vs 48.8°), and for the secondary outcome measurements; VAS (pain) of 4.4 (0 = no pain and 10 = worst imaginable pain) in the mobilization group and 5.4 in the ultrasound and exercise group, and, 21 points in the Constant-Murley Score (50.3 vs 29.7).

Although the findings suggest clinical improvement in all the outcomes of interest in favour of the mobilization and ergometer group, the absence of medium- and long-term follow-up is a clear limitation of this study.

Comparison of static progressive stretching plus multi-modal intervention vs multi-modal intervention

Ibrahim et al. (31) compared the effectiveness of a multi-modal treatment programme consisting of heat packs, therapy to facilitate muscle relaxation and glenohumeral mobilizations (inferior glides, longitudinal caudad) for 2 min, using large-amplitude oscillations and repeated 3 times in a 10-min session (*n* = 30) and a static progressive stretch device with the multi-modal programme alone (*n* = 30). Both groups received treatment 3 times a week for 4 weeks and participants were also provided with a home exercise programme. The static stretch group were asked to apply the static stretch device for a single 30-min session daily for

Table I. Study characteristics of the trials included in the systematic review (n = 30). This table provides information regarding the participants, study aims, interventions, main outcomes and findings.

Study Country Number of participants	Aim	Intervention	Main outcome measures	Summarized main results
Ali & Khan 2015 (62) Pakistan *n* = 44	To evaluate the effectiveness of exercise with manual therapy vs exercise alone.	Two groups. Both had home exercise programme (daily). Exercise and manual therapy group (*n* = 22) = general exercises (flexion, abduction, cross body, internal and external rotation stretches, pendulum exercises) and Maitland mobilizations (grade II and III, 2–3 oscillations per s for 30 s and 5 sets of each); exercise group (*n* = 22) = general exercises. Dose: 45-min sessions 3 times a week for 5 weeks.	Pain visual analogue scale, range of motion, Shoulder Pain and Disability Index (SPADI) Assessments: Baseline, 5 weeks	Within-group significant improvements in all outcomes at 5/52 (*p* < 0.01). Intra-group analysis showed no significant difference between 2 groups (*p* > 0.05).
Badalamente et al. 2016 (63) USA *n* = 60 Study 1, *n* = 50 Study 3	Aim 1. Does a collagenase clostridium histolyticum injection lyse shoulder capsule collagen, and at what dose? Aim 2. Not related to SR. Aim 3. Do (CCH) injections result in better scores for pain and function than exercise?	Study 1. 1 CCH injection vs saline injection: a single injection of placebo (*n* = 15) or 0.145 mg (*n* = 16), 0.29 mg (*n* = 15), or 0.58 mg (*n* = 14) of CCH dissolved in sterile buffer (0.9% saline and 2 mmol/l Ca²+). The volume for all injections was 0.5 ml. Study 3. CCH dose range-volume (plus exercise) vs controls (exercise only). Dose: varied. Exercise: home exercise programme ROM, pulleys, stretches, pendulum 3× day).	Primary: active forward flexion. Secondary: active range of motion (ROM), passive ROM, pain (VAS), and ASES (American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form) function. Assessments: 1 = Baseline and 1, 2, 4, 7, 14, 30 days. 3 = Baseline, day 92 (mid-assessments varied between cohorts)	1. No between-group differences. 3. CCH 0.58 mg/1 ml and 0.58 mg/2 ml more effective than exercise in AFF only.
Bae et al. 2014 (64) South Korea *n* = 64	To evaluate the clinical effects of a fluoroscopy-guided capsular distension (anterior approach) vs ultrasound guided capsular distension (posterior approach).	2 groups: Ultrasound-guided (*n* = 33) postero-lateral approach capsular distension (2% lidocaine (5 ml), triamcinolone (40 mg), and normal saline (14 ml), for a total 20 ml fluid OR fluoroscopy-guided (*n* = 31) posterolateral capsular distension (2% lidocaine (5 ml), contrast dye (5 ml), triamcinolone (40 mg), and normal saline (9 ml), in a total fluid volume of 20 ml). All received physiotherapy (×4 week 1, ×2 week's 2–8) of heat, electrical therapy and therapeutic exercise.	Shoulder Pain and Disability Index (SPADI), PROM, VNS (pain), hand power (grip, pinch). Assessments: Baseline, 1, 5, 9 weeks.	No between-group differences.
Balci et al. 2016 (65) Turkey *n* = 53	To compare the immediate effects of scapular proprioceptive neuromuscular facilitation (PNF) & modalities, exercise & modalities, and modalities alone.	3 groups: 1 (*n* = 18) = PNF & modalities (hot pack, TENS (transcutaneous electrical nerve stimulation), ultrasound), Group 2 (*n* = 18) = exercise group (stretching, strengthening, pendulum exercises 20 reps)+modalities, Group 3 (*n* = 17) = modalities. Single session.	Pain visual analogue scale, Lateral Scapular Slide Test, ROM and Simple Shoulder Test. Assessment: Baseline, post-session.	Groups appear different at baseline. No between-group differences at post-intervention.
Celik & Mutlu 2015 (28) Turkey *n* = 30	To assess the effectiveness of joint mobilization combined with stretching exercises	2 groups: Joint mobilization (*n* = 15) (4 directions – progressing from Gr I/II to III and IV) and stretching (total of 20 min of cyclic stretching – 20 s and 10 s rest applied 10 times; flexion, scapular plane abduction, internal & external rotation) vs stretching exercises alone (*n* = 15). Both groups performed home exercise programme (stretches, strengthening). Duration: 6 weeks (18 sessions).	Primary outcomes: Disabilities of the Arm, Shoulder and Hand score, Constant score. Secondary outcomes: pain (visual analogue scale), range of motion. Assessments: baseline, post-treatment (6 weeks), 1 year.	SD increases in abduction (91.9° [CI: 86.1–96.7] to 172.8° [CI: 169.7–175.5]), external rotation (28.1° [CI:22.2–34.2] to 77.7° [CI: 70.3–83.0]) and Constant score (39.1 [CI: 35.3–42.6] to 80.5 [75.3–86.6]) at 1-year follow-up in favour of the joint mobilization combined with stretching exercise group. Effect sizes: flexion 0.16; abduction 0.44; external rotation 0.29; internal rotation 0.13; VAS 0.13; Constant 0.35; DASH 0.03.
Do Moon et al. 2015 (66) South Korea *n* = 20	To compare Maitland mobilization and Kaltenborn mobilization techniques for improving pain and range of motion	Maitland group (*n* = 10): Grade III anteroposterior oscillation. Kaltenborn group (*n* = 10): Grade III posterior translation. 12 therapy sessions 3 times per week for 4 weeks	Pain (visual analogue scale), range of motion: external and internal rotation (in degrees) pre- and post-intervention in both groups. Assessments: Baseline, 4 weeks.	No significant between-group differences. Significant within-groups differences for pain and rotation. Pre- and post-pain (VAS): Kaltenborn: pre-VAS- 5.58 ± 0.8, post- 2.65 ± 0.67 (*p* < 0.05). Maitland pre-VAS 6.05 ± 1.12, post 3.12 ± 0.98 (*p* < 0.05). Internal rotation: Kaltenborn pre- 31.98 ± 6.17, post 37.32 ± 7.76 (*p* < 0.05). Maitland pre-31.74 ± 6.77, post 36.84 ± 6.90 (*p* < 0.05). External rotation: Kaltenborn: pre- 38.8 ± 5.75, post 49.64 ± 5.17 (*p* < 0.05). Maitland pre-40.85 ± 7.51, post 49.76 ± 8.64 (*p* < 0.05).

Table I. *Cont.*

Study Country Number of participants	Aim	Intervention	Main outcome measures	Summarized main results
Doner et al. 2013 (67) Turkey *n* = 40	To compare Mulligan techniques for relieving pain and improving functional capacity of the shoulder with conventional passive stretching exercises in the stiffness phase	Two groups. All had home exercise programme. Group 1 (*n* = 20) = hot pack, transcutaneous electrical nerve stimulation (TENS) 20 min 100-Hz pulse duration 0.05–0.07 ms, passive stretching exercises: flexion, abduction (scapular plane), internal and external rotation 30 s each with 15 s rest). Group 2 (*n* = 20) = hot pack, TENS (transcutaneous electrical nerve stimulation) and Mulligan techniques (flexion, elevation and internal rotation – 3 sets of 10 repetitions with 30-s rest between sets). Duration: 5 days per week for 3 weeks.	Pain (visual analogue scale), goniometric, Range of motion (ROM) (active and passive) Constant score, Shoulder Disability Questionnaire, patient and physiotherapist satisfaction. Assessments: B/L, post-treatment, 3 months.	Group 2 had significantly less pain at rest (*p* = 0.018) and during activity (*p* = 0.003) at 3 months than Group 1. Group 2 also had significantly more ROM at 3 months: active flexion, internal rotation and abduction *p* = 0.001, external rotation (*p* = 0.041). Constant scores were greater in group 2 than 1 at 3 months (*p* = 0.001).
Elhafez & Elhafez 2016 (68) Egypt *n* = 59	To compare axillary ultrasound, laser, and post-isometric facilitation technique with standard care in the management of frozen shoulder	3 groups. Standard care Group (A) (*n* = 20): "traditional" physical therapy: pulsed ultrasound, scanning laser, supervised exercise program, and home exercise program. Group B (*n* = 19) received the same except that ultrasound and scanning laser were applied to the axillary region of the painful shoulder. Group C (*n* = 20): same as B plus isometric contraction (10 progressing to 20 s) followed by stretching (20 s). Each isometric and stretching session lasted 9–13 min. Duration = 12 sessions (3× week for 4 weeks)	Pain (visual pain scale), range of pain-free movement – flexion, abduction, external rotation. Assessments pre- and post-treatment and 4 weeks post-treatment.	Mixed-design MANOVA indicated significant treatment, time, and treatment × time interaction effect (F8.071, *p* = 000). Between-groups analysis: pain-free shoulder flexion, abduction, external rotation, and pain levels improved significantly in group C compared with A and B post-treatment and at 4 weeks follow-up (*p* < 0.05). Improvements reported in group B is more than in group A, and C is more than in groups A and B. At 4 weeks: Flexion (A = 106.13°, B = 112.8°, C = 118.33°) Abduction (A = 71.73°, B = 72.66°, C = 110. 66°) External rotation (A = 25.26°, B = 34.93°, C = 50.6°)
Ghosh et al. 2012 (69) India *n* = 72	To compare manipulation under anaesthesia, peri-articular injection and physiotherapy treatments	Three groups. All provided with home exercise programme. 1 (*n* = 24) = manipulation under anaesthesia (flexion, extension, abduction, adduction, internal and external rotation). 2 (*n* = 24) = intra-articular injection (methylprednisolone 40 mg, a mean of 3 doses with 3 weeks intervals). 3 (*n* = 24) = active and passive mobilization exercises, shoulder wheel and pulley exercises, ultrasound.	Pain, tenderness, muscular atrophy, range of movement, all combined and graded together after clinical examination as good, fair or poor. Minimum follow up = 6 months post-treatment.	Pain (A = 4.86, B = 4.1, C = 2.56°) Group 1 = 79.2% good and 20.8% fair. Group 2 = 82.6% fair, 17.4% good. Group 3 66.6% good, 12.5% fair and 20.8% poor.
Gutiérrez Espinoza et al. 2015 (30) Chile *n* = 57	To compare short-term efficacy of a glenohumeral posterior mobilization vs modalities for improving external rotation ROM.	Group 1 (*n* = 29) = glenohumeral posterior mobilisation techniques (Kaltenborn: axial distraction type III followed by posterior glide 1 min ×15 with 1-min rest periods) after 15 min training with a cycle ergometer. Group 2 (*n* = 28) = ultrasound (1 MHz, 1.5 W/cm², 10 min, continuous), exercises. Duration: 10 sessions, 2–3 times per week.	Primary outcome: range of passive movement in external rotation. Secondary: flexion and abduction, pain (VAS), Constant-Murley Score. Assessments: Session 1, 10.	Group 1 showed a significant improvement in external rotation with a mean difference of 46.3 degrees (SD = 8.7) compared with 18.1 (SD = 7.2) in Group 2 (*p* < 0.0001). Group 1 improved ROM compared with Group 2. VAS pain decreased (*p* = 0.0002) of 2.7 cms in the Group 1 compared with 1.4 cms in Group 2; and improved function in favour of Group 1 (*p* < 0.0001). Constant-Murley score increased by 38.9 points in Group 1 compared with 18.1 in Group 2 (*p* < 0.0001).
Ibrahim et al. 2014 (31) USA *n* = 60	To compare a static progressive stretch device plus hot pack, home exercise programme (HEP) and manual therapy with hot pack, HEP and manual therapy alone.	Two groups. Both groups received 3 treatment sessions (heat pack, mobilizations) per week, for 4 weeks. All asked to do pulley, wand and pendulum exercises at home 10 reps each 3 times per day. Group 1 (*n* = 30) Group 2 (*n* = 30) = static progressive stretch device 30 min per day week 1, 2 × 30 min per day weeks 2–3 and 3 times per day in week 4.	Primary outcome: Active and passive abduction, passive external rotation. Secondary: function (DASH), pain (visual analogue scale) Assessments: Baseline, 4, 12, 24, 52 weeks.	Significant (*p* < 0.05) differences between the groups, favouring Group 2, for all outcomes at all time-points. At 12 months: VAS difference −2.0 (95% CI −2.9 to −1.2), DASH −53.8 difference (95% CI −64.7 to −42.9), 47.9° for shoulder passive external rotation (95% CI 43.5–52.3), 44.9° for shoulder passive abduction (95% CI 36.0–53.8), and 94.3° for shoulder active abduction (95% CI 87.0–101.7).

Table I. *Cont.*

Study Country Number of participants	Aim	Intervention	Main outcome measures	Summarized main results
Ji et al. 2015 (70) China *n* = 132	To compare sharp-hook acupuncture plus acupoint analgesic injections vs acupoint analgesic injections alone	2 groups. Group 1 (*n* = 66): Sharp-hook acupuncture using Feng Gou Zhen device at 5 acupoints (A-Shi point, Jianyu (LI15), Jianliao (SJ14), Jianzhen (SI9)), and Jianqian (Ex-UE) plus acupint injection (= 1 ml mixture of 2% lidocaine+0.5 mg B$_{12}$+0.9%wv NaCl) at each point. Group 2 (*n* = 66) = acupint injection. Duration: single session.	Primary outcome: Pain (visual analogue scale). Secondary: function (physical examination score) and pain (McGill questionnaire). Assessments: Baseline, 1 and 4 weeks.	Significant differences, favouring Group 1, for all outcomes at 4 weeks (*p* < .0.001): Group 1 VAS = 1.15+0.3, Group 2 = 6.05+1.31. Group 1 McGill = 3.32+1.18, Group 2 = 25.48+3.92. Group 1 shoulder function score = 208.65+12.95, Group 2 = 116.52+9.86.
Joo et al. 2013 (71) South Korea *n* = 28	To compare the effects of intra-articular botulinum toxin Type A with triamcinolone acetate	Two groups. Group 1 (*n* = 15) = single intra-articular BoNT-A (Dysport; 200 IU) injection. Group 2 (*n* = 13) = intra-articular (triamcinolone acetate 20 mg 1 ml and 1 ml of 0.9% NaCl) injection. Injections under fluoroscopic guidance.	Pain (numerical rating scale), active flexion and abduction range of motion and passive flexion, abduction, internal and external rotation. Assessments: Baseline, 30 min after injection and at 2, 4, 8 weeks.	Group 1 greater active abduction than Group 2 (22° vs 69°) *p* < 0.05. Greater passive abduction in Group 1 than Group 2 (22° v 79°) (all *p* < 0.05). No other significant differences between groups. No severe adverse events.
Kim et al. 2015 (47) South Korea *n* = 92	To compare the effectiveness of a 2-staged and conventional GH injection and exercise	Two groups. All received home exercise programme 2 weeks post-injection (for 3 months). Group 1 (*n* = 46) = 2 ml of 1% lidocaine injection into the subacromial space by sonographic imaging guidance. Participants were then asked to simulate the pain-evoking position and report % pain reduction. If pain reduction >than 50%, then a second injection of triamcinolone acetonide (TA) 1 ml 40 mg mixed with 4 ml of 1% lidocaine) was applied (same site). If pain reduction <50%, the same amount of steroid was injected at the GH joint. Group 2 (*n* = 46) received GHJ steroid injection, no lidocaine.	Pain (ordinal scale 0 = not improved, 2 = much improved). Passive range of motion (flexion, abduction, internal and external rotation). Assessments: Baseline, 2, 12 weeks.	Subjective differences were reported between the groups. There were no significant differences between groups.
Kwak et al. 2016 (72) South Korea *n* = 121	To develop a clinical protocol for the treatment of frozen shoulder using applied hydraulic distension plus manual therapy	Two groups, all received home exercise programme. Group 1 (*n* = 60) = hydraulic distension plus manual therapy (Kaltenborn-Evjenth approach, 30 min 3 times a day for 4 weeks). Group 2 (*n* = 61) = hydraulic distension alone.	Pain and satisfaction (VAS – Visual Analogue Scale – and active range of motion of the shoulder (flexion, internal and external rotation). Assessments: pre-treatment, 2, 6, 12, 24 weeks and 1 year.	No significant differences in VAS observed between groups at final follow-up. Pain decreased more rapidly in Group 1 – between-group difference maintained until 12 weeks (*p* < 0.05). Satisfaction increased more rapidly in Group 1 – between-group difference maintained until 6 weeks (*p* < 0.05). Flexion, external and internal rotation increased more rapidly in Group 1 – between-group difference maintained until 6 weeks (*p* < 0.05).
Lee et al. 2016 (73) South Korea *n* = 64	To compare whether capsule-preserved hydrodilatation with corticosteroid improves pain and function better than intra articular CS injection (IACS) alone	Two groups. Group 1 (*n* = 32) = ultrasound-guided IACS alone with 1 ml of 40 mg/ml triamcinolone acetonide and 3 ml of 1% lidocaine. Group 2 (*n* = 32) = ultrasound-guided capsule-preserved hydrodilatation with corticosteroid with a mixture of 1 ml of 40 mg/ml triamcinolone acetonide, 6 ml of 1% lidocaine, and normal saline.	Primary outcome: Shoulder Pain and Disability Index score. Secondary outcomes: pain VAS (visual analogue scale) and passive range of motion (flexion, abduction, extension, external and internal rotation. Assessments: pre-treatment and 3, 6, and 12 weeks.	No significant differences between groups. Rupture occurred in 2 (6.25%) of Group 2. No serious complications.

Table I. *Cont.*

Study Country Number of participants	Aim	Intervention	Main outcome measures	Summarized main results
Lee et al. 2015 (74) South Korea *n* = 81	To compare hypertonic (3% NaCl) saline with normal saline (0.9% NaCl) in capsule-preserved hydrodilatation.	Two groups. Group 1 (*n* = 40) = ultrasound-guided hydrodilatation with hypertonic saline (3% NaCl) and 4 ml lidocaine (1%) and 1 ml triamcinolone (10 mg). Group 2 (*n* = 41) = ultrasound-guided hydrodilatation with hypertonic saline (0.9% NaCl) and 4 ml of lidocaine (1%) and 1 ml triamcinolone (10 mg). The injection was stopped at the point at which US showed no further capsule distension.	Passive range of motion (flexion, abduction, extension, external and internal rotation. Shoulder Pain and Disability Index score. Assessments: Baseline, 2 weeks.	Mean injection volume was 20.2+5.2 ml for Group 1, 19.5+5.9 ml for Group 2. Group 1 showed greater improvement (27.8+21.4) than Group 2 (13.3+18) for flexion (*p* = 0.005), and abduction (Group 1: 30.5+24.0, Group 2: 17.3+25.7 *p* = 0.039) and internal rotation (Group 1: 20.9+19.8, Group 2: 11.7+14.6 *p* = 0.038), and external rotation (Group 1: 17.3+14.1, Group 2: 8.6+10.7 *p* = 0.04). SPADI: Group 1 greater improvement than Group 2 (Group 1: 29.6+19.3, Group 2 14.7+15.9 *p* = 0.001).
Lorbach et al. 2010 (75) Germany *n* = 40	To compare oral and intra-articular injections of cortisone	Two groups. Group 1 (*n* = 20) = 3 fluoroscopically controlled intra-articular injections. Injection consisted of 5 ml of bupivacaine (0.5%), 5 ml mepivacaine (0.5%), and 40 mg triamcinolone at beginning, 4 and 8 weeks. Group 2 (*n* = 20) = oral application of prednisolone beginning with 40 mg daily and decreasing the dose to 5 mg (at 20 days for a further 5 days) together with 40 mg pantoprazole.	Constant-Murley (CM) score, the Simple Shoulder Test (SST) and VAS for pain, function, and satisfaction. ROM: passive external and internal rotation, flexion. Assessments: Baseline, 4, 8, 12, 26, 52 weeks.	Superior results in CM score for Group 1 than 2 at all timepoints at 12 months Group 1: 62.7+16, Group 2: 45.6+ 8 (*p* = 0.001). SST scores at 8 weeks were superior for Group 1 (Group 1: 5.9+3.4, Group 2: 2.9+2.8, *p* = 0.006) and 12 weeks (Group 1:6.3+3.8, Group2: 3.6+3.3, *p* = 0.037) timepoints only. VAS scores for pain and function showed no significant differences at all follow-ups. Satisfaction VAS: significant difference at 8 (Group 1 7.3+2.6, Group 2: 5.3+2.7, *p* = 0.035),12 (Group1:7+2.7, Group 2: 5+2.3 *p* = 0.026) and 52 weeks (Group1: 7.9+2.6, Group 2: 4.7+1.6 *p* = 0.003).
Ma et al. 2013 (27) South Korea *n* = 30	To compare modalities and joint mobilization vs whole-body cryotherapy (WBC) combined with modalities and joint mobilization	Two groups. All had modalities: hot pack (15 min), ultrasound (5 min 1 MHz, 1.5 W/cm² continuous) Interferential (15 min, 25 mA), Gr III and IV mobilizations and stretches (10 min). Duration 3 times week for 4 weeks. Group 1 (*n* = 15) = 2 sessions of WBC (of 6 4-min exposures, 2 temperatures (–50º and –110º C) 3 times a week for 4 weeks (no less than 24 treatments in total). Group 2 (*n* = 15) = modalities and joint mobilisation (no less than 12 treatments).	Visual analoge scale (VAS), active range of motion- flexion, abduction, internal and external rotation, the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES). Assessment: Baseline, post-intervention (4 weeks).	Interaction terms between the pre-intervention and experimental groups were not significant in full factorial models. Main effect models found Group 1 improved more than Group 2. VAS ($F_{1,27}$ = 57.86, *p* < .01), flexion ($F_{1,27}$ = 44.08, *p* < .01), abduction ($F_{1,27}$ = 55.94, *p* < .01), internal rotation ($F_{1,27}$ = 51.62, *p* < .01), and external rotation ($F_{1,27}$ = 33.1, *p* < .01), ASES scores ($F_{1,27}$ = 83.88, *p* < .01). At 4 weeks flexion (Group 1: 162º+5.3, Group 2: 149º+5.9 degrees, *p* = < 0.01), Abduction (Group 1: 158º+5.3, Group 2:145º+5.4 *p* = < 0.01), internal rotation (Group 1: 53º+2.7, Group 2: 44º+3.3 *p* = < 0.01), external rotation (Group 1: 80º+2.6, Group 2: 75º+2.3 *p* = < 0.01), VAS (Group 1: 2.5+0.5, Group 2: 3.7+0.6 *p* = < 0.01), ASES (Group 1: 24+1.4, Group 2: 20+1.2 *p* = < 0.01)

Table I. *Cont.*

Study Country Number of participants	Aim	Intervention	Main outcome measures	Summarized main results
Ohta et al. 2014 (76) Japan $n = 70$	To compare the efficacy of celecoxib and loxoprofen	Two groups. Group 1 ($n = 37$) = celecoxib was administered at a dose level of one 100 mg tablet/dose twice daily. Group 2 ($n = 33$) = loxoprofen was administered at a dose level of one 60 mg tablet/dose 3 times daily. The dosing period was 1–2 weeks.	Pain (Visual analogue score 0–5), M and Japan Society Shoulder Sports Score. Assessment: Baseline, post-treatment (1–2 weeks).	Celecoxib is comparable to loxoprofen in terms of analgesic efficacy. No between-group differences. Reduction in nocturnal pain was greater in the celecoxib group ($p = 0.03$). $n = 2$ in the celecoxib Group and $n = 6$ patients in the loxoprofen Group developed adverse events. Test drug treatment was discontinued due to adverse events in 1 patient in the celecoxib Group and 3 in the loxoprofen Group.
Park et al. 2012 (77) South Korea $n = 48$	To compare the short-term effects and advantages of sono-guided capsular distension with fluoroscopically guided capsular distension	Two groups. Group 1 ($n = 23$) = sono-guided capsular distension, posterolateral approach 9 ml lidocaine (0.5%)+10 ml contrast dye+triamcinolone (20 mg). One injection every 2 weeks for 6 weeks. Group 2 ($n = 25$) = fluoroscopically guided capsular distension (same medications). Participant in prone position. Both groups given self-directed exercise.	Visual numeric scale (VNS), Shoulder Pain and Disability Index (SPADI), active and passive range of motion (ROM) (flexion, abduction, external rotation) Incremental cost-effective ratio (ICER), satisfaction, complications, effectiveness, preference, and procedure duration. Assessments: Baseline, 2, 6 weeks.	No between-group differences in changes of VNS, SPADI, ROM, and effectiveness. Patients preferred ($p = 0.005$) sono-guided to fluoroscopically guided capsular distension due to difference in radiation hazards and positional convenience. Procedure time shorter for sono-guided (119.04±12.17 s) than fluoroscopically guided capsular distension (294.08±24.30 s) ($p < 0.05$). Costs: to acquire the treatment effect of VNS 0.44 units with sono-guided, the cost was an additional 98,926 Korean won, compared with the fluoroscopic-assisted method.
Park et al. 2013 (78) South Korea $n = 100$	To compare the efficacy of ultrasound-guided intra-articular hyaluronic acid injection with capsular distension with steroid injection alone	Two groups. All received 3 US guided IA injections every 2 weeks (a total of 3 injections), posterior approach. Both received an exercise programme of pendulum exercise and isometric scapular setting. Group 1 ($n = 50$) = 0.5% lidocaine (4 ml) plus triamcinolone (40 mg/ml; 1 ml). Group 2 ($n = 50$) = 0.5% lidocaine (18 ml) for capsular distension with high molecular weight sodium hyaluronate (10 mg/ml; 2 ml).	The Shoulder Pain and Disability Index (SPADI), Verbal Numeric Scale (VNS), and passive range of motion of the shoulder (flexion, abduction, external rotation). Assessments: Baseline, 2, 6, weeks after last injections (i.e. 12 weeks after B/L).	No between-group differences for SPADI, VNS, flexion, abduction. External rotation improved more in Group 2 than 1 at 2 (Group 1: 42.9°+7.6, Group 2: 50° ±8.7 $p < 0.05$) and 6 weeks (Group 1: 44.5° ±7.7, Group 2: 56° ±8, $p < 0.05$). $n = 2$ Group1 and $n = 1$ Group 2 experienced pain because of needle contact to the labrum, and $n = 12$ Group 2 reported pain during capsular distension. No severe complications.
Park et al. 2014 (79) South Korea $n = 53$	To compare the synergistic effect of intensive mobilization techniques combined with capsular distension.	Four groups. Group 1 ($n = 16$) = intensive mobilization after one steroid injection with capsular distension (IMSID). Group 2 ($n = 14$) = intensive mobilization (IM). Group 3 ($n = 12$) = one steroid injection with capsular distension (SID). Group 4 ($n = 11$) = modalities (hot pack, transcutaneous electrical nerve stimulation (TENs), Ultrasound). IMSID, IM, and SID groups also received modalities for 20 min. Treatments 2× week for 4 weeks. All given home exercise programme.	Shoulder Pain and Disability Index (SPADI), Constant-Murley Shoulder Function Assessment Score (CS), Hand behind body (HBB), Active range of motion (AROM), and Verbal Numeric Score (VNS). Assessments: pre and post-treatment (4 weeks).	Post hoc Mann-Whitney U test revealed no significant differences between the IMSID and IM groups or between the SID and GroupT Groups. There were significant differences in all values between the IMSID and SID Groups; significant differences in VNS, HBB, SPADI, and CS between the IMSID and GroupT Groups ($p < 0.01$), significant differences in all values between the MI and SID Groups, except SPADI and significant differences in VNS, HBB, and CS between the MI and GroupT Groups ($p < 0.01$).
Schydlowsky et al. 2012 (80) Denmark $n = 18$	To compare the effect of subcutaneous adalimumab injections with intraarticular glucocorticoid injections on pain and ROM.	Two groups. Group 1: ($n = 10$) = 1 ml adalimumab by subcutaneous injection. Group 2: ($n = 8$) = 4 ml of lidocaine 1 % and 40 mg methylprednisolone acetate in the affected glenohumeral joint under ultrasonographic guidance. Treatment repeated once every second week for a maximum of 3 treatments.	Constant score, Shoulder Rating Questionnaire, Shoulder Pain and Disability Index (SPADI) Active and passive range of motion. Assessments: Baseline, 1, 3, 6 months.	Trial halted early: $n = 4/10$ from Group 1 withdrew or were excluded from the study, either because of lack of effect; or because of side effects. No patients withdrew from Group 2. Apart from baseline differences (Group 1 lower values for flexion) there were no other between-group differences. There were within-group improvements for all outcomes in Group 2.

Table I. *Cont.*

Study Country Number of participants	Aim	Intervention	Main outcome measures	Summarized main results
Shin et al. 2013 (81) South Korea *n* = 191	To compare the clinical outcomes after treatment by a single corticosteroid injection in different locations of the shoulder.	Four groups. Group 1–3 received a corticosteroid injection composed of 4 ml of 2% lidocaine and 40 mg of triamcinolone (1 ml). All injections ultrasound guided and delivered by posterior approach. All participants received a weekly rehabilitation programme delivered by a physiotherapist for 1 month followed by a HEP. Passive pendulum and self-assisted movements with a bar from 7 days after treatment. Active-assisted ROM exercises began at 6 weeks and resisted shoulder exercises were started at 3 months. Exercises guided by level of pain. Group 1: (*n* = 49) = subacromial space injection. Group 2: (*n* = 48) = intra-articular Injection. Group 3: (*n* = 47) = intra-articular combined with subacromial space. In Group 3, the injection dose was equally divided between the glenohumeral joint and subacromial bursa. Group 4: (*n* = 49) = oral aceclofenac NSAID (100 mg) twice daily for 6 weeks.	American Shoulder and Elbow Surgeons Score. Visual analogue scale (pain integrity) integrity- and patient satisfaction). Active shoulder range of motion (ROM), pain (flexion, internal and external rotation). Assessments: Baseline, 2, 4, 8, 16, and 24 weeks after treatment.	Those treated with corticosteroids achieved faster pain relief and had greater satisfaction levels than those in Group 4 during the 16 weeks after treatment. No significant between-group differences in pain scores (*p* = 0.670). ROM and functional outcomes (flexion *p* = 0.117, function *p* = 0.651) was observed among the 4 groups at 24-week follow-up visits (*p* = 0.670).
Tanaka et al. 2010 (82) Japan *n* = 120	To assess outcomes based on the frequency of treatment for frozen shoulder.	Three groups. Group 1: (*n* = 40) = high-frequency (HF) group (treatment> 2 times a week). Group 2: (*n* = 40) = moderate-frequency (MF) group (treatment = once a week). Group 3: (*n* = 40) = low-frequency (LF) group (treatment < once a week). All groups received the same standardized intervention (40 min) including joint mobilization (as per Vermeulen et al. (ref)) plus home exercise programme (pendulum exercises, passive stretching such as "climbing the wall exercise") 2–3× per day. Mean duration: 4.6+1.2 months.	The point in time at which range of motion (ROM) improvement plateaued for more than 1 month was defined as "the ROM plateau point." The functional outcome was investigated in terms of improved angle (IA) of the shoulder joint. The time required to reach the ROM plateau point (T). IA and T were compared in terms of: (1) age, (2) gender, (3) handedness, (4) duration before rehabilitative intervention, (5) frequency of sessions (6) self-exercise compliance (Questionnaire). Assessments: Mean follow up time+ 5.9+1.3 months.	No significant differences in IA between male and female. IA of the dominant-handed group was significantly higher than that of the non-dominant handed group (95%CI 7.3–25.6, *p* = 0.010). No significant differences in T between groups. IA of the group that had experienced more than 7 months of the condition was significantly low (95% CI 17.2–54.3, *p* = 0.018) however linear regression did not indicate a relationship of duration with IA or T. Frequency of mobilisations showed no relationship with IA or T. IA was significantly higher and T was significantly shorter in the group that performed self-exercise every day than in those who performed less.
Vahdatpour et al. 2014 (83) Iran *n* = 40	To compare the effect of extracorporeal shockwave therapy (ESWT) in the treatment vs sham shockwave therapy.	Two groups. Prior to ESWT or sham shockwave, all received intra-articular injection of 40 mg triamcinolone. All received activity modification, meloxicam 15 mg daily, and home exercise programme (pendulum, stretching, wall walking 2× daily). Group 1: (*n* = 19) = ESWT 1× week for 4 weeks from anterior and posterior directions (mean 1,200 shocks between 0.1 and 0.3 mJ/mm²) up to the maximum threshold of pain tolerance. Group 2: (*n* = 17) = sham shockwave therapy 1× week for 4 weeks; device was turned off and placed on the patient's shoulder for the same period of time.	Shoulder Pain and Disability Index (SPADI), range of motion. Assessments: Baseline, post-intervention, 2, 5 months after intervention.	Variance analysis at 5 months after intervention showed greater improvement in Group 1: SPADI pain Group 1: 16.2±6.7, Group 2: 39.5± 10.4 *p* < 0.001), SPADI disability Group 1: 19.2±15.8, Group 2: 40.9±8.7 *p* = 0.002), ROM: flexion (Group 1: 111.1±19.4, Group 2: 77.4+8.7 *p* = 0.001), abduction (Group 1: 96.1±20.3, Group 2: 59.5±12.8 *p* < 0.001), Control group had greater extension (Group 1: 37.6±13.1, Group 2: 46.8±9.5 *p* = 0.006) and external rotation (Group 1: 32.6±11.8, Group 2: 36.5±10.4 *p* = 0.004) at 5 months after intervention. No significant difference in internal rotation between groups.

Table I. *Cont.*

Study Country Number of participants	Aim	Intervention	Main outcome measures	Summarized main results
Wu et al. 2014 (84) Taiwan *n* = 60	To compare the effect of physical therapy alone with physical therapy and pulsed radiofrequency (PRF) lesioning of the suprascapular nerve (SSN) using an ultrasound guided (UG) technique.	Two groups. Both groups received multimodal treatment that included: hot pack applications and TENS (transcutaneous electrical nerve stimulation), and stretching exercise, mobilisations and therapeutic exercises (30 min, 3× week for 12 weeks). Group 1: (*n* = 30) = multimodal treatment. Group 2: (*n* = 30) = multimodal and 1 dose of PRF lesioning of the SSN. PRF lesioning was performed for 180 s (2 Hz, 30-ms pulse width, 42°C).	Pain (visual analogue scale), Shoulder Pain and Disability (SPADI), Passive range of motion. Assessments: Baseline, 1, 4, 8 and 12 weeks.	Pain relief: Group 2 had a shorter time to onset of significant pain relief (6.1 ± 3.4 vs 28.1 ± 9.2 days; *p* < 0.001) and reduction of VAS score at week 1 (40% vs 4.7%) than the Group 1 (*p* < 0.001). Comparison of the 2 groups indicated significant improvement in the Group 2 throughout with respect to the VAS and SPADI scores, and for the most gain in PROM (passive flexion: weeks 8 and 12; passive extension in week 12, medial rotation in weeks 4, 8, and 12; all *p* < 0.05).No serious adverse effects or complications in either group.
Yang et al. 2012 (85) Taiwan *n* = 34	To compare the effectiveness of end-range mobilisation/scapular mobilisation treatment approach (EMSMTA) vs control.	3 groups: Group 1: (*n* = 11) assigned to control. N = 23 who met the criteria were randomly assigned to: Group 2: (*n* = 12) criteria-control (*n* = 12) who received a standardized physical therapy program, or to Group 3: (*n* = 11) criteria intervention, the EMSMTA group. Control and criteria control groups had standardized treatment (2× week for 3 months) of passive mid-range mobilization, flexion and abduction stretching techniques, physical modalities (ultrasound, shortwave diathermy, and/or electrotherapy), and active exercises. Participants advised to use the affected shoulder in daily activities whenever possible. No home exercise programme. The EMSMTA Group received mobilisations (Maitland 1991, Vermeulen 2000) 2× week for 8 weeks) end-range mobilization (10–15 reps Grade IV anterior-posterior) and scapular mobilizations (10 sets of 10 reps with 30 s rest between sets).	Range of motion: Passive internal and external rotation and abduction. Hand behind back reach (HBBR). Disability: (FLEX-SF questionnaire). Shoulder complex kinematics (FASTRAK motion analysis). Assessments: Baseline, 4, 8 weeks (not 12 weeks).	Baseline differences (scapular posterior tipping, humeral external rotation and hand behind back reach). 8 weeks: humeral external rotation and HBBR improved in control Group compared with the criteria-control Group (26.4°, 95% CI 10.2, 42.9 and 0.36, 95% CI 0.19, 0.51, *p* = 0.002, *p* < 0.0005). 8 weeks: humeral external rotation and the HBBR improved in the criteria-intervention Group compared with the criteria-control Group (23.4°, 95% CI 18.2, 37.3 and 0.33, 95% CI 0.17, 0.44, *p* = 0.002, < 0.0005). Humeral external rotation and HBBR means not different between the criteria-intervention and control Groups (*p* > 0.05). 8 weeks: FLEX-SF improved in the control Group compared with criteria-control Group (4.9 scores, 95% CI 1.2, 11.2, *p* = 0.03). 8 weeks: FLEX-SF improved in the criteria-intervention Group compared with the criteria-control Group (7.4 scores, 95% CI = 2.6, 12.5, *p* = 0.005). No differences between criteria-intervention Group and control. At 4 and 8 weeks, scapular upward rotation/tipping and the scapulohumeral rhythm improved in the control compared with the criteria-control group. 8 weeks: scapular tipping and the scapulohumeral rhythm improved in the criteria-intervention Group compared with criteria-control (5° tipping, 95% CI 0.1, 10.2 and rhythm ratio = 0.32, 95% CI 0.13, 0.52, *p* = 0.004 and 0.002). No difference between the criteria-intervention and control group.
Yoon et al. 2013 (32) South Korea *n* = 53	To compare intra-articular high dose, low dose and Single injection. 3 groups placebo corticosteroid injections.	Group 1: (*n* = 20) = 4 ml of 10 mg/ml triamcinolone acetonide and 1 ml of 1% lidocaine (high-dose group). Group 2: (*n* = 20) = 2 ml of 10 mg/ml triamcinolone acetonide and 3 ml of 1% lidocaine (low-dose group). Group 3: (*n* = 13) = 5 ml of 1% lidocaine (placebo group). All instructed to carry out HEP (ROM, stretches) for 10 min 3× day.	Shoulder Pain and Disability Index (SPADI), visual analogue scale (VAS) for mean shoulder pain level, and passive range of motion for: flexion, abduction, extension, external and internal rotation. Assessments: B/L 1, 3, 6, 12 weeks after treatment.	No significant difference between the 2 different corticosteroid dose groups (*post-hoc* tests showed improvement in SPADI and VAS scores and in flexion, abduction, and internal rotation for the low- and high-dose groups compared with the placebo).

Ca2+: calcium; ml: millilitres; ml: millilitre; mg: milligram; HF: high-frequency; LF: low-frequency; MF: moderate-frequency; IA: improved angle; ROM: range of movement; T: plateau point; SPADI: Shoulder Pain and Disability Index; ESWT: Extracorporeal Shock Wave Therapy; PRF: pulsed radiofrequency; SSN: suprascapular nerve; UG: ultrasound guided; s: seconds; ms: milliseconds; EMSMTA: effectiveness of end-range mobilisation/ scapular mobilisation treatment approach; HBBR hand behind back reach;.

Table II. Risk of bias assessment for identified trials

Study, year publication, country	Domains							
	Sequence generation	Allocation concealment	Intervention integrity	Effective blinding a) participant b) providers c) objective outcomes	Incomplete outcome data	Selective Outcome reporting	Other sources of bias	Our evaluation of risk of bias
Ali & Khan 2015 (62) Pakistan	Unclear	Unclear	Adequate	a) Not possible b) Not possible c) Unclear	Partial	Adequate	IFU, GC,	High
Bae et al. 2014 (64) South Korea	Adequate	Unclear	Adequate	a) Not possible b) Not possible c) Unclear	Unclear	Unclear	IFU, UFSD, UIV, USS, GC,	High
Badalamente et al. 2016 (63) USA Studies 1&3	Study 1: Unclear Study 3: Unclear	Study 1: Unclear Study 3: Unclear	Adequate	Study 1.a) Unclear b) "investigators blinded" c) unclear Study 3.a) Not possible b) Not possible c) Adequate	Study 1: Study 3: Adequate	Unclear	FSD, OMC, UIV, USS, GC,	High
Balci et al. 2016 (65) Turkey	Partial	Unclear	Adequate	a) Not possible b) Not possible c) Unclear	Single session	Adequate	BLD, GC, IFU, OMC, USS	Moderate
Celik & Kaya Mutlu 2016 (28) Turkey	Adequate	Adequate	Adequate	a) Not possible b) Not possible c) Adequate	Partial	Unclear	GC,	Low
Do Moon et al. 2015 (66) South Korea	Unclear	Unclear	Unclear	a) Not possible b) Not possible c) Unclear	Adequate	Adequate	IFU, OMC, USS, GC,	High
Doner et al. 2013 (67) Turkey	Adequate	Unclear	Unclear	a) Not possible b) Not possible c) Unclear	Unclear	Adequate	GC, USS,	High
Elhafez & Elhafez 2016 (68) Egypt	Unclear	Unclear	Adequate	a) States blinded but unclear how this is possible? b) Not possible c) Adequate	Inadequate	Unclear	BLD, COI, IFU, USS, GC,	High
Ghosh et al. 2012 (69) India	Unclear	Unclear	Unclear	a) Not possible b) Not possible c) Unclear	Unclear	Unclear	FSD, UIV, USS, GC,	High
Gutierrez Espinoza et al. 2015 (30) Chile	Adequate	Adequate	Adequate	a) Not possible b) Not possible c) Adequate	Adequate	Adequate	IFU, GC,	Low
Ibrahim et al. 2014 (31) USA	Adequate	Unclear	Adequate	a) Not possible b) Partial c) Adequate	Adequate	Adequate	COI, USS, GC,	Low
Ji et al. 2015 (70) China	Adequate	Adequate	Partial	a) Not possible b) Not possible c) Unclear	Adequate	Unclear	COI, GC, IFU, USS,	Moderate
Joo et al. 2013 (71) Korea	Unclear	Unclear	Unclear	a) Adequate b) Unclear c) Unclear	Unclear	Adequate	IFU, OMC, USS, GC,	High
Kim et al. 2015 (47) South Korea	Unclear	Unclear	Adequate	a) Unclear b) Adequate where possible c) Unclear	Adequate	Unclear	GC, IFU, OMC, USS,	High
Kwak & Kim 2016 (72) South Korea	Unclear	Unclear	Unclear	a) Not possible b) Not possible c) Unclear	Unclear	Unclear	OMC, USS, GC,	High
Lee et al. 2016 (73) South Korea	Adequate	Unclear	Adequate	a) Unclear b) Not possible c) Adequate	Adequate	Unclear	IFU, GC,	Moderate
Lee et al. 2015 (74) South Korea	Adequate	Unclear	Adequate	a) Adequate b) Unclear c) Unclear	Partial: loss to follow up 21%	Unclear	IFU, USS, GC,	High
Lorbach et al. 2010 (75) Germany	Unclear	Unclear	Unclear	a) Not possible b) Not possible c) Unclear	Unclear	Unclear	OMC, USS, GC,	High
Ma et al. 2013 (27) Korea	Unclear	Adequate	Adequate	a) Not possible b) Not possible c) Adequate	Adequate	Adequate	GC, IFU, USS,	High
Ohta et al. 2014 (76) Japan	Inadequate	Unclear	Unclear	a) Unclear b) Unclear c) Unclear	Unclear	Adequate	IFU, OMC, USS, GC,	High

Table II. *Cont.*

Study, year publication, country	Sequence generation	Allocation concealment	Intervention integrity	Effective blinding a) participant b) providers c) objective outcomes	Incomplete outcome data	Selective Outcome reporting	Other sources of bias	Our evaluation of risk of bias
Park et al. 2013 (78) Korea	Adequate	Unclear	Adequate	a) Not possible b) Not possible c) Adequate	Unclear	Unclear	GC, IFU,	High
Park et al. 2014 (79) South Korea	Unclear	Unclear	Adequate	a) Not possible b) Not possible c) Unclear	Unclear	Adequate	IFU, USS, GC,	High
Schydlowsky et al. 2012 (80) Denmark	Unclear	Unclear	Inadequate	a) Not possible b) Not possible c) Inadequate	Inadequate	Adequate	BLD, GC,	High
Shin et al. 2013 (81) South Korea	Adequate	Adequate	Unclear	a) Not possible b) Not possible c) Adequate	Unclear	Unclear	GC	Moderate
Tanaka et al. 2010 (82) Japan	Unclear	Unclear	Adequate	a) Not possible b) Not possible c) Adequate	Unclear	Adequate	FSD, USS, UIV, GC,	High
Vahdatpour et al. 2014 (83) Iran	Unclear	Unclear	Adequate	a) Adequate b) Not possible c) Unclear	Inadequate	Adequate	GC, OMC, UIV, USS,	High
Wu et al. 2014 (84) Taiwan	Inadequate	Unclear	Inadequate	a) Mixed: not possible/ adequate b) Not possible c) Primary outcome: adequate, Secondary: unclear	Unclear	Unclear	OMC, GC, IFU, UIV, USS,	High
Yang et al. 2012 (85) Taiwan	Inadequate	Inadequate	Adequate	a) Not possible b) Not possible c) Adequate	Adequate	Unclear	GC, BLD,IFU	High
Yoon et al. 2013 (32) South Korea	Adequate	Adequate	Adequate	a) Adequate b) Adequate c) Adequate	Unclear	Adequate	GC, IFU,	Low

Key: adequate, low risk of bias; inadequate, high risk of bias; unclear, potential risk of bias uncertain; partial, high/unclear risk to some procedures or outcomes. BLD: concerns re: baseline differences (unclear/partial); COI: concerns re: conflict of interest (first author providing intervention/authors invented device); FSD: diagnosis of frozen shoulder unclear or diagnosed by symptoms with no imaging; GC: generalizability concerns (e.g. single-site/treatment provider, choice of inclusion/exclusion criteria); IFU: inadequate follow-up (pre-post-intervention or ≤12 weeks); USS: unjustified sample size (for example- not mentioned, no a priori calculation, insufficient detail); OMC: outcome measure concerns (unclear measures/no functional outcome included); UIV: unclear intervention (e.g. lack of detail/ varying durations/pre-trial treatment).

one week, twice a day for 2–3 weeks, and three 30 min sessions per day in week 4. Follow-up assessment occurred at 4, 12, 24 and 52 weeks and at all follow-up time-points the findings favoured the progressive static stretching and multi-modal group for the primary outcome measures of interest. For the primary outcome measures at 1 year there were significant improvements in the progressive static stretching and multi-modal therapy group, for passive external rotation (87° vs 39°), for passive abduction (178° vs 133°), and for active abduction (178° vs 84°). For the secondary outcome measures, the results also favoured the progressive static stretching group for DASH (at 12, 24 and 52 weeks) and for VAS (pain) at 24 and 52 weeks). At 52 weeks the DASH scores were 1.5 vs 55.3 and VAS (pain) were 1.1 vs 3.1 (0 = no pain and 10 = worst imaginable pain). The participants were taught how to use the device by the principal investigator, a potential source of bias, and data was collected at a single centre. Compliance data were collected, but not reported.

Comparison of different doses of intra-articular corticosteroid injections

In a population (*n* = 53) of people in the initial pain (freezing) stage of FS Yoon et al. (32) investigated whether a single intra-articular injection of high-dose (4 ml of 10 mg/ml triamcinolone acetonide and 1 ml of 1% lidocaine) (*n* = 20) improved pain and function in patients with FS more than a low dose (2 ml of 10 mg/ml triamcinolone acetonide and 3 ml of 1% lidocaine) (*n* = 20) or a placebo (5 ml of 1% lidocaine) (*n* = 13). Participants were described as having stage 2 of adhesive capsulitis (freezing stage according to Hannafin & Chiaia (16)) with at least one month of pain duration, and mean pain intensity during a day defined as a score of 3 points or more on a 10-cm visual analogue scale rated from 0 (no pain) to 10 (worst imaginable pain). The injections were performed in a hospital setting and under ultrasound guidance. After the procedures the participants were given a home programme that involved stretching, Codman exercises, wall-climbing

exercises, external and internal rotations using a bar and posterior shoulder stretching. The exercise programme was to be performed for 10-min, 3-times a day. No other treatments or medications were permitted. Follow-up assessments were performed at 1, 3, 6 and 12 weeks. All groups improved over time. There were significant improvements in favour of the high and low dose corticosteroid groups in comparison to the placebo group but no difference between the high and low dose corticosteroid groups, suggesting that in the short term (12 weeks) corticosteroid has a better effect on pain, range of movement (flexion, abduction, extension, internal and external rotation) and functional outcome (SPADI) than lidocaine alone (Table I). Other than facial flushing (3 in the high-dose group and one in the low-dose group) and dizziness (one in the low-dose and one in the lidocaine group), no serious complications (such as infections) were reported. The authors acknowledged that compliance with the home exercises were not checked and people with higher pain scores than reported in the study may have responded differently to the different doses. The findings suggest that in the short term a single ultrasound guided intra-articular injection of low-dose corticosteroid and a home exercise programme is preferable to high-dose corticosteroid or lidocaine in isolation.

DISCUSSION

This review has updated the existing 2012 review (21), evaluating the clinical effectiveness of non-surgical management interventions of primary FS in terms of pain, range of shoulder joint movement, self-reported function and disability, quality of life, recovery time, return to work and recreation, and adverse events.

Manual therapy

Maund et al. (21) concluded: "Based on a single study (33) (2-arm RCT, quality score 8/13, comparing twice weekly, 30-min sessions of high-grade (Maitland grades III and IV) in the stiff zone, to low-grade (Maitland grades I and II) in the pain-free zone, for a maximum of 12 weeks): "and for some outcomes only, high-grade mobilisation may be more effective than low-grade mobilisation in a population of patients who have already had physiotherapy and/or steroid injection" (21, xv).

The findings of the current review identified 3 new trials, deemed to be of low risk of bias that investigated the use of manual therapy as an intervention. Celik & Kaya Mutlu (28) compared joint mobilization and stretching or stretching alone. The reported improvements in symptoms and range of movement need to be interpreted with caution as they may not have achieved clinically important differences (34, 35).

The uncertainty surrounding clinically meaningful findings also exists for the findings of Gutiérrez Espinoza et al. (30). Whether the improvements reported for the passive ranges of shoulder flexion, abduction and external rotation are clinically important remain unclear. Whilst the improvements in pain and Constant score are encouraging; these findings need to be considered cautiously due to the lack of medium- and long-term follow-up data.

That the addition of a daily static stretching programme plus multi-modal treatment improved range of movement, DASH scores and pain when compared with the multi-modal treatment programme alone, requires further investigation and longer term follow-up. For many healthcare systems, including the National Health Service (NHS) in the UK, the number of treatment sessions and resources included in the intervention may prevent the treatment from becoming widely available.

Maund et al. (21) identified one study that compared high- with low-grade mobilization and reported that, for people who had received a previous corticosteroid injection, the addition of high-grade mobilization may be of benefit. No new study investigating the same parameters was identified in the current review. The 3 new studies deemed to be of low risk of bias in the current review tentatively support the use of manual therapy and stretching in the more stiff than painful stage of the condition (15, 28, 31). However, small sample sizes, uncertainty over clinically important differences, no differences for certain outcome measures, and potential cost vs benefit of the interventions challenges the certainty of any recommendations regarding manual therapy in the management of FS.

Injection therapy

Two of 6 studies that investigated the use of corticosteroid injections were considered of satisfactory quality in the earlier review (21). In these 2 studies identified concerns were; uncertainty regarding adequate allocation concealment in one study, adequate power in one study, and loss to follow-up, in both studies. In a 4-arm trial, Carette et al. (36) (quality score 9/13) reported best outcomes for a multi-modal treatment that included corticosteroid injections and physiotherapy. In this group, using the SF-36 Physical Component Summary (PCS), the mean score at baseline was 35.2 and the mean change from baseline at 6 weeks was 6.4, at 3 months 8.6, at 6 months 8.8 and at 12 months, 11.5. Also, in this group, the baseline score for the SF-36 Mental Component Score was 43.1, and the mean change at 6 weeks 5.7, at 3 months 6.6, at 6 months 9.2 and at 12 months 9.3. Ryans et al. (31) (quality score 8/13) reported that the mean daytime resting pain score in the group receiving corticosteroid and physiotherapy

was 31.2 (out of 100) and at 6 weeks was 14.9. In the injection-only group the score was 28.1; in the placebo injection and physiotherapy group, 28.2; and in the placebo injection-only group, 38.7.

Maund et al. (21) concluded that: "There may be short-term benefit from adding a single intra-articular steroid injection to home exercise for patients with primary FS of <6 months' duration. In the same population there may also be benefit from adding physiotherapy (including mobilization in 8–10 sessions over 4 weeks) to a single steroid injection" (p. xv)."

The current review identified one new trial deemed to be at low risk of bias investigating injection therapy for primary FS (32). Concerns included; short-term follow up, 3 groups, and small sample size. No difference between high- and low-dose corticosteroid groups was identified and both performed better than lidocaine only. Based on their findings, Yoon et al. recommended using low-dose corticosteroid (2 ml of 10 mg/ml triamcinolone acetonide and 3 ml of 1% lidocaine) and the home programme.

As such, the findings of the current review support and extend on those published by Maund et al. (21), and recommend the use of corticosteroid and a home exercise programme for people with a duration of FS symptoms less than 6 months.

Shortwave diathermy, passive mobilization and home exercise

Maund et al. (21) concluded: "Based on a single study (3-arm RCT (86) (quality score 7/13) comparing SWD and stretching, heat pack and stretching, and, a home exercise programme), and for some outcomes only, there may be benefit from adding SWD to passive mobilisation and home exercise" (p. xv).

The current review did not identify any new studies that investigated the effectiveness of SWD and, as such, we are not able to add additional information to that provided in the earlier review. In addition, the current review did not find any new research deemed to be at low risk of bias to further inform the use of electrotherapy modalities, acupuncture, taping or dry needling in the management of primary FS.

Time to return to work and recreation, and, adverse events

None of the 4 studies (28, 30–32) deemed to be at low risk of bias reported return to work and/or return to recreation times. Three studies (28, 30, 31) did not report data on the occurrence of any adverse or serious events. Yoon et al. (32) reported no serious complications, such as infections, but they did report 4 cases of facial flushing (3 in the high-dose CS group and one in the low-dose group). Two participants experienced

dizziness due to vasovagal reactions (one in the low-dose CS group and one in the lidocaine-only group).

Limitations

Whilst the search strategy was comprehensive, and was developed and performed by the team together with a healthcare librarian, it remains a possibility that other studies exist and have been missed from the review. As the flow diagram shows, the searches returned 7 studies that were not published in English, which could not be fully screened, and so were excluded from the review. Whilst there is conflicting evidence regarding the extent and effects that language bias may have upon review findings (38) it is possible that these studies might have met the review inclusion criteria and provided additional data pertinent to the review, and this is acknowledged.

Discussions between reviewers (CML, JL) following independent risk of bias assessments achieved consensus, and the third reviewer was not required to discuss studies. It was clear that, due to the variety of participants included/excluded in trials, the low number of studies evaluated as being at low risk of bias and the different methods, interventions and outcomes used across the studies meant that it was not appropriate to conduct meta-analyses in this review. Only 4 trials were evaluated as being at low risk of bias and could be included in the data synthesis stage of the review. Limitations were identified in each of these trials, including; small sample size ($n=30$) (28), short-term follow-up (30, 32), and potential methodological bias (31).

The aim of this study (21) was to update a previous review and provide guidance to clinicians and patients on any new information deemed to be at a low risk of bias on the non-surgical management of idiopathic FS, which may inform clinical practice and shared decision-making. Unfortunately, the majority of studies were evaluated as being at high risk of potential bias, implying that, despite 30 trials meeting the eligibility criteria and being included in the review, there is limited new evidence to inform the non-surgical management and treatment of people with FS. Given that so many trials were evaluated as being at high risk of bias we believe our decision to exclude these trials from data syntheses to be the correct choice for this review; their overwhelming predominance in syntheses might have led to confusing, inappropriate or misleading findings if they had been included (25, 26). None of the included studies had a no-treatment group, and return to work and recreation data were lacking in all. We recommend that, in addition to reporting adverse events, all future research report these aspects.

In conclusion, there is limited additional guidance available to support clinicians and those seeking care

for the non-surgical management of idiopathic FS. An intra-articular corticosteroid injection supported by a home exercise programme may be of benefit for those with symptoms of less than 6 months. In addition, there may be some benefit for including manual therapy and stretching, but due to the high number of treatments required and the uncertainty of achieving clinically meaningful differences, the inclusion of these interventions, must be considered cautiously.

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